

COVID-19 has brought public health and epidemics to the forefront of national debate. The pandemic has wreaked havoc on the world economy and strained international political relationships. What lessons have been learned that might help America combat other epidemics and issues pertaining to global health? To what extent should the U.S. cooperate with other countries concerning global health issues? The response to COVID-19 underscored the capacity of science to develop technologies in the form of vaccines that help manage the threat of global infection. Should the United States use vaccine technology to advance its global interests and values, particularly in competition with China and Russia? To what extent do US-based multinational corporations that control vaccine development and other technologies have influence over U.S. foreign policy, and does such influence hurt or help U.S. interests?

Public Health: Preparing for the Next Pandemic

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I. The COVID-19 Pandemic and Vaccine Technologies

Over the course of the past 180 years, human longevity has increased by nearly three months per year, with the expected lifespan increasing from 40 to over 80 years in the most developed nations¹. Much of this increase is due to advancements in public health and the ability to combat infectious diseases. Beginning with John Snow who traced Cholera outbreaks to a contaminated water pump, scientific advancements such as germ theory of disease and the advent of antibiotics have largely made infectious disease an afterthought in the United States. In recent decades, the medical focus has shifted to combatting chronic illnesses and diseases of aging. However, as the COVID-19 pandemic made clear, infectious disease remains a critical threat. Preparing for the next pandemic requires an understanding of both the causes and consequences of a potential outbreak.

The threat of pandemic disease is not only real, but it is increasing. Dating back to 1918, there have been 11 serious viral outbreaks. Seven of these have occurred in the past 20 years². Modernity is a double-edged sword as advances in medical knowledge, pharmaceuticals, and public health have limited the impact of these more recent outbreaks, yet climate change, population growth, and globalization are increasing the rate at which these outbreaks occur³. For instance, many of these outbreaks are zoonotic, meaning they transferred from animals to humans. Increasing population and climate change mean that humans are increasingly more likely to come in contact with wild animals. Additionally, overuse of antibiotics and other medications has led to “super bugs” – infections that can’t be cured with currently available medications. The World Health Organization lists this “anti-microbial resistance” as a top 10 public health threat⁴. Other major threats include laboratory accidents and bioterrorism⁵.

The COVID-19 pandemic exposed multiple policy debates that the nation will have to reckon with as it prepares to face these emerging and re-emerging threats. What is the role of government and what is the role of the private sector? How should government responsibilities be split across Federal, State, and Municipality? What is the balance between government

mandate and individual freedom in addressing communicable threats? What is the appropriate level of investment in future threats compared to existing needs? How should various future threats be prioritized? What is the appropriate balance between speed of response and safety of new medical interventions (e.g. vaccines)? What weight should the government put on reducing inequities compared to increasing incentives for innovation and production? How should the US balance increasing preparedness with reducing waste?

Technological Innovation

Creating new products and processes is a long and costly process. Science is inherently uncertain with many more failures than successes. Most potential drugs never make it into clinical trials and between 75% and 92% of drugs that do enter clinical trials never make it to market⁶. On average, successful drugs take 12 years from initial development to regulatory approval⁷. A substantial portion of this timeline is due to the Food and Drug Administration (FDA) requirements. The FDA is responsible for ensuring the safety and efficacy of new drugs and vaccines. They do so by requiring a substantial amount of evidence from the pharmaceutical manufacturer in the form of clinical trials. Depending on the disease, clinical trials can be very long and expensive.

While requiring this evidence limits the possibility that dangerous or ineffective drugs become available, it also delays the availability of safe and effective pharmaceuticals. For instance, on July 14th, 2020 there was evidence that Moderna's vaccine was safe and effective based on phase 1 (safety) and phase 2 (small scale safety and efficacy) trials. Phase 3 (much larger and more robust) clinical trial data wouldn't be available until November 16th and the FDA approved the Moderna vaccine for emergency use on December 17th. In protecting the American people from a potentially dangerous or ineffective vaccine, FDA requirements prevented earlier diffusion of the COVID-19 vaccine. There is a policy debate regarding whether the FDA is overly cautious, potentially costing lives or whether these stringent requirements are required to protect the American people.

