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Introduction:

We mark a grim anniversary this month, one year into a global pandemic that has caused unimaginable suffering and loss. But, we also are seeing the beginning of the end of this pandemic. Infections are down nearly 70% since the peak of early January and, while we must keep wearing masks, keep social distancing, and keep being careful, data from the past two months suggests that we are turning a corner in our fight against this deadly pandemic.

As a nation, our 7-day case average has plateaued and now rests in the same realm as our mid-summer peak, at just under 60,000 new cases per day. Accordingly, 7-day average COVID-related hospitalizations and deaths have decreased by 66% and 77%, respectively, from the winter peak. These data reflect a combination of the rebound after a surge of cases during the holidays, increased national attention to masking and social distancing, seasonal trends of the virus, a high level of population immunity, and vaccination efforts ramping up across the country.

More than 2.1 million shots are now administered every day. Since December, more than 87 million doses of vaccine have become vaccinations, and many more are coming. While we began our vaccination efforts in late December with an average of 228,000 doses administered per day, the most recent data indicates that we are consistently administering more than 2 million doses per day, with expected supply over the next weeks and months likely to increase this number to more than 3 million doses per day.

Vaccine appointments across the country are scarce and the supply remains low in comparison to overwhelming demand, but we expect vaccine supply to far outstrip demand over the next month

or so. The Biden Administration <u>recently announced</u> that all willing American adults will be able to receive a COVID-19 vaccine by the end of May. This is an extraordinary achievement on what has been a treacherous road. There is important work ahead.

First, we must ramp up vaccine supply and distribution efforts across the country. Though cases, deaths, and hospitalizations remain at their lowest levels in months, we have entered a plateau phase that, with the addition of viral variants, poses the potential for further spikes which could outpace vaccine distribution. The longer the SARS-CoV-2 virus circulates in our nation and our world, the more it will mutate. These mutations are likely to become more dominant over time, and pose serious risks of rapidly increasing the number of infections, hospitalizations, and deaths. It is imperative that our full efforts and attention be focused on vaccinating as many Americans as we can as quickly as possible over the coming weeks to avoid yet another spike in COVID-19 cases, hospitalizations, and deaths. Vaccinating all willing American adults within the timeframe presented by the Biden Administration mandates that we immediately shift our focus to expand infrastructure for vaccine distribution and administration. Meeting the Biden Administration goal will require a vaccination rate of 3 million doses per day through the end of May.

Simultaneously, we must ensure that we substantially improve the equitable distribution of vaccines. There need not be any tradeoff between speed and equity. The United States right now does not have the ability for equitable and widespread distribution of vaccines to reach all American adults by the end of May -- even with expected increases in supply. Local and federal leaders must continue to establish more high-volume mass vaccination sites across the country, and specifically in communities of color that have been hit hardest by the pandemic. Where people

cannot get to a vaccination site, we must bring the vaccine to them, with credible community voices addressing concerns. And we must continue to systematically collect and publicly report data on vaccinations by race, ethnicity, age, and income to ensure Americans who need the vaccinations the most are getting them.

Global Vaccination Strategy

Second, there must be an aggressive global vaccination strategy to match a rapid, equitable distribution model in the United States. Our federal government has both a domestic and global responsibility to ensure the adequate supply of COVID-19 vaccine. Infectious diseases do not respect national boundaries, so we must establish a global vaccination strategy that aims to protect people around the world as an important mechanism to protect the global economy, global public health, and in the process, the economy and health of the American people. A failure to equitably distribute global vaccines may result in large financial and human costs. Consider the facts: studies suggest an inequitable vaccination distribution may ultimately result in almost twice the number of deaths. Failure to employ an aggressive global strategy will allow more virulent and dangerous strains to emerge. So far, our vaccine candidates have withstood the emerging strains, maintaining their efficacy against these new variants of concerns. But over time, it is possible that strains will emerge that threaten the efficacy of our current vaccines and essentially, render them useless. We will then have to reformulate, retest, and redistribute vaccines and revaccinate our population. Unfortunately, our current global strategy is neither rapid nor equitable. At the current global rate of 6.39 million doses administered per day, it will take nearly 5 years to reach widespread global immunity (assuming 75% protection with a 2-dose vaccine). An estimated 90% of people in lowincome countries will not be vaccinated in 2021. Our government has taken initial steps to advance

an equitable global vaccination process, including rejoining the World Health Organization and engaging with COVAX (COVID-19 Vaccines Global Access).

Our government has committed \$4 billion to COVAX, with a potential new pledge of \$2 billion through 2021 and 2022. But while these contributions are substantial, this budget falls far short of global need. Current estimates suggest that COVAX will secure close to 2 billion doses by the end of the year, with at least 1.3 billion of those directed toward 92 low- and middle-income nations, covering at least 20% of the participating population. However, this is nowhere near the 60 - 70% (or more) of vaccinated individuals required to achieve global immunity. To meet this goal, COVAX should instead aim to procure and distribute enough doses to fully vaccinate four to five billion people by the end of this year. Scaling up its targets to this level will require substantial additional funding but money is not the biggest barrier. Limited supplies and manufacturing capacity will make ramping up global vaccine production a complex endeavor; it will require more than just relaxing intellectual property rights or technology transfers. Rather, it will require global collaboration and solidarity to address challenges at every step of the supply chain. We will need to work closely with our allies and take an aggressive approach. It can be done, but we will need U.S. leadership.

