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Still Waiting for the Call

Do Cellular Phones Cause Brain Tumors? Researchers' Inability To Provide an Answer So Far Is Only Raising More Questions

By Mike Mills

Washington Post Staff Writer

Sunday, April 6 1997; Page H01

The Washington Post

On Jan. 21, 1993, a shock wave hit the cellular telephone industry. Appearing live on "The Larry King Show," a Florida man named David Reynard told a nationwide audience that he was suing two cellular companies because, he said, his wife's pocket phone had caused the brain tumor that killed her.

The enormous media attention given to the suit caused cellular stocks to tumble on Wall Street, even though it was later dismissed because of insufficient evidence. The threat of litigation also sent the \$23 billion cellular industry scrambling to reassure the public that pocket phones weren't slowly baking the brains of millions of users around the world.

To ease public concerns, cellular equipment makers and carriers created the Scientific Advisory Group, which described itself as an "independent" research organization. The industry gave it \$25 million and five years to attempt to answer the crucial question: Do cellular phones cause brain cancer, brain tumors or any other harmful health effects?

But can such an industry-supported research effort truly be independent? And can it provide the kind of scientific evidence that will inform the public whether an increasingly widespread technology is indeed safe? Four years after the research effort began, those questions are being voiced by a growing number of scientists and industry analysts.

The industry-supported research group -- since renamed Wireless Technology Research LLC -- has spent \$17 million since 1993, but it is still far from finding any answers. The WTR says it hasn't completed any biomedical studies; instead, it has focused on collecting existing studies and researching how best to approach future research.

"They have not produced a lot of research for us to really evaluate," said

Elizabeth Jacobson, deputy director for devices and radiological health for the Food and Drug Administration, which has federal responsibility to monitor the group but has no real authority over it. "We would like to have seen results sooner."

Industry leaders said they also are frustrated by the slow pace of research.

"Clearly the industry is awaiting the results. And these results will, I hope, assuage concerns that have been raised," said John Marinho of Lucent Technologies Inc., one of the companies that has been steadily paying its dues to the group.

The head of the research group, George L. Carlo, said he has worked carefully during the past four years to build a foundation for definitive studies. "This is enormously important research," he said in an interview. "We're talking about the lives of millions of people and the livelihood of a major industry. This is not child's play."

Outside critics contend the industry has not played an entirely passive role as financier for Carlo's research agenda. They cite a leaked internal memo from Motorola Inc., which they say shows that the industry leader tried to coordinate strategy with the nominally independent research group. Motorola denies any attempt to interfere.

Through all of this, consumers worldwide have grown increasingly infatuated with wireless phones. There were 15 million people in the United States using cellphones in 1993. Today there are 45 million users, and the vast majority buy pocket phones, whose antennas are placed directly in the handset, next to the brain, rather than on a car roof. By 2002, half a billion people worldwide will be using wireless telephones, according to a District-based research firm, Strategis Group.

Mobilizing a PR Front

From the moment the Larry King episode was broadcast, the industry worked to defuse the public relations problem.

Motorola's head of cellular operations at the time, Edward Staiano, told reporters that "thousands" of studies showed there was no link between cellular phones and ill health effects. That was something of an overstatement: While studies on the health effects of radio waves were indeed common, the industry could not cite any studies in which cellular telephones specifically had been tested for their impact on human tissue or organs.

Within 10 days, Cellular Telecommunications Industry Association President Thomas Wheeler announced that a special "blue-ribbon" panel would be formed. Staffed by representatives from industry and government, it would oversee a newly invigorated research project.

In April 1993, the Scientific Advisory Group was born. One early plan was to have the effort overseen by the Food and Drug Administration and funded by industry. Instead, the industry opted to finance the research through the SAG, which would operate through a peer-review group run by the Harvard University Center for Risk Analysis.

"They thought about it and decided for their own reasons they didn't want to" have the FDA administer the program, Jacobson said. "We basically said, 'It's your money, you get to make the decision.' "

Wheeler hunted for someone to take charge of the program. He found Carlo, an epidemiologist who had previously worked as a consultant for the Chlorine Institute.

Research Challenge

The effort to determine whether cellular telephones cause cancer, brain tumors or any illness is enormously complicated. Light bulbs, overhead power lines and the sun each produce radio or electromagnetic waves that hit our bodies. Sunburns -- or, in the most extreme case, microwaved pork chops -- show what can happen when the power level, intensity and duration of those waves is increased.

To be on the safe side, U.S. standards-setters set a rate for the amount of energy from a cell phone they would allow to be absorbed by the top part of a human body: 1.6 watts per kilogram of upper body tissue. Cellular phones generally transmit below that level, depending on their proximity to the nearest radio tower. (The closer they are to a tower, the less power they radiate.) This standard was set 50 times below the level at which any adverse health effects had been found.

It would seem, judging purely by those numbers, that cellular phones are like light bulbs -- they deliver far too weak a signal to cause any harm. But the problem is that nobody knows for sure -- a situation that trial lawyers are quick to point out.

"Every time you dial and put that thing up to your ear, you're zapping your brain," contends Robert Holstein, an attorney who represents Deborah Wright, an Arizona cellular sales representative who contends that her frequent use of pocket phones caused her chronic brain tumors. "Look," he said. "You can't use them on airplanes. You can't use them in hospitals. If they can cause interference with huge mechanical devices guarded by walls, of course they have an effect on human cell material."

But scientists aren't as certain as tort lawyers. There are endless variables that researchers must consider when assessing cellular phone health effects. They don't know whether 10 one-minute phone calls equal one 10-minute phone call; whether jewelry or wire-rimmed glasses play a role in either deflecting or directing radio waves; or whether it makes a difference if the antenna is up or down. And the density and power level

of each call depends on a pocket phone's proximity to a cellular tower.

Add to that the myriad services and frequencies over which wireless phones operate, including traditional analog cellular phones and an array of new digital services. Then there are the satellite-based phone services coming soon, including the Motorola-funded Iridium project, in which signals will shoot from a pocket phone up to satellites hundreds of miles up in space.

Motorola executives say that decades of internal research have never produced any evidence that cellular telephones are harmful. They point to a 1993 study of death certificates of Motorola employees who died between 1985 and 1992, commissioned just after Reynard went on TV. The study found lower-than-average incidents of all causes of death, including all types of cancers. The company is continuing an aggressive research program, one that many observers say is more ambitious and productive than Carlo's industry-funded effort.

But that hasn't stopped the flow of post-Larry King lawsuits. There have been a dozen to date, six of which remain active.

Getting Ready to Research

Carlo's Wireless Technology Research group has, so far, offered little evidence that those plaintiffs are right or wrong. In fact, the group has spent most of the past four years preparing for research, rather than conducting it.

The first 18 months of the program, Carlo said, were spent creating the world's first comprehensive volume of known data on the subject.

Along the way, the group decided to pursue a related question of whether cellular phones affect the operation of pacemakers. The resulting \$2 million study led to a finding: People should keep wireless phones at least six inches from pacemakers.

The WTR also has developed a database of about 250,000 cellular users, from which future researchers can monitor health effects.

Carlos agreed that "the big-ticket items, the big studies, have yet to be done," but he vigorously defends the pace and scope of the WTR research agenda. All told, about \$17 million has been spent creating what Carlo calls a Rolls-Royce-quality program, one that is now ready to roll up its sleeves and get to work doing actual animal research.

But others contend that more should have been done by now.

"Here we are four years after the fact and not a single test tube has gotten wet yet," said Louis Slesin, editor of Micro Wave News in New York and a sharp critic of the industry's research efforts.

How Independent?

Slesin tweaked the industry earlier this year when he published, in full, a leaked internal Motorola memo dated Dec. 13, 1994.

In it, a Motorola public relations official laid out a media strategy to counter a new study by Henry Lai and Narendra Singh. The two well-regarded University of Washington researchers were about to report finding an increase in damage to DNA in the brain cells of rats after a single two-hour exposure to radio frequencies (at 2.45 gigahertz, where microwave ovens operate) at 1.2 watts per kilogram -- a level considered safe, according to current standards.

In the memo, Motorola spokesman Norman Sandler proposed a way to craft a "statement that puts a damper on speculation arising from this research, as best we can." At the end of the memo, Sandler writes that "I think we have sufficiently war-gamed the Lai-Singh issue, assuming SAG [Carlo's group] and CTIA [the industry trade group] have done their homework. We may want to run this by George Carlo and fill him in on the contacts we've made."

To critics, Motorola appeared to be planning a media campaign to debunk perhaps the most important -- and potentially damaging -- research to emerge in the field. The memo also implied that Motorola felt it should coordinate its media plans with Carlo, who in theory was supposed to be free of influence from the industry.

In an interview last week, Sandler denied that the industry was synchronizing its response with Carlo. He said Motorola merely wanted to "apprise" WTR of the issue, not coordinate with it or dictate to it. "Carlo needed to decide what they were going to do about the Lai-Singh research," he said.

Interviewed in his Seattle laboratory, Lai contended that CTIA, Motorola and Carlo's group had a coordinated agenda to suppress his research.

"It's very common, isn't it? They're just trying to protect their products. If any data that comes out harmful to them, it's a normal reaction," Lai said. He also said Carlo's group "attacked" his data in a panel discussion to which neither he nor Singh was invited.

Carlo defended WTR's treatment of the Lai-Singh study, saying that while the group is "taking it very seriously," the scientists had used techniques that were not commonly accepted.

"People over-interpreted their data," he said. Carlo called Lai a "good researcher" and said WTR agreed several months ago to fund a second proposal submitted by Lai and Singh.

The incident was not the only time questions have been raised about the industry's involvement in the WTR's research agenda.

The FDA's Jacobson admonished Wheeler, the head of the cellular trade group, in a July 1993 letter for making statements to reporters that she said displayed "an unwarranted confidence that these products will be found to be absolutely safe."

She said the public might "wonder how impartial the research can be when its stated goal is a determination to reassure consumers, and when the research sponsors predict in advance that "we expect the new research to reach the same conclusion, that cellular phones are safe."

Wheeler rejects Jacobson's concern: "I don't see how me opining that I don't think there is a [health] issue, and that consumers should be reassured, that it's something that can be translated into me directing WTR," he said.

Money Troubles

Sitting in the WTR boardroom in an old town house near Dupont Circle, Carlo described a new animal research method that, he hopes, may finally lead to some answers.

But this study hasn't yet begun, in part because of funding problems at Carlo's group.

The scientist who is developing this method, C.K. Chou, director of radiation research at City of Hope Medical Center in Duarte, Calif., said he hasn't received any money from Carlo in about four months.

"We can't even boil a pot of water," Chou said. "If this was government money, we trust the government; it has a track record. They sign an agreement and pay you. But when you're dealing with an industry, City of Hope has a policy: Pay first, then we work."

The money trouble began in January, when Wheeler withheld WTR's funding because of a dispute about whether the industry should have to pay \$700,000 in WTR legal bills. Carlo and other scientists had racked up these fees in defending themselves against personal-injury lawsuits such as the one highlighted on the Larry King show.

Given the lack of money, "we had no choice" but to stop progress on research, Carlo said. "We couldn't put scientists at risk. It made no sense for us to bear that cost."

Both men now say they have worked things out, and on Friday they issued new agreements that would give WTR steadier funding in its fifth, and probably final, year and give scientists protection from lawsuits.

@CAPTION: GEORGE L. CARLO

@CAPTION: From the "Safety" section of a manual for one of Motorola's cellular phones.

@CAPTION: GREATER FREQUENCY (This graphic was not available)

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FAX COVER SHEET

Date: July 15, 1997
To: Elizabeth Dry, Domestic Policy
Fax: (202) 456-7028
From: John Nghiem
Number of pages (including cover sheet): 7

Message:

Ms. Dry

I have enclosed the requested information
for your review.

CONFIDENTIALITY NOTICE: The information in this facsimile message is confidential and intended only for the individual or entity named in this transmittal sheet. If you have received this communication in error or if you do not receive all the pages of this communication, please notify us immediately by phone.



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July 15, 1997

Elizabeth Dry
Domestic Policy Staff
The White House

Dear Ms. Dry:

I have enclosed a copy of the letter from our company's CEO, David Nghiem, to Ms. Kagan and the Vice President. In its June/May Issue, *Microwave News*, an industry news letter, reported that the Senate Subcommittee on Communications, part of the Senate Commerce Committee, was to hold hearings on the safety of cellular telephone antennas and towers on May 13. However, those hearings were to be rescheduled due to conflicts with the Subcommittee's other work. I have also enclosed a copy of the article from the news letter.

I hope this information is helpful and look forward to your response.

Best regards,

Sincerely,

A handwritten signature in black ink, appearing to read "John Nghiem", with a stylized flourish at the end.

John Nghiem
Executive Vice President



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July 01, 1997

Vice President Albert Gore
c/o Elena Kagan
2nd Floor West Wing
The White House
Washington, D.C. 20054

Vice President Gore:

As Chief Executive of a telecommunications corporation, I have become deeply concerned about the potential health risks from exposure to cellular telephone antenna emissions. After attending the conference entitled "Cellular Phones: Is There A Health Risk?" in Washington, D.C. this past month, I have gained a better understanding of the urgent concern for an immediate solution to this uncertainty.

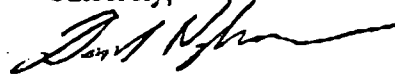
The general consensus among the scientific community, industry, and government agencies maintains that uncertainty exists as to whether there is a causal relationship between cellular telephone radiation and adverse health effects. The need for further research is evident as Wireless Technology Research, the World Health Organization, and the European Commission are investing millions of dollars to provide answers.

While it will take several years before the results become available, the prevention is essential in protecting the public from any potential health risks. With the advent of the Personal Communications System (PCS), which operates at frequencies close to the resonance frequency of water, cellular phones produce the highest levels of radio frequency exposure in the general population.

As a telecommunications equipment corporation, we strive to reach these goals of safety. However, we would like to seek general guidance from your office on this issue of public health. In general terms, would your office support efforts to provide solutions to this potential public health risk? And would you agree that an amount of uncertainty exists as to these health risks? As this matter concerns public health, we find that your input and consideration provides deep insight into these potential health risks.

I thank you for your time and consideration. As a father and scientist, I find this issue of public health of great personal importance. Again thank you and I look forward to your response.

Sincerely,

A handwritten signature in black ink, appearing to read "David Nghiem", with a long horizontal flourish extending to the right.

David Nghiem
President & CEO
USA Wireless, Inc.

MICRO WAVE NEWS

Vol. XVII No. 3

A Report on Non-Ionizing Radiation

May/June 1997

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Digital Mobile Phone Radiation Boosts Cancer Rate in Mice

Twice as many mice exposed to microwave radiation developed lymphoma as did controls, according to an Australian study sponsored by Telstra, formerly called Australian Telecom. The radiation was designed to mimic signals from GSM digital mobile telephones.

One hundred transgenic mice—which were bred to be especially susceptible to lymphomas—were exposed to 900 MHz pulsed radiation for two 30-minute periods per day for up to 18 months. At the end of the experiment, 43% of the exposed mice had lymphoma, as compared to 22% of the unexposed controls. The exposed mice also developed cancer more quickly.

