

UNITED STATES AIR FORCE CENTER FOR STRATEGIC at The Air University DETERRENCE STUDIES



Addressing Biological Threats in the DOD CB Defense Program

By Albert J. Mauroni

http://www.airuniversity.af.edu/csds/

The U.S. government's struggle with mitigating the effects of the 2019 coronavirus (COVID-19) has demonstrated the capability of pandemic outbreaks to cause global disruption and highlighted the weaknesses of the U.S. public health system. Across the world, as of April 2021, there were nearly three million deaths attributed to COVID-19 and more than 75 million people who have recovered from the disease. U.S. citizens account for about 20 percent of those fatalities.

The effects of this latest pandemic have been severe on economic, political, and security interests as well. Even as politicians grapple with strategies to moderate the impact of future pandemics, some national security analysts are suggesting that the United States should re-examine its preparations for deliberate biological releases, and in particular, biological terrorism. The reasoning seems to be, if a natural disease outbreak can be so devastating to the United States, surely a violent extremist group, armed with the latest technology and access to biological organisms, could duplicate such an event.

This concern that COVID-19 has demonstrated vulnerabilities of the general public to biological weapons is unfounded. Let's get past the dubious point of whether any sub-state group could actually develop a biological weapon for the purposes of mass casualties.¹ The COVID-19 virus, despite the high number of deaths and significant illnesses it has caused over months, does not have the desired characteristics of biological weapons developed in the past by the United States and former Soviet Union. While strains of COVID-19 could be acquired and cultured in a laboratory, its ability to be disseminated from a point or line source is questionable and it is too unpredictable as to its effects on a targeted population. If young adults, such as those found in military forces, are at best mildly affected, this would rule against it being a good biological weapon. While it has impacted the U.S. economy, certainly it has not shown itself to be an existential threat. Its contagious factor is significant, but with a two percent lethality rate, it would not be a good candidate as a weapon.² While the short list of biological weapons has originated from nature, naturally-occurring diseases act very differently than deliberately-employed biological weapons.

There is a broader policy aspect associated with comparing COVID-19 with biological weapons, in that the context of the threat sources are very distinctly different. While pandemic outbreaks and deliberate biological attacks are both biological threats, the U.S. government and public view a natural disease outbreak very differently than a deliberate nation-state or substate group attack. A threat source actively targeting the U.S. public with intent to cause mass casualties at a single point and time would cause a particular level of fear that a natural disease outbreak does not. Pandemic outbreaks are not new. While politicians and policy makers have referred to the concern of bioterrorism during public health discussions for literally decades, the possibility of bioterrorist incidents has not been central to government policy development.³ This grouping of natural, accidental, and deliberate biological releases under a general category of "biological threats" is unsupported by the U.S. policy process.

The national security community and public health community continue to discuss how the United States should address pandemic disease outbreaks as a national security concern. While one can agree that COVID-19 has raised geopolitical tensions, there are few agreements on how the United States should address pandemic outbreaks in a security context. This is not a new discussion. The U.S. government has debated its proper role in addressing natural disease outbreaks and bioterrorism incidents for many years. Following the 2001 anthrax incidents, there was a flurry of workshops and articles examining government policies and developing options for responding to bioterrorism.⁴ In fact, the Department of Health and Human Services (HHS) had initiated efforts for bioterrorism response a few years prior to the Amerithrax attacks. The Bush 43 administration released a Biodefense for the 21st Century strategy in 2005 that designated the Department of Homeland Security (DHS) and HHS as the leads for implementing a national biodefense program, with DOD in support. Some point to the billions spent on bioterrorism response over the past 15 years and wonder why this government effort didn't catch the arrival of COVID-19.5

Mr. Al Mauroni is the Director of the USAF Center for Strategic Deterrence Studies

There has been a parallel debate going on for some years as to whether the Department of Defense (DOD) Chemical and Biological (CB) Defense Program should treat emerging infectious diseases as a weapon of mass destruction (WMD). This program, which stood up in 1994 by direction of Congress, was to develop joint CB defense equipment for all U.S. service members to protect them from adversarial nations armed with chemical and biological weapons.⁶ Over the past 15 years, this program has strayed from its original direction and increasingly invested in research and development projects that address emerging infectious diseases. Others argue that this small, niche program is not doing enough to address the general category of "biological threats" and should do more.⁷ This paper will demonstrate that the DOD CB Defense Program has, over the past 15 years, funded medical biodefense projects as a priority over other efforts. However, it should not divert funding to address emerging infectious diseases, given that the DOD and HHS already have distinct agencies, policy direction, and funding sources to meet the future threat of pandemic outbreaks.

- CBDP History and Work -

The U.S. military was unprepared for chemical or biological warfare in 1991, as its forces deployed to liberate Kuwait from Iraqi military forces. While U.S. forces had a good idea of Iraq's chemical weapons program through observations of the earlier Iran-Iraq War, there was little understanding as to Saddam Hussein's capabilities with biological weapons. If Iraq's military attacked U.S. and coalition forces with chemical weapons, there would have been significant casualties, but probably not enough to significantly impact the operation. Biological weapons use, on the other hand, could have been a showstopper and at the least would have caused massive casualties, if Iraq had disseminated anthrax in large amounts against the military camps in Saudi Arabia. There were no automated biological detectors at that time, and the DOD had neglected its biological warfare vaccine research to the point that a crash program was necessary to deliver vaccines against a possible attack.⁸ Fortunately, U.S. government threats of massive retaliation were successful in deterring Saddam from using unconventional weapons.

