## **Testimony before the United States Congress Joint Economic Committee**

# **Hearing Titled:**

**Vaccinations and the Economic Recovery** 

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Written testimony: April 11, 2021

Oral testimony: April 14, 2021

#### **Table of Contents**

### **Summary**

- I. What is the projected trajectory for vaccinations in the United States?
  - A. How can the trajectory be affected by changes in the rate of vaccinations?
  - B. How could the emergence of SARS-CoV-2 variants impact global COVID vaccine supply?
  - C. Should we spread out our supply by delaying second doses of the Pfizer and Moderna vaccines?
  - D. What's being done to increase the pace of vaccination in the U.S.?
  - E. Why are vaccination rates lower among certain populations?
  - F. As more Americans are vaccinated, our challenge will increasingly become one of demand—of people actively seeking out vaccination.
    - 1. Black Americans
    - 2. Hispanics
    - 3. Republicans
    - 4. Rural Americans
    - 5. Women
    - **6. Younger Americans**
    - 7. Essential workers in non-health industries
    - 8. Healthcare workers

G. How do we build confidence in the COVID vaccines and improve vaccinuptake?	<u>1e</u>
1. The right messengers	
2. The right message	
3. The right audience	
H. The Anti-vaccine Industry	
II. What is the projected trajectory for pandemic recovery in the United States?	
A. Ending the emergency	
B. Relaxing mitigation measures	
C. Getting to herd immunity	
D. COVID credentials to reopen safely	
E. The role of COVID vaccination mandates	
F. Long-term control of SARS-CoV-2 in the United States	
1. What's the long-term role of COVID testing?	
2. We need to scale up genomic surveillance for SARS-CoV-2	
3. We need better COVID treatments	
4. Caring for COVID survivors	

G. Long-term control of SARS-CoV-2 globally

5. We need to strengthen our public health infrastructure

# Chairman Donald S. Beyer Jr., Vice Chair Martin Heinrich, Ranking Member Mike Lee, and Members of the Committee:

Thank you for the opportunity to discuss with you today the role of vaccinations in our pandemic and economic recovery. I am double-boarded in both Internal Medicine and Infectious Diseases. I am also an epidemiologist. I have worked in infectious diseases and public health since the 1990s both in the United States and overseas. I am a Clinical Assistant Professor of Medicine and Infectious Diseases at the New York University Grossman School of Medicine. I care for patients at Bellevue Hospital in New York City. I served as an Assistant Commissioner of Health in New York City. I have studied and worked on public health solutions to the tuberculosis and HIV epidemics in Brazil and throughout sub-Saharan Africa. I was an Ebola aid worker in West Africa. I served on the Biden-Harris Transition COVID Advisory Board. I am the CEO of Just Human Productions, a non-profit public health media organization. I educate the public about the COVID pandemic through various media platforms. I am pleased to be here with you today to discuss the role of vaccines and the broader U.S. public health response to the COVID pandemic.

## **Summary**

It's important to give credit where credit is due. The prior administration helped accelerate vaccine development through parallel processes and rigorous clinical trials—safely, scientifically, and in record time. The current administration is helping to scale up manufacturing and speed up distribution of vaccines.

We are currently vaccinating an average of <u>3 million people per day</u>. As of April 11, 2021, <u>35%</u> of the total population had received at least one dose of vaccine, and <u>21% of the total population</u> had been fully vaccinated. Despite recent setbacks involving production of the Johnson and Johnson vaccine, we remain on track to have enough vaccine supply for every adult in the U.S. by the end of May.

Assuming we continue vaccinating at the same pace of 3-3.5 million COVID doses per day, we could vaccinate all adults well before the end of August. If we are able to increase that pace to 4 million doses per day, we could fully vaccinate all adults before the end of July. If our pace of vaccinations slows to 2 million per day starting in May, we could still fully vaccinate all adults before the end of October.

Vaccination rates reflect vaccine supply, access to vaccines, and demand for vaccines.

By expanding distribution through retail pharmacies, mass vaccination sites, and federally qualified health centers, we have accelerated our pace of vaccination. FEMA's community

vaccination centers and federally qualified health centers have played an especially important role in administering vaccines to people of color.

But underinsurance and lack of insurance remain significant obstacles to accessing healthcare, including COVID vaccination, because people who don't have insurance are less likely to have a regular primary care provider or to be affiliated with a health system. COVID vaccines are free, but not everyone knows that, and there are other costs to getting vaccinated, like the cost of transportation, parking, time off work, and childcare.

Although vaccination sites have been located, in part, on the basis of the Centers for Disease Control and Prevention's (CDC) Social Vulnerability Index geography has proven to be essential but not sufficient in ensuring access to vaccination. Vaccines need to be delivered at a time and place that are convenient. Information about vaccines and how to get vaccinated needs to be understandable and in someone's first language. Many immigrants are worried they could jeopardize their immigration status by seeking vaccination.

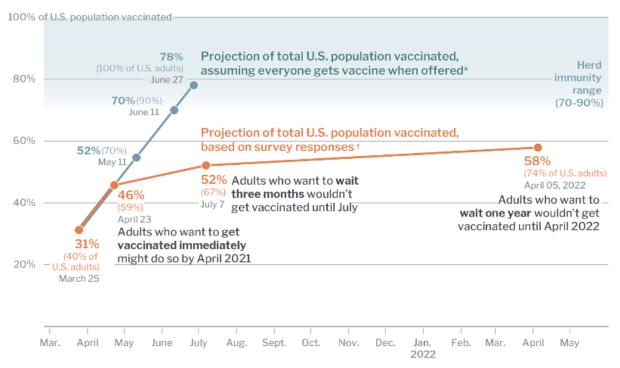
To get vaccinated in this country, you have to be eligible, know that you're eligible, know there's supply in your area, and know who's providing the vaccines. You then need to schedule an appointment for vaccination. The people who've been most adept at navigating these complex systems have higher levels of education and income and are younger, whiter, and less rural. They have better access to broadband internet and computers. They may be more computer literate. They have more flexible jobs that might allow them to multitask, working while periodically refreshing that vaccine appointment website. They're also less likely to have a disability, which can pose additional barriers to making and attending an appointment. 40% of people who've gotten COVID vaccine appointments had help.

Efforts to improve access have already made a significant impact on race-related disparities in COVID vaccination, but there's still much we can still do to improve vaccine access. Meanwhile, there are signs that <u>supply is already outstripping demand</u> in some places.

The good news is that the share of Americans who want to "wait and see" if they will get vaccinated shrank from 39% in December 2020 to 17% in March 2021, according to Kaiser Family Foundation surveys. The non-profit think tank Surgo Ventures has seen similar increases in intent to get vaccinated. We are <a href="making progress">making progress</a> building vaccine confidence among that "moveable middle," especially among communities of color and persons for whom issues of access (e.g. appointment availability and scheduling, time, and cost) are the greatest barriers to vaccination. Trust and perceived risks of vaccination are the biggest barriers among least persuadable segments of the population, according to Surgo Ventures.

The bad news is that 20% of Americans say they will only get vaccinated if required or will definitely not get vaccinated, including many Republicans, Evangelical Christians, rural Americans, and essential workers in non-health industries, according to Kaiser Family Foundation surveys. With 20% of Americans currently unlikely to get vaccinated and another 25% of the population who are children, we won't be reaching herd immunity for some time yet.

The non-profit think tank Surgo Ventures predicts that COVID vaccination rates could slow as soon as this month. These projections are based on a <u>nationally representative survey of adults</u> in the U.S. in March 2021. Respondents were asked about their preferred timelines for getting vaccinated:



<sup>\*</sup> Assuming vaccinations continue at current rate of 0.6% of adults per day receiving their first dose

Source: Surgo Ventures, April 8, 2021.

It's also important to understand that vaccine rollout is necessary but not sufficient for pandemic recovery. I think of pandemic recovery in four phases: ending the emergency, relaxing mitigation measures, getting to herd immunity, and long-term control.

To end the emergency, we have to vaccinate the highest-risk persons who are most likely to develop severe COVID, most likely to be hospitalized, and most likely to die. That means vaccinating older adults and people with chronic medical conditions. We must also pay special

<sup>†</sup> Calculated based on Surgo's nationally representative survey of 1,670 adults in the United States from March 18-March 25, 2021 Source: Surgo Ventures

attention to the hardest-hit, most vulnerable communities, including communities of color and frontline essential workers.

We cannot end the emergency phase of the pandemic by <u>relying only on vaccination</u> without risking another surge in cases, hospitalizations, and deaths. Lifting mitigation measures too soon is like taking your foot off the brake before putting the car into park. With the emergence of more infectious variants, the virus is hitting the gas at the same time. Vaccination is like a parking brake: it works well once a car is in park, but not nearly as well when you're racing down a highway.

Herd immunity is when so many people are immune to the virus, it has no place to go. We don't yet know what proportion of the population we'll need to vaccinate to reach herd immunity because this is highly dependent on how infectious the virus is, and on the emergence of more infectious variants, which is a moving target. The more infectious the virus, the higher the threshold to reach herd immunity. Finally, we don't know how long immunity after vaccination will last. Currently, our best estimate is that we'll reach herd immunity to SARS-CoV-2 when approximately 75-85% of the population is immune.

Most scientists believe that <u>SARS-CoV-2</u> is here to stay and that the virus will become endemic, circulating at some level in many countries for years to come.

