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Medical Countermeasure Manufacturing Zones: A Proposed Tool for the Pandemic Response

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ABSTRACT

Widespread and lingering shortages of medical countermeasures (MCM) continues to hinder the COVID-19 pandemic response. Shortages of personal protective equipment (PPE) have placed healthcare workers, emergency responders, and members of the public at inordinate risk of contracting the disease; a lack of medical supplies, including vaccines, has crippled some hospitals' abilities to provide necessary care. The source of these shortages is a failure to invest in public health resiliency, including an overdependence on the global supply chain. To help solve this problem, this paper proposes the creation of a new special jurisdiction-—Medical Countermeasure Manufacturing Zones (MCMZ). Industries operating in or reshoring production of MCM to these zones would 1) benefit from special tax incentives and 2) gain priority consideration in public purchases, including those made for the Strategic National Stockpile (SNS). Priority purchasing consideration provides the strong demand signal industry requires in order to reshore production. Lastly, these producers would be required to sell to U.S. purchasers before exporting their goods during a declared public health emergency. Making products in the United States and guaranteeing sale of that PPE to U.S. purchasers would help to strengthen the MCM supply chain and ensure that supplies are available in times of public health crisis. This paper takes a United States-centered approach to emergency response, proposing a new type of federal-level special jurisdiction in the United States, called Medical Countermeasure Manufacturing Zones (MCMZ). This model, as we later conclude, could be replicated in other countries in order to grow domestic MCM production and promote greater public health resiliency.

Keywords: Public Health; Medical Countermeasures; Foreign Trade Zones; Manufacturing, United States.

RESUMEN

La escasez generalizada y persistente de contramedidas médicas (MCM) continúa obstaculizando la respuesta a la pandemia de COVID-19. La escasez de equipo de protección personal (EPP) ha puesto a los y las trabajadores(as) de la salud, los servicios de emergencia y el público en un riesgo excesivo de contraer la enfermedad. Igualmente, la falta de suministros médicos, incluidas las vacunas, ha

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mermado la capacidad de algunos hospitales para brindar la atención necesaria. La fuente de esta escasez es la falta de inversión en la resiliencia de la salud pública, incluida una dependencia excesiva de la cadena de suministro global. Para ayudar a resolver este problema, este documento propone la creación de una nueva jurisdicción especial en Estados Unidos: las Zonas de Fabricación de Contramedidas Médicas (MCMZ). Las industrias que operen o reubiquen la producción de MCM en estas zonas 1) se beneficiarían de incentivos fiscales especiales y 2) obtendrían consideración prioritaria en las compras públicas, incluidas las realizadas para la Reserva Nacional Estratégica (SNS). La consideración de compra prioritaria proporciona la fuerte señal de demanda que requiere la industria para repoblar la producción. Por último, estos productores deberían vender a compradores estadounidenses antes de exportar sus productos durante una emergencia de salud pública declarada. Fabricar productos en los Estados Unidos y garantizar la venta de ese PPE a los compradores estadounidenses ayudaría a fortalecer la cadena de suministro de MCM y garantizaría que los suministros estén disponibles en tiempos de crisis de salud pública. Este documento adopta un enfoque centrado en los Estados Unidos para la respuesta de emergencia, proponiendo un nuevo tipo de jurisdicción especial a nivel federal en los Estados Unidos, denominada Zonas de fabricación de contramedidas médicas (MCMZ). Este modelo, como concluimos más adelante, podría replicarse en otros países para aumentar la producción nacional de MCM y promover una mayor resiliencia de la salud pública.

Palabras clave: Salud Pública; Contramedidas médicas; Zonas de Comercio Exterior; Fabricación, Estados Unidos.

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1. INTRODUCTION

By the time it arrived on U.S. shores, the novel coronavirus (COVID-19) confronted a neglected public health and medical infrastructure. The shortages it triggered were predictable and predicted, as was the burden they would impose on frontline workers and healthcare systems across the country. Critics have condemned a lack of preparedness as the root of the issue, citing a lack of sufficient stores and an inability to import and distribute the needed additional medical countermeasures (MCM). What needs further development are solutions that prepare the United States for the next pandemic or other public health emergency. Reshoring manufacturing should be part of that vision.

The Food and Drug Administration (FDA) defines MCM as "products used to diagnose, prevent, protect from, or treat conditions associated with chemical, biological, radiological, or nuclear (CBRN) threats, or emerging infectious diseases." MCM include biologic products, such as vaccines; drugs, such as antibiotics; and devices, including personal protective equipment (PPE) as well as diagnostic tests and ventilators. Both domestically produced and imported products are regulated by the FDA to ensure quality and safety. The existing pandemic response infrastructure, including the Strategic National Stockpile (SNS) and Centers for Disease Control's (CDC) Strategy for Optimizing PPE Supplies, do not offer a sustainable solution for the next pandemic. This is because the existing infrastructure is focused on managing supplies, not creating new ones.

