American Diabetes Association (ADA) reflected in Dr. Kathleen Wishner's presidential comments at the 55th Annual Meeting in Atlanta, Georgia. Dr. Wishner urged, among other things, the assembled health care professionals to anticipate and manage the changes coming.

The implications in this message should be questioned. It sounded like much current political posturing—"find out where the crowd is going and get out in front of them." Rather than leadership, this is trade unionism, which, if adhered to, leads to categorizing diabetes professionals as members of a union professing concern for their "customers" (patients) while functioning in a self-serving and self-preserving manner. While individually we may have to run for cover, one expects ADA at a time of ferocious assault on science and quality of care to focus on a higher standard, for example, highlighting how basic and applied science and clinical research and its application have advanced the care of the diabetic patient since 1921. Leadership should not be defensive but risk-taking to push the frontiers of science forward.

Insulin, oral hypoglycemics, transplants, lasers, antihypertensives, antibiotics, coronary artery bypass—need one go on? Advances in science do not come cheaply. They require dedicated funding and support. The future, never clear, is even more promising with the potential of genetic manipulation on the horizon.

ADA professionals, the public, and politicians need to hear this message. We can do much more for the diabetic patient today than yesterday and, if allowed, much, much more tomorrow. But it is expensive! The least costly way of dealing with a complex chronic disease is to do nothing. Death is cheaper than research and its application! The upward slope of the health care cost curve is largely due to advances in research and its practical applications.

This is the moral and practical voice of leadership and vision that we need to hear. A pep talk on how to survive in hard times is disappointing.

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Reply to Matz

Dr. Matz's letter strikes at the very heart of why the American Diabetes Association must take leadership in the health care advocacy arena. Despite the dramatic advances in diabetes care and treatment since the early 1920s, which have forever changed the prognosis of this disease, he cites that our policymakers are failing to fully grasp the absolute necessity of biomedical research and its application in finding a cure. Additionally, in their zeal to save American taxpayers money and to reform the health care system, many legislators are overlooking the important and legitimate role endocrinologists, diabetes educators, nutritionists, and other diabetes medical professionals play in offering health and hope to people with diabetes.

My address at the 55th Annual Meeting in Atlanta, Georgia, emphasized the importance of individual and association advocacy in anticipating and shaping the changes that are occurring in today's health care environment. In short, my message was as follows: American health care is rapidly changing; every association professional can and should help steer this change by becoming a diabetes advocate; if we do not participate in the process, the work we do on behalf of people with diabetes is in jeopardy.

To avoid this unacceptable situation, the American Diabetes Association is continuing its efforts to promote the need for increased federal funding for research and quality care for all people with diabetes. We are searching for solutions that advance our mission. We are taking risks to "push the frontiers of science and care forward."

I urge Dr. Matz and all of our colleagues to get involved in the debate and ensure that these vital efforts can continue.

KATHLEEN WISHNER, PHD, MD

Dr. Kathleen Wishner is the immediate past president of the American Diabetes Association.

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Frequency of Hypoglycemic Episodes During Intensive Therapy With Human Insulin

Increased frequency of hypoglycemic episodes during intensive insulin therapy may limit its effectiveness in attempting to achieve the level of metabolic control necessary to prevent diabetic complications (1,2).

Unfortunately, the Diabetes Control and Complications Trial (DCCT) design did not include randomization to different intensive treatment regimes to evaluate their possible effects on the frequency of hypoglycemia in relation to the level of metabolic control achieved (3). Therefore, the aim of the present study was to determine the frequency of hypoglycemic episodes during the different modes of intensive therapy with human insulins.

After a 3-month run-in period on conventional therapy (CT), 40 IDDM patients were randomized for a 1-year crossover comparison of multiple injection treatment (MIT) and continuous subcutaneous insulin infusion (CSII). Human insulins produced by Novo Nordisk (Bagsvaerd, Denmark), and pumps manufactured by Disetronic AG (Burgdorf, Switzerland) were used during the study. The patients were trained in blood glucose (BG) awareness and strict prevention of hypoglycemia (4). Mild hypoglycemia was characterized by BG values <2.8 mmol/l and the presence of mild autonomic symptoms recognized and managed by the patients themselves. Severe hypoglycemia was characterized by the presence of severe neuroglycopenic symptoms and the need for help from another person. Hypoglycemic coma was characterized by unconsciousness caused by severe neuroglycopenia, managed by intravenous administration of glucose or glucagon.