Thus, we are likely facing a prolonged interim period, when we can safely lift mitigation measures, because the most at-risk have been shielded by vaccination, but before we've reached herd immunity. This means that even once restrictions are lifted, we're unlikely to get back to business-as-usual right away. Businesses have a legal and ethical obligation to ensure a safe environment for their customers and workers. People need to feel safe traveling, going to the gym, or going out to eat. While some may not need that assurance, many do.

While COVID credentials may not be mandated by the government, the private sector is forging ahead. The purpose of COVID credentials, what some mislabel COVID passports, is to demonstrate that when individuals engage in certain activities, they pose minimal infectious risk to others. COVID credentials may take the form of a COVID test result and/or COVID vaccination status

The current administration has stated that it does not have plans to issue COVID credentials or to require COVID credentials. However, there is a need for the federal government to help coordinate, standardize, and regulate COVID credentialing efforts. COVID credentials protect privacy and should not create or reinforce health disparities.

It is important to distinguish COVID credentials from COVID vaccination mandates. A strict vaccination mandate requires that someone be vaccinated and does not allow for reasonable alternatives. Many of us in the public health community are concerned that vaccination mandates could backfire, especially this early in our COVID vaccine rollout efforts.

Finally, our pandemic recovery plans must address chronic underfunding of the CDC and state and local health departments and build a strong, modern public health infrastructure. We need a professional public health corps and 21st century bioinformatics and laboratory systems. We must acknowledge that new infections are emerging with greater frequency—a trend driven by climate change, environmental degradation, globalization, and overpopulation—in other words anything that brings people in closer contact with wildlife habitats resulting in virus spillover. Our financial and political investment in preparedness for epidemics and pandemics should reflect the serious health, economic, and natural security triple-threat they pose. We must re-engage on the global health stage, beginning with efforts to strengthen surveillance for emerging infectious disease, build local public health capacity, and scale up COVID vaccination in the rest of the world. As long as SARS-CoV-2 continues to spread from person to person anywhere in the world, it will continue to mutate and evolve. New mutant variants may be more infectious, more virulent (causing more severe disease), or could evade our immune responses to natural infection or vaccines. As this pandemic has shown us, the emergence of a new virus halfway around the world poses a very real and present danger to all of us.

## I. What is the projected trajectory for vaccinations in the United States?

It's important to give credit where credit is due. The prior administration helped accelerate vaccine development through parallel processes and rigorous clinical trials—safely, scientifically, and in record time. The current administration is helping to scale up manufacturing and speed up distribution of vaccines.

We are currently vaccinating an average of <u>3 million people per day</u>. As of April 11, 2021, <u>35%</u> of the total population had received at least one dose of vaccine (117,142,879 people) and <u>21%</u> of the total population had been fully vaccinated (70,692,645 people). The Pfizer and Moderna vaccines are two-dose vaccines, while the Johnson and Johnson vaccine is a one-dose vaccine, so the Pfizer and Moderna vaccines get you to half as many people fully vaccinated per day as the Johnson and Johnson vaccines.

Contract production targets by month for the vaccine manufacturers are as follows:

- Pfizer-BioNTech
  - o March 31: 120 million doses
  - o May 31: 80 million doses
  - o July 31: 100 million doses
- Moderna
  - o March 31: 100 million doses
  - o May 31: 100 million doses
  - o July 31: 100 million doses
- Johnson and Johnson
  - o June 30: 100 million doses
  - o TBD: 100 million doses

The U.S. government is currently receiving more than 13 million doses of Pfizer vaccine and about 10 million doses of Moderna vaccine per week. Johnson and Johnson delivered 20 million doses of vaccine in March.

This week, the federal government allocated <u>6,957,000 doses of Moderna vaccine</u> and <u>9,434,880 doses of Pfizer vaccine</u>, and <u>700,000 doses of Johnson and Johnson vaccine</u> (down from about 5 million last week) to the states. The Pfizer and Moderna vaccine doses are apportioned equally to first and second doses.

Production of the vaccines has sped up as manufacturing kinks have been worked out, and companies were given priority access to raw materials and other manufacturing supplies, and facilities to fill and finish their vaccines. Pfizer also added manufacturing sites, is producing some of its own raw materials (e.g. lipids), doubled its batch sizes, and created its own capacity

to package vials for shipment. The Food and Drug Administration (FDA) has granted Moderna permission to package 15 doses per vial, allowing the company to ship more doses.

Production of the Johnson and Johnson vaccine was dealt a setback with recent news of serious manufacturing problems at the <a href="Emergent BioSolutions">Emergent BioSolutions</a> plant in Baltimore, which rendered 15 million doses unusable. An additional 62 million doses of the Johnson and Johnson vaccine are on hold while they're assessed for contamination. It takes two months for batches of the Johnson and Johnson vaccine to brew. It takes another five to six weeks to finish formulating, testing, and packaging for release. If Emergent BioSolutions is cleared to restart production, Johnson and Johnson expects they'll be able to produce up to 8 million doses a week. Merck has also agreed to help manufacture and provide "fill-finish" services for the Johnson and Johnson vaccine, but that additional supply won't be available until later this year. It's anticipated that allocations of the Johnson and Johnson vaccine will <a href="mailto:drop significantly">drop significantly</a> this week.

Another recent potential setback was a report of <u>four cases</u> of blood clots and low platelet counts in recipients of the Johnson and Johnson vaccine. It is not yet known whether these adverse events are associated with the Johnson and Johnson vaccine. The company, the FDA, and the CDC are investigating the events. It's important to note that even if a link is established, the risk of such events appears to be exceedingly low. Although we anticipate still having enough supply by the end of May to vaccinate all adults with the Pfizer and Moderna vaccines, the Johnson and Johnson vaccine is uniquely suited to vaccinating migrant workers, homeless persons, college students, rural areas, and other mobile or hard-to-reach populations given its single dose schedule and less stringent cold chain transport requirements. Others simply like the convenience of a one-shot vaccine.

Yet, despite reduced supply of the Johnson and Johnson vaccine over the next couple of months, we remain on track to have enough vaccine supply for every adult in the U.S. by the end of May.

### A. How can the trajectory be affected by changes in the rate of vaccinations?

Assuming we continue vaccinating at **the same pace of 3-3.5 million vaccinations per day**, and assuming we utilize all of the remaining Johnson and Johnson 20 million vaccine doses delivered to the U.S. government in March, we would administer another 60-70 million doses between now (April 11, 2021) and the end of April, or fully vaccinate an additional 23-28 million people, getting us to well over 100 million people fully vaccinated by the end of April.

So long as Pfizer and Moderna continue to produce and deliver their vaccines on time, we could reach 150 million fully vaccinated by the end of May, 200 million fully vaccinated by the end of June, 250 million fully vaccinated by the end of July, and all adults in the U.S. fully vaccinated well before the end of August.

With additional improvements in distribution our pace of vaccinations could increase to 4 million per day. However, there are signs that <u>supply is already outstripping demand</u> in some places. If vaccine-seeking drops, the pace of vaccination will drop, at least until the FDA issues an emergency use authorization allowing for vaccination of children ages 12 and up. I anticipate that by August, the Pfizer, Moderna, and possibly also Johnson and Johnson vaccines will have received emergency use authorization for use of their vaccines in children 12 and up.

If our pace of vaccinations increases to 4 million per day starting in May, we could fully vaccinate all adults before the end of July.

If our pace of vaccinations slows to 2 million per day starting in May, we could still fully vaccinate all adults before the end of October.

# B. How could the emergence of SARS-CoV-2 variants impact global COVID vaccine supply?

The two vaccines most likely to be affected by SARS-CoV-2 variants in the near term are the Johnson and Johnson and AstraZeneca COVID vaccines. This is significant because these vaccines are inexpensive to produce and don't have stringent cold-chain requirements, making them ideal for global distribution and administration.

The Johnson and Johnson vaccine is highly effective in preventing severe disease, hospitalization, and death from COVID. However, in phase III clinical trials, the Johnson and Johnson vaccine was found to be less effective in preventing moderate to severe COVID in South Africa and Latin America, where the B.1.351 and P.1 variants are each widespread respectively. Johnson and Johnson is currently evaluating a two-dose regimen to determine if it's more effective, particularly against variants of concern, and more durable than the currently approved single-dose regimen. If recommendations changed and the Johnson and Johnson vaccine were to become a two-dose vaccine like the Pfizer and Moderna vaccines, this would have important implications for the global vaccine supply and distribution. In the U.S., we might consider giving a second dose to people who initially received one dose of Johnson and Johnson vaccine. Alternatively, we might only target certain especially high-risk populations for booster shots. Outside the U.S., many countries may opt to stick with a one-dose schedule given that a single dose should still significantly reduce risk of hospitalization and death, is simpler to distribute, and is less costly. However, continuing with a one-dose strategy could come at the risk of creating immune pressure selecting for more vaccine-resistant variants, which would have consequences for everyone the worldover.

AstraZeneca has yet to apply for an emergency use authorization for its vaccine from the FDA. Even if the FDA grants the AstraZeneca vaccine an emergency use authorization, it is unclear whether the AstraZeneca vaccine would ever be used in this country. Furthermore, there are also concerns about decreased effectiveness of the AstraZeneca vaccine against SARS-CoV-2 variants. South Africa is not using the AstraZeneca vaccine due to concerns about reduced vaccine effectiveness against the B.1.351 variant. A recent study also found that the AstraZeneca vaccine elicited lower neutralization antibody activity against B.1.1.7, the variant originally identified in the UK, and now the dominant variant in the U.S.

