Before the

Federal Communications Commission

Washington, DC 20554

In the Matter of Spectrum Policy Task Force Report	ET Docket No. 02-135

COMMENTS OF MEDTRONIC

Medtronic, Inc.,[1] respectfully submits these comments in strong support of the Commission's Spectrum Policy Task Force Report.[2] As discussed below, two specific Task Force recommendations, (1) that the FCC should encourage the use of smart radio transceivers to manage and control interference, and (2) that the FCC should further international harmonization of spectrum allocations, were presaged by the agency's Medical Implant Communications Service (MICS) rulemaking.

I. The Commission's Development Of The MICS Rules Presaged The Findings Of The Spectrum Policy Task Force.

On July 28, 1997, Medtronic filed a petition for rulemaking asking the Commission to create the Medical Implant Communications Service (MICS) by amending Part 95 of the agency's rules. The Commission responded with a *Notice of Proposed Rule Making ("NPRM")*

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[1] Medtronic, headquartered in Minneapolis, Minnesota, is one of the world's leading developers of medical implant devices.

[2] *See* Federal Communications Commission, Spectrum Policy Task Force Report, Nov. 2002, ET Docket No. 02-135 (hereinafter "Report"); *and see* FCC Spectrum Policy Task Force, Report of the Interference Protection Working Group, Nov. 15, 2002 ("Interference Protection WG Report").

on February 24, 1999,[3] and, later that same year on November 29, the agency adopted the MICS regulations in a *Report and Order* issued in WT Docket No. 99-66.[4]

The MICS rules enable the transmission of "operational, diagnostic and therapeutic"[5] medical information between external monitoring and control equipment and implanted devices, such as cardiac pacemakers and defibrillators, neural stimulators, insulin pumps, and other devices – the vast majority of which have yet to be developed.[6] To accommodate a large medical user base in a very limited band of spectrum, the FCC implemented rules that provide for a high level of frequency reuse, a high degree of design freedom for technological innovation, and allow for the management of interference from multiple sources, such as other MICS users, the Meteorological Aids Service ("METAIDS"), and other intentional and unintentional radiators.[7]

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[3] 14 FCC Rcd 3659 (1999) (*NPRM*).

[4] 14 FCC Rcd 21040 (1999) (*Report and Order*).

[5] 47 C.F.R. § 95.1209(a) (2002).

[6] Without a doubt, because we are in the early stages of development of the potential for MICS devices, the efficient interference-free sharing of the limited MICS spectrum will only grow in importance. Over the next decade, Medtronic expects that the vast majority of the several million implanted pacemakers and pacemaker/defibrillators in the United States will be replaced with units incorporating MICS technology and that additional units will be implanted as efforts to identify those in need advance.

There are also a wide variety of other medical applications for MICS technology, including the treatment of Parkinson's disease and diabetes. The use of MICS implants to treat diabetes could easily rival the number of units employed in cardiac therapy. There are over 16 million diabetics in the United States, and roughly 11 million of these persons are aware of their disease and receiving medical care. Medtronic expects that, by the year 2012, over one million diabetics will utilize MICS-enabled devices. These devices will likely make increased use of the MICS band than cardiac devices because of the need to more closely monitor glucose levels.

[7] In this way, the MICS band is a form of the "Commons" model approach described in the Spectrum Policy Task Force Report. The MICS rules provide for equal access by unlimited numbers of medical users to the 3 MHz slice of spectrum from 402 to 405 MHz with usage rights governed by a set of technical rules. The MICS regulations include a spectrum etiquette that precludes interfering with other MICS systems or with the primary METAIDS service in the band but with no rights that protect the receipt of interference from these sources. For such protection, MICS devices must rely on the intelligence built into MICS systems.

The agency's rules were also promulgated in harmonization with international spectrum allocations as the FCC foresaw the need for implant patients who travel abroad to receive effective medical care utilizing the MICS capability of the implanted device.[8]

The Spectrum Policy Task Force likewise noted that interference management and worldwide harmonization of spectrum allocations are significant issues now that will only increase in importance.

With regard to interference management, the Task Force explained:

> Interference management has become more difficult because of the greater density, mobility and variability of radio frequency (RF) emitters. Interference management becomes even more problematic when and if users have been granted increased flexibility in their spectrum use.[9]

To address this issue, the Task Force recommended using smart transceivers that can monitor the RF environment and control the time, frequency and duration of their transmissions.[10] Such systems that incorporate intelligence to avoid the creation and receipt of interference are a cornerstone of the Medical Implant Communications Service.

