

**Before the
Federal Communications Commission
Washington, DC 20554**

In the Matter of

Promoting Expanded Opportunities for
Radio Experimentation and Market Trials
under Part 5 of the Commission's Rules
and Streamlining Other Related Rules

ET Docket No. 10-236

2006 Biennial Review of
Telecommunications Regulations – Part 2
Administered by the Office Of Engineering
and Technology OET

ET Docket No. 06-105

COMMENTS OF MEDTRONIC, INC.

MEDTRONIC, INC.

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COMMENTS OF MEDTRONIC, INC.

Medtronic, Inc., welcomes the opportunity to provide the Commission with comments on the expanded opportunities for radio experimentation and market trials that can be made available through these proceedings.¹ Medtronic applauds the Commission for its initiative in seeking to reduce delays in developing new technologies. This effort will benefit the public by greatly promoting competition and economic growth². In many instances these new technologies

¹ Headquartered in Minneapolis, MN, Medtronic is an internationally recognized pioneer and leader in the development of numerous medical devices, including cardiac pacemakers and defibrillators, infusion pumps, and neural stimulators. Medtronic petitions were integral in the development of the MedRadio Service and its predecessor the Medical Implant Communications Service under Part 95 of the Rules.

² See, Promoting Expanded Opportunities for Radio Experimentation and Market Trials under Part 5 of the Commission's Rules and Streamlining Other Related Rules, ET Docket No. 10-236, FCC 10-197, at ¶ 1 (rel. Nov. 30, 2010) (*Experimental NPRM*).

may be applied across industry sectors. In particular, the medical community will create and use a variety of new medical devices that rely on radio communications for critical time related delivery of therapies to patients. Medtronic encourages the FCC to proceed promptly with the proposed revisions to the experimental licensing program and to make specific modifications in it and in the rules governing investigational use of equipment that has not yet been approved as described in these comments.

I. MEDTRONIC CONCURS WITH THE COMMISSION’S FINDING THAT STREAMLINING OF THE EXPERIMENTAL LICENSE RULES WILL PROMOTE INNOVATION IN THE BROAD FIELD OF WIRELESS COMMUNICATIONS

The FCC has recognized the need to remove, to the extent possible, impediments in the experimental authorization process that cause delays in the development of new wireless communications products. In developing the current proposals the Commission appears to have relied heavily on comments filed in response to the Wireless Innovation Notice of Inquiry³ and in the National Broadband Plan⁴ initiative.

These proceedings provided the basis for the concept of a “program experimental license” that as envisioned by the FCC would have qualified institutions permitted to use a broad range of radio frequencies for research and experimentation on a non-interference basis without having to obtain prior authorization for the use of specific frequencies.⁵

³ See Fostering Innovation and Investment in the Wireless Communications Market, GN Docket No. 09-157; A National Broadband Plan For Our Future, GN Docket No. 09-51; *Notice of Inquiry*, 24 FCC Rcd 11322 (2009) (*Wireless Innovation NOI*).

⁴*Id.*

⁵ See *Experimental NPRM*, ¶ 19.

A. Medtronic supports the FCC’s proposal to define specific entities that would be eligible for a “program experimental license”

Under the “program experimental license” concept, the FCC targeted three types of licenses that would be available to qualifying entities. Research institution, innovation zone and medical research experimental licenses would be available to entities meeting the eligibility requirements. It appears that the FCC is proposing to exclude medical device manufacturers from eligibility for a medical program experimental license. Recent history shows that medical communications system innovation has come primarily from medical device manufacturers. Medtronic submits that in addition to hospitals and other medical facilities, medical device manufacturers should be permitted to hold medical research experimental licenses and urges the Commission to permit them to do so. Permitting medical device manufacturers to hold a medical program experimental license could also cover in some cases the need for an experimental license for conducting “clinical trials” that are required by the FDA before medical devices are offered commercially.⁶

B. The radio service to patients who depend upon devices authorized in the MedRadio Service should be protected from unwanted emissions from equipment operating under an experimental license

