(DESMOND SCHATZ, M.D., PLAINTIFF witness, having been duly sworn, testified as follows:)

DIRECT EXAMINATION

BY MR. GRIFFIN:

Q. Would you please introduce yourself to the jury?

A. My name is Desmond Schatz, I'm a professor of pediatrics in the college of medicine at the University of Florida, and

medical director of the diabetes center at the University of Florida.

Q. How old a gentleman are you, Dr. Schatz?

A. I am now 54 years old.

Q. All right. And what is your life's work?

A. My goal is to do work aimed at the prevention and cure of all people who have diabetes, and to improve the lives of all people who have diabetes. So it takes on multiple facets, from doing research, both basic and clinical, trying to prevent really Type I diabetes, and also involved in treatment to improve their lives, as well as advocacy for all people, children who have Type I diabetes.

Q. Do you teach young medical students seeking to become doctors?

A. Yes, I teach many people, medical students, residents, fellows, physician's assistants, nurses, all in the course of my day-to-day activities.

Q. Are you an endocrinologist?

A. I am a pediatric endocrinologist.

Q. Do you treat patients as well as teach students?

A. I do, yes.

Q. And do you conduct research?

A. Yes.

Q. Tell the jury of organizations to which you belong, and from whom you have received awards for your work in the area of

diabetes.

A. I'm affiliated with many organizations, the American Diabetes Association, for which I have volunteered for now many years, going back to my time as a fellow, which is now almost over 20 years ago. I received an award for excellence in scientific research from the American Diabetes Association earlier this year, and last year was awarded the highest research award for clinical research by Mary Tyler Moore and the Juveniles Diabetes Research Foundation.

Q. Now, Dr. Schatz, we're short on time, but would you mind sharing with the jury your educational background as quickly as you could?

A. Certainly. I went to medical school in South Africa. And having done an externship in the United States in San Francisco, I realized that I wanted to do my subspecialty work in the United States, and I came to a program in Florida which is really internationally recognized for its research and for its advances in Type I diabetes aimed at preventing and curing diabetes. And I came there and have never left.

So I've been part of a very fortunate -- I've been very fortunate to join a wonderful and capable group of individuals who live my dream, which is trying to, again, improve people's lives and conduct experiments both in animals as well as in humans to try and translate them into better therapies.

Q. Do you treat patients and counsel families, both children

and adults, as part of your practice in Gainesville, Florida?
A. Yes. But to give you an idea, being a pediatric endocrinologist, I see mostly children. And I say children as under the age of 21. So many students who are at the University of Florida and around, I see them, but several patients who have seen for many years have elected to continue to be seen by me, and I follow roughly a dozen of those.
Q. And have you been paid by anyone to come and share your knowledge with this jury?
A. None. No.
Q. Dr. Schatz, how many people in the United States have diabetes?
A. There are roughly 24 million Americans who have diabetes. About 10 percent of them have Type I diabetes, which is really the area of my focus and specialty.
Q. And are there also people who have Type II diabetes who have to take insulin?
A. The answer to that is yes, understanding that Type II diabetes is both -- there's both a resistance as well as a deficiency of insulin. You know, roughly one in four, one in five people actually have to take insulin, so there's a considerable number of Type II patients who also take insulin.
Q. So when you combine the Type II's with insulin and the Type I's with insulin, we have millions of Americans who use insulin to manage diabetes?

MR. GARDNER: Objection, Your Honor. Leading.

THE COURT: Actually, I'm going to allow it. It's leading, but I'll allow it.

BY MR. GRIFFIN:

Q. Are they in the millions?

A. Millions.

Q. All right. How many primary therapies are recognized as approved treatments for insulin-treated diabetes?

A. Just insulin.

Q. And what two therapies of ways of introducing insulin into the human body are state of the art ways of introducing insulin into the body?

A. Well, the commonest, by far, is by an injection. And injections can either be given through a syringe, you know, from a vial, or by an insulin pen. And there are different kinds of pens that are on the market by different companies.

And over 90 percent of people who have Type I diabetes are on injections, and a minority of people are on insulin pumps, which is another form of therapy.

Q. Are both of these therapies recognized as state of the art, good therapies for people with diabetes?

A. Both are excellent therapies, and are individualized according to the patient and the patient's lifestyle.

Q. Let me just cut to the chase. If the lifestyle is rough and tumble, going to Iraq, Afghanistan, rolling around on the

ground, taking people down, carrying armor, which of those therapies generally is going to be most practical to avoid a catastrophe?

MR. GARDNER: Your Honor, objection. I don't think Dr. Schatz has been qualified as an expert, and he's offering opinions.

MR. GRIFFIN: He has been qualified to offer opinions on their defense. He's about to offer a very strong opinion on that defense.

THE COURT: Well, but he needs to be qualified in this case, counsel. You need to ask the question and I need him to give the answer. The fact that you've entered his CV doesn't quite do it.

BY MR. GRIFFIN:

Q. What have you been asked to do in this case?

A. I was actually asked two questions. The first question was, does Mr. Kapche pose a danger to himself or to others; and the other thing is, are there any grounds, the way I understand it, for mandating the use of an insulin pump for all patients -- for all persons who are admitted to the FBI.

Q. All right. And as part of your practice, have you maintained years of managing people, treating their diabetes on both injections and on pumps?

A. I have treated people for over 20 years, I have -- our practice has about a thousand patients who have Type I diabetes;

I currently follow personally about 200 of those. About 25 percent of my patients are on insulin pumps, various pumps, but again, the vast majority are on injections and what we call MDI, multiple doses of insulin.

Q. In connection with your practice, have you helped families and people who have occupations or activities that are very rough and tumble?

A. The answer to that is yes. So I have taken care of football players, the University of Florida Gators, and one of the questions has been in a situation where clearly there's going to be a lot of contact sport, what would be the best way of managing. And clearly, because of the -- what I would say is the lesser dependability of an insulin pump, I recommend --

THE COURT: Wait, wait, wait. You're getting into --

A. -- injections.

THE COURT: Counsel, there is a format for qualifying an expert and then getting expert opinions, and I'm waiting for the question, which I think you want to ask.

BY MR. GRIFFIN:

Q. Do you have the necessary expertise, because of your background and experience, that you can offer expertise to the jury on the question of whether an insulin infusion pump is a more reliable or more preferable way of managing diabetes?

A. I feel I have that qualification, yes.

MR. GRIFFIN: Do I need to make a motion in this

jurisdiction to recognize him as an expert?

THE COURT: Yes, yes.

MR. GRIFFIN: Then we would ask the Court to recognize Dr. Schatz as an expert.

THE COURT: Thank you. Do you want any voir dire?

MR. GARDNER: No, Your Honor. Subject to the objections made in the --

THE COURT: He may give opinion testimony in his field. Thank you, sir.

MR. GRIFFIN: Thank you, Your Honor, very much.

BY MR. GRIFFIN:

Q. All right. Moving back to the issue at hand, if the FBI says going to medically austere locations like Iraq and Afghanistan, and things that are out in an austere medical environment, what is your opinion of a ban on patients using injection therapy while giving patients on a pump a case-by-case assessment?

A. It's the reason I got involved. It makes no sense whatsoever to go on to an insulin pump in a situation like that. An insulin pump is a gadget, it is a machine, and for any of you who have seen an insulin pump, it's subject to potential issues. They're subject to having enough insulin, the battery can fail at any time. I just had a patient in which they couldn't get the battery out to replace it. I just had a young child who was sleeping and the infusion set got kinked, and what happened was

that the blood sugar went high because there was no insulin delivery system. Bubbles occur in it; you get leakage; they just come out when you just don't do anything and if you aren't aware of it.

And most importantly - and this is a very important thing - is that alarms go off. So if you were to say to me, you know, using a pump in a situation such as that, I would say to you, you're crazy. I would really recommend that you go on injections because of the problems that are associated with an insulin pump.

Q. Can you buy parts and supplies for an insulin pump at Walgreen's or CVS?

A. No, you can't. You have to order them from a manufacturer, usually, or through a central pharmacy.

Q. You mentioned the situation where a kink stops the flow of insulin. Tell the jury what's the consequence, what's the catastrophe that we want to avoid when a pump kink prevents insulin from going into the stomach.

A. So I started with a story, which is a true story, of a young girl who had a kink while sleeping, just a tubing kink; didn't get insulin, and the mom called me in the morning to say that her daughter had started vomiting. They had checked the blood sugar at 11:00 o'clock at night and gone to sleep, everything was fine, and woke up in the morning, the child was vomiting. They checked the sugar, the sugar was over 300, and there were

large ketones.

And that's what happens when you don't have insulin. With large ketones you can get acid buildup in your body, and you can get ketoacidosis and a coma, which can result because you don't have insulin. And this can occur fairly quickly if you don't have insulin.

Q. And what happens if you don't manage -- let me ask you this: When a patient has a pump problem, what is the way you give them insulin to treat them?

A. So just to let you know what we do, is the first thing we do is immediately we say to the family, give an injection of insulin. And we usually give -- people are different on how they do it. I usually give an injection of regular insulin, but what we then do is because we want to take care of the situation there and then, we make the people change their site because of some potential issues.