II. The MICS Rules Require Smart Transceivers.

The MICS rules require implementation of channel use policy, frequency-agile transceivers and a listen before transmit protocol to control interference to and from other users. In this regard, the MICS regulations require:

> Those using MICS transmitters must cooperate in the selection and use of channels in order to reduce interference and make the most effective use of the authorized facilities. Channels must be

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[8] As discussed in Section III, *infra*, the MICS band was recommended internationally (by the ITU-R) for sharing spectrum with the Meteorological Aids Service.

[9] Report at 4.

[10] *See* Report at 14 ("[S]oftware-defined radios can search the radio spectrum, sense the environment, and operate in spectrum not in use by others."). *See also* Report at 20-21.

> selected in an effort to avoid interference to other MICS transmissions. See § 95.628.[11]

The requirements of this rule Section 95.1211(b) apply to all transmitters operated in the MICS band. Indeed, without a means for monitoring the MICS band before accessing a channel, a MICS device cannot "cooperate in the selection and use channels" to reduce interference.

To use the allotted radio spectrum effectively and efficiently, MICS devices must therefore operate on a frequency that avoids causing interference to other MICS users and also avoids receiving interference from other users of the spectrum.[12] MICS implants work in conjunction with a programmer/control transceiver, which is required to monitor the channel before initiating a "MICS communications session."[13]

The Wireless Telecommunications Bureau, which administers the MICS rules and was primarily responsible for the rule making that led to their adoption, has posted on the FCC's website the following discussion, which just as easily could have been found in the Spectrum Policy Task Force Report.

> Users of MICS transmitters must cooperate in the selection and use of channels in order to reduce interference and to make the most effective use of the authorized facilities. Most importantly, channels must be selected so as to avoid interference to other MICS transmissions. As a safeguard against such MICS-to-MICS interference, all MICS transmitters must incorporate a mechanism for monitoring the channel or channels that the MICS system devices intend to occupy and, unless there is a medical implant

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11 47 C.F.R. § 95.1211(b).

12 In proposing the rules, the Commission emphasized: "We believe that the potential for interference between multiple MICS systems operating in the same area must be minimized to prevent adverse effects on patients." *NPRM* at ¶ 10.

13 *See* 47 C.F.R. § 95.628.

> event, may not initiate a MICS communications session unless certain "access criteria" are met. (See 47 CFR 95.628(a)).[14]

The Commission built in this mechanism to ensure the high likelihood of successful transmissions whether in assisted care facilities, nursing homes, patients' homes, hospitals, physicians' offices or other locations with multiple MICS devices and/or other sources of RF noise.

The Task Force's Interference Protection Working Group cogently explained the importance of interference protection:

> Interference protection is central to effective spectrum management. … In today's radio frequency environment, interference generally limits the useable range or technical effectiveness of communications signals. Its effects on spectrum users and service providers range from annoyance, to economic harm, to threats to the safety of life and property. Interference protection is fundamentally related to spectrum rights and obligations. It also affects the efficiency of spectrum use. Regulatory interference protection standards that are too lax could prove detrimental to existing or planned services.[15]

Indeed, smart MICS transceivers that incorporate spectrum monitoring and the required access management protocol are critically important to the future success of the MICS band. The Task Force's Interference Protection Working Group noted also that "a long-term strategy" is to "promot[e] the use of self-enforcing environmental sensing and adaptive transmitter control

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[14] *See* FCC Wireless Bureau MICS Website, Operations-Interference Safeguards, *available at* <http://wireless.fcc.gov/services/personal/medicalimplant/operations/equipment.html>, *last accessed* Jan. 24, 2003. Section 95.628(b) sets forth an operational exemption for transmission without using the spectrum monitoring protocol when the data to be transmitted relate to a "medical implant event" but includes no language that exempts a MICS transmitter from having the capability of meeting the requirements of Section 95.1211(b).

[15] Interference Protection WG Report at 1. Obviously, any devices that do not comport with the MICS channel access protocol (*e.g.*, "dumb" transmitters) are unable to control the interference they create and could threaten the continued viability of the MICS band.

technology."[16] This long-term goal is already a reality with Medtronic's MICS equipment and any device that comports with the Commission's MICS rules.

MICS equipment can advantageously employ intelligent transceivers, in part, because the higher priority primary services (discussed in Section III below) that share the band with MICS are technically amenable given their operating power and deployment topographies. While the use of smart transceivers yields more efficient use of spectrum, like all such tools, this approach must be employed with an appreciation of the RF environment.[17]

III. The MICS Rules Were Promulgated In Harmonization With International Standards And Spectrum Allocations.

To "foster internationally ubiquitous services and economies of scale," the Spectrum Policy Task Force also highlighted the importance of dedicating spectrum "in conformity with international harmonization considerations."[18] In fact, the Commission decided to allow MICS operation in the 402 to 405 MHz band assigned to the Meteorological Aids Service ("METAIDS") because of the compatibility between MICS and METAIDS operations.[19] Because the band is internationally designated for METAIDS use as the primary service, it can

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16 Interference Protection WG Report at 20.

