THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

DEC 05 2013

The Honorable Richard J. Durbin
Chairman
Subcommittee on Defense
Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

This letter provides the final response to House Report 112-331, page 740, which accompanied H.R. 2055, the Department of Defense Appropriations Act for Fiscal Year 2012, concerning the Joint Warfighter Medical Research Program (JWMRP). The report language requests details of the $50 million directed to the program, including lists of the funded projects, the amount of funding provided to each project, and a thorough description of each project's research.

The Fiscal Year (FY) 2012 JWMRP funded 28 projects across five research management areas. The initial science funding allocation total was $43,850,000 after deducting management and execution costs; however, sequestration reduced the available science dollars to $40,860,000. In response to the decrease in funds, research support funds were moved from management to science to cover the additional efforts, thus the final total expended for science was $41,451,927.98. As a result of the budget reduction, one project selected for award was deferred to FY 2013. A detailed list of awarded projects is enclosed with this final report. A similar letter is being sent to the Chairmen of the congressional defense committees.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families.

Sincerely,

Jonathan Woodson, M.D.

Enclosure:
As stated

cc:
The Honorable Thad Cochran
Vice Chairman

THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

DEC 05 2013

The Honorable Carl Levin
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

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Sincerely,

Jonathan Woodson, M.D.

Enclosure:
As stated

cc:
The Honorable James M. Inhofe
Ranking Member

THE ASSISTANT SECRETARY OF DEFENSE

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WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

DEC 05 2013

The Honorable Howard P. "Buck" McKeon
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

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Sincerely,

Jonathan Woodson, M.D.

Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member

THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

DEC 05 2013

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

Dear Mr. Chairman:

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Jonathan Woodson, M.D.

Enclosure:
As stated

cc:
The Honorable Peter J. Visclosky
Ranking Member

REPORT TO CONGRESS

Fiscal Year 2012 Joint Warfighter Medical Research Program

October 2013

The estimated cost of report or study for the Department of Defense is approximately $7,500 in Fiscal Years 2012 - 2013. This includes $6,880 in expenses and $630 in DoD labor.

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1. BACKGROUND AND PURPOSE

The Deputy Assistant Secretary of Defense (DASD) for Force Health Protection and Readiness (FHP&R) is responsible for oversight and management of appropriated Defense Health Program research, development, test, and evaluation (DHP-RDT&E) funds. FHP&R partners with the Services and other DoD Entities for execution of the DHP-RDT&E funded programs, including the Joint Warfighter Medical Research Program (JWMRP), funded and directed by a DHP-RDT&E Congressional special interest appropriation. The JWMRP is executed by the U.S. Army Medical Research and Materiel Command (USAMRMC) under the oversight of the DASD(FHP&R).

The USAMRMC manages biomedical research and development programs that are part of the DoD and Army Science and Technology Master Plans. The command has a distinguished history in managing and executing Congressional special interest research appropriations across a wide range of diseases, as well as specific military-relevant programs focused on development of products for prevention, treatment, or rehabilitation paradigms in support of our uniformed services.

The USAMRMC is responsible for planning, coordinating, integrating, programming, budgeting, and executing the research programs assigned to the command. The fiscal year (FY) 2012 JWMRP is a Congressionally-directed $50 million (M) appropriation. Congress directed that these funds: "...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." Due to a continuing resolution during 2012, the funding for the FY 2012 program was not received at USAMRMC until March 20, 2012. After all management and execution costs were determined, the initial science funding available was $43.85M ($35M for technology development projects and $8.85M for advanced development medical projects).

The Assistant Secretary of Defense for Health Affairs was requested by the House Appropriations Committee, Sub-committee on Defense, in House Report 112-110 for FY 2012, page 262, to provide a report not later than 120 days after the enactment of the Act to the Congressional defense committees on the status of the JWMRP. The report requested the DoD to list projects that received funding, the amount of funding provided to each project, and a thorough description of each of these research efforts. The JWMRP FY 2012 appropriation and resulting awards provide the DoD great latitude in accelerating prior congressionally funded, high-priority research efforts for military medicine.

2. FY 2012 JWMRP DISTRIBUTION ACROSS RESEARCH AREAS

The FY 2012 JWMRP funded 28 projects across five research management areas. The initial science funding allocation total was $43.85M after deducting management and execution costs; however, sequestration reduced the available science dollars to $40.86M. In response to this decrease in funds, research support funds were moved from management to the science line to cover additional efforts, so the final total expended for science was $41,451,927.98. As a result of the budget reduction, one project selected for award was deferred to FY 2013 for funding. The two prominent parameters in determining projects for funding in this program were to select projects close to achieving their objectives and to select projects having 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 initiation of a clinical trial, or complete requirements that enable progress towards Food and Drug Administration (FDA) approval.

