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**“Road to Recovery: Ramping Up COVID-19 Vaccines, Testing, and Medical Supply Chain”**

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**Subcommittee on Health of the House Committee on Energy and Commerce**

**Introduction**

Good morning, Chairman Eshoo, Ranking Member Guthrie, and members of the Subcommittee. I am Dr. Luciana Borio and have dedicated my career to biodefense. I am grateful for the opportunity to testify before you today. I have had the privilege of serving the American people across four different administrations. Most recently, I had the honor to serve as a member of the Biden-Harris transition team and the transition COVID-19 advisory board.

In 2019, I left government service and joined In-Q-Tel, a non-for-profit strategic investment firm that tailors innovative technology solutions to support the mission of the U.S. national security community. I am appearing before you today in my personal capacity.

**The COVID-19 Pandemic**

The global situation is dire. We are facing the worst pandemic of respiratory disease in the last 102 years with approximately 103mm cases and 2.23mm deaths globally. The United States has been the worst affected country in the world with more than 26.2mm cases and 441,000 deaths to date. We have experienced several surges since the pandemic started, without ever returning fully to baseline. The most recent surge, which occurred in the aftermath of the winter holidays, was very steep. The numbers of new patients seem to be stabilizing but are pushing hospitals and their staff to their limit.

After several months of the SARS-CoV-2 remaining relatively stable, it is now evolving rapidly, as most RNA viruses do. Several variant strains have emerged in the past few months, notably the B.1.1.7 in the United Kingdom, the B.1.351 in South Africa, and the P.1 in Brazil. These variants have not stayed in the countries where they emerged - they have spread globally. The U.K. variant seems to be highly transmissible and is predicted to become the dominant variant circulating in the United States by March. The South African strain is exceptionally concerning since it evades, at least partially, the antibody-based therapies and diminishes the protective effect of at least some vaccines. The next few months are uncertain; our worst days could be ahead of us.

**Past**

Today, I do not want to dwell too much on the past. The previous administration, in which I served, made many mistakes and individuals in key positions of trust and responsibility let the American people down. Some officials promoted divisiveness instead of safeguarding our collective health. Some were more interested in protecting their turf than building bridges to summon our collective strength. I do not believe there was a single point of failure – there were many failures.

I believe the prior administration’s actions were a significant departure from the imperfect but science-driven response undertaken by the U.S. Government during previous public health emergencies.

However, if we are to do better, we must recognize that many of the Federal biodefense enterprise's shortcomings preceded the most recent administration. Repairing our nation's biodefense enterprise will require reckoning with early missteps and continued deficiencies.

There has been much attention on CDC's diagnostic test kits failures that left us blind to the virus's early spread. This type of technical failure was an accident and could have occurred in any laboratory.

However, it was foolish to think that the CDC, in collaboration with public health laboratories, would be able to meet the nation-wide demand for diagnostic tests during a pandemic. The true failing rests with HHS for not establishing a robust national diagnostic capability (similar to what it did for vaccines and other medical countermeasures) prior to this pandemic or in its early days, in cooperation with private laboratories, to respond with the speed and scale that any pandemic requires.

Furthermore, the lack of a robust, large-scale national genomic surveillance system to monitor viral evolution and spread one year after the pandemic began means we are flying blind with respect to detecting the introduction or emergence of new variants or monitoring their geographic spread. That is inexcusable.

## **Present**

### **Vaccines**

Today, we find ourselves amid the most complex and logistically challenging vaccination campaign ever undertaken in America. In many ways, we are fortunate. For the first time in history, two safe and effective vaccines were developed and authorized for use in less than a year. Additional vaccines are on the horizon. This incredible success can be attributed to three main factors: 1) the decades of investment in biomedical research by the U.S. Government that preceded the pandemic alongside a vibrant and innovative U.S. biopharmaceutical sector, 2) the hundreds of career officials at HHS and DoD who worked around the clock under the supervision of Dr. Moncef Slaoui and the leadership of General Gustave Perna to accelerate development and scale up vaccine production, 3) FDA's Office of Vaccines, under the leadership of Drs. Marion Gruber and Phil Krause, who guided the development of these innovative vaccines in an expedited fashion without compromising the highest scientific standards, and ensuring transparency. As a result, we are the only country in the world that has robust, solid, reliable data in tens of thousands of individuals who participated in randomized clinical trials – the gold standard – for evaluating the safety and efficacy of these now authorized vaccines.

