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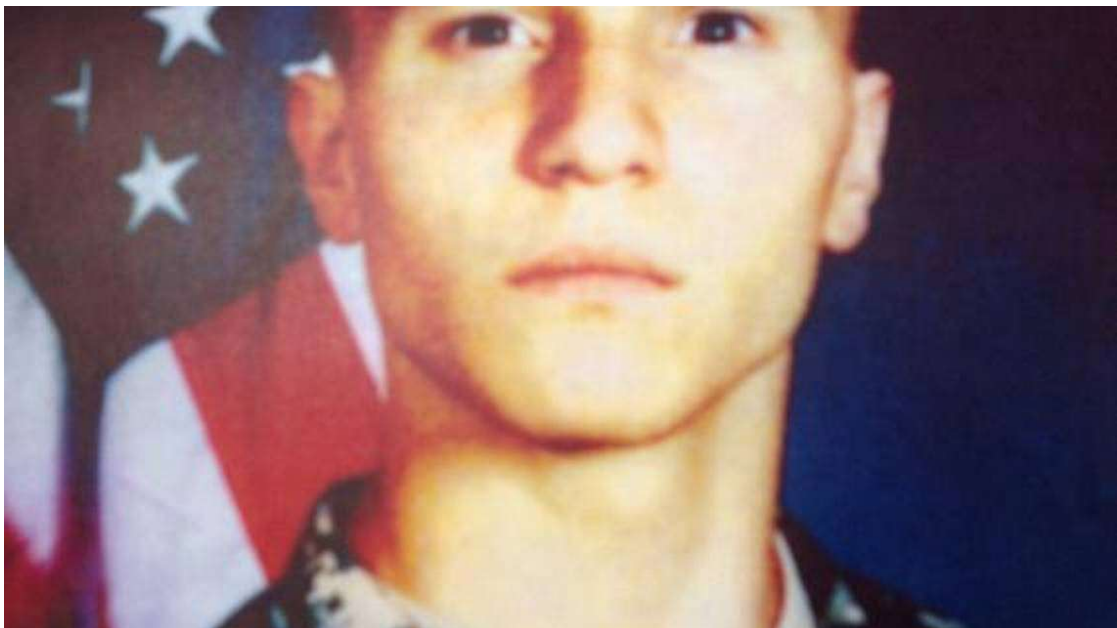
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COURTS & CRIME

An appeals victory might open new inquiries into anti-smoking drug

BY MICHAEL DOYLE - MCCLATCHY WASHINGTON BUREAU
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Army Pfc. George D.B. MacDonald says the smoking-cessation drug Chantix affected his mental health leading to his killing recruit Rick Bulmer. While the drug maker has denied the claims,

others have blamed it for suicides, suicidal thoughts and other psychiatric problems. *MCT*



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Before Pfizer paid at least \$299 million to settle claims that its anti-smoking drug Chantix caused harm, the pharmaceutical giant played hardball with Army Pfc. George D.B. MacDonald.

Charged with murdering fellow soldier and Fresno, Calif., native Rick Bulmer in May 2008, MacDonald claimed his mind snapped after using the medication to stop smoking. Chantix, MacDonald wrote, caused him to “go crazy for a while” before the assault in their Fort Benning, Ga., barracks.

During his court-martial, Pfizer resisted turning over certain documents to the defense team, including clinical trial studies that were conducted on Chantix.

“I mean, it is the United States and Pfizer versus Pfc. MacDonald here,” MacDonald’s attorney, Lt. Col. Jan Aldykiewicz, fumed at a pretrial hearing June 1, 2009, a transcript shows.

The trial judge disagreed and refused to compel the company, which wasn’t a party to the case, to comply with a subpoena for the material. The military jury subsequently convicted MacDonald of murdering Bulmer, a 23-year-old private, and sentenced him to life without the possibility of parole.

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MacDonald has appealed and his case will be heard May 13 by the nation's top military appeals court, which will revisit the trial judge's actions to determine whether they undercut the defense. Three key questions will confront the U.S. Court of Appeals for the Armed Forces when it takes up the case:

- Did the original trial judge, Army Col. James Pohl, err in refusing to compel Pfizer to fully comply with the wide-ranging subpoena for Chantix documents?
- Did Pohl err in not telling jurors about involuntary intoxication as a defense?
- If Pohl made mistakes, is a new trial required?

A lower appeals court concluded last year that the judge had erred in quashing the subpoena but not seriously enough to necessitate a new trial.

