



JUL 9 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

The Honorable William E. Kennard
Chairman
Federal Communications Commission
445 12th Street, S.W.
Washington, D.C. 20554

Dear Mr. Kennard:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration strongly supports the steps the Federal Communications Commission (FCC) has taken to address the potential problem of electromagnetic interference (EMI) with wireless medical telemetry. CDRH endorses the American Hospital Association (AHA) recommendations for separate medical telemetry spectrum and frequency coordination. AHA made these recommendations in its "Report of the American Hospital Association Task Force on Medical Telemetry," sent to you on April 16. We firmly believe that interference-free monitoring of patients by means of biomedical telemetry is essential to the safety and effectiveness of many medical devices.

Because of the expanding use of medical telemetry and "wireless communications" within the same environment, the Center agrees with the AHA task group about the increasing need for safe access to the airways to carry vital patient information. Indeed, we foresee the arrival of new wireless technology in medical devices that will not only monitor patients but also provide treatments.

Assuming new rules for wireless medical telemetry are promulgated by FCC, CDRH has a number of ways to encourage both the manufacturers and clinical community to begin to migrate to the protected spectrum. We will issue guidance describing the new spectrum and encouraging device manufacturers to use these frequencies to minimize the risks of EMI with the patient information signal. Our guidance will describe the least burdensome regulatory pathways that manufacturers can take to adjust their devices to the new spectrum. CDRH has already sent letters to the manufacturers of medical telemetry devices telling them of the activities of the AHA Task Group and the recommendations to the FCC. As soon as the changes become final, we plan to follow this up with a letter to clinicians, hospitals, and health care facilities to inform device users of the changes designed to improve the immunity of telemetry to EMI.



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9200 Corporate Boulevard
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July 29, 1999

Dear Medical Device Manufacturer:

The purpose of this letter is to inform you that on July 14, 1999, the Federal Communication Commission (FCC) unanimously adopted a Notice of Proposed Rule Making (NPRM) to allocate spectrum for wireless medical telemetry. The Food and Drug Administration (FDA) strongly supports the steps the FCC has taken to address the potential problem of electromagnetic interference (EMI) with wireless medical telemetry. The FDA will continue to work with device manufacturers and users to assure that the effects of EMI on wireless medical telemetry are minimized. **We, therefore, encourage you to provide your comments to the FCC regarding this NPRM.** For a copy of the NPRM and recent developments regarding this NPRM, you can visit the FCC web site for up-to-date information:

<http://www.fcc.gov/oet/dockets/et99-255/>

Since our records indicate that you may be marketing a medical device that utilizes wireless telemetry technology, the recommended changes proposed by the FCC may impact the operation of devices marketed by your company. If this is the case, FDA strongly recommends that you evaluate the FCC's NPRM in detail and respond to the Notice in a timely manner. When the FCC's rule is finalized, the FDA is committed to working with device manufacturers and users to facilitate the migration to these frequencies as quickly as possible in a least burdensome manner.

FDA has been an active partner with users, manufacturers, and FCC to address the potential problem of EMI with wireless medical telemetry. In our letter sent to your company, dated March 15, 1999, we informed you of the ongoing efforts that are taking place between the American Hospital Association (AHA), the FDA, and the FCC. As a result of this effort, a Medical Telemetry Task Force was formed by the AHA which includes members from the clinical community, the medical device industry, the FDA, and the FCC. On April 16, 1999, the AHA task force submitted its recommendations, for addressing the telemetry EMI concerns, to the FCC. These recommendations have formed the basis for the FCC NPRM.

In order to address the telemetry EMI concerns, the FCC is planning to establish a new Wireless Medical Telemetry Service (WMTS) for low-power, wireless medical telemetry. This initiative marks the first time in the U.S. that wireless medical telemetry will have primary or co-primary status for use of the airways. The NPRM proposes two options for the WMTS frequencies:

frequency bands 608-614 MHz, 1395-1400 MHz, and 1429-1432 MHz, or
frequency bands 608-614 MHz, and 1391-1400 MHz.

In addition, service rules are being proposed for coordination of the use of these frequencies to minimize problems among users. The NPRM seeks comments on the frequencies, service rules, and coordination.

Finally, we are in the process of developing a guidance document to assist wireless medical telemetry manufacturers in meeting any FDA regulatory requirements that may apply to devices that utilize a new WMTS. When this guidance document is complete, it will be disseminated for comment and use.

If you have any questions regarding these issues, please contact Think X. Nguyen at (301) 443-8262, ext. 162.

Sincerely yours,

A handwritten signature in black ink that reads "Philip J. Phillips". The signature is written in a cursive style with a large, prominent "P" at the beginning.

