Collaboration with Industry:
The Solution for a Sustainable Posture for Biodefense and Global Health Security

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Years later, the impacts of the COVID-19 pandemic on Global Health Security echo on. Memories of closed military treatment facilities, installation and staffing issues, halted recruitment and training efforts, and stopped movements and deployments, continue to haunt the Department of Defense (DOD). Now in 2024, emerging from the aftermath of the COVID-19 pandemic, one lesson is clear: prevention is far more cost-effective than response. Yet, strategizing and preparing for a bioincident can also be costly. If a *reactive* posture has proven unsustainable, sustaining a *proactive* posture will also be unsustainable, if it is not done effectively.

In the November 2021 Biodefense Vision Memorandum,[1] the U.S. Secretary of Defense outlined the post-COVID Defense response after-action review, and areas noted for improvement. In summary, unification of efforts, modernization of DOD operations, and synchronization of biodefense planning all speak to a need to reform: to apply the lessons learned from the COVID-19 response, and to do it all in a way that is sustainable—that a nation can afford in a constrained economic environment. Getting there will require greater engagement with industry and the world.

Sustainable Posture

The concept of a *sustainable posture* is a central requirement for biodefense, but how it is created is not universally understood. *Deterrence by resilience* is the core objective for biodefense and is key to the North Atlantic Treaty Organization's (NATO's) considerations for civil preparedness. Specifically, from a medical standpoint, resilience is viewed as the "…ability to deal with mass casualties and disruptive health crises: ensuring that civilian health systems can cope and that sufficient medical supplies are stocked and secure" (emphasis added).[2] The inability to be flexible and respond to a crisis quickly and effectively introduces a weak link in the armament of resilience. Planning for sufficient medical supplies that are stocked and secure for an unknown threat is no easy task.

At the 2023 Vilnius Summit, a meeting of the NATO Heads of State and Governments of the North Atlantic Alliance, Allied Leaders reiterated strengthening resilience as an essential basis for credible deterrence and defense, highlighting health systems as an area that will require further collective and individual attention.[3] This idea is central to Article 3 as NATO explains: "Resilience relies on strong cooperation between civil and military stakeholders, which is of mutual benefit, both in peacetime and in times of crisis. As the COVID-19 pandemic demonstrated, military assistance to civil authorities can be of critical support when civilian resources are under severe stress. At the same time, civilian support is essential to enable and sustain NATO's military forces in times of crisis, whether through civilian expertise or access to critical commercial services and infrastructure."[4]

Having arrangements, plans, and training is critical to a health system's ability to respond. The ability to respond not only saves lives but enhances global stability, resulting in secure regimes with the military serving in the role of facilitators rather than intervening. Therefore, a sustainable biodefense posture depends on civil health systems that effectively execute

preparedness while executing high quality care—the military alliance and civil systems are inexorably linked. The main challenge that remains is an economic engine that can create and enable a sustainable health system that is fully executable and integrated.

Global Health Security

Domestically, the impact of the COVID-19 pandemic was nothing short of a national security issue. Yet, the reach of the disease and its lightning-fast spread quickly elevated the pandemic to a global health matter. Of concern, this happened with an infectious agent that had only a 1-8.2% case fatality rate.[5] This illustrates that national security and global health security—the practice of mitigating risks posed by infectious diseases—are interconnected.

As detailed in the 2024 Global Health Security Strategy, it is in the interest of national security to strengthen global health security and manage the risks of infectious disease outbreaks.[6] The United States does this through close cooperation and collaboration with international partners to prevent, detect, and respond to bioincidents. While the DOD historically does not address biodefense assertively or in a fully integrated way across the United States Government, the global health security strategy supports the National Security and Biodefense Strategies, and further describes how the United States will prevent, detect, and respond to infectious disease threats globally and domestically. *This is new for the US Government.*

The Global Health Security Strategy also delineates how the United States will achieve the National Security Strategy priority actions of "Detecting and Containing Biothreats at their Source" and "Improving Emergency Response" domestically as part of the global health security system. It is critical that this be elevated in importance in the National Defense Strategy. Unfortunately, the Global Health Security Strategy does not go far enough to clearly articulate how this grand strategy could be achieved or even executed, particularly outside of government offices. Yet, COVID-19 clearly illustrated that success depends critically on strong, operational, public-private partnerships.

