United States General Accounting Office

GAO

Report to Congressional Requesters

May 2001

# TELECOMMUNICATIONS

# Research and Regulatory Efforts on Mobile Phone Health Issues



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## Abbreviations

| | |
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| ANSI | American National Standards Institute |
| CRADA | cooperative research and development agreement |
| CTIA | Cellular Telecommunications & Internet Association |
| EPA | Environmental Protection Agency |
| FCC | Federal Communications Commission |
| FDA | Food and Drug Administration |
| IEEE | Institute of Electrical and Electronics Engineers |
| NCRP | National Council on Radiation Protection and Measurements |
| NIH | National Institutes of Health |
| OET | Office of Engineering and Technology |
| SAR | specific absorption rate |
| TCB | Telecommunications Certification Body |
| WTR | Wireless Technology Research |

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**United States General Accounting Office**
**Washington, DC 20548**

May 7, 2001

The Honorable Joseph I. Lieberman
Ranking Member
Committee on Governmental Affairs
United States Senate

The Honorable Edward J. Markey
Ranking Minority Member
Subcommittee on Telecommunications
and the Internet
Committee on Energy and Commerce
House of Representatives

The number of wireless telephone subscribers in the United States has increased at an extraordinary rate—from 16 million in 1994 to an estimated 110 million by 2001. The rapid adoption of wireless telephones, especially handheld mobile phones,[1] has occurred amidst controversy over whether this technology poses a risk to human health. Like other devices that transmit radio signals, mobile phones emit radiofrequency energy. At high power levels, radiofrequency energy can rapidly heat biological tissue and cause damage, such as burns. Mobile phones operate at power levels well below the level at which such heating effects occur. However, an issue that has been the subject of research and debate for several years is whether long-term exposure to low-level radiofrequency energy from mobile phones could cause other types of adverse health effects, such as cancer.

In 1994, we reported on the status of scientific knowledge about potential health risks of radiofrequency emissions by mobile phones and the federal government's regulatory actions to ensure the safety of mobile phones.[2] We noted at the time that the Food and Drug Administration (FDA) and

[1]In this report, we use the term "mobile phones" to refer to handheld cellular phones, as well as the newer personal communications services (PCS) devices that deliver voice, data, and images. Each is commonly held to the ear when making calls, thereby bringing the user's head close to the device's antenna and the radiofrequency energy being emitted. Our definition excludes cellular car phones and transportable "bag" phones, where the antenna is not located next to the user's head.

[2]*Telecommunications: Status of Research on the Safety of Cellular Telephones* (GAO/RCED-95-32, Nov. 4, 1994).

the Environmental Protection Agency (EPA) believed that there was insufficient evidence to determine whether exposure to low-level radiofrequency energy presents a human health risk. Given the state of scientific knowledge, they told us that they did not have a basis for taking regulatory actions on mobile phones. Our report also discussed federal and industry research efforts that were under way at that time to learn more about potential effects of mobile phones.

At your request, we are providing an update on several issues related to mobile phone health and regulatory issues. Specifically, you asked us to address the following questions:

- What is the general status of scientific research on mobile phone radio-frequency energy as it relates to human health, including current activities of federal agencies in sponsoring, conducting, or overseeing ongoing and planned research?
- What is the status of the cooperative research and development agreement between FDA and the Cellular Telecommunications & Internet Association (CTIA), a trade association representing the wireless industry,[3] to follow up on research previously sponsored by the association?
- How has the federal government set the radiofrequency exposure limit for mobile phones and how does it ensure compliance with it?
- What key actions are federal agencies taking to inform the public about issues related to mobile phone health effects?

## Scope and Methodology

To provide an update on the general status of the scientific research on mobile phone health effects, we reviewed reports by organizations such as FDA, the National Institutes of Health (NIH), the World Health Organization, and by expert panels convened by the governments of the United Kingdom, Canada, and Australia that have reviewed and assessed the peer-reviewed literature on the subject. We also interviewed representatives of these organizations, as well as other scientists prominent in the field of radiofrequency energy health effects in government, industry, and academia. To determine the federal government's role in sponsoring, conducting, or overseeing research on mobile phone health effects, we gathered information from federal agencies—including the Air Force, Army, EPA, the Federal Communications Commission (FCC), FDA, National Cancer Institute,

[3]In October 2000, the Cellular Telecommunications Industry Association changed its name to the Cellular Telecommunications & Internet Association, retaining the acronym CTIA.

National Institute of Environmental Health Sciences, National Institute for Occupational Safety and Health, National Institute of Standards and Technology, National Science Foundation, Navy, and Occupational Safety and Health Administration—on their activities, if any, in this area.

To describe and assess the cooperative research agreement between FDA and CTIA, we conducted interviews with officials of these two organizations. We also reviewed and analyzed documents related to the agreement, including the agreement itself, FDA's working group meetings, and CTIA's request for research proposals. We also discussed the cooperative research agreement with parties outside of FDA and CTIA, including officials at several federal agencies and individual mobile phone manufacturers, as well as independent research scientists and public interest groups. This research agreement follows up on an earlier industry-funded, 5-year research effort run by Wireless Technology Research (WTR). We spoke to the former chairman of WTR, as well as several members of its peer review board and some of the research scientists that WTR funded. We also reviewed documentation related to WTR, including reports that it published, as well as correspondence between WTR and federal agencies, its peer review board, and other parties.

To evaluate issues related to standard setting, testing, and public information, we reviewed federal laws and regulations related to radiofrequency energy and safety standards for mobile phones. We also met with officials at FCC, FDA, EPA, and other agencies to discuss their regulatory roles and activities, and with industry representatives to discuss their views and activities. To gain greater context on all of the objectives, we also interviewed representatives of nonindustry, nongovernment organizations with an interest in mobile phone safety, including consumer groups, advocates, and labor unions.

Our review focused on health issues related to the radiofrequency energy emitted from handheld mobile phones. It did not include issues related to emissions from network base stations, the potential effects of mobile phone emissions on medical devices, or on safety issues related to using a mobile phone while driving. We performed our review from July 2000 through April 2001 in accordance with generally accepted government auditing standards.

## Results in Brief

The consensus of FDA, the World Health Organization, and other major health agencies is that the research to date does not show radiofrequency energy emitted from mobile phones to have adverse health effects but

there is not yet enough information to conclude that they pose no risk. Although most of the epidemiological and laboratory studies conducted on the issue have found no adverse health effects, the findings of some studies have raised questions about possible cancer and noncancer effects that require further investigation. The World Health Organization has identified priorities for further research—including additional epidemiological, laboratory, and animal studies—and a number of major initiatives are under way, particularly in Europe, to address these research priorities. The U.S. government sponsors and supports some of the research; overall this represents a small portion of the total worldwide research effort.

In 1993, CTIA created a nonprofit organization to fund research on the health effects of mobile phone emissions. Although some useful research was conducted, many scientists and government and industry officials that we spoke with raised questions about the productivity and accountability of that organization. In June 2000, a new industry-funded research initiative began that is largely focused on following up on the results of this earlier industry research effort. Unlike the prior effort, this new one is a cooperative research and development agreement that involves direct participation by FDA. CTIA had declined FDA's offer to conduct a joint research program in the early 1990s, but CTIA officials told us that they now believe FDA's involvement will provide additional accountability and scientific credibility to the new effort.

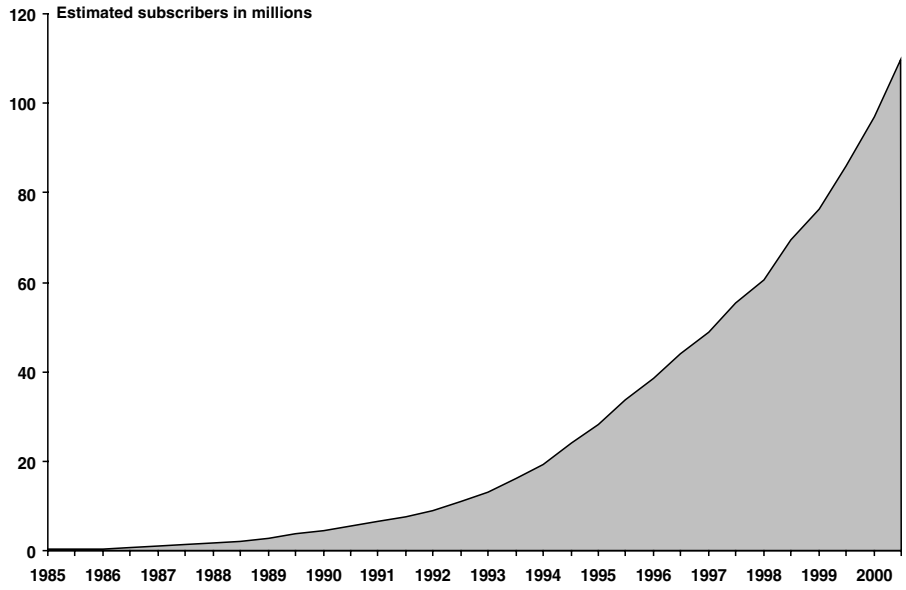
In 1996, FCC, which is responsible for regulating mobile phones, established rules setting a limit for human exposure to radiofrequency energy from mobile phones. These rules are based on criteria developed by private standards-setting organizations and input from other federal agencies, including FDA. Manufacturers are responsible for testing mobile phones to certify compliance with FCC's exposure limit. However, a major engineering organization has not yet completed a long-standing effort to develop uniform procedures for this testing, the lack of which significantly increases variability in test results. FCC has been revising its own non-mandatory guidance on testing procedures, but has not yet issued it. In addition, FCC and FDA differ on how the measurement uncertainty inherent in testing is treated in determining compliance with radiofrequency safety limits. In the area of staffing, FCC has been relying heavily on one staff specialist in radiofrequency exposure issues to review manufacturers' test results for compliance with FCC's exposure limit and to perform some in-house testing of mobile phones. FCC has attempted to recruit an additional specialist but says it is having trouble competing with the private sector for qualified applicants.