# C. Should we spread out our supply by delaying second doses of the Pfizer and Moderna vaccines?

The more infectious and virulent B.1.1.7 variant that was first identified in the UK has become the dominant strain in the U.S. The B.1.1.7 variant is driving a surge in cases and hospitalizations in Michigan, Minnesota, and other states. In light of this latest surge, some have argued for delaying second doses of the Pfizer and Moderna vaccines, as the UK, Germany, and Canada are doing, in order to provide first doses to more people. There are very real risks to this approach, and it's not one I would recommend.

Some have argued that the UK's dose-delay strategy helped curb a surge in cases driven by the emergence of the B.1.1.7 variant. The <u>UK</u> has given first doses to 48% of its population, but only 11% are fully vaccinated. However, they implemented other measures simultaneously, including <u>strict lockdowns</u>, <u>which they're only now starting to lift</u>. We have yet to see if there's a rebound in cases after these restrictions are lifted.

Immunity isn't binary. It's on a continuum. Vaccination may induce full immunity to some strains, partial immunity to variants of concern, and no immunity against vaccine-evading variants. By delaying second doses, we could be creating a several weeks- to months-long window when there are intermediate levels of immunity in the population, putting immune pressure on the virus and selecting for the emergence of variants of concern and vaccine-evading variants. Real world evidence from Scotland shows that the effectiveness of the Pfizer vaccine peaks at 28-34 days after a first dose and then drops in subsequent weeks. Multiple studies have shown that one dose of Pfizer or Moderna vaccine elicits weaker antibody neutralization responses against the B.1.1.7 variant, the B.1.351 variant first identified in South Africa, and the P.1 variant first identified in Brazil as compared to early SARS-CoV-2 strains (see also here, here, and here). The second doses of the Pfizer and Moderna vaccine are important for boosting levels of neutralizing antibodies and to widen coverage of variants of concern. Real-world evidence from Israel suggests that two doses of the Pfizer vaccine are effective against the B.1.1.7 and B.1.351 variants, but breakthrough infections occur after only one dose. This may be

why there was a lag after Israel began vaccinating its citizens and before a drop in COVID cases was observed.

## D. What's being done to increase the pace of vaccination in the U.S.?

A quarter of Americans don't have a primary care provider, and many primary care providers don't have the capacity to vaccinate in their offices. While big hospital systems and academic medical centers can manage the logistics of vaccination—including registration, scheduling, patient observation and follow up, supply chain management, and reporting requirements—this may be challenging for many primary care providers. So additional mechanisms for distributing vaccines have proven and will continue to be essential. These alternative mechanisms include retail pharmacies, mass vaccination sites, and federally qualified health centers.

President Biden recently announced that the federal retail pharmacy program will expand from seventeen thousand to a total of forty thousand retail pharmacies across the country, putting 90% of adults in the U.S. within five miles of a vaccination site.

Mass vaccination sites are also an important tool for getting people vaccinated. An additional twelve FEMA community vaccination centers will be brought online in April, bringing the total to thirty-three. State and local health departments and local partners are also running mass vaccination centers across the country. FEMA, state, and local partners are also supporting smaller vaccination sites as well as mobile vaccination efforts. Homebound persons are among the highest risk for severe COVID, and while many are already eligible for vaccination, they are unable to travel to vaccination sites. In Washington, D.C. and Baltimore, for example, local officials and health workers are going door-to-door, reaching out to elderly and high-risk populations. The federal government is also funding transportation for seniors and people with disabilities to travel to vaccination sites.

Thus far, Americans seem to prefer vaccination at retail pharmacies over mass vaccination sites, and it's proven cheaper and more efficient to distribute vaccines through retail pharmacies than mass vaccination sites. However, FEMA's community vaccination centers are preferentially located in communities of color, and 65% of vaccines administered at these sites go to people of color. And when FEMA vaccination sites have opened up to walk-ins without appointments, they have been able to reach an even more racially and ethnically diverse population. About 70% of people receiving COVID vaccines via federally qualified health centers are people of color. The federal retail pharmacy program has prioritized locations on the basis of the CDC's Social Vulnerability Index, but as the program expands, it will be important to track equity in vaccine distribution. Over the past decade, many pharmacies catering to low-income, uninsured, and publicly insured patients in urban areas have closed. Unless the retail pharmacies can

demonstrate themselves as effective as mass vaccination sites in reaching communities of color, the added cost of mass vaccination sites may be justified.

Although relatively cheap and efficient in administering vaccines, the retail pharmacies have also learned that they won't achieve equitable vaccine distribution without active outreach to communities of color. Some retail pharmacy chains are standing up call centers, collaborating with local community partners, setting up community-based vaccine clinics, and launching texting campaigns at times when appointments are most likely to be scheduled by people of color. Some pharmacies have organized <u>pop-up clinics</u> at churches, housing complexes, parking lots, and schools.

Both retail pharmacies and mass vaccination sites may leave out of the loop primary care providers, who are often a <u>patient's most trusted source of health information</u>. Primary care providers will be important in educating and counseling the "moveable middle" of people who haven't yet decided to be vaccinated but are persuadable to get the vaccine. Even if they aren't managing vaccination themselves, <u>primary care</u> providers should be enlisted to counsel their patients on COVID vaccination and help them navigate the registration and appointment scheduling process.

<u>Federally qualified health centers</u> have also been an important tool for reaching more people of color, low-income populations, and vulnerable communities. Half of people receiving their first dose of COVID vaccine at a federally qualified health center are persons of color.

The CDC has also suggested that <u>employers</u> consider establishing workplace vaccination programs or coordinate with offsite locations to help employees get vaccinated. Medicaid, Medicare, and other payors could be reaching out to their enrollees to help get them registered for vaccination.

### E. Why are vaccination rates lower among certain populations?

Vaccination rates reflect vaccine supply, access to vaccines, *and* demand for vaccines. Vaccine supply is expected to open up dramatically between now and the end of May. But differential access to vaccines and demand for vaccines continue to drive disparities in vaccination rates.

The populations initially prioritized for vaccination included persons <u>over age 65</u>, who skew whiter than the overall population. <u>Communities of color</u> are younger populations. Prioritization for vaccination on the basis of age predictably results in racial disparities in vaccination. But even as we've moved beyond the elderly to other priority groups—healthcare workers, the staff of long-term care facilities, teachers, school bus drivers, childcare workers, other essential

workers, and people with chronic medical conditions—the gap in vaccination rates between White Americans and Americans of color has widened.

Initial vaccine rollout was focused on long-term care facilities, hospitals, and academic medical centers. While many healthcare systems are inviting their patients to schedule appointments, many people in this country remain underinsured or uninsured and aren't affiliated with such a system. Increasing this access problem, about <u>fifty hospitals</u> closed or filed for bankruptcy in 2020, including <u>nineteen rural hospitals</u>. The end result is that many in this country do not have regular health care providers and aren't covered by health system outreach.

Although vaccination sites have been located, in part, on the basis of the CDC's Social Vulnerability Index—a composite of fifteen different variables spanning socioeconomic status, household composition, disability, race and ethnicity, language, housing type, and transportation—geography has proven to be essential but not sufficient in ensuring access to vaccination. Vaccine convenience and quality of service are important, too. Vaccines need to be delivered at a time and place that are convenient. Vaccination sites should be places where people feel comfortable getting vaccinated. Black adults are less likely to get vaccinated at work, government mass vaccination sites, or local schools than Whites or Hispanics; this speaks to a possible lack of trust for employers and government institutions. Information about vaccines and how to get vaccinated needs to be understandable and in someone's first language. COVID vaccines are free, but not everyone knows that, and there are other costs to getting vaccinated, like the cost of transportation, parking, time off work, and childcare. Many immigrants are worried they could jeopardize their immigration status by seeking vaccination.

To get vaccinated in this country, you have to be eligible, know that you're eligible, know there's supply in your area, and know who's providing the vaccines. You then need to schedule an appointment for vaccination. As we all know, the systems to schedule a COVID vaccine appointment in this country are complicated. You might need to sit at your computer for hours reloading a web page. It's difficult to complete all the pages of registration on a smartphone, even if you have one. The people most able to navigate these complex systems have higher levels of education and income and are younger, whiter, and less rural. They have better access to broadband internet and computers. They may be more computer literate. They have more flexible jobs that might allow them to multitask, working while periodically refreshing that vaccine appointment website. They're also less likely to have a disability, which can pose additional barriers to making and attending an appointment. 40% of people who've gotten COVID vaccine appointments had help. Since our social networks tend to mirror our own socioeconomic status, those of us who are wealthier and better educated are also likely to be connected to others who are as well. We rely on our social networks better to help us get an appointment if we can't.

For people who do not have internet access, the federal government will launch by May 1st a 1-800 call center to provide assistance in getting vaccinated. <u>Almost 68 million Americans</u>, or one in five, speak a language other than English at home and have difficulty navigating both telephone and online vaccination scheduling systems.

Finally, we need complete, accurate, real-time, publicly available <u>data on the demographics</u> of those who are being vaccinated—age, sex, race, ethnicity, zip code, and occupation—so that public officials can better target their vaccination efforts and be held accountable.

# F. As more Americans are vaccinated, our challenge will increasingly become one of demand—of people actively seeking out vaccination.

Already we are hearing reports from across the country—in <u>Maine</u>, <u>Georgia</u>, <u>Mississippi</u>, <u>Louisiana</u>, <u>Michigan</u>, <u>Ohio</u>, <u>Illinois</u>, <u>Kansas</u>, <u>Montana</u>, <u>Oregon</u>, and other states—that vaccination appointment slots are going unfilled. Some states, like <u>New Hampshire and Oklahoma</u>, are opening up vaccination appointment slots to residents from other states because they have more than enough supply.

