



# **NATIONAL TRANSPORTATION SAFETY BOARD**

Office of Research and Engineering  
Washington, DC

## **Medical Factual Report**

**July 23, 2021**

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Medical Officer

### **A. ACCIDENT INFORMATION**

Identification: ERA20FA074

Location: Mechanicsburg, Pennsylvania

Date: January 9, 2020 (2029 local time)

### **B. GROUP IDENTIFICATION**

No group was formed for the medical evaluation in this accident.

### **C. DETAILS OF INVESTIGATION**

#### **1. Purpose**

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

#### **2. Methods**

The Federal Aviation Administration (FAA) medical case review and the pilot's FAA medical records (medical certification file and related FAA e-mails). The pilot's autopsy and toxicology reports were reviewed, as were selected pre-accident medical records from his primary care and sleep medicine providers, and reports on selected data from his continuous positive airway pressure (CPAP) device. Investigator reports and relevant regulation and medical literature were also reviewed.

#### **3. Findings**

##### **a. FAA Medical Records/Medical Case Review**

The 58-year-old male pilot's FAA medical records dated back to a 1990 aviation medical examination. According to reviewed records, at an aviation medical examination on January 7, 2013, the pilot newly reported a diagnosis of type II diabetes mellitus, treated with the prescription oral diabetes medications

sitagliptin and glipizide. The aviation medical examiner (AME) deferred that medical certification decision to the FAA due to the recent/new diabetes diagnosis. In February 2013, the FAA sent the pilot a general denial letter, stating that he did not meet standards for medical certification due to his combined use of sitagliptin and glipizide.<sup>1</sup> The denial letter stated that the pilot's qualification could be reconsidered if his treating physician determined that his diabetes could be controlled without sitagliptin, or with sitagliptin alone or in combination with metformin and/or a thiazolidinedione (other prescription diabetes medications).

During September and October 2013, the FAA received additional documentation compiled by the pilot's primary care provider. This included documentation showing that the pilot's diabetes was well controlled, without evidence of diabetes-related kidney, eye, or nerve problems, and without side effects of his medications, which no longer included sitagliptin (sitagliptin was discontinued at the pilot's request in January 2103). The documentation received by the FAA also included information about a diagnosis of obstructive sleep apnea (OSA), adequately treated with a bilevel positive airway pressure (BiPAP) device (documentation of the pilot's compliance with BiPAP treatment was provided), as well as about a diagnosis of coronary artery disease (CAD) that had been made by cardiac catheterization in October 2009.<sup>2</sup> According to the documentation provided to the FAA, the cardiac catheterization had shown mild-to-moderate triple-vessel CAD that did not require stenting or surgery, and the pilot did not have any typical symptoms of CAD-related heart pain or congestive heart failure.<sup>3</sup>

The pilot had his next aviation medical examination on November 4, 2013. That examination was his last aviation medical examination before the accident. At that time, he reported 1885 total civilian flight hours. He was 60 inches tall and weighed 255 pounds. He reported using the prescription diabetes medications metformin and glipizide, as well as rosuvastatin (a prescription medication commonly used to control cholesterol and reduce cardiovascular risk), omeprazole (a stomach-acid-suppression medication available over the counter), aspirin (an over-the-counter anti-inflammatory medication commonly used to reduce cardiovascular risk), the vitamins D and B12, and the supplements coenzyme Q10 and glucosamine + chondroitin. None of those substances is generally considered impairing. The pilot reported his diagnoses of diabetes,

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<sup>1</sup> According to the FAA medical case review, at that time the FAA did not allow use of sitagliptin and glipizide in combination due to concerns over increased risk for low blood sugar; this policy was subsequently changed to permit the combination.

<sup>2</sup> The cardiac catheterization had been performed in follow up of a September 2009 abnormal nuclear stress test, which had been performed to evaluate atypical chest discomfort in the presence of risk factors for CAD.

<sup>3</sup> The report from the cardiologist who performed the catheterization was included in the documents submitted to the FAA. The report noted 50-60% narrowing of the posterolateral branch off the right coronary artery, without evidence that this narrowing was flow-limiting. The report also noted 25-40% narrowing at several other locations within the coronary arterial system.

CAD, and OSA. The AME reviewed available information and discussed the case by telephone with an FAA physician. The FAA physician gave the AME approval to issue the pilot a time-limited second-class medical certificate, also limited by a requirement to have available glasses for near vision. The certificate was not valid for any class after November 30, 2014.

