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February 1, 2000

EX PARTE OR LATE FILED

Ms. Karen Rackley  
Chief, Technical Rules Branch  
Office of Engineering & Technology  
Federal Communications Commission  
445 12<sup>th</sup> Street, SW  
Room 7-A161  
Washington, DC 20554

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Re: Amendment of Parts 2 and 95 to create a Wireless Medical Telemetry Service (WMTS)  
ET Docket No. 99-255  
Ex parte Comments of PCTEST Engineering Laboratory Inc.

Dear Karen:

Per my telephone discussion today with Mr. Hugh Van Tuyl, FCC/OET, PCTEST Engineering Laboratory Inc. (PCTEST) hereby submits the following ex parte comments regarding these recent relevant information in the above-captioned docket proceeding.

PCTEST fully agrees with the Commission and the preponderance of the comments filed that Wireless Medical Telemetry Service (WMTS) devices will offer tremendous health benefits to the American public. However, PCTEST is compelled to caution the Commission that radiofrequency (RF) radiation exposure to patients using devices authorized in this new service must be addressed in order to protect the health and safety of these users. PCTEST believes that the primary RF safety issues are whether WMTS devices will be placed in close proximity to the body (portable or mobile)<sup>1</sup>, whether the power requirements of WMTS create a health risk, and whether these devices will be transmitting for extended periods of time while close to the body.

The Commission has adopted 20-centimeter separation criteria in determining whether a RF exposure evaluation must be performed on portable wireless devices. Portable wireless devices with power levels of 100 – 200 milliwatts or more and operated within 20 centimeters of the body are typically required to be tested to show compliance with the requirements of Section 2.1093 of the Rules. WMTS devices, by virtue of their intended function, will be in direct contact with the patient's body for extended periods of time exposing patients to the potentially harmful effects of RF radiation. Current WMTS transmitters typically use flexible wire antennas that in most instances are in direct contact or have the potential for direct contact with the patient's skin. In previous comments, PCTEST showed that the proposed rules will permit WMTS devices to operate at power levels capable of exceeding the Specific Absorption Rate (SAR) limits specified in the Commission's Rules<sup>2</sup>.

PCTEST agrees with the comments of GE Marquette Medical Systems, Inc. (GE Marquette) that "further studies should be undertaken to establish that higher power levels can be used without compromising patient safety, in view of the fact that the radiating element in a medical telemetry

<sup>1</sup> See 47 CFR § 2.1093 for portable devices and § 2.1091 for mobile devices.

<sup>2</sup> See PCTEST Engineering Laboratory, Inc. Comments at [5], September 16, 1999.



device is frequently in direct contact with a patient's body."<sup>3</sup> GE Marquette implicitly supports PCTEST's assertion that the radiating element in WMTS is usually in direct contact with the patient's body. Further, PCTEST also believes that due to the inherent nature of WMTS in monitoring a patient's vital signs and providing a reliable data link continuously while the patient is hospitalized or under medical care can expose unwitting patients to the danger of prolonged exposure to RF radiation.

Recently the Commission supported a prudent approach in assuring the safety of medical transmitting devices and adopted requirements for routine RF radiation exposure evaluation and certification for implanted wireless medical devices operating in the Medical Implant Communication Service (MICS)<sup>4</sup>. MICS devices operate at a substantially lower power level (25 microwatts) and at lower frequencies (402-405 MHz) than those proposed for WMTS. In the comments filed in the MICS proceeding, it was evident that the direct contact of the radiating element of the MICS devices with the patient's body tissue was a significant factor in requiring implant devices to be routinely evaluated for RF radiation exposure. It would be inconsistent therefore for the Commission to require RF exposure evaluation and certification on wireless medical devices operating under Part 95 Subpart I (MICS) but not on Part 95 Subpart H (WMTS) - particularly where these latter devices operate at a substantially higher power levels (i.e. 100,000 microwatts or more).<sup>5</sup> Furthermore, the proposed rulemaking does not preclude use of the WMTS Services for implanted medical equipment. Wireless medical implant devices using WMTS frequencies and power levels, as proposed, would clearly exceed the Commission's RF exposure limits.

PCTEST also is compelled to address several incorrect and misleading statements contained in Reply Comments submitted by the American Hospital Association Task Force on Medical Telemetry (AHA)<sup>6</sup>. AHA opposed PCTEST's recommendation that routine RF exposure evaluation be required for WMTS devices. AHA claims that wireless devices of similar power to WMTS are "categorically excluded" from routine environmental assessment under Commission rules. AHA also claims that RF exposure evaluation is unnecessary because medical safety of WMTS devices is already the subject of the clearance and approval process of the U.S. Food and Drug Administration (FDA). AHA states further that the SAR test procedures conducted by PCTEST were not representative of WMTS devices worn on the body. Finally, because the operators of most WMTS devices will be health care facilities, AHA asserts that manufacturers have no incentive to market devices that do not comply with the Commission's SAR standards.

AHA's objections have no merit whatsoever; moreover, they serve potentially to expose the public needlessly to unknown health risks. For example, AHA's statement that similar devices

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<sup>3</sup> See GE Marquette Medical Systems, Inc. Comments at footnote [4], September 16, 1999.

