

VA testing drugs on war veterans

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By Audrey Hudson - The Washington Times

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UPDATE: Obama's office sent a letter Tuesday to James Peake, secretary of the Department of Veterans Affairs, on the issue. You can read the full text of the letter here.

UPDATE II: Sen. John Cornyn, Texas Republican, issued his own letter to Peake as well. You can read it here.

The government is testing drugs with severe side effects like psychosis and suicidal behavior on hundreds of military veterans, using small cash payments to attract patients into medical experiments that often target distressed soldiers returning from Iraq and Afghanistan, a Washington Times/ABC News investigation has found.

In one such experiment involving the controversial anti-smoking drug Chantix, the Department of Veterans Affairs (VA) took three months to alert its patients about severe mental side effects. The warning did not arrive until after one of the veterans taking the drug had suffered a psychotic episode that ended in a near lethal confrontation with police.

James Elliott, a decorated Army sharpshooter who suffers from post-traumatic stress disorder (PTSD) after serving 15 months in Iraq, was confused and psychotic when he was Tasered by police in February as he reached for a concealed handgun when officers responded to a 911 call at his Maryland home.

For photos, video of James Elliott, official FDA documents and more, visit the interactive site for the Disposable Heroes report.

Mr. Elliott, a chain smoker, began taking Chantix last fall as part of a VA experiment that specifically targeted veterans with PTSD, opting to collect \$30 a month for enrolling in the clinical trial because he needed cash as he returned to school. He soon began suffering hallucinations and suicidal thoughts, unaware that the new drug he was taking could have caused them.

Just two weeks after Mr. Elliott began taking Chantix in November, the VA learned from the Food and Drug Administration (FDA) that the drug was linked to a large number of hallucinations, suicide attempts and psychotic behavior. But the VA did not alert Mr. Elliott before his own episode in February.

In failing to do so, Mr. Elliott said, the VA treated him like a "disposable hero."

"You're a lab rat for \$30 a month," Mr. Elliott said.

One of the nation's premier medical ethicists said 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," said Arthur Caplan, director of the Center for Bioethics at the University of Pennsylvania.

In all, nearly 1,000 veterans with PTSD were enrolled in the study to test different methods of ending smoking, with 143 using Chantix. Twenty-one veterans reported adverse effects from the drug,

including one who suffered suicidal thoughts, the three-month investigation by The Times and ABC News found. [You are currently viewing the printable version of this article, to return to the normal page, please click here.](#)

Mr. Caplan, who reviewed the consent and notification forms for the study at the request of The Times and ABC News, said the VA deserved an "F" and that it has an obligation to end the study, given the vulnerability of veterans with PTSD and the known side effects of Chantix. "Continuing it doesn't make any ethical sense," he said.

The VA continues to test Chantix on veterans, even as reported problems with the drug increase and have prompted at least one other federal agency to take action. On May 21, the Federal Aviation Administration banned airline pilots and air traffic control personnel from taking Chantix, citing the adverse side effects.

The VA responds

VA officials defend their use of veterans in medical studies, saying that helping PTSD sufferers to stop smoking would prolong their lives. As for the three-month delay in notifying its patients about the Chantix problems, the VA said bureaucracy slowed down their warning because the alert letters had to be issued through an Institutional Review Board (IRB) that oversees the experiment at each VA location.

"We don't have the authority to just send directly to patients material that has not been approved by the IRB sites," said Miles McFall, director of the VA's programs for PTSD sufferers. "We did sense urgency. And we respond to that urgency doing just what we did here, which was, I think, incredibly quick response for a governmental institution.

"We believe that we took responsible action by informing the clinicians who are the people most in touch with the patients to be on the lookout for any potential side effects and to respond appropriately," he said.

While Mr. Elliott blames Chantix for his mental breakdown and confrontation with police, VA officials said they cannot be sure.

"We don't know that Chantix was the cause of this, first of all. And it's presumed that that's the case. We don't know that to be a fact," Mr. McFall said.

Mr. McFall said the veterans with PTSD in the anti-smoking study "are at high risk to use tobacco" and the goal of the experiment is to determine how best to deliver treatment - through a mental health counselor or a smoking clinic. Chantix was one of several options tested on the veterans.

"FDA approved, and that drug is available to help individuals stop smoking and VA makes that drug available," Mr. McFall said. "It does not deny access to them."

Asked about adverse reactions now linked to the drug, Mr. McFall said: "We are certainly aware of FDA warnings and we took all precautions ... so it can be used safely. All drugs have side effects or potential side effects."

Dark history of medical tests

The government has a controversial history of using military personnel as human research subjects.

Mustard gas was tested on the military during World War II, radiation during the early Cold War period, LSD in the 1960s, herbicide in Vietnam and Panama, and chemical and biological warfare drugs during the Gulf War, according to Senate testimony given by the Vietnam Veterans of America (VVA) on July 10, 2002.

