Expanding the Wireless Frontier



Testimony of Gerard Keegan CTIA – THE WIRELESS ASSOCIATION® In Opposition to Maine LD 1013

May 2, 2013

Before the Maine Joint Standing Committee on Energy, Utilities, and Technology

Chairman Cleveland, Chairman Hobbins, and members of the committee, on behalf of CTIA-The Wireless Association®, the trade association for the wireless communications industry, I am here in opposition to Maine LD 1013, which would require cell phone manufacturers to place warning labels on cell phones and force cell phone retailers to issue warning disclosures at the point-of-sale. CTIA believes this legislation is unnecessary, inconsistent with the Food and Drug Administration's conclusion that "[t]he scientific evidence does not show a danger to any users of cell phones from RF exposure, including children and teenagers,"¹ and conflicts with federal law.

CTIA is not an expert scientific body, and I'm not a scientist. That's why, in addressing this issue, we consistently look to the impartial expert agencies for guidance. We start with the Federal Communications Commission (FCC), which Congress has tasked with establishing standards that safeguard the health of wireless users. The FCC, after consultation with the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), and the National Institute for Occupational Safety and Health (NIOSH), has adopted standards governing radiofrequency (RF) energy from cell phones and determined that all cell phones that comply with those standards are safe for use by the general public. The FCC asserted that its standards represent the "best scientific thought and are sufficient to protect the public health."² No

¹ See Children and Cell Phones, available at http://www.fda.gov/Radiation-

EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/CellPhones/ucm116331.htm (last visited May 1, 2013).

² The FCC has explained that its RF testing, certification, and emissions standards "protect the public health with respect to RF radiation from [all] FCC-regulated transmitters," including wireless phones. In re Guidelines for Evaluating the Environmental Effects of Radiofrequency Radiation, Release No. 96-326, 11 F.C.C.R. 15123, 15184 ¶ 169 (1996) ("FCC First Order").

wireless device may be offered for sale or lease in the United States unless the cell phone has been authorized in accordance with the FCC's RF regulations. The FCC states that "[a]ny cell phone at or below these SAR levels (that is, any phone legally sold in the U.S.) is a 'safe' phone, as measured by these standards."³ In addition, the Federal Radiofrequency Interagency Work Group, composed of representatives from FCC, FDA, EPA, NIOSH, OSHA, and National Telecommunications and Information Administration, continues to monitor the medical literature in this area to ensure the FCC standards remain appropriate.⁴

The FCC has expressly evaluated the potential thermal and non-thermal biological effects of RF from FCC-licensed devices. In fact, the FCC in its 1997 RF Order, addressed a series of proposals calling for lower RF exposure limits than those originally adopted by it based on the alleged non-thermal effects of RF emissions, and specifically declined to adopt those proposals.⁵ The FCC's decision not to change its RF standards based on alleged non-thermal effects of RF has been upheld, repeatedly, by federal courts on appeal. In the Cellular Phone Taskforce case, the Second Circuit Court of Appeals specifically rejected the argument that the FCC's standards did not account for "non-thermal effects."⁶ In the EMR Network case, the D.C. Circuit upheld the FCC's decision not to initiate a proceeding to revise its RF regulations.⁷ In fact, the D.C. Circuit found "nothing" in the studies referenced by the petitioners that would have required the FCC to revisit its rules based on alleged non-thermal effects.⁸

On March 29, 2013, the FCC released a Notice of Inquiry (NOI) seeking "to determine whether there is a need for reassessment of the Commission's radiofrequency (RF) exposure limits and policies."9

³ See "Cellular Telephone Specific Absorption Rate (SAR)," available at http://www.fcc.gov/cgb/sar/ (last visited May 1, 2013).

⁴ See Cell Phones, available at: http://www.fda.gov/Radiation-

EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/CellPhones/default.htm (last visited May 1, 2013).

⁵ See In re Guidelines for Evaluating the Environmental Effects of Radiofrequency Radiation, 12 F.C.C.R. 13494, at 13503-06 (¶ 25, ¶ 26, ¶ 28, ¶ 31) (1997). ° Cellular Phone Taskforce v. FCC, 205 F.3d 82, 90 (2d Cir. 2000).

⁷ EMR Network v. FCC, 391 F.3d 269 (D.C. Cir. 2005).

⁸ Id. at 274.

⁹ Reassessment of Federal Communications Commission Radiofrequency Exposure Limits and Policies, Notice of Inquiry, FCC 13-39 (rel Mar. 29, 2013) ("NOI")

In its NOI, the FCC notes that it continues "to have confidence in the current exposure limits"¹⁰ The FCC further notes in its NOI that "[a]s an initial matter, while there has been increasing public discussion about the safety of wireless devices, to date organizations with expertise in the health field such as the FDA have not suggested that there is a basis for changing our standards or similar standards applied in other parts of the world."¹¹ Furthermore, the Commission states in the NOI that its current RF exposure guidelines include a 50 fold safety factor and that this "safety factor can well accommodate a variety of variables such as different physical characteristics and individual sensitivities - and even the potential for exposures to occur in excess of our limits without posing a health hazard to humans."¹²

Leading national and international health and safety organizations have concluded that there are no known adverse health risks associated with the use of wireless devices. In fact, the FDA concludes that, "[t]he scientific evidence does not show a danger to any users of cell phones from RF exposure, including children and teenagers."¹³ Additionally, the FCC advises in its consumer fact sheet on the issue of wireless devices and health concerns that, "[s]ome health and safety interest groups have interpreted certain reports to suggest that wireless device use may be linked to cancer and other illnesses, posing potentially greater risks for children than adults. While these assertions have gained increased public attention, currently no scientific evidence establishes a causal link between wireless device use and cancer or other illnesses."¹⁴ Moreover, in its June 2011 factsheet on this issue, the World Health Organization advises that, "[a] large number of studies have been performed over the last two decades to assess whether

¹⁰ *NOI* at ¶ 205.

