THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

MAR 2 0 2013

The Honorable Barbara A. Mikulski
Chairwoman
Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Madam Chairwoman:

The enclosed report responds to the House Report 112-493, pages 265–266, accompanying H.R. 5658, the Department of Defense Appropriations Bill, 2013, requesting the Assistant Secretary of Defense for Health Affairs to report on the status of the Peer-Reviewed Cancer Research Program (PRCRP). Appendix A details the FY 2009–2011 PRCRP research area investment; Appendix B provides the full PRCRP research list and military relevance of FY 2009–2012 projects.

For FY 2012, Public Law 112-74 appropriated $12.8 million for the PRCRP. Vision setting for the FY 2012 PRCRP was held in March 2012, with program announcements released in April 2012. Application receipt occurred in September 2012, peer review completed in November 2012, and programmatic review concluded in January 2013. Award obligation is anticipated not later than September 30, 2013.

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A similar letter is being sent to the Chairpersons of the other 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.

Enclosures:
As stated

cc:
The Honorable Richard C. Shelby
Vice Chairman

THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
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HEALTH AFFAIRS

MAR 20 2013

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

Dear Mr. Chairman:

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A similar letter is being sent to the Chairperson of the other 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.

Enclosures:
As stated

cc:
The Honorable James M. Inhofe
Ranking Member

THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

MAR 20 2013

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

Dear Mr. Chairman:

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Sincerely,

Jonathan Woodson, M.D.

Enclosures:
As stated

cc:
The Honorable Adam Smith
Ranking Member

THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

MAR 2 0 2013

The Honorable Harold Rogers
Chairman
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The enclosed report responds to the House Report 112-493, pages 265–266, accompanying H.R. 5658, the Department of Defense Appropriations Bill, 2013, requesting the Assistant Secretary of Defense for Health Affairs to report on the status of the Peer-Reviewed Cancer Research Program (PRCRP). Appendix A details the FY 2009–2011 PRCRP research area investment; Appendix B provides the full PRCRP research list and military relevance of FY 2009–2012 projects.

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Sincerely,

Jonathan Woodson, M.D.

Enclosures:
As stated

cc:
The Honorable Nita M. Lowey
Ranking Member

REPORT TO THE CONGRESSIONAL DEFENSE COMMITTEES IN RESPONSE TO HOUSE APPROPRIATIONS COMMITTEE REPORT 112-493, PGS 265-266, ACCOMPANYING H.R. 5658, THE DEPARTMENT OF DEFENSE APPROPRIATIONS BILL, 2013

"PEER-REVIEWED CANCER RESEARCH PROGRAM"

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

SUPPORTED BY THE U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND, CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS

The estimated cost of report for the Department of Defense is approximately $3,960 in Fiscal Years 2012 - 2013. This includes $2,160 in expenses and $1,800 in DoD labor.

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Peer-Reviewed Cancer Research Program
Report to Congress

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BACKGROUND AND PURPOSE

The Assistant Secretary of Defense (Health Affairs) is requested by House Report 112-493, pgs.265-266, accompanying H.R. 5658, the Department of Defense Appropriations Bill, 2013, to provide a report not later than 60 days after enactment of the Act to the congressional defense committees on the status of the Peer-Reviewed Cancer Research Program (PRCRP), see page 4 of this report. This report is being provided through the Intergovernmental Service Agreement with the U.S. Army Medical Research and Materiel Command (USAMRMC) and the Congressionally Directed Medical Research Programs (CDMRP).

