Congressional Research Service
Informing the legislative debate since 1914

TESTIMONY

Statement of

Bryce H. P. Mendez
Specialist in Defense Health Care Policy

Before

Committee on Armed Services
Subcommittee on Personnel
U.S. Senate

Hearing on

"Department of Defense's efforts to ensure servicemembers' access to safe, high-quality pharmaceuticals"

April 30, 2024

Congressional Research Service
https://crsreports.congress.gov
TE10099

Introduction

Chair Warren, Ranking Member Scott, and distinguished members of the subcommittee, thank you for the opportunity to appear before you today to discuss the Department of Defense's efforts to ensure servicemembers' access to safe, high-quality pharmaceuticals. My name is Bryce Mendez, and I am a specialist in defense health care policy at the Congressional Research Service (CRS). CRS provides Congress with policy research and analysis that is authoritative, objective, and nonpartisan in accordance with our authorizing statute (2 U.S.C. §166).

As requested by the committee, my testimony today will provide an overview of Department of Defense (DOD) medical research and development (R&D) capabilities, discuss how and why DOD uses those capabilities to develop drugs and biologics, and how DOD aims to ensure that developed drugs and biologics are safe and effective for human use.[1] I will also discuss several considerations that Congress may face with regard to DOD medical R&D and manufacturing of drugs and biologics.

Background

The U.S. military has a long history of contributing to the discovery of novel drugs, biologics, prophylactics, and other medical countermeasures. Early and well-known contributions took place during and shortly after the Spanish American War when the Army Surgeon General appointed Dr. Walter Reed, a Major in the U.S. Army, to lead investigations into the causes of Typhoid and Yellow fever.[2] At the time, both infectious diseases, among others, plagued the U.S. military. For example, during the Spanish American War in 1898, more servicemembers died from infectious diseases than combat-related injuries.[3] In particular, Typhoid fever infected over 20,000 soldiers and killed 1,590 soldiers across the Army, resulting in degraded fighting capabilities during the war.[4]

Towards the end of the war, President William McKinley appointed retired Army Major General Grenville M. Dodge to lead an investigation (also referred to as the "Dodge Commission") into the War Department's management of the conflict, including the root causes of infectious disease outbreaks across the force.[5] The commission found that, among other findings, preventive health measures could have been implemented to protect servicemembers from infectious diseases of the time, military-supported discoveries in medical science were necessary to fill knowledge and capability gaps and to attract interest

[1] For the purposes of this testimony, CRS utilizes the U.S. Food and Drug Administration (FDA) definition for "drugs," which refers to substances recognized by an official pharmacopoeia or formulary; intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; intended to affect the structure or any function of the body; or intended for use as a component of a medicine but not a device or a component, part, or accessory of a device. CRS also utilizes the FDA definition for "biologics," which refer to a "wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins." For more on these definitions, see https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms.

[2] John R. Pierce, "Walter Reed - A Name for the Ages," *The Micrograph*, December 22, 2022, at https://medicalmuseum.health.mil/micrograph/index.cfm/posts/2022/walter_reed_a_name_for_the_ages; and Patrick Feng, "Major Walter Reed and the Eradication of Yellow Fever," *The Army Historical Foundation*, April 10, 2024.

[3] Vincent J. Cirillo, "Journal of the History of Medicine and Allied Sciences," *Fever and Reform: The Typhoid Epidemic in the Spanish-American War*, vol. 55 (October 2000), p. 396.

[4] Vincent J. Cirillo, *Bullets and Bacilli: The Spanish-American War and Military Medicine* (New Brunswick, NJ: Rutgers University Press, 2003), p. 71.

[5] U.S. Congress, Senate, *Report of the commission appointed by the President to investigate the conduct of the War Department in the war with Spain*, Volume 1, 56th Cong. (Washington: GPO, 1900), pp. 1-734.

among civilian medical researchers, and that the military could benefit from stockpiling medical supplies during peacetime in order to prepare for future and emergent demands during wartime.[6]

After the war, the Army Medical School continued Dr. Reed's work to explore the causes of Typhoid fever and how to protect soldiers from infection. In 1908, the Army developed and produced their version of a Typhoid vaccine building upon research conducted by the Royal Army Medical College and other European researchers.[7] Successes observed throughout the Army's clinical trials of its Typhoid fever vaccine resulted in a compulsory vaccination requirement in 1911 as a means to protect servicemembers from the potential health threat.[8] The Army's historical investment of military personnel, expertise, and resources to understand the causes of infectious diseases helped to inform future development of new drugs, biologics, and medical technologies.

The lessons learned from the Spanish American War and other conflicts throughout American history have laid the groundwork for both Congress and DOD to invest in, build, and sustain medical R&D capabilities. Today, DOD conducts medical R&D as a means to protect servicemembers from current or future health threats, respond to medical capability requirements of the joint force, and meet the research directives of Congress.

