

WHITE PAPER The Truth about Obstructive Sleep Apnea

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Introduction

On March 10, 2016, the Federal Motor Carrier Safety Administration (FMCSA) published a joint advance notice of proposed rulemaking (ANPRM) with the Federal Railroad Administration to gather various data and information concerning the prevalence of moderate-to-severe obstructive sleep apnea (OSA) among individuals who occupy safety sensitive positions in highway and rail transportation and its potential effects on safety. The agencies also requested information on possible costs and benefits that would be incurred if they were to move forward with possible regulatory action.

In the joint ANPRM, the agencies define OSA as "a respiratory disorder characterized by a reduction or cessation of breathing during sleep. OSA is characterized by repeated episodes of upper airway collapse in the region of the upper throat (pharynx) that results in intermittent periods of partial airflow obstruction (hypopneas), complete airflow obstruction (apneas), and respiratory effort-related arousals from sleep (RERAs) in which affected individuals awaken partially and may experience gasping and choking as they struggle to breathe.¹" Mild OSA is generally defined by an apnea-hypopnea index (AHI) between 5 and 15, while moderate-to-severe OSA is designated by an AHI of 15 or greater.

According to a bulletin released by FMCSA in January 2015 to certified medical examiners (CMEs), the Agency believes that "OSA may culminate in unpredictable and sudden incapacitation (e.g., falling asleep at the wheel), thus contributing to the potential for crashes, injuries, and fatalities," and that "OSA raises health and safety concerns beyond those of other sleep disorders. Near-term increases in fatigue and cognitive dysfunction can result. Also, there are long-term adverse health effects such as dramatically increased risk for hypertension, heart disease, stroke, diabetes, and obesity.²" In fact, many proponents of mandatory OSA screening for truck drivers with a body mass index (BMI) of 35 or greater, often refer to a statement released by an international group of scientists which proclaims that fatigue causes between 15 to 20 percent of all large truck accidents. It is important to note however that the document is not exclusive to only truck drivers but also includes commercial operations in the air, at sea, and on railways.³

Regardless, both FMCSA and proponents of OSA screening fail to recognize that sleep apnea is not a new disorder, but a condition that has affected millions of people over several decades and yet there has not been the carnage and devastation on our roadways that FMCSA would have us believe is inevitable without stricter mandatory OSA screening regulations. FMCSA's own studies in particular have found that there is "no link between the severity of sleep apnea and traffic crashes.⁴" Moreover, while FMCSA

¹ Evaluation of Safety Sensitive Personnel for Moderate-to-Severe Obstructive Sleep Apnea, FMCSA-2015-0419 and FRA-2015-0111 (March 2016).

² "FMCSA Bulletin to Medical Examiners and Training Organizations Regarding Obstructive Sleep Apnea," FMCSA (Jan 2015).

³ T Akerstedt, "Consensus Statement: fatigue and accidents in transport operations," *J. Sleep Res* (2000) 9, 395, <u>https://www.researchgate.net/publication/12204395_Consensus_Statement_Fatigue_and_accidents_in_transport</u> operations

⁴ Lawrence C. Barr et al., *Sleep Apnea Crash Risk Study*, FMSCA (2004).

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and various organizations have attempted to correlate OSA with fatigue it is critical to understand that OSA is not necessarily related to fatigue as there are many factors which can cause and influence fatigue. The concept or the definition of fatigue is frequently misunderstood and it should be noted that there is no current consensus about what fatigue is or how it should be measured.

One possible definition provided by the Norwegian Centre for Transport Research explained that, "Fatigue is a suboptimal psychophysiological condition caused by exertion. The degree and dimensional character of the condition depends on the form, dynamics, and context of exertion. The context of exertion is described by the value and meaning of performance to the individual; rest and sleep history; circadian effects; psychosocial factors spanning work and home life; individual traits; diet; health; fitness and other individual states; and environmental conditions. The fatigue condition results in changes in strategies or resource use such that original levels of mental processing or physical activity are maintained or reduced.⁵" Thus, when considering the overarching term of fatigue, OSA only represents a small portion of the equation. This fact is reinforced by the Agency's own data concerning large truck and bus fatal crashes which demonstrates that the percent of fatal accidents involving truck drivers that are related to "asleep or fatigued" are very small. The following table was taken from FMCSA's *Large Truck and Bus Crash Facts* and effectively demonstrates that over the past four years, between 1.4 and 1.8 percent of large truck fatal crashes were related to fatigue.