<sup>4</sup> See *Report and Order*, WT Docket No. 99-66, Amendment of Parts 2 and 95 to Establish a Medical Implant Communications Services (MICS), adopted November 19, 1999.

<sup>5</sup> The NPRM proposed a field strength limit of 740mV/m measured at 3 meters at 1400 MHz. The power required to produce 740mV/m into a tuned dipole using a 1 MHz resolution bandwidth, assuming 0dB reflected component (i.e., no reflected component), is 100,000 microwatts (100mW). As PCTEST previously noted, for wider bandwidth the power levels for WMTS can be as high as 900 mW.

<sup>6</sup> See American Hospital Association Task Force on Medical Telemetry (AHA) Reply Comments at [17], October 18, 1999.

like spread spectrum transmitters are “categorically excluded” from RF exposure evaluation is an inaccurate statement, as it overlooks § 15.247(b)(4) which states clearly that RF exposure evaluation is required for these products:

Systems operating under the provisions of this section shall be operated in a manner that ensures that the public is not exposed to radio frequency energy levels in excess of the Commission’s guidelines. See § 1.1307(b)(1) of this chapter.

Indeed, all devices subject to certification by the Commission under Section 15.247 may be required to perform RF safety evaluation to determine whether actual SAR or Maximum Permissible Exposure (MPE) measurements is necessary and/or whether special operating conditions or warning label should be imposed.

Also incorrect is AHA’s assertion that WMTS devices under the FDA medical device reporting somehow involve an RF exposure evaluation. PCTEST contacted the FDA’s Office of Device Evaluation in the Center for Devices and Radiological Health (CDRH) and was informed that there are no SAR (or MPE) RF safety requirements set forth in any FDA guidelines for WMTS devices. Indeed, FDA-imposed RF safety evaluation are not even being contemplated by the FDA, as the agency is willing to let the FCC take the lead on these matters as it has with other transmitting devices. FCC-imposed RF safety evaluation, therefore, would not “duplicate the FDA’s safety review” of WMTS devices. Just the opposite, there would be no RF safety evaluation of WMTS devices if the FCC accepts AHA’s recommendation. Further, federal statute under the National Environmental Policy Act of 1969 (NEPA) mandates the Commission to evaluate the effects of FCC-regulated transmitters on the quality of human environment<sup>7</sup>. It is incumbent upon the Commission to address the human exposure requirements in the context of transmitters operating in the WMTS service.

Furthermore, AHA’s assertion that the test data on which PCTEST based its comments are not representative of WMTS because testing was performed on a head simulator is pure speculation. PCTEST is a world leader in SAR testing of wireless devices and currently is the only independent laboratory that has acquired both the FCC-accepted IDX and SPEAG SAR Measurement Test Systems. PCTEST’s experience encompasses SAR evaluation and testing of wireless transmitters using head simulators (with right ear and left ear position), a hand simulator, an eye simulator, as well as a body or torso simulator. PCTEST test results show that for the same test distance separation, SAR on the body normally produces a higher result than SAR on the head due to the higher conductivity of body muscle as compared to brain tissue.<sup>8</sup> Moreover, the Commission is already requiring body SAR for portable devices capable of being operated next to the body (i.e., cellular phones).<sup>9</sup>

<sup>7</sup> The Commission has adopted the guidelines for evaluating the environmental effects of RF radiation to meet its responsibilities under NEPA. See *Report and Order*, ET Docket 93-62, released August 1, 1996, FCC 96-326, 11 FCC Rcd 15123 (1997).

<sup>8</sup> Conductivity parameters can be found in FCC Web site which are derived from the 4-Cole-Cole Analysis in “Compilation of the Dielectric Properties of Body Tissues at RF and Microwave Frequencies” by Camelia Gabriel, Brooks Air Force Technical Report AL/OE-TR-1996-0037.

<sup>9</sup> For cellular phones, the FCC currently requires SAR data be submitted for head, body, and hand depending upon the design of the phone and its normal operating use.

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Finally, AHA's contention that RF exposure evaluation for WMTS be "categorically excluded" is not consistent with the Commission's current policy. Medical device safety is and has been the subject of countless national and international regulatory programs involving myriad technical safety standards imposed on manufacturers. Given (i) the importance of ensuring patient safety, (ii) the recent adoption of routine RF exposure evaluation and certification for MICS, (iii) the significantly higher power levels and frequencies proposed for WMTS than MICS, (iv) the issue of "non-thermal" effects on the body, (v) the non-existent measurement procedure coupled with the uncertainty in RF exposure measurements, (vi) the variability in field strength measurements and lack of standards above 1 GHz, (vii) the insufficient SAR or numerical data available, (viii) the relative proximity of the radiating element to the body, (ix) the undetermined RF exposure time to the patient, and (x) the recent public awareness and media focus on RF safety, it is imperative that the Commission establish requirements for routine RF exposure evaluation and initially require certification for WMTS devices until such time as further information and a better understanding of the foregoing concerns are known.

Very truly yours,



Randy Ortanez  
President, PCTEST Engineering Laboratory, Inc.

cc: American Hospital Association Task Force on Medical Telemetry (AHA)  
Magalie Roman Salas, Secretary of FCC  
Hugh Van Tuyl, FCC/OET  
GE Marquette Medical Systems, Inc.  
FDA/CDRH