USAMRMC is a major subordinate Command of the U.S. Army Medical Command. The USAMRMC manages biomedical research and development programs that are part of the Department of Defense (DoD) and Army Science and Technology Master Plans. The Commanding General (CG), USAMRMC, is assigned authority as the Executive Agent for a number of medical research, development, and acquisition programs. Congressional appropriations totaling over $7 billion for fiscal years 1992 to 2012 (FY 1992-FY 2012) assigned to the USAMRMC are managed by the office of the CDMRP, a subordinate organization within the USAMRMC. Biomedical research supported by these funds include research in autism spectrum disorder; breast, prostate, lung, ovarian, melanoma and genetic cancers; pediatric brain tumors, pediatric cancers, neurofibromatosis; tuberous sclerosis complex; Gulf War illness; and other research. In additional efforts, the CDMRP works with the Joint Program Committees (JPCs) to execute a number of extramural programs. The CDMRP assisted with program execution in the areas of neurotrauma, in-home and integrated mental health services, basic and applied psychological health, posttraumatic stress disorder (PTSD), traumatic brain injury (TBI), prosthetics, restoration of eye sight, and other conditions related to battlefield injury and military service.

As tasked to do so for program execution and management, the CDMRP is responsible for planning, coordinating, integrating, programming, budgeting, and executing the research programs. The CDMRP's flexible execution and management cycle includes the receipt of annual congressional appropriations, new research programs stakeholders meeting, vision setting, release of request for pre-proposals or proposals, pre-proposal screening and invitation to submit full applications, full application receipt and review, recommendation of grants for funding, and oversight of research grants.

Each program's advisory board (Integration Panel, Steering Committee, or JPC) of leading scientists, clinicians, military members, and/or disease survivors (consumers), recommends an investment strategy for the upcoming year that meets the unique needs of the research field, consumer community, and the military. The investment strategy is unique to each program and to each fiscal year cycle. By revisiting the investment strategy yearly, the program is able to explore innovative scientific ideas and research gaps spanning from basic laboratory science to clinical trials. Program announcements requesting research applications through specific award mechanisms are subsequently prepared and released.

The basic programmatic cycle for award recommendation is a two tiered system. To ensure that each program's research portfolio reflects not only the most meritorious science, but also the

most programmatically relevant research, the CDMRP developed this two tiered model based upon recommendations from the Institute of Medicine (IOM) 1993 report.[1] The IOM recommended a two step review procedure for research applications composed of a scientific peer review and a separate programmatic review. The scientific peer review is conducted by an external panel recruited specifically for each peer review session. It involves the expertise of scientists, clinicians, military members, and consumers. The peer review process includes evaluation of the applications based on a criterion process as delineated in the program announcements. Each application is judged on its own scientific and technical merit with respect to the described criteria. The second tier of review, the programmatic review, is conducted by the program's designated advisory panel, such as the Integration Panel for the PRCRP. The Integration Panel for each program is charged with reviewing the applications based on the scientific peer review ratings, a balanced portfolio, programmatic intent, and relevance to the congressional language. Scientifically sound applications that best meet the program's interests and goals are recommended to the CG, USAMRMC, for funding. Once the CG approves the funding recommendations, awards are made in the form of one- to five-year grants, contracts, or cooperative agreements, and assigned to Science Officers for full-cycle support of research and outcomes. The programs that comprise the CDMRP are scientifically sound, innovative, and responsive to congressional intent and the needs of the public. The USAMRMC and the CDMRP have been praised by the IOM, which issued a report in 1997 stating it was favorably impressed with the processes implemented by the CDMRP and supported its continuation.[2]

Public Law 110-329 from the Consolidated Security, Disaster Assistance, and Continuing Appropriations Act of 2009, appropriated $16 million (M) for a "peer-reviewed cancer research program." In November 2008, the PRCRP was assigned to the USAMRMC, and subsequently to the CDMRP, for execution by the Assistant Secretary of Defense for Health Affairs. Public Law 111-118 from the 2010 Defense Appropriations Act directed funding of $15M. In April 2011, Public Law 112-10 from the Department of Defense and Full Year Continuing Appropriations Act directed $16M for the PRCRP. For FY 2012, Public Law 112-74 required a detailed status of the PRCRP, including research progress, accomplishments, and relevance to Service members and their families, which was provided in February 2012. This report provides an update on the detailed status of the FY 2009-FY 2012 PRCRP cycle, research accomplishments, and the relevance of this type of research for U.S. military Service members and their families.

