

Response of
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July 27, 1999

Mr. John Sheridan
Conwall Inc.

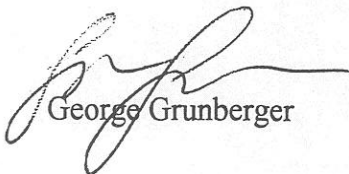
Re: *FHA Medical Panel for Diabetes*

Dear Mr. Sheridan:

It gives me pleasure to jot down a few initial bullets for the upcoming medical panel discussion. A few comments first: I have spent most of the last month on the road (most of it at the bedside of my father in a New Jersey hospice), reading in detail all the enclosed materials but had not prepared anything in writing. Thus, this represents my effort, while I am on my family vacation, to send you something by the end of July. Second, the report "A Preliminary Study of the Risk " even though undated, represents in my opinion an excellent summation of the existing literature on the subject. Therefore, I don't think that my additional literature review would be worth the additional expense to the Agency. Third, as you know from my secretary, I have received a couple of documents with odd-numbered pages only. Even though it was explained to her that apparently these documents were complete, two of these were FedEx'd to me on four separate occasions. Overall, your estimate of my effort in this initial phase is within the ballpark figure.

I am looking forward to our deliberations. Please keep me posted about any information you might need from me in the upcoming weeks. Thank you for your consideration.

Sincerely yours,


George Grunberger

Guidelines for the Diabetes Panel

1. The Federal Diabetes Standard should be amended to allow certain individuals with ITDM to operate CMV's in interstate commerce. I would also include those patients with type 2 diabetes mellitus who are taking hypoglycemic agents (such as sulfonylureas and repaglinide) because the issue is about **hypoglycemia and not about insulin**. Assuming that the previous judgements of the panels allowing the FAA as well as the individual States (for intrastate truck commerce) were rational, there exists an ample experience about the safety or danger of these individuals on the road (or in the air). Both the "Preliminary Report.. ." and the American Diabetes Association (ADA) report cite most of the available literature on the subject.
2. In case a decision is made not to amend the Federal Standard, there could be an exemption program created (as was done before both at the State and Federal levels). I am not a lawyer and thus the practical point of distinguishing between options 1. and 2. escapes me (since certain operators with diabetes using hypoglycemic agents would be able to operate CMV's in interstate commerce under both options).
3. The medical screening program would be, almost by definition, controversial and can not be established beyond reasonable level of certainty (perhaps in analogy to judge's instructions for jury deliberations). Practice of medicine is art (not science) and evolving at that. Our knowledge of pathophysiology, epidemiology, genetics, and therapy of diabetes mellitus and its complications has grown exponentially over the past decade. Translation of the newly-acquired knowledge from research to practice (and into legal regulations) has been painfully slow. However, even with the new knowledge there is no perfectly specific and sensitive test which would predict which individuals (or drivers) are prone *a priori* to severe hypoglycemic reactions, coupled with hypoglycemia unawareness during which that individual would lose judgement and be prone to get involved in an accident. That needs to be kept in mind when some individuals would try to get dogmatic about any possible regulations.
 - Clearly, one reason for the controversy is that we know now that microvascular complications of diabetes (such as retinopathy, neuropathy, and nephropathy) are preventable by meticulous glycemetic control. Furthermore, the most serious complications of diabetes, the macrovascular ones (myocardial infarctions, strokes) are likely to be also positively impacted by excellent glycemetic control. On the other hand, evidence exists, at least for individuals with type 1 diabetes (viz. results of the DCCT with its three-fold increase of severe hypoglycemic reactions in the intensively controlled group) that more aggressive control of glycemia might bring about an increased incidence of severe hypoglycemic reactions. Current epidemiological data indicate that incidence of type 2 diabetes in the U.S. is about 97% of all cases of diabetes (prevalence about 95%); even among insulin-treated individuals most will have type 2 diabetes. That type is less likely to be associated with severe hypoglycemia and hypoglycemia unawareness (the data from the UKPDS about practically non-existence of severe hypoglycemia can be cited).
 - Hypoglycemia (whether caused by insulin or oral hypoglycemic agents) is relevant in this situation (associated with traffic accidents) only when it is unanticipated and not associated with any signs or symptoms which the operator associates with the condition. In any other situation, he/she can pull

off the road and treat the condition and not pose a danger to himself/herself or others on the road.

