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

In the Matter of	)	
	)	
Amendment of Parts 2 and 95 of the Commission's	)	ET Dkt. No. 09-36
Rules to Provide Additional Spectrum for the	)	
Medical Device Radiocommunication Service in	)	RM-11404
the 413-457 MHz Band	)	

COMMENTS

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SUMMARY

AMF urges the Commission promptly to provide spectrum in the 413-457 MHz frequency band and adopt service and technical rules to allow medical micropower network ("MMN") operation on a secondary basis. MMNs offer invaluable health, cost, and other public interest benefits, particularly for U.S. veterans and millions of other Americans suffering from severe spinal cord injury, traumatic brain injury, stroke, cerebral palsy, multiple sclerosis, arthritis, or other neuromuscular injuries or disorders. MMNs represent transformative medical technology that is available now and that will materially improve the quality of life for millions of Americans with disabilities previously considered very difficult or impossible to treat. Because MMNs operate wirelessly, they offer a safer, less surgically invasive, more convenient, and more effective method of treatment than commercially available devices that rely upon cumbersome wire electrodes.

The 413-457 MHz band is ideally suited for MMN operation and falls within the range of spectrum widely viewed as most suitable for radiofrequency signal propagation within the human body. Moreover, frequencies outside of the 413-457 MHz band are generally unavailable or undesirable for MMN use.

MMNs are specifically designed to avoid or eliminate harmful interference to and from incumbent operations in the 413-457 MHz band. MMNs also are designed to protect patient safety by employing various interference mitigation techniques. Collectively, these techniques both mitigate the risk of harmful interference and ensure the proper functioning of the MMN system even in the event of a disruption in communications caused by potentially interfering signals. Consequently, by adopting service and technical rules, the Commission will help usher in a pioneering medical technology that could fundamentally improve the quality of life for

millions of disabled Americans with no adverse impact on incumbent operations in the 413-457 MHz band.

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Amendment of Parts 2 and 95 of the Commission's Rules to Provide Additional Spectrum for the Medical Device Radiocommunication Service in the 413-457 MHz Band	))))	ET Dkt. No. 09-36 RM-11404

COMMENTS

I. INTRODUCTION

The Alfred Mann Foundation for Scientific Research ("AMF") commends the Commission's foresight in initiating of the above-captioned rulemaking and submits these comments in support of the proposal to provide spectrum in the 413-457 MHz frequency band and adopt service and technical rules to allow use by wideband medical micropower network ("MMN") devices on a secondary basis.[1]

Decisive and prompt Commission action in this proceeding is critical to the development and deployment of a breakthrough wireless technology that can restore sensation, mobility, and other functions to paralyzed limbs and organs. This revolutionary, transformative technology is expected to be ready for human feasibility trials commencing as early as next year. Without adequate spectrum and service rules, millions of Americans, and in particular returning wounded American warfighters, will be deprived of a new and innovative method of treatment for their neuromuscular injuries or disorders. By adopting spectrum allocation and service rules, the

[1] *See Amendment of Parts 2 and 95 of the Commission's Rules to Provide Additional Spectrum for the Medical Device Radiocommunication Service in the 413-457 MHz*, Notice of Proposed Rulemaking, FCC 09-20, (2009) ("*NPRM*").

Commission will help usher in a pioneering medical technology that could fundamentally improve the quality of life for seriously disabled people and reduce the skyrocketing costs of their medical care. These extraordinary benefits can be achieved with virtually no impact on incumbent operations in the 413-457 MHz band.

II. MMNs OFFER INVALUABLE PUBLIC INTEREST BENEFITS

As AMF noted in its petition for rulemaking ("Petition"), MMNs offer invaluable health, cost, and other public interest benefits, particularly for U.S. veterans and millions of other Americans suffering from severe spinal cord injury, traumatic brain injury, stroke, cerebral palsy, multiple sclerosis, arthritis, or other neuromuscular injuries or disorders.[2] These benefits are made possible because MMNs provide a unique and revolutionary wireless approach to treating various neuromuscular injuries and disorders by performing a functional electric stimulation ("FES") technique that uses minimal electric currents to monitor and activate nerves and muscles. Specifically, MMN devices more precisely can target a greater number of nerves than other FES systems to promote both gross and fine motor movement. They also can coordinate the delivery of stimulation pulses to best replicate natural movements. As illustrated in Appendix A, the components of an MMN system include (1) a master control unit ("MCU") that is external to the body and coordinates the activities of all other system components; (2) separate miniature, battery-powered, fully implantable microstimulators capable of sensing bodily signals or generating stimulation pulses; and (3) an external charger and coil assemblies to recharge the implant batteries.