It's important not to characterize all persons who don't actively seek out vaccination as vaccine-hesitant. It's <u>stigmatizing</u> and <u>blaming</u>. It's also not granular enough to help us identify and implement the right solutions. Some people have low levels of health literacy or information about COVID and the vaccines. Some people <u>worry the vaccines may not be safe or effective</u>. Many worry about the potential for long-term <u>side-effects</u>. They worry about real risks, such as allergic reactions, as well as fictitious risks promoted by disinformation campaigns, such as impact on fertility and whether the vaccines could change their DNA. Others ask whether the vaccines are safe and effective in <u>people like them</u>—i.e. people of color, people with underlying medical conditions, or pregnant and breastfeeding women. Some worry the vaccines were <u>developed and approved too quickly</u>. Some are still undecided, weighing the risks and benefits of vaccination. Others just haven't gotten around to it or don't know how or aren't able to access vaccination. Some are indifferent, ambivalent, or apathetic—especially younger

Americans—because they don't think they're at risk for COVID. Others falsely think that natural infection is a better path to immunity than vaccination. Some think the risk of COVID has been overplayed by the media. And finally, some are actively skeptical or resistant to vaccination.

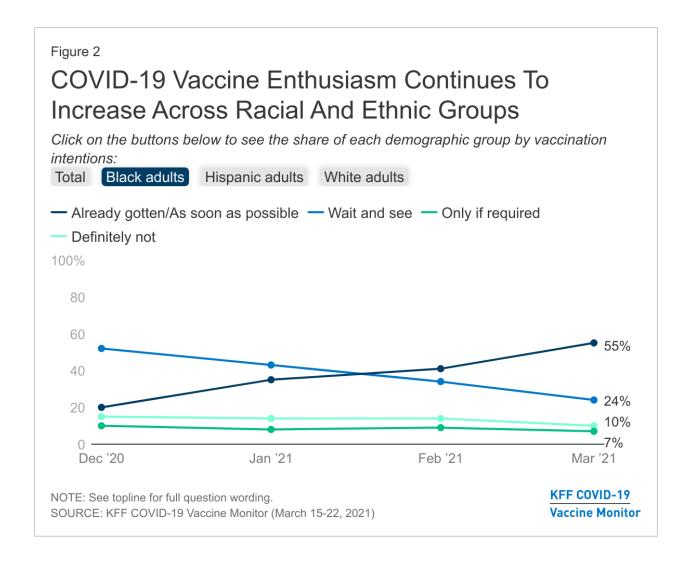
The share of Americans who want to "wait and see" if they will get vaccinated shrank from 39% in December 2020 to 17% in March 2021. We are making progress building vaccine confidence among that "moveable middle." However, the proportion of Americans who say they will only get vaccinated if required or will definitely not get vaccinated remained essentially unchanged at 20% of Americans in March 2021.

We're running months behind on a broader public health campaign to address concerns and educate the American public about COVID and the vaccines. It wasn't until February that the Ad Council and COVID Collaborative—a consortium of major brands, media companies, community-based organizations, faith leaders, and other trust messengers—launched the "It's Up to You" campaign to educate the public about the COVID vaccines. And it was only this month that the Biden Administration announced it was creating a network of volunteer healthcare workers and community leaders, the COVID-19 Community Corps, to build trust in the COVID vaccines. The Department of Health and Human Services and the CDC are providing the COVID-19 Community Corps with guidance on how to talk about the COVID vaccines and resources in the form of social media tool kits, fact sheets, infographics, and videos that can be used in doing grassroots outreach. This volunteer corps will also host virtual events and host vaccination drives.

### 1. Black Americans

Black Americans have been hit especially hard by the COVID pandemic. They have experienced disproportionately high rates of disease, hospitalization, and death. Even if they haven't gotten COVID themselves, the vast majority of Black Americans know someone who has been hospitalized or died from COVID. They know they're at risk, and they're very concerned. Yet Black Americans are less likely than White Americans to say they have been vaccinated or will get vaccinated as soon as possible.

According to the Kaiser Family Foundation COVID-19 Vaccine Monitor, 55% of Black adults have already been vaccinated or plan to get vaccinated as soon as possible; 24% say they will "wait and see"; 10% say they will only get vaccinated if required; and 7% say they will definitely not get vaccinated:



If Black Americans are worried about getting COVID or spreading it to others, why are they more likely to be on the fence about getting vaccinated?

Black Americans are less likely to trust the health system. "I don't trust doctors, nurses, physician assistants, hospitals, emergency rooms, waiting rooms, surgeries, prescriptions, X-rays, MRIs, medical bills, insurance companies or even the food from hospital cafeterias," said Damon Young, a contributing writer for *The New York Times*. But it's overly simplistic and reductive to blame this distrust on the U.S. Public Health Service Syphilis Study at Tuskegee. The history of medical abuse and experimentation among people of color goes back to the days of slavery and extends right up to the present day. Distrust is a *symptom* of structural racism, not a cause of health disparities. If we are to improve vaccine confidence among communities of color, it's essential that we address structural racism by demonstrating trustworthiness, not by blaming disparities in vaccine distribution on vaccine hesitancy. Such trust-building begins with equity in vaccine distribution and access, but it doesn't stop there. We also need to make reparations for the disproportionate toll the pandemic has taken on communities of color. At a

minimum, such reparations should include covering the long-term medical expenses and disability of *all* COVID survivors, much as the <u>September 11th Victim Compensation Fund</u> provided financial compensation to victims of the 9/11 terrorist crashes and first responders suffering from dust-related health effects.

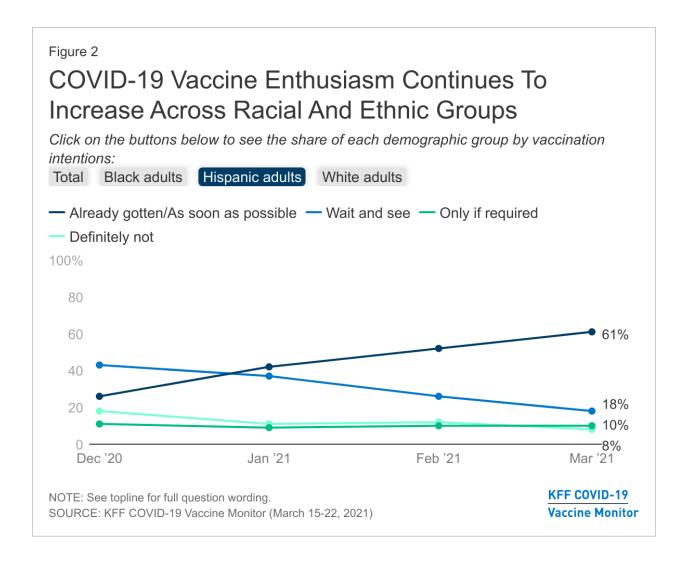
Vaccine confidence among communities of color is not only a question of trust but also a question of information. Official, scientifically accurate information about COVID and the vaccines isn't reaching all Americans equally. Racial disparities in whether this <u>information</u> reaches Black people via social media have been documented. A recent study found that 41% of Black adults said they <u>knew "little or nothing"</u> about how vaccines were developed and tested, and 30% said they knew "only a little or nothing" about how vaccines work. Other information gaps are around the costs of getting vaccinated and how and where to get vaccinated.

<u>Disinformation</u> has also been targeted at communities of color.

<u>Black healthcare workers</u> have taken matters into their own hands to improve vaccine access and to push out quality information to their communities on social media and in other venues, and the good news is that it's working. The proportion of Black Americans reporting they had already gotten vaccinated or wanted to get vaccinated as soon as possible has <u>increased from 20% to 55% since December</u>, and the proportion saying they would "wait and see" has dropped from 52% to 24%.

# 2. Hispanics

Like Black Americans, Hispanics have borne a <u>disproportionate share of COVID infections</u>, <u>hospitalizations</u>, <u>and deaths</u>. According to the Kaiser Family Foundation COVID-19 Vaccine Monitor, 61% of Hispanic adults have already been vaccinated or plan to get vaccinated as soon as possible; <u>18% say they will "wait and see"</u>; 10% say they will only get vaccinated if required; and 8% say they will definitely not get vaccinated:

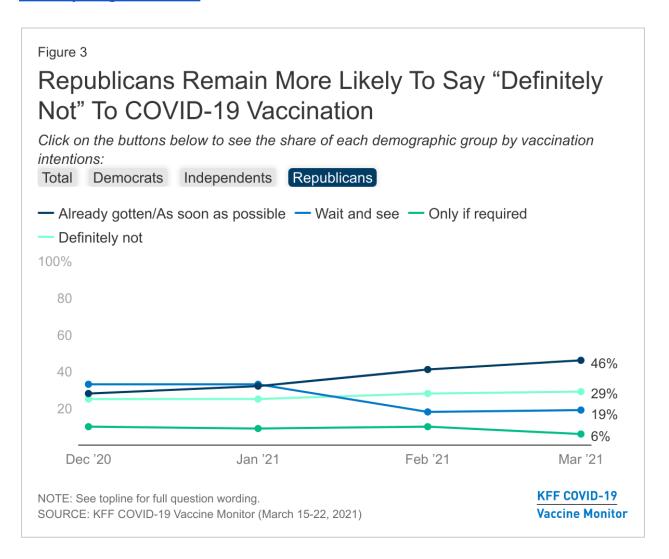


Like Black Americans, Hispanics have also endured a history of medical abuse and experimentation. Concerns about fertility among Hispanics relate to a <u>history of forced sterilizations</u> including <u>forced hysterectomies</u> at immigration detention centers just last year. Many Hispanic families, particularly undocumented persons or mixed-status families, worry that seeking COVID vaccination could jeopardize their <u>immigration status</u>. Scientifically accurate information may be less likely to reach these Hispanics due to language and cultural barriers.