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Impairment-	2011		2012		2013		2014	
Related Factors	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Asleep or Fatigued	64	1.8%	64	1.7%	56	1.4%	68	1.8%
Total Crashes	3,568	100.0%	3,774	100.0%	3,872	100.0%	3,697	100.0%

Table 1: Large Truck Fatal Crashes by Impairment-Related Factors

Source: Large Truck and Bus Crash Facts 2013 and Large Truck and Bus Crash Facts 2014

Irrespective of the facts, FMCSA, as well as others, continue to disseminate misperceptions and falsehoods concerning sleep apnea and its safety impacts in the trucking industry. Therefore, the OOIDA Foundation, Inc. (OOFI), which is the research and educational arm of the Owner-Operator Independent Drivers Association (OOIDA), the largest international non-profit association representing the interests of approximately 160,000 small business owners and professional truck drivers, presents the following known facts based on objective data that calls into question the assertions presented by FMCSA.

Myths of OSA and the Trucking Industry

As a result of a crash in which a truck driver collided with a Tennessee Highway Patrol vehicle in a construction zone on I-40 near Jackson, TN, the National Transportation Safety Board (NTSB) recommended in 2009 that FMCSA implement a program to identify drivers of commercial motor vehicles (CMVs) at high risk for OSA and require them to provide evidence of being appropriately

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⁵ Ross Owen Phillips, *What is fatigue and how does it affect the safety performance of human transport operators? Fatigue in Transport Report I,* Norwegian Centre for Transport Research (2014), pg. ii.

evaluated and, if necessary, receiving effective treatment.⁶ In response, FMCSA commenced work on Task 11-05 with the Motor Carrier Safety Advisory Committee (MCSAC) and the Medical Review Board (MRB) in 2011 to consider developing regulatory guidance for motor carriers, CMV drivers, and CMEs on sleep apnea and whether drivers with this condition should be medically certified to operate CMVs in interstate commerce.

Since the commencement of Task 11-05, FMCSA has released a joint ANPRM concerning OSA and has tasked the MRB to review comments of the rule from medical professionals and associations in order to both identify factors and to make recommendations that the Agency should consider. Other than economic interests from the sleep industry, the primary push for mandatory OSA screening and subsequent treatment is based upon the premise that there is a relationship between sleep apnea and crashes. In the ANPRM, the agencies posed a question about "the number of historical motor carrier or train accidents caused by OSA," but there may in fact be no accidents that have been *caused* by OSA. While the agencies presented four different accidents which were investigated by NTSB in the ANPRM, it is impossible to determine that these crashes were in fact caused by sleep apnea.

In the single accident that involved a CMV, namely the Jackson, TN crash, NTSB determined, "that the probable cause of this accident was the driver's incapacitation, owing to the failure of the medical certification process to detect and remove a medically unfit driver from service." Although the truck driver was shown to have sleep apnea, as well as hypothyroidism, a condition which can cause fatigue, lethargy, and, over time, a slowing of intellectual and motor activity, there is no method that can determine that the driver was incapacitated because of either OSA or hypothyroidism. Instead, the NTSB can only make the *assumption* that the driver's sleep apnea contributed to the crash, as FMCSA's own data demonstrates that there is no relationship between drivers with OSA and crashes.

In 2004, FMCSA released a study entitled *Sleep Apnea Crash Risk Study* in order to (1) obtain additional and more meaningful crash data by linking a sleep apnea database to the Motor Carrier Management Information System crash database; (2) understand the impact of sleep apnea and driver impairment on crash involvement, the number of crashes, and the severity of crashes; and (3) gain insight into how crash rates are impacted before and after drivers are diagnosed with sleep apnea.⁷ The study, "found no association between sleep apnea, as measured by the apnea/hypopnea index, and commercial motor vehicle crashes. Patients with sleep apnea had no greater probability of having a crash than patients without sleep apnea, either before or after their diagnosis. Drivers with sleep apnea were also not found to be at an increased risk for multiple crashes, nor were crash rates impacted by the prevalence of apnea. No link between the severity of sleep apnea and traffic crashes was established in these analyses.⁸"

In a Federal Aviation Administration (FAA) press release concerning sleep apnea, the NTSB determined that OSA was a contributing factor in the 2008 Mesa Airlines Flight 1002 incident. During the incident,

⁶ NTSB Safety Recommendation H-09-15 and -16, NTSB (2009)

⁷ Sleep Apnea Crash Risk Study.

⁸ Ibid.

