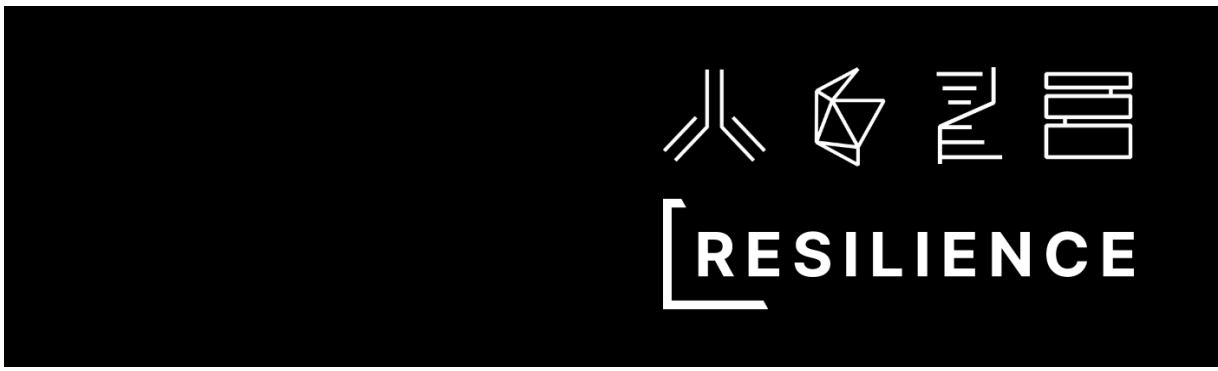

Reimagining Manufacturing for Pandemic Preparedness:

Non-Paper on Public Private Partnerships for the High-Level Independent Panel on Financing the Global Commons for Pandemic Preparedness and Response

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Summary

The COVID-19 pandemic illuminated longstanding challenges in our global ability to respond to pandemic threats, including a global biopharmaceutical manufacturing ecosystem unprepared for crisis response. The lack of manufacturing capacity for vaccines and therapeutics poses a public health risk to the world and prevents new medicines from reaching patients as fast as possible. As the global community looks to prevent, prepare for, and respond to future pandemics, it must commit to a new future for biopharmaceutical manufacturing that reimagines how medicines are made.

A sustainable ecosystem for biopharmaceutical manufacturing requires new manufacturing technologies and flexible, distributed production systems that can respond to diverse disease threats at speed and at scale. Public-private partnerships play a vital role in bringing together the innovation, infrastructure, and human capital that make this new ecosystem possible. This non-paper outlines how biopharmaceutical manufacturing must be enhanced and ways the public and private sector can partner to build flexible, multi-modality manufacturing capacity, invest in novel technologies, and advance manufacturing science.

Key Considerations

The future of preparedness requires truly reimagining the global biopharmaceutical manufacturing ecosystem to better support rapid, pathogen-agnostic response. While expanding existing manufacturing capacity is necessary for immediate COVID-19 response, the pandemic proved that current models cannot protect against future threats. The current system to produce vaccines and therapeutics, whether to combat a pandemic or treat a devastating disease, depends on limited

manufacturing lines, low shelf stock, high demand inputs, and substantial physical requirements, including an extremely skilled workforce and large-scale bioreactors.

This has two implications. First, production primarily occurs in large, centralized, product-specific facilities creating a vulnerable supply chain that cannot endure disruptive shocks or respond quickly and nimbly in times of crisis. Second, limited talent and physical capacity create limits on how far the current manufacturing ecosystem can be scaled. These challenges can only be overcome by new technologies, platforms, and processes that leapfrog existing inefficiencies and provide new ways to make vaccines and therapeutics more effectively.

Despite the critical need for new manufacturing platforms and technologies, the current market disincentivizes the biopharmaceutical industry from investing in manufacturing innovation and new modes of production. Rather, the system prioritizes drug discovery and bringing those discoveries to market as fast as possible – a system that leaves little incentive for industry to take a risk on a new platform or to devote resources to develop new technologies. This trend is reinforced by the lack of regulatory pathways to evaluate advanced manufacturing technologies independent of individual products, as the National Academies of Medicine highlighted in an early 2021 report.

