IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

GARY L. BRANHAM,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	CAUSE NO. IP01-0152-C-T/L
	)	
	)	
PAUL HENRY O'NEILL, SECRETARY, UNITED STATES DEPARTMENT OF TREASURY/INTERNAL REVENUE SERVICE,	)	
	)	
	)	
Defendant.	)	

AFFIDAVIT OF CHARLES M. CLARK, JR., M.D.

I, Charles M. Clark, Jr., M.D., being duly sworn upon my oath, being an adult and based upon personal knowledge, depose and state:

1. PROFESSIONAL BACKGROUND. Currently, I am Associate Dean for Continuing Medical Education and Professor of Medicine and Pharmacology at Indiana University School of Medicine. I am board certified in internal medicine. From 1965-66, I completed a Fellowship at the Joslin Clinic, Boston, Massachusetts, which is both the oldest and largest clinical treatment and research center for diabetes in the United States. From 1966-67, I completed a Fellowship at the Joslin Research Laboratory, Harvard Medical School, Boston, Massachusetts. From 1967-69, I was a Staff Associate at the Laboratory of Nutrition and Endocrinology, The National Institute of Arthritis and Metabolic Diseases, National Institute of Health, Bethesda, Maryland, after which time I received an honorable discharge for my two-years' active duty with the U.S. Public Health Service. I was Editor in Chief of Diabetes Care, an official publication of the American Diabetes Association and I have been on the editorial

board or an editor of many other diabetes publications. I have published four books/monographs, nearly 41 abstracts, and have written over 90 refereed publications/editorials/reviews/Diabetes Control and Complications Trials ("DCCT") Publications. My curriculum vita is attached as Exhibit A to this affidavit.

2. The statements and opinions contained in this affidavit are based upon my clinical, professional, and publication and research experiences since 1965 and are based on a reasonable degree of medical certainty. In evaluating this case I have reviewed the deposition of Gary L. Branham ("Branham") and Richard Miller, M.D. ("Dr. Miller") and all exhibits thereto, including Branham's relevant medical records. I have also reviewed all submissions made by Branham and the Internal Revenue Service ("IRS") to the Equal Employment Opportunity Commission ("EEOC") during its investigation of the case. This information includes, but is not limited to, the declarations of Branham and his treating physician Paul Skierczynski**,** M.D.; the decisions of Dr. Miller and Bruce Butler, M.D. ("Dr. Butler"); the IRS Standard Position Description; the IRS Vacancy Announcement; the Office of Personnel Management Qualification Standards for Criminal Investigator--Treasury Enforcement Agent (GS-1811); and the IRS Memorandum dated October 5, 1998 re: Qualification Requirements and Procedures For Requesting reconsideration, and waivers or exceptions for Special Agent Positions.

3. Based upon my review and evaluation of the above described materials in paragraph 2 herein, I have determined Branham's fitness to serve as a Special Agent for the IRS, given the available medical technology and Branham’s own fastidious compliance with his treatment regimen.

4. In 1988, I was President of the American Diabetes Association ("ADA"). The ADA is the oldest and largest voluntary health organization dealing with diabetes in the world. I

have been involved with the ADA since the early 1970's, and have served on a number of committees and councils. Since 1984, the ADA's policy, which I drafted as Chairman of the Public Policy Committee of the ADA, regarding the employment of persons with diabetes has been:

> Diabetes as such should not be a cause of discriminating against any person in employment. People with diabetes should be individually considered for employment, weighing such factors as the requirement or hazards of the specific job, and the individual's medical condition and treatment regimen (diet, oral hypoglycemia agents and insulin). Any person with diabetes, whether insulin-dependent or non insulin-dependent, should be eligible for employment for which he or she is otherwise qualified. *American Diabetes Association Employment Policy Statement* (1984).

5. In part, this affidavit focuses on the changes and improvements of diabetes care and technology during the last ten years. From the discovery of insulin in 1921 until the mid 1980s, the improvements in technology to treating diabetes rapidly progressed in an almost revolutionary manner that has continued up until the present time. Some of the most effective technology and treatment protocols for diabetes have been developed within the last ten years. 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 diabetic ketoacidosis because of the complete lack of insulin; generally within one year of diagnosis. 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 patients to have lifestyles free of the major complications that previously were prevalent, albeit with great effort on the patient's behalf.

