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BY ELECTRONIC FILING

Ms. Marlene H. Dortch
Secretary
Federal Communications Commission
445 Twelfth Street, S.W.
Washington, D.C. 20554

Re: *Ex Parte* of GE Healthcare
ET Docket Nos. 04-186 and 02-380

Dear Ms. Dortch:

GE Healthcare ("GEHC"), by its attorney, submits this *ex parte* filing to respond to a number of reply comments filed in the above-referenced dockets.

Medical telemetry operations are safety-of-life operations.

In its reply comments, the New America Foundation, *et al*. ("NAF")[1] stated:

> "Despite the characterization of this equipment as safety-of-life by both ASHE and GEHC, this is not explained further. The devices in question are **not** devices that must receive a signal continuously in order to maintain the patient's life. They are passive monitors that report on the patient's condition to medical personnel and that are used to identify life threatening situations promptly. Momentary interference is not life threatening *per se*, otherwise these devices would not have been designated unlicensed Part 15 systems subject to the general conditions of §15.5(b) of accepting interference." [2]

[1] NAF filed two sets of reply comments: *see* Economic/Legal Reply Comments of New America Foundation, Common Cause, Educause, Public Knowledge, U.S. PIRG, Center for Digital Democracy, National Hispanic Media Coalition, Wireless Internet Service Providers Association, Association for Community Networking, CTCNET, CUWIN Foundation, Ethos Group, NYC Wireless, Tribal Digital Village, Newburyopen.net, Acorn Active Media, and Freenetworks.org (filed Mar. 2, 2007) ("NAF Economic/Legal Reply Comments"); Technical Reply Comments of New America Foundation, Dr. Robert Broderson, Dr. Paul Kolodzy, Dr. Haiyun Tang, Marcus Spectrum Solutions, and Media Access Project (filed Mar. 2, 2007) ("NAF Technical Reply Comments").

[2] NAF Technical Reply Comments at 9.

And:

> "Moreover, the hospital community has provided no compelling evidence that several minutes of passing interference from an unlicensed device would be life threatening. In the late 1990s, when high powered TV stations turned on their very high power DTV channels and medical telemetry devices were temporarily disabled across thousands of square miles, there were no reported incidents of death. A low power unlicensed device passing by a hospital room for a few minutes before a problem is identified, or before the person carrying the device moves on, is much less intrusive than the massive shutdown caused by the advent of DTV service. Also noteworthy is that, despite decades of shared use, there have been no reported deaths from higher powered wireless mics or other wireless devices that have shared the same bands with medical telemetry" [3]

Contrary to NAF's statements, medical telemetry is a safety-of-life operation, and has previously been recognized by the Commission as such.[4] Medical telemetry is typically used for real-time monitoring of physiological parameters such as electrocardiogram, oxygen saturation, blood pressure, and respiration in order to detect life-threatening physiological events (*e.g.*, cardiac arrhythmias, apneas, etc.). Because of many distinct benefits, such as promoting accelerated patient recovery through ambulation and increasing the efficiency of providing care, the use of medical telemetry continues to expand to more patients, including more critically-ill patients.

An important distinction between most medical telemetry systems and other types of patient monitors, such as hard-wired "bed-side" monitors, is that, with medical telemetry, the patient-worn device is typically a data acquisition and radio transmission unit only, with the alarming functionality located at a remote site on the other end of the wireless link. Thus, when the wireless link fails, physiological monitoring is lost and life-threatening events may go undetected.

