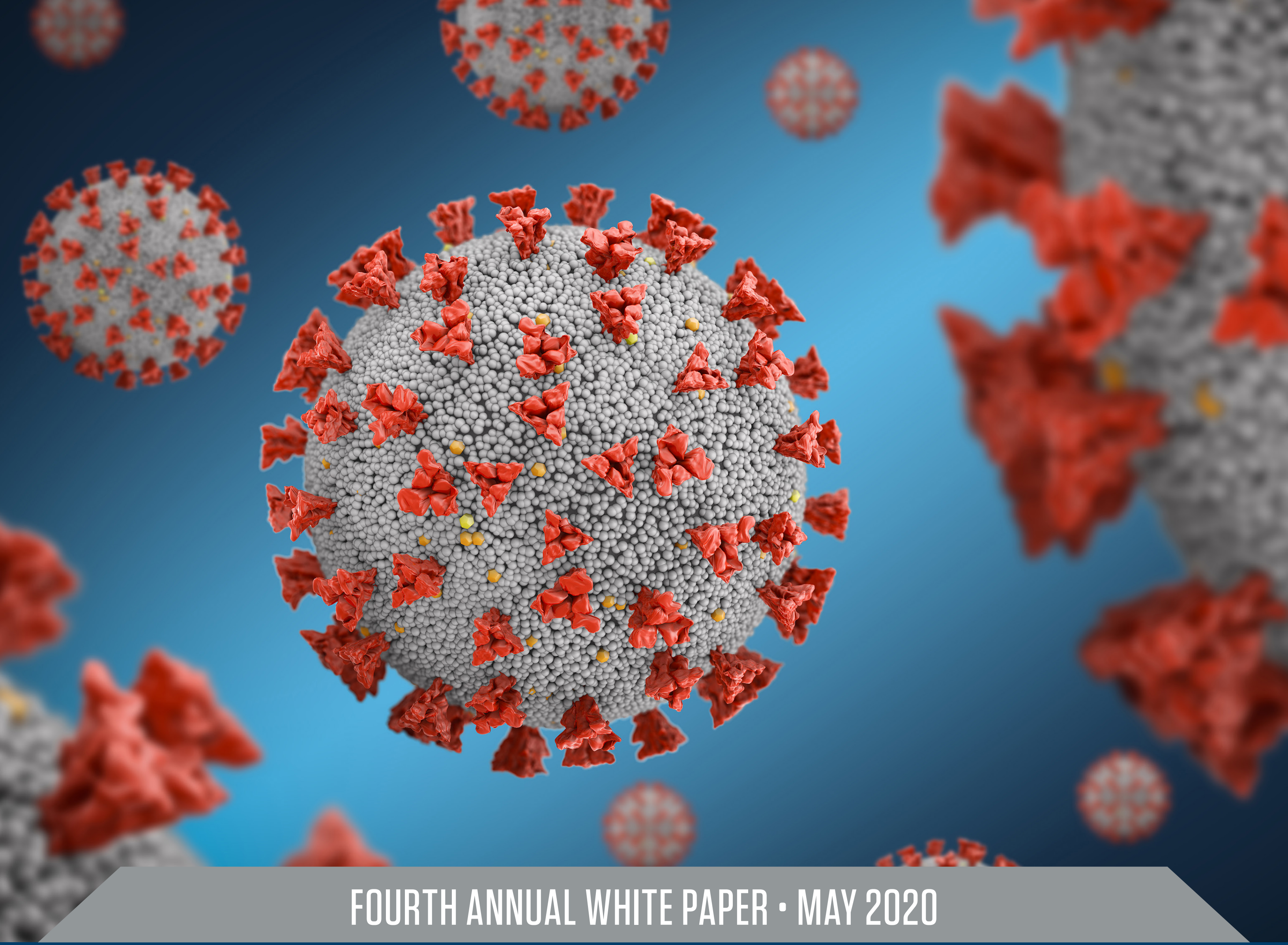

FOURTH ANNUAL WHITE PAPER • MAY 2020

PANDEMIC PREPAREDNESS AND RESPONSE IN THE AGE OF TECHNOLOGY

The Bush School of Government & Public Service
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Designed and printed by CVM Communications | College of Veterinary Medicine & Biomedical Sciences
Texas A&M University | College Station, Texas, USA | *cvmcommunications@cvm.tamu.edu* | *vetmed.tamu.edu/communications*

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Scowcroft Institute of International Affair Fourth Annual White Paper • May 2020

PREFACE

Author: Dr. Oyewale Tomori

Effective pandemic preparedness and response depend on the quality as well as the speed of obtaining relevant information, especially from remote and hard to reach areas of the world, where most known and unknown disease outbreaks occur and originate. Equally important is the local/national ability to collate, analyze, and interpret the information in a form valuable for taking appropriate preventive action and response.

Beginning with the ProMED-Mail in 1994, other web-based systems for gathering information on disease occurrence followed. The systems developed in the U.S. include GOARN, EpiSimS, EpiSpider, Health MAP, and Google Flu Trends. The systems developed in other countries and regions include MedISys (Europe), GPHIN (Canada), BioCaster (Japan), GET WELL (Sweden), and Influenzanet, which was originally started by European countries but which now has multinational participation. These systems supplement national public health surveillance through information provided by volunteers.

While these systems have registered successes in the early detection and implementation of control measures that have prevented large scale epidemics, there have been some failures, such as the Ebola virus disease outbreak of 2014 in West Africa. In general, the web-based systems have not functioned well in the parts of the world that are prone to disease outbreaks. Many countries have limited health and internet infrastructure. Volunteers in these areas with poor internet connectivity are less likely to report occurrence of diseases and are even less likely to do so if there is an atmosphere of strict government regulations against the release of information.

Mobile Phone

The improvement and growth of mobile telephone networks in the developing world have opened opportunities for enhancing the sharing of disease information, even from remote areas. Ministries of health in many countries can now receive information about disease outbreaks from field workers all over the country using mobile phones. In addition, many ministries have better computer and internet services to analyze data and provide feedback to field workers for necessary action. Integrating national facilities into a global network will help with a large-scale integrated alert network for global action.

It is important, however, to take full advantage of mobile networks by creating national capacity to collate, verify, analyze, and interpret data collected from various health workers and volunteers within the country. An example is Nigeria's successful transition from a polio-endemic country to a soon-to-be declared polio-free country. A national emergency operation center (EOC) consisting of programmers, public-health officials, epidemiologists, communication experts, data analysts, and support staff was established in 2012. At the Nigerian EOC, information on polio cases and polio immunization, collected from field staff using mobile phones, is collated and analyzed. The EOC then develops action plans based on data analyses and interpretation to solve the identified problems and improve the functioning of the polio eradication program. The positive turn around for polio eradication in Nigeria was not based solely on the availability of data but in having an operation center that was able to carry out rapid analysis and synthesis of data and make rapid decisions for improved program management.

For web-based surveillance systems to be more effective, it is important that the capacity to collate, analyze, interpret, and disseminate the information in a form that results in appropriate preventive action and response in the countries where these diseases originate.

The COVID-19 pandemic has demonstrated the ability to obtain information from different sources and dissemination of such information globally. Despite the availability of information on the development of the pandemic from a Public Health Emergency of International Concern (PHEIC), many countries were unprepared when the pandemic finally reached their borders. It is not enough for countries to efficiently analyze disease surveillance data, they must actively prepare to prevent the entry of a disease into their territory and, at the same time, prepare plans and identify and initiate containment measures that need to be taken to prevent the establishment of the disease in the country.

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TOPIC AREA 1: TECHNOLOGICAL INNOVATION FOR PANDEMIC PREPAREDNESS AND RESPONSE

Surveillance

Technological innovation has enabled the development of new strategies for infectious disease preparedness and response. Specifically, in the area of surveillance, global interconnectedness through the Internet, the advent of mobile technologies, and various web-based algorithms have expanded the global health community's ability to gather information from remote areas around the globe. The ability to rapidly detect an emerging outbreak is important in order to contain that outbreak at its source. As the ongoing COVID-19 pandemic shows, outbreaks have a tipping point in which the focus shifts from containment to mitigation. If diseases can be brought under control prior to that tipping point, lives will be saved. This is the primary reason that technological innovations in surveillance are so critical. While there are a number of promising advances, the most talked about are web-based data sources and mobile technologies. In this section, we will discuss innovations in these technologies as well as the need to create an umbrella, integrated system that utilizes multiple types of surveillance technology to create a more robust system of surveillance.

