MCMx: A Proposal for a Federal Authority to Enhance Speed, Scale and Access to Medical Countermeasures

Findings from the Program in Global Public Policy and Social Change Medical Countermeasures Taskforce: Partnering for Public Good

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ABSTRACT

The US must be ready to rapidly respond to any pathogen with pandemic potential.
To meet this objective, Harvard Medical School's *Program in Global Public Policy and Social Change (PGPPSC) Task Force on Medical Countermeasures* proposes "MCMx": a federal authority that will improve the speed of development, the scale of production, and accessibility of medical countermeasures (MCMs) for future infectious disease outbreaks.

While Operation Warp Speed (OWS) - the US initiative to accelerate COVID-19 vaccine development- demonstrated the value of leadership, direction, and value-chain integration, this initiative was reactive and time limited. Building on the lessons of OWS and the current work of US agencies like the Biomedical Advanced Research and Development Agency (BARDA), MCMx will anticipate the needs, integrate the functions, and coordinate the partnerships necessary to achieve this mission.

The taskforce identified three main activities for MCMx: create a blueprint for MCM research and development (R&D) that integrates all parts of the development value chain, coordinate with global partners, and refine current approaches to contracting with private sector actors. In so doing, MCMx will build out a matrix of flexible public-private partnerships that will allow the US to ensure speed, scale, and access to MCMs for future health crises.

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I. Introduction

The development of effective COVID-19 vaccines and other medical countermeasures (MCMs), within a year was a historic achievement. Even so, the pandemic continues to claim millions of lives worldwide. As companies struggle to scale production, vaccines may not be available for much of the world for several more years. Meanwhile, variants of the SARS-Cov-2 virus, which causes COVID-19, threaten to diminish the usefulness of existing vaccines ("vaccine escape") and therapies, and may prolong the battle to contain the virus. As this pandemic demonstrates, there is a need to improve the speed of development, the scale of production, and the accessibility of MCMs for future infectious disease outbreaks.

Over the last seven months, Harvard Medical School's *Program in Global Public Policy and Social Change (PGPPSC) Task Force on MCMs* considered what has been learned from COVID-19 vaccine and therapeutic development in order to shed light on the path forward. Historically, the US approach to MCM development has been disjointed, suffering from the challenge that the Task Force identified as a 'conductor-less orchestra'. While Operation Warp Speed (OWS) - the US initiative to accelerate COVID-19 vaccine development- demonstrated the value of leadership, direction and value-chain integration, this initiative was reactive and time limited. The Task Force proposes a more permanent and proactive conductor for the orchestra: "MCMx", a new federal authority that will coordinate MCM development domestically and in concert with international partners.

II. MCMx Mission

The mission of MCMx is to improve MCM development on three dimensions: speed, scale, and access. Building on the lessons of OWS and the current work of US agencies like the Biomedical Advanced Research and Development Agency (BARDA), MCMx will:

- ***Anticipate*** the needs and build the partnerships that will allow the US to move away from a reactive stance toward a broad capability-based strategy.
- ***Integrate*** all parts of the MCM development value chain to maximize speed, scale, and access.
- ***Coordinate*** investments and planning to allow countries and companies to better serve the greater good.

III. MCMx Strategic Plan: Creating a Research and Development Blueprint for MCMs in Future Outbreaks

A. Anticipate and Integrate

To accomplish this mission, MCMx will design an R&D blueprint and implement a strategy that will anticipate the capabilities that are required and build the partnerships that will enable the US to move more quickly and effectively when confronted with a public health crisis and/or pandemic in the future.

MCM development involves multiple steps led by different actors in the value chain ranging from funders to scientists, developers, manufacturers, regulators, and administrators. Each actor brings expertise and focus to their piece of the puzzle, but they may fail to understand upstream or downstream requirements for a seamless hand-off. OWS coordinated these links in the value chain to compress development time. MCMx will draw from this experience to integrate activities that will streamline our response to future disease threats.

MCMx will design a strategic plan for domestic public sector investment priorities. MCM development encompasses surveillance, basic science research, development, clinical testing and evaluation, manufacturing, and distribution. MCMx will invest in each of these links to enhance their ability to both anticipate requirements and to work together to accelerate development.