The media has given widespread attention to the debate over whether mobile phones can cause adverse health effects; thus, the federal government's role in providing the public with clear information on this issue is particularly important. FDA has a consumer information update on mobile phone health issues, but it has not been revised since October 1999, and consequently does not discuss the significance of major, recently published research studies that have been reported and debated in the media. FDA told us that the update has not been revised because the scientific picture has not changed significantly since then. Consumers, however, have no way of knowing this from the update and may be left in doubt about FDA's views on recent research developments. For its part, FCC makes information on radiofrequency exposure issues publicly available, but this information is typically at a level of technical detail that is not well-suited to a general audience. These shortcomings in consumer information are a particular cause for concern because the industry is including information from both FDA and FCC with most new mobile phones. This report makes recommendations to FCC for improving its review of mobile phone testing and to FCC and FDA for improving consumer information on radiofrequency exposure and health issues.

## Background

The United States has experienced a dramatic growth in the number of wireless telephone subscribers since nationwide cellular service became available in the mid-1980s. In 1994, 16 million Americans were subscribers. By 2001, subscribership had reached an estimated 110 million (see fig. 1) and is projected to have strong growth for the foreseeable future. Growth has been strong in other countries as well, with some experts projecting that worldwide subscribership will reach about 1.2 billion by 2005. In countries such as Austria, Finland, Italy, Norway, South Korea, and Sweden, more than half the population are already subscribers.

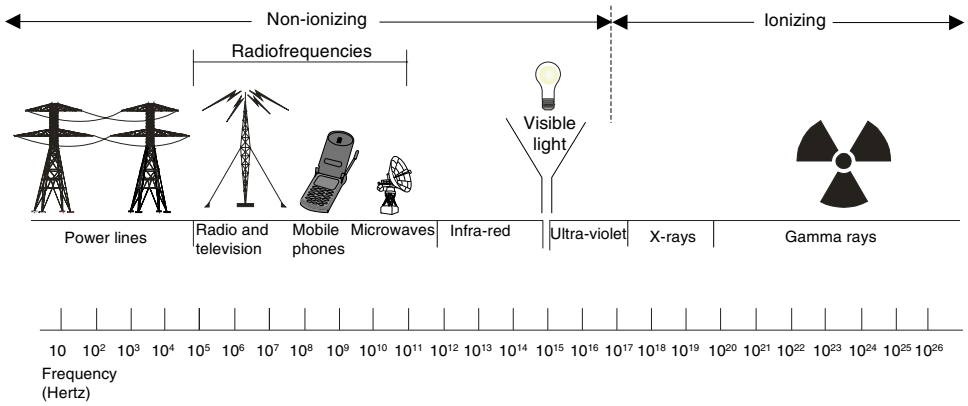
**Figure 1: Growth in U.S. Wireless Telephone Subscribers, 1985-2001**




Source: Cellular Telecommunications & Internet Association (estimates).

The pocket-sized mobile phone in common use today is a low-powered radio transceiver (a combination transmitter and receiver) that uses radio waves to communicate with fixed installations, called base stations or cell towers. The base stations are networked to a central switching station that directs a mobile phone call to the desired location, whether that is another mobile phone or a traditional landline phone. The radio waves used by mobile phones are a form electromagnetic radiation—a series of waves of electric and magnetic energy that move together through space. The spectrum of electromagnetic radiation comprises a range of frequencies from very-low-frequency energy (such as electrical power), through visible light, to extremely high-frequency radiation (such as X-rays and gamma rays), as shown in figure 2. The portion of the electromagnetic spectrum used by mobile phones—as well as other telecommunications services, such as radio and television broadcasting—is generally referred to as the "radiofrequency spectrum." Frequencies in this part of the spectrum are also used for some noncommunications applications, such as microwave ovens and radar.

**Figure 2: The Electromagnetic Spectrum**




Source: FCC.

As figure 2 shows, the electromagnetic spectrum includes ionizing and non-ionizing radiation. Ionizing radiation, such as X-rays and gamma rays, has energy levels high enough to strip electrons from atoms and molecules. Exposure to ionizing radiation can cause serious biological damage, including the production of cancers. Radiofrequencies, on the other hand, are in the "non-ionizing" portion of the electromagnetic spectrum, which lacks the energy needed to cause ionization. However, radiofrequency energy can produce other types of biological effects. For example, it has been known for many years that exposure to high levels of radiofrequency energy, particularly at microwave frequencies, can rapidly heat biological tissue. This heating ("thermal" effect) can cause harm by increasing body temperature, disrupting behavior, and damaging biological tissue. The heating effect can also be usefully harnessed for household and industrial applications, such as cooking food and molding plastics.

Mobile phones are designed to operate at power levels well below the threshold for known thermal effects.[4] Consequently, the mobile phone heath issue has generally focused on whether there are any adverse biological effects from long-term or frequent exposure to low-power radiofrequency emissions that are not caused by heating ("nonthermal" effects). There is particular interest in determining whether using a mobile phone could in some way cause or promote brain cancer, since a user's

[4]A mobile phone is designed to operate at a maximum power level of 0.6 watts—less than the amount of power needed to light a flashlight bulb—and generally uses less than maximum power when operating close to a base station. By contrast, household microwave ovens use between 600 and 1,100 watts of power.

head absorbs some radiofrequency energy when the phone is held to the ear during a call.[5]

## Evidence Does Not Demonstrate Adverse Health Effects, but Additional Research Is Under Way

According to FDA and others, the research to date does not show that mobile phone radiofrequency emissions have adverse health effects but there is not enough information at this point to conclude that these products are without risk. While most epidemiological and laboratory studies related to the radiofrequency emissions of mobile phones have found no adverse health effects, the results of some studies have raised questions that require further research. The World Health Organization, an agency of the United Nations, has identified priorities for this research, and a number of projects are under way internationally to address many of these priorities. The U.S. government sponsors and supports some of the research; overall, this represents a small portion of the total worldwide research effort.

### Research to Date Does Not Demonstrate Adverse Health Effects, but Is Not Conclusive

A number of studies have been conducted on the possible health effects of radiofrequency emissions from mobile phones. FDA's position, first stated in 1993 and still in place today, is that the research to date does not show that radiofrequency emissions from mobile phones have adverse health effects. However, according to FDA, there is not enough information at this point to conclude that the phones pose no risk. Several international bodies, including the World Health Organization[6] and expert panels commissioned by the British[7] and Canadian[8] governments, have drawn similar conclusions. All of these bodies conclude that while most of the studies related to mobile phone radiofrequency emissions have found no

[5]The mobile phone health issue came to national attention in 1993 after a lawsuit was brought against some mobile phone companies by a Florida man claiming that his wife's use of a mobile phone caused her brain cancer. The industry has prevailed in this and other suits that have been brought. Recently, a number of new lawsuits have been filed.

[6]World Health Organization, "Electromagnetic Fields and Public Health: Mobile Telephones and Their Base Stations," Fact Sheet No. 193 (2000).

[7]Independent Expert Group on Mobile Phones, "Mobile Phones and Health," National Radiological Protection Board (UK) (Apr. 1999).

[8]Royal Society of Canada, "A Review of the Potential Health Risks of Radiofrequency Fields From Wireless Telecommunication Devices." Expert panel report prepared for Health Canada (1999).

effect on human health, some studies that have suggested the existence of biological effects require further investigation.

A number of factors makes it difficult to draw definitive conclusions from the existing research about the potential health effects of mobile phones. A relatively large body of research exists on the health effects of radiofrequency energy in general, but most of this research has focused on short-term exposure of the entire body, not on the longer-term exposure of the head that is characteristic of mobile phone use. In addition, much of the research to date has investigated the health effects of emissions at frequencies different from those used by mobile phones; it is not clear how possible health effects found at one frequency on the radiofrequency spectrum apply to other frequencies on the spectrum. Furthermore, much of the research focusing on mobile phones has tested the emissions of analog phones rather than of digital phones, which are rapidly becoming the standard technology. A few researchers have hypothesized that digital phones, which transmit messages as discontinuous pulses, could have different biological effects from analog phones, which transmit messages using a continuously varying radio wave. However, according to FDA, at this point the available scientific literature does not demonstrate convincingly that the biological effects of radiofrequency exposure differ based on specific frequency, or on whether the signal is analog or digital.

Two major categories of studies are used by scientists to assess whether mobile phones present a health risk: epidemiological studies and laboratory studies. Epidemiological studies, sometimes called human health studies, investigate the associations between health effects and the characteristics of people and their environment. Laboratory studies, which can include studies on animals, biological tissue samples, isolated cells, or human volunteers, are used to try to determine a causal relationship between a risk factor and human health, and the mechanism through which that relationship occurs.

## Epidemiological Studies

Several epidemiological studies published in peer-reviewed scientific journals have been conducted on the health effects of radiofrequency emissions from mobile phones. Among them is a study of mobile phone users in Denmark from 1982 through 1995 that found no association between phone use and the incidence of brain or certain other cancers.[9]

[9]C. Johansen and others, "Cellular Telephones and Cancer—A Nationwide Cohort Study in Denmark," *Journal of the National Cancer Institute*, Vol. 93, No. 3 (2001), pp. 203-207.

