Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

In the Matter of	)	
	)	
Reassessment of Federal Communications Commission Radiofrequency Exposure Limits and Policies	)	ET Docket No. 13-84
	)	
	)	
Proposed Changes in the Commission's Rules Regarding Human Exposure to Radiofrequency Electromagnetic Fields	)	ET Docket No. 03-137
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COMMENTS OF MEDTRONIC, INC.

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Medtronic, Inc. ("Medtronic") is pleased to provide the Federal Communications Commission ("Commission") with these opening comments on the Notice of Proposed Rulemaking ("NPRM")[1] and Notice of Inquiry ("NOI")[2] in the above-referenced proceedings.

I. INTRODUCTION AND SUMMARY

First and foremost, Medtronic applauds the Commission for its decades-long commitment to establishing uniform national standards for health and safety of radiofrequency ("RF") emissions from radio transmitters. As new wireless equipment and services continue to develop, the Commission must engage in periodic review of its rules to ensure that safety concerns are properly balanced against the public interest benefit that comes from accelerated deployment of emerging technologies. Medtronic submits that several of the Commission's proposed rules in the NPRM, coupled with certain modifications set forth in these comments, will result in more efficient and consistent application of RF compliance procedures, thereby

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1 *Reassessment of Federal Communications Commission Radiofrequency Exposure Limits and Policies*, Further Notice of Proposed Rulemaking, 28 FCC Rcd 03498 (2013) ("NPRM").

2 *Reassessment of Federal Communications Commission Radiofrequency Exposure Limits and Policies*, Notice of Inquiry, 28 FCC Rcd 03498 (2013) ("NOI").

protecting health while also encouraging innovation. In addition, in response to the NOI, Medtronic identifies certain public safety concerns that should guide and inform Commission policy, as well as areas for coordination with other regulatory agencies and standards development organizations.

II. NOTICE OF PROPOSED RULEMAKING COMMENTS

A. The Commission Should Adopt the Proposed 1 mW Exemption for Single Transmitters

Routine environmental evaluation adds both cost and delay to the introduction of new medical devices. Today, the Commission's MedRadio rules require the submission of burdensome RF exposure reports based on computational modeling or laboratory measurement for each implantable device.[3] Computational modeling requires the use of costly electromagnetic simulation resources and generally requires a month or more to complete. Not only must these costs be recovered through device sales, but delays that result from computational modeling or laboratory measurement cut into the time that the device can meet consumer health needs. Commission rules requiring unneeded demonstrations of compliance with RF exposure requirements amount to an unintended tax on innovation and healthcare.

Of course, Medtronic appreciates the importance of compliance with Specific Absorption Rate ("SAR") rules to protect both occupational users as well as the public. For devices below certain threshold power levels, however, the Commission's exposure limits simply cannot be exceeded as a matter of sound engineering principles. For this reason, Medtronic strongly supports the NPRM's proposal to adopt a blanket exemption from routine environmental evaluation for single transmitters operating with up to one milliwatt available maximum time-

[3] *See* 47 C.F.R. § 95.1221.

averaged power, independent of frequency and service type.[4] The proposed exemption will streamline approval of very low-power implanted and body-worn medical devices, thereby lowering development costs for device manufacturers and reducing time-to-market for new medical devices.

The Commission's localized SAR limit of 1.6 W/kg averaged over 1 gram cannot be exceeded if the available power from a transmitter is less than 1.6 mW, regardless of frequency and distance over the applicable SAR frequency range of 100 kHz to 6 GHz. Put differently, single transmitters operating at 1 mW cannot exceed the Commission's exposure limits based on conservation of energy principles.[5] Thus, a blanket exemption from routine environmental evaluation for these transmitters is appropriate. The proposed exemption also is appropriate in cases of multiple transmitters within two centimeters of each other so long as the transmitters do not operate simultaneously, and the Commission should so clarify. Where such multiple transmitters may operate at the same time, Medtronic agrees with the NPRM's proposed

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[4] NPRM at ¶ 121. The Commission's Office of Engineering and Technology ("OET") already recognizes a SAR test exclusion for transmitters implanted in the body of a user where the aggregate of the maximum power available at the antenna port and radiating structures of an implanted transmitter, under all operating circumstances, is less than or equal to 1.0 mW. *See* Office of Engineering and Technology, Knowledge Database, "Mobile and Portable Devices RF Exposure Procedures and Equipment Authorization Policies," KDB 447498 D01 v05r01, §4.2.4 (May 28, 2013).

