Spring 3-2021

Pandemics: Expediting Medications Through the Trial Period for the Greater Good

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Religion 203: Christian Ethics

PANDEMICS: EXPEDITING MEDICATIONS THROUGH THE TRIAL PERIOD FOR THE GREATER GOOD?

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04/25/20

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Introduction and Background

Vaccines and medications have been around for centuries and as our technology has advanced, so has our healthcare system. The more we learn about viruses and bacteria the more we are able to understand how to treat illnesses that were once fatal. One example of this is the Spanish influenza[1]. Around 100 years ago, one third of the world's population was infected with a deadly virus. While we don't know the actual number, it's estimated that there were over 50 million fatalities. Nowadays, in the United States, alone, there can be up to 49 million cases a year; but since we have vaccines and medications to treat the flu and its related illnesses, the death toll has decreased significantly. Vaccines and medications have helped us advance society in many ways. They have allowed us to stop worrying about sickness and instead focus on improving our standard of living.

The improvement in medicine has allowed us to focus on things like space exploration, conservation and technological advances. In order to be able to focus on those ideas we need to be able to trust our vaccines and medications. The FDA has a very strenuous process that all vaccines and medications go through in order to make effective drugs with minimal side effects. There are six stages that each medication has to go to ensure it is safe before it's put on the market[2]. The six stages that medications go through are the exploratory, pre-clinical, clinical, regulatory review and approval, manufacturing, and quality control stages. The clinical development is a three-step process. During phase I, small groups of people receive the trial drug to see how it affects them in relation to the illness and its initial side effects. Phase II is when the clinical study is expanded, and the vaccine is given to people who have characteristics (such as

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age and physical health) similar to those for whom the new drug is intended. In Phase III, the drug is given to thousands of people and tested for efficacy and safety[2].

The six steps that a vaccine undergoes are as follows: an investigational new drug application, pre-licensure vaccine clinical trials, a Biologics License Application (BLA), an inspection of the manufacturing facility, presenting the findings to the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC), and the usability testing of product labeling. After a vaccine is approved, the FDA will continue to oversee its production ensuring its safe distribution.

In dire circumstances, drugs are rushed to market without proper testing. This doesn't always have to be because of a dramatic reason like a global pandemic, it could simply be because a target group needs a quick fix to an illness. Sometimes the FDA will push a medication to market because it's needed and will discover later that there are severe side effects for a certain demographic of people. Consequently, taken off the market. This can happen because the demand for the drug is so dire that the FDA just rushes through the testing process and shortens the human trial period to the point where certain side effects aren't known by the conclusion of the trial period. When this happens, detrimental side effects will begin to show up in the general population after people have been using the medication for an extended period of time. This causes the FDA to recall the medication, halting further harm. It can cause millions of dollars of damage to the FDA, as well as, to those who then need to receive treatment to alleviate the new side effects.

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Although some individuals believe that pushing a medication to the market is acceptable during pandemics, we shouldn't rush medications to market because it can be risky and cause major health complications to the target population taking the medication.

Current Events

We are currently in the middle of a global pandemic. SARS-CoV-2, or coronavirus, has been wreaking havoc across the globe since December of 2019. It wasn't until last January that the virus began affecting Americans. As COVID-19 emerged in Italy and New York City, we began to see the true horrors of what this virus could do. President Trump began talking about a miracle drug, a combination of the antimalaria drugs hydroxychloroquine and chloroquine, that was being used to help people recover from COVID-19 quickly. As he began to talk about this drug more frequently people began to want to take the risk and use the drug in order to recover as quickly as possible. The FDA gave emergency approval to the Trump administration to distribute millions of doses of the antimalaria drugs on March 30 saying that it "is worth the risk of trying unproven treatments to slow the progression of the disease caused by the novel coronavirus in seriously ill patients[3]". Many health professionals are worried about the speed with which the FDA pushed this drug to the market. The FDA said that the combination of the two drugs could be an effective way to treat coronavirus, but warned the general public of some of the side effects that they have seen in those that took the medication to treat malaria.

There was a study done in mid-April at VA hospitals that found no evidence that the use of hydroxychloroquine and chloroquine reduced mortality or the need for mechanical ventilation when treating COVID-19 patients[4]. This study is the largest study done on COVID-19 patients to

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date and the data shows that the early excitement about this drug combination isn't as effective as it was originally believed. There are also now concerns that this drug combination will prolong the QT interval, or measurements made on an electrocardiogram to assess the electrical properties of the heart, which can cause an irregular heartbeat and increase the risk of sudden cardiac arrest in recovering patients. A study done by researchers associated with New York Langone Health has found that 11% of patients treated with this drug combination of hydroxychloroquine and chloroquine had severely longer QT intervals. The results of these studies show that there should have been many more tests and trials run on hydroxychloroquine and chloroquine before putting them to use to treat those with COVID-19 given there are severe side effects that prolong the recovery period and even increase the chance of death.

