Dear Partner,

HHS Office of Intergovernmental and External Affairs COVID-19 update for March 1, 2021:

Updates from the White House COVID-19 Response Team

Highlights from the press briefings on Friday and Monday include:

Janssen's (Johnson & Johnson) Vaccine Update

- Janssen (Johnson & Johnson) Vaccine Authorization: Over the weekend, the FDA issued an EUA for the Janssen's COVID-19 vaccine and yesterday CDC's ACIP endorsed the safety and efficacy of the vaccine. The Johnson & Johnson vaccine is a single dose vaccine that is easier to store and transport because it does not need to be kept in a freezer.
- Janssen's Vaccine Efficacy: Janssen's 66% vaccine efficacy is measured across three continents (US, South America and South Africa) with varying degrees of infection dynamics as well as varying strains, variants, or lineages. Janssen's data showed 72% efficacy against moderate to severe critical infection in the United States; 85% efficacy against severe COVID-19 globally including the US. This vaccine's efficacy measured very well against the variants in circulation and no hospitalizations or deaths were recorded in any of the studies.
- Allocation of Johnson & Johnson Vaccine: Distribution of 3.9 million doses of the Johnson & Johnson vaccine began yesterday and will arrive as early as tomorrow. The allocation will remain the same as for the Pfizer and Moderna vaccine based on population. Johnson & Johnson expects to delivery approximately 16 million additional doses by the end of March.
- Benefits of Multiple Authorized Vaccines: All of the authorized vaccines will be distributed across states and jurisdictions, and across all of our federal vaccination channels but not every vaccination site will have every vaccine. Different types of vaccines brings more options and flexibilities to providers. For example the Johnson & Johnson vaccine can allow for expanded availability of vaccine in some temporary clinics and pop up mobile sites and locations that do not have cold storage capability. Additionally, some people may have preference for a single dose vaccine, especially if they do not want to or can't return for a second dose. Overall, increased vaccine supply provides greater opportunity for more people to get vaccinated and we encourage all Americans to get the first vaccine that is available to you when it is your turn.
- **CDC Vaccine Recommendations:** CDC is not recommending one vaccine over another, and encourages people to get whatever vaccine is available to them. Each of the vaccines authorized are safe and effective as deemed by the rigorous scientific standards established by FDA.

Andy Slavitt

Partnership with Business Community to Reduce Spread and Encourage Vaccinations: On
Friday, the Administration announced a new partnership with America's leading business
organizations to enlist the full force of the private sector to defeat COVID with a call to action.
Partnerships will be formed with the Chamber of Commerce, leaders of the Black, Latino, and
Asian business community, the National Association of Manufacturers, and the Business
Roundtable to promote three critical efforts across the country:

- 1) require masking and social distancing to protect workers, customers, and others on their premises
- 2) reduce barriers to vaccinations—make a plan to get employees vaccinated and provide incentives like PTO
- 3) communicate with customers and educate the public of the benefits of masking and vaccinations
- **Expanding Vaccination Sites:** On Friday, the Administration announced two new federal vaccination sites in North Carolina and Illinois. In total, the Administration has supported the establishment or expansion of 441 community vaccination centers in over 37 states, territories, and DC.

Dr. Walensky

- Case Trends: Cases, hospitalizations and deaths have been going down, but recent data suggests that these declines may be stalking and leveling off at still a very high number. Now is not the time to relax restrictions.
- Variants Update: The B117 (UK) variants is thought to be about 40-50% more transmissible and could become the predominant variant of COVID by mid-March. New emerging variants have come out in NY (B1526) and CA (B1427) that also appear to spread more easily.

Dr. Fauci

- Vaccines for Variants: One way to address variants is to make a version of the vaccine that actually addresses the particular variant in question. Moderna is beginning clinical trials (both naïve and previously vaccinated adults) to provide booster shots for the variant from South Africa.
- **Vaccinate Now:** Most importantly, a virus can't mutate if it doesn't spread and replicate so it is important to get vaccinated as soon as it is your turn.

