United States Department of Transportation
FEDERAL MOTOR CARRIER SAFETY ADMINISTRATION

Meeting Summary

The Medical Review Board (MRB) of the U.S. Department of Transportation's Federal Motor Carrier Administration (FMCSA) was convened on June 30, 2011, in Arlington, VA. The meeting was open to the public.

Board Members Present:
Benjamin H. Hoffman, M.D., Chairperson
Brian T. Morris, M.D.
Albert J. Osbahr III, M.D.
Gina C. Pervall, M.D.
Carl A. Soderstrom, M.D.

FMCSA Staff:
*Larry W. Minor, Associate Administrator for Policy
Benisse Lester, M.D., Chief Medical Officer
Bill Bronrott, Deputy Administrator
Shannon Watson
Madeline Boyd
Lisa Harris
Valerie Height
Ava Herman
Linda Phillips
Angela Ward

*Designated Federal Official (DFO)

FMCSA Contractors:
Michelle Tregear, Manila Consulting
Stephen Tregear, Manila Consulting

Members of the Public:
Paula J. Caltrider, R.N., Maryland Motor Vehicle Administration (MVA)
John Carter, VGM
Art Cohen, Concorde, Inc.
Cyndi Cramblett, Owner-Operator Independent Driver Association (OOIDA)
Edward Grandi, American Sleep Apnea Association

Sandy Harding, American Academy of Physician Assistants
Natalie Hartenbaum, M.D., American College of Occupational and Environmental Medicine (ACOEM)
Katie Hathaway, American Diabetes Association
David Hobson, National School Transit Association
Nikki Jensen, VGM
Tony Jewell, Philips
Barry Kurtzer, M.D., DriverCheck
Alan Lankford, Sleep Disorders Center of Georgia
Michael Misero, University Services
E. Lynette McMillian, Greyhound
Julie Perrot, National Transportation Safety Board (NTSB)
Andrew Phillips, National Association of the Deaf
Jeff Schnobrich, AFL-CIO
Rick Schweitzer, National Private Truck Council
May Anne Scottino, M.D., Maryland Motor Vehicle Administration (MVA)
Todd Simo, M.D., HireRight
Alan Smith, Greyhound
Boyd Stephenson, American Trucking Associations (ATA)
Jerry Stewart, NDI
Richard Thiel, University Services
Jay Wood, Complete Driver Program

Call to Order

Benjamin H. Hoffman, M.D., chairperson of the FMCSA Medical Review Board (MRB), called the meeting to order.

Larry W. Minor, Associate Administrator for Policy, FMCSA, noted that he is the designated federal official for this committee. He said he was happy to have all five members of the MRB together in person. He said he was looking forward to a productive meeting and hearing from members of the public during the public comment period.

Dr. Hoffman introduced the other members of the MRB: Carl A. Soderstrom, M.D., Brian T. Morris, M.D., Gina C. Pervall, M.D., and Albert J. Osbahr III, M.D. All of these doctors have experience in the transportation industry and have published articles in numerous medical journals. Dr. Hoffman also reviewed the agenda for the meeting. First, there will be the updated evidence report of diabetes mellitus, then the evidence report on cochlear implants, and finally an update on the 2007 evidence report on sleep apnea. Each report will be presented by Michelle Tregear, Ph.D., or Stephen Tregear, D.Phil., followed by MRB deliberation and a public comment period. The meeting is scheduled to conclude at 4 p.m.

Dr. Hoffman also introduced the presenters. Dr. Stephen Tregear is the director of Manila Consulting Group and has 16 years of experience in evidence-based health services. He has a strong background in epidemiology, statistics, and other fields. Dr. Michelle Tregear has about 14 years of experience in health services research.

Presentation of Updated Evidence Report, Diabetes Mellitus

Dr. Michelle Tregear presented the results of the updated evidence report on diabetes and commercial motor vehicle (CMV) driver safety. She started the presentation by providing statistics on the incidence of diabetes. In 2009, there were 24 million individuals with diabetes, representing about 8 percent of the U.S. population. About 11.8 percent of males over age 20 have diabetes. There are just under 6 million undiagnosed cases of diabetes, and the number of new cases is rising. The number of new cases reported is highest among the 46-64 age group.

She provided the risk factors for type 2 diabetes, because 90-95 percent of people have type 2 versus type 1. Risk factors include age over 45 years, excess body weight, family history, and other medical issues. Because she identified obesity as a leading risk factor, Dr. Tregear provided additional information on obesity. Literature shows that close to 70 percent of the U.S. population is overweight or obese. The prevalence of obesity in commercial drivers is thought to be higher. She presented a figure showing the close link between the increasing rates of obesity and diabetes.

Individuals with diabetes may be treated in several different ways. Nearly 60 percent are treated with oral medication, 26 percent are treated with just insulin or insulin plus medication, and a small percentage is treated with just diet. The goal of all treatments is to maintain blood glucose levels.

Current FMCSA regulations at 49 CFR 391.41(b)(3) allow those with diabetes to drive a CMV as long as they do not have an established medical history or clinical diagnosis currently requiring the use of insulin for control. FMCSA does provide an exemption program for drivers that are insulin dependent but are otherwise meet all physical requirements. These drivers have to have no severe hypoglycemic reactions in the previous 12 months, no more than two severe hypoglycemic reactions in the previous five years, no loss of position or pedal sensation, and no peripheral neuropathy or retinopathy that interferes with driving. The exemption program requires these drivers to have a yearly endocrine and visual evaluation.

Dr. Tregear provided background information on the evidence report. The original evidence report was presented in July 2006 and the panel commented in August of that year. In August 2010, Manila Consulting was asked to update the searches for the original key questions and address a new topic on injectable non-insulin based medicines. They found new evidence for each of the key questions. This presentation will present the highlights of the updated report. The following questions were addressed in the report:

Key Question #1: Are individual with diabetes mellitus at increased risk for a motor vehicle crash when compared with comparable individuals who do not have diabetes?

Key Question #2: Is hypoglycemia an important risk factor for a motor vehicle crash among individuals with diabetes mellitus?

Key Question #3: What risk factors are associated with an increased incidence of severe hypoglycemia, and what is incidence of severe hypoglycemia with different treatments and treatment modalities (e.g., use of injectable, non-insulin drugs such as Byetta)?

Key Question #4: How effective is hypoglycemia awareness training in preventing the consequences of hypoglycemia?

Key Question Reponses

Key Question #1: Are individual with diabetes mellitus at increased risk for a motor vehicle crash when compared with comparable individuals who do not have diabetes?

A literature search was conducted to retrieve articles published from the time of the original report in 2006 until the present. They found three additional relevant articles, bringing the total number of studies on this question to 19.

There are two basic types of studies identified in this group. The first type of study identifies a control group and a group with diabetes, and then compares the crash rate of each group. The second type of study classifies people based on whether they have had a crash, and then looks at the prevalence of diabetes in both groups. The first scenario is used in 15 of the 19 studies. Only one study, which used the first scenario, included CMV drivers.

Dr. Tregear described Laberge-Nadeau et al., 2000, the study that looked at the crash risk among CMV drivers in Quebec. It age-matched a group of commercial drivers with diabetes to healthy individuals and categorized them based on the type of truck they were qualified to drive (straight or articulated; articulated trucks have multiple trailers and often go longer distances). Within the diabetes group, individuals were classified as having no complications, some complications, and complications controlled with medication and then matched with controls driving the same truck type. Within the articulated group, the crash risk in drivers with diabetes was no greater than those in good health. With the straight truck drivers, the only subgroup that demonstrated evidence of increased risk was the group with diabetes but no complications. This group was at a 76 percent increased risk compared to the control group. Those with complications or those using insulin did not show evidence of increased risk. The authors of the study theorized that the group with diabetes but no complications did not show evidence of increased risk in the articulated truck group because of stricter medical standards for articulated trucks.

Dr. Osbahr asked whether the study's authors broke down the groups by hemoglobin A1c levels, and Dr. Tregear replied that the authors did not. Dr. Tregear said this retrospective study tied together insurance company and driving license records. The review board should also be mindful that the Canadian government carefully monitors those drivers treated for diabetes, so there are probably not many of them on the road.

Dr. Morris asked what made the quality of the Laberge-Nadeau study moderate. Dr. Tregear said that because the study was retrospective, and because of the study design, none of them could reach high quality. The distinction between moderate and low is related to how well the study was reported, whether it controlled for driving exposure, and whether and how they matched the

control groups. The beginning of the evidence report describes the criteria for the stratification described.

Dr. Tregear then continued her presentation looking at the data from the 15 case-control studies that look at the crash rates of individuals with diabetes versus the controls. She presented a chart showing the individual risk ratios from each study. If the risk ratio is greater than 1, there is evidence for an increased risk of crashes versus the control, and if the risk ratio is below 1, there is evidence for decreased risk. If the error bars (confidence intervals) include 1, there is not a statistically significant difference in risk. About eight studies showed evidence of increased risk, but several showed no evidence of increased risk, or evidence of decreased risk. Summarized together, the risk ratio was 1.126, similar to the previous evidence report that included only 13 studies. This is about a 12-13 percent increased risk. The major difference with this evidence report is that in the previous report this was a significant difference, but in this report the difference is not significant. This suggests that individuals with diabetes do not show evidence of a different crash risk.

Lonnen et al., 2008, a study done in the UK, included a quote from the UK Driver and Vehicle Licensing Agency stating that the risk of crash among individuals with diabetes was underestimated due to a 3-year medical review policy for insulin-dependent people, which removes these individuals from driving. This review process eliminates the potentially highest risk individuals from the driving pool. This comment prompted Manila Consulting to conduct a subgroup analysis that is new to the 2010 updated evidence report.

