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Over-The-Counter Options for Diabetics

### OVER-THE-COUNTER TREATMENTS AND NEW THINGS ON MARKET FOR DIABETIC

Each month Reach MD XM 157 presents a special series. This month is Focused on Diabetes. Listen each hour at this time as we explore with America's top medical thought leaders for latest information on diabetes.

Diabetes has become such a worldwide epidemic that some are turning to over-the-counter products as the way to help patients with the disease that has inflicted nearly 24 million in the US alone. Welcome to a special focus on diabetes on ReachMD. I am Bruce Japsen, the healthcare reporter at the Chicago Tribune and with me today is Dr. Gerald Bernstein, who is the Vice-President of Medical Affairs at GenereX, the biotechnology company based in Toronto working to develop new products to treat diabetes. Dr. Gerald Bernstein is the former President of the American Diabetes Association, who still serves on many ADA committees and groups today. He is currently Vice-President of Medical Affairs at GenereX where he has been working to win US approval of the company's flagship product, an oral insulin, that's already approved in 2 countries around the world. Dr. Bernstein is a graduate of Dartmouth College and Tufts University Medical School and is board-certified in endocrinology and metabolism. He is an associate Clinical Professor at the Albert Einstein College of Medicine in New York and an attending physician at Beth Israel Medical Center, also in New York. He joins us today from his office in New York.

### BRUCE JAPSEN:

Dr. Gerald Bernstein, welcome to Reach MD XM 157, The Channel for Medical Professionals. It's an interesting period that we are in healthcare because diabetes is just this epidemic if you will and GenereX is working on several different products, but some of the interesting things already on the market are some over-the-counter treatments. Now, if you could give us a little background on that and also tell us why these are important because people are entering diabetes at various stages of the disease and they are not all just using prescription products, are they?

### DR. GERALD BERNSTEIN:

No and there are variety of items that are put out from the alternative medicine sector that whether it's different metals or vitamins that suggest that they may be of advantage of diabetes, but for the most part there is no data to back that up. What happened with GenereX is in a brainstorming session, we started looking at what are the inhibitors to people taking insulin, and both from significant major scientific studies and from anybody's clinical experience, one of the greatest inhibitor beyond the fact that someone has to penetrate your skin with a needle is the fact that insulin in many people results in low blood sugar. And if you have experienced a true low blood sugar reaction from an excess of insulin, it is not only dangerous thing, but even in its mildest form can be a very discomforting and life altering in terms of quality of life event. And, we said well, when you put back glucose to reverse the low blood sugar, what's available

and the fact is that almost all of the available items that are sold over-the-counter are gels, tablets, etc., are very, very high doses of glucose and what happens in most people is that they overdose and therefore they get their sugar back to normal, but as they have taken so much that very soon their blood sugar is now escalating to very high levels and that becomes very disturbing to them because they then suffer the consequences of having a blood sugar of 300 or 400, which makes them feel badly, they then take more insulin to try and bring that down. And, it's apparent that if someone really gets a dangerous situation, they have to take a large amount. But, for many people, they know when their blood sugars are going to drop. They get a buzz, they get a signal.

**BRUCE JAPSEN:**

Do they know exactly how much that they need?

**DR. GERALD BERNSTEIN:**

They can learn that and that's part of what it's all about of this relatively simple product that we developed. What we did was put glucose with the same excipients that we use with insulin to help it penetrate the lining of the mouth. We put glucose into solution and it's called Glucose RapidSpray, so that an individual can learn from clinical experience just as they learn how much insulin they need, how much glucose they need to stop the glucose dropping, and what's even equally important to stop the adrenalin reaction, which creates an hour of misery and it's been out there for a couple of years. The entire container has about little more than 8 g and 5 puffs gives you 400 mg. Most of the replacement tools for low blood sugar are in the order of 4 or 5 g and that's why the sugar goes up so high.

**BRUCE JAPSEN:**

And, how long has this product been on the market because a lot of people might not know about these things, I mean, if somebody thinks about their grandfather, who always use to keep a Snicker bar in his pocket. I mean, that type of thing is not out of realm of what some people are using out there.