Based on a comprehensive survey conducted in 2008, nearly two percent of the U.S. population, or approximately 5.6 million people, reported suffering from some form of paralysis,

[2] *See* AMF Petition at 7-11 (Sept. 5, 2007).

caused by stroke, spinal cord injury, multiple sclerosis, cerebral palsy, traumatic brain injury, or other injury or condition.[3] For many of these people, FES has been proven effective in increasing muscle mass and improving cardiopulmonary function.[4] Studies also have linked FES to reduced occurrences of pressure sores, improved bowel and bladder function, and decreased incidence of urinary tract infections.[5]

When successfully implemented, MMNs may be used for applications such as enabling paraplegics to stand (and potentially to walk), restoring hand grasp function for quadriplegics, restoring bowel and bladder function, and alleviating common, but chronic conditions that may not be responsive to pharmaceutical treatment, such as arthritis, and pain. Because MMNs operate wirelessly, they offer a safer, less surgically invasive, more convenient, and more effective method of treatment than commercially available FES devices that rely upon cumbersome wire electrodes. In doing so, MMNs can alleviate the need for costly, long-term medical treatment and thus provide significant cost savings for millions of disabled Americans. Studies show that Americans with disabilities tend to earn below-average incomes while also incurring significantly greater health care expenses than Americans without disabilities.[6]

MMN technology and the benefits it can offer are not hypothetical, but in fact very real. Since obtaining an FCC experimental license in January 2005, AMF has made significant strides toward developing fully functioning MMN equipment and continues to implement improvements that will enhance the radiocommunication performance and reliability of the equipment. To

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[3] *See One Degree of Separation: Paralysis and Spinal Cord Injury in the United States,* Christopher & Dana Reeve Foundation, at 10, *available at* http://www.christopherreeve.org/atf/cf/%7B3d83418f-b967-4c18-8ada-adc2e5355071%7D/8112REPTFINAL.PDF.

[4] *Id.* at 16.

[5] *Id.*

date, AMF has expended approximately one hundred million dollars on research and development of new MMN devices and their application.

In particular, AMF successfully has tested prototypes of the MCU and has implanted microstimulators in animals, thus commencing *in vitro* and *in vivo* testing to verify system biocompatibility and operation. AMF also is completing construction of an updated version of the MCU that will implement the interference mitigation techniques discussed in Section IV below. AMF expects to introduce near-term fully functioning MMN devices in clinical studies involving human patients under the auspices of and pursuant to the rules and regulations administered by the Food and Drug Administration.[7] AMF also is considering research proposals and research teams, as well as coordinating with leading clinicians, including U.S. military personnel, to perform the first human feasibility trial, expected to commence next year. Additionally, AMF has entered into a contract with the Philadelphia Shriners Hospital, a leading provider of FES treatment for children with cerebral palsy, to explore using MMNs to reduce spasticity in these children. Through these and other efforts, AMF continues to develop and refine MMN technology so as to permit commercial deployment in the near future.

Recognizing the extraordinary benefits that MMNs offer, several parties already have filed comments strongly supporting the Commission's proposal to adopt MMN rules. Notably, veterans' organizations, such as the Marines Memorial Association and the Injured Marine Semper Fi Fund, have asserted that "[MMN] equipment would transform the lives of millions of

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[6] *Id.* at 19.