The four services did not take any immediate actions after the conflict to remedy these significant capability gaps, so General Colin Powell directed the formation of a Joint Program Office for Biological Defense in 1993, whose purpose was to develop biological detectors and institute an anthrax vaccination program. This was followed closely by Congressional direction to move all of the services' research, development, and acquisition funding to a program budget line, to be managed by Office of the Secretary of Defense (OSD) under the Assistant to the Secretary of Defense for Atomic Energy. This CB Defense Program was stood up in February 1994, but it would take a year prior to the formal organization and staffing to get organized, with its first official "joint" budget line appearing in Fiscal Year 1996 (FY96). Importantly, the Department of the Army was reaffirmed as the DOD Executive Agent for Chemical and Biological Defense, meaning that it was expected to take the lead in directing and leading the program.¹⁰ This appointment was because the Army has the overwhelming majority of specialized personnel and defense infrastructure in this field. In 2001, the Joint Program Office for Biological Defense was folded into the Army's (later, Joint) Program Executive Office for CB Defense.

is a governance structure that allows a number of joint agencies to determine and allocate funds for developing specialized military equipment, from basic science through advanced research and development and procurement by the services. There is a Joint Science and Technology Office under the Defense Threat Reduction Agency (DTRA), a Joint Requirements Office for Chemical, Biological, Radiological, and Nuclear (CBRN) Defense under the J8 Directorate in the Joint Staff, and a Joint Program Executive Office for CBRN Defense that reports to the Assistant Secretary of the Army for Acquisition, Logistics, and Technology (ASA[ALT]). These offices are overseen by an office in the Office of the Secretary of Defense under the Under Secretary of Defense for Acquisition and Sustainment. These organizations exist to guide and direct service laboratories and industry to develop CB defense equipment, based on validated service requirements. This is particularly important in that the services are not permitted by law to conduct their own research and development, but do still have the responsibility to train, equip, and organize their forces. The services can provide their own money to the program if they want to accelerate ongoing projects, but that rarely happens.

Discussions within the CB Defense Program often fracture along lines of non-medical and medical research, development, and acquisition projects. Non-medical equipment includes manual and automatic detectors, hazard prediction software, protective masks and suits, decontaminants, and collective protection systems. The medical projects include pre-treatments (to include vaccines), post-treatments, and diagnostics. Every year, the four services, the National Guard Bureau, and the U.S. Special Operations Command meet to discuss how they believe the funds should be allocated for the next budget cycle (two to four years out). During this drill, OSD and the Joint Staff offer their guidance and, at the end of the budget process, the sausage is made and the program's funding plan is incorporated into the DOD Program Objective Memorandum. The Chemical and Biological Defense Program works the same way as every other defense acquisition program, except for this joint management aspect. Focusing on the medical component, there is a deliberate distinction between research and development for countermeasures against natural infectious diseases and countermeasures for biological weapons.

In particular, the U.S. Army Medical Research Institute for Infectious Diseases has two research branches – one develops medical countermeasures for natural infectious diseases and the other develops medical countermeasures for chemical and biological weapons. The former is paid for by Army funds, and the latter is paid for by OSD funds. The Air Force and Navy medical agencies generally work with the Army on medical countermeasures for chemical and biological weapons. While both branches work under the same organization and use similar resources, their work is segregated to ensure that distinct policy objectives are met. Failing to do so means that the U.S. military might not have vaccines and post-treatments for biological warfare agents, as had happened in 1991 during the Persian Gulf War. The Army medical community has a long history of developing vaccines for natural infectious diseases, to include the Walter Reed Army Institute of Research's recent work on a COVID-19 vaccine candidate.¹¹ There are a number of other military medical agencies that also research medical countermeasures for natural infectious diseases.

In addition, the DOD Defense Health Agency oversees and funds the military's health system. The DOD Defense Health Agency includes an Armed Forces Health Surveillance Branch that provides a continual focus on global disease outbreaks. The

Army, Air Force, and Navy all have surgeon generals and public health centers that address infectious disease outbreaks as well as other health issues under a "force health protection" concept.¹² In 2020, the Defense Health Program was funded about \$45 billion, of which the majority (\$32 billion) was to run the Military Health System's medical treatment facilities. Similarly, HHS spends about \$20 billion annually on disease prevention projects through its many offices. The CB Defense Program is funded at about \$1.2 billion per year to cover all chemical and biological defense modernization requirements. The Department of Veteran Affairs, U.S. Department of Agriculture, and Department of Homeland Security spend billions on projects addressing biological threats as well.

The CB Defense Program's mission is very clear. It is to enable U.S. military forces to survive, fight, and win in a chemically or biologically contaminated warfare environment.¹³ This does not mean that it has ever been fully funded to develop and procure adequate amounts of defensive equipment in a timely manner. Like any defense program, it competes with other defense initiatives, and ironically, since the services don't have any of their money invested in this program, their level of interest is correspondingly low. The exception to this is the Army's Chemical Corps, which, as the only full-time CB defense specialists in the U.S. military, have a particularly significant interest in this program.

— Mission Creep and Policy Changes —

While this program's mission is clear, its central role in developing specialized CB defense equipment has been adapted for other purposes. In 1998, the DOD directed the U.S. Army to lead the development and execution of a DOD Domestic Preparedness Program that would visit more than 100 cities to train emergency responders on how to respond to a domestic terrorist CB incident. This did not involve the CB Defense Program, but the Army's technical labs that worked this initiative received additional funding to conduct the training, prior to the Department of Justice taking it over in 2000. Between 1998 and 2001, a new OSD acquisition office failed to adequately manage the acquisition of specialized gear for the National Guard's WMD Civil Support Teams (CST), necessitating its movement to the DOD CB Defense Program. Following the 9/11 attack, the CB Defense Program received additional funds to procure specialized equipment for U.S. military installations for the purposes of responding to potential domestic CB terrorist incidents. This initiative was defunded prior to most of the 200 installations receiving any equipment.

