OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND
READINESS

JAN 29 2016

The Honorable John McCain
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The enclosed report responds to the House Report 113-113, page 277, which accompanied H.R. 2397, the Department of Defense (DoD) Appropriations Bill, 2014, and Senate Report 113-85, page 190, which accompanied S. 1429, the DoD Appropriations Bill, 2014, to report on the status of the Joint Warfighter Medical Research Program (JWMRP). This report lists the projects that received funding, along with the amount of funding provided to each project, describes each of these research efforts, and identifies benefits that these projects will provide the DoD.

The Fiscal Year 2014 JWMRP funded 46 projects across six medical research areas: medical simulation and information sciences, military infectious diseases, military operational medicine, combat casualty care, radiation health effects, and clinical and rehabilitative medicine. The total funding allocation available for research and development was $95,031,639.37, after funding requirements for research management. Of the total funding, there were 32 projects funded in science and technology development at a cost of $60,746,328.41, and 14 projects funded in advanced development at a cost of $34,285,310.96.

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,

Brad Carson
Acting Principal Deputy

Enclosure:
As stated

cc:
The Honorable Jack Reed
Ranking Member

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND READINESS

JAN 29 2016

The Honorable William M. "Mac" Thornberry
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The enclosed report responds to the House Report 113-113, page 277, which accompanied H.R. 2397, the Department of Defense (DoD) Appropriations Bill, 2014, and Senate Report 113-85, page 190, which accompanied S. 1429, the DoD Appropriations Bill, 2014, to report on the status of the Joint Warfighter Medical Research Program (JWMRP). This report lists the projects that received funding, along with the amount of funding provided to each project, describes each of these research efforts, and identifies benefits that these projects will provide the DoD.

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Sincerely,

Brad Carson
Acting Principal Deputy

Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND
READINESS

JAN 29 2016

The Honorable Thad Cochran
Chairman
Subcommittee on Defense
Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

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Sincerely,

Brad Carson
Acting Principal Deputy

Enclosure:
As stated

cc:
The Honorable Richard J. Durbin
Vice Chairman

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND
READINESS

JAN 29 2015

The Honorable Rodney P. Frelinghuysen
Chairman
Subcommittee on Defense
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The enclosed report responds to the House Report 113-113, page 277, which accompanied H.R. 2397, the Department of Defense (DoD) Appropriations Bill, 2014, and Senate Report 113-85, page 190, which accompanied S. 1429, the DoD Appropriations Bill, 2014, to report on the status of the Joint Warfighter Medical Research Program (JWMRP). This report lists the projects that received funding, along with the amount of funding provided to each project, describes each of these research efforts, and identifies benefits that these projects will provide the DoD.

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Sincerely,

Brad Carson
Acting Principal Deputy

Enclosure:
As stated

cc:
The Honorable Peter J. Visclosky
Ranking Member

REPORT TO CONGRESS

Fiscal Year 2014 Joint Warfighter Medical Research Program

The estimated cost of report or study for the Department of Defense is approximately $15,290.00 in Fiscal Years 2014 - 2015. This includes $15,000.00 in expenses and $290.00 in DoD labor.

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1. BACKGROUND AND PURPOSE

The Assistant Secretary of Defense for Health Affairs (ASD(HA)), in fiscal year (FY) 2014, was requested by the House Report 113-113, page 277, which accompanied H.R. 2397, the Department of Defense (DoD) Appropriations Bill, 2014, and Senate Report 113-85, page 190, which accompanied S. 1429, the DoD Appropriations Bill, 2014, to provide a report, not later than 180 days after the enactment of the Act, to the Congressional Defense Committees on the status of the Joint Warfighter Medical Research Program (JWMRP). The report requires a list of the projects that received funding, along with the amount of funding provided to each project, a thorough description of each of these research efforts, and the benefit that these projects will provide to the DoD.

The Defense Health Agency (DHA), established under the authority, direction, and control of the Under Secretary of Defense for Personnel and Readiness, through the ASD(HA), supports policy execution, exercises management responsibility, and provides shared services to consolidate common services and to integrate operational missions and capabilities in the Military Health System (MHS). To accomplish its mission, the DHA is comprised of six directorates, one being the Research, Development, and Acquisition (RDA) Directorate. The DHA RDA Directorate manages MHS operations in the area of medical research and development and oversees the execution of the Defense Health Program Research, Development, Test, and Evaluation (DHP RDT&E) appropriation.

The U.S. Army Medical Research and Materiel Command (USAMRMC), a major subordinate Command of the U.S. Army Medical Command, manages biomedical research and development programs that are part of the DoD and Army Science and Technology Master Plans. The USAMRMC is responsible for ensuring statutory and regulatory compliance for research programs aligned to the Command. The Command manages and executes congressional special interest (CSI) research appropriations across a wide range of diseases and specific military-relevant programs focused on the development of products for prevention, diagnosis, treatment, or rehabilitation paradigms supporting Service members.