Testing

In addition to vaccinations, testing must remain a central part of our strategy against COVID-19. As vaccinations increase, it is important to remember that we should not expect to vaccinate 100% of Americans. We know some Americans will forgo vaccinations despite their safety and efficacy.

And that means we will continue to see some outbreaks of COVID for the foreseeable future. For example, more than 90% of American children are vaccinated against measles but the outbreak of over 1,000 measles cases in NY in 2019 highlights what can happen when a disease finds its way to those who are not vaccinated. In recognition of imperfect vaccine coverage and the imperfect protection offered by vaccines, it is important that we build a sustainable viral surveillance and testing system that can help prevent COVID-19 clusters and ensure that we can all engage in things we value, such as getting back to school and work, getting together in large groups, and living our lives in ways that are safe.

While the United States has substantially ramped up its COVID-19 testing infrastructure over the past year, we are still heavily reliant on slow and expensive PCR testing. The accuracy of these tests offers value as we try to curb the pandemic, but in a world of low transmission and high vaccine coverage these tests are not the proper tool for surveillance. Instead, we should be looking to cheap, rapid antigen tests that could be self-administered, cheap, and widely available. We could imagine using these before large gatherings. They could be used during the school year, especially next year when many younger children will not yet be vaccinated. They could be used for high-risk endeavors, such as when a community comes together to watch a play in a packed auditorium. These tests ideally would be available over-the-counter and would make it very easy to continue the simple, low-level testing needed in a world that is post-pandemic but where COVID-19 has not been fully eradicated.

Many companies have developed antigen tests that cost less than five dollars and can return results in less than 15 minutes. The UK has been a leader in distributing and leveraging these tests, and

have relied largely on Innova Medical Group, a California company who ships millions of rapid tests a day to Europe but still does not have FDA approval to distribute tests in the United States. The FDA has been slow to approve these cheap, rapid antigen tests primarily due to concerns about accuracy and lack of thorough data, and maintaining the rigor and high standards of FDA approval are important. However, rapid tests serve a different role than PCR tests and should be evaluated accordingly. Accuracy is undoubtedly important for diagnostic tests, particularly ones used by physicians in a clinical setting. But in the midst of a pandemic, these rapid tests have shown enough efficacy that, in combination with their high speed and low cost, would allow them to play a critical role in keeping our economy open and people safe. It would be beneficial for the FDA to work through these regulatory challenges with the recognition that these tests are different from PCR tests, and offer substantial value despite their reduced accuracy.

Congress, in turn, should make investments to ensure that these tests are easily available to Americans and that there is effective messaging on how these tests should be used in the coming months and years. Doing so would be a valuable step in preparing our country for the post-pandemic world.

Therapeutics

Another key element in establishing pandemic resilience is the development of safe and effective therapeutics, in both inpatient and outpatient settings. As we continue into the Fall and next Winter, we can expect to see a rise in cases once more, even as the majority of Americans are vaccinated. We must ensure these infections do not result in hospitalization or death. A few promising

therapeutics appear to lower death rates in the inpatient setting, but investment in developing effective outpatient treatments has been and remains too limited.

So far, in clinical trials, three inpatient therapies have shown clear promise: remdesivir (likely given early in the disease course), dexamethasone (for advanced disease) and most recently, interleukin-6 receptor blockers, which are also likely useful in advanced disease. We still need more inpatient therapies to save our most critically ill patients.

While effective inpatient therapeutics are important and we are making progress here, the therapeutic landscape for early outpatient interventions has been disappointing. If we are able to develop such therapies, we could dramatically lower the impact of COVID on severe illness and prevent hospitalizations. So far, the NIH has recommended monoclonal antibodies as protective therapeutics, but clinical trial data is still lacking and only a few candidates have presented promising preliminary results. The FDA has approved Emergency Use Authorization for select monoclonal antibodies in outpatients: bamlanivimab (developed by Eli Lilly), casirivimab, and imdevimab (both developed by Regeneron). Monoclonal antibodies are potentially important but they must be given as infusions and given early in the disease course before the patient is hospitalized. These logistics have created a strange situation. Despite their development and availability, monoclonal antibodies are largely underutilized. More concerningly, initial studies suggest the South African and Brazilian variants of concern may demonstrate escapability from these monoclonal antibodies, and we do not yet have enough data to determine efficacy against other new variants. Other companies are developing antivirals for mild outpatient cases, including

Merck's MK-4482 and Synairgen's SNG001. However, these drugs are still in the initial phases of clinical trials and we really don't know if they will work.