Because that's the most common. Sites get disrupted very easily, and if the sites get disrupted and it comes out, then you have to change it. They normally say that you change a site every three days, but particularly in times in which there's a lot of sweating or a lot of physical activity, you may have to change that site daily or even more often than once a day.

Q. And when you say "site," are you talking about the place on the belly where that infusion set is using adhesive to try to

stick on there?
A. That is correct.
Q. And what is the down side of having to change the site many times a week? What's the problem with that?
A. Well, firstly, it's that people don't like it. It's very uncomfortable to have to change it, because it's putting a needle in and then obviously withdrawing it. It has to go in there.

Secondly, you can get infections. Each and every time, you still have to pay attention to that.

Thirdly, you can hit a blood vessel. And then you can also get areas of what we call lipohypertrophy, areas in which you put it in and the absorption is increased.
Q. Dr. Schatz, do you understand the FBI's policy is that they will give a case-by-case assessment only to those patients who are on a pump?
A. That makes no sense to me. Each and every person deserves a case-by-case evaluation.
Q. Why is it important that people be judged individually as opposed to lumping everybody into one barrel?
A. Well, firstly, the course of the disease is so much different. When you talk about Type I diabetes, Type I diabetes is a heterogeneous disease, it means that it affects people differently. Some people have lots of insulin; some people have no insulin. So some of the insulin may be maintained for quite

some years afterwards. Those are really easy to maintain, and really anybody could manage that with a simple injection or however way you were going to do things.

But also, if you were to make policies in which you were to omit people who were qualified, some of the best people would not be able to get very important positions.

Q. Now, I want to ask you, what would happen to that patient who does have high blood sugar when their pump fails if they do not obtain insulin? What's going to happen to them in a matter of a few hours?

A. As I explained to you, you're going to get a very high blood sugar. Because insulin is so important in facilitating the uptake of glucose into the cells and preventing the formation of glucose, you're going to get a very high, very high glucose. And because the body wants to see another source of energy, it makes these ketones. And one of the ketones is vinegar, so it's acid. And that accumulates in the blood, and that acid buildup in the blood can lead to a coma and death, if not treated.

Q. Okay. So in the absence of insulin by injection, when that pump patient has a failure and is in DKA, the only treatment is insulin?

A. That is correct. Insulin and fluids.

Q. Insulin by injection, or intravenous?

A. It's the same thing. We give insulin intravenously, that's correct.

Q. But absent that, the person will die?
A. That is correct.
Q. Now, can you share with the jury whether or not this ban on people who manage diabetes with injections, like Jeff, whether that screens out people with diabetes?
A. Absolutely. As I told you, most people are on injections, and for people who are under very good control, there is no need - in fact, it would be wrong - to switch their therapy.

If I make an analogy, because I'm a sports fan, of a baseball player and a 20-game winner in the Major Leagues, like Nolan Ryan, he had an overpowering fast ball and he won 20 games and he was just great. Greg Maddux, on the other hand, had finesse. And you wouldn't change what Greg Maddux was doing to look like Nolan Ryan, because both of them were different and both achieved the same goal.

Injections are capable of achieving the same outcome as are pumps in the right individual with the right set of circumstances and support.

Q. Let me ask you this: Does this ban have anything -- or let me put it this way: Is this ban a necessity for any occupation in the entire world?

MR. GARDNER: Objection. Lack of foundation.

THE COURT: Repeat the question.

BY MR. GRIFFIN:
Q. Let me just ask you this way: Is there any function of any

job that would be justified in having a ban on all people on insulin injections?

MR. GARDNER: Same objection, Your Honor.

THE COURT: Sustained.

BY MR. GRIFFIN:

Q. Is there any job within your knowledge that Jeff Kapche should be banned as a group of people from performing simply because he manages his diabetes with injections?

THE COURT: Counsel, I'm going to sustain the objection to that question in whatever form you ask it.

BY MR. GRIFFIN:

Q. Let me just ask it this way: Is there any necessity whatsoever for this ban?

MR. GARDNER: Objection. Lack of foundation.

THE COURT: Sustained.

BY MR. GRIFFIN:

Q. Do you have the expertise in order to evaluate the necessity of a ban on people who use insulin injections to perform the job of special agent?

THE COURT: Look, counsel, Dr. Schatz has answered -- already answered your question in any number of ways, and the question -- what you're now doing is building it into an argument. The objection is sustained.

BY MR. GRIFFIN:

Q. Let me ask you this way: Is pump therapy less reliable in

the kinds of environments that we just discussed than injection therapy?

A. Definitely.

Q. The statement was made by Dr. Yoder that once insulin is injected, you can't take it back. Let me just ask you this: What benefit does injection therapy with Mr. Kapche's insulin, Lantus, have that pumps do not have in a location that the FBI is fearful about?

A. That's a very good question. So you have to understand insulin, and Lantus, Glargine insulin, is a 24-hour insulin, so you have an insulin on board for 24 hours which mimics your own body's pancreas' ability to make insulin. So you're making -- or you're giving Lantus to replace the basal production of insulin, so you have some insulin on board for a 24-hour period.

Now, it's only what I would say is supplemental insulin, extra insulin, a different kind of insulin, that you need when you have to eat, that you have to take what we would call a bolus of insulin. There are many different ways of creating what we call basal-bolus, and certainly injections and the new insulins that we have are certainly capable of doing exactly the same as a pump is doing.

Q. Are you against patients using insulin infusion pumps?

A. No. In fact, I really advocate for insulin pumps in the right set of circumstances. There are a lot of people who just don't want to take injections, and they like to have a pump

where they don't have to keep injecting themselves four, five, six, seven times a day.

Q. You have -- have you reviewed many documents in this case?

A. Many.

Q. Any reason whatsoever for Mr. Kapche to change his therapy?

A. Definitely not. When Mr. Kapche's A1c, which is a measure of his glucose, is really in the outstanding control, those that I have seen, and the management that he had seen not only from a point of view of the average blood sugar, but from some records that I've seen in terms of lows and in terms of highs, his range was really outstanding. Based on that evidence, I certainly wouldn't change it at all.

Q. And in terms of the pump in austere medical locations, tell the jury what effect water, temperature, and the like have on pumps.

A. So the first question relates to temperature, which you asked, and there was actually an article in the British Medical Journal in which a young man from Australia had gone into diabetic ketoacidosis because he had been exposed to high temperatures for a shorter period of time.

And so to give you an idea, insulin is a protein, and insulin is denatured by very high temperatures and also by very low temperatures. And what had happened is he had gone out in the sun, and what had happened was he still had insulin, but having been exposed to the sun, the insulin had gone off. It is

recommended that the insulin be kept, if it's stored, between two and eight degrees centigrade, 36 to 46 degrees Farenheit. If you're exposed to insulin for a long periods of time, it could get denatured.

And so that in itself -- what actually happened to this person was that he went into diabetic ketoacidosis because of the high heat and the temperature.

Similarly, if you're exposed to very cold temperatures, something similar could happen. That's why it's not recommended that we freeze the insulin.

Q. Now, with insulin such as Jeff's insulin, the Lantus insulin we've been talking about, can he skip meals or skip all meals for a day if he wants to?

A. Absolutely. So when I say the current therapy that most people would practice is basal-bolus, so he takes a Glargine insulin which would cover his base; the bolus are with those meals that he decides to eat. If he decides to miss breakfast or if he decides to miss lunch, that's okay. He should check his blood sugar and decide what he needs to do, but it's okay for him to skip meals, yes.

Q. All right. Now, somebody like Jeff, who is on Lantus with the record that he has, what's his risk of harm had the FBI decided not to revoke the offer made to him?

MR. GARDNER: Objection, Your Honor. Lack of foundation.

THE COURT: Overruled.
A. Very little. There would be no increased risk to himself or to others because his control is so good.
BY MR. GRIFFIN:
Q. Now, Dr. Schatz, you said a small risk. Do we all as human beings have a small risk that we could have a heart attack during this trial and die?
A. Absolutely. We all have a risk going to work. You know, some of us have more risk than others, but there's clearly risk, a risk that we're prepared to assume in the course of our day-to-day jobs and activities.
Q. Is that because the risk is so small?
MR. GARDNER: Objection. Leading.
THE COURT: Sustained.
A. That is correct.
BY MR. GRIFFIN:
Q. Let me ask you this: In terms of the risk of folks who have hypertension, obesity, and things like that, are they at an increased risk --
MR. GARDNER: Objection.
BY MR. GRIFFIN:
Q. -- of heart -- let me finish my question. Of heart attack?
MR. GARDNER: Objection. Lack of foundation.
THE COURT: I'll allow it. It's argumentative, though. You can do one or two of those, but then we're through.