¹¹ *NOI* at ¶ 219.

¹² *NOI* at ¶ 236.

¹³ See Children and Cell Phones, available at http://www.fda.gov/Radiation-

EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/CellPhones/ucm116331.htm (last visited May 1, 2013).

¹⁴ See Wireless Devices and Health Concerns, available at <u>http://www.fcc.gov/cgb/consumerfacts/mobilephone.html</u> (last visited May 1, 2013).

mobile phones pose a potential health risk. To date, no adverse health effects have been established as being caused by mobile phone use."¹⁵

The bill's labeling mandate on cell phones is intended to serve as a consumer product warning. This Legislature considered and rejected similar proposed warning label bills in 2010 and 2011. In testifying against the bill in 2010, then-director of the Maine Center for Disease Control and Prevention, Dr. Dora Anne Mills summarized it best when she advised this Legislature that "to warn against something, there should be a defined risk. Our [Maine CDC and Department of Health and Human Services] reading of the research, including numerous studies and analyses, does not indicate there is a defined cancer risk to warn against."¹⁶ Moreover, Dr. Mills explained that issuing warnings based on undefined risks would result in an "over-warned and turned-off public as well as a lack of credibility in the warnings themselves."¹⁷ As the Maine CDC found, mandating cell phone warnings is unnecessary and would result in consumers doubting the efficacy of warnings generally, thereby lessening the impact of warnings on other consumer products where they serve to protect consumers from defined risks and true harm.

LD 1013 contradicts the clear message of the federal regulatory agencies that have carefully considered this issue, which is that devices compliant with the federal standards are safe for consumer use. As such it simply does not meet the fundamental purpose of consumer product information: to better inform the consumer about the product. Instead, it constitutes a contradiction to established RF safety levels and, more specifically, challenges the efficacy of the U.S. government's determinations of the safety of wireless products. Such a result will not benefit consumers.

The FCC's March 2013 NOI dispels many misconceptions about RF safety - many that have been repeated in this Legislature's hearing rooms. For example, in the NOI the Commission notes that

¹⁵ See Electromagnetic fields and public health: mobile phones, available at

http://www.who.int/mediacentre/factsheets/fs193/en/index.html (last visited May 1, 2013). ¹⁶ Testimony of Dora Anne Mills, M.D., Ph.D., Director, Maine Center for Disease Control and Prevention, in Opposition to Maine LD 1706, Cell Phone Warning Label Legislation, 03/02/2010 at page 1.

¹⁷ Id at page 4.

"exceeding the SAR limit does not necessarily imply unsafe operation, nor do lower SAR quantities imply 'safer' operation. The limits were set with a large safety factor, to be well below a threshold for unacceptable rises in temperature. As a result, exposure well above the specified SAR limit should not create an unsafe condition."¹⁸ The FCC goes to further state that "[w]e also take this opportunity to clarify a misconception, apparently held by some in the public, of our policy dealing with separation distance between portable devices and the body. Some cell phone users apparently believe that certain devices need to be kept at least a specified distance (up to 2.5 cm) from the head during normal use to ensure compliance with our SAR limits. Such a requirement does not exist and would clearly be impractical."¹⁹ Moreover, the FCC notes that a consumer "use that possibly results in non-compliance with the SAR limit should not be viewed with significantly greater concern than compliant use."²⁰

Finally, any attempt by state governments to regulate cell phone labeling based on alleged safety concerns is preempted by federal law. The federal government's exclusive jurisdiction over radio communications is predicated on a finding that national regulation is not only appropriate, but it is essential to the operation of a seamless, interstate telecommunications network because radio waves operate without regard to any state lines. In light of the federal government's primacy over wireless communications in general and RF in particular, state government authority to regulate in this area is severely constrained.

In addition, under the standard established by the United States Supreme Court in Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626 (1986), any governmentally compelled disclosures to consumers must be "purely factual and uncontroversial." By way of example, after the City of San Francisco adopted a cell phone-related labeling and disclosure ordinance in 2011, CTIA challenged the City arguing that the ordinance abridged cell phone retailers First Amendment rights. In September 2012, a three judge panel of U.S. Court of Appeals for the Ninth Circuit ruled in CTIA's favor, finding that the

¹⁸ *NOI* at ¶ 251.

¹⁹ *NOI* at Note 447.

²⁰ *NOI* at 251.

FCC has concluded that cell phones are safe and the ordinance's requirements were misleading.²¹ Accordingly, the court permanently enjoined the City from enforcing its ordinance. The 9th Circuit subsequently rejected San Francisco's petition for rehearing. CTIA and San Francisco have entered into a settlement agreement that would permanently bar the City from enforcing its cell phone labeling and disclosure ordinance.

In closing, LD 1013 is unnecessary, inconsistent with the FDA's conclusion that "[t]he scientific evidence does not show a danger to any users of cell phones from RF exposure, including children and teenagers," and conflicts with federal law. Accordingly, we urge the Committee to give this bill a unanimous "Ought Not to Pass" report. Thank you for your time.

²¹ CTIA v. City and County of San Francisco, 9th Cir. Nos. 11-77707, 11-7773.

Written Statement of Dr. Howard Ory Submitted in Opposition to the Proposed Children's Wireless Protection Act – LD 1013 May 2, 2013

Introduction

Members of the Committee, my name is Dr. Howard Ory, I am a physician specializing in epidemiology, and I submit this statement on behalf of the wireless industry to address the proposed Children's Wireless Protection Act – LD 1013.

By way of background, I received my MD degree from Tufts University Medical School in 1969 and joined the U.S. Centers for Disease Control (CDC) in 1971. I worked at the CDC as a practicing epidemiologist for twenty-three years until my retirement in 1994. While at the CDC, I held various management positions, including Deputy Director for Epidemiology. I have consulted on numerous public health issues for the CDC, as well as other public health agencies such as the World Health Organization and the Food and Drug Administration. I have published more than 100 scientific articles in peer-reviewed publications on a wide range of subjects. If you would like any additional information about my background, my resume is attached for your convenience.

