SPECIAL FOCUS

DIAGNOSTICS FOR BIODEFENSE

FLYING BLIND WITH NO PLAN TO LAND

A REPORT BY THE
BIPARTISAN COMMISSION ON BIODEFENSE

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EXECUTIVE SUMMARY

As with all large-scale events, novel coronavirus 2019 (COVID-19) reveals our national vulnerabilities. The pandemic casts a bright light on our limited capacity for diagnostic testing and our inability to conduct the necessary research to develop these tests quickly.

When a disease affects the United States, we turn to diagnostic tests first. We want to know what we are dealing with, what might kill the microorganism causing the disease, who has been infected, and how far and how fast it is spreading. Without that information, we fly blind. With a disease like COVID-19, caused by SARS-CoV-2 (a novel version of the Severe Acute Respiratory Syndrome (SARS) virus), the need for this knowledge is greater than ever before. Symptoms of COVID-19 vary greatly and often mimic those of the less deadly coronavirus infections and diseases caused by other pathogens (e.g., rhinoviruses, influenza). With decreased support for diagnostics research and development throughout the federal government, and the underlying assumption that diseases that begin to spread from other countries will not reach the United States, our Nation finds itself unable to track and control the spread of this disease.

The Administration and Congress should not wait until COVID-19 recedes in the United States to take up these recommendations. Instead, they should establish diagnostic testing capacity and support development of new tests to address COVID-19 now and for the pandemics to come. Despite progress made during the COVID-19 pandemic, we cannot expect to be ready for the next biological event without diagnostics.

CHARGE

Ensure that the United States can rapidly develop innovative point-of-care and point-of-need diagnostic tests for COVID-19 and other novel, emerging, and reemerging infectious diseases.

ACTION PLAN

Recommendations for the Executive Branch

- **Purchase Viable Diagnostics.** The federal government must assure industry that it will purchase viable diagnostics and other medical countermeasures (MCM) from them. Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) members should include dedicated diagnostic research and development in their budgets to support rapid response and ensure adequate scalability with the private sector to produce the diagnostics they require to support rapid response. The federal government should also invest in universal, innovative diagnostics.

- **Identify and Articulate Diagnostic Research and Development Requirements.** The Director of the Biomedical Advanced Research and Development Authority should identify requirements for Department of Health and Human Services (HHS) acquisition of diagnostic tests and clearly articulate them to industry and academia. The Biomedical Advanced Research and Development Authority (BARDA) should also harmonize these requirements with those of other agencies.

- **Leverage Defense Research and Expertise.** The Director of the Defense Advanced Research Projects Agency should consider how the Defense Advanced Research Projects Agency (DARPA) diagnostics research could be harnessed for civilian application to deal with pandemics and other large-scale biological events that affect national security.

Recommendations for the Legislative Branch

- **Require a National Plan for COVID-19 Diagnostic Testing.** Congress should amend the Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020 (P.L. 116-136) to direct the Secretary of Health and Human Services, in coordination with the Secretary of Defense, to establish a task force to: (1) develop a national plan for COVID-19 testing; (2) produce innovative diagnostic solutions; and (3) dramatically increase testing across the Nation.

- **Increase Reimbursement for Point-of-Care and Point-of-Need Diagnostic Tests and Increase Testing for Diseases Likely to Produce Widespread Infection in Society.** Congress should amend the Protecting Access to Medicare Act of 2014 to direct the Administrator for the Centers for Medicare and Medicaid Services to reconsider reimbursement rates for point-of-care and point-of-need diagnostic tests and increase reimbursement for testing of diseases that could negatively affect national security.

- **Provide Multi-Year Funding for Diagnostics Research and Development.** Congress should provide advance appropriations that cover multiple years rather than one year at a time for diagnostics research and development.

