Dear Partner,

HHS Office of Intergovernmental and External Affairs COVID-19 update for March 8, 2021:

Highlights from Friday and Monday's White House COVID-19 Response Team briefings:

Andy Slavitt

• Vaccine Administration Updates: On Saturday, a new daily record of 2.9 million vaccine doses were administered; on average, we are vaccinating 2.2 million Americans per day. To date, nearly 55% of people age 65+ have received at least 1 shot, 9.4% of the population is vaccinated; and altogether we have administered 92.1 million shots – more than any country in the world.

Dr. Walensky

- Case Updates: 7-day average of 59,000 cases per day and 2,000 deaths per day. Cases and deaths are still too high and have plateaued for more than a week. When you are at that level of viral activity in a plateau, it almost invariably means that you are at risk for another spike (many places in Europe have seen this). Asking to double down on prevention measures—we have seen it before when prevention measures like mask mandates are rolled back, cases go up.
- New Initial Guidance for Fully Vaccinated People: Fully vaccinated is defined as two weeks after the 2nd dose of the Pfizer/Moderna vaccine or two weeks after a single dose of the Johnson & Johnson vaccine. There is still a small risk that vaccinated people could still be infected with mild or asymptomatic disease and potentially transmit the virus to others who are not vaccinated. This is an ongoing area of research and the guidance will be updated regularly. The guidance must balance the risk to people who are fully vaccinated, the risk to those who have not yet received a vaccine, and the impact on the larger community transmission, with the benefits of resuming everyday activities. Highlights from the guidance include:
- Fully vaccinated people can:
- Visit with other fully vaccinated people indoors, no masks or distancing
- Visit with unvaccinated people from a single household, if low risk, indoors, no masks, and no distancing
- Refrain from quarantine and testing following a known COVID exposure if asymptomatic
- For now, fully vaccinated people should continue to:
- Take precautions in public like wearing a well-fitted mask and physical distancing
- Wear masks, practice physical distancing, and adhere to other prevention measures when
 visiting with unvaccinated people who are at increased risk for severe COVID-19 disease or who
 have an unvaccinated household member who is at increased risk for severe COVID-19 disease
- Wear masks, maintain physical distance, and practice other prevention measures when visiting with unvaccinated people from multiple households

- Avoid medium- and large-sized in-person gatherings
- Get tested if experiencing COVID-19 symptoms
- Follow guidance issued by individual employers
- Follow CDC and health department travel requirements and recommendations
- At this time the CDC is not adjusting current guidance on travel.
- MMWR on the Importance of Prevention Strategies: An MMWR released on Friday (3/5), found that increases in both daily cases and death rates slowed significantly within 20 days of mask mandates being in place; and increases in daily death rates and cases grew more quickly between 40-80 days of restaurants being allowed to resume on-premises dining. Additional information is included below.

Dr. Fauci

- Addressing Viral Variants: The best methods to address viral variants include vaccination and public health measures. An <u>article</u> in JAMA by John P. Moore addresses these issues.
- Investigational Therapeutics for COVID-19: One type of investigational therapy is direct-acting antivirals. This strategy has been successful in the past to treat other infections such as HIV. We are in the beginning of the phase of looking in a strategic way for direct-acting antivirals, which are going to be used to prevent people from progressing in their disease, mainly keeping them out of the need for hospitalization. To learn more about this and other therapeutics for COVID-19, NIH hosted an SARS-CoV2 Antiviral Therapeutics Summit looking at the state of therapeutic gaps in the field and a number of public-private partnerships in this area.