Summary of Testimony

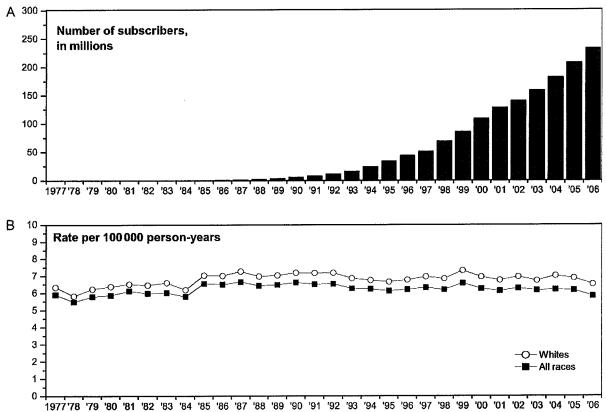
In my opinion, the proposed legislation is unnecessary. To the extent the proposed legislation is motivated by concerns that wireless phone use can cause cancer and that children, in particular, face an increased risk of cancer from cell phone use, the proposed legislation finds no support in the available scientific evidence.

There has not been an increase in the incidence of brain cancer and other nervous system tumors following the introduction of wireless phones.

Brain cancer and other nervous system tumors (which I will refer to collectively as "brain cancer") occurred long before the introduction of wireless phones and would continue to occur even if people no longer used wireless phones. In other words, there is a natural incidence of brain cancer in the population, which includes people who use wireless phones. If, as some people speculate, wireless phone use causes brain cancer, then we would expect to see an increase in the incidence of brain cancer coincident with the use of wireless phones. We have not seen any such increase.

The U.S., like many other countries, has tracked the incidence of brain cancer for many years. These data are collected by the NCI and the CDC and are considered representative of the entire United States. In the U.S., the incidence of brain cancer has not increased since at least 1992. This is demonstrated in the charts below, which are taken from a recent NCI study. This study states, "[d]uring the period of use when mobile phones was increasing sharply, the overall incidence of brain cancer changed little." The NCI report concludes, "Overall, these incidence data from the United States based on high quality cancer registries do not provide support for the view that use of cellular phones causes brain cancer."¹

¹ Inskip, Hoover and Devesa. Neuro Oncol. 2010 Nov;12(11):1147-51.



Year

Recently, in their annual report to the nation on the status of cancer, which had a special focus on brain cancer, the NCI noted that "[a]n important finding of the current analysis is the relative stability of the long-term incidence trends of malignant tumors of the neuroepithelial tissue. During the 27 year (1980–2007) time period studied, an increase of 1.9% per year during 1980 - 1987 was counterbalanced by a decrease of 0.4% per year during the remaining 20 years, resulting in nearly identical incidence rates at the beginning and end of the study."² Later in the same report, the authors note "the relatively low variation in incidence and death rates for cancer of the brain and [other nervous system] tumors nationally and internationally suggests that environmental risk factors do not play a major role in this disease." In early 2013, the NCI published another annual report to the nation on the status of cancer and extended the observation period through 2009; brain cancer incidence remains stable through 2009 in the US.³

Latency

In the U.S. alone, there were almost 40 million users of wireless phones by 1996, almost 80 million by 1999 and by 2012 there were over 300 million subscriptions, essentially one for every American. Even given the latency of brain tumors, by which I mean the time it takes to develop a tumor, the NCI notes that there has been "sufficient time" for an increased incidence of brain

² Kohler, et al. J Natl Cancer Inst. 2011 May 4;103(9):714-36.

³ Jemal, et al. J Natl Cancer Inst. 2013(3):175-201, see tables 1 and 3.

tumors caused by cell phones to begin to be detected in these surveillance data.⁴ Again, however, we do not see any such increase.

Time trend data from other countries strongly reinforce the conclusion that in spite of sufficient time having elapsed, there has been no rise in brain tumor incidence. While cell phone use in those countries began earlier than in the U.S. and has risen at least as dramatically as in the U.S., brain cancer incidence rates have not changed as cell phone use has increased.⁵ The NCI agrees and states in its recent fact sheet "NCI's Surveillance, Epidemiology and End Results (SEER) Program, which tracks cancer incidence in the United States over time, found no increase in the incidence of brain or other central nervous system cancers between 1987 and 2007, despite the dramatic increase in cell phone use in this country during that time (18, 19). Similarly, incidence data from Denmark, Finland, Norway, and Sweden for the period 1974–2008 revealed no increase in age-adjusted incidence of brain tumors (20, 21)."⁶

The most recent Deltour study (2012) addresses the latency issue extensively. They note: "We detected no upward turn in the time trends of glioma incidence rates in the Nordic countries during 1979-2008, overall or in any subgroup by country, age, or sex among adults.... These analyses are based on the entire adult population of Denmark, Finland, Norway, and Sweden (17 million people) and are strengthened by the comprehensive high-quality cancer registration in these countries.... If mobile phone use causes brain tumors, the change in prevalence of use from 0 to nearly 100% over a 20-year period would eventually influence the incidence rates of these tumors. Conversely, a lack of change in the incidence time trends, at any point in time, would constitute evidence against this association.... Our data indicate that, so far, no risk associated with mobile phone use has manifested in adult glioma incidence trends...."

Researchers from the NCI published again on this issue in 2012.⁷ Using SEER (i.e., brain cancer registry) data in the United States between 1992 and 2008, they showed that the purported high relative risks reported in some of the epidemiologic literature are inconsistent with the actual pattern of use of cell phones and glioma incidence in the United States. Specifically, they state, "the results of [our] study suggest that, if the effects of mobile phones on malignant glioma risk are substantial, then the incidence rates in the US population would be far higher than those observed over most of the study period in 1992–2008 (fig 2)."⁸ Basically, they conclude that any increase in glioma risk beyond about 3 to 7% would be detectable in current US cancer incidence data.

