novo (11). Indeed, our first case rapidly developed proliferative retinopathy a few weeks after starting CSII (2). The association between the precipitation of either neuropathy or retinopathy or both and the institution of strict glycemic control is seen too frequently to represent merely a chance occurrence and requires further careful assessment and investigation. Retinopathy has been shown to develop more rapidly in diabetic dogs that are strictly controlled after a period of poor control than in those that remain poorly controlled (12).

J. GARETH LLEWELYN, MRCP
P.K. THOMAS, DSc, MD
VIVIAN FONSECA, MRCP
PARESH DANDONA, DPhil

From the Departments of Neurological Science and of Chemical Pathology and Human Metabolism, Royal Free Hospital School of Medicine, London, United Kingdom.

Address correspondence and reprint requests to Professor P.K. Thomas, Department of Neurological Science, Royal Free Hospital School of Medicine, Pond Street, London NW3 2QG, UK.

REFERENCES

1. Allen DB, MacDonald MJ: Ice-water addiction complicating painful diabetic neuropathy in childhood (Letter). *Diabetes Care* 10:796–97, 1987
2. Llewelyn JG, Thomas PK, Fonseca V, King RHM, Dandona P: Acute painful neuropathy precipitated by strict glycaemic control. *Acta Neuropathol* 72:157–63, 1986
3. Archer AG, Watkins PJ, Thomas PK, Sharma AK, Payan J: The natural history of acute painful neuropathy in diabetes mellitus. *J Neurol Neurosurg Psychiatry* 46:491–99, 1983
4. Steel JM, Young RJ, Lloyd GG, Clarke BF: Clinically apparent eating disorders in young diabetic women: associations with painful neuropathy and other complications. *Br Med J* 294:859–62, 1987
5. Thomas PK, Scadding JW: Treatment of pain in diabetic neuropathy. In *Diabetic Neuropathy*. Dyck PJ, Thomas PK, Asbury AK, Winegrad AJ, Porte D, Eds. Philadelphia, PA, Saunders, 1987, p. 216–22
6. Jamal GA, Carmichael H, Weir AI: Gamma-linolenic acid in diabetic neuropathy. *Lancet* 1:1089, 1986
7. Boulton AJM, Worth RC, Drury J, Clarke B, Ward JD: Continuous subcutaneous insulin infusion in the management of painful diabetic neuropathy. *Diabetes Care* 5:386–90, 1982
8. Young RJ, Ewing DJ, Clarke BF: A controlled trial of sorbinil, an aldose reductase inhibitor, in chronic painful diabetic neuropathy. *Diabetes* 32:938–42, 1983
9. Jaspan J, Masell R, Herold K, Bartkus C: Treatment of severely painful diabetic neuropathy with an aldose reductase inhibitor: relief of pain and improved somatic and autonomic nerve function. *Lancet* 2:758–62, 1983
10. Van Ballegooie E, Hooymans JMM, Timmerman Z, Reitsma WD, Sluiter WJ, Schweitzer NMJ, Doorenbos H: Rapid deterioration of diabetic retinopathy during treatment with continuous subcutaneous insulin infusion. *Diabetes Care* 7:236–42, 1984
11. Dandona P, Bolger J, Boag F, Fonseca V, Abrams JD: Rapid development and progression of proliferative retinopathy after strict glycaemic control. *Br J Med* 290:811–15, 1985
12. Engerman RL, Kern TS: Progression of incipient diabetic retinopathy during good glycemic control. *Diabetes* 36:808–12, 1987

The Diabetic School Bus Driver

Dissenting Opinion

I was recently asked to comment on Civil Action 87-6736 (E.D. PA) filed in the United States District Court against the Commonwealth of Pennsylvania Department of Transportation. The plaintiff, a person with diabetes mellitus requiring oral hypoglycemic therapy, had been denied a license to operate a school bus under 67 Pa. Code §71.3(b)(4), which states an individual is disqualified for licensure if he "has [an] established medical history or clinical diagnosis of diabetes mellitus currently requiring use of insulin or any other hypoglycemic medication." The complaint was that the Department of Transportation was in violation of Section 504 of the Rehabilitation Act of 1973, as amended, 29 U.S.C. §794. A precedent was established in Superior Court (nos. CV-86-124 and CV-86-270), in *Jackson* v. *State of Maine et al.*, in which the state of Maine was found guilty of unlawful discrimination against Jackson, an individual requiring insulin therapy, on the basis that "the plaintiff has presented competent medical evidence that Mr. Jackson is fully able to perform all of the duties of a school bus driver safely and competently."

I undertook my own review with the view that the Pennsylvania regulation was discriminatory, having in mind the position of the American Diabetes Association that "people with diabetes should be individually considered for employment weighing such factors as the requirements or hazards of the specific job, and the individual's medical condition and treatment regimen" (1). I came to the unhappy conclusion that 67 Pa. Code §71.3 is justified as written.

Beyond objectively measurable criteria such as fixed visual disturbances, significant coronary artery disease, and functional or actual limb loss resulting from diabetes mellitus, the risk around which this regulation revolves is clearly, if implicitly, that of hypoglycemia sufficient to interfere with the safe operation of a school bus. The relevant (and scanty) literature that is available suggests that oral hypoglycemic use may be associated with higher rates of symptomatic hypoglycemia than might have been thought, and the ability to predict hypoglycemia in individual patients may be almost nonexistent. Studies recently published by Nathan et al. (2), Beisswinger et al. (3), and Rosenstock et al. (4), show rates of clinical hypoglycemia in patients taking second-generation oral hypoglycemic agents comparable to rates in patients using insulin; all patients in those studies had non-insulin-dependent diabetes mellitus.