In 2005, OSD proposed a Transformational Medical Technology Initiative (TMTI) that proposed to fast-track medical countermeasures research and development for a broadspectrum medical countermeasure – "one drug for many bugs" was its tagline. Its goals were to develop a single vaccine that would be active against multiple viruses (at least all hemorrhagic fever viruses) and a single vaccine that would be active against intracellular pathogens (bacterium) within five years.¹⁵ When the OSD office overseeing the CB Defense Program could not convince DOD leadership to fund the effort, the funds were taken from existing CB defense programs. After about \$1.5 billion and more than five year's work, there were no feasible candidates that met its ambitious goals.¹⁶

Following the Obama administration's release of the National Strategy for Countering Biological Threats in 2009, there was a significant push to move funds within the CB Defense Program from traditional service requirements of chemical and biological defense to "national priorities" that included new medical diagnostic equipment, a global biosurveillance program, and an advanced development and manufacturing facility for medical countermeasures that duplicated three similar centers being built by DHHS.¹⁷ The concept of DOD running a "private-public partnership" for a vaccine manufacturing facility for the purposes of augmenting national production was not new. The CB Defense Program proposed such an effort in 2001, but it was shot down by the Army's Vice Chief of Staff (Gen. John Keane).

More recently, the CB Defense Program funded a "Global Biosurveillance Portal" and "Global Bio Tech Initiative," but they were cut in recent OSD budget drills. All of these diversions, with the exception of the WMD CSTs and the Advanced Development and Manufacturing (ADM) facility, were dropped as their OSD champions transitioned to other endeavors. However, with the recent focus on COVID-19, the idea that the CB Defense Program should refocus its efforts toward "national priorities" of developing capabilities for emerging infectious diseases has returned. Despite the very clear direction in legislative law, some want to use the CB Defense Program's technical expertise to contribute to the national effort to prepare for future pandemics at the cost of reducing the effort to protect U.S. forces from adversarial use of chemical and biological weapons. This is a zero-sum budget process right now, unless DOD views on this topic change dramatically.

The U.S. government's response to the Ebola outbreak in 2014 is illustrative. DOD announced "Operation United Assistance" as its mission to support U.S. government efforts to mitigate the Ebola epidemic in West Africa. This included the construction of field hospitals and transportation of supplies to Liberia. HHS was the lead government agency for the relief efforts, which, in coordination with the World Health Organization and other organizations, worked in Guinea, Sierra Leone, Nigeria, and Liberia. In support of this effort, DTRA announced that it would accelerate two Ebola vaccine candidates and a therapeutic treatment candidate for emergency use authorization.¹⁸ Actually, the U.S. Army Medical Institute for Infectious Diseases had been researching Ebola vaccine candidates since 2004, not as a cure for a natural disease outbreak, but as a countermeasure for a potential biological warfare agent. The vaccine would not be formally approved by the Food and Drug Administration until December 2019.¹⁹ The perception (at the time) was that DTRA had rushed a vaccine to the field in response to an international health crisis, when in fact it was a convenient circumstance with limited impact.

The military is bound by the same long development timeline and regulatory process as the civilian sector. While one might believe that a vaccine developed for a biological warfare agent should be able to be used for natural disease outbreaks, and vice versa, in actuality, the FDA rules are very clear. The vaccine usage is different, and to prove efficacy of the medical treatments, they have to be tested within strict parameters to achieve licensure. For instance, the U.S. military had to get an FDA waiver in 1991 to use an anthrax vaccine developed for veterinarians. There is a waiver process for emergency cases, but the normal process of research and development must be followed carefully to ensure that congressionally-directed funds are spent for their designated purposes. If one intends to develop medical countermeasures for military use or public use, the source of funding and purpose of medical countermeasures is critical.

Operation Warp Speed is another interesting example in which the DOD CB Defense Program was drawn into a public health crisis. This effort was advertised as an HHS-DOD partnership, led by a four-star Army general, to obligate \$17 billion dollars to pharmaceutical firms in an effort to fast-track the development of a vaccine for COVID-19.²⁰ While the U.S. Army Medical Institute for Infectious Diseases was heavily involved, the CB Defense Program's role was largely one of a contracts office. Industry did the heavy lifting; HHS oversaw the licensure and distribution. It is too soon to evaluate the actual merit of this partnership, but it is unclear what value DOD added to what traditionally has been an HHS core mission. Admittedly, HHS may not have acted as fast as it should have, but this may have been due more to leadership challenges than capability failures. Should Operation Warp Speed become the excuse for expanding the DOD CB Defense Program's role in developing medical countermeasures for emerging infectious diseases?

Natural disease outbreaks are becoming more common and have a greater impact on society. We can argue as to the cause or nature of the threat, but sure, there's an ugly trend here. The latest Global Trends report focused on the "disruptive potential" of new diseases and commented in particular about how COVID-19 has "shaken long-held assumptions about resilience and adaptation and created new uncertainties about the economy, governance, geopolitics, and technology."²¹ Certainly there are security concerns that emerge due to this current and future pandemic outbreaks, but declaring a particular public health challenge as an existential security threat – what some call health securitization – has consequences as well.²² Using a national security perspective on global health can actually back-fire, given the current policy process by which public health programs are executed.

This paper cannot delve into the significant challenges of executing public heath programs, other than to say, laserfocusing on COVID-19 or emerging infectious diseases as a security issue ignores the much larger impact of noncommunicable diseases and endemic natural diseases that impact millions of Americans every year. These are also significant public health issues that require funding and attention.

The policy challenge is understanding who should pay for medical countermeasures development – the public health sector or national security – and assessing the programs that are charged with that effort. We will examine next as to whether the DOD CB Defense Program has been deliberately underfunded and whether it has prioritized chemical defense over biological defense projects.

- Budget Trends and Issues -

The budget numbers in this paper come from the OSD comptroller site and other public information sources. The DOD CB Defense Program has taken a fall from the heady post-9/11 days when the defense budget was more robust and we were all worried about CBRN terrorism. The program had a high mark of \$1.7 billion in FY06 (\$2.2 billion in 2021 dollars), in part due to plus-ups related to the DOD Installation Protection Program. While it has declined since, this decline has been relative to that of the overall defense budget (*Figure 1*). The little bounce in 2014-2015 was caused by short-term increases to medical chemical and biological countermeasures research and development projects. Since then, the program has flatlined at about \$1.2 billion, which means it lost overall value due to no adjustments for inflation.