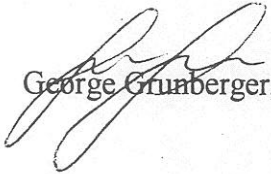
- As stated in the numerous literature reviews distributed in connection with these deliberations, it is the history of severe hypoglycemic episodes and/or hypoglycemic unawareness, which are the best predictors of future problems. If that history can be established (one can argue how many such episodes are significant but hypoglycemia unawareness could be an absolute contraindication), then that driver should not be considered for an exemption. It is the cases where this history can not be established where the medical judgement is important.
- Diabetes education (and demonstration, both theoretical and practical, of the necessary skills required to diagnose and treat hypoglycemia) would need to be an essential element of the Program (as it is for every patient with diabetes) and be required on annual basis.
- Glycated hemoglobin and a patient's log of capillary blood glucose monitoring are two essential pieces of data needed to demonstrate level of diabetes control. If two consecutive glycated hemoglobin tests (half-life of hemoglobin is about 60 days) are not significantly different and no severe hypoglycemic episodes can be documented by history or capillary blood glucose records, one could consider such glyceic control "stable".
- Duration of insulin (or other hypoglycemic agent therapy) prior to consideration of such driver is not as important as the need to establish "stability" as defined above; *i.e.* 2-3 months at a minimum.
- As important as the glyceic control is, it is also mandatory that any individual with diabetes is enrolled in an overall program aimed at prevention/stabilization/amelioration of the cardiovascular risk factors (treatment with aspirin control of dyslipidemia, hypertension, obesity, smoking cessation, increased physical activity, etc.)
- It should be a given that only those individuals who have been previously judged to be qualified CMV operators (definitions used by the States previously could be used as guidelines), should be considered for any exemption program.
- Only medical specialists experienced in dealing with patients with diabetes on regular basis (including the practical aspects of the patients' lifestyles) should be involved in assessment of these drivers. Frequency of those determinations could be argued, but an annual determination (that does not mean a separate physical examination which, in most cases, would be a waste of time) of the continued suitability for the Program might be reasonable. Clearly, this determination would be in addition to meeting the medical standards of care (published by the American Diabetes Association in the first supplement of *the journal Diabetes Care* in January of each year).
- This Program will need to be updated (perhaps annually by an expert panel to take into account medical advances in predicting, diagnosing, monitoring, and treating hypoglycemia among the qualified drivers.
- The screening protocol will have to take into account diabetic complications (diagnosing, preventing, stabilizing, and treating) other than severe

hypoglycemia (again, this is spelled out in the medical standards of care of the ADA). In addition, these drivers need to be screened for presence of relevant non-diabetic conditions as any one else would (visual impairment, seizures, mental capacity, cardiac condition, etc.).

- Drivers meeting the criteria for an exemption program need not be required to have some one else present while driving (clearly, presence of another trained individual in the CMV would provide an additional safety feature but it is difficult to foresee all the logistic implication and practical aspects of such a provision; monitoring of compliance with such a regulation, for example, might present a nightmare).
4. As discussed above, the most controversial part of any Program will be balancing the need for meticulous glycemic control (aimed at preventing diabetic complications) and the possibility, mainly among drivers with type 1 diabetes mellitus, of severe hypoglycemic reaction.
- At this point, no useful threshold for glycemic control has been established. The best compromise is embodied in the current version of the ADA standards which state the goal of HgbA_{1c}, <7% (even though the reference range in most laboratories is <6% and preprandial blood glucose levels between 80 and 120 mg/dl (even though these are typically no higher than in the 90's among healthy individuals).
 - The acceptable glucose range might be the one referred to above (So-120 mg/dl preprandially and not higher than 160-180 mg/dl within 2 hours postprandially, and between 100 and 140 mg/dl at bedtime), detailed in the ADA guidelines.
 - Quarterly evaluations for adequacy of diabetes control (by personnel experienced in dealing with diabetes) among asymptomatic patients would be consistent with standards of medical care.
 - Blood glucose self-monitoring has to be a part of the Program (as it should be for every person with diabetes). The patient's diabetes specialist should be the one determining frequency of the monitoring. However, each driver should keep a record of daily glycemic monitoring assessing glucose levels at the times when one expects the peak of the hypoglycemic agent's action and at 2 hours after the most substantial meal at the minimum.
 - Assessments should be consistent with the ADA standards of medical care; these would include reports of glyated hemoglobin levels, episodes of hypoglycemia, reports (by specialists) of examinations for retinopathy as well as evidence of examinations for albuminuria and neuropathy.
 - All drivers would need to monitor their glucose levels by a device which has memory built into it which would be downloaded into a computer program able to analyze the data.
 - As stated already above, all drivers would need to be continually updated (at least annually) on the state-of-the-art in hypoglycemia awareness and its treatment. This continued education aspect would be a mandatory component of any Program.

