OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND READINESS

APR - 8 2019

The Honorable James M. Inhofe
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The enclosed report is in response to section 736 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Public Law 115-232), "Strategic Medical Research Plan," directing the Secretary of Defense to submit a comprehensive medical research plan to the congressional defense committees. The plan includes descriptions of medical research focus areas, coordination processes, Defense Health Program and Congressionally Directed Medical Research Program medical research projects, and efforts to coordinate across the federal government.

The scope of the plan included all Department of Defense (DoD) biomedical research; the Armed Services Biomedical Research, Evaluation and Management (ASBREM) Community of Interest (CoI) served as the coordination group for developing the strategic medical research plan. The ASBREM CoI is uniquely suited with representatives from 20 departments and agencies across the DoD that perform or sponsor biomedical research. The workgroup came to a consensus with a unified vision, mission, and goals for an integrated DoD medical research and development enterprise approach to meet the needs of the current and the future force.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families. A similar letter is being sent to the other congressional defense committees.

Sincerely,

James N. Stewart
Assistant Secretary of Defense for Manpower and Reserve Affairs, Performing the Duties of the Under Secretary of Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Jack Reed
Ranking Member

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND READINESS

APR - 8 2019

The Honorable Adam Smith
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

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James N. Stewart
Assistant Secretary of Defense for Manpower and Reserve Affairs, Performing the Duties of the Under Secretary of Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable William M. "Mac" Thornberry
Ranking Member

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND READINESS

The Honorable Nita M. Lowey
Chairwoman
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

APR - 8 2019

Dear Madame Chairwoman:

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James N. Stewart
Assistant Secretary of Defense for Manpower and Reserve Affairs, Performing the Duties of the Under Secretary of Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Kay Granger
Ranking Member

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND READINESS

The Honorable Richard C. Shelby
Chairman
Committee on Appropriations
United States Senate
Washington, DC 20510

APR - 8 2019

Dear Mr. Chairman:

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James N. Stewart
Assistant Secretary of Defense for Manpower and Reserve Affairs, Performing the Duties of the Under Secretary of Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Patrick J. Leahy
Vice Chairman

Report to Congress

Department of Defense Strategic Medical Research Plan

Response to Section 736 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Public Law 115-232)

January 2019

The estimated cost of this report or study for the Department of Defense is approximately $94,000 in Fiscal Years 2018 - 2019. This includes $65,000 in expenses and $29,000 in DoD labor.

NDAA 2019 Section 736 Strategic Medical Research Plan

Executive Summary

The 2019 Department of Defense (DoD) Strategic Medical Research Plan responds to section 736 of the John S. McCain National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2019 (Public Law 115-232) to produce a strategic medical research plan that describes DoD medical research focus areas, medical research projects, coordination processes across defense medical research and development (R&D) to ensure alignment with mission, promote synergy, address gaps, and minimize duplication, and efforts to coordinate with other departments and agencies of the federal government.

The strategic medical research plan provides an overarching strategy for achieving the medical advances necessary for ensuring that the U.S. Armed Forces are ready to meet future health services challenges with optimized health, enhanced medical capabilities, seamless medical care for Service members, and optimization of resources.

Vision: An integrated DoD medical R&D enterprise providing timely solutions to enable a healthy and protected military force that is ready for any mission

Mission: Discover, develop, and deliver medical solutions that enable DoD to provide a ready medical force and a medically ready force.

Goals: The Defense medical R&D enterprise strives to ensure that the Joint Force is (1) Better prepared, (2) Better protected, and (3) Better cared for throughout the operational life cycle.

Objectives

1. Drive innovation in DoD medical R&D.
2. Maintain strong medical R&D partnerships and leverage synergies with other government agencies, industry, and academia.
3. Coordinate and integrate medical R&D portfolios across DoD.
4. Further optimize resource management and efficiencies.

In summary, the need for agility and responsiveness across all levels and types of medical care requires an R&D strategy that is nimble, responsive, and attuned to emerging needs of the warfighter, nested within national strategic guidance, and capitalizes on opportunities in science and technology. It also requires partnerships at home and abroad. This strategy offers a common framework to ensure that DoD continues to discover, develop, and deliver the medical capabilities required today and in the future. It provides the basis on which to optimize infrastructure, coordination, and information exchange among the Services and defense agencies across DoD, Federal Interagency, and the civilian sector to continue to be responsive to both contemporary medical readiness requirements and future needs of the warfighter.

I. Introduction

Military medical R&D is a vital national security interest that ensures the readiness of our Service personnel and enables U.S. forces' lethality overmatch in current and future conflicts against peer and near-peer adversaries. The capabilities discovered, developed, and deployed enhance the life cycle of military medicine, from pre-deployment to deployment operations that include pre-hospital and field care, evacuation and en route care, and through to recovery care and rehabilitation. As such, our nation's investment in military medical R&D is central to sustaining and improving a "medically ready force" and a "ready medical force."

In addition to its contribution to supporting military operations, military medical R&D promotes improvements in the practice of medicine and in the overall health of the nation, and more specifically those eligible for care through the Military Health System (MHS). Advances in medicine resulting from DoD and military department investment in medical R&D have provided strategies, for example, for preventing, controlling, and treating infectious disease outbreaks, and for improved trauma care and survival, traumatic brain injury (TBI) identification and treatment, and treatment of multiple chronic and fatal diseases. The advances that result from these investments benefit our warfighters, those eligible for care in the MHS, and the nation.

This document provides DoD's response to a requirement from Congress to produce a strategic medical research plan. The strategic medical research plan provides an overarching strategy for achieving the medical advances necessary for ensuring that the U.S. Armed Forces are ready to meet future health services challenges with optimized health, enhanced medical capabilities, and seamless medical care for Service members.

The challenges on which this strategy focuses include the prerequisite to support forces that are geographically dispersed over great distances and that rapidly aggregate and disaggregate the critical need to provide health services to forces that are increasingly being task organized and employed at lower echelons, and the essential importance to integrate and coordinate with non-DoD mission partners. These challenges must be addressed in a strategic environment that is becoming more fiscally constrained, while still meeting the high expectations for positive health outcomes, even in contested environments. Finally, this strategy requires adherence to the highest standards of any R&D enterprise, but especially one with such a critical national security mission, to include integrity, excellence, innovation, efficiency, and stewardship. Against this backdrop, the Joint Force must be able to rapidly adapt to new threats while maintaining a competitive advantage over existing threats.

II. Congressional Direction for a Strategic Medical Research Plan

In 2018, section 736 of the John S. McCain NDAA for FY 2019 (Public Law 115-232) directs the Secretary of Defense, in consultation with the Secretaries of the military departments, to submit to the congressional defense committees a comprehensive strategic medical research plan.

The plan under subsection (a) shall include the following:

(1) A description of all medical research focus areas of the DoD and a description of the coordination process to ensure the focus areas are linked to military readiness, Joint Force requirements, and relevance to individuals eligible for care at military medical treatment facilities (MTFs) or through the TRICARE program.
(2) A description of the medical research projects funded under the Defense Health Program (DHP) account and the projects under the Congressional Directed Medical Research Programs.
(3) A description of the process to ensure synergy across the military medical research community to address gaps in military medical research, minimize duplication of research, and to promote collaboration within research focus areas.
(4) A description of the efforts of the Secretary to coordinate with other departments and agencies of the federal government to increase awareness of complementary medical research efforts that are being carried out through the federal government.

In developing this response to the congressional defense committees, the medical R&D community formed a work group of representatives from DoD stakeholder organizations to comprehensively address the NDAA request (see Appendix F). This resulting consensus document describes a unified vision, mission, and goals for an integrated DoD medical R&D enterprise approach to meet the needs of the current and the future force and addresses the four points listed above in the body of the document, with additional details in the appendices.

III. Response to Section 736 of the National Defense Authorization Act of the Fiscal Year 2019

This section responds to the specific tasks assigned to DoD to describe the substance of and processes used in the military medical R&D portfolio. Detailed information responding to each task appears in Appendixes A through D.

A. Overview of Department of Defense Medical Research

The overall DoD medical research program can be delineated into two categories that have distinct management structures and responsibilities. Defense medical research focuses on R&D that is responsive to the needs of the Joint Staff, Services, and Combatant Commands. More than 20 DoD entities are involved in the management and oversight of defense medical research within the Services and defense agencies. Each organization manages its medical R&D to support the National Defense Strategy while meeting its Component-specific needs. Cross-Component coordination is essential to ensure that the overall portfolio of defense medical research is comprehensive and non-duplicative. The Armed Services Biomedical Research Evaluation and Management (ASBREM) Community of Interest (CoI) is the DoD's primary coordination body to ensure the Components are communicating, collaborating, and leveraging resources. More information about the ASBREM CoI is discussed in a later section. DoD's congressionally directed medical research focuses on research that is responsive to the directions of Congress and targets health care solutions for Service members, veterans, and the general public. Congressionally directed programs and topics may vary from year to year and, with a few exceptions, most are executed and managed by the Congressionally Directed Medical Research Programs (CDMRP) office in close coordination with other DoD components. In addition, DoD utilizes its Small Business Innovation Research (SBIR) Program and Small Business Technology Transfer (STTR) Program to strengthen the role of innovative small business concerns in federally funded R&D and to stimulate partnerships between innovative small business concerns and research institutions through federally funded R&D.

Department of Defense Medical Research Focus Areas

The programs that comprise the defense medical research focus areas are developed in response to the needs of the National Defense Strategy and Joint Capabilities Integration and Development System (JCIDS). The goal is to advance the state of medical science in those areas of most pressing need and relevance to today's battlefield experience and emerging threats. The objectives are to discover and explore innovative approaches to protect, support, and advance the health and welfare of military personnel and individuals eligible for care in the MHS; to accelerate the transition of medical technologies into deployed products; and to accelerate the translation of advances in knowledge into new standards of care for injury prevention, treatment of casualties, rehabilitation, and training systems that can be applied in theater or in MTFs. The focus areas include the following (see Appendix A for details):

- Biomedical Informatics and Health Information Systems and Technology
- Clinical and Rehabilitative Medicine
- Combat Casualty Care
- Medical Chemical and Biological Defense[1]

[1] Medical Chemical and Biological Defense is the responsibility of the Chemical, Biological Defense Program (CBDP) per DoDD 5160.05E but is coordinated through the respective Joint Program Committee.

- Medical Radiological Defense[2]
- Military Infectious Diseases
- Military Operational Medicine

Each of the major research focus areas is coordinated and synchronized within the ASBREM CoI with joint technical coordinating groups (JTCGs), which consist of DoD and non-DoD medical and military subject matter/technical experts. These experts work through coordinated efforts to enhance transparency and synergy of medical R&D. However, the JTCGs do not have responsibility for or authority to make funding or programmatic decisions; these responsibilities and authorities are retained by the organizations that comprise the ASBREM CoI.

Congressionally Directed Medical Research Focus Areas

The programs and topics that comprise DoD's congressionally directed medical research are specifically identified by Congress each year in the NDAA, and they target areas of importance to Service members, veterans, and the general public. Focus areas, which are not specifically identified by Congress, have been developed for the current congressional programs and topics for the purposes of this report. Research in these focus areas crosses the full spectrum of basic, translational, and clinical research, and collectively supports the goals of advancing paradigm-shifting research, solutions that will lead to cures or improvements in patient care, or breakthrough technologies and resources for clinical benefit. The focus areas include the following (see Appendix A for details):

- Autoimmune and Genetic Disorders
- Cancer
- Cardiovascular and Respiratory Health
- Infectious Diseases
- Neurological and Psychological Health
- Tissue, Organ, and Orthopedic Injuries and Restorative/Rehabilitative Medicine

B. Coordination Processes to Ensure Research Focus Areas Are Aligned with Mission

The DoD deploys a range of coordinated processes to ensure its medical R&D efforts are linked to military readiness, Joint Force requirements, and relevance to individuals eligible for care at MTFs or through the MHS. There are a number of sources for requirements and levels of strategic guidance concerning DoD medical R&D efforts, but the main requirements source that drives DoD

[2] Medical Radiological Defense is partially funded by the Defense Health Program and advanced development is the responsibility of the CBDP per *DoD Directive 5160.05e, Roles and Responsibilities Associated with the Chemical and Biological Defense Program (CBDP)* and is coordinated through the respective Joint Program Committee.

medical research focus area programs of record is the JCIDS, the formal process that defines acquisition requirements and evaluation criteria for future defense programs in order to develop joint requirements to validate medical needs and accelerate the development and fielding of medical operational capabilities. JCIDS is the primary means for the Joint Requirements Oversight Council to fulfill its statutory responsibilities to the Chairman of the Joint Chiefs of Staff, which include assessing joint military capabilities, and identifying, approving, and prioritizing gaps in these capabilities to meet applicable requirements in the National Defense Strategy. Requirements and guidance are further defined by the various sources of medical research funding authorities. (See Appendix A for details; a summary appears below.)

All activities are guided by the National Defense Strategy, which describes the strategic environment as being "defined by rapid technological change, challenges from adversaries in every operating domain, and the impact on current readiness from the longest continuous stretch of armed conflict in our nation's history." The strategy includes as a goal a "more lethal, resilient, and rapidly innovating Joint Force." Further, the *Joint Operating Environment 2035* posits a wide range of threats and persistent conflict over the next 20 years. DoD expects that the joint operating environment will grow more complex as adversaries become more transregional, multi-domain, and multi-functional. Thus, medical R&D must constantly keep pace with the current and future strategic environment.

As mentioned above, the ASBREM CoI is the primary coordinating body across DoD medical R&D efforts. Additional coordination occurs at other levels as summarized below. The ASBREM CoI represents 20 participating departments and agencies across the DoD, Joint Force, and Services that perform or sponsor medical R&D in support of current and emerging needs of U.S. military forces. In response to future operating environments, the ASBREM CoI's vision is to promote the coordination and synergy of DoD medical R&D efforts to provide medical products and information that are required to protect and sustain the health of Soldiers, Sailors, Airmen, and Marines of the U.S. Armed Forces so that they can accomplish the National Security Objectives and execute DoD's mission.

Within DoD, several agencies conduct and sponsor medical research, such as those under the authority of the Under Secretary of Defense for Personnel and Readiness, the Under Secretary of Defense for Research and Engineering, and the Under Secretary of Defense for Acquisition and Sustainment. In addition, each of the Services conducts Service-specific medical R&D. Each of these subordinate organizations have internal mechanisms and processes for directing, coordinating, resourcing, validating, prioritizing, and overseeing research activities to ensure that the R&D investments are linked to military readiness and are responsive to Joint force requirements. The Services have also envisioned the future operating environment, and have identified core challenges to their overarching mission set(s) against which they must prepare today. Each of the Service line strategies reflects the same overarching vision of a complex future environment that is dispersed with rapidly evolving threats.

