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General Accounting Office
Washington, D.C. 20548

Resources, Community, and
Economic Development Division

B-260205

March 17, 1995

The Honorable Carolyn B. Maloney
Ranking Minority Member
Subcommittee on Government Management,
Information, and Technology
Committee on Government Reform
and Oversight
House of Representatives

Dear Ms. Maloney:

As requested, we are providing you with information on electromagnetic interference from signals sent by devices such as cellular telephones and portable radios that could cause sensitive medical devices to fail. Specifically, we are providing information on (1) the oversight roles of the Food and Drug Administration (FDA) and the Federal Communications Commission (FCC) regarding electromagnetic interference with medical devices, (2) the extent to which cases of such interference have been reported to FDA and FCC, and (3) the extent to which FDA and FCC have conducted or reviewed key research on such interference.

In summary, federal oversight responsibilities lie primarily with FDA, which is responsible for ensuring that medical devices marketed in the United States are safe and effective. FCC has a more limited role; it can issue regulations to limit interference from radio frequency emissions, but generally only to prevent interference with transmissions by authorized users of the radio spectrum. FDA officials estimated that FDA's records from 1984 to 1994 could include 1,000 possible cases of electromagnetic interference with medical devices. However, these officials added that such incidents are underreported because not everyone is required to report them and because electromagnetic interference may not be recognized as the cause of a malfunction. FDA has conducted tests on the susceptibility of certain types of medical equipment to electromagnetic interference, but, according to FCC officials, FCC has not. FDA and FCC officials said that

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they were aware of little published research on this topic.

BACKGROUND

Electromagnetic interference (EMI) occurs when electromagnetic energy from one or more sources, such as radio waves emitted by portable radios and cellular telephones, interferes with the normal operation of another device. EMI can come from many sources, since most devices with electronic components can emit electromagnetic energy. Such interference has reportedly caused wheelchairs to move unexpectedly, patient monitors to return false readings, and pacemakers to temporarily malfunction.

Television and newspaper reports detailed several instances in which medical devices malfunctioned, allegedly because of EMI, in 1994. Additionally, some hospitals have recently restricted the use of cellular telephones as a precaution against EMI with medical devices. According to officials from FDA's Center for Devices and Radiological Health and the Chief Scientist at FCC, the increasing use of existing wireless technology, the introduction of new communications services using frequencies and transmission methods not used before, the growth in medical electronics, and the increasing use of sensitive medical devices outside hospital settings all increase the potential for interference among existing electronic equipment, including medical devices.

RESPONSIBILITIES OF FEDERAL AGENCIES

Two federal agencies have responsibilities related to EMI with medical devices: FDA is responsible for ensuring the safety and effectiveness of medical devices, while FCC regulates electromagnetic transmissions, including transmissions generated by some medical devices, that can cause EMI.

FDA's Responsibilities

FDA has the primary federal responsibility for overseeing EMI with medical devices. FDA must ensure that medical devices manufactured and sold in the United States are both safe and effective. According to officials from FDA's Center for Devices and Radiological Health, such interference can best be prevented by using design and construction techniques that protect or shield medical

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devices from reasonably expected interference; specific standards are determined on a device-by-device basis.

FDA's Center for Devices and Radiological Health administers the agency's responsibilities over medical devices. According to officials from the Center, it is responsible for about 13,000 different kinds of devices, ranging from tongue depressors to computer imaging devices. According to these officials, the Center has addressed concerns about EMI by

- requiring test data on the electromagnetic compatibility of medical devices that are subject to FDA's review and/or approval before the devices are marketed commercially,¹
- testing products in its own laboratories when a problem has been identified,
- participating in the development of national and international electromagnetic compatibility standards,
- providing information on potential problems to the professional community and the general public, and
- overseeing products once they are in use.

Furthermore, FDA can require the recall of a device, under certain circumstances, if it determines that there is a reasonable probability that the device could cause serious health problems or death.

FCC's Responsibilities

FCC is responsible for maintaining control of all channels of radio communication within the United States, such as the frequencies used by television stations, cellular telephones, and satellites. In addition, FCC has the authority to regulate devices that are capable of emitting radio frequency energy, including certain medical equipment, in order to prevent harmful interference with the transmissions of authorized users of the spectrum. FCC does not, however, have the authority to set electromagnetic compatibility standards for medical

¹Electromagnetic compatibility means that a device functions in its environment without producing emissions that affect other devices.

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equipment. In a few instances, FCC has limited transmissions that were suspected of interfering with medical devices. For example, in some cases, FCC asked amateur or CB radio operators to limit their transmissions when the transmissions were suspected of interfering with the operation of neighbors' pacemakers.