This study included more than 420,000 mobile phone subscribers, although more than two-thirds of them had been subscribing to mobile phone service for less than two years. Two other studies, one of which was conducted by the National Cancer Institute, compared the frequency and duration of mobile phone use of brain tumor patients and control patients from 1994 to 1998.[10, 11] These studies, too, found no association between mobile phone use and an increased risk for brain tumors. A small Swedish study also did not find an association between the amount of use of mobile phones and the risk of brain tumors. The investigators reported an association between the side of the head on which the tumor occurred and the side of the head where the mobile phone was used, but this was based on a small number of brain tumor cases.[12] In addition, a study of about 250,000 U.S. mobile phone customers found that the overall mortality rates of the users of handheld mobile phones were similar to the users of car phones (where the antenna is not held close to the head).[13]

Epidemiological studies, by nature, have certain limitations. They are not good at detecting increases in risks that are small, and they generally cannot, on their own, demonstrate a cause-and-effect relationship. In addition, because mobile phones have been in widespread use for only a few years, epidemiological studies have limited value in providing information about a possible association with cancers that may have long latency periods. For example, the National Cancer Institute said that its brain cancer study was not sufficient to evaluate the long-term effects of mobile phone use and was not large enough to rule out small increases in the risk of brain tumors in general and larger increases in the risk for different subtypes of brain tumors. If there is an increased risk of brain tumors due to the use of mobile phones that only appears after 5 years or more, or only among very heavy users, it is probable that this study would have failed to detect it. For these reasons, experts we spoke with told us that epidemiological studies, while useful, are only one piece of a larger

[10]P. Inskip and others, "Cellular-Telephone Use and Brain Tumors," *New England Journal of Medicine*, Vol. 344, No. 2 (2001), pp. 79-86.

[11]J. Muscat and others, "Handheld Cellular Telephone Use and Risk of Brain Cancer," *Journal of the American Medical Association*, Vol. 284, No. 23 (2000), pp. 3001-3007.

[12]L. Hardell and others, "Use of Cellular Telephones and the Risk for Brain Tumours: A Case-Control Study," *International Journal of Oncology*, Vol. 15, No. 1 (1999), pp. 113-116.

[13]K.J. Rothman and others, "Overall Mortality of Cellular Telephone Customers," *Epidemiology*, Vol. 7, No. 3 (1996), pp. 303-305.

body of evidence that must be evaluated to assess the health effects of mobile phones.

## Laboratory Studies

Laboratory studies have been conducted to try to determine the effect of radiofrequency emissions from mobile phones on individual human or animal cells, on laboratory animals, or on human test subjects. Studies testing individual cells have exposed samples of human or animal cells to radiofrequency emissions over a range of dose rates, durations, and conditions, and then examined the cells to try to detect any changes. The great majority of these cellular laboratory studies have shown no biological effects, but some studies warrant further additional attention, according to FDA. For example, when researchers performed a battery of tests to assess the effects of exposure to mobile phone radiofrequency energy on the genetic material of blood cells, one type of test, known as a micronucleus assay, detected changes in the genetic material, a common precursor to cancer.[14] FDA says that because the data already in the literature on this topic are conflicting, follow-up research is necessary.

Animal testing related to mobile phone health effects involves exposing laboratory animals (such as rats and mice) to radiofrequency emissions and then examining the animals for changes, compared with a control group, in disease or death rates. This kind of testing has the advantage of allowing researchers to study the effect of radiofrequency emissions on a fully functioning animal system, but it is also limited since the biological effects on rats and mice may not be the same as those on human beings. FDA says that the small number of animal studies that have investigated the effects of radiofrequency exposures characteristic of mobile phones have shown conflicting results, but a few studies have suggested that such exposure could accelerate or contribute to the development of cancer in laboratory animals.

Laboratory studies on human volunteers have investigated whether radiofrequency exposure has certain noncancer effects, such as neurological changes or changes in blood pressure. Some of these studies have reported effects, including changes in brain activity, reaction times, and sleep patterns. According to the World Health Organization, these

[14]R. Tice and others, "Tests of Mobile Phone Signals for Activity in Genotoxicity and Other Laboratory Assays," presented at annual meeting of the Environmental Mutagen Society (Mar. 29, 1999).

effects are small and have no apparent health significance, but more studies are needed to try to confirm these findings.

## Efforts Under Way to Conduct Additional Research

In 1996, the World Health Organization, an agency of the United Nations, established the International Electromagnetic Fields Project, which seeks to assess the health and environmental effects of exposure to electric and magnetic fields, including radiofrequency fields emitted by mobile phones. The agency notes that because the number of people using mobile phones has grown so large, even small adverse effects on health could have major public health implications. The goals of the project include coordinating international research efforts in the area, assessing the scientific literature, and identifying gaps in knowledge needing further research.

In 1998, the project developed an agenda for research priorities on the health effects of electromagnetic fields. This agenda was developed in collaboration with a number of international organizations, such as the United Nations Environment Programme and the European Commission, as well as independent scientific institutions in several countries. FDA officials told us that they participated heavily in the development of this research agenda and that they concur with it. Among the research priorities identified were (1) additional large-scale animal studies that test the effect of long-term exposure to radiofrequency energy; (2) studies that test health effects other than cancer, such as memory loss and effects on the eye or inner ear; and (3) at least two additional large-scale epidemiological studies of people exposed to radiofrequency energy, including mobile phone users.

Officials at the World Health Organization and FDA told us that most of these research needs are being addressed by ongoing or planned studies in countries around the world. Because of the nature of many of these studies, however, it may be several years before results are reported. Highlights of efforts currently under way or planned include the following.

- The International Agency for Research on Cancer, a part of the World Health Organization, is coordinating a series of large epidemiological studies looking at whether there is an association between mobile phone use and brain cancer. At least 13 countries are participating in the studies, with results expected in 2004.
- The European Commission, under its research program known as the Fifth Framework Programme, is sponsoring a number of studies on the health effects of mobile phone emissions that are being funded primarily by the European Commission and the mobile phone industry. The planned

research includes large-scale animal studies designed to follow up on prior research.

- FDA and CTIA have begun a cooperative research effort, discussed below, that initially is focusing on two areas: (1) following up on the previously cited micronucleus assay that found changes in the genetic material of blood cells exposed to radiofrequency energy and (2) epidemiological studies.
- The National Toxicology Program, an interagency program headquartered at NIH, began planning in 2000 a series of long-term animal studies looking at the effect of long-term exposure to the radiofrequency emissions of mobile phones. Officials at the program are determining how their efforts should be coordinated with the European Commission's planned animal studies.
- The United Kingdom's Department of Health announced in December 2000 a research program of up to $10 million on the possible health effects of mobile phone emissions. While the specific areas of research to be conducted are still under review, one strong area of focus is expected to be noncancer effects, such as effects on brain function.
- In addition to these efforts, there are various other government-supported national research programs on mobile phone health issues, including programs in Australia, Finland, France, Germany, Italy, Japan, and Sweden. Most of these programs are being coordinated with, or are being conducted in collaboration with, the programs of the World Health Organization and/or the European Commission.

Many of the initiatives in mobile phone research are funded through a combination of government and industry money. For example, mobile phone research being done under the Fifth Framework Programme is being financed 40 percent by the European Commission and 60 percent by the mobile phone industry. Similarly, the United Kingdom's effort is being financed half by the government and half by the industry. Much of the industry funding is done through the GSM Association, which represents the wireless communications industry, and the Mobile Manufacturers Forum, an international consortium of mobile phone manufacturers that funds and coordinates research efforts on the public health effects of mobile phones and base stations. In addition, some individual mobile phone manufacturing companies conduct their own internal research programs. For example, Motorola has an in-house staff of five scientists and engineers that researches radiofrequency exposure issues as they relate to public health. Motorola also contracts out about $1 million a year on biological research related to radiofrequency energy.

## U.S. Government Is Supporting Some Research on Mobile Phone Health Effects

The U.S. government supports some research on the health effects of mobile phone radiofrequency emissions; overall, this represents a small portion of the research being done in the area worldwide. At present, only one agency, NIH, is providing significant funding for research related directly to the health effects of mobile phone emissions. Other agencies, such as FDA, are providing technical and scientific support to research efforts funded by the mobile phone industry, international organizations, and others. In addition to its cooperative research and development agreement with CTIA, FDA is also an active participant in the World Health Organization effort. For example, an FDA official is serving as an external scientific adviser to the mobile phone research activities being conducted under the European Commission's Fifth Framework Programme.

Depending on what tests it chooses to conduct, NIH's National Toxicology Program may spend as much as $10 million over several years on its long-term animal tests of mobile phone radiofrequency exposure. The National Toxicology Program is an interagency program headquartered at NIH's National Institute of Environmental Health Sciences that routinely solicits nominations for toxicological studies. FDA nominated the review of mobile phone radiofrequency exposure and is providing some input to NIH on the experimental design of the animal studies. In addition, the Department of Commerce's National Institute of Standards and Technology is providing some assistance to NIH on the design and measurement of the radiofrequency exposure systems to be used in the program's animal tests.

The Department of Defense has one of the world's largest research programs on the health effects of radiofrequency energy, with approximately 50 to 60 full-time staff working on the issue in Air Force, Army, and Navy programs. Because the bulk of this research focuses on radar and on microwave-emitting weapon systems, it is not specifically related to mobile phones, but it does add to the general body of knowledge about the subject of radiofrequency health effects. One study being conducted by the Air Force, however, is closely related to mobile phone health effects—a $200,000 study on whether the low-intensity radiofrequency emissions characteristic of some mobile phones have an effect on the protective barrier that prevents the brain from being harmed by certain substances in the blood.

