Future of Work & Business: Planning a Responsible Return
Audience Questions

1. **How effective are these home antibody COVID tests?**
   The at-home rapid tests are actually testing for SARS-CoV-2 viral antigen, not antibodies. The main purpose is to quickly determine if someone has enough infectious virus to be likely to be contagious or infectious. The tests can be done in the home using a normal nasal swab self-administered and give results within 15 minutes. Most of them are intended for you to do two tests over the course of 3 days, with a 36 hour interval between tests. If the test is positive, it is very accurate (> 95%) at indicating that you are infected with SARS-CoV-2 and likely to be infectious to others. If the test is negative (particularly if the repeat is negative as well), it is pretty accurate (probably > 90%) at ruling out infection especially in those who are within the first week of symptoms. Someone who is asymptomatic the test will not be as accurate at ruling out low level infection as a PCR test, but the advantages are the speed and convenience of the test. As I mentioned, this does not fully replace the PCR but does provide an additional tool in our testing kit.

2. **Some hesitancy for vaccination seems to stem from the quick availability of the vaccines. Many say they would like to wait a while to see what happens from vaccinations. What would you say to that person to convince them it's safe?**
   Although the vaccines were able to become available in an unprecedented speed, it is important to understand why we were able to get these vaccines so quickly and that it was NOT at the expense of any safety or efficacy data.

   First, researchers have spent over a decade working on developing the mRNA vaccine technology and specifically working on vaccines for SARS-CoV-1. So much of that work, especially the knowledge to target the spike protein as an effective target, was able to be applied to these vaccines. Second, right after this virus sequence was available, within one week, scientists were able to begin doing lab testing on these vaccines back in January. Third, there was unprecedented pharmaceutical as well as government and philanthropic investment to help fund and advance this research.

   Fourth, the US government specifically through Operation Warp Speed made the strategic decision to go ahead and move forward with mass manufacturing and production of the vaccines prior to the completion of the large trials. This meant that we had millions of doses of vaccine ready for distribution whenever they received emergency use authorization.

   However, the size and rigor of the clinical trials for these vaccines, as well as the independent process of reviewing the data by FDA and CDC, before approval of these vaccines were just as comprehensive and rigorous as for other vaccines. This means that we can have confidence in the effectiveness and safety of these vaccines, and we now have ample real-world data from 100s of millions of people around the world who have been vaccinated to validate those decisions.

   Common, serious side effects from vaccines usually happen within 6 weeks of administration of a vaccine. This is why the FDA required at least 2 months of follow-up data before they would consider any vaccine for approval. Very rare side effects from a vaccine (those that happen in less

than 1 per 100,000 individuals) will not be picked up in clinical trials of a vaccine because they are so rare. However, the CDC and FDA have very robust safety surveillance programs to detect and investigate these rare side effects that may occur as millions of people are vaccinated, as was the case with the rare blood clots after the adenovirus vector vaccines.

3. **How often and/or soon after being fully vaccinated will "booster" shots be necessary?**
   As mentioned on the call, several vaccine companies are already working on and testing "booster" vaccines. This is partially to increase the duration of immune protection, but also to better target some of the new variants. These tests will be smaller studies to ensure that the new vaccine boosters stimulate effective antibodies at the desired levels in a group of volunteers, but will not require large trials of tens of thousands of volunteers because the fundamental way the vaccine works will be the same. We will get more guidance from the CDC and FDA, but I expect there may be recommendations for a booster shot in late summer or fall. Long-term, the virus does not mutate or change as rapidly as the influenza or flu virus so I doubt that we will require an annual COVID-19 vaccine, but we may have to have one or more booster shots in the short-term until the global pandemic is controlled.

4. **How long is it likely to be from submission for full FDA approval to actual approval?**
   There is not much precedent for these types of decisions in a pandemic. While the review of the data is more extensive than what is done for the emergency use approval because there is a larger set of long-term safety data that is considered, I suspect that there will still be a desire to complete the review after submission on a scale of weeks to a few months at most. So, I expect that we will see full FDA approval maybe sometime this summer, at least for the 2 mRNA vaccines (Pfizer and Moderna).

5. **If a person is fully vaccinated, can you technically be an asymptomatic carrier of the virus? That is, can someone still spread the virus if they decide NOT to wear a mask after being fully vaccinated?**

   An individual who is fully vaccinated can still develop mild symptomatic disease or even asymptomatic carriage of the virus, although we now have good data that the vaccines reduce asymptomatic spread as well. This is the reason why the CDC still recommends that someone who is fully vaccinated continue to mask if they are in large public gatherings, particularly indoors, or if they are around unvaccinated individuals who have risk factors like medical conditions that put them at high risk for severe COVID-19.

6. **Are there any insights/indications on when the CDC may lift the indoor masked, 6 ft distancing? (what threshold of vaccination numbers would be the trigger point to adjust?) Helpful to know for planning return to office considerations.**

   While we do not have clear guidance yet on this topic, it will likely be a combination of % of individuals vaccinated as well as considering the incidence or number of new cases of COVID-19 in a particular area. I also expect that the CDC may provide some general guidelines or rules, but local or state jurisdictions will have to apply those to their specific areas. I have described the re-opening and loosening of restrictions like masking and physical distancing to a light "dimmer" switch that we gradually bring the lights up.