NATIONAL TRANSPORTATION SAFETY BOARD

Office of Research and Engineering
Washington, DC

Medical Factual Report

July 29, 2020

Mary Pat McKay, MD, MPH
Chief Medical Officer

A. ACCIDENT: CEN19MA190; Addison, TX

On June 30, 2019, about 0911 central daylight time, a Textron Aviation B300, N534FF, was destroyed when it was involved in an accident near Addison, Texas. The airline transport pilot, the commercial co-pilot, and eight passengers sustained fatal injuries. The airplane was operated as a Title 14 Code of Federal Regulations Part 91 personal flight.

B. GROUP IDENTIFICATION

Chair:
Mary Pat McKay, MD, MPH
Chief Medical Officer,
National Transportation Safety Board

Penny Giovanetti, DO
Director, Medical Specialties Division
Federal Aviation Administration

C. RELEVANT MEDICAL STANDARDS

According to the Federal Aviation Administration's (FAA's) Guide for Aviation Medical Examiners, obstructive sleep apnea (OSA) is a disqualifying condition for pilots. Those diagnosed and treated for the condition may obtain a special issuance medical certificate if they meet specific criteria. For those using continuous positive airway pressure (CPAP) as treatment and who have a recording CPAP device, the criteria are:

> Signed Airman Compliance with Treatment form or equivalent from the airman attesting to absence of OSA symptoms and continued daily use of prescribed therapy; and
>
> A current status report from the treating physician indicating that OSA treatment is still effective.

For CPAP/ BIPAP/ APAP: A copy of the cumulative annual PAP device report which shows **actual time used** (rather than a report typically generated for insurance providers which only shows if use is greater or less than 4 hours). Target goal should show use for at least 75% of sleep periods and an average minimum of 6 hours use per sleep period.[1]

In addition, the FAA requires that the aviation medical examiners (AMEs) evaluate and triage every applicant for a medical certificate into one of 6 groups:

- If the applicant is on a Special Issuance Authorization for OSA
  - Follow AASI/SI for OSA
  - Notate in Block 60; and
  - Issue, if otherwise qualified
- If the applicant has had a prior sleep assessment
  - If the airman is under treatment, provide the requirements of the AASI and advise the airman they must get the Authorization of Special Issuance;
  - Give the applicant Specification Sheet A and advise that a letter will be sent from the Federal Air Surgeon requesting more information. The letter will state that the applicant has 90 days to provide the information to the FAA/AME;
  - Notate in Box 60;
  - Issue, if otherwise qualified
- If the applicant does not have an AASI/SI or has not had a previous assessment, the AME must:
  - Calculate BMI; and
  - Consider American Academy of Sleep Medicine (AASM) risk criteria
  - If the AME determines the applicant is not currently at risk for OSA
    - Notate in Block 60; and
    - Issue, if otherwise qualified
  - If the applicant is at risk for OSA but in the opinion of the AME the applicant is at low risk for OSA, the AME must
    - Discuss OSA risks with applicant;
    - Provide resource and educational information (see: https://www.faa.gov/pilots/safety/pilotsafetybrochures/media/Sleep_Apnea.pdf), as appropriate;
    - Issue, if otherwise qualified; and
    - Notate in Block 60
- If the applicant is at high risk for OSA,
  - Give the applicant Specification Sheet B and advise that a letter will be sent from the Federal Air Surgeon requesting more information. The letter

[1] Federal Aviation Administration. Guide for Aviation Medical Examiners. Decision Considerations Disease Protocols – Obstructive Sleep Apnea (OSA). AME Assisted Special Issuance. https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/media/AASI.pdf Accessed 9/12/2-019.

will state that the applicant has 90 days to provide the information to the FAA/AME;
    - Notate in Block 60; and
    - Issue, if otherwise qualified
- If the AME observes or the applicant reports symptoms which are severe enough to represent an immediate risk to aviation safety of the national airspace
    - Notate in Block 60
    - **THE AME MUST DEFER**[2]

D. DETAILS OF INVESTIGATION

1. Purpose

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

2. Methods

The FAA medical case review, FAA blue ribbon medical files, autopsy reports, toxicology findings, and the investigator's reports were reviewed. Relevant regulation and medical literature were reviewed as appropriate.

Pilot

FAA Medical Case Review and Blue Ribbon Medical File

According to the FAA medical case review, the 71 year old male pilot had reported 16,300 total flight hours as of his last medical exam, dated 12/21/2018. At that time, he was 69 inches tall and weighed 250 pounds. The pilot had reported high blood pressure, hypothyroidism, asthma, and high cholesterol to the FAA. He had also reported surgery for a broken ankle in the distant past. At the time of his last exam, he reported using valsartan and hydrochlorothiazide to treat his blood pressure, levothyroxine for his thyroid condition, and atorvastatin to treat his high cholesterol.

