THE PUBLIC HEALTH COMPANY

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To: United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
Washington, DC 20515-6115

From: Dr. Charity Dean, MD, MPH & TM
Chief Executive Officer
The Public Health Company Group, Inc.

RE: Response to Request for Additional Questions for the Record

Dear Chairman Griffith, Representative Castor, and Representative Burgess,

Thank you for the opportunity to respond to follow-up questions posed by Representative Burgess regarding CDC's testing failures and the effectiveness of public-private partnerships to create testing infrastructure solutions during the COVID-19 pandemic.

From the front lines to the state lines, I've experienced our complex public health system testing capabilities first hand. As the Public Health Officer for Santa Barbara County, I had broad oversight and authority over public health policies and implementation. I also simultaneously served as the Medical Director for the Santa Barbara County Public Health Laboratory. In this role, I spent countless hours at the laboratory bench, personally examining cultures and slides. The study of such samples–i.e., testing–is critical because it provides the earliest warning of a public health threat within a community. In my subsequent roles as the California Department of Public Health Assistant Director and Acting State Health Officer, I interacted on a daily and often hourly basis with the State Public Health Laboratory as well as myriad local public health laboratories across a state of 40 million inhabitants. I am no stranger, in other words, to the macro-level complexities and micro-level necessities of massive public health testing.

The CDC's failure to develop and scale a COVID-19 testing regime in the early days of the pandemic was frustrating. It was also not surprising. The CDC is designed and incentivized to function as a peacetime research institution. It excels at scientific rigor and analysis, serving an important, albeit somewhat academic, function. But the CDC lacks wartime responsiveness: it is not capable of scaling biotechnology solutions to provide for the common biodefense in the face of imminent and massive public health threats. Its failure to implement a coherent testing regime in our recent hour of need is emblematic of this limitation.

By contrast, those of us experienced in local and state public health began preparing for alternative approaches to testing early on in the pandemic. What concerned me most regarding testing in the early days of COVID-19 was twofold: (1) without testing, we were flying blind, and had to implement broad measures rather than operate with surgical precision; and (2) the United States had to rely on *other countries* to tell us about the

novel pathogen, because we couldn't track or characterize it ourselves. These two factors intertwined and threatened our country's economic security and health security.

In March 2020 I was asked to co-found and co-lead the COVID-19 Testing Task Force for California, which was in partnership with the private sector. The biggest challenge in March 2020 was that nothing existed; we had no visibility into what machines, robots, supplies, and personnel could be leveraged. Our goal was to rapidly scale up diagnostic COVID-19 testing for all Californians by creating a unique public-private framework that would harness ingenuity and resources across government, academia, philanthropy, industry, and private citizen volunteers. Effectuating this mission required (1) identifying existing assets across varied stakeholders, (2) determining which such assets were fit for for our purpose, (3) actively seeking participation, (4) crafting a scalable, state-wide testing operation, and (5) tracking and publishing–on a daily basis–our progress against testing number goals. We leveraged public health laboratory capabilities, informal networks, and the goodwill of the private sector to solve the testing crisis in a matter of months. And, by leveraging these resources across public and private stakeholders, we accomplished the collective mission.

This effort succeeded not in spite of, but *because* of, the voluntary participation by thousands of decision-makers who absolutely wanted to participate in a collective public-private partnership response to a shared biological threat. To put it bluntly, the private sector ran to the fight; it enthusiastically leveraged resources, often at its own cost. I have personally been involved with numerous other public-private partnerships in the COVID-19 response since that time, which have also demonstrated the success of such an approach.

My experiences of the last three years, as well as my 24 years in public health, led me to conclude that a public-private testing infrastructure is critical to biosecurity. However, to be most effective and battle-ready, it must sit within a larger systems solution. I believe the contours of such a national-level biosecurity systems architecture would include the following guiding principles:

- **Speed**: Intelligence that goes viral faster than the virus and enables rapid operational activation within minutes or hours
- **Scale**: Situational awareness and operational response scaled across thousands of nodes in near real-time that empowers activation of an entire network or specific nodes in unified alignment with one another
- **Autonomy**: Stand-alone, politically agnostic, not beholden to political interests at any level
- **Whole-of-Society Response**: Enables a whole-of-enterprise, whole-of-government, whole-of-society coordinated response, via networked intelligence and distributed operations
- **Courage**: Empowers leaders to make fast decisions amid uncertainty, when every minute matters. The systems architecture is *designed* to function amid the fog of war and not solely during peacetime
- **Trust**: Trust is the currency of public health. Fairly or unfairly, there is now an absence of trust by the American people in our government's ability to manage large-scale risks such as COVID-19. In developing and maintaining this solution, great care should be taken to earn Americans' trust by involving a diverse coalition in a public-private partnership effort

<u>Outline of a National Biosecurity Systems Architecture</u>

Intelligence Infrastructure

This intelligence infrastructure enables one shared reality, real-time situational awareness, and a coordinated scaled operational response from local to regional to national nodes. It provides this intelligence to all nodes in the network by coalescing disparate data streams, across diverse data, into one shared reality. Built upon a threat-agnostic architecture, every node contributes to and benefits from a multi-dimensional network effect. Pre-determined threat levels correlate with controls, decisions, and actions which are triggered automatically,

by design, by specific threat levels. This enables real-time threat characterization, shared visibility of threat levels and control activations implemented across a large geographic footprint. This intelligence infrastructure is analogous to the use of fire maps in firefighting, which reflect a threat perimeter, hot spots, forecasted spread based on wind patterns, and active containment efforts in play.

