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Introduction

As we enter the fall of 2020, the number of cases of COVID-19 across our nation is starting to grow, a certain degree of fatigue is setting in, and we could be heading into a difficult fall and winter. Unfortunately, more than 200,000 Americans have already died of this disease and many more could die if we are not careful in managing the outbreak. We have to continue to focus our efforts on key public health measures, such as avoiding indoor gatherings, wearing masks, and building up testing and tracing. And we have to focus our attention on protecting lives and livelihoods until a safe and effective vaccine is widely available.

While we all acknowledge that our nation's public health response to COVID-19 has fallen far short of expectations, there is one area where our efforts have been superb. And that is in the effort to identify, test, and scale-up a vaccine for COVID-19. While that effort is hardly finished, we have much to be proud of. But there are very serious challenges ahead in ensuring that these remarkable efforts are not undermined and, ultimately, made less effective. There are three areas that we must focus on to ensure that we turn vaccines into vaccinations – and that we are able to save lives and bring the pandemic under control.

Current Status:

The Administration's COVID-19 vaccine program, known as Operation Warp Speed, is committed to scaling up the production and distribution of a set of vaccines if they receive approval from the Food and Drug Administration. The scientific progress behind the development of the vaccine has been unprecedented. While it generally can take decades (and even in the best of circumstances, years) to build a vaccine, the scientific community has worked effectively and collaboratively

across the globe to launch a series of products into clinical trials. As of September 28, at least 11 vaccine candidates are in Phase III clinical trials, several of which are the candidates identified by OWS. Critically, this initiative has not only invested substantially in the development of vaccine candidates but has directed investments toward manufacturing and distribution. While the approval of a COVID-19 vaccine will certainly mark a turning point in our battle against this virus, it is unlikely to be a silver bullet in ending the pandemic. Should a safe and effective vaccine be approved in the coming months, its success will hinge upon our collective ability to promote its widespread distribution and adoption, turning vaccines into vaccinations. This will undoubtedly be a massive undertaking, and it will require transparent and accessible communication to address vaccine hesitancy, an economic strategy that reduces financial barriers to vaccination, and a comprehensive distribution plan that prioritizes high-risk populations.

Hesitancy and the Need for a Clear Communication Strategy

Many Americans are hesitant about receiving a COVID-19 vaccine and unsure if it will be safe. This concern goes well beyond the baseline vaccine hesitancy present before the pandemic. As the key agency running the evaluation process for vaccine candidates, the Food and Drug Administration is the institution Americans need to be able to trust the most when it comes to assessing if a vaccine is safe. Yet the FDA has made several critical mistakes in this pandemic that have been extremely costly to its credibility and trust with the American people. A fundamental part of reducing vaccine hesitancy will be ensuring that the American people can trust the FDA's decision making.

While several mistakes by the FDA have eroded its credibility with the public, none is worse than the handling of convalescent plasma, which was approved through an Emergency Use Authorization on August 23, 2020, in a highly advertised and widely televised announcement including the president. Some in the scientific community were wary of this approval because there was no randomized-controlled trial, typically the gold standard needed to demonstrate the efficacy of a treatment. A more nuanced view allows us to appreciate the trade-offs: Given the extraordinary circumstances in this pandemic, trying out a new treatment based on preliminary research showing some potential is a reasonable step, as long as there are oversight and follow-up. What made the convalescent plasma EUA so detrimental to our vaccine efforts was the way in which it was announced, and the discredit it brought to the chief of the FDA, Dr. Stephen Hahn. Holding a press conference in which the president announced a miracle treatment (which convalescent plasma is not) and Dr. Hahn backed him up by exaggerating the evidence of its benefits, downplaying the data that failed to show benefit, and dramatically overstating the size of the benefit (in a way that would suggest that either the FDA doesn't understand basic epidemiology or was choosing to mislead the American people) all contributed to most physicians and many Americans assuming that the FDA and its leader were not being straightforward with the American people. That Dr. Hahn then followed up with interviews and tweets suggesting that he did not need to follow the advice of the FDA's scientific advisors and that he was looking to approve the vaccine before the election further eroded his credibility.

