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#2704

2010 FEB 23 PM 2:43

INDEPENDENT REGULATORY REVIEW COMMISSION

February 23, 2010

RE: #18-411 (#2704)
Licensing Criteria for School Bus Drivers with Diabetes

#18-410 (#2705)
Physical and Mental Criteria, Including Vision Standards Relating to the Licensing of Drivers

VIA EMAIL - URGENT

Dear Commissioners of the Independent Regulatory Review Commission:

I am writing with great concern on behalf of the American Diabetes Association with regard to the proposed regulations. **The Association strongly requests that you REJECT the proposed regulations as currently worded at your meeting of Thursday, February 25th.**

Regulation #18-411 would inappropriately use laboratory test results to make licensing related decisions for school bus drivers. These regulations initially came to our attention in draft form in 2008, at which time the attached comment was provided. The tests that have been proposed to use for these decisions DO NOT measure the driver's safety risk, as the proposed regulation suggests. In fact our comments on the school bus driver regulations made this very clear, yet these comments were dismissed in formulating the regulations now before you. Our comment in 2008 read as follows:

> **"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."**

Further, the statement that cognitive impairment occurs for individuals with A1C at or above 9% is incorrect as a blanket statement. Diabetes is a disease that affects individuals differently, and an A1C of 9% or above does not indicate the person has experienced any cognitive impairment. For this reason, school bus drivers with diabetes should be individually assessed to determine whether they can safely operate a school bus, regardless of A1C level.

The Association predicts that the use of these criteria will prohibit some people with diabetes from driving for no valid reason (which in turn puts their employment and medical care at risk). A portion of the commentary in the regulatory analysis form also suggests that the criteria utilized in the regulation were obtained from the American Diabetes Association – this is not accurate. The regulatory commentary

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also incorrectly describes federal regulations for commercial drivers. As a cautionary note, we would add that these proposed regulations may apply to a significant percentage of school bus drivers, given the Pennsylvania Department of Health estimates over 800,000 adults in Pennsylvania have been diagnosed with diabetes.

The American Diabetes Association also has serious concerns about **Regulation #18-410** on the physical and medical criteria for licensing of drivers. Section 83.5(a)(1) indicates that individuals with hypoglycemic unawareness or symptomatic hyperglycemia will not be qualified to drive unless they have been free of such episodes for six months. A person with hypoglycemic unawareness may still be safe to drive with proper precautions, including testing blood glucose before getting behind the wheel of the car, and testing at least hourly on long drives. Further, literature shows that a two- to three-week period of scrupulous avoidance of hypoglycemia is enough to regain hypoglycemic awareness.

Symptomatic hyperglycemia is defined in the regulation as high blood glucose levels that may cause a loss of consciousness or altered state of perception. Hyperglycemia does not always result in loss of consciousness, altered perception, or cognitive impairment and a disqualification based on the current definition of symptomatic hyperglycemia will inappropriately screen out a large number of drivers whose diabetes does not pose any safety concerns.

For these reasons, the American Diabetes Association strongly requests that you reject this restrictive regulation. We attach a letter to the National Highway Traffic Safety Administration on the medical fitness of drivers with diabetes to further illustrate our perspective.

Again, the American Diabetes Association urges that the proposed regulations be rejected. The Association stands ready to work with the Pennsylvania Department of Transportation on this matter, so policies can accurately reflect diabetes care.

Sincerely,

Stephen Habbe
Advocacy Director
shabbe@diabetes.org

enc. ADA Letters of Comment, July 2008 and July 2009

cc: Sen. John C. Rafferty, Jr., Majority Chairman, Senate Committee on Transportation
Sen. J. Barry Stout, Minority Chairman, Senate Committee on Transportation
Rep. Joseph F. Markosek, Majority Chairman, House Committee on Transportation
Rep. Richard Geist, Minority Chairman, House Committee on Transportation
Allen D. Biehler, Secretary of Transportation
Governor Edward Rendell

R. Scott Shenk, Manager, Driver Safety Division, Penn DOT Bureau of Driver Licensing

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July 24, 2008

Janet L. Dolan, Director
Bureau of Driver Licensing
P.O. Box 68676
Harrisburg, PA 17106-8676

RE: Proposed Rule PA 4426, relating to 67 PA Code Ch 71

Dear Ms. Dolan:

I write to provide the comment of the American Diabetes Association on Proposed Rule PA 4426 relating to requirements and standards for school bus drivers that are being treated for diabetes mellitus.

