

# BRIEFER

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## Key U.S. Initiatives for Addressing Biological Threats Part 1: Bolstering the Chemical and Biological Defense Program

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### INTRODUCTION

In 2006, the U.S. Department of Defense (DoD) launched a program to explore new approaches to combating bioterrorism and biological weapons programs.<sup>1</sup> The vision was a versatile process that can be used to drastically reduce the time from spotting a new threat to the manufacture and distribution at scale of therapeutics, vaccines, diagnostics tests and other medical countermeasures. As has been seen during the COVID-19 pandemic, when dealing with a deadly pathogen, speed matters and can save millions of lives. Today, more and more Americans, starting with the most vulnerable, are receiving mRNA vaccines, the development of which the DoD funded through the Defense Advanced Research Projects Agency (DARPA).<sup>2</sup>

In addition to DARPA, DoD houses the Chemical and Biological Defense Program (CBDP) - the center of gravity for biodefense and the department's largest source of funding for research on the subject. CBDP was the home of one of the first initiatives to drastically speed up development of medical countermeasures against new biological threats. The program was called the Transformational Medical

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<sup>1</sup> U.S. Department of Defense, Office of the Undersecretary of Defense (Acquisition, Technology and Logistics), [Transformational Medical Technologies Initiative \(TMTI\) Fiscal Year 2007 \(FY 2007\) Congressional Report](#) (2007), 3-4.

<sup>2</sup> U.S. Department of Defense, Defense Advanced Research Projects Agency, [Adept: Protect](#). Accessed March 11, 2021

Technologies Initiative, and early successes include creation of a therapeutic against the 2009 swine flu.<sup>3</sup> This rapid-response approach, which the CBDP continues to champion, is critical for addressing biological threats before they impact U.S. national security.

The Council on Strategic Risks, in addition to scientists, policymakers, and other organizations, have been calling for a large-scale government effort to meet biological threats and be able to detect and respond faster to the next outbreak.<sup>4</sup> The CBDP should play a central role, including via support for versatile technologies that are essential for addressing biological weapons threats, and helpful in both dealing with lab accidents and fighting emerging infectious diseases such as COVID-19. This will take reversing the erosion of the CBDP's budget that has occurred over the last decade, including during the COVID-19 pandemic.

This briefer describes how CBDP's activities form a significant national asset: funding advances against biological threats, driving their development, taking them through testing and evaluation to avoid promising investments hitting the proverbial valley of death, and working with allies and partners to deploy and improve new technologies. It then describes disturbing downward trends in this program's resources against biological threats, including cuts made during a historic pandemic, and other issues. It concludes with near-term recommendations for Pentagon leaders, Congressional members, and other stakeholders.

The process of maximizing CBDP's contributions to countering biological threats should begin by roughly doubling CBDP's funding to at least \$2 billion in the next year, to be increased to the \$6.5 billion to \$7 billion annual budget range in the following years. These investments should be part of a whole-of-government surge to never again allow the nation to experience the mass effects the COVID-19 pandemic has wrought. Among others, key investment areas should include nucleic-acid based therapeutics, a new approach that relies on gene encoding like the highest efficacy COVID-19 vaccines, and field-and-clinic-deployable early-detection technology that can identify any pathogen by reading its genetic material. To put these investments to best use, the program's leaders should expand international cooperation, launch annual drills to test and evaluate rapid-response capabilities, ensure that intelligence on these threats reaches high-level defense decision makers, and more. These investments and capabilities are not a special interest for the military alone, but one that may be critical to the entire U.S. public's resilience to biological threats.

This briefer is the first in a CSR series highlighting trends in specific offices and programs in the U.S. federal government whose missions include countering biological threats. Across these programs, the U.S. government should aim to invest \$10 billion annually in DoD to address infectious disease threats, plus \$10 billion annually in the Department of Health and Human Services, sustained over 10 years.<sup>5</sup> The CBDP should be a central component. It is the first program highlighted in this series given the critical capabilities it brings to DoD and the nation---and because its contributions have been particularly under-supported for years in a trend that is in urgent need of reversal.

## **CRITICAL WORK YET DECLINING RESOURCES**

The CBDP's critical role can be seen in the history of efforts to combat Ebola. The U.S. government views Ebola as a potential biological weapon threat---and it is an endemic disease in places where U.S.

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<sup>3</sup> David E. Hoffman, "[Going Viral](#)," *The New Yorker*, January 23, 2011.

<sup>4</sup> Anup Singh, Christine Parthemore, and Andrew Weber, "[Making biological weapons Obsolete: A Summary of Workshop Discussions](#)," Council on Strategic Risks and Sandia National Laboratories, August 27, 2019.

<sup>5</sup> Yong-Bee Lim and Andy Weber, "10 + 10 Over 10: How a Clear Vision for Funding Helps the U.S. Address the Rising Tide of Biological Threats," *Council on Strategic Risks*.

defense personnel, including special forces, may operate. In late 2013 in Guinea, West Africa, the largest recorded Ebola outbreak in history began, killing 11,000 through 2016.<sup>6</sup> In January 2021, in the midst of the COVID-19 pandemic, an Ebola outbreak was declared in Guinea again.<sup>7</sup> According to Dr. Ibrahima Socé Fall, the Assistant Director-General of the World Health Organization (WHO), a “ring method” around confirmed cases of Ebola in Guinea was being applied to stop the spread: within a certain geographic space, all those with possible exposure to Ebola are vaccinated.<sup>8</sup>