I trust that these initial thoughts will prove to be helpful in assembling the Medical Panel's opinions prior to the meeting on September 1st. Please feel free to contact me for any clarifications.

Sincerely,



George Grunberger, M.D.

Response of
Edward S. Horton, M.D.



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Edward S. Horton, M.D.
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August 16, 1999

John Sheridan
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Dear John:

I have now had a chance to review all of the material you sent to me regarding the Federal Highway Administration's medical panel on insulin treated diabetes mellitus and the operation of commercial motor vehicles. I will outline my response to your questions in this letter in the hope that it will provide a basis for developing the discussion when we meet in Washington on September 1.

First, I do not yet have a strong opinion as to whether the federal diabetes standard should be amended to allow certain individuals with TDM to operate CMVs in interstate commerce or whether this should be accomplished through an exemption program. I would need to discuss further the pros and cons of these two approaches and what the implications of each would be. I do believe that individuals with ITDM should be allowed to operate CMVs in interstate commerce if, on a case by case basis, they demonstrate that they are able to maintain their blood glucose levels within an acceptable range to avoid either Symptomatic hypoglycemia or hyperglycemia and that they do not have any significant medical disability related to long term diabetic complications such as significant impairment of vision or neurological deficits that may impair their ability to operate a CMV safely. Also, they should meet other health requirements for CMV operators. Particular attention should be paid to cardiovascular disease since people with diabetes are at increased risk for myocardial infarction. They are also at increased risk for cerebral vascular disease and peripheral vascular disease.

If some individuals are permitted to operate CMVs, they would have to undergo a medical screening protocol which would include evaluation of the long term medical risks associated with diabetes such as cardiovascular, neurological, ophthalmological and renal abnormalities. The immediate risks associated with hypoglycemia would also need to be evaluated and the frequency of such episodes documented and evaluated in terms of both severity and frequency. In my opinion, severe hypoglycemic reactions should not occur to drivers more frequently than once a year and perhaps not more frequently than twice in five

years. Newly diagnosed insulin treated patients should be on insulin for at least three months before they are evaluated and preferably should have demonstrated stable blood glucose control for at least six months before being allowed to drive. They should be evaluated by a specialist in diabetes prior to authorization to drive and periodically for evaluation of their level of diabetic control, education and training in self-management and for the presence or absence of long term complications of diabetes. If an individual is found to be well controlled, free of disabling complications and has good knowledge about his or her diabetes and its management, then the individual should be allowed to drive as would any other driver. I do not believe that the diabetic driver should be required to operate a CMV with another driver. I do believe that one should establish a protocol for checking blood glucose levels and responding appropriately if blood glucose is outside of the range of 100 to 400 mg/dl.

With regard to a protocol for effective monitoring, the key thing is to make sure that drivers have a very low risk of symptomatic hypoglycemia while driving and that they do not run excessively elevated blood glucose levels which are associated with blurred vision, decreased alertness and possibly decreased mental function. In the experience from the DCCT, the lower the hemoglobin A1C, the greater the risk for developing severe hypoglycemic reaction. However, there is considerable individual variation and some people are able to obtain near normal blood glucose levels without serious hypoglycemic reactions whereas others may have reactions despite the fact that their average blood glucose level is significantly above normal. In general, I believe that individuals should try to maintain their hemoglobin A1C level in the 6 to 7% range, although occasionally it may be necessary to allow blood glucose to run somewhat higher with a hemoglobin A1C in the 7 to 8% range. This has to be evaluated on an individual basis, however.

As I mentioned above, I believe an acceptable blood range while driving would be 100 to 400 mg/dl. However, the goals for blood glucose control should be to have the fasting blood glucose level 80 to 120 mg/dl, the pre-meal glucose less than 140 mg/dl and the bedtime glucose less than 160 mg/dl. Obviously, when one is operating a motor vehicle one would like a certain cushion for safety and I would generally recommend that blood glucose be at least 100 mg/dl while operating a CMV. One does not generally develop symptoms of excessively high blood glucose until you get up into the 350 to 400 mg/dl range. I believe that brief periods in this range are not deleterious. However, sustained elevation of blood glucose above 400 mg/dl may be associated with impaired alertness and mental function and with blurred vision.