BY MR. GRIFFIN:
Q. Yeah, I'm just going to do one, then.
In terms of the risk, of those who smoke, have hypertension, and obesity, compared to Jeff Kapche, how do you compare the risk of those versus this man as an individual?
A. His risk is very low. But people who have hypertension, who are obese, who smoke, have a greater risk, a far greater risk of having myocardial infarcts, heart attacks, strokes.
Q. So was Jeff Kapche a significant risk to anyone or anybody of harm, had he been able to serve as a special agent?
A. Not he as an individual.
Q. Now, if the FBI brings in a couple of agents to talk about how rough and tumble it is, which therapy is better at being reliable to prevent catastrophe in rough and tumble situations?
MR. GARDNER: I'm going to object, Your Honor. One, lack of foundation; two, beyond the scope of Dr. Schatz's expert opinions.
THE COURT: Well, I'm not sure about expertise, but I would like a little better foundation and a little more discussion of rough and tumble. I mean, football players doesn't do it for me. There's a doctor on the sidelines, and Gatorade.
MR. GRIFFIN: Sure.
BY MR. GRIFFIN:
Q. Thank you. The jury has heard that Dr. Burpeau certified

that he could roll around with a gun, that he could lay in a prone position, that he could tackle people and take subject takedowns. That's the kind of thing I'm asking you about. Which manner of therapy would be more reliable to prevent a catastrophe in that kind of situation?

THE COURT: No, I want to know what basis he has to evaluate --

BY MR. GRIFFIN:

Q. What is your basis for evaluating which would be riskier in that situation, pump therapy or someone on injection?

A. Well, the basis is simply contact and contact sports, and understanding the situations in which pumps work well. Pumps work well in a nice environment where there's not a lot of physical contact, where there's a controlled situation. So for really all my sportsmen or anybody involved with any contact, I actually advise them to take off their pump and to consider what we call a pump holiday, and to consider going on injections.

Q. Does the insulin Jeff uses approximate and mimic the human pancreas in providing 24 hours of basal insulin for the patient?

A. Yes.

Q. Is that an advantage of his therapy versus pump therapy?

A. It's a definite advantage, because you've got 24-hour coverage; whereas if you were on a pump which only delivers, let's say, insulin by the hour, if you think about the

understanding of the insulin, the half-life is very short and it

only lasts a couple of hours. That's the insulin in a pump. Whereas this is 24 hours. So you have coverage for a much longer period of time.

Q. Dr. Schatz, Dr. Yoder said yesterday he didn't know about Lantus, Jeff's insulin. I will ask you this question: How can someone who doesn't know about Jeff's insulin compare that to pump therapy?

MR. GARDNER: Objection, Your Honor.

THE COURT: Sustained.

BY MR. GRIFFIN:

Q. Is there ever a necessity of having non-experts overruling experts in diabetes when it comes to evaluating the risks that a specific patient might pose in a given job?

MR. GARDNER: Objection, Your Honor.

THE COURT: Sustained.

BY MR. GRIFFIN:

Q. Now, Dr. Schatz, let me ask you this: We've been told that an agent may come and testify to the jury that he has a pump, and that he had a gun pulled and he administered insulin with his other hand because he felt like he needed to. Share with the jury whether that is either appropriate or even possible.

MR. GARDNER: Your Honor, objection. Beyond the scope of Dr. Schatz's expert report.

THE COURT: Yeah, and I don't know that -- I mean,

going back to old fashioned expert stuff, counsel, I'm not sure

that's the right hypothetical, and I'm going to sustain that objection.

BY MR. GRIFFIN:

Q. Let me just ask you this. Let me confer and I may be finished.

Let me just ask this, to wrap up: What is the effect of a ban on all people on Jeff's therapy in terms of its -- well, what effect does it have?

MR. GARDNER: Objection, Your Honor. That's not an appropriate question for an expert. It's argumentative.

THE COURT: Sustained.

BY MR. GRIFFIN:

Q. Is there any job in the world that would support a ban on people like Jeff Kapche --

MR. GARDNER: Objection. Lack of foundation.

BY MR. GRIFFIN:

Q. -- just because of their therapy?

THE COURT: Sustained, counsel. Sustained. And I think you're done.

MR. GRIFFIN: Can we share with the jury this chart?

THE COURT: No.

MR. GRIFFIN: All right. Your Honor, I'll pass the witness at this time.

THE COURT: Thank you.

CROSS-EXAMINATION

BY MR. GARDNER:

Q. Good afternoon, Dr. Schatz.

A. Mr. Gardner.

Q. It's great to see you again.

Dr. Schatz, you're not an occupational specialist. Correct?

A. I'm a pediatric endocrinologist, but I'm involved with all aspects of people's lives which involve their day-to-day activities. So in terms of occupation, I feel fairly competent in understanding, you know, what most people do and how they relate this, and how I'm able, with my expertise, to pass opinion on what they do.

Q. You're not board certified in occupational medicine?

A. I'm not board certified.

Q. Your primary specialty is childhood diabetes. Correct?

A. That is correct.

Q. Yeah, and you're board certified in pediatrics and pediatric endocrinology. Correct?

A. Yes. But let me explain that most cases of Type I diabetes are found in children.

Q. Fine.

A. Most of the -- for example, I'm on the CADRE board, and all the therapy for children and adults are entrusted to pediatric

specialists to write the guidelines, if you will, for the specialty.

Q. One of the differences between pediatric diabetes and adult onset diabetes is that children typically require more doses of insulin and find it harder to manage?
A. Correct.
Q. Now, you testified, I think, that you have approximately 12 adult patients. Correct?
A. Correct.
Q. And those 12 adult patients are patients you treated when they were children. Right?
A. Correct.
Q. Of your adult patients, of those 12, half of them currently use insulin pumps?
A. Correct.
Q. And you don't take care of any FBI special agents in your practice. Correct?
A. That is correct. But I do take care of policemen.
Q. Okay. But I'm asking about FBI special agents, CIA agents.
A. No.
Q. Federal marshals?
A. No.
Q. Okay. In fact, Dr. Schatz, you don't take care of any federal law enforcement employees in your practice. Correct?
A. That is correct.

Q. And you've never done any research into the use of insulin pumps?

A. At an individual level, no, but --
Q. Okay. Thank you.
A. -- because I'm a specialist, I read all about it. And my colleagues, who I interact with on a very frequent basis, discuss their findings at scientific meetings in which I'm there. I review their papers for the journals.
Q. Those colleagues include people like Satish Garg. Correct?
A. That is correct.
Q. Bill Tameberlin (ph). Correct?
A. That is correct.
Q. And the insulin pump, that's not an area of your focus. Correct?
A. Of my research focus or of my --
Q. Correct. Your research focus, Dr. Schatz.
A. That is correct.
Q. Now, Dr. Tameberlin, he's an endocrinologist who works at Yale. Is that correct?
A. That's correct.
Q. And Dr. Garg, he's an endocrinologist and he's a professor at the University of Colorado?
A. That's correct.
Q. Now, in terms of the documents that you've considered in this case in reaching your opinions, everything you received

came from Mr. Griffin. Right?
A. That is correct.

Q. And you never asked Mr. Griffin or anyone else for additional documents. Correct?
A. That is correct.
Q. Now, Dr. Schatz, it's your opinion or your view that an individualized assessment needs to be done to determine the right therapy for the right individual. Correct?
A. That is correct.
Q. And your opinion really focuses on the individual and what best meets the individual's needs?
A. That is correct.
Q. You've never conducted a clinical exam of Mr. Kapche. Correct?
A. I have personally not conducted a clinical exam, but I had read the --
Q. So the answer is no. Correct?
A. -- report of Dr. Burpeau, who is --
Q. Dr. Schatz, listen to my question. You've never conducted a clinical exam of Mr. Kapche?
A. No, that's correct.
Q. In fact, if I'm correct, the first time you actually met Mr. Kapche was this morning coming into court. Correct?
A. That is correct.
Q. You didn't review Mr. Kapche's deposition in this case.

Correct?
A. That is correct.

Q. And you've never spoken to any of Mr. Kapche's family members about Mr. Kapche and his treatment?
A. That is correct.
Q. Now, despite the fact that you've never spoken to or examined Mr. Kapche, it's your opinion that Jeff Kapche is an extremely well controlled diabetic?
A. Absolutely.
Q. And when a diabetic tests his blood sugar, he generally does it with a meter. Right?
A. That is correct.
Q. And that meter gives a reading?
A. That is correct.
Q. And the reading tells the diabetic what his blood sugars are?
A. That is correct.
Q. And a diabetic can record those blood sugar numbers over time on a log. Right?
A. That is correct.
Q. For weeks at a time?
A. Yes.
Q. And those are called glucose levels?
A. Yes.
Q. Now, in reaching this conclusion that Jeff Kapche is well

controlled, the only glucose logs that you reviewed were from April 1st, 2006, through June 30th, 2006. Correct?

