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 Safety Administration (FMCSA) was convened on July 1, 2009, in Washington, D.C. The meeting was open to the public.

Board Members Present:
Kurt Hegmann, M.D., Chairperson
Gunnar Andersson, M.D.
Benjamin Hoffman, M.D.
Barbara Phillips, M.D.
Carl Soderstrom, M.D.

FMCSA Staff:
*Mary D. Gunnels, Ph.D., Director, Office of Medical Programs
Charles Horan, Director, Office of Bus and Truck Standards and Operations
Elaine Papp, Chief, Office of Medical Programs
Michael Boyle
Duane DeBruyne
Linda Phillips
Tom Yager

**Designated Federal Official*

FMCSA Contractors:
Glenna Tinney, Axiom Resource Management, Inc.
Purvi Shah, Axiom Resource Management, Inc.
Mary Johnson, Axiom Resource Management, Inc.
Jennifer Musick, Axiom Resource Management, Inc.
Lonnie Weiss, Weiss Consulting, LLC.
Stephen Tregear, D.Phil., Manila Consulting Group, Inc.
Jessica Williams, Ph.D., M.P.H., R.N., Manila Consulting Group, Inc.
James Reston, Ph.D., ECRI Institute, Inc.

Members of the Public:
Annie Berman, Talk Radio/Media News Service
Cynthia Cramblett, Owner-Operator Independent Driver Association (OOIDA)
Christie Cullinan, American Trucking Associations
Gerald Donaldson, Advocates for Highway and Auto Safety
Jonathan Dudek, Executive Action, LLC
Ann-Louise Gates, ICF International
Benjamin Gerson, University Services
Sandy Harding, American Academy of Physician Assistants

Natalie Hartenbaum, OccuMedix, Inc.
Jeffery Heinrich, OOIDA
John McElligott, OOIDA
Barbara Raimondo, National Association for the Deaf
Melissa Rohan, OOIDA
Joel Whiteman, Road Ready, Inc.

Call to Order

Mary D. Gunnels, Ph.D., Director, Office of Medical Programs, FMCSA, called the eleventh public meeting of the MRB to order, noting that she is the Designated Federal Official for the meeting. She introduced and welcomed two new members to the Board, Benjamin Hoffman, M.D., and Carl Soderstrom, M.D. She announced that the MRB would discuss several topics including psychiatric disorders, musculoskeletal disease and spinal cord injury, implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy (CRT), and excessive daytime sleepiness and commercial motor vehicle (CMV) driver safety. She noted the sleep discussion would be on other sleep disorders and not sleep apnea, which the MRB previously addressed and made recommendations on at the January 2008 MRB meeting.

Dr. Gunnels explained that there would be presentations on the evidence report findings for each topic and a presentation of the Medical Expert Panel (MEP) opinions on psychiatric disorders. Each presentation would be followed by a designated public comment period and MRB deliberation.

Dr. Gunnels requested that attendees complete the evaluation form before leaving the meeting. She also announced that a detailed summary of the meeting would be prepared and posted on the MRB Web site at www.mrb.fmcsa.dot.gov.

Before turning the meeting over to Kurt Hegmann, M.D., Dr. Gunnels asked the MRB to consider how the topic of age relates to CMV driver safety. She added that it is important to begin a discussion about the effects of age on various medical conditions and how age could impact drivers.

MRB Approval of January 12, 2009 Meeting Summary

Dr. Hegmann called for official approval of the minutes of the 10th public meeting of the MRB held on January 12, 2009. The minutes were unanimously approved.

Presentation of Evidence Report Findings: Psychiatric Disorders and CMV Driver Safety
James Reston, Ph.D.

James Reston, Ph.D., ECRI Institute, presented an overview of the evidence report findings on psychiatric disorders and CMV driver safety. He noted that FMCSA was interested in the potential risk for CMV crash associated with the following psychiatric disorders: psychotic disorder, mood disorder, anxiety disorder, and personality disorder. The following Key Questions were addressed.

Key Question # 1: Are individuals with a psychiatric disorder at an increased risk for motor vehicle crash? If so, are there specific psychiatric disorders that present a particularly high risk?

Key Question # 2: Are individuals using psychotherapeutics for a psychiatric disorder at an increased risk for crash when compared to individuals not using psychotherapeutics?

Key Question # 3: What traits associated with personality disorders are associated with reductions in motor vehicle driver safety?

Key Question Responses

Key Question # 1: Are individuals with a psychiatric disorder at an increased risk for motor vehicle crash? If so, are there specific psychiatric disorders that present a particularly high risk?

Dr. Reston reported the literature search revealed eight studies that met the inclusion criteria. None of the studies specifically focused on the CMV driver population, so the degree to which these findings can be generalized to the CMV population is unclear. Seven studies were cohort studies and one was a case control study. The average quality of the evidence base was low.

All cohort studies compared drivers with psychiatric disorders to a control population without psychiatric disorders. The case control study compared the prevalence of psychiatric disorders among drivers who crashed to drivers who did not crash. Dr. Reston pointed out that none of the studies differentiated between crashes that occurred during active symptoms and crashes that occurred when no symptoms were present. Only two of the studies reported the types of medications (if any) that some of the drivers were taking. This is a possible confounding factor because some medications can have side effects which may affect driving ability.

Dr. Reston indicated that the findings from the studies are inconclusive. However, the possibility of increased crash risk for some drivers with these disorders cannot be ruled out based on this evidence. He said that evidence points slightly in the direction of increased risk, but the strength of the evidence is minimally acceptable.

Dr. Reston explained that the specific subgroups of psychiatric disorders were investigated separately to determine if any disorder represented a higher risk than others.

Psychotic Disorders
Four studies separately reported data for individuals with psychotic disorders. The data were combined in a meta-analysis which did not reveal any statistically significant findings. Dr. Reston concluded the current evidence does not suggest an increased crash risk for individuals with psychotic disorders, but an increased crash risk cannot be ruled out. The strength of the evidence is minimally acceptable.

Mood Disorders
Three studies were found that separately reported data for mood disorders—two on depression and one on manic depression (bipolar disorder). Dr. Reston explained that none of the studies showed a statistically significant difference indicating an increased risk for crash. The evidence suggests a possibility of increased risk, but more evidence will be needed to reach a firm conclusion.

Anxiety Disorders
Only one study was available that separately reported data for individuals with anxiety disorders. Dr. Reston explained the evidence is too vague to draw firm conclusions about crash risk related to anxiety disorders.

Personality Disorders
Three studies separately reported data for individuals with personality disorders. The data were combined in a meta-analysis; however, no statistically significant difference was found. Dr. Reston explained that due to inconsistencies in the evidence base, a conclusion could not be made about the effect of personality disorders on crash risk.

Key Question # 2: Are individuals using psychotherapeutics for a psychiatric disorder at an increased risk for crash when compared to individuals not using psychotherapeutics?

Researchers investigated the possible effects of psychotherapeutic drugs and crash risk. These drugs may affect cognitive and psychomotor abilities which may contribute to crash risk. Dr. Reston explained evidence was found for three main categories of drugs: anxiolytics, antipsychotics, and antidepressants. He reported the findings for each group.