Global health security is accomplished by developing strong and resilient public health systems that support a global capacity. The United States Government's contribution to global health security is two-fold: internationally, the United States provides support to Global Health Security Agenda partner countries, while domestically working to strengthen national preparedness. Yet the cost of this role is staggering, and within the DOD, in a time of increasingly constrained budgets, another key stakeholder must be considered to find more *sustainable* solutions: Industry.

While highlighted as a collaborative need, industry needs a clearer way to participate that motivates their involvement, so they can effectively balance their share of risks involved with health systems and medical capabilities. global health security has the market size necessary to motivate teamwork and cooperation with private entities if governments, intergovernmental organizations, and industry work together. The U.S. Department of Health and Human Services (HHS) employs an advanced payments system)[7] (refer to the many differences between titles 10, 42, and 50, which cover procurement, HHS acquisitions, and DOD acquisitions), and has the ability to provide materials originally intended for the DOD to other governments and non-governmental organizations (NGOs) for response efforts. The DOD must do its part to develop clearer policies (an advanced payments system like HHS is only the beginning). Both industry and the Federal government require policies that recognize conventional wisdom: industry requires a degree of predictability to invest in capabilities that will be needed in rapid response scenarios, to deliver the capabilities needed for resilience in both biodefense and global health security.

In Practice: Approaches to Partnering with Industry to Provide Medical Countermeasures

The DOD anticipates and deters future chemical and biological threats through the Chemical and Biological Defense Program's four components[8] (see Department of Defense Directives 5134.08[9] and 5160.05E).[10] In accordance with 50 USC 1522 and 1523,[11] the Army operates via its Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND),[12] to manage the nation's research, development, test and evaluation in chemical, biological, radiological, and nuclear (CBRN) defense equipment and medical countermeasure development. The JPEO-CBRND's Joint Project Manager for Chemical, Biological, Radiological, and Nuclear Medical (JPM CBRN Medical) oversees medical countermeasure development, and provides protection to the warfighter against known and unknown CBRN threats via a

three-prong strategy: a broad-spectrum toolkit, speedy response, and targeted capability development.[13]

A toolkit for a *broad-spectrum* response to a threat is often the initial frontline defense mechanism, buying time until a targeted medical countermeasure can be developed (or modified from an existing medical countermeasure). In fact, the latest advancements in biotechnology make the biothreat landscape much more dangerous and difficult to predict. This highlights the need to move beyond the "one bug, one drug" mindset – in biodefense, novel threats are the most worrisome, so we need data tools and existing solutions that address biological concerns to varying degrees. Broad spectrum solutions, while likely somewhat less efficacious, provide an interim solution focused on providing the best initial treatment and supportive care until the threat can be better characterized and a targeted response can be developed.

The JPM CBRN Medical's Countering Emerging Threats - Rapid Acquisition and Investigation of Drugs for Repurposing (CET RAIDR)[14] program investigates existing U.S. Food and Drug Administration (FDA)-approved solutions to bridge gaps, performing advanced development activities to repurpose late-stage or FDA-approved products while delivering data informing clinical practice guidelines (CPGs) supporting interim capabilities, or other early access regulatory mechanisms.[15] CET RAIDR builds a preparedness toolkit with broader spectrum, and potentially, both agent and host-directed drugs that are capabilities ready for immediate use to generate greater decision space for future targeted solutions.

Through a focus on the mechanisms of action, CET RAIDR also informs possible label expansions or therapeutic opportunities, wherein an existing FDA-approved drug is approved for a broader application, such as different patient subpopulations, new lines of therapy, or new uses in combination with other treatments or drugs. This benefits both the governments who allow their use and the companies that fund medical product development, which is inherently risky for both. For industry, because there is significant risk and potential liability, there must be a prospect of reward, which comes in many forms.

CET RAIDR is building an analysis and "data-as-a-product" framework to respond to new or unknown threats quickly, along with a contracting strategy allowing for rapid testing of new candidates for repurposing. This process not only focuses on individual products, but it presents an opportunity to build combination therapies, which can achieve 50% efficacy or better, thereby further reducing the strain on civilian health systems. This supports a biodefense posture sustainably, as there is no need to build and maintain new manufacturing facilities because of the reliance on commercial efforts and immediate use. It also presents market opportunities for private partners, especially if the scope expands to include targets that are relevant to global health security in addition to those already being mitigated for biodefense.