Other important policy debates in this area surround the amount of public funds that should be invested in research and development and the relative role of the public and private sectors. For context, technology (including vaccines and drugs) development begins with basic research. Basic research is the process of figuring out scientific advancements that may not directly relate to a commercial product. Historically, most basic research was funded by federal government agencies including the National Institute for Health (NIH). In 2015, the federal government's share of basic research fell below 50% for the first time in the post-World War 2 era⁹. The next step, applied research, aims to take basic research and begin to try to solve a specific problem or develop new inventions with it. Once the new invention is designed, research moves into advanced development as prototypes are developed and new inventions (e.g. drugs and vaccines) are brought to market. The vast majority of advanced development is funded by the private sector.

Years of publicly funded basic research and privately funded applied research came together to generate a COVID-19 vaccine almost overnight. Using science that had been funded by the federal government during the 1980's and 1990's, the SARS-COV-2 (virus that causes COVID-

19) genetic sequence was published on January 11, 2020. Within days, vaccine candidates were developed. Some of these were based on existing technology, but the most promising candidates (Pfizer and Moderna) were based on Messenger RNA (MRNA) technology. Scientists had been working on MRNA vaccines since the 1960's. After decades of failure, researchers made a critical breakthrough during the Ebola outbreak in 2014. However, that outbreak was contained to a small part of Africa limiting commercial applications within the United States. As COVID-19 spread, private-sector researchers capitalized on almost 60 years of scientific advancement. Without earlier public investments in basic research, it's unclear how long it would have taken to develop a vaccine. At the same time, government funds are limited and there are many alternative investments the government can make such as national defense, repairing infrastructure, or cutting taxes. Additionally, some have criticized Pfizer and Moderna for making a profit from the vaccines when much of the technology was publicly funded.

A counterargument is that these firms may not have invested in developing the vaccines without a profit motive, which included guarantees by the government. Firms that invest in a new technology spend a lot of upfront money without any guarantee of a return. The larger the chance that a pharmaceutical (or any product) will fail, the larger the risk. The potential return on an investment needs to be high enough for a firm to be willing to take on this risk. This was especially true with MRNA technology that had not yet been proven. The government dramatically reduced this risk by offering contracts for advance purchases. Even Pfizer, which claims to have received little government support in its vaccine rollouts, benefited from advance purchase contracts from the US government that approached \$6 billion. This was a mutually beneficial policy as in its support for the development of multiple vaccines, Washington increased the likelihood that at least one effective vaccine would be available for use.¹⁰

Medical Infrastructure

One of the early challenges of the COVID-19 pandemic was the lack of available health care resources. As early as March, 2020 news organizations were reporting that States were expecting shortages of ventilators and intensive care unit beds¹¹. This was not surprising as lack of hospital beds, especially intensive care (ICU) beds, was identified as a critical risk long before the pandemic¹². As of 2018, The United States had approximately 93,000 intensive care beds or 3.6 beds per 10,000 adults¹³. Complicating matters, there is a lot of variation in the availability of beds with some regions in the country having ten times more ICU beds than others. Analysis from the first 5 months of the pandemic showed areas with more ICU beds had significantly lower COVID-19 mortality than regions with fewer ICU beds¹⁴ and non-pandemic related research has shown that hospitals have significantly higher patient mortality when operating closer to capacity¹⁵.

