EXHIBIT B

Additional Comments of the American Diabetes Association
Docket No. FMCSA-2001-9800
February 4, 2002

The American Diabetes Association ("Association") submits these additional comments in response to the January 3, 2002 notice by the Federal Motor Carrier Safety Administration (FMCSA) to reopen the public comment period on its proposal to issue exemptions from the blanket prohibition against individuals who use insulin to treat their diabetes currently contained in Part 391 of the Federal Motor Carrier Safety Regulations. This regulation governs the medical qualifications for drivers of commercial motor vehicles (CMVs) in interstate commerce, and currently makes it impossible for anyone who controls their diabetes with insulin to obtain a commercial driver's license (CDL) for interstate operations.

During the original comment period, which lasted from July 31, 2001, to October 1, 2001, the Association submitted extensive comments. With the comment period having been reopened on January 3, 2002, this document is intended to supplement the Association's original comments.

Background

In general, the Association applauds FMCSA for advancing a proposal to end the current blanket ban that prevents anyone with insulin-treated diabetes from obtaining a CDL. The Association does not believe that every person with insulin-treated diabetes should automatically qualify for a CDL, and supports most aspects of the proposed protocol including almost all of the very stringent assessment to determine if a person is medically qualified to drive a commercial motor vehicle, the specific requirements for monitoring and driving, and the ongoing need for intense medical monitoring. At the same time, the Association very strongly believes that the proposed program fails to achieve the goal of setting up a practicable protocol for individual assessment by unnecessarily including a requirement that applicants must have driven a commercial motor vehicle while using insulin for the three years immediately preceding an application.[1]

The Original Comment Period

The original comment period closed on October 1, 2001. The Association was pleased to see overwhelming and broad support for eliminating the blanket prohibition, as well as significant opposition to the three-year rule. The diversity of the respondents expressing

[1] The Association's opposition to the three-year requirement encompasses the requirement that an applicant possess "a valid intrastate CDL or a license (non-CDL) to operate a CMV" in order to qualify for this exemption program, found in the Applicant Information supporting documentation section (1), as well the requirement in section (2) regarding actual operation of a commercial motor vehicle – as the former requirement is merely a subset of the latter. Together these requirements prevent the vast majority of applicants who would be safe drivers from being qualified for this exemption program. Both provisions should be eliminated.

their support for eliminating the blanket ban is quite notable. Submissions in support of an individual assessment and/or expressing concern with the proposed three-year requirement came from private citizens, industry associations, unions, Members of Congress, state Department of Motor Vehicles administrators, and government agencies including the Department of Justice and the Equal Employment Opportunity Commission.

By the Association's analysis, to date the Department of Transportation (DOT) received comments from nearly 300 individuals or organizations. Among this group of comments, only 10 (about 3%) expressed opposition to the rule. Significantly, nearly two-thirds of the comments (195) expressed opposition to the proposed three-year rule. Based on the comments received to date, it is clear that the general public supports an individual assessment of people with insulin-treated diabetes who wish to obtain a CDL to operate in interstate commerce.

The Expert Medical Panel Letter

It has been the Association's contention that the three-year rule is not based on the current medical practice of diabetes management. Therefore, it is important to note the inclusion of a letter that was submitted to the public docket by the four physicians who were selected by the Department of Transportation to serve on the Medical Advisory Panel as part of the agency's Report to Congress on the Feasibility of a Program to Qualify Individuals with Insulin Treated Diabetes Mellitus to Operate Commercial Motor Vehicles in Interstate Commerce as Directed by the Transportation Equity Act for the 21st Century (July 2000) (hereafter, "Report to Congress"). In their comment, the physicians who served on the agency's own Medical Advisory Panel outlined their objections to the three-year rule, noting that the "three year requirement is simply unsupported by the science of diabetes management and control." The physicians wrote:

> As members of the Expert Medical Panel, we specifically discussed the minimum period of insulin use for a commercial driver before being qualified to drive. As indicated on p. 43 of the Report, we agreed that a period of one month would be sufficient for a driver with type 2 diabetes who was converting to insulin use, and a period of two months would be sufficient for a person who is newly diagnosed with type 1 diabetes.