Finally, the CDMRP represents a unique partnership among the U.S. Congress, the military, and the public to manage individual programs for cancer research, neurological research, military medical research and other disease- and injury-specific research. CDMRP programs and topics are directed by Congress through the annual NDAA. Across all programs, CDMRP coordinates priorities and management with other DoD components and aligns with intramural and extramural military medical research focus areas as applicable to maximize the relevance to military health.

C. Research Projects in the Defense Health Program and Congressionally Directed Medical Research Programs

A major portion of DoD medical R&D is from the DHP Research, Development, Test, and Evaluation (RDT&E) appropriation, which is managed and executed by the DHA Research and Development Directorate, as directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)). The DHA executes this mission in coordination with the Services and other entities. The DHP RDT&E appropriation includes defense medical research investments consisting of research portfolios and programs. The seven research focus areas in defense medical research consist of 31 research portfolios (projects) in total. The six congressionally directed medical research focus areas include within them 34 programs (projects). For the purposes of this report, research projects have been equated with portfolios and programs. The descriptions for these portfolios and programs can be found in Appendix B.

D. Creating Synergies, Addressing Gaps, and Avoiding Duplication

Many of the processes described above for coordinating across DoD R&D are also deployed to ensure synergy across the military medical research community and to address gaps, minimize unwarranted duplication, and promote collaboration within research focus areas. (See Appendix C for details.)

The ASBREM CoI was created in 1981 in response to Congressional mandate and in 2013 became a CoI within the Reliance 21 framework, an Office of the Secretary of Defense-led effort for joint planning and coordination with the goal of reducing unnecessary duplications of work. Reliance 21 is the overarching framework of DoD Science and Technology (S&T) joint planning and coordination process. The ASBREM is unique among the Reliance 21 CoIs because it is the only CoI that includes both science and technology and advanced development efforts to enhance streamlined transition, coordination, and planning. It enables information sharing, alignment of effort, coordination of priorities, and support for scientists and engineers across the DoD. While this body facilitates communication, it does not have any authority over funding or the ability to direct activities.

DoD also supports synergistic R&D activities to address gaps through coordination by JTCGs, Integrated Product Teams (IPTs), the DoD/VA Centers of Excellence (CoEs), and Joint Program Committees (JPCs), which specifically manage the DHP R&D efforts. JPCs have a Service, Unified Combatant Command (COCOM), and portfolio management coordination function to ensure that DHP RDT&E investments support military readiness, Joint Force requirements, and individuals eligible for care.

Coordination through joint programmatic planning and review processes supports synergistic and collaborative medical R&D focused on addressing military medical needs. Coordination with the DoD/VA CoEs ensures that R&D activities affecting clinical practice guidelines are communicated, translated, and implemented within the MHS clinical community. Additionally, joint coordination activities through JTCGs, JPCs, and IPTs ensure that medical product development activities result in technologies transitioning to acquisition programs led by DoD program/project/product managers. This coordination and synergy has allowed the DoD medical R&D enterprise to be successful in fielding new solutions.

The responsibility for avoiding unnecessary duplication ultimately lies with research applicants and their institutional business officials. However, as an additional measure, DoD executes business processes and communications to minimize unwarranted duplicative medical research supported across DoD and the federal government. Investment strategies are specifically designed to complement and synergize with other funding sources, not duplicate them. These strategies derive from program management practices that individualize approaches to each specific disease, condition, or injury addressed, and include military medical subject matter experts (SMEs), end users, and/or patients/consumers.

E. Coordination with Other Federal Departments and Agencies

DoD routinely coordinates with other departments and agencies of the federal government to increase awareness of complementary medical research efforts that are being carried out and to pool resources and expertise to gain synergies. The mechanisms by which coordination occurs include technical and programmatic collaboration (e.g. joint reviews and programmatic planning across agencies for research of critical importance to multiple departments or agencies, through shared resources such as databases and biorepositories, and through joint solicitations for research proposals). Opportunities for collaboration arise from scientific opportunities, clinical needs, and shared missions. Some collaborative efforts are directed at higher levels (Executive or Congressional direction, federal advisory committees) and some are generated from identified needs at lower levels (program panels and working groups, program staff interactions). As such, there are both formal and informal mechanisms of interagency coordination. (See Appendix D for examples of collaborative efforts with the U.S. Food and Drug Administration (FDA), the

Department of Health and Human Services (HHS) through the National Institutes of Health (NIH), the Department of Veterans Affairs (VA), the National Security Council, and other partners.) Leveraging the knowledge and resources of federal partners strengthens the military medical R&D portfolio and optimizes efficiencies.

F. The 2019 Department of Defense Strategic Medical Research Plan

In 2017, the ASBREM CoI developed an Integrated DoD Biomedical R&D Strategy that detailed the history, organization, and high-level goals of the defense medical R&D enterprise. The strategy was developed in coordination with all ASBREM CoI member organizations and published in December 2017 with DoD leadership endorsement. This 2019 Strategic Medical Research Plan leverages the framework already put forth in the previous strategy document and expands upon it with the addition of congressionally directed medical research. This plan also presents strategic objectives that are actionable, and provides a pathway toward achieving a fully integrated and efficient R&D capability that fulfills the promise of providing the best medical treatments and solutions to the Joint Force.

Vision

An integrated DoD medical R&D enterprise will provide timely solutions to enable a healthy and protected military force that is ready for any mission.

Mission

Discover, develop, and deliver medical solutions that enable DoD to provide a ready medical force and a medically ready force.

Goals

Achieving the vision in the current and future strategic environment requires enduring medical R&D goals that are relevant to the full spectrum of challenges facing DoD. These goals are advanced through integrated and synchronized medical research activities that draw on the broad scope of expertise throughout the DoD medical research community. Collaboration across DoD on these research activities will be critical to developing materiel (e.g., devices, biologics, preventive and therapeutic medicines and vaccines) and knowledge (e.g., information, protocols, and methods) products that the Services require for mission success in the future operating environment and that the MHS needs to provide quality care to those eligible to receive it. The Defense medical R&D enterprise strives to ensure that the Joint Force is (1) Better prepared, (2) Better protected, and (3) Better cared for throughout the operational life cycle.

Goal 1: Better Prepared

Warfighters are equipped with capabilities and knowledge to optimize their health and achieve peak performance in all mission domains. This includes providing new approaches to delivering training to ensure that warfighters and medical service providers develop the knowledge, skills, and abilities appropriate to their mission sets; creating new technologies to ensure the retention of these skills and abilities in a network constrained environment to relay critical medical information; anticipating and mitigating exposure to biological and chemical, ionizing and non-ionizing radiation, and combined injury threats as well as other occupational and environmental health threats; developing strategies and interventions to build cognitive and psychological resilience; creating technologies to monitor real-time data regarding warfighter physiology; and developing technologies for sustaining operational performance in environmental extremes.

Goal 2: Better Protected

Warfighters are equipped with a layered protection of materiel and knowledge to minimize or eliminate exposure to, and the consequences of, medical risks, including infectious diseases, preventable injuries, radiation and chemical exposures, and other environmental/workplace hazards. This includes creating new tools to identify and monitor medical threats in the environment; developing tools to monitor an individual warfighter's physiological status and exposure to environmental or occupational threats; accelerating promising, innovative prophylaxis and therapeutics solutions to combat emerging infectious diseases; and developing new approaches to protect against sensory-system injuries.

Goal 3: Better Cared For

Warfighters are provided with multi-layered health services that minimize morbidity and mortality and maximize recovery across the treatment continuum—from the point of injury, during en route care, to definitive care and rehabilitation. This includes developing capabilities to support prolonged field-care and critical-care capabilities, including products for portable diagnostics, resuscitation, hemorrhage control, endovascular stabilization, pain control, organ support, blood replacement, and burn treatment; enhancing patient movement and management during en route care; developing novel therapeutics/delivery technologies against wound infection pathogens and biofilm processes; restoring and rehabilitating injured warfighters (e.g., prosthetics and assistive devices, skin substitutes); providing treatment protocols for physiological and psychological injuries, such as burns, loss of limbs, or post-traumatic stress disorder (PTSD); and improving regenerative medical techniques.

Objectives

1. **Drive innovation in DoD medical R&D.**

R&D is essential to maintaining medical readiness and improving responsiveness to warfighter needs. By driving medical R&D innovation to meet the highest priority needs of the Combatant Commands, the Joint Force will be well positioned to tackle the toughest medical challenges of the future.

1.1. Implement processes to support the transition, dissemination, and implementation of new standards of care for warfighter and beneficiary health.
1.2. Foster a culture of innovation and leverage investments in congressionally directed and SBIR and STTR Programs to seed innovative solutions for the Joint Force.
1.3. Develop evidence-based decision support tools and methodologies to assist in prioritizing R&D investments for greater impact on force readiness and delivery of health services and solutions.
1.4. Ensure and institutionalize flexibilities that facilitate rapid innovation to provide solutions to medical forces that enable them to be immediately responsive to a range of contingencies anytime and anywhere.

2. Maintain strong medical R&D partnerships and leverage synergies with other government agencies, industry, and academia.

Research discoveries and innovation can arise anywhere and anytime. DoD medical R&D stakeholders and SMEs interact with the larger federal, private, industry, and academic medical research communities to ensure that they are aware of the advances made by others and to better inform research objectives, priorities, and investments. Collaborations with academia and industry are leveraged to provide faster, more effective, and more cost-effective military medical solutions for the warfighter.

2.1. Maximize interagency and cross-disciplinary coordination and collaboration to identify and invest in innovative solutions supporting warfighter readiness and beneficiary health.
2.2. Engage in innovative partnership models and public-private collaborations to align military R&D requirements with private sector capabilities.
2.3. Enhance collaboration with the FDA to appropriately accelerate the testing, manufacturing, and fielding of medical products.

3. Coordinate and integrate medical R&D portfolios across DoD.

The unique missions of the Service and agencies are coordinated and integrated. Through the ASBREM CoI, DoD seeks to be a force multiplier by fostering the communication, integration, and synchronization of efforts across the military medical research community, and by including other agencies and departments, as appropriate, in the development of novel medical capabilities for the Joint Force.

3.1. Align efforts in R&D to approved joint requirements and capability gaps and remain agile and responsive to emerging threats to enhance the readiness of the Joint Force.
3.2. Coordinate information to allow responsiveness to DoD's emerging strategic priorities.
3.3. Develop and manage joint medical acquisition strategies and programs of record that enable accelerated integration of research and technology emerging from DoD, academia, and industry to provide solutions for military use.

4. Further optimize resource management and efficiencies.

Promote timely and effective cross-Service and cross-agency R&D collaborations with the intent of increasing productivity, accelerating the delivery of capabilities to end users, and streamlining efforts to reduce unnecessary duplications.

4.1. Support infrastructure and workforce modernization and management approaches that speed the development of products.
4.2. Enhance and validate training platforms for recruiting, training, and retaining a workforce with knowledge, skills, and abilities aligned to medical specialties of the operational force.
4.3. Establish a DoD-wide medical R&D portfolio assessment process and an enterprise portfolio information technology capability that provides rapid and accurate insight into all investment areas.

In summary, the need for agility and responsiveness across all levels and types of care requires a medical R&D strategy that is nimble, responsive, and attuned to emerging needs of the warfighter, is nested with national strategic guidance, and that capitalizes on opportunities in science and technology. It also requires partnerships at home and abroad. Finally, this plan is also responsive to a previous review that emphasized the need for a comprehensive enterprise-wide medical R&D strategy.[3] It provides a common framework to ensure the DoD continues to discover, develop, and deliver the medical capabilities required today and in the future. It

[3] DoD. Defense Health Board. (2017). *Improving Defense Health Program (DHP) Medical Research Processes*. Available at https://health.mil/Reference-Center/Reports/2017/08/08/Improving-Defense-Health-Program-Medical-Research-Process

provides the basis to optimize infrastructure and coordination and information exchange among the Services and defense agencies across the DoD, Federal Interagency, and the civilian sector. Additionally, this strategy enables the DoD to actively partner with academia and industry to infuse a broader range of investments and innovation into DoD medical operations and capabilities. This strategy ensures the DoD's medical R&D investments and structure continue to be responsive to both contemporary medical readiness requirements and future needs of the warfighter.

Appendix A
Department of Defense Medical Research Focus Areas
and
Coordination Process to Ensure Medical Research and Development Efforts are Linked to Military Readiness, Joint Force Requirements, and Relevance to Those Eligible for Care in the Military Health System or Through the TRICARE Program

This appendix responds in detail to language in section 736 of the John S. McCain NDAA for FY 2019 to provide: "A description of all medical research focus areas of the Department of Defense and a description of the coordination process to ensure the focus areas are linked to military readiness, Joint Force requirements, and relevance to individuals eligible for care at military medical treatment facilities or through the TRICARE program."

In Section I, research focus areas are provided. Each of these major research program areas is strategically coordinated and guided by a JTCG, which consists of DoD and non-DoD medical and military technical experts. These experts work through coordinated efforts to enhance transparency and synergy medical research and development.

In addition, DoD relies on its Small Business Innovation Research (SBIR) Program and Small Business Technology Transfer (STTR) Program to strengthen the role of innovative small business concerns in federally funded R&D and to stimulate partnerships between innovative small business concerns) and research institutions through federally funded R&D.

Section II provides an overview of the processes for coordinating medical R&D across DoD.

I. Research Focus Areas

A. Department of Defense Medical Research Focus Areas

These research focus areas reflect the medical portfolios organized by DoD based on the health care capabilities required to provide for optimal military medical readiness and response. The goal of defense medical research is to advance the state of medical science in those areas of most pressing need and relevance to today's battlefield experience in order to be better prepared for the future. The objectives are to discover and explore innovative approaches to protect, support, and advance the health and welfare of military personnel, families, communities, and the general public; to accelerate the transition of medical technologies into deployed products; and to accelerate the translation of advances in knowledge into new standards of care for injury

prevention, treatment of casualties, rehabilitation, and training systems that can be applied in joint theaters of operation and within the clinical facilities of the MHS.

Biomedical Informatics and Health Information Systems and Technology

The Biomedical Informatics and Health Information Systems and Technology research focus area is concentrated on military medical modeling and simulation training and health information technologies/informatics research and transferring research solutions and knowledge to meet DoD's goals. This focus area has two research focus areas: *Health Information Technologies and Informatics* seeks to improve health care data capture, integration, and transmission in and from the theatre operational environment and to improve medical informatics capabilities within the MHS. Research in *Medical Modeling, Simulation and Training Technologies* seeks to advance military medicine training and education using medical simulation tools that extend throughout the entire continuum of care, deliver combat casualty care training to support a high state of readiness and capability for military health care providers, and create predictive models to access health care providers' high-quality military health care management.