While the immediate thought may be to increase ICU bed capacity, these hospital beds come at a significant cost. In fact, since the early 1980's there has been enormous fiscal and political pressure to limit the number of hospital beds in the US. The reason for this pressure is that hospital beds are expensive to maintain because they require constant nursing staff and expensive equipment. This is especially true for Intensive Care Units. For instance, hospitals may require twice as many nurses for patients in the ICU as in other wards. Hospitals are under a lot of financial pressure to use available beds and physicians tend to admit more patients when

there are many beds available. This means that patients that could be treated in lower cost areas are sometimes admitted to intensive care units. To combat this, many states enacted “Certificate of Need” laws that require government approval for opening a hospital or expanding the number of inpatient beds. Planning for the next pandemic requires policy-makers to decide how many of these expensive beds should be available. Note that the US already has many more beds per capita than most other nations¹⁶.

Beyond the physical number of hospital beds, the US is grappling with a shortage of trained clinicians. The US currently has 40,00-60,000 fewer physicians and over 150,000 fewer nurses than needed^{17,18}. Like ICU beds, access to physicians and nurses varies starkly across the country. These shortages endure despite many qualified applicants as there aren’t enough training slots¹⁹.

As we prepare for the next pandemic, policy-makers must grapple with how to build medical capacity including both workforce and physical constraints.

Role of Government

During the recent pandemic, local governments enacted various restrictions that lead to passionate arguments generally along existing political fault-lines. Early in the pandemic, at least twelve states enacted some form of travel restriction or quarantine requirement for out-of-state travelers or returning residents. State and local governments enacted business and school closures and limited social gatherings. Even as these orders were rescinded, governments enacted mask and vaccine mandates.

Each of these restrictions prompts a debate regarding the balance between government power and individual liberty. Historically, the supreme court has held that governments have broad authority when it comes to protecting public health²⁰. A 1904 Supreme Court opinion (*Jacobson v. Massachusetts*) stated that states could compel vaccination when disease is imminent and a 1922 ruling (*Zucht v. King*) upheld school vaccine requirements²¹. It’s unclear whether courts will continue to maintain this precedent. Justice Gorsuch has written that vaccine mandates should be subject to “strict scrutiny” which requires the court to find that a law is narrowly tailored and the least restrictive means to satisfy a compelling state interest²².

Beyond the legal debate, costs and benefits of government restrictions should be considered. For instance, mask mandates limit individual freedom but are fairly low cost while stay at home orders caused significant damage both monetarily and socially. For instance, the World Bank estimates that school closures could lead to future salary losses of \$1500-\$2600 per year due to interrupted education²³ and restrictions on gatherings lead to increased rates loneliness and depression²⁴.

The effects of these policies do not affect everyone equally. During the early years of HIV when the virus seemed to target homosexual men, bathhouses that primarily served this population were closed²⁵. During the COVID-19 pandemic, poorer workers were less likely to stay home from work under stay-at-home orders than wealthier workers, making them more susceptible to the virus²⁶. At the same time, unemployment rates were much higher among Black and Hispanic workers than white workers²⁷. Any policy debate around the role of government should consider the effects on subgroups of people rather than simply an average effect.

II. The Threat of Synthetic Biology²⁸

Whether or not the COVID-19 pandemic originated in pathogens found in the natural environment, man-made biological weapons have long been a very real and deadly threat. Synthetic biology (SynBio) is the scientific discipline that encompasses all aspects of the engineering of biological systems. Beginning with the discovery of the chemical structure of DNA in the 1950s, SynBio tools such as recombinant DNA technology and genome editing tools have developed at a fast pace as the fundamental molecular mechanisms underlying biology are discovered. These SynBio tools are lowering the education, training, cost, time, and equipment threshold required to modify and employ pathogenic organisms as biological weapons.

The asymmetric threat posed by biological weapons will continue to increase as new tools and techniques are developed and as terrorist organizations become aware of and inspired by the society-wide economic, emotional, and government-destabilizing impacts caused by the COVID-19 pandemic. Indeed, it can be argued that the total cost of this pandemic—including the loss of life and the stress to the economy—could be rivaled only by the deployment of an atomic bomb. Therefore, developments in SynBio should be continually monitored and reassessed within the context of technological change and its capacity to shift the geopolitical paradigm.

