Pharmaceutical Development and Importation during the COVID-19 Pandemic

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Abstract

The purpose of this paper is to draw attention to the United States' policies on drug importation and to raise awareness of the current process for obtaining treatment and prevention pharmaceuticals from foreign countries. Pharmaceutical importation has been a subject of global health and economic concern for many years, but it has heightened in intensity with the COVID-19 pandemic. There are concerns regarding government approval, quality regulations, and scarcity. The need for rapid mass production in order to meet the global demand while balancing the risks associated with rushing medical advances are highlighted. Resource-scarce nations will require support to combat the spread of the COVID-19 virus, and companies will face pressure to rush safety procedures. This article explores some of the impending issues facing the importation of pharmaceuticals during the COVID-19 pandemic, and it aims to express the need for ethical and compassionate consideration when dealing with a response to a global health crisis.

Although the risk of a viral pandemic has been on the minds of global leaders for years, little action has been taken by governments to prepare for its inevitable arrival. At the Conference on Influence Pandemic Preparedness in 2001, the European Commission remarked, "Vaccine availability is not secured… In the event of a pandemic millions of people could die, economies will be affected… Members of the public will not excuse authorities, who will be held responsible for not having put in place up-to-date preparedness" (Fedson, 2005). In 2015, Bill Gates presented a TedTalk on the unpreparedness of the world for a viral outbreak, emphasizing the lack of investment in a system to stop an epidemic (Gates, 2015). Faced now with the consequences of failed preparation, governments and international organizations are scrambling to develop treatments and vaccines to combat the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and stop the spread of Coronavirus Disease 2019 (COVID-19). While labs are racing to complete clinical trials for newly developed vaccines and pharmaceutical therapies, governments must also prepare for the economic supply and demand imbalance and questions of adherence to safety regulations that will arise with these advances. As countries progress at their own pace in their research and approval process

for treatments for COVID-19, it is reasonable to predict that U.S. citizens will press for pharmaceuticals that have been approved in other countries regardless of whether they have met the standards for FDA approval. Success on behalf the United States will depend on the vigilance of the FDA to oversee and review pharmaceuticals imported from abroad and developed domestically, as well as government awareness of the need to support developing countries in the rush to distribute a safe vaccine globally. By achieving these measures, manufacturers will not be able to cut corners and develop unsafe or non-efficacious vaccines and global immunity will be obtained more rapidly.

With the hope that effective treatments and a vaccine will soon be available to combat the COVID-19 pandemic, governments must be prepared to identify defective and potentially harmful products being promoted, whether from a company in the US or abroad. The U.S. Food and Drug Administration (FDA) is responsible for ensuring that pharmaceutical imports are safe and effective for Americans (Center for Drug Evaluation and Research, 2019). The FDA reviews shipments and determines whether drugs are admissible into the U.S.. They are barred from entry if they are adulterated (not manufactured in compliance with quality manufacturing regulations), misbranded (missing required appropriate label information), or unapproved (not proven safe and effective before marketing). The US Federal Food, Drug, and Cosmetic Act (21 U.S.C. section 331) prohibits shipment of new drugs that have not been approved. An exception can be made when the following criteria are met: (1) an effective treatment is not available domestically through commercial or clinical means, (2) there is no known promotion to persons in the US by those involved in the distribution of the product, (3) the product is not considered to represent an unreasonable risk, and (4) the individual seeking to import the product affirms that it is for the patient's own use and provides the name and address of the doctor licensed in the U.S. responsible for treatment (Office of Regulatory Affairs, 2015). In this situation, the FDA may make exceptions and grant approval, or potentially a black market will develop for illegally imported treatments.

The United States is heavily dependent on China and India for the importation of pharmaceuticals (Public Citizen, 2020). In 2018, approximately 22% of active pharmaceutical ingredients and 14% of finished dosage form manufacturing facilities that were subject to FDA surveillance inspections were located in China, with respect to foreign human drug manufacturing facilities subject to current good manufacturing practice (Abdoo, 2019). Additionally, in 2019, a study by the Department of Commerce found that 97% of antibiotics in the United States came from China (Huang, 2019). Numerous problems have arisen in recent years with imports from these countries. The FDA inspects factories manufacturing pharmaceuticals for sale in the U.S. and provides them with an inspection score on a 10-point rating scale,

with 10 being the highest. For context, the average global score for manufacturing factories is 7.2. European factories have received the highest average drug quality score of 7.9, followed by U.S. factories at 7.7. China and India average scores of 7.0, below the world average (Alltucker, 2019). In 2013, a generic drug-maker in India pled guilty to charges including shipping adulterated drugs, incomplete testing records, and inadequate drug quality assessments (Huang, 2019). In 2018, at least 250,000 substandard doses of vaccines were sold by one of China's largest domestic vaccine makers (Huang, 2019). These problems occurred without the additional pressure of a global pandemic, and there is a risk that more haste and disregard for protocols will occur as companies try to mass-produce their products during the pandemic.

