

NATIONAL TRANSPORTATION SAFETY BOARD

Office of Research and Engineering Washington, DC

Medical Factual Report March 17, 2020

Michelle Watters, MD, PhD, MPH Medical Officer

A. CRASH INFORMATION: HWY19MH001 – Schoharie, New York

Location: Schoharie, New York - intersection of SR30A and SR-30

Vehicle: 2001 Ford Excursion stretch limousine Operator: Prestige Limousine and Chauffeur LLC

Date: Saturday, October 6, 2018

Time: Approximately 01:55 p.m. (EDT)

B. GROUP IDENTIFICATION

No group was formed for the medical evaluation in this accident.¹

C. RELEVANT STATUTE AND REGULATION

Federal Regulations—Department of Transportation

Commercial drivers must undergo a medical examination including a medical history, review of medications, and physical examination to demonstrate they are medically certified as physically qualified to operate a commercial motor vehicle. Beginning in 2014, health care providers performing these examinations are required to have been certified by the Federal Motor Carrier Safety Administration (FMCSA).

According to Title 49 Code of Federal Regulations (CFR) Section 391.41(a) (3), a person is physically qualified to drive a commercial motor vehicle if:

- (i) That person meets the physical qualification standards in paragraph (b) of this section and has complied with the medical examination requirements in §391.43; or
- (ii) That person obtained from FMCSA a medical variance from the physical qualification standards in paragraph (b) of this section and has complied with the medical examination requirement in §391.43.

¹ Dr. Nicholas Webster (Medical Officer, NTSB) prepared the initial draft of this report. Dr. Webster retired on May 1, 2019.

According to 49 CFR Section 391.41(b) a person is physically qualified to drive a commercial motor vehicle if, among other itemized physical qualifications, that person –

- (7) Has no established medical history or clinical diagnosis of rheumatic, arthritic, orthopedic, muscular, neuromuscular, or vascular disease which interferes with his/her ability to control and operate a commercial motor vehicle safely;
- (9) Has no mental, nervous, organic, or functional disease or psychiatric disorder likely to interfere with his/her ability to drive a commercial motor vehicle safely;
- (12)(i) Does not use any drug or substance identified in 21 CFR 1308.11 Schedule I, an amphetamine, a narcotic, or other habit-forming drug;
- (ii) Does not use any non-Schedule I drug or substance that is identified in the other Schedules in 21 CFR part 1308 except when the use is prescribed by a licensed medical practitioner, as defined in §382.107, who is familiar with the driver's medical history and has advised the driver that the substance will not adversely affect the driver's ability to safely operate a commercial motor vehicle.

Marijuana Legislation

According to Title 21 United States Code (USC) Controlled Substances Act, Section 812, tetrahydrocannabinol (THC), the psychoactive component of marijuana, is listed as a Schedule I controlled substance.² In July 2014, Governor Andrew M. Cuomo and the New York State Legislature enacted the Compassionate Care Act to provide a comprehensive, safe and effective medical marijuana program that meets the needs of New Yorkers.³

While marijuana impairs judgment, reduces coordination, and induces ataxia which can impede driving ability or lead to increased risk-taking behavior, unlike alcohol, there are no established drug levels relating an amount of marijuana in a driver's blood to impairment. According to the Governor's Highway Safety Association, as of March 2020, 9 states have zero tolerance traffic laws for drivers with findings of THC or a metabolite; 3 states have zero tolerance traffic laws for THC but no restriction on metabolites; 6 states have specific *per se* limits indicating impairment while driving for THC (ranging from 1 nanogram per milliliter [ng/mL] to 5 ng/mL), and 1 state (Colorado) has a reasonable inference law for THC set at 5 ng/mL. New York State does not have marijuana specific driving laws. However, New York State Traffic laws prohibits driving while impaired by any drug or alcohol.

⁴ DOJ. DEA. 2017. Drugs of Abuse. A DEA Resource Guide 2017 Edition. https://www.dea.gov/sites/default/files/2018-06/drug_of_abuse.pdf

² U.S. Department of Justice (DOJ), Drug Enforcement Administration (DEA), Office of Diversion Control, http://www.deadiversion.usdoj.gov/21cfr/21usc/812.htm.