Anxiolytics
Dr. Reston reported nine studies were found that met the inclusion criteria. None of the studies specifically focused on CMV drivers, so the degree to which the findings can be generalized to the CMV population is unclear. Six of the studies were case control studies, two were cohort studies, and one was a cross-sectional survey. The average quality of the studies is moderate. All of the studies reported data on benzodiazepines which is the largest class of anxiolytic drugs. However, some of the benzodiazepines are actually hypnotics rather than anxiolytics. Hypnotics are primarily used for treatment of insomnia, so they would not be used in individuals with psychiatric diagnoses. The data from all nine studies were analyzed together and then a subgroup analysis was performed on the five remaining studies that reported separate data for anxiolytics.

Dr. Reston said there is enough evidence to conclude that benzodiazepine use is associated with increased crash risk. The strength of this evidence is moderate. The five studies that separately reported data on anxiolytics confirmed the findings of the larger analysis. This supports the conclusion that anxiolytic use is associated with an increased crash risk. The strength of the evidence is only minimally acceptable because the subgroup meta-analysis was not as robust as the nine study meta-analysis.

The researchers considered other factors that might affect the relationship between increased crash risk and benzodiazepines, such as exposure time. The two studies that reported data on exposure time indicated the risk for crash may be greater during the first week of an index prescription of benzodiazepines. The strength of this evidence is only minimally acceptable. Dr. Reston added there was also some evidence that shows crash risk may be greater for benzodiazepine users who are less than or equal to 40 years of age. This evidence is minimally acceptable.

Antipsychotics
One study on antipsychotics found no increase in crash risk within 2 to 4 weeks of the index prescription of antipsychotics. Dr. Reston said the evidence concerning crash risk associated with antipsychotic use is inconclusive, and more studies are needed to come to an evidence-based conclusion on this question. However, the possibility of increased crash risk cannot be ruled out.

Antidepressants
Seven of the nine studies that reported data on benzodiazepine use also evaluated antidepressant use and possible crash risk. These studies investigated two types of antidepressants: tricyclic antidepressants (TCAs) and selective serotonin reuptake inhibitors (SSRIs). Three studies evaluated only TCAs, two studies evaluated both, and two studies did not specify the type of antidepressants evaluated. Data from six of the seven studies (all antidepressants) were combined

in the initial meta-analysis. Dr. Reston reported the data revealed a trend toward an increased risk, but it was not statistically significant. A subgroup analysis was conducted on the data from the studies that separately reported on TCA use. The findings of this analysis suggested an increased crash risk with those agents; however, the evidence was inconclusive. He noted there were not enough data to conduct a separate subgroup analysis on SSRIs.

Dr. Reston concluded the evidence for crash risk associated with antidepressant use is inconclusive. The possibility of increase crash risk cannot be ruled out—particularly with TCAs. More evidence would be needed to reach a firmer conclusion.

Key Question # 3: What traits associated with personality disorders are associated with reductions in motor vehicle driver safety?

Key Question # 3 assessed the possible association between the traits of personality disorders and crash risk. Dr. Reston reported 21 studies were identified that met the inclusion criteria. There was a mix of study designs including, eight cohort, five case control, and eight surveys. The average quality of the studies was low. Three studies focused specifically on the CMV driver population. The traits evaluated were hostility, aggression, impulsivity, and sensation seeking. These are traits that have been reported to be associated with paranoid personality disorder, antisocial personality disorder, and borderline personality disorder. Dr. Reston noted these studies were not making psychiatric diagnoses. They used 24 separate testing instruments that differed too much to perform a quantitative analysis.

Dr. Reston said the evidence suggests that some of these traits associated with personality disorders lead to an increased risk of CMV crash, including aggression, hostility, and impulsivity. However, inconsistencies in the methodologies of the studies preclude an evidence-based conclusion from being made regarding the strength of the relationship between these traits and crash risk.

Dr. Hegmann thanked Dr. Reston for his presentation and asked the MRB members if they had any questions for Dr. Reston.

MRB Questions and Discussion on Psychiatric Disorders and CMV Driver Safety

Gunnar Andersson, M.D., said that on a previous occasion, Schedule II drugs had been reviewed. He asked if there is any difference in the potential crash risk now compared to the previous research.

Dr. Reston deferred this question to Stephen Tregear, D.Phil., noting that he was involved in the previous report regarding Schedule II drugs. Dr. Tregear responded stating that the report included Schedule II drugs (opioids, amphetamines, etc.); however, benzodiazepines were not included. He noted there is no conflict between the data because the Schedule II report mainly addressed opioid use and not benzodiazepine use. The findings revealed that cognitive function, psychomotor function, and crash risk reduced over time. After about 2 weeks on a regular dose, any deficits that were originally present disappeared. Dr. Tregear added available evidence indicates benzodiazepines are always the biggest problem for driving.

Dr. Hegmann noted Dr. Reston mentioned the word cohort in several of these studies and asked if those studies were mostly retrospective cohort studies of administrative databases. Dr. Reston said that most of these studies were retrospective cohorts. Dr. Hegmann clarified the real issue is the weaknesses in the administrative databases as opposed to having a study constructed to proactively address the questions being raised. Dr. Reston agreed with Dr. Hegmann’s statement.

Dr. Hegmann asked Dr. Reston to highlight some of the weaknesses in the cohort studies. Dr. Reston explained that some of these studies did not control for potential confounding factors, such as driving exposure and medication use. In some cases, outcomes were self-reported rather than derived from a database. Self-reporting may be considered less reliable. There are a number of potential weaknesses in these studies, he said, which is why the quality of the evidence base ranged from low to moderate. These studies generally do not control for all the potential confounders that could affect the observed relationship.

Dr. Hegmann asked to what extent these studies controlled for age or looked for interactions between age and other factors. Dr. Reston explained that the studies on benzodiazepine use for Key Question # 2 specifically looked at age, and the evidence shows an association between younger age, benzodiazepine use, and increased crash risk.

Dr. Andersson asked whether any of the studies controlled for disease severity, noting that the severity of these disorders could potentially impact crash risk. Dr. Reston said that many of these studies did not capture data on the individuals who have the most severe symptoms of psychiatric disorders because many of those individuals would be prohibited from driving. They would most likely be hospitalized undergoing treatment. He added that some of these individuals were taking medication, which is a potential confounding variable, because the medication may be controlling their symptoms and could potentially increase crash risk due to the side effects.

Dr. Hegmann said this indicates that the data were primarily analyzed from a binary standpoint—meaning the individual either has the disorder or does not. Dr. Reston concurred with Dr. Hegmann's statement.

Carl Soderstrom, M.D., noted that in many cases it is difficult to determine if an individual is actually taking the medication they are prescribed. Dr. Reston agreed that compliance is a potential issue. If the data is based on pharmacy records of prescriptions, it is impossible to determine how many patients are actually taking their medication.

Dr. Hegmann introduced Jessica Williams, Ph.D., and explained that she would be presenting an overview of the MEP opinions on psychiatric disorders since none of the MEP members were available to attend this meeting.

Presentation of the MEP Opinions: Psychiatric Disorders and CMV Driver Safety
Jessica Williams, Ph.D.