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both the captain and the first officer fell asleep during the flight and flew 26 miles past their destination and did not respond to air traffic controllers for more than 18 minutes. The captain was later found to have undiagnosed severe OSA.⁹ However, the first officer, who also fell asleep, was not diagnosed with OSA. Additionally, another FAA pamphlet stated that the flight crew's schedule, which included several days of early-morning start times, also played a contributing role in the incident.¹⁰

While the NTSB database concerning airplane crashes listed 34 accidents where sleep apnea was mentioned in the pilot's medical history, sleep apnea was not listed as "causal" or "contributory" in any of those accidents.¹¹ This further demonstrates the lack of any evidence to support the assertion that OSA is directly linked to a causal relationship to crashes.

The Prevalence of OSA among Truck Drivers

Perhaps one of the greatest myths circulated today concerning sleep apnea is that truck drivers, and thereby the trucking industry as a whole, are more prone to be diagnosed with OSA. In a recent article on National Public Radio, it was stated that although 10 to 25 percent of Americans may have sleep apnea, "the sleep disorder is much more common in train operators, and especially so in truck drivers.¹²" Dr. Steven Burks estimated that 17 to 28 percent of the approximately 1.7 to 3.9 million active CMV drivers have OSA with the majority of the drivers thought to be undiagnosed and untreated.¹³

It is difficult however to attribute much accuracy to either of these figures as the prevalence of OSA among the general adult population varies depending on which research is studied and it is difficult to discern what level of OSA those individuals experienced. The American Academy of Sleep Medicine states, "It is now estimated that 26 percent of adults between the ages of 30 and 70 years have sleep apnea.¹⁴" While the American Thoracic Society found, "The prevalence of obstructive sleep apnea associated with accompanying daytime sleepiness is approximately 3 to 7% for adult men and 2 to 5% for adult women in the general population.¹⁵" Thus it is evident that these two well-known and respected academic groups have very different views of the pervasiveness of OSA.

When considering the prevalence of sleep apnea among truck drivers, it is important to note FMCSA's 2002 study conducted by the University of Pennsylvania (UPenn) which found that the prevalence rate

⁹ Fact Sheet – Sleep Apnea in Aviation," Federal Aviation Administration (2015), <u>https://www.faa.gov/news/fact_sheets/news_story.cfm?newsld=18156</u>.

¹⁰ "Obstructive Sleep Apnea," Federal Aviation Administration,

http://www.faa.gov/pilots/safety/pilotsafetybrochures/media/Sleep_Apnea.pdf.

¹¹ "Fact Sheet – Sleep Apnea in Aviation."

¹² David Schaper, "Regulators Want Truckers, Train Operators Tested For Sleep Apnea," *NPR* (Dec 2016), <u>http://www.npr.org/2016/12/27/507142779/regulators-want-truckers-train-operators-tested-for-sleep-apnea</u>

¹³ Steven Burks et al., *Non-Adherence with Employer-Mandated Sleep Apnea Treatment and Increased Risk of Serious Truck Crashes*, University of Minnesota (2016), pg. 6.

¹⁴ "Rising prevalence of sleep apnea in U.S. threatens public health," American Academy of Sleep Medicine (Sept 2014), <u>http://www.aasmnet.org/articles.aspx?id=5043</u>

¹⁵ Naresh M. Punjabi, "The Epidemiology of Adult Obstructive Sleep Apnea," *American Thoracic Society*, Vol. 5, No. 2 (2008), pg. 136-143

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of OSA among commercial truck drivers was *similar* to the general population. The results of the study showed that 17.6 percent of commercial driver license (CDL) holders had mild sleep apnea, while 5.8 percent and 4.7 percent had moderate and severe OSA respectively.¹⁶ Nevertheless, this study is not without its limitations as the sample size for the UPenn study only included CDL holders, not all of whom were truck drivers, within a 50-mile radius of the university. This very well could have led to geographical bias and was not representative of the entire trucking industry.

According to the OOIDA Foundation's *2016 Owner-Operator Member Profile Survey* (2016 Survey), approximately 9 percent of owner-operators are currently receiving treatment for some level of sleep apnea, which would concur with other studies that estimate the prevalence of OSA within the general population to be around 3 to 7 percent.^{17, 18, 19, 20}

Drivers with OSA are Unsafe

As stated previously, FMCSA's own data and research demonstrates that there is no causal link between sleep apnea and CMV accidents, and yet it is frequently stated that between 7 and 20 percent of all large truck crashes are due to drowsy and fatigued driving which in turn is supposedly linked to OSA. This would equate to approximately 2,895 to 8,272 fatal crashes, 53,550 to 153,000 injury crashes, and 218,680 to 624,800 property damage only crashes between 2004 and 2014, or 275,125 to 786,000 total crashes within the ten year time span.²¹

According to OOFI's 2016 Survey however, the small sampling of owner-operators who are currently receiving treatment for OSA have a crash rate of 0.36 crashes per million vehicle miles traveled (MVMT), which is four times better than the national average of 1.47. OOFI's data effectively demonstrates that OSA has little, if any, connection with actual real-world safety performance as the average owner-operator with sleep apnea has over 2 million miles of accident free driving.

