

National Transportation Safety Board

Office of Research and Engineering

Washington, DC 20594



ERA22FA141

MEDICAL

Specialist's Factual Report

November 30, 2022

A. ACCIDENT

Location: St. Augustine, Florida
Date: March 2, 2022
Time: 17:02 Local
Airplane: Extra NG, N100NG

B. MEDICAL SPECIALIST

Specialist Michelle Watters, MD, PhD, MPH
National Transportation Safety Board, RE-1
Washington, DC

C. DETAILS OF THE INVESTIGATION

Purpose

This investigation was performed to evaluate the pilot for medical conditions, the use of medications/illicit drugs, and the presence of toxins.

Methods

The Federal Aviation Administration (FAA) medical certification file, FAA medical case review, the pilot's autopsy and FAA Forensic Sciences Laboratory toxicology reports,¹ and post-accident medical records were reviewed. Other relevant medical and regulatory issues were reviewed.

D. FACTUAL INFORMATION - PILOT

1.0 FAA Medical Certification File and FAA Medical Case Review

According to the FAA medical certification file, at the time of the accident, the 49-year-old female pilot held a third class medical certificate with the limitation that she must wear corrective lenses. At the time of the most recent exam (6/24/21), the pilot was 66 inches tall and weighed 133 pounds. She reported having 250 civil flight hours. She reported taking no medications and no medical conditions. On her previous and first FAA medical certification examination in 2018, the pilot reported a driving under the influence arrest in 2012; there was a letter of eligibility from FAA in April 2019 for this concern.

¹ The FAA Forensic Sciences Laboratory has the capability to test for more than 1,300 substances including toxins, common prescription and over-the-counter medications, and illicit drugs. <https://jag.cami.jccbi.gov/toxicology/>

2.0 Autopsy

According to the autopsy performed by the Office of the Medical Examiner, Jacksonville, Florida, the cause of death in the pilot was drowning and the manner of death was accident. The medical examiner reported evidence of hospital intervention. No significant natural disease was identified.

3.0 Toxicology

Toxicological testing performed by the FAA's Forensic Sciences Laboratory identified the sedatives midazolam at 4 nanograms per milliliter (ng/mL) and lorazepam at 39 ng/mL in the pilot's heart blood and in her liver tissue. The antidepressant vilazodone was detected at 49 ng/mL in heart blood and in liver tissue. The major metabolite of naltrexone, 6-beta-naltrexol, was detected in her heart blood and liver tissue; naltrexone is used to treat alcohol and opiate dependency. Ethanol was detected in the pilot's heart blood at 0.010 grams per deciliter (gm/dL) but was not detected in her vitreous fluid. Her tissues were noted to exhibit putrefaction. Toxicological testing performed for the medical examiner's office detected the opioid fentanyl at 13 ng/mL and caffeine in her hospital blood. Fentanyl is indicated for use during the induction of anesthesia and for short term pain relief.²

Midazolam is a benzodiazepine that is commonly administered by injection before surgery or other medical procedures for its sedative and amnestic effects. Onset of sedative effects is 5 minutes and peaks at 15 to 30 minutes. Midazolam's mean half-life is three hours and its peak concentration is 90 ng/mL for an intramuscular dose of 7.5 milligrams.³

Lorazepam, commonly marketed as Ativan, is a benzodiazepine that is used to treat anxiety and seizure disorders or administered before surgery or other medical procedures to produce sedation, relieve anxiety, or decrease memory recall. The therapeutic range of lorazepam is 80 to 250 ng/mL and its half-life is 10 to 16 hours.^{4,5}

Vilazodone, commonly marketed as Viibryd, is a prescription medication indicated for the treatment of depression. Vilazodone is a serotonin partial-agonist reuptake inhibitor. Vilazodone may cause some people to have suicidal thoughts.

² National Institutes of Health (NIH). U.S. National Library of Medicine (NLM). [DailyMed - FENTANYL CITRATE injection, solution \(nih.gov\)](#). Updated 5/23/22.

³ NIH. NLM. [DailyMed - MIDAZOLAM HYDROCHLORIDE injection, solution \(nih.gov\)](#). Updated 12/14/21.

⁴ NIH. NLM. [DailyMed - LORAZEPAM injection \(nih.gov\)](#) Updated 1/28/22; [DailyMed - LORAZEPAM tablet \(nih.gov\)](#) Updated 2/28/21.

⁵ Schulz, M, A Schmoltdt, H Andresen-Streichert, and S Iwersen-Bergmann. 2020. Revisited: Therapeutic and toxic blood concentrations of more than 1100 drugs and xenobiotics. Additional File 1. *Critical Care* 24(1):195 doi: 10.1186/s13054-020-02915-5.