The studies were sub grouped by U.S. versus non-U.S. studies under the idea that perhaps they should not compare results from studies in other countries where there are different regulations. For those studies conducted outside the United States, the risk ratio was 0.854, which is definitely not significant. In the United States, it was 1.284, which is highly significant. This suggests that in the United States, where there are fewer restrictions on passenger drivers, those drivers with diabetes may be at an increased risk of crashing. They also looked at the six studies that compared individuals who are insulin dependent with those that only take medication. The combined risk ratio of these studies was 1.537, which was not significant because the confidence interval included 1. When this was further categorized by country, the U.S. risk ratio was highly significant at 2.753, and the non-U.S. risk ratio was non significant at 1.036.

Dr. Hoffman asked whether the studies removed the individuals with type 1 diabetes. The vast majority of drivers are type 2. Dr. Tregear replied that there are not enough data. Dr. Stephen Tregear noted that the question they were examining was whether in countries where individuals who are on insulin are restricted from driving, removing these individuals from the driving population impacts the number of crashes. But in the United States, we do not restrict their driving, so there is an increased risk. When you restrict individuals using insulin, you have safer drivers.

Dr. Hoffman commented that in the United States, hypoglycemia is usually self-reported, whereas overseas it is usually taken from the medical record. He expressed interest in how this biases the data. He also said that a major question with regard to comparing the U.S. program to the UK program is who should be the arbiter of whether a person can drive.

Key Question #2: Is hypoglycemia an important risk factor for a motor vehicle crash among individuals with diabetes mellitus?

Dr. Michelle Tregear said that for this question they identified 27 studies. Of those studies, three were driver simulation studies and 25 were cognitive/psychomotor testing studies. None was specific to CMV drivers. There were no new driver simulation studies identified for the 2010 update. The driving simulation studies show that hypoglycemia does impair the driving ability of some individuals with type 1 diabetes, but the type of impairment was variable (e.g., midline crossing, swerving, driving at high speeds) and the blood glucose levels at which impairment becomes apparent was also variable at 3.6-2.6 mmol/L on a average of 4 mmol/L. The hypoglycemic conditions were induced in the study participants. The key result is that not everyone is affected at the same blood glucose level or in the same way.

Dr. Hoffman asked if the individuals' glycemic awareness was noted in the studies. Dr. Tregear replied that it was noted in some of the studies. Some of the participants were unaware that they were experiencing hypoglycemia.

In the cognitive psychomotor tests, hypoglycemia was induced in individuals that were then subjected to various tests. These tests were conducted both before and after the glycemic levels were reduced. The results were similar to the driving simulation studies in that some individuals were affected by lower blood glucose levels while others were not. Those that were affected tended to either be unaware that they were hypoglycemic or underestimated the impact it was having on their cognitive and psychomotor function.

Key Question #3: What risk factors are associated with an increased incidence of severe hypoglycemia, and what is incidence of severe hypoglycemia with different treatments and treatment modalities (e.g., use of injectable, non-insulin drugs such as Byetta)?

As background for this question, Dr. Tregear explained that the primary aim of modern treatments is to keep blood glucose levels as close to normal as possible and reduce the complications of getting blood glucose levels too high. The problem with keeping levels near normal is an increased risk of hypoglycemia. The objective for this question is to identify whether there are treatment-related risk factors for increased hypoglycemia. The risk factors examined included treatment factors such as long duration on insulin and lower HbA1c, as well as demographic factors and behavioral factors.

In systematic reviews looking at short-acting insulin analogues, there were no differences observed in the rate of severe hypoglycemia compared with regular insulin. Long-acting insulin analogues seemed to reduce the risk of severe hypoglycemia. The subcutaneous insulin infusion delivery method was also reviewed; although there were mixed findings on this delivery method, there was a trend toward reducing the occurrence of severe hypoglycemia.

Next, they looked at intensive versus standard glycemic control. Intensive glycemic control increased the incidence of severe hypoglycemia. Self-monitoring (standard glycemic control) was also associated with significant increases in the rate of hypoglycemia.

New to this report was a study of non-insulin injectables such as Byetta and Victoza. These agents work to enhance insulin secretion when blood glucose is high to reduce hypoglycemic situations. Weight gain is a consequence of some medicines, and these medications may help people with diabetes to lose weight or not gain as much. When taken alone, Byetta does not increase the risk of severe hypoglycemia. However, when taken with sulphonylureas it did increase risk. The incidence of hypoglycemia is also higher with higher doses of Byetta. In the UK, CMV drivers are required to be reviewed if they take Byetta or Victoza with a sulphonylurea.

Key Question #4: How effective is hypoglycemia awareness training in preventing the consequences of hypoglycemia?

The 2010 update found one new study for this question, bringing the total to eight studies. As background, blood glucose awareness training programs help people understand how to recognize the signs and symptoms of getting hypoglycemia. Studies have found that awareness training programs do improve individuals' ability to predict what their blood glucose levels are, but they are mixed on whether they actually helped reduce the incidence of severe hypoglycemia. The new study reviewed a slightly revised training program, but the other seven studies all reviewed the same type of program.

MRB Discussion and Deliberation on Diabetes and Commercial Motor Vehicle Safety

Dr. Osbahr asked that the blood glucose levels presented in mmol/L be converted to a more commonly used unit for practicality.

Dr. Morris stated that their primary concern is with individuals with type 2 diabetes, because they do not see many type 1 drivers. Most of them are starting to use the longer acting insulin, and it is encouraging that they show reduced risk. He asked Dr. Tregear to clarify whether they subgrouped the long- and short-term insulin by country, and she said they did not.

Dr. Hoffman commented that these studies are difficult to interpret because many people with diabetes have co-morbidities, such as hypertension. Dr. Stephen Tregear agreed that the data are extremely polluted because patients rarely have just one disorder, but for diabetes, it is mainly an issue of power. If you try to control for the co-morbidities, it is likely you will not have a large enough sample size. The best they can do is present the crash risk amongst individuals with diabetes and then try to figure out why. It could be because of hypoglycemia or because of other factors as well.

Dr. Soderstrom discussed the highest crash rates being among drivers with uncomplicated diabetes and wondered whether they were younger drivers. Dr. Stephen Tregear agreed that perhaps one issue is that younger drivers are less experienced, whereas another issue may be that a small amount of hypoglycemia may be worse for them than other drivers. Another is that straight trucks may be exposed to higher crash risks because they drive more in cities than articulated trucks. Dr. Michelle Tregear stated that some people may also self-select out of the driving population if they have complications or need insulin, which is something that many

people with type 1 do. Individuals with type 2 generally develop it later in life and just keep driving.

Dr. Osbahr said that the distinction between types 1 and 2 is blurring because adults have type 1 now. He commented that many doctors have seen bad diabetics on the road with borderline neuropathy or other symptoms, but they skirt by the FMCSA regulations. It would be nice to see studies that simulate folks that are not taking care of themselves. The majority of patients keep their blood glucose levels normal and away from hypoglycemia, which keeps them on the road.

Dr. Hoffman said that this is a serious problem because lots of drivers have diabetes and they are reluctant to say they are on insulin. There are practicalities to having them demonstrate their control. We have to balance safety, trucking needs, and what is actually going on out there. This issue has already been extensively discussed. The MRB and Medical Expert Panel have already weighed in on this, and we currently have an exemption program which has only had 700 people go through it. They need to look at how other countries stratify risk, but also need to leave some judgment to the clinician because there is some co-morbidity. They also need to have a process to speed approval for driving that goes back to the examiner's discretion. We ask FMCSA to ask Manila Consulting to do an evidence-based process to come up with recommendations for how to certify people with diabetes to drive. They do not want another expert panel because it will slow things down. The MRB can then deliberate those recommendations.

Dr. Morris stated that Manila should also investigate how impairing hemoglobin A1c is at given levels. We need to have a specific blood glucose level to weed out those drivers. Dr. Osbahr agreed on the need to nail down some numbers.

Dr. Soderstrom stated that there is so much concern about hypoglycemia, but the bottom line is that we know people with diabetes have a relative risk of crashing more, even though we do not know whether it is related to their condition.

Dr. Stephen Tregear said that the evidence shows that a common factor of diabetes leads to possibly an increased risk, or at least a trend. The size of the relative crash risk is relatively small at 16 percent. Other factors, such as obstructive sleep apnea, have relative increased risks more like 250-500 percent. The crash risk on its own does not say anything, because it could be a result of another issue, like cardiovascular disease, which happens to be prevalent in people with diabetes.

Dr. Pervall stated that it would be great if they could leave it to the examiners to decide whether a person with diabetes can drive a CMV, but they cannot do that until they have certified examiners. She said that they do need to develop parameters to present to the examiners to show what FMCSA considers to be safe. The chance of a person coming to the examiner with only diabetes is quite slim.

Dr. Hoffman suggested that they ask Manila Consulting to come up with those. The exemption program is well conceived, but there is a need for criteria to allow enough flexibility to take new treatment types into account. Dr. Morris said he envisioned a hierarchical approach where the

examiner would make a recommendation, followed by an endocrinologist. Another person would have to give an opinion in case of a tie.

Dr. Hoffman replied that the MEP report referred to a process like this. This is all about risk stratification. The reality is that most people with diabetes can drive, but not setting standards may create a higher risk than doing something.