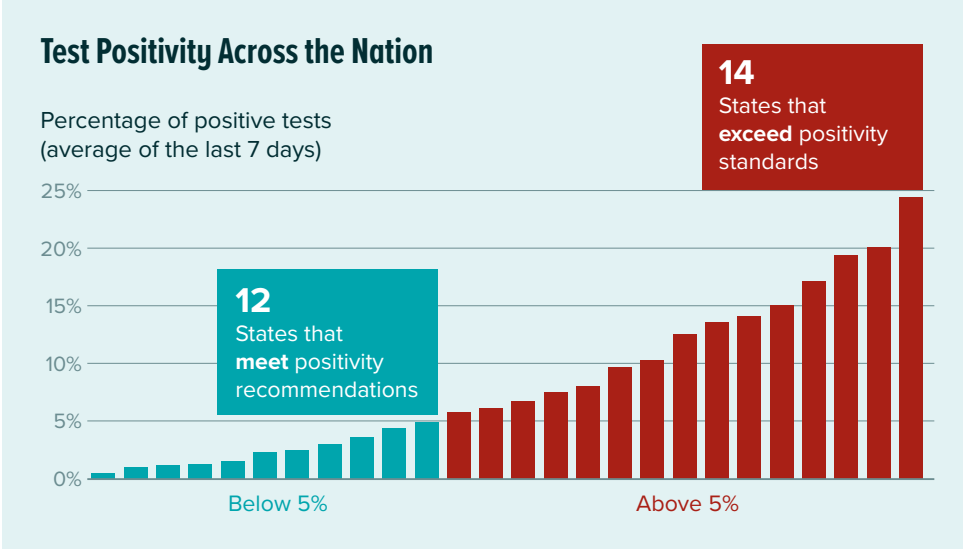
- **Leverage Defense Research and Expertise.** Congress should amend the Project BioShield Act of 2004 to direct the Director of the Biodefense Advanced Research and Development Agency to coordinate with the Director of the Defense Advanced Research Projects Agency and other federal advanced research projects agencies to identify diagnostic technologies progressing to advanced stages and validate them for civilian use.

NOTIONAL DASHBOARD

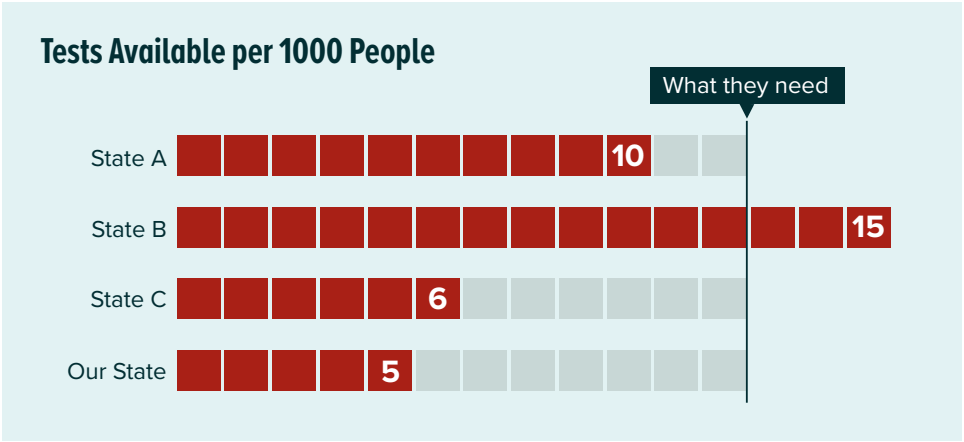
Diagnostics touch every facet of the response to a biological event. Failing to establish a robust testing regimen early in an outbreak has cascading effects that cripple a community's ability to effectively respond and contain spread.

This dashboard shows only a small fraction of the various challenges a state or locality can face when the Nation fails to rapidly develop a diagnostic for a novel pathogen like COVID-19 and implement a robust testing plan for a disease affecting all fifty states.

Test positivity (the number of positive tests out of all tests conducted) can give valuable information about the level of spread of disease in a community. High test positivity means there is more virus spreading in an area than testing and contact tracing can keep up with.

