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

PERSONNEL AND
READINESS

JAN 11 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 request in the Joint Explanatory Statement, to accompany H.R. 83, the Consolidated and Further Continuing Appropriations Act, 2015 (Public Law 113-235), concerning Global Health and, specifically, infectious disease related research. The report provides program funding, accomplishments from fiscal years (FYs) 2011 through 2014, goals moving forward, and funding needs across the Future Years Defense Program for each program within the Department of Defense currently involved in infectious-disease-related research. We submitted an interim report on July 14, 2015.

This report includes information on activities sponsored by the Defense Health Program, the U.S. Army, and the U.S. Special Operations Command from FYs 2011 through 2014. The report provides a list of key areas of research associated with infectious diseases and initiatives undertaken from FYs 2011 through 2014 for those research topics. The data for this report was collected through the Armed Services Biomedical Research Evaluation and Management Community of Interest.

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
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JAN 11 2016

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

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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 11 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 11 2016

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

Dear Mr. Chairman:

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Sincerely,

Brad Carson
Acting Principal Deputy

Enclosure:
As stated

cc:
The Honorable Peter J. Visclosky
Ranking Member

REPORT TO THE CONGRESSIONAL DEFENSE COMMITTEES IN RESPONSE TO JOINT EXPLANATORY STATEMENT, TO ACCOMPANY H.R. 83, THE CONSOLIDATED AND FURTHER CONTINUING APPROPRIATIONS ACT, 2015 (PUBLIC LAW 113-235)

"GLOBAL HEALTH"

SUBMITTED BY THE OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

December 2015

The estimated cost of this report or study for the Department of Defense is approximately $5,220 in Fiscal Year 2015. This includes $4,320 in expenses and $900 in DoD labor.

Generated on December 3, 2015: RefID: 8-ACFBFD6

Introduction

The following information is the final response to the Joint Explanatory Statement, to accompany H.R. 83, the Consolidated and Further Continuing Appropriations Act, 2015 (Public Law 113-235), concerning Global Health, specifically infectious-disease-related research. The report provides program funding, accomplishments from fiscal years (FYs) 2011 through 2014, goals moving forward, and funding needs across the Future Years Defense Program for each program within the Department of Defense (DoD) currently involved in infectious disease related research.

The information below includes information from the Defense Health Program (DHP), United States Army, and United States Special Operations Command (USSOCOM)-sponsored activities from FYs 2011 through 2014.

Fiscal Years 2011-2014 Department of Defense Accomplishments by Component

DEFENSE HEALTH PROGRAM

Rapid Screening of Fresh Whole Blood

1. Developed a prototype immunoassay device for screening blood against HIV1, HIV2, hepatitis B, hepatitis C when blood products approved by the U.S. Food and Drug Administration (FDA) are not available in austere settings.
2. Developed a prototype nucleic acid device for screening blood against HIV1, HIV2, hepatitis B, hepatitis C.

Wound Infection Prevention and Management

1. Developed an automated digital microscopy device that can identify the bacteria and determine if it is resistant to antibiotics within 8 hours – a process that normally takes 48 hours. Pivotal clinical trials are underway to support FDA clearance.
2. Developed clinical practice guidelines for the recognition and comprehensive management of invasive fungal infections in war wounds.
3. Conducted skin and soft tissue staphylococcal infection studies in military basic trainees to develop better prevention and treatment options.

Antimicrobial Countermeasures

1. Developed a human skin substitute with antibiotic properties to facilitate healing of traumatic combat wounds.
2. Developed new topical treatments for infected traumatic wounds.

ARMY (Program Elements 6.1-6.3- Basic Research)

Parasitic Diseases

1. Conducted early clinical trials for three candidate vaccines to prevent malaria infection.

2. Manufactured an intravenous drug (Artesunate) to treat severe and complicated malaria.
3. Successfully implemented a treatment protocol allowing the use of Artesunate, a life-saving drug, prior to FDA licensure.
4. Initiated clinical trials of a new drug (Tafenoquine) to treat relapsing malaria.
5. Completed a pivotal clinical trial of a self-administered topical treatment for cutaneous leishmaniasis; when FDA approved will alleviate the need for evacuation from theater and treatment with toxic, investigational drugs.

Viral Diseases

1. Successfully completed a pivotal clinical trial for a Dengue vaccine that will support future FDA licensure.
2. Licensed a vaccine to prevent Adenovirus infections in Service members during training.
3. Developed the first animal model for Hemorrhagic fever with Renal Syndrome, which is critical to evaluate future vaccine candidates.
4. Initiated clinical trials of a vaccine to prevent infection by Hantaan and Puumala hemorrhagic viruses.
5. Formed a public-private partnership called the AIDS Vaccine Efficacy Consortium to support future HIV vaccine trials in Thailand.

Bacterial Diseases

1. Initiated clinical trials for vaccines to prevent Shigella and E. coli infections, important causative agents for bacterial diarrhea.
2. Completed early clinical trials and transitioned to Merck a vaccine to prevent Meningococcal Meningitis.