Mr. Minor asked the MRB whether FMCSA should rely on the previous MEP report because they disagreed with its findings. Dr. Hoffman replied that there was clearly dissent between the MEP and the MRB. He suggested bringing in one more piece of independent information. Manila Consulting should make their recommendations based on a risk stratification process and based on what several other countries have done, and then the MRB will deliberate on what they find. The MRB can also take into account any previous reports already presented.

Mr. Minor asked the MRB whether they felt that the exemption program should continue to operate while they deliberate, given the Agency's several years of experience with the program. Dr. Hoffman replied that it is essential that the program continue. Drivers are reluctant to go through the process, but there are ways to facilitate it. One issue that drivers face is the logistical challenge of seeing an endocrinologist because of their limited number, but it is a core skill set of an internist to manage diabetes. One recommendation made by the MRB a few years ago was that the medical examiner should be a physician. FMCSA needs to set criteria for appropriate risk with regard to diabetes, and establish certain qualifications for who can conduct the DOT exam.

Dr. Osbahr stated that the information he received about the MEP was that there were irregularities on that panel, so the MRB members decided that they needed to make their recommendations separately. This caused the MRB to question the panel's whole report at that time. He agreed that the exemption program should continue as it is. As an aviation examiner, he said that it was comforting that there was a deferral process for complicated patients where a separate entity (such as the feds in the case of interstate licensing) decides whether the driver is permitted to drive. The medical examiner's report is reviewed by a separate group that is willing to take on the liability of deciding who can drive.

Dr. Lester summarized the MRB's recommendation, which is that for the sake of expediency, they do not want to convene another MEP.

Public Comment on Diabetes and Commercial Motor Vehicle Safety

Dr. Natalie Hartenbaum, American College of Occupational and Environmental Medicine, said she was speaking on behalf of her organization and medical examiners. She asked the MRB to keep in mind that the absence of evidence is not the evidence of absence. The U.S. system is significantly different from the system in other countries. In Canada, drivers are treated by the same doctors that conduct the examination, and a similar system is used in the UK. Australia has a mechanism for at-risk medical issues to be reviewed. America is different because the treating and examining provider are different and there is nothing done to ensure that there is monitoring in the interim between exams. In situations where there is closer monitoring, there is much

clearer guidance and removal of unfit drivers, leading to a lower risk. When monitoring is absent or removal is insufficient, there will be a higher risk. Once a driver is diagnosed, treated, and monitored, he is likely to be safe. Until the American system can ensure that, FMCSA must play it safe. It is an issue of societal acceptable risk. We need to ensure that drivers are safe and healthy.

Mr. Minor asked Dr. Hartenbaum about the vulnerability she highlighted in the lack of connection between the examiner and the treating physician. The current exemption program is designed to bring those two together. He asked whether she believed that this program serves as a basis for a framework for a change in regulation. Dr. Hartenbaum said she believed it could, if they can get adequate information from the treating provider. There are several providers who will say that the driver is fit to drive, but their notes show otherwise. They need to be able to review actual medical records.

Dr. Lester asked whether in the international data there is a confounding factor because the reporting of crashes and the association or causality is better reported in the United States than abroad. This may address Dr. Hartenbaum's comment about the absence of evidence. Dr. Lester also said that FMCSA and the MRB should look more closely at monitoring and better defining acceptable parameters for driving. She said it was her understanding that monitoring may be even less frequent in other countries, and there may be less communication between the doctors. Dr. Hartenbaum replied that in many cases the examiner and the monitoring doctor are the same person. This is because the liability and responsibility sit with the same person.

Dr. Hoffman floated a motion among the MRB asking FMCSA to obtain recommendations regarding a new process that would allow a non-FMCSA exemption process to occur, including criteria for who can be approved that would also include some monitoring to ensure compliance. This motion does not preclude the ability to suggest an MEP be convened on the subject.

Dr. Lester asked whether this must be an exemption program, or a set of parameters. Dr. Hoffman replied that it would be parameters that would be used by the examiners doing the DOT exam. He said he wanted Manila Consulting to determine whether the current DOT examiners can follow those parameters, or whether the exam needs to be done by another physician.

Dr. Osbahr commented that this seems like a motion they would take directly to FMCSA. There is a need to explore a process beyond the current insulin waiver program, perhaps something similar to the FAA program where experts that are not practicing physicians review these types of cases.

Dr. Lester explained the advisory process. She noted that three independent consulting bodies provide information to FMCSA: the MRB, Manila Consulting, and expert panels. Dr. Lester noted that Manila can provide data and analysis without using an expert panel. Dr. Hoffman replied that it would be useful to have Manila Consulting evaluate and describe a more effective program for certifying drivers outside of the current exemption process. Once Manila provides that information, the MRB can evaluate it and move to the next step. This does not preclude the MRB from deliberating based on the information it already has. Dr. Lester said that Manila

consultants are PhDs, not clinicians. Manila interprets and analyzes data, but does not make independent clinical recommendations.

Dr. Morris said he envisioned phasing out the current exemption program in favor of using stringent guidelines for all diabetics. This puts the onus on the medical examiner.

Dr. Soderstrom asked Dr. Hoffman if he wanted Manila Consulting to also look at the type of clinician who is capable of doing effective monitoring. Right now, there are four types of people that can conduct DOT physicals. Dr. Hoffman replied that he thought they could decide that as a board without input from Manila.

Dr. Pervall clarified that they are asking Manila to examine programs in other countries and what their crash risk is as it relates to diabetes and control of diabetes. Dr. Lester cautioned that they should be careful about which countries to consider because of the variability of data. Manila should also consider confounding factors. Dr. Hoffman agreed that the study should be limited to Sweden, Norway, the UK, and Australia because of the available data. Dr. Osbahr suggested that they also look at the FAA system in the United States. Dr. Lester said that the procedure is that FMCSA would take the MRB's recommendation and decide which resources to use to best collect this information. The MRB does not provide direction to other FMCSA consultants; this is outside the MRB's purview. She also said that this recommendation should have latitude to include other pertinent agencies as necessary. Dr. Hoffman agreed that the MRB is asking FMCSA to provide the Board with information on programs in other countries that regulate this issue and sister programs within the United States to see how they handle this. Dr. Hoffman said that this information should not be hard to obtain. Once FMCSA provides this information to the MRB, members can review it individually and then hold a discussion and deliberation process in a public meeting to look at evidence-based conclusions.

Mr. Minor discussed the possible rulemaking tools available to the Agency. He said that there are many different documents related to rulemakings, one of which is the advance notice of proposed rulemaking (ANPRM). They use an ANPRM when they are considering a change but have no evidence or data, and they typically ask a series of questions for public comment. On the topic of diabetes, they issued an ANPRM in 2006 to solicit information and comments. The next step would likely be a notice of proposed rulemaking.

Presentation on Cochlear Implants and Commercial Motor Vehicle Driver Safety

Dr. Michelle Tregear provided an overview of the findings of the evidence report on cochlear implants developed by Michelle Tregear, PhD and Stephen Tregear, DPhil. Dr. Tregear stated that the purpose of the evidence report was to examine potential issues of cochlear implants for severe-to-profound hearing loss on commercial motor vehicle (CMV) driver safety. Statements by Dr. Tregear were based upon the evidence report information. The following questions were addressed by this report:

Key Question #1: How effective are cochlear implants?

Key Question #2: What is the nature of hearing capability following cochlear implantation?

Key Question #3: Are there any other factors associated with cochlear implantation that may increase crash risk?

Before addressing the key evidence-based questions, Dr. Tregear provided background on cochlear implants (CI) and why they are important. Cochlear implants are electronic devices implanted in the inner ear for individuals with severe or profound sensorineural hearing loss (~70 dB thresholds or greater). These implants are inserted into the cochlea and stimulate the auditory nerve, and may enable individuals with severe hearing impairments to pass FMCSA's hearing requirements. The current hearing requirements, per 49 CFR 391.41(b)(11), require that individuals either: 1) Perceive a forced whispered voice, in one ear, at not less than five feet; or 2) Have an average hearing loss (as tested by audiometry), in one ear, less than or equal to 40 dBs. Functional hearing is important for drivers because it allows them to hear warning sounds, detect problems with their vehicle, and facilitates communication with drivers and dispatchers.

Dr. Tregear stated that hearing loss is the sixth leading cause of chronic disability in the United States. Approximately 36 million American adults suffer from hearing loss, and it is primarily age related, with ≥50 percent of all hearing loss occurring over age 65. Men are more likely to be deaf or have hearing loss. Sensor neural hearing loss is the most common form (90 percent) while conductive hearing loss is less common (10 percent).

The primary indication for cochlear implants is sensory neural bilateral hearing loss. To receive a cochlear implant, an individual must have undergone some trial with a hearing aid and not have had benefit from it. Dr. Tregear noted that indications are rapidly evolving and technology is quickly advancing. Originally, only those individuals who were post-lingually deafened and were found to be profoundly deaf were given implants; now, both infants and adults, and both pre- and post-lingually deafened, as well as those with severe to profound hearing loss, are given cochlear implants. Worldwide, about 60,000 CIs have been received, half of which are in adults, and there are currently about 250,000 to 1 million potential candidates. Generally, most people get a unilateral cochlear implant, but there is a growing trend for bilateral implantation.

Key Question #1: How effective are cochlear implants? Is auditory function following cochlear implantation restored to a level that would permit safe driving as established by existing Federal standards for hearing?

The information for this key question was limited to a single systematic evidence review, Bond et al. (2009), which looked at the efficacy of cochlear implants. The report compared hearing ability in individuals with unilateral CI compared to no assistive hearing device; individuals with unilateral CI compared to using hearing aids; and implantation of bilateral CI vs. unilateral CI. These were pre-post implant measures, with subjects acting as their own control. The primary outcomes measured included speech perception, quality of life, and sensitivity to sound. FMCSA does not have a speech quality criterion, but there were not any outcomes comparable to forced whisper, so the study went with the outcomes which were available.