Ebola was long neglected by the private sector, and given its force health and weaponization concerns, DoD was one of the only entities that filled that gap by funding early-stage research and development on vaccines and treatments. The CBDP was pivotal in vaccine development, and this case is illustrative in understanding the various responsibilities the program has. When it was clear that the 2014 outbreak was getting out of hand, work that had already been done by CBDP and other civilian and defense agencies positioned a vaccine candidate to be accelerated with the hope of being authorized for use to save lives. However, once that specific outbreak abated, attention dropped again. CBDP and other DoD programs played key roles in ensuring that work on the vaccine continued, preventing significant resources from being left by the wayside. Along this journey, CBDP’s contributions included accelerated vaccine development, including in research and development and clinical trials; as well as testing and evaluation, creating treatment infrastructure, developing an FDA-approved Ebola virus diagnostic, and deploying therapeutic drugs.<sup>9</sup>

## **CBDP’S HISTORY AND WORK, IN BRIEF**

The program is an umbrella organization under the Office of the Secretary of Defense and is responsible for various defense-wide chemical and biological defense activities. It was created through Congressional action in November 1993 after failures during the First Gulf War. Chemical and biological defense activity had previously been the responsibility of the Department of the Army. According to a government report, if Iraq had used the biological warfare agents that were available to it, such as anthrax and botulinum toxin, there could have been enormous fatalities and the Army’s medical treatment system would have been overtaxed.<sup>10</sup> At that time, limited anthrax vaccinations were available, and the sole source of an essential ingredient for botulinum antitoxin was an elderly horse named First Flight.<sup>11</sup> The creation of the CBDP was meant to ensure that the biological defense mission received the attention and funding that it deserved.

Traditionally, the program’s primary responsibility is viewed as protecting military personnel from deliberate biological threats. While the focus is on weaponized pathogens, this overlaps with natural disease threats in many cases (such as with Ebola). Additionally, one of many challenges of biological weapons is that they may appear to be of natural origin.

Likewise, solutions to biological threats largely overlap no matter their origin. In that regard, the skills and capabilities resident in the CBDP lend themselves to countering all biological threats. Further, as the

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<sup>6</sup> World Health Organization Ebola Response Team, “After Ebola in West Africa - Unpredictable Risks, Preventable Epidemics,” *The New England Journal of Medicine* 375, 2016: 587 - 596.

<sup>7</sup> World Health Organization, “[Ebola virus disease – Guinea - WHO](#),” Accessed March 11, 2021.

<sup>8</sup> United Nations, “[1,600 Vaccinated in Guinea Ebola Virus Outbreak but More Jabs Needed](#),” *World Health Organization*, March 5, 2021, Accessed March 11, 2021.

<sup>9</sup> Crystal Boddie, “[Federal Funding in Support of Ebola Medical Countermeasures R&D](#),” *Health Security*, Feb 1, 2015, 13(1): 3–8; doi: 10.1089/hs.2015.0001.

<sup>10</sup> U.S. Congress, U.S. Government Accountability Office, *[Chemical and Biological Defense: U.S. Forces Are Not Adequately Equipped to Detect All Threats](#)* (Washington, DC: 1993).

<sup>11</sup> Carolyn H. Crowley, “[Race for a Remedy](#),” *The Smithsonian*, December, 2000, Accessed March 11, 2021.

COVID-19 pandemic shows, all such threats are of significant strategic concern and can threaten defense personnel directly.

As a broad enterprise, the CBDP unites several DoD organizations that conduct research, development, testing and procurement of technologies against biological threats. The Joint Science and Technology Office at the Defense Threat Reduction Agency is generally responsible for early-stage research and development. For the Ebola vaccine, it contracted with a small biotech company to speed up development and aid in early-stage testing. After the vaccine transitioned to later-stage development, another part of the program, the Joint Program Executive Office for Chemical, Biological and Radiological Defense, which also is responsible for procurement, helped conduct late-stage clinical trials.<sup>12</sup> Much of this work is conducted in close collaboration with U.S. government agencies such as the U.S. Department of Health and Human Services, as well as with nongovernmental partners.<sup>13</sup>

Such collaborative relationships extend to critical international partnerships. In the Ebola case, CBDP personnel worked closely with the Public Health Agency of Canada and the WHO. These relationships directly bolster U.S. and global defenses against biological threats, as well as chemical and other weapons of mass destruction (WMD). For instance, the security and potential use of the Syrian chemical weapons stockpile became a significant concern after civil war ensued in 2011. This issue rose after the Syrian government's use of sarin (a nerve agent) and later chlorine attacks against its own citizens. Early in this time period, the United States was in short supply of delivery mechanisms for treatments that are required quickly to prevent death from sarin.<sup>14</sup> Via its longstanding relationships, the CBDP identified an Israeli company to fill this need and guided them through the process for an FDA Emergency Use Authorization to ensure the availability of antidotes and auto-injectors for U.S. military personnel and others.<sup>15</sup>

To facilitate this kind of work on urgent needs as well as longer-term solutions, the CBDP maintains a broad network including close allies such as the United Kingdom, Canada, and Australia.<sup>16</sup> It also has worked closely with the Republic of Korea (ROK) on biological defense, a concern in the region because of suspected biological weapons activity in North Korea.<sup>17</sup> Biological defense activities were featured in a series of multi-year, ROK-U.S. exercises called Able Response. Based on scenarios of naturally-occurring outbreaks, over the course of several years these exercises helped both countries identify gaps and needs, test new technologies for disease detection and responses, improve cross-agency coordination, and more.<sup>18</sup> With these capability improvements, it is not surprising that the ROK was among the world's leading countries in early detection and response to COVID-19 when it emerged.

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<sup>12</sup> U.S. Department of Defense, Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND), "[JPEO-CBRND Supports International Partners in Congo Ebola Outbreak](#)," by Hannah Feldman and Rachel Overman, January 16, 2019. Accessed March 11, 2021.