DOD Medical Research and Development

Under Title 10, Section 4001, of the *U.S. Code* (U.S.C.), DOD administers a wide range of R&D programs. DOD R&D primarily focuses on "basic research, applied research, advanced research, and development projects" that are

- necessary to the responsibilities of such Secretary's department in the field of research and development; and either
- relate to weapon systems and other military needs; or
- are of potential interest to the DOD.[9]

In general, DOD conducts medical R&D based on the "needs of the National Defense Strategy and the Joint Capabilities Integration and Development System" and in response to Congressionally Directed

[6] Ibid; Vincent J. Cirillo, *Bullets and Bacilli: The Spanish-American War and Military Medicine* (New Brunswick, NJ: Rutgers University Press, 2003), p. 153; James E. Hewes Jr., "The War Department From Root To Marshall," in *From Root to McNamara: Army Organization and Administration* (Washington, DC: U.S. Army Center of Military History, 1983); and Edward Ranson, "The Investigation of the War Department, 1898-99," *The Historian*, vol. 34, no. 1 (November 1971), pp. 78-99.

[7] Frederick F. Russell, "Anti-Typhoid Vaccination in the American Army," *Journal of the American Public Health Association*, vol. 1, no. 7 (July 1911), pp. 473-479; Robert M. Hardaway III, "Contributions of Army Medicine to Civilian Medicine," *Military Medicine*, vol. 138, no. 7 (July 1973), pp. 409-412; and Rufus L. Holt and Arthur P. Hitchens, "Typhoid Vaccine: The Technique of Its Preparation at the Army Medical School," *Public Health Reports*, vol. 52, no. 26 (June 25, 1937), pp. 829-844.

[8] John D. Grabenstein, Phillip R. Pittman, and John T. Greenwood, et al., "Immunization to Protect the US Armed Forces: Heritage, Current Practice, and Prospects ," *Epidemiologic Reviews*, vol. 28, no. 1 (August 2006), pp. 3-26; W. D. Tiggertt, "The Initial Effort to Immunize American Soldier Volunteers with Typhoid Vaccine," *Military Medicine*, vol. 124, no. 5 (May 1959), pp. 342-349; and Andrew W. Artenstein, Jason M. Opal, and Steven M. Opal, et al., "History of U.S. Military Contributions to the Study of Vaccines," *Military Medicine*, vol. 170, no. Suppl 4 (April 2005), pp. 3-11.

[9] 10 U.S.C. §4001. For FY2024, Congress appropriated $148.3 billion for DOD research, development, test, and evaluation activities (see explanatory statement accompanying P.L. 118-47, *Congressional Record*, March 22, 2024, p. H1644. For more on DOD research and development (R&D) programs and historical funding amounts, see CRS Report R47564, *Federal Research and Development (R&D) Funding: FY2024*, coordinated by John F. Sargent Jr.; CRS Report R44711, *Department of Defense Research, Development, Test, and Evaluation (RDT&E): Appropriations Structure*, by John F. Sargent Jr.; CRS In Focus IF10553, *Defense Primer: RDT&E*, by John F. Sargent Jr. Congressional offices may also contact Marcy E. Gallo, CRS analyst in science and technology policy, for more on DOD R&D programs and funding.

Medical Research Programs (CDMRP).[10] DOD has three goals in conducting medical R&D, which are to ensure that the joint force is "(1) better prepared, (2) better protected, and (3) better cared for throughout the operational life cycle."[11] To achieve these goals, DOD organizes its medical R&D efforts under the following focus areas:

- biomedical informatics and health information systems and technology;
- clinical and rehabilitative medicine;
- combat casualty care;
- medical chemical and biological defense;
- medical radiological defense;
- military infectious diseases; and
- military operational medicine.[12]

DOD Medical R&D Enterprise

The DOD medical R&D enterprise is composed of multiple entities. These entities include the Defense Health Agency (DHA), Uniformed Services University of the Health Sciences (USUHS), the military services' medical departments, Defense Advanced Research Projects Agency, Chemical and Biological Defense Program, and the Defense Threat Reduction Agency. DOD synchronizes these entities through the Armed Services Biomedical Research Evaluation and Management Community of Interest (ASBREM CoI).[13] The ASBREM CoI serves as the primary coordination body for DOD's medical research community and to "prevent unnecessary duplication of effort."[14] While the ASBREM CoI helps advance "communication, coordination, and collaboration" across the DOD medical R&D enterprise, individual entities are responsible for resourcing and performing (or sponsoring) medical R&D projects and activities.[15]