Since 1999, the US CDC has joined forces with the NCI to establish nearly 100% complete surveillance of cancer in the United States. This system is called the United States Cancer Statistics (USCS). Brain cancer incidence rates from this data system are available from the CDC website from 1999 through 2009. This data is shown in the attached table. Age-adjusted

⁴ Inskip, et. al., op. cit.

⁵ Deltour et al. J Natl Cancer Inst. 2009; 101:1-4; Roosli et al. European Journal of Cancer Prevention 2007; 16:77-82; de Vocht et al. <u>Bioelectromagnetics</u>. 2011 Jul;32(5):334-9; Aydin et al. J Natl Cancer Inst. 2011; 103(16):1264-76; Schmidt et al. <u>Pediatr Blood Cancer</u>. 2011 Jan;56(1):65-9; Ahlbom et al. BMJ 2011; 343:d6605; Deltour et. al. Epidemiology 2012; 23: (epub Jan 12 ahead of print).

⁶ National Cancer Institute Fact Sheet. Reviewed 6/18/2012, downloaded 4/25/13.

http://www.cancer.gov/cancertopics/factsheet/Risk/cellphones

⁷ Little, MP et. al. BMJ. 2012;344:e1147.

⁸ Little, MP, et. al., op.cit.

brain cancer incidence falls steadily from 1999 through 2009, from 7.38 per hundred thousand to just below 7 per hundred thousand in 2009.

It should be clear to the lay observer that these data, based on well over 90% of all brain cancers that have occurred in the United States in this time period, are dramatically inconsistent with the hypothesis that cell phones cause brain cancer. After all, given that nearly every person in the US now uses a cell phone, and that these data identify and count nearly every brain cancer that occurs in the US, it's perfectly obvious that if an excess risk of brain cancer was caused by cell phones it would have to show up in this data. The lack of any indication that such is the case means that cell phones have not been shown to cause brain cancer.

Given that nearly 80 million Americans were cell phone users in 1999, they have had more than 10 years' latency to develop brain cancer. If, as the Swedish data suggest, 10 years of latency carries with it a substantially elevated, 2.5 fold risk of brain cancer⁹, at least 80 million American cell phone users have had sufficient time for this risk to manifest itself. Again, the USCS data at the back of this report are inconsistent with such an elevated risk.

Time Trend Data in Children and Adolescents

While the above chart and data from other countries refer to all age groups combined, these studies have also looked specifically at children and adolescents under the age of 20 years. The results are similarly reassuring. In the US, Norway, Finland, Sweden, and England these studies report stable time trends in the incidence of brain tumors in these countries in people under 20 years of age. As the authors of the most recent time-trend study conclude about time trend data relating to those under 20 years of age: "These data are in line with our evaluation of time trends of brain tumor incidence in Sweden and altogether provide little support to the view that mobile phone use increases the risk of brain tumors."¹⁰ In fact, there is now strong, affirmative evidence from time trend data that through 2008 in the U.S. and 2009 in Sweden cell phones have not caused an increase in brain cancer in people less than 20 years of age. Given that trends in brain cancer have remained stable in young people, it is tautological that there has been no increase in brain cancer in young people that could have been caused by cell phones.

Mechanism

There is no known mechanism by which wireless phones could cause cancer.¹¹ Wireless phones emit a form of radiofrequency energy that is part of the electromagnetic spectrum. This energy is called non-ionizing radiation. People use many things that emit non-ionizing radiation, including televisions, radios, baby monitors, and cordless phones. The use of the term "radiation" in connection with the energy from wireless phones can cause confusion and fear. Non-ionizing radiation is different from what people commonly think of as "radiation." An x-ray is a good example of an exposure people think of when "radiation" is mentioned. An x-ray is one of the common forms of ionizing radiation. Non-ionizing radiation and ionizing radiation are quite different. Ionizing radiation, such as an x-ray, has the ability to damage DNA in human

⁹ Carlberg M, Hardell L. Pathophysiology. 2012 Sep;19(4):243-52. doi: 10.1016/j.pathophys.2012.07.001. Epub 2012 Aug 28.

¹⁰ Aydin et al, op. cit.

¹¹ Boice and Tarone. J Natl Cancer Inst. 2011 Aug 17;103(16):1211-3; Repacholi, et. al. Bioelectromagnetics. 2011 Oct 21. doi: 10.1002/bem.20716. [Epub ahead of print]

cells and therefore, can cause cancer at high doses. By contrast, non-ionizing radiation from a wireless phone lacks the ability to damage DNA.¹²¹³ Therefore, there is no reason to believe that wireless phone use could cause cancer.

A prominent researcher in this area discusses the lack of support for any known mechanism this way: "In summary, the results of the *in vitro* [i.e., whole animal] studies are consistent with the results of the mechanistic [i.e., laboratory] studies, and despite extensive research that have failed to establish any relationship between exposure to RF fields and cancer. No clear pattern of evidence identifying a non-thermal mechanism that could underlie any adverse health effects of RF exposure has been identified."¹⁴

Despite the lack of any basis to suspect that wireless phone use could cause cancer, this issue has been studied scientifically for years. The two types of studies that provide the most information are studies in humans and studies in animals.

Epidemiology – Studies in Humans

Epidemiology is the study of causes of disease in human populations. There have been multiple epidemiologic studies of wireless phones and brain cancer. These studies have been conducted in different countries, have used varying methods and cover the time period in which wireless phones have been in use. A review of the overall results of these studies demonstrates the lack of evidence for a causal relationship between wireless phone use and brain cancer.

Conclusions about causation cannot be based on any one particular study; they should be based on the data as a whole. When drawing conclusions from scientific data, scientists look for consistency in the results across studies. One technique used to evaluate multiple epidemiologic studies is called meta-analysis. Meta-analysis is a statistical technique that combines data from multiple studies in order to assess any potential association between the exposure and the disease (here, between wireless phones and brain cancer). In addition, this method identifies which studies are inconsistent with the overall result from the combined data.