The Association is a nationwide, nonprofit, voluntary health organization founded in 1940. It consists of people with diabetes, health professionals who treat people with diabetes, research scientists, and other concerned individuals. With over 400,000 general members, over 17,000 health professional members and over 3 million contributors, the Association is the largest non-governmental organization that deals with the treatment and impact of diabetes. The Association establishes, reviews, and maintains the most authoritative and widely followed clinical practice recommendations, guidelines, and standards for the treatment of diabetes. The Association also publishes the most authoritative professional journals concerning diabetes research and treatment.

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. The Association has long advocated for 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.

The Association submits this comment regarding Pennsylvania's proposed rules for bus drivers with diabetes because we believe certain aspects of the proposed rule do not allow for an individual assessment of each driver's ability to safely operate a school bus. Specifically, requiring an individual to submit proof of an average HbA1C of less than 8% does not measure driving safety. 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.

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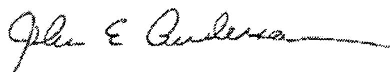
Although the Association recommends that A1C levels be kept below 7%, the purpose of this recommendation has nothing to do with the safety of an individual to currently perform tasks. Rather, this recommendation sets a target in order to lessen the chance of long-term complications of high blood glucose 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 that Pennsylvania eliminate the proposed requirement to maintain an A1C under 8%.

Thank you for considering the Association's perspective.

Sincerely,



John E. Anderson, M.D.
Chairman, Advocacy Committee

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REVIEW COMMISSION

July 27, 2009

Jeffrey Michael, Ed.D
Associate Administrator
Research & Program Development
National Highway Traffic Safety Administration
1200 New Jersey Avenue, SE
West Building
Washington, D.C. 20590

Re: American Diabetes Association Recommendations on NHTSA Proposed Guidelines for Licensing Authorities

Dear Mr. Michael:

This follows up our meeting of July 9, 2009, in which representatives from the American Diabetes Association (ADA) met with you and your colleagues to discuss our concerns regarding NHTSA's draft Guidelines for Licensing Authorities as they pertain to persons with diabetes. We wish to take this opportunity to provide a detailed written statement regarding this document, expanding on our discussion. The following reflects the input of prominent endocrinologists with extensive clinical experience, as well as the input of our staff and ADA Legal Advocacy Committee volunteers.

Below we first address the "Recommendation or Guidance Statement" that appears on page 82 of the document provided to us, as we understand that this will constitute the substance of the guidance provided to DMVs. Our comments on other portions flow from the concerns expressed on this statement. We have also provided a series of recommended questions for treating clinicians, to be included in DMV certification forms.

Recommendation or Guidance Statement
(Pages 82-83)

1. NHTSA Statement --Initial Screening. In relevant part, the recommendation states:

> Persons with a clinical diagnosis or history of diabetes mellitus who seek a license to drive a motor vehicle should be examined and certified by a qualified clinician (MD/DO) periodically. Those who encounter difficulties with control should be seen more frequently in accordance with their treating clinician's assessment of their requirements for follow up and control.

ADA recommendation: The above language should be revised to read as follows:

> Persons with a clinical diagnosis or history of diabetes mellitus who seek a license to drive a motor vehicle should be examined and certified by a qualified clinician (MD/DO) if they have had an episode of severe hypoglycemia (low blood sugar level) requiring intervention from another person to actively administer a carbohydrate, glucagon, or other resuscitative actions within the last three months.