[7] AMF, in collaboration with medical personnel at Walter Reed Army Medical Center, currently is using predecessor MMN devices in a clinical study for the treatment of an incomplete spinal cord injured military officer. Surgeons at Walter Reed implanted three devices on November 5, 2008. Additionally, AMF, in collaboration with medical personnel at the VA Hospital in Cleveland, currently is using predecessor MMN devices in a clinical study for the reanimation of gait in post-stroke patients.

disabled Americans" and that "our injured U.S. service members need the benefits of advancements in medical care potentially offered by the MMN devices."[8] Moreover, the Biomechatronics Development Laboratory of the Rehabilitation Institute of Chicago, which has been involved in the design and development of prosthetic arms and hand systems, noted that "MMN technology provides a unique wireless approach that is unlike any commercially available medical treatment option."[9] Other parties, including Dr. J. Thomas Mortimer, Professor Emeritus of Biomedical Engineering, who have vast expertise in the research and treatment of neuromuscular injuries and conditions, also recognized that "the benefits offered by MMN devices are immeasurable and cannot be replicated by other existing technologies."[10] These parties are unanimous in their call for prompt Commission adoption of MMN rules.

III. THE 413-457 MHz BAND IS IDEALLY SUITED FOR MMNs

A. The 413-457 MHz Band Satisfies MMN Technical and Design Requirements

As noted in the Petition, the 413-457 MHz band falls within the range of spectrum widely viewed as most suitable for radiofrequency ("RF") signal propagation within the human body.[11] In fact, the Commission previously found that frequencies below 216 MHz and above 470 MHz are "outside the range of spectrum generally considered to be the most suitable for propagation

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[8] *See* Letter from General Al Gray, USMC (Ret), Chairman, Injured Marine Semper Fi Fund, to Marlene H. Dortch, Secretary, FCC, at 1-2 (July 3, 2009), *available at* http://fjallfoss.fcc.gov/prod/ecfs/retrieve.cgi?native_or_pdf=pdf&id_document=7019915752; Letter from Major General J. Michael Myatt, USMC (Ret), President and CEO, Marines' Memorial Assocation, to Marlene H. Dortch, Secretary, FCC, at 1 (June 29, 2009).

[9] *See* Letter from Richard F. Weir, Ph.D., Director, Biomechatronics Development Laboratory, Rehabilitation Institute of Chicago, to Marlene H. Dortch, Secretary, FCC, at 1 (July 7, 2009).

[10] *See* Letter from J. Thomas Mortimer, Ph.D., Professor Emeritus of Biomedical Engineering, Case Western Reserve University, to Marlene H. Dortch, Secretary, FCC, at 1 (July 23, 2009).

[11] *See* AMF Petition at 14.

of radio signals within the human body."[12] AMF-conducted tissue tests confirm that frequencies in the lower 400 MHz band are optimal for RF signal propagation through body tissue.

Frequencies in the lower 400 MHz band also are optimal for purposes of conserving MMN battery power and minimizing battery size. MMN microstimulators are 26 mm. in length and 3.5 mm. in diameter, and therefore must use miniature batteries, which are 11.86 mm. in length and 2.9 mm. in diameter. The miniature size allows the microstimulators to be easily injected in a doctor's office on an out-patient basis, thus eliminating the need for invasive surgery, maximizing patient comfort, and minimizing the risk of infection or other complications. These miniature batteries also eliminate the need for patients to wear an external, magnetically coupled coil to transmit power and data to the implanted device, thereby improving acceptance of the technology by patients, enhancing the reliability of the system, and enabling the mobility of patients uninhibited by cumbersome external wires and coils.

The miniature size and limited capacity of the batteries, however, impose severe constraints on battery power consumption, which increases with the operating frequency. Thus, RF operation in the lower 400 MHz band, as opposed to higher frequencies, would allow MMN systems to utilize miniature batteries, conserve battery power, prolong battery life, and minimize the need to replace the implant devices or to recharge the batteries more than once a day.

Furthermore, MMN use of the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands on a secondary basis would be consistent with international spectrum allocations, thus facilitating global deployment and enhancing user mobility. As the Commission noted, in "all or substantial portions of the three International Telecommunication Union regions, the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands are allocated to mobile, except

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[12] *See Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant*

aeronautical mobile, services on a primary basis."[13] International harmonization of this spectrum would expedite global deployment of new wireless wideband medical devices at reduced costs, and would allow patients using these devices to travel domestically and internationally with greater assurance that the devices will operate properly and within legal guidelines wherever they may be.

