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8301 Professional Place, Landover, MD 20785

September 4, 2008

John H. Hill
Administrator
Federal Motor Carrier Safety Administration
1200 New Jersey Avenue, SE
Suite W60-300
Washington, DC 20590

Dear Administrator Hill:

The Epilepsy Foundation wishes to raise serious concerns about the recent recommendations of the Federal Motor Carrier Safety Administration's Medical Review Board (MRB) concerning the medical standards for commercial motor vehicle (CMV) drivers with epilepsy. The MRB, rejecting the recommendations of a Medical Expert Panel (MEP) in the field of neurology convened to advise the MRB, determined that the current medical standards should be retained. These standards provide that CMV drivers with epilepsy may be medically certified only if they have been seizure-free for 10 years or more while off antiseizure medication.

As discussed below, the Foundation believes that the current standard is not justified based on either safety or medical grounds, and therefore, the MRB's recommendation to retain the current standard should be rejected. We believe that the FMCSA should adopt the MEP recommendation in place of the current standard. In essence, the MEP recommended that persons with epilepsy who are seizure-free for eight years -- whether on or off antiseizure medication – may be medically certified.

The Foundation is also concerned that the MRB appears to have arbitrarily ignored the recommendations of the MEP, relying upon its own determination of what is the current state of medical knowledge and the standards that should be applied for the licensing of people with a history of seizures -- without any showing of the scientific or medical validity for the MRB's imposition of its own opinion. This approach may violate the Administrative Procedure Act, which prohibits agency action which is "arbitrary or capricious."

We understand that the MRB's recommendation will be given significant weight as the FMCSA goes forward in developing a proposal to revise the current regulations, and we therefore believe that the MRB's recommendations should be subject to analysis and review prior to further regulatory action being taken. We urge FMCSA to carefully consider this petition in developing any proposal to amend the rules.

The Epilepsy Foundation, founded in 1968, is the national non-profit voluntary agency solely dedicated to the welfare of the more than three million people with epilepsy in the U.S. and their families. The organization works to ensure that people with seizures are able to participate in all life experiences; and prevent, control and cure epilepsy through services, education, advocacy and research. The Foundation has taken a leadership role in fighting discrimination affecting both children and adults with epilepsy since its founding. Therefore, the Foundation has a strong interest in the development of fair regulations concerning commercial motor vehicle drivers with epilepsy.

The following comments were developed in conjunction with the Foundation's Professional Advisory Board, which is comprised of leading experts in the field of epilepsy, including physicians, social workers, researchers, nurses, psychologists and other professionals. Advising the Foundation on various matters regarding medical research, care and standards, the Board reviews educational materials and activities, as well as applications for research grant and fellowship support that the Foundation provides each year.

The Current DOT Rule and Recommendations from the MEP and MRB

The current FMCSA rules prohibit interstate driving of CMVs by anyone with a diagnosis of epilepsy or who uses antiseizure medication, regardless of the present ability to control seizures. 49 CFR 391.41(b)(8). Guidance issued for the current rules states, however, that CMV drivers with a history of epilepsy may be certified to drive if they have been off antiseizure medication and have been seizure-free for 10 years or more. (It appears that this guidance is discretionary and that FMCSA medical examiners, who issue the medical certifications for interstate drivers, generally disqualify drivers with epilepsy, relying on the FMCSA rule rather than the guidance.)

The MRB was established in 2006 to review all FMCSA medical standards for interstate CMV drivers, and charged with making recommendations to FMCSA for revisions to its regulations on this subject. A MEP in the field of neurology was established by the FMCSA to advise the MRB regarding the FMCSA standards regarding seizure disorders. The MEP was comprised of five leading experts on epilepsy. The MEP members unanimously agreed on all recommendations, which were presented during a January 28, 2008 meeting. The minutes of that meeting were approved at the MRB's April 7, 2008 meeting. The recommendations were based in part on an exhaustive "Evidence Report" ("Seizure Disorders and Commercial Motor Vehicle Driver Safety") prepared by an independent, non-profit health services research agency.