Web-based Surveillance

The ability to conduct web-based surveillance has opened the door to gathering information from individuals in isolated regions and from those who may be sick but do not go to a doctor. A 2016 study (Choi et al., 2016) describe web-based systems as "intuitive, adaptable, low-cost, and operated in real-time." One of the well-known web-based systems is the Program for Monitoring Emerging Diseases (ProMED), which was the first to report to the global health community the Severe Acute Respiratory Syndrome (SARS), a respiratory disease that emerged in China in 2003 and the COVID-19 outbreaks. Another well-known web-based system is the Global Outbreak Alert Response Network (GOARN), which helps coordinate responses in epidemic-prone areas. ProMED is the "largest publicly-available system conducting global reporting of infectious disease outbreaks" (ISID, 2020). It collects reports from people around the world, including physicians, researchers, and the general public, and this enables it to provide information to clinics and laboratories in real-time as diseases emerge. GOARN is a program overseen by WHO that "pools human and technical resources for rapid identification, confirmation, and response to outbreaks of international importance" (WHO, 2020). The WHO has worked with its partners in GOARN to support outbreak response in over 100 outbreaks, including the Ebola outbreaks of 2014 and 2018 and the outbreak of COVID-19 in 2019.

In addition to these systems, global influenza tracking through Internet search activity has become increasingly popular. The most prominent of these surveillance platforms is Google Flu Trend, which was recently discontinued largely because it proved inaccurate in its forecasts (Choi et al., 2016). The purpose of Google Flu Trends was to "provide real-time monitoring of flu cases around the world based on Google searches that matched terms for flu-related activity" (Walsh, 2014). While Google Flu Trend proved useful in wealthy countries, it was not always reliable in low- and middle-income countries. To counter the challenges of collecting accurate data in low- and middle-income countries, Clemente et al. (2019) developed a system known as ARGO. This system uses self-correcting machine learning as it combs Internet search data, which it combines with historical flu activity. The authors state that such a system has provided accurate, real-time flu data in a number of Latin American countries.

Other researchers have found the combination of Internet search data and social media information to be useful in accurately determining disease in a population (Deiner et al., 2016). With this system, Internet search data are used in conjunction with what residents in the target area are posting on their social media platforms, which can help to present a fuller picture than Internet search data alone because many people use social media for sources of information.

In line with the concept of combining Internet search information with social media information, some scholars argue that any form of new surveillance and response mechanisms must incorporate the local community. A 2019 study (Bedford et al., 2019) stated that people at the community level are the first responders to any outbreak. As such, any capacity building, whether traditional or based on a new technology platform, must be integrated into community-based programs. This perspective argues that advances in technology make it increasingly possible to expand community involvement, particularly in relation to wireless or mobile technology.

Mobile Technology

The use of mobile technology for infectious disease surveillance has been gaining traction over the past several years. Some scholars found mobile technology particularly promising in low-income countries and saw success in reporting on both human and animal health (Karmuribo et al., 2017; Garattini et al., 2019). In a 2017 study (Karmuribo et al., 2017), researchers found that "the widening use of mobile phones in sub-Saharan Africa, where the penetration rate has reached 67 percent, offers the opportunity to develop innovative participatory surveillance strategies that rely on the design and deployment of digital and mobile technology solutions" (p. e95). The most successful of these systems are those that are able to collect data on a mobile phone regardless of Internet access.

Mobile technology can be combined with geographical data by linking the reporting system to Google Maps. A 2013 study (Li et al. 2013) explains that "users can gain baseline information at sites of emergencies, such as the baseline information of infectious diseases, hosts, vectors, medical services, geographic environment and climate" (p. e54842). All of this information can be integrated within the mobile platform to streamline information to the global health community (Lwin et al., 2019). GPS data can also help healthcare professionals understand when there is a highly contagious disease or an outbreak emerging.

A study conducted in remote areas of Tanzania showed promise in reporting real-time infectious disease data using an application called Epicollect. This was an application on villagers' smartphones that allowed them to upload geographical information about human and animal diseases (Mwabukusi et al., 2014). This and other One Health-oriented surveillance systems have the additional advantage of having the potential to identify zoonotic outbreaks in animals before they spill over into the human population.

Limitations

Despite the promise of Internet and mobile technologies in disease surveillance, there are a number of limitations and drawbacks. First, there is always the possibility that the information collected will be inaccurate or that the predictions based on the information will be inaccurate. A simple example of how this can happen comes from the 2014 case of Ebola in the United States. Once this case appeared, the number of people Googling "Ebola" or "Ebola symptoms" increased dramatically. While this data would typically be used to suggest that there was a growing outbreak of Ebola in the United States, the increase in Google searches in this case was a result of people's lack of understanding about Ebola and fear that they could become infected.

The other significant, but less often discussed, drawback of web-based systems is the ethical concerns regarding gathering users' data without their knowledge, as is done with Internet search data and other types of Big Data. Many people who voluntarily provide their data are not fully aware of how that data will be used, and others might not have any understanding of how the data are actually collected (Garattini et al., 2019).

There are drawbacks and limitations to using Internet search engine data or mobile technology for infectious

TESTING

Once the pathogen (i.e., bacteria, virus, prion, etc.) causing a disease has been identified, we can begin a discussion about testing to determine which individuals are infected. Physical signs and symptoms are usual in evaluating suspect cases of infection but may be insufficient when there are high numbers of asymptomatic individuals. There is no stockpile of "off-the-shelf" tests for unknown diseases. Tests for unknown diseases must be invented, evaluated for false positives and false negatives, validated for accuracy, receive FDA approval, and be manufactured and distributed for use. No element of this is a simple or rapid process. Once laboratories have access to a sample of the pathogen, they can use sophisticated techniques, such as PCR or ELISA, to detect and identify the pathogen. Multiple testing may be necessary to determine if a person continues to have an active infection.

Once an individual has been infected with a pathogen, the person's immune system can develop antibodies against that disease. Testing for these antibodies represents the second form of testing to determine if a patient has had the disease and recovered or, in some cases, has antibodies resulting from a vaccination. In many cases these antibodies can prevent the patient from contracting the disease again following a subsequent exposure to the pathogen. It can be difficult, however, to differentiate patients who have received a vaccine for a disease (and developed antibodies and immunity) from those who have had the disease. Importantly, antibodies commonly do not last forever, making reinfection possible. For those patients who develop antibodies as a result of vaccinations, booster shots may be necessary to maintain a protective level of antibodies. Many researchers and clinicians, who are exposed to infectious agents, have their blood levels of antibodies checked regularly to determine their level of disease resistance. Such testing is referred to as "Titering".

disease surveillance, but there is also great promise. As mobile technology continues to expand into the remote regions of the world, it offers a way to monitor disease and prevent future pandemics.

Creating an Integrated Early Warning System

Web-based surveillance and mobile technologies offer an opportunity for infectious disease surveillance that has never before been possible. As innovative as these methods are, however, there are additional important surveillance technologies, such as Geographic Information System (GIS) technology, that could be used in combination with other technologies. GIS is a tool that can be used for early mapping of infectious disease, giving public health officials a spatial awareness of disease spread that was not previously possible (Musa et al., 2013). The most common way that the technology is used today is to identify disease clusters.

The project PREDICT, which was a part of the United States Agency for International Development's (USAID) Emerging Pandemic Threats program, was another Big Data attempt at early surveillance. The purpose of the program was to identify newly emerging zoonotic diseases that had the potential to spill over into humans (UC Davis, 2020). Utilizing this information, the program worked to targeted response measures before an outbreak occurred. Unfortunately, funding to the program was cut, and the program was discontinued in early 2020.

Technologies like Geographic Information System (GIS) and programs like PREDICT can be integrated with web-based surveillance and mobile technology to create a more robust pandemic surveillance system. In responding to an infectious disease, particularly if it is highly contagious, it is vitally important to enforce containment measures before the disease becomes widespread. An integrated system would provide multiple levels of infectious disease and spillover data, which would result in a system more robust than anything operating today while providing additional tools for healthcare workers.

Field Diagnostics

Rapid and accurate diagnostics are critical to guide disease containment throughout the world. For example, the COVID-19 outbreak may not have reached the scale of a pandemic if it had been possible to diagnose the disease and isolate people when the first cases had appeared. Containing an outbreak at its source is not a new concept, but the application of the concept regularly proves challenging. One reason that point-source containment is difficult is that outbreaks frequently begin in low-income countries that lack adequate health and scientific infrastructure or in authoritarian governments that suppress information and reporting.

The Nobel Prize winning economist, Amartya Sen, has famously argued that no famine has ever taken place in a democracy because of free speech and competitive elections. In a democratic nation, civil society will sound the alarm so that a food emergency does not deteriorate into a famine. The same is true for a major disease outbreak: Freedom of speech and press allow civil society, scientists, media, and members of the legislative branch of government to sound the alarm early on in

ELECTRON BEAM

Every year the Scowcroft Institute of International Affairs in the Bush School of Government and Public Service at Texas A&M University brings together scientists, policy-makers, and researchers from numerous disciplines at the Pandemic Policy Summit. While the Summit focuses on a variety of international problems, it also provides an opportunity for Texas A&M University to highlight new technologies impacting biosecurity that are actively being developed and tested in our research laboratories here on campus. These technologies and their applications to TAMU's Global One Health will be presented in a series of vignettes in this section to provide a broad perspective of the ways we fulfill our mission as a Land-Grant Institution and protect public health.

