

Commentary on Mandatory COVID Vaccines and Fermi's Paradox

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Dr. Berdine raises several important points in his article in the April 2021 issue of the *Southwest Respiratory and Critical Care Chronicles*. However, there are a few elements of his argument I would like to address. He starts by discussing Fermi's paradox which is a fascinating thought experiment involving the probability or improbability of our existence, and attempts to answer the question as to why we have not yet encountered extraterrestrial life. He uses this thought process to frame a discussion about current vaccine controversies.

Dr Berdine argues that the COVID-19 vaccines were rushed and that not enough patients have been studied to establish benefit and identify risks. However, the vaccines have gone through appropriate rigor with many participants in Phase I/II and Phase III trials. The time was truncated due to the amount of people, participants, money, and resources allowing these trials to be done quickly. A data safety monitoring system has been following vaccines during the clinical trials and before approval. This relates to AstraZeneca's pausing trials and having to clear so many hurdles from the United States standpoint. Then the vaccine must clear the Federal Drug Administration (FDA) advisory committee. Finally, the FDA allowed for emergency use with faster approval of the mRNA vaccines and the Johnson and Johnson/Janssen vaccine due to significant efficacy and minimal severe adverse effects. Afterward, the government covered manufacturing costs so that millions of doses would be ready immediately on approval. Despite the shortened time, efficacy and safety were not compromised.¹ The mRNA vaccines will soon go up for full FDA approval this spring due to efficacy >6 months and a favorable safety profile.

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One could argue that we need years of follow-up on a vaccine before mass vaccination, but the vast majority of reactions happen within a day and nearly all by a month.² The Vaccine Adverse Event Reporting System (VAERS) from the Centers for Disease Control and Prevention (CDC) and the FDA has existed since the 1990s and is another tool to detect rare adverse effects that can then be evaluated. Seventy-one percent of reactions to the mRNA vaccines given in December 2020 occurred within 15 minutes.³ Dr. Peter Marks, Director of the Center for Biologics Evaluation and Research with the FDA, felt a two-month follow-up was enough to balance Emergency Use Authorization and to allow for vaccine availability if the trials went well.

Now that we are in the post-production phase for several vaccines, even serious side effects that are less than 1 in 10,000 are being picked up. A recent instance of this is vaccine-induced immune thrombotic thrombocytopenia associated with unusual thrombosis, including cerebral venous thrombosis. A very small subset of patients who have received ChAdOx1 nCov-19 vaccinations developed auto-antibodies against platelet factor 4-heparin.⁴ While the rate is less than 1 in 100,000, Britain recently advised in April 2021 that those under 30 should receive an alternative vaccine. The European Medicines Agency reviewed the data at this time but could not find a risk factor and concluded that the benefits of the AstraZeneca vaccine outweigh the risk. It is important to note that neither of the mRNA vaccines nor the Johnson and Johnson/Janssen COVID-19 vaccine initially showed this risk. However, the Johnson and Johnson/Janssen COVID-19 vaccine distribution is currently paused in the United States while these rare events are evaluated. This shows that physicians, review boards, and agencies have worked together to quickly pinpoint any concerns with the vaccines.

While a reduction in mortality is an important metric for vaccines, and since COVID-19 has a low

mortality rate, the number needed to vaccinate to prevent one death will undoubtedly be very high. Another important metric is the reduction in hospitalizations. All the FDA approved vaccines have shown an almost absolute prevention of severe disease and hospital admission. This is balanced against hospital capacity studies, including one involving VA hospitals that showed mortality almost doubled when units were >75% full, though use of newer treatments could have affected this outcome.⁵ Another benefit of freeing up hospital beds is the economic standpoint due to less expenditure on COVID-19 patients and more earnings from procedures.

The fertility concern between syncytin-1 and the COVID-19 spike protein was initially brought up by a former Pfizer vice president/researcher, who has since left the company.⁶ Pfizer, of course, says there is no evidence of fertility risk. Furthermore, there has been no documented autoantibody against syncytin-1 in women who have had COVID. Also, COVID-19 causes an increased risk for maternal ventilation and perinatal death.⁷ Thus, vaccinations should be a high priority among pregnant women. While there are many socioeconomic and public health reasons that could explain the downtrend in births in the last year,⁸ it should be reassuring that recent preliminary data from the CDC on March 1, 2021, do not show an increased risk in miscarriages or abortions after receiving the vaccine.⁹

Dr. Berdine mentions that, "Humanity is better off with a significant cohort of unvaccinated people to permit long term study of efficacy and safety of the vaccine. If vaccines are mandatory, we will never know whether the vaccines were efficacious or safe." Currently, the vaccine is not mandatory for the public and those who don't wish to take the vaccine won't have to. There has been some discussion about a requirement for travel or for the military. In the setting of international travel, a negative test and/or vaccination status could be used to reduce global spread, especially from countries with low vaccination rates.

In a recent telephone poll done by Monmouth University (West Long Branch, New Jersey) from

February 25 to March 1, 2021, with 802 American adults, 25% are unwilling to get the vaccine.¹⁰ This would represent over 50 million people, more than enough for any long-term efficacy and safety study. Also, consider the rest of the world. Multiple countries are woefully behind on vaccinations, and it will take years to vaccinate most of their populations.

I do agree that it is important for humanity to safeguard against its own destruction. In the situation of a global crisis in which 562,067 have died in the United States with almost 2.9 million deaths worldwide, as of April 12, 2021.¹¹ If a treatment is developed and approved through trials and standard safety protocols, we have a civil duty to respond.

While I do not think COVID represents an existential threat, I also do not believe it is reasonable to argue that responding to a global pandemic with a vaccine developed with rigorous protocols and safeguards in any way represents the end of the world as we know it. Physicians, scientists, and public health experts have the opportunity to protect those in society who are interested and willing. Choosing to engage in certain activities may require a cost of admission. There may be a time in the near future in which, if one wishes to travel internationally, one must test negatively for COVID and offer proof of immunization if required. This may become a part of the price of admission for global travel, an exercise with many already accepted inconveniences. This potential requirement is far from a global vaccination mandate. It is unrealistic to believe that the cacophony of world governmental organizations will ever muster the coordination to create a global vaccination mandate; however, even if this highly improbable event were to occur, there will always be countries and individuals that either cannot or will not comply with said mandate to supply ample unvaccinated citizens to serve as a control group. In the meantime, the COVID vaccines offer the rest of society the fastest means to reach herd immunity and return to feeling fine.

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