A. I can't tell you the exact dates, but I saw blood glucose values, yes.
Q. Okay. You saw those blood glucose levels over a year after the FBI evaluated Mr. Kapche for medical fitness?
A. Time wise, I can't tell you.
Q. Let's see if I can refresh your recollection.
Dr. Schatz, I want to draw your attention to page 91 of your transcript, and I would like you to look at lines 13 through 19 and let me know when you're done. If you can just look up when you're finished reviewing it.
A. (Witness complies.) Okay.
Q. Can I have that back?
A. Yes.
Q. Thank you. Dr. Schatz, does that refresh your recollection that you reviewed three months of glucose logs from a period of April 1st, 2006, through June 30th, 2006?
A. Glucose logs, but I also --
Q. I'm asking about glucose logs.
A. Yes.
Q. And so that's over a year after the FBI evaluated Mr. Kapche for medical fitness. Correct?
A. But I saw hemoglobin --

Q. But I'm asking you a question. That's a year after the FBI reviewed Mr. Kapche for medical fitness. Correct?
A. Yes.

Q. Okay. So you've never seen any blood glucose logs for a period of, say, 2005. Correct?
A. Glucose logs, no.
Q. Okay. We'll talk about the ONCs. We're going to get there, I promise.
Dr. Schatz, one measure of blood glucose control is known as the A1c. Correct?
A. Correct.
Q. Okay. And A1c levels reflect an average blood glucose over a period of time?
A. That's correct.
Q. Traditionally, what, 30 to 60 days?
A. No, 90 to 120.
Q. Ah, okay. Good. Even more. So a longer period of time?
A. Yes.
Q. So it's an average. Right?
A. That is correct.
Q. So you could have someone with a perfect A1c level that had dramatically low blood glucose levels for the first two months and dramatically high blood levels for the other two months, and it would average out?
A. Theoretically, but that's very, very rare.

Q. But you've done nothing in this case to confirm whether that was in fact the case with Mr. Kapche.
A. I asked the question -- you know, I saw the ranges of the

blood glucose, and I asked Mr. Griffin whether he had experienced hypoglycemia according to standard definitions, and whether he had experienced hypoglycemia and ketoacidosis. Plus, I read the report of a very qualified FBI physician, Dr. Burpeau, I think is his name, and then I also read the report of Dr. Tulloch, who was his treating physician.

And over that period of time, they reported no hypoglycemia, hypoglycemia, and the A1c's that I had seen were all in the same excellent range.

So based on those points, I came to the conclusion that he was -- and in fact, if I even remember, another physician saying that he was a role model for people with diabetes.

Q. You mentioned Dr. Burpeau being, I think, eminently qualified or well qualified. Can you tell the jury what Dr. Burpeau's qualifications are?
A. I thought he was the specialist who had been assigned the evaluation of Mr. Kapche by the FBI.
Q. No, my question isn't what he does. You said he's well qualified, eminently qualified. My question is, can you tell the jury what his qualifications are?
A. I understand he's an internist.
Q. But that's it.

Now, Dr. Schatz, it's your opinion that the FBI's policy regarding pump therapy is inappropriate. Correct?
A. It's wrong.

Q. Yeah, it's your view that the FBI's policy is not remotely connected to any ostensible risk of issues on the job?
A. That's correct.
Q. And in offering this opinion, you aren't considering any particular risk?
A. There's no situation --
Q. That's not my question. Dr. Schatz --
MR. GRIFFIN: Your Honor, he's interrupting the witness mid-answer.
MR. GARDNER: Your Honor, I'm entitled to a yes or no.
THE COURT: Well, the answer -- he was not even beginning to answer the question.
Re-ask the question. Let's get the re-answer.
BY MR. GARDNER:
Q. In offering this opinion, Dr. Schatz, you were not considering any particular risk. Correct?
A. No risk.
Q. You don't know exactly what an FBI agent does.
A. I had read the reports that we -- in which I think is a four to six-page description, plus I read and would assume that the FBI physician, who in issuing his report --
Q. Dr. Schatz, my question to you --

MR. GRIFFIN: Objection --
BY MR. GARDNER:
Q. -- is very simple --

THE COURT: That I'm going to let him answer. I'm going to let him complete his answer.
MR. GARDNER: Okay. Okay.
A. And I would assume that the physician was eminently qualified to know the job descriptions of an FBI agent, and in fact, had even put in some very difficult situations which Mr. Kapche was capable of doing that I would suggest that many of us who don't have diabetes are not capable of doing.
Q. Dr. Schatz, do you recall a couple of months back you and I got together in Gainesville, Florida to take your deposition?
A. That's correct, yes.
Q. And you swore to tell the truth. You were under oath the same way you are now. Correct?
A. Yes.
Q. And you did tell the truth then. Correct?
A. Yes.
Q. And in fact, I asked you, if you don't understand any of my questions, you be sure to let me know. Do you recall that?
A. That is correct.
Q. Let's take a look at that deposition.
Now, I would like you to take a look, if you would, Dr. Schatz, at page 68 of your deposition.

A. (Witness complies.) Okay.
Q. And Dr. Schatz, are you with me on page 68?
A. That's correct.

Q. I would like to look at line one, and you were asked the following question: "Let me make sure I understand. Is it your opinion in this case that you analyzed the job requirements for an FBI special agent in reaching your conclusions?"
A. No.
Q. Answer: "I don't know exactly what an FBI agent does per se." Did I read that correctly?
A. That's correct.
Q. Now, in addition to not knowing exactly what an FBI special agent does, you don't know with any sort of specifics what a deployed agent in the field does. Correct?
A. Never having been in the case, the answer is no. But I can just imagine very dangerous situations.
Q. You don't know if there's such a thing as a typical day for an FBI special agent?
A. I think they're variable. I don't know.
Q. And Dr. Schatz, in rendering your opinions in this case about the job functions of an FBI special agent, you relied upon a job position description that plaintiff's counsel provided to you. Correct?
A. Yeah. Yes. And -- yes.
Q. And that job position description is from 1978. Correct?

A. I didn't look and see what the dates were on the description.
Q. All right. Let 's see if I can refresh your recollection.

And Dr. Schatz, I would ask you to take a look at that very first page, and you'll see some dates at the bottom, and let me know when you take a look at it.
A. I'm sorry, which? These dates there?
Q. That's correct, those dates right there.
A. Yes.
Q. Dr. Schatz, does that refresh your recollection that this job position description that plaintiff's counsel provided to you is from 1978?
A. Yes.
Q. So it's a 32-year-old job position description. Correct?
A. That's correct.
Q. Okay. And this job position description is the sole basis for your knowledge about what an FBI special agent does?
A. I again assumed that the FBI -- that the physician knew more than I did when he certified --
Q. My question to you, Dr. Schatz, is: This job position description from 1978, which is 32 years old, is the sole basis for your knowledge about what an FBI special agent does. Correct?
A. Correct.
Q. And you don't know whether this job position description

encompasses the entirety of job responsibilities for an FBI special agent?

A. There is no situation in which --

Q. My question to you, Dr. Schatz --

MR. GRIFFIN: He's interrupting the witness.

THE COURT: Counsel, come to the bench, please.

(BENCH CONFERENCE ON THE RECORD.)

THE COURT: First of all, let me repeat the impeachment lecture. That wasn't impeaching. There should have been an objection.

And secondly, you need to calm down. You're interrupting this guy. You ask him a question -- I don't think you're making any points with the jury by shutting him up and shutting him up and shutting him up. Calm down. Quiet down. Take it easy.

MR. GARDNER: My concern is he has to get on a plane --

THE COURT: You let him worry about his plane. You can keep him here as long as you want to --

MR. GARDNER: That's all I needed to hear, Your Honor.

THE COURT: -- to get your cross.

MR. GARDNER: I didn't want to get into a position like I did with Dr. Yoder.

THE COURT: But slow down. You're too wired.

MR. GARDNER: Okay. I will. I was just concerned about time. That's fine.

(END BENCH CONFERENCE.)

BY MR. GARDNER:

Q. Dr. Schatz, you don't know whether this job position

description encompasses the entirety of job responsibilities for an FBI special agent?

A. No.

Q. And you haven't conducted any qualitative or quantitative analysis in this case as to the various risk factors for Jeff Kapche as an FBI special agent?

A. Could you please repeat your question?

Q. You haven't conducted any qualitative or quantitative analysis in this case as to the various risk factors for Jeff Kapche as an FBI special agent?

A. Well, there's no situation that a pump would be mandated, so I don't understand the focus of your question. There's no situation that I can think of that would preferably have a pump over an injection.

Q. And in reaching that conclusion, Dr. Schatz, you didn't conduct any qualitative or quantitative risk analysis. Correct?

A. No. But it's a clinical decision about reliability and dependability.

Q. Uh-huh. And it's fair to say that you're not offering an opinion that you analyzed the job requirements for an FBI special agent in presenting your opinions in this case?

A. I thought I answered that question. No.
Q. Okay. Now, in conducting your analysis in this case, Dr. Schatz, you reviewed articles and literature that compared pump therapy to insulin injection therapy?

A. I've read some articles, yes.
Q. I think you mentioned one of them in direct. And specifically in reaching your opinions in this case, you looked for articles that addressed the superiority of one therapy over another?
A. No, that's not true. I looked at -- the reason that -- well, two things. Firstly, I was asked to provide a list, and the reason for a list was that one of the doctors, Dr. Crantz, I believe, had said there wasn't much research on injections and pumps. And I provided that list for them.
What I will say to you is that I look at this all the time. Pump therapy is good therapy, injection therapy is good therapy, and for the individual case we make a decision based on what is best for that particular patient.
Q. And Dr. Schatz, in conducting your research in this case, you found some studies that suggested that pumps are superior, and some studies that suggested injection therapies are superior?
A. And invariably those are longer term studies which don't apply to a real day-to-day variation. Those are mostly longer term outcomes, correct.