The JWMRP, a Congressionally-directed DHP RDT&E CSI appropriation, is executed by the USAMRMC in support of the DHA RDA Directorate. In FY 2014, Congress appropriated $100 million for the JWMRP that "...shall be used to augment and accelerate high priority Department of Defense 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 funds shall not be used for new projects or for basic research." The funding for the FY 2014 program was received by USAMRMC on March 25, 2014.

The JWMRP provides the DoD great latitude in accelerating prior congressionally-funded, high-priority research efforts, which will improve military medicine. This vital research program is the venue to bring to fruition products that will benefit our Service members. As the program has progressed, the percentage of the appropriation dedicated to advanced product development has increased, reflecting the progression of the JWMRP-supported research from

technology development to manufacturing development, thus enabling the delivery of a finished product.

The FY 2014 JWMRP funded 46 projects across six medical research areas: medical simulation and information sciences, military infectious diseases, military operational medicine, combat casualty care, radiation health effects, and clinical and rehabilitative medicine. The total funding allocation available for research and development was $95,031,639.37 after funding requirements for research management. In science and technology development, 32 projects were funded at a cost of $60,746,328.41. In advanced development, 14 projects were funded at a cost of $34,285,310.96. The prominent selection criteria in determining funding were: (1) whether the project was close to achieving its objectives, and (2) whether it had a clear benefit to military medicine. All of the projects selected and awarded have discrete deliverables that will either move the project forward to the next phase of development, result in the initiation of a clinical trial, or complete requirements to facilitate Food and Drug Administration (FDA) approval.

Table 1 lists the FY 2014 JWMRP award recipient, the funding amount, and a description of the project, which highlights the potential benefit this effort provides to the DoD.

Table 1

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
1.	Medical Robotic and Telesurgical Simulation and Education Research	Adventist Health System/Sunbelt, INC., d.b.a. Florida Hospital Orlando, FL	This research effort is focused on Telesurgery and Surgical Rehearsal. The Telesurgery component will measure the performance of robotic systems being used across a metropolitan, state, and national area. The Surgical Rehearsal will explore new simulation-based tools and techniques that will be useful for improving robotic surgeon performance. As technological capabilities expand, Telesurgery is a potential force multiplier and enabler to provide the highest level of specialty medical care to our Service members wherever they may be located.	$430,689.45

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
2.	Execution of a Quality Systems Program for FDA Regulated Activities	Amethyst Technologies, LLC Baltimore, MD	This effort involves validation of an automated system for research support and the qualification for the training platform, RIID-TRAIN. Amethyst will provide validation for critical equipment and software, develop innovative quality assurance process improvement tools, and implement quality assured programs for the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID). This initiative will: promote FDA compliance in research for potential biological threats; develop efficient tools to increase program efficiency while ensuring quality assurance to DoD and FDA standards; and increase functionality and applicability of current USAMRIID systems to support FDA-regulated studies. This effort directly supports regulatory compliance standards, which is a critical element in DoD-sponsored research.	$474,975.46
3.	Collaborative Research to Optimize Warrior Nutrition II (CROWN II)	Pennington Biomedical Research Center Baton Rouge, LA	The CROWN II project is an extension of the FY13 JWMRP-funded project. It seeks to discover novel strategies that promote Warfighter health and resilience, improve combat readiness, and sustain performance. Specifically, this project provides for the most efficient and cost-effective execution of the DoD objectives to ensure a healthy fit military that is ready for deployment and is resilient to the stressors of duty. The work is categorized in four thematic areas: 1) Metabolism and Physical Performance, 2) Stress and Inflammation, 3) Nutrition and Resilience, and 4) Healthy Eating and Behavior. This effort meets a critical requirement for the DoD.	$4,927,818.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
4.	Advanced Development of Entolimod (CBLB502) To Mitigate and Treat the Acute Effects of Ionizing Radiation	Cleveland BioLabs, Inc. Buffalo, NY	Entolimod is a novel drug candidate for use as a medical radiation countermeasure to reduce the risk of death following total body irradiation. In previous animal studies the use of Entolimod significantly improved survivability even when administered 24-48 hours after lethal radiation exposure. This effort will fund pivotal studies identified in the regulatory pathway for submission of a Biologics License Application to the FDA. FDA approved treatments for acute radiation syndrome is a high priority national defense initiative.	$9,226,454.64 (total 6.3/6.4): $5,506,165.00 is 6.3 technology development funding $3,720,289.64 is 6.4 advanced development funding
5.	Development of Therapeutic Drugs that Prevent the Triggering of Tinnitus	University of Pittsburgh Pittsburgh, PA	This study will investigate one of the biological mechanisms believed to be involved in the initiation of tinnitus, the number one occupational injury in the DoD. This effort may lead to a therapeutic intervention to treat or prevent tinnitus.	$797,905.00
6.	Robotic Telesurgery Research	University of Nebraska Medical Center Omaha, NE	This proposal will design, prototype, and test a miniaturized, remotely controlled, image-guided, surgical robot or minirobot to enable less invasive surgeries than is available with existing technology. This effort will lay the groundwork for FDA device approval. If successful, this technology will enhance the healing process and reduce the time for return to duty.	$2,755,410.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
7.	Quality Systems Innovations to Protect the Warfighter from Malaria	Amethyst Technologies, LLC Baltimore, MD	Malaria is one of the top infectious disease research priorities in the DoD. This effort supports a Phase III clinical trial currently being conducted by the Walter Reed Army Institute of Research at clinical trial field sites in Africa. It will augment malaria diagnostics with additional quality control and assurance measures, which are appropriate for Phase III malaria prevention trials.	$508,450.00 to Amethyst $499,959.34 sent to Walter Reed Army Institute of Research in support of this project
8.	Tracking the Health of Soldiers With Advanced Implantable Nano-Sensors	University of Connecticut Storrs, CT	This research effort is focused on the development of a totally implantable biosensor platform capable of continuously monitoring glucose, lactate, oxygen and glycerol in an autonomous mode. The study will include validation studies and scaled-up production methodologies for single-analyte (glucose) sensors and fabrication of multi-analyte sensor (glucose, lactate, glycerol, and oxygen) capable of metabolic patterning in order to predict physiological state such as exhaustion/shock. The development of an implantable biosensor will allow medical personnel to monitor key physiological parameters in real time without requiring the Service member to come to a fixed facility for evaluation. This effort has the potential to enhance operational readiness.	$2,248,917.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
9.	Anti-Biofilm Trauma Device Phase Two	Teleflex, Inc. Cambridge, MA	Protecting the surface of trauma implants from biofilm formation is critical to reduce orthopedic infection. This project will evaluate the product on wires and nails used in orthopedic interventions to evaluate protection from both initial bacterial challenges and long-term biofilm formation. The efficacy and biocompatibility of the product will be tested in small animal models to optimize performance and demonstrate efficacy. Once the performance formulation is identified, the full-size tibia nails will be modified and tested in a large animal model. Pending success of these proposed preclinical studies, preparations will be made to develop a process to prepare devices that could be used to support future clinical studies. A portion of the overall funding was provided to the U.S. Army Institute of Surgical Research to conduct animal studies in support of the product development. Reducing infections in orthopedic surgeries will expedite the return to duty for injured personnel.	$2,459,596 $305,221.61 sent to US Army Institute of Surgical Research

