

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

JEFF KAPCHE,

Plaintiff,

vs.

CITY OF SAN ANTONIO

Defendant.

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CIVIL ACTION NO. SA-95-1215 - EP

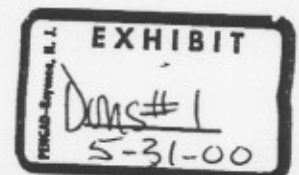
DECLARATION OF ROBERT F. DONS, M.D., PH.D

I. Robert F. Dons, M.D., Ph.D hereby declare as follows:

1. I have been a physician since 1975 and am board certified in endocrinology and metabolism. I am a United States Air Force certified endocrinologist and a fellow of the American College of Endocrinology. I am also a Ph.D. in biochemistry.

2. During November 1990, I served as Military Consultant to the United States Air Force Surgeon General for Endocrinology. From 1990 to 1994, I was the Department of Defense Representative to the National Diabetes Advisory Board. In 1994, I served as a consultant to the United States Air Force Guard and Reserve on Standards for Retention of Type 2 Diabetes Patients on Active Status. I have authored multiple publications in peer review journals. My curriculum vitae is attached hereto as Exhibit "A." I have personal knowledge of all the statements contained in this declaration.

3. I have extensive experience as care giver and advocate for both Type 1 and



Type 2 diabetics. The best interest of the diabetic is of primary concern to me as an endocrinologist.

4. I am familiar with inquiries, presented to me in 1994, regarding the ability of diabetics to serve as active duty and reserve National Guard troops and specifically to operate military aircraft.

5. I am aware of medical advances in the treatment of diabetes.

6. Type 1 diabetes involves the failure of the human pancreas to secrete insulin. The body's inability to convert carbohydrates into energy causes high blood sugar (hyperglycemia). A small amount of insulin circulates throughout the body of a non-diabetic. 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 does not secrete insulin or secretes inadequate amounts, blood glucose concentrations rise. Without treatment, a Type 1 diabetic eventually will become very sick or die from the resulting complications of elevated, toxic levels of glucose (e.g., kidney failure, infections, cardiovascular disease). A major consequence of Type 1 diabetes is loss of the automatic control and regulation of the blood glucose level and of the automatic preprogramming of the body's insulin delivery components. The result is a constant risk of wide fluctuations in blood glucose levels.

7. Type 1 diabetes is treated by self-applied, subcutaneous injection of insulin, the principal purpose of which is to avoid hyperglycemia (high blood glucose) and its

resulting diabetes complications. The insulin administration is integrated with self-monitoring of blood glucose levels, a strict balanced diet and exercise plan.

8. A Type 1 diabetic, being dependent on insulin, is constantly at risk of experiencing hypoglycemia (low blood sugar). A severe hypoglycemic reaction involves the loss of the ability to function mentally or physically without assistance. The risk of a sudden, severe hypoglycemic occurrence may be markedly enhanced in ways beyond the control of even the most conscientious patient.

9. Initial development of the technology permitting self-monitoring of blood glucose levels occurred from 1969 through the mid- to early 1980's. The self glucose monitor first became widely available in the mid-1980's. It should be noted that, since the mid 1980's, those technologies and methods that enable conservation of good blood glucose control by Type 1 diabetics (e.g., self glucose monitoring devices, glycohemoglobin testing, insulins, insulin delivery devices and therapy protocols) have merely been improved and become more widely and economically available and better understood. In of themselves, none is truly new in the sense of an unprecedented breakthrough. Certainly, none yet represents an unprecedented breakthrough for restoration or duplication, in a Type 1 diabetic, of those functions of the pancreas and other body systems which, in a non-diabetic, serve to automatically regulate the blood glucose concentration.

10. While "continuous" glucose monitoring and insulin infusion systems are

expected to become more widely available, existing devices are limited. Specifically, devices, such as the presently available insulin pump, remain "open-loop" systems, which means that the glucose monitoring devices are not automatically "linked" with or govern glucose delivery devices. Such linkage will be essential if the prevention of wide swings in glucose levels is to be achieved with such form of advanced monitoring/drug delivery technology.

11. Artificial pancreases, i.e., "closed loop" systems, by which the blood glucose level information obtained from self-monitoring would prompt the insulin/glucose delivery component to introduce a "correct" amount of insulin or glucose based on preprogrammed guidelines, continue to remain research tools and are not clinical options available in the near future. Even when available, "closed looped" systems will not provide automatic regulation of the blood glucose level in the same manner as the pancreas of a non-diabetic. There will be continuing issues of proper programming decisions relative to the amount of insulin to introduce in light of anticipated variations in food intake and physical exertion.

12. One of the latest advances, human insulin, may still result in the induction of antibodies which can lead to variability in the onset of blood sugar lowering effects, just like antibodies induced by the animal insulins formerly used exclusively, with the result of less predictable glucose levels in some patients.

13. Donor pancreas transplantation may be an effective cure for Type I

diabetes, but is of limited availability and the transplants may fail just like the patient's original pancreas.