Explanation. As stated in our January 2009 comments to AAMVA, the recommendation that all persons with diabetes be evaluated is ill-advised. The implicit assumption that evaluating every person will prevent crashes by a few is shortsighted and ignores the fact that diabetes health care professionals can identify those who are at higher risk. It also poses a real logistical challenge, as states will be faced with millions of unnecessary evaluations, as there are currently nearly 18 million people in the United States diagnosed with diabetes. Moreover many people with diabetes, because of their treatment regimen, cannot possibly experience hypoglycemia, which, as your document recognizes, is the area of concern. Hypoglycemia is only possible if an individual is taking insulin or certain classes of oral medications.

Our recommendation to limit evaluations to those who have experienced an episode of severe hypoglycemia requiring intervention from another person is based on the standards developed by the ADA and its medical experts. See ADA Standards of Medical Care (2009), at page S27; B. Childs, et al., ADA Workgroup on Hypoglycemia, "Defining and Reporting Hypoglycemia in Diabetes," *Diabetes Care* 28:1245 (2005); Philip Cryer, et al., ADA Technical Review – Hypoglycemia in Diabetes, *Diabetes Care* 26:1902 (2003). We have provided below recommended questions for treating clinicians in conducting the evaluation, which should be included in DMV certification forms.

Moreover, the reference to "Those who encounter difficulty with control" is a standard without any meaningful medical, legal or practical significance – and this statement should be deleted. In any case, decisions about the frequency of medical follow up should be left to the discretion of the treating clinician and not be the subject of state regulation.

2. NHTSA Statement – Communication of Status Changes. On this point, the document provides: "Any change in status, for example, the initiation of insulin treatment, should be communicated to the DMV, preferably by the driver himself."

ADA recommendation: This statement should be deleted.

Explanation. It is unclear what is meant by the vague reference to "any change in status," and individuals with diabetes should not be required to report any change in status to the DMV. It is not appropriate for such private medical information to be provided to DMV staff, and DMV staff should not be making any licensing decisions based only on a change in medical status. However, we would agree with DMVs or NHTSA issuing separate guidance for drivers encouraging them to discuss any changes in their condition with their health care providers, including whether driving restrictions should be undertaken.

3. NHTSA Statement – Clinician Certification Following Episode. Here the recommendation states:

> Recurrent hypoglycemic episodes requiring third party assistance are incompatible with safe driving unless certification by the treating clinician demonstrates that the driver has been stable for three months. Following a hypoglycemic episode requiring third party assistance, a driver should not resume driving unless the treating clinician has certified that the diabetes is under control.

ADA recommendation. This section should be revised to read:

> Following a hypoglycemic episode requiring third party intervention, a driver should not resume driving unless examined and certified by the treating clinician. For those drivers who have experienced recurrent episodes, the clinician should determine that the individual has not had a subsequent episode for three months.

Explanation. This statement is revised to omit NHTSA's recommendation that the clinician certify that one is "stable" or "under control," because these terms are entirely subjective and without definition in the diabetes medical community. The recommended series of standard questions below for clinicians should be used in evaluating the person's fitness to drive.

4. NHTSA Statement – Hypoglycemic Awareness. Here the statement provides that "Hypoglycemic unawareness is incompatible with driving."

ADA Recommendation: This statement should be deleted.

Explanation. The literature shows that a two- to three-week period of scrupulous avoidance of hypoglycemia is enough to regain hypoglycemic awareness. See Philip Cryer, et al., ADA Technical Review – Hypoglycemia in Diabetes, *Diabetes Care* 26:1902 at 1909 (2003). In addition, a person with hypoglycemia unawareness may still be safe to drive with proper precautions, including testing blood glucose before getting behind the wheel of the car, and testing at least hourly on long drives.

5. NHTSA Statement – Medical Controls. The statement provides that "Drivers with diabetes who experience hypoglycemic episodes requiring intervention of a third party should be subject to periodic medical controls at a frequency to be determined by the DMV."

ADA recommendation: This statement should be revised to provide that in the case where a driver has experienced a severe hypoglycemic episode requiring intervention of a third party, the treating clinician should be asked whether future medical assessments are necessary, and if so, when.

Explanation. We believe that it is more appropriate for the treating clinician to make a recommendation as to when follow up evaluations are necessary. We have included an appropriate question in the proposed certification (see below) to be supplied to clinicians by DMVs.