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
10.	Keratin Biomaterial-Based Bone Graft, KerGenis Bone, for Military Bone Injuries	KeraNetics, LLC Winston Salem, NC	Treatment options for traumatic bone injuries include a bone graft (autograft) or using InFUSE a collagen carrier of rhBMP-2 which is a growth factor that encourages the body to regrow bone. This study will investigate the efficacy of an injectable keratin hydrogel delivery system for rhBMP-2. The study will 1) determine the optimal dose of rhBMP-2 needed for healing when used in the keratin delivery system 2) complete a non-inferiority efficacy assessment of the keratin system compared to InFUSE 3) assess immunogenicity of the keratin delivery system in nonhuman primates. The results of this study will provide the data elements required for an Investigational Device Exemption submission to the FDA. If successful, this effort will enhance the rehabilitative process for individuals with bone injuries.	$1,407,276.20

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
11.	Advanced Development of Gamma-Tocotrienol as a Radiation Countermeasure	Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. Bethesda, MD	Gamma-tocotrienol (GT3), an antioxidant, protected almost 100% of mice against a lethal dose of radiation when administered subcutaneously 24 hours before exposure. This study will look at different formulations of GT3 to improve its tolerability when administered subcutaneously and evaluate GT3 soft gel capsules for oral efficacy. Also, it will study the efficacy of GT3 in nonhuman primates (NHP) using different doses of radiation for whole body exposure. Finally, it will investigate hematopoietic and gastrointestinal injury, accelerated recovery, and efficacy biomarkers in NHPs. These efforts are the foundation for a safety clinical trial in humans which is a key step in the regulatory pathway. Treatment of radiation exposure was specifically highlighted in the congressional language in FY14 and is a national defense priority.	$5,796,752.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
12.	Effectiveness of a Driving Intervention on Safe Community Mobility for Returning Combat Veterans	University of Florida Gainesville, FL	Motor vehicle crashes among returning combat veterans (CVs) is the leading cause for death, injury, disability, hospitalization and outpatient visits. MVC risk is substantially higher for CVs compared to peers in six months post deployment and remains elevated for 3-6 years. The Occupational Therapy Driving Intervention (OT-DI) is a simulator-based driving assessment and rehabilitation tool which in pilot studies showed a trend toward reduction in driving errors post-intervention. This study will determine if the clinical OT-DI is effective in reducing driving errors and improving driving fitness of CVs. If successful, this simulator training and rehabilitation program could directly impact the safety of our CVs.	$1,781,608.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
13.	Development of Safer Drugs for Malaria in U.S Troops, Civilian Personnel and Travelers: Clinical Evaluation of Primaquine Enantiomers	University of Mississippi University, MS	This project focuses on developing safer drugs that can be used for treatment, prevention and radical cure of relapsing vivax malaria. Primaquine is the only drug useful for relapsing malaria but it causes blood toxicity in people with a G6PD enzyme deficiency. There are two forms of primaquine that combine to make the drug and this study will separate the two forms and test the metabolism and toxicity of each in human volunteers. If the initial studies indicate that one may be safer it will then be tested at low doses in humans with a G6PD enzyme deficiency to confirm safety. If one form of primaquine is found to be safer in G6PD deficiency, it will be tested in malaria infected patients to see if the drug still kills the malaria parasites. This effort could revolutionize the use of primaquine in malaria eradication efforts and directly impact the health of our forces across the globe.	$2,761,018.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
14.	"Warfighter OpenICE" Interoperability Platform to Facilitate Force Health Protection and Readiness	The General Hospital Corporation dba Massachusetts General Hospital Boston, MA	This effort will develop a prototype system, leveraged by previously funded efforts to integrate medical devices in the clinical environment ("OpenICE"). This re-configurable clinical monitoring and decision support capability focuses on improving the efficiency and effectiveness of triage and monitoring of patients. The Warfighter OpenICE system will include device interfaces, wireless connectivity to facilitate collection of data from the medical devices, a computer system that will run the monitoring applications (similarly functional to a nursing central station), and mobile devices that will provide alerts and allow clinicians to interact with the system on the move. This technology enhancement may enable medical personnel to better monitor and treat their patients while improving patient safety and outcomes.	$453,799.47