Four projects were funded in Medical Training and Health Information Sciences research. The key focus areas for research in this area are the development of medical simulation products and intelligent tutoring systems. Four key products will result from these efforts: 1) a needle chest decompression trainer; 2) an intelligent tutoring system for emergency preparedness training; 3) a next-generation medical simulation tool for pararescue forces; and 4) data analysis on competency-based learning outcomes and cost effectiveness between two different simulation training paradigms.

Five projects were funded in Military Infectious Diseases research. The initiatives funded in this area include: 1) expanded Malaria diagnostic quality improvement activities; 2) the development of safer drugs for Malaria prevention; 3) a field portable biological identification and diagnostic system; 4) development of a norovirus gastroenteritis vaccine; and 5) development of the capability for molecular identification of human fungal pathogens. The three most promising products from these efforts will yield: 1) a portable, integrated, automated diagnostic system for the identification of infectious disease threats that is ready for field testing; 2) achievement of key milestones in the FDA approval process for the norovirus vaccine (validation of a manufacturing process for Phase 3, and completion of a 2,000 subject Phase 1/2 human clinical field trial testing the safety of the vaccine); and 3) development of a rapid molecular diagnostic assay for fungal infections in military trauma patients.

Three projects were funded in Military Operational Medicine. The three projects were focused in three distinct areas including: 1) novel strategies that promote warfighter performance; 2) implementation of an intervention to help Service members achieve compliance with body composition and physical standards performance; and 3) development of guidance for the rigorous and efficient evaluation of existing and emerging dietary supplements as well as exploring dietary supplement combinations that may enhance performance. These efforts will address critical research gaps in operational medicine and will help to understand how micronutrients may enhance resilience by optimizing Vitamin D levels during initial military training and the potential for supplementing food ingredients during production to produce cost-effective ways to enhance a warfighter's nutritional status and performance.

Four research projects were funded in Combat Casualty Care. The funded projects include: 1) research in biomarkers for monitoring wound healing and infection in combat wounds; 2) research to reduce cell death and improve axonal regeneration following a spinal cord injury; 3) development of a transportable pathogen reduction and blood safety system; and 4) development of a non-electric disposable IV infusion pump. The first two projects listed will provide invaluable information for treatment of our wounded warriors. The Phase 1 and Phase 2 clinical trials of the transportable pathogen and blood safety system along with the additional pre-clinical trials will significantly move the program forward in obtaining FDA approval of the system. The non-electric disposable IV infusion pump initiative will result in completion of final product manufacturing verification and validation, as well as product toxicity and sterility testing required for FDA approval.

There were twelve awards funded in support of Clinical and Rehabilitative Medicine. The funded projects focused on: 1) regenerative medicine initiatives; 2) sensory systems research; 3) research to improve the performance of prosthetic devices; 4) development of a drug for pain management; and 5) a clinical trial for use of a neuroprotective drug for acute spinal cord injury. The efforts in regenerative medicine are focused on the validation of adipose-derived cells for tissue repair and the development of a bioartifical ligament. There are two projects in the sensory systems area. The first is focused on development of corneal adhesive tissue and the second seeks ways to improve the diagnosis and development of novel treatments for ocular injuries in the military population. The six projects in the prosthetics area include: 1) development of a prosthetic hand that allows for a soft touch; 2) prosthetic sockets with vacuum assisted suspension; 3) improvements in gait feedback systems; 4) development of a hybrid neuromechanical ambulatory system which will improve the ability of amputees to negotiate barriers and uneven terrain; 5) a clinical trial with a sensory feedback device that provides vibrotactile stimulation to work the leg in response to pressure on the foot, which may speed up the rehabilitation process; and 6) developing a body–powered prosthetic hand terminal device that is mechanically compliant and passively adaptive. In the area of pain management, the effort will generate the necessary data for FDA requirements for a Phase 1 clinical trial. In addition, a very promising effort is the Phase 2 clinical trial evaluating the impact of Riluzole as a neuroprotectant for spinal cord injury being conducted by the North American Clinical Trials Network.

Table 1, below, lists the research awards funded by the FY 2012 JWMRP to include the award recipient, a description of the research award, the amount of the research award, and funding associated with supporting the award recipient.