6. NHTSA Statement – Additional Clinician Certifications. The statement provides that: "Before recommending that their patient with diabetes continue driving, the treating clinician should ensure that there is a good understanding of the disease, that the patient is free of hypoglycemic episodes and that the patient is willing to follow the suggested treatment plan."

ADA recommendation: The recommendation should be revised to read: "Before recommending that their patient with diabetes continue driving, the treating clinician should ensure that there is a good understanding of the disease, that the patient and physician have implemented changes in the treatment regimen that significantly reduce the risk of hypoglycemic episodes, and that the patient is willing to follow the suggested treatment plan."

Explanation. The statement regarding ensuring freedom from episodes is redundant, given the certification requirement we recommend above. In addition, the language "free of hypoglycemic episodes" does not narrowly define the category of hypoglycemia that actually poses a safety risk, i.e., severe hypoglycemia requiring the intervention of another person. Appropriate questions have been included in our proposed clinician certification below.

7. NHTSA Statement – Compliance with Therapy. The statement provides that "The patient's compliance with the suggested therapy and the maintenance of blood sugar readings within an acceptable range are important in establishing the patient's understanding and management of the condition."

ADA recommendation: This provision should be omitted.

Explanation. This statement is self-evident and unnecessary. And while an individual's understanding of the management of diabetes is important, because it is a vague standard, it cannot be applied in a meaningful way in the determining whether driving should be restricted. The recommendations concerning clinician certifications adequately address this issue.

8. NHTSA Statement – Recognition of Incipient Hypoglycemia. The statement provides that "The patient should demonstrate that they are able to recognize incipient hypoglycemia and can take appropriate action when they become symptomatic."

ADA Recommendation. The recommendation should be amended to state that "The patient should demonstrate to the clinician that they are able to recognize incipient hypoglycemia and can take appropriate action when they become symptomatic."

Explanation. Although it is important for drivers to be educated in the avoidance of hypoglycemia while driving, any demonstration of this knowledge should be measured only by the treating clinician, who is best suited to determine whether a patient knows what to do to prevent episodes of severe hypoglycemia.

9. NHTSA Statement – Compliance with Diabetes Therapy. The statement provides that "To be certified to drive the applicant should be judged to be compliant with diabetes therapy and unlikely to have reduced driving ability due to diabetes or to complications affecting other organ systems (e.g., vision, cardiovascular, neurological) mediating abilities that are critical to safely operating a motor vehicle."

ADA Recommendation: This statement should be amended to state that "To be certified to drive the applicant should be unlikely to have reduced driving ability due to diabetes or to complications affecting other organ systems (e.g., vision, cardiovascular, neurological) mediating abilities that are critical to safely operating a motor vehicle."

Explanation. The requirement that the applicant be judged compliant with diabetes therapy should be omitted because it is impossible to define "compliant with diabetes therapy," making this an impossible standard to enforce.

10. NHTSA Statement – Pattern of Severe Hypoglycemia/Hypoglycemia Unawareness. The statement reads:

> Before issuing a license, DMVs should require individuals with diabetes who require antihyperglycemic therapy to be free of a pattern of repeated episodes of severe hypoglycemia (i.e., insulin reactions) of 45 mg/dl or less, not have hypoglycemia unawareness, and show that they are willing and able to properly monitor and manage their diabetes.

ADA Recommendation: This statement should be omitted.

Explanation. As noted above and in our January 2009 comments to AAMVA, we strongly oppose any requirement for medical evaluation as a condition of licensure for all individuals with diabetes. A more measured requirement is to request certification from the clinician for only those drivers who are seeking initial issuance of a license or license reissuance following an episode of severe hypoglycemia. Regarding the specific standard for issuance or reissuance, we believe that the requirement that the clinician certify that the individual has not had an episode of hypoglycemia requiring intervention from another person is sufficient and a more reliable and accurate measure as to whether the individual presents a driving risk. Relying on a specified blood glucose level as a measure of safety risk is particularly unreliable. Individuals respond quite differently to varying glucose levels. Indeed, many individuals with type 1 diabetes may experience this blood glucose level, but they do not necessarily experience functional impairment. This issue is also complicated by the fact that glucose meters are not very accurate, especially in the normal to hypoglycemic range.