17 Thus, the use of such intelligent systems should not be viewed as a panacea for solving all electromagnetic compatibility problems. It would not, for example, be appropriate for low-power MICS devices to share a band of spectrum with densely deployed higher-powered services that would "overpower" and, hence, preclude MICS operations.

18 Report at 6.

19 Because the band between 402 to 405 MHz is a shared band and the predominant users of METAIDS facilities are federal agencies, the proposed allocation was coordinated with the National Telecommunications and Information Administration. METAIDS spectrum users, including the National Oceanographic and Atmospheric Administration's National Weather Service and the United States Air Force participated in the compatibility review of MICS with METAIDS. This group effort led to the adoption of a U.S. proposal to the International Telecommunications Union-R, which resulted in the ITU-R Recommendation cited by the FCC.

also be made available internationally for MICS use.[20] In the *Report and Order* adopting the MICS Rules, the Commission highlighted Medtronic's citation of the ITU-R recommendation as a basis for sharing the band with the METAIDS users and in deciding to "designate the MICS as a shared, secondary operation in the 402–405 MHz band."[21]

Similarly, the Task Force's Interference Protection Working Group noted that "[t]echnical compatibility among the radiocommunication systems leads to more efficient use of the spectrum and less constraints on the systems operating within a particular service allocation."[22]

The Task Force also noted that many commenters requested that the Commission build on its efforts to harmonize spectrum management policies and allocations with those of other countries. The Task Force explained:

> To the extent domestic policies and allocations complement international decisions, U.S. consumers and businesses will reap important benefits such as more international roaming and better economies of scale with regard to equipment manufacturing. [While many traditionally trans-border] services have long required and benefited from extensive international coordination, terrestrial services like third generation wireless and radio local area network (*e.g.*, Wi-Fi) services are also becoming increasingly ubiquitous requiring the same level of international coordination.[23]

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[20] The Commission also found that the propagation characteristics in the band are suitable for communications with devices implanted in human beings.

[21] 14 FCC Rcd at 21044 (discussing *Recommendation ITU-R SA.1346,* Sharing Between the Meteorological Aids Service and Medical Implant Communications Service (MICS) Operating in the Mobile Service in the Frequency Band 401 – 406 MHz). The ITU-R recommendation also figured prominently in the FCC's decision to propose the MICS Rules. *NPRM* at ¶¶ 9-10.

[22] Interference Protection WG Report at 20.

[23] Report at 41. *See also id*. at 41 ("because regional and world wide harmonization of band use can have significant advantages both in terms of truly ubiquitous services and economies of scale, in developing domestic spectrum policies and allocations, the Commission should consider the potential impact on international objectives, among other objectives."); *and see* Interference Protection WG Report at 24 (encouraging future Commission involvement in international

This is exactly the path the Commission took with the MICS rulemaking. The agency understood that individuals traveling abroad would be much better served if medical professionals in other countries could use the same type of MICS-based tools and equipment to assist implant patients.

CONCLUSION

Medtronic is pleased with the findings of the Spectrum Policy Task Force and looks forward to future FCC proceedings and policy decisions that use as a basis the Task Force's comprehensive recommendations. In adopting the Medical Implant Communications Service Rules, the Commission strived to implement a regulatory framework that would provide for international compatibility and interference-free operations among MICS devices and between MICS and METAIDS services. It is critical that Commission spectrum policy continue to evolve in order to control interference between RF devices to the greatest extent possible while permitting the greatest freedom for technological development.

As the Task Force noted:

> Section 303(f) of the Communications Act of 1934, as amended, directs the Commission to make regulations "it may deem necessary to prevent interference between stations" as the public interest requires. Sufficient interference protection is a necessary and fundamental building block in any spectrum policy. Indeed, without adequate interference management, new spectrum-based services could be prematurely thwarted and, correspondingly, mature services might not be able to reach their full potential.[24]

Medtronic applauds the Commission's re-affirmation of the policy underlying the MICS rules that smart radio frequency devices "cooperate in the selection and use of channels in order to reduce interference and make the most effective use of the authorized facilities" and select

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spectrum allocation processes to develop rules that mitigate interference, increase technical flexibility and enhance spectrum efficiency)

[24] Report at 25.

channels "to avoid interference to other MICS transmissions."[25] The Commission's enactment of the MICS rules will ensure the effective and efficient use of the band as RF medical devices proliferate during the 21st century.

Respectfully submitted,

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[25] 47 C.F.R. § 95.1211(b).