Q. It's fair to say that studies go both ways on the issue of pump superiority?
A. Absolutely both ways, like most of medicine.
Q. And earlier you mentioned that your colleagues were the real

authorities in pump therapy. Correct?
A. I have some colleagues who are authorities too, who have done a lot of work with pumps. That is correct.
Q. And Dr. Schatz, you're aware that in late 2004, Dr. Garg and Dr. Tameberlin actually disagreed as to whether multiple daily injection therapy using Glargine was equivalent to an insulin pump in terms of achieved A1c's?
A. I disagree with my colleagues all the time, even in our -- clinically we have differences of opinion, and it's based on experience. They're both very good under the right circumstances for the right individual. I agree with what you're saying.
Q. And I just want to make sure. But you are aware that two experts in the field actually disagreed --
A. Absolutely.
Q. -- as to which therapy is superior?
A. Again, those are longer term outcome studies and they've never been done on a day-to-day basis. But realizing that there are more problems with a pump on a more short-term basis, correct.
Q. Now, your view is that the A1c is the golden yardstick of

diabetic control?
A. That is correct.
Q. And in those studies that conclude that the pump is superior, one reason given is because there's a lower frequency

of hypoglycemia. Correct?
A. That's one of the reasons, correct.
Q. Okay. And hypoglycemia means low blood sugars?
A. That is correct.
Q. And another reason that these studies say the pump is superior is because of increased flexibility. Correct?
A. Compared to what, is my question.
Q. Compared to injection therapy.
A. No, that's not true.
Q. Dr. Schatz, I would like you to take a look at your deposition --
A. Okay.
Q. -- and I would like to focus you on page 47, line 25, to page 48, line 14.
A. I'm sorry, line?
Q. Page 47.
A. Okay. I'm sorry.
Q. And I want you to look at the last line, line 25, and I want you to look at page 48 and I want you to go down to line 14. And just let me know when you're done.
A. (Witness complies.) Okay.

Q. Dr. Schatz, do you recall that one of the reasons in the studies that say the pump is superior is because the pump has increased flexibility?
A. Again, I want to perhaps explain to you what I understand by

flexibility. Flexibility is a relative term. And really, we're actually, in Mr. Kapche's case, really not talking about flexibility, we're talking about reliability and we're talking about dependability. But flexibility is a very variable term.

So for my kids who don't want to have to take shots, that's flexible. In other words, they don't have to take the shots, they have a pump. It's there and there; it is more convenient, it is flexible. I also understand flexibility is when you want to eat, you can then just dial up a dose. But you can do that also with MDI.

Now, in the older therapies, pre-2002, where we didn't have Glargines and therapies, we couldn't really do that. But now with Glargine, which mimics the pump, we can do that.

So I think that it's flexibility certainly compared to what we used to do in the past, but if you're comparing it to what I would say is what we think about now for diabetes, which is we anticipate, we compensate, that can be done equally as well with a pump as with an injection.

Q. Let me break down that answer a little bit. You talked about the older insulins. You're referring to things like MPH?
A. That's correct.

Q. So you agree that as compared to insulin injection therapy using MPH, the pump was considered to be more flexible?
A. That's correct.
Q. Okay. And even using Glargine for injecting insulin versus

pumps, you agree it's more flexible in terms of you don't have to take multiple shots a day. Correct?
A. Well, if it's for the person -- but again, it could be more inflexible. Because I can give you examples of children and adults who just don't want to be hooked up to a system on a day-to-day basis, and some people we do a good screening process, but even within a month of putting someone on a pump, they just don't want to be hooked up to it. So therefore it's inflexible and they went off the pump.
Q. Dr. Schatz, are you aware of studies that indicate that insulin pump therapy leads to better control than multiple daily injections?
A. Yes. But again, it relates to who is doing the study. If I tell you that a drug company was doing the study who makes the insulin pump, they will always show that the pump is superior. If the consultant is on the books of a drug company, it is more likely that those studies are going to be shown to be more positive. It depends who is doing the studies, it depends what the management is. So, for example, the key to really good therapy is frequent contact between a doctor, his health care team, and the patient. And if this can be done equally as

effective with a pump as with an injection, you'll have the same outcome.

On the other hand, for example, most people who are on pumps are in more frequent contact, so if you actually analyze

the number of contacts, you would find that. At a diabetes camp that a colleague of mine had done, just checking blood sugars more frequently was associated with better outcome. So there are many, many variables that we look at in these analyses.

Q. Dr. Schatz, I need you to listen to my question. I'm trying to make this pretty simple.

You're aware that there are studies that indicate that insulin pump therapy leads to better control than multiple injections. Correct?

A. I just answered that, "Yes, but."

Q. And you agree that when an insulin pump is properly working, the use of an insulin pump eliminates the need for individual insulin injections. Right?

A. If it's used in the right place under the right circumstances, the answer to that is, if you have a pump, you certainly don't need to take injections, correct.

Q. You talked at the outset about the risks associated with an insulin pump failing. Correct?

A. That is correct.

Q. You agree that the risk of pump failure is minuscule in the hands of a well-managed patient?

A. In a life in which probably you and I lead, but without much physical contact, without being put into very difficult or dangerous situations, which I could imagine for an FBI agent or Mr. Kapche, answer to that would be yes, on a day-to-day basis

without that much activity. Yes.
Q. And actually, Dr. Schatz, take it one step further. By well-managed, you mean a patient who has good blood glucose control, has good A1c levels, and has learned from his experiences and knows how to manage himself?
A. That is correct.

Q. So in that circumstance, with that kind of patient, the risk of pump failure is minuscule. Correct?
A. It depends on the environment. No, that's not true. I have very good people who in a sweaty environment don't know how to manage it, and then have problems. And we have to make some changes.
Q. Dr. Schatz, I've handed you your expert report in this case. You recognize it. Correct?
A. That's correct.
Q. And I would like to take your attention to the second page.
A. Okay.
Q. And I would like to take your attention to the second-to-last paragraph in your second page of your report.
A. Okay.

Q. Dr. Schatz, did you offer the opinion that, "While the risk of pump failure is minuscule in the hand of the well-managed patient"? Is that what you said?
A. Yeah, but I didn't comment on the situation. That's correct, that's an admission.

Q. And you still agree with that opinion. Correct?
A. It depends on the situation.
Q. You didn't qualify the situations in which the risk of pump failure was minuscule in your report, though?
A. I did not.
Q. Now, just as there may be instances of pump failure, you agree that with injection therapy there could be leakage?
A. Yes.
Q. You could hit a blood vessel?
A. That is correct.
Q. You could give the wrong dose?
A. But that's the same thing with a pump.
Q. I'm just asking you.
A. Yes.
Q. You could give the wrong dose.
A. Yes.
Q. By the way, are you aware of some of the safety features that a pump has?
A. In terms of insulin delivery and alarms? Yes.
Q. Let's talk about some of those alarms. Can you describe for

the jury the types of alarm systems that pumps have to prevent the kind of the situations you were talking about?
A. Yeah. An alarm, if there's not enough insulin that's going in, the alarm may go off. It may be either a beep or it may be a vibration. So that typically can happen.

If the battery is not working, it can alarm, that's correct. But we have alarm failures, too.
Q. Uh-huh. You're not aware of any studies showing the incidence of alarm failures on insulin pumps?
A. I can't, but I will tell you that, for unknown reasons, companies do withdraw pumps.
Q. You mean pump recalls?
A. I'm sorry?
Q. You mean pump recalls?
A. Yes.
Q. By the FDA?
A. By the companies.
Q. Sure. Are you aware that the FDA has also recalled recently certain syringes used for injections?
A. Yes. I think it was a short-acting delivery system.
Q. Okay. Now, you mentioned that with Lantus, with Jeff Kapche's insulin regime, he can skip meals. Correct?
A. That is correct.
Q. Are you aware that Mr. Kapche has never skipped a meal using Lantus?

A. I don't know. As you pointed out, I've never met Mr. Kapche until today. But I talk about my experience with other -- many of my patients who are on Glargine insulin. It's what I tell people, it's what I tell my university students who do all kind of the things with the most erratic schedules, that you can eat

whenever you need to, or you don't need to eat as long as you have a basal insulin and you're checking your blood sugars.
Q. And Dr. Schatz, by the way, as an expert endocrinologist, what would your expectation be as to the blood glucose level of a diabetic who uses Lantus, who uses that Lantus in the evening, if you were to test his blood glucose first thing in the morning, so he's had no meals, what would you expect his blood glucose to test at?
A. My target blood sugar is, so I can explain this to you is, 70 to 120, 125. A definition of diabetes is a fasting blood sugar above 125. So we want to keep it in the nondiabetic range. We can take 70 to 125. We try it as best as we possibly can.
Q. My question was slightly different. My question is, what is your expectation for an individual who takes that Lantus, that long-acting insulin in the evening, wakes up in the morning, first thing he does is, he tests his blood sugar.
A. Yes.
Q. What would you as an expert in diabetes expect that blood sugar to look like for a well-controlled diabetic?

