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VIA ECFS AND E-MAIL

Julius 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:

Medtronic is compelled to respond to the February 7, 2008 *ex parte* presentation by AMI Semiconductor ("AMIS") in the above-referenced dockets asking the Commission to allow voice communications within the 405-406 MHz band, which is one-half of the 2 MHz band that the agency has proposed for use by body-worn and implantable medical devices performing diagnostic, therapeutic, and monitoring functions. *See Investigation of the Spectrum Requirements for Advanced Medical Technologies; Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radio Communications Service at 401-402 and 405-406 MHz*, ET Docket No. 06-135, NPRM, NOI, & Order, FCC 06-103 (¶ 20) (July 18, 2006). While wireless hearing aids are critically important to a large segment of the population, they should not be authorized in the MedRadio band for three separate reasons.

First, permitting wireless hearing aid operations in the 405-406 MHz band would effectively preclude use of the entire 1 MHz segment of the MedRadio band by other non-voice wireless medical devices performing important diagnostic, therapeutic, and monitoring functions.

Indeed, AMI concedes that "a hearing aid application with wireless interconnectivity can be a high duty cycle application." AMIS Ex Parte Filing, ET Docket No. 06-135, Oct. 20, 2007. Because of this, both the MICS band rules and the proposed wing-band (aka "MEDS") rules permit only non-voice communications. *See* 47 C.F.R. § 95.401(d) (MICS is "an ultra-low power radio service for the transmission of non-voice data for the purpose of facilitating

diagnostic and/or therapeutic functions involving implanted medical devices."); 47 C.F.R. § 95.1215 ("Analog and digital voice communications are prohibited."); *see also* Petition for Rulemaking to Amend Parts 2 and 95 of the Commission's Rules to Establish The Medical Data Service at 401-402 and 405-406 MHz, RM-11271, filed July 15, 2005 ("MEDS Petition for Rulemaking"), proposed §§ 95.401(h), 95.631(k), 95.1609(a) & 95.1615 (permitting only non-voice communications).

Allowing voice communications at 405-406 MHz would render useless that portion of the band for the many lower-duty cycle medical data applications that MEDS is intended to accommodate. To reliably operate in the variety of wireless environments that tomorrow's mobile medical patient will encounter, body area networks comprised of a coordinated collection of implantable and body-worn medical devices will need channels throughout the entire 401-406 MHz MedRadio band – including channels in *both* the lower and upper wing bands at 401-402 and 405-406 MHz. AMIS's earlier comments in this proceeding explained that the expanded MedRadio band would enable countless patient medical data applications.

> Many developers are investigating the incorporation of wireless body-worn sensors to monitor patients' vital signs, eliminating a wired connection and providing additional patient mobility. These measurements may include temperature, pulse, respiration, blood pressure, blood oxygen saturation, heart data and even brain activity. … Other applications, including the measurement and detection of blood chemistry, medication levels, and identification of conditions such as cancer or other illnesses, are also being investigated. Some of these devices would be, in part, externally worn, penetrating the skin for access to blood for measurements. For many of these proposed applications, AMIS believes that low transmit duty cycles and restricted transmit power levels would provide adequate isolation and prevent interference between large numbers of these wireless medical measurement devices. It will be necessary for manufacturers to provide safeguards, such as multiple retransmissions of data, to increase the probability of receiving and monitoring successful transmission sequences from the sensors or to detect system faults. There are a number of other medical applications that will require much higher transmission duty cycle. These devices include continuous heart and neurological measuring devices [and wireless hearing aid devices].

AMIS Reply Comments, ET Docket No. 06-135 (Oct. 30, 2006). While there is no question that the potential number of non-voice medical uses for the band is far reaching, permitting voice transmissions at the initial stages of device development would have a detrimental impact on the development of all other critical, and non-voice, medical data applications. AMIS is requesting what would amount to an exclusive allocation for one class of devices – wireless hearing aids – which, by AMIS's own admission, would operate with a 100% duty cycle and thus "crowd out" all or nearly all other patient devices that the band is intended to support. The Commission recognized this concern when it promulgated the Wireless Medical Telemetry System ("WMTS") service regulations and decided against allowing voice transmissions in that service: "We are not persuaded that there is currently a need for voice capabilities in telemetry equipment, and we reiterate our concern that allowing such capabilities could encourage use of the equipment for other than its intended purpose of transmitting patient data." *Amendment of Parts 2 and 95 of the Commission's Rules to Create a Wireless Medical Telemetry Service*, Report and Order, 15 FCC Rcd 11206, 11221 (2000).

Second, contrary to AMIS claims that its wireless hearing aid proposals "would be harmonized with international standards," the ETSI standard governing the medical data service at 401-402 and 405-406 MHz (like the MEDS Petition for Rulemaking) is limited to non-voice applications. *See* ETSI EN 302 537-1 V1.1.2 (2007-12) European Standard, 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, § 3.1 (operations limited to "non-voice digital communications").

Medtronic is not aware of any international standard or recommendation that incorporates AMIS's proposals at 405-406 MHz for wireless hearing aids (and AMIS does not identify any). Thus, AMIS's claim that the "MEDS bands would be harmonized with international standards and therefore provide worldwide access and deployment capability for these hearing aids," *see* AMIS Ex Parte Filing at Slide 3 (Feb. 7, 2008), appears to be incorrect.