Vaccine distribution was initially left to states, which were inadequately prepared to handle the complex logistics. The new administration has taken important steps to improve vaccine distribution within states. It is examining ways to maximize production of FDA-authorized vaccines to make more doses available sooner, provide direct assistance to states that need it, open up vaccination to more priority groups faster, establish more vaccination sites, increase use of pharmacies and mobile units for vaccinations, and make it easier for states to recruit vaccinators. These steps, done in conjunction with a campaign to counter misinformation and vaccine hesitancy, and a focus on improving vaccine access for "hard to reach" populations, will enhance the nation-wide vaccination program.

Even as these challenges are slowly resolved, new ones emerge. The Federal government is relying on the Defense Production Act to prioritize the allocation of limited supplies to vaccine manufacturers (as well as secondary and tertiary suppliers) under contract with the U.S. Government. This helps, but the

supply chain remains vulnerable. The interruption of any critical component required for making or distributing vaccine doses (and the list is vast, including, for example, raw materials, consumables, manufacturing and fill/finish equipment, personnel, dry ice and cold storage, and needles and syringes) will disrupt the availability and administration of vaccines.

### Variants

The virus variants pose another challenge. Travel restrictions will not solve this because these variants have spread globally and are already here. Travel measures, such as proof of negative testing before entering the U.S. when combined with a period of quarantine upon arrival, may diminish the number of imported cases, but will not stop the spread of variant strains within our borders.

It is essential that we take urgent measures to diminish the spread of this virus because the more spread there is, the greater the opportunity there is for the virus to further mutate and become even more dangerous. If we reduce the number of people getting infected, the chances for virus mutations go down.

To that end, even as we make a push toward a fast and broad vaccination program, we must redouble our efforts to compel the population to mask up and maintain social distancing through a variety of measures, such as restricting social gatherings and encouraging telework where feasible. This virus continues to burn through our country, while many people continue to gather indoors and in large groups and refuse to wear masks or social distance. The fundamental behavioral interventions — masking, social distancing, and avoidance of indoor gatherings — remain the single best tools we possess in the fight against COVID-19, equal in importance to effective vaccines. This requires careful public messaging, so Americans understand the value of both vaccines and behavioral modifications.

Even if not for one's own health, we must do this for our country's economic health. Small businesses across America that are lucky enough to have survived thus far cannot afford another lockdown. If we care about our jobs, we must mask up and heed public health advice.

As an additional measure to reduce the chances that the virus develops more mutations that could evade the immune system, I would encourage the U.S. Food and Drug Administration to rescind the Emergency Use Authorization (EUA) it issued last year for convalescent plasma. We already know that, in aggregate, this therapy does not help patients with COVID-19. But by using it in circumstances where it does not work, we are providing the virus with a roadmap that could help it develop mutations that evade natural and vaccine-induced immune responses even more rapidly.

I am encouraged to see vaccine manufacturers taking steps now to develop novel vaccine candidates that may be needed to effectively protect against the emerging variant strains. Developing and testing candidates is relatively simple when compared to the difficult decisions ahead regarding triggers for large scale manufacturing, given the finite supply of manufacturing materials and capacity, and deployment of newer vaccines on top of an already strained distribution system.

### Therapies

Even with authorized vaccines being distributed, we still desperately need better therapies for COVID-19, especially ones that can be manufactured at scale and easily administered. A few therapies, such as remdesivir and dexamethasone, have been shown in randomized clinical trials to improve the clinical

outcomes for select patients. Dexamethasone was shown in the RECOVERY trial in the U.K. to reduce deaths in patients requiring oxygen and in those requiring invasive mechanical ventilation.

In the U.S., except for the NIH-led ACTT trials, the system for evaluating new or existing drugs has faltered. Lacking a national capability for conducting simple, pragmatic randomized clinical trials, the U.S. had to repurpose existing clinical trial networks originally designed for other diseases. The process has been slow and inefficient. In the meantime, many industry-driven and independent trials with varying degrees of scientific rigor emerged.