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
15.	Pre-, Peri-, and Post-deployment Trajectories and Mechanisms of Psychopathology, Psychological Health and Resilience over Nine Years of Follow-up in the Reserves	University Hospitals, Case Medical Center Cleveland, OH	The Ohio Army National Guard Mental Health Initiative has evaluated relationships between resilience and risk factors before, during, and after deployment over the past five years. This specific research will extend the study to a nine year effort, an unparalleled longitudinal study. The study assesses the development of mental health problems, including post-traumatic stress, hazardous use of alcohol, depression, suicidality, military sexual trauma, anxiety and other risk-taking behavior. It assesses resilience, social, adjustment, military culture and support, coping factors and health including traumatic brain injury. Finally, it will evaluate the biological underpinnings of these mental health problems and resilience, with genetic and brain imaging studies conducted on the survey platform population. This unprecedented study in reserve component personnel will provide the DoD the data to shape policy and programs to support this population.	$1,664,980.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
16.	Advanced Restoration Therapies in Spinal Cord Injury	Hugo Moser Research Institute at Kennedy Krieger, Inc. Baltimore, MD	This effort will determine if functional electrical stimulation (FES) in a mouse model with chronic spinal cord injury (SCI) induces proliferation and differentiation of genetically labeled oligodendrocyte progenitor cells. The study will also determine if FES induces remyelination in a mouse model with chronic SCI. Finally, this effort will determine if FES in a mouse model with chronic SCI induces cortical plasticity as measured by resting state functional magnetic resonance imaging. This research effort could directly impact therapeutic rehabilitation efforts in support of our Service members with SCI.	$965,926.00
17.	Development of an Implantable Pudendal Nerve Stimulator to Restore Bladder Function in Human after Spinal Cord Injury	University of Pittsburgh Pittsburgh, PA	Currently there is no medication that can treat both incontinence and the ability of the bladder to empty completely after spinal cord injury (SCI). It is believed that bladder functions can be normalized by electrical stimulation and/or blockade of pudendal nerves after chronic SCI using an implantable neuroprosthetic device. This research effort will design and develop an implantable pudendal nerve stimulation system for FDA Investigational Device Exemption approval. The safety and efficacy of the implantable stimulator will be tested in a chronic SCI animal model. This is an extremely high-priority research effort because of the potential high payoff and the possibility to allow SCI patients to function without daily catheterization.	$2,077,000.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
18.	Development of a Simulation Tool for Upper Extremity Prostheses	University of South Florida Tampa, FL	Nearly one third of amputees reported being dissatisfied with the comfort of their device while one in five respondents reported being fit with a new prosthesis at least once a year. Quantification and 3D visualization of the underlying aspects of prosthesis fitting and performance with the robotic human upper body model (RHBM) can lead to significant improvement in their selection, design, rehabilitation and training methods. This effort continues development of the RHBM to produce a simulation tool with an expanded RHBM including a kinetic component, pseudo-joint, and return-to-duty tasks database; an improved graphical user interface with an enhanced visualization using solid modeling animation and avatar overlay capability; and a rehabilitation and training module for a virtual reality environment to incorporate the RHBM predictive visualization. This initiative has the potential to enhance the rehabilitative process for patients with upper extremity prostheses.	$280,465.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
19.	Development of a Bovine Immunoglobulin Supplement That Prevents Travelers' Diarrhea by Blocking Pathogen Adherence	Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. Bethesda, MD	Travelers' diarrhea (TD) is one of the principal causes of non-combat-related disease morbidity among U.S. military forces deployed overseas. Enterotoxigenic *Escherichia coli* (ETEC) cause 30% to 50% of TD in most developing countries. Previous studies found protective efficacy from TD using oral bovine colostrum derived immunoglobulins (BIgG). This effort will assess the protective efficacy of BIgG against one of the most common strains of ETEC. The overarching purpose of this effort is to lay the scientific foundation for development of a multivalent, food-based anti-diarrheal supplement that confers protection against ETEC. The development of a product that will reduce the incidence of TD will directly impact the operational readiness of our deployed forces.	$5,615,801.00
20.	Brain MR Spectroscopy Biomarkers In A Clinical Trial of PTS Patients with Comorbid AUD	Northern California Institute for Research and Education San Francisco, CA	Post-traumatic stress (PTS) and chronic alcohol consumption are common among veterans who served in Iraq and Afghanistan. Topiramate is approved as an anticonvulsant and migraine medication and in separate trials has shown to reduce PTS symptoms and alcohol consumption but has not been tested in dual-diagnosed patients. In this study, patients with PTS and co-morbid chronic alcohol abuse will be treated with topiramate and assessed for clinical improvement. In addition, specific brain chemicals affected by topiramate will be measured which may provide distinct biomarkers for treatment paradigms to improve the psychological health and resilience of our Service members.	$804,884.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
21.	A National Coordinating Center for Prehospital Trauma Research Funding: Detection and Management of Noncompressible Hemorrhage Using Vena Cava Ultrasound	National Trauma Institute San Antonio, TX	This research will refine techniques for early intervention and treatment of hemorrhagic shock using ultrasonic assessment (USA) of the inferior vena cava (IVC) diameter and collapsibility to detect and manage non-compressible hemorrhage. This effort will determine the sensitivity, specificity and accuracy of USA of IVC diameters in detecting traumatic shock compared to vital signs. It will determine the ability of USA of IVC diameters to detect preclinical shock states and will correlate the restoration of IVC diameters and collapsibility to achieve the endpoints of shock resuscitation in the intensive care unit. This technology application may impact clinical assessment protocols and enhance more rapid diagnosis and treatment of patients with hemorrhagic shock which could impact survivability.	$498,269.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