Further, it is sufficient to rely on the intervention-from-another-person standard alone, without referencing hypoglycemia unawareness. People who require such assistance are those who experience unawareness and do not compensate for this knowledge by techniques such as increased frequency of blood glucose self-testing; these individuals will have a history of severe hypoglycemia and thus, will be identified and subject to driving restrictions in this way. In addition, hypoglycemic unawareness is not completely incompatible with safe driving, as long as the driver takes certain measures, such as testing blood glucose before getting behind the wheel of a car, and hourly on long drives.

As noted above, with regard to a willingness to manage diabetes, all individuals can be expected to attest to this, and thus, this should not be a requirement.

11. NHTSA Statement – Maintain an Understanding of Diabetes Management. The statement provides:

> DMVs should require drivers who use insulin to agree and comply with the following: (a) develop and maintain a clear and demonstrable understanding of the relationship between blood sugar levels, food intake, exercise, insulin intake, and temporal effects of different insulins and doses, by means of diabetes training, (b) submit a copy of the clinician's report to the DMV at the time of the recertification.

ADA Recommendation: This provision should be omitted.

Explanation. The requirement that drivers maintain such an understanding of diabetes management is too subjective of a standard to be imposed as a mandatory requirement for licensure. The clinician's report should only address the standards recommended above regarding episodes of hypoglycemia requiring third party intervention and mitigating factors.

12. NHTSA Statement -- Prudent Driving Practices. This section (the last two paragraphs) addresses recommendations for those driving on longer trips, including recommendations on checking glucose, eating and maintaining hydration. In particular, the statement notes that drivers should interrupt their trip if they feel symptoms of impending hypoglycemia or if their blood sugar is lower than 4 mmol/dL.

ADA Recommendation. We do not have any substantive objection to the content of this section. However, we question, whether this should be included in guidance to DMVs, as the agencies are not in a position to restrict driving based on non-compliance with any of these suggestions. Rather, this is more properly included in a background section and/or in information DMVs might provide to the public, for example, the NHTSA brochure "Driving When You Have Diabetes." We do note, however, that the reference to 4 mmol/dL should be converted to 70 mg/dl (the former refers to metric measurements used in Canada).

Diabetes Statement (from page 11).

We assume that the four items listed under this heading simply reflect a summary of the primary elements discussed in "Recommendations or Guidance Statement." We urge NHTSA to simply revise the statement on page 11 to conform to our recommendations discussed above. For instance, item 1 states that a clinician should certify that a driver who experienced recurrent hypoglycemic episodes requiring third party assistance has been stable for three months. This should be revised to reflect our recommendations discussed in connection with NHTSA statements 1 and 3.

Chapter 4: Medical Conditions
Diabetes
(Pages 80-81)

We propose that NHTSA adopt as a complete substitute for this section the language set out below. This language reflects a much more current and accurate discussion of the relevant medical knowledge.

Diabetes mellitus is a group of metabolic diseases characterized by high blood glucose levels resulting from defects in insulin secretion, insulin action, or both. Nearly 24 million people in the United States have diabetes, with nearly six million of those with undiagnosed diabetes and another 57 million with pre-diabetes.

There are two main types of diabetes: type 1 diabetes and type 2 diabetes. In type 1 diabetes, the cause is an absolute deficiency of insulin secretion because the pancreas stops making insulin or makes only a tiny amount. Type 1 develops when the body's immune system destroys beta cells in the pancreas, the only cells in the body that make insulin. Type 2 diabetes, which is much more prevalent, is caused by a combination of resistance to insulin action and an inadequate insulin production. In type 2 diabetes, the body makes some insulin, but either makes too little, or has trouble using the insulin, or both.

Diabetes causes blood sugar levels to be too high, a condition known as hyperglycemia. Symptoms of marked hyperglycemia may include excessive urination, excessive thirst, weight loss, and blurred vision· However, too much insulin or some oral medications used to treat diabetes can cause blood sugar levels to be too low, a condition know as hypoglycemia. Symptoms of hypoglycemia may include shakiness, sweating, and confusion. Severe hypoglycemia, while rare, can cause seizures and loss of consciousness, and therefore, is of particular concern with regard to driving.