6. For the past 25 years, I directed the Diabetes Research and Training Center at Indiana University School of Medicine. This Center, funded by the National Institutes of Health, is a leader in basic, clinical and health services research in the world. Never before has more research been underway concerning the cause of diabetes and its effective treatment. Presently, clinical research directed at developing better treatment of diabetes and its complications is growing at an astounding rate. This research is being funded by the federal government, various voluntary health agencies such as the ADA and the Juvenile Diabetes Foundation ("JDF"), and many for-profit pharmaceutical companies seeking to develop new products for the treatment of diabetes.

7. Diabetes is an incurable disease that affects the way the body uses food. Diabetes causes glucose levels in the blood to be too high. Normally, during digestion the body changes sugars, starches, and other foods into a form of sugar called glucose. Glucose is carried to the body's cells and, with the help of insulin (a hormone), is converted into energy. The process of turning food into energy is crucial because the body depends on energy for every action from pumping blood to thinking to running and jumping. Even in persons without diabetes, blood sugar levels go up and down during the day as food is ingested and energy used. However, in the person without diabetes, this process is finely tuned and the body is able to keep blood sugar levels within normal ranges without any further intervention.

8. In the area of improved technology and treatment methods to care for people with insulin-requiring diabetes, the emphasis has been to improve blood glucose control while avoiding episodes of hypoglycemia. Many of these advances were the result of research at the Indiana University Diabetes Research and Training Center conducted under my direction. Improving blood glucose control while avoiding hypoglycemic episodes has been accomplished

by improved technology to monitor blood sugar levels as well as by better treatment protocols to insure that people with diabetes can effectively manage their own blood sugar level by adjusting their insulin doses and food intake throughout the day. The single most important task for people with diabetes is to maintain their blood sugar level with a near normal range, avoiding the chronic effects of high blood sugar (hyperglycemia) and the acute effects of low blood sugar (hypoglycemia). This balancing act is made possible by consumer-friendly technology to allow self monitoring and self treatment of blood glucose levels and advances in insulin preparations and the means to deliver insulin. Self monitoring and self treatment protocols are now available for persons with diabetes who take insulin to allow them to safely perform virtually any job for which they are qualified.

9. In 1993, the most impactful clinical study of blood sugar regulation in Type 1 diabetes was concluded. I was Chairman of the Data, Safety and Quality Committee of that landmark study. In this Diabetes Control and Complications Trial it was shown that intensive treatment of diabetes resulting in better glucose control, significantly reduced complications related to diabetes in people with Type 1 diabetes. This conclusion was reinforced in 1998 by the United Kingdom Prospective Diabetes Study in people with Type 2 diabetes. There is now ample scientific basis to show that aggressive diabetes self monitoring and self care can result in better control and fewer complications. These studies stimulated the development of many new blood glucose monitoring devices, new insulin preparations and improved insulin delivery systems to provide consumer friendly products to better self monitor and self treat diabetes.

10. Self monitoring by regular blood glucose testing has never been easier, more available, or more consumer friendly. Recently, many of the companies who have historically sold blood glucose monitoring equipment have developed monitors which are small, rapid and

convenient to use. Now the test results come within 15 to 30 seconds with only a small drop of blood which is absorbed and does not need to be wiped off. Many meters have memory systems that allow for review of blood glucose patterns throughout the day. Additionally, new lancets with high tech steel make drawing of blood less painful and very exact. In short, all of the self monitoring technology makes the testing safer, easier, more reliable, and more available.

11. Another very significant development in diabetes technology is in insulin delivery systems. In terms of the daily administration of insulin, there have been major advances in syringe technology. No longer does one have to use large bore, painful and sometimes inaccurate syringes. Modern disposable syringes permit virtually painless insulin injections, facilitating the use of multiple injection regimens and assuring accuracy of the injections. Pen injection systems are also widely available for persons on the move. Additionally, insulin pumps allow for continuous delivery of insulin subcutaneously. An insulin pump provides a particularly appropriate technology for the administration of insulin to people who have an active and variable lifestyle or work requirements. The pumps are very accurate and can be programmed to accommodate a wide range and variety of activity levels during any given time period.