³ New York State Medical Marijuana Program Laws and Regulations.

https://www.health.ny.gov/regulations/medical marijuana/regulations.htm Accessed 12/10/2018

⁴ DOLDEA 2017 Drugs of Abuse A DEA Resource Guide 2017 Edition

⁵ Governors Highway Safety Association, Drug Impaired Driving Issues https://www.ghsa.org/state-laws/issues/drug%20impaired%20driving Accessed 3/10/2020.

⁶ New York State Vehicle & Traffic Law §1192. https://www.nycourts.gov/judges/cji/3-VTL/ocind.shtml

At the Federal level, the U.S. Department of Transportation (DOT) has a longstanding regulation prohibiting the use of recreational or medical marijuana by safety-sensitive transportation employees – pilots, school bus drivers, truck drivers, train engineers, subway operators, aircraft maintenance personnel, transit fire-armed security personnel, ship captains, and pipeline emergency response personnel, among others. Further, the DOT does not authorize "medical marijuana" under a state law to be a valid medical explanation for a transportation employee's positive drug test result.⁷

D. DETAILS OF INVESTIGATION

1. Purpose

This investigation was performed to evaluate the driver involved in this accident for medical conditions, the use of medications/illicit drugs, and the presence of toxins.

2. Methods

The following records were reviewed: the limousine driver's personal medical records, pharmacy records, FMCSA commercial driver's license medical examinations, toxicology report, and death certificate. Other pertinent scientific and regulatory issues were reviewed.

3. Findings – Limousine Driver

3.1 Personal Medical Records

Primary care provider records from January 22, 2016 through January 19, 2018 were reviewed. The 53-year-old male limousine driver's active medical conditions included attention deficit hyperactivity disorder (ADHD) and bipolar I disorder. He had a history of cocaine and marijuana use and a 48-hour voluntary inpatient admission for an exacerbation of psychiatric symptoms in February 2017. Additionally, he had a history of right hip arthritis successfully treated with a total hip replacement in July 2017. He was also being treated for elevated cholesterol and gastric reflux.

On his latest medical examination performed by his primary care provider dated December 18, 2017 he was 5 feet 10 inches tall and he weighed 185 pounds. His physical examination was unremarkable with no neurologic or motor deficits. A limited psychiatric examination documented normal mood and affect with good judgment. Additionally, the primary care provider documented the driver was followed monthly for his bipolar disorder; those records were not available to the investigation. An orthopedic evaluation on January 18, 2018, six months after right total hip surgery, found no motor or neurologic deficits and no limitations.

<u>Information Regarding Psychiatric Conditions</u>

Attention deficit hyperactivity disorder (ADHD)

ADHD is associated with deficits in attention and susceptibility to distraction and with impulsivity and impairments in motor inhibition, reaction time, visual-motor coordination, executive functioning, decision-making, and rule-governed behavior

⁷ U.S. Department of Transportation, DOT "Medical Marijuana" Notice (10/22/2009), Updated 11/19/2019. https://www.transportation.gov/odapc/medical-marijuana-notice.

⁸ Detailed psychiatric records were requested but due to state statutes were not released to the investigation.

that interfere with functioning. Adolescents and young adults with ADHD are two to four times more likely to have been the driver in a motor vehicle accident, have higher rates of moving violations, and are more likely to have had their license revoked or suspended than peers without the illness. 10,11,12,13 When involved in accidents, drivers diagnosed with ADHD are more likely to be the at-fault driver and tend to incur greater damage to their vehicles. The large majority of these driving studies did not differentiate between subjects with ADHD treated with medication and those that were not using medication. Results of a recent meta-analysis indicate there may be a beneficial effect of methylphenidate (and other medications for ADHD) on driving performance but the effect size remains unclear; medication does not appear to fully negate the safety hazards associated with the disorder. 14