A. Between 70 and 120 would be excellent.
Q. Are you aware that Jeff Kapche, when he went to Dr. Burpeau, tested at a fasting blood sugar of 204?
A. Oh, very possible.
Q. Uh-huh. So you're aware of that fact?

A. I wasn't aware of that fact, but it's very possible because of the -- 204 is not very bad. You know, again, we look at the trend, and I say that 204 is really not bad at all.
Q. 204, though, is the beginning of, by definition, hypoglycemia. Correct?
A. Well, it depends what you mean by hypoglycemia. A definition of diabetes is a blood sugar in the fasting state of more than 125, and in the nonfasting state of over 200. But 204 is really not terrible.
Q. Didn't ask if it was terrible. I said that 204 is indicative of hyperglycemia. Correct?
A. Hyperglycemia.
Q. Hyperglycemia.
A. That's correct.
Q. And by the way, that 204 is essentially Jeff Kapche not eating for 10 hours. Right?
A. Yeah.
Q. So we know, then, that when Jeff Kapche takes that Lantus, and we say it can cover meals, he's actually in a state of hyperglycemia eight hours out. Right?

A. Yeah, but 204 is okay. If you look at the average, for many of the people -- I would say, if you look at 99 percent of all people with diabetes, you have blood sugars above 200, at least at one or two stages of the day. With these new sensors, these machines, you find that the variation is tremendous. And you

will find that the more you check, the more you will find blood sugars of over 200.
Q. You don't know if the blood glucose machine that was used to test Jeff Kapche during the medical fitness exam for the FBI was in error. Right?
A. Don't know. That's correct.
Q. Okay. By the way, Dr. Schatz, do you agree that it's responsible for an employer to consider safety first. Correct?
A. Premium, absolutely.
Q. And that's true for an employer to consider for both applicants as well as other employees. Right?
A. That is correct.
Q. Now, you also agree, based upon the articles you reviewed in formulating your opinions in this case, that as a general matter, the use of a pump often improves A1c levels relative to injection therapy. Correct?
A. No. There are articles on both sides of the fence, and it depends what you're comparing to and who did the study.
Q. Well, let me see if I can break it down. You agree there are studies that show that, as a general matter, the use of a

pump often improves A1c levels relative to injections?
A. I think over a period of time, in some cases yes, in other cases, no, and in other cases they're equivalent.
Q. Again, the studies kind of go both ways?
A. That is correct.

Q. And as a general proposition, using an insulin pump can result in fewer large swings in blood glucose levels as compared to injection therapy?
A. The answer to that is no. Compared to conventional therapy, where we used MPH and regular insulin, we now have a system that mimics the pump, Glargine, and the insulin that you give with the injection is exactly the same as the insulin that you give in the pump, so that the swings are not as great as we used to see.
Q. On MPH, you would agree with that statement?
A. On MPH. Although I haven't analyzed it, but I would surmise that that's the case.
Q. By the way, the human pancreas, does that produce short-acting insulin or long-acting insulin?
A. It produces insulin.
Q. And it doesn't produce insulin that lasts for 24 hours. Right? It continuously produces insulin over the course of the day?
A. That's correct.
Q. Like an insulin pump?

A. You've got to understand that there's two kinds of the insulin. There's a basal insulin, and then when you and I eat who don't have diabetes, then what happens is, is that the insulin goes up. But even the injections and the pump that we do that does not mimic exactly what happens in the pancreas. We

try do that, but we're not successful. That's why it's a treatment, not a cure.

Q. Lantus, which Jeff Kapche uses, that's the long-acting insulin. Correct?

A. Correct.

Q. And the human pancreas, because it emits insulin throughout the course of a day, is more similar to how an insulin pump works than taking a 24-hour shot. Correct?

A. No, it's the same. Because really, what you're giving is the basal insulin. The pancreas, the insulin- producing beta cells produce insulin to prevent certain metabolic processes. You mimic that either by giving the short-acting basal insulin, a pump, or by giving a 24-hour insulin such as Glargine is.

Q. The Glargine insulin, that's called a square insulin. Correct?

A. Correct.

Q. Meaning that it peaks, it stays constant, and then ultimately goes down. Correct?

A. I think that's a little thing. It's misleading to say it peaks. It doesn't have a peak. If you think about it, what

happens is, is that when you -- the basal concentration is pretty much same as the pancreas. So once you give it, the absorption is very rapid, there's not much that affects the absorption. Then it just remains like that. And that's why it's such a great insulin, because it doesn't have this peak.

It remains fairly constant.
Q. So in other words, it remains fairly level. Correct?
A. That's right.
Q. Now, the human pancreas doesn't emit just a level amount of insulin. Correct? It varies throughout the day?
A. It's an oscillation. If you were to measure the various things -- but it depends how often you measured it. But you would see that overall, it's a constant. If you measured the individual oscillations with high-technology stuff, you would see, in fact, yes. There's some variations.
Q. So unlike the Lantus, which is straight line, the human pancreas actually does go up and down in terms of the production of insulin?
A. That is correct.
Q. And the insulin pump can mimic or track that up and down. Correct?
A. Absolutely not. If you look at the pulses of insulin, they occur on a second, minute-by-minute basis. Pumps don't do that. I want you to understand that what a pump does is that you give insulin. And what happens is, even with a pump, it starts

working in 10 to 20 minutes, peaks at about an hour, and then lasts over two to three hours. You don't see any of these pulses that you occur in terms of the pump.

So no, we try and look at the stuff, but we certainly don't mimic.

Q. Sorry, I should have said it more closely mimics the human pancreas than just a straight line. Correct?

A. No.

Q. Oh, that's not correct?

A. No. Because you're giving a basal insulin over a 24-hour period, whereas with Glargine insulin, and you're giving a basal insulin over a 24-hour period with short-acting insulin.

Q. Dr. Schatz, do you agree that using an insulin pump makes diabetes management easier in the sense that if your blood glucose level is high or you feel like eating, you figure out how much insulin you need and push a button. Correct?

A. Compared to what? And I said to you before, if you manage a person with diabetes such as Mr. Kapche, we anticipate, we compensate. We can do that either by programming it in and giving an injection, or we can dial it into the pump and we can give a bolus through the pump.

Q. So let's take MPH, because that might be easier for you. Do you agree that using an insulin pump makes diabetes management easier, as compared to MPH injection, and that if your blood glucose level is high, you feel like eating, just figure out how

much insulin you need and you push a button on a pump?

MR. GRIFFIN: Object to the relevance.

THE COURT: I'll allow it.

BY MR. GARDNER:

Q. Is that correct?

A. I would say MPH yes, and it depends on the kind of insulin you're working with. But overall, yes.

Q. And you mentioned this earlier. This whole advent of Glargine insulin really came up in the U.S. markets in 2002. Correct?

A. I think it's around then, yes, 2002.

Q. And --

THE COURT: You about through, Mr. Gardner?

MR. GARDNER: No, unfortunately I'm not. It's taking longer than I would have liked. Sorry. We can break for lunch.

THE COURT: We will break for lunch.

THE COURT: All right, Mr. Gardner. You may continue your cross-examination of Dr. Schatz.

MR. GARDNER: Thank you, Your Honor.

CONTINUED CROSS-EXAMINATION OF DESMOND SCHATZ, M.D.

BY MR. GARDNER:

Q. Welcome back, Dr. Schatz.

Dr. Schatz, you testified on direct examination that the government's expert, Dr. Crantz, failed to present a balanced view of the literature regarding the relative benefits between pump therapy and injection therapy. Do you recall that?

A. That's correct.

Q. Okay. And in fact, Dr. Schatz, you've identified 11 different studies that you believe support your conclusion, correct?

A. The reason for providing that group of studies was to fulfill a request, I think, by Dr. Crantz, that there wasn't much literature available at the time that he came to his conclusion. So, I did just an evaluation of the literature and I provided some of the studies which basically said that in fact there were studies that had confirmed the relative effectiveness of pump and insulin injection therapy.

Q. And that list of studies is accurately reflected right here in these 11 --
A. This is just a partial list of the very many studies that have been done.
Q. These are the 11 you identified?
A. That's correct.
Q. Okay. I would like to go through some of these studies with you, Dr. Schatz, if this stays up.
Now, as an initial matter, studies 3 and 4 that you identified are actually the same study, right?
A. Okay.
Q. So there's a duplicate here. We're down to 10 studies, right?
Is that correct?
A. Yes.
Q. Okay. And of those ten studies, numbers 5, 6 and 10 -- so 5, 6, and 10 are pediatric studies, correct?
A. Correct.
Q. They don't deal with adults with diabetes, correct?
A. That's correct.
Q. Okay. So 5, 6 and 10 --

By the way, Dr. Schatz, none of the studies you identify here deal with the relative benefits between pumps and injections in a law enforcement setting, correct?
A. There are no studies.

