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

HEALTH AFFAIRS

The Honorable Daniel K. Inouye
Chairman, Committee on Appropriations
United States Senate
Washington, DC 20510

Not Required

Dear Mr. Chairman:

The enclosed report is in response to H.R. 2638, Joint Explanatory Statement, which requests that the Secretary of Defense provide a report to the congressional defense committees by March 16, 2009, on the status of the new Peer-Reviewed Cancer Research Program as to the relevance of this type of research for Service members and their families.

We are pleased to provide the final report with the plan for execution and management of the fiscal year 2009 funds for Peer-Reviewed Cancer Research. The U.S. Army Medical Research and Materiel Command (USAMRMC) will manage the $16 million appropriation for the fiscal year 2009 using its established execution and management cycle. The following time line is anticipated:

- Stakeholders will have met by the end of March 2009;
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- Award negotiations will commence following CG's approval, and will be completed by September 2010.

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1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

Not Required

The Honorable David R. Obey
Chairman, Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

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1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

APR 14 2009

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

Dear Mr. Chairman:

The enclosed report is in response to H.R. 2638, Joint Explanatory Statement, which requests that the Secretary of Defense provide a report to the congressional defense committees by March 16, 2009, on the status of the new Peer-Reviewed Cancer Research Program as to the relevance of this type of research for Service members and their families.

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USAMRMC will plan, execute, and manage the fiscal year 2009 Peer-Reviewed Cancer Research funds with the same rigor and integrity as it has done in the past.

Thank you for your continued support of the Military Health System.

Sincerely,

S. Ward Casscells, MD

Enclosure:
As stated

cc:
The Honorable John McCain
Ranking Member

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

HEALTH AFFAIRS

APR 14 2009

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

Dear Mr. Chairman:

The enclosed report is in response to H.R. 2638, Joint Explanatory Statement, which requests that the Secretary of Defense provide a report to the congressional defense committees by March 16, 2009, on the status of the new Peer-Reviewed Cancer Research Program as to the relevance of this type of research for Service members and their families.

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Thank you for your continued support of the Military Health System.

Sincerely,

S. Ward Casscells, MD

Enclosure:
As stated

cc:
The Honorable John M. McHugh
Ranking Member

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

HEALTH AFFAIRS

APR 14 2009

The Honorable Daniel K. Inouye
Chairman, Subcommittee on Defense
Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The enclosed report is in response to H.R. 2638, Joint Explanatory Statement, which requests that the Secretary of Defense provide a report to the congressional defense committees by March 16, 2009, on the status of the new Peer-Reviewed Cancer Research Program as to the relevance of this type of research for Service members and their families.

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USAMRMC will plan, execute, and manage the fiscal year 2009 Peer-Reviewed Cancer Research funds with the same rigor and integrity as it has done in the past.

Thank you for your continued support of the Military Health System.

Sincerely,

S. Ward Casscells, MD

Enclosure:
As stated

cc:
The Honorable Thad Cochran
Ranking Member

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

HEALTH AFFAIRS

APR 14 2009

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

Dear Mr. Chairman:

The enclosed report is in response to H.R. 2638, Joint Explanatory Statement, which requests that the Secretary of Defense provide a report to the congressional defense committees by March 16, 2009, on the status of the new Peer-Reviewed Cancer Research Program as to the relevance of this type of research for Service members and their families.

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- Award negotiations will commence following CG's approval, and will be completed by September 2010.

USAMRMC will plan, execute, and manage the fiscal year 2009 Peer-Reviewed Cancer Research funds with the same rigor and integrity as it has done in the past.

Thank you for your continued support of the Military Health System.

Sir I know you care about this program and - as one & 5 years of metastatic prostate cancer - you can bet I do too!

Gratefully,
Ward

Sincerely,

S. Ward Casscells, MD

Enclosure:
As stated

cc:
The Honorable C. W. Bill Young
Ranking Member

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

HEALTH AFFAIRS

APR 14 2009

The Honorable Ben Nelson
Chairman, Subcommittee on Personnel
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The enclosed report is in response to H.R. 2638, Joint Explanatory Statement, which requests that the Secretary of Defense provide a report to the congressional defense committees by March 16, 2009, on the status of the new Peer-Reviewed Cancer Research Program as to the relevance of this type of research for Service members and their families.

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USAMRMC will plan, execute, and manage the fiscal year 2009 Peer-Reviewed Cancer Research funds with the same rigor and integrity as it has done in the past.

Thank you for your continued support of the Military Health System.

Sincerely,

S. Ward Casscells, MD

Enclosure:
As stated

cc:
The Honorable Lindsey O. Graham
Ranking Member

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

HEALTH AFFAIRS

APR 14 2009

The Honorable Susan Davis
Chairwoman, Subcommittee on Military Personnel
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Madam Chairwoman:

The enclosed report is in response to H.R. 2638, Joint Explanatory Statement, which requests that the Secretary of Defense provide a report to the congressional defense committees by March 16, 2009, on the status of the new Peer-Reviewed Cancer Research Program as to the relevance of this type of research for Service members and their families.

