

**Testimony of the Endocrine Society
Submitted to the
Food and Drug Administration
Clinical Chemistry and Clinical Toxicology Devices Panel
July 21, 2016**

My name is Nicholas Argento. I am a clinical endocrinologist and the Diabetes Technology Director at Maryland Endocrine and Diabetes, in Columbia, MD, and am representing the Endocrine Society.

The Endocrine Society is the world's largest professional organization of endocrinologists, representing the interests of over 18,500 physicians and scientists engaged in the treatment and research of endocrine disorders, including diabetes. I have had 10 years of experience in actively managing hundreds of T1D patients using Dexcom CGM, have performed 3 published research studies on CGM, and have personally used a Dexcom CGM full time for the last 10 years.

The Endocrine Society believes that CGM is lifesaving technology that is yet another tool to help people with diabetes effectively manage their disease. Approving this application will provide people with diabetes greater flexibility in their day-to-day management, which is why I am here today on behalf of the Endocrine Society to testify in strong support of Dexcom's application. Our support is based on the following reasons:

First, Dexcom CGM has been proven to be accurate enough to allow direct treatment, with a MARD of 9%, 8% by day 3, and enables patients to make safe and timely treatment decisions. Egregious errors with Dexcom CGM are rare, and generally evident to the individual at the time.

Second, patients are already making real time treatment decisions based on their CGM data without fingerstick verification, and doing it effectively and safely. I use Dexcom CGM to help manage my diabetes and often make real time treatment decisions without fingerstick verification, as do over half of my patients. I do not recall any instances where I or a patient ended up having adverse outcomes as a result. They do this not because they are lazy, or non-compliant; patients often have no practical choice but to act on the information offered by a highly reliable Dexcom CGM right now, without verification, in order to deal with the many challenges offered by hyperglycemia, and more importantly, the short term risk of potentially life threatening hypoglycemia. Indeed, The European Union has already sanctioned direct treatment.

Third, doing proper and accurate fingerstick verification is often highly impractical if not impossible in the workplace, and doing so could put others in danger of exposure to blood products. Punctured fingers frequently ooze blood unpredictably, sometimes for

several minutes or more. Next time you are in Starbucks, ask yourself what the person making your coffee should do if they are using a Dexcom and it alarms that they are low. Would you like a spot of blood with that Latte?

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Proper fingerstick technique also means removing contaminating substances like food or creams that can lead to highly erroneous falsely high results, and even a small amount of moisture can lead to falsely low results. I see examples of highly erroneous results of fingersticks on meter download on a nearly daily basis. Examples of large fingerstick errors are shown.

Finally, patients need guidance on using unverified CGM data safely and effectively. FDA's approval of this change would enable Dexcom to offer patient support and education on the best ways to use unverified CGM data in real time. It would also allow clinicians to offer cogent advice on how to use the data safely and effectively without verification and for Dexcom to offer appropriate support to clinicians around this important topic.

For all these reasons, the Endocrine Society supports Dexcom's application for a direct treatment indication. Thank you again for allowing me to speak to you about this important issue.

Examples of egregiously erroneous fingerstick results

5 PM	5 PM - 7 PM	7 PM - 10 PM	10 PM - 12 AM
			48
			10:02 PM
			546
			10:41 PM
			198
			10:42 PM

washed hands

			HIGH
			8:42 PM
			123
			8:44 PM
			146
66			9:13 PM
6:34 PM			84
			7:53 PM

moisturize

9 AM	9 AM - 11 AM	11 AM - 2 PM	2 P
			23
			11:17 AM
			59
			11:18 AM
			135
			11:19 AM
			134
			11:19 AM

wet fingers

			28
			7:27 AM
			257
			7:28 AM
			47
			3:25 PM
			95
			6:54 PM
			167
			3:26 PM
			252
			11:40 AM
			194
			1:00 PM

Dexcom correct, SMBG incorrect