Recommendations

As the global community looks to prevent, prepare for, and respond to future pandemics, it must set a new future for biopharmaceutical manufacturing. A next generation manufacturing ecosystem will enhance pandemic preparedness, strengthen global health security, and increase access to manufacturing for a more equitable global public health system. The same ecosystem will also allow manufacturing innovations to advance alongside life science discovery, enabling new medicines to move more quickly from the lab bench to the bedside.

The following recommendations outline specific areas for public sector support to advance biopharmaceutical manufacturing. All four areas would be furthered by financial assistance in the form of grants and low-to-no interest long-term loans that could be facilitated by individual nations and/or established multilateral organizations and development banks. Increased support for these initiatives will help ensure future investment in manufacturing infrastructure and technology.

1. **Expand surge capacity for COVID-19 vaccine and therapeutics production.** Public sector financing can support immediate COVID-19 response by expanding existing manufacturing infrastructure. Additional resourcing can accelerate the build out or retrofit of capacity that can immediately take on vaccine production and offset the high cost of constructing and equipping manufacturing facilities. While this can bolster today's response, it will not overcome the limitations on the current system or create a sustainable model of preparedness for future pandemics.

2. **Create rapid, flexible, multi-modality manufacturing capacity.** Public sector financing can support near-to-medium-term pandemic preparedness by funding the creation of a network of flexible capacity that serves industry during peacetime and can rapidly shift production in times of need. A networked approach reduces supply chain vulnerabilities that come from relying on a single site. By supporting industry and emergency response,

the dual-use model ensures access to talent and operational facilities and saves public sector dollars. It also fuels local economies through well-paying manufacturing jobs. To ensure readiness in times of crisis and to adequately support industry needs, it is essential that sites have the following capabilities:

a. Multi-modality manufacturing capacity (mRNA, protein, and virus-based vaccines and therapeutics) safely managed within a single site or provided by modality-specific sites in the same location.
b. Continuous, real-time biopharmaceutical manufacturing capacity serving industry needs.
c. Manufacturing partners that can support rapid ramp up of production during an emergency.
d. The most current biopharmaceutical manufacturing technologies, platforms, and processes.
e. Access to high-skilled talent and leading experts in vaccine and therapeutics manufacturing.
f. Manufacturing or drug development partners that can hold the Biologics License Application (BLA) for critical products, such as novel public health-oriented vaccines and antibodies.

3. **Invest in novel manufacturing technologies.** The future of prevention, preparedness, and response is dependent on the development of new manufacturing technologies that disrupt current capacity models. For example, miniaturized and decentralized production systems (such as a shift from large-scale bioreactors to biochip-based systems) will bring manufacturing closer to the point of care, reduce production and human capital costs, and ultimately enable more equitable global access to manufacturing capacity. Such innovations are the only way to achieve bold public health missions, including the ambition to develop and deploy new vaccines and therapeutics within 100 days. Public sector programs should be established that fund research and development for novel manufacturing technologies—not just drug discovery. These programs must also encourage technology adoption by supporting applied research and development, modern regulatory schemes, and commercialization pathways.

4. **Establish partnerships to further manufacturing science.** Building speed into preparedness and achieving medical moonshots requires bringing manufacturing closer to drug discovery through partnerships between government, academia, and industry. Current and proposed research programs should include challenge problems and initiatives focused on manufacturing science and bridging the gap between innovation in life science and manufacturing. Connecting these communities to provide manufacturing expertise at the outset of drug development reduces product development and technology transfer timelines. It also minimizes late-stage failures by ensuring translation of laboratory processes to commercial-grade production; enables better features to improve clinical attributes and engineer out uncertainty, resulting in reduced costs; and, ultimately, makes new modalities of medicine possible.