EPA does not currently sponsor or conduct any research related to mobile phone health effects. EPA used to have a substantial in-house program of research on radiofrequency energy, but it was largely eliminated in the

1980s for budgetary reasons. However, EPA scientists with expertise in the area play an active advisory role with regard to research conducted by other federal agencies, foreign governments, and private researchers, and with regard to regulatory actions by FCC.

## FDA and Industry Association Are Following Up on an Earlier Research Effort

In 1993, CTIA created a nonprofit organization to fund research on the health effects of mobile phone emissions. Although some useful research was conducted, questions have been raised about the productivity and accountability of that organization. A new industry-funded research initiative began in June 2000 that is largely focused on following up on the results of two studies under this previous effort. Unlike the prior effort, this new one involves direct participation and oversight by FDA.

### Earlier Industry Research Effort Was Controversial

Responding to public concern that mobile phones may cause health problems such as brain cancer, CTIA, a trade association representing wireless telecommunications manufacturers and service providers, met in the early 1990s with FDA officials to discuss a possible research effort related to mobile phone health effects. FDA proposed that the two organizations engage in a cooperative research effort, but CTIA declined primarily because, they told us, they feared that government involvement would add bureaucratic complexity that would slow down the effort. Instead, on its own, CTIA established the Scientific Advisory Group on Cellular Telephone Research, whose goal was to develop, fund, and manage a research program assessing whether mobile phones pose a public health risk and, if so, what should be done to mitigate that risk. CTIA committed $25 million over 5 years to the group. Using input from outside scientists, the Scientific Advisory Group developed a research agenda that included multidisciplinary studies involving epidemiology, cell cultures, test animals, and dosimetry (the measurement of radiation). The group's activities were reviewed by the Peer Review Board on Cellular Telephones, a board of outside scientists coordinated through Harvard University's Center for Risk Analysis.

In our 1994 report on mobile phone safety, we noted that the Scientific Advisory Group was being directly funded by CTIA on a month-by-month basis, an arrangement that could have raised questions about the objectivity and credibility of the research effort. In 1995, the Scientific Advisory Group was transformed into Wireless Technology Research, L.L.C. (WTR), a nonprofit organization financed by, but autonomous from, CTIA. WTR's structure was designed to maintain independence from industry control. However, several representatives of federal agencies and

industry, as well as members of WTR's Peer Review Board, told us they believe that the structure set up for WTR resulted in too little accountability. WTR had a three-person board of directors, but the chairman of this board also served as the day-to-day manager of WTR's activities and did not report directly to CTIA or to any other body.

Our 1994 report recommended that FDA and EPA, in coordination with FCC, work with the Scientific Advisory Group to maximize the usefulness, independence, and objectivity of the group's research effort. However, in the end, no federal agency had a role overseeing WTR's research activities. FDA officials told us that they did not take an oversight role in WTR because it was a private organization not under FDA's control and that, in any case, WTR rarely solicited input from FDA and did not always follow the input that was given.

WTR spent about $28 million over 5 years, including about $25 million for research on the health effects of mobile phone emissions. A broad array of scientists and government and industry officials we spoke with said that some of the research sponsored by WTR was useful. However, they questioned both the type of projects WTR selected and the amount of research that was produced, given the financial resources it had available. In addition, WTR's Peer Review Board raised concerns about WTR's management in a July 1997 letter to the chairman of WTR. Among other issues, the board expressed concern that WTR was not always open and transparent, particularly with regard to its finances, and that decisions about the direction of its research agenda did not always follow the advice of outside experts. The chairman of WTR told us that in retrospect WTR should have been more transparent about its work and its finances. However, he said that WTR's research agenda incorporated the input of a wide number of outside experts. He also said that WTR's mission was broader in scope than just sponsoring research; it included tracking the emerging scientific information on the topic and identifying strategies for mitigating any public risk.

The WTR effort eventually became caught up in public controversy. In May 1999, near the end of WTR's funding period, the chairman of WTR issued a statement that while the results of WTR research did not show a need for public health intervention, the preliminary findings of two studies raised concerns that warranted follow-up research. The chairman stated that one study (see fn. 14) had found that human blood cells exposed to mobile phone frequency radiation showed genetic damage in the form of micronuclei, which is often considered a precursor to cancer. The second study (see fn. 11) was an epidemiological study that, according to the

chairman, found a statistically significant risk of a certain rare type of tumor. However, the findings of this study were preliminary, the analysis of the data had not yet been completed, and the study had not yet been fully peer-reviewed or published. In addition, the principal researcher of this study disagreed with the chairman's interpretation of his findings. The chairman of WTR told us that he decided to report on these studies before they were published because the potential public health threat of mobile phones made it important to report on the research developments as soon as possible.

## New Industry Research Effort Involves Federal Oversight

In the wake of the WTR controversy, CTIA decided to fund a research effort that would follow up on the two studies conducted under WTR that had raised questions, as well as assess what further research might be needed. The vehicle for this follow-up work is a cooperative research and development agreement (CRADA), signed in June 2000, between CTIA and FDA. In contrast to WTR, which had a broad mission, the scope of the CRADA is limited to addressing the concerns raised by the two previous studies and assessing what further research might be needed. Overall, the research planned under the CRADA represents a small piece of the ongoing research worldwide related to mobile phone safety, government officials and scientists in the area told us.

Unlike the WTR effort, the CRADA involves the direct participation of FDA. CTIA officials told us that their experience with WTR taught them that FDA involvement would be beneficial because it would add accountability and scientific credibility to the new research effort. FDA's role in the CRADA is to (1) determine what types of research studies should be conducted, (2) evaluate and prioritize the research proposals received, and (3) review and assess the results of the research. CTIA is administering the process for procuring the research, and the research studies themselves are being conducted by third parties via contracts with CTIA. Because these are private contracts, CTIA says they will not be made publicly available, although it does plan to release highlights of the contracts' provisions.

All of the research, as well as all costs incurred by FDA, is being paid for by CTIA, which retains the final authority to decide which proposals are chosen and funded. Thus, in contrast to WTR, the CRADA will not include a division between the funding source and management of the research. However, CTIA has said it intends to follow FDA's recommendations concerning the research agenda. The request for proposals that CTIA issued in September 2000 for the first set of studies incorporated FDA's

recommendations with no changes. CTIA and FDA also told us they expect that the contracts with researchers will include provisions to ensure that the research results are published in peer-reviewed journals and that the research data are owned and controlled by the researcher, not by CTIA.

An essential element in building public confidence about the independence and objectivity of this follow-up research effort is keeping the CRADA process open and accessible to the public. The FDA working groups that are developing research recommendations hold publicly announced open meetings. In addition, the research agendas that the working groups propose and the requests for proposals that CTIA issues are publicly available. However, at the time we completed our audit work, FDA had not yet decided the extent to which it would make public its recommendations to CTIA on which proposals to fund. If these recommendations are not publicly available in some form, it will not be possible to ensure that CTIA is following FDA's recommendations. FDA officials told us that making their full recommendations public, including individual reviewers' comments, would undermine the review process, which depends on anonymous reviewers providing candid critiques of research proposals. However, they said that they are considering ways of providing the public with a summary of their recommendations that would still protect the integrity of the review process.

## FCC Set an Exposure Limit for Mobile Phones, but Standardized Testing Procedures Are Lacking

Although several federal agencies are involved in radiofrequency safety issues, FCC is responsible for regulating mobile phones. In 1996, FCC established rules setting a human exposure limit for radiofrequency energy from mobile phones, based on criteria developed by private standard-setting organizations and input from other federal agencies. Manufacturers are responsible for testing mobile phones to certify compliance with FCC's exposure limit, but the industry does not have uniform testing procedures, which significantly increases variability in test results. An international standards-setting organization has been working since 1997 to develop uniform testing procedures. This effort is nearing completion, but there are still some testing issues to resolve. FCC has revised its own nonmandatory guidance on testing to reflect the procedures being developed by the standards-setting organization. However, FCC is waiting for the organization to complete its effort before issuing the revised guidance. In the area of staffing, FCC has been relying heavily on one staff specialist in radiofrequency exposure to review manufacturers' test results for compliance with FCC's exposure limit and to perform some in-house testing of phones. FCC has attempted to recruit an additional specialist but

says that it is having trouble competing with the private sector for qualified applicants.

## Regulatory Roles and Responsibilities of Federal Agencies

Under the Federal Radiation Council Authority, transferred to EPA by Reorganization Plan No. 3 of 1970, EPA is responsible for, among other things, advising the President on radiation matters, including providing guidance to all federal agencies on formulating protective standards on radiation exposure. Upon presidential approval of EPA's recommendation for formulating standards, the pertinent agencies would be responsible for implementing the guidance. EPA chairs the Radiofrequency Interagency Work Group, which coordinates radiofrequency health-related activities among the various federal agencies with responsibilities in this area.[15]

Under the Radiation Control for Health and Safety Act of 1968, as amended, FDA is responsible for establishing and carrying out a program, designed to protect public health and safety, to control radiation from electronic products. Under the law, FDA does not review the safety of radiation-emitting consumer products such as mobile phones before they are marketed, as it does with new drugs or medical devices. However, according to FDA, it has the authority to take action, such as requiring manufacturers to replace or recall phones, if they are shown to emit radiation at a level that is hazardous to the user. The usual way that FDA fulfills its regulatory responsibility is by evaluating industry-generated data from properly conducted studies to determine whether they raise public health questions. According to FDA, the evidence to date does not justify FDA's taking regulatory actions regarding mobile phones. The chief of FDA's Radiation Biology Branch said that the agency keeps abreast of scientific research on the issue, and of changes in mobile phone technologies, to ensure that FDA is aware if evidence of a health hazard emerges.

