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

PERSONNEL AND
READINESS

JUN 30 2011

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

Dear Mr. Chairman:

The enclosed report responds to section 725 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2010 (Public Law 111-84) that requires the Secretary of Defense to provide for the conduct of chiropractic clinical trials by the National Institutes of Health or an independent academic institution.

The U.S. Army Medical Research and Materiel Command (USAMRMC) is executing the NDAA for FY 2010 Chiropractic Clinical Trials mandate using established and highly recognized execution and management processes. Panels of experts knowledgeable about chiropractic care and research, the musculoskeletal system, and the Military Health System conducted a scientific review and made funding recommendations to the Commanding General of USAMRMC and the Office of Force Health Protection and Readiness for approval. A research award was issued in early February 2011, and three clinical trials are planned. The first clinical trial of the program is anticipated to begin enrolling patients in January 2012.

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

Sincerely,

Jo Ann Rooney
Principal Deputy

Enclosure:
As stated

cc:
The Honorable Thad Cochran
Vice Chairman

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

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NOV 30 2011

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Vice Chairman

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PERSONNEL AND
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AUG 30 2011

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

Dear Mr. Chairman:

The enclosed report responds to section 725 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2010 (Public Law 111-84) that requires the Secretary of Defense to provide for the conduct of chiropractic clinical trials by the National Institutes of Health or an independent academic institution.

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Jo Ann Rooney
Principal Deputy

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As stated

cc:
The Honorable John McCain
Ranking Member

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

PERSONNEL AND
READINESS

OCT 30 2011

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

Dear Mr. Chairman:

The enclosed report responds to section 725 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2010 (Public Law 111-84) that requires the Secretary of Defense to provide for the conduct of chiropractic clinical trials by the National Institutes of Health or an independent academic institution.

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Jo Ann Rooney
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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

AUG 30 2011

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

Dear Mr. Chairman:

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Jo Ann Rooney
Principal Deputy

Enclosure:
As stated

cc:
The Honorable Norman D. Dicks
Ranking Member

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

PERSONNEL AND
READINESS

DEC 30 2011

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

Dear Mr. Chairman:

The enclosed report responds to section 725 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2010 (Public Law 111-84) that requires the Secretary of Defense to provide for the conduct of chiropractic clinical trials by the National Institutes of Health or an independent academic institution.

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cc:
The Honorable Lindsey Graham
Ranking Member

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

PERSONNEL AND
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The Honorable Joe Wilson
Chairman
Subcommittee on Military Personnel
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

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As stated

cc:
The Honorable Susan A. Davis
Ranking Member

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
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PERSONNEL AND
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30

The Honorable C.W. Bill Young
Chairman
Subcommittee on Defense
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

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Report to Congress in Response to Section 725 of the National Defense Authorization Act for Fiscal Year 2010, Public Law 111-84

Chiropractic Clinical Trials

Preparation of this report/study cost the Department of Defense a total of approximately $707 for the 2011 Fiscal Year.

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Chiropractic Clinical Trials
Report to Congress

TABLE OF CONTENTS

Purpose of Report 3

Overview and Management of Chiropractic Clinical Trials 4

Chiropractic Award Status 5

Chiropractic Protocol Status 6

Summary 7

PURPOSE OF REPORT

Section 725 of the National Defense Authorization Act for Fiscal Year 2010, Public Law 111-84, directs the Secretary of Defense to provide for the conduct of chiropractic clinical trials by the National Institutes of Health or an independent academic institution. The clinical trials shall include controlled trials that compare the outcomes of chiropractic treatment with conventional treatment on pain management, orthopedic injuries or disorders that do not require surgery, and smoking cessation. The clinical trials shall also include interventional trials that examine the effect of chiropractic treatment on the reflexes and reaction times of special operations forces, and the strength, balance, and injury prevention of the Armed Forces with combat specialties operating in a combat theater. Clinical trial participants shall be members of the Armed Forces on active duty.

The Secretary of Defense is required to submit trial protocol reports to Congress no later than 30 days before each clinical trial is scheduled to begin. This first trial protocol report details the status of the Chiropractic Clinical Trials program and the plans for the initiation of the first chiropractic clinical trial of the program.