Medically Unnecessary Requirement Causes Undue Economic Hardship

The current blanket prohibition causes economic hardship by creating job loss once a commercial motor vehicle operator with diabetes commences insulin use. The Association has heard from its members about a common situation: a seasoned driver with type 2 diabetes who has established a livelihood driving a commercial vehicle in interstate commerce is advised to go on insulin by his or her physician. The driver then faces a choice: go on insulin and lose your job, or don't go on insulin.

Unfortunately, the proposed protocol would do nothing to alleviate the economic hardship created by this situation. Few such drivers will have employers that have intrastate driving opportunities available – even if the employer were willing to assign the driver to those operations for three years. Thus, the three-year rule ensures that people in this situation will face job loss.

As a result, the medically unnecessary three-year requirement will make the availability of an individual assessment meaningless. The Association believes that a better alternative exists in the recommendations of the physicians on the Expert Medical Panel: a one or two month period where an individual would adjust to insulin use. A one or two month adjustment period would be medically sound and would give those commercial operators who can pass the rest of the strict criteria in the proposed protocol the opportunity to continue to earn a livelihood. Failure to provide a reasonable, medically sound adjustment period would only unnecessarily promulgate economic hardship and disruption.

Opposition to the Proposed Exemption Program is Not Based on Current Medical Management of Diabetes

The Association notes that while there was very little opposition in the public docket to the basic concept of moving from the existing blanket-ban to an individual assessment, those comments opposing individual assessment of drivers with insulin-treated diabetes are filled with inaccuracies and outdated information.

Opposition to the proposed exemption program has two facets: concerns with the studies used or not used by FMCSA, and cynical generalizations about people with diabetes. This opposition bases its opinions on fear and conjecture and ignores scientific advances and data collected by the FMCSA.

DCCT, UKPDS, and Clarke Study Misapplied

The risk attendant to allowing individuals who use insulin to drive commercial vehicles is specifically related to the risk of hypoglycemia occurring during the act of driving with a resultant motor vehicle accident. The reality is that hypoglycemia in patients with insulin-treated diabetes is rare, predictable, and preventable. Opposition to allowing individual assessment of commercial drivers who use insulin is based on limited data from two studies initiated in the early 1980's, the Diabetes Control and Complications Trial (DCCT) and United Kingdom Prospective Diabetes Study (UKPDS), and a misapplication of the Clarke et al. study from the Journal of the American Medical Association.[2]

[2] Clarke W, Cox D, Gonder-Frederick L, Kovatchev B: Hypoglycemia and the Decision to Drive a Motor Vehicle by Persons with Diabetes. *Journal of the American Medical Association* 282:750-54 (1999).

The DCCT and UKPDS were pivotal studies in type 1 and type 2 diabetes, respectively, examining the role of tight glycemic control. In the process of striving for intensified glucose control, both studies identified incidence and prevalence rates for hypoglycemia and risk factors for their occurrence. However, in light of the many advances in diabetes management that have occurred since the time of these studies, the data gleaned from these reports by those opposing individual assessment do not provide evidence of anticipated rates of hypoglycemia today – even for those potential drivers who strive for tight glycemic control.

Several initial observations help to put the data on hypoglycemia in these studies into the proper context. Rather than forming the final word on the risk of hypoglycemia in individuals with type 1 diabetes, the initial results of the DCCT, identifying a three-fold increase of severe hypoglycemia in the intensively treated group, were themselves used to identify risk factors that, once taken into account, resulted in a subsequent reduction of risk of severe hypoglycemia in the final results of the DCCT. [3] In addition, the vast majority of potential drivers who use insulin would have type 2 diabetes, as 90 percent of all people with diabetes in the United States have this form of the disease. Major episodes of hypoglycemia are far less common in this patient population. Even in those individuals intensively treated with insulin in the UKPDS, fewer than 5% of individuals experienced a single major hypoglycemic episode in a single year.

Moreover, the science of diabetes management has advanced significantly since the time of these studies, with major advances in the types of insulin available, the methods of insulin delivery, the means of self-monitoring blood glucose levels, and training available to improve self-assessment of hypoglycemia.