[5] The principle of conservation of energy and a worst-case assumption that all energy capable of being transmitted by an implanted device is absorbed by a 1 gram cube of tissue (the smallest tissue cube of interest for SAR) suggests that if the transmitter is conjugately matched to the antenna in body tissue and outputs less than 1.6 mW in this optimally matched condition, and all the transmitted energy is absorbed in 1 gram of tissue, then less than 1.6 mW is absorbed in 1 gram of tissue. *See* SAR Analysis, Certification Submission for Medtronic Evera-Brava-Viva Implantable Devices, FCC ID LF5MICSIMPLANT3, at Appendix A (July 29, 2011).

approach of aggregating the power from all relevant transmitters and comparing against the blanket 1 mW exemption.[6]

The Commission should consider, however, whether the proposed 1 mW threshold is overly conservative. While most implanted RF devices currently fall under the proposed 1 mW threshold due to battery constraints, they may exceed this threshold in the future as technology advances in order to increase telemetry range, data rates, and link reliability. To the extent that the record in this proceeding supports a higher exemption threshold, the Commission should adopt final rules that ensure compliance with relevant exposure limits without sacrificing flexibility or stifling innovation through burdensome and unnecessary environmental evaluation requirements.

B. The Commission Should Permit Usage of Any Valid Method for SAR Computation

In the recent *RF Exposure Order*, the Commission modified its rules to allow for additional flexibility for MedRadio Service transmitters to demonstrate compliance with the Section 2.1093 SAR limits by either finite difference time domain ("FDTD") analysis or the submission of SAR measurement data.[7] The Commission retained the option of requesting measurement data to support an FDTD analysis, if appropriate.[8] The NPRM wisely recognizes, however, that there are other numerical methods that provide equivalent results to FDTD.[9] The NPRM reports, for example, that in a recent complex case, the Commission "permitted the use of

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6 *See* NPRM at ¶ 126.

7 *Reassessment of Federal Communications Commission Radiofrequency Exposure Limits and Policies*, First Report and Order, 28 FCC Rcd 03498, ¶ 55 (2013) ("RF Exposure Order"); *see also* 47 C.F.R. § 2.1093.

8 *See id.*

9 NPRM at ¶ 169.

finite element method (FEM)-based computational modeling as an alternative to [FDTD]-based computational modeling for evaluation of MedRadio devices."[10] Accordingly, the NPRM seeks comment on a proposal to modify its rules so that computational modeling "must be supported by adequate documentation showing that the numerical method as implemented in the computational software has been fully validated."[11] In this regard, the Commission should provide clear guidance to software manufacturers about the requirements for software validation.

Medtronic supports the Commission's proposal to permit any valid computational method to establish SAR compliance. The proposed rule will increase flexibility and accommodate new tools and techniques for RF exposure analysis, thereby permitting more efficient evaluation. Moreover, the proposed rule will reduce costs for manufacturers without sacrificing the quality of simulation data.

C. New Rules Should Ensure Consistency in Testing of Multiple Portable and Mobile Transmitters

The NPRM proposes a summation to determine whether multiple mobile and portable transmitters collectively are exempt from evaluation.[12] Medtronic generally agrees with this proposal, but submits that any new rules relevant to multiple portable and mobile transmitters must incorporate certain definitional concepts. Specifically, the Commission should incorporate into its proposed rules the definitions for "maximum time-averaged ERP,"[13] "available

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10 *Id.* at ¶ 136.