In a departure from prior practice, and under intense political pressure, during this pandemic the FDA has issued a series of EUAs based on a product potentially meeting the EUA statutory bar (which is low and designed to give the Agency maximum flexibility) but with little consideration about the impact of the EUAs on patient outcomes. The EUAs for products that had not been properly evaluated in clinical trials nevertheless provided an “FDA-endorsed” treatment option for patients that could have otherwise enrolled in rigorous yet highly efficient clinical trials, that would have provided definitive answers about a given drug, and allowed patient care to be driven not by hope, but by science.

On 1/30, the New York Times [<https://www.nytimes.com/2021/01/30/health/covid-drugs-antivirals.html>] reported that despite the wealth of evidence against hydroxychloroquine and chloroquine for COVID-19, there are still 179 clinical trials with 169,370 patients in which at least some are receiving the drugs. Convalescent plasma has been used in more than 150,000 patients despite recommendations by the NIH that its use should be limited to randomized controlled trials, and now the possibility that its indiscriminate use could add more selective pressure on the virus and hasten the day when vaccines become less effective.

### Diagnostic Tests

The national diagnostic testing capability remains precarious. To date, the focus has been on managing the supply chain, but the challenges are much broader than that. There is a myriad of diagnostic testing technologies available, but we still lack a national diagnostic testing strategy that can help guide clinical and public health practice.

For example, there is little agreement on the preferred and alternative methods for diagnosing or screening an individual suspected of having COVID-19, and ways to link test results to actionable public health measures (e.g., isolation, quarantine, and contact tracing). We still do not know the optimal strategies for deploying testing programs to workplaces or educational settings, or for screening travelers leaving or coming into the United States.

In addition, there is tremendous confusion about the approach FDA is taking to facilitate access to appropriate tests, while ensuring that tests perform to a minimal standard. In my view, FDA has taken a reasonable and flexible approach to regulating diagnostic and screening tests. At the end of the day, FDA needs some data to allow manufacturers to make certain claims about their tests. These data requirements are not onerous and test developers that want to make their tests available to consumers should embrace the responsibility of properly validating them.

The last administration hurt the American public when it declared that FDA did not have the authority to regulate laboratory-developed tests. Once it became clear that developers of these types of tests wanted to have liability protections available under the EUA framework, HHS directed FDA to review

these tests. FDA rightfully resisted since its staff is stretched to the limit and need to focus their work on tests that have the greatest public health impact. HHS then decided to outsource FDA's review to a private company, which may have the expertise but does not have all of the information necessary for an adequate review or the same robust systems to manage conflicts of interest that are in place for federal employees. It is essential for the new administration to undo the prior administration's attempt to privatize the review of diagnostic tests.

### Data Infrastructure

The U.S. still lacks an interoperable data infrastructure to capture the results of diagnostic tests conducted by so many disparate entities in so many disparate settings. Our data systems are simply not connected despite the existence of technical standards to do so. Even within states, each county sometimes runs their own program. Federal coordination, and in some cases, mandatory provider participation will be required. I would argue that this should be one of the principal areas of attention if we are to build a 21<sup>st</sup> century public health system.

### Supply Chain

Our supply chain remains vulnerable. I am encouraged by the new administration's initial steps to secure the supply chain of critical materials. However, the path ahead is complex. Using the Defense Production Act will help but will not take us far. Onshoring the production of all critical materials may not be possible, economically viable, or necessary. A secure and resilient supply chain is much like a balanced portfolio of investments. All options, including establishing interdependencies and redundancies, fostering regionalization, and applying novel technological solutions to creating materials de novo when needed, should be explored.

### Future

Larry Brilliant, a renowned American physician and epidemiologist, once said "Outbreaks are inevitable. Epidemics are optional." Biological threats are not going away. As we continue to battle this pandemic, we must do so with an eye toward building the system that we need going forward. We must build a system that integrates the private sector and cutting-edge technology; acknowledges and values the critical role of public health in our collective well-being, health and economic security; and realizes that good governance is necessary to bring capabilities to fruition.