The aviation medical examiner who performed the pilot's last exam found him "NOT to be at risk for OSA" at that examination. No significant abnormalities were identified during the exam and the pilot was issued a first class medical certificate limited by a requirement that he wear corrective lenses and possess glasses for near/intermediate vision.

The EKG obtained during the pilot's last exam was found to be abnormal and the FAA requested a comprehensive cardiology evaluation. The pilot's FAA blue ribbon medical file contains data from his cardiology

[2] Federal Aviation Administration. Guide for Aviation Medical Examiners. Decision Considerations Disease Protocols – Obstructive Sleep Apnea (OSA) https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/dec_cons/disease_prot/osa/ Accessed 9/12/2019.

evaluation in February 2019. These records clearly include the information that the pilot had OSA and was using CPAP to treat it. The remainder of the cardiac evaluation, which included an echocardiogram and a nuclear stress test, were unremarkable.

On March 26th, 2019, the FAA confirmed the pilot held a first class medical certificate and that he continued to be in the FAA program for hypothyroidism and hypertension. No mention was made of his OSA.

Autopsy

According to the autopsy performed by the Southwestern Institute of Forensic Sciences at Dallas, Office of the Medical Examiner, the cause of death was inhalation of products of combustion, blunt force injuries, and thermal injuries. The manner of death was accident. The pathologist reported evidence of a remote coil embolization of a right renal artery aneurysm. No other significant natural disease was identified.

Toxicology

Toxicology testing performed by the FAA's Forensic Science Laboratory identified loratadine and its metabolite desloratadine, atorvastatin, hydrochlorothiazide, and valsartan, in blood and urine. In addition, desmethylsildenafil was found in urine but not blood.[3]

Personal Medical Records

Records were obtained from the pilot's usual source of medical care for the three years preceding the accident. The pilot had been diagnosed with asthma, high blood pressure, high cholesterol, hypothyroidism, low testosterone, and in 2013 with severe obstructive sleep apnea (OSA) with an apnea/hypopnea index (AHI) of 95 episodes/hour.[4] He was prescribed continuous positive airway pressure (CPAP) to treat the sleep apnea and routinely reported using it to his treating physicians. However, there are no records of any data having been downloaded from the device or discussed with the pilot such as how many hours a night or how many nights a week he actually used it. The pilot had also had a renal artery aneurysm embolized and kidney stones diagnosed in 2017.

In December 2017, the pilot had an episode of slurred speech, difficulty walking, and double vision associated with dizziness that led him to go to

[3] The FAA Forensic Sciences Laboratory has the capability to test for more than 1300 substances including toxins, common prescription and over-the-counter medications as well as illicit drugs. See: http://jag.cami.jccbi.gov/toxicology/default.asp?offset=0

[4] An apneic episode is the complete absence of airflow though the mouth and nose for at least 10 seconds. A hypopnea episode is when airflow decreases by 50 percent for at least 10 seconds or decreases by 30 percent if there is an associated decrease in the oxygen saturation or an arousal from sleep. The apnea-hypopnea index (AHI) sums the frequency of both types of episodes per hour. An AHI of less than 5 is considered normal. An AHI of 5-15 is mild sleep apnea; 15-30 is moderate and more than 30 events per hour is considered severe sleep apnea.

the emergency department where he had an extensive evaluation for stroke. In the end, his symptoms resolved and he was diagnosed with a transient ischemic attack.

In December 2018, the pilot complained of two days of a sensation of spinning, dizziness, nausea, and vomiting and was admitted to a local hospital.

In February 2019, (as described above) the pilot underwent a cardiac evaluation because an EKG obtained as part of his first class aviation medical certificate examination was abnormal. He had no related complaints. An echocardiogram and nuclear stress test did not reveal any significant cardiac disease.

In April 2019, the pilot visited an orthopedist regarding pain in his right ankle related to a dislocation injury which had required surgery many years previously. The pilot described the pain as medial and that activity made it worse while rest improved it. The exam revealed decreased range of motion but normal strength in the ankle and an X-ray demonstrated severe arthritis in the ankle joint. The plan was to try topical pain medications and discuss further options in a few months.

At the time of his last visit, the pilot's medications included testosterone, levothyroxine, atorvastatin, olmesartan/hydrochlorothiazide, and zolpidem.

Medication Descriptions

Testosterone is a male hormone; levothyroxine is thyroid hormone; atorvastatin is a cholesterol lowering prescription drug often marketed with the name Lipitor; olmesartan/hydrochlorothiazide is a combination drug used to treat high blood pressure.[5,6,7,8] None of these are considered impairing.