¹⁶ Allen Pack et al., A Study of Prevalence of Sleep Apnea among Commercial Truck Drivers: Tech Brief, FMCSA (2002).

¹⁷ "The Epidemiology of Adult Obstructive Sleep Apnea."

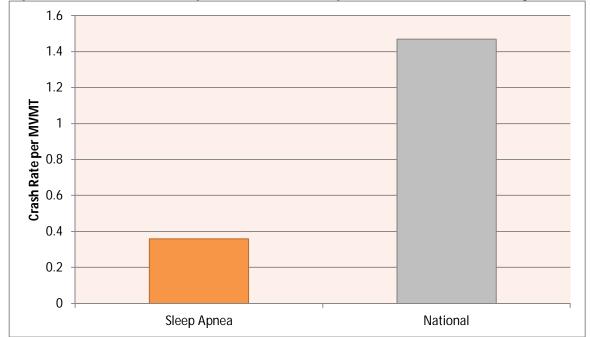
¹⁸ T. Young et al., "The occurrence of sleep-disordered breathing among middle-aged adults," *New England Journal of Medicine* (1993).

¹⁹ EO Bixler et al., "Effects of age on sleep apnea in men," American Journal of Respiratory and Critical Care (1998)

²⁰ EO Bixler et al., "Prevalence of sleep-disordered breathing in women: effects of gender," *American Journal of Respiratory and Critical Care Medicine* (2001).

²¹ Large Truck and Bus Crash Facts 2014, FMCSA (2016).

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Graph 1: Crash Rate of Owner-Operators with OSA compared with the National Average in MVMT

Treating OSA with CPAP

The MRB has recommended that only continuous positive airway pressure, or CPAP, should be prescribed to effectively treat truck drivers who have been diagnosed with sleep apnea, and that in order to be compliant, the driver must demonstrate at least four hours per night use on 70 percent of nights. Both research and the personal experience of truck drivers however indicate that for an individual to benefit from *effective* OSA treatment, that individual must first have OSA *and* have an elevated enough AHI to actually benefit from treatment. The potential benefits therefore are highly individualistic as documented by one OOIDA member who had an in-lab AHI test result of 9 (meaning mild OSA), but was still forced to utilize a CPAP device.²² The result was a decrease in restful sleep. The driver did not just express discomfort, but noted that for the entire four months that the CPAP was required, their sleep periods were absent of dreams, leaving the driver feeling tired. Dream sleep, or rapid eye movement (REM) sleep, is critical because it is the restorative part of our sleep cycle. Even a slight disruption in REM sleep can negatively affect an individual's circadian sleep cycle, which can cause grogginess, a lack of concentration, and fatigue. As soon as the driver stopped using the CPAP, he resumed restful and restorative sleep.

Drivers with mild sleep apnea are frequently prescribed a CPAP machine even though research indicates that treatment in such cases can create negative effects. The American Transportation Research Institute released a study in 2016 which found that 91 percent of truck drivers diagnosed with mild sleep apnea were prescribed CPAP treatment even when no regulations require that commercial drivers

²² OOIDA does not support any particular form of treatment, but many medical professionals require a driver to utilize a CPAP type device. CMEs are relying on the guidance of the FMCSA in making these medical recommendations.

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should be treated for mild OSA. The study also demonstrated that 46 percent of drivers who were diagnosed with mild OSA found CPAP treatment to be ineffective. Additionally, 43 percent reported that they slept less, while 26 percent indicated that they did not feel better when they woke.²³

Rather than prescribe a single form of treatment, such as a CPAP, it is important that a variety of treatment options are available to ensure that the most appropriate treatment necessary is matched to the individual. One of the primary catalysts for OSA being thrust into the forefront was the sudden and shocking death of NFL lineman Reggie White. Mr. White's wife, Sara White, said in a news article, "Reggie had tried conventional therapy to treat sleep apnea, which consists of wearing a facemask that delivers oxygen to the patient during the night. Reggie was unable to wear the facemask because he was claustrophobic. If Reggie would have known about oral appliances he might still be alive today.²⁴" One form of treatment cannot be held as the only standard for acceptable treatment of OSA. There are a variety of other treatment options besides a CPAP, as listed in the FAA's Pilot Safety Brochure on OSA,²⁵ including:

