

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

In the Matter of)	
)	
Amendment of Parts 2 and)	WT Docket No. 99-66
95 of the Commission's Rules)	RM No. 9157
To Establish the Medical Implant)	
Communications Service in the)	
402 - 405 MHz band)	

To: The Commission

REPLY COMMENTS OF MEDTRONIC, INC.

Medtronic, Inc. (AMedtronic),¹ by its attorneys, hereby submits these reply comments in support of the Commission's proposal to create the Medical Implant Communications Service (AMICS) in the 402-405 MHz band.² The record uniformly illustrates how MICS will yield significant public interest benefits by helping both patients and the general health care system. Further, parties commenting in this proceeding join with Medtronic in urging the Commission to act quickly to create MICS. As many of these commenters point out, given the rapid pace of the improvements in medical technologies and the benefits that inure from the implementation of these developments, it is important that the Commission promptly.

¹ Medtronic, Inc., established in 1949, is a world leader in medical implant technology. It conducts business in 120 countries and manufactures medical implants that regulate heart rates, control pain, improve motor functions and administer medication, among other things.

² See Amendment of Parts 2 and 95 of the Commission's Rules To Establish a Medical Implant Communications Service in the 402-405 MHz Band, WT Docket No. 99-66, RM No. 9157, *Notice of Proposed Rulemaking*, FCC 99-23 (rel. Feb. 24, 1999) (AMICS NPRM).

I. ALL COMMENTERS SUPPORT THE CREATION OF MICS AND CITE ITS SIGNIFICANT PUBLIC INTEREST BENEFITS

All of the parties responding to the Commission's invitation to comment on the MICS NPRM urge the Commission to adopt the rules for its creation and point to the significant public interest benefits of MICS to support their positions. Many of the commenters cited two distinct sets of benefits that would result from the adoption of MICS. First, these commenters agreed with the Commission's finding that this new service would generate significant benefits for implant patients. Cardiovascular Consultants, P.C., reiterated its earlier statement that MICS represents "a fairly dramatic improvement in patient care" because it (1) would allow more data to flow between implant and controller, (2) would be less intrusive to the patient, and (3) could be used outside of the sterile field when the device is implanted.³ In addition to these benefits, the American Hospital Association singled out a particular benefit of MICS when it observed that "[i]mplanted MICS devices will also greatly enhance the quality of life for our elderly and fragile patients, by providing more efficient home monitoring of their medical conditions."⁴

Further, the record illustrates that MICS would generate benefits to the medical care system as a whole "by reducing health care expenditures."⁵ As the American Hospital Association explains, MICS would lower costs "through reduced hospitalizations, fewer expensive and invasive diagnostic surgeries, and the elimination of the need to conduct quarterly data collection in the clinical setting."⁶ Other commenters cited the higher data transmission

³ Letter from David M. Steinhaus, M.D., Cardiovascular Consultants, P.C., to Magalie Roman Salas, Secretary, FCC (Mar. 31, 1999) (Attachment) ("Cardiovascular Consultants Letter").

⁴ Letter from Rick Pollack, Exec. Vice Pres., American Hospital Assoc., to Magalie Roman Salas, Secretary, FCC, at 1 (Apr. 9, 1999) ("AHA Letter").

⁵ AHA Letter at 1.

⁶ AHA Letter at 1. The AHA Letter also alludes to other types of medical telemetry that require different spectrum. Those uses and that spectrum are not at issue in this proceeding.

rate which will shorten information transfer sessions and the fact that a MICS device would allow medical personnel to perform other tasks as additional factors that will save the health care system money as a result of these increased efficiencies.⁷

II. CONSISTENT WITH THE ITU RECOMMENDATION AND IN ACCORDANCE WITH SOUND ALLOCATIONS POLICY, THE MICS SHOULD BE ALLOCATED SPECTRUM AS A MOBILE SERVICE ON A SECONDARY BASIS TO METEOROLOGICAL AID, EARTH EXPLORATION SATELLITE, AND METEOROLOGICAL SATELLITE SERVICES

Medtronic understands that NTIA has asked the Commission to clarify footnote 34 of the *MICS NPRM* so as to make it clear that, as an allocation, MICS does not enjoy secondary status but will operate on a non-interference basis.⁸ However, this suggestion runs counter to the recommendation made by the ITU and to the extensive discussions leading to the proposal for the creation of MICS. Further, changing the status of MICS to an undefined tertiary service would inject an unneeded element of uncertainty into the operation of the service. Therefore, Medtronic urges the Commission to refrain from making those changes as proposed by NTIA and to make the allocation of spectrum to MICS on a secondary basis.