Bipolar I Disorder

Bipolar I disorder, or manic-depressive disorder is a mood disorder characterized by manic or hypomanic episode(s) which can include abnormally elevated, expansive, or irritable mood, flight of idea and may include excessive involvement in activities that have a high potential for painful consequences. The manic or hypomanic episodes may be preceded by or followed by a major depressive episode(s) which can manifest in the loss of interest or pleasure in nearly all activities. Additionally, depressive symptoms include changes in weight, sleep, and psychomotor activity, decreased energy, feeling of worthlessness or guilt, difficulty thinking, concentrating, or making decisions and may include thoughts of death or suicidal ideations. Major depression itself is associated with significant cognitive degradation, particularly in executive functioning. 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. 17,18

⁹ American Psychiatric Association. 2013. *Diagnostic and statistical manual of mental disorders* (5th ed.). Arlington, VA: American Psychiatric Publishing.

¹⁰ Barkley, RA et al. 1993. Driving-related risks and outcomes of attention deficit hyperactivity disorder in adolescents and young adults: A 3–5 year follow-up survey. *Pediatrics*. 113: 212–218.

¹¹ Murphy, K, and Barkley, RA. 1996. ADHD in adults: Comorbidities and adaptive impairments. *Comprehensive Psychiatry*. 37: 393–401.

¹² Barkley, RA et al. 1996. Motor vehicle driving performance and risks in young adults with ADHD. *Pediatrics*. 98: 1089–1095.

¹³ Aduen PA, et al. 2015. Motor vehicle driving in high incidence psychiatric disability: comparison of drivers with ADHD, depression, and no known psychopathology. *J Psychiatr Res.* 64:59-66.

¹⁴ Gobbo MA, and Louzã MR. 2014. Influence of stimulant and non-stimulant drug treatment on driving performance in patients with attention deficit hyperactivity disorder: a systematic review. *Eur Neuropsychopharmacol*. 24(9):1425-43.

¹⁵ American Psychiatric Association. 2013. *Diagnostic and statistical manual of mental disorders* (5th ed.). Arlington, VA: American Psychiatric Publishing.

¹⁶ Snyder H. 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.

¹⁷ Nakano Y, et al. 2018. Executive dysfunction in medicated, remitted state of major depression. *J Affect Disord*. 111(1):46-51.

¹⁸ Paelecke-Habermann Y, et al. 2005. Attention and executive functions in remitted major depression patients. *J Affect Disord*. 89(1-3):125-135.

3.2 Pharmacy records

Pharmacy records from October 9, 2016 to October 9, 2018 were reviewed. Table 1 contains the medications that were regularly refilled in 2018.

Table 1. Medications Regularly Refilled in 2018.

Drug / strength / # filled	First filled	Last filled	Indications
Aripiprazole 10 mg #30	12/16	09/18/18	Schizophrenia, bipolar
			disorder, depression
Bupropion SR 200 mg #30	5/18	09/14/18	Major depression
Oxcarbazepine 300 mg #60	10/16	10/02/18	Partial seizures, bipolar
			disorder (off label)
Famotidine 20 mg #60	10/16	09/07/18	Gastroesophageal reflux
Atorvastatin 10 mg #30	10/16	06/12/18	High cholesterol

Information Regarding Prescribed Medications

Aripiprazole, commonly marketed as Abilify, is a psychoactive prescription medication, is indicated in the treatment of schizophrenia and manic episodes associated with bipolar disease. Aripiprazole is a central nervous system depressant and may have the potential to impair judgment, thinking, or motor skills. It carries the following warning, "Despite the relatively modest increased incidence of these events (somnolence) compared to placebo, patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that therapy with aripiprazole does not affect them adversely." ¹⁹

Bupropion, commonly marketed as Wellbutrin, is a prescription antidepressant medication. Its drug information warns of a dose dependent risk of seizures and advises patients not to drive or use heavy machinery until the medication's effects are known.²⁰

Oxcarbazepine, commonly marketed as Trileptal, is a prescription antiepileptic drug that is also used to treat bipolar disorder. It has the potential to impair psychomotor skills, thinking and speech, it may cause sleepiness or fatigue and may affect coordination. It carries the following warning. "Patients should be monitored for these signs and symptoms and advised not to drive or operate machinery until they have gained experience on [oxcarbazepine] to gage whether it adversely affects their ability to drive of operate machinery."²¹

¹⁹ National Institutes of Health (NIH). U.S. National Library of Medicine (NLM). *DailyMed*, Aripiprazole. Updated 8/27/19. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=569f1c32-fb6f-c34f-0894-4b1e7b744a8a.