Viewpoint from Academic Peer Reviewed Articles

I looked into three articles that talked about pandemics in the modern world and medications that were pushed to market before adequate testing was completed. The article "Disease X: accelerating the development of medical countermeasures for the next pandemic", written in early 2020, talks about what to expect when we encounter the next pandemic and how we can speed up the approval process for vaccines[5]. The authors suggested some improvements to the diagnostic portion of identifying the disease. The first suggestion was to expand the use of prequalified diagnostic programs before an outbreak happens so that when an outbreak does happen, they can fast track the approval of pathogen-specific drugs. They also suggested training professionals in low and middle-income countries so when a pandemic does occur, there will be trained professionals on site to take care of the sick. They suggested some improvements for the

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development of the vaccine, itself, including expanding databases of conserved pathogen sequences in order to identify patterns in the new unknown pathogen more quickly and make more standardized animal models to perform initial medical trials on. The authors also suggested standardizing and pre-approving clinical trials, clinical trial locations, and protocols before an outbreak to reduce the confusion and chaos during an epidemic. This article talked about ways to speed up the approval process for vaccines without having to skimp on the testing by simply being prepared as much as possible before the next pandemic occurs[5].

The second article "Lessons from Pandemic Influenza A (H1N1): the research-based vaccine industry's perspective" discussed how the vaccine industry can better prepare for the next pandemic based on how they reacted to the H1N1 outbreak in 2009[6]. During the 2009 influenza outbreak, there was a broad collaboration of international institutions, governments, public health authorities, scientists, and vaccine producers. This unification allowed for the "most complete pandemic response ever undertaken[6]". There was a rapid supply of pandemic vaccines just three months after the H1N1 sickness was declared a pandemic and by December of that year there were over 30 vaccines that had received approval. The vaccine supply was safe and was able to meet health authorities demands. This article used data to show that if health workers unite and prepare for pandemics then the vaccines won't be rushed to market because they were already prepared for a pandemic to happen[6].

The final article, "Thalidomide: the tragedy of birth defects and the effective treatment of disease" doesn't discuss pandemics, it is an example of what can happen if a drug is pushed to market before complete testing is done[7]. Thalidomide was first used as a cure-all for morning sickness in expecting mothers during the 1950s and 1960s. In the late 60s, after not properly

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vetting the medication prior to giving it to pregnant women, it became apparent that thalidomide caused birth defects, such as missing limbs, in an entire generation of children. It was discontinued as a morning sickness treatment but is still used as a treatment for leprosy and multiple myeloma in rural areas of the world. The thalidomide tragedy marked a turning point in toxicity testing in the United States because it prompted regulatory agencies to develop systematic testing protocols. The use of thalidomide as a tool in developmental biology led to important discoveries and have led to stricter regulations for what medications are put on the market[7].

Experts in the Field Viewpoints

I interviewed four medical professionals in order to get their opinions on COVID-19 and whether or not medications should be rushed to market in situations like these. The first question I asked was what their profession was and what they did on a daily basis. I then asked if they were familiar with the FDA approval process for different vaccines and medications. The next question that I asked was how each doctor is involved in the fight against COVID-19, either directly or indirectly. Then I questioned whether or not this new drug combination of hydroxychloroquine and chloroquine should be used to battle coronavirus. The final question was whether or not the FDA should push drugs to market during pandemics in order to help people recover more quickly. After all of these questions, I gave them the opportunity to add any other remarks relating to medications being pushed to market or coronavirus that they felt were necessary or important to know.

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The first doctor that I interviewed was my mother's college roommate's husband, Dr. Phil Siefken. He is a primary care doctor who is double boarded in internal medicine and pediatrics. Being a primary care physician means that he is on the front lines seeing patients every day determining if they are sick, how sick they are, trying to keep them healthy, and giving them preventative care medicine. Dr. Siefken is aware of how the FDA approves of medication and says that it is "significantly bureaucratic with lots of redundancy", meaning that the FDA creates an environment that assures when the drugs are approved, doctors, pharmacists, and the general public can trust they are safe. However, Dr. Siefken said that this approval process is not ideal for a situation like coronavirus when we need a medication immediately. Dr. Siefken sees people and tests people who have COVID-19. He is on the front lines and his office is one of two testing sites in his county. Dr. Siefken said that he doesn't lean either way on hydroxychloroquine, but he believes that there needs to be a study run on 100 patients with coronavirus, 50 being treated with the drug and 50 being treated without it in order to determine whether it's in everyone's best interest to use the drug or not. When asked if the FDA should push drugs to market in a pandemic situation, Dr. Siefken answered with "I'm not going answer yes or no because it's not really a yes or no question. I would lean toward the no side of this teeter totter." He believes that the job of the FDA is to make sure a drug is effective and safe and that the system in place to put drugs on the market is effective. Dr. Siefken believes that while it is going to be difficult to find a vaccine for something of this nature, it won't be impossible. "We have very few drugs in place to fight viruses, let alone a novel one of this nature. Therefore, this is going to require novel development of agents that are effective in treating this illness." Dr. Siefken said that part of the reason this is such a battle is because of the distrust that American

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citizens have in their public health system, but he said nothing else about the FDA and their drug approval process.