MCMx will reinvigorate and build on current U.S. capabilities. The U.S. has laid the groundwork for MCM development with the formation of the Biomedical Advanced Research and Development Authority (BARDA) and BARDA's associated clinical trial network, Centers for Innovation and Advanced Development and Manufacturing (CIADM), and cross-agency coordination mechanisms under the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). BARDA has historically focused on countermeasures for traditional biosecurity concerns (anthrax and smallpox for example) and pandemic flu. MCMx will build on this effort to augment BARDA's activities and to integrate functions along the development continuum.

Leadership from the National Security Council will provide oversight and enterprise-wide coordination for MCMx, coordinating activities across the US public health system and medical care system to develop MCMs for health emergencies. MCMx itself may be situated within the federal health authority ecosystem in any number of ways. For

example, it could endow BARDA with an expanded mandate, subsuming its current portfolio within a broader set of activities—acting as a "BARDA 2.0". Alternatively, it could work alongside BARDA and other agencies with a broad mandate that oversees BARDA and its current portfolio.

i. *Pathogen Surveillance*

Surveillance for emerging pathogens and growing outbreaks is essential to maintain situational awareness and to inform research priorities. In the near term, it will be critical to increase genomic surveillance of new SARS-CoV2 variants to assess current diagnostic accuracy and MCM effectiveness. The US currently sequences only 0.5% of the positive SARS-CoV2 samples collected. A minimum of 5-10% must be sequenced to develop appropriate situational awareness. Initiatives like the Biden Administration's proposed National Center for Epidemic Forecasting and Outbreak Analytics may help organize such a surveillance effort for SARS-CoV2 in the short term and serve as a public health intelligence capability in the future in the U.S. MCMx will utilize data produced by this national surveillance system and spearhead a coordinated response to emerging health threats with other national, state, territorial and regional health agencies.

ii. *Prepare: Priorities, Pathogens, Platforms, and Products*

A serendipitous mix of upstream research investments enabled the rapid development of synthetic COVID-19 vaccines. Previous work on SARS and MERS at the National Institute of Allergy and for Infectious Diseases (NIAID) and academic research institutions illuminated the structure and importance of coronavirus spike proteins as a vaccine target. A 2009 BARDA-funded project advanced the development of rapid synthetic approaches to pandemic flu vaccines. NIAID and Coalition for Epidemic Preparedness Innovations (CEPI), an MCM accelerator for diseases with pandemic potential, also invested in vaccine platform approaches that hastened development times. These prescient investments reduced the development time of COVID-19 vaccines from years to months.

The U.S. can be strategic about similar upstream research and development investments that will enable rapid development if the need arises. For example, Barney Graham and Nancy Sullivan (Vaccine Research Center, NIAID) have outlined an upstream research and development program that could enable more intelligent preparedness investments and real-time candidate choices in the future. This virus prototype program would characterize emerging viruses from 25 families and map them onto a subset of

appropriate vaccine platforms. This research will also advance the development of nimble vaccine platforms such as nucleic acid and viral vector vaccines. The MCMx blueprint will prioritize viruses according to their pandemic potential (i.e., respiratory transmission, prevalence of animal reservoirs, etc.) and platforms according to their suitability for particular viruses and technical feasibility, and develop them through either human safety testing, or even through animal testing approval processes (e.g., via the Animal Rule), depending on the threat and alternative mitigations.

The rise of SARS-Cov2 variants and vaccine hesitancy underscore the important role diagnostics and therapeutics play in mitigating future outbreaks. In addition to vaccines, it will be essential to consider rapid diagnostics and effective treatments as a critical component of MCM preparedness. Building on the pre-existing R&D response strategy from CEPI, MCMx will invest in "just-in-case" disease threats and "just-in-time" capabilities that enable a nimble response to unknown threats, or "Disease X". MCMx should develop this blueprint through consultation with CEPI, HERA, CARBX, FIND [1]and private sector development partners. These efforts should be complimentary and actively coordinated, not competitive. (see Working with Global Partners, section 1)

iii. *Manufacturing to Enable a Nimble Response*

MCMx will invest in continuous small-batch manufacturing to enable a nimble response. Former director of Operation Warp Speed, Moncef Slaoui, cited manufacturing as the biggest challenge in the race to develop COVID-19 vaccines. To mitigate this problem, he referenced a proposal from GSK vaccines to operate a non-profit bioprocessing organization (BPO) to conduct continuous small-batch manufacturing for emergency-use vaccines. The purpose of the facility would be to develop and manufacture sample MCMs—vaccines as well as therapeutics and even diagnostics—for potential outbreak agents. A dedicated small-batch manufacturing facility would pair well with an upstream R&D program to design prototype vaccines for viruses from the 25 families of concern, for example. These vaccines would be produced according to Good Manufacturing Practices and held in reserve for clinical testing in the event of an outbreak.