22.	Investigational New Drug (IND) Filing for Intravenous cP12 and Pre-IND Studies of Intravenous and Topical cNP5 to Limit Burn Injury Progression	Rutgers, the State University of New Jersey New Brunswick, NJ	Burns are dynamic injuries that progress over the course of several days, which increases the potential for infection, the need for skin grafts, and the incidence of scarring and scar contraction. The cP12 peptide has been found to promote cell tissue survival, limit burn injury progression, and reduce scarring in large animals. This development effort will manufacture a cP12 drug product in accordance with FDA requirements and identify the drug's optimal dose and time of administration in an animal model. This will result in a protocol for testing the safety and efficacy of the drug in humans and the filing of an Investigational New Drug application with the FDA leading to a clinical trial. Additionally, the effort will develop a topical formulation of this product. If successful, this effort could significantly reduce morbidity and scarring as a result of severe burns.	$2,713,034.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
23.	Preclinical and Clinical Development of the Next Generation Anti-Malaria Prophylactic Agent	Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. Bethesda, MD	Malaria remains the number one infectious disease threat to deployed U.S. forces. Current medications to protect against malaria must be taken every day, may cause stomach upset or sun sensitivity, and may lead to drug resistance. The focus of this effort is to develop a safe and effective drug that can be taken weekly to prevent malaria. This program is advancing a new class of anti-malarial medicine called triazines which are protective against *Plasmodium falciparum*. Animal studies will be conducted to determine which triazine compound is absorbed, distributed, and metabolized through the body most quickly with the least toxicity at various dose levels. The best product will then be manufactured for use in further animal toxicity studies required by the FDA and an Investigational New Drug submission to the FDA for a Phase I clinical trial. This effort could directly impact operational readiness through a more effective preventive measure against malaria.	$2,553,459.00 sent to HMJF $107,392.00 sent to WRAIR in support of this effort
24.	Does Evidence Based PTS Treatment Reduce PTS Symptoms and Suicide in Iraq and Afghanistan Veterans Seeking VA Care	Northern California Institute for Research and Education San Francisco, CA	The goals of this study are to determine if Prolonged Exposure Therapy and Cognitive Processing Therapy improve post-traumatic stress (PTS) and suicidality symptoms; what factors make it more likely for veterans to complete the therapy; and the impact on when the therapy began, if at all, on PTS and suicidality symptoms. Information from this research will benefit Service members, veterans, and their families, as they deal with PTS, suicide symptoms and other mental health problems.	$377,678.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
25.	A Motion-free Computed Tomography (CT) System for Forward Surgical and En Route Care	The Massachusetts General Hospital Center for Integration of Medicine and Innovative Technology Boston, MA	This development effort will build a prototype motion-free, portable X-ray CT scanner using a distributed X-ray source and advanced reconstruction algorithms based on compressed sensing. The proposed tomographic imaging system will have drastically reduced size, weight, and power requirements compared to existing CT scanners. The development of a portable, motion-free CT scanner will extend the reach of advanced life-saving imaging capabilities to far forward locations which could reduce mortality and morbidity associated with severe traumatic injuries including major battlefield wounds.	$817,181.00
26.	Development of a Vision Assistive Device for Veterans with TBI-Associated Visual Dysfunctions	The Schepens Eye Research Institute Boston, MA	This research will evaluate the functional efficacy of a novel collision warning device for use by visually-impaired and blind patients in their daily activities. The rigorous, extended home use evaluation will generate essential end-user feedback to help accelerate this portable, low-cost device into clinical practice. This mobility research initiative could lead to improved rehabilitation and independence for veterans with blindness or visual field loss due to traumatic eye and brain injuries or age related diseases.	$2,996,199.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
27.	GMP Production and Clinical Trial of a Self-Assembling Protein Nanoparticle and Toll-Like Receptor Liposomal MPL Adjuvanted Malaria Vaccine	Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. Bethesda, MD	Malaria remains a serious disease threat across the globe. This proposal outlines the steps needed to secure both the protein and adjuvant components of the vaccine. These two components will be combined to form the vaccine FMP-014 to be used in a human clinical trial. The objective of the proposal is to conduct a Phase I/IIa clinical trial of a nanoparticle malaria vaccine formulated in a liposome based adjuvant. This effort could lead to a better vaccine that will be more effective in protecting people against malaria and improve the health readiness of our forces worldwide.	$1,113,251.00 to HMJF $1,563,913.70 to WRAIR in support of this effort
28.	Improving Access to Care for Warfighters: Virtual Worlds Technology To Enhance Primary Care Training in Post-traumatic Stress and Motivational Interviewing	Northern California Institute for Research and Education San Francisco, CA	In previous research a pilot web-based post-traumatic stress (PTS) training program for primary care providers (PCP) was evaluated and found to improve PTS related knowledge and clinical skills. This follow-on effort will use Virtual World technology to create a training that is more interactive, engaging and effective and uses gold standard evaluation methods including provider and patient outcomes. The Virtual World training will be compared to the traditional web-based training to evaluate the effectiveness of educational outcomes. If this Virtual World training significantly improves educational outcomes, it will be a valuable tool for PCP in caring for patients with PTS, improve access to quality care, and potentially improve patient outcomes.	$1,015,196.65

