*Docket Comments for the June 30, 2011 MRB Meeting*

The following comments were received for the June 30, 2011 MRB meeting:

Irene Tunanidas – Comments (FMCSA-2011-0362-0023)

## General Comment

July 14, 2011

Re: Document #FMCSA 2011 - 0362.

This above-mentioned document was brought to my attention by the National Association of the Deaf regarding
FMCSA's road safety rules and concerns on hiring truck drivers who are deaf / hard of hearing.

I have read success stories of a few licensed commercial truck drivers who are deaf themselves. One of them, Harold
"Friday" Roach, who worked for FRUEHAUF Trucking Company in the early 80s. He was profoundly deaf and had an excellent driving record. Mr. Roach retired after 30 years with FRUEHAUF. The reason why Mr. Roach achieved success as a deaf truck driver was because his hearing father had faith in his son. The father was confident his son Harold would do the job efficiently. Harold proved to be the best truck driver doing business within New York and out of N.Y.

Today, we are living in a complex world and employers are clueless on the abilities of the Deaf in employment. FMCSA needs to see that truck company employers do their job by going through the screening process of deaf and hearing applicants. They need to check the applicants' employment history, and other backgrounds that require careful scrutiny, such as: one's integrity and ability to communicate with employer.

As a licensed vehicle driver in the state of Ohio, I have seen bad truck drivers weaving in and out of the road. If I had my hearing, I would have picked up the cell phone and report problems to the Ohio Highway Patrol Department.

One September morning last year, on my way to Kent, I witnessed a truck weaving irratically on Rt. 76. I decided to
pass over and, to my horror, the truck driver was texting !!
I am certain that deaf truck drivers are aware of the risks of road driving. I believe that the National Association of the Deaf is making a valid point that deaf drivers have a safety record on the road.

Truck company employers should give deaf truck drivers a chance to prove they are responsible drivers.

American Diabetes Association - Comments (FMCSA-2011-0362-0034)


Docket No. FMCSA-2011-0362

**Comments of the American Diabetes Association**

The American Diabetes Association submits these comments in response to the June 30, 2011 Medical Review Board meeting and in response to the updated Evidence Report on diabetes presented at that meeting.

The American Diabetes Association

The American Diabetes Association (Association) is a nationwide, nonprofit, voluntary health organization founded in 1940, and has over 485,000 general members, 15,000 health professional members, and 1,000,000 volunteers. The mission of the Association is to prevent and cure diabetes and to improve the lives of all people affected by diabetes. Presently, there are 25.8 million Americans with diabetes.[[1]](#footnote-1) The Association is the largest, most prominent nongovernmental organization that deals with the treatment and impact of diabetes. The Association establishes and maintains the most authoritative and widely followed clinical practice recommendations, guidelines, and standards for the treatment of diabetes.[[2]](#footnote-2) The Association publishes the most authoritative professional journals concerning diabetes research and treatment.[[3]](#footnote-3)

The mission of the Association is to prevent and cure diabetes and to improve the lives of all people affected by diabetes. This mission requires supporting a system that provides rigorous safety standards to protect commercial drivers with diabetes and the public, while not unduly denying people with diabetes the same rights granted to other Americans. Based on its scientific and medical expertise, the Association supports the adoption on the state and federal level of programs whereby each person with insulin-treated diabetes is afforded an individual assessment of his or her ability to be a commercial driver.

Background

The Association has long advocated for FMCSA to adopt rules that allow people with diabetes who are qualified and medically able to operate commercial motor vehicles to hold the medical certification required for such work. The Association’s long history of advocating on behalf of commercial drivers with diabetes is reflected in dockets FMCSA 2001-9800 and FMCSA-2005-23151. This history has included the development and refinement of the Diabetes Exemption Program, and review of the first diabetes evidence report and subsequent recommendations of the Medical Expert Panel and Medical Review Board in 2006-07. Throughout this history, the Association has provided expert assistance – both directly and through Association volunteer health care professionals – on diabetes and its management. The Association will gladly continue to provide this assistance, and stands ready to assist the current Medical Review Board or the agency as it deliberates any changes to the diabetes standard.