In September 2009, the International Committee for Non-ionizing Radiation Protection (ICNIRP) published a meta-analysis of all existing studies of wireless phone use and tumor risk.¹⁵ ICNIRP's review included the published studies that have been conducted as part of the thirteen-country INTERPHONE study being coordinated by the World Health Organization as well as studies conducted by Dr. Hardell's group in Sweden. ICNIRP concluded that there was no overall association between wireless phone use and brain cancer, and this result was true even in people who had used a phone for more than ten years. ICNIRP identified only one outlier – the pooled analysis of the studies conducted by Dr. Hardell.

In July of 2011, after the publication of the full INTERPHONE study, ICNIRP reviewed the issue of cell phones and brain cancer again and concluded, "Although there remains some uncertainty, the trend in the accumulating evidence is increasingly against the hypothesis that

¹² National Cancer Institute Fact Sheet. Op. Cit.

¹³ Boice, op. cit.

¹⁴ Repacholi, et. al. Bioelectromagnetics. 2011 Oct 21. doi: 10.1002/bem.20716. [Epub ahead of print]

¹⁵ Ahlbom et al. Epidemiology 2009;20:639-52.

mobile phone use can cause brain tumours in adults."¹⁶ ICNIRP noted that time trend data "can give powerful evidence constraining what can reasonably be proposed as an etiological relationship." They reviewed the same time trend data that I presented above and noted these data "showed no indication of increases in brain tumour incidence in relation to the introduction and growing use of mobile phones, up to 20 years after their introduction and 10 years after their use became widespread." Finally, ICNIRP noted that recent studies dealing with exact location of the brain tumor, "which one would expect to give the most rigorous analysis since it has greater precision without bias, does not support a causal association."

At the end of 2011, a prospective Danish study that included information on 3.8 million personyears of follow-up was published; this study finds no increased risk of brain tumors even after 13 years since beginning cell phone use. While the Danish cohort study, like all epidemiologic studies, has limitations, it is consistent with the time trend data, showing no association of cell phone use and brain cancer over a long time period.

The elevated risks shown in some case-control studies are incompatible with Deltour's (2012) incidence trend findings, discussed earlier. Deltour notes that the many of the elevated risks found in some case-control studies "are implausible, implying that biases and errors in the self-reported use of mobile phone have likely distorted the findings." The NCI Fact Sheet concurs, stating " [a] 2012 study by NCI researchers, which compared observed glioma rates in SEER with projected rates based on risks observed in the Interphone study, found that the projected rates were consistent with observed US rates. The researchers also compared the SEER rates with projected rates based on a Swedish study [Hardell] published in 2011. They determined that the projected rates were at least 40% higher than, and incompatible with, the actual US rates."¹⁷ In other words, the NCI is saying that SEER data showing no increase in brain cancer is inconsistent with elevated risks of brain cancer shown in Hardell's epidemiologic data.

Epidemiology in children and adolescents and pregnant women

The proposed "Children's Wireless Protection Act" suggests that children, in particular, face an increased risk of cancer from cell phone use.

However, the one published epidemiologic study of cell phone use and brain cancer among children and adolescents, "In summary, we did not observe that regular use of a mobile phone increased the risk for brain tumors in children and adolescents."¹⁸

There is also one published study examining the effect on neural development of prenatal exposure to cell phone use. The study concludes, "This study gives little evidence for an adverse effect of maternal cell phone use during pregnancy on the early neurodevelopment of offspring."¹⁹

Animal (or, In Vitro) Data

¹⁶ Swerdlow et al. <u>http://dx.doi.org/10.1289/ehp.1103693</u>, published online July 1, 2011

¹⁷ National Cancer Institute Fact Sheet. Op. Cit.

¹⁸ Aydin, op. cit.

¹⁹ Vrijheid M, et.al. Epidemiology 2010; 21:259-262.

The human epidemiology provides the most information about the effect of wireless phone use on humans. However, animal studies can provide useful information because they permit controlled exposure conditions. Scientists have conducted multiple studies exposing animals to high doses of RF for the life of the animals – that is, while *in utero*, and then from birth to death. Overwhelmingly, these studies do not report an association between wireless phone exposure and cancer, (including tumor initiation, promotion or genotoxicity) even under these extreme exposure conditions. The results of these studies are consistent with those of the time-trend and epidemiologic studies on children and pregnant women that I discussed earlier.

The International Agency for Research on Cancer (IARC) classification of cell phones as showing limited evidence of carcinogenicity

The proposed legislation requires that consumers be provided with a bulletin advising that The World Health Organization (WHO) and IARC classified RF emissions from cell phones as "possibly carcinogenic." However, IARC's classification must be considered in context.

It should first be noted that WHO, IARC's parent organization, noted in the press release accompanying IARC's "possibly carcinogenic" classification that "[a] large number of studies have been performed over the last two decades to assess whether mobile phones pose a potential health risk. To date, no adverse health effects have been established as being caused by mobile phone use."

A recent article by John Boice, a widely respected expert in this field, explains how this IARC classification can be misleading if considered out of context.²⁰ After reviewing the body of research on potential health effects of cell phone RF emissions, Dr. Boice concluded:

Amid this encouraging evidence from human observational studies, coupled with the negative findings from virtually all experimental animal and in vitro studies and the absence of any known biologic mechanism by which weak nonionizing radio waves emitted from cell phones could damage DNA and lead to cancer, it may therefore seem surprising that a monograph committee of the [IARC], an agency of the WHO, recently announced that cell phones may be "possibly carcinogenic to humans". The change from [a prior classification of] "no conclusive evidence" to "possibly carcinogenic" was not new research, and it has understandably led to widespread public as well as media concern and confusion. The footnote accompanying the [IARC] press release [announcing the classification] is often missed – that a "possibly carcinogenic to humans" (2B) classification is based on "limited evidence of carcinogenicity" and that "chance, bias, or confounding could not be ruled out with reasonable confidence" for the few positive associations reported in the literature. A published summary of the IARC working group conclusions noted that some members found the epidemiologic evidence to be inadequate to support the 2B classification. Viewed in this context, "possibly carcinogenic" is not a signal to abandon mobile phones and return the landline phones. Rather it is a signal that there is very little scientific evidence as to the carcinogenicity of cell phone use.

