



PERSONNEL AND
READINESS

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

JUL 12 2019

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

Dear Mr. Chairman:

The enclosed report is in response to House Report 115-769, page 298, to accompany H.R. 6157, the Department of Defense (DoD) Appropriations Bill, 2019, concerning opioid abuse and non-opiate pain management in the military. The House Report requests the Assistant Secretary of Defense for Health Affairs conduct a review of the Department's policies on pain management, and provide a report not later than 90 days after enactment.

The report focuses on a comprehensive approach to pain management, and opioid safety strategies that improve the quality of life and pain care for our DoD beneficiaries. Improved coordination and collaboration across the Military Health System has resulted in pain management policy, the standardization of best practices for clinical care, and research and training in alternative approaches to the treatment of 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,

A handwritten signature in black ink that reads "James N. Stewart". The signature is fluid and cursive, with a large loop at the end.

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 Richard J. Durbin
Vice Chairman



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

PERSONNEL AND
READINESS

The Honorable Peter J. Visclosky
Chairman
Subcommittee on Defense
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

JUL 12 2019

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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 Ken Calvert
Ranking Member



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

JUL 12 2019

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

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James N. Stewart

Assistant Secretary of Defense for Manpower
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of the Under Secretary of Defense for
Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Jack Reed
Ranking Member

Report to Congressional Defense Committees



Opioid Abuse and Non-Opiate Pain Management in the Military

**Requested by: House Report 115-769, page 298 to accompany H.R.
6157, the Department of Defense Appropriations Bill, 2019**

The estimated cost of this report or study for the Department of Defense (DoD) is approximately \$7,210 for the 2019 fiscal year. This includes \$1,500 in expenses and \$5,710 in DoD labor.

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EXECUTIVE SUMMARY

This report on a review of the Department of Defense's (DoD) policies on pain management was requested by House Report 115-769, page 298, to accompany H.R. 6157, the Department of Defense Appropriations Bill, 2019. Key elements include: current policies on prescribing opioid-based pain medication; the DoD's documentation of instances of opioid abuse in the military; current initiatives into alternative pain management treatment; and the status of the DoD's progress in implementing the recommendations made by the 2015 National Advisory Council on Complementary and Integrative Health Working Group Report.

INTRODUCTION

The Military Health System (MHS) has been addressing the national challenges of pain management and prescription medications since the establishment of the Pain Management Task Force in August 2009. The continued progress and improvement of the MHS pain strategy has been supported through the efforts of the MHS Pain Management Clinical Support Service (PMCSS), in collaboration with the Department of Veterans Affairs (VA) and DoD Health Executive Committee Pain Management Working Group. The PMCSS continues to standardize the adoption of key pain strategy initiatives through clinical improvements in pain care, clinician and patient education, and research. Cross-Department collaboration has been critical to many MHS accomplishments and advances in pain management.

MHS PAIN MANAGEMENT CAMPAIGN

The MHS Pain Management Campaign strategy focuses on continued implementation and standardization of best-practices for pain management and opioid safety. The key elements include: MHS Stepped Care Model, pain management and opioid safety education for patients and providers, and the use of more non-pharmacologic treatment options and therapies. Management of pain in the MHS aligns with drivers such as the October 2015 Presidential Memorandum, "Addressing Prescription Drug Abuse and Heroin Use," the 2016 National Pain Strategy, the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain, and the 2017 Presidential Memorandum, "Combatting the National Drug Demand and Opioid Crisis."

CURRENT POLICIES ON PRESCRIBING OPIOID-BASED PAIN MEDICATIONS

POLICIES

Defense Health Agency-Procedural Instruction (DHA-PI) 6025.04, "Pain Management and Opioid Safety in the Military Health System (MHS)"

DHA-PI 6025.04, "Pain Management and Opioid Safety in the Military Health System (MHS)," published June 8, 2018, is a dual effort between the MHS PMCSS and Clinical Communities to

implement the MHS Stepped Care Model and optimize opioid safety. The model, described in more detail on page 6, focuses on clinical practice guidelines (CPGs), effective treatment of acute and chronic pain, promotion of non-pharmacologic treatment, prevention of chronic pain, and minimizing the use of opioids with appropriate prescribing only when indicated. The DHA-PI also details requirements for standardized provider education, beneficiary education, informed consent for opioid therapy, and opioid prescription monitoring and safeguards across the MHS.

