

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

In the Matter of )  
 )  
Amendment of Parts 2 and 95 of the Commission's ) RM-11404  
Rules to Establish the Medical Micropower )  
Network Service in the 413-457 MHz Band )

**REPLY COMMENTS**

The Alfred Mann Foundation for Scientific Research (“AMF”) submits these reply comments regarding its petition (“Petition”) for rulemaking to establish a new wideband medical micropower network service (“MMNS”) in the 413-457 MHz frequency band.<sup>1</sup>

To date, nearly a hundred parties representing a broad spectrum of interests, including government agencies, private industry, public and private medical establishments, doctors, scientists, and individuals with disabilities, filed comments, reply comments, and *ex parte* submissions expressing strong support for the proposed rulemaking. Most of those submissions were filed in support of AMF’s proposal as initially raised in response to the *MedRadio NPRM/NOI*,<sup>2</sup> and AMF requests that those submissions be incorporated by reference into this proceeding.

In addition, numerous parties filed comments supporting the Petition, and no party opposed the petition. Notably, the National Institute on Disability and Rehabilitation Research

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<sup>1</sup> AMF is filing these reply comments pursuant to the Commission’s public notice and Section 1.405 of the Commission’s rules. *See* FCC Public Notice, Consumer & Governmental Affairs Bureau Reference Information Center Petition for Rulemakings Filed, Report No. 2835 (Oct. 3, 2007); 47 C.F.R. § 1.405.

(“NIDRR”), an arm of the U.S. Department of Education, noted that the “establishment of a service allocation is vital to the development of a new generation of wireless wideband medical devices designed to restore sensation and function to paralyzed limbs and organs.”<sup>3</sup> NIDRR further emphasized that “[w]ithout adequate spectrum and service rules to support the operation of these innovative devices, millions of Americans, including U.S. veterans injured in Iraq and Afghanistan, will be deprived of a safe and effective medical treatment for their serious neuromuscular injuries.”<sup>4</sup> Additionally, the Paralyzed Veterans of America, a Congressionally chartered national veterans’ service organization actively involved in research for the treatment of traumatic spinal cord injury and diseases, acknowledged that the new MMNS technology “holds significant real potential to revolutionize the medical treatment and therapy for millions of people living with spinal cord injury and disease such as multiple sclerosis, polio and ALS, as well as numerous other neurological disorders.”<sup>5</sup>

Hospitals, medical research centers, and non-profit organizations, such as the United Cerebral Palsy Research and Educational Foundation, Shriners Hospitals for Children, Henry Mayo Newhall Memorial Hospital, and Neurotech Network, agreed that wideband MMNS devices offer significant advantages over commercially available equipment requiring the use of cumbersome wire electrodes.<sup>6</sup> These parties also recognized that the need for new MMNS

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<sup>2</sup> See *Investigation of the Spectrum Requirements for Advanced Medical Technologies*, Notice of Proposed Rulemaking, Notice of Inquiry, and Order, 21 FCC Rcd 8164 (2006) (“*MedRadio NPRM/NOI*”).

<sup>3</sup> Letter from Arthur M. Sherwood, P.E., Ph.D., NIDRR, to Kevin J. Martin, Chairman, FCC, at 1-2 (Nov. 2, 2007).

<sup>4</sup> *Id.* at 2.

<sup>5</sup> Letter from Thomas E. Stripling, Paralyzed Veterans of America, to Kevin J. Martin, Chairman, FCC, at 2 (Nov. 2, 2007).

<sup>6</sup> See, e.g., Letter from Mindy Aisen, M.D., CEO, United Cerebral Palsy Research and Educational Foundation, to Kevin J. Martin, Chairman, FCC, at 2 (Nov. 2, 2007); Letter from

technology offering effective, long-term medical treatment for U.S. soldiers and other Americans who have sustained severe, life-threatening injuries continues to grow, particularly as modern medicine has made it possible for a greater percentage to survive these injuries.<sup>7</sup> Similarly, scientists and doctors, such as Dr. Paul F. Pasquina, Chief of Physical Medicine and Rehabilitation at Walter Reed Army Medical Center, specializing in the treatment of neuromuscular disorders, stated that “the MMNS equipment that AMF is developing represents a quantum leap in [functional electric stimulation and sensing] technology and in the medical treatment and care of people living with severe disabilities.”<sup>8</sup>

Since obtaining an FCC experimental license in 2005, AMF has made significant progress in testing and developing wideband MMNS equipment, with the goal of producing safe and effective devices for commercial distribution in the near term. AMF expects to complete construction of the first 200 fully functioning, battery-powered MMNS microstimulators by July 2008. Currently, AMF is testing and developing new casing material that will allow the implantable microstimulators to survive longer within the body. AMF expects to develop new casing material for which the verified life expectancy should be four times that of the existing casing material. AMF also has implemented and continues to implement improvements that will enhance the radiocommunication performance and reliability of the MMNS devices.

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Brian Smith, Director of Research Administration, Shriners Hospitals for Children, Philadelphia, to Kevin J. Martin, Chairman, FCC, at 1-2, (Nov. 2, 2007); Letter from Roger Seaver, President & CEO, Henry Mayo Newhall Memorial Hospital, to Kevin J. Martin, Chairman, FCC, at 2, (Nov. 2, 2007); Letter from Jennifer S. French, Executive Director, Neurotech Network, to Kevin J. Martin, Chairman, FCC, at 2, (Nov. 2, 2007).

<sup>7</sup> *Id.*

<sup>8</sup> See Letter from Paul F. Pasquina, M.D., LTC, U.S. Army Medical Corps, and Chief, Physical Medicine and Rehabilitation, Walter Reed Army Medical Center, to Kevin J. Martin, Chairman, FCC, at 1 (Nov. 2, 2007).

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. Full qualification testing of the devices is scheduled to begin in the first quarter of 2008. Upon successful completion of the required testing, AMF expects to introduce fully functioning MMNS 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. AMF currently is considering research proposals and research teams to perform the first human trial, scheduled to commence late next year.

To date, AMF has expended tens of millions of dollars on research and development of new MMNS devices. Its ability to make this breakthrough technology available to the general public, however, depends upon obtaining regulatory certainty and the necessary spectrum allocation and service rules as soon as possible. Because of the time required for the Commission to consider and adopt spectrum allocation and service rules for MMNS, AMF urges the Commission to commence a rulemaking expeditiously. Prompt Commission action is critical to the commercial deployment of MMNS technology, which promises to revolutionize the treatment and care of millions of Americans with disabilities.

Respectfully submitted,

**THE ALFRED MANN FOUNDATION**

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~~/s/ Cheryl A. Tritt~~ \_\_\_\_\_  
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Date: December 3, 2007

## CERTIFICATE OF SERVICE

I hereby certify that on December 3, 2007, a copy of the foregoing Letter was served by U.S. Mail, postage prepaid, upon the following:

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