Dr. Boice's assessment is similar to the recent assessment by ICNIRP that I have reported above.

²⁰ Boice, op.cit.

Following the IARC classification, the NCI reiterated its conclusion that "although there have been some concerns that radiofrequency energy from cell phones held closely to the head may affect the brain and other tissues, to date there is no evidence from studies of cells, animals, or humans that radiofrequency energy can cause cancer." The NCI added, "It is generally accepted that damage to DNA is necessary for cancer to develop. However, radiofrequency energy, unlike ionizing radiation, does not cause DNA damage in cells, and it has not been found to cause cancer in animals or to enhance the cancer causing effects of known chemical carcinogens in animals."

Conclusion

The scientific evidence does not indicate any need for cell phone RF-related legislation at the state level. A large body of high quality scientific evidence shows no adverse health effects, such as brain cancer, from cell phone use.

The lack of association in the epidemiology and in the animal studies is consistent with the fact that brain cancer incidence, in both adults as well as children and adolescents, has not increased since wireless phone use has become common in the U.S as well as countries around the world. These data are also consistent with the fact that there is no known mechanism by which non-ionizing radiation from wireless phones could cause cancer. The FDA has stated "The scientific evidence does not show a danger to any users of cell phones from RF exposure, including children and teenagers."²¹

In addition, the available scientific evidence does not demonstrate any adverse health effects in the offspring of pregnant women. The lack of an increase in the incidence of brain cancer, the lack of any adverse effects in the totality of the animal data and the lack of a known mechanism all apply equally to pregnant women.

U.S. Government agencies that have reviewed the scientific evidence have reached the same conclusion. The federal agency with primary responsibility for regulating wireless phones, the FCC, has stated that "[t] here is no scientific evidence that proves that wireless phone usage can lead to cancer or a variety of other problems, including headaches, dizziness or memory loss."(www.fcc.gov/cgb/cellular.html#evidence). The FDA, which worked with the FCC in developing the current RF safety standard for wireless phones, has also stated "[t] he weight of scientific evidence has not linked cell phones with any health problems."

EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/Ce <u>IIPhones/ucm116282.htm</u>). And, as noted above, the NCI states that "[a]Ithough there have been some concerns that radiofrequency energy from cell phones held closely to the head may affect the brain and other tissues, to date there is no evidence from studies of cells, animals, or humans that radiofrequency energy can cause cancer."²²

²¹See

http://www.fda.gov/RadiationEmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEnterta inment/CellPhones/ucm116331.htm

²² National Cancer Institute Fact Sheet, op. cit.

Based on all of this evidence, it is my opinion that the proposed warning legislation is scientifically unfounded. Imposing warning requirements is a serious responsibility and, as a former public health official, I firmly believe that any such requirements must be grounded in scientific fact. The warning requirement proposed here is not.

May 2, 2013

Note added in proof: On 4/29/13 the NCI released its first data from the 2010 SEER data. Brain cancer rates in 2010 were similar or lower than the rates in the previous decade, again providing no support for the unsubstantiated hypothesis that cell phones increase the risk or promote the development of brain cancer.

Year	Count	Population	Age-Adjusted Rate Per 100,000 (95% Confidence Interval)	Crude Rate Per 100,000 (95% Confidence Interval)
1999	12,526	171,448,434	7.38 (7.25 - 7.51)	7.31 (7.18 - 7.44)
2000	12,495	173,557,527	7.26 (7.14 - 7.39)	7.20 (7.07 - 7.33)
2001	12,989	183,696,355	7.13 (7.01 - 7.25)	7.07 (6.95 - 7.19)
2002	13,704	190,429,047	7.24 (7.12 - 7.36)	7.20 (7.08 - 7.32)
2003	14,286	198,821,914	7.19 (7.08 - 7.31)	7.19 (7.07 - 7.30)
2004	14,500	200,955,159	7.20 (7.08 - 7.32)	7.22 (7.10 - 7.33)
2005	14,639	203,027,879	7.17 (7.05 - 7.28)	7.21 (7.09 - 7.33)
2006	14,852	205,415,402	7.15 (7.04 - 7.27)	7.23 (7.11 - 7.35)
2007	15,140	207,684,352	7.17 (7.06 - 7.29)	7.29 (7.17 - 7.41)
2008	15,288	209,901,497	7.11 (7.00 - 7.23)	7.28 (7.17 - 7.40)
2009	14,756	208,190,584	6.88 (6.76 - 6.99)	7.09 (6.97 - 7.20)
Total	155,175	2,153,128,150	7.17 (7.13 - 7.20)	7.21 (7.17 - 7.24)

United States Cancer Statistics, 1999-2009 Incidence Results

Notes:

Caveats:

Data are suppressed if fewer than 16 cases are reported in the specific category. Data for the "Asian / Pacific Islander", "American Indian or Alaska Native", and the "Other Races Combined" race categories are suppressed at the Metropolitan Statistical Area level for populations less than 50,000 persons. Data are suppressed at the state level for certain race and ethnicity groups: 1) American Indian or Alaska Native data are suppressed at the state level for Delaware, Illinois, Kentucky, Missouri, New Jersey and South Carolina; 2) Asian or Pacific Islander data are suppressed at the state level for Delaware, Kansas, Kentucky, Missouri and South Carolina; 3) Hispanic data are supressed at the state level for Delaware, Kentucky, Missouri, Pennsylvania and South Carolina. <u>More information.</u>

Data are from selected statewide and metropolitan area cancer registries that meet data quality criteria.