<sup>13</sup> U.S. Department of Defense, Military Health System, "[DTRA Contributes to Historic Ebola Vaccine Effort](#)," by Darnell Gardner, January 17, 2020. Accessed: March 11, 2021

<sup>14</sup> Alicia Mundy, "[Sarin Antidote Is Hit With Supply Problems in U.S.](#)," *Wall Street Journal*, September 13, 2013.

<sup>15</sup> U.S. Department of Defense, JPEO-CBRND, "[MCS Instrumental in EUA Approval of Nerve Agent Autoinjector](#)," by Steven Lusher, November 13, 2017, Accessed March 11, 2021.

<sup>16</sup> D. Christian Hassell, "[Leveraging Partnerships to Enhance RDT&E Capabilities within the DoD Chemical and Biological Defense Program](#)" (Presentation, National Academies of Sciences, Engineering and Medicine in *Federal Facilities Workshop*, 2017).

<sup>17</sup> Tak S, Jareb A, Choi S, Sikes M, Choi YH, Boo HW, "Enhancing 'Whole-of-Government' Response to Biological Events in Korea: Able Response 2014," *Osong Public Health and Research Perspectives* 9, no. 1 (2018): 32-35.

<sup>18</sup> Tak, Sangwoo et al. "[Enhancing 'Whole-of-Government' Response to Biological Events in Korea: Able Response 2014](#)," *Osong public health and research perspectives* vol. 9,1 (2018), 32-35; and professional experiences of two of this briefer's authors.

These exercises and relationships have incredible value by directly informing research, development, and acquisition plans to help keep DoD ahead of biological threats and investing in the most effective and efficient technologies and tools for countering them. Moreover, international cooperation is especially important as biological threats are global in nature and difficult to fight alone.<sup>19</sup>

### Examples of CDBP capabilities

**Advanced Development and Manufacturing Facility:** In order to meet the unique needs of the Department of Defense to produce biologics for therapeutics and vaccines, DoD established a public-private partnership “Advanced Development and Manufacturing” facility in Alachua, Florida. It is currently operated by Ology Bioservices, Inc, a biologics contract development and manufacturing organization that specializes in making vaccines, antibodies, viral products and more to be used for the protection of military and civilian populations against infectious diseases. It has played a vital role in producing COVID therapeutics and vaccines.

**Testing and Evaluation:** The CDBP handles some of the most dangerous pathogens for testing and evaluation of early detection technologies and therapeutics. The Dugway Proving Ground is a military testing ground for the purposes of chemical and biological agent defense and is focused on methods of detection and neutralization. In 2015, the largest test chamber in the world, the Whole System Live Agent Test Chamber, was completed at Dugway and is being used to test technologies for detecting weaponized biological agents.<sup>20</sup> The Dugway Proving Ground handles biological agents categorized as BSL-3, which are dangerous but generally have existing treatments. The US Army Medical Research Institute for Infectious Diseases at Fort Detrick, Maryland, operates a BSL-4 lab and allows for testing of treatments of diseases for which no known treatments are available. The institute often conducts testing and evaluation using an FDA process to conduct tests on animals, which is required when testing on a human would be unethical or unfeasible. The institute and others like it in the DoD house the facilities and expertise that allow these tests on the most dangerous pathogens to be conducted. In addition, CDBP is currently investing in organ-on-a-chip technology, which has the potential of allowing for rapid tests of medical countermeasures without animal or human subjects, drastically speeding up the regulatory approval process and reducing accident risk.<sup>21</sup>

## EVOLVING WITH AND DRIVING TECHNOLOGICAL CHANGE

Throughout its history, the CDBP has worked to counter specific, identified biological threats (e.g., Ebola) that the government classifies as having the potential to be weaponized. However, within the program, there is an ongoing shift toward a more flexible approach, which should be a key feature for its future.

In 2004, there was an accident at one of the premier research laboratories of the CDBP. A researcher working at the U.S. Army Medical Research Institute for Infectious Diseases accidentally pricked themselves with a needle being used to inject mice with the Ebola Virus. The researcher was placed in the

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<sup>19</sup> The White House, “[Interim National Security Strategic Guidance](#),” March 3, 2021, Accessed March 16, 2021.

<sup>20</sup> Volpicelli, Gian. “[Inside the Open-Air Lab Testing Viruses and Deadly Chemicals](#).” *WIRED UK*, August 29, 2020.

<sup>21</sup> U.S. Department of Defense, Under Secretary of Defense (Comptroller), “[DoD Joint Service Chemical & Biological Defense Program Fiscal Year 2021 Program and Budget Review Submission](#),” (Washington, DC, 2020)

slammer, a medical isolation unit at Fort Detrick.<sup>22</sup> A scientist named Patrick Iversen, who would later work closely with the CBDP, was called.<sup>23</sup> That day he had made a presentation on rapid creation of therapeutics based on a pathogen’s genetic material. The FDA gave emergency approval of a synthesized drug created by Iversen in two days. Although the researcher was not in the end infected, the turnaround impressed the military, and some of Iversen’s research was funded as part of the Transformational Medical Technologies Program mentioned above, an early effort to rapidly create medical countermeasures against biological weapons. The Transformational Medical Technologies Program and larger CBDP efforts that followed have had success in shifting the DoD towards a faster, more flexible, and more cost-effective response to countering biological threats. For instance, after aiding in the response to the lab accident described above, this rapid-response approach was used to create a therapeutic during the Swine Flu pandemic of 2009.<sup>24</sup>

