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

PERSONNEL AND
READINESS

22 DEC 2017

The Honorable William M. "Mac" Thornberry
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

This interim report is in response to section 746 of the National Defense Authorization Act for Fiscal Year 2017 (Public Law 114–328), which requires the Secretary of Defense to provide a briefing of the study on the feasibility and effectiveness in preventing the diversion of opioid medications by dispensing opioid medications in vials with a locking mechanism and by providing education on the risks of opioid medications.

The Department has completed the first two of three phases of this study. Phase 1 involved a review of the literature and a public request for information, to include vendors that produce medication vials with locking caps. Phase 2 involved the use of two opioid safety workshops to obtain feedback from beneficiaries about the likelihood of their behavior change following education on opioid risks and mitigations strategies. Phase 3 involves a pilot study from November 2017 through December 2017, to determine the feasibility and effectiveness of providing education and using medication vials with locking caps to prevent opioid diversion.

Enclosed is an information paper that provides greater detail on the three phases of this study. The final brief will be submitted in March 2018.

Thank you for your interest in the health and well-being of our Service members and their families. A similar letter is being sent to the Chairman of the Committee on Armed Services of the Senate.

Sincerely,

Robert L. Wilkie

Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member

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

PERSONNEL AND
READINESS

22 DEC 2017

The Honorable John McCain
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

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Sincerely,

Robert L. Wilkie

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Enclosure:
As stated

cc:
The Honorable Jack Reed
Ranking Member

SECTION 746 OF THE NATIONAL DEFENSE AUTHORIZATION ACT FOR FISCAL YEAR 2017

ISSUE:
Section 746 of the National Defense Authorization Act for Fiscal Year 2017 (Public Law 114–328) requires the Secretary of Defense to conduct a study on the feasibility and effectiveness in preventing the diversion of opioid medications on the following measures: (1) requiring that, in appropriate cases, opioid medications be dispensed in vials using affordable technologies designed to prevent access to the medications by anyone other than the intended patient, such as a vial with a locking cap mechanism; and, (2) providing education on the risks of opioid medications to individuals for whom such medications are prescribed, and to their families, with special consideration given to raising awareness among adolescents on such risks.

BACKGROUND:
The following efforts are being developed by the Department of Defense (DoD) to achieve the requirements of section 746 as described above:

- **Phase One:** Literature review and public request for information (RFI)
- **Phase Two:** Opioid safety workshops
- **Phase Three:** Pilot study on use of vials with a locking cap mechanism

DISCUSSION:
Phase 1: The DoD conducted a literature review on existing scientific evidence to support the effectiveness of preventing opioid diversion with the use of technology and education:

- Results of the review revealed minimal evidence for providing education and no evidence that the use of technology significantly prevents the diversion of opioid medication.
- A public RFI resulted in several responses from manufacturers which lacked scientific evidence that their devices are effective at preventing diversion.

Phase 2: Two opioid safety workshops were conducted (Ft. Bragg, North Carolina, on August 16, 2017, and Ft. Leonard Wood, Missouri, on August 17, 2017) with approximately 100 DoD Service members, their families, and health care providers who provided survey feedback regarding their perceptions of likely behavior change following education on pain management and opioid safety. Preliminary results indicate:

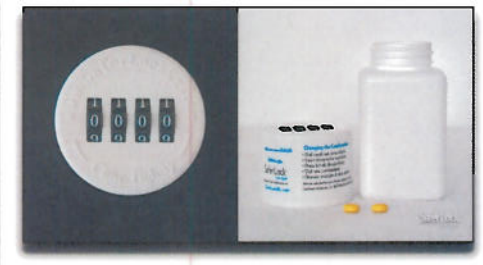
- The majority (75 percent) of attendees never or rarely store opioids in a locked container; only 25 percent of the sample indicated that they dispose of unused prescription pain medication.
- Most attendees stated education would change their behaviors (78 percent) and decisions (82 percent) regarding pain management and safe opioid storage.
- The majority of attendees (65 percent) reported very low to average likelihood of using a medication vial with a combination locking cap after watching the pain education videos.
- Formal results, with conclusions and recommendations, will be included in the final brief.

Phase 3: The DoD will conduct a pilot study in the Primary Care Medical Home (PCMH) setting to obtain feedback on likely behaviors related to education and use of a locking cap vial.

- The pilot study will be conducted from November to December 2017 at Ft. Drum, New York (Army), Cherry Point, North Carolina (Navy), and MacDill AFB, Florida (Air

Force).

- The DoD anticipates 783 opioid prescriptions will be written in the primary care clinics at the three study sites during the study period, with an estimated 78 to 192 patients opting to use the locking caps.
- The DoD will receive feedback from beneficiaries in the PCMH setting on likely behaviors related to:
  - (1) Pain management, opioid safety and diversion education; and,
  - (2) Optional use of locking cap vial.
- Pilot Study Process Flow overview:
  - 1. Identification of the Patient: Patients will include DoD Service members within the PCMH setting who are receiving opioid medications, which includes all acute, chronic, new, and renewed opioid prescriptions. Patients will be identified by Primary Care Team providers during patient appointments.
  - 2. Providing Education: All patients receiving opioid prescriptions in the PCMH setting will be provided standardized, scripted material by a qualified provider focusing on the safe use, associated risks, safeguarding, and proper disposal of opioid medication. Patients will be provided take-home written material for use.
  - 3. Feedback on Education: PCMH providers will ask patients to provide immediate feedback on their perception of likely behavior change following the education.
  - 4. Locking Cap Option: Following the education portion of the pilot, all patients will be offered the option to voluntarily participate in the use of a provided locking cap to safeguard their opioid medications. Patients who decide to participate in the locking cap portion of the study will be educated on use of the locking cap by a qualified PCMH provider.
  - 5. Feedback on Locking Cap: Patients will be asked to complete an online survey 1–2 weeks after obtaining the locking cap in order to provide feedback on the use of the locking cap, any difficulties that were encountered, and their perception of the effectiveness of locking cap in preventing diversion.
- A typical medication vial with locking cap is shown below. The combination lock allows patients to store their medications securely. A reset pin and instructions on the use of the combination lock are pasted on the locking cap.



(https://saferlockrx.com/product/safer-lock/)

Way Ahead: The detailed results of each phase, to include conclusions and recommendations, will be included in the final briefing to the Committees in March 2018.