

variation in the number of accidents). Both of these sources of bias tend to produce false positive (significant) results if not subjected to adjustment. FMCSA analyzed the two sources of potential bias with adjustment procedures, both separately and jointly, and found the results were consistent across all analyses showing no significant difference in risk between the two groups. While the AHAS seemed to characterize this multifaceted approach to analysis as a contrived strategy, it is the approach which is required in an observational study (see U.S. General Accounting Office, "Cross Design Synthesis: A New Strategy for Medical Effectiveness Research," March 1992 GAO/PEMD-92-18). It is the consistent results across the varied adjustment procedures that gives the FMCSA confidence that bias was present in the initial (unadjusted) results and was eliminated in the ensuing analysis.

AHAS also claims that the Federal Aviation Administration (FAA) exemption program for ITDM individuals is an inappropriate model for FMCSA's program for the operation of CMVs. It stated that the FAA program issues exemptions only for third-class airman medical certificates and not for commercial pilots. The AHAS is correct in their assessment of the FAA program; however, the FMCSA had no intention of using the FAA's program as a model for the FMCSA program with respect to type of target population. FMCSA used the FAA program as evidence that it could develop a process of medical examination and screening to issue exemptions to individuals with ITDM. To this end, FMCSA used the FAA process as part of the template for development of the proposed medical examination and screening protocol. That is why the protocol is analogous to that of the FAA.

In its opposition, the California Department of Motor Vehicles (California) states that the proposed FMCSA program will unnecessarily increase the risk to the public and the drivers receiving the exemptions. While California regulatory guidelines allow some experienced ITDM individuals to operate intrastate, it believes that the FMCSA exemption program could greatly expand the number of these drivers who operate interstate and thereby increase risk. California limits the number of exemptions because of the risk of hypoglycemia. It states blood sugar is affected by almost everything including exercise and stress. This in combination with arduous work conditions associated with interstate

operation makes it difficult for drivers with ITDM to control their blood sugar.

California does not believe that the proposed FMCSA screening procedures adequately address the issue of hypoglycemia. The requirement for a complete medical examination, by a board-certified or eligible endocrinologist with a statement of familiarity with the applicant's five-year medical history, will not preclude an ITDM driver from experiencing a hypoglycemia episode.

FMCSA believes it has addressed this type of circumstance in the exemption program's screening protocol. Specifically, the criteria state that the applicant must have had no recurrent (two or more) hypoglycemia reactions resulting in a loss of consciousness or seizure within the past five years. A period of one year of demonstrated stability is required following the first episode of hypoglycemia. Moreover, the criteria require that the applicant does not have recurrent hypoglycemia reactions requiring the assistance of another person and does not have reactions resulting in impaired cognitive function that occurred without warning symptoms within the past five years. In addition, as a test of these responses under arduous working conditions, the screening criteria also require three years of CMV operation with ITDM. The same screening criteria were used in the agency's previous diabetes waiver program, and in the three years of that program, there were no reported cases of impairment due to episodes of hypoglycemia. Moreover, screening is stricter now. In place of a single screening episode under the previous program, the driver must reapply for an exemption every two years, or sooner if the exemption was issued for a shorter period. Screening is performed at each reapplication. In addition, screening is performed annually by an endocrinologist, as well as the medical examiner performing the annual examination and certification required under 49 CFR 391.43.

In another issue of concern for California, it points out that the protocol proposed in the FMCSA program requires the exempted drivers to check their blood sugar levels every two to four hours. Because of this and other measures needed to control blood sugar, California believes that employers would not let the drivers take the time necessary to perform all of these activities. FMCSA, based on its previous experience, is not aware of any evidence to suggest that employers would not allow drivers to take the time needed to check their blood sugar levels.

California points to a 1999 study as another basis for its opposition (Clark, W. L. *et al.* "Hypoglycemia and the Decision to Drive a Motor Vehicle by Persons with Diabetes." JAMA, August 1999, Vol. 282, No. 8, 750-754). An objective of the study was to examine an ITDM individual's decision to drive during the individual's daily routine, based on perception of blood sugar levels compared to actual levels. The researchers found that significant numbers of subjects did not correctly estimate how low their blood sugar was, and therefore decided to drive. The findings also showed that even when individuals accurately estimated low blood sugar levels, a significant portion still decided to drive. California, however, does not indicate the researchers stated that ITDM individuals should not be permitted to drive. California did say the data suggested that individuals with ITDM need to be cautious before driving a motor vehicle. The researchers said that the suggestion that individuals measure their blood sugar levels, and raise potentially low levels before driving, did not seem unreasonable. They said that drivers with diabetes should always carry rapid-acting glucose with them when they drive. Moreover, the researchers claim that individuals with ITDM could benefit from awareness training to help detect blood sugar levels. They stated that this type of training has been shown to improve the detection abilities of even those with reduced awareness of hypoglycemia, and that the improvement has been sustained for at least a year.

The protocol being adopted in this final disposition is very consistent with the conclusions of these researchers. In the screening component the applicant must present a signed statement prepared by the examining endocrinologist indicating that the applicant has been educated in diabetes and its management, thoroughly informed of and understands the procedures which must be followed to monitor and manage his/her diabetes, and what procedures should be followed if complications arise. In addition, the protocol requires, in the guideline component, that the qualified applicant have a supply of rapidly absorbable glucose to be used as necessary. The protocol also requires, in the monitoring component, that the qualified driver provide annual documentation by a specialist of ongoing education in diabetes management and hypoglycemia awareness. While Clark W. L., *et al.* was valuable in identifying the potential