## 3. Republicans

<u>Survey</u> after <u>survey</u> after <u>survey</u> after <u>survey</u> has found that Republicans are the demographic least likely to seek a COVID vaccine, but unlike Black Americans and Hispanics, who have been more likely to say that they want to "wait and see," Republicans are more likely to say they will reject vaccination outright.

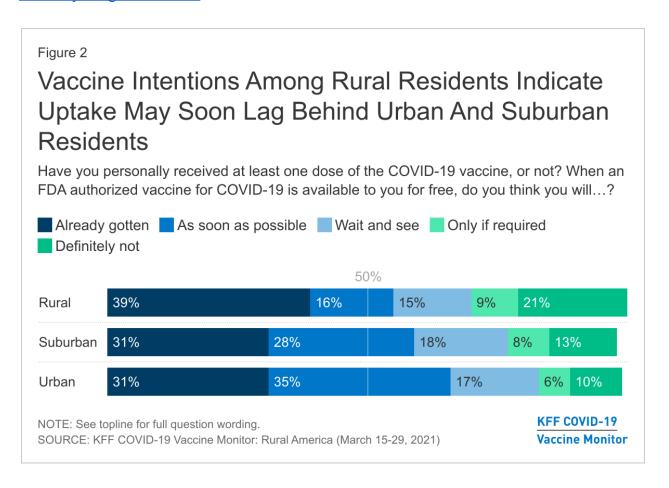
According to the Kaiser Family Foundation COVID-19 Vaccine Monitor, 46% of Republicans have already been vaccinated or plan to get vaccinated as soon as possible; 19% say they will "wait and see"; 6% say they will only get vaccinated if required; and 29% say they will definitely not get vaccinated:



Republicans who aren't confident in the COVID vaccines report many of the same concerns about side-effects, vaccine effectiveness, and vaccine testing as do other groups with low vaccine confidence. But a larger proportion of Republicans who don't plan to get vaccinated say they don't think they need to. Just as Black Americans are less likely to trust the health system, Republicans are less likely to trust the government and the media, which is closely tied to lack of confidence in COVID vaccines. Many are concerned that the pandemic was politicized and weaponized against former President Donald J. Trump during the 2020 election.

#### 4. Rural Americans

According to the Kaiser Family Foundation COVID-19 Vaccine Monitor, 55% of rural residents have already been vaccinated or plan to get vaccinated as soon as possible; 15% say they will "wait and see"; 9% say they will only get vaccinated if required; and 21% say they will definitely not get vaccinated:



Political partisanship appears to be the biggest driver of low vaccine confidence among rural Americans. Rural Americans are also less likely than suburban and urban Americans to believe the pandemic is a serious threat to their families or the country and more likely to believe that the media exaggerates the risk. Rural Americans view the decision to get vaccinated as one of personal choice rather than one of personal responsibility.

Rural Americans report <u>better access to vaccination</u>—being able to get an appointment, adequate vaccine supply, enough vaccination locations—than suburban and urban Americans. It is likely that low vaccine confidence will soon be (if it isn't already) the biggest obstacle to increasing vaccine coverage in rural areas.

### 5. Women

Women are less likely to be vaccinated than men and have lower confidence in the COVID vaccines than men. <u>Young mothers</u> have also been found to have lower vaccine confidence than other parents or non-parents. This is likely related to concerns about the potential impact of COVID vaccines on <u>fertility</u>, but the data is mounting that <u>pregnant and breastfeeding women</u> have robust responses to the Pfizer and Moderna COVID vaccines and pass on immunity to their babies. As with influenza, pregnant women are at higher risk for severe disease from COVID than non-pregnant women. COVID during pregnancy also increases the risk of preterm birth.

Young mothers, in particular, have traditionally been the <u>targets of disinformation</u> by the anti-vaccination movement because they are often responsible for making decisions about whether or not to vaccinate their children.

#### **6. Younger Americans**

According to the Kaiser Family Foundation COVID-19 Vaccine Monitor, 49% of young adults between the ages of 18 and 29 have already been vaccinated or plan to get vaccinated as soon as possible; 25% say they will "wait and see"; 15% say they will only get vaccinated if required; and 11% say they will definitely not get vaccinated. Although this age group is less likely to develop severe COVID, to be hospitalized with COVID, or to die from COVID, a large proportion of SARS-CoV-2 transmission in the community is propagated by young adults. However, public health officials haven't targeted young people in their COVID messaging, which leaves an important information void. Messaging and outreach among young adults is likely to be effective, as it has been among Black Americans, because most of those who don't yet intend to get vaccinated are in the moveable middle, who say they will "wait and see." Colleges and universities are in a good position to educate students about COVID vaccines and offer vaccination, but a third of college-aged Americans aren't enrolled in college. Most colleges and universities are encouraging but not mandating vaccination, though some (e.g. Rutgers University, Cornell University) have recently announced they will require vaccination for students to return to campus in the fall.

### 7. Essential workers in non-health industries

According to the Kaiser Family Foundation COVID-19 Vaccine Monitor, 49% of essential workers in non-health industries have already been vaccinated or plan to get vaccinated as soon as possible; 19% say they will "wait and see"; 11% say they will only get vaccinated if required; and 21% say they will definitely not get vaccinated. People employed in the retail, transportation, food and beverage industries are the least likely to say they'll seek vaccination.

It has been well established that <u>essential workers</u> are among those at highest risk for severe COVID. But many of these workers are chronically underpaid and feel disempowered in the workplace. They don't trust their employers, and sadly, the events of the past year have given them <u>good reason not to</u>. Many feel that the government let them down in their moment of greatest need or never had their backs to begin with.

#### 8. Healthcare workers

Vaccine confidence among healthcare workers is a bellwether for the rest of the American public. They were among the first to be prioritized for vaccination, yet as of early March only about half of frontline healthcare workers had received at least one dose of COVID vaccine. More than a third reported low vaccine confidence. and low vaccine confidence in this group foreshadows what we may be facing among the general public in the coming months.

Healthcare workers aren't a uniform group. They include doctors, with high levels of education and income, as well as <u>nursing home staff</u> and home health aides, with low levels of education and income. But unlike other Americans, they've been on the frontlines of the pandemic and have had a front row seat to the toll it's taken. They're also an important group because they're the most trusted messengers on vaccines, and so any lack of confidence in this group could have a significant impact on the public's confidence in general.

The same demographics that predict vaccine confidence among the general public—race, partisanship, income, and gender—also predict vaccine confidence among healthcare workers. Rates of low vaccine confidence are higher among <u>Black</u> and <u>Hispanic</u> healthcare workers than White healthcare workers; about twice as high among <u>Republicans and Independents</u> as among Democrats; more than twice as high among <u>lower-income</u> than higher-income healthcare workers; and twice as high among <u>female</u> healthcare workers as male healthcare workers. Healthcare workers cite the <u>same reasons for not getting vaccinated</u> as members of the general public.

Other important bellwether populations include members of the military. Almost <u>40% of U.S.</u> <u>Marines</u> are refusing COVID vaccinations. Black Americans are overrepresented in the military accounting for 29% of active-duty women, 17% of active-duty men, and 13% of the total U.S. population.

## G. How do we build confidence in the COVID vaccines and improve vaccine uptake?

Person-to-person, hyperlocal outreach by trusted messengers and community health workers will have a far greater impact on building vaccine confidence than messages coming from politicians or government officials or glitzy public service announcements and ad campaigns. People will

trust people like themselves, who they believe genuinely care about them. People want the <u>freedom to do what others like themselves are doing</u>, and so it's really <u>important to highlight that people are getting vaccinated</u>, especially in communities and social networks where vaccine demand may be lower.

#### 1. The right messengers

Information about vaccines should come from doctors, nurses, and scientists, not politicians. When we hear from politicians, we ask ourselves, "What's their agenda?" Americans of all political stripes feel that the pandemic was politicized, and it makes it all the more important to leave politics out of our vaccine messaging now. It's unclear that the public service announcements featuring four former presidents have had much impact on vaccine confidence, and may in fact have led some to become even more resistant. Only 20% of Republicans report being more likely to get vaccinated if former President Donald Trump strongly urged them to do so. Dr. Anthony Fauci, the Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health and Chief Medical Advisor to the President, is seen by some to be a partisan figure, and messages delivered by Dr. Fauci could strengthen resistance among Republicans. Celebrities and sports figures appear to have minimal impact on building vaccine confidence. Other community organizations—from unions to faith communities to immigrant rights organizations—may have a role in reaching specific demographics.

## 2. The right message

Delivering the right message begins with meeting people where they are, showing that you care, listening to them, acknowledging their concerns, answering their questions, and making it personal. Conversations about vaccine confidence are as much about <u>emotion</u> as they are about facts. Only after caring trust has been established, and with someone's permission, can you begin to offer them information.