Based on a preliminary analysis of CBDP budgets over the last four years, funding for these types of technologies - colloquially referred to as rapid response platforms - appears to be consistently on the rise.<sup>25</sup> Today, examples of ongoing programs include novel vaccine development approaches and continued funding for an advanced facility that is currently being used to manufacture a nucleic-acid-based vaccine against COVID-19. The facility has also been configured to manufacture treatments against botulinum toxin, an upgrade over the DoD’s sole source of botulinum antitoxin prior to the Gulf War - a horse named First Flight.<sup>26</sup> In addition, the program is investing in hypothesis-free detection methods that are necessary against novel biological threats of all types, such as a sequence-based diagnostic test.<sup>27</sup>

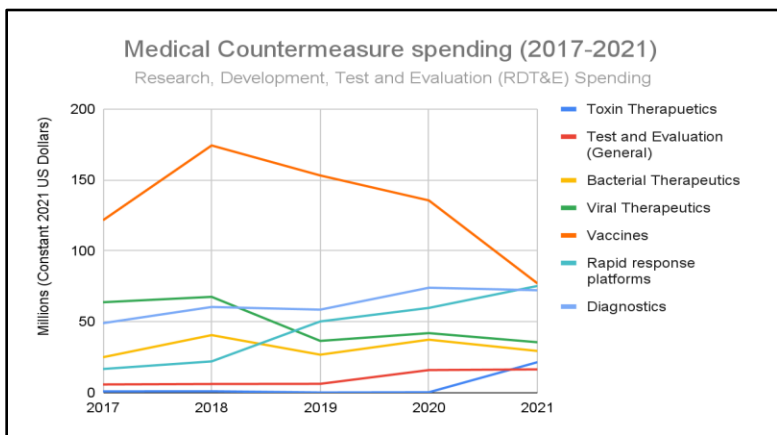


Figure 1: Comparison of RDT&E spending on medical countermeasures at CBDP, 2017-2021<sup>28</sup>

<sup>22</sup> Scott Shane, “[Researcher in Isolation Appears Healthy Despite Possible Ebola Exposure](#),” *The Baltimore Sun*, February 21, 2004.

<sup>23</sup> Thomas H. Maugh II, “[Drugs Block Ebola, Marburg Viruses in Tests](#),” *Los Angeles Times*, August 23, 2010.

<sup>24</sup> Julie Rathbun, “[AVI BioPharma, Inc. Under Contract With U.S. Defense Threat Reduction Agency for Development of Therapeutics Targeting H1N1 Swine Flu](#),” *BioSpace*, June 22, 2009.

<sup>25</sup> U.S. Department of Defense, Under Secretary of Defense (Comptroller), “[DoD Joint Service Chemical & Biological Defense Program Fiscal Year 2017-2021 Program and Budget Review Submission](#)” (Washington, DC, 2016-2020). The data collected is based on a review of DoD budget documents at the source above, in particular the research, development, test and evaluation submissions for the CBDP from 2017-2021.

<sup>26</sup> U.S. Department of Defense, JPEO-CBRND, “[Toxic at Best](#)”, by Hannah Feldman and Dr. Chris Earnhart, and Dr. Traci Pals (2019).

<sup>27</sup> U.S. Department of Defense, Under Secretary of Defense (Comptroller), “[DoD Joint Service Chemical & Biological Defense Program Fiscal Year 2021 Program and Budget Review Submission](#)” (Washington, DC, 2020).

<sup>28</sup> U.S. Department of Defense, Under Secretary of Defense (Comptroller), “[DoD Joint Service Chemical & Biological Defense Program Fiscal Year 2017-2021 Program and Budget Review Submission](#)” (Washington, DC,

The creation of the CBDP was meant to ensure that the organization’s important mission was accomplished. Indeed, its accomplishments have been incredibly important to the safety of defense forces and to global health security, including in the examples cited above. However, similar to the state of U.S. biological defense during the Gulf War, CBDP’s funding has diminished in recent years. These trends, described next, must be reversed.

## BUDGET TRENDS & ISSUES

Biological threats are rising. Unfortunately, many aspects of CBDP’s budgets are trending in the opposite direction. During the most consequential biological event of our lifetimes, the COVID-19 pandemic, the CBDP’s budget was reduced. Over the last decade, the CBDP’s budget (in constant 2021 U.S. dollars) has trended consistently downwards.

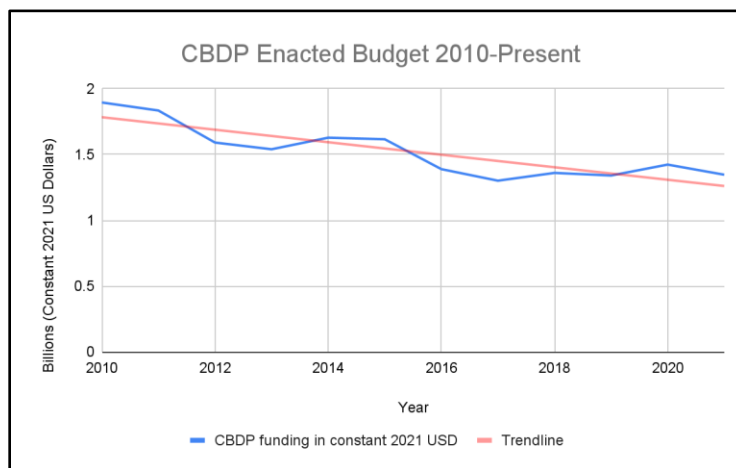


Figure 2: CBDP spending from Fiscal Year 2010-2021<sup>29</sup>

As can be seen in Figure 3 on the following page, since the 2005-2010 average, the budget has been reduced by almost one third.