Of course, mitigations are designed into medical telemetry systems to handle service disruptions, regardless of the causes. Typically, for example, if the wireless signal is not received, an alarm is generated to alert clinicians to the loss of monitoring and the need to intervene. When such a loss of monitoring occurs due to a cause associated with a single patient (*e.g.*, out-of-coverage area, dead battery, acquisition device failure, etc.) or even a small group of patients (*e.g.*, failed antenna or other locally-shared infrastructure component), it is typically manageable by good clinical practice. However, if, as a result of interference, monitoring were *simultaneously* lost for all (*i.e.*, potentially hundreds) of a hospital's medical telemetry patients, there would be great risk of overwhelming the clinical staff and other hospital resources needed to provide alternative monitoring, which could lead, unfortunately, to missed or significantly delayed [5] detection of life threatening events. For this reason, GEHC has specifically designed

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[3] NAF Economic/Legal Reply Comments at 11

[4] *See 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 (2000) ("*WMTS Order*") at ¶¶ 1, 57 (noting an earlier need "to take steps to protect medical telemetry from interference because it is used to protect safety of life").

[5] The industry standard EC13:2002 "time-to-alarm" for cardiac arrhythmias is 10 seconds, up to 80% of which may typically be required just for the physiological waveform processing algorithm to "make the call" – even given a perfect, uninterrupted signal.

its medical telemetry systems with redundancy mechanisms to prevent any single point of failure from causing system-wide loss of monitoring.

As described in previous GEHC comments,[6] due to their low-power transmitters and sensitive receivers, medical telemetry systems are vulnerable to: (i) co-channel interference – either from fundamental or spurious interferer emissions – as well as (ii) overload desensitization from strong adjacent channel signals. Moreover, most medical telemetry systems employ distributed antenna systems that combine received signals from many antennas distributed throughout the entire coverage area – typically hundreds of thousands of square feet. In such systems, a single interferer can cause loss of monitoring to all patients, regardless of their location within the coverage area. In fact, the interferer itself, if transmitting at higher power than the medical telemetry devices, need not even be inside or proximate to the healthcare facility. Therefore, the assumption by NAF that any interference would be highly isolated and transient is simply unfounded.

Finally, GEHC rejects the general assertion by NAF that the design of medical telemetry devices to operate under the Part 15 condition of accepting interference implies that potential interference must not pose a serious, even life-threatening, hazard. Medical telemetry vendors address this hazard as part of the systematic risk management process (*e.g.*, EN ISO 14971, etc.) required by the Food and Drug Administration ("FDA") for identification, evaluation and mitigation of product safety issues. In addition to considering the severity of a potential hazard, another key factor considered in this process is the likelihood of occurrence. In assessing potential interference associated with Part 15 medical telemetry, the likelihood of occurrence is obviously dependent on the type, nature and number of potential interference sources.

Up to this point, the assessment of the potential interference, based on authorized use of the TV bands, has been fairly straightforward. Broadcast television is a fixed service with transmission characteristics that are constant and predictable. Only a limited number of television broadcasters operate in any one location, Part 74 technical requirements invariably result in vacant TV channels, and the process for licensing and deploying a new TV transmitter is relatively lengthy and involves substantial public notification requirements.[7] Low power Part 74 wireless microphones typically have limited interference range and their use in or near hospitals is rare. For these reasons, given good processes for medical telemetry channel selection and the mandated proactive notification of hospitals by new DTV licensees, the likelihood of interference to medical telemetry systems from TV and wireless microphone operations has been quite low and the continued unlicensed use of vacant TV channels for medical telemetry has proven to be effective, safe and reliable. If, however, the current proposals for new ubiquitous, unlicensed consumer devices – especially personal / portable devices – are adopted without the mitigations proposed by GEHC and ASHE , such a change

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[6] GEHC Comments at 7-9.

[7] *See WMTS Order* at ¶ 57 (referencing the "requirement for DTV stations to notify nearby health care facilities"); *see also* Joint Statement of the Federal Communications Commission and the Food and Drug Administration Regarding Avoidance of Interference Between Digital Television and Medical Telemetry Devices (March 25, 1998) ("the FCC will ensure that TV broadcasters communicate with area hospital and other health care facilities to avoid interference to medical telemetry devices"). The requirement to notify nearby hospitals is often contained as a condition on the DTV licensee's authorization.

would radically increase the likelihood of harmful interference and potentially render much of the current Part 15 medical telemetry unsafe.