Furthermore, the ETSI standard provides for a 100 kHz maximum channel bandwidth in the wing bands – not the 300 kHz bandwidth that AMIS is requesting. *See id*.; *see also* ERC Recommendation 70-03, Relating To The Use Of Short Range Devices (SRD), Annex 12 ("maximum bandwidth of 100 kHz is proposed for these bands to ensure that several users could access the band concurrently"). In

addition, the 300 kHz-wide maximum channels that AMIS has proposed could create problems for core MICS band devices. Medtronic studied this issue closely prior to filing the MEDS Petition for Rulemaking to determine suitable levels of out-of-band emissions in the core MICS band created by MEDS devices. Devices limited to a 100 kHz bandwidth (as proposed in the Petition for Rulemaking) typically will have a steeper modulation envelope slope at the band edge compared to the modulation envelope of a 300 kHz bandwidth device (that AMIS is requesting) and thereby reduce the energy spill over from the modulation process into the upper edge of the core MICS band at 402-405 MHz. The need to provide reduced energy ingress into the core MICS band (which was designed to support ultra-low-power transmissions from implantable medical devices exclusively)[1] coupled with the need to support body area networks comprised of many body-worn medical devices compels the 100 kHz channel width in the MEDS bands.

Third, as delineated below, there are other viable spectrum options for wireless hearing aid applications. Tellingly, AMIS does not explain why these other options are not viable.

1. FCC rules already support wireless auditory assistance devices in four separate bands under Part 15 and the Low Power Radio Service ("LPRS") in Part 95. *See* 47 C.F.R. § 15.237 (enabling auditory assistance device operation at 72.0-73.0 MHz, 74.6-74.8 MHz, and 75.2-76.0 MHz); 47 C.F.R. § 95.629 (enabling auditory assistance devices at 216-217 MHz). As the Commission recently explained, "[t]here are already a number of provisions in Part 15 of the rules that permit voice, … and continuous transmissions in other frequency bands, so there is no need to establish additional provisions for them" in the MedRadio band. *Review of Part 15 and Other Parts of the Commission's Rules Amendment of Parts 2 and 15 of the Commission's Rules to Deregulate the Equipment Authorization Requirements for Digital Devices M/A-COM Private Radio Systems, Inc.*, Petition for Declaratory Ruling, 18 FCC Rcd 14741, ¶ 12 (2003).

2. AMIS can also pursue wireless hearing aid development in the U.S. at 169.4-169.8125 MHz, which already is designated for such use in Europe. *See European*

[1] The need to conserve battery power for long-term implanted devices requires use of the minimum necessary communications power. Human tissue also significantly attenuates the radiated signal. For these reasons, signals from implanted devices in the core MICS band are far lower in strength than those of external medical devices such as a programmer/controller. Consequently, undesired emissions from the "wing bands" into the core 402-405 MHz band must be limited.

Commission Decision of 20 Dec. 2005 on the harmonization of the 169.4-169.8125 MHz frequency band, 2005/928/EC.

3. The internationally-compatible Bluetooth standard, which provides short-range wireless voice communications associated with mobile phones and like devices, has been adapted for use in the wireless hearing aid space. *See, e.g.*, Jerry L. Yanz, The Future Of Wireless Devices In Hearing Care: A Technology That Promises To Transform The Hearing Industry, *The Hearing Review* (Jan. 2006) *available at* http://www.hearingreview.com/issues/articles/2006-01_01.asp ("[W]e are witnessing the development of Bluetooth wireless transmitters as the sending portion of the ALD. Bluetooth transmission and reception can be expected to improve performance and security and reduce radio-frequency interference compared with analog FM systems. Furthermore, these devices will be considerably smaller than their FM predecessors."). AMIS itself has partnered with a hearing aid technology company to develop hearing aids that work with Bluetooth technology. *See* AMI News Release - Phonak Selects AMI Semiconductor's BelaSigna™ 200 to Deliver Crystal-Clear Sound Quality in Next-Generation Communication System (Apr. 18, 2005) *available at* http://www.amis.com/news/releases/2005/Q2/050418_phonak.html.

4. Another possibility for wireless hearing aid device development is an ultra-low-power inductive system. One such approach has been developed by Oticon. *See* Interview with Donald Schum, Ph.D., Vice President, Audiology & Professional Relations, Oticon USA (July 7, 2007) *available at* http://www.oticonusa.com/eprise/main/SiteGen/Uploads/Public/Downloads_Oticon/Audiology_Online/Don_Schum_Interview.pdf; George Lindley, Accessing the "Far World": A New Age of Connectivity for Hearing Aids, *The Hearing Review* (May 2007) *available at* http://www.hearingreview.com/issues/articles/2007-05_05.asp. Oticon's Epoq hearing aids communicate binaurally via near-field magnetic inductions technology that operates at 3.84 MHz and less than -42 dBμA/m at 10 meters. This system is especially attractive for wireless hearing aid devices because the short transmission range for these inductive systems can support numerous users in close proximity.

Also, the ITU-R has identified the 3155-3400 kHz band for use by wireless hearing aid inductive systems, as noted below in footnote 5.116:

> "5.116 Administrations are urged to authorize the use of the band 3155–3195 kHz to provide a common worldwide channel for low

> power wireless hearing aids. Additional channels for these devices may be assigned by administrations in the bands between 3155 kHz and 3400 kHz to suit local needs."

This band is a more desirable and likely candidate for international harmonization supporting the development of low power wireless hearing aid inductive systems given its desirable transmission characteristics through tissue, the rapid roll-off of the near field wave, and the express encouragement of the ITU-R.

In conclusion, the Commission should review closely AMIS's request to permit hearing aid devices at 405-406 MHz. Medtronic respectfully requests that the proposed use of the MedRadio band for voice applications be rejected at this time because there are other spectrum options available, and, contrary to AMIS's claims, the proposed use at 405-406 MHz does not appear to be supported by any international standard.

Sincerely,

David E. Hilliard

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