Diagnostics and Vector Control

1. Initiated pivotal clinical trials of a rapid diagnostic device for cutaneous leishmaniasis – FDA cleared in 2014.
2. Fielded a new personal insect repellent to prevent bites from mosquitos, sandflies, ticks and other disease carrying pests.
3. Developed new techniques to collect disease carrying insects/pests.
4. Fielded interactive guides to identify disease carrying insects/pests.
5. Fielded new assays to detect Rift Valley Fever virus and Dengue Fever virus in the insect vectors that carry the diseases.

ARMY (Program Elements 6.4-6.5, Advanced Development)

Topical Antileishmanial Drug (WR279396)

1. Completed the Old World Pivotal Phase 3 Study in Tunisia and initiated a New World Pivotal Phase 3 Study in Panama required by the FDA for licensure.
2. Initiated an FDA approved Expanded Access Treatment Protocol based on clinical and safety data to date to make the product available to DoD Healthcare Beneficiaries prior to final approval.

Combined Camouflage Face Paint

1. In FY 2013, the Combined Camouflage Face Paint program was transitioned into Operations and Support Phase of the acquisition life cycle for sustainment by Defense Logistics Agency-Aviation.

Dengue Tetravalent Vaccine

2. Initiated (in 2010) and completed (in 2011) a phase 2 study in Thailand and the Philippines, which enabled the use of Kamphaeng Phet- Armed Forces Research Institute of Medical Sciences (AFRIMS) Virology Research Unit (KAVRU), and Philippines-AFRIMS Virology Research Unit (PAVRU) sites for a phase 3 study involving the U.S. Army Medical Research and Materiel Command's (USAMRMC's) lead dengue vaccine candidate, a recombinant, live, attenuated-tetravalent dengue vaccine (CYD-TDV). The USAMRMC's commercial partner in this study was Sanofi Pasteur.
3. In August 2011, awarded an approximately $5 million (M) contract to BioPath Clinical Diagnostics, Inc., to conduct a phase 3 study for USAMRMC's lead dengue vaccine candidate CYD-TDV (Sanofi Pasteur).
4. Initiated a phase 3 study at KAVRU and PAVRU sites in September 2011. Together, these sites contributed approximately 1,500 volunteers. In August 2015, Sanofi published year 3 data showing a pooled vaccine efficacy (ages 9-16) of 80.8%.
5. Initiated a phase 2 study (CYD56) at the State University of New York (SUNY) in September 2013. This study utilized Sanofi's CYD-TDV but is focused on an FDA traveler/military indication.
6. Between September 2013 and September 2015, the Dengue Vaccine program produced, tested, and released (for clinical use) three monovalent strains of dengue virus for clinical development.
7. In August 2015, USAMRMC awarded an approximately $12M contract to the Research Foundation of the SUNY for the clinical development of the USAMRMC's Dengue Human Infection Model (DHIM). These DHIM will enable early down selection of dengue vaccine and drug candidates and will foster collaboration with industry.
8. On August 13, 2015, the USAMRMC initiated the first DHIM study at the SUNY.
9. In January 2011, the USAMRMC executed a royalty bearing Patent License Agreement with Glaxo Smith Kline for the co-development of USAMRMC's purified, inactivated dengue vaccine.

Adenovirus Vaccine

1. Fielded the Adenovirus Vaccine in October 2011. Since then, Febrile Respiratory Illness (FRI) surveillance at military basic training sites showed that it was over 99% effective in preventing disease caused by Adenovirus Serotypes 4 and 7. The administration of Adenovirus Vaccine prevented about 15,000 FRI cases and saved 50,000 training days per year that otherwise would have been lost to sickness.

New Standard Military Insect Repellent

1. In April 2013, a National Stock Number (NSN) was assigned to a new standard military insect repellent after Armed Forces Pest Management Board approval. The new repellent was selected after rigorous field, technical, and user acceptability testing; where it proved to perform as well or better than the standard issue Ultrathon DEET repellant. The new repellant (Natrapel) provides Service members with a preferred alternative to DEET based repellents and will serve as a first line of defense against insects carrying infectious diseases like dengue, malaria, and leishmaniasis.

Antimalarial Drug, Artesunate Intravenous

1. Provided continued support for the lifesaving emergency treatment investigational new drugs (INDs) for the Centers for Disease Control and Infection and HealthNet Canada.
2. Established a DoD emergency treatment IND for outside the contiguous United States treatment facilities ensuring that Service Members and beneficiaries can receive the same standard of care as within the United States.
3. Finalized the commercial Good Manufacturing Practice chemistry, manufacturing, and controls methods for bringing IV Artesunate to the United States market.

Leishmania Rapid Diagnostic Device

1. Obtained FDA clearance for a dip-stick device for rapid diagnosis of active Cutaneous Leishmaniasis (CL). This enables battlefield caregivers to diagnose a soldier with CL and make appropriate treatment decisions within minutes.
2. Completed initial fielding of device. The device was designated as a component of all appropriate unit assemblages and an electronic catalog contract was established allowing activities to easily and rapidly procure it.