At its establishment in 1998, the SNS was conceived as "an unprecedented national stockpile of drugs and vaccines for civilian use in case of a bioterrorist attack." Its purpose has since expanded to include measures to respond to CBRN threats; pandemic influenza; and natural disasters. However, the SNS was never intended to provide for the needs of state, local, territorial, and tribal governments simultaneously, nor to serve as the primary source for pandemic response resources (Gerstein, 2019). Considering the problems of product expiration and the substantially different needs imposed by CBRN threats,

pandemics, and natural disasters, stockpiling with the goal of fully providing for all needs across all potential public health emergencies is unfeasible. As such, the shortages of MCM—most notably PPE—stem less from a failure to stockpile as from an inability to acquire a sufficient number of quality products when they are needed.

The Centers for Disease Control and Prevention (CDC) Strategy for Optimizing PPE Supplies iterates three capacity levels containing strategies to ensure supplies are adequately matched to need. These strategies have nothing to say about production, importation, or distribution of supplies. Rather, the CDC provides guidance on how to selectively limit the provision of care in order to eliminate competition for limited supply. The presumption underlying this agenda is that, under emergency circumstances, acquiring additional supplies is so unlikely as to not be worth considering (CDC, 2020). "Steps for acquiring necessary supplies" are not offered. This is not a failure of the CDC, whose jurisdiction does not encompass the medical supply chain. The agency can only offer mitigation techniques. Medical facilities and providers, and other frontline workers, would do well to heed CDC guidance, but policymakers should be concerned with the systematic failures which undermine the opportunity to wage an adaptable response to a public health crisis.

As long as the focus of the United States' pandemic response emphasizes existing ways of sourcing MCM, it will always suffer from the pitfalls associated with global supply chains concentrated in a few countries. Increasing the supply of MCM, both for everyday and pandemic-event use, requires reshoring manufacturing of MCM. Since manufacturing benefits from collocation with research and development (R&D) and other similar activities, special jurisdictions can be an effective way of offering incentives for reshoring production to clusters wherein actors from across the MCM industry can operate in close proximity and thereby gain efficiencies and increase innovation.

This paper is structured in five sections. Section II draws upon the historically broad conception of public health to lay out the public health justification for domestic

manufacturing of MCM. Section III discusses some of the weaknesses in global supply chains, especially as it relates to MCM. Section IV proposes the Medical Countermeasures Manufacturing Zone (MCMZ) special jurisdiction, and places the need for an MCMZ in the context of the "industrial commons," which describes the ecosystem of clustered industrial actors in a certain region. Part IV also discusses some potential attributes of MCMZs related to tax incentives and government contracting to help guide policymakers interested in designing such zones. The paper concludes with a brief summary of the arguments and ideas offered throughout, and suggests how this model can be adapted to other countries with similar problems.

2. PUBLIC HEALTH JUSTIFICATION

Although the global supply chain disruptions experienced in the first months of the pandemic averted catastrophe, U.S. purchasers, and the front-line workers they supplied, were confronted with the reality of a system that was not set up to adapt quickly to crisis. Despite the valuable role that medicines and protective equipment play in the epidemiological tool kit, the early response overemphasized quarantine, isolation, and widespread shutdowns. These strategies continue to play an outsized role in the U.S. pandemic response plan. In the United States, citizens have been asked to limit time interactions for ten months through numerous primaries and a general election, multiple national and religious holidays, and one and a half school semesters. The insurmountable difficulty of maintaining social distancing has demonstrated that these policies, though necessary, are not sufficient to control the spread of COVID-19, nor to protect the health and wellbeing of frontline workers (Soo, K., 2020; Williams J., 2020). Access to physical supplies is also essential (Honein, et al. 2020). The United States must develop a strategy to create and deliver more masks, medicine, and other countermeasures, so that its people can survive this crisis.

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2.1. The Need for PPE and MCM

Demand for PPE is estimated to exceed 21.9 million units weekly in the United States ("Shortage Index," 2020). The sources of need include hospitals and clinics, but the vast majority of facilities without sufficient supplies are non-hospitals, including homeless shelters, dental clinics, nursing homes, and social services. In fact, non-hospitals account for approximately 80 percent of need. The individuals who work within these facilities must have access to PPE in order to safely provide the services that their clients rely upon in order to maintain their health and wellbeing. In October 2020, and for the third month in a row, 70 percent of all facilities were entirely out of at least one type of PPE ("Shortage Index," 2020). Part of the issue stems from a lack of NIOSH/FDA approved medical-grade PPE. Whereas face coverings may generally be widely available, the kind needed by frontline workers to assure the highest level of protection remain hard to acquire and expensive. Frontline workers and industries have struggled as a result.