In general, I believe that insulin treated diabetic patients should have medical evaluations three to four times yearly. It would not be unreasonable to expect CMV operators to have a medical evaluation every three months. This should

include a hemoglobin A1C determination as well as a review of episodes of hypoglycemia or hyperglycemia and any symptoms related to diabetes or its complications. I believe that the driver should have a detailed medical evaluation annually. This should include an examination of the eyes by a qualified ophthalmologist or optometrist as well as evaluation of renal function and cardiovascular disease and a neurologic examination.

I believe that drivers should monitor their blood glucose levels on a regular basis before and during driving. They could use any of the current blood glucose monitoring devices although I do believe they should use a device that has a *memory* and a capability for data downloading for review by the healthcare team. As you know, there are many new devices under development including some that are minimally invasive and some that are capable of providing readings on a very frequent basis. When these have been developed to the point of general use, they should be a great boon to CMV drivers and would provide an excellent way of monitoring glycemic control during driving. Using the current systems which involve obtaining a drop of blood by finger stick, I believe that glucose levels should be checked before starting to drive and then every 2 to 4 hours while driving to be sure that blood glucose is in an acceptable range.

Drivers should be required to receive continuing education in self blood glucose and self-management of their diabetes. For those who have hypoglycemia unawareness, I believe they should not be allowed to operate a CMV because of the increased risk of developing severe hypoglycemic reactions. All drivers should be taught about the signs and symptoms of hypoglycemia and be able to respond appropriately with self-glucose monitoring and ingestion of glucose or appropriate foods.

In order to back up and expand upon the above opinions I would like to review the following points for discussion.

1) The major potential deleterious complications of a person with diabetes being treated with insulin are:

a) Severe hypoglycemia.

b) Severe hyperglycemia.

c) The long term complications of diabetes including damage to the eyes, kidneys, nervous system and the large blood vessels leading to premature atherosclerosis.

The eye lesions can vary and include things such as the premature development of **cataracts, diabetic retinopathy, hemorrhages, neovascularization and**

macular edema which may lead to loss of vision. In the kidneys, progressive renal insufficiency leading to end stage renal disease and the need for chronic dialysis and/or kidney transplantation may occur. In the nervous system, a variety of neurological disorders may occur, The most common is a sensory neuropathy, which usually involves the lower extremities and is associated with loss of sensation in the feet but may on occasion, extend to higher levels. There is usually a loss of sensation to light touch and pin prick. In more severe cases there is loss of vibration sense, cold perception and position sense. Another common form of neuropathy is motor neuropathy involving relatively large nerves. This may result in weakness or paralysis of specific muscle groups and may be relatively rapid in onset and may recover or remain permanent. The atherosclerotic lesions associated with diabetes include increased risk for myocardial infarction, peripheral vascular disease and stroke. It will be extremely important to examine all prospective CMV drivers for presence or absence of all of these complications and to determine whether, if any are present, they would significantly impair the individual's ability to drive safely.

2) There have been major advances in the development of new treatment technologies that make it possible for insulin treated diabetic patients to perform tasks safely. These include the development of new insulins. For example, the new rapid acting insulin, Humalog, developed by Lilly, allows one to take insulin immediately prior to eating. Because of its short duration of action it wears off after the meal is absorbed and digested, thus reducing the risk of hypoglycemic reaction prior to the next meal. There are also new longer acting insulins being developed which are being designed to provide more stable basal therapy. Using the combination of short acting and longer acting insulins, one can use a "basal-bolus" treatment regimen with multiple daily injections that will provide a much more stable glucose regulation for most patients. In addition, the modern insulin pumps are much better than earlier models and also allow for a more stable blood glucose regulation using either regular insulin or Humalog insulin (which is not FDA approved yet) to achieve stable glucose control.

In the long term, I believe that islet cell transplantation will be developed that will also allow stable regulation of blood glucose in insulin requiring patients. However, this is still a ways off.