Dr. Nunez-Smith

- **Update on Case Rates by Race and Ethnicity:** Latinos continue to bear more than their fair share of COVID cases and Black people continue to bear more than their fair share of deaths. The share of vaccinations is significantly lower for Latino and non-Hispanic Black individuals relative to their share of the general population. The same is true for Asian individuals.
- Vaccination Data by Race and Ethnicity: The Administration only has race and ethnicity data for 53% of individuals who have received their first dose of a COVID-19 vaccine and this varies widely among states. We do not have good data on access to the vaccines from individuals, providers or states. There is still room for improvement.
- Vaccine Confidence: Some communities are less inclined to trust the vaccines and we must meet people where they are. The Administration is implementing a comprehensive national public education campaign, hosting roundtables, building relationships with trusted messengers, and working to build the vaccination process towards justice.
- New Vaccination Sites: The Administration has opened or expanded more than 580 federally supported sites and announced two new FEMA supported high volume community vaccination centers, one in Atlanta, Georgia and another in Cleveland, Ohio. The new sites bring the total to 18 FEMA supported sites across seven states with the ability to administer more than 61,000 shots per day. These sites have been designed with key equity oriented features including targeted geographic eligibility and extended weekend hours. Among the Federal Retail

Pharmacy Program sites, one-third are placed in communities with higher scores on the CDC social vulnerability index and in the Federal Community Health Centers Partnership Program, the first 250 centers have been onboarded and provide services for large numbers of public housing residences, people of color, and individuals with limited English proficiency.

Funding

Advancing Health Literacy to Enhance Equitable Community Responses to COVID-19: As part of President Biden's National Strategy for the COVID-19 Response and Pandemic Preparedness today, the Administration is announcing an effort to invest \$250 million to encourage COVID-19 safety and vaccination among underserved populations. The U.S. Department of Health and Human Services (HHS) Office of Minority Health (OMH) will offer the funding as health literacy grants to localities, who will partner with community-based organizations, to reach racial and ethnic minority, rural and other vulnerable populations. The new initiative – Advancing Health Literacy to Enhance Equitable Community Responses to COVID-19 — is expected to fund approximately 30 projects in urban communities and 43 projects in rural communities for two years. Cities, counties, parishes or other similar subdivisions may apply for the funding.

Vaccine Updates

How Fully Vaccinated People Can Visit Safely with Others: Today, the CDC issued its first set of recommendations on activities that people who are fully vaccinated against COVID-19 can safely resume. The new guidance—which is based on the latest science — includes recommendations for how and when a fully vaccinated individual can visit with other people who are fully vaccinated and with other people who are not vaccinated. This guidance represents a first step toward returning to everyday activities in our communities. CDC will update these recommendations as more people are vaccinated, rates of COVID-19 in the community change, and additional scientific evidence becomes available. CDC has released resources to help people make informed decisions when they are fully vaccinated.

Key Things to Know about the COVID-19 Pandemic: CDC updated their information on key things to know about the COVID-19 pandemic. Studies show that COVID-19 vaccines are effective at keeping you from getting COVID-19. Experts also think that getting a COVID-19 vaccine may help keep you from getting seriously ill even if you do get COVID-19. COVID-19 vaccination is an important tool to help us get back to normal. View information about COVID-19 and vaccines.

What to Expect at Your Vaccine Appointment: Because COVID-19 is a new disease with new vaccines, you may have questions about what happens before, during, and after your appointment to get vaccinated. These tips will help you know what to expect when you get vaccinated, what information your provider will give you, and resources you can use to monitor your health after you are vaccinated.

Possible Vaccine Side Effects: COVID-19 vaccination will help protect you from getting COVID-19. You may have some <u>side effects</u>, which are normal signs that your body is building protection. These side effects may affect your ability to do daily activities, but they should go away in a few days. Some people have no side effects.

Workplace Vaccination Program: Making <u>COVID-19 vaccination part of your workplace wellness</u> program offers many benefits to you and your employees. To keep your workplace healthy, consider offering free, on-site COVID-19 vaccination at your business locations.

Vaccine Information for Specific Groups: Although the vaccine supply is currently limited, CDC is working toward making vaccines widely available for everyone at no cost. Learn more about <u>specific populations</u> such as essential workers, healthcare personnel, and more.

Vaccinations for Teachers and Childcare Workers: On March 2nd, HHS issued a directive that all states immediately make <u>eligible teachers</u>, <u>school staff</u>, <u>and childcare workers for COVID-19 vaccination</u> across all vaccination providers. Additionally, pharmacy locations that are part of CDC's Federal Retail Pharmacy Program are now giving priority to school staff and child care workers for COVID-19 vaccination during the month of March. In addition to existing state and local COVID-19 vaccination sites, teachers and staff in pre-Kindergarten to grade 12 (pre-K–12 schools) and childcare workers will be able to sign up for an appointment at more than 9,000 participating pharmacy locations nationwide.