The lack of PPE and MCM at the front lines of the pandemic response has led to horrific outcomes in healthcare and other essential service fields. Shortages of masks and gowns, including reports of doctors and nurses reusing PPE, have come to epitomize the COVID-19 pandemic (Morning Edition, 2020). Healthcare workers have died as a result of this lack of protection (Clark, C., 2020; Karlamange, S., 2020; Gee, A., 2020). When New York City experienced a surge in cases in May 2020, a lack of ventilators threatened to trigger medical rationing (Johnson, M., 2020). Lacking swabs to use for COVID-19 testing, Boston doctors organized former classmates and "an army" of 3D printers to produce their own supply. Overall, the scarcity of swabs has "hobbled" testing in the United States (Mfuson, et al., 2020). So unbalanced are supply and demand for N-95 respirators that an informal market for these supplies has emerged (Clark, D.B., 2020). There is a clear need

for concerted efforts to establish MCM supply chains that can respond quickly and effectively to crisis-level demand.

In recent months, the United States have started to deploy additional MCM in the form of vaccines. Both Pfizer and Moderna—the manufacturers of the two FDA-approved vaccines—are operating at maximum capacity to produce these vaccines (Lupkin); hospitals, pharmacies, and other authorized distributors are operating at maximum capacity within the limitations of their staffing and supplies to deliver them. Vaccines comprise components: mRNA, lipids, potassium chloride, monobasic potassium phosphate, etc. They come in glass vials and are stored in "extreme cold" storage. As with other MCM, a robust vaccine supply chain requires secure and diversified sources for not just the final product, but the component parts as well.

2.2. Toward a Broader Conception of Public Health

Public health is an interdisciplinary field that intersects with medicine and with policy. It aims to promote the health of a population as a whole by dealing with the factors of disease, including hygiene, epidemiology, and disease response, as well as the nonmedical factors of health (also referred to as the "social determinants of health"). One way of conceptualizing public health is to think of illness as something that can be prevented: primary prevention is proactive, aiming to avoid the contraction of disease (i.e. strategies to avoid spreading COVID-19); secondary prevention aims to identify and respond quickly to new cases (i.e. COVID-19 testing and contact tracing); and tertiary prevention seeks to mitigate the effects of a disease that has already been contracted (i.e. reducing the severity of COVID-19 symptoms and avoiding death). MCM plays a role in each of these stages.

In its capacity as advocate for disease prevention, the field of public health ought to be concerned with how the nation shapes and manages the medical supply chain. That the nation has allowed the vast majority of MCM production to offshore demonstrates the lack

of coordination between the public health and manufacturing sectors. It is not that public health officials are unaware of the problem: in early 2020, the U.S. Department of Health and Human Services (HHS) published a report highlighting the problems with the current MCM supply chain under pandemic circumstances (Office of the Assistant Secretary for Preparedness and Response, 2020). It is clear now that HHS was right. The result of a lack of communication between the manufacturing and public health sectors has been an inability to provide a domestic response to material needs during a public health crisis.

At the turn of the last century in American politics, Congress considered some of the first legislation intended to reform the systems which affected public health and wellbeing, including the non-medical factors of health. The proposals of this time understood public health in a way that contemporary politics is only beginning to rediscover. Leadership in the early 1900's "did not simply envision that the sick should be able to purchase medical care," but rather, "viewed poor health as…a problem of the underlying economic structure" (Fairchild, et al., 2010). Though neglected, this viewpoint remains no less pertinent in 2020: when the pandemic hit, insurance could not save the hospital system from collapse; the trade and manufacturing sectors had to do that by ensuring that hospitals and providers were equipped to provide necessary care safely. Moving forward, the United States needs to readopt the early 20th Century's consideration of strategies outside of medicine and money to bolster the nation's defenses against deadly diseases.

The United States' pandemic response problem is contained within its narrow conception of health. Preparedness has similarly been too narrowly conceived. Public health, trade, and manufacturing must work together for the nation to achieve effective pandemic preparedness. Growing the domestic manufacturing sector would enable the nation to scale supply to meet demand during future public health emergencies. Strategic contracts with manufacturers could also sustain spending on the SNS to ensure that stockpiles are sufficiently maintained and consistently replenished.

In addition to providing a more responsive and resilient MCM supply chain, reshoring manufacturing of MCM to the United States could bring about other positive health effects in areas in which factories were reopened. These factories would provide jobs and economic stability to local communities, which can serve to improve health outcomes ("Employment," 2020). The added benefit of domestic MCM manufacturing is renewed investment in an early idea of health promotion: an economic structure more supportive of individual and societal wellbeing.