Under the National Environmental Policy Act of 1969, FCC is required to consider whether its actions (including actions that may lead to human exposure to radiofrequency energy) in authorizing communication equipment significantly affect the quality of the human environment. In 1985, FCC adopted an exposure limit for radiofrequency energy based on

[15]Members of the working group are EPA, FCC, FDA, the National Institute for Occupational Safety and Health, the National Telecommunications and Information Administration, and the Occupational Safety and Health Administration. NIH also participates in the working group.

standards developed by the Institute of Electrical and Electronics Engineers, Inc. (IEEE)[16] and subsequently approved and issued by the American National Standards Institute (ANSI).[17] These standards covered radiofrequency emissions of high-power devices, such as broadcast towers, but not low-power devices, such as mobile phones. In 1993, FCC began updating its radiofrequency exposure limits to reflect subsequent changes made to the ANSI/IEEE standard, which was similar to the limits developed by the National Council on Radiation Protection and Measurements (NCRP).[18] The Telecommunications Act of 1996 required FCC to complete action to prescribe and make effective rules concerning the environmental effects of radiofrequency emissions.[19] Later that year FCC implemented, for the first time, radiofrequency exposure limits that included mobile phones. Because FCC is primarily a regulatory agency and is not an expert on matters pertaining to health and safety, it followed the recommendations of FDA, EPA, and other health agencies and organizations in setting standards for mobile phones.

## Exposure Limit for Mobile Phones Is Derived From Heating Effects

The exposure limit adopted by FCC for mobile phones is based on the heating effects of radiofrequency energy. It has been known for many years that radiofrequency energy at high enough power can heat tissue, causing damage to living organisms. The scientific measure used to characterize the amount of radiofrequency energy absorbed by biological tissue is called the specific absorption rate (SAR).[20] In scientific tests, animals had adverse behavioral effects once they absorbed enough radiofrequency energy to increase their body temperature by 1 degree Celsius. IEEE and NCRP incorporated a substantial safety factor into their standards for general human exposure by setting them at one-fiftieth the

[16]IEEE is a membership organization that develops industry standards, among other activities.

[17]ANSI is a nonprofit, private-membership organization that coordinates the development of voluntary national standards.

[18]The NCRP is a not-for-profit corporation chartered by the Congress to formulate and disseminate information, guidance, and recommendations on radiation protection and measurements.

[19]See Section 704(b) of the Telecommunications Act of 1996, Pub. L. No. 104-104, 110 Stat. 56 (1996).

[20]SAR is the widely accepted measurement of radiofrequency energy absorbed into the body in watts per kilogram (W/kg) averaged over some amount of tissue ranging from the entire body to 1 gram.

exposure shown to cause adverse effects in animals. Because this limit is based on whole-body exposure, it was adjusted to account for the fact that mobile phones expose only a part of the body to radiofrequency energy. The resulting limit adopted by FCC for mobile phones is that their SAR levels may not exceed 1.6 watts per kilogram (W/kg) averaged over one gram of tissue. Some other countries have chosen to adopt a somewhat higher exposure limit than FCC.

Because the only proven adverse health effects of radiofrequency exposure are caused by heat, the exposure limit is not designed to address the possibility of any non-heating-related effects, such as cancer. FCC says that given the lack of evidence of a non-thermal effect, the current exposure limit is reasonable, particularly since it incorporates a large safety factor for known heating effects.[21] FCC added that because it has neither primary jurisdiction nor expertise in health and safety matters, it adopted a radiofrequency exposure limit based on determinations by expert standard-setting organizations and input from various federal health and safety agencies.

## FCC Requires SAR Testing Before Mobile Phones Are Marketed

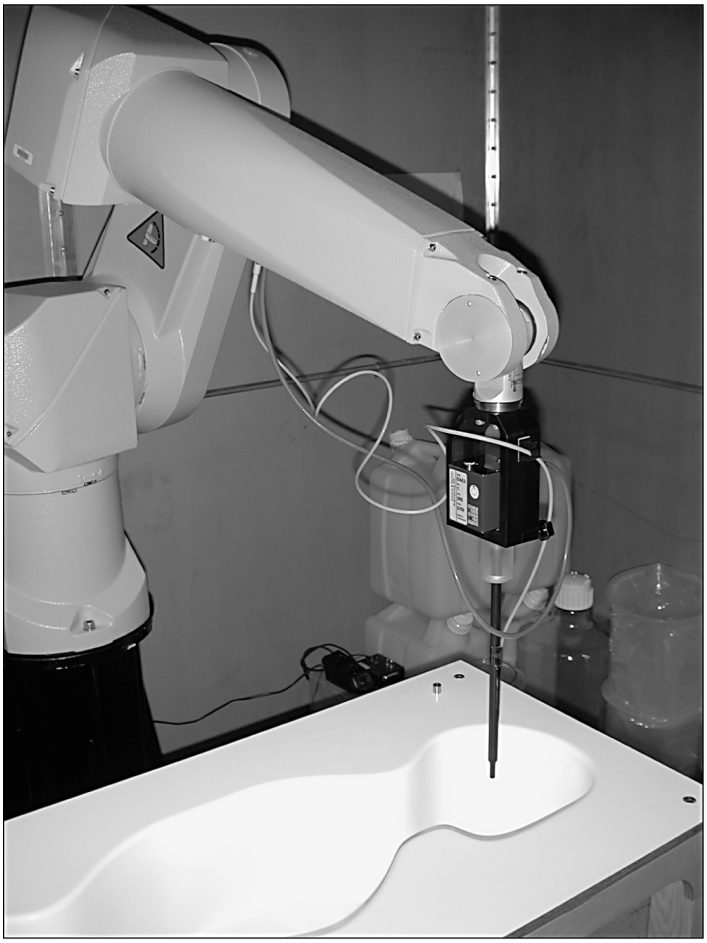
Manufacturers are continually introducing new models of mobile phones with new features and designs. Before a new model can be put on the U.S. market, it must receive a grant of equipment authorization from FCC. In their equipment authorization applications, manufacturers must certify that their mobile phones meet various FCC technical standards, including compliance with FCC's radiofrequency exposure limit. Technical information must be provided upon request, including data on the procedures used to conduct SAR tests on the phones.

Manufacturers may conduct the SAR tests themselves at their own facilities or have the testing done for them by private testing laboratories. A typical SAR testing set-up is shown in figure 3. A mold in the shape of an adult torso or head is filled with a fluid mixture designed to simulate the electrical properties of human tissue. A probe attached to a computer-controlled mechanical arm is inserted into the mixture at various locations, with the phone placed next to the outer surface of the mold. The phone is made to transmit a signal at full power while the probe is moved

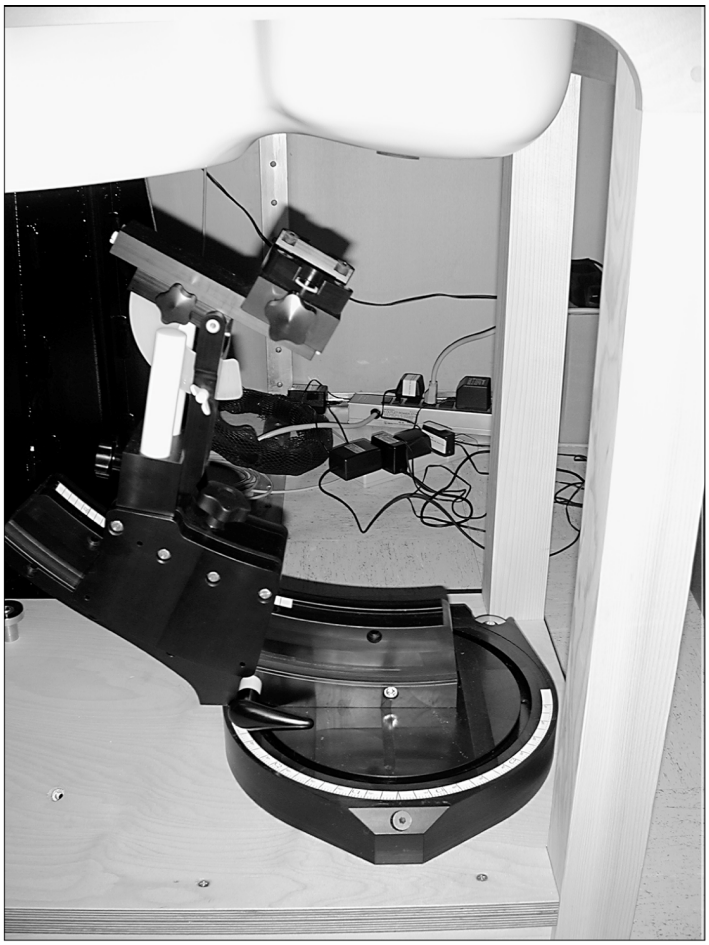
[21]A federal court of appeals upheld FCC's radiofrequency exposure guidelines (Cellular Phone Taskforce v. FCC, 205 F.3d 82 (2d Cir. 2000)), and earlier this year the Supreme Court denied petitions for certiorari challenging this decision.

through the mixture, measuring the radiofrequency energy that is being absorbed at various locations. The phone is tested in several configurations, such as with its antenna extended and retracted, and at different frequencies. The phone's certified SAR level is the highest SAR level measured during these tests. In order to receive FCC authorization, none of the SAR test results for the head or body can exceed FCC's exposure limit of 1.6 W/kg averaged over 1 cubic gram of fluid.