- Behavioral Changes, such as changing sleeping positions, changing the sleeping environment, such as lighting or mattress, and reducing body fat.
- Dental Appliances, which are noted as "an excellent treatment for mild-to-moderate OSA."
- Medications, such as nasal steroid sprays; which must be approved by the FAA.
- Surgical Methods including: Nasal airway surgery, Palate implants, Uvulopalatopharyngoplasty, Tongue reduction surgery, and Genioglossus advancement.

In an article in the *American Trucker*, sleep apnea expert and PhD Michael Decker was asked if CPAP was the only treatment option for sleep apnea. In response, Dr. Decker said, "No. There are others. It's very difficult for people to adapt to CPAP because it's blowing air into your face; it's like having a vacuum cleaner running in reverse connected to a mask attached to your face. It's very difficult to breathe against that. So many people are just unable to tolerate CPAP. They make an honest effort but they're just not able to adapt to that high pressure in their face. There are things like oral appliances and there are neurostimulators that work well."²⁶

One well-known and successful remedy of OSA is oral appliances. In FMCSA's 2012 guidance on OSA entitled "Proposed Recommendations on Obstructive Sleep Apnea," the Agency stated that there was no data to support the use of treatments other than CPAP devices; however the American Academy of Sleep Medicine rated oral appliances as a first choice for patients with mild to moderate sleep apnea in 2006. Dr. Winfried J. Randerath, Professor of Medicine at the Institute of Pneumology at the University of Witten/Herdecke, said that intra-oral appliances have been proven to reduce mild-to-moderate sleep apnea. Sleep medicine specialists from the Walter Reed National Military Medical Center (WRNMMC)

²⁶ Larry Kahaner, "Sleep apnea myths: What truckers (and regulators) should understand," *American Trucker* (Jan 2016) <u>http://trucker.com/trucker-jobs/sleep-apnea-myths-what-truckers-and-regulators-should-understand</u>.

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²³ Commercial Driver Perspectives on Obstructive Sleep Apnea, ATRI (May 2016).

²⁴ http://www.prnewswire.com/news-releases/sleep-apnea-ruled-a-factor-in-reggie-whites-death-56341032.html ²⁵ https://www.fac.acs//wileta/cafetu/pileta/fatu/pileta

²⁵ https://www.faa.gov/pilots/safety/pilotsafetybrochures/media/Sleep_Apnea.pdf

found in two studies that adjustable oral appliances were an effective first-line treatment and were nearly as effective as CPAP treatment.

Lt. Col. Christopher Lettieri, M.D., Chief of Sleep Medicine in Pulmonary, Critical Care and Sleep Medicine department at WRNMMC, and one of the studies' authors, said, "Historically, CPAP has been the primary treatment for OSA, but only half of patients tolerate this therapy, which requires wearing a face mask hooked to a machine each night. This new data offers a fresh look at adjustable oral appliances.²⁷"

In 2012, Virginian Tech Transportation Institute published a report entitled *Case Study on the Impact of Treating Sleep Apnea in Commercial Motor Vehicle Drivers*, which documented drawbacks with two large carriers' OSA programs (Schneider and J.B. Hunt). Drivers enrolled in the OSA programs stated that they experienced discomfort while sleeping with the CPAP device. Additionally, the drivers also complained of mask discomfort and the hassle with the constant cleaning and maintenance involved with the device. Other criticisms included mask leaks, delivery pressure discomfort, claustrophobia, movement restrictions while sleeping, morning congestion, and dry mouth.²⁸ Some drivers reported that CPAP treatment actually gave them less morning energy than they had before they began treatment.²⁹

While a CPAP machine is beneficial in some cases, it is not the only effective method of OSA treatment, and many drivers are unfortunately left unaware of other treatment options. It is also important to consider that "Fifty percent of patients with mild sleep apnea (those who experience anywhere from five to 15 events an hour) and 20 percent of people with moderate sleep apnea (15 to 30 events an hour) have positional sleep apnea.³⁰" Positional sleep apnea can be simply remedied with a variety of inexpensive products designed to depress supine sleeping.

How accurate is BMI as a Screening Tool for OSA?