The FAA followed up with a letter to the pilot dated November 25, 2013. The letter stated that, due to the pilot's history of CAD and OSA, additional information was needed to determine his eligibility for medical certification. Specifically, the letter requested a typed assessment from the pilot's physician, a current exercise stress test per FAA requirements, and a copy of the pilot's most recent sleep study. The FAA received the requested information in January 2014; this included the report of a new, December 20, 2013, exercise stress test, which showed no worrisome findings, and an assessment statement from the pilot's primary physician noting no new concerns (and listing medications consistent with those that the pilot had reported). The most recent sleep study report was from November 2009, showing moderate to severe OSA.

On February 20, 2014, the FAA sent an authorization letter to the pilot for special issuance of medical certification for CAD, diabetes on medication, and OSA on treatment. The authorization expired on November 30, 2014. The authorization letter stated that consideration for new authorization would be contingent upon the pilot meeting specified follow-up requirements. The pilot did not complete those requirements.

According to an e-mail from an FAA investigator, the pilot completed BasicMed requirements in December 2018, comprising a BasicMed training course and a Comprehensive Medical Examination Checklist (CMEC), neither of which was yet due for renewal as of the accident date.<sup>4</sup>

#### b. Personal Medical Records

##### I. Primary Care Records

Records from the pilot's primary care provider were reviewed from the three years before the accident. His most recent primary care visit was on November 27, 2019, for follow up of a lung mass. The note from that visit indicates that the pilot had diagnoses including CAD, OSA, diabetes, high cholesterol, high blood pressure, and asthma. The note indicates that the pilot was taking the prescription diabetes medications sitagliptin, glipizide, and metformin, as well as lisinopril (a prescription blood pressure medication), rosuvastatin (a prescription medication commonly used to control cholesterol and reduce cardiovascular risk), omeprazole (a stomach-acid-suppression medication available over the counter), aspirin

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<sup>4</sup> Effective May 1, 2017, BasicMed allows pilots who meet certain requirements to fly without current medical certification. Among those requirements, a pilot must have had a medical examination with a state-licensed physician using the CMEC within 48 months, and must have completed a BasicMed training course within 24 calendar months. Aircraft and operating restrictions also apply. For details, see [14 Code of Federal Regulations \(CFR\) Part 68](#), [14 CFR 61.113\(i\)](#), [14 CFR 61.23\(c\)\(3\)](#), and [https://www.faa.gov/licenses\\_certificates/airmen\\_certification/basic\\_med/](https://www.faa.gov/licenses_certificates/airmen_certification/basic_med/).

(an over-the-counter anti-inflammatory medication commonly used to reduce cardiovascular risk), albuterol (a prescription medication commonly used to treat asthma and lung tightness), and fluticasone nasal spray (a prescription medication commonly used to treat seasonal allergies). None of those medications is generally considered impairing. According to the visit note, the pilot's medications also included the combination seasonal allergy/nasal decongestant medication cetirizine/pseudoephedrine, to be used only as needed. Because of the potential for sedating effects from the cetirizine component, the FAA states that pilots should not fly within 48 hours of taking it.<sup>5</sup>

According to the most recent primary care visit note, the pilot was using a CPAP device to treat his OSA with good adherence and symptom control. He was not adhering to treatment for high blood pressure but had no cardiovascular symptoms and had a blood pressure of 122/84 at that visit, compared to a goal of less than 120/80. He had no diabetes-related symptoms and had undergone a diabetic eye exam in September 2018 and a diabetic foot exam in November 2019 (results not specified).<sup>6</sup>

According to the reviewed primary care records, the pilot's lung mass had first been identified on September 25, 2019, during an emergency department visit for chest pain and weeks of cough and chills/night sweats. The mass was in the upper lobe of the left lung and measured 4.2 by 4.9 by 5.9 centimeters (cm) on initial imaging. Its appearance on imaging was highly concerning for cancer, but biopsy did not find any cancerous cells. The possibility was considered that the mass was an area of infection, and the pilot seemed to have some response to treatment with antibiotics, but no diagnosis was made despite specialized testing and follow up.

Reviewed primary care records included a copy of a pulmonology visit note from January 2, 2020. That was the most recent reviewed visit note of any kind. At that visit, the pilot was 68 inches tall and weighed 251 pounds. His blood pressure was 118/74. His medication list contained the same medications as were documented at his November 27, 2019, primary care visit. The pulmonologist noted that the pilot was completely without symptoms but needed repeat imaging to reassess the lung mass. According to a report in the reviewed records, that imaging was done on January 6, 2020, and showed no significant change since November 2019.