Similarly, *speed of response* matters. Using repurposed medical countermeasures, we can quickly focus on symptomatic or host-immune targeted treatments. In addition, using Artificial Intelligence (AI) and Machine Learning (ML)-enabled development and care, we can retarget prototype medical countermeasures across threat families, which may create shared opportunities for governments and industry. These AI/ML tools are especially important in that they can facilitate flexible, high-quality manufacturing and speed delivery, while also maintaining a focus on quality, consistency, and reliability (trust), which are of the highest priority for any health system.

Tools for visualization that illustrate opportunities, risks, and track execution are on the horizon as well, which will assist with the goal of promoting participation, cooperation, and maximizing commercial opportunity and engagement. Focusing on shared development is a tangible target for these tools, which presents a challenge given current laws and policies which limit the use of shared information tools. However, the DOD can solve this to have shared venues for communicating global health and biodefense gaps for vetted performers, which would present a notable tool for helping both governments and industry see the markets where their innovations and products can be used. Cost sharing is a natural extension of this approach, where the government is not the only funding source, as tools like this are needed to clearly illustrate the opportunities that will bring industry to the table with little additional resource demand. Here, global health security and biodefense are a market with scalable options to match companies of all sizes of industrial capability and speed of delivery.

Further, an additional approach straddles the broad-spectrum and rapid response prongs of the strategy: Drug Repurposing. Drug repurposing, similar to label expansion, explores whether a drug designed to treat a medical condition is effective for another threat. There are two benefits to this approach: Preparedness (the state of being prepared for a particular situation)

as well as Readiness (the state of being ready for use or action in a particular situation). While similar, preparedness suggests an avenue of success, while readiness infers the mechanism to succeed is in hand.

Ultimately, we will have to develop a *targeted* response to a new or emerging threat, enabling the understanding, mitigation, and protection of the warfighter and affected communities against priority threats with highly specific tests and medical countermeasures. The real goal is efficacious, speedy, high-quality care, which historically is accomplished with targeted prophylaxis, therapeutics, and diagnostic capabilities. In many ways, therapeutic responsiveness is where we failed during COVID. The science for approving drugs and medical devices still depends on focused research demonstrations, which is fully achieved quickly by using research with fewer variables. This involves all facets of the FDA (and related national regulatory authority) licensure processes, from preclinical data packages, candidate validation, to filing with the relevant regulator for approval.

While accelerated and efficient regulatory navigation may sound straight forward, the new drug development process can be exceptionally lengthy and costly, especially if it involves multiple regulatory bodies as is allowed by national sovereignty. The accelerated response to the COVID-19 pandemic was not at all the norm for DOD-managed bioincidents (nor is it sustainable). While programs like the DOD's Generative Unconstrained Intelligent Drug Engineering (GUIDE) effort present a new way to use AI and ML for more efficient pharmaceutical development, the basic scientific approaches and methods have not yet changed.[16] This means that as we continue to realize a new tomorrow, the future looks a lot like the past, and targeted development will still be needed.

The targets that matter for biodefense are not clearly provided using a global health security orientation. However, connecting biodefense and global health security creates shared strategies and markets that can reduce demands on governments to be the only provider by providing the fuel for an economic engine, while addressing biodefensive needs. This article will not fully address the constraints and limitations, but the most prevalent counter-argument to this proposal is that regulatory challenges exist for international alignment. Regardless, starting with stringent regulatory authorities and seeking alignment presents a clear path forward that supports both biodefense and global health security.

Innovation in contracting, agreements, and even the global use of these important tools is paramount to sustainability. The JPM CBRN Medical's Vaccine Acceleration by Modular Progression (VAMP) program leverages lessons learned from the COVID-19 response, employing a modular contracting strategy to accelerate vaccine development.[17] Preparing targeted responses is harder to sustain, but pre-positioning contracts and appropriately flexible agreements for high-impact and probable threats is warranted. Building on platform technologies supports a more easily maintained posture.

The VAMP program leverages an interagency partnership with the HHS' Biomedical Advanced Research and Development Authority (BARDA) - experienced product developers and academia to develop vaccine platform prototypes. The VAMP program delivers prototype vaccines that show immunogenicity and efficacy in animal models and safety in humans. This approach presents a strategic reserve of licensed or authorized for emergency use vaccines against a range of threats that have been identified; the ability to rapidly deploy these vaccines will help to defend the warfighter while acting as a deterrent against adversaries that might exploit perceived vulnerabilities. These same vaccines can be built to target global health security threats, thereby creating a commercial market that can help sustain the capability outside of a warm industrial base.

