

**The Center for Hospital Finance and
Management**

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Senators Marco Rubio and Benjamin Cardin and members of the Committee on Small Business and Entrepreneurship, thank you for inviting me to testify this morning.

My name is Dr. Gerard Anderson. I am a professor of Health Policy and Management and International Health at the Johns Hopkins Bloomberg School of Public Health and a professor of Medicine in the Johns Hopkins School of Medicine. I am also the director of the Johns Hopkins Center for Hospital Finance and Management. I am testifying as a faculty member and not as a representative of Johns Hopkins University.

My testimony will focus on how small businesses can help address the problems created by Coronavirus and specific actions Congress can take to assist small business during this outbreak.

- 1. Perhaps the most important provision for reducing the spread of the novel Coronavirus is to monitor the response to the \$1 billion in loan subsidies for small businesses in the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 to determine if more support is needed. Paying for 14 days of sick leave is a critical addition to consider.**

My concern from a public health perspective is that there is a strong financial need for small businesses to remain open during the Coronavirus outbreak since most of them have limited financial reserves. In addition, many of their employees who have symptoms of Coronavirus will likely continue to work because they cannot afford to take 14 days off or lose their job. However, an infected employee working in a small business that caters to the public would likely spread the infection to many hundreds of people.

If the epidemic gets worse, Congress may need to revisit the \$1 billion dollar appropriation for small businesses so that employees do not inadvertently spread the disease by remaining open. Their employees need paid sick leave.

Small businesses who were otherwise succeeding before Coronavirus will need short-term support that allows them to cover lease obligations and recurring payrolls if they need to shut down for 14 days. A loan will not be sufficient.

We have all read stories of people not going to Chinese restaurants because of misplaced fear that they will contract the Coronavirus. These small businesses are hurting for reasons that are totally outside of their control. There is no reason to expect that you will contract Coronavirus in a Chinese restaurant more than any other restaurant.

Larger companies, like some in the Seattle region (e.g. Amazon) have chosen to voluntarily close their offices and allow people to work from home. Most of these companies offer paid sick leave and can telework. But for many small businesses this is not possible since they must deal with their clients face to face.

In contrast to large businesses, most small business do not have large balance sheets to sustain them through periods of operating losses. Many small businesses depend on short-term cash flow to meet their monthly expenses and keep employees on their payrolls. Small businesses that carry debt may face even greater financial pressures.

2. Small businesses already play a key role in the development of most brand name drugs and could do the same for vaccines to treat Coronavirus.

A portion of the \$3.1 billion in the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 should be earmarked to support small biotech companies, as they are the most likely developers of the vaccines that will treat the novel coronavirus.

A significant portion of the world's new drugs come from a uniquely American public-private partnership that involves the NIH, our universities, medical centers, small biotech companies, small service businesses and large pharmaceutical companies.

One of the small companies with a Coronavirus vaccine already in human clinical trials is Moderna, which began operations in 2011 with key contributions from academic medical centers. Another example is NewLink, which helped develop the Ebola vaccine in 2015. A third example is the Coalition of Epidemic Preparedness Innovations (CEPI). CEPI receives funding from multiple federal governments and invests in small biotech for pre-clinical and early stage development of new vaccines. For COVID-19, CEPI with new funding from the UK and Norway announced support for a small biotech, CureVac AG, to develop a vaccine along with Inovio, University of Queensland, Moderna, and GSK. Novavax (based in Gaithersburg, MD with 375 employees) specializes in clinical-stage vaccine development and funded with a large grant from the Gates Foundation. Novavax has worked to develop vaccines for MERS, SARS, and Ebola.

With the benefit of federal funding from NIH and other sources, our universities and medical centers make important scientific discoveries. Their best insights are typically licensed to venture capital-backed biotech startups. These small biotech firms rely on a network of service providers that allow them to obtain essential services, such as drug manufacturing, animal testing and clinical trial management.

