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Masks for All: Using Purchase Guarantees and Targeted Deregulation to Boost Production of Essential Medical Equipment

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Demand has rapidly outstripped supply as the urgent need for personal protective equipment (PPE) such as surgical masks, respirators, gloves, and gowns, as well as for ventilators, continues to grow apace with the COVID-19 global pandemic.

Despite paying 10 times its usual rate for N95 respirators, the state of New York still cannot source adequate supply.[1] Some factories are trying to retool to start making PPE, but a combination of regulatory barriers and demand uncertainty is limiting them from scaling up and is preventing others from starting at all.

Amid this shortfall in supply, many are calling for the president to invoke the Defense Production Act (DPA) to compel private industry to produce these much-needed supplies.[2] President Trump has started intermittently using the law in recent weeks: commanding General Motors to begin production of ventilators after negotiations broke down and preventing mask manufacturer 3M from partaking in certain types of medical exporting.[3] But pressure for even more aggressive action is mounting as shortages increase across the country.[4] Meanwhile, the FDA has been slow to remove regulatory barriers that add months to production schedules or to authorize the importing of foreign-made mask substitutes.

On April 3, the White House and the Centers for Disease Control and Prevention (CDC) updated their guidance to recommend that the public wear cloth face masks as a stopgap measure until the production of more effective medical masks (such as surgical masks and N95 respirators) can be scaled up. Therefore, government officials need to seriously evaluate the fastest strategy for sub-

stantially increasing supply.[5] According to estimates from the Department of Health and Human Services, the Strategic National Stockpile has about 35 million masks, amounting to only 1 percent of the number the United States will need for medical professionals alone, let alone for the general public, in the event of a full-blown pandemic in the United States.[6] Heavy-handed government mandates may increase supply on the margin, but a more effective approach would be to unleash American industrial capacity through massive government purchase guarantees and the removal of liability risk and regulatory barriers.

OVERVIEW OF THE DEFENSE PRODUCTION ACT

The DPA evokes romantic images of military-industrial production during World War II, and while it does provide the power to effectively nationalize certain sectors, the law is more flexible than is commonly believed.[7] It also grants the authority to pursue a more incentive-driven approach appropriate for this crisis.

The DPA has three primary sections. Title I allows the president to force businesses to accept and prioritize contracts relating to the provision of goods or materials necessary for national defense. Title III offers some tools that can modify the incentives private producers face, including the ability to offer guaranteed loans and purchase guarantees. Title VII is a more general section that provides the ability to create voluntary agreements with private industry and shield them from antitrust liability.

While political calls to simply "mandate production" using Title I are growing,[8] there are a few major differences between previous military contexts in which the law was used and our current medical crisis. First, production of PPE and ventilators requires less secrecy than military production. There is no fear that other countries may discover vulnerabilities in the production of face masks or medical gloves as there might be for an F-16. Second, production knowledge of PPE and ventilators is already widespread in the private sector, whereas many factories did not know how to make the requested military applications and required military supervision to manufacture them to precise specifications.

More practically, using this top-down system, how are government officials to determine the following:

- Which specific factories have the lowest fixed costs required to adapt production processes to start producing PPE or ventilators?
- What quantity of medical goods is optimal for each specific factory to produce, given local labor supply and existing infrastructure constraints?
- Are there simple modifications to the designs of these medical goods that would enable specific manufacturers to ramp up production more quickly?

The dispersed information conveyed in price signals is necessary to answer these questions, and ramping up production as quickly and efficiently as possible requires government officials to leverage the price system rather than work against it.

OFFER PURCHASE GUARANTEES THROUGH TITLE III

While surging market demand for the production of PPE and ventilators has surely increased prices and signaled to manufacturers the need for more supplies, there are several reasons to think additional government support will be needed, through well-structured purchase guarantees, to reach optimal production.

Externalities

For goods like medical masks, for instance, the benefits of wearing a mask are not fully internalized by the consumers who would purchase them in a normal market. If an asymptomatic patient is inadvertently spreading the virus in ways a face mask would have reduced, the cost to society is much larger than the cost of purchasing the mask, but the individual internalizes very little of the benefit of reducing the spread.[9] It is therefore justifiable for the government to try to reduce the cost to consumers as much as possible in an effort to incentivize broad, public use of face masks.

While US public health officials have thus far discouraged widespread medical mask usage for fear of worsening shortages for healthcare workers, the weight of the evidence appears to show significant public health benefits associated with their careful use.[10] Indeed, countries with much higher use of face masks, such as South Korea, Singapore, and Taiwan, have seen slower growth rates in the spread of the virus that causes COVID-19.[11] Influenza modeling efforts have also shown the huge potential impact of public mask wearing. One study argues that "an 80% compliance rate essentially eliminated the [modeled] influenza outbreak."[12] If the United States hopes to reach even close to 80 percent public mask wearing, not only will production need to be massively scaled up, but the cost to consumers should be essentially free.