Since the inception of the National Registry of Certified Medical Examiners ("Registry"), the practice of screening truck drivers for sleep apnea by utilizing a single risk factor, namely BMI, has become increasingly more common. Although BMI, which is a calculation of a person's weight divided by their height squared and multiplied by 705, is not a measure of a person's body fat, it is often used to compare what is considered healthy and what is thought to be overweight or obese.³¹ According to the MRB, a person who has a BMI indicating that they are overweight (25-29.9), obese (30-34.9), or extremely obese (35 or more), is more likely be diagnosed with OSA, thus they have suggested for BMI to be the key factor in determining if a truck driver should be tested.

http://www.thefreelibrary.com/U.S.+Army+Sleep+Apnea+Research+Suggests+Adjustable+Oral+Appliances...a0272994167 (accessed November 19, 2012)

 ²⁷ "U.S. Army Sleep Apnea Research Suggests Adjustable Oral Appliances are a Good First-Line Treatment Option,"
U.S. Army Medical Department (2011)

 ²⁸ J. Erin Mabry et al., Case Study on the Impact of Treating Sleep Apnea in Commercial Motor Vehicle Drivers: Sleep Apnea Programs from Two Leading U.S. Carriers and Focus Group Findings, VTTI (2012), pg. i, 11.
²⁹ Ibid., pg. 56.

³⁰ Science Daily, positional OSA treatment

³¹ Douglas M. Wiegand, *Commercial Motor Vehicle Health and Fatigue Study Final Report*, VTTI (Feb 2009), pg. 3 Owner-Operator Independent Drivers Association Foundation, Inc.

BMI was created by a Belgian statistician named Adolphe Quetelet, and has been in use for over 100 years, mainly because of its simplicity. It is important to note however that the measurement does not take into account a person's body composition, age, or gender. In fact, FMCSA released a study in 2004 which found that 30 percent of those who were diagnosed with OSA had a BMI less than 30, while almost 40 percent of those without OSA had a BMI greater than 30.³² Moreover, a study released by UCLA in 2016 concluded that BMI mislabels approximately 54 million Americans as overweight or obese. The lead author for the study stated, "This should be a final nail in the coffin for BMI. The public is used to hearing 'obesity,' and they mistakenly see it as a death sentence, but obesity is just a number based on BMI, and we think BMI is just a really crude and terrible indicator of someone's health.³³" The study also found that more than 30 percent of those with BMIs in the "normal" range (18.5-24.9), or about 20.7 million people, were actually unhealthy based on other health data, and more than 2 million people who were considered "very obese" by virtue of having a BMI of 35 or greater are actually healthy.³⁴ Hence, BMI should not be utilized as the only indicator for OSA screening, but rather instead CME's should use other comorbidity factors such as hypertension, diabetes, congestive heart failure, atrial fibrillation, etc.

Costs of a Potential Sleep Apnea Rule

In 2016, FMCSA and the FRA held three listening sessions concerning the possibility of promulgating a sleep apnea rule for their respective agencies. It was made evident during these listening sessions that some sleep specialists and proponents of mandatory OSA screening and treatment believed that such a rule would be relatively inexpensive for the trucking industry as some large carriers have already instituted OSA programs while others were believed to be covered by their qualified health insurance plan. The reality is however that 96 percent of the industry is comprised of small carriers who operate 20 trucks or less and who cannot afford such programs, while many others do not have a qualified health plan covered under the Affordable Care Act (ACA), thereby refuting the proponents' claims. It is also crucial to understand that for those individuals who do have an ACA plan, several do not have coverage for OSA screening and treatment.

According to the most recent MRB recommendations, an in-laboratory polysomnogram (PSG) should be the primary method of diagnosis, although there is some flexibility as to allowing at-home sleep tests which ensure chain of custody as well. The PSG is a study that monitors and measures a person's sleep cycle by recording their brain waves, blood oxygen levels, heart rate, eye movement, and muscle

³² Sleep Apnea Crash Risk Study

³³ Amina Khan, "BMI mislabels 54 million Americans as 'overweight' or 'obese,' study says," *Los Angeles Times* (Feb 4, 2016), <u>http://www.latimes.com/science/sciencenow/la-sci-sn-bmi-does-not-measure-health-20160204-story.html</u>

³⁴ Stuart Wolpert, "Don't use BMI to determine whether people are healthy, UCLA-led study says," UCLA Newsroom (Feb 4, 2016), <u>http://newsroom.ucla.edu/releases/dont-use-body-mass-index-to-determine-whether-people-are-healthy-ucla-led-study-says</u>

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activity, and may take between one or two nights to complete depending on the type of testing involved and if subsequent treatment is necessary.