The announcement solidified in the public conversation the impression that, increasingly with this administration, politics are taking over trusted, non-partisan scientific institutions – those

institutions that we desperately need to stay free of politics so people can trust that an approved vaccine is becoming available for only one reason: it is scientifically proven to be ready and safe.

At this point in the pandemic, there is a pattern to these announcements. Months ago, we saw the same forces at work when the FDA approved another experimental COVID-19 treatment, hydroxychloroquine, which showed an even worse scientific promise than convalescent plasma but was a favorite of the president. It was approved through an EUA on March 28, 2020, only to be revoked by mid-June.⁵ What happened between March and June is well-known: Hydroxychloroquine was found to be more harmful than helpful, and the president's continued support of the treatment further divided the nation instead of building trust among all Americans. Instead of praising an unproven treatment, the FDA could have used this moment to build a common understanding of how we best use limited evidence in a pandemic and how to weigh the risk of death or prolonged suffering from the virus against the risk of death or prolonged suffering from treatments.

These failures and mishaps surrounding EUAs for treatments are concerning, given that an EUA for a vaccine presents even higher stakes. While we sometimes accept a certain level of potential harm in experimental treatments for those who are severely ill, vaccines are given to *healthy people* and therefore need to have a substantially higher measure of safety and effectiveness. When it comes to intervening with vaccines for the healthy, even a mild risk of harm needs to be weighed carefully.⁶ Let's remember that an EUA for a COVID-19 vaccine would be unprecedented. The FDA has only once before used this process, approving a vaccine for inhaled anthrax that was mostly distributed only to high-risk soldiers and civilians in war zones.⁷

The fact that an EUA has never before been issued for a vaccine intended for broad distribution to the American public is one more reason our approval process must remain anchored in rigorous analysis to validate safety and efficacy – and our leaders must present decisions and steps along the way with scientific accuracy and utmost clarity. There is no room for ambiguity in an agency leader’s commitment to evidence or to admitting what we know and do not know at any point in time. In this pandemic, we cannot afford our scientific institutions to communicate misinformation and publish confusing or misleading guidance due to political pressure (as we have also seen from the CDC and HHS), only to later apologize and try to correct the record. Research on misinformation repeatedly shows that once the seeds of doubt are sown, the damage is done. A confused public is a public feeling out of control, out of trust, and out of tools to assess evidence. It is a public that is open to polarization and that is increasingly unreachable for those who hope to share the latest science and evidence on a pathway to vaccine acceptance.

As a nation today, this is the struggle we will face once we try to turn approved COVID-19 vaccines into vaccinations: A distrusting public wary of anything and everything coming from the government, regardless of political affiliation. While vaccine hesitancy itself has been growing in recent years – as highlighted by the 2019 measles outbreak in New York City and other metropolitan areas⁹ – the problem has taken on new and unseen proportions in recent months. While in May, 72% of American adults indicated that they would be willing to receive a COVID-19 vaccine, that number has dropped substantially to only 51% indicating their willingness in September (polls by Pew Research Center).¹⁰

Recent polls confirm why this is happening: 77% of Americans worry that the vaccine development process is moving too quickly to identify all of the risks of a new vaccine.¹⁰ A STAT poll further reveals the belief that the approval process has been co-opted and is being driven by politics more than science.¹¹ This belief spanned party lines, with 72% of Republicans and 82% of Democrats expressing worries that politics will influence decisions about the approval of a vaccine.

Patterns of increasing hesitancy regarding a COVID-29 vaccine have also persisted across gender, racial and ethnic groups, and levels of education. In September, only 32% of Black Americans indicated in the Pew poll that they would get a COVID-19 vaccine if one were available today, compared with 52% of White Americans.¹⁰ This level of mistrust amongst people of color is unsurprising, considering the long history of structural racism and unethical medical experimentation on this population. Even over the past few months, efforts by the Trump administration to expand testing in retail locations have largely ignored Black neighborhoods.¹² Given the disproportionate impact that COVID-19 has had on Black, Latino, and Indigenous communities, however, it is especially critical that we work to cultivate confidence within these communities.

