OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

The Honorable Richard C. Shelby
Chairman
Committee on Appropriations
United States Senate
Washington, DC 20510

SEP - 6 2019

Dear Mr. Chairman:

The enclosed report is in response to section 725(f)(2) of the National Defense Authorization Act for Fiscal Year 2010 (Public Law 111–84), which requires the Secretary of Defense to submit a final report on a series of chiropractic clinical trials supported by the Department, and conducted by the National Institutes of Health or an independent academic institution.

The RAND Corporation, in collaboration with the Palmer College of Chiropractic and Samueli Institute, was awarded $7.5 million for the proposal titled "Assessment of Chiropractic Treatment for Low Back Pain, Military Readiness, and Smoking Cessation in Military Active Duty Personnel," or ACT. Three clinical trials were planned in response to the requirement. The Department submitted the final reports on ACT 1 and ACT 2 on February 2, 2018 and April 30, 2018, respectively. This report details the results of ACT 3, which was conducted to determine whether chiropractic care can influence strength, balance, and/or endurance among Active Duty Service members with low back pain. The trial found that chiropractic care improved fitness measures among Active Duty Service members with low back pain.

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,

James N. Stewart
Assistant Secretary of Defense for Manpower and Reserve Affairs, Performing the Duties of the Under Secretary of Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Patrick J. Leahy
Vice Chairman

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND READINESS

The Honorable Nita M. Lowey
Chairwoman
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

SEP - 6 2019

Dear Madam Chairwoman:

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Sincerely,

James N. Stewart
Assistant Secretary of Defense for Manpower and Reserve Affairs, Performing the Duties of the Under Secretary of Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Kay Granger
Ranking Member

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

SEP - 6 2019

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

Dear Mr. Chairman:

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Sincerely,

James N. Stewart
Assistant Secretary of Defense for Manpower and Reserve Affairs, Performing the Duties of the Under Secretary of Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable William M. "Mac" Thornberry
Ranking Member

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND READINESS

SEP - 6 2019

The Honorable James M. Inhofe
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The enclosed report is in response to section 725(f)(2) of the National Defense Authorization Act for Fiscal Year 2010 (Public Law 111–84), which requires the Secretary of Defense to submit a final report on a series of chiropractic clinical trials supported by the Department, and conducted by the National Institutes of Health or an independent academic institution.

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Sincerely,

James N. Stewart
Assistant Secretary of Defense for Manpower and Reserve Affairs, Performing the Duties of the Under Secretary of Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Jack Reed
Ranking Member

FINAL REPORT TO CONGRESSIONAL DEFENSE COMMITTEES

Chiropractic Clinical Trials

In Response to Section 725(f)(2) of the National Defense Authorization Act For Fiscal Year 2010 (Public Law 111–84)

The estimated cost of this report or study for the Department of Defense (DoD) is approximately $3,500 in Fiscal Years 2018 - 2019. This includes $2,900 in expenses and

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BACKGROUND

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. The results of these projects have generally concluded that it is feasible to implement chiropractic services as a military health care benefit, and the resulting patient satisfaction is higher than that seen with traditional medical care.[1,2] Following results of the demonstration projects, the Floyd D. Spence National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2001 (Public Law 106–398) mandated that the DoD develop and implement a plan to make a chiropractic benefit available to all Active Duty personnel in the U.S. Armed Forces. The resulting Chiropractic Care Program established chiropractic care for Active Duty Service members at 49 military clinics and hospitals, which later expanded to a total of 60 locations following the Duncan Hunter NDAA for FY 2009 (Public Law 110–417). Currently, chiropractic care is offered at a total of 65 military clinics and hospitals.[3] At this time, this service is neither available at the remaining Military Health System (MHS) health care facilities, nor for all MHS health care beneficiaries. Chiropractic care is only available to Active Duty Service members and activated Guard/Reserve members.

The NDAA for FY 2010 (Public Law 111–84) provided for additional research on the outcomes of chiropractic treatment in the MHS, while continuing the chiropractic benefit available at select MHS health care facilities. The statute required that the Secretary of Defense provide for the conduct of chiropractic clinical trials, in accordance with the requirements set forth in section 725 of the NDAA for FY 2010. In May 2010, the Assistant Secretary of Defense for Health Affairs (ASD(HA)) assigned the Chiropractic Clinical Trials requirement to the U.S. Army Medical Research and Development Command and to the Congressionally Directed Medical Research Programs (CDMRP) for execution.