The manufacturing program should operate less as a traditional Contract Manufacturing Organization (CMO) and more as a research program to test and refine new techniques.

[1] CEPI is the Coalition for Epidemic Preparedness Innovations; HERA is the European Health Emergency and Response Authority; CARB-X is the Combating Antibiotic Resistant Bacteria non-profit; FIND is the Foundation for Innovation in New Diagnostics.

This "support by use" strategy would circumvent the "build and decay" dynamic that beset some of the HHS Centers for Innovation in Advance Development and Manufacturing (CIADM) facilities in recent years. When GSK originally proposed the BPO, the US government considered the estimated $300-$500 million annual operating cost to be too high. In retrospect, this is a small price to pay for building manufacturing expertise for emergency-use MCMs. Even if none of these "just-in-case" MCMs are used, this program will hone the skills required to rapidly develop small batches of different classes of MCMs using multiple platforms.

iv. *Embed Research in Response (bench to bedside and back)*

MCMx will incorporate MCM research into preparedness and response activities so that researchers capture valuable windows to test the efficacy of MCM interventions, assess results, and adjust strategies in real time. The West African and subsequent Democratic Republic of Congo Ebola outbreaks demonstrated that it is possible, but often challenging, to embed MCM research in outbreak response. On one hand, determining the efficacy of MCMs can only be done during an outbreak when the outcomes of those treated with an MCM can be compared in large enough numbers to those without MCM treatment. On the other hand, hastily organized research efforts in communities experiencing frightening outbreaks often run into trouble. People may be understandably skeptical of experimental treatments and have legitimate questions about their access to successfully developed therapeutics as well as concerns they may not be able to access adequate healthcare if they are harmed by an experimental MCM. Moreover, it can be difficult to quickly assess the results of data such that it informs both subsequent research and the outbreak responses in real time. Crisis-driven MCM research often leads to delays, suboptimal data collection, and missed opportunities to improve outbreak response strategies.

MCMx will incorporate MCM research into response to address many of these issues in advance. First, it can ensure rapid and open access to pre-clinical and clinical data so the whole of the research community can learn quickly and adjust research agendas. Second, it can produce master clinical trial protocols that have been partially negotiated in advance of a crisis to facilitate data sharing and accelerate response times. This has worked well during the COVID crisis when master protocols like those used in the RECOVERY (UK) and SOLIDARITY (WHO) trials reduced duplication of effort, cost, and the time required to conduct the research. Also, MCMx can serve as the critical link between MCM research and outbreak response strategies, working with public health authorities to game out and adjust strategies based on MCM research findings in real time.

B. Coordinate: Work with Global Partners

Insufficient global coordination hampers countries and companies from acting on behalf of the global good. Absent robust global coordination for procurement and distribution, for example, countries compete for MCMs on the basis of price, meaning that wealthy countries can succeed while less resourced countries are left with limited access, which threatens to prolong a global crisis for all.

US capacity for effective and impactful international collaboration starts at home. MCMx will provide a focal point for US efforts to mobilize resources and invest in partnerships to maximize the social value of investment in global health security.

i. Pipeline Accelerator Coordination

MCMx will design its R&D pandemic blueprint in consultation with other emerging innovation pipeline accelerators. Several links in the MCMx value chain, including testing, production, manufacturing, and distribution need to be coordinated with global efforts. New international and regional bodies for all aspects of MCM development and deployment are emerging in response to the COVID-19 crisis. One of the most prominent is the Access to COVID Tools (ACT) Accelerator, a new coordination mechanism that is serving as an essential complement to existing pipeline accelerators such as CEPI and BARDA. Its efforts have facilitated international cooperation for the common good. The ACT Accelerator is, however, a work in progress. It lacks a clear decision-making structure and does not have the mandate to operate beyond the acute phase of the COVID-19 pandemic. Nonetheless, if preserved, it would provide valuable infrastructure for pandemic and epidemic preparedness.