Uncertain Demand

Retooling production facilities for the manufacture of medical supplies entails large fixed costs, and uncertainty about the length and breadth of the excess demand can be a significant deterrent to this effort. For example, after a wave of concern about swine flu boosted medical mask sales in 2009, manufacturers such as Prestige Ameritech responded by doubling their staff and investing millions in new factory equipment, only to find that by the time they had ramped up supply, the crisis was over and demand plunged as hospitals found themselves with a glut of medical equipment. Prestige Ameritech suffered major losses and came to the brink of bankruptcy as a result.[13]

The fear of a similar collapse in demand appears to be a barrier today for businesses considering investing in retooling their factories. According to a report from the *New York Times*,

> Industry executives say companies are reluctant to crank up production lines without purchasing guarantees from the government. With the economy in free-fall and factories shuttering around the country, few manufacturers are eager to invest in new machinery or venture into new products.[13]

Manufacturers face uncertainty about whether this period of surging demand will last only two to three months or eight to ten; whether the CDC will eventually recommend that the general public wear medical face masks or only healthcare workers; and whether globally the virus will continue to spread or whether the sudden development of a vaccine will arrest its progress. These factors lead to a huge amount of investment uncertainty about the expected volume of demand. While almost all manufacturers are ramping up production to some extent, whether they choose to increase their investment in machinery, staffing, and raw materials by two times, five times, or ten times is very dependent on the perception of the risk of a future supply glut.

The federal government has the ability to assuage these fears and give firms more certainty by using purchasing guarantees through Title III of the DPA: essentially, the government can promise to buy enormous quantities of a product for a set time period or to buy any excess supplies if the crisis proves shorter than anticipated. Even if the US government ends up with a surplus of medical equipment, this will provide an excellent opportunity to build up strategic medical stockpiles, whose limited supplies helped accentuate this crisis in the first place.[14]

Speed

Price signals typically help direct various inputs and labor toward their most productive use, but it can take time for markets to adjust to a new equilibrium that enables massively ramped-up production. The government is able to speed up this process by sending a large and credible signal that medical equipment will be purchased at higher-than-normal market rates for a sustained period. The higher the price, the faster manufacturers will start retooling production lines and the faster the producers and shippers of raw materials will begin reforming their supply chains. All else being equal, a higher willingness to pay from the government will lead to faster results. And the "speed premium" in a pandemic is incredibly high.[15]

In early March, the Department of Health and Human Services offered to procure up to 500 million N95 respirators—the primary instance of using a federal purchase guarantee to boost the COVID-19 response to date.[16] While this is a welcome move, its production timeline, which spans 18 months, is hardly sufficient to meet this urgent crisis, and the rigid payment structure effectively bars new entrants from participating.[17]

Furthermore, while this solicitation helps address N95 respirators, purchase guarantees can also be an effective tool for increasing the production of ventilators, surgical masks, gloves, gowns, and other vital equipment.

Indeed, to provide protective masks for all Americans, the magnitude of total mask production needs to be closer to 500 million *per week*.[19] The recent White House and CDC guidance recommends the use of cloth masks to the general public because the production of surgical masks has not yet scaled up to the point where it can support all Americans.[20] While cloth masks are more effective at slowing the spread of disease than wearing no mask at all, surgical masks are more effective than cloth, and N95 respirators are more effective still.[21] If manufacturers could rapidly increase the production of medical masks, public health officials wouldn't be forced to make this tradeoff between effectiveness and availability. The goal of US production efforts should be to make this possible.

To take full advantage of the incentive powers of purchase guarantees, government purchasers should be willing to solicit enormous orders while paying rates significantly above previous market prices. They should also offer guaranteed loans through Title III to firms that need funds to cover fixed costs related to retooling and should structure purchase agreements in a flexible manner so that alternative models that don't meet traditional specifications but still serve the same function are eligible.[22]

ANTITRUST AND LIABILITY PROTECTION

Note that while Title III of the DPA provides a framework, it is not necessarily the only vehicle for offering purchase guarantees. Broad procurement requests similar to those offered by the Department of Health and Human Services can also be used. However, once the government begins operating through the DPA process, it is easy to supply additional protections to the businesses considering production of needed goods. Title VII of the DPA offers the president the ability to enter into voluntary agreements with private firms that are helping to produce essential goods and shield them from possible antitrust suits that could occur while they coordinate mass production.[23]

To complement the antitrust liability protections, Congress should consider issuing liability waivers to any party that receives a government contract to produce PPE or ventilators. In such cases, the government would assume liability for harms to healthcare workers or patients.