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- Award negotiations will commence following CG's approval, and will be completed by September 2010.

USAMRMC will plan, execute, and manage the fiscal year 2009 Peer-Reviewed Cancer Research funds with the same rigor and integrity as it has done in the past.

Thank you for your continued support of the Military Health System.

Susan we are working closely w/ NCI to be complementary.
All Best
Ward

Sincerely,

S. Ward Casscells, MD

Enclosure:
As stated

cc:
The Honorable Joe Wilson
Ranking Member

REPORT TO THE U.S. CONGRESS

U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND

CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS

PEER REVIEWED CANCER RESEARCH PROGRAM

16 March 2009

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BACKGROUND and PURPOSE OF REPORT

The US Army Medical Research and Materiel Command (USAMRMC) is a major subordinate Command of the United States 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 $4.8 billion for fiscal years 1992 to 2008 (FY92-08) assigned to USAMRMC are managed by the Congressionally Directed Medical Research Programs (CDMRP) office, a subordinate organization to the USAMRMC. The biomedical research programs supported by these funds include breast, prostate, and ovarian cancers; neurofibromatosis; tuberous sclerosis complex; autism; Gulf War illness; psychological health and traumatic brain injury; deployment-related medical; and other programs. The CDMRP is responsible for planning, coordinating, integrating, programming, budgeting, and executing these programs. The CDMRP's flexible execution and management cycle includes the receipt of annual congressional appropriations, stakeholders meeting, vision setting, release of request for proposals, proposal review, recommendation of grants for funding, and oversight of research grants. Following receipt of appropriations, each program's external advisory board of leading scientists, clinicians, and disease survivors (Integration Panel) develops an investment strategy for the upcoming year that meets the unique needs of the research field and encourages exploration of innovative, novel, and under-investigated areas spanning from basic laboratory science to clinical trials. Program announcements requesting research proposals through specific award mechanisms are subsequently prepared and released. Integration Panel members are not allowed to be involved either as collaborators or participants in the proposal processes including, but not limited to, concept design, proposal development, and conduct of research. 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 a unique proposal review model based upon recommendations from the Institute of Medicine (IOM) 1993 report.[1] The IOM recommended a two-tier review procedure for research proposals composed of a scientific peer review and a separate

programmatic review. Scientifically sound proposals 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 1- to 5-year grants, contracts, or cooperative agreements and assigned to grants managers for full cycle support of research grants 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 CDMRP have been praised by the IOM, which issued a report in 1997 stating it was favorably impressed with the CDMRP and supported its continuation.[2] More recently, Congress continues to commend the Army for management of peer reviewed medical research programs.

In the Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009, a "peer-reviewed cancer research program" was appropriated $16 million. The program was assigned by the Assistant Secretary of Defense for Health Affairs, Force Health Protection, to USAMRMC and to the CDMRP in November 2008 for execution. The conferees directed that a report on the status of the FY09 Peer Reviewed Cancer Research Program as to the relevance of this type of research for service members and their families be provided to the congressional defense committees 16 March 2009. The current report details the status of the FY09 Peer Reviewed Cancer Research Program.

FY09 PEER REVIEWED CANCER RESEARCH PROGRAM

The Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009, directed that $16 million be appropriated for the FY09 Peer Reviewed Cancer Research Program. Specific topics were noted and funds allocated per topic area. The funds and directed topic areas included: $4,000,000 for research of melanoma and other skin cancers as related to deployments of service members to areas of high exposure; $2,000,000 for research of pediatric brain tumors within the field of childhood cancer research; $8,000,000 for genetic cancer research and its relation to exposure to the various environments that are unique to a military lifestyle; and $2,000,000 research into noninvasive cancer ablation treatment including selective targeting with nano-particles. Planning for the execution of this program is in progress.

Major milestones to be met by the Peer Reviewed Cancer Research Program include the stakeholders meeting, the vision setting, release of program announcements, proposal receipt, scientific peer review, programmatic review, and grant negotiations. The stakeholders meeting is planned for late February 2009 or early March 2009. From the directed areas, leading scientists, clinicians, disease survivors or family members of disease survivors, and members of the military will be invited to participate in targeted working groups for each topic. The working groups will discuss gaps in scientific knowledge and research with respect to each of the topic areas. Military relevance will be noted throughout the discussions as directed by Congress. The resulting conclusions of these discussions will be the product of the stakeholders meeting and will be used as recommendations to the Peer Reviewed Cancer Research Program Integration Panel. The Integration Panel will be comprised of experts in the specified topic areas as well as disease survivors or their family members for each area and members of the military. During the vision setting meeting, tentatively scheduled for March 2009 or early April 2009, the Integration Panel will review the recommendations made by the stakeholders meeting to craft a vision and mission of the program to represent the program priorities. Program priorities will be defined by gaps in the knowledge of each topic, underfunded or underexplored areas of research for identifying, treating, and managing these diseases. The priorities of each topic area will focus on the relevance to service members and their