11 *Id.* at ¶ 169.

12 *Id.* at ¶ 161.

13 *Id.* at ¶ 112, fn. 190 ("[T]he 'maximum time-averaged EIRP' for a mobile or portable RF source is the product of the maximum delivered power to the antenna and its maximum gain as averaged over a period inherent from device transmission characteristics.").

maximum time-averaged power,"[14] and "delivered maximum time-averaged power"[15] as provided in paragraph 112 and footnotes 190, 191, and 192 of the NPRM. Similarly, the Commission should incorporate the definition of "simultaneous" as set forth in Appendix H, allowing for short time average periods for non-overlapping transmissions.[16] By doing so, the Commission will ensure consistency between test procedures.

III. NOTICE OF INQUIRY COMMENTS

A. The Commission Should Coordinate its Efforts with FDA and AAMI to Ensure that RF Exposure Limits Below 300 kHz Do Not Cause Harmful Interference to Implanted Medical Devices

RF sources have proliferated in modern society, including in healthcare facilities. What is more, millions of patients today depend on various electronic medical devices, such as implantable cardiac devices that are required to sense microvolt-level physiological signals for proper operation. It is widely recognized that RF sources that emit various electromagnetic

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[14] *Id.* at ¶ 112, fn. 191 ("[T]he 'available maximum time-averaged power' for a mobile or portable RF source is the maximum available power as averaged over a period inherent from device transmission characteristics.").

[15] *Id.* at ¶ 112, fn. 192 ("[T]he 'delivered maximum time-averaged power' for a mobile or portable RF source is the net maximum delivered or supplied power as averaged over a period inherent from device transmission characteristics.").

[16] *Id.* at Appendix H, fn. 10 ("Exposures due to multiple transmitters are considered 'simultaneous' if these exposures occur in the same time averaging period. For example, for two variable power consumer transmitters averaged over the same source-based time averaging period, the exposure based on the time-averaged SARs must be summed even though either transmitter may not necessarily be transmitting at the same instant. In principle, time averaging periods up to 30 minutes could be required; however, shorter time averaging periods less than 30 minutes are permitted, and in fact are required for mobile and portable consumer devices, to avoid redundant or repetitive measurements, provided that measurements performed using a shorter time averaging period result in the maximum aggregate time-averaged SAR of the multiple transmitters being summed (*i.e.*, accounting for maximum duty cycle, maximum transmitted power, overlapping transmission, etc.). Alternatively, short time averaging periods (*e.g.*, over one pulse at maximum power) may be selected to conservatively measure SAR and avoid the need to sum SARs from multiple transmitters during non-overlapping transmission.").

disturbances may interfere with medical or other devices,[17] including those at field levels lower than the Commission's human exposure limits for the general population.[18] Cardiac pacemakers, defibrillators, and drug delivery systems, for example, may exhibit improper operation when subjected to strong RF fields. Devices and systems that are used external to the body can be substantially more susceptible to this kind of interference.

Typically, general public exposure occurs in uncontrolled environments and affects individuals of all ages and varying health status, including individuals equipped with electronic medical devices. It is critical, therefore, that any new RF rules adopted by the Commission ensure that RF exposure limits below 300 kHz do not cause harmful interference to implanted medical devices used in both uncontrolled or controlled environments. To this end, the Commission should designate a liaison with the Food and Drug Administration ("FDA") and the Association for the Advancement of Medical Instrumentation ("AAMI") Cardiac Rhythm Management Device ("CRMD") Committee[19] to ensure that patients with implantable devices are adequately protected by the Commission's RF rules and policies.