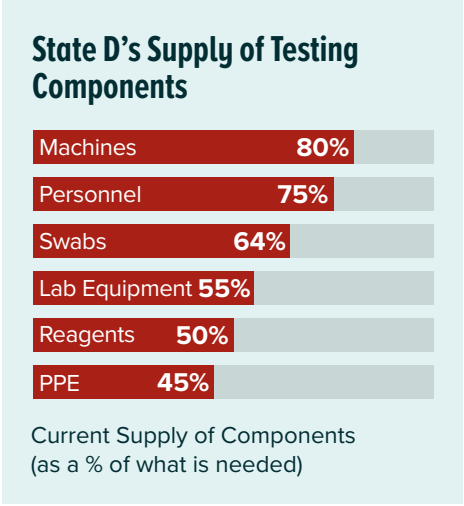


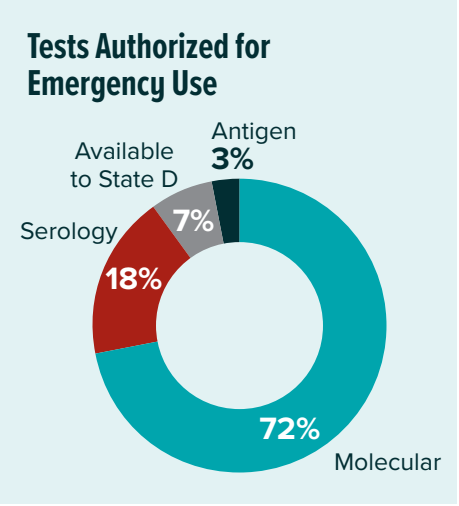
Limited testing availability hinders efforts to track disease spread. The lack of a comprehensive national testing plan raises the prospect of asymmetric distribution across states, localities, tribes, and territories.



Limited testing availability is partially due to supply chain shortages for materials needed to run diagnostic tests and analyze results. They also contribute to long delays before results are returned—increasing the likelihood a potentially infectious person breaks isolation protocols in the interim.

Many tests require similar materials to perform. We must ensure that the supply chain is adequate to address resource shortages and pursue various types of diagnostic tests, rather than relying on only one type.





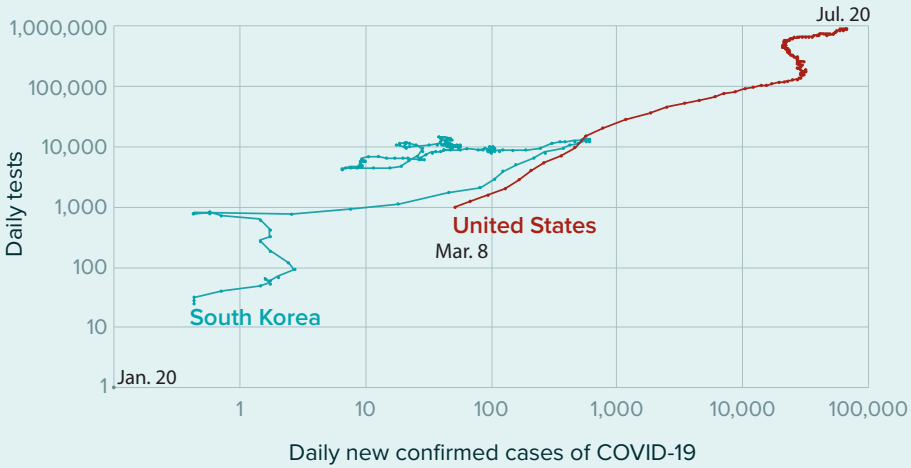
SITUATION

FLYING BLIND WITHOUT DIAGNOSTICS

The United States failed to develop and distribute a reliable diagnostic test when COVID-19 arrived in the Nation. While the country stumbled for weeks, others (e.g., Germany, South Korea, Taiwan) developed diagnostic tests and emplaced testing infrastructure that allowed them to control the spread of the virus and reduce death rates.[1]

Indirect measures (e.g., temperature screening) may only identify a few cases.[2] With diagnostic tests, we can identify and prevent carriers from spreading disease, especially in the absence of symptoms or before symptoms present. Not only do we need centralized laboratory-based diagnostic tests, we need innovative point-of-care and point-of-need diagnostics we can deploy to areas most in need, use with limited training, and from which we can get results in less than 30 minutes.