Clinical and Rehabilitative Medicine

The Clinical and Rehabilitative Medicine research focus area is concentrated on developing knowledge and materiel products to reconstruct, rehabilitate, and provide definitive care for injured Service members with the goals to achieve return to duty and restore quality of life. Portfolios include developmental efforts concentrated on neuromusculoskeletal rehabilitation, regenerative medicine and transplants, sensory systems (vision, auditory, and vestibular), acute pain management, cardiovascular care, and cancer care.

Combat Casualty Care

The Combat Casualty Care research focus area is concentrated on optimizing survival and recovery in Service members injured in combat across the spectrum of care from the point of injury through en route care and definitive care. Portfolios include developmental efforts concentrated on damage control resuscitation, neurotrauma to include traumatic brain injury, prolonged field care and en route care, battlefield resuscitation and immediate stabilization of combat casualties, military medical photonics, combat trauma therapies, blast injury prevention, and combat dentistry.

Medical Chemical and Biological Defense

The Medical Chemical and Biological Defense research focus area is concentrated on the research, development, test, and evaluation of prophylaxis, therapeutics, and diagnostics against

chemical and biological threats of security concern and against novel and emerging infectious diseases threats. The program employs a requirements-driven process to achieve a portfolio of scientifically based, layered, FDA approved medical countermeasures to protect the warfighter and maintain maximal global operational capability with minimal morbidity and mortality. Medical Chemical and Biological Defense is the responsibility of the CBDP per DoDD 5160.05E but is coordinated through the JTCG.

Medical Radiological Defense

The Medical Radiological Defense research focus area is concentrated on discovering and developing materiel and knowledge that reduce medical capability gaps relevant to radiation health effects, enhance military readiness in a radiation environment, and enhance medical capabilities against radiation exposure. Major categories of research focus on the development of medical countermeasures to prevent or treat the effects of acute radiation syndrome. Medical Radiological Defense is partially funded by DHP and advanced development is the responsibility of the Chemical, Biological Defense Program (CBDP) per *DoD Directive 5160.05e, Roles and Responsibilities Associated with the Chemical and Biological Defense Program (CBDP).*

Military Infectious Diseases

The Military Infectious Diseases research focus area is concentrated on infectious diseases research leading to the fielding of effective, improved means of protection and treatment to maintain maximal global operational capability with minimal morbidity and mortality. Research focuses on protecting the warfighter against naturally occurring, known, predictable, endemic disease threats. This focus area supports research to ensure the medical readiness of deployed forces. Its programs are designed to respond to emerging infectious diseases and acute respiratory diseases by accelerating promising and innovative drug and vaccine solutions. In addition, it supports efforts to identify and develop novel approaches to prevent, diagnose, manage, and treat combat wound infections.

Military Operational Medicine

The Military Operational Medicine research focus area is concentrated on developing effective medical countermeasures against operational stressors and preventing physical and psychological injuries during training and operations to maximize the health, performance, and fitness of Service members. This focus area emphasizes research to produce a healthy, ready, and high-performing Joint Force capable of enduring and recovering from the rigors of training and operational environments. It also supports research to ensure the psychological health and well-being of Service members and families.

B. Congressionally Directed Medical Research Programs Research Focus Areas

The programs and topics that comprise DoD's congressionally directed medical research are specifically identified by Congress each year in the NDAA. Focus areas, which are not specifically identified by Congress, have been developed for the current congressional programs and topics for the purposes of this report. Significant focus is on research that is relevant to the overall health of the Service member and on improving medical care for Service members, veterans, retirees, and their family members/beneficiaries, recognizing that all are integral parts of force health protection and readiness that directly contribute to the success of the military mission.

Research in these focus areas crosses the full spectrum of basic, translational, and clinical research and collectively supports the goals of advancing paradigm-shifting research, solutions that will lead to cures or improvements in patient care, or breakthrough technologies and resources for clinical benefit. Congressional programs and topics may vary from year to year, but priorities and management are coordinated among DoD components and aligned with core defense medical research focus areas as applicable to maximize the relevance to military health.

Autoimmune and Genetic Disorders

The Autoimmune and Genetic Disorders research focus area encompasses programs and topic areas concentrated on advancing the understanding, prevention, diagnosis, and treatment of specific autoimmune and genetic disorders for the benefit of Service members and their families, veterans, retirees, and other military beneficiaries. This includes areas such as bone marrow failure, Duchenne's muscular dystrophy, lupus, neurofibromatosis, multiple sclerosis, tuberous sclerosis complex, arthritis, Fragile X Syndrome, Guillain-Barre Syndrome, inflammatory bowel diseases, scleroderma, and Rett syndrome.

Cancer

The Cancer research focus area encompasses programs and topic areas concentrated on advancing the understanding, prevention, detection, diagnosis, and treatment of cancer and related conditions for the benefit of Service members and their families, veterans, retirees, and other military beneficiaries. This includes areas such as breast cancer, kidney cancer, ovarian cancer, lung cancer, prostate cancer, adrenal cancer, bladder cancer, blood cancer, brain cancer, colorectal cancer, liver cancer, lymphoma, melanoma and other skin cancers, mesothelioma, myeloma, neuroblastoma, pancreatic cancer, pediatric brain tumors, stomach cancer, and cancer in children, adolescents, and young adults, as well as immunotherapy and Listeria-based regimens for cancer.

Cardiovascular and Respiratory Health

The Cardiovascular and Respiratory Health research focus area encompasses programs and topic areas concentrated on advancing the understanding, prevention, diagnosis, and treatment of cardiovascular and respiratory health related conditions for the benefit of Service members and their families, veterans, retirees, and other military beneficiaries. This includes areas such as burn pit exposure, cardiomyopathy, constrictive bronchiolitis, hereditary angioedema, lung injury, pathogen-inactivated blood products, pulmonary fibrosis, vascular malformations, women's heart disease, and others.

Infectious Diseases

The Infectious Diseases research focus area encompasses programs and topic areas concentrated on advancing the understanding, prevention, detection, diagnosis, and treatment of infections and infectious disease related conditions for the benefit of Service members and their families, veterans, retirees, and other military beneficiaries. This includes areas such as tick-borne disease, HIV/AIDS, antimicrobial resistance, emerging infectious diseases, Hepatitis B and C, interstitial cystitis, malaria, tuberculosis, vaccine development, wound healing, and others.

Neurological and Psychological Health

The Neurological and Psychological Health research focus area encompasses programs and topic areas concentrated on advancing the understanding, prevention, diagnosis, and treatment of neurological and psychological health conditions or injuries for the benefit of Service members and their families, veterans, retirees, and other military beneficiaries. This includes areas such as alcohol and substance abuse disorders, amyotrophic lateral sclerosis, autism, epilepsy, Gulf War illness, Parkinson's disease, Alzheimer's disease, psychological health, traumatic brain injury, spinal cord injury, cerebellar ataxia, dystonia, frontotemporal degeneration, hydrocephalus, myotonic dystrophy, sleep disorders, spinal muscular atrophy, and others.

Tissue, Organ, and Orthopedic Injuries and Restorative/Rehabilitative Medicine

The Tissue, Organ, and Orthopedic Injuries and Restorative/Rehabilitative Medicine research focus area encompasses programs and topic areas concentrated on advancing the understanding, prevention, diagnosis, and treatment of military-relevant injuries and optimizing restorative and rehabilitative strategies for the benefit of Service members and their families, veterans, retirees, and other military beneficiaries. This includes areas such as hearing restoration, military burn, orthotics and prosthetics outcomes, orthopedic, traumatic brain injury, reconstructive transplant, spinal cord injury, trauma clinical, vision, acute lung injury, chronic migraine and post-traumatic headache, chronic pain management, metals toxicology, musculoskeletal disorders, non-opioid

pain management, pancreatitis, spinal muscular atrophy, sustained-release drug delivery, tinnitus, tissue regeneration, and others.

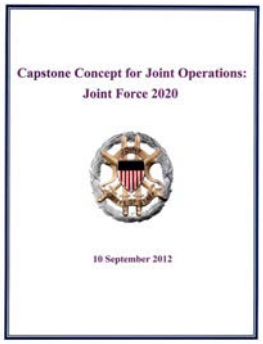
II. Coordination Process to Ensure Medical R&D Efforts are Linked to Military Readiness, Joint Force Requirements, and Relevance to Those Eligible for Care Through the Military Health System or Through the TRICARE Program

DoD deploys a range of coordinated processes to ensure its medical R&D efforts are linked to military readiness, Joint Force requirements, and relevance to individuals eligible for care at military treatment facilities or through the MHS. There are multiple sources for requirements and levels of strategic guidance concerning DoD medical R&D efforts, as described below. In turn, each of these subordinate organizations has internal mechanisms and processes for directing, coordinating, resourcing, and overseeing research activities to ensure that the R&D investments are linked to military readiness and are responsive to Joint Force requirements. Requirements and guidance are further defined by the various sources of medical research funding authorities. The ASBREM CoI is the primary coordinating body across DoD medical R&D.

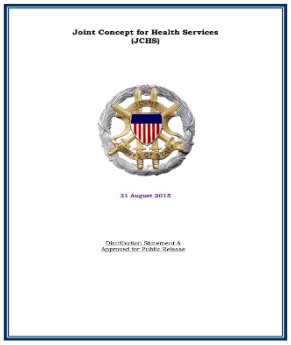
Medical Research and Development Strategic-level Synchronization and Readiness

The 2018 National Defense Strategy describes the strategic environment as being "defined by rapid technological change, challenges from adversaries across every operating domain, and the impact on current readiness from the longest continuous stretch of armed conflict in our Nation's history." The strategy includes as a goal a "more lethal, resilient, and rapidly innovating Joint Force." Further, the *Joint Operating Environment 2035* posits a wide range of threats and persistent conflict over the next 20 years. The DoD expects that the joint operating environment will grow more complex as adversaries become more trans-regional, multi-domain, and multi-functional in their strategic and operational approaches. The National Defense Strategy requires the DoD and key federal agency medical R&D keep pace with the current and future environment in support of maintaining force readiness and competitive advantage on an evolving, hybrid battlespace.

In addition, the *Capstone Concept for Joint Operations: Joint Force 2020* describes the Chairman of the Joint Chiefs of Staff's vision for future joint operations in a rapidly changing and technologically driven operating environment. It proposes the idea of globally integrated operations (GIO) premised on the ability to take elements of a globally postured force, quickly combine the elements, execute the mission, and disaggregate in preparation for the next task.



The *Joint Concept for Health Services* (JCHS) is nested with the Chairman's Joint Force 2020 vision and responds to the future challenges of globally integrated operations; describing how the future Joint Force will provide health services in support of activities across the broad range of military operations. The JCHS highlights medical R&D as a key required capability to enhance the ability to advance the state of medical science, technologies, and practices in areas relevant to GIO; and to ensure the most promising medical solutions are developed and fielded for the future Joint Force in support of maximizing warfighter medical readiness.



The Armed Services Biomedical Research Evaluation and Management Community of Interest (ASBREM CoI)

The ASBREM was created in 1981 in response to Congressional mandate and in 2013 became a CoI within the Reliance 21 framework, an Office of the Secretary of Defense-led effort for joint planning and coordination with the goal of reducing unnecessary duplications of work. Reliance 21 is the overarching framework of the DoD S&T joint planning and coordination process. The ASBREM is unique among the Reliance 21 CoI's because it is the only CoI that includes both science and technology and advanced development efforts to enhance streamlined transition, coordination, and planning. The ASBREM's primary focus remains advancing communication, coordination, and collaboration across the entire DoD medical research enterprise. The ASBREM CoI represents 20 participating departments and agencies across the DoD, Joint Force, and Services that perform or sponsor medical R&D in support of current and emerging needs of U.S. military forces (see Table A.1.). ASBREM CoI members' R&D efforts range from basic research efforts that provide the foundation for future product development, through advanced development efforts that set the stage for fielding and upgrading the full-rate production of materiel capabilities and the integration of evidence-based research into clinical practice.

Table A.1. ASBREM CoI Membership

Organization	For More Information
• Office of the Assistant Secretary of Defense for Health Affairs (ASD(HA)) o Uniformed Services University of the Health Sciences Office of Vice President for Research (USUHS)	https://health.mil/About-MHS/ASDHA https://www.usuhs.edu
• Defense Health Agency (DHA) o Component Acquisition Executive Directorate o Research and Development Directorate	https://health.mil/dha
• Office of the Assistant Secretary of Defense for Research and Engineering (ASD(R&E)) o Defense Advanced Research Projects Agency (DARPA)	http://www.acq.osd.mil/chieftechnologist/ https://www.darpa.mil/
• Office of the Deputy Assistant Secretary of Defense for Chemical and Biological Defense (DASD(CBD)) o Defense Threat Reduction Agency (DTRA) Joint Science and Technology Office for Chemical and Biological Defense (JSTO-CBD) o Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO CBRND)	https://www.acq.osd.mil/ncbdp/cbd/ www.dtra.mil/ https://www.jpeocbd.osd.mil/
• Office of the Joint Staff Surgeon (OJSS)	http://www.jcs.mil/
• Joint Requirements Office for Chemical, Biological, Radiological and Nuclear Defense (JRO-CBRND)	https://jsportal.sp.pentagon.mil/sites/J8/DDFP/JRO/default.aspx (CAC-enabled)
• Deputy for Medical Systems, Office of the Assistant Secretary of the Army for Acquisition, Logistics and Technology (ASA(AL&T))	https://www.army.mil/asaalt
• The Office of Naval Research (ONR)	https://www.onr.navy.mil/

Organization	For More Information
• The Navy Bureau of Medicine and Surgery (BUMED)	http://www.med.navy.mil/Pages/Default.aspx
• The Medical Officer to the Marine Corps	http://www.hqmc.marines.mil/Agencies/Health-Services/Medical-Officer-USMC/
• Office of the Air Force Surgeon General o The 59th Medical Wing o The 711th Human Performance Wing	https://www.airforcemedicine.af.mil/ https://www.59mdw.af.mil/ https://www.wpafb.af.mil/afrl/711HPW/
• United States Special Operations Command (USSOCOM)	https://www.socom.mil/

The operational units of the ASBREM are the seven JTCGs (see Table A.2). The JTCGs are comprised of representatives of the members of the ASBREM CoI and other interagency and MHS representatives. The JTCGs maintain visibility of the complex medical R&D programs across all ASBREM CoI organizations, attempting to ensure strategic and balanced investments and conducting reviews, programmatic studies, and analyses to facilitate coordination, collaboration, and communication among the DoD components and OSD.