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2016-2020). The data collected is based on a review of DoD budget documents at the source above, in particular the research, development, test and evaluation submissions for the CBDP from 2017-2021.

<sup>29</sup> U.S. Department of Defense, Under Secretary of Defense (Comptroller), “[DoD Joint Service Chemical & Biological Defense Program Fiscal Year 2010-2021 Program and Budget Review Submission](#)” (Washington, DC, 2020). The chart is based on the authors’ review of approximately 20 DoD budget documents at the source above, including both procurement and research, development, test and evaluation submissions for the CBDP for all years; U.S. Congress, Senate, Committee on Appropriations, “[Congress Reaches Deal, Files FY21 Omnibus to Fund Govt. Provide COVID Relief, Joint Explanatory Statement C](#)”, 116 Cong., 2nd sess., 2020. To ensure the enacted budget was included for 2021, the Congressional appropriations explanatory document was referenced.

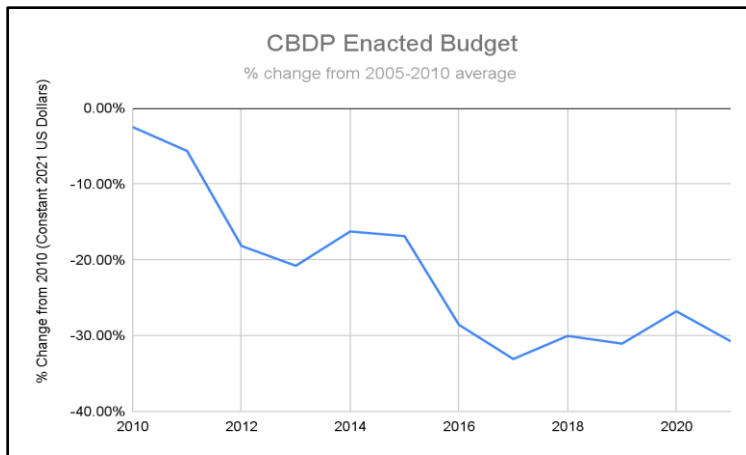


Figure 3: CBDP annual budgets 2010-2021, compared to the program's 2005-2010 average annual spending<sup>30</sup>

These budgets cover work to counter both biological and chemical threats, but reductions are coming mostly at the expense of countering biological threats. Biological defense spending has been on a consistent downswing since 2014, while chemical defense spending has been trending upwards. This is a significant problem, and in 2020 it caught the attention of Senators Mitt Romney and Mike Lee, who introduced an amendment requiring DoD to report on how cuts to the CBDP will have an effect on national security.<sup>31</sup>

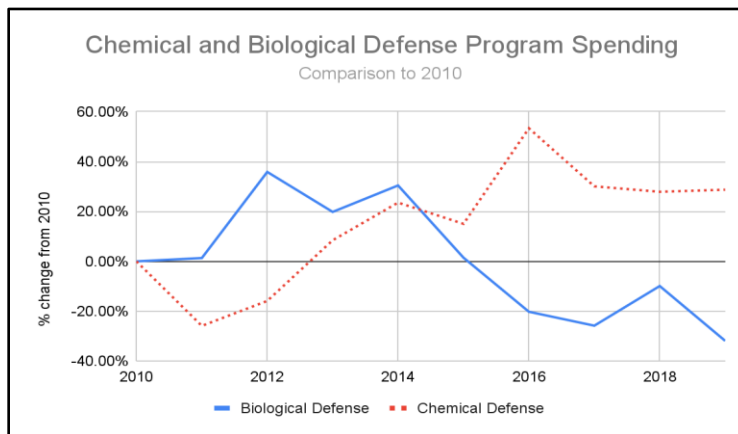


Figure 3: Percentage change from 2010 CBDP spending in biological and chemical defense spending.<sup>32</sup>

As has been observed in the Syrian government’s use of chemical weapons and Russia’s application of the family of nerve agents called Novichok for assassinations, chemical weapons remain a real threat.

<sup>30</sup> U.S. Department of Defense, Under Secretary of Defense (Comptroller), “[DoD Joint Service Chemical & Biological Defense Program Fiscal Year 2017-2021 Program and Budget Review Submission](#).” The data is based on the authors’ review of approximately 30 DoD budget documents at the source above, in particular the procurement and research, Development, test and evaluation submissions for the CBDP from 2005-2021.

<sup>31</sup> The Office of U.S. Senator for Utah Mike Lee, “[Senate Passes NDAA With Lee-Backed Amendments](#),” July 23, 2020. Accessed March 16, 2021.

<sup>32</sup>Crystal Watson, Matthew Watson, Daniel Gastfriend, and Tara Kirk Sell, “Federal Funding for Health Security in FY2019,” *Health Security* 16, no. 5 (2018): 281 - 303. In particular, the source data provided along with the article were drawn upon. 2019 is the last year for which comprehensive data from this source is available.



However, biological weapons are also a serious threat that many experts believe will become more attractive to develop in the wake of the COVID-19 crisis. There are a range of scenarios in which biological weapons may be used and for which U.S. forces need to be prepared. Anthrax, for example, could be used in a targeted manner against specific populations or forces, a large-scale attack, and everything in between. Anti-access/area denial (A2/AD) may be among the intended purposes. The DoD is starting to realize the danger, as seen in its conduct of an exercise in fall 2020 in which the scenario began with a Chinese biological weapon attack on U.S. bases and warships in the Indo-Pacific region.<sup>33</sup>

There are reasons that countries would favor a biological weapon like anthrax, including the incredible effects that can be achieved with small quantities. The Office of Technology Assessment of the U.S. Congress estimated that 100kg of anthrax released over Washington, DC could lead to 130,000 to 3 million deaths, similar in lethality to a hydrogen bomb.<sup>34</sup> Beyond operational applications, biological weapons have been viewed as strategic-level weapons. The Soviet Union weaponized smallpox and conducted tests to prepare to use it against U.S. cities and civilian populations in the event of all-out nuclear war.<sup>35</sup> Countries such as North Korea may also see utility in the deniability that biological weapons can bring.

