

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

JEFF KAPCHE,

Plaintiff,

vs.

CIVIL ACTION NO. SA-95-1215 - EP

CITY OF SAN ANTONIO

Defendant.

DECLARATION OF RALPH DEFONZO, M.D.

I, Ralph DeFronzo, M.D., hereby declare as follows:

1. I am Professor of Medicine and Chief of the Diabetes Division at the University of Texas Health Science Center at San Antonio and have served at this medical school since 1983. I also function as the Deputy Director of the Texas Diabetes Institute. This state of the art facility cares for approximately 8,000 diabetic patients in San Antonio and surrounding area. I have been very active with the American Diabetes Association, and have served as chairman of the following committees for the ADA: Professional Education Committee (1984 - 1987), Professional Practice Committee (1987 - 1989), Research Policy Committee (1989 - 1992), Medical and Scientific Committee (1992 - 1994), and the Research Oversight Committee (1995 - 1998). I also have been awarded the ADA's Lilly Award (1987), which is given to the outstanding investigator in North America. From 1990 to 1992, I was the president of the Texas Affiliate of the American Diabetes Association, and have served on the Board of Directors for both National ADA (1991 - 1994) and the Texas affiliate of the American Diabetes Association (1988 - 1994). I have authored over 350 publications in peer review journals, and am the editor of Current Treatment of Diabetes Mellitus (a



EX 000670

practical guide for the treatment of diabetes mellitus for primary care physicians) and the International Textbook of Diabetes Mellitus (a leading textbook for diabetologists and endocrinologists). I also am the founding editor of the only review journal (Diabetes Reviews) published by the American Diabetes Association. In 1991, I served as the chairman of the NIH special study section for research grants related to glucose sensing and monitoring devices in diabetic patients. My curriculum vitae is attached as Exhibit "A" to this Declaration. I have personal knowledge of all the statements contained in this Declaration. I am acquainted with Jeff Kapche and have evaluated him as a patient and have determined his fitness to serve as a police officer, given the available medical technology and Jeff's own fastidious compliance with his treatment regimen.

2. I keep abreast of the rapidly changing medical advances in the treatment of diabetes, and have appeared as an expert in the courts of the Honorable Judge John D. Rainey, as well as that of the Honorable Judge Ed Prado, dealing with the issue of whether a blanket exclusion of insulin dependent diabetics is warranted, given the advances in treatment of diabetic individuals over the past several years. Specifically, I have observed the improvements in medical technology since Mr. Lyle S. Chandler challenged the City of Dallas' blanket exclusion of insulin dependent diabetics. The Court of Appeals observed that, while employed in the mid to late 1980s, Mr. Chandler repeatedly suffered severe hypoglycemic episodes, and caused serious injuries to himself and other employees in 1986 when he caused an electrical accident while he was hypoglycemic. Also, the Court of Appeals noted that Mr. Chandler's vision was greatly impaired because of his poor glucose control, which causes deterioration of the small blood vessels in the eyes. In Mr. Chandler's case, he could not correct his vision to any better than 20/60 and his field of vision was limited to 70 degrees.

3. Unfortunately, back at the time of Mr. Chandler's difficulties, medical technology was not developed to the point where insulin dependent diabetics could self monitor and self medicate themselves in the manner that today's technology allows. A historical perspective is in order. Diabetes is a disease affecting more than 15 million Americans. It involves either the failure of the human pancreas to secrete insulin (called Type 1 diabetes), or the inability of the body to properly use its own insulin (Type 2, or sometimes called adult onset diabetes). In either case, the body's inability to convert carbohydrates into energy causes hyperglycemia (high blood sugar). In a non diabetic person, the body has a small amount of insulin which circulates throughout the body. The insulin is produced by the pancreas. When a person eats food, the pancreas secretes the perfect amount of insulin to regulate the blood glucose level. When the pancreas doesn't secrete insulin, or secretes inadequate amounts, blood sugars rise.

Diabetes has existed in humankind for thousands of years. There was no treatment for diabetes at all until the twentieth century, when insulin was discovered. Up until that time, Type 1 diabetics simply died of toxic levels of glucose because of the complete lack of insulin. With the discovery of insulin by Banting and Best in 1921, the life expectancy of diabetic individuals increased and over the last decade, advances in blood glucose monitoring equipment, insulin delivery systems, insulin preparations, and patient education have allowed Type 1 diabetic subjects to have lifestyles free of the major complications that previously were prevalent, albeit with great effort on the patient's behalf.