Vaccine Updates:

Over 58.7 Million Shots Administered in 39 Days: The Administration is ahead of their target of 100 million shots in 100 days, even with the setbacks faced during the severe winter storms. Additional data points include:

- We have doubled the pace of administering shots in 6 weeks.
- We've increased vaccine distribution to states by nearly 70%.
- Over 15% of the population have received 1 or more dose; 7.7% of the population have received 2 doses of the vaccine.
- Nearly 60% of people over age 75 now have received at least one shot. That was 14% six weeks ago.

- Close to 50% of people over age 65 have received at least one shot. That was 8% six weeks ago. That is important because people over age 65 account for 80% of COVID deaths.
- 75% of people in long-term care facilities have received their first dose, and those cases are at the lowest level since reporting began in May.

Janssen COVID-19 Vaccine: The FDA issued an emergency use authorization (EUA) for the third vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The EUA allows the Janssen COVID-19 Vaccine to be distributed in the U.S for use in individuals 18 years of age and older. The FDA has determined that the Janssen COVID-19 Vaccine has met the statutory criteria for issuance of an EUA. The totality of the available data provides clear evidence that the Janssen COVID-19 Vaccine may be effective in preventing COVID-19.

ACIP Recommendations for the Janssen Vaccine: Rochelle P. Walensky, MD, MPH, signed the <u>Advisory Committee on Immunization Practices' (ACIP) recommendation to use Janssen's COVID-19 vaccine</u> in people 18 and older. This official CDC recommendation — which follows Saturday's FDA decision to authorize emergency use of the vaccine — is another milestone toward an end to the pandemic.

Federally-Supported Community Vaccination Centers: The Biden-Harris Administration has launched a comprehensive, whole-of-government effort to get more people vaccinated—by increasing vaccine supply, increasing vaccinators, and increasing the number of places to get vaccinated. As part of this strategy, the Administration is <u>supporting and launching federally-supported community vaccination centers nationwide</u> in places people know and trust: community centers, schools, and stadiums. To date, the Administration has announced 18 federally-established community vaccination centers, with the ability to administer a total of 61,000 shots per day at full capacity. For these sites, the federal government is directly working with state and local partners from start to finish, to help select the location for, staff, and operate these sites.

How COVID-19 Vaccines Get to You: Vaccine manufacturers; the federal government; state, local, and territorial jurisdictions; and other partners are working to make sure <u>safe and effective vaccines are getting to you as quickly as possible</u>. This page will help you understand the key steps in this important process and how CDC is tracking vaccine distribution, delivery, and administration throughout the United States.

Community Based Organizations: Soon the communities you serve will have access to vaccines to help protect against COVID-19. CDC has designed a toolkit to help <u>community-based organizations</u> (CBOs) educate communities about this important new prevention tool.

Vaccine Recommendations for People with Allergies: If you have had a severe <u>allergic reaction</u> or an immediate allergic reaction—even if it was not severe—to any ingredient in an mRNA COVID-19 vaccine, you should not get either of the currently available mRNA COVID-19 vaccines. CDC recommends that people with a history of severe allergic reactions not related to vaccines or injectable medications—such as food, pet, venom, environmental, or latex allergies—get vaccinated. People with a history of allergies to oral medications or a family history of severe allergic reactions may also get vaccinated. View information what to do if you have an <u>allergic reaction to the COVID-19 vaccine</u>.

Vaccine Information for Older Adults: CDC updated their resources for <u>older adults</u>. Risk for severe illness with COVID-19 increases with age, with older adults at highest risk. Certain medical conditions

can also increase risk for severe illness. People at increased risk, and those who live or visit with them, need to take precautions to protect themselves from getting COVID-19. View <u>vaccine information for older adults</u>.