Philip J. Phillips
Deputy Director
Office of Device Evaluation
Center for Devices and Radiological Health



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

March 15, 1999

Dear Medical Device Manufacturers:

Recent incidents involving electromagnetic interference (EMI) with wireless medical telemetry have prompted the Food and Drug Administration (FDA) to reassess the vulnerabilities of wireless medical telemetry to EMI and develop plans to minimize the potential risk to patient safety (see Public Health Advisory dated March 20, 1998 "Interference Between Digital TV Transmissions and Medical Telemetry @ www.fda.gov/cdrh/safety). The purpose of this letter is to inform you of discussions that are taking place regarding EMI and medical telemetry and our attempt to minimize the risks of EMI with medical telemetry, and to encourage your participation in the ongoing efforts to address this public health issue.

Because medical telemetry is a secondary user of the radio frequency spectrum, there is a potential for it to be interfered with by other users within the same spectrum. For this reason, FDA has recommended that the Federal Communications Commission (FCC) change the status of medical telemetry to that of a primary user and set up a dedicated medical telemetry spectrum. In addition, the American Hospital Association (AHA) has formed a Telemetry Task Group to address telemetry EMI concerns. The AHA task force group includes members from the clinical community, the manufacturers, FDA, and FCC.

Our records indicate that you may be marketing a medical device that utilizes wireless telemetry technology and therefore, the recommended changes to the operation of wireless medical telemetry devices may impact devices marketed by your company. If this is the case, FDA recommends that you take the initiative to periodically contact the FCC and AHA for more information, and to become involved in the effort toward developing the future direction for wireless medical telemetry. You can visit the following websites for up-to-date information:

www.fcc.gov/healthnet/dtv.html (for FCC technology/news releases); and
www.aha.org (for AHA technology/news releases).

On November 2, 1998, the FCC hosted a public forum to solicit opinions and identify concerns from interested parties regarding the present and future spectrum requirements for medical wireless telemetry equipment. Presenters at this forum included members of the AHA Telemetry Task Group, FCC, FDA, medical telemetry manufacturers, National

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MAR 17 1998

Dear Medical Device Manufacturer:

The Food and Drug Administration (FDA) recently issued a Public Health Advisory (enclosed) to notify hospitals and nursing homes of the potential for interference to wireless telemetry used in certain medical devices from digital television transmissions. To date, there have been two reported incidents of such interference. FDA believes that this is an important public health issue which can be resolved through collaboration and communication between FDA, the Federal Communication Commission (FCC), the medical device industry, and the device user community.

Our records indicate that you may be marketing a medical device that utilizes wireless telemetry technology. If this is the case, we recommend that you take the initiative to add the following information to the labeling for each device that uses telemetry technology:

- a) the frequency band(s) to which the device can be set;
- b) the discrete frequencies within each band to which the device can be set;
- c) the default setting (as shipped) for devices which can operate in multiple bands and/or at multiple frequencies within each band;
- d) a warning to the users that device operation may be interfered with by licensed television stations operating in the same frequency band as the device; and
- e) a caution that users of the device should contact their local television stations and the FCC periodically to determine the frequency bands that may be used for wireless telemetry in their geographical area.

While changes of this type made under these circumstances could require the submission and clearance of a premarket notification (510(k)), or approval of a Special Premarket Approval Application (PMA) supplement, FDA is willing to forego the requirement for submission and preclearance for the addition of the above information to your labeling.

You should note that under section 518 of the Food, Drug, and Cosmetic Act, the Agency may require manufacturers to notify users or purchasers when a device presents an unreasonable risk of substantial harm to public health. This could include devices that fail to operate according to their specifications because of interference from digital television transmissions. While the Agency has elected not to require such notification at this time, FDA encourages you to contact and advise any known users of your wireless telemetry system of this potential problem, and to work with these users to eliminate or mitigate this problem. If you have transferred your legal authority to market a wireless telemetry system, please forward this letter to the current manufacturer (or distributor).

January 21, 1999

The Honorable William E. Kennard
Chairman
Federal Communications Commission
445 12th Street, S.W.
Room 8-B201
Washington, D.C. 20024



Dear Chairman Kennard:

On behalf of the American Hospital Association's (AHA) Medical Telemetry Task Force, I am pleased to forward to the Federal Communications Commission (FCC), our recommendations for addressing the potential critical safety risks to patients from interference with wireless medical telemetry. The AHA, in coordination with the FCC and the Food and Drug Administration (FDA), established the task force in response to the incidences of interference with wireless medical telemetry from DTV that occurred at two hospitals in Dallas last March. The recommendations of the task force were developed with the goal of preventing more occurrences of such electromagnetic interference (EMI) with wireless medical telemetry equipment. **Our recommendations focus on the creation of primary status and new dedicated frequency spectrum for wireless medical telemetry, which we see as fundamental to reducing the potential risks to patients from EMI.**

