

Before the  
**FEDERAL COMMUNICATIONS COMMISSION**  
Washington, D.C. 20554  
and the  
**FOOD AND DRUG ADMINISTRATION**  
Rockville, MD 20852

In the Matter of	)	
	)	
Federal Communications Commission	)	
and Food and Drug Administration	)	FCC Docket No. ET 10-120
to Hold Public Meeting on Regulatory	)	
Issues Arising from Health Care Devices	)	FDC Docket No. FDA-2010-N-0291
That Incorporate Radio Technology	)	
Wireless Communications Networks;	)	
Comments Sought	)	

**COMMENTS OF DEXCOM, INC.**

DexCom, Inc. (“DexCom”), by its attorneys, hereby provides comments on the joint request for comments (“Request”) of the Federal Communications Commission (“FCC”) and the Food and Drug Administration (“FDA”) on the convergence of communications and health care devices, and specifically on developing a forward-looking regulatory scheme for medical devices that use wireless communications.

**INTRODUCTION**

DexCom manufactures SevenPlus, a highly effective continuous glucose monitoring (“CGM”) system that operates on the unlicensed 402-405 MHz medical band. These devices continuously monitor interstitial blood glucose data and periodically transmit such data to an external handheld receiver.

*The Benefits of SevenPlus*

Everyday in the United States:

- 1 in 3 children born will develop diabetes;

- 4,100 people will be diagnosed;
- 55 people with diabetes will go blind;
- 230 amputations will be performed;
- 120 diabetics will enter treatment for kidney failure; and
- 1 in 10 healthcare dollars is spent treating diabetes.

In 2007, poor control of diabetes resulted in \$174 billion in total costs due to chronic complications, diabetic care, and indirect costs. The average medical expenditure for people with diagnosed diabetes was 2.3 times higher than what the expenditure would be in the absence of diabetes.<sup>1</sup>

Studies have shown that the DexCom system is highly effective in allowing diabetics to manage their blood glucose levels and thus avoid the terrible complications of diabetes. The medical community values DexCom's system because of the clinical advantages resulting from CGM.

DexCom's sensors measure a patient's glucose level every five minutes, allowing diabetics to react quickly to changing glucose levels and maintain far more consistent glucose levels than with other methods. Studies have shown that use of the CGM provided significant improvement in glycemic control as compared to patients not using CGM, thereby enabling them to avoid many of the serious complications of the disease. DexCom participated in a large clinical study with the Juvenile Diabetes Research Foundation ("JDRF") to show the benefits of CGM, and JDRF subsequently announced that patients who used CGM devices for at least six days per week achieved significant reductions in HbA1c levels, the most widely accepted indicator of long-term

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<sup>1</sup> See *Economic Cost of Diabetes in the U. S. in 2007*, American Diabetes Association; CDC Diabetes Factsheet (2007); N.R. Klinefeld, *Diabetes and its Awful Toll Quietly Emerge as a Crisis*, N.Y. Times, Jan. 9, 2006.

glucose values in the blood.<sup>2</sup> As a result of large medical studies demonstrating superior clinical outcomes using CGM compared to traditional “fingerstick” methods of managing diabetes, DexCom is extremely confident that CGM will continue to gain rapid acceptance within the medical community. Today, nearly all commercial insurers in the United States recognize the value of CGM. As clinical practice migrates to more cost effective methods of practicing medicine (*e.g.*, remote transmission of medical information), there will be increased value in CGM and easy to use remote monitoring.

DexCom also has partnered with two insulin pump manufacturers, Animas Corp (a Johnson & Johnson Company) and Insulet, to develop integrated systems that combine CGM technology with insulin pumps. These devices give diabetics the ability to better monitor and control their glucose levels, providing greater ease of use for patients.

#### *The Future of Continuous Glucose Monitoring Devices*

DexCom plans to migrate off of the 402-405 MHz band, and is designing a second generation device that will operate on the 2.4 GHz band, which is shared with WiFi. These second generation devices will feature a uni-directional 2.4 GHz receiver, custom handheld device, and the option of an integrated receiver/insulin pump. DexCom’s future vision is for bi-directional devices that could transmit not only to DexCom’s custom handheld receiver and integrated receiver/insulin pump devices, but also to smartphones, PDAs, and other such mobile devices.