Table 1

No.	Research Project Title	Awardee	Description of Research	Award Amount
1	Collaborative Research to Optimize Warfighter Nutrition (CROWN)	Pennington Biomedical Research Baton Rouge, LA	The project's overarching objective is to discover novel strategies that promote warfighter resilience, improve warfighter combat readiness, and assure optimal warfighter performance. The research, in collaboration with the US Army Institute of Environmental Medicine, will continue investigating skeletal muscle and physical performance responses to leucine-enriched nutrition supplementation. The research will assess the effects of deployment on the nutritional, inflammatory, and health status of US Army Special Operations Soldiers during load carriage. Another phase of the study will look at the use of micronutrients and resilience by optimizing Vitamin D levels during Initial Military Training to determine if there are improvements in the markers of bone health for female personnel.	$4,209,370.00
2	Weight Measurements and Standards for Soldiers	Pennington Biomedical Research Baton Rouge, LA	The Pennington Biomedical Research center will collaborate with the US Army Institute of Environmental Medicine and the Louisiana National Guard to implement an intervention designed to help Service personnel achieve compliance with military body composition and physical performance standards.	$3,246,859.00
3	North American Clinical Trials Network (NACTN) for Treatment of Spinal Cord Injury	Christopher Reeve Foundation Short Hills, NJ	Continue the NACTN effort with implementation of an acute spinal cord injury Phase 2 clinical trial of the neuroprotective drug Riluzole.	$2,000,000.00

No.	Research Project Title	Awardee	Description of Research	Award Amount
4	Program for Research on Dietary Supplements in Military Operations and Healthcare Metabolically Optimized Brain	Samueli Institute Alexandria, VA	The goals of this initiative are to develop guidance for the rigorous and efficient evaluation of the clinical efficacy of existing and emerging dietary supplements, to develop a strategy for exploration of dietary supplement combinations to address the identified needs (performance enhancement) of military populations, and to evaluate the potential for supplementing food ingredients during production to produce a cost-effective way to enhance warfighter nutritional status and performance.	$1,329,238.52
5	Engineering of a Next Generation Portable Biological Detection System	Integrated Nano Technologies Rochester, NY	This project will enhance development of a portable diagnostic system that is fully integrated and automated to identify infectious disease threats. The objective of the project is to build out systems and set up production of disposable test cartridges and have a sufficient number of units available for laboratory and field testing.	$1,499,999.99
6	Compliance and Adaptive Underactuation for Prosthetic Terminal Devices	Yale University New Haven, CT	Design, create, and test a compliant and adaptive underactuated prosthetic hand. This mechanically simple device has eleven degrees of freedom and allows for a soft touch with objects in the environment. It is designed to be operated using a body-powered harness.	$496,501.00
7	Spectroscopic Biomarkers for Monitoring Wound Healing and Infection in Wounds	The Geneva Foundation Tacoma, WA	This research will test the hypothesis that the development of an integrated prediction model using spectroscopy and spectroscopic imaging data in addition to clinical data will allow for more accurate assessment of tissue perfusion and oxygenation in extremity injuries, providing improved diagnosis and prognosis of the affected tissue.	$908,416.00 Additional $8,000.00 sent to support Principal Investigator travel requirements.

No.	Research Project Title	Awardee	Description of Research	Award Amount
8	A Prosthesis to Train the Proprioceptive Capabilities of the Residual Limb of Military Personnel Recovering From Lower Limb Amputation	Cadence Biomedical Seattle, WA	This research will seek to reduce rehabilitation time and costs for lower limb amputees by implementing a sensory feedback device during the post operative rehabilitative period. The device will provide vibrotactile stimulation to the leg in response to pressures on the bottom of the foot and will be a self-contained unit suitable for use in the field. A clinical trial will be performed with lower limb amputees to determine if the device can accelerate their rehabilitation.	$495,664.59
9	A Hybrid Neuromechanical Ambulatory Assist System	Case Western Reserve School of Medicine Cleveland, OH	The primary objective of this project is to advance the design of the first generation prototype hybrid neuromechanical ambulatory assist into a self contained, portable and independent system suitable for clinical testing outside the laboratory. The efforts will define a new means to overcome common physical barriers and negotiate uneven terrain, thus enabling ambulation in a wide variety of physical environments.	$502,718.00
10	An Exotendon Orthosis to Improve Mobility for Military Personnel Recovering from Combat-Related Injuries	Cadence Biomedical, Inc. Seattle, WA	This research will develop an outcomes measurement and gait feedback system for a kinetic orthosis and will test outcomes measurements and the gait feedback system in the field.	$497,740.00