Testing and Treatment

Quidel QuickVue At-Home COVID-19 Test: The FDA issued an emergency use authorization (EUA) for the Quidel QuickVue At-Home COVID-19 Test, another antigen test where certain individuals can rapidly collect and test their sample at home, without needing to send a sample to a laboratory for analysis. The QuickVue At-Home COVID-19 Test is authorized for prescription home use with self-collected anterior nasal (nares) swabs from individuals ages 14 and older or individuals ages 8 and older with swabs collected by an adult. The test is authorized for individuals suspected of COVID-19 by their healthcare provider within the first six days of symptom onset.

Independent Evaluation of SARS-CoV-2 Antibody Test Performance: Serology tests play an important role in assessing the immune response to a previous SARS-CoV-2 infection, the virus that causes COVID-19. Evaluation of serology tests with well-characterized clinical samples (serum or plasma) is critical to determine test performance. In collaboration with National Cancer Institute (NCI), Centers for Disease Control and Prevention (CDC), and Biomedical Advanced Research and Development Authority (BARDA), the Food and Drug Administration (FDA) has developed a comprehensive dataset to compare the performance characteristics of different serological tests that were independently evaluated using well-characterized sample panels of positive and negative specimens for SARS-CoV-2 antibodies. This dataset is available for public use.

Specimen Collection: CDC has updated their <u>guidance for specimen collection</u>. CDC added new guidance on capillary finger stick specimen collection.

Supply of New COVID-19 Therapeutic Treatment: The Biden Administration announced that it has secured a supply of a recently authorized COVID-19 therapeutic treatment. The HHS and the DOD collaborated to purchase 100,000 treatment courses of a second therapeutic treatment from Eli Lilly and Company. This treatment uses two monoclonal antibodies, bamlanivimab and etesevimab, to treat non-hospitalized, high-risk COVID-19 patients.

Contact Tracing

Contact Tracing Steps: CDC updated their page with infographics on <u>steps for contact tracing</u>. Find out what you can expect to happen during contact tracing. View <u>contact tracing communications toolkit</u>.

Notification of Exposure: A successful <u>notification of exposure</u> allows for an exchange of information with the person (contact) exposed to COVID-19 and offers an opportunity to answer questions and provide referrals for testing, medical evaluation and other necessary support services. The goals of this interaction are to inform the person that they may have been exposed to COVID-19, assess their medical condition and other risk factors, and gather information for continued monitoring and support.

<u>Information for Specific Populations</u>

Infection Prevention and Control Priorities: CDC updated their <u>COVID-19 overview and infection</u> prevention and control priorities in non-US healthcare settings. This overview was created for

healthcare workers in non-US healthcare settings and government officials working on the Coronavirus Disease 2019 (COVID-19) response. The information in this document draws from the Centers for Disease Control and Prevention (CDC) and World Health Organization (WHO) guidance documents and Infection Prevention and Control (IPC) priorities for the response to COVID-19 in healthcare settings and includes information that can be used in non-US contexts.

COVID-19 in Children & Teens: CDC updated their information for parents and caregivers about <u>COVID-19 in children and teens</u>. While fewer children have been sick with COVID-19 compared to adults, children can be infected with the virus that causes COVID-19, can get sick from COVID-19, and can spread the virus that causes COVID-19 to others. Children, like adults, who have COVID-19 but have no symptoms ("asymptomatic") can still spread the virus to others.

Pregnancy and Breastfeeding: CDC updated their resource page for <u>people who are pregnant or breastfeeding</u>. Based on what we know at this time, pregnant people are at an increased risk for severe illness from COVID-19 and death, compared to non-pregnant people. Additionally, pregnant people with COVID-19 might be at increased risk for other adverse outcomes, such as preterm birth (delivering the baby earlier than 37 weeks).

Ventilation in Schools and Child Care Programs: Ventilation is one component of maintaining healthy environments, and is an important COVID-19 prevention strategy for <u>schools and child care programs</u>. Wearing a well-fitting, multi-layer mask helps prevent virus particles from entering the air or being breathed in by the person wearing a mask. Good ventilation is another step that can reduce the number of virus particles in the air. Along with other preventive actions, ventilation can reduce the likelihood of spreading disease.

Businesses and Employers: CDC updated their guidance for <u>businesses and employers</u>. Businesses and employers can play a key role in preventing and slowing the spread of SARS-CoV-2 within the workplace.