The messages that resonate best focus on the benefits of COVID vaccination and personal experiences with COVID. Tens of thousands of people were vaccinated in clinical trials, and hundreds of millions of people have since been vaccinated around the world. COVID vaccination is one of the best ways we can protect ourselves and our families. While no vaccine is perfect, the COVID vaccines are among the best with respect to vaccine effectiveness. The COVID vaccines are almost 100% effective in preventing hospitalization and death from COVID. When you're infected with SARS-CoV-2, billions of virus particles replicate throughout your body, which we know can cause long-term harm. Patients who suffer from post-acute sequelae SARS-CoV-2 infection (or PASC, also known as long COVID) experience long-term symptoms and disability. Even patients whose initial SARS-CoV-2 infections were mild may develop PASC. Meanwhile

COVID vaccines teach the immune system to respond to infection and then quickly get broken down by the body and disappear. Our COVID vaccines are based on <u>decades of scientific research</u>. The vaccines were approved quickly because the emergency demanded that the <u>government cut red tape</u>. The FDA cut no corners when it established rigorous standards to guide the clinical development of these vaccines and made the deliberations of its independent, external advisory council public. The <u>vast majority of doctors</u> who've been offered the COVID vaccine have gotten vaccinated. COVID vaccinations are our best path out of the pandemic. Getting vaccinated now is a personal investment in getting back to normal life. You deserve a COVID vaccine. Getting vaccinated will help free you from government restrictions.

Americans don't want to be told what to do. They don't want to be made to feel ignorant. They don't want to feel judged. And they may not change their minds right away. It takes time to build vaccine confidence.

## 3. The right audience

We're most likely to be successful in building vaccine confidence among those who currently say they want to "wait and see," the moveable middle. Communities of color and younger Americans, who are more likely to report they'll "wait and see," seem more persuadable, while Republicans, rural Americans, and essential workers, who are more likely to report that they will only get vaccinated if required or will definitely not get vaccinated, will be less persuadable.

## **H.** The Anti-vaccine Industry

Even as we try to reach out to communities with the right messengers and right messages to build vaccine confidence, we also need to address the proliferation of misinformation about COVID and COVID vaccines in the mainstream media and online. Even relatively low-level exposure to online misinformation can significantly reduce vaccine-seeking.

It's low-hanging fruit to deplatform the biggest amplifiers of anti-vaccine misinformation, their organizations, and those they fund. The Center for Countering Digital Hate has identified twelve repeat offenders who are responsible for 65% of COVID vaccine misinformation online: Joseph Mercola, Robert F. Kennedy, Jr., Ty and Charlene Bollinger, Sherri Tenpenny, Rizza Islam, Rashid Buttar, Erin Elizabeth, Sayer Ji, Kelly Brogan, Christiane Northrup, Ben Tapper, and Kevin Jenkins. Their organizations include the Children's Health Defense, the Informed Consent Action Network (ICAN), the National Vaccine Information Center (NVIC), the Organic Consumers Association (OCA), and the Millions Against Medical Mandates. Many make money marketing books, DVDs, and courses about vaccines or sell dietary supplements and false cures as alternatives to vaccines. In short, they stand to profit from the dangerous misinformation they are spreading.

Facebook, Twitter, and Google have policies to prevent amplification of vaccine misinformation, but their enforcement of those policies is woefully inadequate. They <u>fail to act on 95% of the misinformation reported</u> to them. The social media platforms could also adopt a <u>two strikes rule</u>: a warning after a first misinformation post, and deplatforming after the second.

Meanwhile, <u>Russian intelligence agencies</u> are orchestrating their own disinformation campaigns to discredit Western vaccines, amplifying anxieties about vaccine side-effects and effectiveness. Russia and China are seeking to sell their vaccines abroad and to use their vaccine supply as tools of health diplomacy.

## II. What is the projected trajectory for pandemic recovery in the United States?

I think of pandemic recovery in four phases: ending the emergency, relaxing mitigation measures, getting to herd immunity, and long-term control.

## A. Ending the emergency

We remain in the emergency phase as we enter a fourth surge driven by decreased adherence to mitigation measures, travel, and the spread of the <u>more infectious and more virulent B.1.1.7</u> <u>variant</u> first detected in the UK. We currently have <u>over 65 thousand new cases</u> and <u>almost 700 deaths per day</u> from COVID.

To end the emergency, we have to vaccinate the highest-risk persons who are most likely to develop severe COVID, most likely to be hospitalized, and most likely to die. That means vaccinating older adults and people with chronic medical conditions. There are 53 million Americans over the age of 65 and 110 million with chronic medical conditions in the U.S. 79% of those over age 65 have now had at least one dose of COVID vaccine, and 61% are fully vaccinated, and that's a tremendous public health success. As older Americans have gotten vaccinated, we've seen hospitalizations decline sharply in that group. However, we do not know what proportion of people with chronic medical conditions have been vaccinated, and this is an important blindspot.

Some have suggested that we should continue mitigation measures until hospitalizations and deaths from COVID are on par with those from influenza. Averaged over a year, influenza causes 55-140 deaths per day. The seven-day moving average of COVID deaths in the U.S. is currently 663 deaths per day. COVID remains five to twelve times as fatal as the flu.

We must also pay special attention to the hardest-hit, most vulnerable communities, including communities of color, rural communities, and high-risk workplaces like meatpacking and food

processing plants and prisons. Black, Hispanic, and Indigenous Americans are two to three times more likely to be hospitalized with COVID and to die from COVID. Meatpacking and food processing plants and correctional facilities are major employers in many rural towns across the country. An outbreak in one of these facilities doesn't just affect the people working (or incarcerated) there. It can be devastating to the entire community. These rural communities also don't have the same health care capacity to cope with a spike in cases as do many urban centers.

Notably, the B.1.1.7 variant is causing more severe disease in younger adults, and we're seeing more adults in their thirties, forties, and fifties hospitalized for severe COVID due to B.1.1.7. For example, the Michigan Health and Hospital Association found that hospitalizations increased by 633% among adults in their thirties and by 800% for adults in their forties over the course of March, and those are groups that have lower vaccination rates. We must pay close attention to hospitalization rates and vaccination coverage among these younger adults as we weigh when to relax mitigation measures.

In Israel, the B.1.1.7 variant is dominant, as it is now in the U.S. Even as Israel was among the first and most successful to vaccinate its citizens, the country experienced a <u>surge</u> in COVID cases. With the arrival of vaccines, lockdown-weary Israelis lifted other mitigation measures. As we're now seeing in Michigan, younger people started filling hospital beds. We cannot end the emergency phase of the pandemic by <u>relying only on vaccination</u> without risking another surge in cases, hospitalizations, and deaths. Mask-wearing and some restrictions on indoor business remain necessary.

### **B.** Relaxing mitigation measures

We can declare an end to the emergency and *safely* relax mitigation measures once we're on the other side of our fourth surge; the rate of new cases, hospitalizations, and deaths has been suppressed; *and* we've achieved high levels of vaccine coverage among persons over age 65 and persons with chronic medical conditions, who are highest risk for severe COVID disease, hospitalization and death.

Lifting mitigation measures too soon is like taking your foot off the brake before putting the car into park. With the emergence of more infectious variants (e.g. B.1.1.7, B.1.526), the virus is hitting the gas at the same time. Vaccination is like a parking brake: it works well once a car is in park, but not nearly as well when you're racing down a highway.

In Michigan, where <u>58%</u> of 65-74 year-olds, <u>59%</u> of people over 75, and <u>25%</u> overall have been fully vaccinated, hospitalizations are increasing. <u>About 40% of new cases</u> in Michigan are thought to be due to the more infectious and virulent B.1.1.7 variant first identified in the UK.

Fewer people are wearing <u>masks</u>. The state has <u>lifted or loosened</u> many of its restrictions on indoor business.

It does not make sense to surge vaccine supply to Michigan right now because the state has enough vaccine supply but not enough distribution capacity. Furthermore, it's important to remember that vaccination does not have instantaneous impact. It takes 14 days after two doses of Pfizer and Moderna vaccine and 14-28 days after one dose of Johnson and Johnson vaccine to be "fully immunized." COVID has a median incubation period of 4-5 days. So even if a large proportion of Michigan residents are vaccinated now in the middle of their surge, the impact of vaccine-induced immunity won't be seen until more than a month from now, which doesn't help people who are being infected right now. The measures that will help curb the surge are the non-pharmaceutical interventions that take effect instantly: masking, sticking to household bubbles, socializing outdoors, and not gathering indoors. Furthermore, vaccines work best at a population-level. Eventually, as more and more of the population is vaccinated, there will be protection against transmission and a future surge, we won't be as dependent on non-pharmaceutical interventions, and that's when we can *safely* relax mitigation measures.

Real-world evidence has shown that the Pfizer and Moderna vaccines are highly effective in preventing infection, but they are not perfect. The evidence to date shows that there remains a risk, especially so long as community transmission rates remain high. We measure effectiveness as a percent risk reduction, so when the baseline risk is very high, even a significant reduction in risk will not completely eliminate all risk. Although relatively rare, we are seeing reinfections among fully vaccinated persons. Think of vaccines like a raincoat and umbrella. They'll keep you dry in a thunderstorm, but not in a hurricane. With community transmission of SARS-CoV-2 as high as it is right now, we're still in a COVID hurricane. This is why the CDC is counseling fully vaccinated people to avoid crowds and wear masks in public or when around unvaccinated persons at high risk for severe COVID.

We are in a race between vaccination, viral transmission, and the variants, and in the meantime, we need to continue with mitigation measures. These mitigation measures don't need to continue forever. There is an end in sight. Although we'll be able to *safely* relax most mitigation measures before too long, masks may be with us for at least a little while longer.