The Bond et al. report included four studies of 948 patients. The primary outcome was speech perception, since people get these implants so they can improve their ability to communicate and hear. Individuals were tested both before and after their implantation on a series of speech perception tests, anywhere from 3–18 months after surgery. All studies reported improvements in speech perception measures following cochlear implants compared to pre-implant measures with no assistive device.

In examining unilateral CI against hearing aids, the report looked at four studies of 248 patients. The primary outcome tested was speech perception, but also included measures for speech production, localization, and quality of life. Individuals were tested before implantation and 6–12 months after surgery. In all cases, speech perception measures were improved following CI implantation compared to pre-implantation measures with a hearing aid. The study found improved sound production abilities and improved quality of life, though no benefit for sound localization. Hearing aids were found to be no better than single sided cochlear implant in localizing sounds.

The authors also looked at effectiveness of bilateral cochlear implants versus unilateral cochlear implants. There were four studies of 427 patients, with primary outcomes measured including speech perception, sound localization, and quality of life. With bilateral CI, speech perception was found to be improved in both quiet and noisy circumstances, though unilateral implants were found to be reasonably effective as well.

The evidence from these reports suggest that compared with non technological support, CI leads to improvements in functional hearing, ability to understand speech, and quality of life. These improvements were most strongly associated with duration of pre-implementation deafness, as well as age of implantation. Bilateral implants also appear to be associated with improvements in hearing in noisy conditions relative to unilateral CI. However, there was a lot of variability of the levels of effectiveness among individuals.

Key Question 2: What is the nature of hearing capability following cochlear implantation (e.g., sound localization), and are there associated factors that may not be conducive with safe driving?

Dr. Tregear presented the findings from five studies and one systematic review of 29 studies. The relevant comparisons of these studies included sound localization with unilateral CI (alone or bimodally), and sound localization with bilateral CI. Sound localization is the ability to detect where sound is coming from in the environment. Unilateral CI recipients have poor sound localization ability, while bilateral implantation gave rise to 30 degrees improvement in localization ability. The best performing bilateral implants accuracy achieved was 4.4 degrees sound-source discrimination, in terms of discriminating where sound was coming from (with normal being 1.7 degrees). Thus, the study showed improvements in sound localization, though does not show restoration of hearing to normal levels.

Dr. Tregear stated that there are no data available to address the question of whether CI implantation restores sound localization to a level sufficient for driver safety. The current

requirements do not require sound localization, but only require hearing in one ear. Sound localization may or may not be an important function for drivers.

Dr. Pevall asked if there were any studies that compared a unilateral cochlear implant to the sound someone has in one ear with unimpaired hearing. Dr. Tregear responded that the studies did not look at that issue because all studies looked at pre- and post-implantation and did not compare to deaf individuals.

Key Question #3 Are there any other factors associated with cochlear implantation that may increase crash risk (e.g., disrupted vestibular function)?

Dr. Tregear presented the findings from 11 studies of 697 patients that measured vestibular function pre- and post-implantation. The measures included subjective measures (e.g. questionnaires), and objective measures (eye tracking test, Optokinetic nystagmus). Vestibular impairment is very common among individuals with hearing loss. Prior to CI implantation, 26 to 58 percent of individuals have some sort of vestibular impairment. CIs may result in temporary vestibular disruption; 29 to 76 percent of the patients had some form of disruption following the implantation. However, vestibular symptoms were not long-term and can often be fixed by time or rehabilitation.

Conclusions

Dr. Tregear concluded by noting that there was no literature that looks at outcomes for CMV drivers or other safety-sensitive occupations. From the studies that were reviewed, the primary outcomes measured included speech perception, sound localization, and adverse consequences of CI implantation such as vestibular disruption. Cochlear implantation improves hearing performance and speech perception, though not to the degree of normal hearing. Also, the degree varies for each recipient, depending on factors including duration of being deaf, whether an individual was pre- or post-lingually deaf, and the age when implantation occurs. The evidence report also found that bilateral cochlear implantation is an advantage over unilateral cochlear implantation in speech perception and in noise and sound localization tasks. Most individuals currently get a unilateral cochlear implant, though the trend is moving towards implanting bilateral CIs or combining them with hearing aids.

MRB Discussion and Deliberation on Cochlear Implants and Commercial Motor Vehicle Driver Safety

Dr. Osbahr asked if the there was any sense on how much improvement there was for implantation for the extent below 40 decibels. Dr. Tregear responded that this was a challenge, because CI takes sound waves from the environment, creates a signal on an electrode array, and stimulates nerves, which is not the same as hearing thresholds. Some studies varied the sounds at which speech was presented, but they did not cover absolute thresholds.

Dr. Osbahr also commented that the 20–76 percent of vestibular impairment range following CI was fairly significant, and that examiners will have to assess vestibular dysfunction and hold up drivers until the drivers recover. He asked whether data show how long this group remains

impaired. Dr. Tregear responded that for most of the studies, the follow up was from three months to one year. It is unclear how long rehabilitation takes, but likely many months before patients would start to resolve this issue. However, many of these people have vestibular problems before the implantation; also, some studies show some people resolve vestibular problems when CI is implanted.

Dr. Hoffman asked the rest of the MRB panel whether they should recommend some objective testing for vestibular dysfunction for individuals who have undergone implantation. He also asked whether the whisper test at five feet is an acceptable method to assess hearing. Dr. Hoffman felt that the forced whisper test is very subjective and asked whether they should recommend audiometry instead. He also asked whether there should be some test for vestibular dysfunction. Dr. Morris responded that audiometry does provide an objective test; however, he noted that just as people using hearing aids cannot take a traditional audiogram because the cups do not fit over the hearing aids, he did not think that a traditional audiogram could be done on those with CIs either. Dr. Tregear said the CI sits behind the ear typically. Dr. Hoffman commented that since CIs were so expensive and are not commonly being done, individuals that have CIs have likely already been tested at some point in the process, and requesting audiometry data from an examiner or a third party would not be an onerous request. Dr. Morris expressed concern that if you were to request a hearing test from an audiologist for someone with a CI, then you are rejecting the forced whisper test and creating two classes: one class where the test is acceptable, and one in which it is not. Dr. Hoffman stated that he did not have a problem with asking for the audiology test for individuals with a CI because individuals that received these implants in the first place did so because they could not hear. Also, Dr. Hoffman expected that the number of drivers who have received implants to be relatively low because of the expense. Thus, it is likely that asking for a few additional data points would not be unreasonable, an observation with which Dr. Pervall concurred. Dr. Morris asked if an individual were to pass the forced whisper test, whether that individual was still going to be asked for more information and if that would be acceptable. Dr. Hoffman reiterated that he did not think they would be discriminating in an inappropriate way for asking for an audiometry test. Dr. Lester stated that the recommendation sounds consistent with the idea that a person with an implant should not have to exceed the existing baseline for medical requirements for medical certification. Dr. Hoffman commented that the forced whisper is not reliable enough for any driver, let alone someone diagnosed with enough hearing loss to spend $10,000 or more for a CI.

Dr. Hoffman proposed to the MRB two motions: 1) Audiometry should accompany hearing evaluation during an examiner's biennial or more frequent examination. Dr. Pervall agreed, stating that the regulations do not say "forced whisper, then audiogram," but rather says "forced whisper *or* an audiogram." Dr. Hoffman stated that a forced whisper is not an appropriate test once CI had been implanted. Dr. Morris reiterated that this may create two classes of people, though stated that he had no problem with singling out people with CIs for vestibular testing because they are at high risk. Dr. Hoffman stated that he thought the forced whisper test was more of a screening test; if you already have a priori evidence that a person has severe hearing loss, then you know that an individual needs more testing. Dr. Morris stated that he would be more comfortable if they got rid of the forced whisper test for all drivers.

Public Comments on Cochlear Implants and Commercial Motor Vehicle Driver Safety

Dr. Natalie Hartenbaum, American College of Occupational and Environmental Medicine, stated that there were no studies on the relationship of crash risk and cochlear implants. In earlier evidence-based reviews on hearing aids, Manila Consulting Group did find that that those with hearing aids were at an increased risk of crashes. She asked how that data fit together, looking at the CI group as well. She stated that she knew there was a hold to act on the hearing aid review because it was a surprising finding. She also stated that the MRB has already gone on to the next step of how to test an individual with a cochlear implant, but that they first need to establisher whether the CI is a sufficient and acceptable substitute for a hearing aid to meet the current medical standards.

Dr. Hoffman responded that hearing is currently measured with a functional test, as opposed to other medical criteria, which are not examined with a functional test, and that he preferred that everything be measured with a functional test. Dr. Osbahr stated that he had concerns not on the second class issue, but rather on logistics. He commented that there are rural areas where physicians do not have audiometrics, or sometimes the audiometric machines will not work, and physicians need to rely on the forced whisper test. He stated that a forced whisper test is still a good functional test if it is done right. He also sees that audiometrics do not always match up with functional capabilities of an individual. Dr. Osbahr did not want to get rid of the forced whisper because of these logistic issues and because sometimes it does not match up functionally.