The MEP recommended as follows: Interstate CMV drivers with epilepsy may be certified if they are seizure-free for eight years on or off antiseizure medication. If off medication, the individual must have been seizure-free for eight years since medication cessation. If on medication, the individual must have been on a stable medication regime for at least two years.

The MEP based its recommendation on the following conclusions: An annual seizure risk of two percent is an acceptable threshold below which an individual may be considered fit to drive a CMV. The two percent upper limit, the MEP noted, ensures that the annual risk for experiencing a seizure while driving will be less than 0.3% percent, assuming a 50-hour work week. This would be associated with an annual risk of having a seizure-related crash of less than .017 percent. This two-percent upper limit is consistent with the position of agencies within several other countries, including the UK Department of Motor Vehicles. Based upon a review of available medical studies, it was found that persons with epilepsy who are seizure-free for eight years have a two percent risk of experiencing a seizure in the following year.[1] Accordingly, the MEP found that eight years of seizure freedom is an appropriate period.

However, the MRB disagreed with the MEP's recommendation, and concluded that it would be more appropriate for the FMCSA to follow the guidance contained in its current rules – allowing driving by persons with a history of epilepsy only if they have been off antiseizure medication and have been seizure-free for 10 years or more.

This decision was reached following only a brief cursory discussion of the MEP's findings, and the MRB's action appears to be based upon personal opinions rather than upon any analysis or review of current medical evidence. One member of the MRB raised concerns with the two-percent annual risk standard found acceptable by the MEP, stating that this level far exceeds the risk of a person without epilepsy experiencing a seizure. But the MRB did not engage in any specific discussion about the validity of the current standard or justify why its provisions should be deemed preferable to the MEP recommendation.

Importantly, one member objected to the MRB determination. She noted that the current FMCSA standard is overly restrictive and will likely discourage some individuals from disclosing information about seizures – and we agree with this conclusion.

The Epilepsy Foundation believes strongly that the MRB's recommendation is unsupportable and should be rejected in favor of the recommendation of the MEP.[2]

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[1] This conclusion was based on a meta-analysis of data pertaining to seizure recurrence rates following surgery and a study of seizure recurrence rates among persons who have undergone withdrawal of antiseizure drugs.

[2] In addition, the MEP issued recommendations regarding revisions to the FMCSA guidelines for drivers who have experienced a single unprovoked seizure. The current guidelines state that such individuals may be qualified to drive a CMV in interstate commerce if seizure-free and off antiseizure medication for at least five years. The MEP recommended that such individuals should be given conditional certification to drive if they have been seizure-free for a minimum of four years on or off antiseizure medication. However, the MEP stated further, that in the case where antiseizure medication has been stopped, the individual must have been seizure-free for at least four years from the time of medication cessation, or if still using medication, the individual must have been on a stable medication regime for at least two years. Here the MEP concluded that such standards were justified for the same reason as provided in connection with its recommendations concerning epilepsy -- data collected in the Evidence Report indicates that this group of individuals has a two percent annual seizure risk. The MRB rejected this recommendation, deciding instead that the current guidelines should be retained. We also agree with the MEP's recommendations on this issue.

Deficiencies regarding the Current Standard

The current ten-year seizure-free off-medication standard does not appear to be based on any current valid scientific data supporting the need for such a standard. Apparently, the only clearly stated justifications for the current standard were set out in a 1988 report, which was issued when DOT last publicly reviewed its CMV medical standards pertaining to epilepsy (the Federal Highway Administration Report of the Conference on Neurological Disorders and Commercial Drivers).

The current standard relies on an invalid assumption regarding acceptable risk

The primary argument set out in the 1988 report (p. 51) in support of the current standard was as follows: "The data regarding myocardial infarction [heart attack] was used to provide some estimates of the rate of potential occurrence of an adverse event which may be deemed acceptable without obvious restrictions." According to the report, the rate for heart attack among white males between the ages of 45 to 54 is 5/1000 annually, i.e., 0.5 percent. It was also noted that there is a comparable annual risk of seizure recurrence for persons who are seizure-free and off anticonvulsant medication for 10 years. Thus, the report concluded, that given the established tolerable risk, "It would seem that individuals with a history of epilepsy off anticonvulsant medication and seizure-free for 10 years should not be restricted from obtaining a license to operate a motor vehicle."