Appropriate regulation of RF emission levels requires striking the proper balance between encouraging innovation through flexibility and preserving safety. The medical device

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[17] *See, e.g.,* Institute of Electrical and Electronics Engineers, Inc., IEEE Standards Coordinating Committee 39, *Recommended Practice for Radio Frequency Safety Programs, 3 kHz to 300 GHz,* Std. C95.7-2005, Section 4 (2006); *see also* Association for the Advancement of Medical Instrumentation, *Guidance on Electromagnetic Compatibility of Medical Devices in Healthcare Facilities,* AAMI TIR18:2010, at 1 (2010) ("Because the performance of electronic medical devices can be disrupted by electromagnetic energy, patient safety can potentially be put at increased risk because of the effects of electromagnetic interference.").

[18] Currently, the FCC's frequency range is applied through the use of SAR between 100 kHz and 6 GHz and MPE between 300 kHz and 100 GHz. *See* NOI at ¶ 229.

[19] The AAMI CRMD Committee is the U.S. Technical Advisory Group for related work in the International Organization for Standardization ("ISO").

community appreciates this challenge as it balances the needs of patients, practitioners, industry suppliers, and others. While medical device innovation poses some degree of risk because of factors such as human electromagnetic exposure and therapy disruption due to electromagnetic interference, the countervailing healthcare benefits to the public are well documented. In this spirit, the Commission should adopt final rules that encourage the greatest amount of flexibility and innovation in the medical device industry without sacrificing safety.

B. Conductive Implanted Objects Are Regulated by Other Government Agencies

As the NOI notes, "electrically conductive objects in or on the body may interact with sources of RF energy in ways that are not easily predicted."[20] For this reason, the Commission seeks comment on whether the present volume-averaged SAR limits adequately protect for the more localized SAR that may occur near the tip of a conductive object such as the end of an implanted wire.[21] The Commission also asks whether high levels of RF exposure may cause internal thermal injury at the site of conductive implants.[22] In considering these issues, the Commission should recognize first and foremost that, in the medical device context, RF exposure and associated tissue heating already are regulated by the FDA.

The FDA recognizes that excessive temperature from medical diagnostics and medical implants has the potential to harm patients and, for this reason, regulates conductive implanted objects that are medical devices. Existing FDA regulations address RF exposure and associated tissue heating issues, both in cases where a potential temperature increase is due to RF energy incident on the conducted device and where energy is developed within the device itself. The

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20 NOI at ¶ 230.

21 *Id.*

22 *Id.*

FDA has adopted International Electrotechnical Commission ("IEC")-prescribed temperature limits for compliance of medical devices likely to be subjected to MRI scanning, rather than relying only on SAR.[23] In addition, the FDA recognizes IEC 60601-2-33, which provides SAR values derived specifically so that localized temperatures will not result in tissue damage.[24] The FDA also recognizes ASTM International ("ASTM") standards that govern the measurement of heating.[25] For these reasons, conductive implanted medical devices already subject to FDA regulations are unlikely to cause internal thermal injury or associated harm, even in the absence of specific Commission regulations.

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[23] *See* United States Food and Drug Administration, *Guidance for Industry: Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices* (issued November 14, 1998) *available at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073817.htm.

[24] *See* International Electrotechnical Commission, International Standard, Medical Electrical Equipment, IEC 60601-2-33, Edition 3.0 (2010-03); *see also* U.S. Food and Drug Administration, Recognition List Number 031, FDA Recognition Number 12-207 (August 5, 2013) *available at* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard__identification_no=31238.

[25] *See, e.g.,* ASTM, Standard Test Method for Measurement of Radio Frequency Induced Heating on or Near Passive Implants During Magnetic Resonance Imaging, ASTM F2182-11.

IV. CONCLUSION

In reexamining its RF rules, the Commission must not unnecessarily impose burdensome testing requirements on device manufacturers that do not further any public interest benefit, much less safety. The Commission should act, however, to ensure consistency, flexibility, and clarity in its rules, as well as coordination with other regulatory agencies. For these reasons, Medtronic requests that the Commission take into consideration the views expressed above, which support compliance with SAR limits in a practical, consistent, and efficient manner.

Respectfully submitted,

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