OVERVIEW AND MANAGEMENT OF CHIROPRACTIC CLINICAL TRIALS

Since 1985, the Department of Defense (DoD) has conducted several demonstration projects designed to examine the cost and feasibility of chiropractic health care services for its beneficiaries. These projects have generally concluded that it is feasible to implement chiropractic services as a health care benefit,[1] and that the resulting patient satisfaction is higher than that seen with traditional medical care.[2] Following results of the demonstration projects, the Floyd D. Spence National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2001, (Public Law 106-398), directed DoD to develop and implement a plan to make a chiropractic benefit available to all active duty Service members in the U.S. Armed Forces. The resulting Chiropractic Care Program established chiropractic care to active duty Service members at 49 military clinics and hospitals, later expanded to a total of 60 locations by the Duncan Hunter NDAA for FY 2009 (Public Law 110-417). At this time, chiropractic care is neither available at the remaining military health care facilities, nor have chiropractic services and benefits been mandated as a permanent part of the Defense Health Program.

Section 725 of the NDAA for FY 2010 required the conduct of chiropractic clinical trials in the Military Health System, while continuing the chiropractic benefit available at the 60 military health facilities that offer it. In May 2010, the Deputy Assistant Secretary of Defense for Force Health Protection and Readiness (DASD (FHP&R)) assigned the Chiropractic Clinical Trials requirement to the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of the Congressionally Directed Medical Research Programs (CDMRP) for execution.

USAMRMC manages biomedical research and development programs that are part of the DoD and Army Science and Technology Master Plans. Congressional appropriations totaling more than $6 billion for FY 1992-2010 assigned to USAMRMC are managed by the CDMRP, a subordinate organization within the USAMRMC. Biomedical research supported by these funds include research in spinal cord injury; orthopedic injury; breast, prostate, lung, ovarian, melanoma and genetic cancers; pediatric brain tumors; neurofibromatosis; tuberous sclerosis complex; autism; Gulf War illness; psychological health and traumatic brain injury; deployment-related medical; and other research. For all CDMRP research programs, coordination with and oversight by the Defense Health Program is provided through the Joint Program Committees (JPC). CDMRP is responsible for planning, coordinating, integrating, programming, budgeting, and executing the research programs. CDMRP has a flexible execution and management cycle, to include the receipt of annual congressional appropriations, new research program stakeholders meetings, vision setting, release of requests for pre-proposals or proposals, pre-proposal screening and invitation to submit full proposals, full proposal receipt and review, recommendation of grants for funding, and oversight of research grants.

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[1] Birch & Davis Associates, Inc. *Final Report: Chiropractic Health Care Demonstration Program*, Falls Church, VA, February 10, 2000.

[2] Muse & Associates, Inc. *Report on the Department of Defense Chiropractic Health Care Demonstration Project*. Results of independent study conducted by DoD contracted agency. Washington, D.C., March 2000.

To ensure that each program's research portfolio reflects not only the most meritorious science, but also the most programmatically relevant, CDMRP 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 Commanding General, USAMRMC and FHP&R 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 Science Officers to provide full cycle support and monitoring of research grants and outcomes. The JPC provide programmatic oversight through the conduct of in-progress reviews. These well-established processes are scientifically sound, innovative, and responsive to congressional intent and the needs of the public.

CHIROPRACTIC AWARD STATUS

The CDMRP has initiated the execution of the FY10 NDAA Chiropractic Clinical Trials requirement in accordance with its accepted review and management processes. FHP&R has allocated $7.5 Million (M) from FY10 Defense Health Program funds to support the Chiropractic Clinical Trials. A program announcement calling for research proposals from the National Institutes of Health or independent academic institutions was released by CDMRP on May 12, 2010. Full proposal receipt occurred in August 2010. The responses were externally peer reviewed by subject matter experts in chiropractic care, chiropractic research, and musculoskeletal research, as well as consumer representatives (military Service members with orthopedic conditions who have used chiropractic care). Funding recommendations were made in September 2010 by a second-tier programmatic review panel composed of the JPC Chairs for Military Operational Medicine, Combat Casualty Care and Clinical and Rehabilitative Medicine; representatives from the Office of the Surgeon General; FHP&R; Chiropractic practitioners within DoD; and consumers. One proposal was recommended for funding, and the award was issued in February 2011 by USAMRMC.