Figure 1. Comparison of COVID-19 Testing Approaches in the United States and South Korea from January 20 to July 20, 2020.[3]



Point-of-care and point-of-need diagnostics can help prevent small outbreaks from turning into major epidemics. For example, if healthcare practitioners can diagnose Ebola within the first 24 hours after a patient exhibits symptoms, the probability that a major outbreak will occur is around forty percent.[4] That probability increases to seventy percent if they diagnose the disease on the second day after symptoms occur, and eighty percent on the third day. By using point-of-care and point-of-need diagnostic tests along with centralized laboratory-based tests, the epidemic could have been thirty-three percent smaller.[5] With near-perfect tests, the epidemic could have been forty-two percent smaller. The value of these diagnostics increases with diseases that present without obvious symptoms.

> "Testing informs decision-making and saves lives."

The United States did not increase testing sufficiently during lockdowns and tried to return to normal operations without enough testing capacity to track new cases and prevent the spread of the virus. This led to more cases and more testing. We will endlessly be trying to catch up until we have enough diagnostic tests to distribute and use throughout the Nation before new cases occur.

The United States will need a substantial influx of rapid point-of-care and point-of-need diagnostic tests to help bring COVID-19 under control. Long delays associated with centralized laboratory-based testing cripple contact tracing efforts to contain the spread of the disease. We need point-of-care and point-of-need diagnostics that can rapidly return results.[6] We need to prioritize rapid, at-home, point-of-need diagnostics for outbreak control, even if they may be less accurate than centralized laboratory-based tests.[7] We must proactively define detection thresholds for all classes of diagnostics.

Testing informs decision-making and saves lives. New York confirmed the first case of COVID-19 on March 1, 2020, but had the state known that 10,000 infections were already present at that time,[8] they likely would have closed schools, bars, and restaurants in New York City earlier than March 17[9] and issued a statewide stay-at-home order earlier than March 20.[10] Imposing such measures two weeks earlier in March could have prevented 36,000–54,000 deaths.[11]

FLAWED EMERGENCY USE AUTHORIZATION

On January 31, 2020, the Secretary of Health and Human Services, Alex Azar, declared a Public Health Emergency[12] that allowed the Food and Drug Administration (FDA) to provide Emergency Use Authorization (EUA) for some diagnostic tests.[13] Unfortunately, this decision also impeded the efforts of clinical laboratories (who can typically develop and run their own tests without FDA approval) by requiring them to put their tests through the FDA EUA

process. **Clinical laboratories found the EUA process lengthy and cumbersome, and none successfully navigated the process by February 28, nearly a month after the public health emergency declaration.**[14] While the FDA meant for this process to protect against the use of inadequate tests, this inefficiency also meant that the United States could not use tests approved and in use by other countries. By the end of February, nearly all of Europe had established testing capacity[15] and even U.S. companies[16] had developed tests approved by, and fielded in, other parts of the world.

The first company to successfully navigate the EUA process received authorization from the FDA on March 12.[17] While the FDA subsequently issued EUAs for 107 molecular diagnostic tests, 27 serology tests, and 2 antigen tests,[18] only 6 could be used at points-of-care and only 10 allowed for at-home sample collection.[18] FDA overcompensation for bureaucratic delays may also have led to the subsequent deployment of scores of inaccurate tests.[19]

BOTCHED TEST

On February 4, 2020, the FDA issued an EUA for a test developed by the Centers for Disease Control and Prevention (CDC).[20] The CDC began shipping test kits to public health laboratories two days later, but contamination of one of the reagents rendered most kits unusable.[21] By this point, the World Health Organization (WHO) had shipped 250,000 tests to 70 laboratories around the world. On February 28, the CDC announced that laboratories could simply remove the problematic reagents from the test kits.[22] **Poor reliability and validity of the CDC test also significantly delayed nationwide testing.**[23]

> In its rush to get a diagnostic test out, the CDC circumvented its own quality assurance protocols.