A PSG can cost anywhere from \$600 to over \$7,000^{35, 36, 37} according to various medical websites, while an OOFI survey concerning medical examinations produced similar results as OOIDA members indicated that the test can also cost up to \$7,000. It is important to note however that at-home sleep studies, which cost significantly less and allow an individual to obtain a more natural rest period (i.e., not in a laboratory with a variety of sensors attached), have been proven to be accurate in diagnosing sleep apnea. In a study which included fifty-seven commercial driver's license holders, the National Institute for Occupational Safety and Health and the Centers for Disease Control discovered that an in-home abridged study was almost as accurate as a full sleep study in predicting severe OSA.³⁸

	Neck Circumference	BMI	Oximetry	In-home, Abridged Study	Full Sleep Study
AUC†	0.68	0.72	0.91	0.96	1
Number	57	57	57	57	57

Table 2: Usefulness of Screening Tools in Predicting Severe Apnea in 57 CDL Holders

†Area under receiver-operating characteristic curve 0.5 = poor, 1 = perfect

In addition to the PSG, the MRB has recently recommended that a CPAP device be the only acceptable method for treatment with minimal compliance consisting of at least 4 hours per day of use on 70 percent of days. Similar to a PSG, there are a variety of different CPAP machines which can cost anywhere from \$400 to \$5,000,³⁹ and before an individual is prescribed a CPAP, they must first undergo a titration study to determine the optimal CPAP pressure setting required to treat their OSA. The CPAP device itself requires continual maintenance, as filters, hoses, and masks eventually need to be replaced which increases the overall costs of the devices. It should also be noted that a supply of power is needed for the operation of a CPAP. This requires the purchase and installation of a power inverter or a 12 volt converter kit in order to utilize said device while on the road. This too increases cost.

It is also important to consider that the accessorial load placed on the truck's battery to power the CPAP device while a driver is sleeping requires the engine to be idled in order to avoid draining the batteries which could prevent the truck from starting. This problem is even more acute in the winter months and northern regions of the United States. This also incurs costs, primarily the direct cost of fuel to operate the engine as well as the additional maintenance cost to maintain an engine that is idled excessively. The issue of idling however is further complicated by a patchwork of State and local laws across the country which prevent trucks from idling. If an OSA rule was promulgated, drivers would often be left

³⁵ <u>http://www.sleepdisorders.com/qa/how-much-does-polysomnogram-cost</u>

³⁶ http://www.symptomfind.com/procedures-tests/polysomnography/

³⁷ http://clearhealthcosts.com/blog/2013/04/how-much-does-a-sleep-study-cost-well-600-or-5070/

³⁸ NIOSH/CDC R01 OH-009149-3

³⁹ <u>http://sleepapnealife.com/average-cost-of-cpap-machines-354.html</u>

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with the decision to either violate a regulation that requires them to utilize a CPAP or to violate a law that prohibits idling.

Another cost which is not often considered when examining mandatory sleep apnea screening and treatment is the lost opportunity cost incurred by the driver or motor carrier for being off the road in order to meet various medical appointments, such as the in-lab study or titration study. In some instances, a driver might be off the road for at least month, if not more, before they are finally cleared to operate again. It is critical to understand that truck drivers do not dictate their schedule in the vast majority of situations, as they are often at the mercy of numerous variables such as traffic, road conditions, or the time it takes to load or unload their trailer. This uncertainty requires a driver to plan for a wide berth of time in order to meet medical appointments. It is common for a driver to allow for an entire day off work when they "only" need time for one appointment. This leads to a significant amount of lost income and is only compounded with repeated visits.

The average owner-operator receives a net income between \$40,000 and \$50,000 per year; thereby they need to drive an average of 2,500 miles per week at \$1.45 to \$1.50 a mile in order to meet their net income. If an owner-operator is off work for even one day, they will lose over \$500, if they are off for one week, they will lose more than \$3,500. In the case of a professional employee driver or an owner-operator who is leased to a fleet, the motor carrier would also suffer costs due to the lost revenue.

For owner-operators, all the costs associated with screening, evaluation, and treatment of OSA will be directly borne by them, many of whom, as stated previously, do not have a health insurance plan that would pay for these costs, nor are they covered under the ACA. Unless a driver is able to visit their personal care physician to obtain a referral for sleep apnea testing, OSA screening and treatment are not covered by health insurance. This is of course assuming that the physician agrees that the driver has sufficient symptoms of OSA to even warrant the test. When this option is available and deductibles have been met, then insurance does cover testing and treatments to varying degrees, but not all costs are covered and not every time. When the driver is forced to use a specific CME, who then demands a specific testing facility be used, the driver will almost certainly end up covering all the costs out of pocket.