In a paper published in the May issue of *Radiation Research*, Dr. Michael Repacholi and his coauthors call the increased incidence of lymphoma among the exposed mice "highly significant." They add that it is very unlikely that the faster onset of cancer was due to chance.

"I believe this is the first animal study showing a true nonthermal effect," Repacholi told *Microwave News*. "I am pushing for its replication and extension." Repacholi, the director of the International EMF Project at the World Health Organization (WHO) based in Geneva, Switzerland (see p. 8), is on leave from the Royal Adelaide Hospital in Adelaide, Australia.

"It's an interesting study. However, you can't draw any conclusions about
(continued on p. 10)

Views on the News

Secrecy vs. Public Health: Industry Must Not Set the Standard

Imagine this: A company marketing a new fat substitute sponsors a study on its safety. The researchers discover that when rats are fed the fat substitute, their cancer rate doubles. But this finding is kept secret for the next two years. The researcher who led the study even chairs a conference on the safety of fat substitutes, but does not mention his own results. He gives an advance report to the company that sponsored him (as required by contract), but the public and the government are kept in the dark for several more months. In the time between the end of the experiment and the public announcement of its results, sales of the fat substitute double.

Change "fat substitute" to "cellular phone," and you have the story of Dr. Michael Repacholi's recent study, sponsored by the Australian telecom giant Telstra.

Withholding important health data from the public is, to be blunt, unethical. This is as true for wireless phones as it is for food additives or medicines.

Of course, one study cannot be the basis for definitive judgments about human health. But we reach clear conclusions by gaining more information.

(continued on p. 19)

HIGHLIGHTS

« Wireless Notes »

Motorola is getting tough with makers of cellular phone shields. The company's attorneys have threatened to sue Microshield Industries, based in Luton, U.K., over statements in its product literature that Motorola calls "patently false," "deceptive" and "grossly misleading." Microshield makes a cover for mobile telephones that is designed to reduce users' exposure to radiation. In a February 28 letter, Motorola attorney Christine Peterson warned Microshield that its marketing brochure constituted false advertising under U.S. law. Peterson objected to the brochure's suggestions that RF energy from cellular phones heats the user's brain and eye tissue, and that scientific research had linked mobile phone use to various illnesses. She also asserted that the shield does not reduce RF exposure by more than 90%, as advertised, but in fact may increase exposure. Motorola demanded that Microshield stop distributing "any materials or claims that state or imply" that cellular phones are unsafe. If not, Peterson warned, Motorola would "consider more formal action." In its March 14 response, Microshield promised to stop distributing its product literature in the U.S. and to stop selling the shield to U.S. consumers on its Web site.

« « » »

Digital mobile phones are more likely to cause headaches than are analog phones. Dr. Bruce Hocking reported at the *Annual Scientific Meeting of the Royal Australasian College of Physicians*, held in Auckland, New Zealand, in May. Of 40 adults who described "unpleasant symptoms" after using digital or analog phones, he found that 30 had used digital units. Hocking, an occupational health consultant in Melbourne, Australia, who was formerly the chief medical officer of Telstra, the Australian telephone giant, has been tracking down such cases over the last two years (see *MWN*, N/D95). "The symptoms often began minutes after beginning a call but could come on later during the day...sometimes ceased within an hour after the call but could last till evening...did not occur when using a handset and were different from ordinary headaches. There were several reports suggestive of intracranial effects," Hocking stated. A large study of phone users and headaches is ongoing in Norway and Sweden (see *MWN*, N/D96 and M/A97).

« « » »

Dr. Bill Guy has resigned from Wireless Technology Research (WTR). One of the three members of WTR since its founding (see *MWN*, S/O93 and S/O94), Guy told *Microwave News* in early May that he had resigned, at least in part, because, "I was not in a position to make decisions." He will continue to do some work for WTR on a consulting basis until the end of 1997, collaborating with Dr. C.K. Chou of the City of Hope National Medical Center in Duarte, CA, to complete the design of an exposure system for biological experiments (see *MWN*, M/J95). There have also been top-level changes at the Cellular Telecommunications Industry Association (CTIA), where Ron Nessen, vice president for communications and public affairs, has been replaced by Margaret Tutwiler. Nessen had served as press secretary for

President Ford, while Tutwiler was the official spokesperson for the State Department under President Bush. Nessen said in an interview that he had resigned to host a nightly show on Nostalgia Television, a cable channel. Nessen is known among the press for his confrontational style. For example, in 1994 Nessen tried to suppress a UCLA press release on cellular phone dosimetry research by Michael Jensen and Dr. Yahya Rahmat-Samii (see *MWN*, J/F95), prompting this protest to the CTIA in a letter from William Andrews, the public information officer at UCLA's School of Engineering: "His phone manner was a one-way locomotive—him yelling, me constantly telling him to calm down....I put him on hold for a 30-second count, came back on and he was in mid-sentence, still yelling, and unaware I had been off-line. After he twice called me an 'asshole,' I hung up." Andrews also complained that Nessen had threatened to call "many people in the Pentagon," with the intent of "interfering with relationships between faculty and their funding agencies." Nessen's tactics were successful: UCLA withdrew the press release at the request of faculty who had received phone calls from their Department of Defense research program managers. Asked whether the CTIA had been dissatisfied with Nessen's general approach to press relations, CTIA spokesperson Tim Ayers said, "Not at all. I think Ron is appropriately celebrated for his aggressive defense of the industry."

« « » »

As WTR secured coverage for its legal costs and potential liability (see p.9), it was on a winning streak in the courtroom. On May 7, WTR, the CTIA and Ron Nessen were all dismissed as defendants in *Wright v. Motorola*, which is being heard in Illinois state court. Debra Wright's suit charges that use of Motorola cellular phones caused her to develop a brain tumor (see *MWN*, M/A95). The defendants dismissed from the case had been accused of conspiring with Motorola to falsely portray cellular phones as safe. WTR's chair, Dr. George Carlo, had been removed from the case at the end of January. "We'll appeal everything," said Wright's lawyer, Robert Holstein, who is based in Chicago. "We're dedicated to keeping this case going." James Baller, WTR's attorney in Washington, seemed unconcerned. "WTR is pleased with the result," he told *Microwave News*, "and believes it should never have been brought into the litigation in the first place." On April 24, Carlo was dismissed as a defendant in the lawsuit filed by Jerald Busse, which charges that WTR epidemiology studies amount to unauthorized human testing (see *MWN*, J/F96). Baller successfully argued that the Illinois court had no jurisdiction because Carlo neither resided in nor did business in the state. WTR itself and the CTIA remain defendants in the case.

« « » »

A few days before Senator John McCain (R-AZ) was to hold a hearing on the siting of cellular phone and PCS towers, it was abruptly canceled. Cathy Bergman, president of the EMR Alliance in New York City, credits citizen activists and local officials for delaying the May 13 hearing. "McCain's refusal to allow the

public to testify led to a flood of phone calls, faxes, E-mail messages and FedEx packages to his office," she told *Microwave News*. "An embarrassed McCain was forced to rethink the witness list, which reflected only industry views." A spokesperson for the senator denied that public outcry was the reason, saying that the hearing was being put off due to "scheduling conflicts." At press time, a new date had not yet been set.

« « » »

Sometimes a lone activist can cause headaches for a multibillion dollar industry. Last year EPA Administrator **Carol Browner** backed the FCC's new RF/MW exposure standard as providing "adequate protection of public health" (see also *MWN*, M/A96 and J/A96). The limits were stricter than industry would have liked, but it reportedly went along—with the understanding that the EPA would not criticize the new rules. The trade paper *RCR* reported that, "As part of the deal with the FCC, the wireless industry supposedly was assured that EPA would remain in the background on RF safety issues." Signed, sealed and delivered—until October, when **David Fichtenberg** of Olympia, WA, wrote the EPA to ask if the FCC standard gave protection against nonthermal effects. **Norbert Hankin** of the EPA's Office of Radiation and Indoor Air responded that there was not enough data

on nonthermal effects to set specific limits. But, citing EPA policy, he added, "Both the NCRP and ANSI/IEEE standards [the FCC standard is based on both] are thermally based, and do not apply to chronic, nonthermal exposure situations. The statement referring to 'adequate protection' pertains to thermally related effects." Hankin's letter produced strong thermal effects within the wireless industry—company representatives got boiling mad. After a meeting with the EPA, the **Electromagnetic Energy Association (EEA)** was still unhappy; EEA chair **John Welch** of Motorola wrote to the agency to complain about continuing "confusion about EPA's official position." Welch demanded another public statement from the EPA in support of the FCC. On January 17, he got it: Assistant Administrator **Mary Nichols** wrote to the FCC "to reiterate EPA's support" for the FCC exposure rules and repeated Browner's wording. But rather than disavow Hankin's letter on nonthermal effects, she said it had been "incorrectly construed." In May, EEA executive director **Dinah McElfresh** told *Microwave News* that Nichols's letter "clarifies EPA's position," and asserted that "the FCC standard protects against all effects, based on the science known today." But Fichtenberg countered, "Many papers accepted for standard-setting by the IEEE show adverse effects below the FCC's hazard threshold. Prudence requires limits based on these observed effects."

Congressman Markey on Wireless Safety: Answers Needed, but Not with Federal Funds

Rep. **Edward Markey** (D-MA) wants to know whether cellular phones are safe but is unwilling to commit federal funds to the task. "We need to find the best ways to prioritize current research and accelerate getting answers to the public," Markey's legislative assistant, **Colin Crowell**, told *Microwave News*. "Then we can identify where gaps may exist. But we are not yet prepared to say that we need to spend millions of federal dollars."

In an April 7 letter, Markey asked the Food and Drug Administration (FDA) what the government has been doing to determine whether cellular phones pose a health risk. Markey also asked whether the research being done by **Wireless Technology Research (WTR)**, which is funded by the Cellular Telecommunications Industry Association, would settle the safety question.

"The type of research proposed by WTR should provide part of the answer," stated **Diane Thompson**, FDA associate commissioner for legislative affairs, in a May 5 response. Thompson added that the FDA has "no information which would lead us to believe that the federal government and American consumers will not be able to rely on the results of the WTR research."

Thompson noted that there is "no federal government-sponsored research specifically directed toward cellular phone safety," though she pointed to related work sponsored by the Environmental Protection Agency, the Department of Defense and other agencies.

Thompson also described FDA efforts to monitor research

sponsored by industry, including a March 13 letter the agency sent to Dr. **George Carlo**, chair of WTR (see *MWN*, M/A97). In that letter, the FDA recommended that the WTR research give the "highest priority" to lifetime animal exposure studies and stressed the need for replication of studies showing biological effects, such as the **Lai-Singh** experiments (see *MWN*, N/D94).

In a May 6 statement, Markey declared that, "The government has a responsibility to assess for consumers whether portable wireless phones pose a health risk," and that he would "follow up with the appropriate federal agencies and the cellular industry." Crowell said that a second letter with additional questions would soon be sent to the FDA.

The Markey letter concluded by asking when answers to cellular phone safety questions could be expected. The FDA's Thompson responded that, "It is difficult to predict when conclusive statements about health risks can be made."

Markey's renewed interest came in the wake of a detailed article in the April 6 *Washington Post* on the slow pace of industry-funded research (see p. 14). The *Post* article followed stories in the trade publication *RCR* and in *Microwave News*.

In February 1993, Markey held a congressional briefing on cellular phone safety after the **Reynard** brain cancer suit put the issue on the front pages of newspapers around the world (see *MWN*, J/F93). He also asked for a report from the General Accounting Office, which was released in 1994 (see *MWN*, N/D94).

**For Immediate Release:
April 30, 1997**



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**NEWS ADVISORY:
AUSTRALIAN STUDY OF
TUMOR PROMOTION IN MICE**

WASHINGTON, DC--This week, an article is being published in *The Journal of Radiation Research* regarding an Australian study which exposed genetically-engineered mice to wireless phone-like radio signals. In response to questions, Thomas E. Wheeler, president and CEO of the Cellular Telecommunications Industry Association (CTIA) has stated:

"The Australian researchers have cautioned that their findings cannot be extrapolated to humans. The Australian government, citing the researchers' comments, has warned against 'unfounded alarm.' One of the researchers told the Australian press, 'For the time being at least I see no scientific reason to stop using my mobile phone.'

"The Australian research is one data point. This particular data point appears to conflict with other research showing no promotion effect as well as with epidemiological studies which show no difference in mortality rates between those who use a portable phone against their head and those whose phone is mounted in their car with the antenna far away.

"There is a worldwide research program now underway on the relationship of radio frequency energy and cancer. In the United States, the federal government (i.e. EPA, FDA, and FCC) recently completed a re-evaluation of the existing safety standards for RF exposure. The wireless industry is required to meet all the federal safety standards."

Following are some significant points about the study:

- The research was funded by Telstra, the Australian wireless carrier.
- This experimental protocol uses genetically engineered mice--mice that have been injected with a cancer causing gene. In this protocol, all the mice are engineered to have a substantially higher than normal cancer rate and the study looks at the ability of radio waves to further increase the incidence of tumors. In the study, a significant increase in the increase of tumors was observed. It is not a study to see if radio waves causes cancer.
- The investigators emphasized that the design of the study was experimental and the findings cannot be related to human health or to the safety of wireless phones.

Asked what the findings meant for mobile phone users, one of the principal researchers, Professor Tony Basten, said: "Mice and humans absorb energy from RF (radio-frequency) fields differently, so one cannot conclude from this single study that humans have an increased risk of cancer from the use of mobile phones. More research needs to be done."

- The whole-body exposure of the mice was not fixed, ranging from Specific Absorption Rate of .01 Watts per kilogram to 4.2 W/kg. Because of this, it is difficult to determine the exact exposure that caused the effect. The mice were exposed to quarter wave GSM antennas for whole body exposure at the "far field."
- The mice were exposed to radio waves that were more than 1,000 times higher than average exposure to people in the service area covered by a typical cell site.
- In regard to the applicability of drawing conclusions about radio-frequency emissions and the use of hand-held phones, it should be noted that the study examined whole body radiation, not localized radiation that would result from the use of a wireless phone.
- A similar study regarding tumor promotion in rats was announced last June. That study found no tumor promotion. The study, by Dr. Ross Adey of the Loma Linda Medical Center and others, was presented at a meeting of the Bioelectromagnetic Society.
- Last May, an epidemiological study was published in *The Journal of Epidemiology* that reported no increase in mortality rates among humans using hand-held wireless phones in comparison to those who used phones that had a separate car phone antenna. The mortality rate observed in the study was slightly lower than observed in the general population. In other words, the effect of proximity to radio waves showed no increase in mortality rates. The study was conducted by Kenneth J. Rothman of Epidemiology Resources, Inc., and others.
- The results of no single study can be conclusive. A basic tenet of scientific research is the reproducibility of experimental results. Future research will need to validate these results in order to assure their reliability.
- In the United States, the wireless industry is funding an independent scientific group, Wireless Technology Research, LLC, in a \$25 million research program, now in its fourth year. The World Health Organization and European Union also will be carrying out research. U.S. government agencies monitor this research and establish standards based on the best scientific findings. The United States recently went through a re-evaluation of its standards for both phones and antennas. All wireless phone providers are required to meet these standards.