As the successful programs approach FDA approval, large pharmaceutical companies partner with these small businesses, or buy them outright. It is typically the small biotech that makes the initial discovery.

For example, this is how the first drug that was effective in treating hepatitis C was developed. It began in a lab at Emory University with funding from the National Institutes of Health. With promising results, the researchers started a small business and attracted venture capital. After the clinical trials showed very positive results, a big company (Gilead) purchased the small company (Pharmasset). One year after that, the new drug to treat hepatitis C received FDA approval and was brought to market. Most of the development was completed by a small business.

Under non-emergency conditions, funding for vaccines is primarily driven by venture capital, government funding through HHS (BARDA and NIH) and DoD, multi-national organizations (Gavi, CEPI, and UNITAID), and philanthropy (PATH, Gates Foundation, and Wellcome Trust).

Under pandemic conditions, a flood of money comes into the space and there is the challenge of bringing the product to market in as short a time period as possible. In these conditions, we are often funding several duplicative streams of development with the hopes of one product making it to market as quickly as possible. The urgency of the situation fosters several public-private partnerships and some of the companies may not have the expertise to work on a vaccine/treatment.

Despite the additional funding and the urgency, a vaccine is typically 12-18 months from discovery to market. I think the key question is - how do we create the right incentives so we are not in a race to save people after an outbreak occurs but are willing to build a robust system to develop products to prepare for the next epidemic?

In order to sustain development over the long run, the federal government should support small businesses, by guaranteeing the purchase of a certain volume of vaccine (if it is approved by the FDA) at a certain price, or by giving them an advance market commitment to purchase safe and effective products after approval.

3. Telehealth is a critical component of treatment in a public health emergency, especially when

people are quarantined.

Congress permitted waiver of Medicare requirements to allow payment for telehealth services during emergency periods in the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020. This is an important action, but much more can be done. It is important to have telehealth services available to everyone not just Medicare beneficiaries.

In addition, having electronic medical records that are interoperable and can be accessed in a public health emergency is critical so that we can track the outbreak in real time. Currently, most electronic medical system are not interoperable and cannot share information on disease outbreaks easily.

Perhaps the best source of information on the spread of Coronavirus in the world today is the Johns Hopkins database. (<http://www.centerforhealthsecurity.org/resources/COVID-19/>). We have spent years assembling this database. It is what the federal government has been using in this crisis.

Taiwan has taken this a step further and linked the travel documents with electronic health records. (<https://focustaiwan.tw/society/202002160009>) Given that Coronavirus did not begin in the US, it must have been transmitted from people arriving from other countries. Connecting the dots between international travel and disease outbreaks is an important addition to traditional disease tracking.

Addressing the Coronavirus and other disease outbreaks given the high level of international travel that occurs daily is critical. Small businesses could assist in developing this linkage.

4. People with chronic conditions are most susceptible to death from Coronavirus. We need a new source of supply for generic drugs to treat illnesses associated with Coronavirus. Small businesses can help supply these generic drugs.

Many of the people with the most severe reaction to Coronavirus conditions have multiple chronic conditions. Making drugs inexpensive is especially important for people with multiple chronic conditions since they are likely to be taking multiple drugs.

A portion of the \$3.1 billion in the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 should be used to support small businesses that can manufacture generic drugs.

The first step in the drug development process is to develop a branded drug. However, after the patent protection and market exclusivity period for the branded drug has ended, the next step in the process is to manufacture a generic drug that has a lower price than the branded drug. This is a very important way that drug prices are kept down and this an important role for small business.

Small businesses play an important role in manufacturing generic drugs because they do not have to incur the very large cost of doing research and development.

One problem is that the market has placed hurdles for small businesses manufacturing certain categories of generic drugs. Congress has already passed laws such as the CREATES Act that will address some of these problems, but additional problems remain.

One area that Rosemary Gibson highlights is our heavy dependence on China and India for the manufacturing of these drugs. This topic needs to be addressed.