Additionally, invigorating manufacturing innovation and optimization and supply chain risk management are essential components that the DOD has historically addressed in only limited ways, particularly in biotechnology. Extensive efforts in industrial base expansion during the pandemic suggest that these were issues for HHS and the entire biotechnology enterprise in the U.S. The situation where biotechnology is democratized more and more leads to a greater need to involve U.S. companies in the global health security market due to an increasing need for capabilities at the speed of relevance. Seemingly counterintuitive, U.S. companies who build capabilities (including key starting materials, active pharmaceutical ingredients, and internationally supported manufacturing) are needed for both biodefense and global health security.

These initiatives, above all, rely on one key element: **public-private partnership**. The JPM CBRN Medical mission is not unique; it is complementary to the HHS public health mission, among others. It is also a driver of innovation through the investment of federal dollars and an observable commitment. Global health security relies on partnerships with industry, other

Departments and Agencies with complementary missions, and sustained through a posture that supports readiness, flexibility, and response. Thus, in practice, biodefense and global health security must be coordinated to establish a sustainable posture.

Sustainable Posture Practicalities

Achieving a sustainable posture is easier said than done. A 2014 report by the Tufts Center for the Study of Drug Development claims that the development of a new drug—whether in vaccine or medicinal form—takes 10-15 years at a cost of $2.6 billion.[18] This is staggering, and by no means sustainable, neither for the DOD nor for industry investment, particularly given the breadth of the threats that exist within biodefense.

The primary goal of any military health program is to deliver; the JPM CBRN Medical vision of success is to provide a fully layered, medical countermeasure capability to enable a protected and unencumbered Joint Force to fight and win in any CBRN battlespace. This is a combat focused mission. However, for broader defense and national security objectives, the view must be globally oriented to involve public health partnerships. Preventing certain infectious diseases from threatening U.S. national security or military operations is central to all NATO nations and U.S. interests. NATO's Deterrence by Resilience approach captures the critical function of strengthened civil-military cooperation in Article 3.[19] Further, the JPM CBRN Medical mission is complementary to the HHS public health mission, and we work closely with interagency partners to develop medical countermeasures that support not only the U.S. warfighter, but also civilian populations. The JPM CBRN Medical strives to be the partner of choice for all who defend our national values and interests.

The JPM CBRN Medical has a variety of other concerns to consider. Activities must be appropriately regulated and align with international needs that might become, or already are, JPM CBRN Medical needs. Commercial and governmental cooperation is also necessary to streamline strategies and invest in regulatory science and methods of data analysis that will be mutually beneficial to all. The focus should not be just on what will benefit our specific situation, but what might, in the long term, prove to be a reusable response to more than just one threat. The challenge is that regulatory alignment goes beyond national authority and must include multi-national cooperation, possibly up to the need for treaties that operate when there is a shared emergency declaration. Multiple examples from the COVID experience illustrate this need, particularly for low and middle-income countries.

As the DOD progresses toward the nation's sustainable posture goals, we need a transparent gap analysis process that defines clear and measurable criteria related to our goals. These criteria should be based on data, evidence, and standards, and include our objectives, our current state, and our desired state; the criteria should also document corrective actions that will get the DOD to its goals and objectives faster. The DOD can start this process and promote progress by developing tools for communicating integrated biodefense and global health security gaps. Subsequently, via the United States-run Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and various organizations of the United Nations, shared objectives can be identified. Finally, Congress can show their support by continuing to fund these efforts when represented as targeting global health security due to their link to biodefense.

Manufacturing efforts will greatly benefit from AI/ML opportunities. Any data the JPM CBRN Medical generates must be validated and accurately reflect our experiences. This will allow the JPM CBRN Medical to offer "data as a product" to partners, and promote the commercial viability of a given effort. Because information needs to flow in both directions, we can leverage the DOD's current push to incentivize industry to avail their data to foster research collaboration, further enshrining the "data as a product" mindset in our contracting approaches.[20] These include implementation of performance-based contracts and ensuring the DOD's rights to its own data developed in collaboration with industry (a top challenge noted in a January 2024 Data Economy Study for DOD).