Q. There are no studies that do that, correct?
A. No. They're impossible to do.
Q. Why are they impossible to do?
A. For several reasons. Firstly, to do a study scientifically often requires a randomization. I could never randomize a person to a pump because I believe it's the wrong thing to do, number one. Number two is it's impossible to then switch in a situation a person from one therapy to another in a dangerous situation because the dangers are very, very different. And thirdly, a pump company would never do it because they realize that they may be lacking.
So this study has no chance ever of being done. So, I provided a list to show that in fact the insulins had been used and in fact there were studies that were done.
Q. And just to get this out of the way, of these 11 studies -- I guess 10 with the one duplicate that you identify -- none of these are done by pump manufacturers, correct?
A. One has to be very careful as to -- and you probably realize this -- as to how many of the studies in which investigators receive honoraria or in fact have spoken for the

companies. I haven't done an analysis, but I will tell you that there are some people on that list who do receive honoraria from pump companies.

Q. And because they receive honoraria, are they basically

shills for the pump; is that your testimony?

A. I certainly don't want to talk about that, but I would say, you know, there may be an element of bias.

Q. And just -- out of curiosity, of these ten studies you identify, can you point out for me who you think are the biased researchers that you've identified?

A. I would prefer not to do that.

Q. Well, I'm asking you. Unless, of course, none of them are biased and then that way, we can move on.

A. I think that as a group, I can't say that. But what I would say is I don't know which of the investigators have received honoraria for the people, so I can't say as individuals.

Q. Okay. So it's not your testimony -- I just want to make sure I understand this -- that of these 11 studies, any of these studies were performed by, conducted by shills for the pump companies, correct? That's not your testimony?

A. No. I think that each of them -- you know, when you write a paper or I write a paper, I say "supported by grants from the National Institute of Health" or "from the American Diabetes Association." I would have to look at each one to see

"supported in part by a grant from Medtronic" or supported in grant -- I haven't done that analysis.

Q. And by the way, of those studies related to children, study 6, this study right here, that study actually stated that

pumps provide a closer approximation of normal insulin profiles and increased flexibility regarding the timing of meals and snacks as compared to injections, correct?

A. That's what that paper says, correct.

Q. Okay. And you don't disagree with that, do you?

A. I -- well, again, we're back to what we talked about before. I personally disagree --

Q. Okay.

A. -- because, you know, there's papers and there are other papers which show that that's not correct.

Q. Okay. So, in other words, this, again, represents an example of you disagreeing with another researcher as to an issue that is subject to scientific dispute, correct?

A. Firstly, the answer to that is yes. And many of those are longer term effects on hemoglobin A1c and, as you point out, do not relate to an acute situation, a dangerous situation or Mr. Kapche's involvement in what, you know, he had applied for.

Q. Can you identify for me of those ten studies, again taking out the one for duplication, do any of these relate to the evaluation of pumps versus injections in a dangerous setting?

A. None.
Q. None of them do, right?
A. Correct.
Q. Okay. Now, study 6, by the way, also indicates that

pumps have been shown to result in improved metabolic control and reduced frequency of hypoglycemia, correct?
A. In that particular paper, correct.
Q. Now, of the seven remaining studies -- so we're down to seven now, correct?
A. Okay.
Q. Yes?
A. Okay.
Q. Okay. My math might be off. I need you to check me.
Of the seven remaining studies, two of them, numbers 3 and 11, are abstracts, correct?
A. Yes. Yes.
Q. Okay. And abstracts are not generally subject to peer review, correct?
A. It depends what you mean by "peer review." Let me give you an example of what peer review is.
I review and I have to select abstracts for several organizations, the Society For Pediatric Research, the Endocrine Society, American Diabetes Association. What happens is that the abstracts are sent to the reviewers. They're a group of six or seven reviewers. And in fact, what happens is they are rated

as A, B or C in terms of presentation or whatever it is. So, they have got some degree of peer review, but not in the sense of a publication such as that.

Q. Okay. And you don't know the extent of the peer review

for articles 3 and 11 on your list, correct?

A. That's correct.

Q. Okay. Now, I think we're down to about five or so, I think. Of the five remaining studies, Dr. Schatz, numbers 1 and 2 are after the FBI revoked Mr. Kapche's conditional offer, correct?

A. I'm just looking at the dates.

Q. I can give you the dates.

A. 2005 is the one that I -- 2005, yes. So two for sure. Number 1 is incorrectly printed.

Q. Okay. I just took it from what you gave us.

So, 1 and 2 were published after Mr. Kapche's conditional offer was revoked, correct?

A. Yes.

Q. So, the FBI could not have considered studies 1 and 2 at the time that it was considering Mr. Kapche for employment, correct, unless they had a way back machine.

By the way, study 1, actually concluded that pump therapy provides better glycemic control than injections using glargine, correct?

A. That is correct.

Q. Now, study 2 on this list noted that previous studies comparing pumps to injections in Type 1 diabetics found either comparable outcomes or actually favored pumps, correct?

MR. GRIFFIN: Objection to the misrepresentation of the

exhibit. He said Type 1. The exhibit says Type 2.

BY MR. GARDNER:

Q. All right. Dr. Schatz, do you know whether this study actually dealt with Type 1 and Type 2?

A. I'd have to read -- I want you to understand why I provided that list. I didn't provide this as the best articles. I didn't provide it in the sense of evaluating effectiveness. I provided it because the statement was made that there were very few, if any, publications that were done. I didn't look -- I could have provided several more publications and I'm sure I can still do that.

Q. But you didn't, correct?

A. I just provided a few.

Q. Just provided a few. And that's what we're talking about, just these few that you provided, based upon your expertise.

Am I correct, though, that study 2 noted the previous studies comparing pumps to injections in diabetics found either comparable outcomes or actually favored pumps?

A. Again, who have they been compared to? To patients on older insulins, NPH insulins; that is correct.

Q. Although you also just acknowledged that there are also studies on this list that even compare to glargine and pumps are found to be superior?
A. And again, it's a longer term outcome; that is correct.

Q. Okay. Now, on the three remaining studies -- and I hope my math is right here; yes, my math is correct; that's why I went to law school -- 7, 8 and 9 -- of those three remaining studies, study 7 concluded that pumps improve blood glucose variability when compared to injections using glargine, correct?
A. You have to show me.
Q. I'm sorry. I'm sorry. Number 7.
A. Yes.
Q. Okay. So that's another study that showed that the pumps were superior when compared to injections using glargine, correct?
A. I want to say yes, but I please want you to understand that there are studies and there are scientific regal in terms of how it is and how the study is done, who the physicians are, how the blinding is done, what outcome you want, who wants to do it. And I think you have to examine it. You can't just look at a title or look at a conclusion. It's the science that's involved.

It's like where do you publish? You know, don't say that the New England Journal is always the best, but where are they done? And I'm simply saying to you that you have to look at

this to be critical and evaluate.

But I don't disagree. Pumps are effective therapy. I don't disagree with that. But so are injections.

Q. I understand your view, Dr. Schatz. I guess I'm

asking -- you're not deliberately trying to put junk articles out there, right? These articles you identify are because they're rigorous, correct?

A. Well, I think there are many journals. I would say that overall, they are rigorous, but I would have to go back and perhaps sit down with you, individually read over it, look over the study design and pass an opinion as to how really good they are. But I would say to you that this is the information that I provided.

Q. Okay. Now, that's fair.

Study 7 also indicated that the absorption of quick acting forms of insulin that are used in a pump is more predictable than glargine, correct?

A. That's what that article said.

Q. Okay.

A. But I don't know if you know what you mean when you asked me that question.

Q. I think I know what I mean when I asked you the question.

A. Because you're comparing apples and oranges. First, it's injected into the abdomen and the abdomen is the quickest route of administration. Glargine is not always injected into the

abdomen. This is number one.

Number two, one is a long acting insulin. It's a 24-hour insulin, whereas the pump is a very short acting insulin, so I'm not sure that I understand what you mean by --

Q. Predictable?

A. -- by predictability.

Q. Well, did you read this article, Dr. Schatz?

A. I did, but I would have to refresh my memory as to what it is. But again --

Q. But the bottom line is in one of the articles that you identified, that article indicated that the insulin pump was more predictable than using injections with glargine, correct? That's just what the article said, correct?

A. I think it depends on how the multiple dose insulin injections were given. And I have to go back and ask the question: Was this done in anticipatory done [sic]? Did the person do this before a meal? Did they do it after a meal? Did they compensate? I would have to really go back in to answer that question.

Q. Okay. So -- but the bottom line -- I just want to make sure I understand: Whatever the basis may be for the conclusion, you agree that the conclusion was that an insulin pump was more predictable than insulin injections using glargine, correct? That's what the conclusion was?