[10] Department of Defense (DOD), "Department of Defense Strategic Medical Research Plan," January 2019, p. 6, at https://health.mil/Reference-Center/Congressional-Testimonies/2019/04/08/Strategic-Medical-Research-Plan. For more on the National Defense Strategy, see CRS Report R45349, *The 2018 National Defense Strategy: Fact Sheet*, by Kathleen J. McInnis. For more on the Joint Capabilities Integration and Development System, see pp. 3-4 of CRS Report RL34026, *Defense Acquisitions: How DOD Acquires Weapon Systems and Recent Efforts to Reform the Process*, by Heidi M. Peters. For more on Congressionally Directed Medical Research Programs, see CRS Report R46599, *Congressionally Directed Medical Research Programs: Background and Issues for Congress*, by Bryce H. P. Mendez. Congressional offices may contact Alexandra G. Neenan, CRS analyst in U.S. defense acquisition policy, for more on DOD acquisition policy; and John W. Rollins, CRS specialist in terrorism and national security, for more on the National Defense Strategy.

[11] DOD, "Department of Defense Strategic Medical Research Plan," January 2019, p. 11.

[12] Ibid., p. 6.

[13] The role of the Armed Services Biomedical Research Evaluation and Management Community of Interest (ASBREM CoI), formerly known as the ASBREM Committee, is to "promote the coordination and synergy of the DoD biomedical R&D efforts to provide medical products and information" required to protect and sustain servicemembers. For more on the ASBREM, see Department of Defense (DOD), *Integrated DoD Biomedical Research and Development Strategy*, Medical Innovation for the Future Force, December 2017, p. iii, https://defenseinnovationmarketplace.dtic.mil/wp-content/uploads/2018/04/ASBREM_Integrated_RD_Strategy_2017.pdf.

[14] DOD Directive 6025.21E, "Medical Research for Prevention, Mitigation, and Treatment of Blast Injuries," updated October 15, 2018, p. 1, at https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/602521p.pdf.

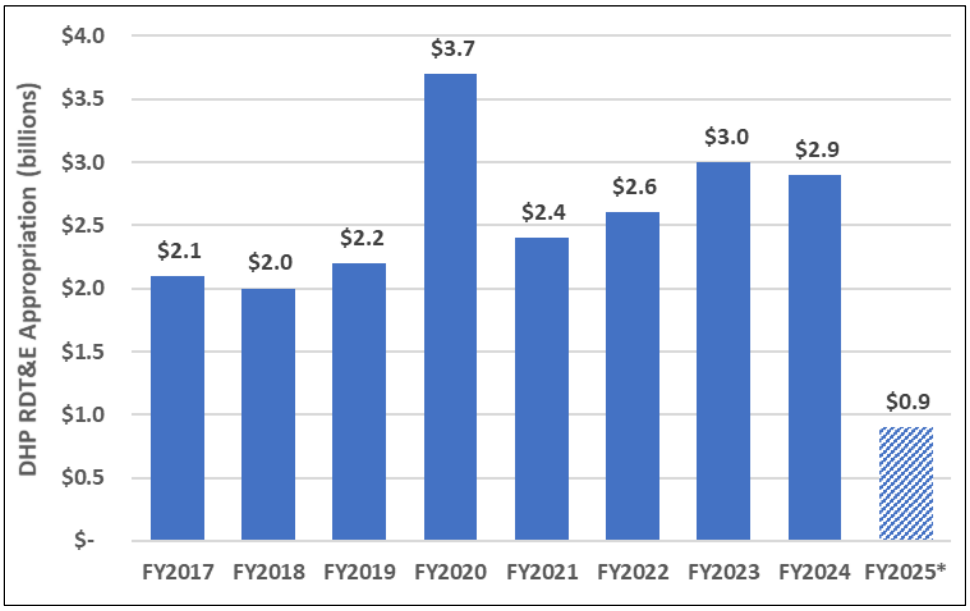
[15] DOD, Department of Defense Strategic Medical Research Plan, January 2019, p. 8.

DOD Medical R&D Funding

DOD has the second-largest departmental expenditures on medical research, after the National Institutes of Health (NIH).[16] Each year, DOD submits its funding request for medical R&D activities and projects as part of the President's annual budget request. Congress evaluates, adjusts, and appropriates discretionary funding for medical R&D activities that DOD may, or may not, have requested. Congress appropriates these funds through an annual DOD appropriations act; the funds are further distributed to the research entities through numerous Research, Development, Test, and Evaluation (RDT&E) budget activities and program elements.[17] Since many DOD entities conduct or fund these activities, there is no consolidated request, appropriations account, budget activity, or program element that incorporates the totality of all medical R&D. One of the DOD accounts that funds medical R&D activities is the Defense Health Program (DHP).[18] The DHP account funds "medical and health care programs," including certain RDT&E programs.[19] DOD often uses DHP RDT&E funding to resource medical research activities throughout the medical R&D enterprise.[20] **Figure 1** shows the amount of RDT&E funding appropriated to the DHP account between FY2017 and FY2024, and the amount requested by DOD for FY2025.

