



1776 K STREET NW  
WASHINGTON, DC 20006  
PHONE 202.719.7000  
FAX 202.719.7049

7925 JONES BRANCH DRIVE  
MCLEAN, VA 22102  
PHONE 703.905.2800  
FAX 703.905.2820

www.wileyrein.com

June 12, 2014

David E. Hilliard  
202.719.7058  
dhilliard@wileyrein.com

**VIA ECFS  
VIA E-MAIL**

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:

Pursuant to Section 1.1206 of the Federal Communications Commission's ("FCC") rules, 47 C.F.R. § 1.1206, Medtronic, Inc. ("Medtronic"), by its attorneys, hereby submits this letter summarizing an *ex parte* presentation in the above-referenced docket.

On June 10, 2014, Charles S. Farlow of Medtronic, along with counsel David E. Hilliard and Umair Javed and outside advisor Phil Inglis, met with Ira Keltz, Deputy Chief, Office of Engineering and Technology ("OET"), Bruce A. Romano, Associate Chief, OET, Geraldine Matise, Associate Chief, OET, Dr. Nnake Nweke, Experimental Radio Branch Chief, OET, and Rodney Small, also from the OET. The attached slides were distributed during the meeting.

The parties discussed Medtronic's Petition for Reconsideration<sup>1</sup> of two narrow aspects of the FCC's *Experimental Radio Service Report and Order*.<sup>2</sup> The Petition for Reconsideration urges the FCC to extend eligibility for medical testing licensees beyond healthcare facilities and asks the FCC to clarify the application of its marketing rules to cost reimbursement for clinical trials as allowed by Federal Food and Drug Administration ("FDA") regulations.

---

<sup>1</sup> Medtronic, Inc., Petition for Reconsideration, ET Docket Nos. 10-236 and 06-155 (filed May 29, 2013).

<sup>2</sup> *Promoting Expanded Opportunities for Radio Experimentation and Market Trials under Part 5 of the Commission's Rules and Streamlining Other Related Rules*, Report and Order, 28 FCC Rcd 758 (2013) ("*ERS Order*").

June 12, 2014

Page 2

After providing a brief overview of Medtronic and its long history with the FCC, the Medtronic representatives discussed the limitations imposed on the FCC's newly-created medical testing license under the *ERS Order*. Specifically, Medtronic noted that under the new rules, eligibility for medical testing licenses is limited to healthcare facilities. As shown in the attached slides, however, medical device manufacturers also are heavily invested in clinical trials and would benefit from the flexibility offered under a medical testing license. Attached slide 1 reflects that Medtronic alone globally employs over 1,000 clinical professionals, has been involved in over 350 clinical trials, and annually invests more than \$300 million in clinical trials. In addition, slide 2 suggests that device manufacturers sponsor a significant number of open clinical trials, comparable to the number of open trials sponsored by healthcare facilities.<sup>3</sup> Medtronic explained that a significant percentage of its products incorporate wireless communications functionality.

Medtronic urged the OET representatives to expand eligibility for medical testing licenses beyond healthcare facilities, and the parties discussed the proper scope of any potential eligibility expansion. In doing so, Medtronic clarified the role of sponsors and sponsor-investigators of clinical trials under FDA rules and explained that the line between healthcare facilities and device manufacturers is blurring as healthcare providers are among those who develop medical devices. Medtronic also explained the burdens imposed on device manufacturers under the current experimental licensing regime and under program experimental licenses, as well as the uneven playing field created under the new rules.

The parties then discussed Medtronic's request for clarification that cost reimbursement for clinical trials, as permitted under the FDA's rules, does not constitute impermissible "marketing" under Sections 2.803 and 2.805 of the FCC's rules, 47 C.F.R. §§ 2.803, 2.805. Medtronic explained that FDA rules allow clinical trial sponsors to seek reimbursement of costs associated with a clinical trial, so long as such reimbursement does not exceed an amount necessary to recover the costs of manufacture, research, development, and handling of an investigational device.

---

<sup>3</sup> Slide 2 reflects data from ClinicalTrials.gov, a registry and results database of publicly and privately supported clinical studies, regarding clinical trials sponsored by Medtronic and other device manufacturers and healthcare centers. Medtronic clarifies that the slide 2 data includes data for clinical trials both in the United States and outside the United States.



June 12, 2014

Page 3

Medtronic offered to follow up with the FCC with additional information on how Medtronic currently seeks reimbursement for costs associated with its clinical trials.

Pursuant to Section 1.1206, a copy of this letter is being filed via ECFS for inclusion in the above-referenced docket. Please contact the undersigned with any questions.

Respectfully,

*/s/ David Hilliard*

David E. Hilliard

Attachments

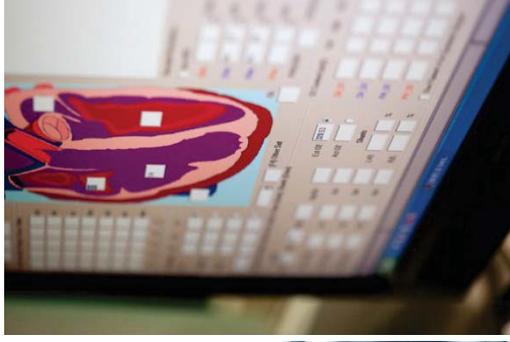
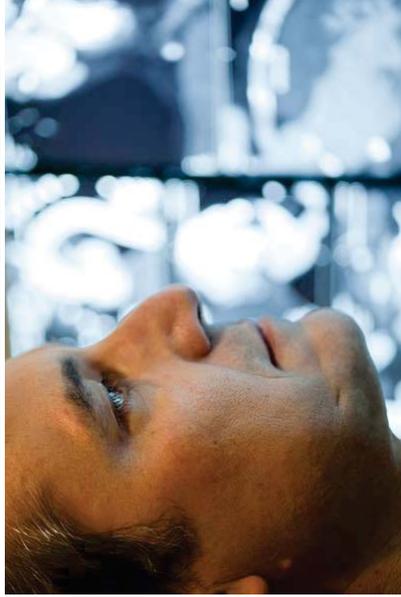
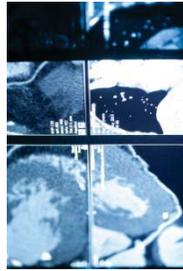
cc (via email):  
Ira Keltz  
Bruce A. Romano  
Geraldine Matise  
Nnake Nweke  
Rodney Small

# Global Clinical Trial Expertise

**1,000+**  
Clinical  
Professionals

**350+**  
Clinical Trials

**\$300M+**  
Annual Clinical  
Investments



# Search Results from [clinicaltrials.gov](http://clinicaltrials.gov)

Representative Clinical Trial Sponsor Figures (Source: [clinicaltrials.gov](http://clinicaltrials.gov), 10 June 2014)