There are also problems with shortages in many generic drugs and this problem is exacerbated by the dependence on China for many of our drugs when there are trade embargos or a Coronavirus outbreak.

One possibility is for small businesses to enter the generic market where there are market failures. The United States could promote "Made in America" generics.

I helped create a small nonprofit small business that manufactures generic drugs that hopefully will fill some

of these market failures. We outlined our vision – for what is now Civica Rx - in a *New England Journal of Medicine* paper in 2018. (<https://www.nejm.org/doi/full/10.1056/NEJMp1800861>) (Liljenquist, Dan, Ge Bai, and Gerard F. Anderson. "Addressing generic-drug market failures—The case for establishing a nonprofit manufacturer." *New England Journal of Medicine* 378.20 (2018): 1857-1859.)

Civica Rx was established in 2018 by health systems and philanthropies to reduce chronic generic drug shortages and high generic drug prices in the United States. It exists in the public interest as a non-profit small business.

Over 250 drugs that hospitals and clinicians need to treat patients have been on and off drug shortage lists. It was necessary to create a non-profit small business to address this market failure. Small businesses like Civica Rx are stepping in to fill these shortages. For Civica Rx to succeed it needed to have a guaranteed market for the drugs that it produces.

The initial market for Civica Rx was hospitals because they offered a guaranteed market to purchase the drugs at a cost plus rate. Having a guaranteed buyer is a critical component for any small business attempting to disrupt the market. The company, Civica Rx, was designed to give hospitals the ability to obtain generic drugs at a reasonable price. Civica Rx now has over 1200 hospitals participating in its network.

Civica Rx recently announced plans to expand its market to include consumers who are purchasing essential medications themselves. Blue Cross recently gave Civica Rx \$55 million dollars to provide select high-priced drugs that are sold in pharmacies. This is an example of a small business filling a niche in the drug supply chain.

While Civica Rx did not need government help to get started, it may be beneficial to create mechanisms to incentivize generic drugs that are made in America. Such policies would protect American consumers from safety risks and potential supply disruptions from dependence on a foreign supply chain for essential medicines – something especially important now, given the impact of the coronavirus on manufacturing in China.

There are other approaches underway. My colleagues and I are working with the State of California to create an entity that would supply drugs for the 13 million people getting drug coverage through the state of California. While the details are still being worked out, there may be the opportunity for a small business to manufacture some of the drugs for California.

The start-up costs in the generic industry are rather small, so it is possible for small businesses to enter the market if they can find market niches. Trade agreements and disease outbreaks can make it challenging to obtain necessary generic drugs and a domestic source of generic drugs could address this challenge. Drugs in shortage are where US small businesses can enter the market. Congress can help small businesses enter this market and have generic drugs “Made in America”.

5. Support for public health preparedness is critical and the need for additional investment in supplies is clearly demonstrated by this Coronavirus outbreak and small business can help fill his void.

Congress appropriated \$3.1 billion in the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 that prioritized “U.S. – based manufacturing capabilities, and the purchases of vaccines, therapeutics, diagnostic, necessary medical supplies, medical surge capacity and related administrative activities.”

We are already seeing a shortage of key materials, such as masks and gowns.

There is a story in Tuesday’s *Washington Post* about the problems Massachusetts General Hospital is having getting prepared for a large number of Coronavirus patients. Johns Hopkins showed the challenges it was having getting prepared in a 60 minutes story on Sunday. If these great institutions are having difficulty can you imagine the small rural hospital?

Perhaps dedicating some resources to promote small business manufacturing would help small businesses

enter the market and help fill this void. These are products that could be manufactured very quickly.

6. There is a strong need to assist first responders and medical professionals to address Coronavirus and small business can assist in several ways.

In the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Congress appropriated \$10 million dollars for “worker-based training to prevent and reduce exposure of hospital employees, emergency first responders, and other workers who are at risk of exposure to Coronavirus through their work duties.”

Dedicating a portion of these resources to education and training to be provided by small business could make sure that health care providers are adequately protected.

I am happy to answer any questions