



DEPARTMENT OF TRANSPORTATION

[4910-EX-P]

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2014-0373]

Qualification of Drivers; Exemption Applications; Narcolepsy

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of denial of exemption applications

SUMMARY: FMCSA announces its decision to deny applications from three individuals seeking exemptions from the prohibitions against operating a commercial motor vehicle (CMV) in interstate commerce by persons with: (1) either a clinical diagnosis of epilepsy or any other condition that is likely to cause a loss of consciousness or any loss of ability to operate a CMV safely, or (2) a mental, nervous, organic, or functional disease or psychiatric disorder likely to interfere with his/her ability to drive a commercial motor vehicle safely. FMCSA has statutory authority to exempt individuals from certain parts of the Federal Motor Carrier Safety Regulations, if the exemptions granted will not compromise safety. The Agency must conclude that granting these exemptions provides a level of safety that will be equivalent to or greater than the level of safety maintained without the exemptions for these CMV drivers. Based on a review of the applications and following an opportunity for public comment, FMCSA has concluded that the individuals did not demonstrate that they could achieve a level of safety that is equivalent to, or greater than, the level of safety that would be obtained by complying with the regulation.

DATES: This decision is effective July 24, 2015.

FOR FURTHER INFORMATION CONTACT: Charles A. Horan III, Director, Office of Carrier, Driver and Vehicle Safety Standards, (202) 366-4001, or via email at fmcsamedical@dot.gov, or by letter FMCSA, Room W64-224, Department of Transportation, 1200 New Jersey Avenue, S.E., Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds “such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.” FMCSA can renew exemptions at the end of each 2-year period. The three individuals listed in this notice have each requested such an exemption from the physical qualification requirements in 49 CFR 391.41(b)(8) and(b) (9), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency evaluates the qualifications of each applicant to determine whether granting an exemption will achieve the required level of safety mandated by statute.

Narcolepsy is a chronic neurological disorder caused by autoimmune destruction of hypocretin-producing neurons inhibiting the brain's ability to regulate sleep-wake cycles normally. Persons with narcolepsy experience frequent excessive daytime sleepiness, comparable to how non-narcoleptics feel after 24 to 48 hours of sleep deprivation, as well as disturbed nocturnal sleep, which often is confused with insomnia.

See NIH Narcolepsy Fact Sheet at

www.ninds.nih.gov/disorders/narcolepsy/detail_narcolepsy.htm.

The Agency considered the topic of narcolepsy and the potential impact on commercial drivers in a 2009 Evidence Report. The Evidence Report “Narcolepsy (with and without cataplexy) and Commercial Motor Vehicle Driver Safety” addressed several key questions¹.

Key Question 1: Are individuals with narcolepsy (with and without cataplexy) at an increased risk for a motor vehicle crash when compared to comparable individuals without the disorder?

Key Question 2: Do currently recommended treatments for narcolepsy reduce the risk for a motor vehicle crash?

Key question 2 was further divided into several questions concerning the impact of various medication therapies for narcolepsy on driver safety. The complete report is included in the docket FMCSA 2014-0373.

The evidence report reviewed studies from the available literature and evaluated outcomes on measures of Excessive Daytime Sleepiness (EDS), cataplexy, event rate, measures of cognitive and psychomotor function, and driving performance. For key question 1, the currently available evidence (both direct and indirect) supports the contention that drivers with narcolepsy are at an increased risk for a motor vehicle crash when compared to otherwise similar individuals who do not have the disorder. The strength of the evidence was rated as strong. The direct evidence (from three crash studies) (study quality rating of “Low”) conducted with non-CMV drivers showed that individuals with narcolepsy are at an increased risk for a crash compared to individuals who do not have narcolepsy. The indirect evidence (studies of driving tests and driving simulation, quality rating “moderate”), examined factors associated with simulated driving outcomes, (driving performance, tracking

¹ Evidence Report: Narcolepsy (with and without cataplexy) and Commercial Motor Vehicle Driver Safety; October 6, 2009

error, fewer correct responses and more instances of going out of bounds compared to healthy controls). In summary, while there are limitations in the quality of the studies that examined direct crash risk in the evidence base, all study results showed a strong effect size and statistical significance. Indirect evidence of crash provides strong support for the direct crash study findings. Based upon available information, there is strong evidence that non-commercial drivers with narcolepsy are at an increased risk of crash.