**Figure 3: FCC's Mobile Phone SAR Test Equipment**



The mechanical arm pictured above is directed by a computer to take SAR measurements throughout the model head and torso below it. During an actual test, the mold will be filled with a fluid mixture designed to simulate the electrical properties of human tissue.



The device pictured is designed to hold a mobile phone in various positions against the model. During SAR testing, the mobile phone is set to emit radiofrequency energy at its maximum power level.

Source: GAO.

## SAR Test Results Can Vary Substantially

SAR test results for mobile phones can vary substantially because of measurement uncertainties and the use of different testing procedures. Variations due to measurement uncertainties are the result of limitations inherent in technological and human accuracy. For example, FCC officials said that small differences in the way different technicians set up the test, mix the tissue fluid, or calibrate the measurement instruments can introduce variation into the test results. Variations also occur because laboratories can use different testing procedures. When FCC established its mobile phone radiofrequency exposure limit in 1996, the industry did not have uniform standards for testing SAR levels. FCC published a technical bulletin in 1997 to assist manufacturers in complying with its radiofrequency exposure limits, but the bulletin was not intended to establish mandatory procedures for testing mobile phones.[22] FCC made it clear that test procedures other than those discussed in its guidance could be acceptable if based on sound engineering practice. For example, a testing facility may use a number of different procedures for positioning the handset, even though small differences in the position of a phone can result in large, unexpected changes in the energy absorption in the head. Other important sources of variability due to differences in testing procedures include the properties of the mixtures used to simulate human tissue, the type of head model used, the type and calibration of the probe used to measure the radiated electric field, and the methods for averaging SAR measurements. FCC officials said that the combined effect of measurement uncertainty and procedural variations could, in some instances, cause a phone's actual maximum SAR level to fall somewhere within a range of plus or minus 50 to 60 percent (at a confidence interval of 95 percent) of the test result.

Given the lack of standardized SAR testing procedures, FCC must evaluate the procedures used by a manufacturer for certifying the SAR level of each new phone model. To do this, FCC examines the test reports provided with the manufacturer's application for equipment authorization. This documentation is supposed to include, among other things, a description of measurement and computational uncertainties in the testing system used; the test positions of the phone; the type of head model used; the properties of the simulated tissue fluid; SAR computation parameters, procedures, and results; and other key pieces of information. FCC

[22]Supplement C to FCC's Office of Engineering and Technology Bulletin 65, *Evaluating Compliance with FCC Guidelines for Human Exposure to Radiofrequency Electromagnetic Fields* (Dec. 1997).

currently has one specialist in radiofrequency exposure who is responsible for reviewing applications that involve SAR testing.

We found that FDA and FCC differ in whether or not they expect manufacturers to incorporate measurement uncertainty in determining compliance with radiofrequency safety limits. FDA rules state that microwave oven manufacturers must take all measurement errors and uncertainty into account when demonstrating compliance with FDA's radiofrequency energy performance standard for these devices. An FDA official said that this rule essentially lowers a microwave oven's maximum level of allowable radiofrequency energy leakage by the margin of measurement uncertainty. FCC, on the other hand, considers a phone to be in compliance if the manufacturer's SAR test result is within FCC's exposure limit, without incorporating the measurement uncertainty associated with the test result. However, to ensure compliance with the radiofrequency exposure limit, FCC looks for specific test procedures and parameters used by manufacturers that would tend to overestimate SAR. In the reviewer's judgment, if an applicant's testing procedures appear to contain irregularities or raise questions, the reviewer can request additional supporting data or further SAR testing. FCC officials responsible for drafting FCC testing guidance were not aware of FDA's different treatment of measurement uncertainty when we discussed it with them. They told us that they intended to contact FDA to discuss this issue and obtain FDA's views and advice.

## Standardization of SAR Testing Procedures Still Not Completed

FCC says that standardizing SAR testing procedures could significantly reduce the variability in test results and speed up the FCC authorization process. In February 1997, IEEE began an effort to set uniform industrywide testing standards. Staff from FDA and FCC participate in this effort. After 4 years of work, IEEE's standards-setting committee has made considerable progress in developing draft standards. Agreement appears to have been reached on many of the important issues, including standardizing the properties of the mixture that simulates human tissue and the testing positions of the phone. However, IEEE's draft standards have not yet been finalized because some technical issues still need to be resolved within the committee.

FCC considers the lack of uniform SAR testing standards to be a major concern. In October 1999, following a media report raising questions about SAR testing, FCC issued a press release stating that if the industry standard-setting committees did not act promptly to finalize standardized testing procedures, FCC would mandate action on its own. In keeping with

this statement, FCC officials said that they have developed a draft revision of their 1997 guidance, which is more inclusive and incorporates features of the testing standards that IEEE is developing. FCC officials said that the issuance of their revised guidance is currently on hold pending the completion of IEEE's testing standards. When we asked if FCC could immediately issue guidance based on those IEEE testing procedures that have already been agreed upon, FCC officials said that this could be done through an FCC public notice. They noted that they have already begun informally advising applicants to use certain of the most widely accepted elements of the test procedures under consideration by IEEE.

FCC officials said that although IEEE's new testing standards will reduce the variations in test results due to the use of different procedures, some level of measurement uncertainty is unavoidable. Thus, FCC officials said that, as with any measurement system, SAR tests can provide only a best estimate of a phone's maximum SAR level. As noted above, the degree of measurement uncertainty depends on a number of factors, including the calibration of the equipment, the precision with which the technician makes the measurements, and the errors due to system instrumentation. Because of these measurement uncertainties, FCC officials said that a phone's actual maximum SAR level could fall somewhere within a range of 30 percent above or below the phone's test results (at a confidence interval of 95 percent), even with uniform IEEE testing procedures in place. An industry-funded project conducted by the University of Maryland in cooperation with FDA will attempt to determine more precisely the degree of measurement uncertainty that can be expected with the new IEEE testing standards.

## FCC Plans to Test Some Phones

To verify the test data provided by mobile phone manufacturers, FCC is planning to conduct spot tests of some phones' SAR levels at its Office of Engineering and Technology laboratory. Although FCC officials had hoped to have the facility operational by fall 2000, some needed equipment was still being procured at the time of our review.

FCC officials noted that because FCC does not have the staff resources to test every mobile phone model that it authorizes, they can only test a sample of these phones. Even so, FCC faces a serious staffing problem in carrying out this initiative. Currently, FCC has only one radiofrequency exposure specialist to both oversee reviews of equipment authorization applications that involve radiofrequency exposure evaluation (about 50 a month, of which 15 to 20 are for mobile phones) and run the new testing facility. FCC and FDA officials have characterized this one specialist as

being FCC's key quality control point for determining whether mobile phones comply with FCC's exposure limits. FCC officials said that they have tried to recruit another radiofrequency exposure specialist but were unable to find a suitable candidate because it is difficult to compete with the private sector for qualified individuals. They stated that they plan to continue their recruiting effort. To help cope with the current staffing situation, FCC recently trained members of its engineering staff to take over reviewing SAR testing reports under the supervision of the specialist. The goal is to have the specialist spend about half of his time overseeing SAR reviews and the rest of his time on the actual testing of phones' SAR levels.

FCC has also turned to Telecommunications Certification Bodies (TCB) to help process equipment authorization applications. A TCB is a private organization that FCC, the National Institute of Standards and Technology, and the American National Standards Institute have accredited to review applications and issue product authorization grants on behalf of FCC. TCBs are processing approximately half of equipment authorization applications, none of which involve SAR tests. Eventually, FCC plans to move the bulk of its application processing to TCBs, including the approval of applications that include SAR tests, while retaining oversight of the TCBs' activities. At the time of our review, however, the transfer of additional authority to the TCBs had been placed on hold because of a lack of published uniform test procedures. In addition, FCC officials said that TCBs have experienced more difficulties in their application reviews than initially anticipated. FCC officials indicated that they are continuing their training and guidance efforts to improve TCBs' overall performance. In the near term, all SAR reviews will be performed at the FCC laboratory.

## Key FDA and FCC Consumer Information Efforts Have Shortcomings

During the past year, as new research studies were published, the print and broadcast media have presented a variety of assessments about the potential health effects of mobile phones. Given this situation, the federal government's role in providing the public with clear information on this issue is particularly important. FDA's consumer information on mobile phone health issues, however, has not been revised since 1999 and does not reflect more recent studies and research developments. Both FCC's Office of Engineering and Technology and its Consumer Information Bureau provide the public with information on radiofrequency exposure issues but do not meet general consumers' need for clear and concise information. These shortcomings are a cause for concern because the industry is including FDA's and FCC's consumer information with most new mobile phones.

## FDA's Consumer Information Update Has Not Been Revised Since 1999

FDA has a short information document, found on its Web site, called "Consumer Update on Mobile Phones." The document, dated October 20, 1999, states that the available scientific evidence does not demonstrate that there are any adverse health effects associated with the use of mobile phones. However, FDA adds that there is not enough evidence to know for sure, either way, whether handheld mobile phones might be harmful. The document discusses several research studies, including the two WTR studies that are being followed up under the cooperative research and development agreement between FDA and CTIA. For consumers who want to take simple precautions to limit their exposure to mobile phone radiofrequency emissions, FDA's update mentions some steps, such as avoiding extended conversations or using a headset while carrying the phone at the waist.