3. GLOBAL SUPPLY CHAINS CAN HURT THE PANDEMIC RESPONSE

3.1. Dependence on Foreign Imports

The United States' pandemic response has been limited by its excessive reliance on MCM produced overseas. Imports account for an overwhelming percentage of the U.S. supply of many types of MCM. For example, China accounted for over 15 percent of U.S. imports of medical ventilators and over 70 percent of medical protective articles, including masks, in 2019 (U.S.-China Economic and Security Review Commission, 2020). Over 70 percent of active pharmaceutical ingredients (APIs) used in the United States are produced in foreign countries, with over 30 percent made in India and China alone (Kota & Mahoney). It is notable that the Peter Institute for International Economics encouraged nations to scale up domestic MCM production, and the European Union (EU) Chamber of Commerce has specifically urged EU member nations to diversify their supply chains away from China (Brown, C., 2020; Crossley, G., 2020).

The United States' dependence on imports for MCM puts public health at the mercy of foreign governments. In February 2020, the Chinese government commandeered all production of medical supplies for domestic use, limiting even U.S. companies from exporting their Chinese-produced goods (Pinghui & Xin, 2020). Twenty-four EU nations imposed similar export restrictions in March (Bayer, et al., 2020). Without U.S.

manufacturing to scale up MCM production, these gaps often went unfilled. The Congressional Research Service posits that China's attempts to secure sufficient MCM to provide for the needs of its citizens during the pandemic "likely exacerbated medical supply shortages in the United States and other countries, particularly in the absence of domestic emergency measures that might have locked in domestic contracts, facilitated an earlier start to alternative points of production, and restricted exports of key medical supplies" (Sutter, et al., 2020). The same policies which facilitated a steep rise in Chinese MCM production also contributed to sharp decreases in exports of these critical supplies. One expert writes:

> In a dark irony, most of the world's face masks—now ubiquitous in China as a precaution—are made in China and Taiwan, and even for those made elsewhere, some component parts are Chinese-sourced. Shortages have led China to declare the masks a "strategic resource," reserving them for medical workers. U.S. hospitals are "critically low" on respiratory masks, according to medical-supply middlemen. Lack of protective gear could increase vulnerability to the virus, and the one place on earth suffering from production shutdowns is the one place where most of the protective gear originates. (Stoller, M., 2020).

Furthermore, there is evidence that China prioritized certain trade partners over others when exporting MCM. Whereas the United State accounted for 40.9 percent of China's export market for N95 respirator masks—the greatest single holder of market share—in 2019, in 2020 the EU usurped the United States, claiming 34.6 percent of Chinese N95 mask exports compared to the 25.5 percent exported to the United States (Sutter, et al., 2020). Because of the United States' dependence on China, China holds a great deal of leverage to determine American's access to lifesaving supplies. The current crises—public

health and economic—which affected the wellbeing of individuals worldwide, "provides the chance to rethink fundamental assumptions about our country's economic and social system," including the role for public health to lay in shaping policies and practices that promote good health (Fairchild, et al., 2010). Defensive policy decisions may have been rational in light of the dire state of public health within the nations which enacted them at the time. But the fact remains that the United States' reliance on foreign nations undermined its own ability to effectively respond to the pandemic.

3.2. Limitations Inherent to the Global Supply Chain

Even if trade had continued as usual during the pandemic, scaling issues and long shipping times might have undermined the speed and deftness of the U.S. public health response to the crisis. The Crimson Contagion Functional Exercise Series, conducted by HHS between 2018 and 2019, tested the nation's ability to respond to a flu pandemic. The After-Action Report (2020) concluded, among other findings, that "Global manufacturing capabilities will not be sufficient to meet demand, resulting in an inability to import adequate quantities of medical countermeasures" in the event of a pandemic. Stockpiles are inherently limited and would be difficult to restock because both complete products as well as components and materials would have to be imported. Importation can become functionally impossible if any point of the supply chain is disrupted.

To counter this threat, HHS recommended that the United States "Promote growth of the domestic medical countermeasure industrial base with a focus on bolstering input supply chain development (raw materials) and enhancing rapid manufacturing supply" (Office of the Assistant Secretary for Preparedness and Response, 2020). A stronger domestic manufacturing sector would shorten the distance between suppliers, producers, and

purchasers, as well as grant the nation greater control over the end-to-end supply chain that cannot be guaranteed when it spans across nations.

To the extent that supplies exist, their availability is limited by long transportation times. Air travel is by far the fastest mode of transportation across the Pacific Ocean, but it is also the most expensive and can handle only relatively small volumes. Ocean freight is cheaper and can handle larger loads but can take up to a month from port to port (Gronkvist, 2018). Loading and unloading the cargo may account for an additional week of transit time. When needs are immediate, that is too long to wait. Moreover, the global supply chain has made it difficult for U.S. producers to compete in the domestic market. The depletion of the domestic manufacturing sector has negatively impacted public health in the United States in a number of ways. Extremely low production costs overseas, disincentivizes the production of American-made goods, even at times of heightened demand.