Other accelerators such as the HERA Incubator are being formed to serve a smaller region. HERA is part of a broader European Commission initiative to centralize European pandemic preparedness and response, to coordinate testing, and to reinforce existing institutions such as the EMA and the European CDC.

Looking ahead, MCMx will coordinate with each of these and other accelerators for diagnostics (FIND) or antibiotics (CARBX) to ensure that it will enhance rather than merely duplicate efforts**.** A loosely tied coalition may suffice and be more practical and effective than trying to coordinate programs through a single point of control. Some aspects of MCM production, however, such as manufacturing or resilient supply chain

management, will require tighter international coordination through high level forums, such as the G20.

Efforts to standardize trial protocols, pre-register potential trial participants, organize global manufacturing networks, and build redundancy in supply chains will bolster the global architecture for MCM preparedness. Another benefit to multiple complementary and loosely coordinated efforts is that they will grow the community of global scientists who are invested in the R&D for MCM enterprise and thus positioned to respond as epidemics wax and wane in the coming decades.

ii. Global Pathogen Surveillance

MCMx will partner with other countries and international organizations to survey emerging pathogens in global hotspots to improve rapid detection capabilities and to inform research priorities. An estimated 60% of emerging human pathogens arise from animals before they transfer to humans. MCMx will work with international partners to set up and maintain global "listing centers" that can rapidly detect new diseases that can spark outbreaks in humans. This data should contribute to open-source platforms such as GISAID—a global initiative for sharing avian influenza genomic data. While this platform was designed for flu surveillance, GISAID played a critical role in allowing rapid open access to SARS-CoV2 genetic data. The first sequences were posted on the site on January 10, 2020, which allowed work on tests and synthetic vaccine approaches to begin worldwide. This open access platform will now help scientists to track and analyze new variants as they continue to emerge across the globe. MCMx will collaborate with global partners to build on this and other open-source platforms for a broader array of pathogens with pandemic potential.

These listening centers and the data they produce, if aligned with other health system and personnel capacity building efforts, can reap dividends in improving health outcomes and research expertise in many other countries. In particular, it will be important to link this effort to the *One Health* initiative that seeks to understand the interplay of humans, animals, plants and microbes to promote early detection and rapid mitigation of emerging pathogens. This holistic understanding, can generate new and important insights about how to address endemic diseases through public health interventions, improve local clinical care, inform better land use and agricultural practices, and mitigate environmental threats.

Data sharing is famously fraught with access versus benefit issues. The task force recognizes that those who share data (samples, IP, clinical data, etc), should benefit

from the tools that are developed from this data. MCMx will tackle these access vs benefit issues as a key component of their contracting process.

iii. Build 'Pivot and Scale' Manufacturing Capabilities

MCMx will work with multilateral partners such as CEPI and the G20 to establish a manufacturing network that will guide and facilitate technology transfer and scale-out manufacturing in health emergencies. Biopharmaceutical development and manufacturing is an inherently global endeavor that relies on large multinational vaccine and drug developers and international partners and supply chains. The mission to build a pivot and scale manufacturing capability is therefore international in scope.

Efforts to build an international manufacturing network should be informed by the challenges that the U.S.-based CIADMs experienced. These partnership models were attractive on paper but struggled to find everyday uses to sustain themselves. Moreover, some of the selected partners had insufficient MCM manufacturing experience and may not have been best suited to scale up in a global crisis. The costs borne by both the public and private sector partners are substantial so future applications require a "neglect-proof" strategy. In some cases, it may be possible to leverage or pivot on everyday uses of these facilities. This may be especially relevant globally in countries with high burdens of infectious diseases and routine outbreaks of dangerous pathogens. In other cases, we must acknowledge that resilience is neither efficient nor free. Industry's efficient "just-in-time" mentality must be augmented with warm-base "just-in-case" activity in partnership with the public sector.

iv. Multilateral Procurement and Distribution

MCMx will work with global partners to enable collective procurement and needs-based distribution of MCMs beyond the current pandemic. Corporations and nations lack robust tools and incentives for collective action in the public interest. MCMx must work with other countries and international organizations to support and optimize multilateral platforms such as the ACT Accelerator and COVAX to facilitate collective procurement and needs-based distribution, which is in the interest of our own national security and global security.