We will begin with our National Center for Electron Beam Research (NCEBR) that is directed by Dr. Suresh Pillai. The NCEBR is an International Atomic Energy Agency Collaborating Center for electron-beam applications in food, health, and environmental applications. This technology uses a beam of electrons (E-beam) to sterilize anything from medical equipment to meals ready-to-eat (MREs). Although the electron beam can be focused, E-Beam devices are not handheld and require facilities designed with the ability to facilitate the passage of materials through the electron beam in order to achieve irradiation.

To provide some perspective, the following numbers may prove helpful. The "Gray" is used as a unit of ionizing radiation dose or absorbed dose in the International System of Units (SI). The Gray is equal to 1 Joule of radiation energy per kilogram of matter. Some may have seen the term "rad" being used, which is 0.01 Gray. A typical x-ray or CT scan may expose the patient to between 0.001 and 0.01 Gray of radiation. The electron beam uses between 1,500 and 10,000 Gray to kill bacteria, fungi, and viruses. The E-beam is capable of producing much higher doses that can alter the physical properties of matter.

Examples of E-beam usage on food include military rations (MREs), food for consumption by astronauts while in space, and diets for pediatric cancer patients. The E-beam eliminates any possibility of contamination by foodborne pathogens, making it particularly useful for immunocompromised patients. E-beam exposure can also extend food shelf life and reduce waste, both of which are important to global food security. The E-Beam has proven valuable in creation of new immunization modalities by altering microorganisms during the production of vaccines that rely upon the use of attenuated pathogens. Once the pathogenicity of a microorganism has been reduced, it may be used in vaccines to produce an immune response (without harming patients) to provide protection against the disease caused by that pathogen. E-beam water treatment for reuse of both industrial and agricultural wastewater along with sludge disinfection has proven successful and issues of scalability for application are currently being studied.

the crisis. A lack of resources within the country of origin of the outbreak makes it harder to identify the disease and act against it. For this reason, proper pandemic preparedness must include the development of field diagnostics that are rapid and accurate in low-resource environments.

Innovations in Field Diagnostics

Field diagnostics is often a weak point in pandemic disease and response. The importance of field diagnostics is most clearly demonstrated in low-resource countries. Places that lack refrigeration, electricity, and Internet access present unique challenges for disease responders. Further complicating the challenge of adequate field diagnostics is the fact that several low-resource countries are “hot spots” of infectious disease. In such places, a lack of infrastructure, disease knowledge, and surveillance merge with tropical or subtropical climates, a plethora of vectors, and vulnerable populations. The potential disease threat in these “hot spots” is one reason that the U.S. and countries around the world must focus the development of field diagnostics that are rapid and accurate in low-resource environments.

A 2019 study by Tembo et al. stated, “The physical fragility of most thermocycling [a laboratory technique that amplifies DNA] platforms presents fundamental limitations for their deployment to field clinics ....” The authors go on to state that, despite the specificity offered by Polymerase Chain Reaction (PCR)-based assays (a laboratory technique that amplifies small segments of DNA), they do not transition well for the purpose of field diagnostics. In order to bolster diagnostics in the field, many scholars have promoted nanotechnology and other forms of biosensors, which are devices that convert biological responses into electronic signals (Chaplin, 2014). The benefits of nanotechnology include their simplicity, small size, and fast results (Fejzic et al., 2019). The most useful field diagnostics, however,

are those that do not require cold chain reagents, thus eliminating the importance of refrigeration.

There are several promising advancements in biosensors that could have a direct application to field diagnostics. These include magnetic particle-based sensors, peptide nucleic acid probes, and the Single Particle Interferometric Reflectance Imaging Sensor (SP-IRIS) (Tembo et al., 2019). Magnetic particle-based sensors bind particles to a magnetic surface, and this binding results in an electrical charge to the sensor (Koh & Josephson, 2009). Peptide nucleic acid probes are artificially synthesized molecules similar to DNA or RNA (Paulasova & Pellestor, 2004) and have allowed for the development of a wide array of laboratory tests. Finally, SP-IRIS is an optical signaling technology with high sensitivity in virus detection (Avci et al., 2015). There is also a recently patented integrated membrane sensor capable of detecting both DNA and RNA (U.S. Patent # US 10,247,720 B2). The most exciting element of this sensor is that it has proven fast and effective for point-of-care screening and diagnostics. Nanotechnology in general and biosensors in particular offer a possible solution to the challenge of diagnostics in low-resource environments because they eliminate many of the factors that lead to diagnostic failure, such as refrigeration. Advancements such as the integrated membrane sensor and other nanotechnology developments offer an opportunity to strengthen field diagnostics and contain diseases at the source.

Intellectual Property Challenges in Biotechnology

The development of field diagnostics, like many other developments in the realm of biotechnology, is a lucrative business. Berger (2019) explained that "financial forecasts estimate the size of the global biotechnology market by 2021 to be between $2 and $6 billion dollars …." As technological advances occur more rapidly than ever before, biotechnology companies have an opportunity and a market to address challenges in antimicrobial resistance, diagnostics, surveillance, vaccines, and numerous elements of infectious disease response. U.S. governmental organizations like Defense Advanced Research Projects Agency (DARPA) have been at the leading edge in tackling numerous biomedical challenges, but private sector companies have also entered the marketplace. Despite the market potential in the field of biotechnology, there are some obstacles still deterring private industry involvement. One of the most prominent obstacles is the theft of intellectual property. The threat of intellectual property theft is a global problem, but China has been the primary violator. Such theft makes it more difficult to encourage private corporations to enter the biotechnology market and creates great uncertainty surrounding the protection of trade secrets. China is responsible for theft of intellectual property from the United States, both through the firms operating in the U.S. and U.S. firms operating in China (White House, 2018; National Counterintelligence and Security Center, 2018). Theft from companies and universities located in the U.S. occurs as a result of hacking or physical theft. Theft from American companies located in China is a result of Chinese restrictions on and control over intellectual property produced at those companies. Protecting intellectual property in the realm of biotechnology is vital to encouraging private sector participation in the development of rapid, accurate, field diagnostics.

Remote Sensing

Remote sensing provides another option for tracking epidemic disease outbreaks in conflict settings or in countries ruled by authoritarian governments. U.S. government satellite photography was used effectively to publicize the destruction of 3,800 villages in Darfur that had been burned to the ground by the Janjiweed militia in 2003-2006, a charge which the Sudanese government had been denying (Natsios, 2012). On March 12, 2020, the *Washington Post* published satellite photographs of mass graves being dug in Qom, Iran, presumably for the victims of the COVID-19 pandemic, which the Iranian government had denied had spread across the country. In countries with repressive governments that are trying to hide a disease outbreak, aerial photography could be used to monitor excessive activity at crematoriums, the digging of mass grave sites, and unusual volume of people going to health clinics or hospital emergency rooms. Such photographs could provide evidence of an epidemic. A similar system of aerial photography has been used in USAID since 1985 as part of the Famine Early Warning System (FEWS). FEWS was established after the Ethiopian famine to show warning signs of crop

failures that could lead to famine. Aerial photography is not sufficient to prove either a famine or a disease outbreak on a mass scale without on-the-ground analysis, but it can be an effective tool in alerting policy makers that something might be wrong.

Vaccine Innovation

Disease-causing microbial pathogens have proteins on their surfaces that are referred to as antigens, which allow the human immune system to recognize the pathogen and produce antibodies to kill it. In the majority of cases, the body can respond to both bacterial and viral infections, but it may take several days to produce antibodies following initial exposure to the pathogen. Once a person has encountered a pathogen, the immune system has the unique ability to remember the infectious agents' antigenic characteristics so that the next time a patient is exposed to it, the body can act quickly to fight off the infection. This is referred to as developing immunity.

The concept just described may be applied to the production of vaccines. A vaccine essentially tricks the body into thinking it has been infected by the pathogen of interest. In some cases, infection with a similar, although nonlethal, organism may cause the body to develop antibodies that overlap and protect one from a serious pathogen. For example, in the past milkmaids who contracted cowpox – a relatively benign infection – developed immunity to smallpox, a deadly pathogen. Vaccines typically act in conjunction with the patient's own immune system to protect the individual from the disease.

Some infectious agents, such as the human immunodeficiency virus (HIV) and herpes simplex, have proven highly problematic when attempting to develop a protective vaccine. This is because the HIV and herpes viruses actually attack the human immune system, preventing the production of antibodies against the virus. Some viruses, like influenza, mutate at an extremely rapid rate, which makes it difficult to develop a vaccine that is useful every year without having to guess which strain will predominate in that given year.

The importance of vaccinations as a public health tool cannot be overemphasized. Outbreaks of potentially deadly diseases, such as polio and measles, have been reported by the news media in recent years. Many of these re-emerging diseases disproportionately impact children, and these outbreaks are completely preventable by the use of vaccines. The outbreaks in the U.S. are a result of vaccination rates falling below the levels required for herd immunity, which is the level of immunity within a population – a rate that varies based on the reproductive ratio of the diseases in question – that is necessary to protect individuals who are unable to get vaccinated. Myths about the safety of vaccines have led to decreased vaccination rates, which in turn has caused disastrous outbreaks of vaccine-preventable diseases.