From the very beginning, it was envisioned by the parties working to create and implement MICS that allocations of spectrum to this service would be secondary to the primary services on the band B Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite (EES).⁹ First, the allocation at 402-405 MHz already contemplates use of that band *on a*

⁷ See Letter from Douglas P. Zipes, M.D., Krannert Institute of Cardiology, Indiana Univ., to Magalie Roman Salas, Secretary, FCC (Mar. 26, 1999) (Attachment); Letter from Edward V. Platia, M.D., Washington Hospital Center, to Magalie Roman Salas, Secretary, FCC (Mar. 24, 1999) (Attachment) (noting that more information can be obtained in less time, thereby saving health care dollars and permitting a physician to treat more patients and to do so more effectively).

⁸ See Letter from William T. Hatch, Acting Assoc. Administrator, NTIA, to Dale Hatfield, Chief, OET/FCC (Apr. 1999) (Hatch Letter).

⁹ The Meteorological Satellite (earth-to-space) and Earth Exploration Satellite (earth-to-space) are co-primary services with the Meteids as a result of the Final Acts of the 1997 WRC.

secondary basis by mobile services.¹⁰ Given the fact that one of the key benefits of medical implants is that they allow the patient to resume a normal life -- a life that includes mobility -- and that one of the prime goals leading to the development of the MICS was to increase the flexibility afforded in medical device follow-up, MICS is by its very nature a mobile service.¹¹ In fact, during the U.S. Working Party 7C deliberations that led to the ITU-R recommendation for sharing spectrum with Metajids, the existing secondary mobile allocation quickly emerged as a reason why no separate allocation to MICS would be needed. MICS could utilize the existing allocation as a mobile service.¹²

Second, classification of MICS as a secondary service carries with it the *same obligations* that the NTIA proposal contemplates with respect to Metajids and other primary services. As a secondary service, MICS operators are obligated not to Acause harmful interference to stations of primary or permitted services to which the frequencies are already assigned or to which frequencies may be assigned at a later date.¹³ Further, such stations A[c]annot claim protection from harmful interference¹⁴ from those same stations enjoying primary status.¹⁴ In other words, as a secondary service, MICS will be obligated to protect the Metajids, Meteorological Satellite and EES services from harmful interference and will be obligated to accept harmful interference from the same, which is exactly what the footnote proposed by NITA states.

In this respect, the original rules recommended by Medtronic and the rules proposed by

¹⁰ See 47 C.F.R. § 2.106 (1998) (including an allocation in all three ITU regions for AMobile except aeronautical mobile¹⁰).

¹¹ See 47 C.F.R. § 2.1 (defining a mobile station as one Aintended to be used while in motion or during halts at unspecified points¹¹).

¹² See *RECOMMENDATION ITU-R SA.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* (1998).

¹³ 47 C.F.R. § 2.105(c)(3)(i).

¹⁴ 47 C.F.R. § 2.105(c)(3)(ii).

the Commission both call for MICS equipment to carry with it clear information to users that operations would be subject to the obligation that operations would not cause harmful interference to Metacids and EES stations and that MICS devices would be required to accept harmful interference from primary service operations.¹⁵ In short, the burden both to avoid causing interference and to deal with any interference received was placed on those who would utilize the MICS.

Additionally, Medtronic in its Comments proposed a Δ listen before transmit \cong requirement for most MICS transmissions as another way to help to prevent any harmful interference to stations in the primary services. This requirement would also minimize interference received within MICS from the primary services or other MICS systems such as might be found within a clinical setting.¹⁶

However, there is a difference between what Medtronic understands the NTIA proposal to be and that of a *secondary* classification. A secondary service receives some measure of interference protection from those secondary services that are allocated the same spectrum at a later date.¹⁷ However, NTIA apparently contemplates placing MICS in a Δ tertiary \cong non-interference status with no protection whatsoever. Thus, under the NTIA proposal, the MICS would be subject to the interference of *all* secondary services receiving allocations without regard to when the allocation is made.

This is not a distinction without a difference. The failure to provide MICS with this modicum of protection would introduce an element of undesirable uncertainty into the use of MICS implants. For instance, the loss of such protection would negatively impact the certainty

¹⁵ See Sections 95.1115 and 95.1117 (proposed) of the draft regulations set forth in Appendix B to the NPRM.

¹⁶ Medtronic Comments, Appendix A, at 5 (Apr. 9, 1999) (recommended rule Section 95.630).

surrounding the longevity of the *use* of the medical implant. Longevity of the implant is one of the most important factors entering into its design. One reason is that the removal of the implant, often is a major surgical procedure carrying with it all of the attendant risks accompanying such surgery.

If future secondary mobile services are to be allocated spectrum in the 402 - 405 MHz bands, the presumption should be that these will not be allowed to cause interference to MICS operations. Of course, the Commission would retain the authority to determine if, and to what extent, any such future operations would be allowed to affect MICS stations. The point, however, is that any such decision should be reached after an examination of MICS usage and not simply premised on the allocation having been made on a non-interference basis.¹⁸

The Commission is aware of the damage that uncertainty can bring. Despite its efforts at making clear the limits of regulatory protection, the agency has grappled with such uncertainty in connection with the operation of medical telemetry systems in television broadcast spectrum.¹⁹ The Commission has also had to focus on the special problems of higher powered medical telemetry as the agency has worked to accommodate such operations in light of land mobile refarming.