B. Alternative Spectrum Options Are Inadequate for MMNs

Frequencies outside of the 413-457 MHz band are generally unavailable or undesirable for MMN use. As noted in Section III(A) above, the Commission already found that frequencies below 216 MHz and above 470 MHz are not the most suitable for propagation of radio signals within the human body. Thus, wireless medical telemetry service spectrum in the 608-614 MHz, 1395-1400 MHz, and 1429-1432 MHz bands is unsuitable for MMN operation.

Additionally, although spectrum in the 457-470 MHz band may be assigned for medical telemetry systems under Part 90 of the Commission's rules,[14] these systems are subject to channel bandwidth limits of 12.5 kHz to 25 kHz and therefore cannot accommodate wideband MMN operations requiring as much as 5 MHz of channel bandwidth. Moreover, the 457-470 MHz band, particularly in urban areas, is generally congested, populated with other commercial, high-power transmitters, and adjacent to spectrum occupied by high-power UHF TV transmitters, thus rendering the RF interference environment highly challenging for MMNs.

Furthermore, medical device radiocommunication ("MedRadio") service spectrum in the 401-406 MHz band is insufficient to accommodate MMNs, which require much larger emission bandwidths and higher transmit power levels than existing MedRadio devices to support more

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Communications Service in the 402-405 MHz Band, 14 FCC Rcd 21040, ¶ 6 (1999).

[13] *See NPRM* ¶ 25 (citing 47 C.F.R. § 2.106, n.5.276).

[14] *See* 47 C.F.R. §§ 90.35(c)(30), (67), and (69), 90.238(e), and 90.267(h)(2).

complex functions required for monitoring and activating nerves and muscles, as well restoring sensation, mobility, and other functions to those nerves and muscles. To conserve battery power and mitigate potential interference, MMN microstimulators must transmit data at a very low duty cycle—approximately 5 microseconds per 11 milliseconds (*i.e.,* less than 0.05 percent transmit duty cycle). Transmitting even small bursts of data within a few microseconds requires substantial bandwidth—approximately 20 times that used by existing MedRadio devices. Moreover, the power limits on existing MedRadio devices do not permit reliable data transmissions over the larger channel bandwidth required for MMN operation.

IV. MMNs ARE DESIGNED TO PROTECT PATIENT SAFETY AND AVOID HARMFUL INTERFERENCE

As discussed in the Petition, MMNs pose virtually no risk of harmful interference to incumbent government or non-government operations in the 413-457 MHz band. They also are specifically designed to avoid or eliminate harmful interference from incumbent operations.[15] MMNs are designed to protect patient safety by employing various interference mitigation techniques, as discussed in Subsection (B) below. Collectively, these techniques both mitigate the risk of harmful interference and ensure the proper functioning of the MMN system even in the event of a disruption in communications caused by potentially interfering signals. AMF has conducted and continues to conduct technical analyses and testing to demonstrate no harmful interference between MMNs and incumbent operations. AMF also continues to monitor activity in the 413-457 MHz band to collect data that will assist in refining its MMN equipment to further mitigate potential interference.

[15] *See* AMF Petition at 17-21.

A. MMNs Will Not Cause Harmful Interference to Incumbent Operations

The following factors ensure that MMNs will not cause harmful interference *to* incumbent primary and secondary operations in the 413-457 MHz band: (1) low power operation; (2) low duty cycle; (3) wideband operation; and (4) near-ground operation.

1. Low Power Operation

As NTIA has acknowledged, the proposed MMN power limits are "low when compared to that of the incumbent federal systems."[16] The maximum output power levels of the MCU and microstimulators are, respectively, one milliwatt and 200 microwatts. In comparison, the output power levels of land mobile systems and radar systems in the 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands typically are 5 to 250 watts and one to two megawatts, respectively. Consequently, the substantially higher power levels of other incumbent systems in the band will allow those systems to overcome any interference that might be received from the lower power MMNS system.

2. Low Duty Cycle

MMNs transmit for only a small fraction of the available time. Specifically, each MMN microstimulator transmits data for approximately 5 microseconds per 11 milliseconds (*i.e.,* less than 0.05 percent transmit duty cycle). For a system with 10 to 20 microstimulators, the transmit duty cycle of the MCU is approximately 3 percent, or 334 microseconds per 11 milliseconds. This low duty cycle operation effectively limits the average power available for interference to a few percent of that of a continuously operating transmitter.