Despite these threats and many more, biodefense investment is trending downwards in high-priority areas. For the FY21 president's budget request in 2020, significant cuts to vaccine-related activities were originally proposed.<sup>36</sup> These reductions were partially restored in a last-minute legislative maneuver in Congress in December 2020.<sup>37</sup> However, there are concerns that similar cuts will be proposed again for the FY22 defense budget. The effects of cuts in vaccine investments in and of themselves might be mitigated if the funding was then transferred to rapid response platforms. However, instead, the trend is that funds are shifted out of the CBDP.

In addition, tools used to inform the DoD about biological threats and aid in decision-making are being cut. Most of these reductions are coming from the data and software backbone of capabilities to collect and share biothreat information.<sup>38</sup> The importance of situational awareness for biological threats has become clear during the pandemic. The early 2020 SARS-CoV-2 infections among the crew of the *USS Theodore Roosevelt* aircraft carrier stemmed from the ship entering port in Vietnam during the pandemic--shore leave for the crew that included a 400-person reception---out of a belief that the country was low risk.<sup>39</sup>

The CBDP has significant capabilities that can be used for pandemic detection and response. Yet during the COVID-19 pandemic, which clearly requires an all-hands approach, CBDP's funding was reduced.

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<sup>33</sup> James Kitfield, "[We're Going to Lose Fast': U.S. Air Force Held a War Game that Started with a Chinese Biological Attack](#)," *Yahoo News*, March 10, 2021. Accessed March 15, 2021.

<sup>34</sup> Office of Technology Assessment, *Proliferation of Weapons of Mass Destruction: Assessing the Risks* (Washington DC: U.S. Government Printing Office, August 1993), 54.

<sup>35</sup> David McGlinchey, "[Soviet Union Once Deployed Smallpox-Tipped ICBMs](#)," *Nuclear Threat Initiative*, October 22, 2003.

<sup>36</sup> U.S. Department of Defense, Under Secretary of Defense (Comptroller), "[Department of Defense Fiscal Year \(FY\) 2021 Budget Estimates - Chemical and Biological Defense Program, Defense-Wide Justification Book Volume 4 of 5](#)," (Washington, DC, 2020).

<sup>37</sup> U.S. Congress, Senate, Committee on Appropriations, "[Congress Reaches Deal, Files FY21 Omnibus to Fund Govt, Provide COVID Relief, Joint Explanatory Statement C](#)," 116 Cong., 2nd sess., 2020.

<sup>38</sup> U.S. Department of Defense, Under Secretary of Defense (Comptroller), "[Department of Defense Fiscal Year \(FY\) 2021 Budget Estimates - Chemical and Biological Defense Program, Defense-Wide Justification Book Volume 4 of 5](#)," (Washington, DC, 2020); U.S. Congress, Senate, Committee on Appropriations, "[Congress Reaches Deal, Files FY21 Omnibus to Fund Govt, Provide COVID Relief, Joint Explanatory Statement C](#)." December 21, 2020.

<sup>39</sup> "[Timeline: Theodore Roosevelt COVID-19 Outbreak Investigation](#)," *U.S. Naval Institute News*, June 23, 2020.

There were opportunities for the CBDP to receive funding through emergency spending bills in response to the pandemic, but DoD was hesitant to request further funding because of confusing guidance from the Secretary of Defense and uncertainty within the DoD around the use of CBDP resources against a naturally arising pandemic. Secretary of Defense Mark Esper's *Defense Wide Review* in late 2019 slashed the CBDP top line nearly 10 percent and the medical biodefense component one third. This worsened an already-long cycle of neglect against biological threats, including a halt in the above-mentioned biological threat exercises with the ROK.

Weaknesses in the U.S. response to COVID-19 may also perversely incentivize nations that may be interested in biological weapons to hedge more toward latent capabilities to create them, or worse. The effects of infectious disease threats on the American people, economy, and national security organizations are clear. Restoring and augmenting the CBDP's budget is one of many critical steps to strengthen U.S. defenses against these threats---and with the same work, signal to potential adversaries that any future use of pathogens as weapons will be ineffective at causing mass destruction.

In one of the most worrisome issues of the U.S. COVID-19 pandemic response, CBDP's potential contributions were limited and at times altogether disallowed. This stems from disagreements within the DoD on whether the CBDP should be involved in responding to natural infectious disease outbreaks given that its mission has been to counter biological weapons.<sup>40</sup> This instruction is especially unhelpful given that a deliberate biological attack may appear to be a naturally-occurring outbreak. The lack of clarity around this question has real consequences. As we have seen, the CBDP has played critical roles in the response to the Swine Flu pandemic of 2009 and the Ebola outbreak that began in 2013. CBDP could have contributed similarly in the COVID-19 response. Instead, U.S. government assets developed over years to counter biological threats were left unused as Americans died.

## RECOMMENDATIONS

The CBDP's mission is difficult: to research, develop, and deploy assets, equipment, and technologies against biological threats that could impact force performance in specific regions and across the globe. This mission is becoming tougher with time as the threat space grows larger on all three dimensions: natural, accidental, and deliberate.