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
29.	A National Coordinating Center for Pre-Hospital Trauma Research Funding; Transfusion Using Stored Fresh Whole Blood	National Trauma Institute	Strategies to enhance survivability after significant blood loss is a major focus of combat casualty care research. Recent studies from military medical centers indicate that transfusion of Fresh Whole Blood (FWB) may be more beneficial than individual blood components in patients with severe hemorrhage. This effort is a feasibility and hospital outcomes study using FWB for resuscitation of trauma patients with significant bleeding. A cohort of adult trauma patients presenting with severe hemorrhage and receiving resuscitation with FWB will be prospectively compared to a control group of patients receiving standard component therapy. The study is designed to determine whether FWB transfusions are feasible in a civilian trauma center and whether resuscitation using FWB is superior to component therapy in patients with severe hemorrhage.	$499,995.00

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30.	Enhancing the Immunogenicity of a Tetravalent Dengue DNA Vaccine	Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. Bethesda, MD	Dengue virus infections ranks second for infectious disease in our deployed Service members and if untreated can lead to the lethal Dengue Hemorrhagic Fever. Currently there are no licensed vaccines to prevent dengue infections. The Naval Medical Research Center developed a Dengue vaccine based on plasmid DNA. This project will test an enhanced vaccine using different combinations of live attenuated virus or inactivated virus in either the priming or boosting mode. The product will be evaluated using a needle-free injection or in vivo electroporation. Through these efforts, it will be determined which paradigm significantly increases the immune response. If successful, this strategy will provide a promising vaccination strategy for further clinical trials and at the end of this project the product will be ready for manufacturing and safety studies required by the FDA.	$687,615.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
31.	Psychobiological Assessment and Enhancement of Unit Cohesion and Psychological Resilience in ROTC Cadets Using a Virtual-Reality Team Cohesion Test	Northern California Institute for Research and Education San Francisco, CA	High military unit cohesion is a critical factor that enhances unit performance and promotes individual resilience to combat-related trauma. The precise psychobiological mechanisms that subserve unit cohesion remain unknown. This study will identify the psychological, behavioral, physiological, and hormonal predictors and mechanisms of an individual's ability to develop cohesion in a group working together as a team. Second, it will examine if administration of the neuropeptide oxytocin enhances the development of team cohesion. If oxytocin enhances the development of team performance and cohesion, it may become a powerful performance enhancing and therapeutic intervention as enhanced cohesion is associated with improved Warfighter performance and resilience and decreased susceptibility to the negative health effects of trauma exposure and combat.	$437,514.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
32.	Adaptive Orthopedic Biologics for Highly Targeted Regeneration	The Geneva Foundation Tacoma, WA	This proposed research targets the development of a product to treat the two most common injuries Service members experience in combat and on the home-front, traumatic bone injury and spinal disc degeneration. Using a bone morphogenic protein-2 (BMP-2) product modified with beta tricalcium phosphate the developmental effort will create tBMP-2 which will be used in preclinical evaluations. The effort will establish a scalable recombinant production method for the tBMP-2, conduct various animal studies to evaluate the product, file a Request for Designation with the FDA to designate the product as a Class III device, and prepare an Investigational Device Exemption submission to the FDA in order to begin a Phase I safety trial. This product may improve outcomes for patients with traumatic bone injuries or spinal disc degeneration.	$1,228,814.00
33.	Transportable Pathogen Reduction & Blood Safety System	Terumo BCT Biotechnologies, LLC Lakewood, CO	The Whole Blood Pathogen Reduction Device (WBPRD) will reduce the risk of pathogen transmission and graft versus host disease in wounded Warfighters receiving emergency whole blood transfusions. The WBPRD uses ultraviolet light illumination combined with riboflavin administration to reduce and/or eliminate pathogens (viruses, bacteria, parasites) and white blood cells in donor whole blood. FY14 funding will be applied toward the execution of a pivotal clinical trial, a critical component of the FY17 Premarket Approval submission to the FDA.	$669,716.60