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<sup>5</sup> Federal Aviation Administration. Allergy – antihistamine & immunotherapy medication. Guide for Aviation Medical Examiners. [https://www.faa.gov/about/office\\_org/headquarters\\_offices/avs/offices/aam/ame/guide/media/AllergyAntihistamineImmunotherapyMedication.pdf](https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/media/AllergyAntihistamineImmunotherapyMedication.pdf). Updated February 24, 2021. Accessed July 16, 2021.

<sup>6</sup> Diabetic neuropathy was documented in the pilot's problem list, and physical exam documentation indicated abnormal sensation in the lower extremities, but this was not detailed in reviewed records, and the most recent primary care visit note stated the pilot did not have a history of extremity numbness or tingling.

The most recent specifically documented hemoglobin A1c (HbA1c) result in reviewed records was 7.8% in late August 2019.<sup>7</sup> A copy of an eye examination report from September 2017 was also included in reviewed records. In it, the ophthalmologist noted that the pilot reported mild blurry vision in both eyes when reading, made better by glasses, without other visual symptoms. The ophthalmologist diagnosed cataracts (central lens clouding) of both eyes, and documented sharp vision without diabetes-related eye disease. A copy of a hearing test from October 2018 was included in reviewed records, showing mild high-frequency hearing loss in the right ear and mild-to-moderate high-frequency hearing loss in the left ear. Reviewed primary care records did not include any mention of the medication clonazepam. Anxiety screening questions were most recently documented on the November 27, 2019, visit date, with no anxiety noted.

## II. Sleep Apnea Records

Selected records from the pilot's sleep medicine specialist were reviewed. According to those records, the pilot had been diagnosed with OSA in 2001. He had not initially tolerated CPAP treatment but had restarted treatment around the time that his CAD had been diagnosed in 2009, visiting the sleep medicine specialist shortly thereafter for a repeat sleep study (the November 2009 study in the FAA records). The most recent reviewed record from the sleep medicine specialist was a report from a September 2018 study conducted to help determine the best CPAP pressure setting.

Selected CPAP download reports detailing the pilot's CPAP use leading up to the accident date were also reviewed. According to those reports, in the year preceding the accident the pilot used CPAP on 85% of days, with a total average use of 6 hours 54 minutes per day, and an average use of 8 hours 6 minutes on days used.<sup>8</sup> In the 7 days preceding the accident the pilot used CPAP every night, with an average use of 7 hours 38 minutes per night, and 8 hours 6 minutes of use on the night before the accident. Reviewed reports also indicated that his disordered breathing episodes were effectively reduced to a normal range during CPAP treatment.

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<sup>7</sup> HbA1c is an indirect measure of a person's average blood sugar over the lifespan of that person's red blood cells, which is usually about 3 months. In general, HbA1c of 6.5% or higher diagnoses diabetes, and good control of diabetes is considered an HbA1c of less than 7%. Typically, HbA1c of 7.8% represents an estimated average blood sugar of 177 milligrams/deciliter (mg/dL) over the 3 months before blood sample collection. For many adults with diabetes, recommended pre-meal blood sugars are between 80 and 130 mg/dL, and recommended peak after-meal blood sugars are less than 180 mg/dL.

[American Diabetes Association. Standards of medical care in diabetes – 2020. *Diabetes Care*. 2020;43(Suppl. 1):S1-S212. [http://care.diabetesjournals.org/content/43/Supplement\\_1](http://care.diabetesjournals.org/content/43/Supplement_1). Accessed December 2, 2020.]

<sup>8</sup> The FAA generally considers the target goal for effective CPAP treatment of pilots to be use for at least 75% of sleep periods, with an average use of at least 6 hours per sleep period.