CTIA is the international association for the wireless telecommunication industry. It represents more PCS and cellular carriers than any other association in the world.

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FOR ADDITIONAL INFORMATION CONTACT: Tim Ayers (202) 736-3203.

INTERNET USERS: News about the wireless telecommunications industry is updated several times each day on CTIA's World Wide Web site (<http://www.wow-com.com>). CTIA news releases and other information also are available on WOW-COM.

TRANSGENIC MOUSE STUDY

Q1: What does this say about the safety of mobile phones?

A1: In a word, nothing. That's not our position, but the position of the scientists who did this study. Their clear position is that it can't be directly related to human health. And that means it definitely can't be related to the safety of mobile phones.

Q2: But weren't these animals exposed to mobile phone signals?

A2: The animals were exposed to a type of radio signal common to some digital phone systems. However, the conditions and levels of exposure were quite different from the use of those phones.

Q3: How so?

A3: In short, the animals were in cages at a certain distance from an antenna operating at higher power than mobile phones. They were exposed in a way and at levels unlike those of mobile phones. In fact, in humans, whole body exposures of this kind would be in excess of recognized safety standards.

Q4: You seem to be dismissing this study as completely irrelevant?

A4: Not at all. As the researchers have said, it raises some interesting questions. Those questions involve the use of a certain genetically engineered mouse in research of this kind. That warrants further independent, focused investigation. But as the researchers say, their findings cannot and should not be interpreted as bearing on human health or the safety of cellular phones.

Q5: You say this raises "interesting questions." What do you mean?

A5: Well, there seems to be general agreement that issues about the kind of mouse used, the exposure conditions and other factors need further investigation to more fully assess the significance of this study.

Q6: But in the meantime, that's not a cause for concern by cellular phone users?

A6: Not at all. The researchers themselves have said their findings cannot be directly related to human health. In fact, they stated that no single study can yield qualified judgments about human health risks. The scientific community understands that, government and international health authorities understand that, and the public should understand that.

Q7: What's going to be done to follow up on this research?

A7: That remains to be seen, but the Australian government is in the process of developing priorities for its own research program in this area and I suspect this latest study may be a subject for consideration in those deliberations.

Q8: What do you say to those who contend there has been far too little research to conclude the safety of cellular phones?

A8: I say they're wrong. The safety of cellular phones is supported by a broad and expanding body of scientific knowledge. Anyone claiming evidence of risk in this latest study ignores the fact that it was done with a highly experimental model and produced results contrary to other animal studies. Research continues and more will be done. We anticipate it will provide further support for the safety of cellular phones.



THE CENTENARY INSTITUTE OF CANCER MEDICINE & CELL BIOLOGY

NEWS RELEASE
MONDAY 28 APRIL 1997

AUSTRALIAN STUDY HIGHLIGHTS NEED FOR FURTHER RESEARCH INTO MOBILE 'PHONE CANCER RISKS

An Australian study has found an increased incidence of lymphoma in mice after prolonged exposure to the type of radiofrequency (RF) electromagnetic fields emitted by digital mobile telephones.

Published in the latest issue of the prestigious American scientific journal *Radiation Research*, the study is the first of its kind to appear in international scientific literature.

The study was conducted with mice carrying a cancer-causing gene which made them prone to develop lymphomas and found that exposure to RF electromagnetic fields increased the incidence of these tumours from a spontaneous rate of 22% to 43% over a period of 18 months.

Funded by the Telstra Corporation, the study was initiated by Australian biophysicist Dr Michael Repacholi and supervised by a group of scientists consisting of Professor Tony Basten, Executive Director of the Centenary Institute of Cancer Medicine and Cell Biology in Sydney, Dr Alan Harris, a cancer biologist from the Walter and Eliza Hall Institute of Medical Research in Melbourne, Mr Val Gebiski, a statistician from the National Health & Medical Research Council's (NHMRC) Clinical Trials Centre in Sydney and Dr Michael Repacholi. The study's design was approved by the National Health and Medical Research Council.

Chairman of the supervising research committee, Professor Tony Basten, says the key issue arising from the study is determining what the results mean for the millions of digital mobile telephone users within Australia and around the world.

"In our opinion the findings are valid for this genetically-engineered mouse model, but they must be put in context," Professor Basten said.

"Mice and humans absorb energy from these fields differently so we cannot conclude from this single study that humans have an increased risk of cancer from the use of digital mobile phones.

"More focused research needs to be done to resolve that issue."

continued on page 2...

According to Dr Alan Harris, the study has provided a useful assay for studying the interactions between RF fields and biological systems.

"This is important," he said, "because at present there is no convincing evidence that RF fields, in contrast to X, gamma, atomic or ultraviolet radiation, can directly cause the changes in genes responsible for cancer development.

"In fact, on this basis our results are unexpected."

According to Dr Harris, further studies are necessary.

"The first priority should be to get independent confirmation of our results and to test the effects of varying exposure doses. The second would be to test whether similar results can be obtained in experimental models involving other kinds of cancer," Dr Harris said.

According to Dr Repacholi, now in Geneva as manager of the World Health Organisation's (WHO) International Electromagnetic Fields Project, WHO has already noted the lack of good animal studies when planning its future research program on the health effects of low-level exposure to RF fields.

"WHO urgently needs more studies such as this in order to better assess any health risks," Dr Repacholi said.

"Such research might also be an appropriate target for support by the Australian Government, which recently established a \$4.5 million fund to encourage research on low-frequency electromagnetic fields."

Professor Basten believes that the study is a major contribution to research on low-frequency electromagnetic fields.

"With the rapid expansion in the use of mobile telecommunications, a reliable assay for the biological effects of RF field exposure is required to establish the basis for a rational assessment of safety standards," he said.

"For the time being, at least, I see no scientific reason to stop using my own mobile phone," he concluded.

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MEDIA RELEASE

Committee on Electromagnetic Energy Public Health Issues comment on mouse research

The Committee on Electromagnetic Energy Public Health Issues welcomes recent research results published in the journal Radiation Research as adding to the available scientific information on exposure to low level electromagnetic energy (EME).

While the Committee is yet to look at the study in detail, it is concerned that the results are considered in their scientific context and do not cause any unnecessary public alarm.

Exposures were modelled on use of mobile phone handsets, not general public exposure from mobile phone towers, and the study used mice predisposed to develop cancer.

The study's authors have indicated that we cannot conclude from this single study that humans have an increased risk of cancer from the use of mobile phones.

The study needs to be independently replicated to confirm the results. Further testing is also needed to establish if there is a 'dose-response effect', or direct link between EME exposure and any cancer growth.

These may be the sorts of tests funded through the Commonwealth's \$4.5 million Radiofrequency Electromagnetic Energy Program.

As part of that program, the Committee recently invited public comment on its Australian research priorities paper, which will soon be provided to the National Health and Medical Research Council (NHMRC).

The NHMRC will then invite research proposals and make decisions on funding based on the identified priorities. The significance of this latest research will be assessed in this process.

The Radiofrequency Electromagnetic Energy Program is coordinated by the Committee on Electromagnetic Energy Public Health Issues. The committee includes representatives from the Department of Communications and the Arts, the Department of Health and Family Services, the Australian Radiation Laboratory, the Spectrum Management Agency, the Therapeutic Goods Administration, AUSTEL and the CSIRO.

There will be no further comment from the Committee until it has considered the report fully.

28 April 1997

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AUSTRALIAN
MOBILE TELECOMMUNICATIONS
ASSOCIATION
ACH 065 814 315

Media Release

Mobile phones are safe says industry

The public can continue to use mobile phones with confidence in their safety, Australian Mobile Telecommunications Association (AMTA) Executive Director, Peter Russell said today. He made the comment in response to the release of an Australian study which involved special genetically engineered mice never before used in radio frequency research.

"Put simply, mobile phone users are not genetically engineered mice. More importantly, this study is no reason for the public to be in any way concerned about the safety of mobile phones. Because the study used genetically engineered mice which had cancer-causing mutation not known in humans, and because the biology and energy absorption of a mouse are quite different than humans, the findings cannot be used to support any conclusions about possible human health effects," he said.

"This research does not provide a substantive basis for judgments about possible human health risk or the safety of mobile phones. The research requires further independent validation because of the use of genetically engineered mice and the way in which the mice were exposed," he said.

"The researchers themselves have made it clear that we should not conclude from this single study that humans have an increased risk of cancer from the use of mobile phones," he said.

A gene that causes lymphoma (a tumor of the lymphoid tissue) was artificially inserted into fertilized mouse eggs, and the mice reared from these eggs were engineered to spontaneously develop lymphomas. This gene is not known to occur in humans and the biology and energy absorption of a mouse are quite different than humans.

"The use of genetically engineered mice which were bred to spontaneously contract cancer, and particularly the mouse strain used in this study, is not accepted by health authorities as a valid experimental model. Therefore the results of such studies must be treated with caution," he said.

"Anyone reading more into this study, other than more focused independent validation is needed, is scaremongering and will undermine public confidence in a product that is of great benefit in business and in the personal lives of millions of Australians," he said.



The results of the study vary considerably with other international studies, which show no evidence of tumor promotion in rats. Therefore, the Australian telecommunications industry supports further independent validation of this research which is more rigorous and relevant to mobile phone use, he said.

AMTA are sensitive to the questions and concerns that have been raised by the media and the community and AMTA members will continue to support efforts to expand the already substantial body of scientific knowledge on the possible health effects of electromagnetic emissions. In the meantime, the public can be confident that mobile phones comply with safety standards set by national and international bodies.

However, we anticipate that additional research will continue to strengthen the consensus of scientific opinion that using mobile phones do not cause adverse health effects, he said.

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28 April 1997

144/97

TELSTRA SUPPORTS INDEPENDENT MOBILE PHONE SAFETY RESEARCH

Telstra has funded independent research by leading Australian researchers into possible health effects from digital mobile phone handset radio signals.

Dr Hugh Bradlow, Director of Telstra Research Laboratories, said that Telstra supported the open research by some of Australia's most respected specialists in response to safety concerns raised by its customers, staff and the community.

The study, published in the May 1997 edition of the journal *Radiation Research*, used mice genetically engineered with a natural tendency to develop lymphoma (a cancer of the immune system) and exposed for most of their lives to simulated digital mobile phone handset signals.

While the study reports an increased rate of lymphoma among the exposed mice, the authors have advised that these initial results do not constitute a scientific reason for digital mobile phone users to change their phone use. The authors also point out that more research is necessary as mice and humans absorb radio signals in different ways.

"Telstra welcomes the recommendations of the research committee that further investigations be funded to independently extend the study as it is necessary to understand if the result has significance for human health," Dr Bradlow said. "The study could be considered by the Federal Government as part of its current \$4.5 million research and public information program."

Dr Bradlow added that we live with electromagnetic energy as part of our everyday life. "It comes from natural sources such as the sun and the Earth and from man-made sources such as remote controlled model aeroplanes, baby-monitoring devices and AM radio broadcasts," he said.

"And Telstra relies on the advice of leading medical specialists and the World Health Organisation regarding the safety of radio-based services.

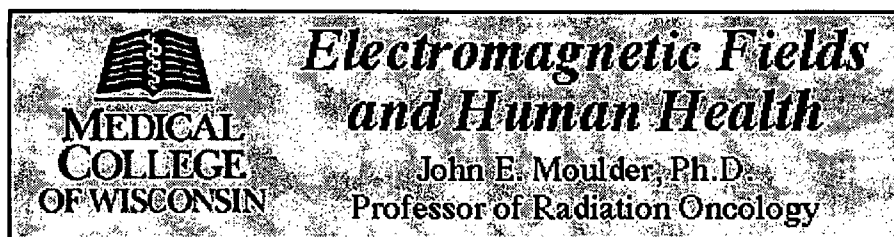
"Australian mobile phone users should be aware that all mobile handsets sold in Australia must comply with AUSTEL safety standards. In addition, more than 6,000 worldwide reports and a 40 year body of research have shown no substantiated scientific evidence of radio signals, which comply with the Australian Standard AS2772.1, adversely affecting human health.

"Importantly, the study can't be applied to digital base stations because the mice were exposed to signals between 100 and more than 46,000 times higher than the maximum base station transmissions at ground level."

Telstra has an extensive program examining radio frequency safety at its internationally respected Research Laboratories and supports the Federal Government's \$4.5 million research and public information program

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Cellular Phone Antennas and Human Health

Version: 1.7.1

Last-modified: 30-Apr-97

Maintainer: jmoulder@its.mcw.edu

- This FAQ addresses the issue of whether cellular (and PCS) phone base station antennas are a risk to human health.
- Issues surrounding the phones themselves are not directly addressed.
- Some aspects of the FAQ are also relevant to other types of broadcast antennas.
- Specific technical and regulatory sections have a strong US bias, but the basic engineering and biology are relevant to any country
- There are two related FAQs:
 - Powerlines and Cancer FAQs
(<http://www.mcw.edu/gcrc/cop/powerlines-cancer-FAQ/toc.html>)
 - Static Electromagnetic Fields and Cancer FAQs
(<http://www.mcw.edu/gcrc/cop/static-fields-cancer-FAQ/toc.html>)
- This FAQ was designed for Netscape v3; if you encounter problems with other browsers, please notify jmoulder@its.mcw.edu about the problem.

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per day for up to 18 months to plane wave fields of 900 MHz with a pulse repetition frequency of 217 Hz and a pulse width of 0.6 ms. Incident power densities were 2.6-13 W/m-sq [0.26-1.3 mW/cm-sq] and [average SAR was] 0.13-1.4 W/kg. Lymphoma risk was found to be significantly higher in the exposed mice than in the controls (OR=2.4, p=0.006, 95% CI=1.3-4.5)... Thus long-term intermittent exposure to RF fields can enhance the probability that mice carrying a lymphomagenic oncogene will develop lymphomas".

39. Quotes from the discussion in Repacholi et al [37]: ~~NEW~~

"A number of previous attempts to discern effects of RF exposure on lymphoid cells in vitro have been documented... [the literature] does not seem to offer a mechanism by which RF field exposure... could increase the incidence of lymphoid malignancy"

"While the increase in the incidence of lymphoma found here was highly significant statistically, and the exposure conditions were designed to mimic the fields generated by a digital mobile telephone, the implications of the study for risk of carcinogenesis in humans are unclear. It is difficult to extrapolate directly from mice to humans due to differences in their absorption of energy from RF fields."

"It seems important in light of the present results to determine the relationship between exposure dose and lymphoma incidence"

"We would not interpret these studies as indicating that RF-field exposure would be specifically lymphomagenic in normal animals."

"That is not imply that any humans at all are necessarily at increased risk of cancer as a consequence of exposure to RF fields. No single experiment on animals can allow such a conclusion."