Request for Comments

The agency requests comments on the updated evidence report presented at the June 30 Medical Review Board meeting. Our comments are organized around two main principles:

* Development of a new diabetes standard or a new process for certifying commercial drivers with diabetes must be done with the input of experts in the treatment of diabetes.
* The risk ratio identified in the updated evidence report does not justify additional restrictions for people with diabetes.

***Development of a new diabetes standard or a new process for certifying commercial drivers with diabetes must be done with the input of experts in the treatment of diabetes.***

FMCSA is well aware of the essential role diabetes experts have played in developing the current Diabetes Exemption Program and in advising the agency about diabetes in light of the conclusions of the original evidence report. Doctors Michael Brennan, George Grunberger, Edward Horton, Christopher Saudek, Patricia Daly, Luciano Kolodny and Daniel Lorber have all helped the agency develop the standards and processes that to date have been used to certify more than 1,600 commercial drivers with diabetes. FMCSA needs similar experts in the field of diabetes to provide input as the agency undertakes another review of the evidence and possible changes to the way commercial drivers with diabetes are medically certified.

Such expertise is needed to both develop standards and to implement them. Indeed, the prior Medical Expert Panel recommended the creation of a diabetes expert panel whose members could serve as consultants to medical examiners on issues related to diabetes. These consultants would receive training in the Federal Motor Carrier Safety Regulations, as well as training on issues related to the job of commercial driver. The Medical Expert Panel went further and developed basic training for these expert consultants, and concluded that their role could include mediating disputes between a driver’s treating physician and the medical examiner.

In response to the Advance Notice of Proposed Rulemaking (ANPRM) submitted in June 2006, the Association stated:

The Association believes that a physician knowledgeable in diabetes should be involved in the decision as to whether an individual with insulin-treated diabetes is medically qualified to operate a CMV. Endocrinologists and other physicians who regularly care for patients with diabetes have specialized knowledge of the disease and treatment regimens. The input of these physicians is essential to assess an individual’s diabetes management and determine whether CMV operation is safe and practicable in accordance with the revised standard and accompanying diabetes guidelines.

In addition, the Association provided comments during the ANPRM about the provisions in the Diabetes Exemption Program, identifying areas to revisit during the development of physician guidelines. As the Medical Review Board undertakes its evaluation of the exemption program and the criteria on which to evaluate commercial drivers with diabetes, the Association offers its input on these and any new criteria to best evaluate drivers with diabetes.

In sum, diabetes experts are crucial not just to the development of rules and processes relating to commercial drivers with diabetes, but also to the actual certification of these drivers. Because there is no representation by a diabetes expert on the Medical Review Board, the agency is at a significant disadvantage if it chooses to move forward without convening a Medical Expert Panel or otherwise seeking input from diabetes experts on how to certify commercial drivers with diabetes.

***The risk ratio identified in the updated evidence report does not justify additional restrictions for people with diabetes.***

The original evidence report noted a 19% increased crash risk based on a review of 16 studies. The updated report, based on an additional three studies,[[4]](#footnote-4) [[5]](#footnote-5) [[6]](#footnote-6) found a decreased crash risk, at 12-13%. Neither crash risk is statistically significant or justifies additional driving restrictions for people with diabetes.

Of the three additional studies included in the updated report,[[7]](#footnote-7) the study by Skurtveit et al found only a “slightly increased” risk of crash for drivers using insulin (standardized incidence ratio of 1.4), and no increased risk of crash for drivers using oral glucose-lowering agents (standardized incidence ratio of 1.2). Further, the crash risk observed for insulin users was found to be similar to that of users of drugs for peptic ulcer and gastroesophageal reflux (standardized incidence ratio of 1.3) – neither of which condition is subject to driving restrictions in the United States.