Dr. Jessica Williams, Manila Consulting Group, Inc., presented an overview of the MEP report on psychiatric disorders. She outlined the MEP opinions and corresponding justifications for psychiatric disorders and CMV drivers.

Opinion # 1: Psychiatric Disorders and CMV Driver Certification

It is the opinion of the MEP that all individuals with a history of the following psychiatric disorders should undergo additional medical and psychiatric evaluation to further assess functional ability before being considered qualified to drive a CMV:

- Psychotic disorder.
- Bipolar disorder.
- Major depressive disorder with a history of psychosis, suicidal ideation, homicidal ideation or a suicide attempt.
- Obsessive compulsive disorder.

- Antisocial personality disorder.

Such individuals must demonstrate they are likely to be able to perform their normal duties by undergoing a thorough evaluation of physical and mental function by a qualified psychiatrist.

It is the opinion of the MEP that the two question version of the Patient Health Questionnaire (PHQ-2) should be added to the medical examination questionnaire to screen for depression.

- If the PHQ-2 is positive for a possible significant depressive disorder, the medical examiner should then refer the patient to a psychiatrist to conduct an interview for major depression, including suicidal ideation and/or suicide attempts.

Justification:
These psychiatric disorders all have the potential to impact driver safety due to their associated symptomatology:

- Psychotic disorder: cognitive impairment, slowed reaction times, distraction, and distorted thinking.
- Bipolar disorder: impulsivity and poor judgment.
- Major depressive disorder: impaired cognitive function, suicidal ideation, suicide attempts, and homicidal thoughts.
- Obsessive compulsive disorder: impaired concentration and motor/functional skills.
- Antisocial personality disorder: aggression, egocentricity, impulsiveness, resentment of authority, disregard of rules, intolerance of frustration, substance misuse, and irresponsibility.

Opinion # 2: Medications for Psychiatric Disorders and CMV Driver Certification

Benzodiazepines:
The MEP believes all individuals currently taking benzodiazepines or similar drugs which act on benzodiazepine receptors should be immediately prohibited from driving a CMV.

- Individuals who take benzodiazepines for any length of time should not be allowed to drive until the drug has been cleared from their system (i.e., within seven half-lives of the drug and active metabolites).
- Chronic users of benzodiazepines (i.e., regular use for more than a month) should also wait an additional week after the drug has cleared from their system before resuming driving to ensure that the drug has been completely eliminated.
- FMCSA should provide information regarding the half-life and seven half-lives of benzodiazepines and active metabolites to medical examiners for use at the time of examination.

Justification:
Benzodiazepine properties include anxiolytic, sedative, hypnotic, anticonvulsant, muscle relaxant, and amnesic properties. These properties can have significant effects on the central nervous system with the potential to impair driving ability.

- Prior research has shown potential associations between benzodiazepines and impaired driving ability.
- The evidence report found the crash odds ratio associated with benzodiazepines is between 1.28 and 2.20, $p<0.0001$.

Lithium:
The MEP is of the opinion that all individuals currently taking lithium should be excluded from driving a CMV at night.

Justification:
Lithium can impair night vision and cognition which can negatively impact a driver's ability to drive safely.

Antipsychotics:
The MEP is of the opinion that all individuals currently taking antipsychotics should undergo additional evaluation before being allowed to operate a CMV.

- The medical examiner should obtain a neuropsychological battery from a referral specialist for individuals currently taking antipsychotic medications to screen for psychomotor impairments.
- If the neuropsychological screening tests suggest impairment, then a road test must be administered.
- Individuals starting a new antipsychotic medication must be evaluated within 1 month.

Justification:
Prior research has shown potential associations between various antipsychotic medications and impaired driving ability.

- For example, several studies have found an association between antipsychotics and impaired psychomotor function or simulated driving performance in patients with schizophrenia.

Antidepressants:
The MEP is of the opinion that all individuals currently taking antidepressants should undergo additional evaluation before being allowed to operate a CMV.

- The medical examiner should use clinical judgment to determine if the patient is too sedated to drive. This should include consideration of:
  - Acute effects of the specific antidepressant(s).
  - The additive effects of other medications the examinee is currently taking.
  - The additive and cumulative effects of job demands such as long hours of driving, often over extended periods of many days.
- For individuals currently taking SSRIs, additional evaluations should include assessments of psychomotor function.
  - The medical examiner should assess balance and coordination with heel-to-toe walking, rapid alternating movement, and measures of perseveration.
  - If impairment is suggested by clinical examination, the medical examiner must obtain a neuropsychological battery of tests from a referral specialist to further test for psychomotor impairment.

Justification:

- Prior research has shown an association between certain antidepressants (usually TCAs) and impaired driving performance.
- Antidepressants can affect the central nervous system and impair driving ability, including:
  - Sedation.
  - Psychomotor function (SSRIs).

Anticonvulsants:
The MEP is of the opinion that all individuals currently taking anticonvulsants should undergo additional evaluation before being allowed to operate a CMV.

- The medical examiner should use clinical judgment to determine if the patient is too sedated to drive. This should include consideration of:
  - Acute effects of the specific anticonvulsant(s).
  - The additive effects of other medications the examinee is currently taking.
  - The additive and cumulative effects of job demands such as long hours of driving, often over extended periods of many days.
- The medical examiner should assess balance and coordination as noted above.
- If impairment is found on clinical examination, a neuropsychological battery of tests should be obtained from a referral specialist to further test for psychomotor impairment.

Justification:

- Anticonvulsants affect the central nervous system with the potential to impair driving ability, including:
  - Sedation.
  - Psychomotor function.

Opinion # 3: National Database of CMV Driver Medical History and Medication Use

It is the opinion of the MEP that FMCSA should create a national database containing the medical histories and medication use of CMV drivers to facilitate future research on possible risk factors for CMV crashes.

Justification:
Given the lack of data regarding medical history, medication use, and crash risk, a national database is needed containing the medical histories and medication use of CMV drivers to facilitate future research on possible risk factors for CMV crashes.

Opinion # 4: Differentiation of Acute and Chronic Psychiatric Disorders

The MEP believes that FMCSA should define acute psychiatric disorders as those that have occurred for less than 6 months and chronic as those which have lasted more than 6 months.

- Remission is defined as having no or minimal symptoms and no longer meeting the diagnostic criteria for the disorder. Determining whether or not an individual is in remission is often a difficult judgment call as it involves assessment of functioning as well as symptoms.
- Anyone who has had a history of a psychiatric disorder of concern, as previously defined, within the past 3 years, or a history of a recurrent disorder of concern, should be re-evaluated intermittently by a qualified psychologist or psychiatrist upon referral from the medical examiner.

Justification:

- Individuals with a history of a psychiatric disorder of concern within the past 3 years may be asymptomatic at the time of the medical evaluation but at risk for recurrence.
- Mental health assessment by a qualified psychologist or psychiatrist should assist the medical examiner in assessing the likelihood of a recurrence and/or need for treatment.

Dr. Hegmann expressed appreciation to Dr. Williams for her presentation and turned the meeting over to Dr. Gunnels for public comment on psychiatric disorders.