Dr. Hoffman stated that if an examiner does not have an audiometer—a machine that costs only $100— then he/she should not be doing DOT exams. He stated that you do not need an OSHA-approved booth for audiometry, and that in almost every community there is someone who can assess hearing. Also, he stated that the individuals who receive a CI are severely hearing impaired. He also agreed that lack of a matchup is an issue, but a clinical one that needs to be looked at further by an audiologist. Dr. Osbahr disagreed, stating that with rising costs of health care, fewer people have these machines in their offices because of costs and maintenance. If audiometrics or booths go down, or audiometrics are not done correctly, it is helpful to have the forced whisper test. Dr. Osbahr did not want to extend functional hearing requirements to remove the forced whisper, stating that if an audiometric test is unavailable, then there might be a problem for trucking companies and their truckers who cannot get on the road. From his personal experience with failed audiometrics, Dr. Osbahr thought it was helpful to have a forced whisper test available. However, Dr. Osbahr though that it is a different story if the patient had received a CI; those drivers, he stated, should either prove they have the post-op ability to function, or drivers should be held up until the audiometrics are done.

Dr. Lester agreed with Dr. Pervall's point that this was currently an "or" situation in the existing examination process between the whisper test and audiometry. She stated that from a rulemaking perspective, part of the process would be justifying that the change from forced whisper to audiometry is not unduly burdensome.

Dr. Morris asked if there was a study that looked at the forced whisper test as a hearing test; in particular, a study that looks at the test not under perfect conditions, but how the test is carried

out throughout the country. Dr. Morris stated that he would be fine with the forced whisper test if it was determined as a good test, but if there were pitfalls found with it, then, from a public safety standpoint, he would want to require an audiogram.

Dr. Stephen Tregear commented that in the previous review on hearing and vestibular function, they found that the forced whisper, though a useful screen, was not useful for diagnostic distinctions for hearing loss. They also found evidence that those individuals who were supposed to be using hearing aids had higher crash risks, though it was difficult to draw any strong conclusions from this because there was anecdotal evidence that those who were supposed to wear hearing aids were not actually wearing them. Another important finding from Dr. Tregear's research was that sound localization is important, though he mentioned that this is not considered in current rules and regulations.

Dr. Hoffman noted that people with hearing aids may have a higher crash incidence because they do not clarify in the studies why they are wearing hearing aids, and there are a substantial number of people that have a hearing loss that is not amenable to a hearing aid, so there is a moral hazard within the provider community which pollutes the data. He also stated that doing a forced whisper test for hearing loss is like doing an EKG for a patient who comes in with chest pain.

Dr. Hoffman proposed two motions. The first was to vote on whether to promote either audiometry or only a forced whisper test as evaluation tool for cochlear implants. Dr. Osbahr made the motion to vote that those patients who are post implantation should have audiometric testing to demonstrate function, and Dr. Pervall seconded the motion. Dr. Osbahr, Dr. Pervall, and Dr. Soderstrom were all in favor of the motion; Dr. Morris opposed the motion because it would create a second class of drivers.

The second proposal was to discuss the need for any type of vestibular testing or a waiting period prior to approval to drive for anyone waiting for this type of evaluation. Dr. Hoffman asked FMCSA whether there was any practical testing for vestibular malfunction. Dr. Osbahr also asked that FMCSA explore how long, post surgery, to assess vestibular malfunction, since it can go from 3 to 12 months. Dr. Morris added that it sounds like the research might have already been done on these issues. Dr. Lester added that the MRB might want to be more specific on the definition of vestibular malfunction, since there are many different types of vestibular malfunction. Dr. Hoffman said you want to make sure that someone who gets into the truck after one of these implants is not at a risk for vertigo. It did not come up in the expert review of this material, but he did not know how to go about finding that information.

Presentation on Update on 2007 Evidence Report on Sleep Apnea

Dr. Stephen Tregear presented an overview of the update to the 2007 evidence report prepared by the Manila Consulting Group on obstructive sleep apnea (OSA) and commercial motor vehicle (CMV) driver safety. Dr. Tregear stated that the evidence report focused on why sleep apnea is important to CMV driver safety and how it may impact the task of driving. Dr. Tregear reviewed the actions that can be considered to be involved in the task of driving, as well as the

problems that can be associated with sleep apnea. In addition, Dr. Tregear provided a brief background of the evidence report, and noted that the original evidence report was presented to the Federal Motor Carrier Safety Administration (FMCSA) in July 2007, with further discussion by the Medical Expert Panel (MEP) in August 2007. The MEP's recommendations were presented to the Medical Review Board (MRB) and FMCSA in January 2008. Subsequent journal articles published after 2007 prompted FMCSA to request an update to the report in late April 2011. Statements by Dr. Tregear wer report update information. The following questions were addressed in this report:

Key Question #1: Are individuals with OSA at an increased risk for a motor vehicle crash when compared to comparable individuals who do not have OSA?

Key Question # 2: What disease-related factors are associated with an increased motor vehicle crash risk among individuals with OSA?

Key Question #3: Given the findings of Key Question 2, are individuals with OSA unaware of the presence of the factors that appear to be associated with an increased motor vehicle crash risk?

Key Question # 4: Are there screening/diagnostic tests available that will enable examiners to identify those individuals with OSA who are at an increased risk for a motor vehicle crash?

Key Question # 5: Which treatments have been shown to effectively reduce crash risk among individuals with OSA?

Key Question # 6: What is the length of time required following initiation of an effective treatment for individuals with OSA to reach a degree of improvement that would permit safe driving?

Key Question #7: How soon, following cessation of treatment (i.e., as a consequence of non-compliance), will individuals with OSA demonstrate reduced driver safety?

Key Question Responses

Key Question #1: **Are individuals with OSA at an increased risk for a motor vehicle crash when compared to comparable individuals who do not have OSA?**

In preparing the update to the evidence report, the Manila Consulting Group identified 17 studies that addressed Key Question #1 out of 252 potentially relevant studies, two of which included CMV drivers. All 17 selected studies were case-controlled. The selected studies were chosen in part due to design characteristics, including the degree to which outcomes of interests were reported, whether the study design would be useful in ultimately making a determination, and whether exposure was considered. Those studies relying on anecdotal evidence were not included, due to the need to compare risk.

Dr. Tregear provided an overview of the two studies relevant to CMV drivers: Howard et al., 2004 and Stoohs et al., 1994. Howard et al., 2004 focused on CMV drivers in Australia and found that individuals with sleep apnea—ranging from mild to severe—experienced a higher crash risk than similar individuals who did not. Stoohs et al, 1994 looked at a cross-sectional population of 90 CMV drivers ranging in age from 20–64 who agreed to undergo overnight recordings of oxygen saturation levels, heart rate, snoring sounds, and body position and movement. The study then compared the recording findings to self-reported crash data over the previous five years. The study found that having a diagnosis of sleep apnea alone did not correlate to an increased crash risk; however, when looking at the self-reported crash data compared to the measure of excessive daytime sleepiness, the study found a correlation between the level of daytime sleepiness and an increased crash risk. Additionally, the study found a relationship between high body mass index (BMI) and increased crash risk, for those diagnosed with sleep apnea. Dr. Tregear noted that the study's findings are important because they indicate that BMI could potentially be used to screen for sleep apnea; it indicates a correlation between BMI and the severity of sleep apnea.

Dr. Osbahr requested clarification as to whether the term "sleep disordered breathing" (which includes OSA) is considered a catch-all term for the purposes of the Stoohs et al. study, as it could be considered to apply to a large group of individuals. If the term is considered to apply to a broad range of individuals, the study's findings would therefore indicate a significant correlation with increased crash risk among a large group covered under the term "sleep disordered breathing." Dr. Tregear responded that the study did not measure "sleep disordered breathing" in a sleep lab, but rather using a portable system. Dr. Osbahr requested further clarification as to whether, for the purposes of the study, "excessive daytime sleepiness" was measured using the Berlin scale. Dr. Tregear responded that the study measured "excessive daytime sleepiness" using the Epworth Sleepiness Scale (ESS).

The evidence related to Key Question #1 suggests that CMV drivers with OSA are at an increased risk for a crash when compared to their counterparts who do not have the disorder. Dr. Tregear noted that a precise estimate of the magnitude of this increased risk cannot be determined at present.

Dr. Tregear reviewed the findings of the rate ratio studies for Key Question #1. The rate ratio studies included 15 studies, all of which covered the general driving population, and looked at the crash rate among individuals with OSA as compared to the crash rate among comparable individuals without OSA. For the purposes of the comparison, Manila Consulting Group wished to conduct a meta-analysis and pool data from the 15 relevant studies. Due to an inadequate quantity of data for these purposes, only nine studies were ultimately pooled. For the nine studies that could be pooled, the random-effects meta-analysis was significant and found a 2.722 relative crash risk. The findings of the remaining six studies that could not be included in the pool did not contradict the findings from this meta-analysis, and neither did the sensitivity analyses. This meta-analysis indicates that, as a group, drivers with OSA are at an increased risk for a motor vehicle crash when compared with comparable drivers who do not have the disorder. The precise estimate of magnitude of this increased risk could not be calculated. The findings demonstrated that the crash risk among individuals with a diagnosis of OSA is between 30 percent and 572 percent higher than comparable individuals without the disorder.

When the Manila Consulting Group updated the 2007 evidence report, they conducted an updated search, including studies through May 2011. Through this search, they identified an additional study to include: Komdama et al., 2009, which looked at crash and crash risk. Komada et al. found that crash risk is higher for those individuals with OSA. Dr. Tregear also noted that the group identified some new studies that examined the impact of OSA on driving performance. These studies used simulation, visual vigilance testing, and naturalistic driving, and found that individuals with OSA showed reductions in driving-related performance across the board. Due to the large volume of crash data, the Manila Consulting Group did not look at less direct measures of simulated studies. Rather, the Manila Consulting Group focused on new information—the Komada et al., 2009 study. Including this new study did not change the original findings, but rather verified the 2007 results. The updated results still indicate a greater crash risk—243 percent—for those with OSA.