To address these significant challenges and work towards broad acceptance of a vaccine, we must start today with rebuilding trust within all segments of the American population. A few key steps that can get us there are:

- 1) Transparency.**

People have to trust that the vaccine is developed without cutting corners for political gain.

Ensuring this trust requires an unprecedented level of transparency. While some trial

materials have been made available by companies in recent weeks, there remains a lack of candor on some essential vaccine safety topics. For example, the Astra-Zeneca Phase III trial was recently paused following an unexpected safety event, a normal procedure in clinical trials. Through a transparent explanation of what had occurred and what their investigation had found, Astra-Zeneca and agencies including the FDA could have reassured the public and strengthened confidence by demonstrating that their protocols to evaluate safety were working. Instead, Astra-Zeneca released a brief and veiled statement that acknowledged the pause without providing any information on what had occurred or why.¹³ Though at first, it appeared this was simply an example of waiting to gather complete information before making it public, Astra-Zeneca soon provided more information on the pause to investors on a private call while continuing to withhold this information from the public. Such behavior reinforces concerns that companies and government organizations are hiding safety risks in the interest of profit or political gain.¹⁴ Though Astra-Zeneca is a private company, it has received a large amount of support from the U.S. government and is dependent on the FDA for permission to market and distribute its vaccine. Astra-Zeneca should be far more transparent about these pauses and issues at hand – and the FDA should signal to Astra-Zeneca and all manufacturers that they need to be more forthcoming with side-effects and other concerns that might arise during the trials. This new level of transparency is a critical step we can take today to combat vaccine hesitancy.

2) Value independent experts and allow for a robust scientific debate.

Most members of the public will not be concerned with details such as the intricacies of trial designs and outcomes, but they have come to trust independent scientific experts.

Throughout this pandemic, public health experts and independent scientists have fact-checked research, framed FDA, HHS, and CDC decisions for diverse audiences, and served as trusted voices in the midst of a chaotic response to the pandemic. These experts are key to regaining the public's confidence that the process has not been corrupted. Several pharmaceutical companies recently took positive steps by releasing their designs of the Phase III clinical trials currently underway. Trial design is critical to defining what goals we are aiming for and ensuring that any effect seen in the resulting data is legitimate. Able to review these trial designs, many in the public health community have expressed concern regarding the differences in endpoints between these trials, noting that in some cases they are focused more on whether the vaccines can prevent mild cases of COVID-19 than whether they can prevent the severe and sometimes fatal cases that are of most concern. Drs. Topol and Doshi outlined this problem in a recent New York Times Op-ed, for example, and many others have commented on social media platforms.¹⁵ Physicians from Brigham and Women's Hospital have similarly questioned the criteria the FDA has established for reviewing the trial data.¹⁶ This is a healthy process that does not undermine but rather builds trust: By allowing transparency and outside feedback, the FDA can improve its process and gain trust at the same time. It is crucial now that the FDA engages with this feedback and works to improve the trial designs. Ignoring these experts would further deteriorate trust in the agency.

3) Engage with local community leaders and identify trusted messengers now.

With trust in government voices at a historic low, identifying and engaging community leaders, religious and civil society leaders, and other trusted messengers is essential to combating vaccine hesitancy. To succeed with broad public acceptance of a COVID-19

vaccine, we must not just rebuild trust in the process of vaccine development but also rebuild the strained relationship between governments and the people they serve. We can do so by engaging with community leaders in hearing their concerns, and in offering vaccines as a way to keep their communities safe. This is especially true for communities of color, as fewer than 1 in 5 Black Americans trust the federal government, and the numbers look similar for Latinx and immigrant communities. Lifting up and empowering local voices is a valuable asset to help reassure populations whose personal and learned experiences in healthcare settings have led them to question scientific and medical advice. It is especially critical at a time when minority communities have faced considerably higher rates of COVID-19 infection and mortality than the overall population.