Great advances have been made in self-glucose monitoring. Currently, there are a number of non-invasive or minimally invasive glucose monitoring systems being developed that allow for frequent testing of blood glucose without major discomfort for patients. Self-blood glucose monitoring combined with appropriate training in self management will undoubtedly decrease the risk of severe hypo- or hyperglycemic reactions

3) There are a number of factors that should be considered in screening ITDM individuals for the potential of safely operating a CMV.

a) A detailed history of hypoglycemic reactions or lack thereof. Reactions should be graded according to the DCCT criteria and severe reactions particularly noted.

b) A history of persistent, symptomatic hyperglycemia (glucose >400 mg/dl) or diabetic ketoacidosis

c) Screening for hypoglycemia unawareness. Does the individual get warning signs or symptoms of impending hypoglycemia?

d) Screening for long term complications of diabetes including examinations of the eyes, kidneys, nervous system and cardiovascular system.

4) Factors that could be used for monitoring ITDM individuals who are allowed to operate a CMV.

a) A periodic examination by a qualified physician, preferably an endocrinologist. This should occur 4 times a year, ideally every 3 months, and should include a detailed history of any episodes of hypoglycemia, severe or prolonged hyperglycemia or DKA. The individual's glucose monitoring data should be reviewed and appropriate adjustments made to the treatment program. A glucose meter with memory and downloading capacity should be used for this purpose. Some of the more advanced meter systems have the capability to transmit data by modem and this could be done and reviewed as frequently as every two to four weeks if desired.

b) Adequate patient education and understanding of self management should be documented at least annually.

c) Hemoglobin A1C should be measured quarterly.

d) A complete physical exam should be done annually. There should be an annual eye exam done by a trained ophthalmologist or optometrist. Renal function should be assessed annually.

5) The following is a suggested protocol for monitoring and maintaining appropriate blood glucose levels while driving:

a) Check glucose before starting to drive and take corrective action if necessary. If glucose is <100 mg/dl take glucose or food and recheck in 30 minutes. Do not drive if glucose is <100 mg/dl. Repeat this process until glucose is >100 mg/dl.

b) While driving check glucose every 2 to 4 hours and take appropriate action to maintain it in the range of 100 to 400 mg/dl.

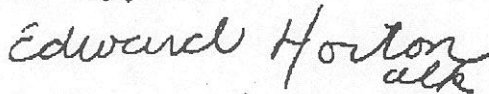
c) Have food available at all times while driving. If glucose is < 100 mg/dl stop driving and eat. Recheck in 30 min and repeat procedure until glucose is > 100 mg/dl.

d) If glucose is > 400 mg/dl stop driving until glucose returns to the 100-400 mg/dl range. If more than 2 hours after last insulin injection and eating, take additional insulin. Recheck blood glucose in 30 minutes. Don't resume driving until glucose is < 400 mg/dl.

e) Using this protocol it should be possible to avoid hypoglycemia or severe hyperglycemia while operating a CMV and thus make it safe for ITDM individuals to do so.

I hope this will give you enough information to focus the discussion and topics for our meeting. Please let me know if you need anything more at this time.

Sincerely yours,

Handwritten signature of Edward Horton, MD, in cursive script. The signature includes the name "Edward Horton" and a small "alk" below it.

Edward S. Horton, MD
VP & Director of Clinical Research
Joslin Diabetes Center
Professor of Medicine
Harvard Medical School

cmv

Reponse of
Christopher D. Saudek, M.D.

7/27/99

Written Preparatory Comments of Christopher D. Saudek, M.D.

Question 1.

Yes, the Federal Diabetes Standard should be amended to allow certain individuals with ITDM to operate CMVs in interstate commerce. To answer otherwise, the data must convincingly show that people with ITDM, selected as discussed below, pose significantly increased risk to the safety of the driving public and to themselves as part of that driving public. If a significant safety risk is not posed, it is unfair public policy to deprive them of this livelihood.

I maintain that there are certain issues that sometimes enter the discussion which should be discarded at the outset. Among these are the following:

- Since hyperglycemia (*high* blood glucose) increases the risk of long term complications of diabetes, allowing it or encouraging it in ITDM individuals puts them at risk to themselves.

This is a non-issue because people with diabetes like anyone else make their own health decisions. Many, many people with diabetes allow their blood glucose to be higher than would be ideal. This is their personal decision, not an issue that can or should be affected by a Federal Standard.

The only time when hyperglycemia becomes an issue is when it rises to a level that causes acute changes in behavior and thus driving safety. That level is probably in the range of 300-350 mg/dl, when drowsiness occurs and the need to urinate frequently.