In establishing minimal provisions for the issuance of program experimental licenses, the FCC proposed a minimal technical restriction for avoiding certain frequency ranges. Sensitive bands below 38.6 GHz identified as “restricted bands” in Section 15.205(a) were excluded from

⁶ Such use for clinical trials could be appropriate when devices under development are operated at clinical facilities working with medical device manufacturers and which are included in the geographic scope of a medical program experimental license. As noted, *infra*, however, devices that are designed to comply with existing rules should be permitted to be operated under Section 2.803 and 2.805 of the regulations when operation is initiated pursuant to an FDA sanctioned clinical trial. Medical program experimental licenses would be most beneficial when manufacturers are developing new devices that have not yet reached the clinical trial stage.

these licenses as were certain bands above 38.6 GHz that are listed in footnote US242 of the Table of Frequency Allocations to ensure fundamental emissions in these bands would not cause interference . Additionally, the FCC asked if other technical parameters such as power limits, power spectral density, etc., should be specified.

Medtronic supports the proposal that program experimental licenses not allow experiments on frequency bands that are listed in Section 15.205(a) but remains concerned that simply restricting operation in the band by itself is insufficient to ensure that no harmful interference will occur to MedRadio equipment operation in the 401 – 406 MHz portion of the restricted Meteorological Aids band, 399.1 – 406.1 MHz. Many MedRadio equipments operate with transmit power levels below 100 nanowatts EIRP. Desired communications between MedRadio devices transmitting at this level could be susceptible to disruption from unwanted emissions (out-of-band and spurious emissions) from experimental radio devices, particularly when collocation of medical implant and peripheral devices within facilities capable of holding medical program experimental licenses is highly likely. Medtronic suggests that a limit of 100 uV/m at 3 meters on unwanted emissions into the MedRadio band be a condition attendant to all medical program experimental licenses that are issued.

II. FCC AND FDA COOPERATION CAN FACILITATE ISSUANCE OF MEDICAL PROGRAM EXPERIMENTAL AUTHORIZATIONS

The FCC clearly contemplated the issuance of a medical program experimental license for operations that may involve input from the FDA as noted in the Experimental NPRM: “A medical experimental authorization would allow for the testing and operation of new medical devices that use wireless telecommunications technology for therapeutic, monitoring, or diagnostic purposes that have not yet been submitted for equipment certification, or for devices that use RF for ablation, so long as the equipment is designed to meet the FCC’s technical rules.

The FDA's investigational device exemption (IDE) may be applicable when these experiments involve patients.⁷ The Experimental NPRM also noted that the FDA and the FCC will engage in a consultation process to "streamline IDEs for wireless medical processes" with the FCC supervising the medical experimental license program.⁸

While the goal of improving speeding up the issuance of medical research licenses through consultation between the two agencies is commendable, the FCC and the FDA should first issue clear guidelines as to what their respective separate responsibilities are in the application, review, and approval processes. The process for review and approval of IDEs should remain exclusively with the FDA. The agencies should clearly delineate the responsibilities for risk management oversight so there will not be duplication and/or potentially conflicting opinions between FDA and FCC. Any changes in these roles should be the subject of a notice and comment rule making.

III. THE COMMISSION SHOULD REVISE PROPOSED SECTIONS 2.803 AND 2.805 TO PERMIT COST REIMBURSEMENT TO DEVICE MANUFACTURERS ENGAGED IN CLINICAL TRIALS UNDER FDA REGULATION AND TO ALLOW MEDICAL DEVICES THAT ARE THE SUBJECT OF SUCH TRIALS TO BE USED IN RESIDENTIAL SETTINGS

Section 2.803 of the Commission's Rules permits the operation of devices that have not yet been approved, provided the devices have been designed to comply with the FCC rules, are not marketed and are not used in residential locations. The FDA relies upon clinical trials to allow the evaluation of devices that have not yet been approved by the FDA as medical devices. Clinical trials normally occur relatively late in the product development cycle and are an

⁷ See *Experimental NPRM*, ¶ 48.