4) Act to stop the spread of misinformation.

The pandemic has radically sharpened our understanding of the tremendous cost to lives and livelihoods of allowing misinformation to spread freely online. Congress can act to increase platform accountability in this crisis, and members of Congress must consider their own role as key communicators who can bring a focus on evidence and accuracy to the public conversation.

Pricing and Payment

While hesitancy and distrust from the American people is perhaps the greatest barrier to widespread COVID-19 vaccine adoption, there are potentially substantial financial barriers as well. A vaccine against COVID-19 will only be effective if a large majority of the United States population gets vaccinated, and therefore every vaccination benefits the public good. As such, we must seek to remove all barriers to vaccination and that includes ensuring that there is no direct cost of COVID-19 vaccination to individuals. This is essential, whether people have health

insurance or not. The U.S. government has indicated broadly that they intend to make the vaccine free for all Americans, but it is imperative that policies and procedures are instituted to ensure that this is the case. Further, it is critical that this information is incorporated into the overall vaccine communications strategy to ensure that Americans are aware that they will not need to pay for a vaccine. According to a recent Pew survey, 32% of those who indicated they did not intend to get vaccinated cited financial barriers as a factor in their reticence.¹⁰ Even among those who indicated they were planning to get vaccinated, one in five said that they would be considerably less likely to follow through if they ended up having to pay out of pocket.

There have already been major steps in guaranteeing that the American people will not have to pay out of pocket for a COVID-19 vaccine. In addition to mandating that insurers cover the costs of COVID-19 testing, the CARES act included language which will require all private insurers to cover the costs of a COVID-19 vaccine within fifteen days of when one is made available.¹⁸ However, our political leaders must make sure that this commitment is true for all Americans and not solely those with private insurance. Medicare does not generally cover drugs approved through the emergency use pathway.¹⁹ This is easily remediable and should be done quickly. We must also not forget the millions of Americans who do not currently have health insurance. Setting aside any debates regarding insurance coverage in this country, a vaccination campaign targeting widespread immunity benefits from maximizing the number of people who receive vaccines. Thus, the American people stand to benefit from removing financial barriers to vaccination for all people who currently reside in the country. Lastly, we must remember that the cost of a vaccine is not the only financial barrier Americans may face in seeking to get vaccinated. If physicians and health systems charge fees for the service of providing a vaccination, that could result in out-of-pocket spending even in a situation where there was no cost for the vaccine itself.

Given that one-third of those who do not plan to get vaccinated are concerned about cost, it is clear that the commitment to removing out-of-pocket costs and the steps taken in the CARES act have not been communicated effectively. Our political and civic leaders must clearly, widely, and repeatedly remind the American people that there will not be out-of-pocket costs associated with a COVID-19 vaccine. If policies cannot be put in place to avoid costs associated with receiving the vaccine and independent of the vaccine itself, then this must be honestly and transparently communicated in order to avoid a situation in which people receive an unexpected bill after getting vaccinated. This would result in the spread of misinformation about vaccine costs, further weakening trust in the government's management of a COVID-19 vaccine. Ideally, though, we will be able to establish policies that can indeed eliminate out-of-pocket spending on COVID-19 vaccinations and spread awareness of this to the American people, removing a formidable barrier to widespread vaccination.

Distribution

A final critical piece in guaranteeing the success of a COVID-19 vaccine is establishing an equitable and transparent distribution strategy. We must focus on first vaccinating the highest risk individuals. Our allocation of COVID-19 testing over the course of the pandemic is a great example of what not to do. It has taken us over 8 months to perform 100 million tests – and testing is substantially easier than vaccinations. Further, testing has been done largely inequitably, ensuring that the wealthy and the well-connected get testing before those who are at highest risk. Our vaccination strategy must be different – and better. Our strategy should ensure that the allocation of vaccinations (as well as other resources) in this pandemic is structured around

maximizing benefit and promoting equity.²⁰ Given the unequal burden of the pandemic borne by minority populations, the goals of maximal benefit and of promoting equity often overlap.