The Chief of FCC's Office of Engineering Technology agreed with FDA officials that one of the most effective ways to prevent EMI is through shielding medical devices from expected sources of interference. Officials from both agencies told us that they have historically worked together at the staff level to address concerns about EMI with medical devices on an ad hoc basis, and they agreed that such a relationship should continue.

EMI INCIDENT REPORTS

FDA officials told us that they have both mandatory and voluntary systems to collect data on problems with medical devices, including those caused by EMI. The Federal Food, Drug, and Cosmetic Act, as amended, and regulations thereunder require manufacturers and distributors of medical devices to report deaths and serious injuries related to certain devices, as well as malfunctions of these devices, to FDA. Facilities where devices are used, such as hospitals, are required to report to FDA and the manufacturer information that reasonably suggests that a device has or may have caused a death. In addition, these facilities are required to report to the manufacturer, or to FDA if the manufacturer is unknown, information that reasonably suggests that a device caused, may have caused, or may have contributed to a serious illness or a serious injury. FDA maintains records of these reports in its mandatory Medical Device Reporting System. Reports of malfunctions that do not meet the criteria for mandatory reporting are maintained in a separate voluntary reporting system. Both systems are used by FDA to identify problems that could require regulatory action.

In 1993, an FDA researcher reported,² on the basis of data from FDA and other sources, that about 100 cases identified as problems involving EMI with medical devices occurred between 1979 and 1993. FDA officials told us

²Jeffrey L. Silberberg, "Performance Degradation of Electronic Medical Devices Due to Electromagnetic Interference," Compliance Engineering (Fall 1993).

that because this report was based only on anecdotal evidence, they are currently reexamining the 400,000 mandatory reports of device malfunctions collected between 1984 and 1994 to identify cases that may have been caused by EMI but were not reported as such. FDA officials estimated that their search, when completed later this year, could identify about 1,000 possible cases of EMI.

FDA officials added, however, that their reporting system does not capture all EMI incidents. Underreporting exists, first, because only manufacturers, distributors, and user facilities must report incidents; other users, such as those using medical devices at home, need not report such problems and may not be aware that FDA accepts voluntary reports. Also, according to FDA officials, users may not identify or suspect EMI as the cause of problems in reported or unreported cases. If, for example, the source of the interference (such as a radio transmitting from the next room) is not visible, an operator may not suspect EMI when a problem occurs.

According to FCC officials, FCC receives relatively few reports of EMI with medical devices. FCC's field offices collect complaints of interference with or from radio signals, but the agency does not have a nationwide compilation of all of its filed reports. An official with FCC's Compliance and Information Branch estimated that about 6 reports of EMI with medical devices are filed with FCC annually, out of a total of 37,000 reports of all types of radio frequency interference. The scientist responsible for EMI at FCC added that cases involving medical devices are generally referred to FDA, but referral is not required.

EMI RESEARCH

Because of concerns raised by reports of EMI with motorized wheelchairs and breathing monitors, FDA has conducted laboratory tests on the susceptibility of these devices to electromagnetic transmissions. The studies found that the devices in question could be susceptible to some types of EMI and led FDA to take regulatory actions, including changes in labeling and in the design of the devices. According to FCC officials, FCC has not conducted controlled tests of EMI with medical equipment.

FDA and FCC officials told us that they were aware of few studies dealing with the effects of EMI on medical devices conducted by researchers outside the federal government.

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According to these officials, most studies they have reviewed focus on a specific type of device. For example, an FDA official told us of several recent studies by scientists outside the United States indicating that digital cellular telephones can affect the operation of pacemakers under certain circumstances. While the results of these studies have been presented at professional conferences, they have not yet been published in peer-reviewed journals.

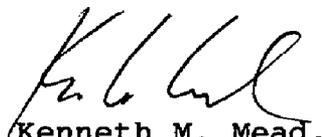
A new industry initiative may provide additional research on the question of EMI with medical devices. Early in 1994, a research center was established at the University of Oklahoma to study EMI issues. Funded with seed money from the cellular telephone manufacturers and service providers, the center will initially study the compatibility of pacemakers and defibrillators with wireless technologies proposed for use in North America.

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We discussed the issues addressed in this correspondence with FDA's Deputy Director for Science, FCC's Chief Scientist, and other officials from these agencies, as well as with industry representatives and professional researchers familiar with this topic. We also reviewed the relevant statutes and agency regulations, testimony from a congressional hearing, and publications on this issue. We did not, however, evaluate any of the data or studies that federal officials identified. FDA officials reviewed a draft of this correspondence and concluded that it accurately reflects the relevant issues. Their technical comments were incorporated where appropriate.

Our review was conducted between October 1994 and February 1995 in accordance with generally accepted government auditing standards. Should you have any questions about this information, you can reach me at (202) 512-2834.

Sincerely yours,



Kenneth M. Mead,
Director, Transportation and
Telecommunications Issues

cc: Representative Gary A. Condit

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