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October 12, 2006

ELECTRONIC SUBMISSION

Marlene H. Dortch, Secretary
Federal Communications Commission
445 12th Street, S.W.
Washington, D.C. 20554

Re: ET Docket No. 06-135
RM-11271
Ex Parte

Dear Ms. Dortch:

This is to inform you that, on Wednesday, October 11, 2006, in connection with the above-referenced docket, George Valdes and Jake Leach, of Dexcom, Inc., and the undersigned, met with Julius Knapp, Bruce Romano, Karen Rackley, Geraldine Matise (by telephone), Alan Stillwell, and Jamison Prime, all of the Office of Engineering and Technology. The purpose of the meeting was to discuss the Commission's NPRM in the above-referenced proceeding. A copy of the presentation that was provided is attached hereto.

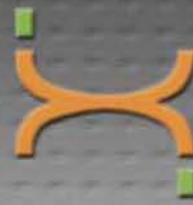
Please direct any questions regarding this matter to the undersigned.

Respectfully submitted,



Henry Goldberg
Attorney for Dexcom, Inc.

cc: Julius Knapp
Bruce Romano
Karen Rackley
Geraldine Matise
Alan Stillwell
Jamison Prime



Dexcom

Technologies for Diabetes Care

DexCom Comments on NPRM October 11, 2006



Meeting Objectives

- Diabetes Overview
 - Largest Chronic Disease State in the U.S.
 - Goal of Normalizing Glucose Levels
 - Limitations of Current Monitoring Technologies
- Overview of DexCom™ STS® Continuous Monitor
 - Superior Patient Outcomes
 - National Availability
 - Strong Patient and Political Support
- Problems with Proposal to Reduce Output Power
 - Low Probability of Interference
 - Interference Mitigation
- Conclusion

Diabetes: Largest Chronic Disease State in the U.S.

2005 U.S. Diabetic Population

Millions of Patients

6.2

14.6

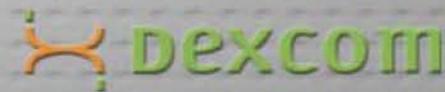
Diagnosed

Undiagnosed

- Increasing prevalence of diabetes
- 1.5 million new cases of diabetes diagnosed in 2005

- Diabetes related costs expected to grow from \$132 billion in 2002 to \$156 billion in 2010

Source: Center for Disease Control, the American Diabetes Association



The goal of all diabetes management is to normalize glucose levels

NORMAL

LOW

HIGH

Hypoglycemia

- Loss of consciousness
- Diminished cognitive function
- Potential death

Hyperglycemia

- Blindness
- Kidney failure
- Amputation
- Cardiovascular disease
- Nerve degeneration