The MHS opioid prescribing guidelines for military medical treatment facility (MTF) providers are described in the DHA-PI and are consistent with VA/DoD CPGs, including: acquiring informed consent for patients who require opioids, prescribing less than a 5-day supply of short-acting opioids for acute pain episodes and minor procedures in opioid-naïve patients, prescribing less than a 10-day supply of short-acting opioids for major procedures in opioid-naïve patients, providing medication assisted therapy for those with opioid use disorders (OUDs), and providing naloxone (opioid reversal) for those at risk for opioid induced respiratory depression or upon beneficiary request for naloxone.

The DHA-PI addresses the identification, monitoring, and care for patients on long-term opioid therapy, patients at risk for OUD, and patients who are escalating doses of opioids and/or unable to taper opioid use. These patients require evaluation from the integrated pain team found in the secondary or tertiary levels of the MHS Stepped Care Model for Pain.

The DHA-PI also provides guidance for TRICARE® Health Plan to collaborate with managed care support contractors to minimize inappropriate opioid prescribing. The DHA-PI mandates solutions for the both MHS and non-MHS prescribers to be able to see controlled substance prescribing information for TRICARE beneficiaries through state prescription drug monitoring programs (PDMPs).

As an adjunct to the existing monitoring capabilities for providers at the MTF, the MHS PDMP has been developed and will permit bidirectional sharing of federal Schedule II-V controlled substance dispensing information between state healthcare providers and MTF providers. This ensures a patient's complete controlled substance medication history is available to a prescriber or pharmacist regardless of where or how the patient had the prescription filled. The method selected to achieve this was to become part of the National Association of Boards of Pharmacy's Prescription Monitoring Program (PMP) Interconnect® System as it is an established process already in use by the states. The MHS PDMP data is retroactive to December 20, 2018, and will be accessed in the same way as a provider would request prescription information from a state's PDMP.

DHA-PI 6025.07, “Naloxone Prescribing and Dispensing by Pharmacist in the Medical Treatment Facilities (MTFs)”

This DHA-PI provides guidance and procedures by which MTF pharmacists, at the point of reviewing opioid prescriptions, can identify, prescribe, and dispense Naloxone to eligible beneficiaries upon beneficiary request, or when the pharmacist determines the beneficiary meets the established criteria for being at risk for a life threatening opiate overdose. An MTF pharmacist assesses a beneficiary's risk of life threatening opiate overdose by using the standardized Patient Look Up Tool an automated tool on CarePoint as a component of the MHS

Opioid Registry. The MHS Opioid Registry is a collaborative, multi-disciplinary tool developed by the DHA and the subject matter experts, which will be explored below in greater detail.

The procedural guidance includes initial and sustainment training requirements for pharmacists to include continuing education. Education of beneficiaries is also a key component of DHA-PI 6025.07. Standardized Naloxone education products focus on safe use of opioid medications, overdose prevention, overdose recognition, administration of naloxone, calling Emergency Medical Services, and maintaining active relationships with prescribers.

MHS Opioid Registry

The MHS Opioid Registry supports providers, staff, and decision-makers in improving safety and quality of care of patients on opioid prescriptions. It was developed and tested in 2016 with a phased rollout in 2017. The registry offers MHS leaders and clinicians access to near-real time demographic, clinical, and pharmaceutical data related to opioids such as morphine equivalent daily dosages. High-risk opioids and other medications such as antidepressants, benzodiazepines, and sleep medications concurrently prescribed with opioids are flagged, alerting staff of potential fatal drug interactions.