NIH. NLM. *DailyMed*, Wellbutrin - bupropion. Updated 8/11/17.
 https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=cbc8c074-f080-4489-a5ae-207b5fadeba3.
 NIH. NLM. *DailyMed*, Oxcarbazepine. Updated 8/8/14.
 https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=17325a80-fb9c-4a83-b4b4-98e0b999d852.

Famotidine, commonly marketed as Pepcid, is used to treat heart burn.²² Atorvastatin, commonly marketed as Lipitor, is used to treat elevated cholesterol.²³ Both medications are generally not considered to be impairing.

3.3 Commercial Driver's License Medical Examination

The limousine driver's most recent examination, dated September 6, 2017, documented his height as 5 feet 10 inches and weight as 188 pounds. The driver reported taking no prescription or over-the-counter medications, herbal remedies, or dietary supplements. He reported a hernia repair in 2010 and a right hip replacement now with full strength and range of motion. The driver marked "NO" to following questions: "Do you have or have you ever had: 14) anxiety, depression, nervousness, other mental health problems; 27) Have you ever spent the night in a hospital; and 31) Have you used illegal an substance in the past two years?" He also responded "NO" to having high blood pressure, high cholesterol, and stomach problems.

The examining certified medical examiner, an advanced practice nurse, documented the driver's visual acuity corrected to 20/20 with 80 degree field of vision in each eye. No abnormalities were documented in the physical exam; specifically, the driver had normal extremities/joints, neurological system including reflexes, and gait. The examiner recorded the driver met the requirements established by 49 CFR 391.41 and qualified him for 2 years with a requirement to wear corrective lenses.

3.4 Toxicology

Postmortem toxicological testing was conducted by the Federal Aviation Administration (FAA) Forensic Sciences laboratory.²⁴ Blood samples were not available for testing. No ethanol was detected in muscle or brain. Testing detected marijuana's primary psychoactive chemical deta-9-tetrahydrocannabinol (THC) in bile, gastric, kidney, brain, spleen, muscle, lung, liver, and heart. THC's most prominent equipotent psychoactive metabolite 11-hydroxy-delta-9-THC (11-OH-THC) was detected in bile, kidney, brain, spleen, heart, and liver. THC's inactive metabolite carboxy-delta-9-THC (THC-COOH) was detected in bile, kidney, brain, spleen, lung, muscle, heart, and liver. The antidepressant bupropion, its metabolite hydroxybupropion, the antiepileptic/bipolar disorder medication oxcarbazepine, and the heart burn medication famotidine were detected in liver and muscle.

Information Regarding Drugs Detected on Toxicology

THC is the primary psychoactive chemical in the marijuana plant (*Cannabis sativa*) with reported therapeutic levels as low as 1.00 ng/mL.²⁵ THC has multiple effects on the central nervous system (CNS) including distorted perception, euphoria, difficulty

²² NIH. NLM. *DailyMed*. Famotidine. Updated 11/16/17.

https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=653c165e-3e22-4796-b170-cc87547574c4.

²³ NIH. NLM. *DailyMed*, Atorvastatin. Updated 5/6/19.

https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4d7150a0-9593-46ab-b8a2-8f6fe0e483b6.

²⁴ The FAA Forensic Sciences Laboratory tests for more than 1,300 substances including toxins, common prescription and over-the-counter medications and illicit drugs. http://jag.cami.jccbi.gov/toxicology/. FAA. Updated 1/16/19. Forensic Toxicology Drug Information. Marijuana.

http://jag.cami.jccbi.gov/toxicology/DrugDetail.asp?did=154

thinking, impaired psychomotor performance, and CNS depression. Specific performance effects include decreased ability to concentrate and maintain attention. Impairment in retention time and tracking, subjective sleepiness, distortion of time and distance, vigilance, and loss of coordination in divided attention tasks have been reported.²⁶