For the 2005 year, the Census Bureau estimates that 173,227 persons were displaced from Alabama, Louisiana, Mississippi and Texas due to Hurricanes Katrina and Rita. CDC WONDER does not include the displaced persons in the 2005

population counts for these states, nor are these counts included in the summary populations for the affected division, regions or national population. However, the USCS web site does include these displaced persons in the national population figures for 2005.

Information on primary site, behavior, and histology was coded according to the International Classification of Diseases for Oncology, Third Edition (ICD-O-3) and categorized according to the revised SEER recodes dated January 27, 2003, which define standard groupings of primary cancer sites.

Help: See <u>United States Cancer Statistics</u>, 1999-2009 Incidence Documentation for more information.

Query Date: Feb 12, 2013 4:58:04 PM

Suggested Citation:

United States Cancer Statistics: 1999 - 2009 Incidence, WONDER Online Database. United States Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; 2011. Accessed at http://wonder.cdc.gov/cancer-v2009.html on Feb 12, 2013 4:58:04 PM

Query Criteria:

Title:

Age Group:	20-24 years, 25-29 years, 30-34 years, 35-39 years, 40-44 years, 45-49 years, 50-54 years, 55-59 years, 60-64 years , 65-69 years, 70-74 years, 75-79 years
Cancer Sites:	Brain
Ethnicity:	All
Race:	All
Sex:	All
State:	All
Year:	All
Group By:	Year
Show Totals:	True
Show Zero Values:	False
Show Suppressed:	False
Calculate Rates Per:	100,000
Standard Population:	2000 U.S. Std. Million

CURRICULUM VITAE

Howard William Ory

May 2013

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BORN:	October 1, 1944 Worcester, Massachusetts
EDUCATION:	BSUniversity of Wisconsin, Madison, Wisconsin, 1966 MDTufts University School of Medicine, Boston, Massachusetts, 1969 MSc (Epidemiology)Harvard School of Public Health, Boston, Massachusetts, 1974
HONORS:	 Career Development USPHS1973-1974 United States Public Health Service Commendation Medal, 1978 Elected to membership in the American Epidemiologic Society, 1980 Accelerated Promotion to 0-6 (Colonel) for "exceptional capability," 1980 Elected as an Associate Fellow of the American College of Obstetricians and Gynecologists, 1981 Arthur S. Flemming Award, 1983. "One of the Ten Outstanding Young Men and Women in the Federal Service." Philip S. Brachman Award, 1985. "in Recognition of Outstanding Service in the Education of EIS Officers." PHS Meritorious Service Medal, 1987 Interagency Committee on Information Management Award for Management Administrative Excellence, June 1989 PHS Outstanding Service Medal, 1990 PHS Unit Commendation Medal, 1991 PHS Unit Commendation Medal, 1992 PHS Distinguished Service Medal, 1993
EMPLOYMENT HISTORY:	 Consultant in Epidemiology and Health Care Information Systems, 12/96 to present VP, Health Care Information Systems, Prudential Health Care Systems, 4/95 to 12/96 VP and Senior Researcher, Prudential Center for Health Care Research, 6/94 to 12/96 Consultant in Epidemiology and Health Care Information Systems, 1/1994 to 6/94 Director, Information Resources Management Office, Office of Program Support, Centers for Disease Control, 4/85 through 12/93. Deputy Director for Research, Epidemiology Program Office, Centers for Disease Control, 4/83-3/85. Deputy Director, Division of Reproductive Health (Formerly Family Planning Evaluation Division), Centers for Disease Control, 7/82-3/83. Chief, Epidemiologic Studies Branch, Family Planning Evaluation Division, Center for Disease Control, 10/74-6/82. Medical OfficerFamily Planning Evaluation Division, Bureau of Epidemiology, Center for Disease Control, 7/71-9/74. Medical ResidentMetropolitan Hospital, New York City, New York, 7/70-6/71. Medical InternMetropolitan Hospital, New York City, New York, 7/69-6/70.
APPOINTMENTS:	 Consultant to the Human Reproduction Program, World Health Organization, January, 1997 Adjunct Professor, Department of Epidemiology, Emory University School of Public Health, 1975-Present. Member, Obstetrics and Gynecology Advisory Committee of the United States Food and Drug Administration, 1976-1979. Consultant, Obstetrics and Gynecology Advisory Committee of the USFDA, 1979-1985.

	Interdisciplinary Group in Community Health and Health Care Delivery, Emory School of Medicine, 1976- 1983.
	National Medical CommitteePlanned ParenthoodWorld Population, 1977-1979.
	Nominating Committee, National Medical Committee, Planned Parenthood, 1977-1979.
	Vice Chairman, Research Committee, Planned Parenthood, 1977-1979.
	DHEW-DES Task Force, 1978.
	World Health Organization Task Force on Neoplasia and Steroid Contraceptives, 1978.
	Biomedical Advisory Committee, Population Resource Center, 1978-present.
	Steering Committee, Women's Health Study, 1975-1980.
	Member, India-United States Task Force on Reproduction and Contraception Research, 1979.
	Member, US Delegation on Population and Family Planning under US-China Science and Technology Agreement, 1981.
BOARDS:	Preventive Medicine, 1976, #410
LICENSURE TO	
PRACTICE	
MEDICINE:	Georgia #17257
MEDICINE.	Ocolgia #17237
GRANTS:	National Science Foundation grant to do research on reproductive endocrinology at the Worcester
	Foundation for Experimental Biology, 1964 (Summer).
	National Science Foundation grant to do research on reproductive endocrinology at the Worcester
	Foundation for Experimental Biology, 1965 (Summer).
	National Science Foundation grant to do research on reproductive endocrinology at Tufts University School
	of Medicine, 1966 (Summer).
	Principal Investigator - Interagency Agreement between NIH and CDC to study the association of
	hepatocellular adenomas and oral contraceptives, 1976.
	Principal Investigator - Interagency Agreement between NIH and CDC to develop a study of the
	Association of Breast, Ovary, and Uterine Cancers and Oral Contraceptives, 1978 to 1983.
PROFESSIONAL	
AFFILIATIONS:	National OrganizationsAmerican Public Health Association:
	Member, APHA Epidemiology Section, 1973 - present.
	Society for Epidemiologic Research, 1974 - present.
	American College of Preventive Medicine, 1977 - present.
	Fellow, American College of Preventive Medicine, #2410.
	American Epidemiology Society, 1981 - present.
	Fellow, American College of Epidemiology, 1998 – present.