Dr. Osbahr requested clarification regarding Dr. Tregear's statement that the quality of the data used for pooling in the meta-analysis was low. Dr. Tregear noted that a study was considered low quality because of the quality of the study analysis overall, and was not because the study was being used to conduct meta-analysis. Dr. Osbahr requested further clarification, noting that, even when the quality of the study is listed as "low," the p-value resulting from the meta-analysis indicates that the evidence is strong. Dr. Tregear responded that the strength of a body of evidence was determined by looking at the quality of the study and the consistency of the data. In this case, the studies were consistent in that they all showed an increased crash risk. The magnitude of effect was large, increasing confidence in the final conclusion. For the sensitivity analysis, the group examined the assumptions used in carrying out the analysis, whether something was wrong with them, and the effect of removing those studies with small confidence intervals. The group found that the data was extremely robust. When a study is listed as "strong," this indicates that there is confidence in the study results as time goes by, and that the group feels it is unlikely that later results will contradict the study's conclusion.

Dr. Hoffman asked Dr. Tregear to provide further explanation on the magnitude of the issue of the relationship between crash risk and an OSA diagnosis as compared to the crash risk in other areas that FMCSA is currently regulating. Dr. Tregear responded that the issue of the relationship between crash risk and an OSA diagnosis is at a much larger order of magnitude than other areas that FMCSA is currently regulating. While the findings on the relationship between crash risk and OSA have not been controversial and new studies have confirmed previous findings, the issue lies in how to address the issue in terms of treatment and diagnosing OSA.

Key Question # 2: What disease-related factors are associated with an increased motor vehicle crash risk among individuals with OSA?

Ten studies were found that met the inclusion criteria for Key Question #2. All of these studies were case-controlled, and one was specific to CMV drivers. In looking at these studies, the Manila Consulting Group sought to examine what about OSA leads to an increased crash risk. Stoohs et al., 1994 examined the relationship between several potential risk factors for CMV drivers. These potential risk factors were presence of excessive daytime sleepiness, severity of

sleep disordered breathing, and BMI. The study found that excessive daytime sleepiness was associated with an increased crash risk among CMV drivers, and that neither the severity of sleep disordered breathing nor BMI was significantly associated with crash risk.

Dr. Tregear reviewed that four factors have consistently been shown to be associated with crash risk among the general driving population:

1. Severity of disordered respiration during sleep (as measured by the Apnea-Hypopnea Index or the Respiratory Disturbance Index);
2. Presence and degree of daytime sleepiness (as measured using the ESS but not the Multiple Sleep Latency Test (MSLT) or the Maintenance of Wakefulness Test (MWT));
3. Blood oxygen saturation levels; and
4. BMI.

Dr. Tregear noted that one of the easiest factors to focus on is BMI, as it is an objective measurement, and is easy to measure. Blood oxygen saturation levels are not easy to measure, and the presence and degree of daytime sleepiness is often measured using subjective self-evaluation scales such as ESS. To overcome the subjectivity involved in measuring sleepiness and its severity, a person would need to have an overnight sonogram or be tested using a portable instrument. Overall, out of these four measures, the two most useful measures on which to focus for the purposes of the report were BMI and the presence and degree of sleepiness.

When the Manila Consulting Group updated the 2007 evidence report, they conducted an updated search, including studies through May 2011. Through this search, they identified three additional studies to include: Amra et al., 2011, Komada et al., 2009, and Phillip et al., 2008. All three of these studies came to the same finding as the Stoohs et al., 1994 report regarding daytime sleepiness.

Dr. Pervall requested clarification from Dr. Tregear regarding the study results showing that the degree of daytime sleepiness is correlated using the ESS, but not the MWT or MSLT. Dr. Pervall asked whether this result was because these tests were not used, or because they were used and no correlation was found. Dr. Tregear responded that the MWT and MSLT showed trends, but were not statistically significant and were therefore inconclusive. Dr. Tregear suggested that more objective measures would likely find an association.

Dr. Osbahr commented that, if people responded to the ESS honestly and truthfully reported whether they experienced daytime sleepiness, more robust information would be available and additional tests would not be needed. Dr. Tregear responded that, with this study, people did not face disincentives for answering the questions truthfully.

Key Question #3: Given the findings of Key Question #2, are individuals with OSA unaware of the presence of the factors that appear to be associated with an increased motor vehicle crash risk?

Three studies were found that met the inclusion criteria for Key Question #3. These studies were all case-series and used different approaches to answer the same problem. The results of the studies indicate that individuals with OSA may not be aware of the extent to which they are affected by daytime sleepiness.

When the Manila Consulting Group updated the 2007 evidence report, they conducted an updated search, including studies through May 2011. Through this search, they did not identify any additional studies to include.

Key Question # 4: Are there screening/diagnostic tests available that will enable examiners to identify those individuals with OSA who are at an increased risk for a motor vehicle crash?

In 2007, 43 studies met the inclusion criteria for Key Question #4. Forty-two of these studies assessed the diagnostic performance of a portable sleep monitoring system. One study assessed the effectiveness of a clinical model in addition to a portable sleep monitoring system, and was the only study to have enrolled only CMV drivers. In analyzing these studies, the Manila Consulting Group only examined sensitivities and specificities presented in the report, as the measures were not specific enough to predict values in a diagnostic test.

The findings from the studies indicate that no model or psychometric instrument has been shown to accurately stratify individuals with OSA by disease severity (as a surrogate marker for crash risk) and that a number of portable sleep monitoring systems, though not as accurate as the current reference standard of a polysomnogram, offer an alternative method for assessing the severity of OSA in a large number of individuals at a relatively low cost. The Manila Consulting Group determined that it is not clear whether these systems are accurate enough to be considered acceptable alternatives for a polysomnogram for stratifying individuals by OSA severity for the purposes of making decisions about the fitness of an individual to drive a CMV. In evaluating whether the data could be used to conduct a cost/benefit analysis in helping to make a decision about whether an individual should be permitted to have a diagnosis based on evidence from a portable, take-home system, Dr. Tregear noted that, while portable devices seem to be fairly effective, further analysis is needed to determine the specific risks and benefits.

Dr. Hoffman noted that, by combining the predictive value of a questionnaire with the predictive value of the portable equipment, the positive predictive value is likely to be high. If a person tests negative on a portable test, it would make sense to send them for further screening at an overnight facility. Dr. Tregear agreed that the additional testing would likely be helpful and the results could be modeled. Dr. Hoffman suggested that modeling these outcomes should be a recommendation of the MRB.

Dr. Tregear noted that the overall conclusion regarding Key Question #4 was that portable sleep study systems have good sensitivities and specificities, but require further study for what this means in real terms. He noted that it is important to look at the impact of making false negative or false positive decisions. Dr. Tregear added that many modeling studies can be conducted using this data to generate different scenarios and combinations.

When the Manila Consulting Group updated the 2007 evidence report, they conducted an updated search, including studies through May 2011. Through this search, they identified 10 additional studies to include. The Manila Consulting Group recommended that FMCSA consider commissioning a new set of analyses to include this new data. The tests have not yet been conducted, as the time required for diagnostic meta-analysis is much lengthier than other meta-analyses.

Key Question # 5: Which treatments have been shown to effectively reduce crash risk among individuals with OSA?

Dr. Tregear noted that a large volume of evidence was available on treatment effectiveness; however, no crash studies were conducted looking at the use of such things as dental devices, etc. The most information was available on continuous positive air pressure (CPAP). Nine crash studies, 10 studies on simulated driving performance, and 48 studies on indirect measures were identified. As it relates to crash risk, there is strong evidence that the use of CPAP is effective in reducing crash risk. For individuals who had been using CPAP for a period of time, their crash risk was reduced by 72 percent. Evidence also indicates that the impact on crash risk for starting and stopping CPAP use is compelling. For driver simulation studies, individuals were tested initially, and then given a CPAP machine and asked to return a few days later for re-testing. Individuals improved, indicating that CPAP is effective in reducing crash risk during driver simulation studies as well. The study found that CPAP provides the most convincing evidence for reducing crash risk. Mandibular advancement splints were found to improve simulated driver performance as well.

Dr. Hoffman noted that, with the mandibular advancement splints, unless one is looking at milder forms of sleep apnea, it is likely that one will not be able to detect whether the device works reasonably well. Dr. Tregear responded that, with new studies, it is likely that groups will be able to be stratified based on OSA severity. These studies may or may not strengthen current conclusions.

When the Manila Consulting Group updated the 2007 evidence report, they conducted an updated search, including studies through May 2011, and identified over 30 new studies. This search involved conducting a systematic review on the impact of CPAP on crash risk identified. One study, Antonopoulos et al., 2010 suggests that nasal CPAP is more effective among patients entering the studies with a higher baseline of accident rates. Due to the high volume of new information, the Manila Consulting Group recommended that FMCSA consider commissioning a new set of analyses to include the new data.

The Manila Consulting Group identified a follow-up question to Key Question #5: is the crash reduction large enough to reduce the crash risk to "normal" levels? Dr. Tregear noted that only three studies could be used to respond to the follow-up question. The evidence indicated no significant difference, which proved that CPAP is effective in reducing the crash risk to "normal" levels. Indirect measures suggest that not all individuals will attain normal levels of function.