Controlling the presence of personal/portable devices within the premises of healthcare facilities is an intractable challenge.

In its reply comments, NAF stated:

> "Hospitals and similar medical facilities can and do restrict use of wireless equipment within their facilities. This is apparent to anyone visiting a hospital these days. The devices considered here are critical care devices, so restrictions in such areas are more practical to enforce. Thus, the scenario portrayed by GEHC of unlicensed users operating "within only a few meters of a WMTS receive antenna" are difficult to credit and can be prevented by normal hospital practice of restricting transmitters within hospitals." [8]

And:

> "[H]ospitals already have to manage a lot of unlicensed interference within their own premises. That is because any medical telemetry device in a hospital can potentially interfere with any other one. With hundreds of medical telemetry devices in some hospitals (one per bed), that's a lot of unlicensed interference management. Those hospitals have for decades also had to manage potential interference with wireless mics and other portable devices that use the same TV channels. An extension of those interference avoidance methods can also be used to deal with personal/portable unlicensed devices. Hospitals, and especially Intensive Care Units, tightly control their premises. For example, notice could be given that unlicensed use of TV channels 36 and 38 on hospital premises is not permitted and that anyone who violates such an edict will be evicted from hospital premises. If that wasn't enough protection, spectrum analyzers could be placed in sensitive locations to alert hospital staff of violations of the rule."[9]

NAF does not have a complete understanding of the issue. The reality is that in most cases, interference management involving a hospital's own medical telemetry devices is a straight-forward matter of assigning a unique channel number to each device, which is easily done, typically by a centralized biomedical engineering department. Programming of channels is performed with special configuration tools, making it impossible for patients or clinicians to accidentally change frequencies and cause interference. As noted above, Part 74 wireless microphones in the hospital setting are rare and in any event are sufficiently low in power and narrow in bandwidth that they would, at worst, likely cause only co-channel interference to a few medical telemetry channels. Although bans on the use of cellular phones were commonplace for years in many hospitals, as caregivers have begun to realize the significant potential benefits and limited actual risks of these devices,[10] the bans are rapidly giving way to institutional promotion. In addition to cellular devices, numerous other wireless devices are becoming commonplace in

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[8] NAF Technical Reply Comments at 9.

[9] NAF Economic/Legal Reply Comments at 10.

[10] Tri, Jeffery, *et al*., "Use of Cellular Telephones in the Hospital Environment," Mayo Clinic Proc., March 2007.

hospitals. Nevertheless, many users of these devices – even if they know the devices to be "wireless" – are not even aware that they are RF emitters, let alone in what frequency band or specific channel the devices radiate. For these reasons, policies, policing and signage simply cannot be expected to effectively prevent the proposed unlicensed TV band devices from coming within interference range of hospitals' medical telemetry systems.

As a practical matter, more time is required for users of grandfathered Part 15 medical telemetry to vacate the band.

In its reply comments, the White Spaces Coalition stated:

> "Health care providers can —and most certainly should— stop operating in unprotected spectrum within the next two years if they have not done so already. The Commission cannot allow its policy goals to be thwarted by those too cheap or irresponsible to buy appropriate equipment even with almost ten years' advance notice."[11]

