

MAY - 3 2010

HEALTH AFFAIRS

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

Dear Mr. Chairman:

The enclosed report is provided in response to the House Appropriations Committee Report 111-230, which requests the Secretary of Defense provide a report to the defense committees not later than 120 days after enactment of the legislation on how funds are to be allocated for the Spinal Cord Injury Research Program.

The U.S. Army Medical Research and Materiel Command (USAMRMC) will manage this spinal cord research using its established execution and management cycle. USAMRMC anticipates that program announcements will request research proposals in May 2010, an external scientific peer review will evaluate proposals for scientific merit in September, a programmatic review of proposals should occur in December, and awards should be complete September 2011.

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

Sincerely,

Charles L. Rice, M.D.

Charles L. R:

President, Uniformed Services University of the Health Sciences

Performing the Duties of the

Assistant Secretary of Defense

(Health Affairs)

Enclosure: As stated

cc:

The Honorable John McCain Ranking Member



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HEALTH AFFAIRS

The Honorable James H. Webb Chairman, Subcommittee on Personnel Committee on Armed Services United States Senate Washington, DC 20510

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cc:

The Honorable Lindsey O. Graham Ranking Member



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

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The Honorable Howard P. "Buck" McKeon Ranking Member



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HEALTH AFFAIRS

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

Dear Madam Chairwoman:

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The Honorable Joe Wilson Ranking Member



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

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The Honorable Thad Cochran Ranking Member



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The Honorable Jerry Lewis Ranking Member



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

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Enclosure: As stated

CC:

The Honorable C. W. Bill Young Ranking Member

REPORT TO THE U.S. CONGRESS

U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND

CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS

SPINAL CORD INJURY RESEARCH PROGRAM FUND ALLOCATION PLAN FOR FISCAL YEAR 2010 (FY 10)

Spinal Cord Injury Research Program Report to Congress

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19 February 2010

PURPOSE OF REPORT

The 2010 Defense Appropriations Bill directed funding of \$11.25M and required the Secretary of Defense to report to the congressional defense committees 120 days after enactment of the Act (by 18 April 2010) on how these funds are to be allocated. This report details the status of the FY 09 Spinal Cord Injury Research Program and how the FY 10 funds are to be allocated.

OVERVIEW OF MANAGEMENT OF THE SPINAL CORD INJURY RESEARCH PROGRAM

At the direction of the United States Congress, the Department of Defense (DoD) manages targeted biomedical research. The U.S. Army Medical Research and Materiel Command (USAMRMC) is responsible for administering many of these appropriations. The USAMRMC is a major subordinate Command of the United States Army Medical Command. The Commanding General (CG), USAMRMC is assigned authority as the Executive Agent for a number of medical research, development, and acquisition programs. Additionally, as directed by Congress, the USAMRMC manages Congressional Special Interest (CSI) medical research programs. CSI funds are not in the President's Budget: Congress adds them annually to the DoD appropriation to fund new programs or to augment DoD or Army programs. The Command's CSI vision is to ensure the sponsorship of good science that fulfills the intent of Congress. When appropriate, the research results have been applied within the DoD as well as the civilian sector.

The USAMRMC is responsible for planning, coordinating, integrating, programming, budgeting, and executing CSI programs using a two-tier review process. The USAMRMC's flexible 7-year execution and management cycle includes the receipt of annual congressional appropriations, stakeholders meeting, vision setting, proposal review, and oversight of research grants. Briefly, following receipt of appropriations, each program's external advisory board (Integration Panel [IP]) of leading scientists, clinicians, Joint Technology Coordinating Group members, and disease survivors develops an investment strategy for the upcoming year that meets the unique needs of the research field and encourages exploration of innovative, novel, and underinvestigated areas spanning from basic laboratory science to clinical trials. Program Announcements requesting research proposals through specific award mechanisms are subsequently prepared and released. To ensure that each program's research portfolio reflects not only the most meritorious science, but also the most programmatically relevant, the USAMRMC developed a unique two-tier review procedure for research proposals, composed of 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 and the Assistant Secretary of Defense for Health Affairs [ASD(HA)] for funding. Once the funding recommendations are approved, awards are made in the form of 1- to 5-year grants, contracts, or cooperative agreements and assigned to Grants Managers for providing full cycle support of research grants and outcomes. These well-established processes are scientifically sound, innovative, and responsive to congressional intent and the needs of the public.