The reported rates of untoward events in patients taking oral hypoglycemic drugs may be underestimated; the literature suggests that individuals at risk for hypoglycemia may significantly underreport episodes of hypoglycemia or hypoglycemic symptoms (5,6). Indeed, the study by Mazze et al. (7), in which apparently

motivated patients were given the opportunity to monitor their own blood glucose as an adjunct to therapy, shows an astonishingly high frequency of inaccurate reporting of the results of home testing by these patients; the errors in reporting included a high frequency of data frankly fabricated by the patients. In the study by Steel et al. (5), 82% of applicants for motor vehicle licensure failed to report their diabetes, in violation of the law. Among the 49 subjects in the study who were receiving oral hypoglycemic therapy, 10.2% reported hypoglycemic episodes, but all denied these had ever occurred while they were operating a motor vehicle. Potter et al. (6), in reviewing the incidence of hypoglycemia in the catchment area of a Nottingham, England, Emergency Department, concluded

> There are two main reasons why the frequency of hypoglycemia is not known; hospital admission is mandatory for ketoacidosis but hypoglycemia may be treated at home, in the casualty department, or on a hospital ward, and records from these sources are difficult to amalgamate. Secondly, information supplied by patients is often unreliable, perhaps because of retrograde amnesia, and we have noticed that our patients may not report episodes of severe hypoglycemia even when questioned directly in the clinic.

The United States Department of Transportation Medical Advisory Board has apparently decided that in spite of "a lack of data on the effect of hypoglycemia on driving safety and historical precedents on which to base a decision" (8), licensure restrictions for the individual with diabetes mellitus ought to be liberalized. I look forward to the full report from the advisory board and would like to be convinced that my conservative position is unwarranted. However, I fail to understand how the liberalization of the regulations regarding various classes of motor vehicle licensure for the individual with diabetes mellitus is in anyone's best interests, given the lack of relevant data pertaining to the potential impact of such changes. I strongly argue that, rather than making these decisions now (which might have the tendency to render the questions silent, precluding further study), the acquisition of such data ought to become a priority. In 1986, 21.7 million children were transported 3.7 billion miles in 350,000 school buses; there were 37,000 school bus accidents and 6900 pupils injured (9). Data are missing from several major states, including Illinois, New York, and Ohio, and in no state are applicable medical data available regarding these accident rates. Given our inability to reliably predict the occurrence of significant hypoglycemia in our patients with diabetes mellitus, I cannot accept that those accident/injury numbers would not be changed by liberalization of licensure regulations. I urge that our advocacy of those unfortunate to have diabetes mellitus be tempered by the realization that our treatment of diabetes entails risks and that we are not truly aware of the extent of those risks.

D. MARK POTTER, MD

From the Division of Endocrinology and the Diabetes Clinic, University Hospital, Pennsylvania State University College of Medicine, Hershey, Pennsylvania.

Address correspondence and reprint requests to Dr. D. Mark Potter, Division of Endocrinology, The Milton S. Hershey Medical Center, Hershey, PA 17033.

REFERENCES

1. *A Word to Employers*. Alexandria, VA, Am. Diabetes Assoc., 1986
2. Nathan DM, Roussell A, Godine JE: Glyburide or insulin for metabolic control in non-insulin-dependent diabetes mellitus. *Ann Intern Med* 108:334–40, 1988
3. Beisswinger PJ, Dias N, Beckman F: Evaluation of first generation sulfonylureas and glipizide in non-insulin-dependent mellitus. *Am J Med* 83 (Suppl. 34):16–21, 1987
4. Rosenstock J, Meisch A, Raskin P: Conversion from low-dose insulin therapy to glipizide in patients with non-insulin-dependent diabetes mellitus. *Am J Med* 83 (Suppl. 34):10–15, 1987
5. Steel JM, Young RJ, Frier BM, Duncan LJP: Occasional survey: driving and insulin-independent diabetes. *Lancet* 1:354–56, 1981
6. Potter J, Clarke P, Gale EAM, Dane SH, Tattershall RB: Insulin-induced hypoglycemia in an accident and emergency department: the tip of an iceberg? *Br Med J* 285:1180–82, 1982
7. Mazze RS, Shamoon H, Pasmantier R, Lucido D, Murphy J, Hartmann K, Kuykendall V, Lopatin W: Reliability of blood glucose monitoring by patients with diabetes mellitus. *Am J Med* 77:211–17, 1984
8. DOT conference proposes licensing of insulin-treated commercial drivers. *Diabetes Dateline* 9:1–2, 1988
9. School bus accidents, 1986. *Accident Facts*. Chicago, IL, National Safety Council, 1987, p. 98–99

Reduction of Blood Glucose Concentration With Insulin Eye Drops

Recent advancement in recombinant DNA biotechnology results in mass production of various polypeptides. One that has been approved for clinical use by the FDA is insulin. As biotechnology becomes a routine tool for polypeptide production, it is no longer a question of whether the polypeptides can be prepared; rather, it is a question of how the peptide products can be delivered systemically.

It is well known that polypeptides such as insulin, cannot be administered orally because they are digested and degraded in the gastrointestinal tract. Therefore, parenteral administration is commonly practiced. However, many patients are unable or unwilling to give injections to themselves several times a day. Furthermore, the subcutaneously injected insulin shows marked individual variability of absorption (1). Consequently, numerous attempts have been made to deliver poly-