The reality is that although the WMTS rules were put in place in 2000, no actual notice of the potential opening of vacant TV channels to ubiquitous unlicensed devices was made at that time. To the contrary, the Commission's *WMTS Order* permitted the continued certification of Part 15 and Part 90 medical telemetry equipment for two years, and their continued sale and use indefinitely. While, in theory, public notice of the proposed opening of TV "white spaces" was available in 2004, users and even vendors of medical telemetry devices have, in reality, remained largely unaware of the proposal. As similar recent experience with grandfathered 460-470 MHz band medical telemetry equipment has shown,[12] it is unlikely that healthcare providers can be made aware of this new issue and be able to complete a transition away from their current Part 15 solutions in less than two years. GEHC's proposed one-year delay, until 2010, in the opening of TV channels 33-36 is consistent with the Commission's policy goals, expressed in the WMTS proceeding, to protect the "safety of life" telemetry applications from interference and to minimize the financial burdens on healthcare providers that will need to purchase new equipment to avoid interference from new uses in the band. The American Society for Healthcare Engineering ("ASHE") has also stated that "health care facilities in which such [Part 15] legacy equipment is currently installed have not been provided adequate notice of the adverse effects that TV band devices could have on their operations. The Commission should, therefore, address how it can provide reasonable notice to, and interim protection of, users of legacy pre-WMTS medical telemetry devices."[13]

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[11] Dell Inc., Google, Inc., The Hewlett-Packard Co., Intel Corp., Microsoft Corp., and Philips Electronics North America Corp. ("White Spaces Coalition") Reply Comments at 35..

[12] The *WMTS Order* determined to maintain the freeze on high power land mobile operations in the 460-470 MHz band for another three years and the Commission subsequently extended the freeze three additional times. *See* Wireless Telecommunications Bureau Extends Freeze on High Power Use of 460-470 MHz Band Offset Channels and Seeks Comment on American Hospital Association's Proposal for Migration of Medical Telemetry Equipment to Wireless Medical Telemetry Service, Public Notice, DA 03-3178, 18 FCC Rcd 21014 (rel. Oct. 15, 2003); Wireless Telecommunications Bureau Extends the Freeze on High Power Use of the 460-470 MHz Band Offset Channels, Public Notice, DA 04-987, 19 FCC Rcd 6374 (rel. Apr. 9, 2004); Wireless Telecommunications Bureau Extends the Freeze on High Power Use of the 460-470 MHz Band Offset Channels Until December 31, 2005, Public Notice, DA 04-2071, 19 FCC Rcd 12414 (rel. Jul. 8, 2004).

[13] ASHE Comments at 4.

Adjacent-channel operation to WMTS operations should not be permitted.

Several parties in this proceeding have noted the need to exclude unlicensed devices not only from occupied TV channels, but also from channels adjacent to occupied channels.[14] These suggestions are consistent with GEHC's proposal[15] to completely prohibit operation in channels 36 and 38 to protect WMTS because, unlike broadcast TV channels, WMTS channel 37 will generally be occupied in most geographical areas.

A licensed regime would afford much stronger interference protection.

GEHC agrees with Sprint Nextel[16] and McGraw-Hill[17] that a licensed regime for new services in the TV bands would ensure accountability and greatly increase the ability to resolve any interference problems and generally enforce FCC rules. The actual compatibility of any proposed licensed service with medical telemetry operations, of course, would depend on its specific technical characteristics and other details such as intended deployment scenarios, coordination mechanisms, etc.

A white space set-aside, including channels 33-38, is advisable.

In its May 24, 2007 *ex parte* submission, Sprint Nextel commented that:

> "If the Commission remains committed to permitting unlicensed operations in the TV white spaces, it should set aside a portion of the spectrum for future use, after unlicensed technologies and interference-avoidance mechanisms are fully mature and adequately tested."[18]

GEHC supports Sprint Nextel's proposal, provided that any set-aside include, at a minimum, channels 36 and 38, and preferably also channels 33-35. GEHC has previously proposed that channels 36 and 38 be excluded from unlicensed use to protect WMTS operations or that in the alternative additional restrictions be imposed on their use, including coordination by the WMTS frequency coordinator.[19] GEHC has also separately proposed a one-year delay in new unlicensed use of channels 33-36 to allow adequate time for a full, safe and economical transition by grandfathered users of Part 15 medical telemetry to WMTS operations.[20]

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[14] National Radio Astronomy Observatory Comments at ¶ 24; 802.18 RR-TAG Comments at 8; MSTV and NAB Comments at 16; MSTV and NAB Comments at 18; LG Electronics USA, Inc., Panasonic Corporation of North America and TTE Corporation Reply Comments at 4; McGraw-Hill Broadcasting Company Comments at 3-4; Media General Comments at 2; Cox Broadcasting Comments at 4.