40. Further technical notes concerning Repacholi et al [37]: ~~NEW~~

- Mice used in these studies are transgenic animals that are born with an activated oncogene that predisposes them to develop lymphoma. By the age of 10 months 5-10% of these mice develop lymphomas, and by 18 months (quite old for a mouse) about 15% develop lymphomas. The incidence of lymphoma in normal mice is very much lower.
- The data analysis was blinded; that is, the experimenters determining which animals developed lymphoma did not know which animals had been exposed and which had not. The exposures themselves were not completely blinded; during the course of the experiments the investigators knew which mice were being exposed and which were not, but the people caring for the animals did not.
- Mice were exposed in the far-field. The 900 MHz field was pulse modulated at 217 Hz.
- The RF field was not uniform in the exposure room, and the animals were allowed to move freely in their cages during the exposure. As a result, the actual exposure levels of the animals are not known. All that is known is that the SAR range was 0.007 to 4.3 W/kg and that the average SAR for the mice was 0.14 to 1.4 W/kg.
- The ANSE/IEEE standard for exposure of the general public to RF is based on keeping exposures below 0.08 W/kg. The ANSE/IEEE standard for occupational exposure to RF is based on keeping exposures below 0.4 W/kg. The SAR level in publicly-accessible locations near cellular phone of PCS base stations is in the 0.0005-0.005 W/kg range[16]. Thus the exposure levels used in this mouse study are well above those to which people are actually exposed.
- The SAR levels, even at their extreme, do not appear high enough to cause thermal stress, and the authors report no evidence of thermal stress.
- Because the animals used in the study are genetically predisposed to lymphoma it is difficult to decide whether this should be viewed as a test for genotoxic activity or a test for epigenetic activity (see the [powerline-cancer FAQ](#) for a discussion of the distinction).

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21. These effects have included changes in the electrical activity of the brain, changes in enzyme activity, and changes in calcium ion transport across membranes [1, 5, 6, 7 and 14].
22. RA Tell and RF Cleveland: An Investigation of Radiofrequency Fields Near Base-Station Antennas Used for Cellular Radio. BEMS, Victoria, June 1996.
23. W Irnich, L Batz et al: Interference of Pacemakers by Mobile Phones. BEMS, Victoria, June 1996.
24. WR Adey, CV Byus et al: Brain Tumor Incidence in Rats Chronically Exposed to Digital Cellular Telephone Fields in an Initiation-Promotion Model. BEMS, Victoria, June 1996.
25. RS Malyapa, EW Ahern et al: Measurement of DNA Damage by the Alkaline Comet Assay after in vitro Exposure to 835 MHz Electromagnetic Radiation. BEMS, Victoria, June 1996.
26. R Fitzner, E Langer et al: Long-Term Influence of High Frequency Electromagnetic Fields on Growth Behavior of HL60 Cells to Investigate Cancer Promoting Effects. BEMS, Victoria, June 1996.
27. MP Dooley, BL Cobb et al: Development of Rat Embryos Exposed to an Ultrawideband Electromagnetic Field. BEMS, Victoria, June 1996.
28. B Hocking, IR Gordon et al: Cancer incidence and mortality and proximity to TV towers. Med J Austral 165:601-605, 1996.
29. JR Goldsmith: Epidemiologic evidence of radiofrequency (microwave) effects on health in military, broadcasting, and occupational studies. Int J Occup Environ Health 1:47-57, 1995.
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35. H Dolk, P Elliott et al: Cancer incidence near radio and television transmitters in Great Britain. II. All high power transmitters. Amer J Epidemiol 145:10-17, 1997. NEW
36. MR Scarfi et al: Genotoxic effects of mitomycin-C and microwave radiation on bovine lymphocytes. Electro Magnetobio 15:99-107, 1996. NEW
37. MH Repacholi, A Basten et al: Lymphomas in E μ -Pim1 Transgenic Mice Exposed to Pulsed 900 MHz Electromagnetic Fields. Rad Res 147:631-640, 1997. NEW
38. Quotes from the abstract of Repacholi et al [37] : NEW
"...One hundred E μ -Pim1 mice were sham-exposed and 101 were exposed for two 30-min periods

- Dooley et al [27]: Wideband RF exposure did not cause birth defects in rats.

23B) What do recent reports from journals say?

Relevant peer-reviewed publications include:

- Lai and Singh [31]: Exposure of rats to 2450 MHz RF at 1.2 W/kg caused an increase in DNA strand breaks in brain cells.
- A Maes et al [32]: Exposure of human blood cells to 954 MHz RF at 1.5 W/kg did not cause chromosome damage, but increased the amount of chromosome damage produced by a chemical carcinogen.
- MR Scarfi et al [36]: Exposure of animal white blood cells to 9000 MHz RF at 70 W/kg produced evidence of both genotoxic and epigenetic damage.
- JK Grayson [33]: US air force personnel exposed to RF had an increased incidence of brain cancer, but the increase did not correlate with the level of exposure.
- Hocking et al [28]: See Q15B.
- Dolk et al [34 & 35]: See Q15D.

23C) What about the new report that exposure of mice to cell phone radiation causes cancer?

~~NEW~~

A recently published study [37] reports that lymphoma-prone mice exposed for 18 months to intense, but intermittent, radio-frequency fields of the type used by cellular phones have an increased incidence of lymphomas. No increases in the incidence of other types of tumors were found. The field intensities used are above the guidelines for public exposure recommended in the ANSI/IEEE standard (Q8), and are far above those that exist in publicly-accessible areas near cellular phone and PCS base station antennas [16].

While this study is very interesting, its impact on regulation of RF exposure of the general public is quite unclear:

- It cannot be determined from this study whether lymphomas, or other types of tumors, can be induced in normal (as opposed to cancer-prone) animals by exposure to RF.
- It cannot be determined from this study what exposure level is required for induction of lymphoma in these mice.

Clearly the study will need to be repeated with both normal and lymphoma-prone mice. If the effect can be replicated, it will be critical to determine the dose-response relationship for lymphoma induction, and to determine whether the effect occurs for other tumors and/or in other species.

See the Technical notes for the reference [37], quotes from the authors' abstract [38], quotes from the authors' discussion [39], and for further technical details [40].

24) Where can I get more information?

The documentation of the various radiofrequency standards [5, 6, 7 and 14] contain extensive references. The most up-to-date review of this area is the recent ICNIRP publication on hand-held phones [1].

25) Who wrote these Questions and Answers?

This FAQ sheet was written by Dr. John Moulder, a Professor of Radiation Oncology, Radiology and Pharmacology/Toxicology at the Medical College of Wisconsin. Dr. Moulder has taught, lectured and written on the biological effects of non-ionizing radiation and electromagnetic fields for nearly two decades. The original version of this FAQ was developed under a contract with the City of Brookfield, Wisconsin.

Overall Mortality of Cellular Telephone Customers

Kenneth J. Rothman, Jeanne E. Loughlin, Donna P. Funch, and Nancy A. Dreyer

Unlike mobile cellular telephones, in which the antenna is not part of the handset, a portable cellular telephone exposes the user's head to radio frequency energy transmitted from the antenna. This exposure has prompted concerns about potential biological effects, including brain cancer. As a first step in a record-based mortality surveillance of cellular telephone customers, we report on overall mortality of a cohort of more than

250,000 portable and mobile telephone customers during 1994. We found age-specific rates to be similar for users of the two types of telephones. For customers with accounts at least 3 years old, the ratio of mortality rates in 1994 for portable telephone users, compared with mobile telephone users, was 0.86 (90% confidence interval = 0.47–1.53). (*Epidemiology* 1996;7:303–305)

Keywords: cellular telephones, mortality, electromagnetic energy, radio frequency energy.

Case reports of brain cancer among cellular telephone users have prompted investigations into the possibility that exposure to cellular radio frequency energy may have adverse health effects.¹ For cellular telephone users, the main determinant of exposure is the type of cellular telephone. Handheld portable models have the antenna in the hand piece, in close proximity to the head. In contrast, the antenna for mobile or transportable bag phones is located separately from the hand piece, and the radio frequency energy dissipates before reaching the body.² To evaluate the possible effect of using cellular telephones on risk of death, we have begun mortality surveillance of a cohort of telephone users. We here report preliminary findings regarding overall mortality rates of customers of a large cellular telephone carrier.

Methods

We obtained data from all cellular telephone markets covered by one of the larger U.S. cellular telephone carriers. The markets, which cover the metropolitan areas of Boston, Chicago, Dallas, and Washington DC, are served by four different data processing systems. We requested representatives of each data processing system to provide a computer file of all noncorporate, single-phone customers who had active accounts as of January 1, 1994, and who had at least two complete billing cycles

with the company during November and December 1993. We excluded accounts that were clearly corporations, because it is difficult to link a corporate telephone to a specific user from the data that were available to us. We also excluded accounts that listed multiple telephones, for which we are less likely to be able to identify the actual user of each telephone. We received a total of 770,390 records from the four markets.

We requested information about each customer regarding name, address, city, state, zip code, date of birth, mobile telephone number, account number, electronic serial number (ESN) (a unique serial number embedded into each cellular telephone at the time of manufacture), Social Security number (SSN), type of telephone, and start of service date. Some of these data items were not available from the cellular carrier: date of birth, gender, and type of cellular telephone were never recorded; SSN was available for 83% of the 770,390 customers in the cohort. We contracted with a credit bureau to provide SSN, date of birth, and gender for the cohort. The credit bureau was able to find SSN for 65% of subjects, date of birth or year of birth for 63%, and gender for 78% of the records searched.

Although type of telephone (mobile vs portable) was not available from the billing data, we were able to assign telephone type for a large subset of customers based on the ESN. The first few characters of the ESN identify the manufacturer of the telephone. With the help of Motorola Corporation, the largest manufacturer of cellular telephones in the United States, we were able to identify the telephone type for 99% of the customers in the study who used Motorola telephones.

After receiving the raw data, we eliminated all records that had a SSN that was also listed for another record, which indicated a household with more than one telephone. This procedure reduced the file to 603,843 records with uniquely occurring SSNs. To these records, we added the data obtained from the credit bureau, and

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TABLE 1. Number of 1994 Deaths and Persons at Risk by Age, Gender, and Telephone Type

Age (Years)	Men			Women		
	Mobile	Portable	Unknown	Mobile	Portable	Unknown
20-24	0/1,023	2/1,904	2/3,069	1/1,075	0/1,263	2/2,376
25-29	2/2,985	2/3,782	7/8,406	0/2,143	1/1,923	1/5,117
30-34	1/4,879	1/5,071	8/13,801	0/2,857	0/2,238	4/6,746
35-39	3/5,723	4/5,283	15/15,293	2/3,156	0/2,384	3/7,687
40-44	1/5,540	4/4,801	16/15,011	1/3,312	0/2,480	0/7,881
45-49	8/5,442	5/4,018	28/13,773	0/3,038	0/2,091	3/6,995
50-54	9/4,135	8/2,826	21/9,850	3/2,119	6/1,497	5/4,955
55-59	13/2,770	5/1,837	21/6,661	3/1,413	2/936	4/3,237
60-64	16/2,096	8/1,317	43/4,633	5/906	1/650	8/2,124
65-69	26/1,563	17/920	55/3,210	3/708	1/450	7/1,571
70-74	30/946	10/497	44/1,932	4/454	1/255	5/1,003
75-79	9/445	6/236	28/860	3/207	1/100	7/508
80-84	7/148	5/89	18/325	1/83	0/38	0/143
≥85	3/59	2/36	3/115	0/20	0/10	0/58
Total	128/37,754	79/32,617	309/96,939	26/21,491	13/16,315	49/50,401

then we eliminated records that did not have identical SSNs and name fields from the two data sources. By limiting our selection to those customers who had identical information from two different sources, we restricted the cohort to a subset that had some validation of the information used for linkage. A total of 316,084 records remained. We eliminated an additional 75 records that had account names suggestive of a corporate account. Finally, we excluded records that lacked a year of birth or for which gender information was unconfirmed, leaving 256,284 records for linkage.

At this early stage in our surveillance, we do not yet have access to data on specific causes of death; here, we report on overall mortality during calendar year 1994. The only death file available now with data on 1994 deaths is the Social Security Administration's Death Master File, the latest release of which has deaths recorded through the first quarter of 1995. We searched this file for matches with our cohort. We considered a death record to be matched to a cohort member if the SSN matched exactly, the first five characters of the last name matched, the first letter of the first name matched, and the year of birth matched within 3 years.

Results

We found 408 deaths among cohort members that occurred before the start of 1994; we excluded these individuals from our analyses. The final cohort therefore comprised 255,868 individuals. Of these, 65% were male. The median age among the men was 42 years, and for women, 41 years. Median age was similar for users of different types of cellular telephone (mobile, 43 years; portable, 40 years; unknown telephone type, 42 years). Twenty-three per cent of the customers in the final cohort had a Motorola mobile telephone; 19% of the final cohort had a Motorola portable telephone; telephone type was unknown for the remaining 58%.

We identified 604 deaths among cohort members that occurred during 1994. In Table 1, we present the distribution of the entire cohort and those who died during 1994 by gender, age, and type of telephone used. Figure

1 gives age-specific mortality rates for portable and mobile telephone users; for this analysis, we standardized the rates among men and women to the gender distribution among portable telephone users, which is two-thirds male. The mortality curves for portable and mobile telephone users showed little difference.

We also compared mortality rates between portable telephone users and mobile telephone users who had been listed as continuing customers with the same cellular provider for at least 2 years, and, in a separate analysis, at least 3 years. For these analyses, we had fewer subjects (≥ 2 years of continuous use, 148,723 subjects; ≥ 3 years of continuous use, 63,309 subjects), but the results bear more closely on the overall effect on mortality of continuing use of portable cellular telephones. We partitioned the data into 28 strata, 14 categories of age and two of gender, and obtained the maximum likelihood estimate of the mortality rate in portable telephone users vs mobile telephone users.¹⁴ The results of the stratified analysis are given in Table 2. They show

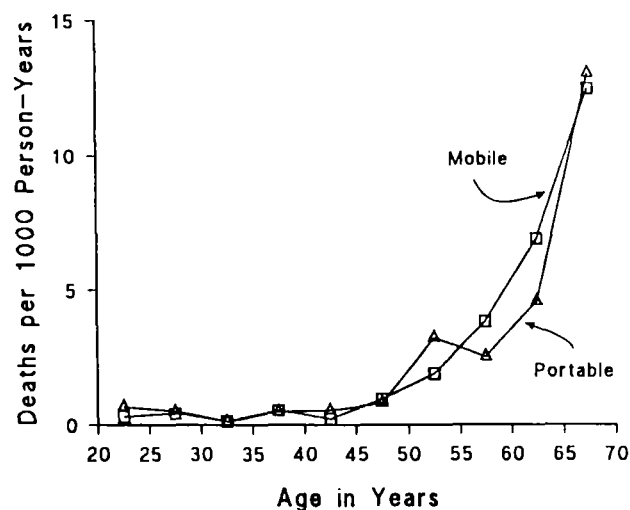


FIGURE 1. Age-specific mortality rates among users of mobile and portable cellular telephones.