During the researchers’ updating of the evidence report, the study by Lonnen et al seemed to generate the most attention and led to further analysis of crash risk broken out by the country in which the study took place. This study found a decrease in the crash risk for drivers with diabetes, which prompted the Driver Vehicle Licensing Authority (DVLA) in the U.K. to publish a statement stating this crash risk was underestimated because of a three-year medical review required for license renewal in the U.K., which the DVLA states removes from the road drivers who have experienced dangerous hypoglycemia in that period. The DVLA’s characterization of this study, and the subgroup analysis by country, should not be used to attach any greater restrictions on commercial drivers in the U.S. For one thing, all but the Laberge-Nadeau study out of Canada involve non-commercial drivers, a population and set of rules that differs greatly from those seeking medical certification through the Diabetes Exemption Program in the U.S. Similar to the rules in the U.K. that remove drivers who have experienced hypoglycemia in the past three years, the Diabetes Exemption Program restricts those who have experienced severe hypoglycemia in the past five years – an arguably even tougher standard than that of the U.K. The program also requires ongoing monitoring of diabetes, with submission of quarterly endocrinologist reports and an annual assessment of diabetes.

As we noted in our February 5, 2008 letter to Administrator Hill, the original evidence report presented to the Medical Review Board was flawed in several aspects, primarily the exclusive reliance on studies that did not replicate the commercial driving environment or include any screening criteria to determine who could and could not drive safely. Because none of the three new studies involve commercial drivers either, the same problem exists in the updated report.

It is notable that the study by Skurtveit et al echoes many of the Association’s concerns. About other research studying the relationship between diabetes and driving, the authors note, “Studies often fail to distinguish between types of diabetes, rely on self-reporting of accidents and use highly selected study populations . . . a number of studies on diabetes and driving originate from the 1970s, when traffic was very different from today and treatment of diabetes differed from current practice.”[[8]](#footnote-8) Thus, the 1.284 crash risk found in the updated report for studies conducted in the U.S., which was found to be statistically significant, is not very meaningful given the conditions that were present in these studies. Accordingly, the updated report, and in particular the subgroup analysis, is not sufficient to form the basis of federal commercial driving policy.

Rather, the Laberge-Nadeau study – to date the only examination of diabetes and operation of commercial motor vehicles – provides better guidance. Notably, the original report said about this study, “it is not a high-quality study and its findings have not been replicated. Consequently, one cannot draw an evidence-based conclusion pertaining to whether CMV drivers with diabetes are at an increased risk for a motor vehicle accident.”[[9]](#footnote-9) And yet, this study is characterized as a “well-designed case-control study” of moderate quality, while many other studies that do not involve commercial drivers are deemed of low quality – and, according the reports’ authors are “not necessarily directly generalizable to CMV drivers”[[10]](#footnote-10).

Laberge-Nadeau posits that individuals with diabetes self-select and those who are most severely affected by diabetes remove themselves from the road or restrict their driving, and that this self-selection leads to lower estimates of crash risk. It should be noted that the current U.S. system – the Diabetes Exemption Program – does not rely on voluntary self-selection, but was designed to include a very rigorous set of rules that is arguably even safer.

The Association argues that this study cannot be dismissed, even if it has not been replicated, because it is the ONLY study directly on point. Further, as the updated evidence report illustrates, recent studies indicate the crash risk is actually declining.

June 30, 2011 Medical Review Board meeting & public discussion

The Association will next address two specific medical issues that were noted during the discussion of the updated diabetes evidence report at the June 30, 2011 Medical Review Board meeting.

The first issue concerns the use of hemoglobin A1C to determine which individuals are qualified to operate commercial motor vehicles. Although the Board did not make any recommendations relative to A1C, there was concern over the lack of an A1C requirement in the current rules. Board members expressed a fear that some drivers with higher A1C levels could be driving impaired due to hyperglycemia (high blood glucose), and there were comments made that drivers with an A1C over 8% are “bad diabetics” who shouldn’t be on the road. In response, the Association notes that A1C represents an average of blood glucose over a three month period, and does not indicate whether a person can safely operate a motor vehicle. A1C values provide health care providers with important information about the effectiveness of an individual’s treatment regimen, but are often misused in assessing whether an individual can safely perform a job. Hemoglobin A1C results are of no value in predicting short-term complications of diabetes, such as hypoglycemia, and thus have very limited use in evaluating individuals in licensing or employment situations.