Lastly, the role that the U.S. manufacturing sector could play in promoting healthier American communities is undermined by a global supply chain that incentivizes the production of goods offshore. Reshoring manufacturing would also help domestic producers to the healthiness of their communities, through both their production practices and the quality of their products (West & Langsang, 2018). At the same time, reshoring would recreate manufacturing jobs, which would help to address the widespread poverty and poor mental health that arose in many working-class communities as a result of the loss of industry. Poverty and poor mental health have proven to exacerbate the adverse impacts of events like the COVID-19 pandemic (Reeves & Rothwell, 2020). What manufacturing jobs may not be able to offer in work-from-home flexibilities during the pandemic, they may have made up for in providing families with financial safety nets and, indeed, access to supplies that could protect them and others from the virus. When the United States overlooks reshoring, it not only undermines pandemic preparedness but misses an opportunity to promote greater environmental stewardship, worker protections, quality standards, and to reenforce the economic factors that promote wellbeing in local communities.

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4. MEDICAL COUNTERMEASURE MANUFACTURING ZONES

In response to the great reliance that the United States has on foreign suppliers—and in particular China—for MCM, this paper proposes a new type of special jurisdiction to incentivize the reshoring of production of MCM to the United States. Defined by alternative rules that apply with the special jurisdiction, but not the areas outside that jurisdiction, a Medical Countermeasures Manufacturing Zone (MCMZ) would mimic other special jurisdictions already in use (Foreign Trade Zones Act, 1934). MCMZs would be created by the federal government, which would bestow a number of unique privileges upon entities operating within the MCMZ. In this way MCMZs are like other special jurisdictions in both origin and operation.

How MCMZs differ is in their ability to create synergies from the agglomeration of entities engaged in similar activities. Unlike Foreign Trade Zones (FTZs), for example, which are agnostic as to industry, MCMZs would be designed specifically for use by those manufacturing MCM, PPE, and other goods deemed essential to ensure public health preparedness (Foreign Trade Zones Act, 1934).

4.1. Rationale for a Special Jurisdiction

At first it seems unclear why a special jurisdiction would be necessary to encourage reshoring production of MCM. Certainly, the federal government could provide lower taxes or longer contract awards to companies manufacturing MCM anywhere in the United States. What is the need to tie these incentives to a special jurisdiction?

4.1.1. The Case for an Industrial Commons

The short answer is that place matters. When located near each other, different companies from the same industry—even companies in the same industry but specializing in different subsets of that industry—interact in ways that drive innovation, boost efficiencies, and achieve greater success. This concept of an "industrial commons" is what makes special jurisdictions potentially so helpful for improving pandemic responsiveness (Pisano & Shih, 2009).

The industrial commons refers to local or regional "Concentrations involving a particular industry…on the presumption that they will gain an advantage in learning or in hiring workers with relevant skills and knowledge, and by being near suppliers and complementary businesses" (Shih & Chai, 2015). Think Detroit for automobiles, Silicon Valley for computers, the Raleigh-Durham Research Triangle for pharmaceuticals, Pittsburgh for autonomous vehicles, and Boston for biotech. The physical proximity of entities within these industrial commons generates a mass of workers moving between firms and bringing their creativity and expertise with them. This energy can supercharge companies (Shih & Chai, 2015). As one expert notes:

> The potential sources of agglomeration advantages include cheaper and faster supply of intermediate goods and services, proximity to workers or consumers, better quality of worker-firm matches in thicker labor markets, lower risk of unemployment for workers and lower risk of unfilled vacancies for firms following idiosyncratic shocks, and knowledge spillovers. (Greenstone, et al., 2010)

There's good evidence confirming the sound intuition that being physically closer to other experts and workers in one's field generates more success for everyone than if those individuals were scattered. The Internet has been remarkable, especially during the pandemic, at permitting individuals to communicate and collaborate almost as effectively

virtually as in-person. But only almost. Nothing can replicate a chance interaction with a potential collaborator while waiting in line at the coffee shop, or the efficacy of negotiating a solution around a physical table (Pisano & Shih, 2009).