Should the program be better funded? From an agnostic perspective, it's hard to say. Like any defense program, it probably could deliver more equipment if better funded, but this funding pattern is more the indication of benign neglect than any deliberate underfunding. When the DOD budget goes up, the CB Defense Program gets more funds. When the DOD budget goes down, the CB Defense Program loses funds. The

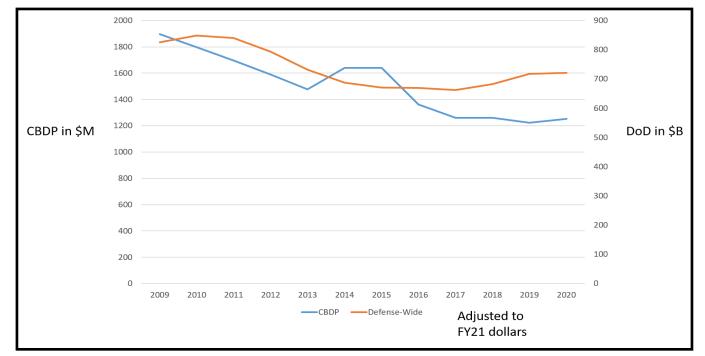


Figure 1. DOD CB Defense Program Top Line Budget

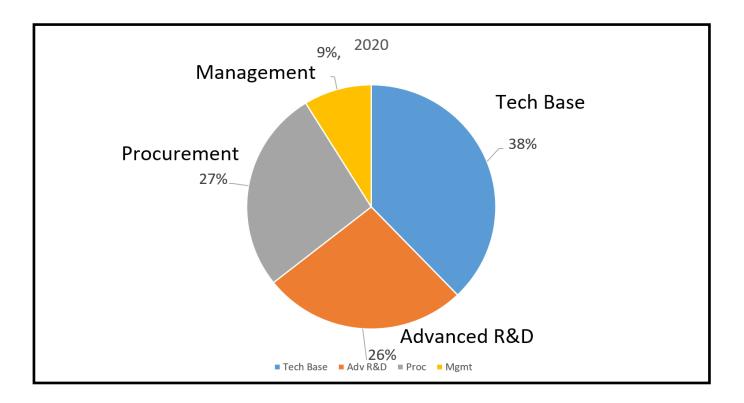
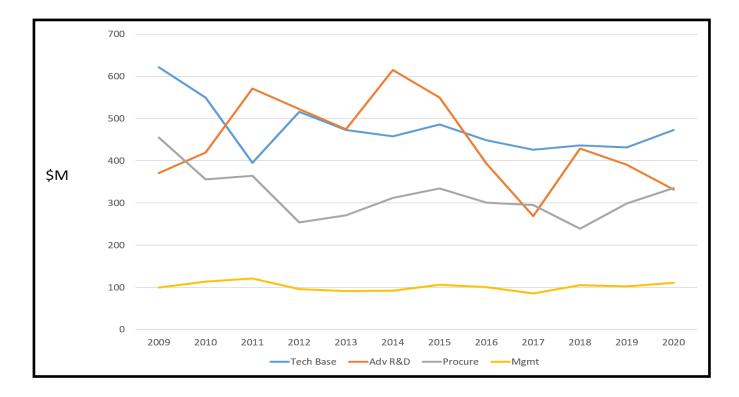
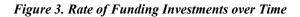


Figure 2. Apportionment of Defense Dollars in the CB Defense Program (2020)





more important question is what should it be funding? There is no senior leader advocacy for this program in OSD Policy or within the services' headquarters. No one has evaluated the program against national defense policy objectives within the last decade (to include the Congressional Research Service or Government Accountability Office),²³ so there is no contemporary argument to convince DOD leadership for a change in the status quo. There are always other defense priorities.

The program has, for the past decade, been split roughly 66 percent to research and development, 20 to 25 percent to procurement, and at around eight to 10 percent for management costs. (See *Figure 2* on the top of Page 5) Between 1998 and 2009, procurement took up 40 to 50 percent of the budget, perhaps because technology was more mature and there was a lot of old equipment to replace. As user requirements became more demanding and research for medical defense took a higher priority, research and development costs grew due to the increased time to develop and field new technologies.

Specifically, the funding stream for projects in advanced research and development has been sporadic over time. (See *Figure 3* on the bottom of Page 5) However, this can be largely explained to trends caused by individual projects funded in significant increments before either being moved into procurement or slipped in the schedule into later years. In particular, due to very demanding key performance parameters of biodetection and medical countermeasures in particular, the advanced research and development programs often have to move fielding dates farther out than expected. It's hard to judge much by this data other than to say, the services are not getting as much modern equipment in their units as they used to. It would take a more detailed discussion to explain why this is, but it is not directly relevant to the immediate discussion.

Focusing on the issue of biological defense versus chemical defense, there is no question that biological defense funds have had the priority over the past 12 years. (See *Figure 4* at the top of Page 7) One can argue as to the relative value of the projects as to what was actually delivered to the field (and how much), but there is no doubt as to where the money is going. Of importance, a number of CB defense projects are "dual-use," in that protective clothing, hazard prediction software, collective protection systems, and decontaminants address both chemical and biological threats. None of these individual "dual-use" categories represent a significant portion of the budget in and of themselves.