FY 2009-FY 2012 PEER REVIEWED CANCER RESEARCH PROGRAM

Public Law 110-329 from the Consolidated Security, Disaster Assistance, and Continuing Appropriations Act of 2009, appropriated $16M for the FY 2009 PRCRP. The funds and directed research topic areas included $4M for melanoma and other skin cancers as related to deployments of Service members to areas of high exposure; $2M for pediatric brain tumors within the field of childhood cancer research; $8M for genetic cancer and its relation to exposure to the various environments that are unique to a military lifestyle; and $2M for noninvasive cancer ablation treatment, including selective targeting with nanoparticles. An inaugural stakeholders meeting was held on February 23-34, 2009, which included leading scientists, clinicians, military members, and consumers. Working groups from each topic area discussed

gaps in scientific knowledge and research, consumer concerns, and military medicine. The PRCRP Integration Panel was established in April 2009, to conduct vision setting to review the recommendations made at the stakeholders meeting, to craft a vision and mission of the program, and to develop an investment strategy. The vision of the FY 2009 PRCRP was to improve quality of life by significantly decreasing the impact of cancer on Service members, their families, and the American public. To attain this goal, the FY 2009 PRCRP mission was to foster groundbreaking research, team science, and partnerships for the development of better prevention, earlier detection, and more effective treatments for cancer. Several program announcements were released in June 2009. Following the two levels of review, 38 awards across the four different topic areas were approved by the CG, USAMRMC.

In FY 2010, Public Law 111-118 from the 2010 Defense Appropriations Act appropriated $15M in funding for a "peer reviewed cancer research program" that would research cancers not addressed in the breast, prostate, lung, and ovarian cancer research programs currently executed by the DoD and, specifically, the USAMRMC. Specific topics included melanoma and other skin cancers, pediatric brain tumors within the field of childhood cancer research, genetic cancer research and genomic medicine, kidney cancer, blood cancer, colorectal cancer, *Listeria* vaccine for cancer, and radiation protection utilizing nanotechnology. An Integration Panel consisting of members of the FY 2009 PRCRP Integration Panel and new members to represent the congressional target areas was convened in March 2010. The Integration Panel recommended that the vision of the FY 2010 PRCRP remain unchanged from FY 2009, but that the mission be revised to read "to foster groundbreaking and collaborative research to accelerate progress in cancer prevention, detection, and therapeutic interventions." FY 2010 focus areas were defined for each topic area. Program announcements were released in May and June 2010. Relevance to military beneficiaries was required and reviewed at both peer and programmatic review. Following the two levels of review, 32 awards across the different topic areas were approved by the CG, USAMRMC.

For FY 2011, Public Law 112-10 from the Department of Defense and Full-Year Continuing Appropriations Act appropriated $16M for the PRCRP. The Congressional Record of the Senate, dated December 14, 2010, specified topics areas of melanoma and other skin cancers, pediatric cancer research, genetic cancer research, kidney cancer, blood cancer, colorectal cancer, pancreatic cancer, mesothelioma, *Listeria* vaccine for infectious disease and cancer, and radiation protection utilizing nanotechnology. This was later revised to remove *Listeria* vaccine for infectious disease. Further clarification acknowledged the requirement for relevance to Service members and their families and that the funding would be directed toward research on cancers not addressed in the breast, prostate, lung (with the exception of mesothelioma), and ovarian cancer research programs currently executed by the DoD and, specifically, the USAMRMC. Vision setting was held on April 19, 2011. The FY 2011 Integration Panel consisting of members of the FY 2010 PRCRP Integration Panel and new members to represent the congressional target areas was convened to discuss research gaps, community needs, focus areas, and an investment strategy. Program announcements were released in June and September of 2011. Full application receipt was in October and November 2011. Peer review was in January 2012, followed by programmatic review in March 2012. The final recommendation for funding list of 43 awards was approved by the CG, USAMRMC.