12. An insulin pump, much like one which Branham now uses, is one of the latest developments in the continuum of care where a person with Type 1 diabetes can replicate the "normal" baseline (also referred to as "basal") measure of insulin in the blood. In persons who do not suffer from diabetes, the pancreas puts out a small amount of insulin all of the time and then produces a spike in insulin immediately after a meal or snack. In this particular case, Branham replicated the body's steady production of insulin by injecting himself four times a day with a long-lasting insulin. Then, when he ate, Branham also injected Humalog, a fast-acting

insulin, to replicate the body's "normal" reaction to the increase of insulin associated with food intake. Currently, Branham is using the insulin pump to achieve the same results. The pump continuously injects a small amount of insulin over a 24-hour period and Branham manually increases the dosage at meal times, just as the body "spikes" insulin production when food is eaten by a person without diabetes. The use of an insulin pump versus the multiple-injection regimen is merely a matter of convenience and does not alter the fact that Branham has achieved excellent control and, through education and experience, essentially re-creating "normal" basal readings. Further, when an appropriate basal insulin concentration is achieved with either multiple injections or using the insulin pump, a person with Type 1 diabetes is in little danger of having a hypoglycemic episode if he is unable to eat because, by maintaining only a basal insulin concentration, the body can produce glucose to maintain blood sugars in the normal range. Following this regimen, such as when Branham only takes the bolus of insulin, that is an amount of extra rapid acting insulin, with meals, thereby significantly minimizing the risk of hypoglycemia. Thus, Dr. Miller's fear that Branham might experience a debilitating hypoglycemic episode due to a missed meal or a prolonged assignment is unfounded given Branham's treatment regimen. It is inaccurate to conclude that a Type 1 diabetic has a propensity for hypoglycemia solely because he or she is a diabetic. Hypoglycemia only results when insulin concentrations are inappropriately high in the absence of food. Branham's regimen virtually eliminates this possibility. Branham's personal history of a complete absence of severe hypoglycemia is the best predictor of future hypoglycemic episodes, meaning that it is highly unlikely that Branham will ever experience a severe hypoglycemic episode.

13. Beginning in the early 1990's, several new insulins were developed to accommodate a variety of needs for people with diabetes. In particular, in 1996, Eli Lilly & Co.

("Lilly") developed a very rapid acting insulin (Humalog), which acts within minutes to lower blood sugars and lasts only approximately two hours, which is just the right amount of time to cover a meal. In addition, this insulin is particularly ideal for use with an insulin pump as well as by people who have a very active lifestyle or employment. This type of insulin in conjunction with other insulins is now available to allow a person with diabetes to custom fit the insulin type and dosage to the variability of their daily activities. In addition, a long-acting "basal" insulin has been developed by Aventis. It has been approved by the FDA and is now available for use. Never before have people with diabetes been able to develop and use such customized and effective insulin regimens.

14. 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, Ultralente, and the recently introduced Lantus, which when used appropriately, can simulate the basal insulin production that occurs in non diabetic subjects. Some of these insulins (i.e., Ultralente and Lantus) can last up to 24 hours. And now we have two (2) rapid acting insulins, aspart and lispro insulins, 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 and are completely metabolized by the next meal, they help to prevent hypoglycemia. That is, 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. Lispro 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.

15. In addition to the above technological advances, in recent years there have been a number of employment protocols developed for people with diabetes who take insulin. In 1996, the Federal Aviation Administration ("FAA") approved a protocol to allow a person who takes insulin to obtain a private pilot's license. The FAA protocol required a variety of monitoring techniques to insure that a person with insulin does not suffer a hypoglycemic episode while flying an airplane. *See* 14 C.F.R. §67.401 & 61 Fed.Reg. 226 at 39282 (11/21/96). A similar protocol has also been adopted by the Department of Transportation regarding commercial driving license approval for persons who take insulin to treat their diabetes. From 1993 to 1996, the Federal Highway Administration created a protocol to test the safety of allowing persons to take insulin to obtain commercial driver's license ("CDL"). The result of that study was that drivers with a CDL who took insulin had a lower accident rate if they followed the protocol. *See* 49 C.F.R §§391.49 & 391.64 & 61 Fed.Reg. at 609 (1/8/96). Additionally, in 1998, the Department of Justice compelled both Arizona and North Carolina to adopt driving protocols for self-monitoring school bus drivers who take insulin to treat their diabetes. All these protocols show that there are a variety of ways to structure self monitoring and self treatment so as to allow a person with diabetes to safely perform a job that requires driving a vehicle.

