

Congress of the United States

Washington, DC 20515

June 18, 2008

The Honorable James B. Peake
Secretary
U.S. Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, D.C. 20420

Dear Secretary Peake:

According to an ABC News-Washington Times report on June 17, 2008, the Department of Veterans Affairs (VA) conducted a smoking cessation drug study on veterans with Post Traumatic Stress Disorder (PTSD) that may have exposed these veterans to possible harmful side effects that could exacerbate their mental health conditions and possibly lead to suicidal thoughts. ("VA Testing Drugs on War Veterans; Experiments Raise Ethical Questions" A1). This report raises serious questions about how the VA and Food and Drug Administration (FDA) coordinate their studies, and how the VA responds to FDA post-approval alerts, particularly when vulnerable segments of the veteran population are involved in the studies. Although the VA reportedly screened participants for extreme PTSD tendencies before the study began, veterans were exposed to a drug that could, in some instances, prompt, exacerbate or cause a recurrence of PTSD symptoms.

Accordingly, I am concerned about the significant issues raised in this report and request that the Department provide responses to the questions that follow:

1. Please provide copies of the consent and notification forms that the VA utilized for the smoking cessation clinical trial.
2. According to the Washington Times article, on May 21, 2008, the Federal Aviation Administration (FAA) banned airline pilots and air traffic control personnel from taking Chantix, the anti-smoking drug, due to concerns about its adverse side effects. Prior to the publication of the Washington Times article, was the VA aware of the FAA ban? If not, why not? If the VA was aware of the FAA ban, when did it become aware of it?
3. Does the VA terminate studies involving drugs that are the subject of FDA advisory notices? If not, why not? Does the VA terminate studies involving drugs that are the subject of formal FDA alerts? If not, why not? What is the protocol for notifying study participants of the release of both of these types of FDA notices?
4. According to the Washington Times report, the VA took almost three months to alert participants in the Chantix trial of the possible severe mental side effects. The Washington Times article quotes the director of the VA's PTSD program, who justified the three month delay by saying "we respond to that urgency [to notify participants] doing just what we did

here, which was, I think, incredibly quick response for a governmental institution.” Do you agree that a three-month delay in notification of such serious side effects qualifies as an “incredibly quick response” for the VA? If not, what is the VA doing to ensure that such notifications occur more quickly in the future?

5. The report also included the VA’s assertion that the need to involve Institutional Review Boards (IRB) at each site delayed the notification of study participants. On what date did the VA learn of the possible mental health side effects of Chantix? On what date(s) did the VA inform the IRBs at each site?
6. While the VA refers study participants who demonstrate possible side effects to mental health professionals, are there on-site professionals to address the immediate mental healthcare needs of program participants?
7. Why did the VA fail to mention “suicidal thoughts” as a possible side effect in its notification to study participants on February 29, 2008, when the FDA explicitly listed “suicidal ideation” in its official alert on February 1, 2008? Has the VA subsequently informed those involved in the study about this side effect? If so, when? If not, why not?
8. The original notification agreement states that some veterans may have been charged co-payments for smoking cessation treatment. Given that some veterans may have been exposed to negative side effects, were there any instances when a veteran who experienced negative side effects also was charged a co-pay?
9. The Washington Times report notes that the Pfizer clinical trials for Chantix did not include individuals with “serious psychiatric illnesses.” Did the VA consider this exclusion when choosing to study the drug’s effect on a population group that may exhibit some signs of serious psychiatric problems? If not, why not?
10. A prominent medical ethicist said in the above referenced report that the VA's behavior in the anti-smoking study violated basic protections for humans in medical experiments: "When you're taking advantage of a very vulnerable population, people who have served the country, and the agency that's responsible for their welfare isn't putting their welfare first, that's a pretty serious breach of ethics." Do you agree with this assessment? If yes, what will the VA do in the future to ensure that medical ethics are followed in the conduct of clinical trials? If not, why not?

Thank you for your attention to this important issue. Please provide a response within 15 business days or no later than July 8, 2008. If you have questions regarding

this request, please have a member of your staff contact Roberto Peña (Markey) at (202) 225-2836, Cathy Wiblemo (Filner) at (202) 225-9154 or Sarah Levin (Hodes) at (202) 225-5206.

Sincerely,


Edward J. Markey
Member of Congress


Bob Filner
Chairman of the House Committee on Veteran Affairs


Paul Hodes
Member of Congress