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John Griffin
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Dear Mr Griffin

I am Professor and Associate Chairman of Pediatrics, Medical Director of the Diabetes Center and Associate Director of the GCRC at the University of Florida, Gainesville. Our program has achieved international acclaim for sustained excellence in clinical care for children and adults with diabetes as well as pioneering innovative research in the field of diabetes. I have been involved in clinical care, education of patients and health care providers since the mid 80s and have published over 170 manuscripts, the majority related to the clinical care of patients with diabetes as well as the prediction, natural history, genetics, immunopathogenesis and prevention of the disease. I am either now or have been the Principal Investigator on several National Institute of Health, Juvenile Diabetes Foundation and American Diabetes Association studies aimed at preventing and reversing Type 1 diabetes using autologous stem cells and am currently PI of the University of Florida Clinical Center participating in the NIH-funded TrialNet. I also serve as co-PI on a Program Project Grant looking at the immunopathogenesis of Type 1 diabetes, and as co-PI for NIH-funded newborn genetic screening (PANDA) studies in North Central Florida as well as the international TEDDY consortium. I have served in numerous capacities for the American Diabetes Association and on study sections and site visits for the JDRF. As a physician-scientist focused in the area of Type 1 diabetes and having taken care of thousands of patients with diabetes for over 20 years, I feel I am well qualified to pass an opinion. My curriculum vitae is attached with this letter.

I have reviewed the FBI's answers to questions directed to the Agency, and can see that the Agency unfortunately and erroneously takes the position that insulin infusion pump therapy is a more stable method of insulin administration than injection therapy. I have also reviewed the reports of Ralph A. DeFronzo, who is and has been familiar with Mr. Kapche for many years, as well as a report from Dr. Tulloch, the endocrinologist who has been caring for him. I have been asked to utilize my expertise in reviewing the FBI's decision to ban those individuals who utilize insulin injection therapy from being hired as Special Agents.

From reviewing the FBI's answers to the questions, it is clear that the Agency chose not to involve any experts in clinical diabetes care in reaching that conclusion. If it had, it could have discovered that state of the art diabetes care for patients needing insulin for management includes injection therapy and pump therapy.

The world's most authoritative reference on diabetes care is the American Diabetes Association Clinical Practice Recommendations 31, suppl 1 (pp19-20), 2008. That document does not support a preference of one therapy over the other. To the contrary, patients should be managed in a manner that leads to the best glycemic control. While there is no question that Jeff Kapche does have Type 1 insulin treated diabetes, and thereby undergoes the substantial sacrifices and limitations in the manner in which he cares for himself and eats, the manner in which he administers insulin, whether by injections or by use of a pump is unimportant. The only factor in that choice is which therapy works best for the patient, and for Mr. Kapche; it is quite obvious that he has maintained excellent management of his diabetes with injection therapy.

Insulin injection therapy is by far the most prevalent therapy among patients needing insulin. Over 90% of insulin treated patients utilize injections as opposed to insulin infusion pump therapy. That is not to say that pump therapy is not efficacious in certain patients. It clearly is.

Yet the rationale for the FBI's ban on injection therapy rests on the proposition that it is less stable an insulin delivery system than pump therapy. That is incorrect. There are several studies which have compared injections to pump which show similar improvement in metabolic control and frequency of hypoglycemia. Some even show more frequent episodes of diabetic ketoacidosis with pump therapy. Pump therapy is also far more expensive. I cite one such reference from an outstanding group of internationally acclaimed investigators from Denver (Glycemic Parameters with Multiple Daily Injections Using Insulin Glargine Versus Insulin Pump. Satish K. Garg, Andrew J. Walker, Halsley K. Hoff, Anna O. D'Souza, Peter A. Gottlieb, H. Peter Chase. *Diabetes Technology & Therapeutics*. February 1, 2004, 6(1): 9-15. doi:10.1089/152091504322783350).

Infusion pump therapy requires many components, unlike injection therapy, which involves one device: an insulin pen (or for some, an insulin syringe). By contrast, an insulin infusion pump has the following components: batteries, tubing, cartridges, insulin, and infusion sets that are inserted into the body. Any one of these components which fail interrupts the flow of insulin and thereby necessitates none other than injection therapy. While the risk of pump failure is miniscule in the hands of a well managed patient, there is no such risk with injection therapy. Insulin is available at virtually every pharmacy in the world, even in third world countries. This is in stark contrast to pump supplies, which are largely proprietary and must be special ordered. They are generally not available in pharmacies. Also, not all insulin infusion pump companies support their products in all countries, unlike insulin and syringe makers.

A good indicator of the error of the FBI's conclusion that pump therapy is a more stable insulin delivery system is this. When insulin dependent patients are hospitalized, they generally are not managed by insulin infusion pump therapy.

Although it is not clear from the FBI's answers to questions, it appears as if there is some fear that agents might have to be stationed in third world countries. To my knowledge, no such country is without a supply of insulin. Even if there were such countries, insulin can be stored as long as two years. Even after opening a package of insulin, most insulins are fully potent for 30 days. And now there are highly advanced storage methods for insulin that keep it cool and potent, even in the unlikely event that an agent is without electricity for months at a time. Regardless, the fact remains that there is absolutely no scientific or practical justification for the FBI's ban on the employment of agents who manage their diabetes with insulin injection therapy. Such a ban is not only unnecessary, it is not remotely connected to any ostensible risk of issues on the job. Finally, it is equally clear that a ban on patients who utilize insulin injection therapy screens out, or tends to screen out those with the disability of diabetes, because the only people who need insulin are those with diabetes. To be sure, the only individuals screened out by this ban are those with insulin treated diabetes.

It has been reported to me that one FBI physician believes that all insulin treated special agents should be banned from locations with austere medical support, because, in his view, the individual could have their insulin taken away from them. I do not believe there is any support for that notion and believe it is wholly unreasonable.

In conclusion, it is my firm view that the FBI's employment ban on men and women who utilize insulin injection therapy is not supported by medicine, the literature or common sense. This ban screens out well managed people with diabetes who would otherwise be fine assets to the ranks of FBI Special Agents.

Sincerely

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