Vaccine Production

Vaccine production occurs in several phases, the first of which is identification of the virus or bacterium for which the vaccine is to be made. During this process, scientists must generate the antigen used in immune response, which includes harvesting the pathogen itself. At this stage, it is still a live virus (College of Physicians of Philadelphia, 2020). Once the antigen is identified, it has to be isolated and purified. Before the final vaccine can be mass produced, scientists must weaken or inactivate the virus with a chemical or other mechanism. The reason that it is often most beneficial to inactivate or kill the pathogen is because inactivation prevents the vaccine from creating even a mild form of the disease it is designed to prevent, and it can be given to people with weakened immune systems (Offit, 2019).

Small quantities of a vaccine may be produced in a laboratory setting. Scaling up to produce or manufacture millions of vaccine doses is not a simple process and requires very specialized equipment. Consideration must be given to how the vaccine will be administered – i.e., by injection, oral administration, or inhalation – in order to produce a vaccine with the correct physical characteristics. The federal government has sponsored the construction of several facilities across the country, including here at Texas A&M University, equipped to produce approximately 50 million doses of an approved vaccine within three months, if called upon to do so. These facilities also have the laboratory capabilities for the creation of new vaccines.

Once large quantities of a vaccine have been produced and packaged under sterile conditions, they are ready for dissemination. At this stage of the process, considerations must be made for the potential necessity of maintaining vaccine viability through the cold chain. Failure to keep vaccines cold during the transportation process can significantly reduce or eliminate their effectiveness upon administration. This is a particularly

PHAGES

Patients with infections that are very difficult or impossible to treat due to antibiotic/antimicrobial resistance (AR/AMR) are presenting at an increasing rate. Penicillin was discovered and utilized prior to World War II, but it did not become widely available until 1945. Since that time antibiotics have proven less and less effective at killing pathogenic microorganisms. This includes newer antibiotics such as Vancomycin and Methicillin. When used to treat Vancomycin-resistant Enterococci (VRE) and Methicillin-resistant *Staphylococcus aureus* (MRSA), along with many other resistant bacteria, patients are at risk of succumbing to their infections. These microorganisms are often referred to as "Superbugs" and their lack of response to antibiotics presents a global health problem. Not only have the microorganisms evolved mechanisms to become antibiotic resistant, they can transfer this resistance characteristic to other bacteria. The United Nations Ad Hoc Interagency Coordinating Group on Antimicrobial Resistance predicts 10 million people will die annually from AMR infections by 2050, if no action is taken.

It is well known that there are many deadly viruses that can infect humans. In the early twentieth century, British and German scientists discovered that viruses can attack and kill bacteria. Other viruses infect bacteria but do not kill them, rather they integrate into the bacterial genome in order to replicate additional viruses. A virus that kills bacteria is called a bacteriophage or just "phage" (from the Greek word "to devour"). The concept was proposed that the bacteria-killing phage could be used alone or in conjunction with traditional antibiotics to treat human patients with AR/AMR infections. Both RNA-based and DNA-based bacteriophages have been discovered and are much more specific as to the bacteria they kill than the antibiotics typically used to treat patients. Importantly, phages do not attack human cells and are typically harmless to beneficial bacteria, such as those found in our gastrointestinal system. Synthetic biology or gene editing may be used to increase the specificity of a phage for a "specific bacteria" infecting a "specific patent". This is referred to as "precision medicine".

Dr. Ry Young of Texas A&M University heads the Center for Phage Technology. This center conducts research on identifying phages that are lethal to specific pathogens. Once identified, issues associated with producing the virus, storage, administration, and FDA approval for use of the phage must be pursued. Tremendous progress is being made. In 2016, a patient in California was fighting for his life from an antibiotic resistant *Acinetobacter baumannii* infection. Permission was sought and received under the special emergency/compassionate use guidelines to treat the patient with a phage designed to kill the bacterium. Within 48 hours of administering the phage to the patient, he regained consciousness and began to recover. This incredible example of how a phage can be used to kill AR/AMR organisms in humans opens a new world of medical promise for control of bacterial pathogens.

relevant challenge in low-income countries without reliable electricity or refrigeration. Finding solutions to cold chain problems is important for creating more effective pandemic preparedness and response.

Vaccine Development Timelines

Vaccines are a vital tool in preventing outbreaks of infectious disease. Vaccines create immunity in a population, which prevents diseases from taking hold. They have also been an indispensable tool in disease eradication campaigns, such as in the campaign to eradicate smallpox. When a vaccine is available, utilization of that vaccine can prevent a pandemic from occurring. Unfortunately, most pandemics are the result of emerging diseases, such as SARS, 2009 H1N1, or SARS-CoV-2. In these cases, vaccines were not available at the time of the outbreak and had to be developed after the fact.

In instances where vaccines must be developed in the midst of an outbreak, the public health community and the general population should expect lengthy delays between the first stages of research and the dissemination of a finalized vaccine. This delay is the result of scientific development and discovery as well as the clinical trials process to make sure that the vaccine will be safe for use in humans. According to the WHO, it takes approximately six months for a new vaccine for pandemic influenza to become available once the virus is identified (WHO, 2009). In the ongoing outbreak of SARS-CoV-2 (the COVID-19 pandemic), the timeline for developing and approving a vaccine is predicted to be 12 to 18 months (Soucheray, 2020), though this process could take much longer. For diseases in which we have no precedent, for example the SARS virus in 2003, vaccine development can take years. Thus, vaccines are important to public health protection and pandemic response, but they do not always provide a rapid disease containment option.

RECOMMENDATIONS:

1) Create an integrated surveillance system for infectious disease – Pandemic Early Warning System (PEWS).

To create more robust infectious disease surveillance, which allows for a higher likelihood of containment at the source, we recommend developing an integrated surveillance network that utilizes mobile data, web-based data, GIS data, and scientific databases like the one created by the PREDICT program. This surveillance network, which we have named Pandemic Early Warning System (PEWS), would provide a multi-tiered approach to disease surveillance. Collecting surveillance data from varying sources that are not reliant on self-reporting can speed up the time to recognition of an outbreak and lessen the chances of a pandemic. Even if such a system is set up in an international body, a parallel but independent system should be developed by the U.S.

government to ensure alternate sources of information if the international system fails or vice versa. Redundant early warning systems are needed to protect the integrity of data capture and analysis. Politics often intervenes to distort facts in a crisis.

In addition, an epidemic response system should be created within the US government that does not require high level authorization to initiate a disease outbreak containment response. We have an existing and historically successful model for doing this for other natural disasters in USAID's Office of Foreign Disaster Assistance (OFDA), which can mobilize a Disaster Assistance Response Team (DART) within 48 hours to travel to remote locations in the world to begin a humanitarian response. These DART teams are expeditionary (i.e., they are self-contained and self-supporting), flexible in size, have authorization to spend money without going through the lengthy U.S. government procurement process (from which they are exempt under the notwithstanding clause in their enabling legislation), and have access to unencumbered financial resources. DART teams may be mobilized with no more than the approval of the U.S. Ambassador to the country receiving assistance and the OFDA office director. OFDA had a budget of $1.7 billion in 2019 and more than 700 staff.