Current monitoring technology has limitations

Inconvenient/Indiscreet

Limited/Static Information



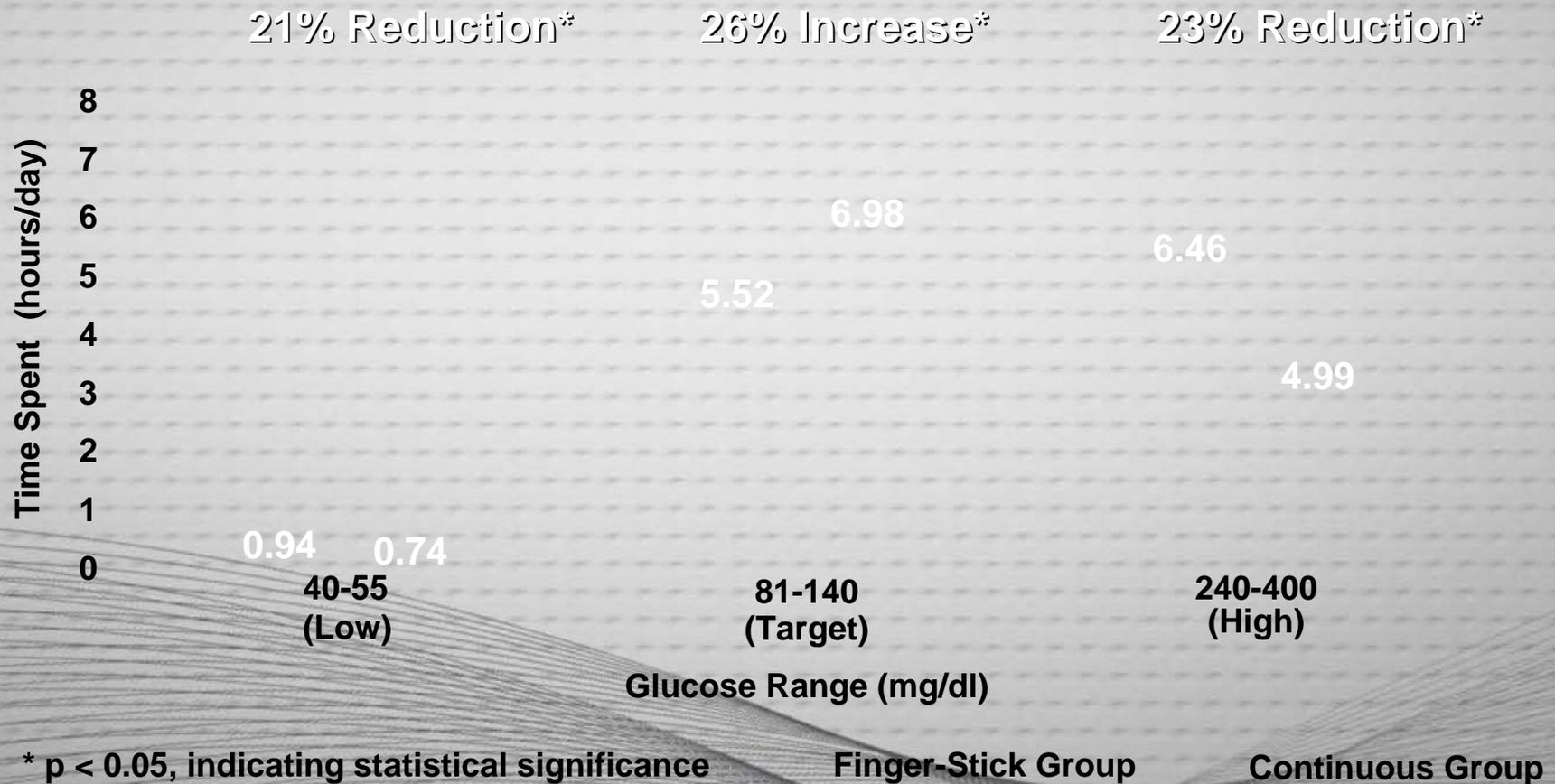
Intensive management using current monitoring technologies, even in landmark trials like DCCT, has failed to achieve normal glucose control or A1c levels

Intensive management using current monitoring technologies increases the risk of hypoglycemia

DexCom STS[®] System



Results from a two-arm, randomized, prospective trial demonstrate CGM is superior to finger-sticks in normalizing glucose



Published in *Diabetes Care*, January 2006

DexCom STS[®] in National Launch

- Technology is diffusing rapidly and is currently available on the national market
- DexCom began nationally marketing its STS[®] device on March 28, 2006 immediately following notification of FDA approval

Strong Patient Support....

- **The Busy Professional**

In the first 14 days, I have challenged it [the DexCom™ STS® System] by working full time, spending a week on the road traveling for work, eating at restaurants, and living alone in a hotel — which is a great environment to stress any Type I's management skills. I have exercised heavily in that I have been to the gym on numerous occasions and worked weights, and a treadmill. I have also played two rounds of golf. My first impressions are very favorable in that I have no discomfort whatsoever, from the device on my abdomen, which was my single apprehension.
-- Jim in New Jersey

- **The Trend Tracker**

This product has been a life saver! I have been amazed on how accurate it is and its' ability to alert me in advance of a trending up or down. There is a lot of information I have learned on how my body reacts to certain foods. I think anyone who is diabetic, should have one of these... the DexCom™ [STS® System] takes all this into account and gives you a more accurate trending and level. You do have to calibrate twice a day. But, the information you get from the DexCom will help a diabetic lower the A1C and manage diabetes better. I hope this helps anyone that is on the fence and thinking about it. -- **Greg in Texas**

- **The Life Changer**

I am really thrilled about this. I have been out of control for a while, but this has me feeling hopeful about my diabetes for the first time in a long time! I'm ready!! Thank you!!! Thank you!! Thank you!! -- **Cindy in Texas**

...and Strong Political Support

Congress of the United States
Washington, DC 20515

May 16, 2006

Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

Dear Secretary Leavitt:

We are writing today about new technological developments that have the potential to greatly improve the quality of diabetes care and prevent deadly and costly complications such as blindness, heart attacks, kidney failure, and amputations.