Public Comment on Psychiatric Disorders and CMV Driver Safety

Natalie Hartenbaum, M.D., OccuMedix, Inc., asked Dr. Reston to clarify the data on why individuals less than 40 years of age have a higher crash risk. She added that it seems counterintuitive because older individuals metabolize medications slower, and they are more often taking multiple medications. Dr. Reston explained that there were only a couple of studies that reported this finding, and they were not necessarily high quality studies. However, there is some evidence that younger drivers sometimes engage in more risk-taking behavior when driving. It is possible the combination of drugs and people who have a tendency toward risky behavior result in a higher crash risk. He added that among individuals taking benzodiazepines, those younger than 40 years of age have a slightly higher risk.

Barbara Phillips, M.D., noted that older people tend to do less driving and are also likely to better resist sleepiness, which is a side effect of benzodiazepines. Also in one study in Australia, older people were less likely to report sleepiness than younger people, and older people were less likely to crash when controlling for other confounders.

Dr. Hartenbaum expressed a concern about individuals being forthright in answering the PHQ if it is added to the form. She noted that when the questions about sleepiness and snoring were first put on the exam form, a lot of drivers responded yes, and they were all sent for sleep studies. Now medical examiners see very few drivers answering yes to the questions about sleepiness and snoring. She added that she was more concerned about the intermittent use of benzodiazepines rather than chronic use of benzodiazepines as it is more common and does not seem to be addressed. Also, she agreed that restricting lithium use at night would be a good idea, but noted for this to be implemented, the Agency would have to permit medical examiners to put restrictions on drivers. Dr. Hartenbaum also expressed a concern about the administration, reimbursement, and timing of neuropsychological tests. She added that it may also be an issue with training because the of range of medical staff that serve as medical examiners may or may not have the skill and training to adequately administer those types of tests.

Dr. Gunnels asked Dr. Hartenbaum which of the five psychiatric disorders she was most concerned about. Dr. Hartenbaum said that she is concerned with antisocial behavior, risk-taking behavior, and hostile behavior. She noted that depression is a potential problem because of the medications, and anxiety is also a potential problem because of the intermittent use of medications. She added that the biggest problem with these diagnoses is not the name but who is treating them. The majority of individuals are being treated by a general practitioner or family practitioner diagnosing and prescribing drugs without a thorough evaluation.

John McElligott, M.D., OOIDA, asked whether the infrastructure exists to make such referrals. He noted that a lot of drivers are prescribed benzodiazepines for sleep problems. He explained that most drivers are given TCAs and told to take them at bedtime because it helps them sleep and also helps their aching bones and joints. He asked if any of the studies report on the timing of taking these medications.

Dr. Reston noted that only a few studies reported on the timing of the medications. A couple of the studies showed the highest risk was with benzodiazepine users within the first week of an index prescription. The risk may drop slightly over time, but it does not completely go away.

Dr. Tregear added that seven and a half half-lives for a drug like benzodiazepine is a long time and will continue to impact the individual the following day. Individuals are advised to take SSRIs in the morning because the metabolism of the drug is slowed down at night. He said that the real problem is not when a person takes these drugs or the kind of countermeasures they may take. The fact that these drugs are not metabolized very quickly does not alleviate the problems that are associated with these drugs.

Jonathan Dudek, Ph.D., Executive Action, LLC, explained that he runs a forensic and police psychology practice that helps mitigate liability with police officers. He noted that in his practice, they employ a lot of actuarial methodology to assess liability-based behaviors. He asked whether there was another way to screen CVM drivers looking at liability-based behaviors at the pre-employment phase, keeping it consistent with the Americans with Disabilities Act (ADA). He asked the MRB whether there might be a way to design a similar screening measure to mitigate crash risk for CMV drivers.

Dr. Hoffman asked Dr. Dudek to explain the actuarial process.

Dr. Dudek explained that the actuarial process is similar to what a life insurance company would do when underwriting a policy. The medical history is reviewed to determine whether or not to write a policy based on medical risk factors.

Barbara Romano, National Association for the Deaf (NAD), explained that her organization has been concerned with the hearing requirements for quite some time as they potentially deny a livelihood to many individuals. The evidence does not show that it is necessary to be able hear to be a safe driver. She pointed out that the evidence regarding the relationship between hearing loss and increased risk for a crash is inconclusive based on the report presented at the October 6, 2008, MRB meeting. She added that FMCSA allows drivers who have lost a foot, leg, hand, or arm to drive if they have obtained a Skill Performance Evaluation certification. She noted that this also applies to drivers with visual impairments or diabetes, if they meet certain requirements for the waiver program. There is a precedent for waiving these rules for some categories of drivers. The NAD requests that FMCSA establish and implement a system through which deaf and hard-of-hearing drivers who meet other established criteria are permitted to obtain a commercial driver's license that is valid for interstate transportation.

Dr. Gunnels said that the MRB was not scheduled to deliberate on this topic today, but it is something that they can revisit in the future. She noted that the MRB and MEP made recommendations on hearing last year. FMCSA will look at these issues and will stay in contact with the NAD.

MRB Deliberation on Psychiatric Disorders and CMV Driver Safety

Dr. Hegmann noted that some of the issues surrounding this topic have been dealt with at previous meetings. In July 2008, the MRB addressed multiple conditions, including benzodiazepine use. In April 2008, the MRB recommended a nationwide database on all CMV drivers involved in fatal crashes. Following his comments, Dr. Hegmann invited discussion and deliberation of the MRB on the topic of psychiatric disorders.

Dr. Andersson noted that there have been several references to individuals being evaluated by a qualified psychiatrist. He asked how one defines a qualified psychiatrist. It is assumed that a physician who has completed a residency in psychiatry is a qualified psychiatrist. He added that some of the evaluations suggested by the MEP could be done by a psychologist. He expressed the concern that there are not enough psychiatrists to evaluate all the individuals being suggested.

Dr. Soderstrom added there are a large number of mental health clinicians and advanced practice psychiatric/mental health nurses who are more than qualified to perform evaluations.
Dr. Hoffman agreed with Drs. Andersson and Soderstrom and noted that from a practical perspective, it is difficult or nearly impossible to expect a person to see a psychiatrist for an evaluation for the five noted psychiatric disorders. He said the evaluation process needs to be expanded to a broader scope of mental health professionals.

Dr. Hoffman made the following motion: The MRB recommends to FMCSA that the evaluation not be limited to a psychiatrist but include any master's degree or higher level licensed mental health professional. The motion was seconded.

Dr. Andersson said he is in favor of this motion. He asked if Dr. Hoffman was suggesting that the MRB accept all of the MEP opinions for evaluations. Dr. Hoffman clarified that this proposed recommendation would only apply to MEP Opinion # 1.

Dr. Phillips asked for clarification, noting that the MEP Opinion # 1 currently states, "All individuals with a history of the following psychiatric disorders undergo additional medical and psychiatric evaluation." She asked if Dr. Hoffman recommends that it be changed to "licensed mental health professional." Dr. Hoffman confirmed that he did and added that it would also have to be changed from "psychiatric" to "psychological" evaluation.

Dr. Hegmann asked the intent regarding severity. For example, what if an individual is on three different medications; is a psychologist going to be the clinician recommended to handle that case? Dr. Hoffmann said that a psychologist would be capable of making that determination and can escalate the case if necessary. He added that the majority of these treatment decisions can be made by a lower-level practitioner. From a practical perspective, it is very difficult to get in to see a psychiatrist, which could delay the process and may be an unnecessary level of clinical evaluation.