Zolpidem is a prescription sleep aid often marketed with the name Ambien. It carries a warning about complex behaviors such as "sleep-

[5] National Institutes of Health. US National Library of Medicine. DailyMed. Depo-Testosterone https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=fe808a56-7542-4d23-97b4-d98a3ef63016 Accessed 11/25/2019.
[6] National Institutes of Health. US National Library of Medicine. DailyMed. Levothyroxine. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a3845f91-e0fe-42aa-8043-aeaac43f8eef Accessed 11/25/2019.
[7] National Institutes of Health. US National Library of Medicine. DailyMed. Atorvastatin. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6ccdb6f3-22c7-5b48-46bc-ce4a4c65eb4d Accessed 11/6/2019.
[8] National Institutes of Health. US National Library of Medicine. DailyMed. Olmesartan medoxomil and hydrochlorothiazide tablet https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ca1a0aac-d81d-4c0a-91ea-cb719af772bf Accessed 11/25/2019.

driving" (i.e., driving while not fully awake after ingestion of a sedative-hypnotic, with amnesia for the event). Other complex behaviors (e.g., preparing and eating food, making phone calls, or having sex) have been reported in patients who are not fully awake after taking a sedative-hypnotic. As with "sleep-driving", patients usually do not remember these events. Amnesia, anxiety and other neuro-psychiatric symptoms may occur unpredictably.[9]

Loratadine is a non-sedating antihistamine commonly marketed with the name Claritin, valsartan is another prescription medication used to treat high blood pressure.[10, 11] Desmethylsildenafil is a metabolite of sildenafil, a prescription drug used to treat erectile dysfunction, commonly marketed with the name Viagra.[12] None of these medications are considered impairing.

Copilot

FAA Medical Case Review and Blue Ribbon Medical File

According to the FAA medical case review, the 28 year old male copilot reported 2,050 total flight hours as of his last exam, dated 4/3/2018. At that time, he was 72 inches tall and weighed 196 pounds. He reported no chronic medical problems and no use of medications to the FAA. No significant abnormalities were identified on the physical exam and he was issued a first class medical certificate without limitations.

Autopsy

According to the autopsy performed by the Southwestern Institute of Forensic Sciences at Dallas, Office of the Medical Examiner, the cause of death was thermal and inhalational injuries and the manner of death was accident. No significant natural disease was identified.

Toxicology

Toxicology testing performed by the Southwestern Institute of Forensic Sciences at Dallas, Office of the Medical Examiner, Laboratory identified carboxyhemoglobin at 19% in the copilot's blood.

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[9] National Institutes of Health. US National Library of Medicine. DailyMed. Zolpidem. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=1f1490cd-b11b-40cb-96be-865730c989e1 Accessed 11/25/2019.

[10] National Institutes of Health. US National Library of Medicine. DailyMed. Loratadine. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=55d3ee36-116b-4ec6-b409-79d67a2b54ae Accessed 11/25/2019.

[11] National Institutes of Health. US National Library of Medicine. DailyMed. Valsartan. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9402b022-5809-4251-dfef-54f6ef5723fe Accessed 11/25/2019.

[12] National Institutes of Health. US National Library of Medicine. DailyMed. Sildenafil. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=56a962e8-de00-4a97-8904-0b1bd217dd83 Accessed 11/25/2019.

Toxicology testing performed by the FAA's Forensic Science Laboratory identified carboxyhemoglobin at 18% in the copilot's blood. No other tested-for drugs were identified.[3]

E. SUMMARY OF MEDICAL FINDINGS

The 71 year old male pilot had reported having high blood pressure, hypothyroidism, asthma, and high cholesterol to the FAA. He had also reported an embolization of a right renal artery aneurysm and surgery for a broken ankle in the distant past. At the time of his last exam, he reported using valsartan and hydrochlorothiazide to treat his blood pressure, levothyroxine for his thyroid condition, and atorvastatin to treat his high cholesterol. Personal medical records revealed he also had severe obstructive sleep apnea and was using a continuous positive airway pressure device to treat it, although the details of his use of the machine were not recorded. The FAA records contain the information that the pilot had sleep apnea but the issue was not addressed by them. The pilot had also had a transient ischemic attack and had been diagnosed with severe arthritis in his right ankle.

According to the autopsy performed by the Southwestern Institute of Forensic Sciences at Dallas, Office of the Medical Examiner, the cause of death was inhalation of products of combustion, blunt force injuries, and thermal injuries. The manner of death was accident. The pathologist reported evidence of a remote coil embolization of a right renal artery aneurysm. No other significant natural disease was identified. Toxicology testing identified loratadine and its metabolite desloratadine, atorvastatin, hydrochlorothiazide, and valsartan in blood and urine. In addition, desmethylsildenafil was found in urine but not blood.

The 28 year old male copilot had reported no chronic medical conditions and no use of medication to the FAA. According to the autopsy performed by the Southwestern Institute of Forensic Sciences at Dallas, Office of the Medical Examiner, the cause of death was thermal and inhalational injuries and the manner of death was accident. No significant natural disease was identified.

Toxicology testing performed two laboratories carboxyhemoglobin at 18% and 19% in the copilot's blood. No other tested-for drugs were identified.