TABLE 2. Mortality Rate Ratio Estimates for Portable vs Mobile Cellular Telephone Users of at Least 2 or 3 Years' Duration, Controlling for Age and Gender

Length of Service (Years)	Mortality Rate Ratio	90% Confidence Interval
2	0.93	0.67-1.29
3	0.86	0.47-1.53

a slightly lower rate of mortality for portable cellular telephone users. There was substantial confounding by age and gender in these analyses; the corresponding crude point estimates of the mortality rate ratio were, for those with at least 2 years of use, 0.74 rather than the unconfounded 0.93, and for 3 years of use, 0.64 rather than 0.86.

Discussion

The overall mortality rates of portable and mobile cellular telephone users are similar. The mortality rates reported here are much lower than corresponding rates for the general population, especially in the older age categories. In part, the low mortality presumably reflects the higher socioeconomic status of cellular telephone account holders. There may be additional selection factors explaining the low rates, since people who are not mobile may have little need for a cellular telephone. The Death Master File also misses some deaths and thus results in an unknown degree of underascertainment.

We expect that underascertainment should be equal, however, for the users of different types of cellular telephones and therefore would not bias our comparison. Low mortality rates for cellular telephone users in general should also affect users of different types of cellular telephones nearly equally. Missing information, which led to the discarding of a substantial proportion of the original cohort, likewise should be unrelated to type of cellular telephone used.

These preliminary findings have two important limitations. First, they do not directly address the issue of the relation between cellular telephone use and brain cancer, which comprises only a small proportion of deaths. Second, the time between the exposure to radio frequency energy from portable cellular telephones and the death endpoints that we measured was comparatively short, and our study therefore addresses only short-term effects. The findings do provide evidence that there is no large short-term effect on overall mortality, and they provide a starting point for future surveillance efforts.

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BRAIN TUMOR INCIDENCE IN RATS CHRONICALLY EXPOSED TO DIGITAL CELLULAR TELEPHONE FIELDS IN AN INITIATION-PROMOTION MODEL. W.R.

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Risk ratios > 10 for malignant brain tumors have been reported in microwave workers after 20 years' occupational exposure in environments with electronic solvents or soldering fumes. Portable cellular phones produce near-fields at the user's head with surface incident energies around 1mW/cm² in the 800 MHz spectrum. Digital phone systems, replacing older FM technology, operate in a packet mode, producing pulsed fields at the user's head (North American Digital Cellular (NADC) standard, 50/sec, 33% duty cycle). Body tissues absorb up to 40% of the radiated signal.

OBJECTIVE: Since this mode of personal communication is expected to be life-long, it will be important to evaluate possible brain tumor risk in suitable animal models. We have therefore sought evidence of brain tumor promotion by digital phone fields in rats exposed to a single dose of the short-lived carcinogen ENU *in utero*, and thereafter, exposed intermittently to digital phone fields for 24 months. (Mean life span 26 months). Low ENU dosage was selected to give maximum sensitivity to possible tumor promotion by phone fields over the lifetime of the animals.

METHODS: We tested an 836.55 MHz signal with a 3:1 multiplexed TDMA (Time-Division-Multiple-Access) modulation conforming to the NADC standard. Pregnant Fischer 344 rats were randomly assigned to 4 groups. They received either a single tail-vein injection of the carcinogen ethyl nitrosourea (ENU, 4mg/kg) or inert buffer solution on pregnancy Day 18. Far-field exposures (horn radiator, 836MHz circularly polarized) began on Day 19 and continued after parturition until weaning at age 23 days. Offspring (n = 236) of the 4 maternal groups then became treatment cohorts: 1) ENU/Field (EF), n=56, 30M, 26F; 2) ENU/Sham (ES), n=60, 30M, 30F; 3) Sham/Field (SF), n=60, 30M, 30F; 4) Sham/Sham (SS), n=60, 30M, 30F. Near-field exposures simulating user's head began at 35 days, and continued for the next 22 months, 4 days weekly. Exposures were for 2h daily, field-on 7.5 min, field-off 7.5 min. Far-field time-averaged SARs (modeled): pregnant dam (uterus) 0.3W/kg; fetus (brain) 0.29W/kg; isolated pup (brain) 0.035W/kg; young rat (brain) 0.13W/kg. Time-averaged near-field thermographic SARs: larger males, 0.75W/kg (1.0W/kg localized maximum); smaller females, 0.58W/kg (0.75W/kg localized maximum). Survivors (n = 182, 77%) of the original 236 rats were sacrificed at age 709-712 days.

RESULTS: The TDMA field had no enhancing effect on incidence, type or location of spontaneous nervous system tumors. At experiment termination, the TDMA field appeared to reduce incidence of brain malignant glial cell tumors in Group EF vs Group ES (4 vs 13). The TDMA field also appeared to reduce incidence of spontaneous glial tumors in Group SF vs Group SS (2 vs 7). Tumors in exposed rats were smaller in volume. There were no gender differences in tumor incidence. In rats not surviving to full term (n = 54, 22%), the TDMA field appeared to prolong latency of appearance of both spontaneous and ENU-induced glial cell tumors, but did not alter histological criteria of tumor types. In comparison of survival rates, consistent nonsignificant differences were noted between groups throughout the experiment: higher death rates were in a progression SF-SS-EF-ES.

DISCUSSION: Small experimental numbers emphasize caution in interpreting these data. However, all findings are clear and consistent in showing no tumor-enhancing field effect. Our experiment design and low ENU dosage were predicated on a promotional field effect. Therefore, apparent "protective" field effects do not gain statistical support. ENU has a brain half-life of 8-10 min and causes irreversible alkylation of DNA 0-6 guanine. Ionizing radiation at the time of rat ENU dosage has been reported to reduced brain glial tumor incidence. Consistent with that model, an interpretation of this study may suggest an action of TDMA fields in mechanisms of DNA repair.

This study was supported by the Motorola Corporation.

RECENT RESEARCH FINDINGS

- **"837 MHz Digital Cellular Telephone RF Fields and Copromotion Focus Formation *In Vitro*,"** Cain, C.D., D.L Thomas, L. Jimenez, R.A. Jones and W.R. Adey. J.L. Pettis Memorial VA Medical Center, Loma Linda, California. Presented at the 1994 Bioelectromagnetics Society (BEMS) meeting in Copenhagen, Denmark.

This study examined the effects of RF exposure to a 837 MHz time division multiple access (TDMA) signal on the communication between C3H/10T1/2 fibroblasts and their daughter mutant cells, UV-TDTx10e, by the measure of focus formation by UV-TDTx10e in co-culture with the C3H/10T1/2 fibroblasts. In co-cultures of C3H/10T1/2 cells with UV-TDTx cells, the chemical tumor promoter, 12-O-tetradecanoylphorbol-13-acetate (TPA) dose dependently induced focus formation at 10, 30 and 50 ng/ml in eight consecutive experiments. There was no difference in focus formation in terms of number, area and density of foci between sham exposed and those exposed to power densities of 0.037 and 0.37 mW/cm² in two and three experiments, respectively. However, at 3.7 mW/cm², the focus formation of exposed cultures was significantly different from the sham exposed cultures in three experiments although the pattern was not consistent across the three experiments.

- **"DNA Synthesis and Cell Proliferation in Glioma and Primary Glial Cells Exposed to a 837 MHz Modulated Radio Frequency Field,"** Stagg, R.B., W.J. Thomas and W.R. Adey. J.L. Pettis Memorial VA Medical Center, Loma Linda, California. Presented at BEMS 1994 in Copenhagen, Denmark.

This study explored whether a modulated RF field of the type employed by North American Digital Cellular telephones could act as a tumor-promoting agent by altering DNA synthesis leading to increased cell proliferation. When compared, sham-exposed and RF-exposed cultures of primary rat glial cells showed no significant difference for either the log phase or the serum starved condition. After two weeks, growth curves of both normal and transformed glial cells showed no differences between sham exposed and exposed cultures at any of the power densities tested. Cell doubling times of C₆ glioma cells also demonstrated no significant differences that could be attributed to altered DNA synthesis rates. Under these conditions, modulated RF does not increase cell proliferation of normal and transformed cultures of glial origin.

- **"Exposure of Nerve Growth Factor-Treated PC12 Cells to a Radio Frequency Field: Effect on Expression of *c-fos* and *c-jun*,"** Phillips, J.L., O. Ivaschuk, T. Ishida-Jones, W. Haggren and W.R. Adey. J.L. Pettis Memorial VA Medical Center, Loma Linda, California. Presented at BEMS 1994 in Copenhagen, Denmark.

This study used nerve growth factor (NGF)-treated PC12 pheochromocytoma cells to study the effects of RF exposure on the expression of the immediate early genes *c-fos* and *c-jun*. The researchers found that exposure to a modulated RF field at 836.55 MHz (North American Digital Cellular) did not alter the expression of *c-fos* and *c-jun* as compared to control, unexposed cells.

- **"Cell Proliferation in C₆ Glioma Cells Exposed to 836.55 MHz Frequency Modulated Radiofrequency Field,"** Stagg, R.B., W.J. Thomas, R.A. Jones and W.R. Adey. J.L. Pettis Memorial VA Medical Center, Loma Linda, California. Presented at BEMS 1995 in Boston, Massachusetts.

This study explored whether frequency-modulated (FM) RF fields similar to those used for personal communications could affect the proliferation of transformed brain tumor (glioma) cells. The researchers found no changes. RF exposure at the power levels tested did not increase the cell doubling times.

- **"837 MHz Digital Cellular Telephone RF Fields and Induced Ornithine Decarboxylase Activity in C3H/10T1/2 Cells,"** Cain, C.D., D.L. Thomas, M. Ghaffari and W.R. Adey. J.L. Pettis Memorial VA Medical Center, Loma Linda, California. Presented at BEMS 1996 in Victoria, British Columbia.

This study explored whether extremely low frequency (ELF)-modulated RF (TDMA) fields could influence induced activity of the ornithine decarboxylase (ODC) enzyme in cells. [As described below in the section titled "Other Research Issues," ODC is of interest to scientists for the role it plays in regulating cell growth.] The researchers found evidence of inhibited ODC activity at three and four hours after exposure at 8.4 mW/cm² (comparable to specific absorption rate (SAR) = 7.8 mW/kg), but no such effects at other times or exposures.

- **"Brain Tumor Incidence in Rats Chronically Exposed to Digital Cellular Telephone Fields in an Initiation-Promotion Model,"** Adey, W.R. et al. J.L. Pettis Memorial VA Medical Center and Loma Linda School of Applied Health Professionals, Loma Linda, California; University of California Davis and Riverside. Presented at BEMS 1996 in Victoria, British Columbia.

This study, perhaps the most significant lifetime animal experiment to date, explored possible tumor promotion in rats exposed to time division multiple access (TDMA) digital fields over a two-year period from birth to old age. No tumor enhancement was found. This lifetime study thus provides additional evidence pointing to a lack of adverse health effects related to the use of cellular phones. Though the data was suggestive of a

possible tumor-inhibitive effect, it lacked statistical significance and therefore must be interpreted cautiously.

- **“Does 835 MHz FMCW Irradiation Alter Nitric Oxide Production by the J774.16 Mouse Macrophage Cell Line?”** Spitz, D.R., J.E. Sim and L.A. Rodnour, Radiation Oncology Center, Washington University School of Medicine, St. Louis, Missouri. Presented at BEMS 1996 in Victoria, British Columbia.

This study explored whether exposure to an FM continuous wave signal could alter the production of nitric oxide in mouse cells. Nitric oxide is a free radical that could play a role in cancer development. The results showed no differences in nitric oxide production between exposed and unexposed cells.

- **“Effects on Human of Microwaves Emitted by GSM-Type Mobile Telephones: Chronobiological Rhythm of ACTH,”** de Seze, R., V. Albertin, R. Rouzier-Panis, P. Fabbro-Peray, Y. Toulton and L. Miro. Laboratoire de Biophysique Médicale, Faculté de Médecine; CAP; and Département d’Information Médicale – Nîmes, France/ Biochimie Médicale – Paris, France. Presented at BEMS 1996 in Victoria, British Columbia.

This study explored the possible effects of RF exposure from GSM telephone use on endocrine hormones in healthy male volunteers. Levels of a number of hormones, including melatonin, were examined. Results related to the main stress hormone ACTH were presented at the 1996 BEMS conference with no significant changes in the exposed vs. unexposed subjects.

- **“Exposure of Nerve Growth Factor-Treated PC12 Cells to an 836.55 MHz Frequency-Modulated Radio Frequency Field: Effect on Expression of *c-fos* and *c-jun*,”** Ivaschuk, O., T. Ishida-Jones, W. Haggren, W.R. Adey and J.L. Phillips. J.L. Pettis Memorial VA Medical Center, Loma Linda, California. Presented at BEMS 1996 in Victoria, British Columbia.

This was a further investigation of the gene expression issues previously discussed by the Loma Linda team at BEMS 1994. As in the earlier *in vitro* research, this study found no significant alterations in the expression of either *c-fos* or *c-jun* in exposed PC12 cells.

- **“Measurement of DNA Damage by the Alkaline Comet Assay After *In Vitro* Exposure to 835 MHz Electromagnetic Radiation,”** Malyapa, R.S., E.W. Ahern, C.H. Cheng, W.D. Wright and J.L. Roti Roti. Radiation Oncology Center, Washington University School of Medicine, St. Louis, Missouri. Presented at BEMS 1996 in Victoria, British Columbia.

This study explored possible DNA damage (single-strand breaks) in mammalian cells (mouse fibroblasts) exposed to FM continuous wave and code division multiple access (CDMA) digital signals. Upon exposure, no significant differences were observed between the exposed vs. unexposed cells.

- **“Acute Effects of GSM Signals on the Rat CNS,”** Wiessner, C., K. Fritze, B. Schmitz, N. Kuster and K.A. Hossmann, Max Planck Institute for Neurological Research, Cologne, Germany. Presented at URSI 1996 in Lille, France.

This study explored possible acute effects of pulsed or continuous wave GSM signals on the central nervous systems of exposed rats, as determined by measured levels of the genes *hsp70* and *c-fos*. Exposed rats were subjected for four hours to SARs of 0.4 mW/g, 2 mW/g brain tissue and 10 mW/g brain tissue. The researchers concluded there were no exposure-related genomic changes at SARs up to 2 W/kg, which compares to an exposure limit of 1.6 W/kg established by internationally recognized RF safety standards for cellular telephones and related wireless communications products. At the highest level of exposure, 10 W/kg, the researchers found a minor focal expression of *hsp70*, but concluded it was most likely the combined effect of immobilization and thermal effects related to the high SAR.

In a second aspect of this research, researchers explored whether the RF exposures in question could cause alterations in the blood-brain barrier (BBB). The researchers concluded there were no BBB-related changes at the SARs of 0.4 W/kg and 2 W/kg. A higher incidence of BBB effects was noticed at the SAR of 10 W/kg, outside the range of exposures from portable communications devices operating within internationally recognized safety guidelines. The researchers said further studies would be necessary to confirm these results at 10 W/kg, evaluate their possible significance and assess the role such factors as stress and heating might have in producing such effects.

- **“Overall Mortality of Cellular Telephone Customers,”** Rothman, K., J. Loughlin, D. Funch and N. Dreyer. *Epidemiology* 1996; 7 (3): 303-305.