The DCCT and UKPDS were initiated with insulin regimens based upon the types of insulin available at the time, including animal source (beef, pork) insulins and extremely long acting Ultralente insulin, which has a notorious history of unpredictability and hypoglycemia. Newer more predictable insulin preparations – which have been shown to significantly reduce the risk of hypoglycemia – have replaced the preparations that were used at the time of these studies. Very rapid acting insulin (Insulin Lispro and Insulin Aspart) begins to work within 10 minutes of injection, as opposed to the traditional short acting regular insulin which requires injection 30 to 60 minutes prior to eating. Thus, under the prior insulin regimen, a driver would have had to stop, take insulin, continue driving while the insulin took effect, and then stop to eat. Today, a driver stops, takes insulin, eats immediately, and the insulin action is available while needed to store the ingested calories then is gone when the food has been absorbed. Insulins available at the time of these studies, on the other hand, continued to work for 4 to 6 hours after injection – long after food absorption had been completed. This

[3] Diabetes Control and Complications Trial Research Group: Epidemiology of Severe Hypoglycemia in the Diabetes Control and Complications Trial. *Am J Med* 90:450-459 (1991).

theoretical benefit has translated into clinical reductions in severe and nocturnal[4] hypoglycemia events in patients with diabetes. A 47% reduction in nocturnal reactions and severe hypoglycemia was noted with the use of Insulin Lispro as compared with regular human insulin in subjects with type 1 diabetes despite use in subjects with a history of severe hypoglycemia.[5] Comparable data were noted in subjects with type 2 diabetes new to insulin therapy who experienced a 24% reduction in prevalence of nocturnal hypoglycemia in those treated with Lispro.[6] Similar findings have been demonstrated with insulin Aspart in both European and American trials.[7]

Of particular interest, investigators found the use of Ultralente insulin (the formulation utilized in UKPDS) to be associated with an increased risk of hypoglycemia.[8] Not only has the availability of very rapid acting insulin reduced the risk and occurrence of hypoglycemia, but new long-acting insulin preparations have minimized hypoglycemia risk as well. In type 1 diabetes, all hypoglycemia was reduced by 43% and severe hypoglycemia by 40% with insulin Glargine as compared to intermediate-acting NPH insulin.[9] A fifty percent reduction in nocturnal hypoglycemia was found in patients with type 2 diabetes treated with insulin Glargine as opposed to NPH insulin.[10]

Thus, the UKPDS and DCCT provided important baseline information on risks and predictability of hypoglycemia in patients who choose to seek very tight control, but newer

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[4] Incidence of nocturnal hypoglycemia is relevant because it tracks a long period of time in which the patient does not eat, as might be the case of a long haul driver.

[5] Ferguson SC, Strachan MW, Janes JM, Frier BW: Severe Hypoglycaemia in Patients with Type 1 Diabetes and Impaired Awareness of Hypoglycaemia: A Comparative Study of Insulin Lispro and Regular Human Insulin. *Diabetes Metabolism Research Review* 17(4):285-91 (July – Aug 2001).

[6] Bastyr EJ III, Huang Y, Brunelle RL, Vignati, L, Cox DJ, Kotsanos JG: Factors Associated with Nocturnal Hypoglycaemia Among Patients with Type 2 Diabetes New to Insulin Therapy: Experience with Insulin Lispro. *Diabetes, Obesity and Metabolism* 2:39-46 (2000).

[7] Raskin P, Guthrie RA, Leiter L, Riis A, Jovanovic L: Use of Insulin Aspart, a Fast-Acting Insulin Analog, as the Mealtime Insulin in the Management of Patients with Type 1 Diabetes. *Diabetes Care* 2000 23: 583-588; and Heller S, Colagiuri S, Vaaler S, Wolffenbuttel B, Koelendorf K, Friberg H, Windfeld K, Sondergaard K, Linholm A: Reduced Hypoglycemia with Insulin Aspart: A Double-Blind Randomized, Crossover Trail in Type 1 Diabetic Patients. *Diabetes* 50(Supplement 2): A137 (2001) (abstract).