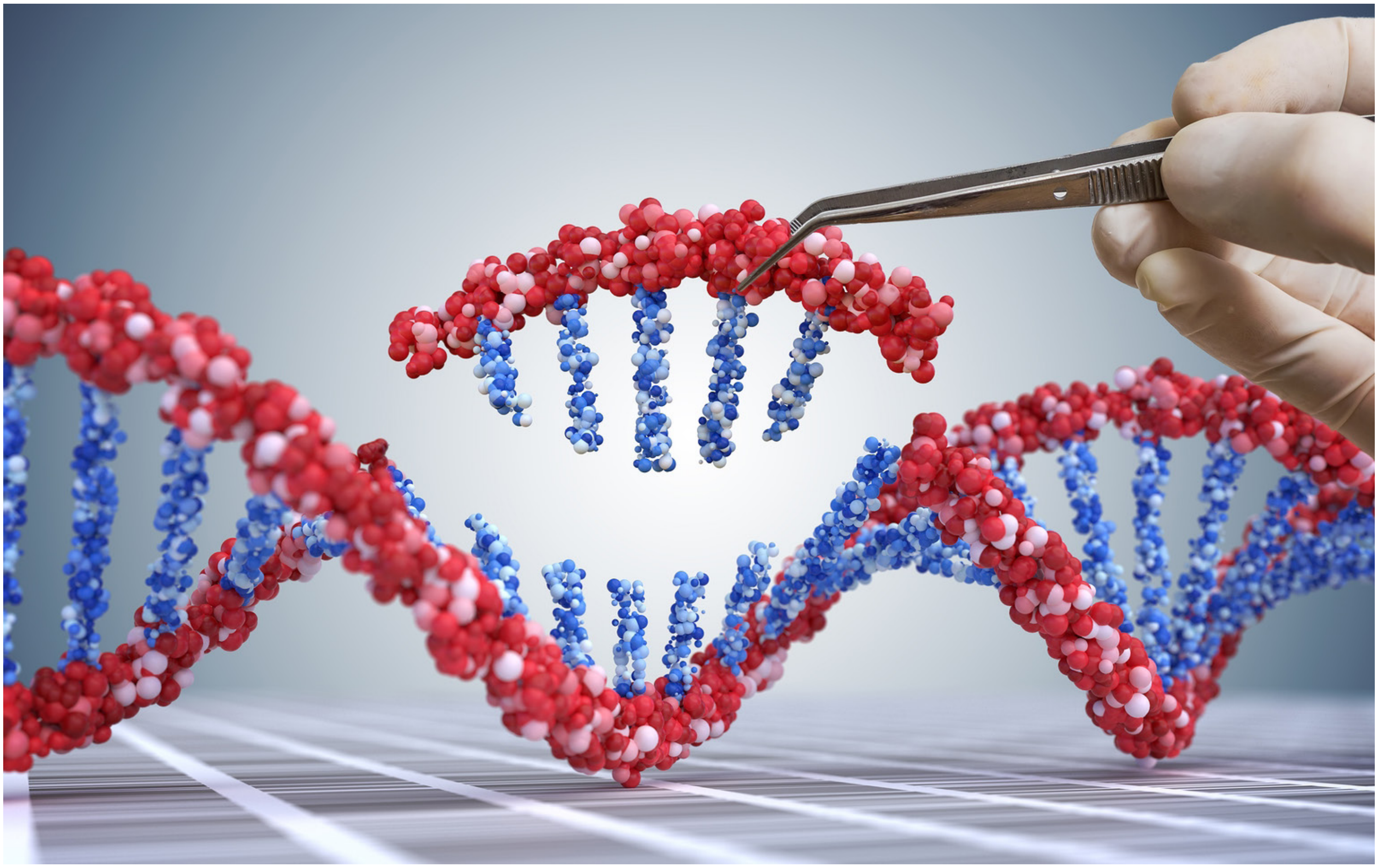
The greatest enemy of disaster response is time. Thus, any pandemic early warning system should be organizationally linked to a rapid response team at the lowest level of the federal government to avoid invariable bureaucratic delays up the chain of command.

2) Expand research and development into promising biosensors.

Biosensors have proven useful in creating rapid diagnostics in low-resource settings, but there is still a long way to go before we have solved the problem of disease detection in such settings. Thus, we must continue to support research and development efforts in biosensor technology. This technology provides the best opportunity for rapid diagnostics in high-risk, low-resources settings and can prove valuable in containing an outbreak before it becomes a pandemic.

3) Develop more efficient vaccine dissemination plans.

As a country, we are constantly working to improve our vaccine dissemination plans. Each new presidential administration develops priorities for who will be the first in society to receive vaccines. For example, will it be the military, healthcare workers, transportation workers, or the most vulnerable in society? However, dissemination to those individuals, once vaccines are available, is an ongoing challenge that requires the resources of both the public and private sectors. Investigating how we can use companies, such as UPS and FedEx, to move vaccines around the country is an important component in developing an effective vaccine dissemination policy.



TOPIC AREA 2: **DUAL USE RESEARCH OF CONCERN**

CRISPR

Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) is a segment of DNA that is involved in defense against viruses. Over the last decade, scientists have developed tools that can use CRISPR to modify genes. The development and use of CRISPR-based techniques for genetic engineering have increased since they first showed effectiveness in the cells of mammals in 2013 (Cong et al. 2013). Such strategies have significant implications for scientific research, medicine, agriculture, and manufacturing, because they offer affordable and accessible ways to make targeted genetic changes. Since 2013, CRISPR has been commercialized and is now used in laboratories around the world.

Until the introduction of CRISPR, the major limitation blocking the development and use of genetic engineering was the lack of an effective and accessible means of editing DNA. Following the development of CRISPR technology, however, all of that changed.

Seemingly overnight, CRISPR and its associated Cas proteins provided a cheap and relatively easy way to "cut and paste" genetic changes. This was revolutionary, because producing custom RNA sequences is orders of magnitude cheaper than producing custom proteins. Additionally, the Cas proteins, particularly Cas9, are inexpensive and available commercially. Because of the accessibility and standardized nature of CRISPR/Cas, it can quickly be adapted to a variety of gene modifications in a variety of organisms. By 2014, approximately one year after the first publication of its use for genome engineering, researchers had demonstrated that CRISPR/Cas9 could be used for gene editing in human, mouse, rat, fruit fly, nematode, salamander, frog, rice, wheat, sorghum, and tobacco cells, among others (Doudna and Charpentier, 2014). Additionally, the originally published CRISPR/Cas system continues to be improved and adapted to new uses. For example, it has been found that a new Cas protein (i.e., Cas13) can be used in editing RNA, which makes up the genome of many viruses (Abudayyeh et al., 2017).

There are many advantages to the development of CRISPR/Cas, but likely the most valuable has been in the biomedical and biopharmaceutical industry. In addition to the design, testing, and manufacture of new therapeutic drugs, CRISPR/Cas itself can improve human health. Recently, CRISPR/Cas was directly applied in a human patient for the first time to correct a degenerative genetic vision disorder (White, 2020). Gene and cell

RAMAN SPECTROSCOPY

Raman spectroscopy is an analytical tool used to determine the chemical bonds present in a sample of material. These chemical bonds are uniquely related to the identification of the sample. When a sample is exposed to a high intensity laser, light is scattered in two different forms, including (1) Rayleigh scatter that is at the same wavelength as the incident laser and (2) Raman scatter that is at different wavelengths and is unique to the sample's chemical structure but at a much lower signal strength. Texas A&M University's research into Raman spectroscopy is carried out in the Dwight Look College of Engineering and the College of AgriLife Sciences. Our Institute for Quantum Science and Engineering is led by Dr. Martin Scully, who is working closely with investigators at Princeton University.

Raman spectroscopy has been used for some years in the physical sciences for the detection of explosives and other inorganic compounds and is available in hand-held units. In recent years Raman spectroscopy has been utilized for the culture-free identification of microbial pathogens. Samples of infectious agents typically would have to be cultured from patients and allowed to grow in a laboratory setting until sufficient numbers were available to provide an accurate identification. Unfortunately, during the time it might take to grow the culture, the patient might succumb to the infection. Raman spectroscopy allows for the rapid identification of pathogens resulting in the timely initiation of appropriate therapeutic interventions.

Following the 9/11 attacks and in conjunction with the United States Postal Service, researchers here at Texas A&M University (TAMU) refined Raman spectroscopy for the detection of pathogenic microorganisms contained in letters. Multiple cases of inhalation anthrax, including five deaths, resulted from this USPS attack and method of disease propagation. The TAMU research focused on the detection of *Bacillus anthracis* (the agent responsible for anthrax and used in the attacks) directly through an envelope containing the microbial spores. This technique is currently in use and alerts officials of danger before having to open potentially lethal envelopes containing and spreading inhalation anthrax.

Efforts are currently underway to further develop the concept of "Standoff Raman spectroscopy". This technique addresses the concept of being able to use Raman spectroscopy from further and further distances from the object being analyzed (millimeters to kilometers). Two approaches for utilizing standoff Raman spectroscopy are being investigated. The first technique focuses on detection of pollutants, poison gases, and microbes with a ground-based laser directed into the atmosphere. The second technique extends use to a drone that could be flown over crops or herds of animals to evaluate potential infections from a variety of pathogenic agents. Research at TAMU also continues on batteries to provide sufficient power to the Raman laser at a weight acceptable for use in drones.

therapies using CRISPR/Cas have the potential to treat cancer, cardiovascular disease, metabolic diseases, neurodegenerative diseases, viral diseases, hereditary eye diseases, blood diseases (Li et al., 2020) and to target human immune cells to fight tumors (Eyquem et al., 2017; Jung and Lee, 2018; Hu et al., 2019).

However, CRISPR/Cas also comes with risks. While there is potential to use genome editing to cure genetic diseases, many have worried about its use for creating bioweapons or new diseases. As an example of this concern, a team of Canadian researchers published their method of constructing the extinct horsepox virus using synthetic biology techniques in 2018 (Noyce et al., 2018). Thus, the national security and global health communities must come to agreement on the use and monitoring of CRISPR technologies.

Promises and Perils

Dual Use Research of Concern (DURC) refers to life sciences research that could pose a threat to public health and safety, agriculture, the environment, or national security. Dual-use research topics walk the line between serving as a driver of innovation and a national security threat. On the one hand, if we aspire to move to the next steps in modern technological advances in the life sciences, cutting edge research must be pursued. On the other, we must use established frameworks to determine the risk associated with research that is being proposed. The U.S. must understand that any decisions to limit research on specific topics or those using select agents could cost American interests in the long run as other nations may not hold the same reservations. The readily available information on the internet and in the public domain has lowered the barriers to entry for people across the world. The proliferation of information, knowledge, and skills has only moved the timeline forward on many dual-use research topics. Stakeholders must be aware of both the promises and perils associated with Dual Use Research of Concern.