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[16] *See* Letter from Karl B. Nebbia, Assoc. Administrator, Off. of Spectrum Management, NTIA, to Marlene H. Dortch, Secretary, FCC, Encl. 2 at 1 (Feb. 27, 2009).

3. Wideband Operation

The wideband operation of MMNs further reduces the risk of harmful interference to land mobile radio systems, which typically employ narrowband technology. Based upon research and testing, AMF has determined that these narrowband receivers filter out 99.9% of the spectral energy transmitted by an MMN system. This filtering allows a one-milliwatt signal from the MCU to appear as a one-microwatt signal.

4. Near-ground Operation

MMNs typically will operate close to the ground, and each MCU will operate within a few meters of its associated microstimulators. Consequently, emissions radiating from an MMN transmitter will reflect off the ground and will be canceled when combined with signals traveling directly toward another system's receiver, thus resulting in a dramatic reduction in received power. Based upon research and testing, AMF has determined that, at distances beyond 7 meters, this significant drop in signal level will cause any interference from MMN devices located near the ground to disappear rapidly. Specifically, AMF measurements confirm that the received power from a transmitter at a height of 1.1 meter from the ground begins to drop off substantially at a distance of approximately seven meters.

B. MMNs Will Employ Sophisticated Techniques to Mitigate Harmful Interference from Incumbent Systems

MMNs are designed to mitigate potential interference *from* incumbent operations in the 413-457 MHz band through the following means: (1) message coding; (2) spectral notching; (3) dynamic channel switching; (4) wideband operation; and (5) timing and filtering. Specifically, both the MCU and microstimulators implement message coding, dynamic channel switching, and wideband operation techniques. The MCU also implements spectral notching, timing, and filtering techniques.

1. Message Coding

All MMN messages are heavily coded. Coding is the first line of defense in detecting and limiting the effects of harmful interference. Coding permits detection and correction of errors from any source. When an MMN system detects message errors that cannot be corrected reliably, the system engages the retransmission protocol. The system message rate (approximately one message in both directions every 11 milliseconds) is sufficiently high that at least one-half of the message frames are available for miscellaneous messages in all but very brief periods. This message space permits ample time for retransmission of missed messages in addition to time for housekeeping and other low-priority data.

2. Spectral Notching

To address narrowband interferers, the most common form of expected interference in the 413-457 MHz band, the MCU is designed with the ability to create spectral "notches" to filter out interference noise from narrowband systems. This notching can be accomplished with only a minimal loss in receiver performance. The MMN notching technique can be understood by viewing each of the proposed four MMN channels as consisting of numerous subchannels, each with its own filter. Through spectral notching, any received narrowband signal found to be uncharacteristically strong can be isolated to a few subchannels, thus allowing an MMN receiver simply to turn off, or ignore, those subchannels. The remaining filter output signals then would be recombined to create the desired signal free from narrowband interference. As NTIA previously acknowledged, "techniques of this sort have been used in military applications for some time and more recently have been found to be effective in non-military applications." [17]

[17] *See id.*, Encl. 2 at 3 (citation omitted).

3. Dynamic Channel Switching

MMNs are designed to be capable of dynamically switching to alternate channels. This capability allows the MCU to continually assess channel quality by monitoring the transmissions from the implants in addition to status information describing the quality of the signal received from the implant. Additionally, the quality of the other channels can be assessed to avoid shifting to another overloaded channel. When a channel becomes degraded due to strong wideband interferers or a large number of narrowband interferers, the MCU will identify an alternate channel and will switch to that channel using a protocol that instructs the implants where to tune their radios. To prevent loss of data, the timing of the message frame will be maintained while switching to the new channel.

4. Wideband Operation

The wideband operation of MMNs mitigates potential interference not only *from MMNs to incumbent narrowband systems* (as discussed in Section IV(A)(3) above), but also *from those incumbent systems to MMNs*. This interference mitigation results from the difference in bandwidth between typical narrowband land mobile systems and wideband MMNs. Specifically, the noise floor of a wideband MMN receiver is considerably higher—typically 25 to 30 dB higher—than that of narrowband land mobile devices, such that many of the weaker narrowband signals are lost in the noise floor of the MMN receivers, and only the stronger signals can be detected.