The next person that was interviewed was my neighbor, Dr. Brett Davies. He is an ophthalmologist that specializes in trauma and reconstruction of the face. He works at a level 1 trauma military hospital. Dr. Davies agrees with the way that the FDA approves medications for general use. He said, "I appreciate the job the FDA does to make sure these treatments do not cause undue harm to patients." He is indirectly involved in the fight against coronavirus by occasionally evaluating the eyes and facial region of patients with COVID-19 but said that he doesn't manage the effects of the virus directly. Dr. Davies said that while hydroxychloroquine is FDA approved to treat malaria, it is not approved to treat coronavirus and can cause serious side effects such as vision loss and heart arrhythmias. He said that "If the FDA can determine that the medication is effective in treating COVID-19, the benefits of treatment may outweigh the risks of side effects." Dr. Davies believes that in a time of a global emergency an expedited approval process should be put in place to help as many people as possible. He believes that "An effective treatment will save lives and is worth the risks of medication side effects." He strongly advised everyone to take social distancing seriously but had nothing more to say about the push of medications to market.

The final doctor that was interviewed was my old teammate's father, Dr. Bill Atlas. He is an internal medicine physician and has a Concierge practice. This means he provides comprehensive care to a small group of people who pay an annual fee for his services. This includes all health maintenance and exams as well as care for illnesses and chronic diseases. Dr. Atlas also serves as the hospitalist for this group of patients should they require inpatient care.

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Dr. Atlas had a lot to say about the FDA approval process. He likes the fact that the FDA has the independence to allow a very select panel of experts to weigh scientific evidence prior to approving a drug. However, he dislikes that nowadays FDA approvals are done much quicker and "without proper vetting, seemingly for political purposes." He believes that this harms the American public and physicians in their ability to trust in the process for approvals. As the primary physician for about 560 patients, Dr. Atlas provides advice and testing for patients who believe that they may have COVID-19. He is also their attending physician, meaning that if they needed immediate care he would go to the hospital and treat them. The drug combination of chloroquine and hydroxychloroquine has been studied and used because of its potential antiviral effects, but these effects have yet to be proven in any viral disease, including COVID-19. Dr. Atlas said that "This drug, like any drug being used for COVID-19, should be used in controlled trials so that we can learn whether it is an effective treatment, understand its limitations and toxicities, and also define appropriate candidates for its use." Dr. Atlas believes that while the current treatments available for COVID-19 are inadequate, "the process cannot be ignored or circumvented" in order to push a drug to market. Dr. Atlas wanted to add that while a drug has not been approved by the FDA, physicians can still prescribe medications and initiate treatments, as long as the patient is given informed consent about the medication.

My Viewpoint

This is a complicated topic because when looking into the wellbeing of the total population it makes sense to some to push a medication or vaccine through as soon as there is an option to do so. Allowing fewer people to get sick will mean that the population as a whole will

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get better quicker. I can understand where these people are coming from after living in quarantine for the past month and a half. I miss seeing my friends, going to my favorite restaurants, and just being outside of my house. It's hard when everything comes to a screeching halt. We've gone from constant contact with others to online schooling, online work, and an extended stay-at-home order. Since being in this situation with COVID-19, I can now understand why some people want to push medications to market, especially in a global pandemic like the one we're in now. They want to get things up and running and back to normal as quickly as possible because while we're all trying our best to adapt to this situation, it's hard to adjust to all the changes that have been put in place. A medication might help save more people's lives from the virus and could curb how many people will get infected the future.

As much as I can understand where people are coming from, I think that it's still unethical to push medications to market before the proper testing has been done. While it may save a lot of lives, it can also risk a lot of lives by giving people something that could end up hurting them. Finding a medication or vaccine that safely helps people recover is why there are regulations in place. When we look back at some of the things that have happened because pharmaceutical companies rushed a drug to market, you can find an entire generation of children with birth defects. If you want to cure a disease or find a vaccine for something like coronavirus, you have to take the proper steps in order to ensure that the drug is safe because if you don't, then you give people a false sense of both hope and security. People begin to believe that things will get better and start ignoring shelter in place orders or go out and interact with others when they are still sick. In order to get the most reliable medication, you have to go through the testing

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and trial process. If that process is skipped, it's more harmful than helpful to people who are already suffering.

Concluding Statements

While it is understandable that people want to push medications through to market in instances like global pandemics it is not morally right to give people medication that hasn't completed the proper testing. In theory it could be helping the greater good, but if you end up giving a large portion of a sick population a drug that doesn't work and causes complications, then there will be an even larger problem at hand. The faster that doctors and scientists can come up with a reliable solution to COVID-19, the better.

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