Figure 1. RDT&E Appropriations for the Defense Health Program Account

FY2017-FY2025 Request*



Source: CRS In Focus IF12377, *FY2024 Budget Request for the Military Health System*, by Bryce H. P. Mendez; CRS In Focus IF11206, *FY2020 Budget Request for the Military Health System*, by Bryce H. P. Mendez; Explanatory Statement accompanying P.L. 118-47, *Congressional Record*, March 22, 2024, p. H1718; and DOD, "Defense Health Program, Fiscal Year (FY) 2025

[16] Research America, *U.S. Investments in Medical and Health Research and Development, 2016-2020*, January 2022, p. 7, at https://www.researchamerica.org/wp-content/uploads/2022/09/ResearchAmerica-Investment-Report.Final_.January-2022-1.pdf.

[17] For more on DOD appropriations for RDT&E, see CRS Report R44711, *Department of Defense Research, Development, Test, and Evaluation (RDT&E): Appropriations Structure*, by John F. Sargent Jr.

[18] For more on the DHP account, see CRS In Focus IF12377, *FY2024 Budget Request for the Military Health System*, by Bryce H. P. Mendez; and Question 2 ("How is the Military Health System Funded?") of CRS Report R45399, *Military Medical Care: Frequently Asked Questions*, by Bryce H. P. Mendez.

[19] 10 U.S.C. §1100.

[20] Defense Health Board, *Improving Defense Health Program Medical Research Processes*, August 8, 2017, pp. 9-14, 44-54; at https://health.mil/Reference-Center/Reports/2017/08/08/Improving-Defense-Health-Program-Medical-Research-Process.

President's Budget," March 2024, p. 1, at https://comptroller.defense.gov/Portals/45/Documents/defbudget/FY2025/budget_justification/pdfs/09_Defense_Health_Program/00-DHP_Vols_I_and_II_PB25.pdf.

Notes: *Dollar amount represents DOD request for FY2025 DHP RDT&E. Since 1992, Congress has typically appropriated additional dollars to the DHP RDT&E account for the Congressionally Directed Medical Research Programs (CDMRP). The FY2025 request does not reflect an amount for the CDMRP. RDT&E = Research, Development, Test, and Evaluation.

DOD Capabilities to Develop Drugs and Biologics

DOD has existing capabilities to develop and manufacture (on a limited scale) drugs and biologics to protect servicemembers from current or future health threats. These capabilities use different manufacturing approaches, including strategic partnerships with public and private entities, to meet certain medical R&D objectives and other military requirements for *force health protection*.[21] These partnerships can take many forms, including a contractual agreement, grant award, cooperative research and development agreement (CRADA), or Other Transaction Authority.[22] In addition, DOD typically negotiates terms for medical technology transfer, allowing a partner entity to retain certain intellectual property rights for further development or commercial use purposes.[23]

Army Pilot Bioproduction Facility

The Walter Reed Army Institute of Research (WRAIR) administers a "pharmaceutical manufacturing facility" in Silver Spring, MD, known as the Pilot Bioproduction Facility (PBF). In 1953, the Army Medical Department established the PBF as a government-owned, government-operated manufacturing capability.[24] The function of the PBF is to assist in the early development and small-scale production of drugs and biologics to defend against "military-relevant infectious disease threats."[25] According to WRAIR, the PBF is compliant with U.S. Food and Drug Administration (FDA) regulations on current Good Manufacturing Practice (cGMP),[26] certified for biosafety level-2 (BSL-2) research,[27] and has developed drugs and biologics to address Hepatitis A, Japanese encephalitis, Malaria, Zika, COVID-19, and others.[28] The PBF capability allows WRAIR to provide a test ground to produce and transition newly

[21] DOD defines *force health protection* (FHP) as measures taken to "promote, protect, improve, conserve, and restore the mental and physical well being of Service members across the range of military activities and operations." For more on FHP, see DOD Directive 6200.04, *Force Health Protection (FHP)*, updated April 23, 2007, at https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/620004p.pdf.

[22] Army Medical Research and Development Command, "Medical Technology Transfer," May 17, 2019, at https://technologytransfer.health.mil/index.cfm?pageID=about_tech_transfer; CRS Report R45521, *Department of Defense Use of Other Transaction Authority: Background, Analysis, and Issues for Congress*, by Heidi M. Peters; and DOD, "Other Transactions Guide," July 2023, at https://www.acq.osd.mil/asda/dpc/cp/policy/docs/guidebook/TAB%20A1%20-%20DoD%20OT%20Guide%20JUL%202023_final.pdf.