Dr. David Fedson, Former Professor of Medicine at the University of Virginia School of Medicine, discussed the concerns regarding vaccination for a pandemic and wrote: "millions of people living in many 'have not' countries will not be able to obtain any supplies of pandemic vaccines" (Fedson, 2005). Governments of countries producing vaccines will prioritize their own citizens and provide for resource-scarce countries after, if possible. As the U.S. funds drug production through domestic contracts, such as the $354 million contract with Phlow Corporation (a pharmaceutical manufacturing company in Virginia working on producing active pharmaceutical ingredients and finished dosage forms for medicines to treat patients with COVID-19-related illnesses), the government hopes to ensure the safety of its own citizens by investing in production that does not have the vulnerabilities associated with offshore investment (Delaney, 2020). Peter Navarro, the Director of Trade and Manufacturing Policy under the Trump Administration, addressed this dependence on foreign drug production stating that it "places America's health, safety, and national security at grave risk" (Delaney, 2020). Through the investment in Phlow Corporation, the U.S. hopes to build its first Strategic Active Pharmaceutical Ingredients Reserve (Delaney, 2020). This will allow the country to combat the current pandemic and also allow for a stronger defense against future disease outbreaks.

During a global crisis, it is important to recognize how privileged the U.S. is to have the financial availability to invest in its own drug research and production. While the U.S. may be concerned with obtaining contaminated or faulty vaccines, other countries may lack the ability to import any medical vaccines or treatments. By looking at the influenza vaccine as an example, it is clear that many countries are entirely dependent on importation from others for the health of their citizens. Almost 40% of the world's supply of influenza vaccines are used in countries that do not produce their own vaccines (Fedson, 2005). Normally this is not an issue because the vaccine supply is sufficient to meet the global demand, but when demand far outpaces supply, countries with limited resources suffer. To minimize the suffering of developing countries around the world, it will be imperative that

pharmaceutical companies mass-produce vaccines to rapidly develop a large supply. By meeting the needs of their own citizens quickly, developed countries will then be able to export vaccines to other countries and minimize this disparity.

The benefits of mass production of pharmaceuticals and vaccines in a pandemic situation are obvious but must not be considered without the recognition of the risks that come with hurriedness. Dr. Kirsten Lyke, an infectious disease specialist at the University of Maryland School of Medicine, warns that "premature endorsement for treatment can carry risks" (Simon, 2020). In addition to potential harm from the intervention, rushing results can also erode public trust (Simon, 2020). Regulatory agencies around the world must find the careful balance between maintaining proper care and oversight for research, development, and production, while also providing care quickly as COVID-19 continues to take lives and spread through communities around the world.

Agencies such as the FDA play a critical role in ensuring the safety of pharmaceuticals in the U.S., and so do healthcare providers. Knowledge of COVID-19, including its treatment and prevention, is rapidly evolving, and healthcare providers are tasked with staying up to date with the most current advances and standards of practice for the disease. As a profession dependent upon evidence and methodological studies, it is necessary to continuously be learning about the most recent discoveries in order to deliver the best care to patients in respect to effective available pharmaceuticals.

In conclusion, the development and production of treatments and vaccines for COVID-19 have accentuated problems in international importations and global supply and demand. The FDA will play a critical role in ensuring that developments from other countries are safe and effective for Americans, but this will create problems in and of itself as there will inevitably be inequalities between what is offered in the U.S. and abroad. The potential for flaws in manufacturing and poor quality assurance add additional risk to pharmaceutical production, especially as there will be enhanced pressure to distribute products to match the supply with the immense demand. The U.S. has invested in domestic production in hopes to minimize these risks, but many other countries do not have this opportunity and will depend on importation from countries that can mass-produce their pharmaceuticals. Physicians must remain aware of the pressures placed on manufacturing companies and remain vigilant when prescribing new treatments and administering vaccines to patients. The risks are heightened with novel pharmaceuticals, and healthcare professionals will have the responsibility of recognizing when oversights have been made and treatments may be ineffective or even harmful as the attempt to stop the spread of COVID-19 continues.

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