This approach has already been successful in a limited test case. Masks for healthcare workers typically have to be produced on manufacturing lines certified by the FDA, while masks for industrial workers are produced in facilities regulated by the National Institute for Occupational Safety and Health (NIOSH).[24] Congress recently passed legislation that extended liability protection for producers of industrial PPE to include sales to healthcare customers.[25] Before the waiver,

to industrial customers. Following the exemption, 90 percent of masks are going to healthcare workers. This liability protection should also be expanded to include more mask types (including reusable masks).

By reducing liability on both these margins, businesses should be able to rapidly scale up production processes with more confidence.

REGULATORY AND LEGAL BARRIERS

Regulatory agencies also need to reduce barriers that significantly slow down medical equipment production processes and deter new entrants. In addressing these shortages, the FDA should learn from its difficult experience ramping up diagnostic testing for COVID-19.

In early February, the FDA granted an emergency use authorization (EUA) to only the CDC for its testing protocol.[25] After the CDC testing kits were distributed to hundreds of partner labs across the country, it was discovered that one of the reagents was faulty, rendering the kits unusable. The FDA attempted to resolve this issue for weeks but was unsuccessful.

At the end of February, after increasing public pressure, the FDA granted a temporary EUA exemption for labs certified to perform high-complexity testing consistent with requirements under the Clinical Laboratory Improvement Amendments to develop their own tests.

Two weeks later, after these half measures proved insufficient, the FDA granted all high-complexity testing labs a permanent EUA exemption and devolved oversight to the states. The FDA also issued temporary EUA exemptions to all commercial labs and manufacturers for COVID-19 diagnostic testing. Up to that point, the United States had only conducted about 25,000 diagnostic tests. In the following two weeks, the total reached almost a million.[26]

Unfortunately, the United States is still in the "half measures" stage of FDA support for PPE and ventilator production. The normal FDA approval process takes months or even years. For example, the average approval time for a production facility that is certified to make N95 respirators is more than three months.[27] Typically, these long approval timelines can be circumvented by the EUA process, and, in recent days, the FDA has provided some regulatory relief:

- *Expired respirators.* On March 2, the FDA issued an EUA for respirators that have "since passed the manufacturers' recommended shelf-life, are not damaged, and have been held in accordance with manufacturers' storage conditions in strategic stockpiles."[28]
- *Industrial respirators.* On March 2, the FDA granted an EUA for respirators produced in NIOSH-approved facilities but originally intended for industrial use to be used in healthcare settings.[29]

- *Imported respirators.* On March 24, the FDA issued an EUA for imported respirators that are not manufactured in NIOSH-approved facilities but meet a given performance standard in Australia, Brazil, Europe, Japan, South Korea, or Mexico and fall within certain product classifications (notably omitting Chinese KN95s).[30]
- *Improvised ventilators.* On March 27, the FDA issued new guidance allowing healthcare providers to modify anesthesia gas machines and positive-pressure breathing devices for use as ventilators.[31]
- *Decontaminated respirators.* On March 28, the FDA issued an EUA for a decontaminating system from the Battelle Memorial Institute that cleans single-use disposable respirators and makes them reusable.[32]
- *Chinese KN95 respirators.* On April 3, the FDA issued an EUA for "non-NIOSH-approved N95 respirators made in China, which makes KN95 respirators eligible for authorization if certain criteria are met, including evidence demonstrating that the respirator is authentic."[33]

In announcing the decision to not block KN95s, an FDA official said, "There are a number of countries that we feel are as vigorous as US standards and China is one of them."[34] The CDC has stated that KN95s are "suitable alternatives" to N95 respirators and "are expected to provide protection to workers."[35] A report from the personal safety division of 3M, a leader in respirator production based in Minnesota, concluded that "it is reasonable to consider China KN95 . . . as 'equivalent' to US NIOSH N95 . . . for filtering non-oil-based particles such as those resulting from wildfires, PM 2.5 air pollution, volcanic eruptions, or bioaerosols (e.g. viruses)."[36]

However, by making KN95 respirators only "eligible for authorization if certain criteria are met," the FDA is leaving the vast majority of Chinese manufacturers on an uneven playing field relative to US manufacturers, at a time when China is the only country with a readily exportable surplus of PPE (as a result of increasing production more than tenfold and forcing producers to sell every unit they made to the government in January and February).[37] In fact, the FDA has "so far authorized one specific model of KN95 mask, manufactured by BYD Precision Manufacture Co., a Shenzen-based company," which means that every other non-NIOSH-approved Chinese manufacturer remains in legal limbo without liability protection (i.e., not blocked from exporting to the United States, but not authorized to do so either).