Next Generation Malaria Prophylaxis (Tafenoquine)

1. Successfully negotiated partnering and licensing agreements with a new development partner paving the way for a successful US New Drug Application to the FDA.
2. Successfully converted the legacy data package into a modern electronic form suitable for electronic filing of the New Drug Application.
3. Established a key partnership with the Australia Malaria Institute to eventually bring tafenoquine successfully to the Australian market as well for use within their military and civilian sectors.

Q Fever Vaccine

1. Conducted a key gap analysis of the regulatory filing dossier in 2014. This will enable the program to identify critical path activities FY 15 and beyond culminating in an FDA-licensed vaccine for Q-Fever.

Regional HIV Vaccine

1. Initiated and completed a randomized, double blind evaluation of late boost strategies for HIV-Uninfected participants in the HIV Vaccine efficacy trial with live recombinant ALVAC-HIV priming with AIDSVAX B/E boosting in HIV-Uninfected Thail adults.
2. Initiated a randomized, double blind evaluation of ALVAC-HIV (VCP1521) priming and multiple boosting strategies with and without AIDSVAX B/E in HIV-Uninfected Thai adults.
3. Initiated and fully enrolled a double blind, randomized, placebo controlled clinical vaccine trial of AIDSVAX B/E protein boost vaccine.

Carbon Dioxide Generator

1. Achieved successful Milestone B in April 2015.
2. Completed operational testing and all but one surveillance test for Milestone C.

Improved Dual-Insecticide Impregnated Bed Net

1. Developed a bed net impregnated with delamethrin and permethrin that is lightweight, is durable, and has maximum air flow.
2. Obtained Environmental Protection Agency registration in December 2014.
3. Received NSN assignment for the bed net from the Armed Forces Pest Management Board in April 2015.

USSOCOM

Blood Donor Pathogen Kit

1. Developed an integrated multi-pathogen detection test kit prototype (HIV, Hepatitis C, and Malaria) for pre-screening blood of donor candidates when FDA-approved blood products are not available in austere settings. Project was focused on the integration of currently FDA-approved LFIs and use of advanced manufacturing techniques. Project was not continued at this time due to concerns of the regulatory pathway for blood donor screening devices and funding available. USSOCOM still has interest in this capability.

Funding Overview of Department of Defense Infectious Disease Research Activities

PROJECT	FY11	FY12	FY13	FY14
DHP				
GDF - Basic Operational Medical Research Sciences	$ 13,371	$ -	$ -	$ -
GDF - Applied Biomedical Technology	$ 22,415	$ 2,279	$ 4,944	$ 4,656
GDF - Medical Technology Development	$ 9,999	$ 2,333	$ 1,620	$ 5,719
GDF - Medical Products Support and Advanced Concept Development	$ 5,476	$ 4,834	$ 4,894	$ 6,651
GDF-Medical Products and Support System Development	$ -	$ -	$ -	$ -
Military HIV Research Program				$ 8,976
Military HIV Research Program				$ 7,111
ARMY (6.1-6.3)				
Science Base/Medical Research Infectious Diseases	$ 10,652	$ 10,900	$ 12,099	$ 10,702
DoD Medical Defense Against Infectious Diseases	$ 13,914	$ 16,869	$ 18,987	$ 19,072
HIV Exploratory Research	$ 9,243	$ 9,392	$ 8,986	$ -
Industrial Base Infectious Disease Vaccines and Drugs	$ 18,185	$ 18,646	$ 19,574	$ 17,413
Medical Protection Against HIV	$ 6,688	$ 6,796	$ 6,984	$ -
Military HIV Initiatives	$ 20,000	$ 16,000	$ 16,000	$ 7,000
DoD Drugs and Vaccines	$ 7,225	$ 11,569	$ 9,987	$ 6,892
Military HIV Vaccines and Drugs Development	$ 2,923	$ 2,348	$ 2,294	$ 550
Military HIV Vaccines and Drugs Development	$ 4,456	$ 3,866	$ 3,232	$ 3,902
Infectious Disease Drugs and Vaccines Engineering Development	$ 12,227	$ 8,487	$ 13,771	$ 12,517
ARMY (6.4-6.5)				
DoD Drugs and Vaccines Advanced Development	$ 7,006	$ 11,970	$ 8,732	$ 6,712
Infectious Diseases Drugs and Vaccines Engineering Development	$ 11,806	$ 8,238	$ 12,998	$ 12,039
Military HIV Vaccine & Drug Development	$ 2,819	$ 2,273	$ 2,052	$ 532
HIV Vaccine and Drug Development	$ 4,297	$ 3,742	$ 3,134	$ 3,770
Field Medical Systems Advanced Development	$ 17,422	$ 19,003	$ 11,102	$ 9,738
Field Medical Systems Engineering Development	$ 17,159	$ 14,336	$ 19,378	$ 18,081
USSOCOM				
Blood Donor Pathogen Kit	$ -	$ 756	$ -	$ 4
TOTAL:	**$ 217,283**	**$ 174,636**	**$ 180,768**	**$ 162,037**

In closing, the overall goal of the Department of Defense is to conduct a focused and responsive world class infectious diseases research and development program leading to fielding effective and improved means of protection and treatment necessary to maintain maximal global operational capability with minimal morbidity and mortality.