For FY 2012, Public Law 112-74 appropriated $12.8M for the PRCRP. The committee provided funds to conduct research in melanoma and other skin cancers, pediatric brain tumors, genetic cancer, pancreatic cancer, kidney cancer, blood cancer, colorectal cancer, mesothelioma, and *Listeria* vaccine for infectious disease and cancer. This was later revised to remove *Listeria* vaccine for infectious disease. The DoD has been directed to submit a report to the congressional defense committees on the status of the PRCRP, and, for each research area, include the funding amount awarded, the progress of research, and the relevance to Service members and their families.

Vision setting for FY 2012 PRCRP was held in March 2012, with program announcements released in April 2012. Pre-application receipt was in June 2012. Pre-application screening was completed in July 2012. Application receipt was in September 2012, with peer review in November 2012, followed by programmatic review in January 2013. Award obligation is anticipated by no later than September 30, 2013.

FY 2013 PEER REVIEWED CANCER RESEARCH PROGRAM

The U.S. House of Representatives 112th Congress released the DoD Appropriations Bill Report for 2013 on May 17, 2012. Within the report, the committee appropriated $15M for the PRCRP. This report provides funds for research into melanoma and other skin cancers, pediatric brain tumors, genetic cancer, pancreatic cancer, kidney cancer, blood cancers, colorectal cancer, mesothelioma and *Listeria* vaccine for infectious disease and cancer. The report requests the DoD to submit an update to the congressional defense committees on the status of the PRCRP, and, for each research area, include the funding amount awarded, the progress of research, and the relevance to service members and their families.

Vision setting for FY 2013 PRCRP was held in January 2013. At the present time, we are awaiting clarification of funding availability for FY 2013 research grants after sequestration reductions. If funds are available, pre-application receipt would occur 60 days following release of the program announcements and pre-application screening would take place approximately 30 days later. Full application receipt would be scheduled approximately eight weeks, or about 60 days, following the invitation to submit. Peer review would be scheduled about eight weeks later, followed by programmatic review at approximately 60 days later. Award obligation would be no later than September 30, 2014.

RESEARCH AREA INVESTMENT AND PROGRESS

For FY 2009 –FY 2011, all assistance agreements have been made and funds obligated to the institutions. Research area investment is detailed in Appendix A. Research areas included are blood cancer, colorectal cancer, genetic cancer (and genomic medicine), kidney cancer, *Listeria* vaccine for cancer, melanoma and other skin cancers, non-invasive cancer ablation, and pediatric brain tumor. In FY 2010, no applications in the research areas of radiation protection utilizing nanotechnology were recommended or selected for funding. Information for FY 2012 is presented in Table II in Appendix A. These funds have not yet been obligated to the individual institution and are undergoing negotiations. Final awards are expected no later than

September 30, 2013. In FY 2012, no awards were recommended for *Listeria* vaccine for cancer because there were no full applications submitted.

A tabular summary of the proposed work and progress for each of the awards for FY 2009 and FY 2012 is contained in Appendix B. The log number, topic area, last name of principal investigator, award amount, institution, title, research progress, and military relevance are noted for each award. Awards for FY 2011 were obligated by September 30, 2012, and therefore investigations have just been initiated. Funding notification has occurred for the FY 2012 cycle, and award negotiations have started. Final obligation is anticipated by no later than September 30, 2013. Research will begin for FY 2012 according to the agreed upon start date, and the progress throughout the lifecycle of the award will be monitored by Science Officers at the CDMRP.

RELEVANCE TO SERVICE MEMBERS AND THEIR FAMILIES

The relevance of the PRCRP to Service members and their families is determined by the impact of cancer on military service. Members of the military are exposed to hazardous environments and dangerous deployments due to the nature of their service and thus are at risk for the development of different types of cancers.[3] The Veterans Health Administration (VHA) identified malignancies that may be associated with military service (VHA-Directive 2003-34, Attachment B).