In total, 35 patients completed the entire study. During the first 6-month period, HbA_{1c} values were significantly lower in the CSII group compared with the MIT group (6.09 ± 0.49 vs. 6.91 ± 1.3%; $P < 0.001$) as well as during the 6 months after the crossover (6.34 ± 0.34 vs. 7.35 ± 1.16%, $P <$

0.001). There was no significant difference in the frequency of mild hypoglycemia during CT (20.46 per patient-year), MIT (18.06 per patient-year), and CSII (16.07 per patient-year), respectively. Although a decrease in the rate of severe hypoglycemia was noticed after the change from CT (1.71 per patient-year) to MIT (0.57 per patient-year) or CSII (0.80 per patient-year), those differences were not significant. The frequency of hypoglycemic comas was similar during MIT (0.17 per patient-year) and CSII (0.23 per patient-year) using human insulin in comparison with that during CT (0.23 per patient-year) using animal insulin during the previous year (retrospective analysis).

There was no significant difference in the frequency of hypoglycemia between MIT and CSII, in spite of significantly lower levels of HbA_{1c} achieved during the pump therapy. The change from CT to CSII or MIT in general does not increase the risk of hypoglycemia in patients trained in hypoglycemia awareness and strict prevention of hypoglycemia. Even a further decrease in frequency of hypoglycemia could be expected during both kinds of intensive therapy as a result of better and more stable metabolic control, strict prevention of hypoglycemia, and acquired patient experience. We are performing a larger study to confirm these results.

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U.K. Prospective Diabetes Study

In *Diabetes Care*, a conference report (1) mistakenly stated that the U.K. Prospective Diabetes Study (UKPDS) primary endpoint was glycemic regulation and that there was loss of separation of glucose control between conventional and intensive groups so that the study may not be able to address the question as to whether improved glycemic control decreases the incidence of cardiovascular disease. We wish to state the following:

1. The primary endpoint of UKPDS has always been prevention of clinical complications (2). To determine whether clinical complications can be delayed by improved diabetes control, newly diagnosed type II diabetic patients were allocated either to a conventional treatment policy, primarily with diet, or to an intensive policy with sulfonylurea, insulin, or metformin therapy. By 7.8 years (median) from the randomization dates, 33% of the 4,108 randomized patients had a clinical endpoint; 22% had a cardiovascular endpoint.
2. The study has maintained separation of glycemic control between the two allocated policies over 9 years (see Fig. 1), with a median difference of 1.7 mmol/l fasting plasma glucose and 0.8% HbA_{1c}.

The glycemic increase with time is an inevitable feature of type II diabetes given the progressive impairment of β-cell function (3). Nevertheless, this does not prevent the study from determining whether the improved blood glucose control that can be obtained with current therapies will be clinically beneficial. The study, which is planned to report in 1998, has an 81% power of determining, at the 1% level of significance, whether improved blood glucose control for a median of 11 years decreases or increases the incidence of clinical complications.

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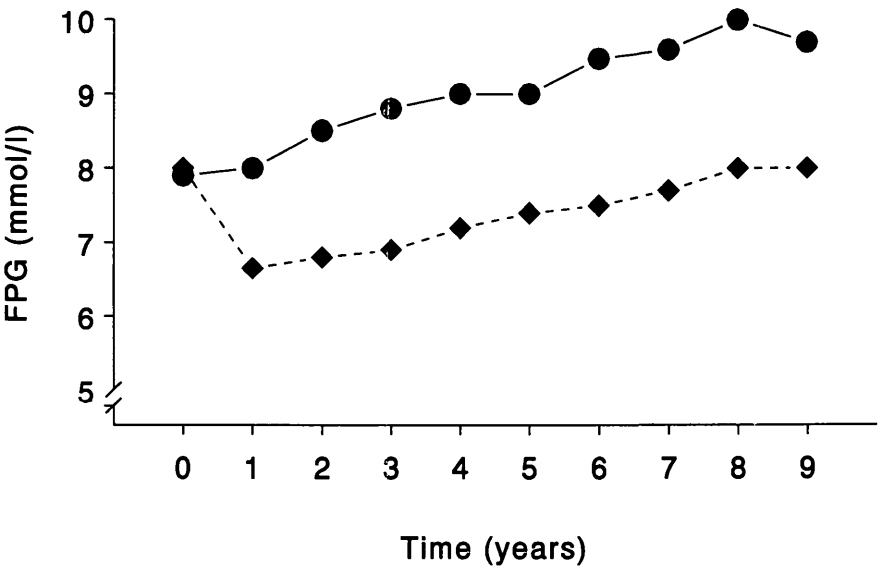

Figure 1—*Median fasting plasma glucose in subjects studied over 9 years in those allocated to conventional policy and those allocated to intensive policy with sulfonylurea or insulin therapy.* ●, *conventional, n = 378;* ◆, *intensive, n = 965.*