The RAND Corporation, in collaboration with the Palmer College of Chiropractic and the Samueli Institute, was awarded $7.5M for the proposal, "Assessment of Chiropractic Treatment for Low Back Pain, Military Readiness and Smoking Cessation in Military Active Duty Personnel," or ACT. ACT is a multi-institutional effort with several military sites designed to carry out the following specific aims: 1) to compare pain and functional outcomes of chiropractic manipulation therapy plus standard care to standard care alone in a randomized, controlled trial of active duty military Service members ages 18-50 with non-surgical acute, sub-acute or chronic low back pain; 2) to measure and compare changes in smoking behavior after participation in a smoking cessation program offered with chiropractic manipulation therapy plus standard care or with standard care alone; 3) to assess the effect of chiropractic manipulation therapy on military readiness, by comparing pre- and post-treatment differences in reflexes and reaction times in Special Operation Forces; and 4) to determine differences in strength, balance and likelihood of re-injury between combat ready Service members receiving either chiropractic manipulation therapy or sham manipulation.

Three clinical trials are planned, with the first two Aims addressed in an initial clinical trial (ACT1), and two additional clinical trials planned for Aims 3 and 4 (ACT 2 and ACT 3, respectively).

CHIROPRACTIC PROTOCOL STATUS

ACT 1

The first chiropractic clinical trial, ACT 1, is a four-site, comparative effectiveness, randomized controlled trial of chiropractic manipulation therapy plus standard care versus standard care alone. The trial will focus on pain relief and work-related function in acute, sub-acute, and chronic low back pain in active duty Service members. The chiropractic treatment will include chiropractic manipulation therapy plus ancillary physiotherapeutic interventions, and the standard care will be based on the current DoD/Veterans Affairs Guidelines for low back pain. Participants who identify themselves as smokers will be given the opportunity to enroll in a smoking cessation program, and response to the program will be compared between the two arms of the study (chiropractic manipulation therapy plus standard care or standard care alone). Active duty participants will be recruited from National Naval Medical Center in Bethesda, MD; Naval Air Station in Pensacola, FL; Naval Medical Center in San Diego, CA; and Rock Island Arsenal in Rock Island, IL. The study will begin enrolling within 2 months of receiving final Institutional Review Board (IRB) and DoD regulatory approvals. At the time of this report, IRB approval has been granted for Palmer College of Chiropractic, and IRB approval with contingencies has been granted for RAND Corporation and Samueli Institute. IRB submissions for the four military sites are pending. It is estimated that ACT 1 will begin enrolling patients in January 2012. Subject recruitment is planned to last two years, enrolling 250 participants, followed by several months of data analysis and manuscript preparation.

ACT 2 & ACT 3

Protocol development for ACT 2, a study of reflexes, movement time, and reaction times prior to and after chiropractic treatment in Special Operations Forces, were initiated in June 2011. Recruitment for ACT 2 will occur at Madigan Army Medical Center at Fort Lewis-McChord, WA; Blanchfield Army Community Hospital at Fort Campbell, KY; and Naval Medical Center in San Diego, CA. Protocol development for ACT 3, a randomized controlled trial comparing strength, balance, and risk of re-injury as markers of combat readiness in deploying troops following chiropractic or sham treatment, was initiated in June 2011. ACT 3 will recruit study subjects from the National Naval Medical Center in Bethesda, MD. Both studies will begin enrolling during the second year of the performance period of the award. Trial protocol reports will be provided to Congress at least 30 days before each trial is scheduled to begin.

SUMMARY

In summary, USAMRMC is executing the FY10 NDAA Chiropractic Clinical Trials mandate using established and highly recognized execution and management processes. Panels of experts knowledgeable about chiropractic care and research, the musculoskeletal system, and the Military Health System conducted a scientific review and made funding recommendations to the Commanding General, USAMRMC, and the FHP&R for approval. A research award was issued in early February 2011, and three clinical trials are planned. The first clinical trial of the program is anticipated to begin enrolling patients in January 2012. USAMRMC will continue to manage the Chiropractic Clinical Trials with the same rigor and integrity it has demonstrated for other research programs.