Dr. Hegmann noted that a majority of individuals with these conditions have rarely seen a mental health professional. There are many people with mild schizophrenia who are on antipsychotics that were prescribed by their family doctor. There are people on lithium for bipolar disorder that might have seen a psychiatrist 15 years ago and are now being treated by their primary care physician. He added that the hurdles that are being created by this proposed motion are massive, and he is opposed to this motion.

Dr. Hoffman asked Dr. Hegmann if he had an alternative suggestion.

Dr. Hegmann suggested that the entire topic, because it has not had adequate time for consideration by the MRB, be put into a subcommittee and brought before the Board at a subsequent meeting. He added that the latest conference report on this topic was from 1991, and there is no question that further guidance is needed because there has certainly been some progress in the last 18 years. He emphasized that it is a massive topic, and the issues that have been raised by the public comment are major and need to be adequately considered. He said that it is his opinion that rushing to motions at this point in time is inappropriate.

Dr. Hoffman said that he accepted Dr. Hegmann's comments and noted that there is no reason that this topic cannot be further studied.

Dr. Phillips raised a concern that the MEP report is now final and will be published on the FMCSA Web site at some point in the near future. When the MEP and evidence reports are

posted on the Web site, some percentage of particularly large trucking firms begin to adopt and employ these recommendations. She noted that it could be a problem for this to be on the Web site without the MRB recommendations on the issue. For example, she has already heard from people who are trying to implement previous recommendations, and to some extent they are being penalized because they are applying unusually stricter standards based on the MEP opinions or the MRB recommendations.

Dr. Hegmann asked if there was any further discussion on Dr. Hoffman's original motion as it stands. The motion was restated as follows:

The MRB recommends to FMCSA that all individuals with the following psychiatric disorders undergo psychological evaluation by a licensed mental health professional that is prepared at or above the master's degree level in order to further assess the functional ability of the driver:

- Psychotic disorder.
- Bipolar disorder.
- Major depressive disorder with a history of psychosis, suicidal ideation, homicidal ideation, or a suicide attempt.
- Obsessive compulsive disorder.
- Antisocial personality disorder.

Noting no further discussion, Dr. Hegmann called for a vote on this motion.

The MRB approved the motion with three affirmative votes, one opposed, and one abstention.

Dr. Andersson clarified his abstention noting while he is generally in favor of this motion, he agreed with Dr. Hegmann that it should be placed in the context of a subcommittee.

Dr. Soderstrom explained that he shared the same concern that Dr. Phillips pointed out earlier about the MEP report. It is going to be posted and available and there are some problems. The MRB recommendations should be posted alongside the MEP opinions.

Dr. Andersson suggested that when FMCSA posts the MEP report, they also post a disclaimer stating the MRB is further analyzing this topic. He added that this would solve the concerns that are being raised, which makes it clear that these recommendations are not necessarily MRB recommendations.

Dr. Hegmann noted that the MEP members talked about submitting an addendum report to deal with some of the issues that were raised during the discussion session, including the fact that the current report does not indicate intervals for the evaluations. He noted that the MEP mentioned that it would be a graded process. This clarification is not in the current version of the report which speaks to the lack of clarity in this report.

Dr. Gunnels said there is more work that needs to be done to further consider this issue. She clarified for the MRB and the public that the Federal regulations are minimum standards. Industry, motor coach, and trucking companies can, and often do, have stricter medical standards than the Agency. Individual States also have that option as well. She asked Dr. Hegmann if the MRB was going to continue to review the other MEP opinions or if they were going to wait.

Dr. Hegmann said if there was no further discussion, the Board would form a subcommittee on psychiatric disorders.

Dr. Phillips expressed a concern regarding MEP Opinion # 2 on benzodiazepines. The types of drugs that act on the benzodiazepine receptors are the most commonly prescribed hypnotics, (i.e., zolpidem, zaleplon, and eszopiclone) that have been approved by the U.S. Food and Drug Administration (FDA). This means that a driver who is taking an FDA-approved hypnotic would, based on this recommendation, be immediately prohibited from driving a CMV. She further explained that this is a contradiction to the recommendation the MRB made in April 2007 about benzodiazepines. At that time, the MRB recommended that individuals not get a commercial driver's license if they are using benzodiazepines, except if it is prescribed for a legitimate medical reason by an M.D. or D.O. with many caveats. Dr. Phillips said there are going to be confusing, conflicting, and sometimes unenforceable and unrealistic recommendations because of this report. She said waiting another 3 or 4 months to address this issue is not a good idea.

Dr. Andersson pointed out that Drs. Tregear and Reston reported that there has not been new evidence on this topic since 2007.

Dr. Hegmann clarified that they did not conduct a comprehensive literature search and review in 2007. The MRB added benzodiazepine into the Schedule II medications topic. This would ultimately end up being guidance. He asked if there was any further discussion.

Dr. Hoffman had a comment regarding MEP Opinion # 3 on the exclusion of anyone taking lithium from driving a vehicle at night. He suggested that rather than exclude these drivers, they should undergo a functional evaluation to assess their ability to drive at night. After the evaluation then make a determination as to whether or not they should be excluded from being medically certified to drive a CMV.

Dr. Hegmann said he understood the concerns, but he felt that this was getting into the details and these issues would be taken into consideration by the subcommittee.

Noting no further discussion, Dr. Hegmann said that the MRB will form a subcommittee for psychiatric disorders. He added that the MRB will determine which Board members will serve on this subcommittee at a later time.

Dr. Gunnels clarified that the MRB made one recommendation related to evaluation of individuals with psychiatric disorders. The MRB plans to form a subcommittee to do more work on this topic.

Presentation of Evidence Report Findings: Excessive Daytime Sleepiness and CMV Driver Safety
Stephen Tregear, D.Phil.

Dr. Stephen Tregear, Manila Consulting Group, Inc., presented an overview of the findings of the evidence report on Excessive Daytime Sleepiness and CMV Driver Safety. He explained that the objectives of this report were to identify and describe the literature on the impact of daytime sleepiness on CMV driver safety.

Dr. Tregear explained they also reviewed the literature on awareness of sleepiness and the methodologies that might be used by medical examiners to identify individuals that are at risk for excessive daytime sleepiness. He noted the following questions were addressed in this report:

- Is excessive daytime sleepiness and fatigue related to crash risk?
- Are there other sleep-related risk factors associated with crash and/or falling asleep while driving?

- Are there screening tests available that will enable medical examiners to identify those individuals with relevant sleep disorders and/or disturbances who are at increased risk for a motor vehicle crash?

Dr. Tregear reported the findings of this report revealed a significant relationship between excessive daytime sleepiness and crash risk. Two different types of studies were evaluated—acute sleepiness and simulator studies. The studies that looked at acute sleepiness assessed a direct relationship between feeling sleepy and the occurrence of a crash event. In the simulator studies, they made a group of individuals sleepy and then assessed their performance in a simulator. These participants did not actually have a sleep disorder; rather, they were kept awake for a long period of time.