In addition, the MHS Opioid Registry provides a comprehensive view of patient information to include mental health co-morbidities, current and past urine drug testing, healthcare utilization practices, and other patient-associated behaviors. This comprehensive patient profile enables providers to prioritize and stratify populations according to risk category. Clinicians can use the comprehensive registry to: monitor opioid activity across the entire continuum of care from as early as a patient's first dispensing event, detect potential harm or misuse of opioid medications in non-cancer patients via flagging and validated risk scores, evaluate effectiveness of opioid safety programs using opioid measures and reports, and share relevant data such as medication history and opioid risk profiles for those patients transitioning from the DoD to the VA.

Opioid prescribing practices are also monitored and shared through the Opioid Registry. The Controlled Substance Provider Profile quarterly report allows leaders to monitor opioid prescribing practices and identify variance requiring interventions at the provider level. The MHS also developed a pilot to track purchased care provider prescribing practices with the goal of identifying and addressing providers who are over-prescribing opiates.

PMP

The PMP identifies TRICARE beneficiaries who exhibit possible unsafe behavior with regard to controlled medications and implements restrictions to prevent or decrease the risk of substance abuse. Beneficiaries can be enrolled in the program via MTFs or Express Scripts in conjunction with the TRICARE Managed Care Support Contractor. An analysis was conducted on the number of TRICARE beneficiaries categorized by the DHA PMP as having demonstrated a high use of controlled substances. The fiscal year (FY) 2017 data showed a total of 3,184 beneficiaries enrolled in the program, with 24 percent Active Duty, 20 percent Active Duty dependent, 26 percent retiree, and 30 percent retiree dependent.

MHS Drug Take Back Program

The DoD became the first federal agency to establish an agency-wide Drug Take Back Program that allows beneficiaries to easily and safely dispose of unused opioids. As of September 2018, more than 254,000 pounds of drugs were collected.

DOCUMENTATION OF INSTANCES OF OPIOID ABUSE IN THE MILITARY

The prevalence of opioid abuse and dependence in Service members is low at less than 1 percent. Among Active Duty, the prevalence of those diagnosed with OUD has decreased — from just over 3,000 in 2013 to just over 1,000 in 2017 — about 0.07 percent of the Active Duty population. This rate is significantly lower than the U.S. adult population where 8-12 percent develop an OUD from a prescription (Substance Abuse and Mental Health Service Administration, FY 2017 data). The Active Duty Service member overdose death rate from opioids is 2.7/100K (Armed Forces Medical Examiner System, March 2017). The comparable civilian rate is 10.4/100K (CDC, Dec 2016). Even after controlling for demographic differences, the DoD's rate is less than half the civilian rate. The DoD's opioid safety strategy acknowledges quality pain management is critical in addressing the national opioid epidemic.

To combat opioid overuse, misuse, and diversion, the DoD is addressing the problem at all touch points through implementation of improved pain management strategies to efforts to improve DoD prescriber and beneficiary education, prescription monitoring and safeguards, and treatment and emergency response systems. The Military Services have Service-specific policies for tracking opioid abuse. For example, Army requires a profile generated on Service members prescribed opioids and opioid profile templates are found in e-Profile. Any documentation triggering a concern for symptoms of abuse are referred to Behavioral Health for assessment of OUD.

CURRENT INITIATIVES INTO ALTERNATIVE PAIN MANAGEMENT TREATMENT

The MHS Stepped Care Mode for Pain

The MHS Stepped Care Model for Pain is a standardized, interdisciplinary approach to delivering pain care. “Stepped care” starts in the Patient-Centered Medical Home (PCMH) or primary care, moving patients forward on the continuum of care only as clinically required. Early identification and intervention occurs in the PCMHs with a team to include a full-time internal behavioral health consultant (IBHC) embedded in the primary care clinics. The IBHC is a psychologist, social worker, or psychiatric nurse practitioner specially trained to work as a member of the PCMH team. This team approach allows the PCMH team and patients to consider physical, behavioral, and emotional aspects of health. These consultants support patients and their primary care managers with pain management and opioid medication use; specifically they provide patients with non-pharmacological approaches to pain control and symptom management to limit opioid prescriptions. Within the primary and secondary care

levels, the model leverages primary care pain champions as well as IBHCs and clinical pharmacists to assist providers in managing acute and chronic pain while minimizing the use of opioids. At the tertiary level of care, interdisciplinary pain management centers (comprised of interventional, rehabilitative and complementary/integrative health therapies) deliver holistic, multimodal pain care. Patients and providers are educated on interdisciplinary care enabling the team to address pain with non-pharmacologic therapies, such as physical therapy, acupuncture, movement therapy, biofeedback, and manual manipulation.