Table A.2. ASBREM CoI Joint Technology Coordinating Groups
JTCG – 1: Biomedical Informatics and Health Information Systems and Technology
JTCG – 2: Military Infectious Diseases
JTCG – 5: Military Operational Medicine
JTCG – 6: Combat Casualty Care
JTCG – 7: Medical Radiological Defense
JTCG – 8: Clinical and Rehabilitative Medicine
JTCG – 9: Medical Chemical and Biological Defense

In response to future operating environments, the ASBREM CoI's vision is to promote the coordination and synergy of the DoD biomedical R&D efforts to provide medical products and information that are required to protect and sustain the health of Soldiers, Sailors, Airmen, Marines, and Coast Guardsmen of the U.S. Armed Forces so that they can accomplish the National Security Objectives and execute the DoD's mission. Collectively, the ASBREM community realizes this vision and goals through its members by delivering quality medical materiel and knowledge products by conducting innovative R&D that is aligned to validated capability gaps.

ASBREM CoI's efforts are guided by three overarching goals to ensure the Joint Force is: (1) Better prepared, (2) Better protected, and (3) Better cared for throughout the operational life cycle. These goals are supported by the JTCG-specific strategic drivers stemming from the Joint Capabilities Based Assessments (CBAs), JCIDS, Service level technical and programmatic level guidance, and the JCHS.

The ASBREM CoI maintains strong biomedical connections between S&T and the medical material acquisition process, which is critical to product transition and to the integrated life cycle management of medical products from concept to disposal. The life-cycle management can be viewed from user need and laboratory investigations—through clinical trials, FDA approval, and manufacturing processes—to the delivery of the product to the warfighter and/or warfighter medic/corpsman. The product development teams specifically work to transition S&T discoveries and products through clinical trials, FDA approval, and manufacturing to the materiel delivery community.

The ASBREM CoI strategy provides a common framework to ensure that its CoI members continue to discover, develop, and deliver the medical capabilities required today and in the future. It provides the basis for ASBREM CoI members to optimize infrastructure and coordination and information exchange among the Services and defense agencies across the DoD, as well as the federal government, and the civilian sector. Additionally, this strategy enables ASBREM CoI members to partner with academia and industry to infuse investments and innovation into DoD medical operations and capabilities. This strategy ensures that the DoD's medical investments continue to be responsive to medical readiness and the warfighting needs today and well into the future.

Defense Health Agency (DHA)

The DHA is a joint, integrated combat support agency that reports to the ASD(HA). The DHA enables the Army, Navy, and Air Force medical services to provide both a medically ready force and ready medical force to Combatant Commands in both peacetime and wartime. Research as a shared service was established within the DHA underneath the DHA Research and Development Directorate in 2014 to help coordinate and enhance the related medical research and development programs of the Army, Navy, and Air Force and to support the development and delivery of joint research solutions. As directed by the OASD(HA), the DHA Research and Development Directorate provides oversight on the management and execution on the majority all of DHP funded medical research and the CDMRP, and has the following commitments:

- Oversight of DHP-funded RDT&E grants, projects, and initiatives across the Services and MHS to eliminate redundancy and reduce variance

- Prioritization and direction of medical research to ensure maximal impact for Service members and beneficiaries
- Alignment of DHP RDT&E funds to the highest medical operational priorities to ensure the development and delivery of medical products to warfighters
- Ensuring transparency of DHP efforts through portfolio review and analysis (R&A) on multiple levels
- Coordination of DHP RDT&E-funded activities with the Combatant Commands, Services, defense agencies, and other DoD components to avoid duplicative efforts
- Leveraging established governance to receive input from Combatant Commands, Services, defense agencies, and other DoD components regarding activities and issues related to the dispensation and use of DHP RDT&E Program funding
- Leveraging the JCIDS, the formal process which defines acquisition requirements and evaluation criteria for future defense programs, to develop joint requirements to validate medical needs, to accelerate the development and fielding of medical operational capabilities

Joint Program Committees

Coordination processes exist to ensure investments align with joint medical capability requirements documents approved through the processes and procedures of the Office of the Joint Staff Surgeon and the Joint Chiefs of Staff. By leveraging the JCIDS, the DHA, as a joint, integrated combat support agency supports planning, programming, budget, and execution processes to align resources to Joint Force requirements in order to accelerate the development and fielding of medical operational capabilities.

Through authorities vested within the DHA, JPCs are chartered to support the discovery and development of materiel, knowledge, and training solutions associated with medical capability gaps identified in joint requirements documents (e.g., Initial Capabilities Document for Combat Casualty Care Training Technologies) (see Table A.3). JPCs are comprised of medical research, development, and acquisition SMEs, requirements developers and end users across the DoD. Through the coordination of planning, programming, budgeting, and execution activities, JPCs provide strategic medical R&D investment recommendations to senior DoD leadership aimed at closing gaps identified in joint requirements documents and developing products that can be integrated into and implemented by the MHS and Services. To ensure continued alignment of current and future investments with Joint Force and combatant commands requirements, JPCs are required to provide annual updates to the Joint Staff regarding the status of addressing capability gaps outlined in joint requirements documents. Updates must also include solutions that have been developed to address gaps and the status of being fielded, research priorities for the next fiscal year, and any gaps that cannot be effectively addressed based on an assessment of research conducted to date.

Table A.3 Joint Program Committees
JPC-1: Medical Simulation & Information Sciences
JPC-2: Military Infectious Diseases
JPC-5: Military Operational Medicine
JPC-6: Combat Casualty Care
JPC-7: Radiation Health Effects
JPC-8: Clinical & Rehabilitative Medicine

Military Departments

The three military departments and the defense agencies have their own policies and programs for conducting and supporting medical research administered through their respective Surgeons General and agency directors. The Army, Navy, and Air Force also each conduct Service-specific research that is not DHP-funded and supports the readiness mission of the Service. Service-specific research laboratories support the conduct of medical research and have command and control over research executed through their subordinate organizations. Although the Director of the DHA "exercises management responsibility" over DHP-funded medical R&D, the Services maintain command and control of their personnel, infrastructure, and the research they fund.

Other Defense Research Agencies

Two key agencies provide additional critical expertise to DoD medical R&D related to military readiness and Joint Force requirements. The Defense Advanced Research Projects Agency (DARPA) is in the Office of the USD(R&E) and the Defense Threat Reduction Agency (DTRA) is in the Office of the ASD(NCB).

Defense Advanced Research Projects Agency. The DARPA's mission is to make pivotal investments in breakthrough technologies for national security. The DARPA leverages world-class researchers and leaders from academia, industry, government agencies and the uniformed services for limited program manager tenures—generally three to five years. This timeline also serves as a catalyst for the DARPA's signature urgency to achieve success in less time than a more conventional RDT&E setting. The DARPA Director approves each new program and reviews ongoing programs, while setting agency-wide priorities and ensuring a balanced investment portfolio. Current focus areas of the DARPA's efforts and contributions to DoD-focused biomedical R&D include: improving individual and unit readiness and resilience, creating technologies to restore function to injured warfighters, as well as promoting optimal performance through revolutionary, prophylactic treatment and battlefield care.

Defense Threat Reduction Agency. The DTRA was created in 1998 from a number of other entities to focus efforts on terrorism, nuclear surety, and counter-proliferation. The DTRA's

mission is to enable DoD, the U.S. Government, and international partners to counter and deter weapons of mass destruction and improvised threats networks. In addition to basic and applied science, the DTRA's research efforts focus include areas specifically linked to nuclear, biological, and chemical (NBC) threats and hazards, countering weapons of mass destruction (WMD), data integration and analysis, and providing DoD (and other interagencies) with a research/data repository and consulting services on related subject areas such asUS: x-rays, radiation effects, and survivability. The DTRA provides critical technical support and fundamental investigations to advance the knowledge of physical, biological, chemical, and engineering sciences critical to DoD medical research and development of prophylactic countermeasures and medical response /treatment to WMD-based threats.

Congressionally Directed Medical Research Programs

The CDMRP is an office within the U.S. Army Medical Research and Materiel Command (USAMRMC) that implements funding and serves as the executive management agency for a majority of the DHP and Army medical research programs directed by Congress in addition to providing support for DHP RDT&E medical research program areas. The CDMRP originated in 1992 via a Congressional appropriation to foster novel approaches to medical research in response to the expressed needs of its stakeholders—Service members, Congress, and the general public–and for FY 2018 manages 30 programs that target specific diseases, injuries, or conditions in cancer, neuropathology, and other areas that are relevant to military health and readiness (http://cdmrp.army.mil/researchprograms).

CDMRP programs and topics are directed by Congress through the annual NDAA, and they may vary from year to year. Funds for CDMRP are added to the DoD's budget during the yearly budget appropriations approval cycle. Across all programs, CDMRP coordinates priorities and management with other DoD components and aligns with intramural and extramural military medical research focus areas as applicable to maximize the relevance to military health.

CDMRP program goals and investment strategies integrate input from a wide variety of stakeholders (including academia, industry, consumer, nongovernmental organizations, DoD, the NIH, and the VA as appropriate) and are revisited and adjusted as needed on a yearly basis at Vision Setting. The CDMRP's unique yearly approach enables programs to consider the latest scientific and technological advancements, respond rapidly to emerging needs, and push for innovative and impactful research to fill important gaps, and it often serves as a critical complement to other research funding efforts.

JPC/program area directors, and portfolio managers provide guidance on military-relevant research priorities and capability gaps and utilize their oversight of other core and congressionally funded research efforts across the DoD Services in their respective program

areas to complement ongoing projects and leverage resources to support critical needs. DoD representatives provide direct input that helps to inform and more efficiently target funding to research with the greatest potential for impact to benefit military health.

Transition to Acquisition Program for Materiel Products

Research can result in technologies that transition to acquisition programs as an insertion within an existing acquisition program or as a new development and acquisition program. Acquisition programs are led by DoD program/project/product managers (PMs). PMs transition technologies from industry, academia, DoD laboratories, and other government agencies.

Programs to address DoD requirements can be linear and can initiate with research and transition to an acquisition program, or if solutions are already available in industry or academia that meet DoD requirements, acquisition programs can be initiated without starting with DoD research.

PMs respond to a balance of requirements "pull" and technology "push." In a requirements "pull" scenario, Service and Combatant Command users document requirements that serve as the basis for a PM to initiate a new acquisition program. In areas where technology may be advancing more rapidly than the user community is tracking, technology "push" can result in PMs identifying promising solutions that may align to user needs and coordinating with the user community to determine if there is a requirement.

In the medical environment, PMs tailor acquisition strategies to integrate the requirements of the DoD 5000 series and FDA requirements to achieve approval of new medical products. PMs develop and execute acquisition strategies to mature technology, reduce risk, conduct test and evaluation, field, improve, and sustain new safe, effective, affordable, and sustainable capabilities. Through collaboration with partners, both government and industry, DoD PMs translate research into fielded products.

While the DoD medical acquisition enterprise includes multiple acquisition authorities (Milestone Decision Authorities), the acquisition community is in close collaboration and has defined mission areas. For example, the Joint Program Executive Office for JPEO-CBRND and DHA have collaborated on the Next Generation Diagnostic System. Through this synergistic partnership, JPEO-CBRND has been focused on the biodefense aspects of that system, and the DHA has leveraged its program and funded infectious disease assay panels. There are numerous similar collaborations across the joint enterprise. The Services have medical acquisition programs and DHA also established a medical acquisition program but chose to leverage existing Service/Component assets to create a Joint capability rather than creating a new structure. This has allowed the DHA to be successful in fielding new solutions.

The DoD medical research, development, and acquisition enterprise has established strong relationships between research and acquisition and will continue to improve transition through the use of:

- Transition agreements: an agreement between S&T manager and PM to establish a joint commitment to plan a future program based on a shared understanding of technology objectives and the associated risks
- Integrated Product Teams: multi-disciplinary teams that evolve throughout the research, development, and acquisition lifecycle to include all necessary subject matter expertise to support the PM in the acquisition program
- Prototyping: demonstrating and evaluating technologies to validate technical feasibility and to advance capabilities that have already demonstrated technical and operational promise

Appendix B

Defense Health Program Medical Research Projects and Projects Under the Congressionally Directed Medical Research Programs

This appendix responds in detail to language in section 736 of the John S. McCain NDAA for FY 2019 to provide: "(2) A description of the medical research projects funded under the Defense Health Program account and the projects under the Congressional Directed Medical Research Programs." The first table describes defense medical research projects as grouped in the operational units (focus areas) of the Joint Technology Coordinating Groups of the ASBREM CoI (see Appendix A). The second and third tables provide descriptions of research programs and topics in DoD congressionally directed medical research for FY 2018. Focus areas for congressionally directed medical research are not specifically identified by Congress but were developed for the purposes of this report (see Appendix A). For the purposes of this appendix, congressionally directed medical research programs have been equated with portfolios.

I. Defense Health Program; Defense Medical Research

Focus Area	Research Portfolio(s)	Portfolio Descriptions
Biomedical Informatics & Health Information Systems and Technology	Medical Modeling, Simulation and Training Technologies	Plans, coordinates, and oversees a joint RDT&E program focused on improving military medical modeling and simulation being applied to MHS educational and operational environments through integrated live, virtual, constructive, gaming, globally distributed virtual engagement, autonomous and predictive systems, interoperable training platforms, and objective metrics.
	Health Information Technologies and Informatics (HITI)	HITI develops, selects, oversees, and transitions studies in health information technology, informatics, data capture/transfer/management, and prototype systems in theater/operational medicine environments for all Services/COCOMs in the form of material and knowledge solutions. The materiel and knowledge solutions include software tool(s), hardware, data repositories, closed loop medical device interoperability during prolonged care in place and medical evacuation, hands-free medical data capture/data entry, best industry practices in medical logistics (MEDLOG), and medical device interoperability data/black box recorder for the Joint Theater Trauma Registry/electronic health record/patient safety.

Clinical and Rehabilitative Medicine	Neuromusculoskeletal Injury Rehabilitation	This research is directed toward optimal treatment, rehabilitation, and reintegration following service-related neuromusculoskeletal injury including: Service-related acute and repetitive overuse injury management, limb loss rehabilitation and prosthetic management, and limb trauma rehabilitation and orthotic management.
	Pain Management	This research is focused on the management of pain ranging from acute pain at point of injury to chronic pain management, with a view spanning basic research through clinical development.
	Regenerative and Rehabilitative Medicine	Regenerative medicine is the process of replacing or regenerating human cells, tissues, or organs to restore or establish normal tissue function. The regenerative medicine portfolio pursues research to provide products and solutions to repair, reconstruct, or regenerate tissue lost or damaged due to traumatic injury.
	Sensory Systems (Vision, Hearing, Balance)	This research program is focused on understanding the mechanisms of and developing treatment strategies for traumatic injuries resulting in visual, auditory, and vestibular dysfunction. The portfolio supports basic research, preclinical and early clinical studies to advance the development of devices and therapeutics for vision, hearing, and balance restoration and rehabilitation following traumatic injury.
	TBI Rehabilitation Research Program	This research is focused on understanding mechanisms of recovery and developing treatment strategies for traumatic injuries resulting in cognitive, sensorimotor, somatic, and multi-modal deficits.
	Cardiovascular Care	The Integrative Cardiac Health Project (ICHP) is a Center of Excellence for Cardiovascular (CV) Care and R&D, where CV care is provided at ICHP and Service MTFs for all DoD beneficiaries. ICHP has an advanced, systems medicine (personalized, proactive, predictive, participatory) approach to CV risk assessment and reduction, especially targeting sex/ethnicity differences, combat trauma, sleep disorders, and other occupational and environmental exposures in military populations.
	Cancer Care	The Murtha Cancer Center (MCC) is the DoD Center of Excellence for Cancer Care and R&D, funded through MCC Research Program (MCCRP) at USUHS. Cancer care research is provided at MCC Bethesda and Service MTFs for active duty, veterans, and DoD beneficiaries. MCCRP researches cancers that primarily affect active duty Service members and have a Force Readiness aspect, including cancers related to DoD occupational and environmental exposures.

