

Redefining Goals?

Reaching herd immunity and eliminating COVID illness appears to be <u>less likely</u>. This is true on a local level where vaccination rates are slowing and most certainly on a global level where vaccine supply and distribution mean that much of the world will be waiting months to a year (or more?) for a chance to be vaccinated. The estimated vaccination rates needed to reach herd immunity have also risen over time, due in part to variants with higher transmissibility.

The good news is that the change in the frequency of COVID illness is not an all or none response to the effect of population immunity, but more of a sliding scale effect. Rising vaccination rates will reduce COVID transmission and illness even if not far enough to snuff it out. If we continue to focus vaccination efforts on the populations most likely to have severe disease and death we can limit the severity of the outbreaks that still occur. This doesn't mean that lower-risk individuals should take a pass on vaccination; lower risk of severe disease and death is not the same as zero risk. We know that even mild COVID can result in "long COVID" symptoms of uncertain duration. Immunity in these lower risk persons contributes to the overall lower transmission of COVID.

How much disease and death will we accept from COVID? The answer is likely to vary a lot based on cultural, ethical, and political considerations, and will be influenced by what we learn over time about the duration and severity of "long COVID" symptoms. Nations will do their best to avoid their healthcare systems buckling under COVID. Perhaps our current coexistence with influenza could be a gauge. In the US, there has been an average of 35,000 influenza deaths annually in the ten years prior to COVID. Current deaths due to COVID in the US are over six times higher than that at the 7-day moving average of 608 deaths per day on May 9th.

What Patent Waivers Might Accomplish

On 5/5/21 President Biden proposed a temporary <u>waiver of intellectual property rights</u> for COVID vaccines at the World Trade Organization (WTO) general council. Low- and middle-income countries have been pushing for months to find ways to accelerate both vaccine production and their access to vaccines. COVAX, the vaccine access program set up by the World Health Organization, has had difficulty in competing with wealthy nations for the limited vaccine supply, in part due to <u>underfunding</u>. CARE International, a global humanitarian organization dedicated to saving lives and ending poverty, estimates that for every \$1 Of COVID vaccine on the runway in a developing country it will cost another \$5 to complete a vaccination.

There are numerous hurdles to a patent waiver. The WTO won't negotiate details of adjusting patents unless all the member countries agree on a waiver, which until now had been blocked by the UK, the European Union, Japan and the US. Ngozi Okonjo Iweala, director general of the WTO, has set a target of December 2021 for reaching agreement on a waiver. In

addition to concerns that waiving patent rights would remove needed incentives and threaten future innovation, some in the pharmaceutical industry argue that intellectual property is not the main barrier to vaccine access. Some suggest that the US waiver proposal is an effort to spur vaccine manufacturers and other developed countries to find more practical ways to increase vaccination in the developing world. Maybe the US could start with more information on completing safety checks for the Astra Zeneca doses in the US that we have said we would share. Even when there is no easy fix, the global response has become more important as national borders rarely protect any nation from pandemic disease.

Some Further Data of Pfizer Efficacy for Variants

Over 385,000 Pfizer vaccine recipients in Qatar were followed from December 2020 through March 2021 with over 265,000 becoming fully vaccinated. During this time, Qatar's new COVID infections came to be evenly split between the B.1.1.7 and the B.1.351 variants. For fully vaccinated persons the vaccine efficacy for preventing any documented infection with B.1.1.7 was 90% and B.1.351 was 75%. Vaccine efficacy for preventing severe disease and death was 97% for both variants. The data underscored the importance of getting both doses; efficacy for preventing any documented infection with only one dose was 30% for B.1.1.7 and 17% for B.1.351. A single dose of vaccine had an efficacy of only 40% for preventing severe disease and death for both variants.

Pfizer's Next Steps

Pfizer BioNTech has requested <u>full approval</u> from the FDA for its COVID vaccine for persons age 16 and older. It may take two months to review the 6 months of follow-up data submitted. On May 10, the FDA expanded the Emergency Use Authorization for the Pfizer vaccine to include <u>children ages 12 through 15</u>. The Advisory Committee on Immunization Practices is expected to review the data and make recommendations about its use through the CDC. Pfizer is also anticipating submitting an EUA application for use in <u>children ages 2 through 11</u> in December 2021 pending the result from trials that started in March and April of 2021.

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