“There is no reasonable probability that had the evidence been produced, disclosed and used, the outcome of the proceeding would have been different,” the U.S. Army Court of Criminal Appeals said in an unpublished opinion. MacDonald, it said, “appreciated the nature, quality and wrongfulness of his acts in stabbing and killing Pvt. Bulmer.”

For MacDonald, the upcoming hearing is a chance to regain his freedom. For Bulmer's family, which wants MacDonald to remain incarcerated at the U.S. Disciplinary Barracks at Fort Leavenworth, Kan., the appeal is a bitter pill.



“I think he needs to stay in for as long as possible,” Bulmer's widow, Beth Bulmer, said in a telephone interview. “He stood over Rick and thought what he was going to do for 30 seconds. That's premeditated murder.”

A MacDonald victory at the hearing could force Pfizer to face subpoenas, this time enforced by a judge's order to comply. Clinical trial documents and more might have to be disclosed, potentially opening new inquiries into a medication that generated \$486 million in sales during the first nine months of last year.

“If there’s a medical explanation for what occurred in this case, it would be important beyond” MacDonald, said his Augusta, Ga.-based appellate attorney, William E. Cassara, suggesting the possibility that the case could reveal “further examples” of Chantix allegedly causing harm.

Pfizer countered, in a statement to McClatchy, that “there is no reliable scientific evidence that Chantix causes serious neuropsychiatric events including those at issue here.”

“Chantix is an important, effective, FDA-approved treatment option for adult smokers who want to quit,” Pfizer added in the statement. “Chantix is approved for use in more than 100 countries and has been prescribed to over 20 million patients worldwide, including more than 10 million in the United States.”



Questions about the drug’s safety have dogged the company. Within weeks of the military trial judge’s decision in 2009 to quash the subpoena, Pfizer began getting hit with civil lawsuits claiming Chantix had caused suicides, suicide attempts or other neuropsychiatric problems.

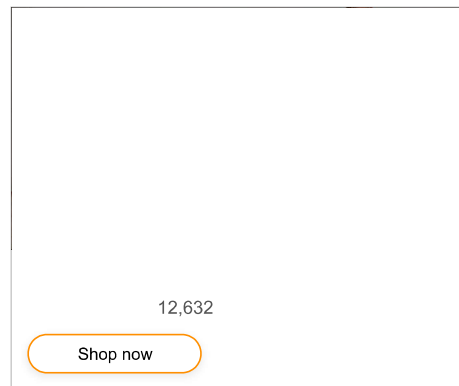
One claim came from Melanie Presley of Tacoma, Wash., who said she used Chantix briefly in 2007. She was also taking medication for other conditions, but all seemed well until one day in early February 2007.

“I woke up in the morning, and I got my daughter off to school,” Presley recalled in a telephone interview, “and the next thing I remember, I was standing in the kitchen in a puddle of blood.”

Six hours had somehow passed, Presley said, during which time she had used a kitchen knife to cut her left arm. She drove herself to the emergency room, shaken, she said, at the thought that she might have hurt someone else.

Presley was one of some 2,700 former Chantix users who ultimately sued Pfizer. On just one day in mid-July 2011, for instance, 92 individuals from cities including

Charlotte, N.C., Olathe, Kan., Owensboro, Ky., and Atlantic Beach, Fla., claimed the drug caused suicidal thoughts or other problems.



The swarm of civil lawsuits started piling up after the Food and Drug Administration imposed a “black box” warning on the Chantix label on July 1, 2009. The most serious warning a medication can have and still be sold in the U.S., it appeared about six weeks after Bulmer’s killing.

The warning cautioned Chantix users to be on the lookout for signs of hostility or agitation, among other potential symptoms. The FDA added that those “who feel like hurting themselves or someone else should stop taking the medicine and call their health care professional right away.”

One lawsuit was originally filed in Dallas by the parents of the late keyboard player Jeffrey Carter Albrecht, a member of Edie Brickell & New Bohemians. Albrecht died in September 2007 after he was shot by a Dallas homeowner who said the musician had violently battered his door late one night. Albrecht had been drinking. His parents, Ken and Judy Albrecht, blamed Chantix for their son’s outburst.

A few other violent actions allegedly tied to Chantix caused second thoughts among prosecutors.