Combat Casualty Care	Prolonged Care	The prolonged care portfolio focuses on provision of medical care within future operational scenarios projected to occur in multi-domain operations. Research focuses on understanding the unique needs of prolonged field care scenarios in a tactical environment, innovating to move interventions closer to the point of need, and enabling providers by automating and developing closed loop systems, and miniaturizing/ruggedizing technologies.
	Advanced Diagnostics	This portfolio seeks to respond to military medical problems with diagnostic, imaging, and therapeutic solutions based on optical science and technology, in combination with other technologies, e.g., acoustics, electronics, micromechanical, and nanotechnology.
	Battlefield Resuscitation Immediate Stabilization of Combat Casualties (BRISCC)	The program's purpose is to develop next generation blood products and pharmaceutical coagulopathy of trauma to be used for resuscitation to maintain survival and maximize recovery in interventions for hemorrhage in the setting of the battlefield. R&D is focused on innovative ways to provide immediate stabilization by utilizing pharmaceuticals and blood and blood products to include other resuscitation products such as dried or Lyophilized formulations of blood, blood substitutes and blood components (i.e., plasma and fibrinogen), as well as compounds to modulate the adverse effects of inflammation and immune response. There is also a focus on prehospital-driven research to decrease morbidity and mortality from injury on the battlefield. This R&D focuses on novel approaches that leads to the implementation of innovative technologies and clinical practice guidelines, which aids in the prehospital assessment and monitoring of casualties, with emphasis on adequacy of resuscitation and immediate cardiopulmonary stabilization.
	En Route Care	Research is focused on understanding patient physiology and the effects of transportation (air, rail, ground, and sea) on patient illness, injury, treatments, and outcomes. Research to advance the understanding of patient staging and transport needs after prolonged care scenarios and from austere/remote environments is included. The task area also includes research to advance knowledge in unmanned patient movement and medical capabilities during transport.

Combat Casualty Care (Cont)	Neurotrauma and TBI	The neurotrauma program is focused on closing military relevant gaps across a broad range of research areas to improve the diagnosis, management, and treatment of TBIs and related neurotrauma from point of injury through transport and acute hospitalization. The mission is to: decrease morbidity and mortality from neurotrauma; mitigate secondary brain injury across all TBI severities and all echelons of care through requirements-driven research; advance materiel and knowledge development to expand and develop new clinical guidelines, care algorithms, therapies, devices, and procedures that advance the decision-making capabilities of medical personnel; and promote earlier intervention and improve outcomes.
Medical Chemical and Biological Defense	Integrated and Layered Defense (ILD)	The integration of protection and recovery allows for layered defense across medical and non-medical focus areas to ensure emerging capabilities work together to both protect the warfighter from chemical biological (CB) exposure and ensure a more rapid return to sustainable operations in a CB threat environment. The ILD portfolio includes S&T investments aligned to the following CB Defense Program Core Capability Areas: Chemical Prophylaxis, Biological Prophylaxis, Respiratory & Ocular Protection, Percutaneous Protection, Expeditionary Collective Protection, Chemical Therapeutics, Biological Therapeutics, Personnel Contamination Mitigation, Materiel Contamination Mitigation, and Tactical Disablement.
	Anticipating and Preventing Surprise	This portfolio areas focuses on properties (physical, chemical, biological), environmental, and human response behavior. Research efforts also examine characterization of dispersion mechanisms, hazard modeling, plume analysis, and other investigations into potential threat agent employment as well as threat awareness scanning capabilities and emerging technologies that allow for real-time monitoring for identifying emerging threats and maintaining situational awareness of the threat environment. The portfolio further seeks to assess technical enhancements that alter or increase the threat of CB agents (e.g., encapsulation technologies), and to assess the impact of improved processes used to produce chemical and biological threats.
	Integrated Early Warning (IEW)	Integrated warning enables commanders to achieve a level of understanding as early as possible to make proactive risk-based decisions to protect the force in a CB threat environment. In a CB environment, situational awareness is achieved through gathering information and understanding the CB threats within time and space that allow decision makers to make good choices. The analysis of these results allows for an assessment of risk that can be used to lower a warfighter's chance of CB exposure or improve survivability if already contaminated. IEW portfolio includes S&T investments aligned to the following CB Defense Program Core Capability Areas: Chemical

Medical Chemical and Biological Defense (cont)		Detection, Biological Detection, Medical Diagnostics, CBRN Warning and Reporting, and Decision Analysis and Management.
	Enabling S&T Focus Areas	Research to enable science provides the knowledge that informs capability development, joint concepts of operations, and multi-Service tactics, techniques, and procedures to protect the warfighter. In addition, enabling science provides critical characterization of current and emerging CB threats to: inform capability development; focus on fundamental efforts to understand living systems' response to CB agents; and support detection, diagnostics, protection, and medical treatment.
Medical Radiological Defense	Pharmaceuticals for Prevention, Mitigation, and Treatment	This portfolio seeks to advance new products to FDA approval for Acute Radiation Syndrome (ARS) or to repurpose existing products for ARS. There is a heightened interest in products with dual purpose indications for other commercially or militarily relevant indications, for example, cancer treatment.
	Diagnosis by Using Biophysical Dosimetry Methods and Devices	Triage and treatment of potential radiation casualties requires new technologies to inform health care providers of the extent of radiation exposure and the likelihood of illness requiring treatment to ensue. This program is exploring various approaches to dose estimation from tracking of clinical symptoms to measurements of various biological markers of radiation exposure.
	Basic Molecular Radiation Biology	The key to better understanding of radiation injury to humans requires knowledge at the cellular level of the biologic basis of radiation injury, including the molecular targets and mechanisms of injury. This program seeks to advance the state of knowledge in this discipline through cutting-edge research.
	Enabling Technologies, Including Qualified Animal Models for Product Development	The path to FDA approval for ARS countermeasures requires demonstration of efficacy in animal models. This program supports the development of an "innovation ecosystem" to put forth new techniques and generate the capabilities needed to support the drug discovery and development pipeline for ARS countermeasures.
	Development of Medical Radiological Response Capability for Acute and Long-Term Recovery	Due to extensive experience treating patients with whole body radiation and other toxic therapies, bone marrow transplant physicians can modify these technologies to treat radiation injured casualties, grading the therapy from medical support to hematopoietic transplantation. Systems to treat potential radiation mass casualties are being developed and many technologies developed for radiation casualties can be used to treat patients with other diseases.

Military Infectious Diseases	Bacterial Diseases	This program aims to discover, characterize, and develop host immune response and pathogen biomarkers associated with infection to inform clinical wound-management decisions. This includes identification of nosocomial pathogens and characterization of antimicrobial resistance patterns and identification of new drug targets against wound infection pathogens and biofilm processes. The effort funds the transition of new candidate therapeutics to preclinical testing and accelerates promising early leads to first-in-human clinical trials. Additional goals are to develop novel and innovative delivery technologies to treat wound infections.
	Viral Diseases	This program: (1) responds to emerging infectious disease threats; (2) maintains scientific awareness and a capability to respond to emerging infectious diseases; and (3) partners with other entities to rapidly accelerate promising, innovative drug and vaccine solutions to combat emerging infectious diseases (e.g., Chikungunya, Middle East Respiratory Syndrome, Zika).
	Diagnostic Development	This involves an FDA-cleared in vitro diagnostic capability for infectious diseases that supports near real-time patient treatment and force health protection decision making.
Military Operational Medicine	Injury Prevention and Readiness	This research aims to advance knowledge in methods to detect or assess musculoskeletal injury, human load capacity, and evidence-based return-to-duty criteria for various military occupational specialties. This research also leverages existing DoD expertise to elucidate key physiological and biochemical events underlying repeated head trauma, which will lead to the development of countermeasures that prevent and mitigate subclinical TBI resulting from blast exposures. This research also focuses on preventing or reducing warfighter injury in the neurosensory domain and will involve improved hearing and vestibular protection strategies as well as tinnitus mitigation.
	Psychological Health & Resilience	This research is focused on providing solutions that build Service member, family, and community resilience in order to sustain and restore behavioral health and resilience. This research is also focused on diagnosing and treating psychiatric and clinical psychological disorders in warfighters through the development of interventions, treatment and prevention strategies, and computational modeling. A major emphasis is research focused on PTSD and common co-occurring psychiatric or medical conditions. The portfolio directly supports the National Research Action Plan in response to the White House Executive Order released in 2012 on improving access to mental health services for the Service members, veterans, and military families.
	Performance in Extreme Environments	This research focuses on optimization and sustainment of physiological and cognitive performance of the individual warfighter subjected to extreme environmental stressors (e.g., heat, cold, altitude,

Military Operational Medicine (cont.)		hyperbaria, undersea) and toxic environmental exposures during operations. This research supports multi-domain operations in dense urban environments and subterranean spaces and impacts lethality and performance of the warfighter.
	Optimized Cognition and Fatigue Mitigation	This research explores and develops pharmacologic and nonpharmacological interventions for enhancing the recuperative value of sleep in order to restore/enhance cognitive ability for warfighter readiness, thus improving performance, safety, and health. This research will also provide the scientific evidence basis for DoD policies, programs, and strategies to optimize 21st century warrior health and performance through improved nutrition.
	Millennium Cohort Study	This is a longitudinal study to evaluate data on the health conditions of Service members following deployment. It is a population-based prospective cohort study of specific impacts of military service and deployments on health outcomes in military personnel (Active Duty, Reserve/National Guard) and their families across the lifecycle.

II. Congressionally Directed Medical Research Programs: (DHP and Army; Managed by CDMRP)

Research Program Area	Research Description
Alcohol and Substance Abuse Disorders Research Program (ASADRP)	The ASADRP (est. FY 2010) addresses growing concerns about the problem of alcohol and substance abuse among the general public, military personnel, and veterans. Impacts of this abuse are both personal and societal, and include reduced levels of readiness, mental health problems, increased crime, sexual assaults and suicides. Supports research to accelerate the delivery of new or improved treatments for alcohol and substance use disorders, especially as related to PTSD and TBI, to improve the health and lives of Service members, families, veterans, and the American public. The program's approach to achieving this has been to organize networks of multidisciplinary, team-based translational research efforts to identify promising compounds, conduct proof-of-principle research to determine which compounds are most appropriate for human research trials, and then conduct human proof-of-principle trials with promising compounds to improve treatment outcomes.
Amyotrophic Lateral Sclerosis Research Program (ALSRP)	The ALSRP (est. FY 2007) continues to be guided by a vision to improve treatment and find a cure for ALS. Service Members are 60% more likely than civilians to develop neurodegenerative diseases such as ALS. Resources are needed to care for Service Members, veterans, their family members and the American public living with ALS. Strategic guidance each year has resulted in a narrow focus to leverage ALSRP funds to promote preclinical development of ALS therapeutics, an identified gap in the research continuum. Areas of emphasis include development and/or validation of high-throughput screens to exploit novel targets with therapeutic potential and development of candidate therapeutic agents through the many steps required before FDA approval as an investigational new drug.
Autism Research Program (ARP)	The ARP (est. FY 2007) encompasses a range of complex developmental disorders characterized by mild to severe challenges to social, emotional, and communication abilities. The causes of ASD are unknown. The ARP seeks to fund innovative and highly impactful ASD research with the ultimate goal of improving the lives of those living with the disorder. The program focuses on ways to improve diagnosis, treatment, and on studying psychosocial factors affecting key life time transitions to independence and a better life for those with autism and their families.
Bone Marrow Failure Research Program (BMFRP)	The BMFRP (est. FY 2008) supports research focused on bone marrow failure diseases. Disorders that affect stem cells or progenitor cells can lead to bone marrow failure; rare, potentially life-threatening diseases in which the bone marrow stops functioning or produces abnormal blood cells. These diseases can be either inherited or acquired. Acquired BMF includes diseases that can occur following an environmental exposure such as ionizing radiation, chemical contamination, or the long-term effects of chemotherapeutics. BMF can lead to lifelong chronic illnesses with the potential to develop cancer.
Breast Cancer Research Program (BCRP)	The BCRP (est. FY 1992-1993) continues to address research gaps in breast cancer. More than 266,000 women and 2,500 men will be diagnosed with invasive breast cancer in 2018, and an estimated 41,400 breast cancer deaths will occur in the U.S. There is a higher incidence rate of breast cancer among active duty Service members compared to the general population, and it is the single greatest cause of cancer deaths among women under 40. The BCRP has been instrumental in supporting research that led to clinical breakthroughs, including current standard of care treatments, imaging approaches, and diagnostic procedures, as well as genetic risk assessment tools. Despite the significant progress made in the breast