Recently, the National Academy of Medicine (NAM) assembled a committee of U.S. health experts to develop a framework for the equitable distribution of a COVID-19 vaccine. This committee has since released a clear framework for vaccine allocation to guide policymakers and the public health community in determining priorities for vaccination.²¹ The framework works to comprehensively account for the many factors that determine COVID-19 risk by considering health disparities, occupation, living conditions, health status, and local levels of viral spread. The NAM framework puts healthcare workers at the top of their list, followed by individuals with comorbidities and elderly individuals living in congregate living facilities.²² By recognizing and prioritizing groups that are at higher risk, such as incarcerated individuals, the elderly, health care workers, those with underlying health conditions, and more, this framework will hopefully provide the pathway for a vaccine distribution process that has the maximum impact on disease spread and reduces health disparities in our nation that have been exacerbated by this pandemic. Not only has the panel been tasked with determining who to prioritize when it comes to vaccine distribution, but it has also been key in guiding how to transparently communicate these decisions to the broader public. NAM published the preliminary framework early in September for public feedback.

There are, obviously, other critical organizations whose advisory role to the U.S. government is vital, including the Advisory Committee on Immunization Practices (ACIP), a panel that has, in the past, advised the CDC on vaccination priorities. While the ACIP supports the NAM recommendations that healthcare workers should be first priority, followed by essential workers,

those with high-risk comorbidities, and the elderly, the ACIP has yet to formalize their recommendations.

The bottom line is this: There is relatively broad agreement in the public health and scientific community that vaccine distribution should be guided by risk – that those who are at highest risk of getting infected as well as those who are highest risk of suffering complications from COVID-19, should be prioritized first. This is clearly the right approach.

It is essential to get a detailed map from the Administration outlining the plan for vaccine distribution as well as a clear communication strategy of how that will be shared with the American people. This will be critical in ensuring that Americans know when they might expect to be eligible to be vaccinated. An uncoordinated, poorly communicated strategy would not only reduce the population-level benefits of vaccination, but it would breed further mistrust. The creation of a successful distribution strategy for a COVID-19 vaccine will require coordination across multiple government agencies, in which each group has a clear and distinct role. It will rely upon priority recommendations that reflect guidance from the top trusted public health experts, and it must not be swayed or thwarted by political interference.

Conclusion

As expectations grow for an approved vaccine in the coming months, we are preparing to undertake one of the largest and most complex vaccination campaigns in history. Success could help us bring the pandemic under control, allow us to reboot our economy, and enable us to return to our lives. Failure to vaccinate a sufficient fraction of our population could instead bring a false sense of

security, lead to ongoing infections and deaths, and further damage our economy. As preparation for a vaccine continues, there are three main goals we should be targeting.

The first is to ensure the safety and efficacy of the vaccines through careful, complete, apolitical, and highly transparent Phase III trials and scientific review. We cannot afford to vaccinate hundreds of millions of Americans with a vaccine that could cause harm, nor can we afford to grant the public a sense of false confidence from a vaccine with inadequate efficacy, leading to a breakdown of the masking, distancing, and other public health measures that continue to be critical to effectively combatting this pandemic.

Second, we must introduce policies that guarantee that there will be no financial barriers to getting vaccinated. We must make sure that this policy extends to every American, regardless of insurance status.

Lastly, we must establish a distribution plan for an eventual vaccine that recognizes the elevated risks and burdens faced by certain populations and communities and works to avoid previous missteps, and instead ensures an equitable allocation of vaccines.

Hovering above each of these three areas is the need for a comprehensive, clear, and transparent communications strategy. We have brought unprecedented resources and the energy of the U.S. government to get us to where we are. This has been superb work. We must continue by partnering with state and local officials, civil society and religious leaders, and the scientific community to ensure that we make available vaccines that are safe and effective and that we do so in a way that

poses no financial burden to the American people and that maximizes health and well-being for all Americans.

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