families as directed by Congress. The investment strategies for each topic area will be discussed and recommendations forwarded to USAMRMC. The CDMRP staff will prepare and release the program announcements in May 2009 to request proposals from investigators interested in competing for funds to conduct research on the FY09 Peer Reviewed Cancer Research Program priorities with respect to each topic area. Members of the Peer Reviewed Cancer Research Program Integration Panel are not allowed to participate in the design, development, or execution of a research proposal submitted to this program.

The two-tier review process used by the CDMRP includes scientific peer review as the first tier and programmatic review as the second tier. The scientific peer review *for the* FY09 Peer Reviewed Cancer Research Program will be held in September/October 2009 by an external panel recruited specifically for this review. It will include experts (scientists, clinicians, military members) in the topic areas and disease survivors and/or their family members. The peer review process includes evaluation of the proposals based on a criterion process as delineated in the program announcements. Each proposal is judged on its own scientific and technical merit with respect to the described criteria. As the second tier of review, the programmatic review will be held in November/December 2009 and will be conducted by the same Integration Panel that assisted in setting the vision and mission program priorities. The Integration Panel will be charged with reviewing the proposals based on programmatic goals for the FY09 Peer Reviewed Cancer Research Program. The funding recommendations will be based on these ratings and recommendations from the scientific peer review with respect to a balanced portfolio and congressional language for each of the topic areas.

The Peer Reviewed Cancer Research Program provides funding for cancer research in topic areas not currently executed by the USAMRMC. Managing cancer research programs has been a hallmark accomplishment of the Department of Defense USAMRMC executed by the CDMRP. The program funds are implemented as directed by Congress. The Peer Reviewed Cancer Research Program funds will be directed to the specific topic areas including melanoma and other skin cancers as related to deployments

of service members to areas of high exposure; pediatric brain tumors; genetic cancer research and its relation to exposure to the various environments that are unique to a military lifestyle; and noninvasive cancer treatment including selective targeting with nano-particles. Members of the military are exposed to hazardous environments due to the nature of their service and deployments and, thus, are at risk for the development of different types of cancers. A recent review of the military beneficiary population with respect to patient cancer care and cost in 2002 showed a total of 355,442 military beneficiaries had a cancer diagnosis, a prevalence of 4.1%.[3] These diagnoses were identified to be over 60 different cancer types with 27% being cancers other than breast, prostate, and lung.[3] It was noted that the Military Health System costs had doubled from 2001 to 2005 with the overall cost of cancer medical care for military beneficiaries in FY02 at over $1 billion.[3] Further, pediatric brain tumors are the leading cause of death from childhood cancers.[4] 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, will manage the $16 million appropriation for the FY09 Peer Reviewed Cancer Research Program using its established and highly recognized management process. Members of the various services will provide input and recommendations to assist in the request for militarily relevant research proposals. The timeline for this program is anticipated to be a stakeholders meeting in February/March 2009 with the vision setting meeting in March/April 2009. Program announcements requesting research proposals will be released in May 2009. It is anticipated that the scientific peer review will be September/October 2009 with the second tier of review, the programmatic review, in November/December 2009. The recommended for funding list of proposals will be briefed to the CG, USAMRMC, for review and concurrence after which grant negotiations will begin. All awards are anticipated to be made no later than September 2010. The FY09 Peer Reviewed Cancer Research Program directly impacts military welfare by providing research into cancers that may develop due to exposure in various uniquely military environments. Pursuant to congressional direction specific topic areas of the Peer Reviewed Cancer Research Program will focus on militarily

relevant areas of cancer research. The CDMRP will plan, execute, and manage the FY09 Peer Reviewed Cancer Research Program with the same rigor and integrity it has demonstrated for other research programs.

REFERENCES

1. Strategies for Managing the Breast Cancer Research Program: A Report to the U.S. Army Medical Research and Development Command (1993) Committee to Advise the Department of Defense on Its Fiscal Year 1993 Breast Cancer Program, Institute of Medicine, National Academy Press, Washington, DC.

2. A Review of the Department of Defense's Program for Breast Cancer Research (1997) Committee to Review the Department of Defense's Breast Cancer Research Program, Institute of Medicine, National Academy Press, Washington, DC.

3. Crawford RS, Wu J, Park D, and Barbour GL. 2007. A Study of Cancer in the Military Beneficiary Population. Military Medicine 172:1084-1088.

4. Pediatric Brain Tumors Program Review Group, http://prg.nci.nih.gov/pediatrics.html