Dr. Osbahr requested to know the degree to which the crash rate dropped for this measure from the baseline for those with OSA prior to treatment. Dr. Tregear responded that there was a 60 percent drop from the baseline. Dr. Osbahr noted that the studies still indicate a 100 percent difference between the two groups. Dr. Tregear responded that it is difficult to draw conclusions from the limited number of studies available.

When the Manila Consulting Group updated the 2007 evidence report, they conducted an updated search, including studies through May 2011, and did not identify any new studies that looked at the issue of CPAP. The Manila Consulting Group did find over 30 new studies that looked at all treatment options. Due to the volume of new studies identified, the Manila Consulting Group recommended that FMCSA consider commissioning a new set of analyses to include the new data.

Key Question # 6: What is the length of time required following initiation of an effective treatment for individuals with OSA to reach a degree of improvement that would permit safe driving?

In 2007, 24 studies met the inclusion criteria for Key Question #6. Twelve of these studies looked at CPAP only, one looked at CPAP and other appliances, one looked at CPAP and medication, nine studies looked at medication only, and one looked at oral appliances only. The studies indicate that CPAP's impact on crash risk reduction among individuals with OSA is seen after as little as one night of treatment. For simulated driving performance studies, the severity of disordered respiration, blood oxygen saturation, and some (but not all) measures of cognitive and psychomotor performance improved significantly following one night of treatment. Given the results of these studies, questions remain regarding exactly how many nights of treatment are required until CPAP exerts its maximum benefit on reducing crash risk to "normal" levels. While this number is not known exactly, evidence suggests it to be less than two weeks.

When the Manila Consulting Group updated the 2007 evidence report, they conducted an updated search, including studies through May 2011, and did not identify any new studies.

Key Question #7: How soon, following cessation of treatment (i.e., as a consequence of non-compliance), will individuals with OSA demonstrate reduced driver safety?

In 2007, four studies met the inclusion criteria for Key Question #7. Dr. Tregear noted that one of the biggest issues facing CPAP is compliance and having people use the mask every single night. Extensive research has been conducted on compliance and how to improve it, including behavioral treatments. Evidence indicated that cessation of CPAP leads to a decrease in simulated driving ability and increases in both OSA severity and daytime sleepiness. While the exact rate at which deterioration occurs cannot be determined, this deterioration may occur as soon as 24 hours following cessation of treatment. Dr. Tregear noted that the evidence demonstrates CPAP's effectiveness in improving OSA, and underscores the importance of ensuring that drivers are compliant before being allowed to drive again.

When the Manila Consulting Group updated the 2007 evidence report, they conducted an updated search, including studies through May 2011, and did not identify any new studies.

Dr. Tregear provided a general overview of the report findings: if someone has sleep apnea, he/she is at an increased risk for a crash, particularly if he/she experiences excessive daytime sleepiness. He also noted that there is a strong correlation between OSA and BMI levels. While many treatments are available, CPAP is the only treatment that has been shown, up to this point in time, to decrease crash risk. One issue with CPAP involves compliance, and the demonstrated increase in crash risk involved in non-compliance.

Dr. Tregear stated that many new studies were identified that looked at crash risk, and these supported the original findings. The new meta-analysis that was conducted also supports the original findings. Two areas require further research, as the findings are inconclusive: the effectiveness of portable sleep apnea machines and how they might be used in an algorithm; and treatment effectiveness, as CPAP has demonstrated effectiveness, but other treatments may be available that are equally effective.

MRB Discussion and Deliberation on Obstructive Sleep Apnea

Dr. Morris noted that, for clinicians, an important concern regarding this data is identifying an easy way to assess risk for sleep apnea in a doctor's office. Given this, Dr. Morris asked Dr. Tregear to comment on whether he thought BMI would be an effective screening tool for drivers, and if so, the BMI level at which further testing for OSA should occur.

Dr. Tregear responded that the MEP recommended BMI as a useful means by which to determine who should be selected for further testing. The MEP selected a BMI of 33 as a reasonable cut-off, above which people should be given a sleep test. The MEP also considered the proportion of individuals who would not be captured if the cutoff were to be raised. Dr. Tregear elaborated on the MEP's recommendation, noting that they selected 33 because it is an inflection point. If the MRB recommended a cutoff of 35, the percentage of individuals with OSA would increase rapidly. To make this determination, Dr. Tregear stressed the importance of using good data, and highlighted that the determination is largely a cost/benefit exercise.

Dr. Osbahr commented that the American Sleep Apnea Association found that the majority of people with sleep apnea are not obese. He also highlighted a study demonstrating a linear relationship between sleep apnea and BMI, which the MEP used to develop their recommendation. Dr. Osbahr recommended the MRB look at this study as well.

Dr. Hoffman mentioned an additional study that demonstrates a linear relationship where an increase in OSA prevalence starts at 25, and high prevalence is demonstrated at 30. He noted that the importance of making a recommendation to FMCSA on a cutoff is clear.

Dr. Lester noted that, in examining these studies, it is important to keep in mind that they may be written from the perspective of the authoring organization. Thus, methods and strength of studies vary widely. Techniques for generating results also vary widely, which is seen clearly with BMI where the measurements differ depending on who is conducting them.

Dr. Hoffman commented that a high percentage of those with sleep apnea have been found not to have high BMI. In FMCSA's current screening questionnaire, people are asked about factors other than biometric information. The information is therefore being captured, but the accuracy cannot be verified. Dr. Hoffman suggested that, given minor differences between the prior MEP and MRB recommendations, it may help to have a physician familiar with sleep apnea make recommendations on the BMI cutoff.

Dr. Hoffman recommended that the Board finalize its recommendations as to whether it would like to adopt the prior recommendations, or identify the additional studies that are needed.

Public Comments on Obstructive Sleep Apnea

Mr. Edward Grandi, Executive Director of the American Sleep Apnea Association, requested that MRB confirm a recommendation about commercial drivers and OSA, as the community is currently relying on a wide range of criteria that can be applied to drivers. By promulgating the rule, the medical community will be able to comment and a decision can be enacted. Mr. Grandi indicated his support for CPAP machines, noting that CPAP compliance would be a barrier to ensuring drivers are treated adequately.

Dr. Natalie Hartenbaum from the American College of Occupational and Environmental Medicine indicated support for Mr. Grandi's comments and noted that medical examiners would benefit from a recommendation from MRB. Without a regulation, many examiners face pushback from employers to conduct an initial screening test. This results in drivers receiving the lowest quality exam possible. Dr. Hartenbaum noted that the ESS is no longer an effective diagnostic test, as many drivers are trained to answer the questions to avoid diagnosis. Dr. Hartenbaum requested that MRB select a BMI number for screening, as this will reduce crash risk at some level.

Dr. Osbahr asked Dr. Hartenbaum for a recommendation on what number she would select. Dr. Hartenbaum responded that she would select 35, as this would ensure that drivers with the highest risk of crashes would be tested. Dr. Hartenbaum noted that this number may need to change depending on the prevalence of OSA diagnosis for drivers at this level. If 90 percent of drivers have a BMI of 35 or over, and 40 percent are found to have OSA, it indicates that screening for OSA may need to occur at a lower BMI level.

Mr. Rick Schweitzer from the National Private Truck Council commented that the lack of a specific regulation and clarity in the information provided by FMCSA on OSA makes it difficult to advise truck companies on how to address sleep apnea in their drivers. The National Private Truck Council has put together a task force of company representatives, medical community members, and vendors to review the information available on treatment and screening and identify effective ways of identifying and treating OSA. Mr. Schweitzer noted that plaintiff lawyers are taking advantage of the gray areas in the regulations to use any potential diagnosis of untreated sleep apnea as evidence of fatigue and crash causation, which is presenting issues for internal company human resources and is related to insurance. The National Private Truck Council is concerned that a future regulation could disqualify a substantial percentage of the driver pool, and so has advised companies to take a proactive approach and take an interest in

their driver's health as a way to ensure drivers are treated and have medical benefit support. The National Private Truck Council feels that this approach could help companies attract and retain drivers while also improving road safety. For the National Private Truck Council, the most important outcome from MRB will not be the specific cutoff number, but rather having a cutoff number identified.

Dr. Osbahr requested that Mr. Schweitzer recommend a BMI cutoff. Mr. Schweitzer recommended either 33 or 35, noting that picking a higher number would ensure the most severe cases are identified and would hopefully minimize the impact on disqualifying a larger portion of the driver pool than would result from picking a lower number.

Dr. Alan Lankford, speaking on behalf of both the Sleep Disorders Center of Georgia and Sleep Safe Drivers, discussed the value of portable monitoring. One issue involved with portable monitoring, however, is chain of custody, as it is important to ensure the driver who should be tested is the one for whom data is being collected. Dr. Lankford encouraged the MRB to consider other potential paper-and-pencil initial screening tools to stratify drivers. The Allan Pack test and the multivariable sleep apnea predictor test combine self-reported factors with other measures, and scores above a certain level indicate an issue. In Dr. Lankford's practice, these tests have proven fairly accurate. Dr. Lankford recommended a BMI cutoff of 33. He encouraged the MRB not to rely on BMI alone, but rather to use it in combination with other factors such as neck size (17 inches for males and 16.5 inches for females), sex, and age. Currently, Dr. Lankford is using a portable monitor with wireless technology to monitor users on a daily basis in an effort to document compliance.

Dr. Osbahr thanked Dr. Lankford for raising the issue of chain of custody. Dr. Osbahr asked Dr. Lankford if requiring a fingerprint match to operate a portable machine would remedy this issue. Dr. Lankford responded that using identifiable wristbands can help ensure chain of custody.

