

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

In the Matter of	)	
	)	
Regulatory Issues Arising from Health	)	FCC Docket No. ET 10-120
Care Devices that Incorporate	)	FDA Docket No. FDA-2010-N-0291
Wireless Communications Networks	)	
	)	

To: The Federal Communications Commission and the Food and Drug Administration

**Comments of EIBASS**

Engineers for the Integrity of Broadcast Auxiliary Services Spectrum (EIBASS) hereby respectfully submits its comments in the above-captioned Federal Communications Commission (FCC) and Food and Drug Administration (FDA) rulemakings relating to the Commission's June 15, 2010, public notice, DA 10-1071. That public notice requested comment on regulatory issues arising from health care devices that incorporate wireless communications networks, by June 25, 2010. Accordingly, these comments are timely filed.

**I. EIBASS Applauds This Joint FCC/FDA Effort**

1. EIBASS applauds this joint effort by the FCC and the FDA. The FCC has expertise regarding radio frequency (RF) allocation issues, but not medical devices; the FDA has expertise regarding medical devices, but not spectrum allocation issues. A joint inquiry by both regulatory agencies is appropriate.

**II. EIBASS Questions Whether It Is Appropriate To Allow FCC Part 15 Devices, or Secondary Spectrum Use, for Medical Devices**

2. EIBASS also applauds the use of RF signals in support of medical technologies that allow treatments not previously possible, as long as frequency selection for the new technology is done in a responsible manner. That is, consistent with the goals, ethics and standards of both the medical arts and engineering; these principles are deeply rooted in the proper practice of both professions. For example, implantable devices intended to restore muscle control and use of body parts damaged by disease or traumatic injury offer wonderful opportunities to improve the quality of life of persons suffering nerve damage. However, if radio frequency signals are to be used in such medical applications, they should not be unprotected, bottom-of-the-RF-food-chain

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FCC Part 15 devices, or even systems using spectrum on a secondary basis. Rather, such applications need their own allocation, entitled to protection from harmful interference from others. The more critical the medical application, the more important that unprotected, Part 15 use, or secondary use, be avoided. EIBASS submits that the public interest for using an unprotected frequency for a medical application is inversely proportional to the consequences of malfunction. If the consequences of malfunction are minor, then with clear and proper disclosure about the unprotected nature of Part 15 or secondary operation, such use might be in the public interest. But if the consequences of malfunction are not minor, then EIBASS believes that unprotected spectrum use is *per se* not in the public interest.

3. There is ample and recent precedent demonstrating this. The FDA, in concert with the FCC, allowed medical devices to operate as Part 15 license-exempt devices on vacant TV channels, to send electrocardiogram and related medical data signals from patients in coronary care units (CCUs) to a receiver that could then be monitored by health care providers staffing the CCU. This allowed patients to be freed from multiple wires connecting them to bedside monitors, making life easier for both the patients and their health care providers. Unfortunately, when these previously vacant TV channels then had a new DTV station appear on the unlicensed medical device's operating frequency, the monitoring system quit working. As a result, all DTV construction permits then were issued with a condition that before the station could commence operation on its new DTV channel, it had to check all hospitals and similar medical care providers in its coverage area to ensure that they didn't have a Part 15 medical telemetry system on the newly allocated DTV channel.<sup>1</sup> Thus, a primary, Part 73, DTV station was forced to spend its time and money protecting a Part 15 application, which, by definition, is not entitled to

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<sup>1</sup> The DTV construction permit special condition was as follows:

The grant of this construction permit is subject to the condition that, with ample time before commencing operation, you make a good faith effort to identify and notify health care facilities (e.g., hospitals, nursing home, see 47 CFR 15.242(a)(1)) within your service area potentially affected by your DTV operations. Contact with state and/or local hospital associations and local governmental health care licensing authorities may prove helpful in this process. During this pre-broadcast period, you must provide all notified entities with relevant technical details of your operation, such as DTV channel, targeted on-air date, effective radiated power, antenna locations, and antenna height. You are required to place in the station's public inspection file documentation of the notifications and contacts made and you may not commence operations until good faith efforts have been made to notify affected health care facilities. During this pre-broadcast period and for up to twenty (20) days after commencing operations, you must cooperate with the health care facility so that it is afforded a reasonable opportunity to resolve the interference problem. At such time as all provisions of this condition have been fulfilled, and either upon the expiration of twenty (20) days following commencement of operations or when all known interference problems have been resolved, whichever is later, this condition lapses.

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any such protection. The problem was not the use of wireless communications for a medical application, but rather the use of unprotected frequencies.

4. Thus, EIBASS can only hope that both the FCC and FDA learned from this gaff: important medical applications should never be on a Part 15 basis, or even on a secondary use (allocations) basis. Yet, ironically, that is precisely what has been proposed by the Alfred Mann Foundation (AMF) for its Medical Micropower Network Service (MMNS), now pending ET Docket 09-36. EIBASS finds it appalling that in order to create a market for its for-profit development of implantable muscle stimulation devices, AMF is proposing use of frequencies between 413–457 MHz on a secondary, must-accept-interference from primary users, basis.

5. Of the four six-MHz wide bands proposed by AMF, 413–419 MHz; 426–432 MHz; 438–444 MHz; and 451–457 MHz, the last band would make the proposed medical device operate co-channel with 455–456 MHz Part 74, Subpart D, Remote Pickup (RPU) stations. EIBASS will not repeat here all of the many technical reasons why RPU stations would be likely to cause debilitating interference to MMNS devices at 451–457 MHz, which would then require patients implanted with such devices to at best forgo their benefits, and at worst suffer serious medical consequences. Thus, EIBASS submits that it should be obvious that medical applications that use RF signals to communicate should only be authorized in a band where such operation is primary and protected.

6. If the FCC/FDA find it necessary to allow medical devices to operate on a secondary or unlicensed basis in any frequency band, the manufacturer must be required to provide sufficient documentation in this rulemaking that the device is capable of operating in a fail-safe mode when encountering interference from a primary user, or even from a Part 15 device. The FCC and the FDA must not allow the manufacturer to hide behind "trade secrets" when petitioning to allow the device to use spectrum that could cause the device to suffer interference.

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**III. Summary**

7. EIBASS urges the FDA to prohibit medical devices using RF communications from being marketed if they would be using frequencies on an unprotected or secondary basis. Patients deserve better. The record shows that manufacturers will market unprotected Part 15 medical devices if allowed to do so to make a profit, leaving the likely uninformed patient to suffer the consequences when interference to the medical device is then caused. When the unlicensed or secondary medical device encounters interference, the primary, licensed user would likely then be blamed for the interference, and have to invest its time and resources to defend from liability and correct a situation for which it has no duty under the FCC rules to avert, no control over, and that should not have been allowed to occur in the first place. EIBASS hopes that the FDA and FCC will ensure that medical devices using FCC-regulated spectrum for communications are deployed only when that spectrum use is primary. Failure to do so risks violating the Hippocratic Oath to first do no harm to a patient.

Respectfully submitted,

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