## C. Getting to herd immunity

Herd immunity is when so many people are immune to the virus, it has no place to go. We don't yet know what proportion of the population we'll need to vaccinate to reach herd immunity because this is highly dependent on how infectious the virus is, and on the emergence of more infectious variants, which is a moving target. The more infectious the virus, the higher the threshold to reach herd immunity. Finally, we don't know how long immunity after vaccination will last. Currently, our best estimate is that we'll reach herd immunity to SARS-CoV-2 when approximately 75-85% of the population is immune.

We also don't know how much vaccination will prevent infection and transmission. The clinical trials were designed only to assess whether the vaccines prevent serious illness, hospitalization, and death, and, to be clear, by that measure, the Pfizer, Moderna, and Johnson & Johnson vaccines were all 100% effective in clinical trials. Preliminary data suggests that vaccination will reduce transmission significantly but not completely. Real-world evidence has shown that the Pfizer and Moderna vaccines are 80% effective against infection fourteen days after the first dose of vaccine but prior to the second dose, and 90% protective against infection fourteen days after the second dose (pretty close to sterilizing immunity). We don't yet have analogous data for the Johnson and Johnson vaccine, which received emergency use authorization from the FDA more recently. The Prevent COVID U Study will yield more definitive data on whether mRNA COVID vaccines prevent transmission and by how much. Researchers will be enrolling twelve thousand students at twenty universities nationwide in this study. Half will receive the Moderna vaccine at the start of the study, and half will be vaccinated four months later, at the end of the study in July. Scientists will measure infection and transmission in both groups and their close contacts. If infection and transmission are only partially reduced, then you'd need a higher level of vaccination coverage to reach herd immunity.

We aren't yet vaccinating children under the age of 16. Children account for about a quarter of the U.S. population, so to get to herd immunity, we'll have to vaccinate kids. In addition, COVID is not a benign disease in all children. About 2% of children who get COVID are hospitalized, and almost three hundred kids have died from COVID in the U.S. Furthermore, even children with mild or symptomless cases of COVID have experienced multiple inflammatory syndrome in children (MIS-C), including gastrointestinal symptoms and cardiac dysfunction. We also don't know the long-term impacts of mild SARS-CoV-2 infections in children (or adults). We anticipate having data on the safety and effectiveness of the COVID vaccines in children 12 and up this summer and to begin vaccinating that age group by late summer.

Pfizer recently announced that its phase 3 clinical trial among <u>children ages 12 to 15</u> in the U.S. found the vaccine was safe and 100% effective in preventing infection. <u>Pfizer has requested</u> <u>emergency use authorization</u> for its vaccine to be used in children as young as age 12. Pfizer is

now testing its vaccine in children ages 6 months to 11 years. We expect trial results by the end of 2021. Moderna is testing its vaccine among <u>adolescents 12 to 17</u> and <u>children 6 months and 11 years</u> in two separate clinical trials. Meanwhile, Johnson and Johnson is enrolling <u>adolescents 12 to 17</u> in a phase 2 trial.

We anticipate vaccination of children 12 and up will begin in July or August, before the start of the next school year. Younger children will likely be vaccinated starting in late 2021 or in early 2022.

## **D. COVID credentials to reopen safely**

We are likely facing a prolonged interim period, when we can safely lift mitigation measures because the most at-risk have been shielded by vaccination, but before we've reached herd immunity. This means that even once restrictions are lifted, we're unlikely to get back to business-as-usual right away. Businesses have a legal and ethical obligation to ensure a safe environment for their customers and workers. People need to feel safe traveling, going to the gym, or going out to eat. While some may not need that assurance, many do.

While COVID credentials may not be mandated by the government, the private sector is forging ahead. The purpose of COVID credentials, what some mislabel COVID passports, is to demonstrate that when individuals engage in certain activities—for example, returning to college campuses or attending live sporting events—they pose minimal infectious risk to others. COVID credentials help provide that assurance and are an important tool to help reopen the economy.

COVID credentials are already here. They may take the form of a COVID test result and/or COVID vaccination status. During the pandemic, many public and private institutions have been screening people for COVID symptoms, conducting temperature checks, and testing people before entry. State health departments already require proof of other vaccinations to attend K-12 schools and colleges and universities and to work in healthcare. What is new is the range of public and private venues where COVID credentials may be requested and the proportion of the population being asked to produce them.

The ethics of public health dictate that "the least restrictive alternative" should be used. What that least restrictive alternative looks like may not be the same for everyone. It's important that we create a pathway for people to opt out of vaccination while minimizing the infectious risk to others. In lieu of providing proof of COVID vaccination status, individuals could be required to undergo COVID testing or to wear a mask. There is a precedent for this approach. In <a href="New York State">New York</a> State, for example, where I practice medicine, healthcare providers are required to be vaccinated against influenza every year *or* to wear a surgical face mask for the duration of flu season while

at work. People should not be denied jobs, services, or an education because they can't or won't get vaccinated, so long as they are compliant with alternatives like masking or testing.

Former FDA Commissioner Dr. Scott Gottlieb has likened COVID credentials to an <u>EZ pass</u>. You can present COVID credentials showing that you're fully vaccinated or have recently tested negative for COVID in the same way that you can speed through the EZ pass lane. But if you don't want to present COVID credentials, you can still stop and get screened and tested, much as you might stop and pay in cash at a toll both.

The current administration has stated that it does not have plans to issue COVID credentials or to require COVID credentials. However, there is a need for the federal government to help coordinate, standardize, and regulate COVID credentialing efforts to ensure accessibility, standardization, reliability, interoperability, individual privacy, system security, and fraud prevention. COVID credentials should not create or reinforce health disparities.

COVID credential systems consist of a digital record of someone's COVID test result and/or COVID vaccination status and an app or website that allows for downloading of that data to a smartphone or for printing. COVID credentialing systems must be free and open source, so that they can be adapted as needed for local use. COVID credentials must be accessible digitally and in paper form so that people without <a href="mailto:smartphone access">smartphone access</a> can still use them. There must also be clear legal restrictions on state powers and its use of COVID credential data. COVID credentials should not, for example, be accessible for use by federal, state, or local law enforcement or the Department of Homeland Security.

There are additional issues when considering the use of COVID credentials for international travel. There are precedents for vaccination requirements for travel, as with yellow fever vaccination. Countries like Israel, the UK, and the United States are far ahead the rest of the world in vaccinating their citizens. The COVID vaccines are new, and not all vaccines have been authorized for use in every country. For example, the Oxford-AstraZeneca, which is being used in much of the world, has not yet been granted emergency use authorization by the FDA in the U.S. Some vaccines may be more protective against the B.1.351 variant first identified in South Africa, the P.1 variant first identified in Brazil, and other variants, and so vaccines that are appropriate in some countries may not be appropriate in others. China has said it would allow foreigners to enter the country only if they have received a Chinese COVID vaccine. The Chinese Sinovac vaccine appears significantly less effective compared to those authorized for use here in the U.S. There needs to be global agreement on which COVID credentials, including which vaccinations, would be accepted. As with domestic COVID credentials, alternatives to pre-travel vaccination should also be offered, such as pre-travel testing, quarantine upon arrival, and post-travel vaccination. Low- and middle-income countries are at the back of the line in securing vaccine supply and are far behind in vaccination rollout. COVID credentials that allow

citizens of high income countries to travel freely but restrict the movement of persons from lowand middle-income countries would <u>exacerbate inequities</u> and limit access to work, financial, educational, and personal opportunities.

### E. The role of COVID vaccination mandates

It is important to distinguish COVID credentials from COVID vaccination mandates. COVID credentials may take the form of a COVID test result and/or COVID vaccination status documenting that someone poses minimal infectious risk to others. A strict vaccination mandate requires that someone be vaccinated and does not allow for reasonable alternatives.

Many of us in the public health community are concerned that vaccination mandates could backfire, especially this early in our COVID vaccine rollout efforts. The history of the anti-vaccination movement is rooted in the late 1800s, when <u>smallpox vaccination mandates</u> were punitive and targeted the poor. We must not repeat the mistakes of the past. Vaccination mandates for childcare, school, and college attendance have been shown to <u>increase vaccine uptake</u>, but these requirements should be flexible. If we impose strict COVID vaccination mandates, people who might eventually have come around to getting vaccinated might become actively resistant, and this resistance could reduce uptake of all vaccinations.

Vaccination mandates should only be considered after everyone who wants to get vaccinated has access; federal, state, and local governments have done the hard work of building confidence in the vaccines and ensuring equity in distribution and access; federal, state, and local governments have addressed financial and logistical barriers to accessing vaccination; we observe a significant drop in vaccine-seeking by unvaccinated individuals; the FDA issues <u>full approval for a COVID vaccine</u>, not just emergency use authorization; and the federal government establishes a fund like the <u>Smallpox Vaccine Injury Compensation Program</u> to compensate people who have serious adverse reactions attributable to COVID vaccination. The <u>military</u> as well as <u>state and local health preparedness programs</u> offer smallpox vaccination to service members, some civilian workers, and designated emergency responders who might be on the frontlines of a bioterrorist attack.

As demand for vaccination drops, more infectious and virulent SARS-CoV-2 variants spread, and economic pressures continue to mount, the question of whether to impose COVID vaccination mandates will become more urgent. Vaccine certificates and mandates could be effective with the 7% of Americans who report they'll only get vaccinated if required and, if enforced, at least some of the 13% who say they will definitely not get vaccinated.