Research Program Area	Research Description
	cancer field, the BCRP recognizes that many overarching questions still remain unanswered, and funding must be invested in critical areas of research in order to make breakthroughs that will save lives.
Breast Cancer Semipostal	As a result of the efforts of breast cancer advocates, the Stamp Out Breast Cancer Act (Public Law 105-41) led to the U.S. Postal Service's issuance of a new first-class stamp, the Breast Cancer Research Semipostal (BCRS) in 1998. It was the first semipostal in U.S. history. Net revenues from sales of the BCRS, which currently costs 60 cents, are provided to two designated funding agencies, the DoD BCRP and NIH, to support breast cancer research. The Breast Cancer Research Stamp Reauthorization Act of 2015 reauthorized the stamp through 2019. Breast cancer stamp funding has been used to fund projects through BCRP award mechanisms that support research that could lead to major advancements in breast cancer.
Duchenne's Muscular Dystrophy Research Program (DMDRP)	Duchenne Muscular Dystrophy (DMD) is a severe, progressive disease that causes muscles to become weaker over time. It affects approximately 1 in 5,000 male infants and 20,000 new cases a year. Currently there is no treatment, but research has identified many new potential therapeutic targets and significantly expanded the number of potential therapeutics in the pipeline. The DMDRP program (est. FY 2011)funds research directed toward accelerating promising therapeutic ideas into clinical applications.
Epilepsy Research Program (EPR)	The ERP (est. FY 2015) was created in response to concerns about the long-term consequences of TBIs and the subsequent development of post-traumatic epilepsy (PTE). It is estimated that over 350,000 Service members returning from the wars in the Persian Gulf and Afghanistan have sustained TBIs. The ERP is interested in longitudinal research and epidemiological research in order to understand what the risk factors are for developing PTE after TBI. The ERP is also interested in comorbidities, such as psychogenic seizures. Psychogenic seizures display many of the symptoms of PTE but represent a different treatment challenge. These research challenges, together with the development of diagnostic and mechanistic studies, are intended to improve patient outcomes and understand the magnitude of PTE within the military.
Gulf War Illness Research Program (GWIRP)	The GWIRP (est. FY 2006) provides support for research to study the health effects of deployment on U.S. warfighters during the 1990-1991 Persian Gulf War. The multitude of symptoms experienced and reported by Gulf War veterans are of a similar clinical description and usually include combinations of widespread pain, muscle aches, headache, persistent problems with memory and thinking, fatigue, breathing problems, stomach and intestinal symptoms and skin abnormalities. Studies indicate that approximately 25-32% of Gulf War veterans continue to experience symptoms associated with their deployment that cannot be explained by established medical diagnoses or standard laboratory tests. The GWIRP focuses on funding innovative, competitively peer-reviewed GWI research to identify effective treatments and accelerate their clinical application, improve definition and diagnosis, and better understand pathobiology and symptoms.
Hearing Restoration Research Program (HRRP)	The HRRP (est. FY 2017) supports research that pursues the treatment of auditory system injuries and the restoration of hearing. It is estimated that more than 30 million Americans over the age of 12 years have hearing loss in both ears, and an estimated 48 million have hearing loss in at least one ear. Hearing loss may be congenital or may be induced by diseases,

Research Program Area	Research Description
Hearing Restoration Research Program (Cont)	medication, aging, injury, or exposure to excessive noise. Hearing loss is highly prevalent in the military population. More than 1.1 million veterans suffer from Service-connected disability due to hearing loss. In comparison to the general public, military personnel are at higher risks of noise-induced hearing loss and auditory system injury. Service members are exposed to high levels of noise (e.g., gunshots, carrier decks, helicopters, explosions) that are unique to combat and the combat training environment. Unlike noise in construction, agriculture and recreation, encountering combat noise is not predictable, and protection against combat noise is further complicated by the need for warfighters to hear sound and communicate. Exposure to loud and/or chronic noise triggers hearing loss and auditory dysfunction that affect not only operational performance and medical readiness of warfighters, but also health and quality of life of veterans and their families. The HRRP strives to advance the science of hearing restoration by delivering research and solutions that remove barriers to the successful treatment of auditory system injury.
Joint Warfighter Medical Research Program (JWMRP)	The JWMRP (est. FY 2012) augments and accelerates high-priority DoD and Service medical requirements and to continue prior year initiatives that are close to achieving their objectives and yielding a benefit to military medicine. The ultimate goal of the program is to expedite product development initiatives in support of our Armed Forces. The JWMRP is a congressionally directed program stipulating that the funds from the JWMRP shall not be used for new projects or for basic research. The funding shall be awarded at DoD discretion following a review of medical research and development gaps as well as unfinanced medical requirements of the Services. The projects funded through this appropriation are expected to benefit both civilian and military communities with particular focus on initiatives that impact our forward deployed forces and rehabilitation efforts for injured military personnel. JWMRP is a dynamic program that facilitates the maturation of previously funded research efforts that demonstrate the potential to close identified military medical capability gaps. By focusing on both early and advanced technology development, the JWMRP provides a pathway to transition products to military healthcare providers and the warfighter. The vision of the program is to move military relevant medical solutions forward in the acquisition lifecycle to meet the needs of Service Members, veterans, and other MHS beneficiaries.
Kidney Cancer Research Program (KCRP)	In FY 2017, Congress directed funding for kidney cancer research through an appropriation for the KCRP. According to the American Cancer Society approximately 63,990 new cases of kidney cancer will occur in the U.S. and 14,400 people will die from the disease. Kidney cancer is twice as common among men as it is among women and is more common among African Americans. Lifestyle factors have been associated with kidney cancer, as have exposures to industrial solvents and other environmental carcinogens.
Lung Cancer Research Program (LCRP)	The LCRP (est. FY 2009) has played a critical role in supporting research within the MHS and general public for risk assessment, prevention, early detection, diagnosis, and treatment for the control and cure of lung cancer. Lung cancer is the leading cause of cancer deaths in the U.S. as well as worldwide. Military personnel are at a higher risk of developing lung cancer than the general population due to increased rates of smoking, especial during deployment, as well as an increased likelihood of exposure to environmental carcinogens during their service. The LCRP invests in research across the full spectrum of basic, translational, and clinical research. The LCRP also promotes collaborations across disciplines and with the MHS to develop meaningful research partnerships.

Research Program Area	Research Description
Lupus Research Program (LRP)	The LRP (est. FY 2017) supports research that addresses significant issues and gaps in lupus diagnosis and treatment. Lupus is a heterogeneous autoimmune disease that is difficult to diagnosis and treat. There is currently no test available to diagnose lupus, and it may take months or years for a person to be correctly diagnosed. Because lupus attacks healthy cells and tissues in many parts of the body, patients can experience a wide range of symptoms such as fatigue, joint pain, skin lesions, and headaches. Treatment options for lupus are highly dependent on an individual patient's symptoms and long-term use of these treatments can result in serious side effects, including kidney problems, stomach bleeding, liver damage, increased risk of infection, decreased fertility, and increased risk of cancer. Better treatment options are a critical need for lupus patients.
Military Burn Research Program (MBRP)	The MBRP (est. FY 2011) addresses combat-related and trauma-induced burn injuries, as well as improved health and performance outcomes for Service members and the general public at large. For the military, burn injuries have comprised 5-20% of the casualties sustained in post-World War II conflicts. Military burns are often devastating and more severe than burns obtained in the civilian setting. In addition to their burns, Service members may also suffer from fractures, amputations, smoke inhalation, and head injuries at the same time. This traumatic assault adds additional burden to the body's innate immune response and, thus, increases the likelihood of infections and organ damage that the research field has yet to fully elucidate. Research topics of interests to the MBRP have included accelerating wound healing, infection, rehabilitation, lung injury, hypertrophic scarring, and many more. The MBRP congressional appropriations allow the program to continue its mission to identify and address gaps in burn trauma care through military-focused research so that the best burn trauma care can be delivered to improve health and performance outcomes in support of the warfighter, veterans, MHS beneficiaries, and the general public.
Multiple Sclerosis Research Program (MSRP)	The MSRP (est. FY 2009) focuses on MS, a degenerative, chronic, immune-mediated disease that worsens over the years. The etiology and pathogenesis of MS are largely unknown. It is usually diagnosed between the ages 20 and 50 years, although it can occur in young children and significantly older adults. It can be difficult to diagnose and since there is no single test for MS, and the diagnosis can be missed, delayed or even incorrect. MS has a significant impact on active duty and veterans. A 2012 study showed that in the U.S. Armed Forces, personnel have a higher MS incidence than the general population. To address this issue, the VA established two MS CoEs. The MSRP invests in research across the full spectrum of basic, translational, and clinical research. To accomplish its vision to prevent, cure, reverse, or slow the progression, and lessen the personal and societal impact of MS, MSRP seeks to support pioneering concepts and high impact research relevant to the prevention, etiology, pathogenesis, assessment and treatment of multiple sclerosis.
Neurofibromatosis Research Program (NFRP) **Neurofibromatosis Research Program (NFRP)**	The NFRP (est. FY 1996) aims to decrease the clinical impact of NF by promoting research that will enhance the quality of life of persons with NF. An estimated 100,000 Americans have an NF disorder, which occurs in both sexes and in all races and ethnic groups. There are multiple clinical manifestations including learning deficits, cognitive disorders, malignancies, musculoskeletal disorders, nervous system disorders, visual impairments, vascular disease, skin conditions, brain tumors and chronic pain. The NFRP supports research that will foster new directions for and address neglected issues in NF research; sponsors multidisciplinary and multi-institutional collaborations that bring new perspectives to the field; promotes

Research Program Area	Research Description
(cont)	translational and clinical studies to move promising ideas from bench to bedside; and develops a balanced portfolio of meritorious research related to all aspects of NF.
Orthotics and Prosthetics Outcomes Research Program (OPORP)	The OPORP (est. FY 2014) supports research of with the potential to improve the health and well-being of Service members, veterans, and other individuals living with limb deficit. OPORP supports research to evaluate the comparative effectiveness and functional outcomes associated with prosthetic and orthotic clinical interventions. The purpose of the research is to ultimately advance implementation of the most effective prosthetic or orthotic device prescription, treatment, rehabilitation, and secondary health effect prevention options for patients, clinicians, other caregivers, and policymakers. OPORP has funded applied research; basic/discovery research; behavioral/psychosocial research; clinical trials; epidemiology/public health research; novel outcome development; quality of life studies; and translational research. Through continued funding of current and future projects OPORP endeavors to improve clinical decision-making and, ultimately, clinical outcomes for injured Service members with military-related neuromusculoskeletal injury.
Ovarian Cancer Research Program (OCRP)	The OCRP (est. FY 1997) establishes priorities to target the most critical needs along the research development pipeline from basic to translational to clinical research, including clinical trials, and to push the field of ovarian cancer forward through the MHS vision to "Eliminate ovarian cancer." Gynecologic cancers have a disproportionately high mortality rate and economic impact. The OCRP is dedicated to supporting patient-centered research to prevent, detect, treat, and cure ovarian cancer.
Parkinson's Research Program (PRP)	The PRP (funded under the Neurotoxin Exposure Treatment Parkinson's Research [NETPR] appropriation) was initiated in 1997 to provide support for research of exceptional scientific merit. Parkinson's disease (PD) is a degenerative movement disorder of the central nervous system resulting from a loss of neurons in a region of the brain called the substantia nigra. These neurons produce dopamine, a neurotransmitter important for motor control; however, as PD progresses, the death of dopaminergic neurons results in reduced dopamine levels and impairment of motor control. PRP projects examine neurodegenerative mechanisms and compensatory effects that compromise motor, autonomic, and cognitive systems that are characteristic alterations in PD patients and also present performance and health risks for military personnel. The PRP challenges the scientific community to develop research that will advance the understanding of the cause, prevention, and treatment of the loss of dopaminergic neurons in the substantia nigra that result in PD, with the ultimate goal of ending this disease.
Peer Reviewed Alzheimer's Research Program (PRARP)	The PRARP (est. FY 2011) addresses the long-term consequences of TBI as they pertain to Alzheimer's disease (AD) and AD-related dementias (ADRD). Military personnel, veterans and other individuals living with TBI face an increased risk for developing several long-term health problems. These include dementia, aggression, memory loss, depression, and symptoms similar to those of other neurodegenerative diseases. The PRARP's mission is devoted to (1) understanding the association between TBI and AD/ADRD, and (2) reducing the burden on affected individuals and caregivers, especially in the military and veteran communities.

Research Program Area	Research Description
Peer Reviewed Cancer Research Program (PRCRP) (multiple topics)	The PRCRP (est. FY 2009) has been charged by the U.S. Congress to fund innovative basic, applied, and translational cancer research to support the health of Service members, their families, veterans, and other military beneficiaries. Members of the military may be exposed to hazardous environments due to the nature of their service and deployments and, thus, may be at risk for the development of many different cancer types. Additionally, the PRCRP addresses underfunded and under developed areas of cancer research that may have an effect on mission readiness due to gaps in prevention and treatment. With a funding program focused on military health and welfare in cancer research, the PRCRP strives to improve the quality of life by decreasing the impact of cancer. Fiscal year 2018 topic areas include: adrenal cancer, bladder cancer, blood cancers, brain cancer, cancer in children, adolescents, and young adults, colorectal cancer, immunotherapy, Listeria-based regimens for cancer, liver cancer, lymphoma, melanoma and other skin cancers, mesothelioma, myeloma, neuroblastoma, pancreatic cancer, pediatric brain tumors, and stomach cancer.
Peer Reviewed Medical Research Program (PRMRP)(multiple topics)	The PRMRP (est. FY 1999) supports medical research projects of clear scientific merit and direct relevance to military health across the full range of science and medicine, with an underlying goal of enhancing the health, care, and well-being of military Service members, veterans, retirees, and their family members. Program oversight is provided by a programmatic panel with joint military service and interagency representation. Throughout history, military medical research to support war time needs has led to breakthroughs in areas such as reconstructive surgery, the use of antibiotics, intensive care, burn care, and kidney dialysis that benefit Service members and civilians alike. Medical research supported by the PRMRP to address near- and long-term military needs, including Service member and family readiness, continues this tradition. In addition, Service members, their dependents, military retirees, and veterans receive medical services through the MHS, furthering the critical need to support research on a broad spectrum of medical issues affecting these diverse populations, which include children and the elderly. The PRMRP is committed to supporting research that has the potential to profoundly impact the development and implementation of medical devices, drugs, and clinical guidance that will enhance the precision and efficacy of prevention, diagnosis, and treatment across a wide range of disciplines including cardiovascular and endocrine health, autoimmune diseases and immunology, infectious diseases, internal medicine, neurological and psychological health, orthopedic and regenerative medicine, and respiratory and environmental health and injury. Fiscal year 2018 topic areas include: acute lung injury, antimicrobial resistance, arthritis, burn pit exposure, cardiomyopathy, cerebellar ataxia, chronic migraine and post-traumatic headache, chronic pain management, congenital heart disease, constrictive bronchiolitis, diabetes, dystonia, eating disorders, emerging infectious diseases, endometriosis, epidermolysis bullosa, focal segmental glomerulosclerosis, Fragile X, frontotemporal degeneration, Guillain-Barre syndrome, hepatitis B and C, hereditary angioedema, hydrocephalus, immunomonitoring of intestinal transplants, inflammatory bowel diseases, interstitial cystitis, lung injury, malaria, metals toxicology, mitochondrial disease, musculoskeletal disorders, myotonic dystrophy, non-opioid pain management, nutrition optimization, pancreatitis, pathogen-inactivated blood products, post-traumatic osteoarthritis, pressure ulcers, pulmonary fibrosis, respiratory health, Rett syndrome, rheumatoid arthritis, scleroderma, sleep disorders, spinal muscular atrophy, sustained-release drug delivery,