Promises of Technological Development in the Biological Sciences

Innovations spawned by Dual Use Research of Concern have the potential to save lives in the future while raising the quality of life for many in the near term. Current advances using CRISPR Cas9 and Cas13 may eventually lead to the eradication of some of humanity's most debilitating genetic diseases. It is important for research related to such conditions as Huntington's disease, muscular dystrophy, HIV/AIDs, and cancers, among others, to continue to be pursued. With current technological advancements, scientists are finding ways to use gene editing to "attack" infected cells to remove HIV from an individual (Khalili et al., 2017). This type of research could change the world as we know it if it is successful in eliminating HIV/AIDS. Advancements currently underway offer to people all over the world the potential to be free from painful, chronic, or life-shortening diseases. Because of this, it is important that the U.S. continue to allow work that may lead to such developments and implement proper vetting and review of projects to decrease the likelihood that such work would be used for nefarious purposes. Through responsible oversight and review of dual-use scientific research efforts, we can allow for scientific innovation while expanding all hazards preparations to mitigate any adverse cascading effects from misuse.

Perils of Technological Development in the Biological Sciences

While Dual Use Research of Concern offers many promises, it could also lead to novel threats from practices, methods, and materials that may initially appear benign. The risk of bioterrorism from Dual Use Research of Concern is present, even if the likelihood is slim. Arguably there has been a normalization of the use of chemical agents across the world with little repercussions. Below, we outline a scenario that demonstrates how quickly work done for scientific advancement can be transitioned and implemented in a harmful manner.

BIOTERROR SCENARIO: TERRORIST WEAPONIZATION OF *BACILLUS ANTHRACIS* HARVESTED FROM RANCHLANDS

In the western U.S., an outlier political faction supported by wealthy benefactors has slowly increased their membership and political activity. They have a private cattle ranch secluded from traditional society. The faction is a driver of much of the local ranching economy and employs members of the community on their cattle operation. The faction has supported local candidates for office and has influence throughout the region. Local law enforcement gives them a wide berth. All of their political donations and community improvements have bought them loyalty from county and state officials. At some point, disagreement emerges between the faction and a lawmaker in the capital of their state. The faction leaders have already expressed interest in the use of chemical and biological agents in a manner similar to the poisoning of Sergei and Yulia Skripal in the United Kingdom (OPCW, 2018), the Aleph doomsday cult in Japan (Olson, 1999), and the Rajneeshee salmonella attack in Oregon (Torok et al., 1997). They believe that the answer to their political problems is to make a statement and to eliminate their opponents in the state legislature.

The determination is made to use something that has been found to kill their cattle: Anthrax. They discovered the deposit on the ranch after a local veterinarian was called to do a necropsy on a few head of cattle that died unexpectedly. Once the decision is made, the faction begins diverting funds into creating a laboratory on their compound to weaponize anthrax and to recruit scientists aligned with their cause. Their unlimited funding and off-the-grid lifestyle help them stay under the radar as they operate their private laboratory. The faction harvests anthrax on their ranch and begins using research in the public domain to assist in weaponizing the agent. The research work takes time, but the faction is well-funded and patient. Faction scientists are successful and test their agent on livestock before moving to the next step of deploying the weaponized anthrax.

Once they are ready to carry out their attack, three faction members enter the state capitol building, don protective equipment, and throw aerosolized canisters to disperse highly concentrated amounts of the agent into the chambers where members of the legislature are meeting. Members are confused and initially believe that the fumes coming from the canisters are botched tear gas grenades. Due to this misunderstanding, they do not initially flee. The faction members leave and bar the chamber doors behind them, leaving the members for dead.

A scenario like the one described here may seem unlikely, but it is possible. Information, ideology, and methods can move at the speed of light across the globe due to the Internet and the growing connectivity it allows. If determined individuals have the funds and access, they could strive to use Dual Use Research of Concern for malicious purposes. Stakeholders in the life sciences and national security community must understand the nature of the promises and perils of Dual Use Research of Concern. By acknowledging the risk, working toward better active surveillance, proper vetting, education, and other national security steps, the U.S. can lead the world in pursuing Dual Use Research of Concern responsibly, while also maintaining vigilance for potential misuse.

Existing Laws and Regulations

To date, the regulatory statutes surrounding Dual Use Research of Concern have lacked clarity. The Fink Report, produced in 2004, supplied recommendations for Dual Use Research of Concern oversights and supported the formation of the National Science Advisory Board for Biosecurity (NSABB) (Tomlinson, 2018; National Academies, 2017; National Advisory Board for Biosecurity, 2007; National Research Council, 2004). These recommendations, which included implementation of a review process at both the project planning and publication stage, provide multiple places where officials can identify scientific processes that may pose a threat to national security. Lastly, the Fink Report acknowledged that Dual Use Research of Concern was an international problem and that there was a need for international cooperation.

On the international level, the 2000 Cartagena Protocol and the Nagoya Protocol both provided provisions regarding genetic engineering research (Tomlinson, 2018). The Australian Group also serves as an international guiding body and tracks dual-use technologies and agents through a common control list (National Academies of Sciences, Engineering, and Medicine, Policy and Global Affairs; Committee on Science, Technology, 2017). Ultimately, the NSABB, which was formed in 2012, has supplied the frameworks and guidance for Dual Use Research of Concern in combination with a 2012 National Institutes of Health policy that provides additional oversights for life sciences involving Dual Use Research of Concern (National Academies, 2017). The two main policies that the federal government has created at the recommendation of the NSABB are requiring both federal funding agencies and federally-funded research institutions (1) to identify Dual Use Research of Concern and (2) to take action to reduce the risk (Wolinetz, 2017). It should be noted that institutions that do not receive federal funding are not subject to oversight.

What does Dual Use Research of Concern Mean for Pandemics?

The paradox of the necessity for Dual Use Research of Concern is especially evident in the area of pandemic preparedness. The world is dealing with one of the greatest global challenges in modern history, namely, the COVID-19 pandemic. The exponential spread of COVID-19 across the globe has frozen commerce, overwhelmed healthcare systems, and will likely change the world as we know it (CDC, 2020; Sohrabi et. al, 2020). The state of the planet today illustrates both the necessity for pandemic research and the very real concern for its potential danger if applied to the development of bioweaponry. To fully appreciate the scope of the challenge, both the benefits to humanity through pandemic research and the dangers of the misuse of such research need to be appreciated.

CDC Guidelines on Infectious Disease Dual Use Research of Concern

There exist 15 select agents on which the CDC considers research to be dual-use. These include, among others, highly pathogenic avian influenza viruses, *Bacillus anthracis* (anthrax), Ebola virus, and *Variola major* (smallpox) (CDC, 2020). Furthermore, the aim of the research done with these and other agents could be dual-use. As listed in the CDC Dual Use Research of Concern Avian Flu press release (2019), such research of concern includes efforts to achieve the following:

1. Enhance the harmful consequences of the agent or toxin;
2. Disrupt immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification;
3. Confer on the agent or toxin resistance to clinically and/or agriculturally useful preventative or treatment interventions against that agent or toxin, or facilitate their ability to evade methods of detection;
4. Increase the stability, transmissibility, or ability to disseminate the agent or toxin;
5. Alter the host range or tropism of the agent or toxin;
6. Enhance the susceptibility of a host population to the agent or toxin; and
7. Generate or reconstitute an eradicated or extinct agent or one of the 15 Dual Use Research of Concern toxins or agents.

Research conducted with these agents makes it critical for the global health effort to be prepared for potential natural pandemics or biological warfare, but the applications of this research must be closely monitored and the methods scrutinized in order to assure public safety and national security. Misappropriation of research on these agents could be disastrous.