14. In my opinion, the most dramatic advances in diabetes care in the last 10-15 years has been self management training. While not specifically a "technology", training is largely responsible for the shift in the locus of control for self-care management to the diabetes patient. Because of training, patients experience a reduction in marked swings of their glucose levels. However, diabetes patients are still prone to such swings in the event of even temporary lapses in diet, exercise programs, proper drug therapy or the effects of intercurrent illness such as infections.

15. No technology exists to prevent an unexpected and precipitous fall in glucose occurring as a result of medication error, unpredictability in onset of insulin action, dietary lapses or indiscretion, or unplanned change in physical activity. Routine glycohemoglobin testing reflects only the mean glucose over a six week or longer period and thereby gives an accurate picture of the degree of patient compliance over that previous period. The result of the test cannot be used to establish consistent behavior nor does it assure absence of previous transient occurrence of severe hypo or hyperglycemia. Certainly, the behavior of the Type 1 diabetic patient over the preceding period does not reliably predict similar behavior for the subsequent similar period.

16. Current glucose monitoring technology is able to give feedback in terms of minutes, but not seconds.

17. Some job assignments might involve available response time measured in seconds. Thus, a worker and those around him affected by his job performance are placed at risk in job deployment circumstances that could involve prolonged or sustained responsibility and activity, perhaps initiated without advanced planning on very short notice, during which food or medication is unavailable, the time afforded to measure blood glucose is severely limited and/or assistance from a colleague or medical support system is denied. In the case of police or other emergency public safety work, such circumstances might conceivably include high speed car chases or emergency driving, the physical exertion of foot races to apprehend suspects, hostage situations, odd hours or any physical activity for which planning could be limited (e.g., emergency or rescue activity, fire fighting, riot or crowd control, etc.).

18. There is presently no device or method of testing to reliably predict whether, when and under what circumstances an insulin-dependent diabetic will or will not have an sudden and unexpected hypoglycemic episode. That may change in the future with the availability of better, more portable transcutaneous, "continuous" (glucose) monitoring devices. The "GlucoWatch" monitoring device approved March 2000 is presently limited to cumulative readings of only the previous 15-20 minutes and, once its application is initiated, takes three hours to interact with the skin sufficiently to first produce a useful reading. In addition, its skin pad interface has to be changed every twelve hours.

19. There is currently no method of testing by which it can be established with reasonable medical certainty that an individual Type 1 diabetic presents no or very little risk of a sudden and unexpected severe hypoglycemic occurrence. Only the patient's previous record of accomplishment can presently be used to predict risk.

20. No basis is available by which can be quantified the risk of a sudden and unexpected hypoglycemic occurrence in the future either as to an individual generally or as to individuals in likely job situations.

21. Disabling hypoglycemia or hyperglycemia remain real possibilities for Type 1 patients. Modern advances have significantly reduced the occurrence of these disabling episodes, but individuals and groups remain vulnerable. An "increased" risk of hypoglycemic episodes was quantified in the DCCT study of 1440 type diabetics in 1993. The degree of glycemic control achieved in that study is considered standard even with the increased risk of hypoglycemia. The study demonstrated a higher incidence of hypoglycemia with intensification of control.

22. The technology that is available today could permit an individual with uncomplicated, well-controlled Type 1 diabetes to operate a motor vehicle safely in ordinary driving conditions. The technology that is available today still does not permit an individual (even one with uncomplicated, well-controlled Type 1 diabetes) to, without creating a real substantial risk of injury to self or another, safely operate a motor vehicle or perform other duties in higher risk job circumstances which, by themselves or when

combined with the undertaking of high risk job responsibilities, threaten to compromise the individual's ability to conserve his blood glucose level within a healthy range.

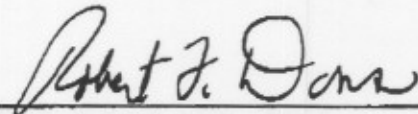
23. When the scheduling of intake of carbohydrates through ingestion of food is uncertain or meals are long delayed or missed, or unexpected physical exertion is required, controlling the appropriate blood glucose level of a Type 1 diabetic becomes more complex and problematic and the risks of a severe hypoglycemic episode substantially increases. A Type 1 diabetic seeking tight control incurs such a risk if, for example, he takes an injection of insulin immediately before eating a meal, and the meal and/or some form of carbohydrate or glucose becomes unavailable or is missed because of job or other constraints.

24. In my opinion, inevitable physical demands and unpredictability of police public safety work justify a blanket assessment that Type 1 diabetics would not, without posing a real substantial risk of injury to themselves, fellow officers or third parties, be able to drive a police vehicle or engage in high risk job duties of a police officer in higher risk job circumstances that impose a significant degree of unpredictability in activity, diet and medical support. Such blanket bans are similarly justifiable with respect to any job that could similarly involve a greatly reduced margin for error, great responsibility for the safety of others, and potentially greater harm to others in the event of incapacity of the employee during performance of job duties. In addition to police public safety jobs, these might include, but are not hereby limited to, military combatants, airline or military pilots

and Secret Service agents assigned to protect the President of the United States. The training that permits an individual with uncomplicated, well-controlled Type 1 diabetes to avoid hypoglycemic episodes in circumstances within his or her control will not always equip him or her to do so in threatening circumstances beyond his or her control.

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

Executed on May 23, 2000.



ROBERT F. DONS, M.D., PH.D