- Diabetes is associated with an increased *risk* of long term complications such as eye involvement and cardiovascular disease that may impair driving.

This is also a non-issue, since any number of other conditions (family history, smoking, high cholesterol, cataracts, etc.) are also associated with increased risk.. Existing medical standards exist, screening out people with unacceptable medical conditions. People with diabetes can no more be excluded for increased risk than can people who smoke.

- Self-care and reporting requirements that might be imposed on people with diabetes are unrealistic.

People with diabetes, particularly those with ITDM, routinely follow a series of self care behaviors that the general public regard as being loathsome or impossible. Self-monitoring of blood glucose (SMBG), for example, is a technique that a great many people with diabetes find makes them feel better, not worse. Recognizing that they would rather not have diabetes at all, it does not follow that regular SMBG, or regular meals, or record keeping, are unrealistic expectations.

- Sometimes, hypoglycemia is lumped together as though it were one syndrome, whereas in fact all hypoglycemia is not equal or equally relevant. The DCCT established definitions that are important and applicable: *mild hypoglycemia is symptomatic but self-treated; severe hypoglycemia requires a separate person to intervene*. These definitions should be accepted, with the realization that mild hypoglycemia is very much more common and less relevant to safe driving. It is more in the category of an acute stressor (like being caught in aggravating traffic). Severe hypoglycemia is the danger in people with diabetes driving.

- The distinction between intrastate and interstate, while central to the jurisdiction of the FHWA and thus this group's discussion, should not be taken too seriously. The experience of drivers permitted to drive CMVs on intrastate routes is very relevant. If they drive many hours in the day, there is no intrinsic reason why their experience in driving with ITDM should be very different just because they drive within one state.

The most relevant question regarding the Federal Standard, then, is whether the risk of acute, severe hypoglycemia will impair their driving ability to the extent of increasing risk to the public (including themselves). *Prevention* of severe hypoglycemia is essential; treatment of severe hyperglycemia is sometimes an issue, but less serious.

Review of the literature on the potential risk of people with ITDM driving is, overall, reassuring. Best exemplified by the reviews by LaPorte's group, it requires some clarification, in my view, if it is to be interpreted correctly. The methodology in general draws on population data for people with ITDM, assuming no screening for people applying to drive CMVs. Applying the sort of screens to be proposed will reduce the risk of MVAs. Severe hypoglycemia does not occur in a random distribution of people with ITDM; there are predictors. In the DCCT, the most well documented experience of extremely tight blood glucose control, 55% of severe reactions occurred during sleep (which is not during driving) (Am J. Med. 90:450-9, 1991). 77% occurred in intensively treated subjects, in which the treatment goal was to keep blood glucose as low as possible. This context must be kept in mind, since the DCCT Intensive Care group is treated with a very different goal than would apply when the object is to avoid severe hypoglycemia.

Another protection against hypoglycemia is the conscious, enforced ability to ingest calories. In the DCCT, missed meals cause 23% of severe insulin reactions. Whether it is by regular meal intake or portable snacks/glucose tablets, people with ITDM can easily and effectively reduce their risk of hypoglycemia by ingesting food.

Applying regular SMBG before and during driving will further reduce risk. One way to know if you are going too fast or too slow is by feel (looking out the window); a better way is to look at the speedometer. By self-monitoring, people get a regular, reliable check on their blood glucose that quantitatively confirms how they feel.

The above points emphasize that the risk of MVAs in ITDM can be effectively minimized by basic screening of drivers and enforced self-care requirements. The issue is then whether risk can be eliminated, and risk can never be eliminated. But it is incumbent on people arguing against a Federal Standard permitting people with ITDM to drive, to prove that the risk from such people cannot be minimized to an acceptable level.

Question 2.

From my understanding of the question, the Federal Diabetes Standard should be amended rather than establishing an exemption program. This conclusion seems to be all the more important given the interpretation of the recent Supreme Court decision that allows employers to apply federal standards even against drivers who obtain a waiver. To me, this focuses on the importance of having the federal standard correct and fair, rather than on providing a waiver program.

Question 3.

(i) As mentioned above, the *risk* of long term complications is not a consideration. The issue is whether such complications exist and, if so, do they keep a given individual from driving safely based on other, non-diabetes, criteria.