For example, a study of the professional networks in two different research clusters in Denmark—a vibrant life sciences cluster and another a stagnant wireless telecommunications cluster—demonstrates the value of place-based clusters (Shih & Chai, 2015). The thriving life sciences cluster in Copenhagen drew heavily on Danish university students and local talent, cultivating unique local expertise that stayed and flourished in the area. The slack telecommunications cluster, in North Jutland, started strong—Denmark pioneered the development of mobile phones—but began to lag after a series of acquisitions by foreign entities and a weakening pipeline of local talent dispersed expertise (Shih & Chai, 2015). Another study of over 800,000 inventors between the years of 1971 and 2007 found that upon moving to an innovation cluster—the backbone of the industrial commons—an inventor significantly increased the number of patents they produced (Moretti, 2019). Moreover, clustering increased the overall efficiency of both an industry and the rate of innovation within the cluster's home country. According to the same study, the total number of computer science patents in the United States would be more than 13 percent lower if those inventors had been evenly distributed across the country (Moretti, 2019).

4.1.2. The Unraveling of the Industrial Commons in the United States

Unfortunately, the United States has seen a hollowing out of its industrial commons spanning at least the past generation. U.S. manufacturing has dropped from nearly 27 percent of gross domestic product (GDP) in 1990 to 11 percent of GDP today (Kota & Mahoney; FRED, 2020). This decline in manufacturing has been driven by offshoring in pursuit of cost cutting (Kota & Mahoney). Such offshoring has devastated the United States' industrial commons by degrading manufacturing clusters across the country. The ease of

offshoring and the allure of its cost savings makes it difficult for companies to keep their production in the United States. In the case of one study by the Massachusetts Institute of Technology (MIT), 150 start-ups utilizing MIT research relied on domestic skills and financing until it came time to scale production. Then those start-ups were pushed to move production overseas, especially to China (Reynolds, et al., 2014). Even worse, the long-time reassurance—that high-value activities like innovation and research and development (R&D) would stay in the United States even as lower cost manufacturing went overseas—has proven incorrect. In 2000, prior to China's accession to the World Trade Organization (WTO), U.S. corporate R&D expenditures in China were $506 million (U.S.-China Economic and Security Review Commission, 2020). From when China joined the WTO in 2001 until 2018 the U.S. trade deficit with China exploded, and the United States lost 3.7 million jobs (75 percent of which were in manufacturing) to China (Scott & Mokhiber, 2020). Unsurprisingly, R&D has since begun to leave too. As U.S. manufacturing went offshore to China, U.S. R&D expenditures in China ballooned more than 631 percent to $3.7 billion by 2017 (U.S.-China Economic and Security Review Commission, 2020). The tendency for R&D to follow production offshore has not been limited to manufacturing. The same has been true in the pharmaceutical industry (U.S.-China Economic and Security Review Commission, 2020).

The success of the industrial commons derives from its comprehensiveness. Manufacturing, design, and R&D must all be part of the equation in order for companies to see the gains that the industrial commons offers. But when manufacturing moves offshore, R&D follows, leaving behind no commons at all, but instead a wasteland of U.S. headquarters missing innovative vitality that they may not even realize they could have.

4.1.3. MCMZs as Industrial Commons

Special jurisdictions offer an opportunity to rebuild the industrial commons by helping to cluster manufacturing and R&D in certain regions and communities. By their nature,

special jurisdictions involve placing limits on to whom benefits are conferred, and where those entities may be established. In the case of the industrial commons, geographic boundaries are essential because the benefits of the industrial commons only presents itself upon the agglomeration of industrial actors.

By offering a number of special privileges to companies operating in, or relocating to, an area designated as an MCMZ, the United States can not only improve its access to PPE, essential medicines, and other MCM, but also catalyze innovations that are thwarted by distance. An MCMZ focused on PPE manufacturing might be located in parts of the southern United States to draw upon the region's history and expertise in textile manufacturing (Thomas, D., 2020). Ideally, the MCMZ would not just be focused on PPE manufacturing or pharmaceutical production, but instead bring players from these and other related industries together to draw synergies from their physical closeness. Just like in the Danish life sciences cluster, employees taking new jobs with different firms in the cluster would bring with them ideas and expertise that further drive innovation and efficiencies.

The location of MCMZs might even be determined by a competitive application process, with localities competing for the designation and its attendant benefits. The competition for Amazon's second headquarters (HQ2) demonstrated the desire of countless cities to boost their economies with the kind of big investment Amazon promised (over 238 jurisdictions threw their hat in the ring to win the location of HQ2). Yet, the fact that HQ2 was ultimately awarded to communities in New York City and near Washington, D.C. demonstrated the shortcomings of relying upon a single large corporation to be a catalyst for local economic development (Gruber & Johnson, 2019). A similarly competitive process facilitated by the federal government, whose priorities were more holistic than a private sector actor, might motivate experts in MCM research, development, and manufacturing to design for themselves the clusters that make up a healthy industrial commons. The federal benefits associated with designation as an MCMZ would incentivize this collaboration.