There are several flaws with this reasoning. The first relates to the determination of acceptable risk. As noted above, this determination was based on the conclusion regarding the likelihood of experiencing a heart attack among white men aged 45-54. Although it does seem reasonable to adopt a level of acceptable risk based on the likelihood of heart attack (given that heart attack victims, like persons who experience some types of seizures, may unexpectedly lose consciousness), the chosen age range, 45-54, does not reflect the highest level of "acceptable" risk. It would only be valid to rely on the higher risk level found in men aged 55-65 – because this is in fact the true acceptable risk, not the lower level cited in the 1988 report.[3] Men in this age range, of course, are not restricted from driving CMVs, and many in this age bracket are still doing so.[4]

Moreover, the 1988 report failed to look at specific common risk factors for heart attack other than age. Again, this is a flawed approach since a sizable proportion of middle aged and older men have such risk factors, including high blood pressure. Indeed, the American Heart Association estimates that one third of Americans has high blood

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[3] Moreover, it does not appear that the FMCSA applies such a strict risk tolerance level in other regulations governing drivers of CMVs. For instance, the FMCSA regulations, at 49 CFR 391.11(b)(1), permit driving by persons who are 21 years of age. In light of the considerable risk of accidents among male drivers under the age of 25, it is clear that the presumably much more stringent risk threshold for persons with epilepsy is inequitable.

[4] According to data contained in the 2000 U.S. Census, 13.9% of truck drivers are aged 55-64.

pressure, in most cases undetected. And studies have determined that truck drivers as a group have a higher incidence of such risk factors than the general population, and such risks increase more significantly with age than they do in the general population.[5]

The FMCSA's determination of acceptable risk in this regard should be based on the comprehensive long-term study of heart attack risk -- the Framingham Heart Study – which provides accurate data concerning the risk among older men with a variety of common risk factors contributing to overall heart attack risk.[6] In addition to age and gender, the factors the study examined were: total cholesterol, diminished HDL cholesterol (i.e., high density lipoproteins or "good" cholesterol), smoking, high systolic blood pressure and use of blood pressure medication. The presence of these factors do not necessarily prevent one from being medically certified,[7] and it may be assumed that at least a sizable minority of drivers aged 60-65 will have some or all of these additional risk factors. Accordingly, persons in this age group possessing these risk factors (at moderate levels) represent the appropriate pool for determining the acceptable risk.

Relying on a risk assessment tool developed by the Framingham Heart Study, the level of heart attack risk among men aged 55, possessing these risk factors at a moderate level, is actually two percent per year.[8] This matches the risk level determined appropriate by the MEP, and this is the level we believe should be adopted by the FMCSA.

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[5] For instance, one study reviewed risk factors for coronary heart disease (CHD) among male truck and bus drivers as compared to a control group of male industrial workers. The main results were: higher mean values for serum cholesterol, serum triglycerides and blood pressure in the driver group, indicating a markedly higher risk of CHD in the driver group. The study concluded that the higher CHD-risk in the driver group is associated with two factors: (1) greater psychic pressure in the working situation; and (2) the selection of more type-A persons to driver occupations. P. Hartvig and O. Midttun, Coronary heart disease risk factors in bus and truck drivers, International Archives of Occupational and Environmental Health, pp. 353-360, Oct. 1983.

[6] The objective of the Framingham Heart Study was to identify the common factors or characteristics that contribute to cardio vascular disease (CVD) by following its development over a long period of time in a large group of participants who had not yet developed overt symptoms of CVD or suffered a heart attack or stroke. An explanation of the Study is available on the Web site for NIH's National Heart Lung and Blood Institute at www.nhlbi.nih.gov/about/framingham.