Although the Association recommends that A1C levels be kept below 7%, this recommendation is not based on the safety of an individual to currently perform tasks. Rather, this recommendation sets a target in order to lessen the chance of long-term complications of high blood glucose levels. An A1C cut off score is not medically justified in licensing or employment evaluations, and should never be considered a determinative factor in such evaluations. The Association therefore urges FMCSA not to adopt an A1C requirement for commercial drivers with diabetes.

The second issue concerns what can be described as the cumulative effect of crash risk data. Although the two evidence reports note a crash risk between 12-19%, the updated report also touches on the incidence of diabetes in the U.S. and the rising number of new cases of diabetes.[[11]](#footnote-11) During the June 30 meeting, comments were made that the risk of driving and diabetes is not captured by solely looking at the crash risk data presented in the evidence report, but rather, this risk should be multiplied by the number of people who have diabetes, as a more accurate representation of the severity of the situation.

The Association urges FMCSA to develop rules based on sound medicine and science, and not overblown estimates of crash risk based on a belief that the incidence of diabetes makes the risk of crash greater. Certainly, only a very small percentage of the 25.8 million people with diabetes in the U.S. both seek to be commercial drivers and have additional risk associated with the course of their disease or their treatment regimens. Even for those who fit both of these categories their added risk compares favorably with many other common characteristics that we accept in the commercial driving populations ranging from young males to middle-aged and elderly males (including those who smoke), who have an elevated risk of a cardiac event or stroke, to people who use over-the-counter medications such as Sudafed. [People with diabetes who can safely operate a commercial motor vehicle should not be restricted from doing so simply because there is a national diabetes epidemic. To do so violates the notion of individual assessment that is fundamental to our country’s approach to equal opportunity

Conclusion

The Association appreciates the opportunity to comment on the updated evidence report, the June 30 Medical Review Board meeting, and the work of the Board going forward. We reiterate our strong desire for the agency to include diabetes experts in the review of current procedures and the development of any new rules related to diabetes, and stand ready to assist FMCSA in this effort.

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1. Centers for Disease Control & Prevention, *National Diabetes Fact Sheet* (2011). [↑](#footnote-ref-1)
2. American Diabetes Ass’n, *Clinical Practice Recommendations 2011*, 34 Diabetes Care S1 (2011). [↑](#footnote-ref-2)
3. The Association publishes four professional journals with widespread circulation: (1) Diabetes (original scientific research about diabetes); Diabetes Care (original human studies about diabetes treatment); (3) Clinical Diabetes (information about state-of-the-art care for people with diabetes); and, (4) Diabetes Spectrum (review and original articles on clinical diabetes management). [↑](#footnote-ref-3)
4. Skurtveit S, et al., *Road traffic accident risk in patients with diabetes mellitus receiving blood glucose-lowering drugs. Prospective follow-up study.*  Diabet Med, 2009. 26(4):404-408. [↑](#footnote-ref-4)
5. Lonnen KF, et al., *Road traffic accidents and diabetes: insulin use does not determine risk.* Diabet Med, 2008. 25(5):578-584. [↑](#footnote-ref-5)
6. Hemmelgarn B, Levesque LE, Suissa S, *Anti-diabeti drug use and the risk of motor vehicle crash in the elderly.* Can J Clin Pharmacol, 2006. 13(1):e112-120. [↑](#footnote-ref-6)
7. The study by Hemmelgarn was not a case-control study and seems to have dropped in prominence in the updated report given the exploration of crash risk by country. [↑](#footnote-ref-7)
8. Skurtveit S, et al., *Road traffic accident risk in patients with diabetes mellitus receiving blood glucose-lowering drugs.* *Prospective follow-up study.* Diabet Med, 2009. 26:404-408, 407. [↑](#footnote-ref-8)
9. ECRI, *Final Evidence Report: Diabetes and Commercial Motor Vehicle Driver Safety*, 2006. [↑](#footnote-ref-9)
10. Manila, *Evidence Report: 2010 Update: Diabetes and Commercial Motor Vehicle Driver Safety* at section 4.1.5.1. [↑](#footnote-ref-10)
11. Note, the evidence report references the 2009 statistics for diabetes from the Centers for Disease Control and Prevention, however, there are updated statistics in the National Diabetes Fact Sheet, 2011, available at: <http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2011.pdf> [↑](#footnote-ref-11)