As to the drop in biodefense funds in 2016-2017 – this does not represent a sudden change in direction as much as it is an indication that either 1) some biodefense projects could not execute their research and development funding and the program had to move that funding into chemical defense or dual-use equipment, or 2) the sub-organizations in the CB Defense Program were correcting a significant past deviation in the biodefense funding (the hump seen between 2012 and 2015) or both. It would take some additional research to determine the exact causes. Focusing on medical funding in particular does reveal some more information. (See *Figure 5* at the bottom of Page 7)

Figure 5 demonstrates that it wasn't the biodetection programs or chemical defense projects stealing money away from medical biological countermeasures funding. In fact, biodetection funding has been rather low, and this is due to two things – first, the technical challenges in developing a small, rugged, automated biodetector for a small range of high-threat biological warfare agents, and the relative mature technology in chemical detectors that has allowed for a relatively easier procurement strategy. Two projects in particular make up the hump in the medical biodefense funding, those being the Transformational Medical Technology Initiative and the standup of the ADM facility. The TMTI was not extended as it had no useful end-products other than lessons learned from an overly ambitious science and technology venture, while the reoccurring ADM facility operational costs were absorbed by medical research and development projects.

Now one could make the argument that the science and technology costs are obscuring the spending profile of the CB Defense Program, and the tech base budget is very significant, so we can account for that as well. (See *Figure 6* at the top of Page 8) However, the medical technology base funding has certainly dominated the budget portfolio, so it remains true that biodefense funding has been doing very well over time, if without actually procuring much in the way of end products. The recent exception in 2020 is due to the Army's request to put some significant funding into modernizing its reconnaissance vehicles, and the National Guard's request to fund a particular detection suite for its WMD Civil Support Teams. This isn't a conscious decision to not fund biodefense in as much as there are no near-term biodefense requirements that require funding and so these procurement efforts could proceed.

The argument heard now is, given the program's focus on medical biodefense, why not give them more funding so as to support the U.S. government response to COVID-19 and future pandemics? The response comes in two forms. First, it's not their mission. It never was their mission to address emerging infectious diseases because there's a much larger capability in the U.S. Army Medical Research and Development Command that does have that mission. Second, it's HHS that has the significant resources and infrastructure to take on the billions of dollars necessary to execute a national and international response to pandemic outbreak. The CB Defense Program lacks the infrastructure to even nudge the nation's disease prevention capabilities the smallest degree forward. Could the CB Defense Program use more dollars? Sure. Absolutely, but the funding needs to go toward improving the military's capabilities against adversarial nation-states with chemical and biological weapons programs.

I haven't addressed the Defense Advanced Research Project Agency (DARPA) largely because, while DARPA has an independent budget, it's a very small budget, and they are largely limited to basic science efforts and incentives to industry on biotech challenges. They participate with, but do not significantly advance, the DOD CB Defense Program. However, this needs to be emphasized – the CB Defense Program, and the OSD acquisition offices overseeing its execution, are not the right agencies to be leading the nation's or international community's pandemic response. It's not even a close question. HHS is the identified lead for Global Health Security Agenda – not DOD, not the counter-WMD community, not the CB Defense Program. HHS can do this mission without support from the counter-WMD or CBRN defense community.

The DOD has an Assistant Secretary of Defense (ASD) for Health Affairs, a Joint Staff Surgeon, three Surgeon Generals, and a large community of doctors, medical researchers, and staff that regularly work with HHS and Veterans Affairs on public health issues. Let them do their jobs. We need the DOD CB Defense Program to do its core mission of ensuring the military has the ability to survive and operate in future operating environments that feature the adversarial use of chemical and biological weapons.

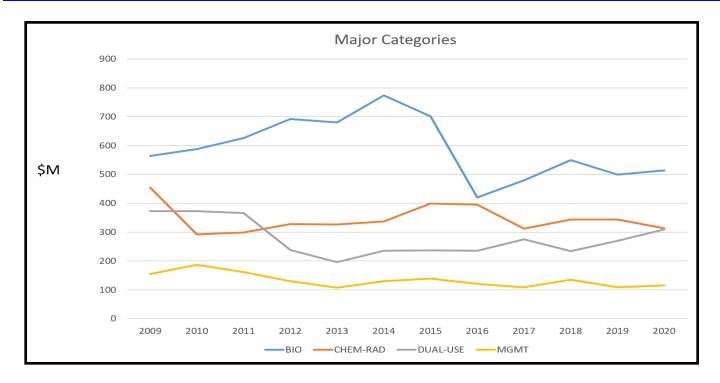
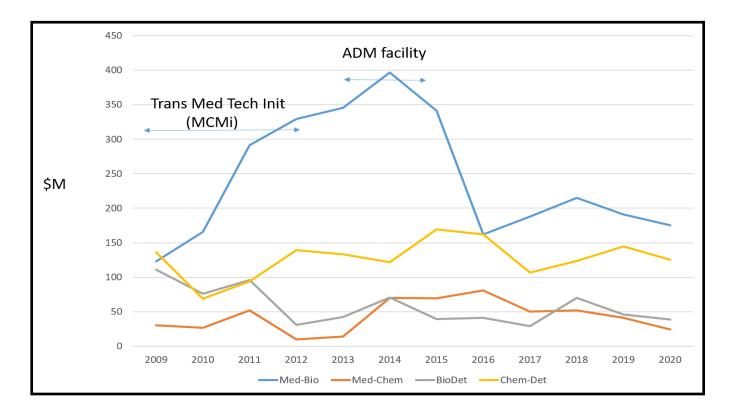
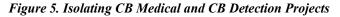