## **DISCUSSION**

The Request notes that smartphones and other mobile devices are playing a larger role in health care solutions. These comments will focus on two topics: 1) security and reliability when using unlicensed spectrum, and specifically with regard to

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<sup>2</sup> See JDRF Continuous Glucose Monitoring Study Group, *New Eng. J. Med.* 359(14):1464-1476 (2009); Robert Tomsho, *Adult Diabetics Benefit from Device, Study Says*, *Wall Street Journal*, September 9, 2008, at D2 (discussing results of the JDRF study).

continuous glucose monitoring communications; and 2) future regulatory issues stemming from the use of smartphones, PDAs, and other mobile devices in conjunction with the transmission of medical data.

DexCom notes that two types of wireless networks are involved in its medical communications: Sensor Area Networks (SAN), which provide a limited range wireless transmission between sensors and handheld devices, and cellular networks, which handle wireless transmission between handheld and cellular network. These comments will focus only on the use of SAN over unlicensed spectrum.

#### *Medical Device Needs, Goals and Stakeholders*

The Request seeks information on the identification of the needs, goals, and stakeholders involved in wireless communications from medical devices. In DexCom's view, there are three needs that must be met by its system and other like it. These are: 1) secure transmission and reception; 2) reliable transmission and reception; and 3) data integrity during transmission and reception. DexCom's goals are secure and reliable communications for Continuous Glucose Monitoring, and in its view the stakeholders are the patients, medical providers and payers, and medical device manufacturers.

#### *Security and Reliability*

With regard to secure transmission and reception, DexCom's first concern is avoiding inadvertent and intentional intrusion. The risk of this occurring is similar to applications that transfer credit card transactions, stock trades, etc., over WiFi, and the solution is to use proven encryption techniques. DexCom's next concern is reliable transmission and reception. This risk also is similar to applications that transfer data over WiFi networks, and numerous techniques already exist to guarantee reliable communications, such as re-transmissions and time outs. DexCom's third interest is maintaining data integrity during transmission and reception. The risks here also are similar to applications that transfer data over WiFi networks. Numerous techniques already exist to guarantee data integrity, including framing patterns, CRC checks, and bit error checks.

Overall, existing technologies are sufficient to ensure secure and reliable transmissions of medical information. DexCom does not see the need for “medical-grade” wireless technology and communications, given that many standard communication applications face the same risks and have addressed the risks with standard RF techniques. The medical community should leverage technology already defined, implemented, and tested through the various standards of the data and telecommunication industry. Standards and protocols are already in place to address wireless data applications that require a high level of security, robustness, and data integrity. This is proven technology, with off-the-shelf components. Using this standard equipment also will help in future medical device development in terms of interoperability. Additionally, standards and protocols are already in place or close to finalization to directly apply data telecommunications standards to medical device applications. These include Bluetooth SIG Health Device Profile and ANT+ Blood Glucose Monitoring Device Profile.

The alternative is for medical device companies to develop this technology organically, which would equate to several years of R&D with similar results while delaying the benefits these applications will provide to patients and the health care industry. In DexCom’s view, there is no need for this.

#### *The Future Regulatory Environment*

As more medical applications are being created for or moved to displays on smartphones, PDAs and other mobile devices, everyday non-medical devices become “channels” for medical devices. DexCom questions when the line between FCC and FDA regulatory authority will be crossed. Regulating these everyday devices as “medical devices” under FDA authority would undermine FCC authority to regulate general-purpose communications devices, and would create additional unnecessary regulatory approval processes for medical device manufacturers. And, putting these devices under FDA authority would hamper advancement of wireless medical devices,

as no smartphone or similar device manufacturer would want to come under the regulatory purview of the FDA.

Mobile devices like smartphones and PDAs should be viewed as secondary display devices, subject only to ordinary FCC regulations for wireless devices. Alternatively, the medical data transmitters installed in the body worn or implanted sensors could be viewed as the "medical device," subjecting just those transmitters to both FDA and FCC regulatory authority. Additionally, the software application ("app") that provides for communications between smartphones/PDAs and the medical devices could be placed under FDA authority, similar to today's PC programs that communicate with medical devices.

### CONCLUSION

DexCom believes that existing communications technologies can be utilized for secure and reliable medical data transmissions. And, in terms of regulating smartphones and other everyday devices that operate merely as "channels" for medical devices, DexCom recommends that the FCC and FDA tread lightly and regulate these devices no more than the ordinary mobile communications devices.

Respectfully submitted,

DEXCOM, INC.



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