The increase in the understanding of biological systems and the development of the tools of molecular biology that occurred in the late 20th and early 21st centuries were paralleled by commensurate developments in automation, engineering, computer science, and information technology. In particular, the ease of scaling up the production of bacteria and viruses has increased exponentially in recent decades due to the availability of inexpensive instrumentation for the growth, or culture, of biological material, and the development of standardized reagents such as bacterial growth media by commercial laboratories. Once the purview of scientists with doctorates in microbiology, genetic engineering is practiced every day in high schools and colleges across the world. The instruction or protocols, for these processes, are freely available on the internet and in undergraduate microbiology and cell biology textbooks

Policy Responses to the Potential Threats Posed by Synthetic Biology

An effective response to the threats posed by those using synthetic biology for nefarious purposes will require vigilance on the part of military planners, the development of effective medical counter-measures by the research community, and the development of diagnostic and characterization technologies capable of discriminating between natural and engineered pathogens. A 2002 biological warfare counterproliferation study identified six key basic biological research areas that should be emphasized to protect against the threat: human genomics; immunology and the development of methods for boosting the immune response; bacterial and viral genomics; bacterial and viral assay development; vaccine development; and the development of novel antiviral agents and antibiotics. A continued research and education effort within the Department of Defense will be required to develop and maintain expertise in each of these areas.

The rapid availability of experienced civilian and military personnel is a prerequisite for effective incident response. Therefore, training and education in SynBio, biological engineering, and related disciplines should be emphasized and funded. Many organizations already exist to meet the threat of natural, man-made and weaponized biological material. These organizations include the Defense Threat Reduction Agency (DTRA); the Chemical and Biological Center (CBC) at Edgewood, Maryland; the Defense Advanced Research Projects Agency (DARPA); the Biomedical Advanced Research and Development Authority (BARDA); the National Institutes of Health (NIH); the Centers for Disease Control (CDC); and United States Department of Agriculture-Agricultural Research Service within the United States Research Service (USDA-ARS). The World Health Organization (WHO), a specialized organization within the United Nations, and several research and response organizations in other countries have historically served similar purposes.

Each of these entities deals with systems rooted in the natural world, and while some organizations restrict their focus to naturally occurring threats, they all deal—in one way or another—with the extraordinary pace of technology development unique to the biomedical community. Every advancement in biomedicine is dual-use, and so it is incumbent upon those who work in the scientific field to predict the ways that these technologies might be used for a harmful purpose and to develop the technologies and systems necessary to undermine the efforts of those who might use these unique biological entities as weapons.

III. Questions for Discussion

1. What are the roles of government, business, and individual responsibility in public health? How do these roles interact?
2. How can the government create the necessary foundation for future technological advancement? What is the appropriate tradeoff between speed and safety of new technology?
3. How much slack should the US maintain in medical capabilities? Given that it takes years to develop a workforce, what (if any) policies should be implemented now to prevent shortages later?
4. Should the US join efforts to bolster institutions like the World Health Organization to better equip them to forge a united global response?²⁹ Do international agreements require better enforcement mechanisms?
5. Should the United States use vaccine technology to advance its global interests and values? If yes, how? If not, why not?
6. Further, what can be done to alleviate the enormous inequalities that exist globally in terms of vaccination rates?
7. How much should other societal objectives be considered when implementing policies aimed at public health? For instance, if a disease is percolating across one sub-population, should the government impose limitations on that specific group?
8. While advanced technology has been mobilized to fight the COVID-19 pandemic, we should keep in mind that science can also be used by humans in malign ways, including the development of biological weapons. How serious is this threat to the United States on the part of our adversaries, at both state and non-state levels?

9. What are US defense mechanisms against biological weapons and how effective would they be against this threat? How might these defensive measures be enhanced?

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Please refer to the original article for the complete list of endnotes.

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