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VIA EMAIL & ECFS FILING

Julius P. Knapp
Chief of the Office of Engineering and Technology
Federal Communications Commission
445 12th Street, SW
Washington, DC 20554

**Re: *Ex Parte* Presentation - Investigation of the Spectrum Requirements for Advanced Medical Technologies – ET Docket No. 06-135
Amendment of Parts 2 and 95 of the Commission’s Rules To Establish The Medical Data Service at 401-402 and 405-406 MHz – RM-11271**

Dear Mr. Knapp:

As you know, Medtronic’s Petition for Reconsideration in the above-referenced rulemaking dockets asks the FCC to reconsider, among other items, its decision not to provide an optional relaxation in the Listen-Before-Talk (“LBT”) monitoring threshold power level in order to support an ultra-low-power MedRadio programmer/control transmitter that is worn on the body (hereinafter a “BMPC”).¹

The optional provision would allow the monitoring threshold level that a BMPC uses to determine whether communications can take place on a given channel to be adjusted “1 dB higher for every 1 dB the EIRP of the transmitter is below the maximum permitted level of 25 microwatts EIRP.”² This option is critically important to the successful development and evolution of advanced body area networks that automatically administer medical therapies and monitor vital signs of patients as they go about their daily routines.

The proposed option is squarely within the scope of the rulemaking and is ripe for the FCC’s consideration. As Medtronic explains in Section A below, the *NPRM* specifically asked whether the frequency monitoring rules should be modified, focusing on the need to provide effective frequency reuse. The *NPRM* also stressed the need to enable innovative medical technologies that deliver therapy and transmit

¹ See Petition for Reconsideration of Medtronic (June 15, 2009) at 7-9.

² See Attachment to Medtronic *Ex Parte* Letter in ET Docket No. 06-135 (Jan. 10, 2008) (“Medtronic *Ex Parte*”), attached to Petition for Reconsideration.

January 29, 2010

Page 2

physiological data at reduced costs. The proposed dB-for-dB threshold relaxation option would facilitate body area networks that serve each of these crucial needs.

These body area networks would consist of an ultra-low-power BMPC (body-worn MedRadio programmer/control transmitter) that manages communications with one or more body-worn and implanted devices. As explained in Section B of this letter, each of the devices in these networks will need to have a miniaturized form factor due to their “on- or in-the-body” application. They will use ultra-low transmit power to support frequency reuse and extend battery life. And, to be deployed ubiquitously, they will need to be manufactured at a much lower cost than the standalone MedRadio programmer/control transmitters used today in clinical settings and for home monitoring (which are hereinafter referred to as “standalone programmer/control transmitters”). Furthermore, the optional provision will not affect the BMPC’s ability to correctly identify an open communications channel on which a successful MedRadio communications session can occur.

A. **The Optional Threshold Relaxation Is Well Within The Scope Of The Rulemaking, And The Petition for Reconsideration Gave All Parties Adequate Notice Of The Proposed Optional Threshold Relaxation.**

In the *MedRadio Report and Order*, the FCC addressed Medtronic’s request to relax the LBT monitoring threshold on a dB-for-dB basis as follows: “We note that the question of possibly modifying the LBT threshold that appears in the present MICS rules was not raised in the *MedRadio Notice*, and thus there is insufficient notice and little substantive basis in the record for departing from the status quo.”³ As noted above, however, Medtronic is not proposing to modify the LBT threshold for standalone MedRadio programmer/control transmitters. Medtronic simply is proposing that *body-worn MedRadio programmer/control transmitters* that operate with lower power, *viz.* BMPCs, be given the option of increasing the interference monitoring threshold detection level in direct proportion to the level that the BMPC is below the maximum transmit power level.

For three separate reasons detailed below, the request is squarely within the scope of the rulemaking. It is well-established that the FCC may adopt on reconsideration of

³ *MedRadio Report and Order* at ¶ 55 n.76.

January 29, 2010

Page 3

a report and order any modification of a rule that is within the scope of the rulemaking proceeding.⁴

First, the *MedRadio NPRM* was issued in direct response to, and requested comment upon, a petition for rulemaking that specifically proposed revisions to the frequency monitoring rule section at issue here.⁵ Also, the *NPRM* asked whether the frequency monitoring rules should be modified⁶ and posed the broader question of “whether the various current MICS rules” – of which the frequency monitoring rules are a cornerstone – “would continue to be appropriate for operations under the new allocation.”⁷

As Medtronic has explained, the optional threshold level modification is needed to support next-generation body area networks comprised of implantable medical devices and body-worn medical devices that are controlled by a BMPC. Indeed, the FCC stated that the *MedRadio* proceeding was focused on “the spectrum needs and appropriate operational protocols” of “implanted and body-worn medical radiocommunication devices that serve to actively manage and maintain body functions and/or health conditions.”⁸ Operational parameters of the monitoring mechanism unquestionably are within the purview of the *MedRadio* rulemaking.