5. Timing and Filtering

Signals from incumbent high-power pulse radar systems are expected to have a very limited effect on MMNs. This immunity is a result of the basic timing and structure of the MMN communication link. The receiver of each MMN microstimulator is activated for only a few microseconds during each 11-millisecond timeframe and is completely powered off for the

remainder of that 11-millisecond timeframe. Thus, in order to disrupt a communication signal received by the microstimulator, a radar pulse must collide directly with the received MMN signal during the few microseconds that the microstimulator receiver is activated.

Based upon research and testing, AMF has determined that these collisions would be very rare—less than one percent of the time. In the rare event of a collision, the lost data can be recovered easily using a retransmission protocol requiring the data to be retransmitted following a disruption in communications.

Additionally, AMF has designed the MCU to be capable of resisting pulses up to approximately -15 dBm at the receiver input with only a few percent of data loss. The MCU also contains very effective filtering located in front of any active circuitry. Based upon research and testing, AMF has determined that this filtering significantly reduces the MCU's susceptibility to interference by approximately 45 dB. In the unlikely event that a radar pulse signal is not filtered out, any lost message can be easily recovered using the retransmission protocol.

VI. THE COMMISSION SHOULD ADOPT SERVICE AND TECHNICAL RULES THAT REFLECT MMN TECHNICAL REQUIREMENTS

In its Petition, AMF proposed MMN service and technical rules as a separate subpart of Part 95 of the Commission's rules. The Commission, however, has proposed MMN service and technical rules that apparently would be incorporated within the MedRadio service rules under Part 95.[18] AMF does not object to this approach, provided that the substance of its proposed rules (attached as Appendix B to the Petition) is incorporated within the MedRadio service rules. Accordingly, AMF is attaching a revised set of proposed service and technical rules to conform to the Commission's proposed approach and to provide additional revisions to ensure successful MMN operations.

[18] *See NPRM* ¶ 27.

A. Service Rules

Because MMNs and existing MedRadio devices share some similarities, AMF agrees with the Commission that MMNs could be regulated under the MedRadio service rules, with modifications to accommodate certain differences in design, function, and technical requirements. The MedRadio service rules generally have worked well for MedRadio devices and thus could be extended to MMNs to the extent feasible. Specifically, AMF supports applying the license-by-rule framework to MMNs because this approach, as the Commission has found, "will minimize regulatory procedures and thus facilitate deployment [of new wireless medical devices]."[19] AMF further recommends that the Commission adopt the definitions for various MMN components, as set forth in Appendix B. These definitions are fairly broad and technology-neutral, but also are limited to devices designed to facilitate FES. This limitation is necessary both to foster deployment of wireless FES devices and to ensure that the RF interference environment in the 413-457 MHz band remains manageable.

B. Technical Rules

The technical rules proposed in Appendix B strike a proper balance between (1) allowing flexibility to develop and improve MMN technology and (2) ensuring that MMN devices can co-exist with each other and with incumbent systems. With these goals in mind, AMF recommends adoption of a specific channel plan with a maximum emission bandwidth of 5 MHz, as set forth in Appendix B. A uniform channel plan for all MMN devices would mitigate the risk of adverse mutual interactions between MMN devices using differing center frequencies and bandwidths. Mitigating this risk is particularly important for MMN devices, which, in comparison to existing

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[19] *See Amendment of Parts 2 and 95 of the Commission's Rules to Create a Wireless Medical Telemetry Service,* 15 FCC Rcd 11206, ¶ 27 (2000).

MedRadio devices, perform more complex functions and require greater coordination with other MMN devices.

Additionally, the restriction on the wireless retransmission of information under Section 95.1209(e) of the Commission's rules should not be extended to MMNs. This rule would limit or prevent MMN systems from exchanging information and coordinating with each other to mitigate potential inference between different MMN systems. Accordingly, the rule should be revised to apply only to MedRadio devices in the 401-406 MHz band.

VII. CONCLUSION

Based upon the foregoing, AMF urges the Commission to provide spectrum in the 413-457 MHz frequency band and adopt appropriate rules to allow MMN operation on a secondary basis. MMN devices represent transformative medical technology that is available now and that will materially improve the quality of life for millions of Americans with disabilities previously considered very difficult or impossible to treat.

Respectfully submitted,

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