Although the DHA has limited ability to cover certain non-conventional treatments in complementary integrative medicine (CIM) therapies outside MTFs, the organization acknowledges the role of CIM in pain management. The conventional CIM therapies include stress management, physical and occupational therapies, and pharmacological management by clinical pharmacists. Additional CIM therapies such as acupuncture, chiropractic care, and therapeutic massage are available in the MHS but are limited to Active Duty Service members due to capacity limitations. A 2017 RAND study surveyed MTFs and found 83 percent offer CIM therapies of some type with over 66 percent of those offering acupuncture and over 50 percent offering progressive muscle relaxation, guided imagery, chiropractic care, and mindfulness. An estimated 76,000 CIM encounters per month occur across the MHS in MTFs. Acupuncture treatment is available to non-active duty beneficiaries on a space available basis only at some MTFs. Currently, the additional CIM therapies are not part of the TRICARE-covered medical benefits; however, acupuncture and chiropractic care are currently being reviewed by the DHA for possible inclusion in the benefit.

Defense and Veterans Pain Rating Scale (DVPRS)

As part of the MHS Pain Management Campaign, the MHS adopted the DVPRS as the designated pain scale for assessment of pain in the MHS adult population. DVPRS is an innovative and validated pain scale developed by the DoD, in collaboration with the VA, building on the familiar 0-10 Numeric Pain Rating Scale (NRS). DVPRS was developed to improve on the utility and clarity of the NRS by incorporating visual cues and functional word descriptors, providing patients with a more objective method of selecting a number representing their pain level. Additionally, DVPRS integrates an assessment of pain interference with physical function, sleep, activity, mood, and stress. Efforts continue to integrate DVPRS in the legacy and emerging electronic health records.

Pain Assessment Screening Tool and Outcomes Registry (PASTOR)

PASTOR utilizes evidence-based patient reported outcomes to assess effectiveness of pain management interventions at both the individual and population health levels. PASTOR leverages the National Institutes of Health's (NIH) Patient-Reported Outcomes Measurement Information System (PROMIS®) initiative, an evidence-based series of validated item banks that utilize computer adaptive technology to improve efficiency for measuring and interpreting patient-reported outcomes while decreasing testing burden. PROMIS measures have greater precision than most conventional measures, utilizing patient-reported measures of global, physical, mental, and social health for adults and children in the U.S. general population and those living with a chronic conditions.

The DHA is conducting a phased rollout of PASTOR to the MTFs. In line with the directives in DHA-PI 6025.04, priorities for initial PASTOR rollout sites are targeting MTFs with tertiary pain management specialty clinics. As of December 2018, over 1,200 patients have been registered in PASTOR at the following eight MTFs: Brooke Army Medical Center, Joint Base Elmendorf-Richardson, Landstuhl Army Medical Center, Madigan Army Medical Center, Naval Hospital Pensacola, Walter Reed National Military Medical Center (WRNMMC), Naval Hospital San Diego, and Womack Army Medical Center.

IMPLEMENTATION UPDATE ON THE RECOMMENDATIONS MADE BY THE 2015 NATIONAL ADVISORY COUNCIL ON COMPLEMENTARY AND INTEGRATIVE HEALTH WORKING GROUP REPORT

Make improvements in existing programs if a need is identified and find ways to leverage and optimize

The MHS continues to expand the reach of pain specialists beyond their clinics and expand capacity for pain management services in primary care via telehealth modalities such as the MHS Extension for Community Healthcare Outcomes (Project ECHO®). Project ECHO® is a tele-mentoring model using secure, audio-visual networks to connect pain medicine specialists (hubs) with remote primary care providers (spokes) to increase providers' pain management competencies. Currently, the MHS has seven hubs and nearly 80 spokes participating in Project ECHO®.