Research Program Area	Research Description
	tinnitus, tissue regeneration, tuberculosis, vaccine development for infectious diseases, vascular malformations, and women's heart disease.
Peer Reviewed Orthopedic (PRORP)	The PRORP (est. FY 2009) supports military-relevant orthopedic research and has continued its mission to address the most significant gaps in care for the leading burden of injury for facilitating return-to-duty by funding research to advance optimal treatment and rehabilitation from musculoskeletal injuries sustained during combat and combat-related activities. Advances in protective gear for military Service members have led to an increase in survivability. Many Service members involved in once-fatal incidents have been saved and/or resuscitated with the help of advances in care and materiel products derived from modern research. The combination of increased blast and orthopedic injuries in recent conflicts and use of modern body protective gear has also resulted in an increase in the number of Service members and veterans living with extremity injuries. The PRORP works closely and synergistically with its partners across the military and nonmilitary medical research community to minimize duplication of research, promote collaborations, and identify medical capability gaps that affect military readiness, take into account Joint Force requirements, and maintain relevance to orthopedically injured individuals and their beneficiaries. Outcomes of the PRORP-funded projects in fields such as tissue engineering and repair, prosthetics and orthotics, prevention and treatment of complications, rehabilitations and biomechanics, and pain management will continue to also benefit veterans, MHS beneficiaries, and the general public.
Prostate Cancer Research Program (PCRP)	The PCRP (est. 1997) has changed the landscape of medical research and energized the prostate cancer research community to conduct high-risk research, ultimately aiming to conquer the disease. Prostate cancer is the most commonly diagnosed non-skin cancer in men and is the second most common cause of male death from cancer. Prostate cancer is a real threat to U.S. Service members, as 80% of the active duty population are men. According to the DHA Medical Surveillance Monthly Report (MSMR), 8,973 new cancers were diagnosed among active duty members of the U.S. Armed Forces between 2005 and 2014, and of these, 1,046 (11.7%) were prostate cancer diagnoses. Similarly, the DHA MSMR reported that, among active duty military personnel, prostate cancer occurred 2.5 times more frequently in African American Service members compared to Caucasian American Service members. To achieve its vision of conquering prostate cancer, the PCRP has focused on targeting underrepresented avenues of research and novel applications of existing techniques to achieve innovative solutions to critical challenges faced by prostate cancer patients. In spite of many PCRP-led advancements in prostate cancer detection, diagnosis, treatment, and patient care, critical issues related to prostate cancer incidence and mortality remain unanswered.
Reconstructive Transplant Research Program (RTRP)	Congress initiated the RTRP in FY 2012 to provide support for research that has the potential to make a significant impact on improving the function, wellness, and overall quality of life for injured military Service members and veterans, their caregivers and family members, and the American public. Many factors related to weaponry, personal protection, and trauma care during Operations Enduring Freedom and Iraqi Freedom resulted in greater survival of those sustaining increasingly severe combat injuries, particularly injuries to the face and extremities. These types of injuries often involve damage to and/or loss of multiple tissue types (i.e., composite tissues), including skin, muscle, bone, nerve, and vasculature.

Research Program Area	Research Description
Reconstructive Transplant Research Program (RTRP) (cont.)	Congress recognized the importance of vascularized composite allotransplantation (VCA) as an alternative to prosthetics for restoring function and sensation to the recipient, and also recognized the need for research to advance the science and medical capabilities for transplanting and maintaining these complex composite tissues. The RTRP challenges the scientific community to design innovative research that will foster new directions for, and address neglected issues in, the field of reconstructive transplantation, specifically focused on VCA research.
Spinal Cord Injury Research Program (SCIRP)	The SCIRP (est. FY 2009) was created by the recognition of SCI as one of the many serious wounds resulting from conflicts in Iraq and Afghanistan. SCI remains a complex neurotrauma, with devastating impact on the injured individual and his/her family members/caregivers, and no current cure available. Regaining and retaining function after injury requires multiple approaches to address problems of management of the acute injury, rehabilitation, and care throughout the lifetime of the individual. The SCIRP continues to address the most significant gaps in: 1. Management of the acute injury to minimize neuronal loss and maximize neurologic outcomes; 2. Rehabilitation to restore function; and 3. Development and testing of drug, device and other interventions to address serious sequlae of SCI, including bladder and bowel dysfunction, neuropathic pain, and depression- with the goal of restoring and maintaining health and quality of life. There are an estimated 12,500 new SCIs every year in the U.S. with a reported 276,000 persons in the U.S. living with a SCI and an estimated 42,000 veterans with spinal cord injuries/disorders. SCIRP closely coordinates funding efforts with the VA, the NIH, and non-governmental funding entities (including the Paralyzed Veterans of America) and uses input from active duty and retired military medical officers and representatives from MTFs to keep focus areas relevant to the needs of the military, veteran, and civilian populations and to synergize investments and avoid duplication of effort. Emerging technical and scientific developments in neuroprostheses, electrical stimulation, activation of neuroplasticity, and stem cells are areas of current opportunity in the SCI field where SCIRP-funded projects have the potential to change health care for veterans, MHS beneficiaries, and the general public.
Tick-Borne Disease Research Program (TBDRP)	The TBDRP was established in FY 2016, when the efforts of Lyme disease advocates led to a congressional appropriation. There are currently at least 16 known tick-borne illnesses, with tick populations spreading and emerging diseases being discovered all the time. In the U.S., cases of Lyme disease and other tick-borne diseases including spotted fever rickettsiosis, anaplasmosis, and ehrlichiosis have been increasing steadily for years and currently total tens of thousands of people diagnosed annually, with more likely going undiagnosed. For military forces and their dependents, Lyme and other tick-borne diseases are a significant threat, not only at domestic bases and training facilities, but worldwide. The intent of the TBDRP is to support innovative and impactful research that addresses its mission to understand the pathogenesis of Lyme disease and other tick-borne illnesses and deliver innovative solutions to prevent, diagnose, and treat their manifestations for the benefit of U.S. Service members and the American public. To maximize the program's ability to fill these research gaps and leverage the findings of others, while avoiding research duplication, the TBDRP coordinates with other major funding agencies and research initiatives both internal and external to the DoD.

Research Program Area	Research Description
Tuberous Sclerosis Complex Research Program (TSCRP)	The TSCRP (est. FY 2002) focuses on TSC, a rare genetic disorder that causes tumors to form in many different organs, primarily in the brain, eyes, heart, kidney, skin and lungs. The aspects of TSC that most strongly impact quality of life are generally associated with the brain: seizures, developmental delay, intellectual disability, and autism. TSC affects approximately 50,000 individuals in the U.S. and 1 to 2 million individuals worldwide. While there is no cure for TSC, earlier diagnosis and better treatments are helping those with TSC live healthier and fuller lives. The TSCRP invests in research across the full spectrum of basic, translational, and clinical research.
Vision Research Program (VRP)	The VRP (est. FY 2009) funds military-relevant vision research that has the potential to significantly improve the health care and well-being of Service members, veterans, their family members and caregivers, and the American public. Eye injury and visual dysfunction resulting from battlefield trauma affect a large number of Service members and Veterans. Surveillance data from the DoD indicate that eye injury accounts for approximately 15% of all injuries from battlefield trauma sustained during the wars in Afghanistan and Iraq, resulting in more than 182,000 ambulatory patients and 4,000 hospitalizations between 2000 and 2011. In addition, TBI, which affects more than 380,000 Service members between 2000 and 2018, can have significant impact on vision even when there is no injury to the eye. Research sponsored by the VA showed that as many as 75% of Service members who had suffered a TBI had visual dysfunction. The VRP's vision is to transform vision trauma care for our Armed Forces and the nation.

III. Additional Congressionally Directed Medical Research Programs (not managed by CDMRP)

Research Programs Area	Research Description
HIV/AIDS (Managed by USAMRMC-MIDRP)	Supports research to develop an effective HIV vaccine and integrates prevention, diagnostics, treatment and monitoring as part of an international effort to protect U.S. and allied troops and reduce the impact of HIV infection worldwide
Global HIV/AIDS Prevention (Managed by Navy)	Supports the development and implementation of culturally focused, military-specific HIV/AIDS prevention, care, and treatment programs in more than 55 countries around the globe and also supports implementation of the President's Emergency Plan for AIDS Relief (PEPFAR)
Psychological Health and Traumatic Brain Injury (USAMRMC)	Supports research to prevent, mitigate, and treat the effects of traumatic stress and traumatic brain injury on function, wellness, and overall quality of life for Service members as well as their caregivers and families
Trauma Clinical (USAMRMC - CCCRP)	Supports prospective, multi-center injury care and outcomes research of relevance to the DoD as well as research projects that will facilitate the transition of lessons learned from combat into improvements in trauma care practice

Appendix C
Process to Ensure Synergy Across the Military Medical Research Community to Address Gaps in Military Medical Research, Minimize Duplication of Research, and Promote Collaboration Within Research Focus Areas

This appendix responds in detail to language in section 736 of the John S. McCain NDAA for FY 2019 to provide: "(3) A description of the process to ensure synergy across the military medical research community to address gaps in military medical research, minimize duplication of research, and to promote collaboration within research focus areas."

Many of the processes described in Appendix B for coordinating across DoD R&D are also deployed to ensure synergy across the military medical research community and to address gaps, minimize duplication, and promote collaboration within research focus areas. Those and additional processes are summarized here, including collaborative efforts to ensure newly developed technologies are transitioned to other partners.

Addressing Gaps in Military Medical Research

As described in Appendix A, in 2013, the ASBREM reorganized into a CoI within the Reliance 21 framework, an Office of the Secretary of Defense-led effort for joint planning and coordination with the goal of reducing unnecessary duplications of work. Reliance 21 is the overarching framework of DoD S&T joint planning and coordination process. It enables information sharing, alignment of effort, coordination of priorities, and support for scientists and engineers across the DoD.

Reliance 21 is led by the DoD S&T Executive Committee, whose role is to prioritize resources and provide strategic oversight and guidance to the combined S&T workforce, laboratories, and facilities of DoD. The S&T Executive Committee ensures that DoD's S&T priorities correspond with broader defense needs and strategic guidance, and that the DoD S&T community provides solutions and advice to the DoD's senior-level decision makers, warfighters, Congress, and other stakeholders in the most effective and efficient manner possible.

The ASBREM plays a key role in synchronizing a multidisciplinary team approach across the DoD, Services, and Federal Interagency. Staffs, commands, organizations, and agencies address gaps identified through the JCIDS (established as the primary means for the Joint Requirements Oversight Council to fulfill its statutory responsibilities to the Chairman of the Joint Chiefs of Staff). These responsibilities include assessing joint military capabilities, and identifying, approving, and prioritizing gaps in these capabilities, to meet applicable requirements in the National Defense Strategy. The JCIDS Manual provides detailed guidelines and procedures to

facilitate robust capability requirements portfolio management and the timely and cost-effective development of capability solutions for the warfighter.

The ASBREM strategy provides a common framework to ensure that its CoI members continue to discover, develop, and deliver the medical capabilities required today and in the future. It provides the basis for ASBREM CoI members to optimize infrastructure and coordination and information exchange among the Services and defense agencies across the DoD, as well as the federal government, and the civilian sector. Additionally, this strategy enables ASBREM CoI members to partner with academia and industry to infuse investments and innovation into DoD medical operations and capabilities. This strategy is shaped to ensure the DoD's medical investments continue to be responsive to medical readiness and the warfighting needs today and well into the future.

Minimizing Duplication of Effort in Medical R&D

Unnecessary duplication of funding or accepting funding from more than one source for the same research is prohibited. The Government Accountability Office defines unnecessary duplication as "duplicative research funding that is not necessary to corroborate or replicate prior research results for scientific purpose." While investigators are allowed to apply for funding for the same research from different funding agencies, applicants may not accept funding from more than one source. While the responsibility for avoiding unnecessary duplication of funding ultimately lies with research applicants and their institutional business officials, the organization represented within the ASBREM CoI uses multiple standard processes and communications to minimize the likelihood of duplicating medical research funded by other agencies.

Although the NIH, CDC, and VA also fund medical research, the ASBREM CoI engages these partners to complement and synergize with other funding sources, not duplicate them.

The JPC process relies on two tiers of review to avoid unnecessary duplication of efforts. In addition, the CDMRP specifically conducts a two-tier review of every application received, intensified when applications are recommended for funding, and enhanced through multiple collaborations with other funding agencies and organizations. Programs are continuously subjected to scrutiny and ongoing improvements toward eliminating all duplicative research funding while preserving the replicative/confirmatory efforts vital to scientific advancement. (See the website for a detailed description of CDMRP Procedures to Avoid Research Duplication: http://cdmrp.army.mil/funding/researchDup.)

The DoD also promotes transparency and avoids duplication through active management of funded research projects, closely monitoring progress and requiring reports and presentations of research findings at conferences, sharing data, and registration of clinical trials. The STAR

METRICS® Federal RePORTER initiative (http://federalreporter.nih.gov) shares data from multiple agencies for federally-funded projects, and in addition the CDMRP website provides a searchable interface for all CDMRP awards (http://cdmrp.army.mil/search.aspx).

Promoting Collaboration within Critical Medical R&D Focus Areas

The DoD routinely coordinates with other departments and agencies of the federal government to increase synergy and awareness of complementary medical research and to pool resources and expertise to gain synergies (see also Appendix E). Additionally, DHA CoEs provide a responsive, holistic, longitudinal, and standardized framework/venue to consolidate key medical R&D efforts and nest DoD's collective expertise. This framework enables the DoD, through DHA as the lead agent, to manage programs, develop resources, and execute medical R&D more effectively in support of warfighters. The mechanisms by which coordination occurs include programmatic collaboration (e.g. joint reviews and programmatic planning across agencies for research of critical importance to multiple departments or agencies, through shared resources such as databases and biorepositories, and through joint solicitations for research proposals). Opportunities for collaboration arise from scientific opportunities, clinical needs, and shared missions.

DoD Centers of Excellence (CoEs)

The CoEs primarily reside within DHA although some exist within the USUHS and Services, and the Extremity Trauma and Amputation Center of Excellence resides within the Army. The centers provide a standardized framework for multiple functions to inform prioritization of medical R&D efforts, such as program evaluation, education and training, and knowledge translation and management. They also provide enhanced opportunities for cross-collaboration throughout the DHA in support of improving and sustaining operational readiness. They are instrumental in convening experts from around the world to review the scientific evidence base for the development of clinical practice guidelines for treating injuries and illnesses resulting from combat. The standardization of clinical practice guidelines is foundational to improving efficiencies, and a more efficient medical force allows health care providers to focus on patient satisfaction and quality of care. Many of these guidelines can be immediately adapted for use in the civilian sector.

Medical Capabilities Working Group (MCWG)

The purpose of the Chemical and Biological Defense Program (CBDP) Medical Capabilities Working Group (MCWG) is to provide a recommendation on CBDP medical countermeasure (MCM) program planning for the program objective memorandum (POM). This recommendation will inform Joint Service priorities for MCMs, as well as POM baselines and alignment plans for the Joint Science and Technology Office (JSTO) and Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD). The MCWG will ensure that issues and concerns with Component (JSTO and JPEO-CBD) plans are mediated prior to overarching CBDP POM planning and programming discussions. The ultimate goal is to gain stakeholder agreements on a POM position, an understanding of the alignment between Component efforts, and, as appropriate, input on key programmatic changes and/or reprogramming decisions to be addressed during the year of execution.