⁴ See 47 U.S.C. § 405(a); *AT&T Corp. v. FCC*, 113 F.3d 225, 229 (D.C. Cir. 1997); *Ethyl Corp. v. EPA*, 541 F.2d 1, 48 (D.C. Cir. 1976) (en banc).

⁵ See *MedRadio NPRM* at ¶ 1; see also Medtronic Petition for Rulemaking (July 15, 2005) at A-4 to A-6 (proposing extensive revisions to Section 95.628(a)); and see Attachment to Medtronic *Ex Parte*.

⁶ See *MedRadio NPRM* at ¶ 19 (“Biotronik recommends that ... the Commission consider changes in the present MICS regime in the 402-405 MHz band to accommodate a wider range of devices, including devices that do not meet the current frequency monitoring requirements.”).

⁷ *MedRadio NPRM* at ¶ 20. Modifying the frequency monitoring rules was explicitly included in two of the captioned proceedings on the front page of the *MedRadio NPRM* addressed “Request[s] for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules.”⁷

⁸ *MedRadio NPRM* at ¶ 5; see also *id.* at ¶ 11 (“The [prior MICS] rules require that the programmer/control transmitter incorporate a frequency monitoring (*viz.*,
(Continued)

January 29, 2010

Page 4

Second, the *NPRM* focused on the need to provide for intensive spectrum use and effective frequency reuse, which the proposed dB-for-dB option would support.⁹ There is no more effective tool for enabling intensive spectrum use and frequency reuse than to adopt the proposed option allowing next generation body-worn devices to perform frequency monitoring and channel selection based on lowest ambient levels, as ETSI ERM TG30 (Wireless Medical Devices) acknowledged when it adopted this approach following extensive study.¹⁰

Third, the need to enable innovative medical technology to deliver therapy and transmit physiological data at reduced costs was another key point of the *NPRM*. See *MedRadio NPRM* at ¶ 23 (modifying the frequency monitoring rules “could simplify device designs, reduce their size, extend their operational life, [and thus] help lower the cost of medical data collection and therapy”). In this way, the FCC acknowledged that modifications to the frequency monitoring provisions applicable to BMPCs can bring significant benefits to patients.

“listen-before-talk”) mechanism to determine whether a channel is available for operation.”).

⁹ See *MedRadio NPRM* at ¶ 4 (“[W]e seek detailed comment on new implant and body-worn medical [RF] technologies and how the Commission could anticipate and proactively address the challenging array of RF spectrum sharing issues raised by their increasing use.”) and at ¶ 30 (“Our intention in proposing these rules is to provide for more efficient and intensive spectrum use in the near term by advanced medical technologies that feature implantable and body-worn transmitters.”).

¹⁰ See ETSI EN 302 537-1 V1.1.2 (2007-12) European Standard (Telecommunications series) Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Medical Data Service Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz; Part 1: Technical characteristics and test methods, 10.2 LBT threshold power level. Notably, the standard adopted by the Australian regulatory authority, ACMA, contains the same option, and Industry Canada has issued a draft standard incorporating the option. Indeed, the FCC has recognized in this proceeding that internationally-harmonized regulations are a worthwhile goal as patients equipped with MedRadio devices will travel around the globe. See *MedRadio Report and Order* at ¶ 12.

January 29, 2010

Page 5

For these reasons, the proposed optional dB-for-dB threshold relaxation is a “logical outgrowth” of the rules proposed in the *MedRadio NPRM*.¹¹ In fact, the scope of the *MedRadio NPRM* was even broader, as it also explicitly included the wide-ranging issues raised in Notice of Inquiry portion of the document.¹² As the Court of Appeals for the D.C. Circuit explains:

After all, if we were to say that regulatory agencies could only promulgate the exact rules noticed originally, we would compel the agencies to choose between (1) ignoring all comments and all that the agency might learn from interested parties to improve the proposed rules, or (2) engaging in an interminable step-by-step process of a new notice and comment on rules only slightly changed from the original proposals. The whole rationale of notice and comment rests on the expectation that the final rules will be somewhat different and improved from the rules originally proposed by the agency.

Trans-Pacific Freight Conference, 650 F.2d at 1249.