Project ECHO® is an evidence-based model that provides high quality medical education for common and complex diseases through tele-mentoring and co-management of patients with primary care clinicians. In a “one-to-many” tele-mentoring knowledge network, the Project ECHO® model helps to bridge the gap between primary care clinicians and specialists by enhancing the knowledge, skills, confidence, and practice of primary care clinicians in their local communities. A 2018 analysis of Army and Navy Project ECHO® pain clinics' effect on opioid prescribing habits indicates clinicians participating in ECHO® had a 23 percent reduction in opioid prescriptions versus a 9 percent reduction among clinicians in clinics without Project ECHO®. The Project ECHO® group also has a 28 percent decline in the average morphine milligram equivalents prescribed per patient compared to 7 percent in the non-Project ECHO® group¹.

Continue to support a variety of clinical-scientist career paths through training – Graduate Medical Education

The DoD continues to support four Accreditation Council for Graduate Medical Education accredited Pain Medicine Fellowships — WRNMMC, San Antonio Military Medical Center, Naval Hospital Pensacola, and National Medical Center San Diego. These programs collaborate

¹ Katzman, J. G., Qualls, C. R., Satterfield, W. A., Martin, K., Greenberg, N., Swift, R., Comerci, G. G., Fowler, R., and Arora, S. (2018). Army and Navy ECHO Pain Telementoring Improves Clinician Opioid Prescribing for Military Patient: An Observational Cohort Study. *Journal of General Internal Medicine*, 34 (3), 387-395.

with monthly web-based journal clubs and grand rounds, which are attended by MHS and VA pain specialists. These fellowships provide sub-specialty board certification to specialists in physical medicine and rehabilitation, anesthesiology, and neurology who, upon graduation, are assigned throughout the MHS to lead tri-Service specialty pain clinics.

Additionally, the first pain fellowship-trained family medicine physician graduated in 2018, with another selected to start training for 2018-2019 training year. This opportunity paves the way for effective utilization of pain management at the primary level of the MHS Stepped Care Model for Pain within the PCMH.

The DoD Physical Medicine and Rehabilitation community, in collaboration with the Primary Care Sports Medicine Fellowship at the Uniformed Services University of the Health Sciences (USUHS), continues to host annual tri-Service training within the National Capital Region on using ultrasound and injection techniques for treating conditions such as musculoskeletal pain and post-traumatic headaches. Specialists in physical medicine and rehabilitation, primary care sports medicine, anesthesia, and primary care are also engaged in ongoing education and certification in alternative treatments to pain, including acupuncture, and contributing to local, national, and international pain education conferences and workshops.

In the summer of 2017, a total of 20 physicians completed a 300-hour certification course in medical acupuncture while in the summer of 2018, 80 physicians completed the course and graduated. Approximately 40 percent of family medicine residents who completed the course became certified medical acupuncturists. In addition, Quarterly Battlefield Acupuncture (BFA) training has been incorporated into the course curricula, ensuring 100 percent of the residents graduate with this important skill, which can be used at their next duty station and while deployed.

Develop programs to support the host environment at all types of institutions involved in research training

DoD entities engaged in pain management research include the U.S. Army Medical Research and Materiel Command's (USAMRMC) Clinical and Rehabilitative Medicine Research Program (CRM RP) and Institute for Surgical Research, USUHS, Defense and Veterans Center for Integrative Pain Management (DVCIPM), WRNMMC, Naval Hospital San Diego and Naval Hospital Portsmouth. The CRM RP portfolio spans basic research through clinical development projects that address pain management from the point of injury to chronic pain management. CRM RP provides products and information solutions for the diagnosis and alleviation of battlefield, acute, and chronic pain, as well as related sequelae.

DVCIPM's current research priorities include developing a pain registry biobank, improving the predictive modeling for pain management decision-making, promoting expanded use of CIM treatments for pain, developing novel analgesic use of interventional pain procedures, and promoting evidence-based provider training that is synchronized with patient pain management education.