To expand the diversity of locations that aspire for MCMZ designations, the determination process may include state and local matching investments, partnerships between industry and area universities, or assessments of affordability or expansion potential. MCMZ designations are ultimately most capable of producing the full span of their benefits if they do not merely double down on established, high-performing cities, but look more broadly (Gruber & Johnson, 2019). Communities throughout the South and industrial heartland possess potential as innovation and manufacturing hubs, yet are often overlooked (Dizikes, P., 2019). A federally run competition for MCMZ status might help to facilitate growth in underdeveloped parts of the United States by prioritizing the creation of MCMZs in these areas.

4.2. Potential Attributes of MCMZs

There are any number of ways to design an MCMZ program in order to incentivize reshoring and the creation of an MCM industrial commons. Below, two possible and probable attributes of MCMZs are considered: tax reduction on corporate income, investment, and research; and greater length of, and priority consideration for, government contract awards. Tying these incentives to a specific geographic location could encourage the creation of clusters that support a healthy industrial commons. While not an exhaustive or exclusive list, these attributes are among the most effective tools that the federal government may have available to incentivize reshoring and encourage manufacturing sector growth in the parts of the United States where such growth is most needed.

4.2.1. Lower Taxes on Income, Investment, and Research

Favorable tax treatment has consistently been a favorite tool of policymakers designing special jurisdictions. Since 1934, FTZs have provided a reduction in tariffs to companies operating within them (Foreign Trade Zones Act, 1934). More recently, Opportunity Zones

provide tax deferral and incentives to those investing in an economically distressed area. With regard to MCMZs, policymakers could consider tax incentives involving multiple aspects. Policymakers might consider reducing the corporate income tax on producers of MCM operating within the MCMZ. They might also consider providing increases for existing tax credits, or the creation of new tax credits, for investment and other R&D activities that occur in the MCMZ.

Policymakers might also consider linking an MCMZ program with the existing FTZ program. Collocation of MCMZs and FTZs would provide duty free access to certain inputs in the manufacturing of MCM. Such collocation would be especially beneficial for companies seeking to export MCM from the zone. Although the purpose of MCMZs are to reshore production to the United States, collocation would not necessarily undermine that aim. Certain inputs or raw materials for different MCM may not be available in the United States, or impossible to reshore. In those situations, collocation with FTZs would further the aim by giving manufacturers less expensive access to those goods, thus making it easier to produce MCM in the United States rather than near the source of those overseas inputs.

4.2.2. Longer Duration of, and Priority Consideration for, Government Contracts

A unique feature of MCMZs would be its ability to offer a federal contracting preference to those companies manufacturing MCM in the zone. Federal contracts are an effective way to send a strong demand signal to private industry assuring manufactures that there will be a market for their products. Combined with domestic content requirements, such as the Berry Amendment for PPE and textile products, federal contracting can be an effective way to incentivize reshoring. But a weak demand signal can be just as useless in this regard as no demand signal.

For this reason, long-term, or multi-year, contracts are the most effective ways to use the government's contracting power to incentivize reshoring. Yet, almost all of the federal contracts for PPE issued since the start of the COVID-19 pandemic have been short-term: 90 to 120 days. Short-term contracts fail to give industry the certainty that investments in the United States will pay off. Why pay the expense to move a factory from China if after three months no one is around to buy what it produces? This is why industry experts recommend three to five-year long contracts for PPE as one of the most effective means by which the government can incentivize the reshoring of PPE (Glass, K., 2020).

Throughout the pandemic, experts have called for long-term contracts as one of the best policies available to incentivize reshoring of MCM (Adler & Breznitz, 2020). The United States government is the world's largest purchaser of goods and therefore is able to use that immense procurement volume to move markets in strategic directions (Collins & Erickson, 2020). In addition to awarding longer-term contracts, the federal government could also generally give priority consideration for contracts to manufacturers within the MCMZ. The federal government already gives contract preferences to meet specified public policy aims via contracting preferences for veterans or small businesses (Williams, J.T., 2012). Although some might see a contracting preference for a business within an MCMZ as unusual—since the entity in the MCMZ would not necessarily have special status based on its owner's background or size—the federal government does have an existing and geographically based contracting preference: the Buy American Act.

In fact, domestic contract requirements, like the Buy American Act or the Berry Amendment, are already preferences that help incentivize reshoring and limit offshoring. Policymakers could build upon the existing statutory architecture of domestic content requirements to add requirements for longer-term contracts as well as priority consideration for those contracts, when the business being contracted is in an MCMZ. Most relevant to MCMZs and the pandemic response is the Berry Amendment, which requires the Department of Defense to purchase only textile products, clothing, and footwear that are

made entirely in the United States from materials of entirely U.S. origin. Its requirement that the components be U.S. made makes the Berry Amendment one of the strongest of the domestic content requirements in U.S. law (Manuel, et al., 2016). Since the Department of Defense is the agency currently managing pandemic-related procurement, PPE purchases are required to be compliant with the Berry Amendment (Muhammah & Reece, 2020).