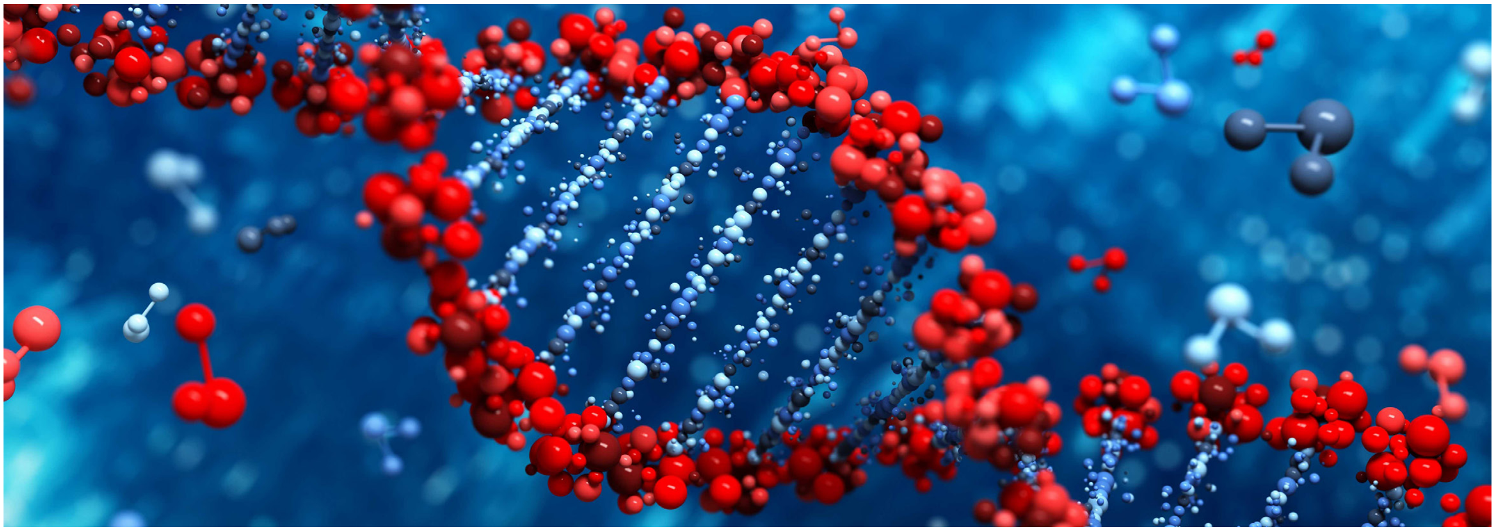
Synthetic Biology and the Cheapening of Biological Dual Use Research of Concern

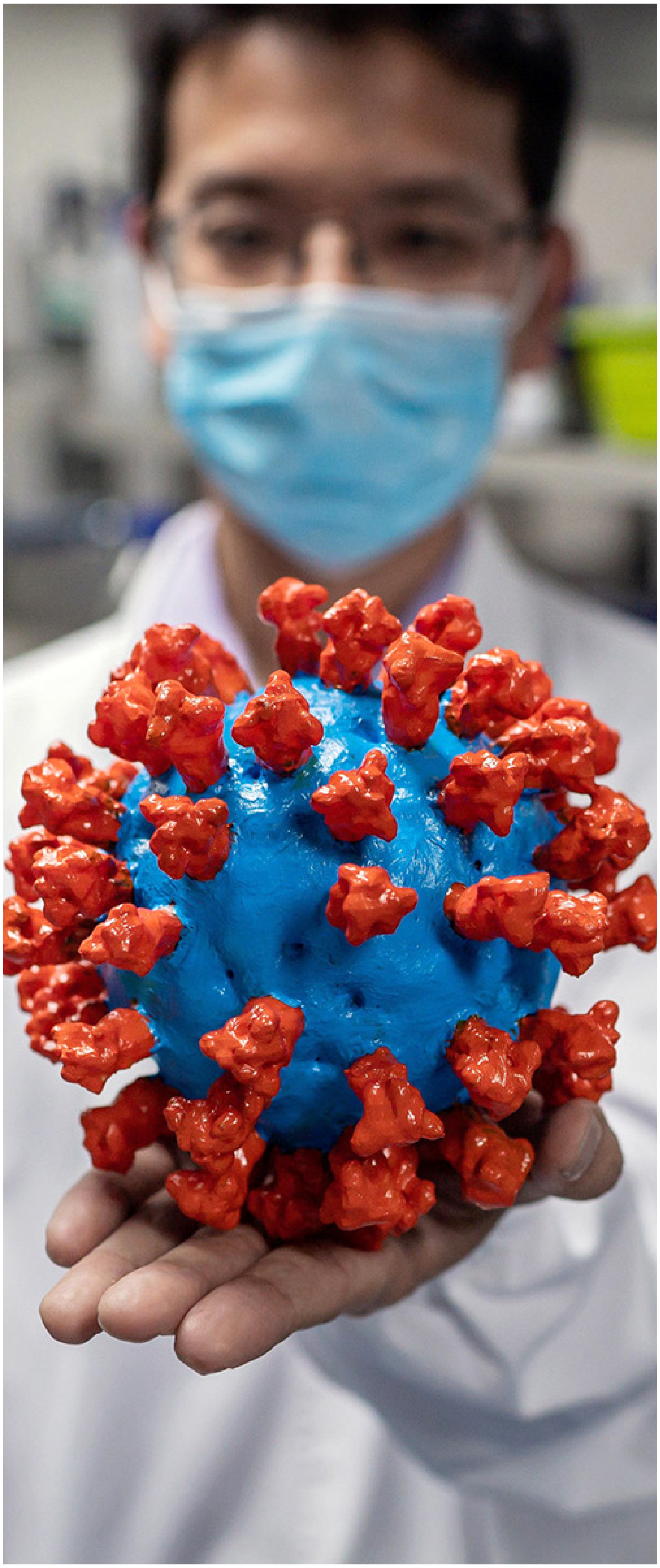
The widespread availability and adoption of synthetic biology technology have exacerbated the concerns about the misappropriation of pandemic and infectious agent research. Synthetic biology is an emerging field of research that applies engineering practices to biology. Evolving research in this area lessens the effort required to manipulate DNA and potentially allows for the creation of novel infectious agents or enhanced virulence of existing infectious agents. For example, it is conceivable that someone with access to the appropriate lab equipment and a strain of an infectious agent, such as anthrax, could manipulate the DNA of their infectious strain to make the pathogen hardier, or airborne, or target populations of people with specific ethnic backgrounds. Furthermore, experiments conducted with synthetic biology on infectious agents, whether by amateurs or legitimate research institutions, have the potential for mishap, possibly leaking dangerous manufactured pathogens into the outside world. Finally, while the vast majority of legitimate research conducted with synthetic biology produces enormous gains in the fields of medicine, agricultural science, and environmental science, off-target effects in synthetic biology pandemic research could lead to unforeseen public health dangers.

Gain-of-Function Research: Implications for Pandemics

Even without the aid of synthetic biology, research on infectious pathogens has the potential for misuse and is a matter of concern for regulatory agencies and research ethicists. Most notably, in 2014, the Obama administration called for a freeze in government funding for gain-of-function research (Selgelid, 2016). Gain-of-function research aims to increase the transmissibility or virulence of a pathogen. Understandably, the administration was concerned that this sort of experiment could lead to a highly infectious agent with the potential to create a pandemic. However, it must be understood that research in this arena is critical to understanding the nature of pathogens and predicting how they may behave in certain environments. In this way, gain-of-function research can be both a public health threat and a necessary means to protect the public.

At the time of this publication, concerns over the use of synthetic biology as an instrument for bioterrorism are yet to be validated. However, thoughtful legislation and preparedness could prevent catastrophe. Effective measures to prevent misuse of pandemic research could include continued scrutiny of research that utilizes any pathogen in the CDC's list of select agents or involves research practices that fall under the CDC's list of dual-use experiments (CDC, 2019). In this vein, an international body of experts on infectious disease research is recommended to provide guidance on which experiments are and are not necessary and the appropriate way to conduct the ones that are (Fauci & Collins, 2012). Finally, involving civil society early in the discourse on research plans will provide a public perspective for the discussion (Fadden & Karron 2012).





RECOMMENDATIONS:

1) Continue communication between federal law enforcement and both the amateur and professional scientific community to strengthen biosecurity understanding and processes.

When DIY bio laboratories began to increase in popularity, the FBI actively sought to build relationships with amateur scientists working in those labs. The purpose of establishing these relationships was to provide the FBI with knowledge regarding what type of science was being conducted, but it also served to build a relationship between DIY biohackers and the law enforcement agency with the hope that people would feel more comfortable reporting any suspicious experiments. Continuing to build and strengthen these relationships as well as extending the relationships into formalized science (i.e., academic institutes, research centers, and the private sector) would help scientists look beyond the science and better understand the possible national security implications of their work.

2) Create an international body of experts to review experiments.

An international body of infectious disease experts should be created to review Dual Use Research of Concern from around the world. This panel will set standards and provide recommendations for the global community to help countries find a balance between scientific innovation and national security.

3) Continue to strengthen policies and protocols for reviewing the funding and publication of Dual Use of Research Concern.

The Fink Report and the formation of the NSABB were important steps toward increasing safety around Dual Use Research of Concern, but there is still work that needs to be done. In particular, regulations and oversight apply almost exclusively to federally-funded research. This leaves a significant gap in national security oversight and pandemic preparedness. If terrorist organizations or individuals are able to secure private funding for their work, there is limited action that the federal government is able to take with regards to regulation of research or even knowledge that such research is happening.

TOPIC AREA 3: THE BIOECONOMY

What is the Bioeconomy?