[8] Bastyr EJ III, Huang Y, Brunelle RL, Vignati, L, Cox DJ, Kotsanos JG: Factors Associated with Nocturnal Hypoglycaemia Among Patients with Type 2 Diabetes New to Insulin Therapy: Experience with Insulin Ispro. *Diabetes, Obesity and Metabolism* 2:39-46 (2000).

[9] Ratner R, Hirsch E, Neifing J, Garg S, Mecca T, Wilson C: Less Hypoglycemia with Insulin Glargine in Intensive Insulin Therapy for Type 1 Diabetes. *Diabetes Care* 23:639 (2000).

[10] Yki-Jarvinen H, Dressler A, Zeimen M: Less Nocturnal Hypoglycemia and Better Post-Dinner Glucose Control with Bedtime Insulin Glargine Compared with Bedtime NHP Insulin During Insulin Combination Therapy in Type 2 Diabetes. *Diabetes Care* 23:1130-36 (2000).

insulin preparations have resulted in marked reductions in hypoglycemia incidence and prevalence even among this population.

In addition to the improvements in insulin, newer and far more rapid and sophisticated blood glucose monitoring systems – unavailable at the time of DCCT and UKPDS – facilitate successful patient monitoring of glucose status. New glucose monitoring systems can easily fit in a pocket, utilize miniscule quantities of blood, and provide accurate results in as short as five seconds. At the time of DCCT, blood glucose monitoring required volumes of blood more than ten times greater, took two minutes to obtain a value, and required either visual interpretation of estimated glucose or use of a bulky meter.

Newer developments in blood glucose monitoring include the approval and availability of two separate continuous glucose monitoring devices. The Minimed CGMS provides continuous glucose measurements over a three-day period of time. The Cygnus Glucowatch is worn on the wrist like a watch and provides continuous monitoring for a twelve-hour period. With these systems no interruption of daily activities is required for glucose determinations. These systems also include intrinsic alarms for hypoglycemia but, even more interestingly, will alarm for rapidly falling glucose even before hypoglycemia is reached.

Insulin delivery systems have also improved. During the last five years, technology has advanced to the point where insulin can be delivered without syringes and refrigerated insulin, as previously required. Insulin is now widely available in pens that fit in a shirt pocket, so that the patient can simply set the dosage and push the button to inject the insulin. Not only is this system more convenient, it virtually eliminates the errors that were common with the old system where the patient had to use a syringe to carefully draw out the correct dosage from the refrigerated vial. In addition, many patients are turning to pump therapy as an alternative to traditional injections of insulin. With insulin pump therapy, a device the size of a beeper continuously delivers a small amount of insulin via a small opening just under the skin of the abdomen. Pump therapy is personalized to an individual's own needs and adjusts for dietary changes.

In addition, patient education has improved allowing patients to better understand the warning signs of hypoglycemia and how to take action prior to any impairment. [11] Such training is an integral part of the proposed protocol.

Thus, data taking into account the important medical advances since the time when data was gathered for the DCCT and UKPDS demonstrate the fallacy of using the initial results from these studies to justify continuing a blanket prohibition of commercial drivers who use insulin. Moreover, the subjects of these studies were drawn from the general population of people with diabetes; they did not have to pass the strict assessment, driving, and medical monitoring requirements that would be imposed on commercial drivers under the proposed program.

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[11] Clement S: Diabetes Self-Management Education. *Diabetes Care* 18:1204-13 (1995).

Similar problems are attendant in using the Clarke study to oppose lifting the blanket ban on commercial drivers who use insulin. Use of this study, as a gauge for whether or not there should be an exemption program for commercial operators, particularly one that has a strictly defined protocol with accountability mechanisms, is misleading at best.

Proponents of using the Clarke study to deny individual evaluation to drivers who use insulin fail to consider that:

- None of the participants in the Clarke study were given a thorough medical screening by an endocrinologist who certified that the applicant both had been educated in diabetes management and had the ability and demonstrated willingness to properly monitor and manage his or her diabetes, as would be participants in the proposed exemption program.