According to a survey by the Department of Commerce, two-thirds of companies providing textiles to the U.S. government said that the Berry Amendment had a positive impact on their business (Office of Technology Evaluation, 2017). Of course, those companies' success is in part a result of the business they receive thanks to the Berry Amendment requirement (which limits the amount of competition firms face for federal textile contracts). But, that's the point. If policymakers believe that reshoring MCM is vital for the country's pandemic response—and the evidence seems to suggest that it is—it is necessary for policies to preference those producing in the United States over those producing overseas. The Berry Amendment's popularity with domestic producers demonstrates it success for domestic industry, and combined with the additional attributes discussed above, can be leveraged as part of a contracting strategy designed specifically to target and foster MCMZs as pandemic-fighting industrial commons (Muhammad & Reece, 2020).

5. CONCLUSION

At this point in the COVID-19 pandemic, the death rate is at record highs, shortages of MCM continue, and little ambiguity remains regarding the insufficiency of the global MCM supply chain to respond to U.S. demand during a pandemic. While there are important benefits to trade, undeniable drawbacks emerge where reliance upon global supply chains conflicts with the ability of the United States to respond quickly to demand surges during a pandemic.

Offshoring U.S. manufacturing has undermined preparedness and left the nation vulnerable during a pandemic-level crisis.

The simplest solution is to reshore MCM production, and as this paper argues, to do so using a new type of special jurisdiction designed to foster not just domestic manufacturing of medical countermeasures, but an industrial ecosystem to go with it. This action would not only advance pandemic preparedness by establishing a rapid and scalable domestic supply chain, but also contribute to overall public health by creating jobs and bringing wealth back to depressed communities. While there are a variety of ways for policymakers to design such a zone, this paper contemplated a handful of possible options for MCMZs. But regardless of what they look like, medical countermeasure manufacturing zones offer a fresh answer to the thorny questions that policymakers, for more than a generation, have asked about the difficulty of sparking a manufacturing renaissance in the United States.

The aim of this paper has been to articulate the broad and theoretical case for MCMZs as part of the pandemic response and manufacturing policy tool kit, and urge others in the special jurisdiction, public health, and manufacturing communities to continue to think about, and expand upon, the concepts introduced here. Though focused on the United States, the model presented here is above all an argument in favor of utilizing tax and trade strategies to grow a domestic medical countermeasure manufacturing base that can support any nation through times of heightened need. Using this model, virtually any country could encourage collaboration between their public health and manufacturing sectors, in order to promote greater resiliency and innovation among both.

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Special Economic Zone: A Path to Increase Brazil's Economic Position with Chinese FDI

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Abstract

This paper examines the creation of a Special Economic Zone (SEZ) in the city of Pouso Alegre (in the state of Minas Gerais, Brazil) as a way to attract Foreign Direct Investment (FDI) from China. The author's hypothesis is that Minas Gerais would receive more FDI if the right incentives were put into place. SEZs are such a tool to foster Pouso Alegre's economic and social development. This paper analyzes the micro and macro environments of the zone's strategic planning to understand the endeavor's viability and what this says about Pouso Alegre city's choice. The paper also presents Brazil's and Minas Gerais' economic backgrounds to showcase the investment opportunities already in place. This paper highlights how the economic measures necessary to implement the SEZ are a formidable route to reduce bureaucratic obstacles and promote international investment from places like China.

Keywords Special Economic Zone; Economic Development; Foreign Investment; Minas Gerais; Brazil; China.

Resumen

Este artículo examina la creación de una Zona Económica Especial (ZEE) en la ciudad de Pouso Alegre (en el estado de Minas Gerais, Brasil) como una forma de atraer Inversión Extranjera Directa (IED) de China. La hipótesis de la autora es que Minas Gerais recibiría más IED si se implementaran los incentivos adecuados. Las ZEE son una herramienta de este tipo para fomentar el desarrollo económico y social de Pouso Alegre. Este documento analiza los entornos micro y macro de la planificación estratégica de la zona para comprender la viabilidad del esfuerzo y lo que dice sobre la elección de la ciudad de Pouso Alegre. El documento también presenta los antecedentes económicos de Brasil y Minas Gerais para mostrar las oportunidades de inversión que ya existen. Este documento destaca cómo las medidas económicas necesarias para implementar las ZEE son una ruta formidable para reducir los obstáculos burocráticos y promover la inversión internacional desde lugares como China.

Palabras clave: Zona Económica Especial; Desarrollo económico; Inversión extranjera; Minas Gerais; Brasil; China.