Principal membership reflects stakeholders with direct responsibility for CBDP POM planning and programming activities, and will be appointed from the following organizations:

- Office of the Deputy Assistant Secretary of Defense for Chemical and Biological Defense (Co-chair)
- Office of the Assistant Secretary of the Army for Acquisition, Logistics and Technology (Co-chair)
- Office of the Deputy Chief of Staff, G-8, U.S. Army
- Deputy Commandant for Combat Development and Integration, Headquarters, U.S. Marine Corps
- Army Office of the Surgeon General
- Navy Bureau of Medicine and Surgery
- Air Force Office of the Surgeon General
- Joint Program Executive Office for Chemical and Biological Defense
- Joint Requirements Office for Chemical, Biological, Radiological, and Nuclear Defense
- Joint Science and Technology Office for Chemical and Biological Defense
- Joint Chemical, Biological, Radiological, and Nuclear Defense Program Analysis and Integration Office

Advisory Membership reflects stakeholders who provide input to CBDP POM planning activities based on overarching doctrine, policy, or subject matter expertise.

Appendix D
Coordination with Other Federal Departments and Agencies

This appendix responds in detail to language in section 736 of the John S. McCain NDAA for FY 2019 to provide: ("4) A description of the efforts of the Secretary to coordinate with other departments and agencies of the Federal Government to increase awareness of complementary medical research efforts that are being carried out through the Federal Government."

The DoD routinely coordinates with other departments and agencies of the federal government to increase awareness of complementary medical research efforts that are being carried out and to pool resources and expertise to gain synergies. The mechanisms by which coordination occurs include programmatic collaboration, for example, joint reviews and programmatic planning across agencies for research of critical importance to multiple departments or agencies, through shared resources such as databases and biorepositories, and through joint solicitations for research proposals. Opportunities for collaboration arise from scientific opportunities, clinical needs, and shared missions. Some collaborative efforts are directed at higher levels (executive or congressional direction, federal advisory committees) and some generated from identified needs at lower levels (program panels and working groups, program staff interactions). As such, there are both formal and informal mechanisms of interagency coordination.

Defense medical research and the CDMRP regularly coordinate with the NIH, the CDC, the VA, and other federal agencies. For example:

- Representatives from the NIH, CDC, VA and other federal agencies serve on peer and programmatic panels and provide input at stakeholder's and vision setting meetings for program planning; there is close coordination between program staff where research areas align.
- Interagency committees/working groups engage in reciprocal sharing of information between government and other partners (e.g., International Cancer Research Partners, Metastasis Cancer Research Task Force, National Alzheimer's Project Act, Interagency Urology Coordinating Committee).
- Joint Interagency Funding Opportunities coordinate on funding and research initiatives (e.g., Chronic Effects of Neurotrauma Consortium [DoD/VA], Consortium to Alleviate PTSD [DoD/VA], Pain Management Collaboratory [DoD/NIH/VA]).

The defense medical programs and the CDMRP also coordinate with nongovernmental organizations such as non-profit organizations (advocacy, funding, research), and academic and industry. Representatives from these organizations serve on peer and programmatic panels to provide expertise, identify emerging technologies and opportunities, and coordinate on strategy and policy.

Some notable examples of DoD collaboration with other federal departments and agencies follow (this list is not all-inclusive).

National Research Action Plan for Posttraumatic Stress Disorder (PTSD), Suicide Prevention, and Traumatic Brain Injury (TBI)

The National Research Action Plan (NRAP) was established by Executive Order in 2012 to provide a 10-year blueprint for interagency research to enhance the diagnosis, prevention, and treatment of PTSD and TBI, and to improve suicide prevention. The NRAP includes 86 immediate, short-term, and long-term initiatives and represents both a strengthening of ongoing coordination and collaboration activities as well as directing new activities. Representatives of the DoD, VA, and Health and Human Services sit on the interagency committee that develops, implements, and manages the NRAP. Interagency collaboration occurs programmatically, over resources, and through clinical trials funding opportunities and projects.

One example of an initiative within the NRAP is Army STARRS (Army Study to Assess Risk and Resilience in Service members) and STARRS-LS (Longitudinal Study), intended to yield information about the nature of suicide in the military context and produce a better understanding of variables associated with individuals at high risk to inform policy and intervention research and development, with a focus on early detection of suicidality and PTSD. The U.S. Army and the National Institute of Mental Health funded the Army STARRS for the period of 2009-2015. This study has enrolled 107,000 soldiers, and it focuses on suicidal behavior, PTSD, TBI, and other mental health issues. DoD Health Affairs, the Army, and the National Institutes of Health launched the long-term follow-up of this cohort. DoD Health Affairs funded the longitudinal study in 2015-2020. The long-term study will provide actionable findings to senior DoD leaders to develop interventions, as well as to the Military Suicide Research Consortium (an ongoing DoD-funded project) to translate findings into improved prevention and treatments. In addition, the DoD and VA have collaborated to jointly funded two consortia in response to the NRAP.

Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System

TBI is a major medical problem for both military and civilian populations. There are many critical gaps in our knowledge regarding how to diagnose and treat people who sustain a TBI. High priority gaps include the need for an objective diagnosis for mild TBI, biomarkers to track recovery or progression of injury, a biologically based classification system, and comparative effectiveness research to determine which treatments are effective and for whom. To address these gaps, as well as other important questions on how to improve outcomes, the NIH, in partnership with the DoD, built a secure, centralized informatics system (database) for TBI research. It serves as a central repository for new data, links to current databases and allows

valid comparison of results across studies. The database builds on an effort to create common data elements for the study of TBI, which are essentially definitions and guidelines about the kinds of data that should be collected, and how to collect these data in clinical studies.

The FITBIR informatics system was developed to share data across the entire TBI research field and to facilitate collaboration between laboratories, as well as interconnectivity with other informatics platforms. Sharing data, methodologies, and associated tools, rather than summaries or interpretations of this information, can accelerate research progress by allowing re-analysis of data, as well as re-aggregation, integration, and rigorous comparison with other data, tools, and methods. This community-wide sharing requires common data definitions and standards, as well as comprehensive and coherent informatics approaches. There are currently more than 69,000 subjects in the database.

Collaboration with the U.S. Food and Drug Administration on Medical Product Development

The DoD and FDA have collaborated on medical product development priorities to address the unique needs of the warfighter since the original 1964 Memorandum of Understanding between the department and agency. DoD has long-standing policy to: (1) provide U.S. forces the best possible health care, including safe and effective medical products to address chemical, biological, radiological, or nuclear (CBRN) warfare; endemic disease threats; battlefield trauma and injury; and other conditions; and (2) to make preferential use of products approved by the FDA for general commercial marketing, when available, to provide the needed medical product.

Increased DoD-FDA collaboration was addressed in the NDAA for FY 2018 (§716 of P.L. 115-91), leading to the enactment of P.L. 115-92 (Dec. 12, 2017). This law amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to provide specific policy for increased DoD-FDA collaboration on medical product priorities. It allows the FDA to issue emergency use approvals for unapproved medical products or unapproved uses of approved medical products to address additional types of threats (beyond CBRN threats) related to a threat of attack with an "agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to the United States military forces" (§1(a), P.L. 115-92). It also allows the Secretary of Defense to request and authorizes FDA to take specific actions to expedite the development of medical products and the review of investigational submissions, applications for approval/licensure, and submissions/notifications for clearance for such medical products reasonably likely to diagnose, prevent, treat, or mitigate a specific and life-threatening risk to the U.S. military (§1(b)(1)-(2), P.L. 115-92). The DoD and FDA meet on a regular schedule to conduct a review of priorities. The agencies have codified implementation of PL115-92 in a memorandum of understanding, signed at the level of the ASD(HA) and the FDA Commissioner.

Interagency Campaign on Hemorrhage Control

The "Stop the Bleed" campaign was officially launched at the White House on October 6, 2015 via Presidential Proclamation and stands as an enduring partnership among the Combat Casualty Care Research Program (CCCRP), the DHA, and the National Security Council. It is an effort designed to raise public awareness and build resiliency with regards to scenarios of life-threatening bleeding in everyday situations. The initiative seeks to increase the U.S. public's understanding of its own capacity to respond to situations of major injury and to render basic, life-saving aid. The campaign has several important functions for both the DoD and the country. First, it stands as a clarion example of military lessons from war being translated to the civilian community for the purpose of saving lives. Second, it raises public awareness regarding citizens' capacity to respond to matters of trauma and render aid, which in turn builds national resilience.

Both the logo and the campaign style guide were developed internally at the CCCRP. Currently, the campaign continues to add licensed partners in at an accelerated rate, boasting more than 300 licensed partners across the U.S., Japan, Australia, Canada, and the United Kingdom. These partners include the American Red Cross, the FBI, the Walt Disney Company, Baylor University Medical Center, and numerous major universities, trauma centers, and local first responder agencies across the nation. Over the first three years, the "Stop the Bleed" campaign has added approximately 100 licensed partners per year.

Combating Antibiotic-Resistant Bacteria

Antibiotic resistance is a growing public health threat, and results in infections that are difficult or even impossible to treat. Some bacteria can also directly transfer their drug-resistance to other bacteria, further spreading resistance and threatening the effectiveness of existing antibiotics. To address this threat, the U.S. Government developed a National Strategy and accompanying National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB), which provides a road map to guide the nation toward five goals over 5-year periods that aim to (1) slow the emergence of resistant bacteria and prevent the spread of resistant infections, (2) strengthen national surveillance efforts to combat resistance, (3) advance development and use of rapid and innovative diagnostic tests for identification and characterization of resistant bacteria, (4) accelerate basic and applied research and development for new antibiotics, other therapeutics, and vaccines, and (5) improve international collaboration and capacities for antibiotic-resistance prevention, surveillance, control, and antibiotic research and development. The CARB Task Force facilitates implementation of the plan and is chaired by the Secretaries of the U.S. Departments of Health and Human Services (HHS), Agriculture (USDA), and Defense. The departments are in the processing of developing the next five years of the plan (2020-2025).

Uniformed Services University of the Health Sciences (USUHS)

The USUHS, located in Bethesda, Maryland, partners with the Walter Reed National Military Medical Center and NIH in a Unity of Effort, sharing resources and capabilities for the most advanced clinical care and research in the nation and the world. The university educates medical, nursing, allied health, and dental officers for the Army, Navy, Air Force and U.S. Public Health Service and is the leadership academy for military health care worldwide. The USUHS conducts foundational research in public health, infectious disease, rehabilitative medicine and readiness.

The USUHS has also strengthened its ties to several DoD and HHS research agencies—most notably, NIH. The result is an exceptional group of interdisciplinary research centers dedicated to solving some of the military's most pressing health care challenges. Examples include the Infectious Disease Clinical Research Program (IDCRP), which focuses on infectious disease challenges of particular importance to military personnel in deployed settings and is jointly sponsored by DoD and the National Institute of Allergy and Infectious Diseases.

Additionally, the Center for Neuroscience and Regenerative Medicine, jointly sponsored by the DoD and the National Institute of Neurological Disorders and Stroke, is tackling one of the greatest challenges in medical research—development of effective treatments for TBI. The John P. Murtha Cancer Center is dedicated to reducing the toll of cancer on the health and readiness of active-duty service members, the wellbeing of their families, and the lifespans of military retirees. DoD and the National Cancer Institute sponsor the center.

The Collaborative Health Initiative Research Program, a joint effort supported by DoD and the National Heart, Lung and Blood Institute, is applying precision medicine to tackle high-priority cardiovascular, pulmonary and sleep problems of relevance to military service members, retirees and their families.

Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)

The PHEMCE is charged with addressing the development, production, and availability of medical countermeasures to limit potential adverse health impacts on the large and diverse U.S. civilian population. The PHEMCE is working to meet the public health emergency needs of the entire civilian population, including groups that require special medical considerations, such as children, pregnant women, and older adults, as well as first responders, health care personnel, and other critical infrastructure personnel, by taking a "whole of community" approach in planning, response, and recovery efforts.

The PHEMCE is led by the Assistant Secretary for Preparedness and Response (ASPR). Core HHS members are the Director of the CDC, the Director of the National Institute of Allergy and Infectious Diseases (NIAID) within NIH, and the FDA Commissioner. Key PHEMCE interagency partners include senior leadership from the VA, DoD, Department of Homeland Security (DHS), and USDA. Additionally, the PHEMCE works with other HHS and U.S. Government partners, when appropriate, to consider international aspects of its mission. The PHEMCE also works closely with non-federal partners including state, local, tribal, and territorial governments, health systems, academia, private industry, and ultimately the American people.

Appendix E
Source Documents

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Appendix F
NDAA 2019 Section 736 Work Group Members

Organization	Representative
Office of the Under Secretary of Defense for Research and Engineering (OUSD(R&E))	Dr. Ben Petro
Defense Advanced Research Project Agency (DARPA)	Dr. Brad Ringeisen
Office of the Assistant Secretary of Defense for Health Affairs, (OASD(HA))	COL Jennifer Kishimori
Defense Health Agency Component Acquisition Executive (DHA J4)	Ms. Kathy Berst
Defense Health Agency Research and Development (DHA J9)	Dr. Sean Biggerstaff
Office of the Deputy Assistant Secretary of Defense for Chemical and Biological Defense (DASD(CBD))	LTC Mark Hartell
Defense Threat Reduction Agency (DTRA)	LTC Claire Cornelius
Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND)	Mr. Dave Williams
Office of the Joint Staff Surgeon (OJSS)	COL Patrick Garman
US Special Operations Command (USSOCOM)	LTC Chad Vermillion
US Army Medical Research and Materiel Command (USAMRMC) Office of the Principal Assistant for Research and Technology	Dr. Jonathan Miller
US Army Medical Research and Materiel Command (USAMRMC) Office of the Principal Assistant for Acquisition	Dr. Patricia Reilly
US Army Medical Research and Materiel Command (USAMRMC) Congressionally Directed Medical Research Program (CDMRP)	Dr. Rebecca Fisher
US Navy Bureau of Medicine and Surgery (BUMED)	Dr. David Neri
US Navy Bureau of Medicine and Surgery (BUMED)	CDR Paul Hauerstein
Office of Naval Research (ONR)	CAPT Matthew Swiergosz
Air Force Surgeon General (AFSG)	Mr. Brian McCarty
Uniformed Services University for the Health Sciences (USUHS)	Dr. Toya Randolph
Armed Services Biomedical Research Evaluation and Management Community of Interest (ASBREM CoI)	LTC Eric Midboe