Concerning key question 2 and its sub-questions, the American Academy of Sleep Medicine (AASM) and the European Federation of Neurological Societies recommend modafinil as the first-line of treatment and methylphenidate as the second-line of treatment. The AASM also recommends amphetamine, methamphetamine, or dextroamphetamine as alternative second –line treatments. No studies that directly examined the impact of treatment with modafinil, armodafinil, sodium oxybate (used with narcolepsy with cataplexy), or antidepressants on crash risk or driving performance were identified during the literature searches. Evidence-based conclusions pertaining to treatment with these medications on crash risk and driving performance could not be drawn.

Currently available evidence suggests that amphetamines and/or methylphenidate are effective in improving symptoms of EDS in individuals with narcolepsy (quality of studies range from “moderate to low”). However, these improvements do not result in levels of daytime sleepiness that can be considered to be normal in the vast majority of individuals. Evidence-based conclusions pertaining to the impact of treatment with amphetamines, methylphenidate, or other related stimulant drugs on cognitive and psychomotor function among individuals with narcolepsy cannot be drawn at this time.

In January 2010, the FMCSA's Medical Review Board (MRB) recommended that individuals with narcolepsy be ineligible for a commercial driver's license, even with treatment.²

Discussion of Public Comments

The FMCSA published the names of three individuals seeking exemption in a Federal Register Notice, on April 17, 2015, and requested public comment. The public comment period closed on May 18, 2015. A total of 17 commenters responded. The majority of commenters were in favor of the applicants continuing to drive CMV's with Narcolepsy. Fourteen commenters consisting mainly of private citizens stated that the individual drivers listed in the notice were responsible drivers, were stable and compliant with their medication therapy, had safe driving histories, and believed that the individuals would continue to be safe drivers while on medication. The State of New York's medical consultants reviewed the docket and suggested that drivers with narcolepsy be allowed to operate commercially only if they have been treated medically and have been event-free for at least one year. Three commenters did not support exemption for drivers with narcolepsy. One anonymous commenter encouraged the FMCSA not to grant exemptions to these individuals due to concerns of the high risk of the underlying medical condition in combination with operating a large CMV.

FMCSA Response

To evaluate the effects of these exemption requests on safety, FMCSA reviewed and considered the content of each request individually and all comments received.

² Medical Review Board Meeting; January 6, 2010;
http://www.mrb.fmcsa.dot.gov/documents/Final_Jan_6_2010_MRB_Meeting_Summary.pdf

FMCSA acknowledges comments received attesting that individual applicants are responsible drivers currently on a stable therapeutic regimen which includes medication therapy. The Agency considered available medical and scientific data concerning medication therapy for narcolepsy. As discussed in the background section of this notice, evidence-based conclusions pertaining to treatment with medications on crash risk and driving performance could not be drawn.

Concerning ATAs comments recommending granting fewer exemptions and revising the current medical standards, FMCSA acknowledges ATA's concerns. The FMCSA has statutory authority (49 U.S.C. 31136(e) and 31315), to consider granting exemptions from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds "such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption." The FMCSA reviews its medical standards through the use of evidence reports, various medical expert panels and the Agency's Medical Review Board and proposes evidence-based revisions to the medical standards through the rulemaking process which takes a considerable length of time.

The exemption process is the Agency's most viable alternative in the short term to consider whether drivers with disqualifying medical conditions and who are found to meet an equivalent level of safety, should be permitted to operate in interstate commerce.

Conclusion

FMCSA evaluated the three individual exemption requests on their merits and available data from FMCSA's Evidence Reports, the Medical Review Board recommendations and public comments received. The Agency has determined that the available medical and scientific literature and research provides insufficient data to

enable the Agency to conclude that granting the exemptions would achieve a level of safety equivalent to or greater than the level of safety maintained without the exemption. Each applicant has, prior to this notice, received a letter of final disposition on his/her exemption request. Those decision letters outlined fully the basis for the denial and

constitute final Agency action. The list published today summarizes the Agency's recent denials as required under 49 U.S.C. 31315(b)(4).

The following three applicants are denied exemptions from the physical qualification standards in [49 CFR 391.41(b)(8)] and [49 CFR 391.41(b)(9)]:

Thomas Skagen, Charles Larry Peterson, and Stanley Jandreau

Issued on: August 3, 2015

Larry W. Minor
Associate Administrator for Policy

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