Typically, the CDC assesses the threat posed by a pathogen, develops a reliable and valid diagnostic, and distributes it to state, local, tribal, and territorial (SLTT) public health laboratories. However, in its rush to get a diagnostic test out, the CDC circumvented its own quality assurance protocols.[24] Public health and commercial labs called the test a "nightmare" to run.[27]

FRACTURED RESOURCES

In April 2020, testing capacity plateaued due to shortages of trained personnel, reagents, swabs, equipment, and personal protective equipment (PPE), and supply chains were in danger of failing again.[25] On July 10, clinical laboratories sent a letter to Vice President Michael R. Pence asking that the White House Coronavirus Task Force address problems with supply chains for diagnostic testing immediately.[26]

Additionally, administrative and logistical barriers prevented the use of thousands of tests.[27] Some hospitals preferred to stick with diagnostic companies with which they usually worked, even if turnaround times were longer and testing more expensive.[27] Testing capacity and capability still varies across the Nation. Some SLTT laboratories struggle to return results promptly (i.e., longer than a week),[28] while others possess more testing capacity than they need.[29]

> To date, the federal government has failed to coordinate and optimize testing across the Nation effectively.

The FDA has authorized a variety of molecular diagnostic tests for COVID-19 for use during this emergency. The FDA provides information about these tests on their website, but those searching for information find the data hard to extricate. Recognizing this problem, experts at In-Q-Tel[30] and Arizona State University[31] developed user-friendly, searchable databases containing information about the tests for which the FDA provided EUA to help hospitals, health officials, employers, and others identify and locate tests and manufacturers that could meet their needs. They would, however, need to know that these databases exist. To date, the federal government has failed to coordinate and optimize testing across the Nation effectively.

LOW PRIORITY

The current COVID-19 testing situation and events leading up to it reflect the low priority the federal government places on research and development of diagnostics. Even with adequate support for research and development, a company can still fail due to the lack of a viable commercial market. The federal government has not played enough of a role in overcoming this market failure. As a result, industry makes diagnostic research and development a low priority as well. While the federal government continues to spend billions on vaccines and therapeutics, it does not make similar investments in diagnostics (see Figure 2 below). Earlier investments in diagnostic research and development could have strengthened the fundamental science and knowledge base of the field and resulted in more rapid development of a diagnostic for COVID-19.

The Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response (ASPR) places great importance on the ability to rapidly respond to biological events. To the ASPR, rapid response entails: (1) using diagnostics to identify pathogens quickly; and (2) once identified, using MCM to treat and limit the spread of disease.[32] However, according to the PHEMCE current five-year budget, BARDA (which is part of the Office of the ASPR) only budgeted for point-of-need diagnostics for influenza.[33] This budget also indicates that funding for biological threat diagnostic research and development will decrease by 2022.

Diagnostics influence sixty to seventy percent of healthcare decisions but account for only five percent of hospital, and less than two percent of Medicare, spending.[34] Pricing imbalances and limited reimbursement inhibit corporate and venture capital investments in the development of new diagnostics.[35] Development companies aim to partner with commercialization entities to help transition their research to market, but the level of risk in getting a product to market often prevents these entities from engaging with diagnostics at all. This transitional stage remains one of the chief weaknesses in diagnostic development.

Annual appropriations drive government contracting for MCM, but research, development, and validation of an innovative diagnostic may take years. **Therefore, investors often shy away from companies whose sole customer is the government, and who receive government funding annually (and often late).** Even with funding, industry researchers find it difficult to obtain the rare clinical specimens they require to develop and validate diagnostics, especially for novel, emerging, and reemerging pathogens.[36]

Federal reimbursement policy also impedes innovative diagnostic development. Budgetary constraints lead to cost controls and reimbursement challenges, particularly when it comes to more innovative and higher-priced diagnostics. For example, despite the high cost to develop point-of-care and point-of-need diagnostics, the Centers for Medicare and Medicaid Services (CMS) cut reimbursement rates to use those tests.[37] They undermined development by reducing return on investment (ROI). What makes tests valuable in an outbreak does not necessarily make them valuable in the regular marketplace. Without commercial value, it is difficult to achieve the level of reimbursement needed to justify development, despite compelling public benefit.

> The failure to rapidly develop and scale a functional test for COVID-19 reflects the federal government's historical and continued neglect of infectious disease diagnostics.