Figure 4. Rates of Investment of Particular CB Defense Sectors





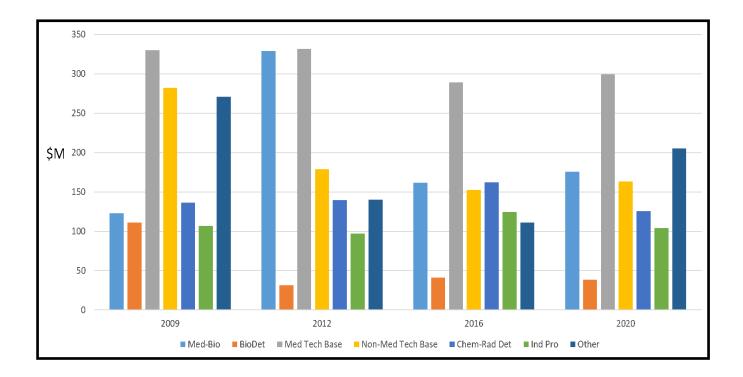


Figure 6. Breakout of Adv R&D and Tech Base Funding over Time

— Recommendations —

The DOD CB Defense Program is a small, technicallyoriented community that has been largely ignored by the larger national security community, in no small part because its services have not been in demand in contemporary military operations. When we see national guidance about WMD proliferation, the unstated message is "deal with WMD through arms control and deterrence threats" so as to remove the threat and not to suffer possible attacks that would need to be blunted by defensive countermeasures. At the same time, over the past two decades, the national security community has become fascinated with the shiny new concept of health security, of which the public health community has been addressing for the past 100 or so years. We desperately need a cold, clear assessment of what the White House wants the DOD to do in both areas of biodefense as an aspect of countering WMD and disease prevention as an aspect of public health.

1. DOD should clarify the term "biological threats" and outline specific measures on how it addresses natural disease outbreaks through the context of force health protection, how it addresses biological warfare threats through the context of counter-WMD operations, and how it addresses biosurety concerns through the context of military laboratory practices.

The nebulous definition of "biological threats" as being inclusive of all natural, accidental, and deliberate biological releases is causing irreparable harm to national security deliberations. It is naïve to believe that focusing on a threat without considering the threat source will somehow lead to improvements in defense capability. In actual practice, public health officials continuously tackle natural disease outbreaks. Law enforcement and the intelligence community seek to prevent biological terrorism incidents. The military and diplomats worry about biological weapons use. Laboratory professionals practice biosurety principles, and the farming industry works agricultural biosecurity and food safety issues with Congress. All of these groups endorse the need for national biopreparedness, but they need more guidance than just this simplistic focus on spending more money on medical countermeasures and global biosurveillance initiatives.

If the DOD leadership wants to focus on threat of future pandemics, then it needs to direct the ASD for Health Affairs and the Defense Health Agency to work with the Joint Staff Surgeon and the surgeon generals on this topic, and we need to listen to them. They've been working disease prevention since the Civil War, and it's well-funded. They're not going to replace the many offices under HHS that address biological threats, and I don't think they want to in any event. The medical

community doesn't need security analysts telling them how to address endemic and emerging disease outbreaks, and the national security community can't "defeat" emerging biological threats. The only sure outcome of using the general term "biological threats" will be a significant diversion away from deliberate biological threats and toward natural disease outbreaks, because service members (and Americans in general) get sick from natural diseases every year. Then, we'll be right back to 1991 and the Persian Gulf War again.

2. Before any new budget recommendations are made, the National Security Council should establish a new national strategy for countering WMD and direct OSD Policy to outline CB defense objectives.

The only unclassified (and therefore accessible) national strategy for countering WMD was released in 2002. A lot has changed over that time, and the national security community has failed examine how it intends to address WMD by means and ways provided by the U.S. military. If we believe that countering WMD is a "whole of government" mission, then we ought to walk that talk and stop duplicating efforts that HHS and other government agencies are doing. This is especially true with regards to public health threats such as natural infectious diseases. We need a new national strategy for countering WMD that moves away from a threat-actor agnostic concept and toward specific guidance for executive agencies. The 2014 DOD Strategy for Countering WMD failed to provide adequate guidance for CB defense equipment modernization, in particular, and it needs to be replaced – after a national strategy is developed, not before.

The national security community has ignored counterproliferation and CBRN defense capabilities for years, perhaps because they had no place in a defense context focused on countering insurgents in the Middle East. The shiny new watch of biological threats should not distract them from the real mission. The DOD CB Defense Program will not, in and of its own, deter adversarial nation-states or sub-state groups from using biological weapons if they choose to do so. Biodefense capabilities are needed if strategic deterrence fails, and if funds are diverted from deliberate biological threats to emerging infectious diseases, then our forces will be unprepared for the next conflict. DOD leadership needs to explicitly state that this program must focus on deliberate biological threats, given the significant resources already allocated by other agencies on natural disease outbreaks.

The DOD CB Defense Program was designed for one purpose – to protect U.S. forces from adversarial nation-states that have chemical and biological weapons. The efforts of the highly trained and talented technicians working under this program are wasted if diverted to tangential missions that ought to have other billpayers – such as procuring commercial gear for the National Guard's CBRN Response Enterprise and Marine Corps Chemical-Biological Incident Response Force, developing medical countermeasures for influenza flu and pandemic response, and creating "biosurveillance portals" that duplicate the efforts of other government agencies. It's time to assess the CB Defense Program and determine what it should do.

3. The Secretary of the Army should, in coordination with the other services and Joint Staff, assess and reassert control over the DOD CB Defense Program and develop a long-term acquisition roadmap.

The Army has been the DOD Executive Agent for CB Defense for 35 years now, and the only constant is that there has been no consistent direction or coordinated approach to overseeing the development of the military's CB defense capabilities. The Army's leadership in this area has been highly dependent upon personalities in power, who are often unwilling to build a multi-service agenda or engage OSD on the program's direction and funding. It's certainly not due to lack of personnel - there are Army Chemical Corps colonels in all of the top positions of OSD, the Army and Joint Staff, and defense agencies. While they may be experts in the CBRN defense field, the politics of the Beltway seem to elude them. By the time they figure out how to work defense politics, they leave the Pentagon and the cycle of neglect resumes. The ASA(ALT) needs a dedicated staff and frequent engagement with the Deputy Assistant Secretary of Defense (DASD) to ensure that this program delivers to the four services' benefit. This should include a long-term acquisition map that explains how the money moves, and more importantly, explains the consequences of inaction. Because the other services lack general officer advocates, it becomes imperative that the Army include its sister services' requirements in its portfolio moving forward.