Advance Purchase Commitments (APCs), such as COVAX, play an important role by shaping the market through collective procurement and ensuring needs-based distribution. APCs wield power when they can place orders at risk and in advance. COVAX

experienced some setbacks in part because the entity was built after the pandemic's start; it was thus not able to negotiate and confirm orders until many companies had already struck lucrative bilateral deals with wealthy countries. While COVAX was delayed, it will still play an important role in equitable distribution and access by acquiring—either through direct purchase or donations—and distributing COVID-19 vaccines to Low and Middle Income Countries (LMICs) and other underserved populations as well as High Income Countries that help to fund the system.

APCs will continue to have an important role to play in future outbreaks. APCs have a proven track record for incentivizing socially desirable vaccine development. GAVI piloted an APC that sped the development and roll out of pneumococcal vaccines in LMICs. If the next outbreak does not reach pandemic proportions that generate global demand, an APC will be the strongest - and perhaps only- incentive for companies to produce MCMs at sufficient speed and scale with provisions for equitable access. Delivery of targeted MCMs at this scale have significant positive public health and economic impact. Other market shaping mechanisms that de-link reimbursement from volume sold, such as a subscription models, are essential to sustain and steward the development and distribution of new antibiotics as well. For these mechanisms to realize their true potential to serve the public good, it will be essential to sustain them beyond the current pandemic and adapt them to serve in future outbreaks.

v. Resource Mobilization

End-to-end preparedness requires sustainable financing. MCMx will work with global partners to devise a resource mobilization strategy for preparedness and response. For example, MCMx could leverage the World Bank's Health Emergencies Preparedness and Response Multi-Donor Fund (HEPRF) to finance select short-term R&D capacity-building programs for COVID-19. This effort would include rapidly increasing regional diagnostics manufacturing capacity, expanding clinical trial capabilities in LMICs, and supporting regional regulatory processes to speed the uptake and use of these new technologies. MCMx can help vet and enable solutions such as a Global Health Security Challenge Fund and other sustainable financing mechanisms that have been proposed to ensure support for global and regional capacity-building activities, including laboratory and clinical trial strengthening, supporting manufacturing capacity, and research networks. Furthermore, MCMx should explore making R&D investments eligible for financing from the World Bank and other international financing institutions and develop mechanisms to provide financing for global R&D for health emergencies, as recommended by the 2020 Global Preparedness Monitoring Board report.

IV. MCMx Strategic Priority: Contracting

Contracts lie at the heart of the ability of MCMx to execute its plan. MCMx will refine and reform contracting terms and practices that accelerate MCM development and protect public interests in advance of the next outbreak.

A. Adopt New Approaches to Contracting

i. Create a Single Point of Contact

From developing and distributing diagnostics, therapeutics, and PPE, the vast capabilities of the private sector and non-profits have been underleveraged throughout the COVID crisis. Partner selection should not privilege companies that are most familiar with Federal Acquisition Rules (FAR) or that have spent the most money on lobbyists who can offer access to the government. Rather, partners should be selected based on their technology, capabilities, and skill sets. MCMx will have a dedicated private sector liaison who will serve as an initial point of contact for industry on MCMx issues. This person will work with companies to direct them to the appropriate public sector authority relevant to their work, streamline information, and categorize corporate capabilities. While many companies have a strong understanding of how to work with the government on MCM development and response efforts, others do not. This centralized point of contact will allow the federal government to rationalize partner selection and better leverage the diverse skill sets of independent firms.

ii. Build Flexibility into Contracts

To move from a threat-based to a capability-based strategy, MCMx will expand and refine flexible contracting. Other Transactional Authorities (OTAs), which design federally funded contracts not bound by traditional contracting rules, can facilitate long-standing partnerships and build a portfolio of capabilities. OTAs are attractive to industry partners in the sense that they are fast and flexible, are much easier to repurpose when priorities change, and are free from cumbersome FAR. However, what OTAs gain in flexibility, they lose in transparency and accountability. Efforts to adopt OTAs more broadly must be accompanied by a process in which stakeholders can assess best practices and refine these agreements to include clauses to better ensure goals such as transparency, equitable access, and accountability in future partnership agreements.

iii. Identify and Share Best Contracting Practices

Contracts give U.S. government funders an opportunity to negotiate public interest provisions with MCM developers up front and are a key means by which MCMx can maximize the social benefit of health security investments. Internationally, contracts may offer the most durable and effective tool available to public funders given the vicissitudes of political support for international cooperation through partnerships such as CEPI and COVAX.