In 2023, the JPEO-CBRND initiated the development of an analytical dashboard as a centralized platform for management of clinical and nonclinical efficacy and safety data of MCMs. The intent of the effort is to enable rapid information transmission and enhanced decision making within advanced development and science and technology programs, while also promoting the idea of data as a product. Access to trusted, validated data from manufacturing and scale-up provides a mechanism for rapid response in the event of a bioincident. Also, in the way of data sharing, there is much to be gained from partner organizations supporting biosurveillance, such as the U.S. Army Combat Capabilities Development Command (DEVCOM) Chemical Biological

Center, U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), the HHS, and the Administration for Strategic Preparedness and Response (ASPR). Implementation of a mechanism for integration with some of these partner organizations' risk and data management tools – such as a blanket memorandum of understanding or memorandum of agreement – would allow disparate organizations access to reliable data while improving efficiency.

In the way of contract modernization, contract writers must accurately define objectives and service levels and ensure that contractors understand what is expected of them. The VAMP program's modular contracting strategy is an example of the benefits of "fit for purpose" agreements. Over the last two years, the JPM CBRN Medical has added flexibility to all contracts to ensure they can pivot towards action in the event of an emergent scenario. This must be institutionalized across the medical research, development, and acquisition space across the government and legislative support is needed to facilitate this area. Liability, no-fault compensation, and risk cannot be a delay in future capability development for tools that will be used internationally.

Maintaining a sustainable posture requires decentralization while simultaneously maintaining local availability. Efforts that are globally distributed run the risk of logistics and supply issues. Globalization affects all supply chains, so from a sustainable posture standpoint, it is important to onshore our efforts and stockpile as required for raw material availability.

It is important to be able to monitor and understand the industrial base and the manufacturing effort required to generate capability. Through the use of flexible manufacturing capabilities, maintaining a resource focus, and creating tools that promote collaboration and data awareness, commercial opportunity can be maximized. These tools, including AI/ML tools, are especially important in that they can facilitate manufacturing and delivery, while also maintaining a focus on quality, consistency, and reliability (trust), which are of the highest priority. Tools for visualization that illustrate opportunities, risks, and track execution are on the horizon as well, which will assist with the goal of promoting partnerships and maximizing commercial opportunity.

For the sustainable posture to stand the test of time, the arrangements between the partners should be resilient, repeatable, and scalable. Contracts, for example, will need to be adaptable to sudden changes. Repeatable processes will ensure that there will be no need to "re-invent the wheel" and cause unnecessary delays. Lastly, scalability should be paramount, allowing the requirements of the mission to easily and quickly ramp up or down based on the need at hand. Requirements, inventory, and early access mechanisms link for an effective biodefense posture; programmatic considerations make it sustainable.

Commercial viability is the engine for biodefense, global health security, and collective defense in the ever-growing field of biotechnology. This includes unleashing the innovation engine housed within industry through use of dual benefit solutions. Industrial might can be mobilized through commercially sustained inventories, contractual flexibility, manufacturing, and innovation. As a result, the capacity for global response—not just military defense—is achieved. And further, this approach affords economies of scale within a commercial model that does not rely on the DOD as a sole source for continuation. The future for a sustainable posture that generates deterrence through resilience for biodefense is decidedly through an integrated approach with a shared focus on global health security. ■

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Notes

1. Lloyd J. Austin, *Biodefense Vision*, Memorandum prepared by the U.S. Department of Defense, November 1, 2021, https://media.defense.gov/2021/Dec/03/2002903201/-1/-1/0/BIODEFENSE-VISION-FINAL.PDF.

2. North Atlantic Treaty Organization, "Resilience, civil preparedness and Article 3," North Atlantic Treaty Organization, last modified November 13, 2024, https://www.nato.int/cps/en/natohq/topics_132722.htm.

3. North Atlantic Treaty Organization, "Vilnius Summit Communiqué," North Atlantic Treaty Organization, July 11, 2023, https://www.nato.int/cps/en/natohq/official_texts_217320.htm.

4. North Atlantic Treaty Organization, "Vilnius Summit."

5. Ramy Abou Ghayda et al., "Estimation of global case fatality rate of coronavirus disease 2019 (COVID-19) using meta-analyses: Comparison between calendar date and days since the outbreak of the first confirmed case," *International Journal of Infectious Diseases* 100, (November 2020): 302-308, https://doi.org/10.1016/j.ijid.2020.08.065.