Unfortunately, the Army does not have a good plan to address future biological threats. The Army recently released a Biological Defense Strategy on LinkedIn,²⁴ and it shows a fundamental lack of understanding as to how health policy works. It proposes to focus resources on improving its capabilities against biological threats and hazards (natural, accidental, and deliberate) as if this was a stand-alone military function. It calls for a shift in governance from the Army Chemical Corps and Medical Corps executing discrete biodefense projects to a single office (the U.S. Army Nuclear and Countering WMD Agency) working across all Army stakeholders. This approach conspicuously ignores the medical community's significant investments in force health protection and shows a lack of understanding of the unique aspects of laboratory biosecurity as opposed to biological terrorism and biological warfare. This "paradigm shift" will inevitably fail because the topics of natural disease outbreaks and deliberate biological attacks are executed under different authorities and are funded under different commands.

The Assistant Secretary of Defense for Nuclear, Chemical and Biological Defense Programs focuses on nuclear weapons requirements as a primary function, because, well, nuclear weapons are kind of a big deal. As a result, much of the oversight of the CB Defense Program falls to the Deputy Assistant Secretary of Defense for Chemical and Biological Defense. There is a question of what "oversight" means, exactly. The traditional use of the term applies to the review, monitoring, and supervision of a particular policy area. The DASD ensures that the annual budget drill is in line with OSD guidance, and supports interagency coordination on acquisition projects. Oversight does not mean directing the initiation of new projects that lack a basis in a military service's requirements or arbitrarily defining emerging infectious diseases as an element of this defense program. This is the services' program. OSD should not act as a milestone decision authority for the Chemical Biological Defense Program.

4. The national security community must distinguish objectives for military biodefense capabilities as distinct from desired national biopreparedness improvements.

The Bipartisan Commission on Biodefense is perhaps one of the most vocal non-governmental organizations that fre-

quently voices concern over the national state of biological defense, writ large, and has recommended several actions to remedy this perceived state of unpreparedness. While its leadership and staff are certainly steeped in government affairs, this does not mean that all of its recommendations are sound, affordable, or implementable. Its report, "The Apollo Program for Biodefense: Winning the Race against Biological Threats" warns that the United States needs "to take biological threats seriously," that "U.S. vulnerabilities to biological attacks have never been clearer to our adversaries."²⁵ So we have to ask, what threats specifically are they talking about and whose vulnerabilities? The general public or the U.S. military? What exactly is the context? It's unclear.

The Commission recommends significantly funding ("incentivizing") projects for medical countermeasures, medical diagnostics, and environmental detection systems; developing a National Biodefense Science and Technology Strategy to guide interagency research and development; and creating a unified, multi-year budget appropriations to enact their recommendations across the government. The report overinflates the threat and ignores budget realities, which is the most surprising thing given the Commission's membership. Infectious diseases are not the most dangerous threat to Americans - heart disease, cancer, and unintentional injuries make up 50 percent of total deaths. Influenza and pneumonia ranked at Number 9 of the Top 10 health threats in 2019.²⁶ Preventive medicine and therapeutics have significantly reduced the threat of infectious disease. Not that the U.S. public health program couldn't be improved, but creating a single budget line (which Congress won't do) to broadly address natural, accidental, and deliberate biological threats (which Congress also won't do) will not help. Throwing billions of federal dollars at a poorly defined problem is not a solution.

We do need better biodefense capabilities for the military. The DOD CB Defense Program has a sound process to develop on specific defensive countermeasures for a specific threat, the possibility that adversarial nation-states may use a small set of highly-lethal and persistent biological weapons during a future military conflict. The program could be better administered, but that would take 1) clear definitions of what "WMD" and "biological threats" mean in context of military operations; 2) engaged military and civilian leaders who integrate biodefense and countering WMD into their operational plans; and 3) a clear long-term strategy that focuses on fielding capabilities for the military. The future threat of biological weapons use is not growing, but is significant. Our military forces need to be better prepared in the event that adversarial nation-states are not deterred from using them.



The mission of the U.S. Air Force Center for Strategic Deterrence Studies is to develop Air Force, DoD, and other USG leaders to advance the state of knowledge, policy, and practices within strategic defense issues involving nuclear, biological, and chemical weapons



The Trinity Site Papers present key discussions, ideas, and conclusions that are directly relevant to developing defense policy and strategy relating to countering weapons of mass destruction and developing the nuclear enterprise.

The opinions, conclusions, and recommendations expressed or implied in this article are those of the author and do not necessarily reflect the views of the Air University, Air Force, or Department of Defense.

— Notes —

1. See for instance, Milton Leitenberg, *Assessing the Biological Weapons and Bioterrorism Threat* (Carlisle, PA: Army War College Press, 2005), available at <u>https://press.armywarcollege.edu/monographs/30</u>.

2. Mark Kortepeter, "A Defense Expert Explores Whether the Covid-19 Coronavirus Makes a Good Bioweapon," *Forbes*, Aug. 21, 2020, available at <u>www.forbes.com/sites/</u> <u>coronavirusfrontlines/2020/08/21/a-defense-expert-explores-</u> <u>whether-the-covid-19-coronavirus-makes-a-good-bioweapon/?</u> <u>sh=2b42f3e37ece</u>.

3. Michelle Bentley, "Known Unknowns: Covid-19 and Biological Warfare," *E-International Relations*, Aug. 8, 2020, available at <u>www.e-ir.info/2020/08/08/known-unknowns-covid-</u><u>19-and-biological-warfare</u>.

4. See for instance, *Institute for Medicine, Biological Threats and Terrorism: Assessing the Science and Response Capabilities* (Washington, D.C.: National Academy Press, 2002), in particular, quote by Dr. Anthony Fauci (Director, NIAID) on p. 26, "In conclusion, we have been facing emerging and re-emerging diseases throughout history. From an infectious disease perspective, the only difference between bioterrorism and any of these naturally occurring diseases is that bioterrorism is deliberate."

5. W. J. Hennigan, "The U.S. Spent Billions of Dollars on Biodefense, COVID-19 Was the Attack It Never Saw Coming," *Time*, Oct. 9, 2020, available at <u>https://time.com/5898120/</u> america-biodefense-covid.