[7] With regard to these factors, the FMCSA's regulations only address high blood pressure. The regulations do not impose restrictions on those with a borderline high level of blood pressure (below 140), also know as a pre-hypertension level. And they permit a one-year medical certification of those with higher levels, and allow subsequent annual recertifications based on a showing that the individual's pressure has dropped to 140 or less. See 49 CFR 391.41(b)(6) and accompanying medical advisory criteria.

[8] This risk assessment tool is used to determine the risk of heart attack over a ten-year period. This tool is designed for adults aged 20 and older who do not have heart disease or diabetes. The tool is available at http://www.nhlbi.nih.gov/health/public/heart/#ami. The following represents an assessment of a man aged 55 with a moderate level of risk factors:

Age:	55
Gender:	male
Total Cholesterol:	230 mg/dL
HDL Cholesterol:	40 mg/dL

We believe that applying a more stringent standard to persons with epilepsy would be medically unjustified and would help to perpetuate the stigma and fear associated with this condition.

The current standard erroneously relies on an assumption that persons on antiseizure medication present a greater risk

A second deficiency with the current standard is the fact that it disqualifies all persons with epilepsy who are on medication – without regard to the length of time they have been seizure-free. There are no data supporting the idea that people with epilepsy who are seizure-free for an extended period, but on medication, are less safe than those who are off medication. The MRB did not articulate any reason for rejecting the MEP recommendation that persons with epilepsy who are on medication be treated identically to those who are off medication.

In the absence of any articulated basis for rejecting the MEP recommendation, it could be inferred that the MRB accepted the justification stated in the 1988 report. In this regard, the report noted (at p. 49) that the restrictive criteria for licensing is based on the fact that CMV drivers "are frequently required to work long distances from home, and because of driving schedules, maintain irregular eating and sleeping habits which will alter circadian rhythms." The report also noted that commercial drivers may have inconsistent access to medical care or may experience difficulties in replacing medications if lost.

As we have observed in our November 14, 2006 comments to FMCSA regarding its processing of rule exemption requests from persons with epilepsy, while the considerations noted above with regard to persons with epilepsy on medication may be viewed as reasonable in some cases, it is inappropriate to apply them on a blanket basis to all drivers. These factors, for the most part, would come into play only when an individual acts irresponsibly by driving more hours than permitted, or by failing to take prescribed medications or pay attention to personal medical needs. In fact, just the opposite behavior may be true about the population of persons with epilepsy who have achieved long-term seizure control on medication.

Smoker:	Yes
Systolic Blood Pressure:	139 mm/Hg
On medication for HBP:	No
Risk Score	20%

The 20% risk score for a ten-year period is equivalent to an annual risk of 2%. At either age 60 or 65 (with the same common risk factors), the annual risk would be 2.1%. With regard to the variables chosen for the risk assessment, note the following: the Total Cholesterol level of 230 is deemed borderline high; an HDL of 40 mg/dL is fairly common and presents a slightly increased risk of heart attack; and a systolic blood pressure of 139 represents borderline high blood pressure.

Such persons have demonstrated that they are responsible about taking their medications and that they know how to manage their condition. They also have a clear incentive to pay attention to their health and to remain seizure-free. Their lives, as well as their employment, depend on this. Moreover, it is highly unlikely that a driver would be unable to obtain needed emergency medical care or medication in any part of the United States served by interstate carriers.

Assuming that persons who wish to drive CMVs are faithful about taking their medication, there is no reason to believe that they present a greater risk of seizure recurrence than persons with a history of epilepsy who are off medication. Indeed, there is nothing in the medical literature to support a heightened risk among those on medication.

In addition, the Foundation believes that requiring that one be off medication is arbitrary, unsupported by medical data, and actually encourages risk taking that is directly contrary to promoting public safety. If safety is the paramount issue, as we believe it is, it is far safer for individuals to stay on antiseizure medications than to go off them. We are aware of many people who have been seizure-free on medications for years who will not consider removal of antiseizure medications, because they do not want to risk a seizure. For instance, primary generalized epilepsy is frequently well controlled on a single medication, and even though patients are frequently seizure-free for many years, neurologists generally do not recommend drug withdrawal for these individuals.