[15] GEHC Comments at 8-10.

[16] *Ex Parte* filing of Sprint Nextel Corporation (May 24, 2007) ("Sprint *Ex Parte*").

[17] McGraw-Hill Broadcasting Company Comments at 3-5.

[18] Sprint *Ex Parte* at 5.

[19] GEHC Comments at 8-10.

[20] *Id.* at 5.

The beacon mechanism is potentially useful.

Several parties in this proceeding [21] have concurred with GEHC's assertions [22] that sensing alone will not be sufficient to protect incumbent operations that depend on the reception of weak signals, including medical telemetry, wireless microphones, and TV reception at the fringes of protected contours. OET's recent testing of prototype white space devices provides empirical justification for these concerns. Despite all of the advantages associated with controlled laboratory testing, sophisticated bench-top prototype electronics affording "bleeding-edge" performance beyond anything actually achievable in a small, low-cost consumer device and impractically long scan times,[23] OET's testing showed that the "Prototype A device was generally unable to sense wireless microphones"[24] and that Prototype B, in addition to exhibiting a high number of false detections, completely failed to detect wireless microphone signals while DTV signals of -53 dBm or stronger were simultaneously present on another channel.[25]

GEHC has proposed a complete prohibition on operations in channels 36 and 38 to protect WMTS operations from adjacent channel desensitization and, separately, a one-year delay, until February 2010, of new operations in channels 33-36, to protect grandfathered Part 15 medical telemetry from co-channel interference. However, in the event that the Commission elects not to implement both of these preferred recommendations, GEHC proposes that a beacon mechanism, as proposed by several commenters,[26] be defined to allow for the creation of a protective "bubble" around medical telemetry installations.

If a beacon system is defined for the protection of WMTS installations, it is critical, due to WMTS capacity constraints, that the beacon not require a significant portion of the 608-614 MHz WMTS bandwidth. Preferably, any beacon should be able to reside completely within adjacent TV channel 36 and/or 38, one or both of which would presumably be vacant if such a beacon were needed. In the alternative, the beacon should require no more than 5 kHz of spectrum at either edge of the 608-614 MHz WMTS band. It would also be important that any beacon scheme be simple and inexpensive to develop and deploy. For example, a beacon mechanism along the lines of that proposed by NAF that emulates a DTV pilot tone[27] would be preferred to more complex schemes involving beacons modulated with information.

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[21] Motorola Comments at 18 and 23; Shure Comments at 16; IEEE 802.18 RR-TAG Comments at 6; Professional Audio Manufacturers Alliance Comments at 7.

[22] GEHC Comments at 7-8.

[23] Per-channel scan times were 27 seconds and 8 seconds respectively for prototype devices A and B. *See* "Initial Evaluation of the Performance of Prototype TV-Band White Space Devices, OET Report FCC/OET 07-TR-1006, Office of Engineering and Technology, FCC (Jul. 31, 2007) at 57 ("OET Test Report")

[24] *Id*. at 63.

[25] *Id.* at 66.

[26] Motorola Comments at 19; Shure Comments at 16-19; IEEE 802.18 RR-TAG Comments at 10.

[27] NAF Technical Reply Comments at 9-10.

More stringent spurious emission limits are required for TV white space devices.