Other studies asked individuals who were suffering from excessive daytime sleepiness whether they crashed in a previous period of time. The overall quality of this data was low. Dr. Tregear noted that just because an individual crashed 5 years ago does not mean it was related to the current incident. However, it does suggest that excessive daytime sleepiness is a real risk factor for crash.

Dr. Tregear explained the research revealed a variety of risk factors for excessive daytime sleepiness. He noted that any symptom related to a sleep disorder that leads an individual to have disturbed sleep that may cause fatigue and/or excessive daytime sleepiness can lead to an increased crash risk. Other findings revealed that driving exposure, age combined with an existing sleep-related disorder, and medication use (for treatment of a sleep disorder) increases the potential for crash.

Dr. Tregear said there is no reliable system available for medical examiners to use to predict crash risk that cannot be circumvented by drivers. He explained an example of this is the Epworth Sleepiness Scale which is the most commonly used scale for measuring sleepiness. Basically, the individual who is being tested is asked about feeling sleepy under certain circumstances and scored accordingly (e.g., Are you likely to fall asleep if you are sitting and reading?). These types of questionnaires are not effective when working with individuals whose livelihood depends on not having excessive daytime sleepiness. Currently, there are no other tools that can be used by a physician to accurately determine whether someone is suffering from excessive daytime sleepiness.

Dr. Tregear noted the relevant rules and recommendations made by a previous group in 1988 suggested that if an individual is suffering from a whole list of indications that can lead to excessive daytime sleepiness, then he/she should not be able to drive until treated. He added there is no new data that would support a change to the status quo. In reviewing relevant regulations overseas, it is apparent that other countries face similar problems. All countries address excessive daytime sleepiness as the prominent measure of whether a person should be able to drive. In Australia, a person can drive if cleared by a treating physician which is similar to the practice in the United States.

Dr. Tregear concluded there is a link between excessive daytime sleepiness and crash risk. He added that the remaining problem is how to measure excessive daytime sleepiness in a physician's office.

Dr. Hegmann expressed appreciation to Dr. Tregear for his presentation and asked the MRB members if they had any questions on this topic.

MRB Questions and Discussion on Excessive Daytime Sleepiness and CMV Driver Safety

Dr. Phillips noted that the most common cause of sleepiness is not narcolepsy or sleep apnea—it is not getting enough sleep at night. Some of these guidelines are very outdated and need to be revised, particularly she felt guidance that patients with restless leg syndrome (RLS) should not be allowed to drive a CMV needed updating. Also, the issues of sleep duration and finding an effective way to measure sleepiness need to be addressed. Dr. Phillips added that even the instruments we consider the "gold standard" like the Multiple Sleep Latency Test or the Maintenance of Wakefulness Test do not predict the risk of crash. She suggested that it would be beneficial to have an expert panel address these issues.

Dr. Hegmann requested Dr. Phillips to wait to make recommendations until after the public comment period. He asked if the MRB had any additional questions for Dr. Tregear.

Dr. Tregear clarified that current recommendations indicate that an individual should be precluded from driving when a disorder or disorders are associated with excessive daytime sleepiness. He added that having RLS on its own is not a reason to preclude a person from driving a CMV.

Dr. Gunnels invited public comment on the topic of excessive daytime sleepiness.

Public Comment on Excessive Daytime Sleepiness and CMV Driver Safety

Gerald Donaldson, Advocates for Highway and Auto Safety, asked Dr. Tregear if he looked at the two other major sleep scales—the Stanford Sleepiness Scale and Karolinska Sleepiness Scale, and if one was better than the other.

Dr. Tregear said no evidence was found that indicates there is a benefit of one scale over the other. He added the primary concern is not necessarily with the instruments themselves, it is the fact that they are so easily circumvented. He added one of the studies indicated a relationship between the Epworth Sleepiness Scale and crash, but it did not include a group of individuals whose livelihood depended on the outcome. The main concern is how to develop a test that is less likely to be undermined by the driver.

Dr. Hartenbaum said carriers and medical examiners are having problems with the current regulation and guidance on sleep apnea. Medical examiners are trying to use some type of guidance to advise that these drivers need screening for sleep apnea. There are a number of large motor carriers that will not have the screening done unless it is stated in the regulation. The guidance may be out there, but it is not really officially endorsed yet. Conversely, there are other motor carriers that are following the regulation that permits them to have more stringent medical criteria than the medical standards. However, the new the Americans with Disabilities Act Amendment Act (ADAAA) of 2008 has changed that, and a lot of companies are being challenged and are losing in court by enforcing more stringent standards than required. Both motor carriers and medical examiners are in a no-win situation of trying to do the right thing, maintain business, and yet not end up in court.

Dr. Gunnels asked Dr. Hartenbaum if that is the case even with the definition of transportation safety sensitive positions as exempt. Dr. Hartenbaum said yes and added that she has been involved with some of these cases. Some companies have followed medical standards, guidelines, recommendations, and conference reports and are running into a lot of problems and challenges. The anticipation is that it will get worse with the ADAAA.

Dr. McElligott said that a lot of doctors are getting out of the medical examiner business because they do not understand what standard of care means, and they do not know the difference between standards, guidance, and recommendations. It is important to be very clear. He added that when something becomes the "standard of care," it creates a whole new issue for what doctors can or cannot do and what their liabilities are if there is a crash.

MRB Deliberation on Excessive Daytime Sleepiness and CMV Driver Safety

Dr. Andersson said there really is no argument that if an individual falls asleep at the wheel, there is an increased risk of having a crash. The issue is whether this is something that can be determined ahead of time.

Dr. Phillips said measuring an individual's sleepiness today is not going to predict how sleepy the person will be 6 weeks from now. Several factors influence sleepiness, including prior sleep time, medications, and time of day, so it is a very difficult thing to assess. She pointed out in the full report there is some discussion about the technologies that can be used to assess sleepiness in the cab of a truck. She suggested that FMCSA issue a request for proposal for the creation of the technology to identify and disable the sleepy driver.

Dr. Hegmann asked for clarification about how this issue differs from some of the other conditions the MRB has addressed that are probabilistic issues. Dealing with probabilities of how likely a person is to have a worse day of sleepiness in the future is similar to the probability of how likely a person is to have a seizure in the future.

Dr. Phillips pointed out that much of sleepiness depends on behavior. If a person is at risk for a myocardial infarction, they have some control over it through exercising or quitting smoking, etc. A person does not need to have an illness to be at risk for crash from sleepiness—it can happen to anyone. She added there are other issues that influence sleepiness, such as whether the person takes sleeping pills, antihistamines, or uses a continuous positive airway pressure machine. It is not possible to measure these factors accurately much less predict actual risk for crash from sleepiness. It needs to be measured in real time in order to have reasonable meaning to apply to drivers.

Dr. Andersson asked whether these devices indicate to the driver an increased risk or if they just awaken the driver.

Dr. Phillips explained the data suggest that the biggest risk from sleepiness is not that the driver falls asleep but that sleepiness affects reaction time and vigilance. If there was a device that could detect, awaken, and alert the driver, it would save lives.

Dr. Hegmann asked if there was any further discussion or motions on this topic.