The CDMRP initiated the execution of the NDAA for FY 2010 Chiropractic Clinical Trials requirement in accordance with its accepted execution management processes. The ASD(HA) allocated $7.5 million from FY 2010 Defense Health Program funds to support the Chiropractic Clinical Trials. The CDMRP released a program announcement on May 12, 2010, and full proposal receipt occurred in August 2010. These responses underwent external peer review by subject matter experts in chiropractic care, chiropractic research, and musculoskeletal research, as well as consumer representatives (military Service members with orthopedic conditions who utilized chiropractic care). A programmatic review panel issued funding recommendations in September 2010. Panel membership consisted of the Joint Program Committee Chairs from the Military Operational Medicine Research Program, Combat Casualty Care Research Program, and Clinical and Rehabilitative Medicine Research Program; a representative from the Office of the Army Surgeon General; a representative from the Office of the ASD(HA); a chiropractic practitioner within the DoD; and a consumer representative. One proposal was recommended for funding, and the award was issued in February 2011, as detailed below.

The RAND Corporation, along with collaborating institutions Palmer College of Chiropractic and Samueli Institute, was awarded $7.5 million for the proposal titled "Assessment of Chiropractic Treatment for Low Back Pain, Military Readiness and Smoking Cessation in

Military Active Duty Personnel," or ACT. The ACT was a multi-institutional effort across several military sites, designed to carry out the following objectives aligned with the requirements set forth in section 725 of the NDAA for FY 2010: (1a) compare pain and functional outcomes of chiropractic manipulation therapy plus usual medical care (UMC) to UMC alone in a randomized controlled trial (RCT) of Active Duty military personnel aged 18–50 years with non-surgical acute, sub-acute, or chronic low back pain; (1b) measure and compare changes in smoking behavior after participation in a smoking cessation program offered with chiropractic manipulation therapy and UMC or with UMC alone; (2) assess the effect of chiropractic manipulation therapy on military readiness by comparing pre- and post-treatment differences in reflexes and reaction times in Special Operations Forces (SOF); (3) determine differences in strength, balance, and endurance between combat-ready troops receiving either chiropractic manipulation therapy or sham manipulation.

Three clinical trials were planned, with an initial clinical trial to address objectives 1a and 1b (ACT 1); a second trial to address objective 2 (ACT 2); and a third trial to address objective 3 (ACT 3). The performance period of the award was February 15, 2011 through February 14, 2019. The results from ACT 1 and ACT 2 were reported to Congress on February 2, 2018 and April 30, 2018, respectively. This final report details the results of ACT 3.

ACT 3 INTRODUCTION

Conditions that cause low back pain (LBP) are common worldwide, with an estimated global prevalence of 12 percent.[4] LBP is one of the most common reasons Service members seek medical care, and is a leading cause of medical evacuation from combat theaters.[5] Furthermore, LBP can negatively impact trunk muscle strength, balance, and endurance- factors that contribute to overall fitness and influence military readiness.[6] ACT 3 was conducted to determine whether chiropractic care can influence strength, balance, and/or endurance among Active Duty Service members with LBP.

ACT 3 METHODS

ACT 3 was designed as a prospective clinical RCT, and was conducted at the Naval Air Technical Training Center clinic at the Naval Hospital Pensacola, Florida. Active Duty military personnel 18-40 years of age with chronic, subacute, or acute non-surgical LBP participated in the study. Exclusion criteria included conditions best managed by other health disciplines, such as LBP from a visceral pain source, spinal pathology, recent spinal surgery or fracture, or inflammatory spinal arthropathy. The trial was registered at ClinicalTrials.gov on February 1, 2016 (Identifier: NCT02670148). The study design, summarized in brief below, is detailed in a 2018 publication.[7]

Participants were allocated to one of two groups: (a) chiropractic care; or (b) wait-list control. Upon determination of eligibility, all participants (chiropractic care and wait-list control groups) underwent a baseline assessment that included balance, strength, and endurance testing. Participants also completed patient reported outcome (PRO) instruments, including a numerical rating for pain intensity (0–10) using the Roland Morris Disability Questionnaire; a

"bothersomeness" of symptoms questionnaire that assesses health-related quality of life, the Patient-Reported Outcomes Measurement Information System®-29; the Fear-Avoidance Beliefs Questionnaire; a global improvement question; and questions regarding expectations for care and physical activity outside of work duties.

