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June 19, 2008

CARDIN URGES VA TO HALT CLINICAL TRIALS ON VETERANS USING DRUGS QUESTIONED BY FDA

Chantix studies amplifying nightmares in PTSD Veterans

WASHINGTON, DC – **U.S. Senator Benjamin L. Cardin** (D-MD) Wednesday issued a letter to Veterans' Affairs Secretary James Peake urging him to immediately suspend clinical trials with veterans suffering from post-traumatic stress disorder (PTSD) using the drug Chantix, which has been under FDA warnings since November 2007. The drug, also known as Varenicline, has been shown to cause psychotic and suicidal episodes. In addition, the Veterans' Administration (VA) waited a full month after the FDA issued a Public Health Alert on Chantix to notify participating veterans of the possible side-effects.

“We have an obligation to protect and support our brave veterans, not exacerbate their illnesses,” said **Senator Cardin**. “I understand that clinical trials can lead to life-saving medical advances, but if the FDA issues warnings about the use of a drug, as they did with Chantix, the Veterans' Administration should immediately cease any activity that might risk the health and mental welfare of our veterans.”

Senator Cardin's letter to Secretary Peake is below:

June 18, 2008

The Honorable James Peake
Secretary of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

Dear Mr. Secretary:

This week, several news outlets reported the story of Maryland resident James Elliott, a PTSD-diagnosed Iraq war veteran whose participation in a VA clinical trial for the drug Varenicline, or Chantix, is cited as the cause of psychotic, suicidal episodes. For the health and safety of our veterans, I urge you to immediately suspend the Chantix trial and to conduct a thorough investigation of this and any other VA-sponsored trials involving drugs for which FDA alerts may have been issued.

According to news reports, Mr. Elliott was diagnosed with Post Traumatic Stress Disorder after serving in Iraq from 2003 until 2004. Enrolled in a clinical trial for the drug Chantix, after taking the drug, Mr. Elliott began to experience “recurring nightmares of exploding bombs...a child’s head blown off its body and other war horrors from his Iraq tour.” Several months into the study, on February 5, 2008, Mr. Elliott exhibited strange behavior and left home armed with a gun, prompting his fiancée to alert the police. Police responded and, following a confrontation, used a Taser to stun him, and placed him under arrest.

Reports indicate that your agency has continued the Chantix studies even after the FDA’s November 20, 2007 recommendation that “health care providers monitor patients taking Chantix for behavior and mood changes,” and that the VA failed to notify the veterans in the study of the possible side effects, including “anxiety, nervousness, tension, depression, thoughts of suicide, and attempted and completed suicide” until February 29, 2008, a full month after the FDA’s February 1 Public Health Alert.

Your department’s statement released on Tuesday afternoon raises additional concerns. According to the press release, the trial in which Mr. Elliott participated was designed to determine the effectiveness of Chantix when used in combination with PTSD therapy. VA researchers, who were, according to your release, “closely monitor(ing) clinically” the participants, should have been particularly sensitive to the FDA’s warnings, given that PTSD-diagnosed veterans are known to be at risk for depression and destructive behavior. Additionally, your statement that “neither the FDA nor the manufacturer has ever recalled Varenicline and VA has never been asked to do so,” does not justify continuing the drug’s use in a study of PTSD-diagnosed veterans.

Please provide a response to this letter by Friday, June 27, 2008.