Dr. Phillips made the following motion:

The MRB recommends to FMCSA that an MEP be convened to review the excessive daytime sleepiness evidence report and to consider the issues with sleeping pills (hypnotics) and RLS. The motion was seconded.

The MRB unanimously approved this motion.

Presentation of Evidence Report Findings: Musculoskeletal Disorders II, Spinal Cord Injury and CMV Driver Safety
James Reston, Ph.D.

Dr. Reston presented an overview of the findings of the evidence report on Musculoskeletal Disorders II, Spinal Cord Injury and CMV Driver Safety. This report covered the conditions that were not covered in the previous report, including: nerve compression syndrome, such as carpal tunnel syndrome; ulnar neuropathies; radial neuropathies; tarsal tunnel syndrome; tendonitis/tenosynovitis; bursitis; and plantar fasciitis.

This report also addressed the potential risk associated with various types of spinal cord injuries, including, paraplegia and tetraplegia.

The following Key Questions were addressed in this report.

Key Questions # 1: Do musculoskeletal disorders of the hand, wrist, elbow, or shoulder (specifically carpal tunnel syndrome, ulnar neuropathies, radial neuropathies, tendonitis/tenosynovitis, and bursitis) increase crash risk and/or affect driving ability?

Key Question # 2: Do musculoskeletal disorders of the foot, ankle, or knee (specifically plantar fasciitis, tarsal tunnel syndrome, tendonitis/tenosynovitis, and bursitis) increase crash risk and/or affect driving ability?

Key Question # 3: Does reduced limb mobility and/or control resulting from spinal cord injury increase crash risk and/or affect driving ability?

Key Question Responses

Key Questions # 1: Do musculoskeletal disorders of the hand, wrist, elbow, or shoulder (specifically carpal tunnel syndrome, ulnar neuropathies, radial neuropathies, tendonitis/tenosynovitis, and bursitis) increase crash risk and/or affect driving ability?

Dr. Reston reported none of the 20 articles that were found through the literature review addressed this question. He concluded there is insufficient evidence to determine whether any of these musculoskeletal disorders of the upper extremities increased crash risk or decreased driving performance.

Key Question # 2: Do musculoskeletal disorders of the foot, ankle, or knee (specifically plantar fasciitis, tarsal tunnel syndrome, tendonitis/tenosynovitis, and bursitis) increase crash risk and/or affect driving ability?

Dr. Reston said no studies were found that specifically address the lower extremity disorders. He concluded the evidence is insufficient to come to a conclusion regarding Key Question # 2.

Key Question # 3: Does reduced limb mobility and/or control resulting from spinal cord injury increase crash risk and/or affect driving ability?

Dr. Reston said limited evidence regarding spinal cord injury and crash risk was found. None of the evidence looked at crash data; it was from simulation studies or road performance tests. The evidence included three cohort studies—two of the studies were moderate quality and one was low quality. None of them addressed the CMV population.

The first simulator study observed 15 individuals with paraplegia and found that those individuals in a simulator drove at a significantly slower speed than able-bodied individuals. However, there were no significant differences in steering stability, center line violations, traffic signal violations, and driving time. Dr. Reston pointed out that slower driving speed is not necessarily a surrogate for unsafe driving.

The second simulator study evaluated 26 individuals with tetraplegia and found significantly reduced break reaction times and workload factors, including time, pressure, and effort among individuals with tetraplegia compared to able-bodied individuals. Dr. Reston said it is unclear whether these differences in simulated driving outcomes have a relationship to safe driving ability.

The third study observed on-road driving performance of eight individuals with spinal cord injury (type of injury undefined). Dr. Reston said no statistically significant difference in the driving performance measures during closed-course or open-road driving was found between individuals with spinal cord injuries and able-bodied individuals.

Dr. Reston pointed out that none of these studies looked at crash data or driving a large truck, which may require greater functional ability than driving smaller vehicles. It still remains a legitimate question as to whether the magnitude of difficulty of driving a large truck would make the task impractical for some individuals with spinal cord injury. One of the requirements for operating a CMV is to check and adjust loads during a long trip, which may be beyond the capability of a lone driver with spinal cord injury. A possible exception would be a sealed vehicle that did not require pre-trip or post-trip inspections. Obviously, loading and unloading a vehicle might be problematic without help. Dr. Reston suggested that driving a modified CMV with a partner might be an option for drivers with spinal cord injury.

Dr. Reston concluded certain individuals with spinal cord injury appear to have adequate driving ability in specially modified cars. Individuals with paraplegia are less likely to have limitations that decrease driving ability than individuals with tetraplegia. He reiterated there are certain requirements that CMV drivers have to meet including pre-trip and post-trip inspections and adjustment of loads that may exceed the capabilities of individuals with spinal cord injury.

Noting no questions from MRB members, Dr. Hegmann thanked Dr. Reston for his presentation and turned the meeting over to Dr. Gunnels for public comment.

Public Comment on Musculoskeletal Disorders II, Spinal Cord Injury and CMV Driver Safety

Noting no public comments on this topic, Dr. Gunnels turned the meeting over to the MRB for deliberation.

MRB Deliberation on Musculoskeletal Disorders II, Spinal Cord Injury and CMV Driver Safety

Dr. Hegmann invited discussion and deliberation from MRB members on musculoskeletal disorders, spinal cord injury and CMV driver safety.

Dr. Andersson said there is no question that many people can drive safely with one of these conditions. However, the problem is the driver has to be able to inspect a vehicle before the trip and do safety inspections while on the road. This is clearly not possible for some individuals with these conditions—particularly individuals with paraplegia and tetraplegia. Currently, there is only

one evaluation, and there is no guidance that allows the evaluating physician to indicate that someone other than the driver perform safety inspections and other non-driving related tasks.

Dr. Hegmann indicated that Dr. Andersson's statement was correct—the person signing the medical certificate has signified that the individual can do all the non-driving related tasks that have been indicated.

Dr. Hegmann and Dr. Andersson formulated the following motion:

The MRB recommends to FMCSA that the Agency develop procedures to allow for restricted licensure for individuals with disabilities and impairments. The motion was seconded.

The MRB unanimously approved this motion.

Dr. Andersson pointed out that the MRB previously made recommendations on musculoskeletal disorders at the April 2008 MRB meeting. He moved that the MRB repeat those recommendations for Musculoskeletal Disorders II, Spinal Cord Injury and CMV Driver Safety.

Those recommendations are as follows:

Recommendation # 1*
The focus of the evaluation of musculoskeletal conditions should be on function rather than diagnosis.

Recommendation # 2
FMCSA should obtain information about the physical requirements needed to safely drive a CMV, to include pre-trip and en route safety inspections.

Recommendation # 3
FMCSA should convene an expert panel tasked with developing a physical screening instrument for the medical examiner.

Recommendation # 4
FMCSA should standardize the driving-specific work capacity evaluation (road test) to include pre-trip and en route safety inspections.

Recommendation # 5
FMCSA should stimulate research on the effect of musculoskeletal injuries on driver safety.

Dr. Hegmann noted that this motion reaffirms prior guidance on musculoskeletal disorders that applies to Musculoskeletal Disorders II, Spinal Cord Injury and CMV Driver Safety.

The motion was seconded. The MRB unanimously approved this motion.