Furthermore, because the proposal was squarely presented in the Petition for Reconsideration, any issue as to insufficient notice clearly has been addressed. Notwithstanding that the Commission and other interested parties had more than fifteen months to consider Medtronic’s proposal prior to the release of the *MedRadio Report and Order*,¹³ Medtronic again presented the request in its Petition for Reconsideration to give all parties a further chance to examine the proposal.¹⁴

¹¹ See *National Black Media Coalition v. FCC*, 791 F.2d 1016 (D.C. Cir. 1986) (“While a final rule need not be an exact replica of the rule proposed in the Notice, the final rule must be a logical outgrowth of the rule proposed.” (citing *AFL-CIO v. Donovan*, 757 F.2d 330, 338 (D.C. Cir. 1985); *United Steelworkers v. Marshall*, 647 F.2d 1189, 1221 (D.C. Cir. 1980))).

¹² See *MedRadio NPRM* at ¶ 30 (“We will also take into consideration ... information provided in response to our Inquiry ... regarding anticipated future developments in implanted and body-worn medical devices that may rely, in varying degrees, on radiocommunication for their functionality.”).

¹³ *Ex parte* notices can satisfy Section 405 of the Communications Act, which requires parties to first afford the FCC an “opportunity to pass” on the arguments (Continued)

January 29, 2010

Page 6

Thus, there can be no question that the industry is well aware of the proposal and the issue is now squarely before the Commission.¹⁵ The fact that no other parties commented on Medtronic's proposal prior to issuance of the *MedRadio Report and Order* or in response to the Commission's formal request for comment on Medtronic's Petition for Reconsideration demonstrates the medical device industry's acceptance of the proposal. This is not surprising, as the proposal already has been adopted by industry consensus in Europe and Australia.¹⁶

B. The Proposed Option Will Allow The Development of Economically- and Technically-Viable BMPCs.

The proposed threshold relaxation is essential to the successful development and deployment of body-worn MedRadio programmer/control transmitters ("BMPCs") that can support reliable LBT operations. The next-generation wireless medical devices that will be worn on the human body face several technical limitations due to the fact that the devices must be lightweight and small so they can be worn on an armband or bandage. As a result, BMPCs' antennas will be much less efficient than those used in standalone programmer/control transmitters. The size limitation also restricts battery capacity, which places a premium on battery power preservation. Thus, to conserve battery power, BMPC systems will transmit with substantially less power than a standalone programmer/control transmitter.

before seeking judicial review. *See Sprint Nextel Corp. v. FCC*, 524 F.3d 253, 257 (D.C. Cir. 2008); *MCI WorldCom, Inc. v. FCC*, 209 F.3d 760, 765 (D.C. Cir. 2000); *see also Trans-Pacific Freight Conference of Japan/Korea v. Federal Maritime Commission*, 650 F.2d 1235, 1248 (D.C. Cir. 1980) ("[N]otice is sufficient if the description of the 'subjects and issues involved' affords interested parties a reasonable opportunity to participate in the rulemaking.").

¹⁴ *See* FCC Report No. 2892, Petitions for Reconsideration of Action in Rulemaking Proceeding: Investigation of the Spectrum Requirements for Advanced Medical Technologies, ET Docket No. 06-135, 74 Fed. Reg. 37035 (July 27, 2009).

¹⁵ *See* 47 U.S.C. § 405(a). *See, e.g.*, Amendment of Section 73.202(b), Table of Allotments, FM Broadcast Stations, *Report and Order*, 23 FCC Rcd 447, ¶ 6 (2008) (requesting public comment on a proposal satisfies the APA's notice and comment mandate).

¹⁶ *See* n.10, *supra*.

January 29, 2010

Page 7

The relaxation in the monitoring threshold power level is needed because these technical limitations (*e.g.*, antenna gain) restrict the miniaturized BMPC's ability to monitor signals at the currently prescribed levels. Importantly, the proposed relaxation would not materially affect the BMPC's ability to choose a suitable communications channel. As shown in the technical attachment to this letter, under typical operating conditions a BMPC receiver operating under the proposed threshold level relaxation will receive a higher desired signal from an implanted MedRadio device than the receiver of a standalone programmer/control transmitter.

In addition, the levels at which BMPCs will operate are expected to be comparable to the levels that the Commission currently allows for low-power, low-duty-cycle ("LPLDC") operation within the MedRadio band.¹⁷ Thus, devices with no frequency monitoring capabilities can transmit on any channels within the 401-402 and 405-406 MHz wing bands at the same levels as LBT devices operating under the proposed threshold relaxation that – in contrast to LPLDC devices – can avoid blocked channels. The FCC would not have allowed LPLDC operations had it believed that they routinely would suffer interference from METAIDS devices.