In developing these recommendations, the task force established four workgroups comprised of members representing hospitals, manufacturers of medical telemetry equipment, physicians, the Veteran's Administration and liaisons from the FCC and the FDA. The four workgroups are as follows:

- The definition workgroup was tasked with defining what is meant by "wireless medical telemetry;"
- The physiologic parameters workgroup identified the parameters driving allocation of spectrum for medical telemetry equipment;
- The spectrum selection workgroup was responsible for determining what frequency bands are preferable; and,
- The education workgroup was tasked with developing an action plan to educate the health care community about EMI with medical telemetry equipment.

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The enclosed workgroup reports are the consensus recommendations of the AHA's Medical Telemetry task force. As you will see, these reports represent countless hours spent by many dedicated professionals without whose outstanding efforts such important work on behalf of patients would not have been possible. The AHA is most grateful to these task force members.

The recommendations of the AHA's Medical Telemetry Task Force are summarized as follows:

- **Definition.** "Wireless medical telemetry is defined as the measurement and recording of physiological parameters and other patient-related information via radiated bi- or unidirectional electromagnetic signals. This technology may be contained within a health care facility or extend beyond to other buildings and locations." This definition was determined with input from the user community, manufacturers of wireless medical telemetry equipment, members of the task force, and information from professional societies. The effort to develop a workable definition of medical telemetry was focused on patients' needs and the safe and effective delivery of critical patient information.
- **Spectrum Needs.** The spectrum needs for wireless medical telemetry in the next ten years is projected to be at least 12 MHz. A minimum spectrum bandwidth of 6.125 MHz is needed to meet today's patient care needs for wireless medical telemetry, but the need is likely to increase rapidly. These recommendations are based on the assumption of 500 concurrently operating telemetry transmitters and a 0.8 bit per second per hertz spectral efficiency metric currently recommended by the FCC. The work of the physiologic parameters workgroup was developed through surveying hospitals of various sizes in both metropolitan and suburban/rural areas and various professional groups. Based on these survey results, the workgroup addressed medical telemetry needs today and 10 years into the future with the underlying premise that appropriate patient care and communication technology would be available to the medical community.
- **Frequency Allocation.** Three frequency bands are recommended for dedicated spectrum allocation for medical telemetry operations: 608 MHz to 614 MHz; 1385 MHz to 1390 MHz; and 1432 MHz to 1435 MHz. Medical telemetry operation would be considered as "primary" status on these bands. These three frequency bands are in addition to present medical telemetry spectrum allocations under 47CFR Part 15 and Part 90 of the FCC Rules. Medical telemetry would still be permitted to operate at its present frequencies but would do as a "secondary" status user, having to accept potential interference from, and having to avoid interference to, "primary" status users. The spectrum selection workgroup identified spectrum candidates for future medical telemetry use including dedicated spectrum for medical telemetry needs, and evaluated the spectrum candidates against objective criteria such as radiation safety and patient use locations.

- ***Transition Period.*** A minimum period of three to five years is needed, following the allocation of the dedicated spectrum by the FCC, for hospitals to transition to the dedicated spectrum. The manufacturer representatives on the task force estimate that a three-year period will be required following the allocation to bring products to market. This product development will include the necessary regulatory processes applicable to medical devices. The hospital representatives estimate that a three-year period will be required to prepare the hospitals to acquire that technology. That preparation will accommodate the budgeting cycle and installation activities related to the telemetry monitoring. These two three year periods are not necessarily concurrent, hence the recommendation for 3 to 5 years transition.
- ***User Education.*** The task force supports the need to develop training manuals for hospitals, physicians and other health care providers to use in increasing employee awareness of electromagnetic interference. The education workgroup is developing an action plan for educating the medical and health care community about EMI, with the intention of providing concrete suggestions to this community for minimizing the risk of interference with wireless medical telemetry as well as other critical medical equipment.

The AHA believes that these recommendations will serve as a solid foundation for the current and future needs of medical telemetry. Based upon these recommendations, the task force plans, in the next several weeks, to file a petition for rulemaking with the FCC seeking dedicated spectrum for medical telemetry.

Mr. Chairman, we are most grateful to the FCC for its willingness to work with the health care community and others to address this important patient safety issue. We look forward to our continued work together as this process moves ahead.

Should you have any questions about our recommendations, please don't hesitate to contact Mary Beth Savary Taylor at 202-626-2270.

Sincerely,



Rick Pollack
Executive Vice President
Government and Public Affairs

Enclosures