For these reasons, we believe that the MEP was correct in recommending that persons with epilepsy who are on antiseizure medication be treated identically to those who are not.

Retention of the Current Rule Will Likely Violate the Administrative Procedure Act

Moreover, the Foundation believes that if FMCSA retained the current 10-year off-medication seizure-free rule (or issued a substantially similar rule), notwithstanding the recommendations to the contrary from its expert panel, that action would violate the Administrative Procedure Act (APA). Under the APA, a court will invalidate an agency action which is found to be “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. 706(2)(A). Although a court is not to substitute its judgment for the agency’s on a regulatory matter, the agency must offer a satisfactory explanation of its reasons for a regulatory decision based on relevant data. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 436 U.S. 29, 43 (1983). The agency must examine relevant data and demonstrate a rational connection between the facts found and the choice made. *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962). Normally, an agency action would be arbitrary and capricious if the agency offered an explanation for its decision that runs counter to the evidence before it. *Motor Vehicle Mfrs. Ass'n of U.S,* 463 U.S. at 43.

The Supreme Court’s decision in *Motor Vehicle Manufacturers*, *supra*, upholding a lower court finding that a DOT rule was arbitrary and capricious, is instructive concerning FMCSA’s action in this matter. In this case, the Court held that the National Highway

Traffic Safety Administration acted arbitrarily and capriciously in revoking the requirement that new motor vehicles produced after September of 1982 be equipped with passive restraints to protect the safety of the occupants of the vehicle in the event of a collision. NHTSA, the Court concluded, was too quick to dismiss the safety benefits of automatic seatbelts and its explanation for the rescission of the passive restraint requirement was not sufficient to enable the Court to conclude that the rescission was the product of reasoned decisionmaking. Thus, the Court found that the agency either had to consider the matter further or amend its standard along the lines which its analysis supported.

With respect to the agency analysis on passive restraints, the Court noted that various public surveys commissioned by the NHTSA found that a large proportion of the public would in fact welcome automatic seat belts, contradicting the agency's view that no evidence supports the conclusion that passive restraint usage would increase if the technology were available. Further, the agency took no account of the critical safety difference between detachable automatic seatbelts and current manual seatbelts and failed to articulate a basis for not requiring nondetachable belts (as a response to its concerns that drivers would simply disable the detachable belts in an effort to avoid their use), and thus failed to offer the rational connection between the facts at hand and the agency's decision required to pass muster under the "arbitrary and capricious" standard.[9]

Similar to this case, if FMCSA decided -- based on the data presented to date -- to retain the current rule (or one substantially similar), that action likely would be deemed arbitrary and capricious and invalid. As is discussed above, the MRB, in rejecting the MEP's recommendations, failed to engage in any substantive analysis or provide a reasoned explanation for retaining the current rule.

The MEP, which is comprised of leading national experts in the field of neurology, issued unanimous recommendations. These recommendations were based on a comprehensive report commissioned by the FMCSA. The MEP's decision -- that there should be a

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[9] The Court also found that the agency similarly failed to provide any reasons for declining to issue a rule requiring installation of air bags as a substitute for automatic seat belts. The Court held that "given [a prior agency judgment] that airbags are an effective and cost-beneficial life-saving technology, the mandatory passive restraint rule may not be abandoned without any consideration whatsoever of an airbags-only requirement." *Id.* at 51.