Side effects are typically mild or moderate and include diarrhea, nausea, and dizziness; most effects occur within the first week and last one week. The mean maximum plasma concentration is 156 ng/mL for a 40-milligram daily dose, and it has a half-life of about 25 hours.^{6,7}

Major depression itself is associated with significant cognitive degradation, particularly in executive functioning.⁸ The cognitive degradation may not improve even with remission of the depressed episode, and patients with severe disease are more significantly affected than those with fewer symptoms or episodes.^{9,10} The FAA finds depression and use of antidepressants to be disqualifying, although pilots who can demonstrate they are clinically stable and in remission after six months of treatment on a small set of approved medications may be issued a special issuance medical certificate. Vilazodone, which was approved in 2011, is not one of the FAA approved antidepressant medications.¹¹

Naltrexone is an opioid antagonist indicated for the treatment of alcohol dependence and to block the effects of opioids. It is prescribed as part of the management plan for addiction. Naltrexone does not lead to physical or psychological dependence. The major metabolite of naltrexone is 6-beta-naltrexol, which is also active.¹² The mean half-life values for naltrexone and 6-beta-naltrexol are 4 hours and 13 hours, respectively.¹³ The therapeutic range for naltrexone is 3 to 50 ng/mL; plasma concentrations of 6-beta-naltrexol are usually 1.5 to 10 times higher.¹⁴

Ethanol is a social drug commonly consumed by drinking beer, wine, or liquor. It acts as a central nervous system depressant; it impairs judgment, psychomotor

⁶ NIH. NLM. [DailyMed - VILAZODONE HYDROCHLORIDE tablet \(nih.gov\)](#) Updated 6/7/22.

⁷ Chauhan, M, R Parry, WV Bobo. 2022. Vilazodone for major depression in adults: Pharmacological profile and an updated review for clinical practice. *Neuropsychiatric disease and treatment* 18:1175-1193.

⁸ Snyder HR. 2013. Major depressive disorder is associated with broad impairments on neuropsychological measures of executive function: A meta-analysis and review. *Psychol Bull.* 139(1):81-132.

⁹ Nakano Y, Baba H, Maeshima H, Kitajima A, Sakai Y, Baba K, Suzuki T, Mimura M, Arai H. 2008. Executive dysfunction in medicated, remitted state of major depression. *J Affect Disord.* 111(1):46-51.

¹⁰ Paelecke-Habermann Y, Pohl J, Leplow B. 2005. Attention and executive functions in remitted major depression patients. *J Affect Disord.* 89(1-3):125-135.

¹¹ FAA. Last modified 7/23/18. Guide for Aviation Medical Examiners, Item 47. Psychiatric Conditions - Use of Antidepressant Medications. https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/app_process/exam_tech/item47/amd/antidepressants/

¹² Heinala, P, T Lahti, D Sinclair, K Ariniemi, P Lillsunde, H Alho. 2012. Analysis of naltrexone and its metabolite 6-beta-naltrexol in serum with high-performance liquid chromatography. *Biomed Center Research Notes* 5:439

¹³ NIH. NLM. [DailyMed - NALTREXONE HYDROCHLORIDE tablet, film coated \(nih.gov\)](#) Updated 12/22/21.

¹⁴ Schulz, M, et al. 2020.

functioning, and vigilance. Ethanol is water soluble, and after absorption it quickly and uniformly distributes throughout the body's tissues and fluids. The distribution pattern parallels water content and blood supply of the tissue. Ethanol can be produced after death by microbial activity, sometimes in conjunction with other alcohols. Extensive trauma increases the spread of bacteria and raises the risk of ethanol production after death.¹⁵

4.0 Post-accident Medical Records

Post-accident medical records were obtained for the pilot. According to these records, the pilot landed in the marsh awake and verbal but was submerged for 3 minutes before she could be extricated. She then went into cardiac arrest; after 30 minutes, paramedics achieved her return to spontaneous circulation. The pilot was stabilized and received fentanyl at the local hospital prior to transfer to a trauma center. Local hospital blood alcohol screening was negative. The pilot was administered midazolam and lorazepam at the trauma center. CT scans at the trauma center did not show major traumatic injuries. The pilot's respiratory and cardiac condition deteriorated, and she died about 13 hours after the accident.

E. SUMMARY OF MEDICAL FACTS

The 49-year-old female pilot held a third class medical certificate with the limitation that she must wear corrective lenses. At the time of the most recent exam (6/24/21), she reported no medical conditions or medications. According to the autopsy, the cause of the pilot's death was drowning, and the manner of death was accident. No significant natural disease was identified.

Toxicological testing detected midazolam at 4 ng/mL, lorazepam at 39 ng/mL, and vilazodone at 49 ng/mL in the pilot's heart blood; 6-beta-naltrexol was also detected in her heart blood. All four compounds were detected in her liver tissue. Fentanyl was detected at 13 ng/mL in her hospital blood. Ethanol was detected in the pilot's heart blood at 0.010 gm/dL but was not detected in her vitreous fluid.

According to post accident medical records, the pilot landed in the marsh awake and verbal but was submerged for 3 minutes before she could be extricated. She then went into cardiac arrest but returned to spontaneous circulation. The pilot was stabilized and received fentanyl at the local hospital prior to transfer to a trauma center. Local hospital blood alcohol screening was negative. The pilot was administered midazolam and lorazepam at the trauma center. The pilot died about 13 hours after the accident.

¹⁵ Kugelberg, FC and AW Jones. 2007. Interpreting results of ethanol analysis in postmortem specimens: a review of the literature. *Forensic Science International* 165(1):10-29.

Submitted by:

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