

AHAS also took exception to FMCSA's interpretation of four recent risk studies presented in the TEA-21 Report to Congress and the July 2001 notice of intent. It first addressed two Canadian studies:

1. Dionne, G. *et al.* "Medical Conditions, Risk Exposure, and Truck Drivers' Accidents: An Analysis with Count Data Regression Models," *Accident and Prevention*, 27(3): 295-305 (1995); and

2. Dionne G. *et al.* "Analysis of the Economic Impact of Medical and Optometric Driving Standards on Costs Incurred By Trucking Firms and on the Social Costs of Traffic Accidents" in Dionne, G. and Laberge-Nadeau, C. (Eds.) *Automobile Insurance: Road Safety, New Drivers, Risk Insurance Fraud and Regulation*, Kluwer Academic Publishers, Boston (1999).

AHAS states that these studies do not offer any evidence in support of an exemption program.

The first of these studies (1995) examined truck drivers in two licensure classes. One class was for the operation of large combination trucks, while the other included truck drivers holding all other classes of license that were mostly holders of permits for straight trucks. The risk analysis in each class considered diabetic drivers versus all other drivers. The diabetic drivers of large combination trucks had an accident rate that was not significant, while the diabetic drivers of small trucks had a significantly higher accident rate. The analysis did not consider the use of insulin by the diabetic drivers. Relative to this, AHAS alleges that FMCSA's notice of intent does not state to the public that although the researchers were actually at a loss to explain the results, they believed that the results could be due to the use of insulin since the diabetic drivers of large trucks had fewer individuals treated in this manner than those with other classes of license.

For the second study, AHAS states that the results FMCSA relies on were not the focus of the study nor its primary consideration, and that the primary focus of the study was estimation of cost per accident. FMCSA reported a secondary finding, according to AHAS, in that the data showed that drivers with diabetes did not have significantly more severe accidents than those in the comparison groups. Severity was measured as the total number of individuals injured or killed in an accident. AHAS points out that the work in the second study was based on the data used in the first and was a continuation of that study. It also states

that the use of insulin was not considered in the second study.

FMCSA believes the AHAS claim that the studies do not contribute to the finding that ITDM drivers have an acceptable level of risk is unfounded. Aside from the finding that diabetic drivers of small truck CMVs had a significantly higher accident rate, none of the other findings refute the position that diabetics could operate CMVs in interstate commerce with a level of safety that is the same or better than the prevailing standard. While insulin was not taken into consideration in the analyses, the studies do nonetheless offer evidence in support of the exemption program by virtue of not contradicting the conceptual design. Contradiction and refutation are acceptable approaches in science to revise a stated theory. None of the work contradicts the determination that diabetic drivers have an acceptable level of risk. In performing risk assessments through observational studies, it is necessary to examine all of the evidence to determine the direction the preponderance of evidence supports.

After the FMCSA issued the notice of intent, there has been an additional contribution to the collection of evidence on this issue. Some of the same Canadian researchers who conducted the previous studies used the same insurance database to conduct a third study (Laberge-Nadeau, C. *et al.* "Impact of Diabetes on Crash Risks of Truck-Permit Holders and Commercial Drivers." *Diabetes Care*, Vol. 23(5): 612-617, 2000). These data were augmented with health status data from a public health insurer where insulin use was identified, along with the existence of complications due to diabetes. Portions of the database were analyzed with the new information in a new research design where diabetic driver permit holders were group-matched by age to a random sample of healthy permit-holders. Risk was analyzed relative to type of permit holder (large combination trucks and straight trucks), use of insulin, and diabetic complications. Relative to both classes of trucks, insulin-using diabetics showed no significant risk regardless of complication status. The only group of diabetics to show significant risk was the permit holders for straight trucks who did not use insulin and were without complications. To explain the results concerning insulin use and complications, the researchers stated that employers hiring drivers for large combination trucks use higher medical standards presumably for insulin-using diabetics and other drivers. This is what

the protocols in the FMCSA diabetes exemption program are designed to do.

Many of the points argued by AHAS in relation to their criticism of the research design in the waiver program and their rejection of the legal basis for the exemption program, have been previously presented and have been addressed at length in 58 FR 40690 (July 29, 1993) (FHWA Docket No. MC-87-17), 61 FR 13337 (March 26, 1996) (FHWA Docket No. MC-96-2), 63 FR 67601 (December 8, 1998) (DMS Docket No. FMCSA-1998-4145) and 64 FR 51568 (September 23, 1999) (DMS Docket No. FMCSA-1999-5578). FMCSA will not address the points again here. Interested parties are referred to the earlier discussions.

In its comments to this notice, AHAS also raises some new issues. In particular, it has some concerns relative to the most recent risk study conducted by the agency ("A Study of the Risk Associated with the Operation of Commercial Motor Vehicles by Drivers with Insulin-Treated Diabetes Mellitus," FHWA, 1999). AHAS states that the comparisons made in the study could be suspect because the comparison group was composed of interstate drivers, while the diabetes group contained mostly intrastate drivers. While it is true that the diabetes group did primarily contain intrastate drivers, the comparison group of CDL holders also had intrastate drivers, albeit in smaller proportion. This disparity in representation by the two groups did contribute to the range of CMV operation (intrastate versus interstate) being identified as a confounding factor in the study. As a result, FMCSA used the factor to adjust the initial results. Observational study research literature supports this type of adjustment. Had this factor and others been ignored in the analyses, the unadjusted results would have been biased and detracted from the internal validity of the study.

This aspect of FMCSA's response also addresses another AHAS concern involving the nature of the unadjusted study results. AHAS correctly pointed out that the initial (unadjusted) results show that the diabetes group had a higher crash rate than the comparison group. However, since this study was observational in nature, as are almost all practical risk investigations, it is necessary to assess the factors that could introduce bias into the results and invalidate the findings. FMCSA did this and found several factors, including intrastate versus interstate operation and marital status. The other source of potential bias that FMCSA found was over-dispersion in the distribution of accidents (a larger than expected