Members of President Biden's COVID-19 Advisory Board have argued for a three-pronged approach to ending the pandemic, alongside a robust vaccination campaign: 1) improve genomic surveillance 2) develop multivalent vaccines (vaccines which are protective against more than a single strain of the virus) and 3) develop scalable treatment options to mitigate severe cases. This last prong is absolutely crucial to ensuring a stable recovery. Efforts by the NIH's ACTIV program began far too late, and targeted expensive therapies with limited applications. We need a renewed focus by the NIH on practical outpatient therapies (ideally those administered orally) for COVID-19. To achieve this, we must increase funding for research and development, scale up recruitment in clinical trials, and rapidly assess which drugs are safe and effective for use.

Building an Equitable Recovery

As we build robust models of vaccination, testing, and therapeutics in our recovery, equity must be at the center of our strategies. So far, there have been clear disparities we are still working to repair. Investments in our public health infrastructure must be made equitably to build a healthier society, and Congress has an important role to play in funding these investments. A comprehensive national public health system incorporates both disease prevention and health education, incorporating state, local, and federal agencies to promote health, surveil and predict emerging threats, and retain the capacity to respond to emergencies. The United States Public Health system is fragmented across local, state, and federal jurisdictions and consistently underfunded. In 1969, the Federal government contributed almost 50% to total public health expenditures. But, by 2013,

that number had fallen to less than 15%. The Prevention and Public Health Fund, established by the Affordable Care Act and designed to sustain investment in public health at the federal level, remains at 50% of what should have been funded due to the reappropriation of money to other programs.

This consistent underfunding and underinvestment in public health is not without its consequences, consequences too often felt by America's most vulnerable populations. For example, analyses by our research group show a direct correlation between hospitals where Intensive Care Units reached capacity due to a larger number of COVID-19 patients faster, and the social-vulnerability index (SVI). Underinvestment in public health aligns with structural inequalities and has left people in these communities, including communities of color and rural areas, vulnerable to the disparate impact of the pandemic. Additionally, a lack of data infrastructure has led to difficulties in collecting data related to cases and deaths by race early in the pandemic. This issue continues within the vaccine roll-out. As the Biden administration has prioritized, key changes must be made to improve the nation's public health data-collection capacity to allow us to recognize and improve racial disparities in health.

Public health funding must anticipate rather than react to public health emergencies. We saw an increase in funding in 2009 during the H1N1 pandemic, and slight increases in supplementary funding in 2014 and 2016 in response to Zika and Ebola respectively. After these viruses came under control, investments stopped and there has not been continued growth in improving our public health systems.

We have built up our public health infrastructure during the pandemic, and now must continue past the COVID-19 crisis and continue allocating money and resources to public health agencies. Currently, as the vaccine rollout continues, federal and philanthropic efforts are spending money on vaccine education campaigns, and are funding local community-based organizations to increase communication and access. We cannot let these investments stop after the pandemic is over. Giving community-based organizations and local health departments the money and resources to continue to engage their constituencies in public health education will be necessary to reduce the disparities made clear by the pandemic so we emerge from this crisis a healthier, more resilient society.

A New Age of Pandemics

Investment in public health infrastructure is all the more important when we consider that pandemics will start to become recurring events in our lives. As a result of climate change, deforestation, agricultural intensification, and globalization, infectious diseases caused by a pathogen jumping from animal to human are spreading throughout global society and are increasing in probability as a consequence of continued development destroying or diminishing animal habitats. Of all new and emerging human infectious diseases, 75% can be traced to animals, mostly from wildlife.

Additionally, as global travel becomes more pervasive, epidemics are more likely to turn into pandemics. The number of Chinese passengers who traveled by air in 2019 was 7 times higher than in 2003, when the original SARS pandemic hit. World Bank data shows that the global

increase of passengers went from 1.7 billion in 2003 to 4.2 billion in 2018. Thus, it is imperative that we continue to allocate resources to prepare for this future reality.

Conclusion

We are at a critical point in our response to the COVID-19 pandemic. If vaccine supply projections hold and distribution and administration efforts are rapidly increased across the country, we should be able to begin vaccinating the general population by the end of April or early May. If we accomplish this goal with the speed, equity, and efficiency required, we should begin to bring the acute stage of this pandemic to an end by early summer.

While there is much work that remains and we will be combatting this virus for years, important public health restrictions can begin to be eased by late spring into summer. From there, we can begin to build a new normal, that can be even better than where we were before this pandemic struck. All of this is contingent on vaccinating a vast majority of Americans, having an effective testing and surveillance infrastructure that lets us monitor and manage the disease, and applying some common-sense public health measures that will prevent new flare ups.

Congress must allocate for key investments, both nationally and globally, in disease surveillance, stockpiling healthcare supplies, equitably increasing the capacity and resilience of our public health infrastructure, just to name a few. Only then will we emerge from this crisis as an America that is prepared and ready for what the future may bring.