[Federal Aviation Administration. Decision considerations for disease protocols - obstructive sleep apnea (OSA): OSA reference materials. Guide for Aviation Medical Examiners. [https://www.faa.gov/about/office\\_org/headquarters\\_offices/avs/offices/aam/ame/guide/dec\\_cons/disease\\_prot/osa/ref\\_materials/](https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/dec_cons/disease_prot/osa/ref_materials/). Updated April 3, 2017. Accessed July 21, 2021.]

c. Autopsy

The Cumberland County Coroner's Office performed the pilot's autopsy. According to the autopsy report, the cause of death was multiple traumatic injuries, and the manner of death was accidental. Autopsy evaluation of the heart was limited by the severity of injury, which prevented identification of the coronary arteries and assessment of the heart's chamber sizes and right ventricle. Within those limitations, visual (non-microscopic) examination of the heart did not identify any heart disease. A mass measuring 5.5 cm by 3 cm was identified in the upper lobe of the left lung, and the lung tissue contained excess fluid. The autopsy, including examination of lung blood vessels, did not identify any other significant natural disease.

d. Toxicology

The FAA Forensic Sciences Laboratory performed toxicological testing on specimens from the pilot.<sup>9</sup> The clonazepam metabolite 7-aminoclonazepam was detected at 18 nanograms per milliliter (ng/mL) in liver and 5 ng/mL in muscle. Clonazepam itself was not detected in liver or muscle. Ethanol was detected at 0.013 grams per deciliter (g/dL) in liver and 0.021 g/dL in muscle. N-propanol was also detected in muscle. Glipizide was detected in liver and muscle. No blood was available for testing.

e. Descriptions of Detected Substances

7-aminoclonazepam is the major metabolite of clonazepam.<sup>10</sup> Clonazepam is a prescription benzodiazepine medication commonly used to treat seizure disorder, panic disorder, anxiety, and certain other conditions. Clonazepam generally carries a warning that it may depress the function of the central nervous system (CNS), impairing cognitive and motor performance, and that users should be cautioned against engaging in hazardous occupations requiring mental alertness such as operating machinery or driving a motor vehicle. Clonazepam is a United States Drug Enforcement Agency (DEA) Schedule IV controlled substance, with potential for abuse, dependence, and withdrawal.<sup>11</sup> The FAA states that pilots should not fly with clonazepam in their systems, and considers an open prescription for clonazepam generally disqualifying for medical certification.<sup>12</sup> In addition to being metabolized in the body during life,

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<sup>9</sup> The FAA Forensic Sciences Laboratory tests specimens for over 1,300 compounds including toxins, prescription and over-the-counter medications, and illicit drugs; information about these compounds can be found at the Civil Aerospace Medical Institute WebDrugs website (<https://jag.cami.jccbi.gov/toxicology>).

<sup>10</sup> Federal Aviation Administration Civil Aerospace Medical Institute. Amino-clonazepam (7-). Forensic Toxicology's WebDrugs. <https://jag.cami.jccbi.gov/toxicology/DrugDetail.asp?did=257>. Updated January 16, 2019. Accessed July 21, 2021.

<sup>11</sup> National Institutes of Health National Library of Medicine. Klonopin. DailyMed. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=542f22e8-dad2-47a8-93b6-30936715d73b>. Updated February 18, 2021. Accessed July 21, 2021.

<sup>12</sup> Federal Aviation Administration. Guide for aviation medical examiners: pharmaceuticals (therapeutic medications) do not issue - do not fly. Federal Aviation Administration website. <https://www.faa.gov/go/dni>. Updated February 19, 2021. Accessed July 21, 2021.

clonazepam may be metabolized to 7-aminoclonazepam by microbes in body tissues after death.<sup>13</sup>

Ethanol is the intoxicating alcohol in beer, wine, and liquor. It is a CNS depressant that can impair judgment, psychomotor performance, cognition, and vigilance, and can make the impairing effects of other CNS depressant drugs (including clonazepam) worse.<sup>11,14,15</sup> FAA regulation imposes strict limits on flying after consuming ethanol. This includes a prohibition on acting as a crewmember of a civil aircraft while having a blood ethanol level of 0.04 g/dL or greater.<sup>16</sup> Ethanol can also be produced by microbes in a person's body tissues after death.<sup>14</sup>

N-propanol is another alcohol that can be produced by microbes in a person's body tissues after death.<sup>17</sup> It is also an industrial solvent and is present in small amounts in some foods and drinks.<sup>18</sup> It is not considered impairing at the detected level, which was below the threshold for quantification. Glipizide is a prescription oral medication used to help control blood sugar in diabetes.<sup>19</sup> It is generally not considered impairing.

#### D. SUMMARY OF MEDICAL FINDINGS

The 58-year-old male pilot's most recent aviation medical examination was on November 4, 2013. At that time, he reported having coronary artery disease (CAD) diagnosed by cardiac catheterization in 2009, diabetes treated with oral medications, and obstructive sleep apnea (OSA) treated with a bilevel positive airway pressure device. The aviation medical examiner reviewed available information and discussed the case by telephone with a Federal Aviation Administration (FAA) physician, who gave approval to issue the pilot a time-limited second-class medical certificate, not valid for any class after November 30, 2014. On February 20, 2014, after requesting

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<sup>13</sup> Robertson MD, Drummer OH. Postmortem distribution and redistribution of nitrobenzodiazepines in man. *J Forensic Sci.* 1998;43(1):9-13.