Operational Infrastructure

This operational infrastructure is a national biosecurity entity which does not need to be assembled amid a crisis, but rather is maintained during peacetime, and designed to activate scalable capabilities and controls during wartime. With federal leadership, it would build and maintain wartime public-private coalitions, capabilities, and controls that are practical, tactical, and fully operational. It would capitalize on public-private partnerships, escalate mutual aid to any node, activate medical countermeasures and their supply chains, coordinate a unified command for whole-of-society response, and balance public health requirements with practical and social issues. During an activation, it would choreograph the operational response across thousands of nodes and the whole of society, leveraging the intelligence infrastructure as a source of truth and shared visibility. An analogue to this is fire response. From city fire departments to county and state fire agencies, to the national forest service, there is much biosecurity can learn from their successful model. Firefighters developed the Incident Command System and continue to be one of my inspirations.

The Testing Infrastructure component of the larger infrastructure is critical. Unlike a fire we can see and smell, biological threats only become visible through microbiological testing. Without testing, we are blind. A baseline, national, scalable diagnostic testing infrastructure would be established and maintained, becoming a quietly humming machine during peacetime which can be operationally activated and scaled during wartime. The foundation of this testing infrastructure is public-private partnerships, as the commercial resources already exist within industry. This will require ongoing, base-level federal funding to enable the maintenance of industry-developed, commercial-grade capabilities because though they may be revenue generating for industry, market forces alone are unlikely to sustain this capability.

Given the national security importance of this infrastructure and participation across industry, academia, philanthropy, and the private sector, it should exist within a federal entity responsible for the larger operational infrastructure. That is to say, it should *not* be developed or maintained in any one federal department, including the CDC. When activated, these operational capabilities are critical to all federal agencies and bodies, and should be housed appropriately.

Diagnostic Testing Infrastructure

I am not in a position to comment on the ability to mandate participation in a peacetime/wartime testing infrastructure for entities that receive federal funding. However, a promising alternative (or parallel) approach exists, and in fact we have already used it during COVID-19: establishing voluntary opt-in participation across the vast ecosystem of bioresearch, life sciences industry, academic and philanthropic institutions, and government. This would create a visible, national network of assets and personnel which can be activated under specific operational responses. Instead of doing this on the fly in the midst of a crisis, as we did in March 2020, it would become a pre-existing and scalable “national guard” of testing capabilities. When activated, whether a regional or national activation, the laboratories and assets would be pre-validated for the right equipment and expertise.

A shared database of these assets would exist within the intelligence infrastructure, empowering the operational infrastructure to make fast decisions and escalate response in coordination across large geographies. Every colleague I have spoken with over the past three years would sign up again to participate in an approach like this. Indeed, they signed up in March 2020 amid total mayhem; the thought of an organized,

pre-planned “national guard” of peacetime/wartime testing infrastructure was met with enthusiasm. I believe there will be support among private-sector leadership to participate in providing for the national biodefense by opting in to this approach.

Pathogen Genomic-Clinical Characterization Infrastructure

A critical component of both biosecurity intelligence and operational response is the ability to characterize a novel pathogen in near real-time. The ability to test—to capture it—is not enough. We must be able to quickly study it, and answer key questions that inform how we contain and treat the disease. What is the attack rate, mode of transmission, incubation period, infectious period, R0, case fatality rate, hospitalization rate? What demographics of Americans are at higher risk? What about children?

Key clinical and epidemiological questions can be quickly answered, even early on in an emerging biological threat, by combining pathogen genomic sequencing data with diagnostic testing data and clinical outcomes data. Instead of waiting for academic journals to publish retrospective studies, this platform would characterize the pathogen in near real-time and serve as a critical component of both the intelligence and operational infrastructure. Similar to diagnostic testing capabilities, it would be developed and maintained in peacetime by a public-private partnership including commercial-grade technology developed by industry. In peacetime, this pathogen genomic sequencing capability and data integration platform would continue to operate for known pathogens we contend with on a regular basis across the healthcare and public health ecosystems. In wartime, it scales up and is able to focus on characterizing a novel emerging pathogen. The output of this platform feeds back into our intelligence infrastructure, allowing shared visibility on what medical countermeasures (vaccines, prophylaxis, medications) are working in the field.

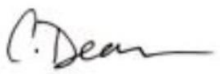
It is notable that industry has already begun building capabilities in this realm over the past few years, and they are now at risk of shutting down without ongoing sustainable funding. The cost of maintaining the equipment, processes, and personnel during peacetime is a fraction of the cost to acquire it during an emergency situation. Flipping a switch to activate capabilities is a fraction of the time it takes to build them from scratch. We learned these painful lessons during COVID-19 that both time and money are critical during an emergency.

Authority Infrastructure

The authority infrastructure of this solution includes the right decisional authority, at the right level, under the right conditions. In the current public health system in the United States, the layered jurisdictional authorities form a patch-work quilt of confusing and sometimes contradictory authorities as a relic from past centuries. Under a 21st century system, these authorities would be aligned around predetermined threat levels and a shared operational response.

As our democracy approaches its 250th birthday, I believe the United States is still capable of solving hard problems. We eliminated smallpox. And polio. We put a man on the moon and architected the interstate highway system. We stood up Homeland Security after 9/11. Surely we do not become shrinking violets in the face of a need for a national biosecurity architecture solution to provide for the common biodefense. I have dedicated my own life to building solutions, and am grateful for the opportunity to share my thoughts with this Committee.

Sincerely,



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