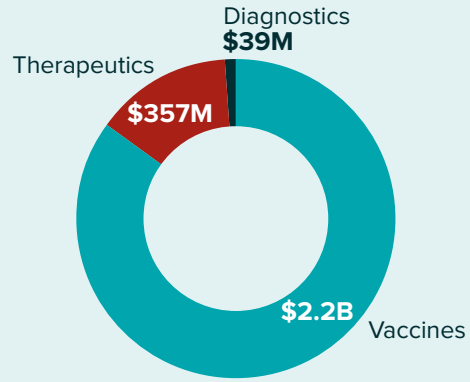
The Clinical Laboratory Improvement Amendments (CLIA) of 1988[38] regulate all U.S. clinical laboratories that test human samples for the diagnosis, treatment, or prevention of disease. These regulations can be waived for certain devices, including those cleared by the FDA for home use. The innovative diagnostics we address in this report would likely fall into this category.

In February 2019, the CDC, CMS, and FDA established a Tri-Agency Task Force for Emergency Diagnostics, but it is unclear what actions were taken by this task force as the pandemic spread in the United States.[39] While it is encouraging that HHS and the Federal Emergency Management Agency set up a joint federal Laboratory Diagnostics

Task Force to address related supply chain issues,[40] **the supply chain is still not fully optimized, and we still lack a comprehensive national plan for testing**. Also, this task force does not consider how to develop and field innovative diagnostic technologies that could aid our current situation. Neither of these task forces have successfully and comprehensively addressed U.S. diagnostic testing needs.

COVID-19 spurred some investment in novel diagnostics,[41] but not to the degree required to keep the Nation safe from biological threats. Despite top U.S. health officials recognizing that existing diagnostic technology cannot cope with COVID-19 and that the Nation requires new, innovative technologies,[42] the federal government continues to more highly prioritize and invest in vaccines and therapeutics (see Figure 2).

Figure 2. BARDA Award Amounts for COVID-19 (as of June 23, 2020)[43]



On a more positive note, the National Institutes of Health (NIH), in partnership with BARDA, CDC, and FDA, launched RADx (a $1.5 billion Shark Tank-like initiative) to accelerate the development of diagnostics as part of the public-private partnership known as Operation Warp Speed.[45] However, that amount only accounts for fifteen percent of the Operation's $10 billion budget.[46]

IMPLEMENTATION

In accordance with Recommendation 30 of the *National Blueprint for Biodefense* to incentivize development of rapid point-of-care and point-of-need diagnostics,[47] the Commission also recommends the following to execute this charge.

DEVELOP A NATIONAL PLAN FOR COVID-19 TESTING

Neither the Tri-Agency Task Force for Emergency Diagnostics nor the Laboratory Diagnostics Task Force adequately addresses national needs for diagnostic testing.

Congress should amend the CARES Act of 2020 (P.L. 116-136) to direct the Secretary of Health and Human Services, in coordination with the Secretary of Defense, to:

- Establish a new task force to develop innovative rapid diagnostic solutions and scale up testing dramatically across the Nation;
- Eliminate supply chain disruptions; and
- Pursue advances in diagnostic technology.[48]

The task force should include federal and non-federal government officials, as well as representatives from commercial, academic, clinical, and public health laboratories.

Congress should require this task force to develop and implement a national plan to:

- Organize and optimize the development and deployment of COVID-19 testing throughout the United States;
- Identify and determine how to overcome the complex logistical and administrative impediments posed by government bureaucracies, commercial self-interest, and inefficient local acquisition mechanisms;
- Overcome these obstacles;
- Identify and determine how to overcome supply shortages that prevent testing;
- Actively seek out alternative diagnostic methods that would require different supplies (so as not to put the same strain on the supply chain currently seen); and
- Evaluate strategies that could alleviate pressure on the supply chain, such as pool testing[49] (which must be complemented by a low positivity rate and robust test and trace capabilities to provide value).