6. The White House, "U.S. Global Health Security Strategy 2024," The White House, April 2024, https://www.whitehouse.gov/wp-content/uploads/2024/04/Global-Health-Security-Strategy-2024-1.pdf.

7. Jeremiah J. Kelly, "Enhanced Engagement: The Evolving Relationship Between FDA and DoD Regulatory Authorities," *Food and Drug Law Journal* 78, no. 2 (2023): https://www.fdli.org/wp-content/uploads/2023/10/Kelly-Enhanced-Engagement-FDLJ-78-2.pdf; "42 U.S. Code § 247d–7e - Biomedical Advanced Research and Development Authority," Legal Information Institute, accessed December 9, 2024, https://www.law.cornell.edu/uscode/text/42/247d-7e.

8. "Chemical and Biological Defense," Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense, accessed December 9, 2024, https://www.acq.osd.mil/ncbdp/cbd/.

9. "Department of Defense Directive 5134.08, Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs (ASD(NCB))," Executive Services Directorate, accessed December 9, 2024, https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/513408p.pdf?ver=2019-03-27-080414-680.

10. "Department of Defense Directive 5160.05E, Roles and Responsibilities Associated with the Chemical and

Biological Defense Program," Executive Services Directorate, accessed December 9, 2024, https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/516005E.pdf?ver=jWsvS5dgM_U5ZATowKbE6Q%3d%3d.

11. "50 U.S. Code Chapter 32: Chemical and Biological Warfare Program, Sections 1522 and 1523," accessed December 9, 2024, https://uscode.house.gov/view.xhtml?hl=false&edition=prelim&req=granuleid%3AUSC-prelim-title50-chapter32&num=0&saved=%7CKHRpdGxlOjUwIHNlY3Rpb246MTUyMiBlZGl0aW9uOnByZWxpbSkgT1IgKGdyYW51bGVpZDpVU0MtcHJlbGltLXRpdGxlNTAtc2VjdGlvbjE1MjIp%7CdHJlZXNvcnQ%3D%7C%7C0%7Cfalse%7Cprelim

12. "We Are JPEO," Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense, accessed December 9, 2024, https://www.jpeocbrnd.osd.mil/.

13. "About," Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense, accessed December 9, 2024, https://www.jpeocbrnd.osd.mil/About/.

14. "JPM CBRN Medical Countering Emerging Threats – Rapid Acquisition and Investigation of Drugs for Repurposing (CET RAIDR)," JPEO-CBRND, accessed December 9, 2024, https://www.jpeocbrnd.osd.mil/About/Leadership/Joint-Project-Managers-Joint-Project-Leads/JPM-CBRN-Medical-CET-RAIDR/.

15. "Strengthening Warfighter Resiliency Using Broad-Spectrum or Host-Directed Therapies within the Rapid Acquisition and Investigation of Drugs for Repurposing (RAIDR) Program," *Journal of Pharmacology and Experimental Therapeutics* 391, No. 3, (October 2023): https://jpet.aspetjournals.org/content/early/2023/10/12/jpet.123.001721.

16. Kelly Burkhalter, "GUIDE Program Prepares DOD to Defend Against the Unknown," JPEO-CBRND, February 27, 2024, https://www.jpeocbrnd.osd.mil/Media/News/Article/3685461/guide-program-prepares-dod-to-defend-against-the-unknown/.

17. "JPM CBRN Medical Vaccine Acceleration by Modular Progression (VAMP)," JPEO-CBRND, accessed December 9, 2024, https://www.jpeocbrnd.osd.mil/About/Leadership/Joint-Project-Managers-Joint-Project-Leads/JPM-CBRN-Medical-VAMP/.

18. Mullin, Rick. "Cost to Develop New Pharmaceutical Drug Now Exceeds $2.5B," Scientific American, November 24, 2014, https://www.scientificamerican.com/article/cost-to-develop-new-pharmaceutical-drug-now-exceeds-2-5b/.

19. North Atlantic Treaty Organization, "Resilience, civil preparedness and Article 3," North Atlantic Treaty Organization, last updated November 13, 2024, https://www.nato.int/cps/en/natohq/topics_132722.htm.

20. "Building a DOD Data Economy," Defense Innovation Board, accessed 08 12, 2024, https://innovation.defense.gov/Portals/63/20240118%20DIB%20Data%20Economy%20Study_Approved-compressed.pdf.