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April 1, 2015

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VIA ELECTRONIC FILING

Ms. Marlene H. Dortch
Secretary
Federal Communications Commission
445 12th Street, S.W.
Room TW-A325
Washington, D.C. 20554

Re: Notice of *Ex Parte* Presentation, ET Docket Nos. 10-236 and 06-155

Dear Ms. Dortch:

On March 30, 2015, Charles Farlow, Program Director, Regulatory Affairs of Medtronic, Inc. (“Medtronic”), accompanied Nancy Victory and me from Wiley Rein, LLP, counsel for Medtronic, to meet separately with Renee Gregory, Legal Advisor to Chairman Wheeler; Louis Peraertz, Senior Legal Advisor to Commissioner Clyburn; Jessica Delgado Argeris, Senior Legal Advisor to Commissioner Rosenworcel; Brendan Carr, Legal Advisor to Commissioner Pai; and Erin McGrath, Legal Advisor to Commissioner O’Rielly, to discuss Medtronic’s Petition for Reconsideration in ET Dockets 10-236 and 06-155 concerning changes to the rules that regulate the Experimental Radio Service. Specifically, Medtronic discussed the importance of full and fair eligibility of medical device manufacturers for the Medical Testing License, as well as the need for clarification of the cost reimbursement rules for clinical trials.

Medtronic expressed its support for the new Medical Testing License, which was adopted in the *Report and Order* in the above-captioned proceedings, as a mechanism for permitting more flexibility in to conduct FDA-approved clinical trials of the equipment before obtaining FCC equipment certification. However, currently eligibility for this license is limited to “health care facilities” and excludes traditional medical device manufacturers like Medtronic. This restricted eligibility creates substantial competitive inequity given that a number of health care facilities also are device manufacturers and operate in direct competition with device manufacturers that do not also own health care facilities.¹ As a result, a device created by a manufacturer that is also a health care facility would be eligible for operation under the Medical Testing License, while a similar device created by a

¹ Medtronic invests over \$300 million to support clinical trials each year.

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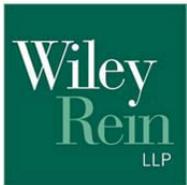
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traditional device manufacturer like Medtronic would require FCC authority through another type of experimental license that would not be as flexible. Such disparate treatment of similar devices made by competing manufacturers makes no sense and would be contrary to the public interest. Accordingly, Medtronic urged that eligibility for the Medical Testing License be broadened to include all manufacturers of medical devices that can demonstrate that they are authorized by the FDA to conduct the trial, that they will have control over the devices throughout the trial (including the ability to shut off interfering devices), and that they meet other eligibility criteria necessary to demonstrate their bona fides and responsibility.

Medtronic explained that other types of experimental licenses, such as the Conventional Experimental License and the Program Experimental License, do not offer the same flexibility to conduct clinical trials as the Medical Testing License. For example, Program Experimental Licenses may not be issued for operation on frequencies listed in Section 15.205 of the rules, which includes the 401 – 406 MHz Medical Device Radiocommunications Service (“MedRadio”) band often employed by makers of implanted and body-worn medical devices. In addition, Program Experimental Licenses and Conventional Experimental Licenses are limited to “defined geographic areas,” which is impractical for testing body worn medical devices (e.g. insulin pumps) and implanted devices (e.g. pacemakers, defibrillators and cardiac diagnostic devices) as patients participating in clinical trials are encouraged to return to their daily lives, which includes returning home, going to work and traveling. This geographic limitation may also require multiple applications for a clinical trial conducted in multiple locations (as is common with such trials).

Finally, Medtronic discussed the need to clarify that end users may reimburse the medical device manufacturer for a portion of the costs of manufacture, research, development and handling of the investigational device consistent with FDA policy without running afoul of prohibitions in Section 2.803 and 2.805 of the Commission’s Rules. In this regard, Medtronic noted that leasing is not a satisfactory option for providing patients with such devices as the devices are used only by one patient and the life of the device will vary dramatically from patient to patient and is difficult to predict. Medtronic further explained that although a profit is never made on investigational devices, the charges for such a device are based on the price of a predicate device in order not to bias decisions to participate in a clinical trial on the basis of a charge or lack thereof.



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Should you have any questions, please contact the undersigned counsel for Medtronic.

Respectfully submitted,

David E. Hilliard

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Counsel for Medtronic, Inc.

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