A medical evaluation form to be completed initially and periodically (such as annually) could screen out people with complications significant enough to pose a risk. Those specifically related to diabetes would include documentation of peripheral nerve function and retinal status.

Neuropathy only comes into play if it is severe enough to impair proper foot control- a "monofilament" test to assess grossly abnormal foot sensation.

Retinopathy would not be a factor unless there is visual impairment; background retinopathy does not impair the ability to drive. But since advanced background or proliferative retinopathy, even without impairing the ability to drive, could cause an acute bleed that does impair vision in that eye, an extra measure of safety could be imposed by requiring an ophthalmologic examination annually and eliminating those deemed to have unstable, high risk retinopathy.

Cardiac and cerebrovascular disease are not specific to diabetes. They should be assessed in people with ITDM just as they are for people whose disease was "caused" by family history, smoking, cholesterol level or any other risk factor. No special consideration need be taken for people with ITDM.

Likewise, renal disease is not specific to diabetes and is, additionally, asymptomatic until late stage, at which time it is a general medical condition that may well preclude safe driving. Certainly, the early sign of diabetic renal disease—proteinuria—is not a risk to safe driving, and would ordinarily precede symptoms by 10–15 years.

(ii) The immediate risk posed by hypoglycemia with impaired cognitive function is the precise, relevant issue at hand in establishing a safe Federal Standard. It is unnecessarily alarming by pointing to unconsciousness, seizure, or the very rare death from hypoglycemia. The Panel should be at the job of reducing the risk of hypoglycemia-induced impaired cognitive function to a level that is small and within the risk of other unforeseen adverse events.

(iii) The history of recurrent severe hypoglycemia is a good predictor of risk for subsequent severe hypoglycemia. The DCCT's report on the epidemiology of hypoglycemia provides the best data on this score. The average number of severe insulin reactions per person who had one was 3.3, over an average of 21 months. This indicates that in a two-year window of time, most people who will have severe reactions will have more than one.

The exact numbers put on acceptable/unacceptable medical history will be debated. My impression would be to stick with the FAA rule, which I read as excluding people with a history two or more episodes of severe hypoglycemia within five years, and no such episodes within one year.

There are two other gauges of hypoglycemia: a) self-treated symptoms of mild hypoglycemia. These are difficult to count reliably and therefore had to rely on, but if they occur more than weekly the person probably should not drive. b) the number of hypoglycemic readings on a meter when down-loaded. A figure that might exclude drivers might be agreed to until they improve their avoidance of hypoglycemia.

(iv) Education: The more extensive programs of Hypoglycemia Awareness Training really apply to people who have a poor history of severe hypoglycemia, and would be screened out of driving much earlier. However, a simple questionnaire might be required in which a potential driver is required to demonstrate that he/she knows the basic causes, symptoms, and avoidance strategies. Sometimes, people taking insulin have simply never been given this basic instruction.

(v) “Stable control” is subject so fraught with uncertainty as to be useless. The period of time should be set during which there has been no severe hypoglycemia. As suggested, a year without such episode, and five years without more than one episode, would be a very rigorous standard to apply.

(vi) The issue here is whether a person is more likely to have severe hypoglycemia because he/she is unfamiliar with taking insulin. The important problem is that it would be entirely unreasonable to require a driver controlled on oral agents to stop

driving, say for a year, when starting insulin, just to assure that he/she is safe. Perhaps a regulation would be reasonable that said the driver should not drive for at least one month after starting insulin, and then apply, showing they meet the standards.

(vii) "The efficacy of an individual's efforts to control the disease", like "stable control", is too vague to be meaningful. The only public interest is in avoiding dangerous driving, and that relates entirely to the issues discussed above.

(viii) "The time frame for having experience in operating a CMV while receiving insulin treatment" again has the potential mentioned in answer to (vi) to be a Catch 22 in which they cannot drive until they have already driven. It is an unacceptable criterion.

(ix) The need for specialist evaluation is in my view over emphasized, with the possible exception of an ophthalmologist. A few basic physical findings and the basic evaluation of history of hypoglycemia, are all that is necessary. These can be highlighted in a standard medical history form.

(x) The data downloading capability of meters is not new, but does offer the chance to verify glucose testing and its results. Greatly increased attention to hypoglycemic reactions and their prevention was stimulated by the DCCT study results. There is increasing science applied to the prevention of hypoglycemia.