⁸ *Id.*

important tool for assessing the safety and efficacy of devices before the devices are permitted to become generally available to the medical community.⁹ Although manufacturers are not permitted by the FDA to profit from clinical trials, they are allowed to recover certain costs associated with the devices being trialed.

The FDA has an information sheet: “Charging for Investigational Medical Devices and Radiological Health Products”. This document provides a brief overview of the FDA cost recovery provisions:

The Investigational Device Exemption (IDE) regulations allow sponsors to charge for an investigational device, however, the charge should not exceed an amount necessary to recover the costs of manufacture, research, development, and handling of the investigational device [21 CFR 812.7(b)]. A sponsor justifies the proposed charges for the device in the IDE application, states the amount to be charged, and explains why the charge does not constitute commercialization [21 CFR 812.20(b)(8)]. FDA generally allows sponsors to charge investigators for investigational devices, and this cost usually is passed on to the subjects.”¹⁰

As it reviews possible changes to its regulations governing experimental operation, the Commission should take this opportunity to clarify that the cost reimbursement to manufacturers allowed by the FDA would not be considered to be impermissible “marketing” under Section 2.803 for devices that have not been approved.

⁹ The number of units to be included in a clinical trial depends on the nature of the device. The clinical trial of the Medtronic Concerto AT for providing cardiac resynchronization therapy and implantable cardioverter defibrillator therapies involved 270 patients. The Medtronic Revo MRI SureScan Pacing System, an MRI-compatible implantable cardiac pacemaker, involved 484 patients.

¹⁰ Additional details are available at:
<http://www.fda.gov/RegulatoryInformation/Guidances/ucm126427.htm>.

Similarly, at least for devices that have been designed to comply with either Part 15 or Part 95 of the FCC Rules, the Commission should allow such devices to be used in residential settings when operation is initiated through a clinical trial authorized by the FDA.¹¹ For example, most medical implant devices studied in clinical trials are implanted at medical facilities but eventually will be used by participating patients outside of such facilities. Accordingly, authority to operate in residential areas without seeking a separate experimental authorization or certification for a device in the latter stages of development would facilitate completion of the clinical trial process leading to the eventual availability of new medical technologies.

The prohibition on operation in a residential environment appears to have been intended to reduce the possibility of radio frequency interference to broadcast reception within homes, especially interference that might be caused to neighbors. Medical devices that are designed for use under the MedRadio Service rules of Part 95 and those that would operate under Part 15 of the Rules pose little risk of such interference because of the spectrum typically selected for such use (e.g. 401 – 406 MHz) and the various ISM bands (including 2.450 GHz). Moreover, such devices usually operate at very low powers (e.g. less than 25 microwatts and often less than 250 nanowatts in the case of Part 95 MedRadio devices). As such, the likelihood of interference is remote.

¹¹ When physicians attending patients who have participated in clinical trials conclude that the patient would be well-served medically by continuing to use the device after the conclusion of the trial and such use is permitted by the FDA, the Commission should allow such use rather than require the patient to cease using an otherwise functioning device, especially where the device is implanted.

IV. CONCLUSION

In revising the Experimental Radio Service Rules, the Commission should take its cue from the Hippocratic Oath and first do no harm inasmuch as the current rules have, to a great extent, served to encourage innovation. Steps should be taken to reduce the likelihood of harmful interference from unwanted emissions to MedRadio Service devices, from medical program experimental licenses. At the same time, the rules should permit medical device manufacturers to apply for medical program experimental licenses based on the recent innovations in medical telemetry from medical device manufacturers. While cooperation with the FDA is commendable and should be encouraged, it is vital that the respective roles of both agencies be set forth clearly and that cooperation not become a vehicle for unnecessary delay. Finally, the Commission should clarify that cost reimbursement, permitted under the FDA's guidelines for clinical trials, does not run afoul of the marketing regulations in Section 2.803 for devices made available to patients in such trials. Additionally, the Commission should permit

medical devices designed to comply with the technical rules in Parts 15 and 95 to be used in residential settings under Section 2.805 if the operation is initiated pursuant to an FDA sanctioned clinical trial.

Respectfully submitted,

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