In most of those cases, few if any military test subjects were informed of the potential health consequences of the exposure.

"We have a phrase to describe this phenomenon - the disposable soldier syndrome," said Richard Weidman, former VVA director of government relations.

The most infamous government experiment is the Tuskegee Syphilis Study conducted by the U.S. Public Health Service from 1932 through 1972, which used 400 poor and uneducated black male sharecroppers who carried the sexually transmitted disease.

The men were purposely undiagnosed and untreated for a disease that already had progressed to late stages, and were studied through autopsy. [You are currently viewing the printable version of this article, to return to the normal page, please click here.](#)

The government effectively blocked the unwitting participants, who also were drafted in 1940 to serve in WWII, from receiving medical treatment for symptoms they were told were caused by "bad blood." Of the participants, 28 men died of the disease, 100 others died from complications brought on by syphilis, and the disease spread to 40 wives and 19 children.

Ongoing tests with vets

The VA has extensive screening of veterans who enroll in medical experiments and requires detailed consent forms to ensure patients know about the potential complications and benefits.

Currently, the VA and other federal agencies are conducting nearly 300 clinical studies involving veterans with PTSD. Most studies are behavioral, including one that tests the effects of yoga on PTSD sufferers.

Twenty-five, however, are testing drugs on 4,796 veterans, more than half (2,488) of whom are just returning from the wars in Iraq and Afghanistan, according to clinical trials filed with the National Institutes of Health (NIH) and reviewed by The Times.

One study conducted by the National Institute of Mental Health is using virtual-reality exposure - sights, sounds and smells from the Iraq battlefield, along with a drug called D-Cycloserine that reduces fear.

Other studies are testing drugs on veterans with PTSD, including the antidepressants paroxetine, mirtazapine and citalopram - all carry warnings of suicidal side effects.

"Over 150,000 soldiers are currently deployed in Iraq as part of Operation Iraqi Freedom (OIF) and 12 percent of returning OIF veterans have PTSD," said one study that is using the drug paroxetine on 160 veterans "who have returned from the Iraq theater within the past six months."

Warnings about taking paroxetine include "suicidal thinking about harming or killing oneself or planning to trying to do so" among young adults up to 24 years of age, according to NIH.

Another study on the use of mirtazapine for veterans of Iraq and Afghanistan is testing the efficacy and tolerability of the drug on 100 veterans. Citalopram is being tested on 300 veterans "exposed to high levels of combat stress."

The NIH warning for paroxetine also applies to mirtazapine and citalopram.

The VA has not revealed how many veterans are registered in an experiment to study the effects of divalproex in the treatment of PTSD, but the FDA warned health care professionals on Jan. 31 it had received reports of suicide and suicidal thoughts linked to the anticonvulsant drug.

Smoking study's fine print

Mr. Elliott was one of 940 veterans with PTSD who participated in the Veterans Affairs Cooperative Studies Program (CSP) # 519, "smoking-cessation treatment for veterans with post traumatic stress disorder" ongoing at 10 VA clinics.

The CSP studies date back to the 1940s, when 10,000 veterans suffering from tuberculosis were recruited into VA studies to test different drugs to treat the disease.

The smoking-cessation study uses nicotine replacement products like gum and patches as well as Chantix - a drug that is supposed to block certain brain receptors that make smoking pleasurable. The \$11 million taxpayer-funded study was approved in 2004, two years before the FDA approved Chantix for prescription use.

The FDA says that nearly 40 suicides and more than 400 incidents of suicidal behavior have since been linked to Chantix.

Mr. Elliott began taking Chantix on Nov. 6. Two weeks later, on Nov. 20, the FDA issued its first alert that it had "received reports of suicidal thoughts and aggressive and erratic behavior in patients who have taken Chantix," also known as varenicline.

"A preliminary assessment reveals that many of the cases reflect new-onset of depressed mood, suicidal ideation, and changes in emotion and behavior within days to weeks of initiating Chantix treatment," the November FDA alert said.

"The role of Chantix in these cases is not clear because smoking cessation, with or without treatment, is associated with nicotine withdrawal symptoms and has also been associated with the exacerbation of underlying psychiatric illness. However, not all patients described in these cases had pre-existing psychiatric illness and not all had discontinued smoking," the FDA said.

On Jan. 18, the drug manufacturer Pfizer revised its warning label to state "patients who are attempting to quit smoking with Chantix should be observed for serious neuropsychiatric symptoms, including changes in behavior, agitation, depressed mood, suicidal ideation and suicidal behavior."

On Feb. 1, the FDA held a news conference to announce that new health risks have been associated with the drug.

VA officials started addressing the FDA alert on Nov. 26 and Dec. 4 with conference calls among government officials "to inform prescribers about these potential problems and advise patients accordingly," according to a timeline agency officials provided The Times.