4. Among the advancements since the time of Mr. Chandler's difficulties are regular blood glucose monitoring by the patients themselves. In the past ten years, we have seen the advent of affordable portable monitors the size of a stop watch, which literally can be carried in a person's

pocket or purse. These glucose monitoring devices can provide a measure of the blood glucose within 15 - 30 seconds with a tiny drop of blood which can be obtained from the finger, arm, leg or abdomen. The blood glucose monitoring devices are very accurate, temperature independent, inexpensive, and very user friendly, such that user error is negligible. Before the advent of these tiny portable monitors, patients were relegated to quarterly blood tests at laboratories. These blood tests simply gave patients and doctors a snap shot of the patient's blood glucose level. This of course did nothing to assist the diabetic in the day to day, hour to hour, control of blood glucose levels, and did nothing to ward off the potential of hypoglycemia. Thus, in those days, people did not discover hypoglycemia until they actually could *feel* the low blood glucose value. Today, however, people can self monitor multiple times per day, maintain good blood glucose control, and prevent the development of hypoglycemia by appropriately adjusting their insulin dose and carbohydrate intake. For example, Mr. Kapchie himself self monitors several times per day, and that is how he can ward off even the potential of a hypoglycemic episode by simply keeping his blood glucose values in the acceptable range.

5. Within the last several years, there has been another important advancement in blood glucose monitoring for diabetic subjects. Portable monitors now have memories and their readings can be downloaded onto a computer, so that patients, physicians and even employers can see for themselves the patient's control. If a patient is having borderline low readings, this can be discovered and dealt with appropriately. This simply was not an option for Mr. Chandler.

6. In the past several months, another major advancement in blood glucose monitoring has come to fruition. An implanted blood glucose monitor has been devised and allows for the measurement of blood glucose levels every 5-10 minutes for patients who require continuous

monitoring. It is implanted under the skin of the patient, allows the patient to observe changes in blood glucose levels, and the data can be transmitted to the physician within minutes so that good blood glucose control can be maintained. Currently, this device (made by MiniMed) is available only for use in doctors offices, but soon will be available to diabetic people throughout the U.S. Another device called the Glucowatch, also is close to approval by the FDA for diabetic patient use. It is worn like a watch and provides three readings of the blood glucose level every hour.

7. Another advance in control of diabetes is the advent of routine glycosated hemoglobin tests in laboratories all over the United States. This test measures the mean day-long blood glucose level of patients over a ninety day period. It is a rather new development, and for a time, only big city laboratories could perform the tests. In the old days, the physician could determine the blood glucose level at the moment that he saw the patient, but have no clue as to the patient's compliance for the preceding months. Now, during a quarterly checkup both the patient and his/her doctor can have an accurate picture, not only of their *current* blood glucose value, but also *their degree of compliance for the preceding 90 days*. This glycosated hemoglobin value is very helpful in maintaining the patient's blood glucose levels within an acceptable range that will prevent the development of diabetic complications, including eye, nerve and kidney damage.

8. Not only has there been dramatic improvement in glucose monitoring, there have been dramatic technological improvements in insulin delivery systems and in the *types* of insulin available to diabetics. When Mr. Chandler was having his difficulties, the only insulin delivery system was the use of a refrigerated vial of insulin and a syringe. This required the patient to take the vial out of the refrigerator, carefully draw out the recommended insulin dose, and then inject the insulin. Errors in measuring were common, and they occasionally led to hypoglycemia due to

these errors. During the past five years, technology has advanced to the point where insulin can be delivered without syringes and refrigerated insulin. In fact, insulin is now widely available in pens which fit in a shirt pocket. There is no manual drawing up of the insulin. There is a dial on the pen. The patient sets the dosage amount, and simply pushes the button to inject the insulin. We also have seen the advent of portable insulin pumps that are quite small, can be attached to the belt of a diabetic, and provide a basal level of insulin to meet the body's need while at rest as well as providing a programable bolus injection of insulin that can be given with each meal by simply pushing a button on the pump. The bolus injection of insulin can be precisely regulated to burn up the amount of carbohydrate in the meal, thereby maintaining the blood glucose level at the acceptable range.

9. Further adding to the technological improvements in treatment, we now have new and better types of insulin which are identical to *human* insulin. In the days of Mr. Chandler's difficulties, the types of insulin that were available were limited and were derived from cows and pigs. These insulins often times were associated with the development of antibodies which decreased their effectiveness. The body needs some insulin at all times, and the non diabetic individual has a pancreas which produces the exact amount of insulin needed at any given time. For example, between meals and during the sleeping hours, a non diabetic individual has what we call a basal insulin level which regulates blood glucose levels under resting or basal conditions. Upon eating, the pancreas squirts out an additional amount of insulin to "cover" for the ingestion of carbohydrates which otherwise would raise the blood glucose values.