In March 2008, federal prosecutors cited a psychiatrist’s diagnosis of “Chantix-induced psychotic disorder” in dropping charges against Andrew James Smith. The prosecutors said Smith had been “extremely psychotic and disorganized” the previous November aboard a United Airlines flight headed to Sacramento, Calif. Alarmed pilots diverted the plane to Fargo, N.D.

Six months after Smith’s charges were dropped, Vermont resident Kenneth Heath shot his 80-year-old mother. Heath had a history of mental illness prior to his Chantix prescription. Prosecutors settled for a charge of voluntary manslaughter in June 2011 after evaluating the potential Chantix defense.

“They were highly skeptical of it at first,” Heath’s attorney, David Sleight, said in an interview, “but both psychiatrists agreed that given the nature of his symptoms, it was a classic case of Chantix-induced delusional behavior.”

Essex County, Vt., State’s Attorney Vincent Illuzzi, who prosecuted the case, said in an interview that he’d accepted the lesser plea over concern that “a jury may have found (Heath) was insane at the time of the offense.”

Heath is now serving a six- to 15-year sentence

Pfizer began serious settlement discussions in 2012 with the lawyers representing the mass of Chantix civil lawsuits. Most have since been settled at a cost to the company of \$299 million through the first quarter of 2013. Pfizer says the settlements will allow the focus to remain on the benefits of the drug.

“The Chantix litigation involves fundamental issues of science and medicine that often are uncertain and continue to evolve,” Pfizer told the Securities and Exchange Commission last year.

MacDonald’s case, meanwhile, remains unresolved. His appeals hearing this month will focus on the trial judge’s denial of the defense’s request in March 2009 for a variety of Chantix documents, including clinical trial records, adverse event reports and other materials.

They also wanted Pfizer’s stability studies, showing how long the drug stays in the bloodstream. These were key because prosecutors were challenging whether MacDonald had even used the drug. The company responded that, except for the stability studies, it would not hand over the documents.

“What I am hearing,” Pohl, the trial judge, said on June 1, 2009, “is that nothing is being done on this case because everyone is waiting for Pfizer to be nice . . . and you are telling me Pfizer will ignore your subpoena.”

“In part, yes, sir,” said an Army prosecutor, Capt. David Dulaney, adding at another point that “they are flat out just going to defy that subpoena.”

Calling the subpoena “overbroad, oppressive and unreasonable,” Pfizer attorney Joseph Petrosinelli said in a June 23, 2009, letter that it “would require the review and production of literally millions of pages of documents, at enormous expense to Pfizer, which is not a party to this case.”

The day after getting Pfizer’s response, the judge quashed the subpoena.

“This is an FDA-approved drug,” Pohl said. “It is still on the market. There is no showing of an adverse impact on this particular accused or how it relates to any type

of mental responsibility defense, state of mind defense or any other matter involved in this case.”

Pohl also observed that two military lab tests hadn't detected Chantix in MacDonald's blood or urine. Retesting by a private lab about a week later reported finding Chantix residue in MacDonald's urine, though not in his blood.

The judge's refusal angered the defense attorney, who contended that subpoenas are routinely granted for salient documents and materials.

“If this were some mom and pop store down the road where, you know, somebody wasn't producing a video, we wouldn't be having this debate,” Aldykiewicz told the trial judge, the transcript shows. “But because it is somebody with an LLP and a significant law firm by their name, Pfizer doesn't get a court order.”

In an appellate brief, Army lawyers argued that even if Pohl had erred in not compelling Pfizer to comply with the subpoena, “it appears all the relevant and necessary documents were given to defense by the government and by the Food and Drug Administration.”

The FDA documents the defense ultimately obtained included a 1,443-page printout of the “adverse event reports” filed with the agency concerning Chantix. One hundred and fifty-six of the reports mentioned suicide, aggression or “homicidal ideation,” according to a defense analysis. The adverse event reports can be filed by anyone and need no corroboration,

Since the trial, MacDonald has studied Buddhism, yoga and meditation, according to his half sister, Paige MacDonald. She added in an email that MacDonald “is an optimist in the face of adversity” and is “hopeful his sentence will be reduced to a number, so he can start working off his time with good behavior.”

In California, Bulmer's family members struggle on. Some don't want to talk about the case, still an open wound.

Beth Bulmer, for one, has endured occasional health problems and financial challenges. Sometimes, the 25-year-old single mother doesn't feel like leaving home other than for necessities, such as dropping off at school her daughter Izzabella, the living reminder of her love for Rick.

“It's just too much to bear sometimes,” Beth Bulmer said. “It's just too hard.”

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