The Automated Central Tumor Registry of the DoD published data demonstrating that the incidence of melanoma was higher in the U.S. military population in comparison to the U.S. general population.[4] A meta-analysis using published epidemiological data on cancer risk in male military pilots, civilian pilots, and flight attendants revealed a higher standardized incidence ratio for melanoma and other skin cancers in those with exposure to specific physical, chemical, or biological factors (electromagnetic fields, jet fuel, volatile organic materials, etc.).[5] In addition, studies of common military exposures, such as aircraft maintenance, have been associated with an increased risk of cancer.[6] A recent study by Fastje, et. al.,[7] and funded by the PRCRP, showed that *in utero* exposure to tungsten and other environmental agents primed the immune system for aberrant responses to infectious agents and may lead to carcinogenic risk.

Yamane reported that the most frequent cancers diagnosed in Air Force Service members between 1989 and 2002 were different from the general U.S. population, with a higher[8,9] incidence of melanoma, testicular, thyroid, cervical, and vulvar cancers in the Air Force population,[8] particularly cervical and vulvar cancer. Another review demonstrated a higher rate of prostate cancer in the military beneficiary population compared to the general population.[10] Occupational exposures are a frequent risk of military service. Asbestos-related lung diseases, such as mesothelioma, are a known risk to Naval shipyard work.[11] It is generally accepted that nearly 95% of all mesothelioma cases are due to asbestos exposure.

Hodgkin's disease, a blood cancer, was the most common cancer diagnosis in men who served in the U.S. Navy.[12] The Selected Cancers Cooperative Study Group showed that veterans of the Vietnam War had a 50% increase in risk of Hodgkin's disease as compared to subjects who had not served in Vietnam.[13] Evidence links an increased risk for soft tissue sarcomas,

non-Hodgkin's lymphoma, Hodgkin's disease, and chronic lymphocytic leukemia to Vietnam War service and exposure to herbicides such as Agent Orange.[14] Cancer patterns of Vietnam War military women nurses in comparison to non-Vietnam War military women nurses and the general population showed that site-specific cancer patterns were different, with excess deaths from pancreatic and uterine corpus cancers in the Vietnam War military women nurses.[15] As the configuration of the military population changes to include more women, consideration into research on their risks and exposures is critical.

Two studies funded by the PRCRP recently published results which linked higher stress to increased cancer risk.[16, 17] Chronic stress murine models revealed an important link to attenuation of p53 (a tumor suppressor) and tumorigenesis.[16] Another study demonstrated the potent effect of neuropeptides and other stress mediators on tumor development and progression.[17] Stress and related issues are a concern of the military and the ultimate health and well-being of service members both during and after deployment.

Military families may also be at risk for developing cancers due to environmental exposures, as shown by investigations into leukemia clusters near military aviation facilities.[18] Additionally, transgenerational occupational exposures may lead to increased risk of cancer development in progeny. Children of Vietnam War veterans have an increased risk of developing acute myeloid leukemia.[14] As shown by Hicks, et. al.,[19] children of men in the Air Force had a higher incidence of tumors of the central nervous system (brain and spinal cord) and lymphatic system. The VHA acknowledged the toll of cancer on Service members and their families when releasing its National Cancer Strategy in 2003 (VHA-Directive 2003-34). A serious illness in a family member, such as cancer, may have consequences on the warfighter's ability to complete the mission. A healthy family unit, free of serious illnesses, allows the Service member to focus on his or her role as a warfighter and facilitates the overarching military mission. There are a total of 355,442 military beneficiaries with a cancer diagnosis, for a prevalence of 4.1%, comprised of over 60 different cancer types.[20] The cost of cancer care within the Military Health System in FY 2002 was over $1 billion.[20] Funding studies on the detection, diagnosis, treatment, and prevention of these diseases benefits both the warfighter and the American public, ultimately leading to increased survival rates and decreased costs of medical care.

In summary, the CDMRP, USAMRMC, manages the FY 2009-FY 2013 PRCRP using its established and highly recognized management process. The FY 2013 PRCRP directly impacts military welfare by providing research into cancers that may develop due to exposure in various uniquely military environments. The CDMRP will plan, execute, and manage the FY 2009-FY 2013 PRCRP with the same rigor and integrity it has demonstrated for other research programs.

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