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Before the

Federal Communications Commission

Washington, DC 20554

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Federal Communications Commission
Office of Secretary

In the Matter of 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 No. 11271

COMMENTS OF MEDTRONIC, INC.

Medtronic, Inc., respectfully submits these comments in support of the Medical Data Service ("MEDS") Petition for Rulemaking. Medtronic applauds the Commission for taking the first step towards realizing the promise of a MEDS allocation at 401-402 and 405-406 MHz. As detailed in the Petition, the MEDS offers a unique opportunity to provide improved medical care to millions of Americans. The new service will facilitate wireless communications among medical devices worn by or implanted in patients and external monitoring and control equipment in hospital rooms, physicians' offices, assisted living facilities, and patient homes.

The MEDS would be an ultra-low-power, private land mobile radio service and operate under Part 95 of the Commission's rules on a non-interference basis with primary users of the 401-406 MHz band – the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services (collectively "METAIDS"). Thus, the MEDS spectrum will share spectrum with vitally important federal weather services.

There is a pressing need for coordinated communications among implanted and body-worn medical devices and external equipment. Many aspects of a patient's health now can be

monitored or regulated by implanted and body-worn sensors. Such devices are used to monitor and adjust blood glucose levels, regulate heart activity, treat epilepsy, obesity, incontinence, and even depression. A MEDS allocation would improve these medical applications and spur the introduction of new lower cost wireless medical data services, enhancing medical care and patient quality of life. The new service would allow physicians to read data from and adjust parameters of patient medical devices, such as insulin pumps and neural stimulators, with greater ease and accuracy than the wired connections this equipment currently uses.[1] The FCC should promptly allocate the 401-402 and 405-406 MHz bands for the MEDS to enable short-range wireless medical connectivity.

The MEDS would take advantage of recent advances in medical and wireless technology to offer a wide range of improvements in healthcare. The expanded use of wireless implantable and body-worn MEDS devices would offer patients added comfort, more accurate diagnoses, more responsive and lower-cost therapy, enhanced mobility, peace of mind, higher quality of service, and protection from human error.[2]

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[1] *See* Chappell Brown, *Real-World Implants Are Arriving*, EE TIMES, Sept. 12, 2005, *available at* http://www.eetimes.com/news/latest/showArticle.jhtml?articleID=170701430 *last* accessed Sept. 22, 2005 ("In the near term, electrodes that can be implanted and communicate with the nervous system are being used in products marketed by Medtronic Inc. (Minneapolis). Applications include controlling Parkinson's tremors, alleviating pain and controlling heart rhythms to avoid attacks.").

See also Ciaran Buckley, *SFI Invests EUR16.5m In Bio-Chip Research*, ENN ELECTRICNEWS.NET, Sept. 7, 2005 ("[B]io-chips will be used for cancer detection and assessing cardiac health, and will also be used in systems that monitor the coagulation of blood. ... [D]iagnostic medical devices being developed at the centre would help to make medicine more pro-active, helping health professionals and individuals to identify health issues before they become chronic problems.").

[2] Accuracy of medical data and prevention of human error is especially critical. *See* Milt Freudenheim, *Doctors Join to Promote Electronic Record Keeping,* N.Y. TIMES, Sept. 19, 2005 (Continued)

Remote monitoring of patients via the MEDS is a valuable application. Physicians could receive detailed updates of patient status in between visits and may be able to counsel patients remotely. Remote communication of patient medical data could allow a patient to skip an appointment if conditions are normal or prompt a physician to request that the patient come to the office or hospital if an irregularity is detected. Because physicians will have increased access to medical data from patients that are being remotely monitored, patients are likely to spend less time in doctors' offices when they do come into the office.

Remote monitoring, diagnosis, and therapy by medical providers would allow Americans to live independently for longer periods of time and offer peace of mind to patients and their families. Keeping otherwise healthy individuals out of hospital beds and nursing facilities with lower-cost alternatives made possible by the MEDS will lower substantially the cost of medical care and greatly benefit the U.S. economy.

Wireless communications from patient medical devices via the MEDS would enhance administrative efficiencies at medical facilities, and thereby lower costs. Patient data from MEDS devices could be transmitted automatically into patient records. And, wireless vital sign sensors could be affixed to a patient during triage to alert medical staff when the patient's condition worsens and/or collect data for later review. Thus, the MEDS would improve the level of care in hospitals and other locations where trained medical personnel are in attendance.

("Electronic records, particularly ones that can be shared online by different doctors and hospitals, can improve the quality and safety of patient care by reducing errors that kill tens of thousands of patients each year."); *In Hospital Deaths from Medical Errors at 195,000 per Year USA*, MEDICAL NEWS TODAY, Aug. 9, 2004 (nearly 200,000 Americans reportedly die each year in hospitals due to medical errors).

These MEDS applications would reduce the cost of medical care and benefit the U.S. economy. They are fully consistent with the President's Health Information Technology Program.[3] As President Bush explained in last year's State of the Union Address: "By computerizing health records, we can avoid dangerous medical mistakes, reduce costs, and improve care."[4]

A very recent study by the RAND Corporation confirms President Bush's statement: "Properly implemented and widely adopted, Health Information Technology would save money and significantly improve healthcare quality."[5] RAND estimates that annual savings due to efficiency gains alone could be $77 billion.[6]

Finally, FCC allocation of the 401-402 and 405-406 MHz bands for the MEDS would encourage worldwide harmonization of a service band that the ITU-R has already found to be compatible with the incumbent users of the band, METAIDS.[7] International harmonization would serve the public interest by offering the international traveler with implanted or body-

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[3] *See A New Generation of American Innovation*, Apr. 26, 2004, part of President Bush's Technology Agenda: Promoting Innovation and Competitiveness, *available at* http://www.whitehouse.gov/infocus/technology/ *last accessed* Sept. 23, 2005.

[4] *Id.* at 7. *See also id.* at 1 ("President Bush believes that innovations in electronic medical records and the secure exchange of medical information will help transform health care in America - improving health care quality, reducing health care costs, preventing medical errors, improving administrative efficiencies, reducing paperwork, and increasing access to affordable health care.").

[5] RAND Corporation, *Health Information Technology: Can HIT Lower Costs and Improve Quality?* Sept. 2005, *available at* http://www.rand.org/publications/RB/RB9136/ *last accessed* Sept. 23, 2005.

[6] *See id.*

[7] *See* Recommendation ITU-R SA.1346, Sharing Between The Meteorological Aids Service and Medical Implant Communications Systems (MICS) Operating in the Mobile Service In the Frequency Band 401-406 MHz.

worn medical device technology an enhanced degree of freedom by ensuring that the traveler can receive appropriate medical attention at home and abroad. And, for the medical device manufacturers, international compatibility would allow development costs to be spread among multiple national markets. This would allow MEDS devices to be made available at lower cost.

CONCLUSION

Medtronic applauds the FCC for taking the first step towards authorization of the Medical Data Service at 401-402 and 405-406 MHz. The proposed MEDS rules, which allow ultra-low-power medical communications in a band that will continue to support METAIDS, provide the opportunity for improved, cost-effective medical care to millions of Americans using spectrum that supports important government functions. Medtronic urges the Commission to move swiftly towards authorizing operations as set forth in the Petition for Rulemaking.

Respectfully submitted,

MEDTRONIC, INC.

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September 23, 2005

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