Another case illustrating these points is *Crowley's Yacht Yard, Inc. v. Pena*, 863 F.Supp. 18 (D.D.C. 1994); *appeal dismissed by* 1994 WL 814240 (D.C.Cir. Dec 22, 1994). In this case, the plaintiff brought an action challenging a DOT rule governing drawbridge operation on the Chicago River; the rule effectively banned weekday daytime water travel. The court found that the agency's conclusion that the restrictions were necessary to accommodate the needs of vehicular land traffic was not supported by substantial evidence. It was undisputed, the court noted, that only one traffic study was submitted to the agency in support of a ban on weekday daytime travel, a study which the agency conceded should be discredited. Moreover, other evidence in the record indicated that, on the contrary, daytime traffic patterns did not support the restrictions on weekday daytime travel that the City sought. The court concluded that the agency has not pointed to any data in the administrative record that support the agency's position on land traffic needs, and therefore, the Court found the rule is arbitrary and capricious and invalidated it.

required eight-year seizure-free period (whether one is on or off antiseizure medication) – was based on a finding that this period is correlated with the "acceptable risk" of seizure recurrence. It was also based on the conclusion that there is no heightened risk of seizure recurrence among persons with epilepsy who are on antiseizure medication (provided they are on a stable medication regime for at least two years) as compared to those who are not.

The MRB decided to reject this recommendation following only a brief cursory discussion of the MEP's findings. The MRB did not consider or present any data that would undermine the MEP's recommendations or support the conclusion that its decision is preferable. The MRB, for instance, did not dispute the MEP's finding regarding acceptable risk. In fact, as discussed above, the current rule, which the MRB voted to retain, is based on an overly narrow view of acceptable risk – one tied to heart attack risk among middle aged men. As discussed above, that acceptable risk determination fails to factor in common risk factors for cardiac arrest (which would raise the level of acceptable risk significantly) or assess the risk in older men. Similarly, the current rule relies on an erroneous assumption that persons on antiseizure medication present a higher risk of seizure recurrence than those who are not.

It is apparent that, to date, FMCSA has failed to present a satisfactory explanation as to why the evidence presented to the agency in favor of a less restrictive standard should be discounted. Accordingly, if the current rule or a similar one were carried forward, that action likely would be found arbitrary and capricious. *See Motor Vehicle Mfrs. Ass'n. of U.S., Inc.*

Determinations on Exemption Requests should be made Promptly

In addition to our concerns about the MRB recommendations above, we urge the FMCSA to promptly issue determinations, relying on reasonable individualized assessments, pertaining to the applications for exemptions from the epilepsy medical standard that have been submitted to the agency. As we stated in comments submitted to FMCSA on November 14, 2006, a thoughtful individualized assessment process is required by Section 504 of the Rehabilitation Act (29 U.S.C. 794), which prohibits discrimination against qualified persons with disabilities in programs conducted by federal agencies. Prior to denying participation in a federal program based on safety concerns related to one's disability, Section 504 requires the agency to conduct an individualized assessment to determine the actual safety risks involved and whether risks render the individual unqualified for participation. *See, e.g., Rauenhorst v. U.S. Department of Transportation*, 95 F.3d 715 (8th Cir. 1996) (holding that given requirements of Section 504, DOT acted arbitrarily and capriciously in failing to apply an individualized assessment of the merits of an application for a waiver from the binocular vision requirement for CMV drivers). The FMCSA's medical standards' exemption process is the vehicle by which the agency can comply with this mandate. *See Rauenhorst* case. Please see our 2006 comments for more details on this concern.

To date, we understand that the FMCSA has apparently failed to issue determinations regarding any of the many exemption applications the agency has received. Some of these applications were submitted at least as early as 2006. The statutory provisions governing exemption requests require that the agency “grant or deny an exemption request after a thorough review of its safety implications, but in no case later than 180 days after the filing date of such request.” 49 U.S.C. 31315(b)(3). It appears that the FMCSA has failed to comply with this mandate.

If we can provide any further information, please do not hesitate to contact us at 313-916-2451 (Brien Smith) or at 301-918-3762 (Gary Gross). Thank you very much for your consideration of our comments.

Sincerely,

Brien J. Smith, MD
Chair, Legal & Government Affairs Committee

Gary Gross, Esq.
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cc: Alexandra K. Finucane
Vice President, Legal and Government Affairs