Allocation of participants to each study arm occurred randomly through a computer-generated scheme in a 1:1 ratio. Participants in the chiropractic care group received treatment and evaluation from a chiropractor during eight visits over a 4-week period. Spinal manipulation therapy was customized to each participant as determined by the provider, and the nature of the care was tracked by the study team. At the end of the 4-week period, participants completed the same PRO questionnaires and were re-assessed via the balance, strength, and endurance tests. Wait-list control group participants were asked to refrain from receiving chiropractic care for the four-week period following enrollment, at which point they, too, were re-assessed via PRO questionnaires and balance, strength, and endurance testing. After trial completion, the wait-list control group participants were offered the option to be scheduled for chiropractic care.

The primary outcome measure for the trial was a change in peak isometric strength following the four-week intervention period. Strength was assessed as the maximum pulling force recorded in an exercise involving isometric pulling on a bimanual handle while in a semi-squat position. Secondary outcomes included changes in balance and endurance and PRO measures. Balance testing was performed first to eliminate any potential carryover effects from the strength or endurance tests, and measured as the longest holding time in a specific, one-legged balancing position on a pressure-sensitive pad. Endurance, assessed last to ensure fatigue would not interfere with the strength and balance tests, was evaluated by the Biering-Sorenson test, which measures the duration a person can hold his/her upper body unsupported in a horizontal prone position, while the lower body is stabilized with straps on a table.

ACT 3 RESULTS

ACT 3 study enrollment occurred between April 2016 and December 2018. In total, 202 individuals underwent screening. The study enrolled 110 Active Duty Service members (55 members allocated to each study group). The mean age was 30 years, and 75 percent reported experiencing LBP symptoms for over one year. Demographics (e.g., age, race, ethnicity, sex/gender) were similar between the intervention and control groups. Overall, 20 percent of the participants were Hispanic or Latino; 67 percent were white; 13 percent were Black/African American; 1 percent was Asian; 1 percent was Native Hawaiian/Pacific Islander; and 18 percent were of an unspecified race or multi-racial. Additionally, 17 percent of study participants were female. During the course of the study, four participants withdrew and four more were lost to follow-up. There were no serious adverse events reported.

Following initial data analysis, the chiropractic care group demonstrated a five percent increase in isometric strength, compared to a six percent decrease by the control group. Balance increased 28 percent in the chiropractic group, compared to no change in the control group. Finally, endurance increased 14 percent in the chiropractic group, compared to a decrease of 10 percent in the control group. The differences in the chiropractic care group over the four-week

intervention period were significantly greater than the wait-list control group for all three physical outcome measures. Over the 4 weeks, changes from baseline measurements in these three outcome variables were assessed with an analysis of covariance adjusting for the baseline value of the respective outcome variable. Details of the methods are included in the published clinical protocol.[7]. Based on the results, the investigators concluded that chiropractic care improves key fitness characteristics among Active Duty Service members with LBP, and could lead to improved military readiness in such individuals. Full analyses of primary and secondary outcomes (such as changes in PRO measures) are ongoing, with plans to publish the results upon their completion.

DISCUSSION AND SUMMARY

The RAND Corporation and its partners have completed three clinical trials in accordance with section 725 of the NDAA for FY 2010. Each of the three trials has provided insight regarding the feasibility and value of providing a chiropractic care benefit to Active Duty Service members. ACT 1 consisted of a RCT designed to test whether chiropractic care combined with UMC provided a greater reduction in pain and disability among Service members with LBP than UMC alone. This large, multi-site study successfully enrolled 750 Service members at 3 military sites. It found that chiropractic care combined with usual medical care led to moderate, statistically significant improvements in outcomes, including LBP intensity, disability, and satisfaction. ACT I included a nested study measuring the impact of a smoking cessation program delivered by a chiropractor. The study enrolled 35 participants across the 3 sites; results of the data analysis with the small sample size were not statistically significant, and no definitive results could be determined. Approximately 200 participants from the ACT I study were also enrolled for long-term follow up assessments to capture low back pain recurrence after chiropractic treatment. Data analysis on this sub-study is ongoing, with plans to submit a manuscript for publication by December 2019. The ACT 2 trial was the first randomized controlled study to examine the impact of a brief course of chiropractic therapy on the reaction and response times of Active Duty SOF personnel. While a sustained improvement in reaction or response times was not associated with the short course of chiropractic therapy provided, a single session had an immediate effect of reducing the time for asymptomatic SOF personnel to complete a complex motor response test. Finally, ACT 3 demonstrated that chiropractic care can improve fitness measures among Active Duty Service members with LBP.