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
34.	MOVES – Life Support System for the Continuum of Care	Thornhill Research, Inc. Toronto, Canada	This effort will complete enhancements to an integrated transport life support system which monitors patient ventilation, oxygen, and suction through a wireless display and control. This specific effort provides an update to the wireless system. Once approved by the FDA, this device will provide a portable life support system that supports all Services on all transportation platforms across the continuum of care.	$66,000.00 Funds sent to Navy to execute this task
35.	Prosthetic Knee-Ankle-Foot System With Biomechatronic Sensing, Control, and Power Generation	Massachusetts Institute of Technology Boston, MA	The purpose of this effort is to develop a transfemoral bionic limb that will enable amputees to walk on level surfaces and inclines with a walking gait that is biomechanically and energetically equivalent to non-amputees. There are two primary development components to this effort: 1) inverse and forward modeling of the reflex-based neuromuscular simulation and 2) implementation of the forward model in a control system developed for the powered transfemoral prosthesis. The prototype prosthesis and control scheme will be tested in a full biomechanical study with ten transfemoral amputees.	$743,928.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
36.	Powered Leg Prosthesis for the Restoration of Amputee Balance, Locomotory Metabolism and Speed	Massachusetts Institute of Technology Boston, MA	This development effort will design and implement a controller that will predict terrain transitions and allow for volitional adjustment of a powered ankle-foot prosthesis. The intrinsically-predictive controller will enable amputees to instinctively transition between terrains, such as ramps or stairs, by classifying data from intrinsic sensors and adjusting ankle position in real-time. A second component of the effort will pair this controller with volitionally-adjusted, myoelectric control. This will further enable transtibial amputees to fine-tune the position of their prosthesis around the biomimetic intrinsic default by activating their residual limb muscles.	$265,486.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
37.	ARX-04 Sufentanil Microtablet Program: Phase III Through New Drug Application Budget	AcelRx Pharmaceuticals Inc. Redwood City, CA	The Sufentanil Microtablet (SM) ARX-04 is a non-invasive method of delivering a high therapeutic index opoid, sufentanil, for the treatment of acute pain. This development effort will manufacture, test and package the SM; conduct verification and validation testing; complete a Phase 1 clinical trial to demonstrate the highly consistent pharmacokinetics of SM; and complete two Phase III clinical trials to determine safety, tolerability, and efficacy for treating moderate to severe acute pain. The advantages of SM over currently used morphine injections is the small, lightweight product allows ease of portability when compared to larger morphine syringes. It is a noninvasive sublingual tablet so no risk of local and systemic infection or accidental needle sticks and it provides an even drug uptake into the muscles which improves pain relief. This project may revolutionize pain management paradigms.	$7,000,000.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
38.	Clinical Development of a Norovirus Gastroenteritis Vaccine	Takeda Vaccines, Inc. Bozeman, MT	Human Norovirus(NoV) remains the major unaddressed cause of infectious acute gastroenteritis (AGE) throughout the world. NoV is thought to cause nearly 90% of all non-bacterial incidents of AGE disease with more than 21M cases annually in the United States. This development effort will manufacture the vaccine; perform the conformance manufacturing required to validate the processes at the facility are reproducible and meet specifications and quality characteristics; and conduct a Phase III double-blind, randomized controlled trial to determine the safety, immunogenicity and efficacy of this vaccine in healthy young adults. Each of these tasks is on the regulatory pathway for FDA licensure. Once the vaccine is approved it will improve the operational readiness of our forces worldwide.	$4,999,869.00
39.	Electronic Capture and Seamless Communication of Point-of-Injury Patient Information Utilizing Ultra-Wide-Band Technology Integrated With Nett Warrior Platform	Sierra Nevada Corporation Sparks, NV	This effort proposes to wirelessly connect existing medical devices such as monitors for blood pressure or heart beat to hand-held portable computers used by U.S. Army combat medics via invisible, low power, hard to detect radio waves called ultra wide band (UWB). The project will transmit clinical data from patient care devices using UWB technology to the Nett Warrior Electronic User Device (EUD) to populate an automated Tactical Combat Casualty Care Card. The focus of the effort is to make patient care and condition information widely visible throughout all phases of evacuation. This information can then be part of the permanent health record which is an overarching precept in the defense health arena.	$2,402,792.72