[23] Army Medical Research and Development Command, "Medical Technology Transfer," May 17, 2019; WRAIR briefing and discussions with CRS, October 2023; DOD Instruction 5535.08, *DoD Domestic Technology Transfer Program*, September 22, 2022, at https://www.esd.whs.mil/portals/54/documents/dd/issuances/dodi/553508p.pdf; and Defense Health Agency Procedural Instruction 3201.05, *Technology Transfer (T2) Program*, June 20, 2019, at https://www.health.mil/Reference-Center/DHA-Publications/2019/06/20/DHA-PI-320105.

[24] Walter Reed Army Institute of Research (WRAIR), "Pilot Bioproduction Facility," accessed April 5, 2024, at https://wrair.health.mil/Collaborate/Pilot-Bioproduction-Facility/.

[25] Ibid.

[26] For more on current Good Manufacturing Practice (cGMP) regulations, see https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations; and CRS In Focus IF11083, *Medical Product Regulation: Drugs, Biologics, and Devices*, by Amanda K. Sarata and Hassan Z. Sheikh.

[27] For more on laboratory biosafety levels, see https://www.phe.gov/s3/BioriskManagement/biocontainment/Pages/BSL-Requirements.aspx.

[28] Kenneth H. Eckels, "Product Development for the Warfighter," presentation to the Association of the U.S. Army, Washington, (continued...)

developed drugs and biologics into "advanced clinical trials and licensure."[29] WRAIR partners with public and private biomedical research entities to explore and develop drugs and biologics that address current and future health threats.[30]

DOD Advanced Development and Manufacturing Biopharmaceutical Facility

The Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND), an office under the Chemical and Biological Defense Program, administers the DOD Advanced Development and Manufacturing (ADM) Biopharmaceutical Facility located in Alachua, FL.[31] The ADM facility is a contractor-owned, contractor-operated facility that provides DOD with an "enduring capability and infrastructure" to meet military medical requirements and the "capability for agile and flexible advanced development and manufacturing" of medical countermeasures.[32] In December 2010, then-Assistant to the President for Homeland Security, John O. Brennan, transmitted a memorandum calling for the Secretary of Defense to "establish agile and flexible advanced development and manufacturing capabilities to support the development, licensure, and production of medical countermeasures."[33] In response to this directive, on March 21, 2013, Army Contracting Command awarded a $135.8 million contract to then-Nanotherapeutics Inc. to build and operate the ADM facility, which provides DOD with "priority access" to the contractor's manufacturing capabilities in order to "produce medical countermeasures more quickly and more effectively than other drug makers."[34] According to JPEO-CBRND, the ADM facility is compliant with cGMP regulations, certified for biosafety level-3 (BSL-3) research, and has developed biologics to address COVID-19, Botulism neurotoxin, and other health threats.[35]

DC, July 25, 2017, at https://www.ausa.org/sites/default/files/army-medical-eckels.pdf; and WRAIR, "Pilot Bioproduction Facility (PBF)," fact sheet, November 2022, at https://wrair.health.mil/Portals/87/Documents/PBF%20Handout%202022_Updated_21NOV22_final.pdf.

[29] Ibid; and WRAIR briefing and discussions with CRS, October 2023.

[30] Ibid.

[31] Kelly Burkhalter and Chris Southworth, "Enduring Capability: JPEO-CBRND evolves public/private partnership with National Resilience," *JPEO-CBRND News*, December 5, 2023, at https://www.jpeocbrnd.osd.mil/Media/News/Article/3607443/enduring-capability-jpeo-cbrnd-evolves-publicprivate-partnership-with-national/#:~:text=Located%20in%20Alachua%2C%20Florida%2C%20the,agents%20and%20emerging%20infectious%20 diseases.

[32] SAM.gov, "A—Medical Countermeasure Manufacturing Advanced Development Manufacturing (ADM) Capability," Presolicitation Notice ID W911QY11R0023, August 9, 2011, at https://sam.gov/opp/6d98c844d9d76510d7cf6bfdeffcf33e/view.

[33] U.S. Government Accountability Office (GAO), *Biological Defense: Additional information that Congress may find useful as it considered DOD's advanced development and manufacturing capability*, GAO-17-701, July 2017, p. 7, at https://www.gao.gov/assets/gao-17-701.pdf; and White House, Memorandum for the Secretary of Defense, "Medical Countermeasures against Biological and Other Public Health Threats," December 29, 2010.