As you are well aware, diabetes is a costly and debilitating disease. Nearly 21 million Americans have diabetes, and one in three American children born today will develop the disease. Thirty two percent of Medicare expenditures are spent on people with diabetes, and in 2002 diabetes-related costs totaled \$132 billion nationwide. Diabetes is the leading cause of kidney failure and adult-onset blindness. Diabetes increases the risk of heart attack deaths by two to four times, and causes more than 80,000 amputations each year. People with diabetes are also at risk for seizures, comas, and sudden death. Quite simply, current diabetes care is not meeting the challenges of this growing epidemic.

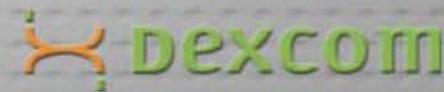
Recent research confirms that current diabetes technology is inadequate. For example, a study by Bode et. al. published in *Diabetes Care* last year found that patients who were intensively managing their disease – measuring their glucose an average of nine times a day – spent less than 30 percent of the day in normal glucose range. The rest of the time their glucose was either too high (which can cause eye, heart, kidney, and nerve disease), or too low (which can cause seizures, comas, and death).

Fortunately, there are new technologies on the horizon that hold great promise in improving health outcomes of people with diabetes. These technologies, known as continuous glucose sensors, appear to enable people with diabetes to continuously monitor their glucose levels and use that information to ward off deadly highs and lows by taking insulin or eating carbohydrates. One recent study by Garg et. al. published in *Diabetes Care*, found people with diabetes using continuous glucose sensors spent 26 percent more time in normal glucose range, and research presented at the European Association for the Study of Diabetes and Diabetes Technology Society meetings last year found people using these sensors have statistically significant improvements in HbA1c levels, an important measure of glucose control.

Within the Department, both FDA and CMS will play an important role in determining the availability and accessibility of continuous glucose sensors. In fact, FDA has approved at least one such device and others are under review. We are very pleased that both FDA and CMS have

PRINTED ON RECYCLED PAPER

- May 2006 – two letters signed by 68 Senators and 241 members of the House sent to HHS in support of CGM technologies
- September 2006 – additional letters from the Congressional Diabetes Caucus sent to CMS in support of CGM technologies



Proposal to Reduce Output Power Will Render DexCom STS Unusable by Patients

	Current MICS Design	Proposed MedRadio Design
Receiver Noise Floor	-97dBm	-97dBm
Receive Antenna Gain	-2dBi	-2dBi
Required SNR	14dB	14dB
Fade Margin	10 dB	10 dB
Excess Loss (Polarization, obstructions)	15 dB	15 dB
Body Absorbption	4 dB	Accounted for in EIRP Test
EIRP	-20 dBm	-36 dBm
Allowable Free Space Path Loss	32 dB	20 dB
Useful Operating Range	7.5 ft	1.9 ft

- Reducing the output power of the DexCom STS transmitter would dramatically decrease the effectiveness of the system. To require patients to keep the handheld receiver less than two feet from the body worn transmitter to ensure reliable communication is not realistic
- Other devices like DexCom's which utilize miniature transmitters and receivers will have similar difficulty operating at a reduced output power

Transmit Frequency Results in Low Probability of Interference by DexCom STS

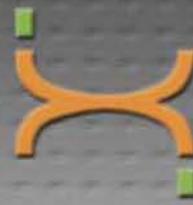
- The DexCom STS system currently operates at a single fixed frequency of 402.142MHz
- The duty cycle of the DexCom STS transmitter is 0.003%
- Transmitting on a single fixed frequency with ultra low duty cycle make interference with other devices extremely unlikely

Interference Mitigation

- Mitigation at LBT device level will prevent unlikely interference from creating a patient hazard
 - Retransmission of missed packets
 - CRC checks with error correction
 - Device fail-safe will maintain operation in the event of a communications failure
- Mitigation for non-LBT devices
 - Device will continue to operate correctly with missed packets

Conclusion

- Transmit frequency
 - DexCom STS presents a minimal interference risk on MICS band
- Transmit power
 - DexCom STS requires the maximum power approved under the current waiver to operate within a practical range
- The nature of the MICS band requires that devices include mitigation
 - LBT mitigation techniques will virtually eliminate harmful effects of interference
 - Non-LBT devices will continue to operate properly with missed packets



Dexcom

Technologies for Diabetes Care