**DR. GERALD BERNSTEIN:**

That's right and they love it because one of the only positive thought of having a low blood sugar is that you have a whole bunch of Snicker bar, you know you are savoring the Snickers, but you are doing it mentally because you think that you are getting your blood sugar back and therefore it's okay, but invariably ends up in the overshooting with the blood sugar. Glucose RapidSpray came on the market in June 2006, and has slowly won over a good part of the diabetes educator community, as we found out at our booth at the diabetes educator's meeting this August. The people who came up and raved about the experience with it because what they found, which is what we thought they would find, and what one of our scientific studies showed was that by using the glucose spray in moderated amounts and again people determined what they need that their pathway of normalizing their blood sugar is smooth and what they are actually doing is dosing glucose replacement. It is not arbitrary. It is not throwing the kitchen sink when you only need perhaps the equivalent of a cup and so people find that they don't need 5 whereas they may need a gram. They need a gram and a half or half a gram. So, it's different for everybody they find out what they need and then they can begin to use it on preventative phases. Dr. Pizzoli in Italy along with a group at the Pediatric Endocrine Center in Moscow studied a group of children under the age of five with type 1 diabetes. Half of the group, the mothers were instructed just do what you always do. When you recognize that your child's blood sugar is dropping give them juice, whatever it is that you usually do, continue to do this and this went on for six months or more. In the other group, the mothers were instructed to apply to the child's mouth. At that time, I think they were using 10 puffs from the viola and that was an earlier iteration. So, it was about 400 mg and the mothers did that rather than again juices and foods and stuff. At the end of 6 months, there were two things that came out of it. One, the quality of life was much better. Two, the A1c hemoglobin, the ultimate measure of diabetes control actually dropped a little bit because these children using the Glucose RapidSpray did not have the extraordinary peaks that was associated again with the kitchen sink approach. And when I discussed this with a lot of pediatric

endocrinologists that are leading this year, they said the greatest value that they could see was not only for the child, but for the mother. Because the mother now is self-empowered that she was in control of what the child was getting rather than the arbitrary nature of just giving them everything.

**BRUCE JAPSEN:**

Well, that's interesting doctor and you said this product has been around June 2006. What other products does Generex have that are out there because I know that based in Chicago I have read a lot about Abbott laboratories and then there is also Mead Johnson and they have, you know, your nutrition bars and so forth, but it seems that Generex is looking at a different way to help diabetics with actually sort of substituting you know the juices and the bars and so forth and giving someone something that actually would look like a medical product.

**DR. GERALD BERNSTEIN:**

There are a couple of other things. We have modified the Glucose RapidSpray into a product called Gluco Break for people, who exercise and I run and I carry it with me when I run, and if I feel that I need a little boost during it, I can take, you know, five puffs or something and it's a very easy delivery system.

**BRUCE JAPSEN:**

It's fat free if I understand it.

**DR. GERALD BERNSTEIN:**

Yes.

**BRUCE JAPSEN:**

That would have a certain appeal and it's predominantly for diabetics or is it for other people as well?

**DR. GERALD BERNSTEIN:**

Anybody could use that, I mean anybody could use both of them because it is just replacing glucose. What is unique is that in many people the glucose is going to be get absorbed through the buccal mucosa and therefore may enter the blood stream a little earlier and therefore give a quicker benefit. But, let me qualify that Glucose RapidSpray is not a rescue item. For people who have severe hypoglycemia, this is not what they should use. They need the big doses and they need an injection of glucagon, but for people, and that is the majority, who have these mild, but disconcerting episodes of low blood sugar, Glucose RapidSpray is probably the most efficient and clean way of replacing glucose, shutting down the adrenaline reaction that creates this body misery and preventing excessive rises in blood sugar.

**BRUCE JAPSEN:**

And also doctor, where can physicians tell their patients about this, I mean a Glucose RapidSpray, I mean it has only been in the market since June 2006, is it something that you can find at a CVS or at Walgreens?

**DR. GERALD BERNSTEIN:**

It's in Walgreens, Rite Aid, and at a couple of dozen pharmacies throughout the US and Canada. You can get it from Amazon. I happened to look it up one day and there it was.

**BRUCE JAPSEN:**

And also, how are the sales going. I mean, is it, and also are there competitor products out there because this would seem to be a market that's growing and when you consider the poor economy and people looking for all sorts of quick and simple options that this would seem to have a potential market.

**DR. GERALD BERNSTEIN:**

The market is enormous and I am not in any way a financial person with the company. I know that the product is showing extremely well, not only here, but in the couple of other places around the world because as the more people who finds benefit from it, they then pass the word on to their own doctors, to their educators or the educators to them, and therefore word of mouth if nothing else, has been extremely valuable because of the satisfaction with the product.

**BRUCE JAPSEN:**

With that I would like to thank Dr. Gerald Bernstein who has been our guest. He is with the company called Generex and we have been talking about over-the-counter treatments and some of the new things that this company and others have on the market for diabetics. This is a huge problem in this country. Physicians and their patients will be finding out more about these options for patients and I would like to thank him again for joining us from his offices in New York.

I am Bruce Japsen, the healthcare reporter at the Chicago Tribune. I have been your host and you have been listening to ReachMD, The Channel for Medical Professionals. If you have comments or questions about today's show, please call us at (888 MD-XM157) and I would like to thank you today for listening.

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