[34] DOD, "Contracts for March 21, 2013," accessed April 8, 2024, at https://web.archive.org/web/20130408205027/http://www.defense.gov/contracts/contract.aspx?contractid=5002; Kelly Burkhalter, "Enduring Capability: JPEO-CBRND evolves public/private partnership with National Resilience," *JPEO-CBRND News*, December 4, 2023, at https://www.dvidshub.net/news/459375/enduring-capability-jpeo-cbrnd-evolves-public-private-partnership-with-national-resilience; and Anthony Clark, "U.S. Department of Defense Expands Medical Countermeasure Capabilities," *JPEO-CBRND News*, December 20, 2016, at https://www.jpeocbrnd.osd.mil/Media/News/Article/2597346/us-department-of-defense-expands-medical-countermeasure-capabilities/. In 2017, Nanotherapeutics, Inc. was renamed to Ology Bioservices, Inc. In 2021, National Resilience, Inc. acquired Ology Bioservices.

[35] Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND), "Medical Countermeasures Advanced Development and Manufacturing (ADM), accessed April 8, 2024, at https://www.jpeocbrnd.osd.mil/Portals/90/fact-sheet_adm.pdf; JPEO-CBRND, "JPEO-CBRND Capabilities Catalog," 2023, at https://www.jpeocbrnd.osd.mil/Portals/90/Documents/JPEO-CBRND_Capabilities%20Catalog_20%20April%202023_Final.pdf; and Hannah Feldman, Chris Earhart, and Traci Pals, "Toxic at Best," *JPEO-CBRND News*, January 22, 2019, at https://www.jpeocbrnd.osd.mil/Media/News/Article/2593990/toxic-at-best/.

Ensuring Safe and Effective Drugs and Biologics

Prior to the enactment of the Federal Food, Drug, and Cosmetic Act (FFDCA; 52 Stat. 1040) in 1938, the military administered its own procedures to ensure drugs and biologics used on servicemembers were safe and effective.[36] In 1964, DOD and FDA entered into a Memorandum of Understanding (MOU) to ensure requirements enacted in the FFDCA, the Drug Amendments Act of 1962 (P.L. 87-781), and related regulations were "fully met without jeopardizing or impeding the requirements of national security or the requirements of Federal laws and regulations related to such use of drugs."[37] Under a 1974 MOU, DOD agreed to adhere to the FDA regulatory requirements governing the "investigational use of new drugs and medical devices in human beings," informed consent, and Institutional Review Board procedures.[38] Today, DOD generally adheres to FDA requirements and procedures designed to ensure developed drugs and biologics are deemed safe and effective for human use.[39]

Congress has enacted several laws to provide DOD with a process to request a presidential waiver of certain FDA requirements, including requirements for administering investigational new drugs or off-label uses of a drug,[40] and informed consent for certain "products authorized for emergency use."[41] In addition, Congress has authorized DOD to request an expedited FDA review, approval, and clearance process for certain medical products when there is an existing or "significant potential for a military emergency, involving a specific and imminently life-threatening risk to United States military forces of attack with an agent or agents, and the medical product that is the subject of such application, submission, or notification would be reasonably likely to diagnose, prevent, treat, or mitigate such life-threatening risk."[42]

In January 2018, DOD and FDA outlined their initial work plan to enhance collaboration and coordination to "see safe and effective products more efficiently reach those protecting our Nation."[43]As of March 2024, DOD and FDA have 10 MOUs in effect that provide frameworks on how both federal entities are to interact in the development of safe and effective medical products that serve the military's needs, facilitate information sharing, and to clarify interagency cooperation on issues relating to safety and effectiveness of drugs, biologics, and other medical products.[44]

---

[36] Guy R. Hasegawa, "Pharmacy in the American Civil War," *Pharmacy in History*, vol. 42, no. 3/4 (2000), pp. 67-86.

[37] Jeremiah J. Kelly, "Enhanced Engagement: The Evolving Relationship between FDA and DoD Regulatory Authorities," *Food and Drug Law Journal*, vol. 78, no. 2 (October 2023), p. 159, at https://www.fdli.org/2023/10/enhanced-engagement-the-evolving-relationship-between-fda-and-dod-regulatory-authorities-open-access/.

[38] FDA, "Memorandum of Understanding between the Food and Drug Administration and the Department of Defense Concerning Investigational Use of Drugs, Antibiotics, Biologics, and Medical Devices by the Department of Defense," MOU 224-75-3003, accessed April 8, 2024, at https://www.fda.gov/about-fda/domestic-mous/mou-224-75-3003. The regulatory requirements include those specified in Parts 50, 56, 312, and 812 of Title 21, *Code of Federal Regulations*. DOD and FDA last updated the MOU in 1987, which is still in effect.

[39] For more on how FDA approves new drugs and biologics, see CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, by Hassan Z. Sheikh.

[40] 10 U.S.C. §1107. DOD Instruction 6200.02, *Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs*, implements this statutory authority.

[41] 10 U.S.C. §1107a. DOD Instruction 6200.02, *Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs*, implements this statutory authority.

[42] P.L. 115-92.

[43] FDA, "Initial Work Plan for Products Relevant to the Department of Defense (DoD), January 2018, at https://www.fda.gov/media/110237/download.