There also is no real risk that the low-power BMPCs will cause interference to primary METAIDS operations in the 401 - 406 MHz MedRadio band. The ITU-R determined that interference to METAIDS from secondary medical systems was negligible based on the maximum power output from medical devices of 25 microwatts EIRP.¹⁸ Devices using less than the maximum permitted power – as would be the case for BMPCs implementing the dB-for-dB threshold relaxation option – will result in a smaller zone of interference than MedRadio operations at maximum power levels.

In sum, the proposed option will allow patients to reap the benefits of patient frequency monitoring systems without the need for a standalone external programmer/control transmitter. This optional mode of operation makes sound spectrum management sense for it would allow successful implementation of multiple uncoordinated body area networks in close proximity. Moreover, patients

¹⁷ See 47 C.F.R. § 95.628(b).

¹⁸ ITU-R RS 1346, Sharing Between The Meteorological Aids Service And Medical Implant Communication Systems (MICS) Operating In The Mobile Service In The Frequency Band 401-406 MHz.



January 29, 2010

Page 8

equipped with BMPCs operating under the threshold relaxation option will experience improved medical care, reduced medical costs, greater freedom of movement, and a reduced risk of interference from other users of the band.

* * *

Accordingly, Medtronic respectfully requests that the FCC implement as an option in the frequency monitoring provision in Rule Section 95.628(a) the proposed relaxation in the monitoring threshold power level for use by BMPCs, *i.e.*, body-worn MedRadio programmer/control transmitters.

Please do not hesitate to contact the undersigned if the Commission has any questions regarding this letter.

Sincerely,

David E. Hilliard

David E. Hilliard
John W. Kuzin

Att.

cc (via e-mail):

Bruce Romano
Alan Stillwell
Geraldine Matise
Ira Keltz
Mark Settle
Gary Thayer

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Technical Attachment

Link Analysis Comparison of a BMPC Operating Under The Proposed dB-for-dB Relaxation Option to a Standalone MedRadio Programmer/Control Transmitter Operating Under Current Rule Section 95.628(a)(3)

Link Analysis Comparison for BMPC and Standalone Programmer/Control Transmitter Communications Systems

Assumptions (based on typical operating parameters):

	Ant. Gain (dBi)	Tx Power Out (dBm EIRP)	Receiver Bandwidth (kHz)	Receiver Noise Figure (dB)
BMPC:	-20	-36	100	9
Standalone Pgmr/Cntl Xmtr	0	-16	100	6
Implant:	-32	-37	50	9

Analysis:

The equivalent input referred noise floor of the receiver is defined as: $= -174 \text{ dBm/Hz} + 10 \cdot \log(\text{BW in Hz}) + \text{Rx Noise Figure}$

Therefore:

BMPC Rx Noise Floor = -115.0 dBm

Standalone Pgmr/Cntl Xmtr Noise Flr = -118.0 dBm

Implant Rx Noisefloor = -118.0 dBm

Range for Implant to Standalone Pgmr/Cntl Xmtr =	6 m	Range: (m)	Pathloss for n = 3.14 (dB)
Range for Implant to BMPC =	1 m	1	24.6
Propagation Exponent "n" = 3.14, breakpoint = 1m [*]		6	49.0

* Theodore Rappaport, "Wireless Communications Principles and Practice", 1st Ed., p 129.

Typical received signal at receiver input port: $= \text{Tx (E.I.R.P.)} - \text{Path Loss (dB)} + \text{Rx Antenna Gain (dBi)}$

At BMPC Rx from Implant @ 1m range: -81.6 dBm 33.4 C/N (dB)

At Standalone Pgmr/Cntl Rx from Implant @ 6m range: -86.0 dBm 32.0 C/N (dB)

Delta of BMPC Rx Signal v. Standalone Pgmr/Cntl Rx Signal 4.4 dB 1.4 C/N (dB)

At Implant Rx from BMPC at 1 m range: -92.6 dBm 25.4 C/N (dB)

At Implant Rx from Standalone Pgmr/Cntl Xmtr @ 6m range: -97.0 dBm 21.0 C/N (dB)

Delta of Implant Rx Signal for BMPC v. Standalone Pgmr/Cntl Xmtr 4.4 dB 4.4 C/N (dB)

Conclusion:

The above analysis illustrates that the BMPC-to-Implant MedRadio communications system has received signal powers at a 1 m distance that are 4.4 dB stronger than those received by the Standalone MedRadio Programmer/Control Transmitter-to-Implant communication system operating at a distance of 6 m. Thus, the likelihood that the BMPC-to-Implant MedRadio communication system operating under the proposed option will receive interference from other users of the MedRadio spectrum is comparable to that of the Standalone system operating under the current rules.