Multifamily Housing: <u>Multifamily housing</u> (e.g., apartments, condominiums, townhouses, duplexes, and quadruplexes) pose a challenge during the COVID-19 pandemic due to potential for increased risk of exposure for residents and staff. The following guidance is provided to help owners, administrators, and operators of multifamily housing work together with residents, staff, and public health officials to create a safe living environment and prevent the spread of COVID-19.

Funeral and Burial Services FAQs for Tribes: At the request of tribal leaders, federal partners developed this Coronavirus Disease 2019 (COVID-19) fact sheet to help guide <u>tribes with funeral and burial health</u> <u>and safety</u>. This fact sheet also helps tribes plan for an increase in deaths within a community. Tribes and families practice unique traditions and refer to death in varying ways as they honor those who have passed on. We share this public health guidance with sincere respect for those traditions.

Migration and Border Health: CDC updated their guidance and resources on preventing and controlling COVID-19 infections in globally mobile populations.

Community-Related Exposures: The CDC updated their guidance on <u>management of contacts of people</u> <u>with COVID-19</u>. Public health recommendations have been updated to accommodate new scientific evidence, evolving epidemiology, and the need to simplify risk assessment.

People Experiencing Unsheltered Homelessness: CDC updated their interim guidance <u>on people experiencing unsheltered homelessness</u>. People experiencing unsheltered homelessness (those sleeping outside or in places not meant for human habitation) may be at risk for infection when there is community spread of COVID-19. This interim guidance is intended to support response to COVID-19 by local and state health departments, homelessness service systems, housing authorities, emergency planners, healthcare facilities, and homeless outreach services. CDC also updated their <u>frequently asked questions for homeless shelters</u>.

CMS Updates

Removing Barriers to COVID-19 Diagnostic Testing and COVID-19 Vaccines: In accordance with the Executive Order President Biden signed on January 21, 2021, the Centers for Medicare & Medicaid Services (CMS), together with the Department of Labor and the Department of the Treasury, (collectively, the Departments) issued new <u>guidance</u> today <u>removing barriers to COVID-19 diagnostic testing and vaccinations</u> and strengthening requirements that plans and issuers cover diagnostic testing without cost sharing. This guidance makes clear that private group health plans and issuers generally cannot use medical screening criteria to deny coverage for COVID-19 diagnostic tests for individuals with health coverage who are asymptomatic, and who have no known or suspected exposure to COVID-19. Such testing must be covered without cost sharing, prior authorization, or other medical management requirements imposed by the plan or issuer.

Additional Navigator Funding to Support Marketplace Enrollment: CMS is making approximately \$2.3 million in additional funding available to current Navigator grantees in Federally-facilitated Marketplace (FFM) states to support the outreach, education and enrollment efforts around the 2021 Special Enrollment Period (SEP) that runs through May 15, 2021. The 30 organizations eligible to receive these funds work across 28 FFM states to help consumers access financial assistance through HealthCare.gov, complete their applications, and enroll in coverage through the Marketplace, Medicaid, or the Children's Health Insurance Program (CHIP). CMS Acting Deputy Administrator Jeff Wu noted "During a public health emergency, it is critical for consumers to have access to assistance with finding affordable, comprehensive health coverage that best fits their needs."

Research

Reduction in COVID-19 Patients Requiring Mechanical Ventilation: CDC released an MMWR on the reduction in COIVD-19 patients requiring mechanical ventilation following implementation of a national COVID-19 vaccination program in Israel. By February 2021, 2-dose vaccination coverage was 84% among persons aged ≥70 years and 10% among those aged <50 years. The ratio of COVID-19 patients aged ≥70 years requiring mechanical ventilation to those aged <50 years declined 67% from October–December 2020 to February 2021. These findings provide preliminary evidence of the effectiveness of vaccines in preventing severe cases of COVID-19 at the national level in Israel.

COVID-19 Science Update: CDC released their 78th edition of COVID-19 science update.

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