Vaccinations for Long-Term Care Facility Residents: CDC recommends <u>residents of long-term care</u> <u>facilities</u> (LTCF) be included among those offered the first supply of COVID-19 vaccines. Making sure LTCF residents can receive COVID-19 vaccination as soon as vaccines are available will help save the lives of those who are most at risk of dying from COVID-19.

Customizable Content for School Leadership and Childcare Program Directors to Encourage Vaccination: School district leadership, K-12 administrators, and directors of childcare programs can use customizable materials to encourage COVID-19 vaccination. You can customize the text to make it appropriate for your school district or childcare program.

ASL Interpreters for Federal Vaccine Centers: FEMA continues working to ensure anyone who wants a vaccine can get one. <u>To ensure accessibility</u> for the deaf and hard-of-hearing community, American Sign Language (ASL) interpreters are available on demand at all federally supported community vaccination centers. The service is available every day of the week during each center's hours of operation.

Things You Need to Know about COVID-19: CDC updated their page on things you need to know about COVID-19. Find information on getting a vaccine, what to do if you're sick, and more. Learn more about how to best protect yourself and others.

Testing

Adaptive Biotechnologies T-Detect COVID Test: The FDA issued an emergency use authorization (EUA) for the <u>T-Detect COVID Test developed by Adaptive Biotechnologies</u>. The T-Detect COVID Test is a next generation sequencing based (NGS) test to aid in identifying individuals with an adaptive T cell immune response to SARS-CoV-2, indicating recent or prior infection with SARS-CoV-2.

First Molecular Non-Prescription, At-Home Test: The FDA issued an emergency use authorization (EUA) for the <u>Cue COVID-19 Test for Home and Over The Counter (OTC) Use</u>. The product is a molecular nucleic acid amplification test (NAAT) that is intended to detect genetic material from SARS-CoV-2 virus present in the nostrils. The test is the first molecular test authorized for at-home use without a prescription.

Guidance for Industry on Glass Vials and Stoppers: On March 4, the FDA <u>issued guidance</u> on reporting and implementation recommendations to drug application holders about some common manufacturing changes to container closure system components that use glass vials and stoppers for approved sterile drug and biological products given by injection or other non-oral routes. The FDA recognizes that injectable products may need some changes to packaging components due to supply chain issues.

Serology Surveillance: CDC is working with state, local, territorial, academic, and commercial partners to better understand COVID-19 in the United States. <u>Serology tests</u> look for antibodies in blood. If antibodies are found, that means there has been a previous infection. Antibodies are proteins that can fight off infections.

Adapting a Contact Tracing Program: Contact tracing, including case and source investigation, is a key component of controlling transmission of infectious diseases. Contact tracing for the current COVID-19 pandemic, however, is distinct from that undertaken for other diseases (e.g., Ebola, HIV, TB) because in nearly all countries the number of cases and contacts has outpaced the capacity of the public health system to quickly notify and quarantine all contacts and isolate all cases.

Treatment

Use of Tocilizumab for the Treatment of COVID-19: Tocilizumab is a recombinant humanized antiinterleukin (IL)-6 receptor monoclonal antibody approved by the Food and Drug Administration (FDA)
for the treatment of certain rheumatologic disorders and cytokine release syndrome induced by
chimeric antigen receptor T cell (CAR-T cell) therapy. It is hypothesized that modulating the levels of
proinflammatory IL-6 or its effects may reduce the duration and/or severity of COVID-19 illness. To date,
no IL-6 inhibitor is FDA-approved or authorized for the treatment of COVID-19. On February 3, 2021, the
Panel issued a <u>statement on the use of tocilizumab for the treatment of COVID-19</u>. The statement
included recommendations based on a preliminary report of results from Randomized, Embedded,
Multifactorial Adaptive Platform Trial for Community-Acquired Pneumonia (REMAP-CAP). Since the
statement was issued, the Panel has reviewed the published results of REMAP-CAP and the preliminary
results of the open-label, pragmatic Randomized Evaluation of COVID-19 Therapy (RECOVERY) trial,
released on February 11, 2021.