- None of the participants in the Clarke study had to follow a protocol to regularly monitor their blood glucose while operating a vehicle, as in the proposed exemption program.

- None of the participants in the Clarke study had to submit to long-term accountability measures, including ongoing education in diabetes management and hypoglycemia awareness, as in the proposed exemption program.

- None of the participants in the Clarke study were professional drivers, as would be every participant the proposed exemption program.

In sum, using the Clarke study to corroborate a position against the proposed exemption program is fallacious because it extrapolates a conclusion for one population (medically-screened commercial drivers with insulin-treated diabetes subject to operational guidelines and accountability measures) from the actions of a very different population (the general public with type 1 diabetes).

The argument that Clarke's driving simulator study is applicable is also specious because of the conditions under which data was obtained. Individuals enrolled in the study were quite aware that they were at no personal risk for continuing to drive under artificial conditions of hypoglycemia. None of those citing this study can demonstrate translation of this laboratory observation to real life.

In fact, the Clarke study itself cautions against the type of conclusions that were reached by those opposing individual assessment of commercial drivers with insulin-treated diabetes:

> These data should not be construed to mean that individuals with type 1 diabetes should not be permitted to drive or that their privilege to drive should be restricted. Indeed, the frequency of motor vehicle crashes is not known to be higher among drivers with type 1 diabetes.

The study goes on to suggest that drivers should measure their blood glucose level and raise potentially low levels prior to driving, should always carry rapid-acting glucose with them, and should obtain diabetes management education – all integral parts of the protocol proposed by FMCSA.

FMCSA Study Provides Key Data

While those opposing lifting the blanket ban are left to base their position on outdated or inapplicable data, the data from *A Study of the Risk Associated with the Operation of Commercial Motor Vehicles by Drivers with Insulin-Treated Diabetes* Mellitus (Federal Motor Carrier Safety Administration 2001) (hereafter, "FMCSA Study") looked at the applicable population, current drivers with insulin-treated diabetes, doing the applicable task, commercial driving. [12] Using sound principals of statistical analysis the results found no statistical difference in accident rate among drivers with diabetes as compared to the general population. Assessing all available data, the FMCSA Study found "there was no significant difference in the accident rates for ITDM drivers and the comparisons." The study goes on to note: "A more direct comparison to the [General Estimates System][13] shows that the ITDM group has an accident rate lower than the national rate."

The bottom line is clear:

> The variety of evidence in this study reveals a compelling picture. Almost without exception, all results point to the driving safety of CMV operators with ITDM.

State Experience and Other Waiver Programs Should Not Be Dismissed

Significantly, most of those who oppose ending the blanket ban in interstate commerce do not oppose allowing drivers with insulin-treated diabetes to operate in intrastate commerce. This admission follows from the fact that they are unable to cite any adverse state experiences with intrastate waiver programs for drivers with insulin-treated diabetes. Rather, those opposing an individual assessment of drivers with insulin-treated diabetes in interstate commerce are forced to argue that this positive experience in states across the country is irrelevant.

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[12] The study population contained drivers who were driving commercial vehicles in interstate commerce pursuant to the grandfather provision from the prior Federal Highway Administration waiver program as well as drivers working in intrastate commerce pursuant to state waiver programs. It bears noting that because the proposed FMCSA protocol contains more rigorous screening, driving, and monitoring mechanisms than the study population, those driving pursuant to the proposed protocol would constitute an even safer group of drivers.

[13] The General Estimates System is operated by the National Highway Traffic Safety Administration and is a survey of police accident reports.