10. Recent medical technology has brought forth insulins which are compatible to the pancreas' own production of insulin. Importantly, these insulins have been manufactured by

genetic engineering to be identical to the insulin which is produced by the human body. We now have long acting insulins such as Lente, NPH, and Ultralente, which when used appropriately, can simulate the basal insulin production that occurs in non diabetic subjects. Some of these insulins (i.e. Ultralente can last up to 24 hours. And now we have very rapid acting insulins such as lyspro insulin, whose function is to "cover" a meal, similar to the way the pancreas would "cover a meal". These new insulins act very rapidly, within minutes, and allow much tighter blood glucose control. Moreover, because they can be given immediately before a meal, they help to prevent hypoglycemia. Another important aspect of Lyspro insulin is that it stops working after approximately 2 hours. Thus, by the time the food has been absorbed from the stomach, the blood insulin level has returned to baseline, another feature which helps to minimize hypoglycemia. Lyspro insulin is ideal for use in insulin pumps because of its very rapid onset and very rapid offset of action, thereby providing excellent blood glucose control while minimizing hypoglycemia.

11. Thus there is a difference of night and day between the days of Mr. Chandler's difficulties and the current state of medical technology, and there is absolutely no rational reason for any blanket exclusion of insulin dependent diabetics from employment. These Americans with Type 1 or insulin dependant diabetes range from professional athletes such as Chris Dudley (NBA), Ron Santo (MLB), Bobby Clark (NHL), Jay Leewwenburg (NFL), Kelli Kuehne (LPGA), and Marcelo Ferreira (Triathlete) to ordinary law enforcement officers such as Jeff Kapche. Every person should be evaluated on his or her own merit and treatment regimen. Medical technology has now developed to the point that many motivated people are able to avoid hypoglycemia and with hard work and dedication, avoid long term complications. Jeff Kapche is

a good example of such a person, and that's why in four years as a deputy sheriff, he has maintained good blood glucose control and is not a risk for himself or anyone else. Certainly, there are patients who are not able, because of either the disease or treatment regimen, to make the daily adjustments to maintain good control, and those who may present risks to themselves or others. These people may not be suitable for certain jobs. But medical technology and common sense require that these decisions be made on an individualized basis and not be a one size fits all rigid exclusion. I shared the statement of the Judge in Mr. Chandler's case that "medical science will soon progress to the point that exclusions on a case by case basis will be the only permissible procedure." That day has undoubtedly arrived.

12. Turning specifically to Jeff Kapche, he has Type 1 diabetes mellitus and as a result must inject himself several times a day with insulin, perform finger stick blood glucose testing, and maintain an appropriate diet and exercise regimen. By complying with this treatment regimen, Mr. Kapche has not suffered any threatening hypoglycemic episodes, and his glycosated hemoglobin tests, which measure patient compliance for a ninety day period, show excellent control. Jeff is very qualified to perform the requirements and duties of a police officer. In fact, Mr. Kapche has controlled his condition to the extent that he has thrived for four years as a Fort Bend County Sheriff's Deputy. Through patient education, he has learned the appropriate foods for a diabetic to eat, how to monitor his blood glucose levels, and how to adjust his daily insulin dose to match his food intake.

13. Since diabetes that is not well-controlled can result in either dangerously high or low blood sugar levels, the goal of Mr. Kapche's treatment is to try to balance the blood sugar level within a safe range that avoids hypoglycemia (low blood sugar) or hyperglycemia (too high

of a blood sugar) that can, after many years, lead to diabetic complications. The result is a balancing act, which Jeff, through diabetes education and hard work, has attained.

14. Mr. Kapche must monitor his blood glucose levels through self-administration of blood tests which are done a number of times each day. The result of these blood tests give Mr. Kapche the information that allows him to make appropriate adjustments in insulin dosage and injection schedule, nutritional intake, and activity level – as well as providing vital information to his physician. It is important that careful records be kept of all test results, and Mr. Kapche keeps these types of records.

15. At this point, diabetes has no cure, and Mr. Kapche will require insulin treatment for the the rest of his life. This will require certain lifestyle modifications and blood glucose monitoring in order to maintain good control of diabetes. It is my expert opinion that Mr. Jeff Kapche is medically qualified to be a police officer and that he is not a direct or indirect threat to himself or others, as exemplified by his career as a peace officer in Fort Bend County.

I declare under penalty of perjury that the foregoing is true and correct.

Signed this April 7, 2000.

Ralph A. DeFronzo, M.D.
Ralph A. DeFronzo, M.D.