Owing to the worldwide shortage of N95 respirators, the operative question for FDA regulators is not whether a Chinese KN95 respirator is preferable to an American N95 respirator. The question is whether it is better than the CDC's recommendation that healthcare professionals "might use homemade masks (e.g., bandana, scarf) for care of patients with COVID-19 as a last resort."[38]

Until the acute shortage of respirators for healthcare workers has been resolved, the FDA should grant an EUA, including a liability waiver, for Chinese manufacturers that have been authorized to market PPE (including KN95s) or ventilators in any country that is a member of the Organisation

for Economic Co-operation and Development. There is not enough time to demand certification of factories before commencing production, especially considering that the FDA has postponed most foreign inspections through April.[39]

Instead, the government should inspect samples during the customs process and verify that they meet a minimum quality standard. Furthermore, hospitals can conduct random quality checks after accepting delivery but before handing out PPE to healthcare workers or using ventilators on patients. Suppliers that deliver counterfeit or low-quality products could be banned from future imports. This is broadly the model European countries have followed, which has allowed them to maintain the flow of imports from China while blocking inauthentic products.[40]

While all of the other half measures from the FDA in the last month were helpful in expanding the supply of PPE and ventilators for US healthcare providers, they will likely still fall short of meeting peak demand, just as the FDA's actions at the end of February did not go far enough to ensure widespread testing. Our proposed deregulatory solutions, in conjunction with purchase guarantees for manufacturers, would go much further and be more likely to address the shortages.

The FDA should issue temporary EUA exemptions for all domestic manufacturers of PPE and ventilators, just as it did for diagnostic testing. The CDC should delegate the testing currently done at the National Personal Protective Technology Laboratory within NIOSH to university and private labs. The particulate matter testing gear used by that laboratory is widely available and university and private labs are capable of verifying that products meet performance standards.

The FDA should also remove quantity limits when any entity has been granted an EUA. For example, Battelle Memorial Institute was recently granted an EUA for its system that decontaminates single-use N95 respirators so that they can be reused by frontline healthcare workers. The EUA was initially limited to 10,000 N95 respirators per day per machine, even though Battelle claimed each machine could decontaminate up to 80,000 per day.[41] The EUA was later increased after a public pressure campaign.[42] The FDA should grant EUAs based on the *process* or *product* being proposed, not on the agency's estimation of maximum production capacity.

Lastly, the government should waive price gouging laws as related to PPE for the duration of the crisis. According to Melissa Chen, the New York editor of *Spectator USA*, price gouging laws cause importers and suppliers to be "reluctant to order PPEs from vendors for fear of being penalized" and, as a result, they "get outbid by foreign competitors so the US loses out."[43] An extended period of high demand—months if not years—means that there is more time for suppliers to respond. And the higher the price signal, the more likely it is that producers will be willing to retool their factories, even if their cost structures are higher than average and doing so would have been unprofitable at normal market prices.

CONCLUSION

Healthcare workers are rightly outraged that they are being asked to take care of infected patients without the proper protective gear. Patients are rightly worried that they might not be able to go on a ventilator if their symptoms become more severe. These concerns have led the FDA to issue partial regulatory exemptions and President Trump to invoke Title I of the DPA in a negotiation with General Motors.

But if the United States is truly going to address its PPE and ventilator shortage, much more aggressive measures are needed. The executive branch should use Titles III and VII of the DPA to unleash American industrial capacity through purchase guarantees, allowing firms to cover their fixed costs and rapidly scale up production. Congress should issue liability waivers for manufacturers outside the healthcare industry, which would encourage more market entry. Lastly, the FDA should waive all EUA requirements for domestic manufacturers and expand the exemptions list for imported PPE.

These measures are necessary to deliver on the latest and most urgent American entitlement—Masks for All.

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NOTES

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18. Not only must manufacturers comply with all existing face mask production regulations, but the pricing must be deemed "fair and reasonable," which in this case means within 10 percent of the firms' "established and published commercial market prices." Practically, it will be very difficult for any new entrants to undertake the costs necessary to retool production lines and begin producing face masks within 10 percent of incumbent firms' traditional prices. See the Q&A document provided by HHS, "RFP 75A50120R00008," accessed April 3, 2020, https://beta.sam.gov/api/prod/opps/v3/opportunities/resources/files/32330105ea844fc9966d72e1dd47d51f/download?api_key=null&token=.

19. This is not meant to be a formal estimate; it is more an order-of-magnitude adjustment. However, if all 327 million Americans are to be provided with a mask on a weekly basis (and healthcare workers will need significantly more than that), 500 million may be a lower-bound estimate. Granted, the frequency of replacement will vary greatly between N95 respirators (which can be sterilized and reused in some cases) and surgical masks (which need to be disposed of more frequently). In South Korea, the goal of mask distribution is two masks per person per week, which if applied to the United States would raise its production goal to around 654 million per week for the general public alone. Andrew Jeong, "South Korea Rations Face Masks in Coronavirus Fight," *Wall Street Journal*, March 15, 2020.

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