The actions that follow are necessary and within reach in the near or mid-term, but many will require support from Congress:

1. To ensure the ability to monitor viral evolution and spread, the CDC must immediately expand its genomic surveillance system and analytic capabilities in collaboration with private and academic laboratories. Currently, approximately 3,000 specimens are sequenced each week, out of 1.4 million positive tests. These efforts are principally led by a patchwork of academic, state and commercial laboratories rather than a formal, centralized, and coordinated national system.
2. To ensure Americans understand the necessity to wear masks, HHS, in collaboration with the Ad Council and others, must launch a national "Mask Up" communication campaign to achieve greater compliance with mask use. At the same time, the CDC should immediately make more specific mask recommendations to the public. Should we "double mask" by donning a fabric

mask on top of a surgical mask? Should some people consider wearing a KN95 or N95 masks? Even in the absence of quality data, the CDC is best equipped to make judgements about relative benefits of the different strategies and guide us through these difficult choices. The U.S. Government should also issue a challenge for the development of protective, comfortable, and easy to use masks for the public.

3. To maximize the impact of testing and efficiently use finite testing resources, the CDC, in collaboration with the FDA, should develop a national testing strategy.
4. To save the greatest numbers of lives, mitigate against viral evolution, and help restore our economy, the Federal government must accelerate vaccination campaigns to shorten the time between vaccine production and delivery into people's arms. It must not waver in its commitment to reach hard to reach areas, to counter misinformation, and promote informed decisions by the public and health-care workers.
5. To make sure we are ready to pivot toward second generation vaccines, if needed, in light of new and emerging variants, HHS should develop the triggers that would direct vaccine manufacturers to scale up production of new candidates and plan for a vaccine program that incorporates additional vaccine candidates.
6. To ensure the U.S. has sufficient supplies for this and future pandemics, HHS should expand the industrial base for critical supplies required for medical countermeasures manufacturing and administration.
7. To ensure high quality vaccines are made available in low- and middle-income countries, the Federal government should develop a framework for contributing safe and effective vaccines internationally. America's scientific prowess and stringent regulatory standards have brought Americans high quality vaccines, in contrast to some very low efficacy vaccines produced elsewhere. If we do not act, these low-quality vaccines will dominate the world, which will not help individuals or pandemic containment, and may add selective pressure on the virus.
8. To accelerate development of potential therapies, the NIH should establish a national infrastructure for the conduct of simple, randomized clinical trials for infectious diseases that can be used during a crisis and in the interpandemic period to study infectious diseases and promising therapies quickly and efficiently. In addition, the NIH should immediately notify institutions that receive NIH funding that they must prioritize the nationally-coordinated ACTIV trials over smaller and independent trials at their respective institutions.
9. The Federal government needs to acknowledge the central role of the private sector in achieving national preparedness and engage with it in pandemic planning. Private laboratories should receive priority access to the tools needed to validate their tests at the onset of potential emergencies, on par with public health laboratories. An industrial base for diagnostics and

vaccines manufacturing will be required. This base should be built with cutting-edge and flexible technology, adapt to innovations, and be of good value to the taxpayer.

10. The Federal government should reimagine the 21<sup>st</sup> century public health system. The CDC should not be simply the place where the best public health experts and best laboratories reside, who are called upon to backstop a gap at the State or local level. Rather, CDC should be a coordinating entity that establishes public health standards, interoperable data systems, and a fully integrated national system at every level.

## **Conclusion**

I would like to acknowledge the role of Congress for providing the Federal government many laws that provide the executive branch many vital authorities and critical funding to perform its duties, such as the Project BioShield Act of 2004, the Pandemic and All-Hazards Preparedness Act of 2006, and its subsequent reauthorizations.

Unfortunately, we thought we were better prepared today than we were in 2001, but our systems did not stand up to the challenge of this pandemic. We must do better.

Finally, I would like to recognize the staff at the CDC, NIH, HHS, FEMA, the Department of Defense, and my former colleagues at the FDA, who I know continue to work around the clock to protect Americans from harm and from this epidemic. A better day will soon come upon us if we let science and American innovation lead the way.