Dr. Osbahr requested clarification regarding the potential difference between the validity of data between a portable monitoring system and a polysomnogram, wondering if it correlated to a one-to-one ratio. Dr. Lankford responded that, in his practice, he only uses previously tested devices that have demonstrated validity. In general, he prefers level 3 devices rather than level 4, as they enable one to ascertain certain types of sleep disorder breathing, which provides more complete data capture.

Dr. Pervall requested more information on the percentage of people who use portable devices and need to come in for re-testing or for a polysomnogram. Dr. Lankford responded that the decision to re-test a person is made based on evaluation of the data in addition to comorbidities including other sleep disorders. In the over 6,000 tests that Dr. Lankford has conducted, he has experienced a failure rate of 10–20 percent, resulting in part from incorrect use of the portable system (despite training) or a sensor falling off.

Dr. Hoffman noted that, in looking for a screening test to determine who should be tested further, multivariable testing appears like a potentially favorable option. To evaluate this option more effectively, he requested further information regarding the time involved, the cost, and how burdensome it is for both the examiner and the driver. Dr. Lankford responded that the

multivariable test he uses is a 15-item exam during which the driver reports on a number of subjective items. The exam also considers a number of objective parameters, including age, BMI, neck size, etc. Each of these responses is entered into a handheld device that calculates the scores immediately. Other tests are available, including the Berlin questionnaire, the multivariable apnea prediction test, and the STOP-Bang. By combining appropriate patient selection tools up front with portable monitoring, screening can be effective.

Dr. Hoffman noted that the predictive value of good screening tools and portable testing appears to be high such that if someone fails this testing, they should be moved to overnight testing. Policy considerations could help ensure screening is addressed effectively. Dr. Lankford confirmed that the predictive value is high, noting that when screening indicates someone needs further testing, 90 percent of the time this person has OSA. Dr. Hoffman added that another value to using screening tools and portable monitors is the lower cost, which would enable the testing to be available to a wide range of people.

Dr. Morris requested that MRB consider developing a step-wise approach where a screening test would be applied initially, with further testing to be conducted later depending on the results. He asked whether a BMI cutoff level would be appropriate to use during initial screening to determine whether to administer further testing. Dr. Lankford suggested that BMI could be used in addition to other factors such as sex and neck size, in order to identify whether additional screening would be needed. For a BMI cutoff, he recommended using a BMI of 33, and not to use a cutoff lower than 30.

Dr. Hoffman noted that there is a need to improve positive predictive value and reduce negative predictive value with testing. Dr. Lankford noted that he has conducted testing for the Federal Aviation Administration, and they permit pilots with sleep apnea to fly if they use a CPAP and pass the MWT. Dr. Lankford recommended using a MWT over a MSLT; however, these are both time-consuming and may not be practical for testing. Dr. Lankford commented that CPAP has demonstrated benefits, and methods exist to document compliance immediately, and from anywhere in the country. By documenting CPAP compliance on an up-front basis, and continuing to document compliance, results can be achieved. Dr. Lankford did note one caveat, that some studies indicate that up to 30 percent of all patients who have sleep disordered breathing controlled through CPAP still have some residual sleepiness. The reasons for this are not known. For the drivers in this category, it may make sense to use the MSLT.

Dr. Hoffman reminded the MRB that there is a joint meeting between the MRB and the Motor Carrier Safety Advisory Committee in August, during which sleep apnea will be discussed. Given this, Dr. Hoffman recommended that the MRB wait to provide recommendations to FMCSA until after the meeting. Ms. Shannon Watson supported this recommendation. In preparing for this August meeting, Dr. Hoffman requested that the predictive value associated with various types of screening be modeled so that the MRB has a better understanding of the chance of someone being falsely diagnosed with sleep apnea. Dr. Lester added that there is a need to crosswalk the options that are available, and that FMCSA should look into the constraints surrounding both physical and other parameters to identify the sensitivity and specificity that would be applied to each group of parameters.

Dr. Hoffman commented that, ultimately, MRB's recommendation should allow a driver to go to an examiner's office and be tested through a tiered process to ensure the lowest necessary cost possible for an examiner to identify those drivers at the highest risk. In the end, those identified should include a group with reasonable specificity and sensitivity who have been identified using the lowest cost possible.

Dr. Lester said that safety should be considered. With portable devices, there are limited studies defining the sensitivity and specificity for identifying sleep apnea, compared with gold standard polysomnography. Therefore, the challenge in developing this regulation lies in the need to rely on answers to subjective questions, as the technology has not yet reached the point of being able to answer all questions objectively.

Dr. Hoffman noted that collecting biometric information such as BMI and blood pressure will be an important tool for screening, particularly when combined with a self-reported questionnaire such as the Allan Pack test. Further research should be done to investigate instruments that are continually improving specificity without increasing sensitivity. The ultimate goal is to find a portable test that can measure to the gold standard.

Dr. Tregear noted that Dr. Allan Pack served as a member of the MEP. The MEP's screening method of choice was BMI, simply because of its objective nature. Dr. Tregear noted that there are many ways of measuring BMI, including the idea of an algorithm. The MEP suggested looking into the impact of having a multi-level screening test set up before putting someone into a sleep study. The MEP decided that portable studies would suffice and an overnight sleep study would not be needed. They felt that the portable study results would act as a diagnostic that would determine whether the person should use a CPAP or not.

Dr. Hoffman clarified his comment, noting that if someone had a negative sleep study where no presence of sleep apnea was found, this could potentially serve as a trigger within the step-wise algorithm for determining whether someone should be tested in a sleep study lab. The predictive value for finding a negative result is high, such that it may be helpful to have this serve as a trigger. Dr. Hoffman noted that one of the most important factors to him is identifying the least onerous and least costly option as possible.

Dr. Osbahr noted that while portable monitoring systems increase the ease with which one can test someone for sleep apnea, these systems also pick up other factors such as restless leg syndrome and disordered breathing issues. What the portable does not pick up is how sleep issues affect daytime sleepiness. When a portable system returns a positive result, someone is still required to have an additional CPAP study. For the study information, an examiner would have been provided with the sleep study information and the level at which they responded to CPAP. Dr. Hoffman responded that existing technology is advanced enough that examiners should not be required to send everyone into a lab to titrate them.

Dr. Lankford commented that it is important to identify valuable up-front screening techniques, as these can identify sleeping issues. From his experience, answers to certain questions and prior diagnoses can suggest whether a person may suffer from OSA. For example, if it seems likely that someone would have OSA with arrhythmia, this may be associated with sleep disordered

breathing. It is also important to consider whether someone is on nasal CPAP. One of the most important considerations for this issue is constantly monitoring those who are on portable monitoring devices so that treatment can be adjusted immediately, as needed.

Dr. Pervall stated that the issue of sleep apnea is vast and complex. She noted that the MRB has only covered criteria to include and has not yet begun to consider the diagnostic test. Given this, Dr. Pervall recommended that the MRB focus on identifying criteria—whether this is a screening tool or a BMI number—and the parameters for determining when a person should be recommended to go in for a sleep study.

Dr. Morris recommended that the MRB ask the Manila Consulting Group to generate an algorithm to serve as a screening technique to determine whether a portable study should be conducted.

Dr. Lester recommended that the MRB look at the update to the 2007 report when determining the parameters that would be the most likely to return the highest yield of drivers at the greatest risk.

Additional Public Comments

Mr. Boyd Stephenson, American Trucking Associations, asked to speak to the MRB on the Hours of Service (HOS) rulemaking. He provided a background of the rulemaking, stating that the rules were initially promulgated in 1939 and were not changed again until 2004. Since then, three iterations were promulgated in some final form, all of which have been litigated, and a fourth set of proposed rules was recently promulgated. In the fall of 2009, the third rule was being litigated and FMCSA settled and agreed to revisit the rule. In the past, the rule's benefits were based solely on safety benefits. For this fourth iteration, FMCSA made claims not only based on safety benefits, but also on medical and health benefits resulting from shorter driving hours. MRB is tasked through its charter from FMCSA to advise the FMCSA Administrator and Secretary of Transportation on driver medical health issues. Mr. Stephenson directly asked the board whether, since FMCSA settled that lawsuit in fall of 2009 and when they issued the fourth proposed rule in December 2010, had the Agency come to MRB for advice on the medical health issues?

Dr. Hoffman deferred to Larry Minor on the issue. Mr. Minor stated that the Agency did not request the opinion from MRB to generate the 2010 HOS Notice of Proposed Rulemaking. The Agency relied on its team to look at the research reports published in the past and concluded that there would be health benefits by reducing the length of the work week. They found a correlation between long work hours during the work day and work week with hypertension and obesity. If FMCSA can shorten the work week, it would reduce incidence of various health conditions and would provide some health benefits. Mr. Stephenson asked to clarify whether those were individual medical studies, and not research reports that were part of FMCSA medical process or medical expert panels. Mr. Minor confirmed this and stated that all studies were in rulemaking docket. The MRB asked Mr. Stephenson to explain the current rule, which Mr. Stephenson explained. Dr. Osbahr stated that among the issues they encounter are problems with Circadian rhythm and problems of fatigue, and knows that these are issues they need to assess. Mr.

Stephenson stated that he was pleased with the current rule and said there had seen a dramatic decrease in accidents.

Dr. Hoffman adjourned the meeting.

CERTIFICATION

The minutes were approved by the Medical Review Board on 8/22/11.
(Date)

We hereby certify that, to the best of our knowledge, the foregoing minutes are accurate and complete.

Benjamin H. Hoffman, M.D.
Chairperson
Medical Review Board

Larry W. Minor
Designated Federal Official
Medical Review Board