6. Department of Defense, *Chemical and Biological Defense Program Annual Report to Congress* (Washington, D.C.: DTIC, March 2000), available at <u>https://biotech.law.lsu.edu/ blaw/DOD/ConRpt2000.pdf</u>.

7. Bill Beaver, Yong-Bee Lim, Christine Parthemore, and Andy Weber, "Key U.S. Initiatives for Addressing Biological Threats, Part 1: Bolstering the Chemical and Biological Defense Program," Council on Strategic Risks, April 9, 2021, available at <u>https://councilonstrategicrisks.org/wp-content/</u> <u>uploads/2021/03/Key-U.S.-Initiatives-for-Addressing-</u> <u>Biological-Threats-Part-1</u> <u>Bolstering-the-Chemical-and-</u> <u>Biological-Defense-Program BRIEFER-16</u> 2021 04 09.pdf.

8. Government Accountability Office/NSAID-93-2, *Chemical and Biological Defense: U.S. Forces Are Not Adequately Equipped to Detect All Threats* (Washington, D.C.: Government Accountability Office, 1993), available at <u>www.gao.gov/assets/</u> <u>nsiad-93-2.pdf</u>.

9. Albert Mauroni, *Chemical and Biological Defense:* U.S. Policy Decisions in the Gulf War (Westport, Conn.: Praeger Publishers, 1998).

10. The Army had actually been the Department of Defense Executive Agent for Chemical and Biological Defense since 1976, but the congressional language that created the CB

Defense Program reaffirmed and strengthened its role.

11. Kyle Rempfer, "Army's own vaccine that could fight COVID variants begins clinical trials," *Army Times*, April 7, 2021, available at www.armytimes.com/news/your-army/2021/04/07/armys-own-vaccine-that-could-fight-covid-variants-begins-clinical-trials.

12. Department of Defense Directive 6200.04, Force Health Protection (FHP), dated April 23, 2007.

13. Annual Report to Congress, 2000, p. i.

14. Office of the Secretary of Defense, Joint Service Chemical and Biological Defense Program Fiscal Year 2006-07 Overview (Washington, D.C.: Office of the Secretary of Defense PA, 2006), p. 92-93.

15. Department of Defense, Transformational Medical Technologies Initiative (TMTI) Fiscal Year 2007 *Congressional Report* (Washington, D.C.: USD(AT&L), 2007), p. 4, available at <u>https://biosecurity.fas.org/resource/documents/</u> <u>dod_2007_transformational_medical_technologies_initiative.pd</u> <u>f</u>.

16. Erika Check Hayden, "Pentagon rethinks bioterror effort," *Nature*, Sept. 21, 2011, available at <u>www.nature.com/</u><u>news/2011/110921/full/477380a.html</u>.

17. See DHHS, "Department of Health and Human Services' Centers for Innovation in Advanced Development and Manufacturing," available at www.medicalcountermeasures.gov/barda/core-services/ ciadm.aspx, and JPEO-CBRND, "Medical Countermeasures Advanced Development and Manufacturing (ADM)", available at www.jpeocbrnd.osd.mil/docs/default-source/default-document-library/fact-sheet adm.pdf?sfvrsn=7e242dd7 2.

18. Cheryl Pellerin, "DTRA Medical Countermeasures Help West African Ebola Crisis," Department of Defense News, Dec. 12, 2014, available at <u>www.defense.gov/Explore/Inside-DOD/Blog/Article/2064716/defense-research-contributes-to-ebola-vaccine-effort</u>.

19. Ramin Khalili, "New Ebola Vaccine a Win for USAMRDC, *Global Health*," U.S. Army Medical Research and Development Command, Feb. 6, 2020, available at <u>https://mrdc.amedd.army.mil/index.cfm/media/articles/2020/</u>new_ebola_vaccine_a_win_for_USAMRDC.

20. JPEO-CBRND website, "Support to National COVID-19 Response," as of March 5, 2021, available at www.jpeocbrnd.osd.mil/coronavirus.

21. National Intelligence Council, *Global Trends 2040* (Washington, D.C.: Office of the Director of National Intelligence, 2021), available at <u>www.dni.gov/files/ODNI/documents/</u> <u>assessments/GlobalTrends 2040.pdf</u>.

- Notes Continued -

22. Brittany Bowman, "Securitization Undermines Global Health Governance Efforts," *ISGlobal*, Feb. 27, 2018, available at www.isglobal.org/en/healthisglobal/-/custom-blog-portlet/isthe-gradual-securitization-of-most-health-issues-a-positive-or-anegative-development-for-effective-global-health-governanc-1/5083982/9003? customblogportlet_WAR_customblogportlet_entryId=629873 7.

23. The last relevant Government Accountability Office report may have been in 2007, *Chemical and Biological Defense: Management Actions Are Needed to Close the Gap between Army Chemical Unit Preparedness and Stated National Priorities*, available at www.gao.gov/assets/gao-07-143.pdf.

24. US Army, Army Biological Defense Strategy, 2021, available at www.linkedin.com/feed/update/ urn:li:activity:6777951470764486656/?updateEntityUrn=urn% <u>3Ali%3Afs_feedUpdate%3A%28V2%2Curn%3Ali%</u> <u>3Aactivity%3A6777951470764486656%29</u>.

25. Bipartisan Commission on Biodefense, The Apollo Program for Biodefense: Winning the Race against Biological Threats, January 2021, p. 1, available at <u>https:// biodefensecommission.org/wp-content/uploads/2021/01/</u> Apollo report final v7 031521 web.pdf.

26. Kenneth Kochanek, Jiaquan Xu, and Elizabeth Arias, *Mortality in the United States, 2019* (Atlanta, Ga.: Centers for Disease Control and Prevention, December 2020), available at www.cdc.gov/nchs/fastats/deaths.htm.