The task force should prioritize rapid point-of-care and point-of-need diagnostics, especially those with low reliance on reagents. Such diagnostics may include those that leverage different methods of sample collection (e.g. saliva tests, simple dipstick immunoassays),[50] high-throughput next-generation sequencing,[51] CRISPR (clustered regularly interspaced short palindromic repeats) tests,[52] and antigen tests.[53] The task force might even consider leveraging canine units capable of COVID-19 detection as a rapid, supplementary method of screening in high traffic areas rather than using ineffective and nonspecific temperature screening.[54]

Congress should also require the task force to:

- Identify lessons learned from the failure to produce a scalable diagnostic test early in the COVID-19 pandemic;
- Determine how to improve development processes and more rapidly produce diagnostics when biological events occur in the future;
- Define the roles of relevant agencies;
- Evaluate the Tri-Agency Task Force for Emergency Diagnostics, the Laboratory Diagnostics Task Force, and any other relevant federal efforts; and
- Propose improvements for effectiveness, sustained collaboration, and rapid response. As illustrated by COVID-19, success depends on engagement of the private sector.

Congress should additionally require the Secretary of Health and Human Services, in coordination with every federal agency involved with diagnostics and informed by the work of the task force above, to develop:

- A national framework for rapidly developing and distributing diagnostics in the event of a public health emergency with a novel pathogen; and
- An implementation plan for this framework.

INCREASE REIMBURSEMENT FOR POINT-OF-CARE AND POINT-OF-NEED TESTS AND INCREASE TESTING FOR DISEASES LIKELY TO PRODUCE WIDESPREAD INFECTION IN SOCIETY

The ability to conduct a rapid test in physicians' offices, hospitals, clinics, and pharmacies could quickly inform clinical decision-making and guide treatment options without having to send samples to an external laboratory for testing. Low reimbursement means less money and low ROI.

CMS increased reimbursement rates for high-throughput COVID-19 tests after acknowledging that low reimbursement contributed to testing shortages early in the U.S. outbreak.[55] **CMS should apply the lessons learned from COVID-19 by increasing reimbursement for accurate, reliable, and rapid point-of-care and point-of-need diagnostics for other infectious diseases as well.** Increased reimbursement means practitioners will be more inclined to use diagnostic tests, resulting in more data that would help the healthcare and public health communities:

- Manage endemic, emerging, and reemerging infectious diseases; and
- Generate more interest in the development of diagnostic tests for biodefense.

Congress should amend the Protecting Access to Medicare Act of 2014 (P.L. 113-93, a law designed in part to alter the way that CMS reimburses diagnostic testing) to direct the Administrator for the Centers for Medicare and Medicaid Services to reconsider reimbursement rates for point-of-care and point-of-need diagnostic tests and increase reimbursement for testing of diseases that could negatively affect national security.

PURCHASE VIABLE DIAGNOSTICS FOR BIOLOGICAL THREATS

Industry will invest its own money to develop vaccines, antibiotics, diagnostics, and other MCM if they think they will achieve a high return on their investment. For many biological agents (i.e., weaponized diseases like anthrax, botulism, brucellosis, plague, smallpox, tularemia) and other diseases that do or could affect national security (e.g., SARS) that MCM industry could develop, the potential ROI is low under normal circumstances, but high if a biological attack occurs or a disease like SARS mutates and creates a pandemic like COVID-19. The only sure customer base for diseases that could be used to attack the Nation or that could produce pandemics that would affect national security is the U.S. government.[56] **The federal government must assure industry that it will purchase viable diagnostics and other MCM for these biological threats.**

All PHEMCE members should include diagnostics research and development in their budgets. Additionally, Congress should provide advance appropriations over multiple years rather than one year at a time. The federal government should demonstrate its commitment to rapid response and prevention by pursuing more capable and innovative diagnostics so that technologies are ready or in development when biological events occur (instead of waiting until they occur before beginning research and development). This means supporting pathogen-agnostic platforms (i.e., those that can test for many pathogens, not just one),[57] exploring technologies for rapid identification of previously unknown pathogens, and prioritizing rapid point-of-care and point-of-need tests. Such technology could apply to all pathogens without knowing what diseases we will face next. These tests could be used just as easily for biological weapons agents as for novel and common diseases, thereby reducing the risk associated with investing in their development. The federal government should invest in such technologies as part of a larger strategy that prioritizes development and regulatory approval of innovative diagnostics that could come to maturity in the nearer term.

The federal government should invest in such technologies as part of a larger strategy that prioritizes development and regulatory approval of innovative diagnostics that could come to maturity in the nearer term.