The DoD biodefense community, CBDP and DARPA in particular, have shown an ability to make game-changing contributions to the U.S. efforts against biological threats despite relatively modest budgets. This work, especially when focused on versatile technologies maximally useful against engineered biological weapons but also helpful against novel emerging infectious diseases and other biological threats, has significant potential.

CBDP investment now in technologies against biological threats can allow us to get ahead of these threats and create strong defenses. Increasing the CBDP medical biological defense budget will also augment its ability to leverage national assets that have been built over decades of investment. Put simply, this work is crucial to U.S. national security and the health security of every American. As such, we recommend the following steps.

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<sup>40</sup> "[CBD Mission](#)," Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs, U.S. Department of Defense, accessed March 25, 2021.

**The President's next budget request should roughly double CBDP funding to at least \$2 billion and be increased to the \$6.5 billion to \$7 billion annual budget range in the following years. Congress should support this request---or help push toward this goal if the President's next budget request is insufficient.**

This resource level, which should be held consistent and be adjusted for inflation over time, is a minimum requirement to show that the nation is serious about addressing biological threats and is robustly increasing its capabilities in this area. This investment should of course be coupled with substantial, complementary increases in budgets for HHS, the Departments of Energy and State, and other components of the U.S. ecosystem for defending against biological threats. These resources will also encourage innovation in the U.S. economy.

Most of this increase should focus on biological threats, including restoring significant funding to CBDP's unique capabilities regarding medical countermeasure development and international partnership activities. There is some overlap between capabilities for countering biological and chemical threats, but it is clear that a substantial topline budget increase is required to meet national security needs against biological threats without cutting into equally-important work against chemical weapons threats.

These additional resources are also required in order for DoD to take full advantage of the fact that the world is on the cusp of bringing game-changing technologies to the fight against biological threats. Breakthroughs in the biological sciences, combined with those in robotics, machine learning and AI, advanced manufacturing capabilities, and others have positioned the United States and its partners around the world to drive a new era in more rapidly and effectively countering infectious disease threats. The United States should absolutely seek to be the world leader in bringing these advances fully to market, and in using them to meet national security needs. The CBDP is already ideally positioned to play a central role in this.

One function of these resources should be to meet a goal of advancing new medical countermeasures to FDA approval and licensure. The CBDP has already invested significantly in research and development for many countermeasures that may be needed against disease threats to U.S. forces (and which may have substantial benefit for public health as well). For all promising medical countermeasures, DoD should be capitalizing on these past investments.

With its unique range of research and development work, as well as significant testing and evaluation capacities, the CBDP should develop a plan and seek resources to execute an annual program to exercise its capabilities for rapidly developing new diagnostics, medical countermeasures, and more. This can be done in coordination with other government agencies, and eventually also with international partners. The COVID-19 pandemic has shown that fast development and fielding of diagnostic tests, vaccines, and therapeutics can make the difference in being able to contain an infectious disease outbreak. If a biological threat, possibly an engineered one, is deliberately introduced, the effects on the public and U.S. forces may be far beyond the effects of the current pandemic. Showcasing rapid response capabilities---especially doing so every year---may also help deter adversaries from considering development and use of biological weapons.

Rapid response platform technologies, such as those used to create some types of SARS-CoV-2 vaccines, should naturally be a component of such a development and testing program. Additional priorities may include:

- Building additional “Advanced Development and Manufacturing” facilities that are versatile and can be used for rapidly responding to a biological weapons attack or infectious disease outbreak. Ideally, this infrastructure will be kept warm by being used in exercises or in responding to natural disease outbreaks or even seasonal influenza.
- Investing in development of hand-held, user-friendly metagenomic sequencing technologies that can be used in the field or clinic to detect biological weapons or emerging infectious diseases.
- Leaning into the promise of nucleic acid-based therapeutics, which should continue to receive the investments needed to fully advance them to potential use authorization.
- Developing next generation personal protective equipment that is more effective against viruses. The technology is here to create masks far superior to N95s and specifically targeted against viruses and bacteria.
- Researching sterilization and pathogen transmission suppression within buildings, planes and ships, a key issue during both a pandemic and biological weapons attack.
- Developing point-of-person diagnostic platforms to be used routinely in the field.
- Continuing broad-spectrum, small-molecule antiviral research.

Many of these funding areas were also recommended in the Bipartisan Commission on Biodefense’s recent report *The Apollo Program for Biodefense – Winning the Race Against Biological Threats*.<sup>41</sup> This increase in funding can help incentivize the private sector to view the DoD as an attractive partner. However, the funding must be maintained over the longer term to ensure it makes sense as a business case for private sector partners, and it will require Congress and the DoD to work closely together.

Leadership in both Congress and the DoD (especially the Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs and the Office of the Secretary of the Army) will be needed in ensuring this funding remains at this level. Because of this year’s change in administration, it is likely that the next budget that is submitted to Congress largely reflects the last administration’s priorities. Hence, Congress may be able to play a unique leadership role in moving the nation toward this goal.

**The Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs (ASD(NCB)), in cooperation with the Secretary of the Army and others, should rejuvenate DoD’s leadership against biological threats.**

For the vast majority of the last seven years, the ASD (NCB) role has been filled by an acting official who was neither presidentially appointed nor Senate confirmed. This can result in a dynamic where the acting official’s top cover and self-assurance to enact change are limited.<sup>42</sup> As a result, a significant leadership void has opened in DoD efforts to address biological threats, including how to appropriately and effectively leverage assets like CBDP to contribute to national responses against the COVID-19 pandemic. The administration and Congress should fill this post as quickly as possible and ensure that it remains filled by a candidate with a strong vision for how CBDP and other programs can best meet defense needs, mitigate national security threats, and fuel U.S. innovation.