The Global Bioeconomy Summit (2018) defines the bioeconomy as "the production, utilization and conservation of biological resources, including related knowledge, science, technology, and innovation, to provide information, products, processes and services across all economic sectors aiming toward a sustainable economy" (FAO, 2020). On paper, the use of biological resources, whether that be knowledge or technology, is considered part of the bioeconomy. In practice, this means that everything from pharmaceuticals to the food on grocery store shelves are important concerns for biosecurity. In a U.S. Senate hearing held on March 3, 2020, Dr. Jason Kelly from Ginkgo Bioworks noted that as the ability to produce things using synthetic biology is increasing, the cost of this production is decreasing (U.S. Senate, 2020). In other words, knowledge and technologies that are at the core of the bioeconomy are becoming easier and more accessible. While there are numerous positive aspects of the bioeconomy, "...the powerful technologies encompassed by the bioeconomy can also lead to national security and economic vulnerabilities" (National Academies of Sciences, 2020). The growing importance of such knowledge and technologies is the primary reason that the U.S. must focus on the physical and economic impacts of the bioeconomy domestically and abroad.

Why Does the Bioeconomy Matter?

In our February 11, 2020, article in *The Conversation* titled "The silent threat of the coronavirus: America's dependence on Chinese pharmaceuticals," we discussed the dangerous nature of America's reliance on China for the production of active ingredients and finished pharmaceutical products. Eighty percent of our pharmaceuticals are produced in China, and for some medications China produces almost 100 percent of the active ingredients (Blackburn et al., 2020; Gibson & Singh, 2018). A near-monopoly on the pharmaceutical market gives the Chinese government unprecedented power over the health and safety of Americans. Additionally, the COVID-19 pandemic is demonstrating the possible impact of disease on the medical supply chain: When China nationalized factories producing masks, the U.S. quickly found itself with a shortage (Bradsher & Alderman, 2020). Imagine the impact if shortages were to occur with medicines necessary to keep people alive, such as cancer treatment drugs or insulin.

The bioeconomy also matters for reasons outside of pharmaceuticals. Developments in synthetic biology, genetic information (such as 23andMe, Inc.), and vaccine development are all vital components of the growing bioeconomy. As artificial intelligence increases, the ways in which we will be able to use biological information will expand. Control over and protection of biological data will play a substantial role in the health and well-being of countries around the globe.

National Security Issues within the Bioeconomy

A 2020 report from the National Academy of Sciences lists several economic and national security risks that exist in the realm of the bioeconomy. Among these risks are the failure of the U.S. to promote the bioeconomy domestically, which has resulted in "diminished U.S. scientific leadership in the global bioeconomy," and a failure to protect the U.S. bioeconomy from intentional acts that could result in harm or misuse. Regarding the loss of scientific leadership, the report charges that there has been insufficient support for vital research, and this lack of investment could have long-term detrimental impacts on the ability of the U.S. to act as a leader in the scientific community. The report also acknowledges asymmetric research constraints that often limit the types of experiments American scientists can conduct.

Regarding the failure to protect the bioeconomy from intentional acts of harm and misuse, the report points out numerous concerns, including genetic targeting of populations. Genetic weapons could be developed, the report argues, that would have "the ability to attack a specific individual or group of individuals on the basis of distinctive genetic traits" (National Academies, 2020, p. 298). This is just one of many examples that illustrate the ways that information in the bioeconomy could be misused, but it can clearly demonstrate why understanding and safeguarding the bioeconomy are vital to U.S. interests.

Coronavirus Outbreak and Data Ownership

The ongoing COVID-19 pandemic has demonstrated in more ways than one why the U.S. needs to turn its attention to the bioeconomy. As mentioned above, our reliance on pharmaceuticals from China puts us in a dangerous situation in the event of a pandemic or any other natural or human-made event that would prevent China from continuing to supply the necessary medicines and medical equipment to the U.S. The pandemic has also demonstrated the importance of data ownership as seen when China shared the SARS-CoV-2 genome (digitally), but did not share the actual samples. This may seem like a small distinction, but it has large implications for the ability of the U.S. to produce a vaccine for COVID-19. Without physical samples, the U.S. was unable to gather any information about the virus/host interaction. By sharing only portions of the genetic information, the Chinese government is able to ensure that the U.S. remains at a disadvantage in the development of vaccines and treatments.

There are numerous examples of how the U.S. is falling behind in the bioeconomy. What have been touched on in this section are just two specific examples that have come to light as a result of COVID-19. During our Fall 2020 Annual Pandemic Policy Summit, the Scowcroft Institute will explore the bioeconomy in more detail and work toward developing policy solutions for some of the most pressing problems.

INFRASTRUCTURE

In order to conduct cutting-edge research critical to national security, state-of-the-art research facilities are required. Texas A&M University in conjunction with both State of Texas and U.S. governmental agencies has constructed and equipped the following biosecurity research facilities:

National Center for Therapeutics Manufacturing (NCTM). The NCTM is a 156,000 square-foot interdisciplinary research and workforce education center that serves the global biopharmaceutical and vaccine manufacturing industries. The NCTM operates as a dedicated vaccine facility that is capable of manufacturing vaccines for seasonal influenza strains as well as other approved vaccines, such as for coronavirus. The NCTM also develops hands-on learning experiences to train scientists and technicians to develop new medicines to deal with tomorrow's public health challenges. When at maximum surge capacity, the center contributes to the country's pandemic response by being able to produce 50 million doses of an approved vaccine within three months for the federal government.

Texas A&M Institute for Preclinical Studies (TIPS). TIPS provides large animal translational research studies as well as access to expertise in all major medical and scientific disciplines, such as surgery engineering, nephrology, and pathology, among others. TIPS is fully capable of providing preclinical (safety and efficacy) Food and Drug Administration-required testing of both biomedical devices and pharmaceuticals. The 112,000 square-foot facility maintains 240 individual large animal housing units with good laboratory practice compliance, three 600 square-foot surgical suites, and all state-of-the-art imaging modalities. Conference facilities complete with auditoriums for teaching and training are located within the facility.

Texas A&M Institute for Genomic Medicine (TIGM). TIGM has one of the largest libraries of embryonic cells in multiple mice strains in the world as well as transgenic services, such as CRISPR/Cas9-based genome modification. In addition, TIGM houses on site molecular biology and tissue culture facilities as well as laboratories for microinjecting stem cells and cryopreservation of stem cells, embryos, and sperm.

Global Health Research Complex (GHRC). The GHRC is a Biosafety Level 3 agriculture containment facility and is one of only a couple of such complexes capable of conducting world class global health research on higher level pathogens. This 130,000 square-foot facility provides new and innovative methods for monitoring, detecting, and preventing emerging zoonotic infectious diseases that pose the greatest threat to the world's public health and agricultural food supply. The GHRC supports global health through new technologies in the development of vaccines, diagnostics, and modes of transmission utilizing its state-of-the-art large animal facilities, laboratories, and insect vector housing.

Disaster City. This 52-acre training facility is designed to simulate disasters ranging from natural occurrences, such as earthquakes to terrorist attacks using bioweapons. Disaster City allows training for emergency response professionals in a variety of scenarios. The facility has collapsible building structures designed to mimic different types of emergencies. First responders from around the world travel to TAMU to experience the best training and exercises in the most realistic disaster settings. Training exercises can be designed to be conducted in full Personal Protective Equipment (PPE) for biological, chemical, and/or nuclear exposures.

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ACKNOWLEDGMENTS

We would like to thank Dean Mark A. Welsh III, President Michael K. Young, and Chancellor John Sharp for their continued support of our pandemic program.

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The Bush School of Government and Public Service
Holder of the Edward & Howard Kruse Endowed Chair,
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Michael K. Young
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We also would like to express our gratitude to George and Judy Marcus for their support of the pandemic program and the white paper. Donors like you are vital to our cause and our ability to achieve our mission.

The George H.W. Bush Presidential Library & Museum and The Bush School of Government & Public Service at Texas A&M University, College Station, Texas, USA

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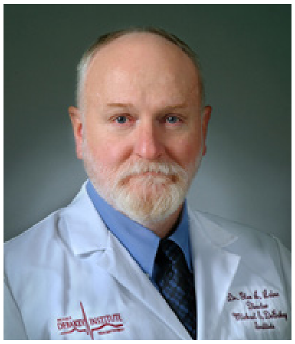

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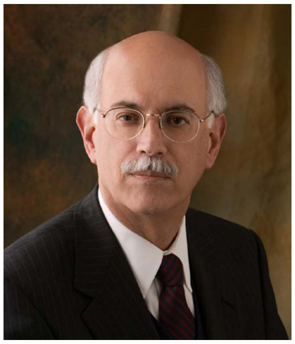

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President George H.W. Bush & Lt. Gen. Brent Scowcroft

"We live in an era of tremendous global change. Policy makers will confront unfamiliar challenges, new opportunities, and difficult choices in the years ahead. I look forward to the Scowcroft Institute supporting policy-relevant research that will contribute to our understanding of these changes, illuminating their implications for our national interest, and fostering lively exchanges about how the United States can help shape a world that best serves our interests and reflects our values."

— Lt. Gen. Brent Scowcroft, USAF (Ret.)

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Texas A&M University | College Station, Texas, USA | *cvmcommunications@cvm.tamu.edu* | *vetmed.tamu.edu/communications*