(. . continued)

¹⁷ See 47 C.F.R. 2.105(c)(3)(iii).

¹⁸ Treating the allocation for MICS as a mobile service allowed on a secondary basis is consistent with the Commission's point that stations in Part 95 are neither primary nor secondary. *MICS NPRM*, n.34. Part 95 deals with the service rules, while Part 2 of the regulations sets forth the allocation for the service.

¹⁹ Unlike Part 15 medical telemetry operations in broadcast spectrum in which utilization of the spectrum for its primary purpose (*i.e.* television broadcasting) would be incompatible with use of the spectrum for medical telemetry, the MICS allocation rests on a careful analysis of Medtronic's operations and both the proposed allocation and the proposed service rules support the sort of flexibility needed to minimize the chances of any interference to either the primary or the secondary users. Moreover, Medtronic is under no illusion that even sound regulations can take the place of careful and rigorous engineering. MICS systems will, of necessity, be designed to minimize the chances of interference that would impair their operation. Medtronic expects that other developers of MICS systems will also work toward this objective.

In conclusion, the FCC should clarify that MICS is a secondary service. As such it will operate in the same manner as the NTIA proposal asks. Also, Medtronic agrees that the footnote designator should be changed to a AUS≡ as recommended by NTIA. MICS operations will likely be conducted by both federal and non-federal government users. In order to minimize the chances of any misunderstanding, Medtronic suggests that the footnote be worded as follows:

US XXX - Mobile services allocated on a secondary basis in the bands 402 - 405 MHz are limited to the Medical Implant Communications Service (MICS). Stations in the MICS are authorized by rule on the conditions that harmful interference is not caused to stations in the Meteorological Aids, Meteorological Satellite and Earth Exploration Satellite Services and that MICS stations accept interference from stations in the Meteorological Aids, Meteorological Satellite and Earth Exploration Satellite Services. Certain MICS stations are subject to the registration requirements set forth in Section 95.1115 of this Chapter.

By doing so, the Commission will ensure that the benefits MICS promises will be realized and that the operations of the primary services will not be impaired.

III. THE COMMISSION MUST ACT QUICKLY TO ELIMINATE THE WEAK LINK IN THE CHAIN OF CURRENT IMPLANT TECHNOLOGY

The capabilities that MICS would bring to medical implant technology have been described as no less than a true breakthrough in this field.²⁰ It is a breakthrough not so much for what MICS represents (wireless communications), but for what it will allow medical implant devices to do. MICS represents the replacement of the existing weak link in implant technology, which happens to be a vital link in the chain of that technology B the communications link between the implant and the Aoutside world.²¹ This one improvement will allow medical implant devices to take advantage of newly emerging techniques and medical technologies. Given what is at stake and the uniform agreement to take this action, it makes perfect sense for the Commission to act as quickly as it can.

Several parties noted that advances in implant capabilities and technology are poised to outstrip the ability of these devices to take advantage of these improvements. Dr. Ben Johnson of the Iowa Heart Center pointed out that the Aamount of information now being stored within these implantable devices is very rapidly increasing.²¹ For example, such levels of information are required to treat and monitor such conditions as congestive heart failure.²² However, the current technology does not permit the transfer of data at the speeds needed to exploit fully the capabilities of the implant technology that is available to be implemented.

²⁰ Cardiovascular Consultant=s Letter at 1.

²¹ Letter from W. Ben Johnson, M.D., Iowa Heart Center, P.C., to Magalie Roman Salas, Secretary, FCC, 1 (Apr. 2, 1999) (AIHC Letter²¹).

²² *Id.*

The establishment of MICS, on the other hand, will promote the development of a *new generation of implant devices* that will provide a safer, less costly, and less invasive method to diagnose and manage patient conditions than the systems currently utilized.²³ The current system relies on a dated, slow technology that is holding back the further development and exploitation of dramatic new capabilities in the field of medical implants. MICS will allow this new generation of implant devices to develop by replacing the weak link in the implant technology chain with a modern, faster communications system. In short, the timely adoption of MICS will allow medical implant technology on all fronts to move forward²⁴ and implement new technologies and techniques to expand the life-giving benefits of medical implants.

IV. CONCLUSION

The Commission has the opportunity before it to save lives and enhance the quality of life for those relying on medical implants. As the record clearly demonstrates, the adoption of rules to create MICS will generate significant public interest benefits to patients, doctors, and the health care system at large. Medical implant technology stands poised for a breakthrough, if only the weak link in the chain of that technology is upgraded and replaced. This breakthrough can only happen if the Commission acts to implement the rules to create MICS. Thus, in the

²³ AHA Letter at 1 (emphasis supplied).

²⁴ IHC Letter at 2.

interest of those who rely and depend upon medical implants for life, Medtronic respectfully asks that the Commission act quickly.

Respectfully submitted,

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April 26, 1999