Presentation of Evidence Report Findings: ICDs and CRT: Implications for Driving a CMV
Dr. Stephen Tregear, D.Phil.

Dr. Tregear presented an overview of the evidence report findings on ICDs and cardiac resynchronization therapy (CRT) and implications for driving a CMV. He explained that this report is about dual functioning ICDs and pacemakers. These devices are otherwise called CRT-

* The MRB previously approved these recommendations during the April 7, 2008, MRB meeting.

Ds, or cardiac resynchronization therapy plus defibrillation. This a specific type of device that is implanted in the person with heart failure.

Dr. Tregear noted that within the last year a cardiovascular disease expert panel was held in which they discussed a variety of cardiovascular diseases, including whether the current guidance was relevant. It was recommended that individuals who have an ICD implanted should not drive a CMV under any circumstances. FMCSA posed another, related question: if an individual has a CRT-D implanted and the defibrillator component is turned off, should that individual be able to drive? Current guidance states that under certain circumstances individuals with pacemakers can drive.

Dr. Tregear said there is not a practice of implanting a CRT-D and leaving the defibrillator component turned off. This is based on a review of related clinical trials, patient indications, clinical practice guidelines, and coverage policies.

He noted individuals who have a CRT should meet the following criteria:

- Moderate to severe chronic heart failure (NYHA Functional Class III or IV);
- Symptomatic disease despite stable, optimal heart failure drug therapy;
- Left ventricular ejection fraction ≤ 35%; and
- QRS duration > 120 ms.

Dr. Tregear pointed out these criteria are exclusionary even before the defibrillator component is added. Individuals who meet the criteria for a CRT, according to these indications, should not be driving a CMV. He added individuals typically treated with an ICD fit into one of the two following groups:

- Primary prevention—is the prevention of sudden cardiac arrest. Individuals in this category have had a myocardial infarction in the past and are at very high risk of having cardiac arrest, but they have not had an episode yet.

- Secondary prevention—involves individuals who have had cardiac arrest before.

Dr. Tregear concluded individuals with indications for a CRT, regardless of whether or not an ICD is included in the device, do not meet FMCSA's current guidance to be qualified to drive a CMV. Therefore, the question about whether or not the defibrillator is switched on or off is irrelevant because these individuals do not meet the criteria. He noted there are issues of off-label use, where the simplicity of this argument falls apart.

Dr. Gunnels asked Dr. Tregear to explain what off-label use means.

Dr. Tregear explained that implanting a device or taking a drug when it is not an indicated use defined by the FDA is called an off-label use.

Dr. Hegmann expressed thanks to Dr. Tregear for his presentation.

MRB Questions and Discussion on ICD, CRT, and CMV Driver Safety

Dr. Hegmann asked if hospital discharge data regarding pacemakers encompasses outpatient procedures done in ambulatory surgery centers.

Dr. Tregear said the data is from the Healthcare Cost and Utilization Project (HCUP) which is a government database of all hospital discharges. He said he was unsure if it included absolutely everybody and that he would need to investigate further.

Dr. Hegmann added it is becoming more common for these procedures to be done in outpatient settings which could explain the data.

Dr. Andersson said there are no data registries currently in place in the United States for outpatient data, including surgery centers.

Public Comment on ICD, CRT, and CMV Driver Safety

Dr. Hartenbaum asked if an individual who has a defibrillator implanted and improved cardiac function would be permitted to drive if he/she no longer meets the criteria and the defibrillator is turned off or removed.

Dr. Gunnels said the Agency handles all requests for exemptions on a case-by-case basis. The underlying disease is the primary indicator for denying an individual's ability to drive. This question has been raised a number of times—even by an electrocardiophysiologist who manages this device. This is why this issue is being revisited.

MRB Deliberation on ICD, CRT, and CMV Driver Safety

Dr. Hegmann noted the MRB dealt with this topic in April 2007, at which time there was not enough evidence to change existing guidance. He clarified that current guidance indicates an individual is not permitted to drive with an ICD implanted, whether it is turned on or off.

Dr. Hoffman asked if the device is removed, then there is no longer an issue, correct?

Dr. Hegmann said yes, provided that the other criteria are met.

Dr. Andersson asked if there was any reason to change the existing standards.

Dr. Hegmann stated there has been no additional evidence on this issue to support a change. There is guidance in place, and the Agency handles any requests for exemptions on case-by-case basis.

Dr. Hoffman asked if there are exceptions for drivers who have defibrillators implanted that are turned off and they no longer fit the criteria for having a defibrillator.

Dr. Gunnels explained that every individual has the right to apply for an exemption based on the Federal rules. The Agency has never granted an individual exemption for an implanted defibrillator that is turned off. The majority of requests that have been received have been for people with the device in place with proper indication.

Noting no further discussion on this topic, Dr. Hegmann moved on to MRB discussion of other business.

MRB Other Business

Dr. Hegmann noted there are two outstanding issues that were raised earlier in the meeting, the aging issue raised by Dr. Gunnels and guidance on sleep apnea raised by Dr. Hartenbaum.

Dr. Phillips reiterated her concern that if an MEP report is posted to the FMCSA Web site before the MRB recommendations are posted, it could result in confusion for the general public.

Dr. Hegmann clarified that he was referring to the issue raised during the public comment period about sleep apnea and the fact that there is currently is no guidance from the Agency on this topic, though the MEP report and MRB recommendations have been made. He asked the MRB if they wanted to discuss or propose a motion.

Dr. Phillips said the MRB certainly urges FMCSA to get the regulations changed.

Dr. Gunnels said the first regulatory proposals will include proposing a change to the pulmonary standard (which includes sleep apnea). The MRB has already deliberated on several topics, including pulmonary, cardiology, diabetes, vision, and neurological disease. There is additional work to do in some of these areas. The Agency plans to move forward with regulatory proposals on several of these topics, as it can take several years to move through the rulemaking process. The public will be involved throughout the notice-and-comment process. Guidance can be developed throughout the process as most of these topics will need to have guidance that accompanies the regulation. She noted that the regulatory agenda is published in both the spring and the fall and will provide a better sense of the timeline.

Dr. Hegmann invited discussion from MRB members on the issue of aging.

Dr. Gunnels clarified that she would like the MRB to address the spectrum of age, how it affects driving, and how it is incorporated into the medical standards.

Dr. Phillips asked if there is an upper age limit.

Dr. Gunnels clarified that you have to be 21 years old to drive a CMV, but some States handle age differently.

Dr. Hoffman said that driver medical fitness testing needs to be based on function as opposed to being based on disease.

Dr. Phillips noted that the other motion the MRB recommended related to musculoskeletal disorders was to consider restrictions based on function which could make many people eligible to drive that are not currently eligible.

Dr. Hegmann said this issue would be very hard to deal with in an MEP because experts do not specialize in aging drivers. It would be helpful to be sure that the aging influences are captured each time an evidence review is done.

Adjournment

Noting no further comments, Dr. Hegmann adjourned the meeting.

CERTIFICATION

The minutes were approved by the Medical Review Board on _____.
(Date)

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

Kurt Hegmann, M.D.
Chairperson
Medical Review Board

Mary D. Gunnels, Ph.D.
Designated Federal Official
Medical Review Board