<sup>14</sup> Spitz WU. Forensic aspects of alcohol. In: Spitz WU, Spitz DJ, eds. *Spitz and Fisher's Medicolegal Investigation of Death: Guidelines for the Application of Pathology to Crime Investigation*. 4th ed. Springfield, IL: Charles C Thomas; 2006:1218-1229.

<sup>15</sup> Cook CCH. Alcohol and aviation. *Addiction.* 1997;92(5):539-555.

<sup>16</sup> Office of the Federal Register. 14 CFR 91.17. Electronic Code of Federal Regulations. [https://www.ecfr.gov/cgi-bin/text-idx?node=se14.2.91\\_117](https://www.ecfr.gov/cgi-bin/text-idx?node=se14.2.91_117). Updated December 9, 2020. Accessed December 11, 2020.

<sup>17</sup> Kugelberg FC, Jones AW. Interpreting results of ethanol analysis in postmortem specimens: a review of the literature. *Forensic Sci Int.* 2007;165(1):10-29. doi: 10.1016/j.forsciint.2006.05.004.

<sup>18</sup> United States Environmental Protection Agency. Inert reassessment document for -n-Propanol - CAS No. 71-23-8. <https://www.epa.gov/sites/default/files/2015-04/documents/propanol.pdf>. Published August 24, 2005. Accessed July 21, 2021.

<sup>19</sup> National Institutes of Health National Library of Medicine. Glucotrol. DailyMed. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b4f55916-91a2-4171-a361-919e7cb329b0>. Updated June 7, 2021. Accessed July 21, 2021.

and receiving additional medical documentation, including results of a December 2013 exercise stress test, the FAA sent an authorization letter to the pilot for special issuance of medical certification for CAD, diabetes on medication, and OSA on treatment. The authorization expired on November 30, 2014. The pilot completed BasicMed requirements in December 2018.

The pilot's most recent primary care visit in reviewed records was on November 27, 2019, for follow up of a lung mass that had been identified the preceding month. The note from the pilot's most recent primary care visit documented diagnoses including CAD, OSA, diabetes, high cholesterol, high blood pressure, and asthma. The note indicated that the pilot was taking the medications sitagliptin, glipizide, metformin, lisinopril, rosuvastatin, omeprazole, aspirin, albuterol, and fluticasone nasal spray. Those medications generally are not considered impairing. The pilot's medications also included the potentially sedating medication cetirizine/pseudoephedrine, to be used only as needed. He was using a continuous positive airway pressure (CPAP) device to treat his OSA with good symptom control. He had no cardiovascular symptoms. The visit note indicated he had some abnormal sensation in his lower extremities but stated he did not have numbness or tingling. He had no other diabetes-related symptoms. He had prior diagnoses of mild cataracts and mild-to-moderate high-frequency hearing loss.

Although the appearance of his lung mass on imaging was highly concerning for cancer, no diagnosis was made despite specialized evaluation including biopsy. As of a January 2, 2020, pulmonology visit, he had no associated symptoms.

Reports downloaded from his CPAP device indicated that he had good adherence with his CPAP treatment for OSA prior to the accident, including the night before, with effective reduction of disordered breathing episodes to a normal range during CPAP treatment.

The Cumberland County Coroner's Office performed the pilot's autopsy. According to the autopsy report, the cause of death was multiple traumatic injuries. Autopsy evaluation of the heart was limited by the severity of injury, which prevented identification of the coronary arteries and assessment of the heart's chamber sizes and right ventricle. A mass measuring 5.5 cm by 3 cm was identified in the upper lobe of the left lung, and the lung tissue contained excess fluid. The autopsy did not identify any other significant natural disease.

The FAA Forensic Sciences Laboratory detected the clonazepam metabolite 7-aminoclonazepam at 18 nanograms per milliliter (ng/mL) in liver and 5 ng/mL in muscle. Clonazepam itself was not detected in liver or muscle. Ethanol was detected at 0.013 grams per deciliter (g/dL) in liver and 0.021 g/dL in muscle. N-propanol was detected in muscle. Glipizide was detected in liver and muscle.