ARTICULATE ACQUISITION REQUIREMENTS FOR DIAGNOSTIC TESTS

The Director of the Biomedical Advanced Research and Development Authority should identify requirements for federal acquisition of diagnostic tests and clearly articulate these requirements to industry and academia. BARDA should also harmonize these requirements with those of other agencies such as the Department of Defense (DOD). Requirements shared by BARDA and DOD could result in purchasing agreements that attract more private sector interest and involvement in needed diagnostic research and development.

LEVERAGE DEFENSE RESEARCH AND EXPERTISE

Enhanced collaboration across military and civilian agencies supported the development of innovative diagnostics for COVID-19. For example, DOD, HHS, and industry collaborated to develop one of the first FDA diagnostic tests for COVID-19 authorized for emergency use in March 2020.[58]

There are also many innovative diagnostic technologies under development with support from the military that could have civilian applications. For instance, the FDA recently issued an EUA for an innovative point-of-care diagnostic based on CRISPR technology developed with support from DARPA.[59]

DARPA also supports the development of a point-of-care device that could analyze an individual's epigenetic fingerprint to reveal a detailed history of their exposure to a variety of pathogens, chemicals, and weapons of mass destruction.[60] DARPA believes the same technology could serve as a rapid diagnostic for COVID-19 and an EUA for that purpose is pending with the FDA.[61]

The Director of the Defense Advanced Research Projects Agency should consider how DARPA diagnostic research could be harnessed for civilian application to deal with pandemics and other large-scale biological events that affect national security. In the past, DARPA and BARDA have coordinated on detection technologies through BARDA's Division of Research, Innovation, and Ventures (DRIVe).[62] DRIVe's mission is to accelerate the development and availability of transformative technologies to protect against public health security threats,[63] but it lacks a robust budget to help achieve this mission. DRIVe needs to operate more like DARPA to improve their ability to accelerate innovative technologies.

Congress should amend the Project BioShield Act of 2004 (P.L. 108-276, a law which directed coordination between HHS, DHS, and DOD) to direct the Director of the Biomedical Advanced Research and Development Agency to coordinate with the Director of the Defense Advanced Research Projects Agency and other federal advanced research projects agencies to identify diagnostic technologies that are progressing to advanced stages and validate them for civilian use.

CONCLUSION

PUBLIC EXPECTATIONS

The public believes that diagnostic tests for all diseases either already exist or could be produced quickly by the scientific community. They do not pay attention to monetary amounts for this purpose included in the President's Budget Request or congressional appropriations. Instead, an American culture steeped in science and technology shapes public beliefs.

The Administration and Congress provided more funds for research and development after COVID-19 spread to the United States, but science takes time. Had the government continued support for research and development of a vaccine[64] and diagnostic tests for SARS-CoV-1,[65] we would have been in far better stead when SARS-CoV-2 appeared.

The next pandemic could occur as early as next year and before COVID-19 recedes. Our country must invest in the research and development base needed to develop diagnostic tests for COVID-19 and other diseases now. By addressing the Commission's 2015 recommendation to incentivize development of rapid point-of-care diagnostics,[66] by developing a national plan for testing, increasing reimbursement for point-of-care and point-of-need tests, purchasing viable diagnostics for diseases that threaten national security, articulating acquisition requirements, and leveraging defense research and expertise, **we can seize upon the opportunity provided by COVID-19 to ensure that our Nation possesses or can develop the diagnostic tests it needs when it needs them**.

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[3] This chart shows how the daily number of confirmed cases (horizontal axis) and the daily number of tests (vertical axis) has changed over their respective outbreaks. When a country moves in a flat line to the right, daily confirmed cases are increasing while testing stays the same.When a country moves up vertically, testing is increasing while daily cases stay the same. When a country bends to the left, daily confirmed cases are decreasing, and the country has passed its peak. Hasell, J. (2020). Testing early, testing late: four countries' approaches to COVID-19 testing compared — Our World in Data – tests vs confirmed cases – up to 7th May. Retrieved July 30, 2020, from Our World in Data website: https://ourworldindata.org/covid-testing-us-uk-korea-italy.

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