[44] FDA, "Domestic MOUs," March 21, 2024, at https://www.fda.gov/about-fda/fda-memoranda-understanding/domestic-mous.

Considerations for Congress

Defining the Role of DOD Manufacturing Capabilities

The role of DOD's government-owned (sometimes referred to as *organic*) manufacturing capabilities is limited to the early research and development phases of novel drugs and biologics intended to protect servicemembers from certain health threats. Since the 1950s, the Army Pilot Bioproduction Facility (PBF) has supported this function by conducting limited, in-house manufacturing of newly developed drugs and biologics for the clinical trials process.[45] WRAIR asserts that the PBF "fills a crucial need in a very important part of the vaccine production pipeline" since the "the availability of independent facilities willing to manufacture a full range of Phase 1 production under one roof is extremely limited."[46] Army scientists have also suggested that facilities like the PBF "remove some of the risk perceived by commercial partners looking for products emerging from early research and development phases," while acknowledging that DOD "does not have a suitable mechanism for manufacturing and fill/finish capability" in late-stage product development and scaling.[47]

Congress could consider further defining or clarifying any role DOD has or might have in conducting in-house manufacturing of drugs and biologics. Congress could direct DOD to expand, contract, or sustain its drug and biologics manufacturing capabilities or capacity based on Congress's assessment of needs to mitigate broader supply chain resiliency challenges, to meet military requirements for medical countermeasures, or to avoid unintended effects on the commercial market. Another question that Congress could consider is whether or not DOD's capabilities to manufacture drugs and biologics should extend to non-military purposes (e.g., supporting the availability of medical countermeasures for public health emergencies or to address existing drug shortages). In calendar year 2022, the FDA was notified of 1,293 potential drug and biological product shortage situations.[48] An FDA-led interagency task force found three major root causes of drug shortages:

- lack of incentives to produce less profitable drugs;
- the market does not recognize and reward manufactures for mature quality management systems; and
- logistical and regulatory challenges make it difficult for the market to recover after a disruption.[49]

Expanded DOD manufacturing capabilities or capacity could address some of these root causes since the military is not a profit-driven entity and DOD adheres to quality management standards (e.g., cGMP regulations) and quality control measures throughout the medical R&D and manufacturing continuum. If Congress were to assess that DOD's manufacturing capabilities should be used to mitigate national drug

[45] For more on clinical trials, see CRS Legal Sidebar LSB10483, *Testing, Testing, (Phase) 1-2-3: Legal Considerations for Clinical Trials of Potential COVID-19 Vaccines*, by Erin H. Ward.

[46] Samir Deshpande, "WRAIR Re-launches Vaccine Manufacturing Facility," *Defense Visual Information Distribution Service*, May 6, 2021, at https://www.dvidshub.net/news/395778/wrair-re-launches-vaccine-manufacturing-facility. "Phase 1 production" refers to small-batch manufacturing of drugs or biologics used to evaluate its safety in a small group of test subjects and to identify side effects (i.e., Phase 1 clinical trial).

[47] Jeffrey M. Osgood, Jeffrey W. Froude, and Sherri P. Daye, et al., "Cross-Cutting Lessons Learned During the COVID-19 Pandemic—the Walter Reed Army Institute of Research Experience," *Military Medicine*, vol. 188, no. 1-2 (January-February 2023), pp. 158-165. "Fill/finish capability" refers to a portion of the manufacturing process that includes filling, labeling, packaging, and quality inspection of drugs or biologics prior to distribution.

[48] FDA, "Report to Congress, Drug Shortages CY2022," June 7, 2023, p. 9, at https://www.fda.gov/media/169302/download?attachment.

[49] FDA, "Drug Shortages: Root Causes and Potential Solutions," updated February 21, 2020, p. 6, at https://www.fda.gov/media/131130/download?attachment.

shortage issues, additional authorities or investments may be necessary. In 2019, the Defense Health Agency Deputy Assistant Director for Healthcare Operations testified to the U.S.-China Economic and Security Review Commission that DOD is "neither authorized, by law, nor funded to produce commercial pharmaceuticals."[50] Congress could consider whether or not to provide an explicit authority, appropriations, or parameters for DOD to expand its manufacturing capabilities for non-military purposes. Congress also could assess whether DOD's manufacturing capabilities should be utilized only for military-specific requirements and to prevent a duplication of effort with existing whole-of-government actions that "enable investment in domestic manufacturing."[51]

Addressing Commercial Interest and Perceptions of Risk

Since at least 1990, DOD has identified concerns with its ability to "acquire and maintain the capability to research, develop and manufacture medical countermeasures."[52] A 2009 study found that biopharmaceutical companies had few incentives to work with DOD on the development of medical countermeasures, citing "low profit margins, the risk of liability for adverse reactions to the products, marginal federal funding … and inconsistent priorities" as obstacles to public-private cooperation in this area.[53] Some biopharmaceutical companies have expressed that certain incentives could be used by the federal government to encourage companies to partner with DOD and other U.S. government agencies, including