16. As a result of the development and improvement of diabetes technology and treatment protocols, people with diabetes are much better able to self monitor, self control and self treat their diabetes and can be anticipated to lead long and healthy lives without long term diabetic complications. In the 1960's, people who lived with diabetes and without complications for 25 years were given medals by the Joslin Diabetes Center, affiliated with Harvard Medical

School. Today, survival of 50 years or more is commonplace. Additionally, people with diabetes who take insulin are now employed in almost every type of work for which they are qualified. It is simply not consistent with current medical research or knowledge to treat people with diabetes in any way other than as an individual. All protocols for the treatment of diabetes now require individual assessment and the creation of a treatment program that is tailor fit to each individual's needs. There are both appropriate technology and treatment protocols to provide effective, workable and safe management of diabetes in the workplace. A blanket prohibition against driving by people with diabetes who take insulin has been recognized as being both archaic and unnecessary.

17. Given the current state of medical technology, there is absolutely no rational reason for any blanket exclusion of insulin treated diabetics from employment in high risk or arduous professions. Americans with Type 1 or insulin dependent diabetes range from professional athletes such as Chris Dudley (NBA), Ron Santo (MLB), Bobby Clark (NHL), Jay Leevwenburg (NFL), Kelli Kuehne (LPGA), and Marcelo Ferreira (Triathlete) to ordinary law enforcement officers such as Jeff Kapche (Fort Bend County Sheriff's Office, Texas). 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 diabetics are able to avoid hypoglycemia and with hard work and dedication, avoid long term complications. 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 individual basis and not be a one size fits all rigid

exclusion. Similarly, a "zero tolerance" policy unilaterally used to exclude even a slight risk of threat to self or others is inconsistent with an individualized assessment of a Type I diabetic.

18. In my official capacity as Chairman of the Data, Safety, and Quality Committee of the DCCT and as a clinical investigator in diabetes for 35 years, I have reviewed the data on thousands of people with Type 1 diabetes whose treatment with insulin was studied. I have also treated hundreds of patients with Type 1 diabetes, including an NFL Hall of Fame running back. There is no reason why a person with insulin treated diabetes cannot be an effective and safe law enforcement officer if they are committed to following an appropriate protocol to insure effective self-monitoring and self treatment of their diabetes, as Branham is.

19. Turning specifically to Branham, he has Type 1 diabetes mellitus. Prior to using an insulin pump, Branham injected himself several times a day with insulin, performed finger stick blood glucose testing, and maintained an appropriate diet and exercise regimen. By complying with this treatment regimen, Branham has not suffered any threatening hypoglycemic episodes, and his glycosated hemoglobin tests ("A1Cs"), which measure patient compliance for a ninety day period, show excellent control. In fact, in my 35 years of treating diabetic patients, Branham is one of the better controlled Type 1 diabetics that I have seen. The treatment goal for persons with diabetes is to maintain their blood glucose readings within 1% of the upper limits of "normal" persons. In other words, if the "normal" person has an upper limit of 7%, then Branham's goal would be an 8%; if the limit is 8%, then Branham's goal is 9%, etc. My review of Branham's blood glucose logs indicate that his values, when read correctly, indicate that each was generally within the targeted goals.

20. If Branham is not medically qualified for the Special Agent position because of his alleged inability to "control" his disease based on his six month glucose log, AIC readings,

treatment regimen of four doses of insulin per day and 3/99 change in insulin dosage as opined by Drs. Miller and Butler, it is difficult to imagine a Type 1 diabetic who would qualify. No diabetic is going to be able to control his disease 100% of the time. The issue is whether the diabetic can properly manage his blood glucose level so as to avoid any debilitating symptoms. Not only can Branham do this, but he seems to be able to do this very effectively through diet, exercise, constant blood sugar monitoring, administration of the correct types and dosages of insulin as needed, and immediate ingestion of glucose tabs upon experiencing the symptoms of mild hypoglycemia. Even non-diabetics can have low blood sugar readings. An occasional high or low reading is not an indication that the person does not maintain good control over the treatment of his diabetes**.** Further, there is ample clinical data indicating that most hypoglycemic episodes occur during sleep hours when people are generally not aware of, and therefore do not respond to, low blood sugar indicators such as sweating or thirst. In Branham's case, it is more likely than not that he could experience similar lows in his sleep. It is also more likely that during waking and work hours Branham would be aware of and therefore capable of adjusting his insulin needs.