- DVCIPM is conducting a multi-site study to examine implementation of the DoD/VA Joint Pain Education Program (JPEP) (completion July 2020). The study focuses on

identifying education delivery methods, their acceptability, and the impact of training on several clinical outcomes (e.g., safe opioid prescribing patterns). As an adjunct to this research, DVCIPM is supporting a set of quality improvement projects that utilize the patient-focused JPEP videos to enhance understanding of pain, reduce pain and pain impact, and facilitate discussions regarding opioid-therapy informed consent.

- In collaboration with the DHA, DVCIPM is conducting a health services research study that is aimed at assessing selected U.S. counties that have high-density populations of TRICARE beneficiaries who may be at greater risk of increased opioid use, related to CDC data demonstrating high rates of opioid prescribing. This project will explore relationships between local prescribing rates (county-level), TRICARE prescribing rates, healthcare delivery type (purchased vs. direct), and beneficiary type (Active Duty versus non-Active Duty). These results can be used to directly tailor prevention and intervention strategies in targeted areas.
- Several completed retrospective studies have examined the optimization of the perioperative analgesia pathway. Results have demonstrated the value of multimodal approaches in reducing hospital length of stay, post-anesthesia care unit duration, pain and opioid use, as well as improving functional outcomes.

DVCIPM and USUHS have established a Cooperative Research and Development Agreement (CRADA) with West Virginia University (WVU). The state of West Virginia is at the epicenter of the national epidemic of opioid overuse, abuse, diversion, and overdoses. The collaboration between USUHS/DVCIPM and WVU provides the opportunity to leverage appropriate tools and strategies developed in the DoD for use in West Virginia's pain management and opioids safety strategies. This collaboration has already resulted in the following:

- WVU has integrated DVPRS into its health system and is adapting DoD PASTOR as its pain outcomes tool.
- WVU utilized the DoD model for interdisciplinary pain centers to accelerate the opening of its first interdisciplinary pain center.
- WVU is utilizing JPEP education materials to train its medical providers on fundamentals of quality pain management.
- Following an introduction to DoD BFA, WVU is developing a self-sustaining process for training, credentialing, and promoting BFA.

DVCIPM will leverage the CRADA with WVU to continue validating DoD tools and products through ongoing implementation and effectiveness research. Additional CRADAs have been established with the University of New Mexico, Virginia Tech/Carillion Health, and an agreement is pending with the University of Washington.

In addition, the National Capital Region is a member of the NIH Pain Management Collaboratory Coordinating Center – MTF Engagement Committee.

Raise the visibility of complementary and integrative health in the research and clinical community at large.

One randomized control trial conducted in a military medical center² tested the effects of an individualized eight-week yoga treatment compared to standard of care in 68 patients with chronic lower back pain. Those receiving yoga reported significantly greater decreases in back pain-related disability, which was maintained at the six-month follow-up. A higher proportion of yoga group participants reported clinically-meaningful reductions in symptom burden (e.g., fatigue, anxiety, depression, sleep disturbances, pain interference) at the six-month follow-up than those receiving standard of care.

The DoD is investigating safer, more effective alternatives for pain management in theatre. Combat medics' current morphine sulfate auto-injector is the primary treatment option for pain management on the battlefield and in other austere environments. Morphine cannot completely reduce pain, and it poses significant risks to the wounded Service member, including respiratory depression, hypotension, nausea, vomiting, and potential psychological and physical dependence with continued use.

Sufentanil Nanotab (Dsuvia) is a rapid acting product designed to relieve acute pain with minimal side effects and is currently under study by CRMRP. The CRMRP objectives for FY 2017 through FY 2021 include the following:

- Successful completion of Phase III Clinical Trial for Sufentanil Nanotab (Dsuvia) in FY 2017.
- Start Phase III clinical trial for NerveSpace therapy, a novel non-narcotic pain relief therapy to improve functional outcomes of combat-injured warfighters by relieving post-amputation pain.
- Investigate precision medicine and personalized pain management treatment strategies.
- Investigate treatment approaches for chronic pain in complex patients.
- Validate non-pharmacological approaches to pain management.