An epidemiological study funded by WTR compared users of portable, handheld cellular telephones with users of mobile, mostly car-mounted or bag-type phones, and found nearly identical mortality rates, indicating that the presumed difference in RF radiation exposure did not appear to influence mortality. According to the authors, “The findings do provide evidence that there is no large short-term effect on overall mortality.”

Forschungsgemeinschaft Funk (FGF)

- **“Cytogenic Studies of the Effects of Mobile Telephone Radio Waves,” Diener, S. and P. Eberle, Institute for Human Biology, Human Genetics and Cytogenetics Department, Technical University of Braunschweig, 1994.**

This study explored whether RF fields such as those generated by cellular telephones had a carcinogenic effect. The researchers found no evidence that the processes recorded in the test parameters (chromosome aberration rate, sister chromatid exchange and cell proliferation) were affected by exposure.

- **“The Influence of High-frequency Electromagnetic Fields on Calcium Concentrations,” Meyer, R., Physiological Institute of the Rhine Friedrich-Wilhelm University, Bonn, 1994.**

This study explored the possible effects of RF fields such as those used by cellular telephones on the calcium concentration in cells. The researchers found that exposure to alternating fields and pulsed signals had no effect on calcium concentration.

- **“Study of the Carcinogenic Effect of Electromagnetic Fields,” Fitzner, R. and E. Langer, Institute of Clinical Chemistry and Clinical Biochemistry at the Benjamin Franklin Clinic, Free University of Berlin, 1994.**

This study exposed human leukemia cells to pulsed RF fields such as those used by digital cellular telephones to explore possible effects on speed of tumor cell division or DNA. After exposure to pulsed alternating fields at 1.8 GHz, no increased growth was observed in the cells (doubling time remained constant).

- **Molecular Genetics Working Group, Professor Reuger, Ruhr University, Bochum, 1996.**

This study explored the possible effects of pulsed RF fields used by cellular telephones (GSM standard) on simple organisms (viruses and bacteria). The researchers found no damage to the genetic substances of exposed bacteria and viruses.

- **“Effects of Electromagnetic Waves on Brain Waves,” Professor Gehlen, Neurological University Clinic at Knappschaft Hospital, Bochum-Langendreer, 1996.**

This study exposed 52 human volunteers, aged 20 to 38, to RF fields at cellular phone frequencies to explore possible effects on brain activity. The researchers reported no

effect on electric brain activity, general intellectual capacity or learning, attention or comprehension capacities.

Jacqui
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Liz Jacobson

Reid Klausner

Dr. ^{Joe} Paunoni, division of cancer Epi and
genetics.

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CTFA - Tom Wheeler

WTR - research grp.

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Possible Biological Effects of Radiofrequency Radiation in the Context of Wireless Communications

Animal Studies

Most of the studies of radiofrequency radiation (RFR) in the published literature investigated health effects of exposure to radiofrequency radiation characteristic of radar or microwave ovens. Many of the published studies involved acute exposure of animals or cells in vitro to short, intense RFR doses which did not use the frequencies or modulations used for cellular phones. Cellular phone exposures are at lower RFR doses and are chronic. Higher dose exposures are thought to produce effects as a result of increased temperature. It is not known whether lower doses, which do not seem to increase temperature, produce bioeffects through non-thermal mechanisms or whether they produce cumulative effects.

The most often cited study, and one of the most reliable, was conducted in the early 1980's at the University of Washington for the U.S. Air Force and is usually referred to as the Guy study. Two groups of 100 rats were used in the study, with one group being exposed to RFR for 22 hours each day for approximately two years. The other group of rats was an unexposed control group. The frequency and modulation of the RFR was different from that used in cellular phones, but the energy deposited in the rats' bodies was similar to the maximum doses in the heads of cellular phone users. Eighteen rats in the exposed group developed tumors of any type, while only five rats in the control group developed tumors. The difference is statistically significant, but raises technical questions about pooling tumors and thus has been criticized as not indicative of a biological effect. Since the study has never been replicated, it is possible that the results were due to some factor other than RFR exposure.

In a more recent study conducted for Motorola at the Veterans Administration Hospital in Loma Linda, California, by Ross Adey's group, rats were exposed to a chemical carcinogen that causes brain tumors and then to an actual cellular phone RFR source. There were slightly fewer brain tumors in the exposed group, but the numbers of animals that developed tumors was not large enough to support a finding that cellular phone RFR protects against tumors. Dr. Adey has reported the experiment at scientific meetings and said it is being repeated with larger numbers of rats.

Another recent study, referred to as the Lai-Singh study, has also aroused considerable interest. In this study rats were exposed for two hours to RFR exposures comparable to those received by cellular phone users. Again the frequency and modulation of the RFR was different from cellular phones. Using a novel technique, the investigators studied cells isolated from the rats' brains, and found that rats exposed to RFR had an increased number of DNA strand breaks relative to the unexposed controls. Some scientists have interpreted these results as suggesting a

possible mechanism whereby RFR might influence tumor development.

The studies cited above are pertinent to the concerns raised by cases of brain tumors in humans. Other bioeffects associated with radiofrequency exposure have been investigated over the years. Cataract is an established bioeffect and thought to be a thermal effect. Calcium effects were examined in the 1970s and early 1980s. Most studies reported increased calcium efflux in brain tissue; at least one current investigator has tried to confirm with negative results. The European Commission report called the findings inconclusive but meriting further research. The blood-aqueous barrier in the eye has been investigated by Kues and coworkers at Johns Hopkins. They found an increase in permeability at 2450 Hz. Little work on mutation effects has been done; note the Lai-Singh report above.

In summary, there is currently no specific information that clearly indicates that use of cellular phones is a human health risk. On the other hand, there is not enough information available to permit a determination that there is no health risk. A significant research effort, involving exposures of large numbers of animals to the various types of cellular phone modulation in current or expected use, is badly needed to provide a further basis for risk assessment of these devices.

Headaches

When some factory workers in Sweden switched from analog to digital cellular phones at work, they reported headaches which apparently went away when they resumed using analog phones. The Institute for Working Life in Sweden is conducting a study examining self reports of headaches and other symptoms as a result. They have been in communication with WTR, FDA, and NIOSH (through the RF Interagency Work Group).

Epidemiology

Kenneth Rothman, through WTR, has published a study indicating that mortality and morbidity are decreased in cellular phones users, which may be related to their higher socioeconomic status. The primary criticisms of the Rothman study are its duration and the relatively small contribution which brain cancer makes to total mortality.

~~NCI is including cellular phone use in a current study of brain cancer.~~
Dr. Martha Linnet is the contact.

Sources of Information on the Possible Health Effects of the Use
of Cell Phones and Other Wireless Communications Devices

Radiofrequency Inter-Agency Work Group

The FDA Center for Devices and Radiological Health has been coordinating the Federal health and safety agencies' responses to issues in the area of possible health effects of the use of cell phones and other wireless communications devices through the Radiofrequency Inter-Agency Work Group. The Group has representatives from FDA/CDRH, CDC/NIOSH, EPA, OSHA, FCC, and NTIA.

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Janet Healer

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909-422-3050

Henry C. Lai

University of Washington
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Center for Bioengineering
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Seattle, Washington 98195
206-543-1071

Cellular Studies:

Theodore Aaron Litovitz
Catholic University of America
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Hannan Hall, Room 407
Washington, District of Columbia 20064
202-319-5328

Bioelectromagnetics Society (BEMS)

BEMS is the primary scientific society for studies of the biological and health effects of exposure to radiofrequency radiation. The current president is Dr. Richard Luben. The next BEMS annual meeting is to be held in June, 1997, in conjunction with other major international societies with interests in bioelectromagnetics at the World Congress on Electricity and Magnetism in Biology and Medicine in Bologna, Italy. It is anticipated that several reports at the upcoming meeting will bear directly on the subject of biological effects of exposure to cell phone radiofrequency radiation. FDA will be represented at this meeting by Dr. Russell D. Owen.

Dr. Richard A. Luben
University of California at Riverside
Professor, Biomedical Sciences
7217 Lenox Avenue
Riverside, California 92504
909-787-5991

World Health Organization (WHO)

The WHO Research Program in Electric and Magnetic Field Bioeffects is directed by Dr. Michael Repacholi. It is to be financed by member countries and by the cell phone industry. At the initial meeting at WHO in May, 1996, cellular phone research was the top priority of the participating countries, because of the widespread use of wireless communications devices and the lack of conclusive scientific information on the possible health effects of the types of radiofrequency radiation exposure characteristic of cell phones and other wireless communications devices. The second meeting is to be held in Geneva, Switzerland in June, 1997 (shortly before the World Congress on Electricity and Magnetism in Biology and Medicine).

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Cell Phone Industry-Sponsored Research

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George L. Carlo
Chairman
Wireless Technologies Research, L.L.C.
1711 N Street, N.W.
Washington, District of Columbia 20036-2811
703-589-1320

Press

Two reporters have followed cellular phone issues, including scientific, legal, and research progress. They are:

Louis Slesin
Microwave News
212-517-2800

Jeff Silva
RCR Publications
202-662-7213



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 1997

George L. Carlo, Ph.D., M.S., J.D.
Chairman
Wireless Technologies Research, L.L.C.
1711 N Street, N.W.
Suite 400
Washington, DC 20036-2811

Dear Dr. Carlo:

As the lead federal agency charged with regulation of radiation-emitting consumer products, the Food and Drug Administration (FDA) has followed the progress of your research effort into the possible health effects of wireless technology with great interest. We are continuing to work with the other members of the Radiofrequency Inter-Agency Work Group in order to provide a coordinated set of comments on your program, as was recommended by the U.S. General Accounting Office in their 1994 report to the Chairman of the House Subcommittee on Telecommunications and Finance, Committee on Energy and Commerce. We were pleased that we could participate in your Cellular Telephone Research and Cancer Symposium held in December 1993, and we benefited greatly from the informative briefings you delivered to the Inter-Agency Work Group in March 1995 and August 1996. We are also pleased to give you the suggestions of the Inter-Agency Work Group regarding priorities for the directions your research should take, as you and the Cellular Telecommunications Industry Association have requested. A number of these suggestions have been voiced at our meetings with you, but we would like to take this opportunity to reiterate them here.

Our suggestions for research priorities should in no way be construed as a rank ordering of priorities; we simply wish to state some of our views of what a well-balanced program of research should look like. As was noted in the proceedings of your 1993 symposium, "A balance seems best between epidemiological studies, animal studies, and mechanistic studies, even if the last category cannot be extrapolated". Since your resources are limited, we will attempt to offer our views on how your program could be redirected in order to best answer the questions that the regulatory agencies believe are relevant to our concerns.

Page 2 - Dr. George Carlo

As it is currently planned, the Wireless Technologies Research, L.L.C. (WTR) research program consists of five elements: dosimetry and exposure system issues, epidemiology, in vitro genotoxicology, and rodent bioassays, both chronic and subchronic. We would like to offer the following points that we believe should be considered in deciding which of these elements to pursue in the near term, given the lack of resources to pursue them as a comprehensive program:

- Chronic (lifetime) animal exposures should be given highest priority.
- Chronic animal exposures should be performed both with and without the application of chemical initiating agents to investigate tumor promotion in addition to tumorigenesis.
- Identification of potential risks should include endpoints other than brain cancer (e.g., ocular effects of radiofrequency radiation exposure).
- Replication of prior studies demonstrating positive biological effects work is needed. A careful replication of the Chou and Guy study (Bioelectromagnetics 13:469-496, 1992) which suggests that chronic exposure of rats to microwaves is associated with an increase in tumors would contribute a great deal to the risk identification process for wireless communication products.
- Genetic toxicology studies should focus on single cell gel studies of DNA strand breakage and on induction of micronuclei. (These are the only direct genotoxic effects suggested at this time.) The need to replicate the Lai and Singh experiments used to demonstrate microwave-induced DNA strand breakage (Int. J. Radiat. Biol. 69: 513-521, 1996) is strengthened by Dr. Lai's recent reports in scientific meetings that this effect is suppressed by melatonin exposure.
- Epidemiology studies focused on approaches optimized for hazard identification are warranted (e.g., case control studies are well suited to studying rare diseases such as brain cancer).

Page 3 - Dr. George Carlo

Due to the latency of some of the health effects that have been suggested to be associated with exposure to non-ionizing radiation, long term study is essential to test such associations. Indeed, we believe that continuing postmarketing surveillance is important in ensuring the safety of wireless technologies.

We believe that products of the WTR research program could have lasting benefit to any organization that may conduct research on the possible health effects of exposure to radiation from wireless communications devices. We hope that WTR finds these suggestions helpful as you enter the implementation stage of your biological research. If we can be of further assistance, please don't hesitate to contact me.

Sincerely yours,



Elizabeth D. Jacobson, Ph.D.
Deputy Director for Science
Center for Devices and
Radiological Health

cc: Thomas E. Wheeler, CTIA



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 1996

Mr. Richard M. Smith
Chief, Office of Engineering and Technology
Federal Communications Commission
Washington, D.C. 20554

Dear Mr. Smith:

Thank you for your letter of July 2, 1996 to Dr. Burlington requesting that we review and comment on your proposed guidelines for limits on exposure to radiofrequency (RF) radiation. We agree that it is important for the federal health agencies to develop a consensus with respect to the final guidelines adopted by your agency.

We would first like to point out that your proposed guidelines for evaluating the environmental effects of radio frequency radiation do not address the indirect, but potentially harmful effects of electromagnetic interference with medical devices. These environmental effects can induce failures in medical devices that can cause injury or death. We would encourage you to continue to work with our agency to address separately this issue.

As we stated in our letter of November 10, 1993 commenting on the Notice of Proposed Rulemaking FCC 93-142, we believe that the FCC should replace its present guidelines with most, but not all, of the material contained in the ANSI/IEEE C95.1-1992 standard. We also stated that we did not believe that C95.1-1992 addresses the issue of long-term, chronic exposures to RF fields, and that the relevance of such questions would only increase as the use of portable and hand-held devices grows. For these reasons we believe that it is appropriate to adopt a hybrid standard which incorporates the more protective limits of the National Council for Radiation Protection and Measurement (NCRP) at frequencies above 1.5 GHz, as you have proposed. Since the National Institute of Occupational Safety and Health and the Environmental Protection Agency have previously supported the adoption of the more protective NCRP guidelines (in their comments on the Notice of Proposed Rulemaking), we believe that your approach of a hybrid guideline is supported by a consensus of opinion within the federal health agencies.

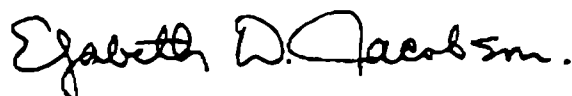
Page 2 - Mr. Richard M. Smith

We also stated in our 1993 letter that we disagreed with, and recommended against, the adoption of the "low power exclusion clause" that exempts certain devices from the provisions of the standard only because they emit less than a specified amount of power. We noted that some devices that meet the requirements of the low power exclusion clause can induce energy depositions that exceed those limits specified elsewhere in the C95.1-1992 guidelines. We therefore support your current proposal to apply the energy deposition guidelines to specific classes of low-power devices that are designed to be used in the immediate vicinity of a user, including hand-held cellular telephones. We also agree with your decision to apply the uncontrolled or general population exposure criteria to devices used primarily by consumers.