Although informative, the update has not been revised since 1999, and consequently does not discuss the significance of major, recently published research studies that have been reported and debated in the media. An FDA official told us that the update had not been revised because the scientific picture had not changed significantly since then. Consumers, however, have no way of knowing this from the update and may be left in doubt about FDA's views on recent research developments. Another problem with the update is that much of its discussion of health research is written in a technical manner that may be confusing to the general public. This issue is particularly important because CTIA has been using FDA's consumer update as part of its voluntary program that enables manufacturers of mobile phones to receive CTIA certification that their phones meet certain performance, safety, and labeling standards. CTIA officials estimate that 70 to 75 percent of the mobile phones currently sold in the United States are certified under this program. One of the requirements for CTIA certification is that manufacturers include the text of FDA's "Consumer Update on Mobile Phones" in the packaging of the phones. According to FDA, however, this document was not designed for mass distribution as an insert in mobile phone packaging. Rather, the information was for use in responding to inquiries received by FDA about the safety of mobile phones.

## FCC's Consumer Information Efforts Need Improvement

The consumers' primary source of information from FCC on radiofrequency exposure is its Office of Engineering and Technology's (OET) "RF Safety Program" Web page.[23] Among the documents found at this site is OET's "Questions and Answers About Biological Effects and Potential Hazards of Radiofrequency Electromagnetic Fields."[24] This is a well-written presentation of radiofrequency radiation and SAR measurement. However, because this document is long (over 30 pages) and technically detailed, it does not satisfy the need of general consumers for clear, concise information on this issue. Other OET documents on the mobile phone issue also do not meet this need. For example, OET's "Radiofrequency Energy: Frequently Asked Questions" responds to the question "Is it safe to use a cellular phone?" with technical details on industry guidelines for SAR levels that do not answer the question and would baffle most consumers.[25] OET officials said that the technical nature of radiofrequency exposure and testing makes it difficult to develop a concise, consumer-oriented document that does not oversimplify the issue.

This information shortcoming is particularly evident with regard to OET's recent initiative to provide the public with Internet access to its equipment authorization database. This database includes SAR testing results for mobile phones that have application receipt dates after April 15, 1998. Consumers can access the database by entering a phone's FCC identification number (usually found on a label on the phone's case) on the database's search screen. Some additional searching is needed to locate the document that has the phone's SAR number. For a recently authorized phone, the SAR number is on the one-page authorization grant for that phone. For an older phone, the consumer must examine a technical exhibit to locate the phone's SAR test results. Because the database was developed to support application processing, it does not include an explanation of what SAR numbers measure or what their

[23]OET's "RF Safety Program" Web page address is http://www.fcc.gov/oet/rfsafety/.

[24]OET Bulletin 56 (4th edition, Aug. 1999).

[25]This document includes the question: "*Is it safe to use a cellular phone*?" with this answer: "The ANSI/IEEE and NCRP RF safety guidelines recommend that low-power devices such as cellular hand-held phones not cause a localized exposure in excess of specific absorption rate (SAR) of 1.6W/kg. Studies of human head models using cellular phones have generally reported that the SAR levels are below 1.6W/kg level as averaged over 1 gram of tissue under normal conditions of use. However, some recent studies have reported higher peak levels under 'worst-case' conditions that suggest the need for further dosimetric studies."

significance is in relation to the health issue. Without a context for SAR numbers, consumers will have difficulty understanding what to make of the SAR information they find.

OET officials noted that information on SARs is provided on its "RF Safety Program" Web page, which also contains instructions on using the equipment authorization database. However, we found that this information does not provide adequate consumer-oriented information on radiofrequency exposure and SAR issues. In addition, consumers may access the database directly, without first accessing any other FCC material, because organizations outside of FCC are providing the database's Web address to consumers. For example, CTIA announced last summer that all new mobile phones receiving CTIA certification after August 1, 2000, would include labeling on the outside of the phone's box that includes both the phone's FCC identification number and the Internet address for the equipment authorization database.[26]

OET has been taking some actions to better respond to consumer inquiries on the mobile phone safety issue. In June 2000, OET added a staff member whose full-time job is to answer questions on radiofrequency safety issues that come in by letter, e-mail, or OET's public information telephone number (about 300 telephone inquiries a month). Currently, OET is revising its "Frequently Asked Questions" to include more and simpler information regarding the mobile phone safety issue. It is not yet clear how well this revision will meet the need for a consumer-friendly explanation of SAR measurements and radiofrequency exposure issues.

Another part of FCC, the Consumer Information Bureau, provides the public with information on many telecommunications topics, including mobile phones, through its Web page and toll-free consumer information telephone number. Here again, we found the lack of clear, consumer-oriented information on radiofrequency exposure and SAR measurement issues. For example, the Bureau's Web page for consumers contains a short brochure related to mobile phones entitled, *Market Sense: Cell Phones—Facts, Fiction, Frequency.* The brochure covers a variety of wireless service issues, but has only a couple of sentences on radiofrequency exposure. Specifically, it puts the statement "Cell Phones Cause Medical Problems" into the category of "fiction," noting that "[t]here

[26]These CTIA-certified phones will also include text material inside the boxes that provides each phone's SAR number and information on radiofrequency exposure issues.

is no scientific evidence that proves wireless phone usage can cause cancer, increased blood pressure, memory loss, or other health problems," though research is continuing. When they were asked to comment on it, OET officials shared our concern that this characterization could be misleading, because it implies that the health issue is settled. We also pointed out that the Bureau's Web page did not direct consumers to information resources on radiofrequency exposure issues found elsewhere on the FCC Web site, such as OET's documents. After we brought these issues to the attention of officials in the Consumer Information Bureau and OET, they began discussions to improve this situation. By the time we concluded our review, the Bureau had created Web links between its consumer Web page and OET's RF Safety Web page and began working with OET to revise the Market Sense brochure. Though these steps to improve coordination are in the right direction, there is still a need for a consumer-oriented FCC document that provides lay readers with clear, concise, and accurate information on radiofrequency exposure and SAR issues.

## Conclusions

Scientific research to date does not demonstrate that the radiofrequency energy emitted from mobile phones has adverse health effects, but the findings of some studies have raised questions indicating the need for further investigation. The U.S. government sponsors and supports some research efforts on mobile phone health issues, but wider research efforts are under way internationally. The World Health Organization has identified priorities for research on mobile phone health issues, and a variety of organizations in Europe, the United States, and elsewhere, have begun efforts to address these research needs. Given the long-term nature of much of the research being conducted—particularly the epidemiological and animal studies—it will likely be many more years before a definitive conclusion can be reached on whether mobile phone emissions pose any risk to human health.

While limited in scope, the cooperative research and development agreement between FDA and the mobile phone industry is among the research efforts being undertaken internationally that may help provide answers. Although the initiative is being funded solely by the industry, FDA's active role in setting the research agenda and providing scientific oversight should help alleviate concerns about the objectivity of industry-funded research. However, FDA has not yet decided the extent to which it will make public its recommendations to CTIA as to which specific research proposals should be funded. There is no way for the public to be

sure that CTIA is following FDA's recommendations unless these recommendations are publicly available in some form.

There still are no standardized procedures on how phones should be tested for compliance with FCC's 1996 radiofrequency exposure limit. This results in substantial variation in testing, complicating FCC's review of manufacturers' test results. This variation could be reduced with uniform testing procedures, though the test results will still include some unavoidable measurement uncertainties. Having only one specialist to oversee the review of manufacturers' SAR testing and operate FCC's in-house mobile phone test facility also creates a human capital problem for FCC. FCC recognizes that additional resources are needed in this area, but is having difficulty competing with the private sector for qualified individuals.[27]

Given the prominence of the mobile phone health issue, FDA and FCC need to provide the public with clear, accurate, and timely information so that they can make informed decisions. The information that FDA and FCC provides consumers on health and radiofrequency exposure issues is not always up to date or written for a general consumer audience. Given that industry is including information from FDA and FCC with most new phones, it is particularly important that these shortcomings be corrected.

## Recommendations for Executive Action

We recommend that the Chairman of the Federal Communications Commission take the following actions:

- Direct the Office of Engineering and Technology to issue revised guidance on SAR testing procedures to reduce variations in test results caused by a lack of standardized procedures. This guidance should be kept current as industry standards evolve.
- Direct the Office of Engineering and Technology to consult with FDA on the advisability of adopting FDA's method of incorporating measurement uncertainty in determining compliance with radiofrequency safety limits, and make the results of this communication publicly available.
- Direct the Consumer Information Bureau and the Office of Engineering and Technology to work together to develop clear, consistent, and easily

[27]FCC is not unique in this regard. See our discussion of federal human capital issues in *Major Management Challenges and Program Risks: A Governmentwide Perspective* (GAO-01-241, Jan. 2001). We have designated federal agencies' strategic human capital management as a high-risk area that needs urgent attention.

accessible consumer materials on mobile phone radiofrequency exposure issues. In particular, these offices should modify the product authorization database Web site so that it links consumers to clear, concise information on radiofrequency exposure issues and the meaning of SAR data.
- Direct the Office of Managing Director, as part of human capital planning, to develop a strategy for meeting the need for additional expertise in radiofrequency exposure and testing issues.

In addition, we recommend that the Administrator of the Food and Drug Administration direct the Center for Devices and Radiological Health to take the following actions:

- Publicly report on the extent to which CTIA is following FDA's recommendations in choosing and funding the specific research proposals conducted under the cooperative research and development agreement between FDA and CTIA.
- Develop a new consumer update document that provides a current overview of the status of health issues and research related to mobile phones. Because the industry trade association requires manufacturers to include the text of this document in the packaging of mobile phones that it certifies, the document should be written with a broad consumer audience in mind. Given the fast pace of developments on these issues, FDA should revise this document as significant research and policy events occur.