A. In that particular set, yes.

Q. In one of the ten you cited?
A. Yes.
Q. Okay. Okay. Now, similarly, study 9 -- let me turn this around for you -- study 9, this one right here (indicating) by

Follman, study 9 indicated "as between pumps and injections that use glargine, pumps resulted in a significantly higher reduction in A1c levels," correct?
A. That's in that study.
Q. Okay. In fact, one of the pediatric studies that you cite to, number 10 here, which I'm not even going to pronounce that last name, number 10 said that "glargine is not the ideal basal insulin because it does not provide a variable basal rate and that the pump remains the only current method of providing the correct basal insulin supplementation on a physiological manner," correct?
A. That's what it says, but I disagree.
Q. Okay. But at least there is someone out there that does take the opposition, correct?
A. That is correct.
Q. And again, I guess, at the end of the day, Dr. Schatz, your conclusion is that reasonable scientists can disagree?
A. That is correct.
Q. Now, last few questions, I promise. I know we've been here a long time.
Dr. Schatz, you actually consider yourself a default pump

person, correct?
A. Yes.
Q. And by that, you mean you'll recommend pump therapy unless there's a good reason to use injection therapy?

A. That's correct.
Q. And you apply that default rule to both your adolescent patients and your adult patients?
A. At the individual level --
Q. Yep.
A. -- right. So if a person -- and this is a very interesting thing, is you have to understand the circumstances of the individual. The patient must want it, the family must want it if, in fact, it's a younger person over [sic] the age of 18. The financial situation -- it costs a lot of money to be on a pump. It cost $6,000 and a couple of hundred dollars per month in terms of having a pump. You've got to be able to be dedicated to checking your blood sugars on a regular basis. You have to anticipate. You have to compensate.

If the child and the family and the person don't want to give insulin injections anymore, then I say to themselves [sic], that's good, you do not need to give shots. We can give you a pump. For kids in particular who really don't want to give shots, I recommend that they do that.
Q. So, in other words, if the balance is like this (indicating) and there's no strong preference one way or the

other, as a default pump person, you would recommend pump?
A. Depends on the family, the person, and it depends on the situation. Again, if it's a football player, if it's a sportsman, I would probably not recommend a pump. I evaluate

the situation. I also look at the hemoglobin A1c. And if, for example, the A1c is 6.3 and they are really doing well, I would say do not switch current therapies.
Q. Sure. And all I'm saying is that at the end of the day, if everything else washes out in the mix and there's no real -- no opinion one way or the other, as a default pump person, you recommend the pump?
A. Because children particularly do not like injections.
Q. But again, you're a default pump person for children and adults, correct?
A. Well, most people don't like injections. But there are many people who don't want a pump because they don't want to carry around a pump.
MR. GARDNER: Your Honor, the government has no further questions.
THE COURT: Thank you.
MR. GRIFFIN: May I proceed, Your Honor?
THE COURT: You may.
MR. GRIFFIN: I expect to be done with this witness within 15 minutes, so if I get close to that, Your Honor, let me know.
THE COURT: It's your witness, counsel.

MR. GRIFFIN: Thank you, Your Honor.

REDIRECT EXAMINATION OF DESMOND SCHATZ, M.D.

BY MR. GRIFFIN:

Q. Dr. Schatz, were you asked about study number 8?

Dr. Schatz, I'm just going to move this over here so you can see it. I'm not going to get deep into the science here. But did Mr. Gardner ask you about study number 8?

A. No. He left it out.

Q. All right. Now, was study number 8 done by any scientists who were on the pay of a drug company or a pump company?

A. Knowing the senior author and having read that paper, there was no acknowledgment at all about any funding by industry in the study.

Q. Now, did you cite this study in your first report to the FBI?

A. I did.

Q. All right. And do you personally know the lead investigator of that study?

A. I do. And the senior author as well.

Q. What are the qualifications and expertise of those two investigators?

A. These are two of the leading authorities. In fact, there are three leading authorities in the field of Type 1 diabetes: Degauge, Peter Chase, Peter Gocci.

Q. And what is the brief conclusion of the whole study when it comes to this issue of pump versus glargine?
A. May I read the conclusion?
Q. You may.

A. "Similar glycemic control can be achieved with either pump or insulin glargine therapy without increasing hypoglycemic episodes. Based on the cost estimates" --

MR. GARDNER: Your Honor, I will object. He's summarizing.

THE WITNESS: It's three lines.

THE COURT: I think he can read it. Remember, he's an expert; he can rely on hearsay. And you certainly opened this door wide.

MR. GARDNER: That's fine.

THE COURT: Go ahead.

THE WITNESS: "Based on the cost estimates and the increased frequency of diabetic ketone acidosis for pump users, we recommend that MDI therapy using insulin glargine be routinely utilized prior to considering insulin pump therapy."

BY MR. GRIFFIN:

Q. Now, is the DKA referred to there done in situations that were not in challenging environments, such as zones of vigorous strenuous physical activity?
A. They were not.
Q. Is the risk for DKA higher in those situations than in

the controlled situations of the study?
A. Far higher.
Q. And are there any studies anywhere in the world that support the notion that pump therapy is safer and more reliable

than injection therapy in strenuous environments?
MR. GARDNER: Objection, lack of foundation.
THE COURT: Overruled.
BY MR. GRIFFIN:
Q. Now you --
A. Do I answer? I'm sorry.
Q. Yes.
A. Mr. Gardner had asked me that question and there is no study and there never will be a study. It's an impossible study to do.
Q. I'll briefly go through a few exhibits. I'm going to show you what's been marked as Defendant's Exhibit Number 2, about an agent that the FBI offered a job who was on the pump therapy. And he was --
MR. GARDNER: I'm going to object now. It's beyond the scope of Dr. Schatz expertise. He did not rely on it in offering his opinions. This was available to him at the time he issued his report, should he have chosen to consider it.
THE COURT: What's your response to that, counsel?
MR. GRIFFIN: He has not seen this document. The evidence this morning was that he asked a question about Mr. Kapche having

an isolated 203 blood sugar level. That's what I want to address.

THE COURT: I'm going to sustain the objection. You can move on.

BY MR. GRIFFIN:

Q. All right. When you were talking this morning, Dr. Schatz, with Mr. Gardner, would you please read the rest of the sentence that Mr. Gardner did not allow you to read in your report about the risk of pump failure as opposed to injection therapy.

A. "While the risk of pump failure is minuscule in the hands of a well-managed patient, there is no such risk with injection therapy."

Q. And has your position been, start to finish in this case, that the risk with injection therapy is less than that with pump therapy?

A. Far less. My opinion has not changed.

Q. All right. You were asked a number of questions about studies that show that pump therapy or injection therapy lower A1c values -- lower A1c values. Regardless of which therapy, did Mr. Kapche as an individual need to lower his A1c?

A. No. That would be very dangerous. Mr. Kapche's hemoglobin A1c average was in the low 6s. We're actually -- to give you an idea, we're actually revolve -- reassessing the diagnosis of diabetes and in fact his A1c, if we do adopt those

criteria, which are likely, would be in the nondiabetic range.
Q. Thank you. Let me -- last of all, last subject, I'm going to ask you to look at Defendant's Exhibit 43A.
MR. GARDNER: Sorry. That was defense Exhibit 43A,

counsel?
MR. GRIFFIN: Yes.
MR. GARDNER: What is it?
MR. GRIFFIN: A list of the essential functions.
MR. GARDNER: Your Honor, I'm going to object once again. Dr. Schatz record -- he did not consider this when he formed this opinion.
THE COURT: I don't know what the question is, counsel. I'm not going to sustain an objection to his looking at it.
MR. GARDNER: All right.
BY MR. GRIFFIN:
Q. Dr. Schatz, do you have that now before you?
A. I do.
Q. And have you reviewed it?
A. I have.
Q. In your experience and expertise as a physician, have you managed patients and treated patients in a variety of tasks?
A. Yes.
Q. For example, have you treated patients who have to push and pull?
A. Yes.

Q. And carry?
A. Yes.
Q. And perform manual labor?
A. Yes.

Q. In challenging environments?
A. Yes.
Q. All right. Is there any function on that list that you have before you --
MR. GARDNER: Objection, Your Honor.
THE COURT: I'm going to allow it. This is what this whole case is about. I don't -- I'm going to allow it.
BY MR. GRIFFIN:
Q. Is there any function on that entire list that a ban on injected patients has any connection to whatsoever?
A. So I just want to -- because I had to -- I've read it, and it asks questions about lifting, carrying, pushing, pulling, climbing, bending, stooping, squatting, walking, standing, jumping, crawling, sitting, carrying of firearms. There is no -- nothing that Mr. Kapche or otherwise in good control on injections could not do.
Q. So let me ask this question in a little bit different way: Is there any relationship with a ban on the one hand of all injected patients and those job functions?
A. Makes no sense.
MR. GARDNER: Objection, Your Honor.

THE COURT: Overruled.

BY MR. GRIFFIN:

Q. What was your answer?

A. Makes no sense at all.

MR. GRIFFIN: Pass the witness, Your Honor.

MR. GARDNER: Could I ask just one?

THE COURT: One or a few. Go ahead.

RECROSS-EXAMINATION OF DESMOND SCHATZ, M.D.

BY MR. GARDNER:

Q. Dr. Schatz, Defendant's Exhibit 43 that you were just looking at --

A. Yeah.

Q. -- that's not something you had at the time that you offered your opinion; is that correct?

A. That's correct.

MR. GARDNER: No further questions.

MR. GRIFFIN: I don't have any redirect, Your Honor.

THE COURT: Doctor, thank you. That completes your testimony. You're excused.

THE WITNESS: Thank you.