The investigators note that each study had limitations that potentially impacted the results obtained. Two of the trials, ACT 1 and ACT 3, focused on LBP. While a significant medical issue for Service members, the origin of LBP is often difficult to diagnose, which can result in patient heterogeneity, a factor that can contribute to treatment effect variability. Also, given the nature of chiropractic manipulation therapy, it is difficult to mask participants in terms of their study group assignment and it is not feasible to blind the practitioners delivering the intervention, both of which can affect results. With regard to ACT 2, SOF personnel are highly trained with high-level physical conditioning, which may make it more difficult to detect any significant improvement in reaction or response times, regardless of intervention. ACT 2 also involved a relatively short course of chiropractic care. The number of sessions was chosen to ensure busy SOF personnel would be able to complete the study, but may not have been a long enough course

to induce a measureable, sustained improvement in reaction or response times in the study population.

The RAND Corporation and its partners achieved recruitment goals and completed all three clinical trials. The sum of their results indicate that chiropractic care in Active Duty populations can improve fitness measures and short-term motor responses, and improves outcomes when combined with UMC in the treatment of LBP. To date, the award has resulted in five publications, which are listed in Appendix I, as well as multiple presentations at national meetings.

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1. Birch & Davis Associates, Inc. "Final Report: Chiropractic Health Care Demonstration Program." Falls Church, VA, 2000.

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

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7. Vining Robert, Amy Minkalis, Cynthia R. Long, Lance Corber, Crystal Franklin, M. Ram Gudavalli, Ting Xia, and Christine M. Goertz. "Assessment of chiropractic care on strength, balance, and endurance in active-duty U.S. military personnel with low back pain: a protocol for a randomized controlled trial." *Trials* 19, no.1 (December 2018): 671-684. https://doi.org/10.1186/s13063-018-3041-5.

APPENDIX I

ACT Publications

ACT 1

Goertz Christine M., Cynthia R. Long, Robert D. Vining, Katherine A. Pohlman, Bridget Kane, Lance Corber, Joan Walter, and Ian Coulter. "Assessment of chiropractic treatment for active duty, U.S. military personnel with low back pain: study protocol for a randomized controlled trial." *Trials* 17, no.1 (February 2016): 70-81. https://doi.org/10.1186/s13063-016-1193-8.

Goertz Christine M., Cynthia R. Long, Robert D. Vining, Katherine A. Pohlman, Joan Walter, and Ian Coulter. "Effect of usual medical care plus chiropractic care vs usual medical care alone on pain and disability among U.S. Service members with low back pain: A comparative effectiveness clinical trial." *Journal of the American Medical Association Network Open* 1, no.1 (May 2018): e180105. https://doi.org/10.1001/jamanetworkopen.2018.0105.

ACT 2

DeVocht James W., Dean L. Smith, Cynthia R. Long, Lance Corber, Bridget Kane, Thomas M. Jones, and Christine M. Goertz. "The effect of chiropractic treatment on the reaction and response times of special operation forces military personnel: study protocol for a randomized controlled trial." *Trials* 17, no.1 (September 2016): 457-469. https://doi.org/10.1186/s13063-016-1580-1.

DeVocht James W., Robert Vining, Dean L. Smith, Cynthia Long, Thomas Jones, and Christine Goertz. "Effect of chiropractic manipulative therapy on reaction time in special operations forces military personnel: a randomized controlled trial." *Trials* 20, no.1 (January 2019): 5-12. https://doi.org/10.1186/s13063-018-3133-2.

ACT 3

Vining Robert, Amy Minkalis, Cynthia R. Long, Lance Corber, Crystal Frankin, M. Ram Gudavalli, Ting Xia, and Christine M. Goertz. "Assessment of chiropractic care on strength, balance, and endurance in active-duty U.S. military personnel with low back pain: a protocol for a randomized controlled trial." *Trials* 19, no.1 (December 2018): 671-684. https://doi.org/10.1186/s13063-018-3041-5.