While contracts are a powerful lever, public-private agreements are beset by a recurring set of issues around intellectual property, price, volume requirements, access, and sustainability, which impede negotiations and compromise their effectiveness. Tools and guidelines developed up front that inform and empower public sector contracting would help to create a common understanding of what works best in these agreements and will ensure that the urgent need for MCMs is met in a timely and sustainable fashion with the greatest good and, not just for this pandemic, but for all future health threats. It is also essential to capture lessons learned from previous OTA agreements and to refine OTA clauses in advance of the next health event.

Public interest pipeline accelerators such as CEPI and initiatives such as the MAPGuide facilitate efforts to identify and share options and best practices in these agreements. The MAPGuide provides options to promulgate best practices in contracting so that public sector actors do not have to reinvent the wheel with each new contract. This is an important resource to be further expanded to improve awareness of contract terms, best practices, and approaches across different firms and public sector groups. MCMx will contribute to efforts to identify and promulgate best practices to maximize the social benefit of health security investments.

iv. Standardize Contract Practices and Terminology

U.S. agencies involved in MCM development do not always use the same terminology or follow the same practices when contracting with private sector partners. Variation occurs even among contract officers within the same agency. Building on best practices, MCMx will harmonize contracting practices across agencies and to standardize terms. This exercise will level the playing field and facilitate access for all companies attempting to work with the government.

v. Establish a Concept of Fair Price

A primary goal of MCMx is to establish and support public private partnerships to develop, manufacture, and distribute essential MCMs for health emergencies. For these partnerships to be successful and sustainable, the terms, particularly around pricing, must reflect the degree of risk and investment that each partner has assumed.

The economics of medical MCM development and sustained manufacturing at scale are complex. MCMs are needed for a wide range of health emergencies. These range from regional outbreaks of Ebolavirus, to global pandemics such as H5N1 or COVID-19, to low probability threats like bioterrorism. Demand for a specific MCM could be on a global scale, or a smaller regional scale, or the demand forecast could be uncertain. An MCM could be relatively simple to manufacture or highly complex. As a result, the associated manufacturing scale up and financing needed to produce the MCM are often difficult to predict and thus quantify, and even more difficult to manage as a supplier.

In some cases, private partners underwrite a large portion of the lifecycle investments needed to develop and sustain the production of an MCM and incur some opportunity cost associated with redirecting R&D and manufacturing resources to support a health emergency response. Products that are expected to generate significant annual revenues (COVID-19 is one example) will attract the interest of large global manufacturers. The company that has put capital at risk needs to recoup a reasonable return on investment.

It is important to note that there are also non-monetary benefits and “value” to any firm that effectively supports a global health crisis. This comes in the form of good press, which may positively impact the stock price of publicly traded firms. This also comes in the form of positive reputational effects and goodwill from public and private sector partners, which may favor future negotiations.

When companies have largely self-funded the development of a new vaccine or countermeasure, pricing will be dependent on a variety of issues. These include projected market size (annual sales), manufacturing complexity; the certainty, consistency, size, and geographic scope of demand; and associated life cycle costs including securing and maintaining licensure in multiple countries, fulfilling post-market regulatory obligations, and future re-scaling of manufacturing capacity to meet uncertain demand. There is a need for sufficient returns on investment to continue financing the development and planning for scaled production of new technologies. In parallel, there is a need to incrementally innovate to make existing MCMs more effective, easier to administer, more efficient to manufacture, and faster to deliver.