Finally, our 1993 comments on the Notice of Proposed Rulemaking supported the FCC proposal to endorse the RF exposure and power deposition measurement procedures specified in the "IEEE Recommended Practices for the Measurements of Potentially Hazardous Electromagnetic Fields - RF and Microwave", designated ANSI C95.3-1992. Your current proposed guidelines endorse ANSI C95.3-1992 and in addition note that NCRP has recently published Report 119, "A Practical Guide to the Determination of Human Exposure to Radiofrequency Fields", which you also endorse. We believe that both documents are useful and support their use for determining compliance with the RF exposure guidelines.

In summary, we believe that the RF exposure guidelines currently proposed by the FCC are responsive to our earlier comments on the 1993 Notice of Proposed Rulemaking. The current FCC proposal represents a significant step toward achieving a consensus guideline on RF exposure which will have the support of the federal agencies responsible for protecting the public from nonionizing radiation injury. We appreciate this opportunity to offer our comments and support.

Sincerely yours,



Elizabeth D. Jacobson, Ph.D.
Deputy Director for Science
Center for Devices and
Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

February 4, 1993

UPDATE ON CELLULAR PHONES

The Food and Drug Administration has recently received a number of inquiries about the safety of cellular phones. FDA has prepared the following information to summarize what is known -- and what remains unknown -- about whether these products can pose a hazard to health, and what can be done to minimize any potential risk.

Why the concern?

Cellular phones emit low levels of radiofrequency energy (specifically, microwave energy) while being used. (No significant amounts of radiofrequency energy are emitted when the phones are not in use.) It is known that high levels of radiofrequency energy can produce biological damage, and there is limited evidence that suggests that lower levels might cause adverse health effects as well. However, there is no proof at this point that cellular phones are harmful.

What kind of phones are in question?

Questions have been raised about hand-held cellular phones, the kind that have a built-in antenna which is positioned close to the user's head during normal telephone conversations. These types of cellular phones are of particular concern because of the short distance between the phone's antenna -- the source of the radiofrequency energy -- and the person's body. Cellular phones in which the antenna is located at greater distances from the user or other people (on the outside of a car, for example) are generally of little concern, because a person's exposure to a radiofrequency source decreases rapidly with distance. The safety of so-called "cordless phones," which have a base unit connected to the telephone wiring in a house and which operate at far lower power levels and frequencies, has not been questioned.

How much evidence is there that hand-held cellular phones might be harmful?

Briefly, there is not enough evidence to know for sure, either way. Although it is known that high levels of radiofrequency energy that are absorbed by the body can be harmful, the effect of lower levels, such as those emitted by hand-held cellular

-2-

phones, is far less clear. A few studies suggest that these levels can accelerate the development of cancer in laboratory animals, but there is much uncertainty among scientists about whether these results apply to the use of cellular phones. For example, it is uncertain whether the results obtained in rats and mice are applicable to humans. Further, most of the studies that showed increased tumor development used animals that had already been treated with cancer-causing chemicals, and other studies exposed the animals to the radiofrequency energy virtually continuously -- up to 22 hours a day. Nonetheless, we cannot dismiss these studies as irrelevant to cellular phone users. We simply don't have enough information at this point to rule out the possibility of a risk. FDA is working with all parties, including other federal agencies and industry, to assure that research is undertaken which will provide the needed answers.

What about cases of human cancer that have been reported in users of hand-held cellular phones?

It is true that some people who have used these phones have experienced brain cancer. But it is important to understand that this type of cancer also occurs among people who have not used cellular phones. In fact, brain cancer occurs in the U.S. population at a rate of about 6 new cases per 100,000 people each year. At that rate, assuming 3 million users of hand-held cellular phones, about 180 cases of brain cancer would be expected each year among those people, whether or not they used their phones. Thus it is not possible to tell whether any individual's cancer arose because of the phone or whether it would have happened anyway. A key question is whether the risk of getting a particular form of cancer is greater among people who use these phones than among the rest of the population. One way to answer that question is to compare the cancer rates among people using hand-held cellular phones with people who do not use them. These kinds of human studies do not exist at this time.

What's FDA's role concerning the safety of cellular phones?

Under the law, FDA does not review the safety of cellular phones prior to marketing, as it does with new drugs or medical devices. However, because the phones emit radiofrequency energy, the Agency could impose certain restrictions if health problems were to arise after marketing. For example, FDA could impose a performance standard on the manufacturers of these products if the scientific evidence showed a public health need. Such a standard might require that the phones emit radiofrequency energy below a certain level. But existing scientific data do not justify FDA's taking this action. However, FDA is exploring

-3-

with the manufacturers of hand-held cellular phones ways minimize exposure of users to radiofrequency energy, such as changes in antenna design and better instructions for use, as well as areas for needed research.

In the absence of conclusive information about any possible risk, what should people do?

It is not necessary that people stop using their hand-held cellular phones. If there is a risk from these devices -- and at this point we don't know if there is -- it is probably small. But if people are concerned about avoiding even potential risks, there are simple steps they can take to do so.

For example, since time is a key factor in how much exposure a person receives, those who spend long periods of time on their hand-held cellular phones could consider holding lengthy conversations on conventional phones and reserving the hand-held cellular model for shorter conversations or for situations when conventional phones are not available.

People who must conduct extended conversations in their cars every day could switch to a type of cellular phone which places more distance between their bodies and the source of the radiofrequency energy, since the exposure level drops off dramatically with distance. For example, they could switch to a cellular phone in which the antenna is located outside the vehicle; in some cases, a hand-held phone with a built-in antenna can be connected to a different antenna mounted on the outside of the car or built into a separate package. Note that outside antennas should be mounted as far as possible from passengers.

Again, there is no proof at this point that cellular phones can be harmful. But if people are concerned about the radiofrequency energy from these products, taking the simple precautions outlined above can reduce any possible risk.

February 19, 1993

Statement on Cellular Phones Meeting

On Friday, February 19, 1993, FDA met in Rockville, Md. with manufacturers and distributors of cellular phones, communications firms, and related trade associations to discuss issues related to radiofrequency energy emitted by hand-held cellular phones.

Questions have been raised that hand-held cellular phones might cause adverse health risks, but there is not enough evidence to know for sure. Although it is known that high levels of radiofrequency energy that are absorbed by the body can be harmful, the effect of lower levels, such as those emitted by hand-held cellular phones, is far less clear.

A few studies suggest that these levels can accelerate the development of cancer in laboratory animals, but there is much uncertainty among scientists about whether these results apply to the use of cellular phones. For example, it is uncertain whether the results obtained in rats and mice are applicable to humans. Further, most of the studies that showed increased tumor development used animals that had already been treated with cancer-causing chemicals, and other studies exposed the animals to the radiofrequency energy virtually continuously -- up to 22 hours a day.

Nonetheless, we cannot dismiss these studies as irrelevant to cellular phone users. We simply don't have enough information at this point to rule out the possibility of a risk. FDA is actively working with all parties, including other federal agencies and industry, to assure that research is undertaken to provide the necessary answers to outstanding public health questions.

At the morning session of the February 19 meeting, issues concerning the pertinent scientific data and future research were discussed. This portion of the meeting was requested by the trade associations. In the afternoon, regulatory issues, exposure and bioeffects, design considerations and labeling issues were examined.

At the close of the meeting, the industry agreed to explore specific steps that could be taken to minimize exposure of users to radiofrequency energy from the phones.

4/4/97

Mich Kaussner — Epi discussion —

Cancer —

— Epi study — Joe Fraumeni
496-1611 —

— Have a whole program of non-ionizing, —
radiation
— brain cancer studies —

Thinks we can show that epi —
"rules out" nutrition.

— Solvents, pesticides
— higher incidence of brain cancer in
certain industries, including agriculture

— Extensive research portfolio —

— brain —
— non-Hodgkins —
— lymphoma —
— kidney —

Dr. Fraumeni. —

— Cell phones —

book F. edited —

Time trends — brain tumors —

Brain tumor incidents rates have been rising — some diagnostic. — but not clear how much is. S

Multicenter Case-control Study

- 3 cities in middle - 1st years from completion.
- over 1000 cases
 - environmental chemicals — 291 methylene chloride
 - viruses
 - Similian virus^{SV} - 40. — (Polo vaccines)
 - nitrosamines
 - cell phones.
 - other electromagnetic radiation
- IARC ^{national} ~~interagency~~ research center — Lyon, France.
So. Cal Woman
- EU — This is the year of the brain. —
USC. —

Am health foundation - NY - hospital-based
Case control study. Multiple risk factors -
added cellular phone. —

NIOSH. — Case control - focused on OCC. exposures.

Gene on chromosome 10 - been identified. —
gene alterations found in tumors themselves.

"Cowden's Syndrome" — have gene sequence,
germ line defects.

R-53 ^{gene} related to brain cancer.

Some times

NIHHS —

Think the idea of animal studies
is a good one — but it's a long
shot — but we have to look it. —

Solvent. — Methylene chloride —

Unhed occupational — used in cleaning agents
— biological agent — virus.

for ENF

— Clues aren't as persuasive —
— biological plausibility. —

epi - changing dramatically - observational sciences.

Molecular epi - allows us in a much more sophisticated way - to connect causation w/ genetic responses.

- bladder cancer
- benzidine metabolized by enzymes
- genetic make up effects - enzymes vary
- powerful. —

interplay between environmental factors and genes.

- We will be able to figure out who is at risk for what environmental exposure
- important public policy issue. —
- genetic predisposition to industrial exposure. —



Bruce N. Reed
03/28/97 03:07:18 PM

Record Type: Record

To: Elizabeth Drye/OPD/EOP
cc: Christopher C. Jennings/OPD/EOP
Subject: Cell phones and cancer

The President asked if we could look into the issue of any possible links between cell phone use and brain cancer. He's had a number of friends die from brain cancer lately, and wonders if there's some connection. He wants to work with the VP on this.

I remember a study that came out in 92 suggesting a possible link -- and I remember the VP saying he believed it. Can you find out what the current scientific view is?

Bruce Burlington
Joe Leavitt FDA
301-443-4690

Liz Jacobson

- Act: - Radiation Control for Health and Safety Act.
1968
- Goal to eliminate unnecessary radiation
Covers all products
 - majority authority is performance standard
 - can take action if FDA can show that there
is a hazard (e.g. took action against night
vision goggles).
 - recall
 - replace, repair, refund
 - performance standard - by regulation
 - 1/2 ~ dozen performance standards
x-rays, microwaves,
 - Rad Health Act - reduce unnecessary
and hazardous radiation.

- Lang King - brain tumor - ^{wife} had used cell phone in her work.

- Post Reporter - Sunday business section -

- 4 years after Lang King

- 4 years in April.

- FDA asked phone industry - manufacturers / carriers - to come in and talk to FDA

- Since q. had been raised

Surf industry - regardless of level of risk - ^① ~~stand~~ research. -
large pop'n exposed - ^② look at labeling

^③ look at product design

ALARA

As low as reasonably achievable

(April?) 1993 - formed a science advisory group.

GAO did study for Congressman Markley

Oct - Nov 94

- recommended to industry they find through blind trust. - Wireless Technology Research

- Agencies coordinate - FDA leads -

- asked grp to comment on research agenda
- recently August CTIA Cellular
tech. Ind. Assn. -

WTR Research

- set up peer review system
- in vitro / in vivo dosimetry tools
- but didn't get back to this research
- Administrator wants WTR lifetime animal study. —
- also want WTR to make dosimetry work available to others e.g. WHO
- have published EPI studies
 - laying groundwork
 - tracking phone users vs. non phone users.
 - need to continue doing that.
- ~~Strong~~ Moving toward more use of stronger cell phones.

Other agencies

- FCC — has mandatory standard — FDA / NIOSH / EPA provide technical assistance
- ANSI / NCRP standard. — SAR level — Specific absorption rate.
 - based on acute effects
 - not on long term — builds in safety factor

EPA — did report

NIOSH — Gross Loti — serves on ANSI / NCRP

CEO's — annoyed they haven't got more for their research dollar. —

message to industry — responsible —
Continues

- Give them \$10 more million; have individual projects funded how?

Tom Wheeler President / CEO CTIA.

- Will continue funding epi studies.

- Two years of studies

NTP do research — \$8 million to do the study

NCTR — Could be done at FDA
National Center for Tox Research. —

Post asked — why we weren't speaking out more strongly —

- FDA said — we have to get research done but don't think confrontational helps.

Industry hasn't done right to know the disclosure statement.

— How ^{will} you continue

- more animal

- more and continuing epi, —

- lower exposure designs (energy that goes in head is wasted).

1ST STORY of Level 1 printed in FULL format.

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The Washington Post

April 06, 1997, Sunday, Final Edition

SECTION: FINANCIAL; Pg. H01

LENGTH: 2410 words

HEADLINE: Still Waiting for the Call; Do Cellular Phones Cause Brain Tumors?
Researchers' Inability To Provide an Answer So Far Is Only Raising More
Questions

BYLINE: Mike Mills, Washington Post Staff Writer

BODY:

On Jan. 21, 1993, a shock wave hit the cellular telephone industry. Appearing live on "The Larry King Show," a Florida man named David Reynard told a nationwide audience that he was suing two cellular companies because, he said, his wife's pocket phone had caused the brain tumor that killed her.

The enormous media attention given to the suit caused cellular stocks to tumble on Wall Street, even though it was later dismissed because of insufficient evidence. The threat of litigation also sent the \$ 23 billion cellular industry scrambling to reassure the public that pocket phones weren't slowly baking the brains of millions of users around the world.

To ease public concerns, cellular equipment makers and carriers created the Scientific Advisory Group, which described itself as an "independent" research organization. The industry gave it \$ 25 million and five years to attempt to answer the crucial question: Do cellular phones cause brain cancer, brain tumors or any other harmful health effects?

But can such an industry-supported research effort truly be independent? And can it provide the kind of scientific evidence that will inform the public whether an increasingly widespread technology is indeed safe? Four years after the research effort began, those questions are being voiced by a growing number of scientists and industry analysts.

The industry-supported research group -- since renamed Wireless Technology Research LLC -- has spent \$ 17 million since 1993, but it is still far from finding any answers. The WTR says it hasn't completed any biomedical studies; instead, it has focused on collecting existing studies and researching how best to approach future research.

"They have not produced a lot of research for us to really evaluate," said Elizabeth Jacobson, deputy director for devices and radiological health for the Food and Drug Administration, which has federal responsibility to monitor the group but has no real authority over it. "We would like to have seen results sooner."

Industry leaders said they also are frustrated by the slow pace of research.

"Clearly the industry is awaiting the results. And these results will, I hope, assuage concerns that have been raised," said John Marinho of Lucent

The Washington Post, April 06, 1997

Technologies Inc., one of the companies that has been steadily paying its dues to the group.