No.	Research Project Title	Awardee	Description of Research	Award Amount
11	Development of Novel Bioartificial Ligament Using Autologous Biological Scaffold and Cells	Tissue Genesis, Inc. Honolulu, HI	The focus of this research is to develop novel cell-based therapies to treat injured ligaments and tendons using autologous biological materials.	$1,299,999.93
12	Development of Safer Drugs for Malaria in U.S Troops, Civilian Personnel and Travelers	University of Mississippi University, MS	This effort is aimed at identification of safe and effective drugs for prophylaxis and treatment of Malaria. The 8-aminoquinoline which includes primaquine and tafenoquine is the only drug class effective against all life-cycle stages of the malaria parasite. This effort will seek to reduce the toxicity of the currently available 8-aminoquine products which will result in safer drug candidates with broader clinical utility. The effort will complete testing in animals to identify products with an improved therapeutic index which will then progress to clinical trials.	$1,376,305.10 $1,694,000.00 sent to Walter Reed Army Institute of Research in collaborative support of this project.

No.	Research Project Title	Awardee	Description of Research	Award Amount
13	U.S. Army Battlefield Exercise and Combat Related Spinal Cord Injury (SCI) Research: Neuroprotection & Repair After SCI	University of Miami Miami, FL	The global objective of this research is to develop new therapeutic strategies targeting acute and chronic spinal cord injury. This research effort uses state of the art approaches to identify and specifically target molecules that may protect against cell death, as well as promote axonal regeneration and repair after SCI. The specific aims are the following: 1. examine the role of dependence receptors in regulating cell survival following SCI, 2. determine the effect of tranexamic acid treatment on SCI pathology and locomotor recovery, 3. determine the effects of enhancing transcriptional and mitochondrial STAT3 functions on rubrospinal axon re-growth after contusive SCI, 4. evaluate combined strategies to promote axon regeneration, and 5. determine if the FDA approved cytokine-mediated mobilization of mesenchymal stem cells (MSCs) improves outcome after experimental SCI.	$2,494,140.00
14	Next Generation Simulation Training for Pararescue Forces (Phase III)	National Center for Health Care Informatics Butte, MT	This research will incorporate additional medical tasks and scenarios in the medical simulation product. The current effort provides a prototype with one scenario and five medical tasks. This effort will expand a more fully immersive display environment, expand the capabilities of the product, expand the simulation framework, add six medical simulation procedures, and add sympathetic nervous system simulations.	$1,846,190.00

No.	Research Project Title	Awardee	Description of Research	Award Amount
15	Quality Systems Innovations to Protect the Warfighter from Malaria	Amethyst Technologies, LLC Baltimore, MD	The Walter Reed Army Institute of Research (WRAIR) is preparing to conduct the first field Malaria prophylaxis trials in over a decade. Quality control and quality assurance is required in resources limited environments located in areas throughout Africa. This effort will support WRAIR Malaria clinical trials and research programs by ensuring accurate malaria diagnostics are available at the research site This effort will expand Malaria diagnosis activities with quality controls and quality assurance measures to additional sites which are appropriate for Phase 3 Malaria prevention trials.	$1,205,322.88 $594,477.00 sent to Walter Reed Army Institute of Research in collaborative support of this project.
16	Development of Subischial Prosthetic Sockets with Vacuum-Assisted Suspension for Highly Active Persons with Transfemoral Amputations	Northwestern University Chicago, IL	Develop prosthetic socket technology that will maintain residual limb volume; improve active range of motion of the hip; and improve coupling between the interior of a prosthetic socket and the surface of the residual limb. This prosthetic socket technology will result in better functional performance for individuals with transfemoral amputations. This funding will provide the characteristic prototyping and testing of three hybrid vacuum pump designs.	$86,634.00

No.	Research Project Title	Awardee	Description of Research	Award Amount
17	NOP-Related Agonists as Analgesics in Primates	University of Michigan Ann Arbor, MI	This study is designed to address the critical need for non-opiate (NOP) analgesics in managing pain arising as the result of field injuries. The major objective of the study is to extend and advance research and development of NOP-related agonists as analgesics in a primate model and to generate preclinical efficacy data required for an IND application. This pre-clinical study has the potential to lead to non-narcotic pharmacologic preparations which will dramatically alter the range of analgesics available for both acute and chronic administration.	$1,300,749.00
18	A Recombinant Human Collagen Corneal Adhesive	Cellular Bioengineering, Inc. Honolulu, HI	Develop and characterize recombinant human collagen (RHC) corneal adhesives using photosensitizers to crosslink the polymer *in situ*. Create a corneal adhesive RHC for corneal tissue repair and suture-less corneal transplantation.	$380,428.00
19	Standards-Based Intelligent Tutoring: Building the First Major Commercial ITS-Enabled Learning Management System	Accella Learning Company, LLC Louisville, KY	Accella Learning, LLC will continue the work performed over the past 4 years on successful Phase 1 and Phase 2 efforts, culminating at the end of Phase 3 with a thoroughly tested, commercially viable, Intelligent Tutoring System and associated infrastructure. The University of Louisville, Division of Protective Medicine, as a partner in this effort, will demonstrate the practical utility of the technology in important emergency preparedness training.	$1,000,000.00