Overall, 30 percent of owner-operators do not have medical coverage and for those that do, 64 percent have medical policies which do not cover sleep apnea expenses.⁴⁰ The American Transportation Research Institute (ATRI) released a study which documented that drivers without health care incurred out-of-pocket costs exceeding \$1,000, some even reporting out-of-pocket costs over \$6,000.⁴¹

The MRB has recommended that individuals with a BMI of 33 or greater, who also demonstrate at least three or more of the following should be referred for diagnostic sleep evaluations: (1) hypertension (treated or untreated); (2) type 2 diabetes (treated or untreated); (3) history of stroke, coronary artery disease, or arrhythmias; (4) micrognathia or retrognathia; (5) loud snoring; (6) witnessed apneas; (7) small airway (Mallampati Classification of Class III or IV); (8) neck size greater than 17 inches for males

⁴⁰ 2016 Owner-Operator Member Profile Survey, OOIDA Foundation (2016).

⁴¹ Commercial Driver Perspectives on Obstructive Sleep Apnea

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and 15.5 inches for female; (9) hypothyroidism (untreated); (10) age 42 and above; or (11) male or postmenopausal female. Although the MRB ultimately decided to utilize more than just BMI to screen for OSA, two of the eleven factors, namely age and sex, are almost a given as a vast majority of the trucking industry is comprised of men who are over fifty years old.

The 2016 Member Profile Survey indicated that 27 percent of owner-operators have a BMI of 33 or greater, while 24 percent of professional employee drivers have BMI of 33 or greater. According to the FMCSA's *Final Rule Regulatory Evaluation of National Registry of Certified Examiners*, there are 4 million drivers that are required to undergo a medical examination. If a conservative 26 percent of all truck drivers had a BMI of 33 along with at least three other factors recommend by the MRB, which would require them to undergo a PSG, it would cost the trucking industry between \$624 million and \$7.3 billion (4 million x 26% = 1,040,000; 1,040,000 x \$600 = \$624,000,000; 1,040,000 x \$7,000 = \$7,280,000,000).

As mentioned previously, a University of Minnesota study by Dr. Stephen Burks claimed that there are approximately 290,000 to 1.1 million truck drivers expected to have OSA in the U.S.⁴² Thus, the potential cost of treatment for the trucking industry would be between \$116 million to \$1.5 billion and \$440 million to \$5.5 billion (290,000 x \$400 = \$116,000,000; 290,000 x \$5,000 = \$1,450,000,000; 1.1 million x \$400 = \$440,000,000; 1.1 million x \$5,000 = \$5,500,000,000), as studies have shown and OOIDA members have experienced that even drivers diagnosed with mild sleep apnea are prescribed a CPAP. The total potential cost to the industry, not including costs for travel, time off work, and maintenance, is approximately \$740 million to \$2.07 billion or \$7.7 billion to \$12.8 billion.

Cost	Low End Estimate	High End Estimate			
Sleep Test	\$624	\$7,300			
Treatment	\$116-\$1,500	\$440-5,500			
Total	\$740-\$2,070	\$7,700-12,800			

Table 3: Total Cost Estimate for Potential OSA Rule, in millions

Conclusion

Both OOFI and OOIDA support the overall effort to increase safety on our nation's highways when those efforts are reinforced by clear and distinguishable connections to the safe operation of CMVs. OOIDA members have driven millions of accident free miles by ensuring that they are properly rested and fit to operate their vehicle at all times. A proposal to screen drivers for OSA, especially when FMCSA's own research and data demonstrate that there is no valid or reliable evidence which shows that sleep apnea is the cause for CMV crashes, is not an effective effort to improve highway safety. Instead it is an effort propelled by special interest groups who already profit at the expense of drivers due to the currently flawed NRCME program. According to OOFI's estimates, a potential sleep apnea rulemaking would be

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⁴² Non-Adherence with Employer-Mandated Sleep Apnea Treatment and Increase Risk of Serious Truck Crashes, pg. 6.

the most expensive rule ever proposed by FMCSA, and yet without any demonstrable relationship with safety. OOFI therefore strongly recommends that no further effort to screen CMV operators for OSA should proceed without true empirical research showing a definitive link to CMV safety.

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