- direct incentives that provide a "steady revenue commensurate with shareholder expectations" through guaranteed payments for developed and manufactured products, or
- indirect incentives that offer provisions to financially benefit a company's commercial efforts, including excess capability to produce commercial products in a government-owned, contractor-operated manufacturing model, intellectual property rights, and expedited FDA reviews and approvals.[54]

Congress could assess the effectiveness of DOD's medical R&D and manufacturing approach on the propensity of the commercial biopharmaceutical industry to work with the military. Congress has given

[50] Testimony of Defense Health Agency Deputy Assistant Director for Healthcare Operations, in U.S. Congress, U.S.-China Economic and Security Review Commission, "Exploring the Growing U.S. Reliance on China's Biotech and Pharmaceutical Products," hearings, 116th Cong., 1st sess., July 31, 2019, at https://www.uscc.gov/sites/default/files/Priest%20US-China%20Commission%20Statement.pdf.

[51] Department of Health and Human Services, "Biden-Harris Administration Announces Actions to Bolster Medical Supply Chain," press release, November 27, 2023, at https://www.hhs.gov/about/news/2023/11/27/biden-harris-administration-announces-actions-bolster-medical-supply-chain.html; and Executive Office of the President, National Science and Technology Council, "National Strategy for Advanced Manufacturing," October 2022, at https://www.whitehouse.gov/wp-content/uploads/2022/10/National-Strategy-for-Advanced-Manufacturing-10072022.pdf.

[52] Secretary of Defense Memorandum to the Assistant Secretary of Defense for Health Affairs, "Expansion of Industrial Base for Biological Vaccine Production," October 3, 1990, at https://gulflink.health.mil/va/va_refs/n46en061/970107_sep96_decls48_0001.htm; DOD Memorandum for the Record, "Fourth Tri-Service Task Force (Project Badger) Meeting," October 26, 1990, at https://gulflink.health.mil/va/va_refs/n46en067/102596_sep96_decls4_0002.htm; and GAO, *Biological Defense: Additional information that Congress may find useful as it considered DOD's advanced development and manufacturing capability*, GAO-17-701, July 2017, p. 1.

[53] Thomas Fuerst, Kim Wallace, and Phillip Gomez, et al., *Ensuring Biologics Advanced Development and Manufacturing for the United States Government: A Summary of Key Findings and Conclusions*, University of Pittsburgh Medical Center, October 6, 2009, pp. 1-2, at https://apps.dtic.mil/sti/tr/pdf/ADA506569.pdf.

[54] Ibid., pp. 79-80; Bobby Clark and Jeff Callis, "Public Good vs. Private Gain: The Role of Public–Private Partnerships in Drug Innovation and Pricing," *The Commonwealth Fund*, June 8, 2022, at https://www.commonwealthfund.org/blog/2022/public-good-vs-private-gain-role-public-private-partnerships-drug-innovation-and-pricing; and PhRMA, *The Power and Promise of a Collaborative Biopharmaceutical Ecosystem*, March 2021, pp. 22-23, at https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/PhRMA_EcosystemMarch-Report_FINAL.pdf.

DOD certain authorities and tools that it may use to generate interest among potential industry partners, reduce regulatory barriers, and mitigate some associated risks. These include traditional and non-traditional contracting approaches under the Defense Acquisition System,[55] technology transfer

[55] Traditional federal contracting mechanisms include those subject to the Federal Acquisition Regulation (FAR) and Defense Federal Acquisition Regulation Supplement (DFARS), while non-traditional federal contracting mechanisms include Other Transaction Authorities, procurement for experimental purposes, and R&D agreements. For more on DOD contracting mechanisms, see CRS Report RL34026, *Defense Acquisitions: How DOD Acquires Weapon Systems and Recent Efforts to Reform the Process*, by Heidi M. Peters; and CRS Report R45521, *Department of Defense Use of Other Transaction Authority: Background, Analysis, and Issues for Congress*, by Heidi M. Peters. Congressional offices may contact Alexandra G. Neenan, CRS analyst in U.S. defense acquisition policy, for more on DOD acquisition policy.

opportunities, and a process for expedited FDA reviews and approvals. Congress could evaluate whether DOD has used these authorities and tools as Congress intended, including whether or not it has been utilized to alleviate industry concerns or to address commercial interest in doing business with the military for advanced development and manufacturing of drugs and biologics.

Conclusion

Thank you for the opportunity to testify. I look forward to responding to any questions that you may have. If additional research and analysis related to these issues would be helpful, CRS is prepared to assist.

Disclaimer