The DoD successfully completed a Phase III clinical trial using Sufentanil Nanotab (Dsuvia) with patients following bunionectomy surgery. There was a statistically significant ($p=0.003$) difference in pain for 30g sufentanil-treated patients and for placebo-treated patients. Sufentanil Nanotab (Dsuvia) was approved by the Food and Drug Administration in November 2018. AcclRx is targeting a release date of quarter one of FY 2019 for commercial product (estimated February 2019). AcclRx estimates that the first lot of product with DoD-specific markings (e.g. National Stock Number) will be available in Q3 of FY 2019 (estimated June 2019). AcclRx must complete administrative requirements to enter the Federal market and establish an

² Highland, K.B., et al. (2018). Benefits of the Restorative Exercise and Strength Training for Operational Resilience and Excellence Yoga Program for Chronic Low Back Pain in Service Members: A Pilot Randomized Controlled Trial. *Archives of Physical Medicine and Rehabilitation*, 99(1), 91-98.

agreement with one of our distributors. The intent is to field Dsuvia first to the special operations units for use in the combat / deployed environments.

The DoD is also conducting a randomized controlled trial of a novel integrative approach to pain management: combining conventional opioid treatment with Mindfulness-Oriented Recovery Enhancement, a training program designed to target the bio-behavioral mechanisms of the feedback loop among pain, psychological distress, and opioid misuse.

There are two ongoing randomized clinical trials measuring the impact of complementary and integrative therapies. The Integrative Modalities plus Psychological, Physical, Occupational Restorative Therapies (IMPPORT) trial is a four-year trial designed to determine if complementary and integrative therapies (e.g., chiropractic, acupuncture, yoga) enhance outcomes when added to standard rehabilitative therapies (e.g., physical therapy, occupational therapy, health psychology). Target enrollment of 210 participants was achieved in May 2018, and the clinical phase of the study was completed in September 2018. Collection of 6-month follow-up measures will be complete in March 2019, and data analysis will be complete during 2019.

The Determinants of Optimal Dose and Sequence of Functional Restoration and Integrative Therapies (DODFIT) study is a four-year trial that will evaluate optimal duration and sequence of standard rehabilitative therapies. The first participant was enrolled in June 2018 and recruitment is on-going. The IMPPORT and DODFIT studies were funded by programs coordinated by the USAMRMC and done in collaboration with the University of Washington.

SUMMARY

The MHS continues to focus on a comprehensive approach to pain management and opioid safety strategies that improve the quality of life and pain care of DoD beneficiaries. Improved coordination and collaboration across the MHS has resulted in pain management policy, the standardization of best-practices for clinical care, and research and training in alternative approaches to the treatment of pain. The implementation of the aforementioned priorities not only addresses the important goal of serving MHS beneficiaries, but also provides an example of the high standard of care for the nation. The MHS will continue to address the national challenges of pain management and prescription medications through support from efforts of the MHS PMCSS. The commitment of the MHS to cross-Department collaboration will also be critical to future advances and accomplishments in pain management.



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JUL 12 2019

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

Dear Mr. Chairman:

The enclosed report is in response to House Report 115-769, page 298, to accompany H.R. 6157, the Department of Defense (DoD) Appropriations Bill, 2019, concerning opioid abuse and non-opiate pain management in the military. The House Report requests the Assistant Secretary of Defense for Health Affairs conduct a review of the Department's policies on pain management, and provide a report not later than 90 days after enactment.

The report focuses on a comprehensive approach to pain management, and opioid safety strategies that improve the quality of life and pain care for our DoD beneficiaries. Improved coordination and collaboration across the Military Health System has resulted in pain management policy, the standardization of best practices for clinical care, and research and training in alternative approaches to the treatment of 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,

A handwritten signature in black ink that reads "James N. Stewart". The signature is fluid and cursive, with a long horizontal stroke at the end.

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