THC is rapidly metabolized, but the rate of metabolism is not linear. THC is fat soluble, so is stored in fatty tissues and can be released back into the blood long after consumption. There are two primary metabolites of THC, the psychoactive metabolite 11-OH-THC and the inactive (non-psychoactive) metabolite THC-COOH. Concentrations of the parent drug THC and metabolites are very dependent on pattern of use as well as dose. Concentrations vary depending on the potency of marijuana and the way the drug is used; however, peak plasma concentrations of THC of 100-200 ng/mL are routinely encountered shortly after smoking. Plasma concentrations of THC decline rapidly and are often less than 5.00 ng/mL at 3 hours. THC-COOH can be detectable in plasma up to 2-7 days. In driving under the influence cases, blood is generally not collected until 1.5 to 4 hours after the incident and the time from last THC intake is often unknown. While the half-life of THC varies significantly based on frequency of use and body habitus, controlled studies demonstrate that detectable THC blood levels decrease by an average of 90.3% from its maximum level within 1.4 hours of last use. ^{27,28,29} Most behavioral and physiological effects return to baseline levels within 3-5 hours after drug use, although some studies have demonstrated residual effects up to 24 hours in specific behaviors such as complex divided attention tasks. In long term users, even after periods of abstinence, selective attention (ability to filter out irrelevant information) has been shown to be adversely affected with increasing duration of use, and speed of information processing has been shown to be impaired with increasing frequency of use. 30 Furthermore, studies of the effects of cannabis on driving found drivers with an average THC levels of 13.0 ng/mL demonstrated lane weaving similar to that of drivers with a breath alcohol of 0.08 grams per 210 liters (blood alcohol of about 0.08%). According to drug interaction information, THC may enhance the CNS depressant effect of other CNS depressants including aripiprazole.³²

Information on bupropion, oxcarbazepine, and famotidine were provided previously.

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²⁶ Compton, R. July 2017. Marijuana-Impaired Driving - A Report to Congress. (DOT HS 812 440). Washington, DC: National Highway Traffic Safety Administration. https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/812440-marijuana-impaired-driving-report-to-congress.pdf

²⁷ *Ibid.* Compton, R. July 2017.

²⁸ Baselt RC (ed). 2014. Disposition of Toxic Drugs and Chemicals in Man, 10th Edition. Tetrahydrocannabinol. Pages 1948-1952. Biomedical Publications, Seal Beach, California.

²⁹ Hartman RL et al. 2016. Effect of blood collection time on measured Δ9-tetrahydrocannabinol concentrations: Implications for driving interpretation and drug policy. *Clin Chem* 2016; 62:2: 367–377.

³⁰ National Highway Traffic Safety Administration. April 2014. Drugs and Human Performance Fact Sheets. Cannabis/Marijuana. https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/809725-drugshumanperformfs.pdf

³¹ Hartman RL et al. 2015. Cannabis effects on driving lateral control with and without alcohol. *Drug Alcohol Depend*. 154: 25–37.

³² Wolters Kluwer Clinical Drug Information UpToDate, 2018, Lexicomp Drug Interactions.

3.4 Death Certificate

Attempts to obtain the autopsy report performed for the Schoharie County Coroner, Middleburg, NY were unsuccessful; no autopsy report was received as of March 10, 2020. However, according to the death certificate issued by the New York State Department of Health, the immediate cause of the limousine driver's death was multiple severe traumatic blunt force injuries and the manner of death was accident. The interval between onset and death was immediate.

E. SUMMARY OF MEDICAL FINDINGS

The 53-year-old male limousine driver had a history of a right hip replacement, attention deficit hyperactivity disorder, bipolar I disorder, high cholesterol, and gastric reflux controlled with diet and medication.

The death certificate reported the immediate cause of death was multiple severe traumatic blunt force injuries and the manner of death was accident.

Forensic toxicology detected marijuana's potent potentially impairing psychoactive compound deta-9-THC, its active metabolite 11-hydroxy-delta-9-THC, and its inactive metabolite carboxy-delta-9-THC in multiple tissues. Additionally, the heart burn medication famotidine and the antiepileptic / bipolar disorder medication oxcarbazepine were detected