FY 2009 SPINAL CORD INJURY RESEARCH PROGRAM

In response to FY 09 appropriations, the USAMRMC established the Spinal Cord Injury Research Program. The first major task for the program was to access the current state of spinal cord injury science and identify potential gaps by holding a stakeholders meeting. Renowned scientists and clinicians representing academia and government (military, Department of Veterans Affairs, National Institutes of Health, and the U.S. Food and Drug Administration) as well as spinal cord injury advocacies participated in the meeting, which took place on 27 April 2009. Following the meeting, an IP was formed, primarily from stakeholder meeting attendees. On 8 May 2009, the Spinal Cord Injury Research Program Integration Panel assembled to recommend a vision and investment strategy for the FY 09 program based on information

gathered at the stakeholders meeting. In June 2009, five Program announcements were released, which sought research proposals to address the strategy established. Four of the five announcements called for preproposals, which resulted in 372 submissions. Of these, 143 were invited for full proposal submission by the deadline of 10 December 2009. One announcement did not require preproposals and resulted in the submission of 128 proposals by the deadline of 20 November 2009. Peer review took place from 24-26 January 2010. Programmatic review will be conducted on 19 April 2010 to make funding recommendations. Following CG, USAMRMC and ASD(HA) approval, FY 09 proposals recommended for funding will be awarded by 30 September 2010.

FY 2010 SPINAL CORD INJURY RESEARCH PROGRAM

The first major milestone in the execution and management cycle of the FY 10 Spinal Cord Injury Research Program is the vision setting meeting, currently scheduled for 20 April 2010, at which the IP will develop and recommend a vision and investment strategy for the FY10 Spinal Cord Injury Research Program. USAMRMC staff will then prepare and release program announcements in May 2010 to request proposals from investigators interested in competing for funds to conduct research on FY 10 Spinal Cord Injury Research Program priorities.

In keeping with USAMRMC's two-tier proposal review process, scientific (peer) review, the first level of review for the FY10 Spinal Cord Injury Research Program is tentatively scheduled for September 2010 by an external panel that includes scientific experts and spinal cord injury survivors. Peer review is a criterion-based process whereby proposals are judged on their own scientific and technical merit based on established evaluation criteria. The second tier of review, programmatic review, is tentatively scheduled for December 2010-January 2011 by the same IP that previously established the program priorities and investment strategy. In contrast to the scientific peer review, the goal of programmatic review is to develop funding recommendations based on the ratings and recommendations of scientific peer review that balance the most meritorious and innovative science across many disciplines and offer the highest promise for fulfilling the programmatic goals of the FY 10 Spinal Cord Injury Research Program. Following CG, USAMRMC and ASD(HA) approval, FY 10 proposals recommended for funding will be awarded by 30 September 2011.

SUMMARY

In summary, the USAMRMC will manage the \$11.25M appropriation for the FY 10 Spinal Cord Injury Research Program using its established execution and management cycle. The following timeline is anticipated. A vision setting meeting with the IP will take place on 20 April 2010. Program announcements requesting research proposals will be released in May 2010. An external scientific peer review will evaluate proposals for scientific merit in September 2010, and the IP will programmatically review proposals in December 2010-January 2011. Funding recommendations will be submitted to the CG. USAMRMC and ASD(HA) for approval following programmatic review. Award negotiations will commence following approval and will be completed by 30 September 2011. The USAMRMC will plan, execute, and manage the FY 10 Spinal Cord Injury Research Program with the same rigor and integrity as it has done in the past.