It is possible that within the next, say, three years there will be a generally available wearable continuous glucose monitor that could reliably provide an alarm that signals the development of hypoglycemia. This does not mean that a Federal Standard allowing certain people with ITDM should be delayed waiting for such a monitor; but it does suggest that hypoglycemia may become even more easily and more reliably prevented within several years.

(xi) I believe that diabetes must be considered as a single medical issue, and people with diabetes as single individuals. Other medical conditions should be considered independently and on their own.

(xii) All the above discussion is directed toward minimizing the chance of severe hypoglycemia causing a MVA. If implemented, the point is that selected people with ITDM would drive safely. There is no reason to suggest, therefore, that they would need a companion any more than the average driver.

Question 4:

the question premises that qualification of people with ITDM would qualify "through exemption". As I understand it, that is not the only option; the Federal Standard could be written to allow them to drive.

(i) As mentioned at the top, the issue of whether allowing some degree of hyperglycemia is detrimental to health should be eliminated from the discussion. Even the most careful people with diabetes are hyperglycemic much of the time. They protect themselves from hypoglycemia during important work activities, driving children to school, attending important functions, etc. There is, furthermore, a considerable cushion between normal glycemia and the level of glycemia associated, at least in the DCCT, with diabetic complications.

(ii) There is no precise answer to this question, only extremes. The extreme at the low end is whatever blood glucose causes a change in mental status. Many people tolerate what seem to be alarmingly low blood glucose (e.g. 45 mg/dl) without a sign or symptom. This is not to say that blood glucose below, for example, 60 mg/dl should not be taken seriously and acted upon; but it is to say that blood glucose numbers alone cannot be used to exclude people from a CMV drivers license.

At the high end, as mentioned, the only blood glucose levels that raise legitimate concern would be when they are high enough to cause drowsiness, or significant polyuria causing the need to stop frequently to urinate. Levels above about 300-350 mg/dl could cause this, and thus should trigger a response by the driver. But, again, hitting these numbers occasionally cannot be used to prohibit people from obtaining drivers licenses.

(iii) Annual evaluations is plenty to detect long term complications that would affect driving. More frequent reviews would be necessary of blood glucose records to see that standards are maintained while driving.

(iv) This is at the hub of the discussions to be held. My recommendation would be that glucose levels be tested before driving and then the driver be required *either to eat a meal or to monitor each hour* while driving.

(v) I have emphasized above that the important thing is the medical history with regard to the occurrence of severe hypoglycemia over the previous five years. The physical examination can concentrate on serious medical conditions that would in any case disqualify people from driving, and, for diabetes, specifically on the presence or absence of severe peripheral neuropathy.

The result of the glycated hemoglobin assay is only relevant, I would say, at the very high end (e.g. >1%), indicating really very poor diabetic control and suggesting that the person is so often over the 300 range that driving is not safe.. If glycated hemoglobin is normal, the question remains unchanged: is there any history of severe hypoglycemia? The person may have stable, well controlled diabetes. If it is moderately elevated, this simply suggests that the person is seldom near hypoglycemic ranges.

(vi) Yes, blood glucose monitors that record values by time and date should be used. The reporting of these results is a matter for discussion. They could be routinely reported or audited at random.

(vii) As mentioned, drivers should be aware of hypoglycemia—symptoms, pre-disposing factors, treatment. This would require relatively simple training.

APPENDIX E

**Attendees at the Medical Panel
Meeting in Washington, DC**

September 1, 1999

List of Attendees

<u>Name</u>	<u>Title/Office/Agency</u>
Paul Brennan	Director, Office of Motor Carrier Research and Standards, Department of Transportation
Sandra Zywokarte	Program Manager, Office of Motor Carrier Research and Standards, Department of Transportation
Albert Alvarez	Office of Motor Carrier Research and Standards, Department of Transportation
Teresa Doggett	Office of Motor Carrier Research and Standards, Department of Transportation
Jack Jackson	Attorney, Disability Rights Section, Civil Rights Division, Department of Justice
Steve Butler	Attorney, Disability Rights Section, Civil Rights Division, Department of Justice
Mary Kay Mauren	Equal Employment Opportunity Commission
Linda Contnier	Presidents Task Force on Employment of Adults with Disabilities
Mike Mawby	Vice President, American Diabetes Association
Terene Arent	National Director of Legal Advocacy, American Diabetes Association
Alan DuLaney	Project Manager, Conwal Inc.
John Sheridan	Moderator