The Association strongly disagrees with those who dismiss the experience of intrastate operators as irrelevant to interstate commercial operations. Distances traveled within Oregon, for example, can match or exceed distances traveled in interstate commercial transport. Road mileage sometimes exceeds 500 miles, a distance which is about the same as a trip from Baltimore, Maryland to Detroit, Michigan, which includes travel in five states. Oregon reported that their commercial drivers with insulin-treated diabetes are safer than commercial drivers as a whole. The preventable accident rate per million miles traveled was 0.59 for commercial drivers with insulin-treated diabetes as opposed to 0.75 for all commercial drivers. In fact, many other large states also license qualified commercial drivers with insulin-treated diabetes, but none of these states report problems with commercial drivers with insulin-treated diabetes.[14]

Cynical Views of People with Diabetes

The experience of the states, combined with the federal waiver programs in both commercial motor vehicles and aviation, demonstrates that fears about people with insulin-treated diabetes are rooted in misconceptions and outdated medical science. The Association has made it a priority to fight misinformation about diabetes and discriminatory views of people with diabetes, and, as such, is concerned about the cynical generalizations about people with diabetes found in several comments in the public docket.

The negative assertions regarding insulin-treated commercial drivers are wholly based on conjecture. According to these few comments, people with insulin-treated diabetes who are, or would be, commercial drivers:

- Cannot comply with the "rigors…and inherent danger of interstate driving."
- Are unable to adjust their food and insulin intake to account for unexpected exertion.
- Lack the ability to "determine which foods are appropriate for their dietary needs, or accurate serving amounts."
- "…will do their best to hide any [hypoglycemic] episodes."

[14] The current system also perpetuates geographic discrimination by prohibiting drivers in many parts of the East Coast from doing even short haul driving which, because of the size of states and the proximity of major cities to nearby states, often encompasses travel through several jurisdictions. For example, a half-hour trip in the Metropolitan Washington, DC area can include travel in three jurisdictions.

- Will "choose to erase hypoglycemic blood sugar measurements if they feel their employment would be threatened by [the records from their blood glucose monitor]."[15]

- "…with low blood sugar would often decide to drive anyway because of job demands."

- Would actually attempt to check their blood glucose levels while driving a commercial vehicle as opposed to pulling over at a rest stop and doing this procedure – which takes less than a minute to perform.

These generalizations assume the worst about people with insulin-treated diabetes.[16] They assume drivers with diabetes have no incentive to maintain safety for themselves and for others on the road. Such remarks also fail to take into account the explosion of advances in diabetes self-management techniques and tools over the last 15 years. The fact is that there are many people with insulin-treated diabetes who are more than capable of handling the responsibilities of commercial driving and other physically demanding occupations. For many people with insulin-treated diabetes, the only barriers they face on the job are those imposed by people and organizations that base their actions on stereotypes and misconceptions about diabetes management today.

Exemption Program Provides Limited Protections

The Association believes the change from a blanket ban to an individual assessment should take the form a change in the driver qualification standards themselves, rather than through an exemption program. This is consistent with the legislative mandate by Congress on this issue. It also is warranted by the data in the FMCSA's Report to Congress on this issue, and is necessary for consistency with our Nation's civil rights laws. The proposed protocol would have a dramatic impact both on potential commercial drivers and on thousands of people in professions beyond the commercial motor vehicle industry, and the Association strongly urges the Department of Transportation to change the driver qualification standards themselves.

Conclusion

[15] Contrary to such assertions, standard blood glucose meters do not erase information, even if actions such as removing the battery are taken. Moreover, the proposed FMCSA protocol *requires* drivers to submit this information to their physicians on a quarterly basis.

[16] Similarly, one comment assumes the worst about employers arguing that "It seems unlikely that . . . employers would let [insulin-treated drivers] take all the time necessary to check, recheck, and take corrective measures." The Americans with Disabilities Act would require such easily accomplished accommodations. Moreover, the Association believes most employers would be quite willing to accommodate their employees' needs. In fact, one comment submitted to the docket was from a company that was willing to pay a fine rather than terminate one of its drivers with insulin-treated diabetes because the company knew how valuable and capable the driver was.

With the major exceptions of the three-year requirement and the decision to pursue an exemption program rather than a change in the regulation, the Association supports the proposed protocol and commends the Department of Transportation for their efforts on this issue. The Association urges the Department to make modifications to ensure that the proposed protocol is based on current medical practice and structured in a manner that will allow people to take advantage of it.

The Association reiterates its desire to work with FMCSA and provide any assistance necessary to support a practicable and workable protocol to end discrimination against individuals with insulin-treated diabetes.

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