Information for Specific Populations

Pregnant People: Although the overall risk of severe illness is low, <u>pregnant people</u> are at an increased risk for severe illness from COVID-19 when compared to non-pregnant people. Find information about pregnancy and COVID-19. View the <u>toolkit for pregnancy people and new parents</u>.

People Living in Prisons and Jails: Living in prisons and jails puts you at higher risk for getting COVID-19 because: it may be hard to stay at least 6 feet away (2 arm lengths) from other people, there may not be enough space to keep people with COVID-19 away from others, you may be sharing space with someone who has the virus and does not know it, because they are not coughing or showing other symptoms, staff or visitors may have the virus and not know it.

People at High Risk for Severe Illness: Adults of any age with certain underlying medical conditions are at <u>increased risk for severe illness from the virus that causes COVID-19</u>. COVID-19 vaccines are recommended for and can be administered to most people with underlying medical conditions.

Mental Health Training and Technical Assistance Related to COVID-19: SAMHSA updated their <u>training</u> and technical assistance resource related to COVID-19. Find resources for Mental Health Technology Transfer Center, serious mental illness advisers, and more.

Disaster Sheltering of Household Pets, Service Animals, and Support Animals: This information is provided to assist emergency planners who may need to consider local conditions, statutory authorities, resources, agreements, and other critical factors to form the final plan for disaster sheltering of household pets, service animals, and support animals during the pandemic. Emergency managers will face many challenges pertaining to both the pandemic and a disaster that requires evacuation and sheltering. There are no perfect solutions, and all strategies could contain an element of risk for SARS-CoV-2 transmission in people.

Staffing Resources: CDC is using a multi-pronged approach to help enhance and complement the efforts of state, tribal, local, and territorial staff. This initiative will help health departments with the <u>staffing resources</u> they need for their programs to get and keep America open.

Research

Mask Mandates and Allowing On-Premises Restaurant Dining: CDC released an MMWR on association of state-issued mask mandates and allowing on-premises restaurant dining with country-level COVID-19 cases and death growth rates in the US. Mandating masks was associated with a decrease in daily COVID-19 case and death growth rates within 20 days of implementation. Allowing on-premises restaurant dining was associated with an increase in daily COVID-19 case growth rates 41–100 days after implementation and an increase in daily death growth rates 61–100 days after implementation. Mask mandates and restricting any on-premises dining at restaurants can help limit community transmission of COVID-19 and reduce case and death growth rates. These findings can inform public policies to reduce community spread of COVID-19.

Body Mass Index and Risk for COVID-19 Related Hospitalization: CDC released an MMWR on hospitalization, intensive care unit admission, invasive mechanical ventilation, and death risk related to body mass index. Among 148,494 U.S. adults with COVID-19, a nonlinear relationship was found between body mass index (BMI) and COVID-19 severity, with lowest risks at BMIs near the threshold between healthy weight and overweight in most instances, then increasing with higher BMI. Overweight and obesity were risk factors for invasive mechanical ventilation. Obesity was a risk factor for hospitalization and death, particularly among adults aged <65 years. These findings highlight clinical and public health implications of higher BMIs, including the need for intensive management of COVID-19—associated illness, continued vaccine prioritization and masking, and policies to support healthy behaviors.

Third Trial of Blood Clotting Treatments for COVID-19: The National Institutes of Health has launched the last of three Phase 3 clinical trials to evaluate the safety and effectiveness of blood thinners to prevent life-threatening blood clots in adults diagnosed with COVID-19. The first patient in the trial was enrolled on February 15. Part of the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) initiative, the trial explores the use of Eliquis® (apixaban 2.5 mg), a blood thinner, or anticoagulant, donated by Bristol Myers Squibb/Pfizer, in patients who have been discharged from the hospital following a diagnosis of moderate-to-severe COVID-19, the disease caused by SARS-CoV-2.

COVID-19 Science Update: CDC released their <u>79th edition of their COVID-19 science update</u>. This update includes peer reviewed and non-peer reviewed findings on all things COVID-19.

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