Hyperglycemia causes the long-term complications of diabetes that may include retinopathy (eye damage) with potential loss of vision; kidney failure; and peripheral neuropathy (nerve damage) with risk of foot ulcers and amputations. People with diabetes are at higher risk for cardiovascular disease and cerebrovascular disease, but these conditions are also more likely in people with abdominal obesity, hypertension, or high blood cholesterol. It is important to note that many people with diabetes have no significant complications even after years with the disease.

Despite these potential complications, diabetes is a disease that can be successfully managed. The treatment of diabetes depends upon many factors and may vary from individual to individual. Current approaches attempt to keep blood sugar levels as close to normal as possible. People with type 1 diabetes are always treated with injected insulin. This may be administered in the form of multiple daily injections of different types of insulin or by a small electronic pump that gives constant small amounts of insulin throughout the day. Type 2 diabetes may be treated with a variety of different approaches, beginning with diet and exercise. Medication for type 2 diabetes may treat either insulin resistance or decreased insulin production. These medications may include oral agents (pills) or injections (including insulin). There is no "one size fits all" for diabetes treatment; each individual has different medical and personal needs, thus, treatment approaches are necessarily modified for the individual.

Review of Evidence on Driver Safety and Performance with Respect to Diabetes:
(Pages 81-82)

In the section on Driver Safety, it states, "One possible mechanism for crashes is hypoglycemia. While some case reports support this, no well-designed study has provided direct evidence . . . yet evidence is not yet clear on whether insulin dependent drivers are at a greater risk for a motor vehicle collision than non-insulin treated drivers." In the next section on Driver Performance, it states, "Although it is agreed that the major risk involved is that associated with hypoglycemia . . ." These are inconsistent statements. The latter statement should be omitted.

ADA Recommendation (Page 82)

Despite the fact that the evidence is of low to moderate quality, and does not provide direct evidence that insulin-treated drivers are at a greater risk for motor vehicle collision than non-insulin treated drivers, the box is checked for "Evidence is relatively clear and allows for a recommendation." We suggest that the more appropriate box is "Evidence is not so clear cut but is suggestive and allows for a guidance statement." This is because only indirect evidence suggests that hypoglycemia is a key factor to increased crash risk.

Further, the discussion in the subsection on "Driver Performance" at page 81 (beginning with the second paragraph) should be revised to conform to the recommendations that we have made above regarding the Recommendation or Guidance Statement. For instance, the statement here provides that "Any driver who experiences [a hypoglycemic episode requiring third party assistance] must not drive until their treating clinician is certain that the risk of a repetition has been minimized." Instead, the document, consistent with our recommendation above, should state that driving should be restricted for persons with diabetes who have had an episode of severe hypoglycemia "requiring intervention from another person to actively administer a carbohydrate, glucagon, or other resuscitative actions." And it should further state that such persons should be certified by their treating clinician as fit to drive.

Recommended Questions for Treating Clinicians (to be included in State DMV forms)

[Note: The following questions should be used as the basis of any certification required of the driver's treating clinician.]

1. What was the date of the driver's last episode of severe hypoglycemia requiring the intervention of another person?

2. Is the driver likely to experience further episodes of severe hypoglycemia?

3. Does the driver have the ability to recognize incipient hypoglycemia and take appropriate corrective action?

4. Does the driver have a good understanding of the disease, and willingness to follow the suggested treatment plan?

5. Has the driver been educated on the avoidance of hypoglycemia while driving?

6. Does the driver have any diabetes-related complications affecting safe driving that should be assessed by the DMV?

a. If yes, how should these complications be assessed? (Road test, functional assessment, evaluation by specialist)

b. Should the driver cease driving while awaiting these assessments?

7. Are future medical assessments necessary based on this driver's diabetes; if so, when?

Thanks very much for your consideration of our views.

Sincerely,

Gary Gross
Director, Legal Advocacy