<u>States</u> have the authority to require vaccination for <u>school attendance</u> and <u>employment in healthcare</u>. It is unclear whether the <u>federal government</u> has the authority to mandate

vaccination, but under the Commerce Clause of the U.S. Constitution and the Public Health Service Act, the U.S. Department of Health and Human Services has the authority to implement isolation and quarantine measures to prevent the spread of infectious diseases between states. In December, the <a href="Equal Employment Opportunity Commission">Equal Employment Opportunity Commission</a> ruled that employers could make COVID vaccination mandatory for their workers, subject to reasonable accommodation requests under the American Disabilities Act and Section 504 of the Rehabilitation Act. Vaccine mandates may be subject to exemptions on the basis of disability or religious objection.

## F. Long-term control of SARS-CoV-2 in the United States

Most scientists believe that <u>SARS-CoV-2</u> is here to stay and that the virus will become endemic, circulating at some level in many countries for years to come. Elimination of the virus requires high and sustained vaccination coverage to achieve herd immunity, and it's unclear whether and how quickly we in the United States will get there. Currently, <u>13%</u> of adults report that they would definitely not get vaccinated, and <u>7%</u> say they would only get vaccinated if required, which means that we're right on the edge of being able to reach the 75-85% vaccination coverage likely needed to reach herd immunity. To maintain elimination, we'll also likely need to implement restrictions around travel, including requirements that travelers produce documentation of vaccination or a negative test.

Once the vast majority of people in the U.S. who want to be vaccinated have been vaccinated (adults by late summer 2021, adolescents by winter 2021, younger children in 2022), the COVID vaccine will increasingly be seen as a childhood, old age, and traveler's vaccination. Newborns, persons with waning immunity (the elderly and immunocompromised persons), vaccine skeptical persons, and travelers from overseas will then make up the vast majority of susceptible persons in this country. Given that most of those currently reporting that they definitely will not get vaccinated also <u>cluster geographically</u>, it is highly likely that there will remain pockets of susceptibility where outbreaks will occur periodically and seed wider transmission.

It may not be enough to fully vaccinate 75-85% of the population once. We don't know how long vaccine-induced immunity will last. It may be that we have enough long-term immunity that symptoms are mild upon reinfection, along the lines of the common cold. We don't know how the virus will continue to mutate and evolve. Reinfections will be more likely the more the virus mutates to evade our immune response to prior infection or the vaccines. It's likely that there will be much more viral heterogeneity in the early years after the virus has jumped into humans and that the virus will stabilize over time. We're already observing convergent evolution. But we don't yet know whether we'll need one-time revaccination for protection against emerging mutant variants or whether we'll need an updated vaccine every couple years.

So long as the virus is allowed to spread anywhere in the world and it will continue to mutate, more variants will emerge—some more infectious (spreading more easily from person to person), some more virulent (causing more severe disease), and some more resistant to our immune responses to natural infection and vaccination. The Pfizer, Moderna, and Johnson & Johnson vaccines remain protective against hospitalization and death due to infection with B.1.1.7, B.1.351 and P.1, but we have seen that <u>higher neutralizing antibody levels</u> are necessary to protect against these variants. The NIH and pharmaceutical companies are studying boosters using current vaccines as well as second-generation vaccines against variants.

## 1. What's the long-term role of COVID testing?

COVID is here to stay. We'll continue to need COVID testing for both diagnostic and screening purposes, particularly since a significant proportion of the population may not opt seek vaccination. Over the past year, we have learned that people who have pre-symptomatic or asymptomatic SARS-CoV-2 infection contribute significantly to the spread of the virus. Last month, the FDA approved two relatively inexpensive at-home, over-the-counter SARS-CoV-2 tests: the Quidel QuickVue At-Home OTC COVID-19 test and the Abbott BinaxNOW Antigen Self Test. These tests have been approved for serial screening—twice over two or three days 24-36 hours apart—of asymptomatic persons for SARS-CoV-2 infection. These tests will allow schools, workplaces, and other public and private spaces to quickly and cheaply screen for asymptomatic carriers of infection. These are not diagnostic tests to be used in patient care. However, pooled saliva PCR testing, may be cheaper and may better suited for most K-12 school environments and many workplaces.

#### 2. We need to scale up genomic surveillance for SARS-CoV-2.

The only way to know how the SARS-CoV-2 virus is mutating and evolving is to dramatically scale up genomic surveillance. The CDC has contracted with universities and Quest, LabCorp, Illumina, and Helix to scale up genomic testing capacity. Although we've increased the volume of genomic testing from under four thousand tests per week to over seven thousand tests per week since January 2020, this is not nearly enough. We should be sequencing at least 5% of SARS-CoV-2 infections to detect a new variant causing 0.1-1% of the nation's COVID cases. This currently amounts to about twenty-three thousand tests per week. We need to be detecting and characterizing new variants when they're still relatively rare and we have time to prepare and take action. In this we are not a world leader. The U.S. ranks behind more than thirty countries—including Rwanda, Equatorial Guinea, Thailand, and Vietnam—in reporting genomic sequencing data. The American Rescue Plan Act includes new funding to support American genomic surveillance efforts, but that funding isn't flowing fast enough and coordination of efforts and data across academic medical centers, commercial labs, hospitals, and health departments has been challenging. Furthermore, we need real-time data. The CDC is publicly

reporting its genomic surveillance data <u>only every two weeks</u>, and there's a lag between when outside labs perform genomic testing and when they report the results to the CDC. We're essentially functioning with month-old data.

### 3. We need better COVID treatments.

We need to develop more drugs to prevent severe COVID and to treat COVID, including post-acute sequelae of SARS-CoV-2 infection (PASC, or "long COVID"). These <u>drugs</u> need to be affordable and deliverable at scale. People will be getting sick and hospitalized from COVID for years to come. We need better tools at our disposal. Some promising candidates include <u>colchicine</u>, <u>inhaled interferon</u>, and <u>fluvoxamine</u>. Operation Warp Speed helped overcome market failures and spur the development and testing of multiple new COVID vaccines. We need a similar effort for COVID treatments.

## 4. Caring for COVID survivors

We are only beginning to recognize and understand post-acute sequelae of SARS-CoV-2 Infection (PASC), also known as "long COVID." It's estimated that <u>about a third</u> of patients who recover from COVID will develop PASC, even if their initial infections were asymptomatic or mildly symptomatic. <u>Fatigue</u>, <u>headache</u>, <u>respiratory</u>, <u>cognitive</u>, <u>psychiatric</u>, <u>and gastrointestinal symptoms</u> are common (see also <u>here</u> and <u>here</u>). Many have difficulty working. Some may be permanently disabled. COVID survivors will have ongoing healthcare and rehabilitation needs.

## 5. We need to strengthen our public health infrastructure.

The CDC, state, and local health departments have been chronically underfunded. Since the 2008-09 recession, we've lost <u>over fifty thousand</u> public health workers across the country. Some experts have estimated that we currently have a <u>deficit of 250,000 public health workers</u> to meet the needs on the ground. President Biden's America Rescue Plan calls for a public health jobs program: 100,000 community health workers, contact tracers, and public health nurses to help fight the pandemic. But we need more than a <u>surge</u> in workforce for the duration of the pandemic. We need a professional public health corps, not quick patchwork fixes when emergencies strike.

We also need to strengthen public health bioinformatics systems to better track data and potential public health threats in real time. We need to have the capacity to integrate clinical, epidemiologic, and laboratory data. So we'll need better systems to manage vaccine operations: tracking who's been vaccinated and who needs vaccination, registering patients, scheduling appointments, reaching out to the community, and managing staff and supply chains. We need to

be upgrading our public health infrastructure for the long-term so we're better prepared to cope with future public health crises.

We also need to acknowledge that new infections are emerging with greater frequency—something that's being driven by climate change, environmental degradation, globalization, and overpopulation—in other words anything that brings people in closer contact with wildlife habitats resulting in virus spillover. This means that in our new normal post-COVID, we need to better insulate ourselves against the next COVID.

We need to do a better job of pandemic-proofing especially high-risk settings like <u>meatpacking</u>, <u>food processing</u>, and <u>prisons</u>. We need to improve access to screening and testing, improve ventilation, and ensure adequate supply and availability of personal protective equipment in these settings. These measures will not only prevent transmission of SARS-CoV-2, but also of other infectious pathogens. Meatpacking and food processing plants and prisons are major employers in many rural towns across the country. An outbreak in one of these facilities doesn't just affect the people working (or incarcerated) there, but can be devastating to the entire community. Rural communities have less health system capacity to cope with outbreaks, so it's even more essential to prevent outbreaks from occurring there in the first place.

## G. Long-term control of SARS-CoV-2 globally

As long as SARS-CoV-2 continues to spread from person to person anywhere in the world, it will continue to mutate and evolve. New mutant variants may be more infectious (spreading more easily from person to person), some more virulent (causing more severe disease), more virulent (causing more severe disease), or could evade our immune responses to natural infection or vaccines. As this pandemic has shown us, the emergence of a new virus halfway around the world poses a very real and present danger to all of us. We must contribute to global vaccine supply, but we should be thinking even bigger. Former President George W. Bush understood that the AIDS pandemic was not only a threat to public health, but also a threat to economic and political stability. He launched the President's Emergency Fund for AIDS Relief (PEPFAR), which is the largest commitment by any nation to address a single disease in history. We need a PEPFAR for global COVID vaccination, providing not only vaccine supply, but also managing vaccine logistics and distribution. It is in the interest of American public health, the American economy, American diplomacy, and American national security that we contribute to global COVID vaccination efforts.