## Agency Comments

We provided a draft of this report to NIH, FDA, and FCC for review and comment. NIH recommended some technical changes, which we incorporated into the report where appropriate. FDA said that the report accurately summarizes the public health concerns relating to mobile phones, FDA's role in addressing these concerns, and the current state of the scientific knowledge. FDA provided us with some technical changes, which we incorporated into the report where appropriate. FDA also said our recommendations to them—regarding the CRADA and consumer information efforts—are consistent with FDA's plans and goals, and that it expects to implement them shortly.

FCC said that the report appropriately describes the roles of federal agencies regarding radiofrequency energy health issues. It emphasized that because FCC does not have primary jurisdiction or expertise in health and safety matters, it relies on the guidance of other federal agencies and on expert standard-setting organizations to set exposure limits. FCC also provided certain clarifications to our draft, which we incorporated where appropriate. It also described actions that are planned or underway to

address issues raised in our report, including those related to staffing, measurement uncertainty, and public information. FCC's written comments and our responses appear in appendix I.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report for 30 days after the date of this letter. At that time, we will send copies to interested congressional committees; Michael K. Powell, Chairman, Federal Communications Commission; Dr. Bernard A. Schwetz, Acting Principal Deputy Commissioner, Food and Drug Administration; Dr. Ruth Kirschstein, Acting Director, National Institutes of Health; Mitchell E. Daniels, Jr., Director, Office of Management and Budget; and other interested parties. We will also make copies available to others upon request. If you have any questions about this report, please call me at 202-512-2834. Key contacts and major contributors to this report are listed in appendix II.

Sincerely yours,

Peter Guerrero
Director, Physical Infrastructure Issues

# Appendix I: Comments From the Federal Communications Commission

FEDERAL COMMUNICATIONS COMMISSION
Washington, D. C. 20554

OFFICE OF
MANAGING DIRECTOR

April 12, 2001

Mr. Peter Guerrero
Director, Physical Infrastructure Issues
U.S. General Accounting Office
Washington, DC 20548

Dear Mr. Guerrero:

Thank you for providing the Federal Communications Commission with the opportunity to comment on your Report: *Telecommunications: Research and Regulatory Efforts on Mobile Phone Health Issues.*

The staff and I appreciate your informative and productive effort. We particularly appreciate the Report's suggestions regarding ways in which this agency can better serve the American public in providing pertinent information on this subject that is within our jurisdiction and expertise. We will take this opportunity to advise you of steps we have already taken and our plans for additional action, and to clarify a few of the points in the Report related to these efforts.

I first note that the Report contains appropriate descriptions of the roles of the various federal agencies regarding radiofrequency (RF) energy health issues. In particular, the Report accurately describes the expertise of this agency as technical assessment and measurement for the purposes of regulation of devices, and identifies the role of this agency as effectively implementing the safety measures determined appropriate by other agencies and organizations that are expert in the areas of health and biological effects of radiofrequency energy.

See comment 1.

Consistent with the Report's understanding of our role, I point out that certain remarks concerning the biological basis of the FCC's limits may require some clarification. The Report, in explaining the basis for the FCC's exposure limit (pp. 21-22), could be misinterpreted as implying that the FCC has come to its own conclusions regarding the adequacy of our exposure limits with respect to the incorporation of safety margins and the evaluation as to whether "non-thermal" biological effects are addressed by them. I reiterate, as the Report notes elsewhere, the FCC has neither primary jurisdiction nor expertise in health and safety matters. The determinations the Report refers to have been made, not by us, but by the expert standards-setting organizations which developed the recommendations upon which our exposure criteria are based and also by the various federal health and safety agencies consulted by the FCC in developing the exposure limits.

With regard to the important difficulty noted in the Report regarding the FCC's ability to develop an adequate number of RF exposure specialists, you note the recruitment efforts that the Office of Engineering and Technology (OET) has already made, and the recent retraining of its existing staff that it has undertaken. The Office of the Managing Director is now assisting OET in restructuring the RF exposure specialist position to attract a broader applicant pool and plans to promptly renew its recruitment effort with these changes. I also note that the Commission is undertaking a concerted effort to find creative ways to attract technical talent throughout the agency and to provide them a supportive environment in which to work. OET also plans to upgrade the facilities at its laboratory in Columbia, Maryland, to improve the tools available to staff to engage in their critical and challenging work.

The Report notes that there is presently some measurement uncertainty in mobile phone testing due to a lack of standardized testing procedures. As the Report recognizes, FCC staff has been working with the standards-setting body (the Institute of Electrical and Electronics Engineers) on this complex and multi-faceted topic for some time now. Another extensive meeting occurred during the second week of April. As a result, the staff expects standards for various measurement factors to be finalized soon. If it appears that conclusion cannot be reached promptly, the staff will act unilaterally to standardize all factors for which it can make definitive determinations and then notify industry by means of a Public Notice. In the meantime, OET staff evaluates each manufacturer's test procedure individually to determine the degree of measurement uncertainty it entails, and then uses that information in calculating whether each mobile phone's test adequately demonstrates that it meets the SAR (specific absorption rate) limits.

See comment 2.

The Report also points to an apparent difference in the way that the Food and Drug Administration (FDA) accounts for measurement uncertainty in its testing of microwave ovens as compared to this agency's application of mobile phone SAR limits. The Report recommends that we consult with the FDA and that we develop standardized testing procedures. OET staff already met with FDA experts on April 3, 2001. During that conference, our staff identified the methods used by FDA in applying its limits, and the reasons for its procedures. It discovered that the FDA's process for applying its measurement standard in sampling for compliance is essentially the same as ours. I caution that the description in the Report could be somewhat misinterpreted. FDA recommends that microwave oven manufacturers set their assembly line test limits at a threshold that is below the allowable measurement limit by the amount of their measurement uncertainty; this will provide the manufacturer a degree of certainty that all of its manufactured units will be able to pass if measured by the FDA. When the FDA conducts a post-production test, however, it will pass an oven that measures anywhere within the margin of error of the FDA's test equipment. This is the same as the OET's current practice in measuring EMC (electromagnetic compatibility), and is how OET anticipates it will conduct post-grant sampling of cell phones for SAR compliance. Our staff will continue to consult with FDA on this topic, however, until it is satisfied that it fully understands the safety and regulatory implications of each agency's testing procedures.

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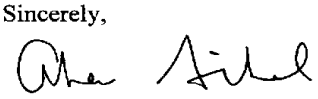
FCC staff has already modified the information on certain FCC web pages to make them more easily understood, as the Report recommends. OET and the FCC's Consumer Information Bureau (CIB) have modified the *Market Sense* brochure referred to in the Report, and have placed it on the web, and a new print version has been ordered. OET is finalizing new text in both a Fact Sheet and a set of Frequently Asked Questions, and these should be placed on the web within two weeks, by the time the Report is delivered to the Congressional requesters. CIB has also added additional links to the OET RF Safety web page, as has the FCC's Wireless Telecommunications Bureau. As GAO staff realizes, FCC staff shares your concern that consumers who access the SAR database do not have an understanding of the meaning of the data, or of other pertinent information regarding RF energy. Accordingly, access to the SAR database will continue to be provided only through the RF Safety web page, so that consumers will have an opportunity to see all of our information on RF before accessing the database. In addition, our staff has spoken with representatives of the Cellular Telecommunications Industry Association (CTIA) to ask them to encourage industry members to include the RF Safety web page URL, rather than the database URL, in their cell phone packages. CTIA staff has indicated that they will modify the web links on their own web pages and that CTIA members will modify the information provided on future cell phone packages and with cell phone literature to refer to the RF Safety web page, rather than directly to the SAR database. The staff will similarly bring this concern to the attention of other organizations and associations that serve as reference points for SAR information.

Finally, our staff regrets the misimpression it apparently gave GAO staff regarding the development of the information currently available on FCC web pages. While current OET staff would now opine, upon reflection, that the health effects discussion in the *Market Sense* brochure might have been inappropriately labeled, this did not mean to suggest that it was considered wrong at the time or that no one in OET had considered the language prior to its inclusion by CIB. In any event, OET and CIB have reviewed and clarified its content to ensure that the information on mobile phone RF exposure issues is accurate, clear, and current. CIB and OET continue to meet to coordinate and upgrade all information on the RF-related web pages maintained by each office, and are committed to reviewing those web pages to keep them current and accurate in the future.

Thank you again for the opportunity to provide further information and clarification in conjunction with this GAO Report. If you have any questions, please contact Dr. Robert Cleveland at 418-2422.

Sincerely,



Andrew S. Fishel
Managing Director

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## GAO Comments

1. We added text that further emphasizes that FCC is not a health and safety agency.

2. As we note in our report, FDA rules regarding microwave ovens state that manufacturers must take into account all of the measurement errors and uncertainty when demonstrating compliance with the radiofrequency energy performance standard for these devices. The issue we are raising is whether FCC should adopt a similar approach as part of its equipment authorization process for mobile phones. We have changed our report to emphasize that we are referring to differences in FDA's and FCC's approach to the uncertainties associated with manufacturers' own testing. We look forward to the outcome of FCC's continued consultations with FDA on this issue.

# Appendix II: GAO Contacts and Staff Acknowledgments

## GAO Contacts

Peter Guerrero (202) 512-2834
John P. Finedore (202) 512-2834

## Acknowledgments

In addition to those named above, Jason Bromberg, A. Don Cowan, Keith Cunningham, Gregory Ferrante, Janet Heinrich, and Mindi Weisenbloom made key contributions to this report.

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