In other instances, when products are not expected to generate significant annual revenue, much of the risk and cost of development is incurred by the U.S. federal government. Given the uncertain and often small market for MCMs, their development, production, and procurement is often heavily subsidized with public money. Different U.S. government agencies (e.g., NIH, BARDA, DoD, CDC) often support and fund every stage of the MCM process. The amount and type of public support varies by MCM, but in some cases a manufacturer will have put little capital at risk, and yet the return on investment may be substantial. For example, the price of the anthrax vaccine to the U.S. government has increased by 800% since 1998 despite the fact that the government has funded much of the research, manufacturing and development of this product.

The price that the government must pay for MCMs that are developed largely with their support should be evaluated to inform future "fair practices" and fair pricing models. For example, a proportional pricing model that rebalances the share of risk and reward for both parties may be more appropriate for cases in which MCM development has been heavily subsidized with public money. This may look like a simple "cost -plus" pricing model. Even with cost-plus models, the question remains: what is a fair and reasonable amount of profit? MCMx will commission research to determine a concept of fair price for heavily subsidized MCMs. This research will also investigate other factors that may reduce access to resulting products.

B. Promoting Sustainable Public-Private Partnerships

i. Move from Threats to Capabilities

MCMx will optimize partnership agreements to improve MCM development outcomes. Traditionally, the US government has contracted for MCMs that target specific threats that may never materialize. For example, over the past decade nearly half of the Strategic National Stockpile budget was spent solely on Emergent's anthrax vaccine. This "just-in-case" approach is practical for only a small number of high consequence threats. During the COVID-19 pandemic, the US government faced critical shortages of personal protective equipment and stumbled in their approach to manufacture or acquire them in time.

The US does not have a well-developed "just-in-time" response strategy that can respond to unforeseen threats. As a result, outbreaks of unexpected pathogens are often addressed through crisis-driven partnerships that are neither scalable nor sustainable.

For example, COVID-19 testing was severely restricted by shortages of nasal swabs and other test kit components, a problem that ultimately had life and death consequences as states were left to compete with one another for limited supplies. Even crisis contracting can be slow and inefficient, often failing to build on hard-won lessons or focus on sustainable partnerships for the future.

In order to avoid the "panic and neglect" investment cycles that have characterized crisis response, MCMx will require a permanent funding line to develop, integrate, and maintain essential capabilities, thereby moving away from emergency supplemental appropriations. A permanent funding line will enable MCMx to build out partnership agreements that are designed to pivot to address an emerging pathogen and scale production in advance of the next outbreak.

ii. Match Capital to Capabilities

MCMx will match private sector capability with the appropriate government partner and funding source. Aggregating and sequencing capital to support the development life cycle of key technologies for different partners is critical, as different forms of support and incentives are required for different technologies and partners. Larger corporations like Pfizer will have the assets and capabilities required to self-fund development, manufacturing, clinical evaluation, and distribution. Other partners will need more direct support and guidance. Tailoring incentives to a range of partners will broaden the potential field of innovators and determine the range and type of solutions available for public interest innovation.

iii. Make Direct Requests and Award Good Actors

Industry leaders can contribute to platforms for data sharing, assist with technology transfer, and abide by fair pricing and access provisions. In public health emergencies, MCMx will make direct requests and acknowledge companies that act in the public interest. There is historical precedent for this. During World War II, the US forged new partnerships and practices that generated a record number of new vaccines. As part of this effort, the government made explicit efforts to stoke patriotism among industrial leaders and to equate productivity with freedom. In some cases, the military presented vaccine producers with awards, such as the Army-Navy "E" award for excellence in the production of war equipment.

V. Conclusion

The US must be ready to rapidly respond to any pathogen with pandemic potential. The development of vaccines and therapeutics within a year of this pandemic was a remarkable achievement, but COVID-19 has claimed more than half a million lives in the US, and more than 3 million worldwide, with hundreds of millions infected. Globally, many more will likely be infected and die before the crisis ends. We can and must move more quickly. Indeed, already there has been a unified call to action to develop MCMs within 100 days of detection of a new pathogen. Sustainable public-private partnerships and global coordination are necessary to achieve this goal.

The task force proposes MCMx: a new federal authority that would give the US the ability to lead in this mission with national and global impact. MCMx, through innovations in contracting, will build out a matrix of public private partnerships that can develop MCMs rapidly for emerging infectious disease threats. MCMx will work with and amplify the efforts of its counterparts around the world and streamline global MCM development efforts to ensure speed, scale, and access to MCMs for future health crises.

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