No.	Research Project Title	Awardee	Description of Research	Award Amount
20	Center for Ophthalmic Innovation-ONOVA	University of Miami Miami, FL	This effort will compare the Drone Slit-Lamp with the conventional slit-lamp, test the safety of artificial cornea and biological integration in an animal model, characterize therapeutic phospholipids from alkali exposure, identify therapeutic phospholipids in thermal corneal injury and determine treatment windows for gene therapy and nanoparticle therapy for traumatic optic nerve injury. The objective of this effort is to improve the diagnosis and development of novel treatments for ocular injuries in the military population	$1,186,707.00
21	Clinical Validation of Adipose-derived Regenerative Cells for Tissue Repair: Accelerated Pilot-phase Clinical Trial	Tissue Genesis, Inc. Honolulu, HI	Continue research to determine whether Adipose-derived stromal cell (ASCs) can be delivered directly to ischemic tissue by intramuscular injection into ischemic tissues or through *in situ* vasculature to impart a therapeutic benefit by increasing distal circulation and relieving the symptoms of peripheral vascular disease (PVD).	$987,772.38
22	Self-Powered Prosthetic Limb Technology	KCF Technologies, Inc. State College, PA	Refine system of scavenging power from the force of walking that will demonstrate running capability (4 m/s), stair climbing (100 stairs/min), walking (1.75 m/s) in unilateral and bilateral military amputees.	$1,499,999.94
23	Simulation Learning: Personal Computer (PC) Screen-Based vs High Fidelity	University of Hawaii Honolulu, HI	The specific goal of this project is to develop and then test a model that can be used to evaluate differences in learning outcomes and cost effectiveness for military and civilian nursing trauma nursing skills.	$457,108.71

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24	Transportable Pathogen Reduction & Blood Safety System	Terumo BCT Biotechnologies, LLC Lakewood, CO	Terumo BCT Biotechnologies developed a portable device that provides pathogen reduction (PR) and white blood cell inactivation in fresh whole blood. The first generation device treats one unit of whole blood at a time and treatment time can take more than an hour. The objectives of this work are to enhance the usability of the PR reduction device by reducing treatment time to less than 30 minutes and obtain additional pre-clinical data to support FDA approval of the first generation device.	$3,460,000.00
25	Non-Electric Disposable IV Infusion Pump	BioQuiddity Inc. San Francisco, CA	The objective of the proposed work is to complete the advanced development requirements for BioQuiddity's Non-Electric Disposable IV infusion pump. The proposed use for this pump is en-route pain management and anesthesia/sedation. The pump must go through final assembly manufacturing validations, clinical production, final verification testing, biocompatibility studies, toxicological safety analysis, and clinical evaluation as part of the FDA approval process.	$1,659,100.00
26	Clinical Development of a Norovirus Gastroenteritis Vaccine	LigoCyte Pharmaceuticals, Inc. Bozeman, MT	The goal of this research is to develop a safe and effective vaccine for the prevention of human Norovirus. Validate manufacturing process for Phase 3 manufacturing. Complete a 2000 subject Phase 1/2 human clinical field trial testing safety, immunogenicity and efficacy of a bivalent virus-like particle norovirus vaccine. Initiate epidemiological studies on past-infectious chronic sequelae and cost-of-illness utilizing DoD medical encounter databases and serum repository.	$2,600,000.00 $400,000.00 sent to Naval Health Research Center in collaborative support of this project.

No.	Research Project Title	Awardee	Description of Research	Award Amount
27	Development of HAPMED Needle Chest Decompression Trainer	CHI Systems, Inc. Fort Washington, PA	The specific aim of this study is to develop a training system that offers pre-tests, demonstration, practice and objective hands-on performance feedback to build decision making skills to perform life-saving needle chest decompression.	$579,970.94
28	Molecular Identification of Human Fungal Pathogens	The University of Texas Health Science Center, San Antonio, TX	The objective of this proposal is to develop a rapid molecular diagnostic assay using a new polymerase chain reaction (PCR) technology called LATE-PCR. If successful, this assay, which is a variation of real time PCR, will allow rapid diagnosis of fungal infections in military trauma patients within a matter of hours instead of days or weeks.	$148,516.00