On Feb. 4, VA officials were told to "formulate and approve an action plan," and on Feb. 13, a second consent form and letter was submitted for approval by VA officials.

The letter received by Mr. Elliott and other veterans was dated Feb. 29, more than three weeks after he already had suffered his mental breakdown and confrontation with police.

VA letter watered down?

While the alerts from Pfizer and the FDA clearly mentioned suicide and suicidal thoughts as possible side effects, the VA's letter to its veterans used no such language.

"Scientists have recently learned that varenicline can sometimes have serious side effects in some people," the VA letter said. "These side effects may include an increase in psychiatric symptoms such as anxiety, nervousness, tension and depression as well as untoward changes in behavior."

Asked why the letter omitted the most significant side effect, Mr. McFall said "the more verbiage you use, the more difficult and lengthy it becomes, hard to read. It's more likely veterans won't pay attention to it if you overdo."

However, a secondary research consent form sent with the letter that participants are now being asked to sign cites "changes in behavior, anxiety, nervousness, tension, depression, thoughts of suicide, and attempted and completed suicide."

Mr. McFall said the serious side effects were included in the secondary consent form, and not the notification letter, because "it's better to have the letter be brief" so that it is not a "burden for people who sometimes have problems reading."

"They have eyesight problems," Mr. McFall said. "Many of our veterans are getting elderly, so we're trying to keep things simple and to the point, while at the same time pointing them to the most important document, which is the consent form."

Veterans who are participating in the smoking-cessation program are carefully screened to ensure they are not suicidal, psychotic or homicidal, Mr. McFall said.

According to the VA research consent form Mr. Elliott initially signed, he would be required to fill out questionnaires "about some war zone events that you may have experienced" and interviews "regarding symptoms of other psychiatric disorders and your use of drugs and alcohol."

"Has there been a time in the past month when things were so bad that you were thinking a lot about death or that you would be better off dead?" is one example question listed on the consent form.

Mr. Elliott filled out monthly checklists on the extent to which he had nightmares about his military experience or flashbacks, became "super alert" or on guard, and whether he had a "feeling as if your future will somehow be cut short."

Chantix debate You are currently viewing the printable version of this article, to return to the normal page, please [click here](#).

New York Magazine writer Derek De Koff detailed the nightmares and suicidal behavior he suffered while on Chantix in a Feb. 10 article, and said that at one point he felt like throwing himself in front of a tour bus or crashing his head into a computer screen.

"All this seemed logical, but also weirdly funny, even at the time: I could see how crazy these impulses were, I could recognize them as suicidal clichés. But I couldn't make them go away," Mr. De Koff wrote.

In September, musician Jeffrey Carter Albrecht was shot by a neighbor who mistook him for a burglar. The guitarist and keyboardist who once played with Edie Brickell & New Bohemians went on a rant that friends say was fueled by alcohol and the drug Chantix.

A spokesman for Pfizer could not be reached after three calls seeking comment. However, in full-page ads published May 29 in several newspapers including USA Today, Dr. Joseph Feczko, Pfizer chief medical officer, said the company is "committed to patient safety" and "furthering our knowledge of Chantix."

The FDA has declined to pull Chantix from the market, citing the health benefits of smoking cessation.

"This actually is a very important drug," Dr. Celia Winchell, team leader for the FDA division of anesthesia, analgesia and rheumatology, said during the February teleconference announcing the new warning.

"Although we are getting these reports, there's also a lot of anecdotal reports out there where this drug has worked when no other drug would," Dr. Winchell said.

"Smoking itself has very serious consequences. And so I think it's important to try to manage the risk associated with the drug, also realizing that it has a lot of benefits for some folks," Dr. Winchell said.

More than 5,000 people were treated with the drug in preliminary trials before it was approved for prescription use. However, patients with serious psychiatric illness such as schizophrenia, bipolar disorder and major depressive disorder did not participate in those tests.

Ethics of future VA tests

Mr. Caplan, the bioethicist, said that using veterans with PTSD in clinical trials carries a "high risk" that must be addressed by the VA.

"Researchers have a special obligation to vets with PTSD since they are a vulnerable population somewhat prone to threats or even violence against themselves or others," he said. "They need to keep a hawklike eye on subjects involved in high stress experiments and make sure that families and friends are involved and on board any research projects to help monitor subjects."

"I am not against research to try and improve the health of those with PTSD but only if it is done with the highest levels of consent, transparency, supervision and accountability," he said.

Mr. Caplan recommended several steps the government should adopt before allowing future testing on vulnerable veterans, including more participation by families and veterans on committees that review and approve research proposals.

Future studies that involve veterans with PTSD also should receive special approval from the VA secretary.

And a clear policy should be established that prohibits drugs reported to have serious side effects be tested on populations at risk of those side effects, including veterans with PTSD, he said.