In addition to showing personal support for the CBDP enterprise and fighting for the above-listed sufficient resources, specific actions should include the following:

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<sup>41</sup> Bipartisan Commission on Biodefense, *The Apollo Program for Biodefense: Winning the Race Against Biological Threats*. Bipartisan Commission on Biodefense (Washington DC: Bipartisan Commission on Biodefense, 2021): 11-25.

<sup>42</sup> Berman, Russell, “[President Trump's 'Substitute Teacher' Problem](#),” *The Atlantic*, April 26, 2017.

*Coordinate with the DARPA director.* Many of the technologies of high potential have come from DARPA. Because of its relatively flat structure and deliberate frequent personnel changes, DARPA more often spots and encourages development of new, high-potential technologies more easily than other DoD organizations. The CBDP is already working with DARPA on transitioning its technologies to use in the military.<sup>43</sup> However, more direct cooperation and simultaneous exploration of technologies should be considered as a form of healthy competition and a means to increase investment in these important areas. The ASD(NCB), DARPA Director, and Secretary of the Army could begin expanding collaboration with a joint meeting among them to set some priorities and general vision, followed by memos to their respective staffs with implementation instructions regarding those high-level goals and priorities.

*Be a good consumer of bio threat intelligence---and be sure that other senior DoD leaders are too.* Senior leaders that oversee most of DoD's investments against biological threats should help create a demand signal for strong intelligence in this space. Perhaps just as important, they should ensure that key intelligence is provided to defense leaders who need to understand the threat when making budget and leadership decisions, such as the Secretary and Deputy Secretary, all relevant Under Secretaries, Service Secretaries, and the Commander of Special Operations Command. After the COVID-19 pandemic, it will be important to keep a close watch on potential efforts by state and non-state actors to develop or hedge toward biological weapons. In addition, more generally, intelligence briefings will aid in investment decisions.

*Direct the Deputy Assistant Secretary of Defense for Chemical and Biological Defense to organize additional annual exercises with partners.* In cooperation with intragovernmental, private sector, and international partners, the CBDP should conduct annual exercises to test its early warning capabilities for novel pathogens and rapid responses. This will regularize cooperation between the CBDP and its partners, increase deterrence against adversaries considering developing or using biological weapons, and also help ensure that the United States and the world are prepared for the next high-consequence biological threat.

*Broaden international cooperation to include identifying opportunities for technology development and sharing with allies and partners.* As described above, regular discussion and cooperation with allies and partners is an important way to augment capabilities. Depending on its sensitivities, the CBDP can also help identify some technologies and tools that may be shared or sold to key partners. This cooperation may also make an important contribution to deterrence.

**Senior DoD leaders should clarify the mission of the CBDP in high-level documents to move beyond the limited mission of ensuring continuity of military operations in the case of biological and chemical weapons being used against defense forces.**

First and foremost, those volunteering to defend the United States deserve technologies that help them avoid the risk of operating in such environments as part of their military missions---not just protective gear that may be needed for such operations.

Second, in many potential conflict environments, protecting military families, embassy staffs, and preventing mass-casualty events among the public should be seen as mission support as well. The CBDP's work should also be recognized for its contributions to deterrence. Indeed, a mission of the CBDP should be to deter biological attacks against the United States, its allies and partners. It is clear that biological threats pose a significant strategic threat. As part of whole-of-nation preparedness to mitigate this threat, CBDP investments for DoD that at the same time benefit the American public writ large

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<sup>43</sup> U.S. Department of Defense, JPEO-CBRND, "[DARPA and JPEO-CBRND Formalize Collaborative Efforts to Support American Military Personnel](#)," by Amber Kreisel, December 13, 2018.

should be explicitly recognized and encouraged. As stated above, it is quite possible that early in the use of a biological weapon, that distinction of whether it is of natural or deliberate origin may remain ambiguous. The CBDP's contributions to the nation's effective responses should never again be constrained by lack of clarity on its scope of mission.

The ASD(NCB) should also direct the DASD for Chemical and Biological Defense to confer with DoD lawyers to get a clear decision on any perceived limitations on CBDP authorities regarding its mission scope, if they exist. Congress in the FY22 NDAA should explicitly state that CBDP funds can be used against the full range of biological threats, to include potential pandemic pathogens. This should be part of a continued shift away from the outdated approach of developing technologies based on a specific, relatively static list of pathogens (the Select Agents List) viewed as having potential as a bioweapon.

**DoD should set a process for balancing risk and reward, including consideration of dual-use risks, and to consider measures to increase transparency.**

Increased investment in biodefense runs the risk of causing concern among allies and adversaries about the character of DoD investments. It is important to ensure that technologies are chosen that have a clear intention and application for defensive purposes only. Transparency measures, including confidence building ones with third-party states, can increase transparency while not sacrificing national security.

Organizations such as the Intelligence Advanced Research Projects Agency (IARPA) have in the past had particularly forward-thinking review processes of this type in place that should be considered when making decisions about programs to fund. As funding is being restored to the CBDP, it will be important to ensure that additional activity does not give rise to misunderstandings about the defensive nature of increased CBDP investments. Red-teaming ideas with experts from the National Labs, Department of State, and health and intelligence agencies could help in that regard.

## CONCLUSION

There is a growing gap in U.S. biodefense that is making the country as a whole, including the U.S. military, vulnerable. This has become apparent during the COVID-19 crisis - the largest biological incident of our lifetimes. A substantial increase in CBDP investments, together with the shifts in CBDP activities outlined above, will help shore up U.S. biodefense and rapid response capacities, and better protect the nation in the present time and the coming decades.

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