Out-of-channel spurious emissions pose a significant interference risk to sensitive adjacent channel operations, as was illustrated in the recent OET Test Report, which found that the transmitter-equipped prototype white space device submitted for testing caused interference to TV receivers and wireless microphones. According to the OET Test Report:

> "First adjacent-channel interference with the WSD transmitting without the external filter was observed out to a distance of 47-50 meters, and second adjacent-channel interference was observed at a distance of 11-14 meters." [28]

The OET Test Report also stated:

> "The measured out-of-channel emissions data demonstrate that without additional filtering, the out-of-band emissions from the prototype transmitter are likely to be inadequately suppressed in the immediately adjacent channels (approximately -28 dBc) and the skirts fall off very gradually out to five channels removed from the fundamental channel (-55 dBc)." [29]

Indeed, in order to suppress these out of band emissions to the levels claimed in their reply comments, the White Space Coalition provided a rather extreme[30] external RF band pass filter for channel 30. This approach, of course, would be completely impractical for actual white space devices that must be tunable and have reasonable cost and size, as the OET has acknowledged: "However, it remains to be seen whether or not this degree of filtering can actually be realized in a tunable BPF implemented at base-band."[31]

MSTV and NAB[32] have correctly pointed out that, contrary to statements by NAF[33] and the White Spaces Coalition,[34] the lack of widespread interference problems – even given the ubiquity of existing devices designed pursuant to the Section 15.209 limit of 200 uV/m @ 3m – does <u>not</u> serve to establish the sufficiency of this limit, for two reasons:

> (1) The strongest spurious emissions generally occur near the fundamental operating frequency of a device, and the unlicensed devices pointed to by the advocates have never previously been allowed to operate in the TV band; and

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[28] *See* OET Test Report at x.

[29] *Id.* at 58.

[30] The filter had approximately 0.4% bandwidth. It attenuated fundamental emissions 14 dB in its passband and rendered approximately 58% of the 6-MHz channel totally unusable for communications by the TV band device. *See id.* at 39-40, 44-46.

[31] *See id.* at 58.

[32] MSTV and NAB Comments at 22; MSTV and NAB Reply Comments at 23; *Ex Parte* filing of MSTV (Apr. 20, 2007) at 5; *Ex Parte* filing of MSTV (May 4, 2007) at 2-6.

[33] *Ex Parte* filing of NAF *et al.* (Apr. 2, 2007) at 2-3.

[34] *Ex Parte* filing of WSC (Mar. 28, 2007) at 3.

(2) Spurious emissions of unintentional radiators such as fluorescent lights, electric blankets, air conditioners, home computers, etc. do not typically have the same spectral characteristics as the out-of-band emissions of an intentional radiator.

These assertions are consistent with GEHC's previous statement that, "although the lack of more stringent Part 15 spurious emissions limits has not previously posed many problems for low power WMTS systems, the likelihood has been limited because no other Part 15 devices have been permitted to have fundamental emissions near in frequency to the WMTS band."[35] Notably, the 802.18 RR-TAG has indicated in this proceeding that: (1) the Section 15.209 limit of 200 uV/m @ 3m is sufficient for adjacent-channel spurious emissions of a TV band device only if the TV band device is somehow prevented from operating on the first-adjacent channel to an occupied channel, so that the spurious emissions will not be co-channel from the perspective of the victim receiver; and (2) that a significantly more restrictive limit of 4.8 uV/m @ 3m is generally required for spurious emissions that could be co-channel with the TV or wireless microphone receiver.[36] GEHC believes such a limit would also be sufficient to generally protect medical telemetry.

Fixed base station registration.

GEHC agrees with recommendations by ASHE,[37] Shure[38] and NAF[39] that fixed base stations should be required to register in a public database.

Initial device certification process.

GEHC agrees with Shure that initial device certifications should be performed by the Commission (and not by TCBs) until substantial experience has been gained to demonstrate sufficient interference protection.[40]

Should you have any questions regarding this submission, please feel free to contact me.

Respectfully submitted,

/s/ Ari Q. Fitzgerald

Ari Q. Fitzgerald
Counsel to GE Healthcare

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[35] GEHC Comments at 7.

[36] 802.18 RR-TAG Comments at 27.

[37] ASHE Comments at 5.

[38] Shure Comments at 21.

[39] NAF Technical Reply Comments at 9-10.

[40] Shure Comments at 21.