21. It is important to note that the primary predictor of hypoglycemia in the DCCT was a history of hypoglycemia. *See The Diabetes Control and Compliance Trial Research Group- Hypoglycemia in the Diabetes Control and Complications Trial*, Diabetes 46:271-286: 1997. Branham has no such history, making him unlikely to have hypoglycemia. Additionally, when severe hypoglycemic reactions do occur, they generally occur during sleep. Thus, even if Branham were to have a severe hypoglycemic reaction, it would be unlikely to occur at work.

22. After reviewing Dr. Miller's training and experience as contained in his curriculum vita and testified to in his deposition, I conclude that he does not have the experience

or training experience necessary to render an opinion as to the effect of Branham's disease on his ability to perform the job of IRS Special Agent. Dr. Miller has had no formal training in endocrinology or diabetology, other than what he may have received during a 12 month flexible residency in which he rotated through various medical disciplines. He also has admitted that he has treated less than fifteen Type 1 people with diabetes in his entire career. He has never made any formal presentations on diabetes to the medical community, has never participated in any diabetic studies or clinical trials, has never done any research or writing on the subject of diabetes and subscribes to no journals or periodicals dealing with diabetes. Although the 1990s proved a prolific decade in the advancement of diabetes treatment, Dr. Miller could not think of any advancement other than the insulin pump. He also was unsure of whether intensive insulin treatment has allowed diabetics to do things they could not do before.

23. I agree with Branham's treating physician, Dr. Skierczynski, when he stated in his July 27, 1999 declaration that Branham's chances of suffering from a severe hypoglycemic reaction, especially on the job, one in which he would suffer from impaired judgment up to and including loss of consciousness, is no greater than 0.2% per year. This amounts to 1/500. To put this figure in perspective, according to the Harvard Risk Analysis website, this risk is similar to a 1/397 risk of dying from heart disease or a 1/511 risk of dying from cancer. I agree with Dr. Skierczynski conclusion based on the fact that: (1) Branham's insulin regimen greatly reduces the risk; (2) Branham monitors his blood sugar frequently and is therefore able to predict and prevent hypoglycemia; (3) Branham can detect warning signs of hypoglycemia very early and carries simple carbohydrates and glucose tablets with him; (4) Humalog insulin is now available, which can reduce post-meal and nocturnal hypoglycemia; and (5) Branham has no personal history of sever hypoglycemia.

24. Therefore, in my opinion Branham is very qualified to perform the requirements and duties of an IRS Special Agent. 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 to his daily insulin dose to match his food intake.

25. Dr. Miller's conclusion that Branham suffered from a severe hypoglycemic reaction in March of 1999 based on Branham's low blood sugar readings (31, 27 and 42) is misplaced. Whereas each individual reacts differently to different levels, blood glucose that low would almost always be associated with severe symptoms-- which Branham did not have! It is both Branham's and his treating physician's opinions that these readings were a result of a malfunctioning glucose meter. I agree. Branham or his treating physician is the best person to render an opinion as the blood sugar level at which Branham's judgment would become impaired. At a minimum, this can not be accurately determined by someone who has never treated or even examined Branham. Further, certain of Branham's glucose readings registered above normal ranges during a period of time when he was ill with the flu. There is nothing medically remarkable about those readings. Blood glucose levels rise during and shortly after an illness.

26. Since diabetes that is not well-controlled can result in either dangerously high or low blood sugar levels, the goal of Branham'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 Branham, through diabetes education and hard work, has attained.

27. Mr. Branham 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. Branham the information that allows him to make appropriate adjustments in insulin dosage, 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. Branham keeps these types of records. Branham, through either multiple insulin injections or now with the use of the insulin pump, has been able to achieve better control over his diabetes than most people with Type 1 diabetes. Contrary to Dr. Miller's conclusion, this is a positive, not negative, factor to consider in assessing Branham's ability to perform the Special Agent position.

28. At this point, diabetes has no cure, and Branham will require insulin treatment for 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 Branham is medically qualified to be an IRS Special Agent and that he is not a direct or indirect threat to himself or others.

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

Signed this 21st day of April, 2003.

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Charles M. Clark, Jr., MD.

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