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
40.	Phase 2 Clinical Development of the PfSPZ Vaccine to Protect the Warfighter from Malaria	Sanaria, Inc. Rockville, MD	The PfSPZ malaria vaccine development initiative has been a collaborative effort and initial clinical trials demonstrate the vaccine is safe and well tolerated. This effort is focused on improving the manufacturing process for the PfSPZ vaccine in preparation for licensure and commercialization. Further, knowledge gained from six ongoing trials with this product will be used to design and conduct a pivotal late Phase II study that will provide the foundation for Phase III studies and licensure of the PfSPZ vaccine. This effort is extremely important to the DoD and fulfills a critical requirement for vaccines for the prevention of malaria.	$5,293,693.00
41.	Bioengineered Corneas for Transplantation	Cellular Bioengineering, Inc. Honolulu, HI	The goal of this research is to improve or restore sight to people who are blind because of injury or disease to their corneas by developing a bioengineered cornea (BEC). The development effort includes: seeking premarket approval from the FDA to market the device; optimize the formulation of the BEC; submit an Investigational Device Exemption to the FDA for approval to conduct human clinical trials to demonstrate safety and efficacy of the BEC and scale-up manufacturing of the BEC for production volume beyond the initial clinical trial. If successful, this effort will change the rehabilitation paradigm for patients with ocular injuries.	$1,928,926.35

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
42.	Effectiveness and Safety of Non-Compressible Intracavitary Hemostatic Agent Clotfoam	Biomedica Management Corporation	The purpose of this development effort is to produce a disposable, biocompatible, low weight, thermally isolated application device to be used on the battlefield. The project will advance ClotFoam through the regulatory pathway as a primary treatment for profuse bleeding. A Phase II clinical trial in a liver surgery protocol followed by a Phase IIb clinical trial in a spleen laceration protocol will be completed. Products to mitigate hemorrhage loss are a high priority in the DoD medical community.	$1,852,125.98
43.	LifeChair for Passive Physiological Monitoring in MEDEVAC	Oceanit Laboratories Honolulu, HI	The Passive Physiological Monitor and LifeBed provide continual patient vital signs through a passive and unobtrusive sensor array. The sensor requires no physical connection to the patient yet reliably monitors and displays respiratory and heart rates even in high-noise environments. This project will fabricate the LifeChair using the same technology and leverage the existing FDA approved market ready LifeBed product. The hardware will be converted for a chair format, meet wireless communications needs, and be ruggedized for medical evacuation platforms. This development effort will refine the current device, conduct preliminary verification testing and a validation study to verify the accuracy of the physiology measures in a Blackhawk helicopter, and collect all necessary data for an FDA submission of the Life Chair device. This device will meet a critical requirement of vital signs monitoring during patient evacuation.	$1,000.000.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
44.	Development of Highly Functional, Neurally Controlled, Skeletally Attached, and Intelligent Prosthetic Devices	Western Institute for Biomedical Research Salt Lake City, UT	The goal of this project is to maximize the functional recovery of patients with above elbow amputations (AEA) so that they may return to pre-amputation levels of duty, performance, and quality of life. It is difficult to fit a prosthesis that is comfortable and functional for patients with short residual limbs when shrapnel remains embedded in the residual limb or when additional bone tissue forms. This effort will develop a Percutaneous Osseointegrated Docking System (PODS) prosthesis that is ready for translation to human clinical trials. The deliverables are AEA PODS medical devices, the instrumentation for development of the PODS, and written surgical procedures for submission to the FDA to conduct human clinical trials with the device. This project meets a critical need in the rehabilitation of our Service members and veterans.	$1,755,069.00

NO.	PROJECT TITLE	AWARDEE	DESCRIPTION OF RESEARCH OR PRODUCT DEVELOPMENT EFFORT	AWARDED AMOUNT
45.	Amputee Testing and Technology Transfer of High Performance Sensing and Variable Volume Prosthetic Liner	Sandia National Laboratories Albuquerque, NM	One of the most significant challenges when fitting a prosthetic device to a patient who has lost a leg is creating a comfortable socket interface because the limb volume and shape do not stay constant over time. Systems that can monitor socket fit using normal and shear pressure sensors and make appropriate adjustments by moving liquid into or out of bladders inside the socket were developed in previous efforts. A key benefit is that both the sensors and bladders are integrated into elastomeric liners so that no socket refitting or modifications are required, which facilitates rapid clinical adoption. The objective of this effort is to continue to refine, develop, and test elastomeric liner systems with integrated sensors, wiring, bladders, and fluid paths to facilitate transition to commercial and clinical use.	$1,016,897.00
46.	Portable Ultrasound Imaging of the Brain for Use in Forward Battlefield Areas	UltraDiagnostics, Inc. Ponte Vedra Beach, FL	A previous project demonstrated the feasibility of noninvasive ultrasound imaging through the skull using shear waves. This development project will build an ultrasound tomographic device capable of assessing critical head trauma. The focus will be on improving the imaging hardware and image reconstruction software and perfecting a clinical interface. At the conclusion of the project, an optimized and thoroughly tested transcranial ultrasound imager will be complete and ready for human clinical testing. This technology development effort will afford the DoD the potential to provide portable ultrasound devices with the capability to quickly and non-invasively assess brain injuries on the most forward areas of the battlefield.	$1,182,718.20