The head of the research group, George L. Carlo, said he has worked carefully during the past four years to build a foundation for definitive studies. "This is enormously important research," he said in an interview. "We're talking about the lives of millions of people and the livelihood of a major industry. This is not child's play."

Outside critics contend the industry has not played an entirely passive role as financier for Carlo's research agenda. They cite a leaked internal memo from Motorola Inc., which they say shows that the industry leader tried to coordinate strategy with the nominally independent research group. Motorola denies any attempt to interfere.

Through all of this, consumers worldwide have grown increasingly infatuated with wireless phones. There were 15 million people in the United States using cellphones in 1993. Today there are 45 million users, and the vast majority buy pocket phones, whose antennas are placed directly in the handset, next to the brain, rather than on a car roof. By 2002, half a billion people worldwide will be using wireless telephones, according to a District-based research firm, Strategis Group.

Mobilizing a PR Front

From the moment the Larry King episode was broadcast, the industry worked to defuse the public relations problem.

Motorola's head of cellular operations at the time, Edward Staiano, told reporters that "thousands" of studies showed there was no link between cellular phones and ill health effects. That was something of an overstatement: While studies on the health effects of radio waves were indeed common, the industry could not cite any studies in which cellular telephones specifically had been tested for their impact on human tissue or organs.

Within 10 days, Cellular Telecommunications Industry Association President Thomas Wheeler announced that a special "blue-ribbon" panel would be formed. Staffed by representatives from industry and government, it would oversee a newly invigorated research project.

In April 1993, the Scientific Advisory Group was born. One early plan was to have the effort overseen by the Food and Drug Administration and funded by industry. Instead, the industry opted to finance the research through the SAG, which would operate through a peer-review group run by the Harvard University Center for Risk Analysis.

"They thought about it and decided for their own reasons they didn't want to" have the FDA administer the program, Jacobson said. "We basically said, 'It's your money, you get to make the decision.' "

Wheeler hunted for someone to take charge of the program. He found Carlo, an epidemiologist who had previously worked as a consultant for the Chlorine Institute.

The Washington Post, April 06, 1997

Research Challenge

The effort to determine whether cellular telephones cause cancer, brain tumors or any illness is enormously complicated. Light bulbs, overhead power lines and the sun each produce radio or electromagnetic waves that hit our bodies. Sunburns -- or, in the most extreme case, microwaved pork chops -- show what can happen when the power level, intensity and duration of those waves is increased.

To be on the safe side, U.S. standards-setters set a rate for the amount of energy from a cell phone they would allow to be absorbed by the top part of a human body: 1.6 watts per kilogram of upper body tissue. Cellular phones generally transmit below that level, depending on their proximity to the nearest radio tower. (The closer they are to a tower, the less power they radiate.) This standard was set 50 times below the level at which any adverse health effects had been found.

It would seem, judging purely by those numbers, that cellular phones are like light bulbs -- they deliver far too weak a signal to cause any harm. But the problem is that nobody knows for sure -- a situation that trial lawyers are quick to point out.

"Every time you dial and put that thing up to your ear, you're zapping your brain," contends Robert Holstein, an attorney who represents Deborah Wright, an Arizona cellular sales representative who contends that her frequent use of pocket phones caused her chronic brain tumors. "Look," he said. "You can't use them on airplanes. You can't use them in hospitals. If they can cause interference with huge mechanical devices guarded by walls, of course they have an effect on human cell material."

But scientists aren't as certain as tort lawyers. There are endless variables that researchers must consider when assessing cellular phone health effects. They don't know whether 10 one-minute phone calls equal one 10-minute phone call; whether jewelry or wire-rimmed glasses play a role in either deflecting or directing radio waves; or whether it makes a difference if the antenna is up or down. And the density and power level of each call depends on a pocket phone's proximity to a cellular tower.

Add to that the myriad services and frequencies over which wireless phones operate, including traditional analog cellular phones and an array of new digital services. Then there are the satellite-based phone services coming soon, including the Motorola-funded Iridium project, in which signals will shoot from a pocket phone up to satellites hundreds of miles up in space.

Motorola executives say that decades of internal research have never produced any evidence that cellular telephones are harmful. They point to a 1993 study of death certificates of Motorola employees who died between 1985 and 1992, commissioned just after Reynard went on TV. The study found lower-than-average incidents of all causes of death, including all types of cancers. The company is continuing an aggressive research program, one that many observers say is more ambitious and productive than Carlo's industry-funded effort.

But that hasn't stopped the flow of post-Larry King lawsuits. There have been a dozen to date, six of which remain active.

The Washington Post, April 06, 1997

Getting Ready to Research

Carlo's Wireless Technology Research group has, so far, offered little evidence that those plaintiffs are right or wrong. In fact, the group has spent most of the past four years preparing for research, rather than conducting it.

The first 18 months of the program, Carlo said, were spent creating the world's first comprehensive volume of known data on the subject.

Along the way, the group decided to pursue a related question of whether cellular phones affect the operation of pacemakers. The resulting \$ 2 million study led to a finding: People should keep wireless phones at least six inches from pacemakers.

The WTR also has developed a database of about 250,000 cellular users, from which future researchers can monitor health effects.

Carlos agreed that "the big-ticket items, the big studies, have yet to be done," but he vigorously defends the pace and scope of the WTR research agenda. All told, about \$ 17 million has been spent creating what Carlo calls a Rolls-Royce-quality program, one that is now ready to roll up its sleeves and get to work doing actual animal research.

But others contend that more should have been done by now.

"Here we are four years after the fact and not a single test tube has gotten wet yet," said Louis Slesin, editor of Micro Wave News in New York and a sharp critic of the industry's research efforts.

How Independent?

Slesin tweaked the industry earlier this year when he published, in full, a leaked internal Motorola memo dated Dec. 13, 1994.

In it, a Motorola public relations official laid out a media strategy to counter a new study by Henry Lai and Narendra Singh. The two well-regarded University of Washington researchers were about to report finding an increase in damage to DNA in the brain cells of rats after a single two-hour exposure to radio frequencies (at 2.45 gigahertz, where microwave ovens operate) at 1.2 watts per kilogram -- a level considered safe, according to current standards.

In the memo, Motorola spokesman Norman Sandler proposed a way to craft a "statement that puts a damper on speculation arising from this research, as best we can." At the end of the memo, Sandler writes that "I think we have sufficiently war-gamed the Lai-Singh issue, assuming SAG [Carlo's group] and CTIA [the industry trade group] have done their homework. We may want to run this by George Carlo and fill him in on the contacts we've made."

To critics, Motorola appeared to be planning a media campaign to debunk perhaps the most important -- and potentially damaging -- research to emerge in the field. The memo also implied that Motorola felt it should coordinate its media plans with Carlo, who in theory was supposed to be free of influence from the industry.

The Washington Post, April 06, 1997

In an interview last week, Sandler denied that the industry was synchronizing its response with Carlo. He said Motorola merely wanted to "apprise" WTR of the issue, not coordinate with it or dictate to it. "Carlo needed to decide what they were going to do about the Lai-Singh research," he said.

Interviewed in his Seattle laboratory, Lai contended that CTIA, Motorola and Carlo's group had a coordinated agenda to suppress his research.

"It's very common, isn't it? They're just trying to protect their products. If any data that comes out harmful to them, it's a normal reaction," Lai said. He also said Carlo's group "attacked" his data in a panel discussion to which neither he nor Singh was invited.

Carlo defended WTR's treatment of the Lai-Singh study, saying that while the group is "taking it very seriously," the scientists had used techniques that were not commonly accepted.

"People over-interpreted their data," he said. Carlo called Lai a "good researcher" and said WTR agreed several months ago to fund a second proposal submitted by Lai and Singh.

The incident was not the only time questions have been raised about the industry's involvement in the WTR's research agenda.

The FDA's Jacobson admonished Wheeler, the head of the cellular trade group, in a July 1993 letter for making statements to reporters that she said displayed "an unwarranted confidence that these products will be found to be absolutely safe."

She said the public might "wonder how impartial the research can be when its stated goal is a determination to reassure consumers, and when the research sponsors predict in advance that "we expect the new research to reach the same conclusion, that cellular phones are safe."

Wheeler rejects Jacobson's concern: "I don't see how me opining that I don't think there is a [health] issue, and that consumers should be reassured, that it's something that can be translated into me directing WTR," he said.

Money Troubles

Sitting in the WTR boardroom in an old town house near Dupont Circle, Carlo described a new animal research method that, he hopes, may finally lead to some answers.

But this study hasn't yet begun, in part because of funding problems at Carlo's group.

The scientist who is developing this method, C.K. Chou, director of radiation research at City of Hope Medical Center in Duarte, Calif., said he hasn't received any money from Carlo in about four months.

"We can't even boil a pot of water," Chou said. "If this was government money, we trust the government; it has a track record. They sign an agreement and pay you. But when you're dealing with an industry, City of Hope has a policy: Pay first, then we work."

The Washington Post, April 06, 1997

The money trouble began in January, when Wheeler withheld WTR's funding because of a dispute about whether the industry should have to pay \$ 700,000 in WTR legal bills. Carlo and other scientists had racked up these fees in defending themselves against personal-injury lawsuits such as the one highlighted on the Larry King show.

Given the lack of money, "we had no choice" but to stop progress on research, Carlo said. "We couldn't put scientists at risk. It made no sense for us to bear that cost."

Both men now say they have worked things out, and on Friday they issued new agreements that would give WTR steadier funding in its fifth, and probably final, year and give scientists protection from lawsuits.

GRAPHIC: Photo, randy mays for The Washington Post; Photo, wireless technology research llc; Chart, The Washington Post, GEORGE L. CARLO From the "Safety" section of a manual for one of Motorola's cellular phones. GREATER FREQUENCY (This chart was not available)

LANGUAGE: ENGLISH

LOAD-DATE: April 06, 1997



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Executive Plaza North EPN/543
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Bethesda MD 20892-7399

April 4, 1997

Ms. Elizabeth Drye
Domestic Policy Council
Old Executive Office Building
Room 213 ½
The White House
Washington, DC 20502

Dear Ms. Drye:

As I mentioned by telephone, I am enclosing a review paper on the causes of brain tumors by our NCI group involved in the case-control study of brain tumors. Under separate cover I am sending you two books, one dealing with cancer epidemiology and one with time trends in cancer, both of which have chapters devoted to brain tumors.

I hope this information is helpful to you.

Sincerely,

A handwritten signature in black ink, reading "Joseph F. Fraumeni, Jr.", is written over a large, stylized capital "J".

Joseph F. Fraumeni, Jr., M.D.
Director
Division of Cancer Epidemiology and Genetics
National Cancer Institute

Enclosure

cc: Dr. Klausner

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Etiology of Brain Tumors in Adults

Peter D. Inskip,^{1,2} Martha S. Linet,¹ and Ellen F. Heineman¹

INTRODUCTION

Brain cancer is among the more lethal of adult cancers (1-year relative survival, 52 percent) (1), and there is concern that incidence *might* be increasing. Whether incidence rates have, in fact, increased is a fundamental but still unresolved and controversial issue (2–9). Upward trends might reflect improvements in the diagnosis of brain tumors rather than real changes in the underlying rate. In either case, the etiology of this deadly and debilitating disease, or group of diseases, remains largely unknown.

Both genetic and environmental factors have been implicated in the pathogenesis of brain tumors, though only changes in exposure to environmental agents could account for a measurable change in incidence rates on the time-scale of decades. The list of putative environmental determinants is long and diverse, encompassing physical, chemical, and biologic agents, but few have been convincingly linked to brain tumors. Known risk factors, such as radiotherapy to the head during childhood and hereditary predisposing conditions, are quite uncommon and explain only a small percentage of brain tumor cases. Even the relative importance of extrinsic, or environmental, factors versus intrinsic, or constitutional, determinants is unclear. Against this backdrop of poorly understood etiology and possibly rising incidence rates has arisen concern that exposure to electromagnetic fields, food additives, and synthetic organic chemicals might cause brain tumors (4, 5, 10).

In this paper we review the epidemiology of brain tumors occurring in adults, focusing on glioma, and

consider childhood brain tumors only in the context of possible risk factors for neuroepithelial tumors in adults. Childhood brain tumors differ from adult tumors in terms of histology, anatomic site, the commonly associated chromosomal aberrations and point mutations, and the relevant time periods, developmental phases, and circumstances of exposure (11–13). The etiology of childhood brain tumors was the subject of a recent review (12).

We begin with a discussion of brain tumor classification and then briefly consider descriptive epidemiology, results from animal studies, and the role of the blood-brain barrier, with a view to possible clues about etiology. Next, we review the evidence concerning specific environmental and host factors, including inherited predisposition. We include a summary of recent findings concerning the cytogenetics and molecular biology of brain tumors, which suggest the existence of multiple genetic pathways even among histopathologically indistinguishable tumors. In closing, we attempt to identify promising leads for future epidemiologic studies.

CLASSIFICATION OF BRAIN TUMORS

The majority of malignant brain tumors in adults are gliomas (11) which are composed of neuroglial cells, the cells that surround and support neurons. Different subtypes of glioma are recognized depending on the resemblance of tumor cells to a particular glial cell type, including astrocytoma (astrocyte), oligodendroglioma (oligodendrocyte), and ependymoma (ependymal cell) (14, 15). Papillomas and carcinomas of the choroid plexus also sometimes are grouped with gliomas (15). Tumor cell type is often presumed to indicate the cell of origin (16), although intervening metaplastic or anaplastic change may alter the phenotype from that of the initial transformed cell (17, 18).

Astrocytic tumors, including astrocytomas and glioblastomas, account for a large majority of gliomas in adults (11). They are heterogeneous in morphology, biologic behavior, and clinical course, ranging from relatively slow-growing and noninfiltrating benign forms (pilocytic astrocytoma or subependymal giant cell astrocytoma) to an extremely anaplastic and ag-

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Abbreviations: ICD9, *International Classification of Diseases*, Ninth Revision; MDM2, murine double minute 2; NOS, not otherwise specified; SEER, Surveillance, Epidemiology and End Results; SV40, simian virus 40.

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Don Gips

- Tuesday -

~~CDC Mike Evilsen - 770-488-5701~~

~~NIE Mark Morley - 301-496-8584~~

biological changes - don't translate into
health effects. ^{DNA} - changes in cell movement
across membranes
- DNA breakage, -

NIEHS - EMF research, but on
different frequency, -

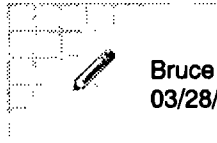
gov GAO study -

- Morley, -

- Consumer outreach

- Congressional

- Liability



Bruce N. Reed
03/28/97 03:07:18 PM

Record Type: Record

To: Elizabeth Drye/OPD/EOP
cc: Christopher C. Jennings/OPD/EOP
Subject: Cell phones and cancer

The President asked if we could look into the issue of any possible links between cell phone use and brain cancer. He's had a number of friends die from brain cancer lately, and wonders if there's some connection. He wants to work with the VP on this.

I remember a study that came out in 92 suggesting a possible link -- and I remember the VP saying he believed it. Can you find out what the current scientific view is?