PUBLICATIONS:

Cancer and Steroid Hormone Study Group (CASH)

Dr. Ory initiated the Cancer and Steroid Hormone Study in October, 1977. A pilot study was run in 1979 and the full-scale data collection was run in 1980-81. Subsequent to that, a series of papers were produced. From its inception until 1983, Dr. Ory was Principal Investigator of the study. Since that time he has remained as a consultant to the project. The following manuscripts have resulted from that study.

<u>1982</u>	Centers for Disease Control (including <u>Ory HW</u>). Oral contraceptives and cancer risk. Morbidity and Mortality Weekly Report 1982;31:393-394.
<u>1983</u>	Layde PM, Webster LA, Wingo PA, Schlesselman JJ, <u>Ory HW</u> , and the Cancer and Steroid Hormone Study Group. Long-term oral contraceptive use and the risk of breast cancer. JAMA 1983;249:1591- 1595.
	 Dicker RC, Webster LA, Layde PM, Wingo PA, <u>Ory HW</u>, and the Cancer and Steroid Hormone Study Group. Oral contraceptive use and the risk of ovarian cancer. JAMA 1983;249:1596-1599. Rubin GL, Wingo PA, Layde PM, Webster LA, <u>Ory HW</u>, and the Cancer and Steroid Hormone Study
	Group. Oral contraceptive use and the risk of endometrial cancer. JAMA 1983;249:1600-1604.
	Webster LA, Layde PM, Wingo PA, <u>Ory HW</u> . Alcohol consumption and risk of breast cancer. Lancet 1983; 1:724-726.
<u>1984</u>	Rubin GL. Oral contraceptives and neoplasia. New Perspectives on Oral Contraception. KPR Informedia Newsletter April 1984;1:#2.
<u>1985</u>	Tyler CW Jr., Webster LA, <u>Ory HW</u> , Rubin GL. Endometrial cancer: How does cigarette smoking influence the risk of women under age 55 years having this tumor? Am J Obstet Gynecol 1985;151:899-905.
	Sattin RW, Rubin GL, Webster LA, Huezo CM, Wingo PA, Ory HW, Layde PM. Family history and the risk of breast cancer. JAMA 1985;253:1908-1913.
	Rubin GL, Peterson HB. Researchers can now investigate long-term effects of OCs on cancer. Contraceptive Technology Update 1985;6:7-12.
	Stadel BS, Rubin GL, Webster LA, Schlesselman JJ, Wingo PA, the Cancer and Steroid Hormone Study Group (Ory HW, Principal Investigator). Oral contraceptives and breast cancer in young women. Lancet Nov 1985;2:970-973.
<u>1986</u>	Lee NC, Wingo PA, Peterson HB, Rubin GL, Sattin RW. Estrogen therapy and the risk of breast, ovarian and endometrial cancer. ed. Mastroianni L, Paulsen CA, Aging, Reproduction and the Climacteric. Plenum Press, New York, 1986.
	Stadel BV, Rubin GL, Wingo PA, Schlesselman JJ. Oral contraceptives and breast cancer in young women: Reply to letters to the editor. Lancet 1986;1:436-437.
	Sattin RW, Rubin GL, Wingo PA, Webster LA, <u>Ory HW</u> , and the Cancer and Steroid Hormone Study Group. Oral contraceptive use and the risk of breast cancer. N Engl J Med 1986;315:405-411.
	Gwinn ML, Webster LA, Lee NC, Layde PM, Rubin GL, the Cancer and Steroid Hormone Study Group (<u>Ory HW</u> , Principal Investigator). Alcohol consumption and ovarian cancer risk. Am J Epidemiol 1986;123:759-766.

<u>1987</u>	 Wingo PA, Layde PM, Lee NC, Rubin GL, <u>Ory HW</u>. The risk of breast cancer in postmenopausal women who have used estrogen replacement therapy. JAMA 1987;257:209-215. Franks AL, Kendrick JS, Tyler CW. Postmenopausal smoking, estrogen replacement therapy, and the risk
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	Sattin RW, Wingo PA, Lee NC. Oral contraceptive use and the risk of breast cancer: Reply to letters to the editor. N Engl J Med 1987;316:163-164.
	Kendrick JS, Wingo PA, Rubin GL, Lee NC, Webster LA, <u>Ory HW</u> , and the Cancer and Steroid Hormone Study Group. Combination oral contraceptive use and the risk of endometrial cancer. JAMA 1987;257:796-800.
	Lee NC, Wingo PA, Gwinn ML, Rubin GL, Kendrick JS, Webster LA, <u>Ory HW</u> . The reduction in risk of ovarian cancer associated with oral contraceptive use. N Engl J Med 1987;316:650-655.
<u>1988</u>	Wingo PA, <u>Ory HW</u> , Layde, PM, Lee NC. The evaluation of the data collection process for a multicenter, population-based, case-control design. Am J Epidemiol 1988;123:206-217.
<u>1989</u>	Layde PM, Webster LA, Baughman AL, Wingo PA, Rubin GL, <u>Ory HW</u> . The independent associations of parity, age at first full term pregnancy, and duration of breastfeeding with the risk of breast cancer. J Clin Epidemiol 1989;42:963-973.
<u>1990</u>	Wingo PA, Lee NC, <u>Ory HW</u> , et al. Oral contraceptives and the risk of breast cancer. Ch. 4, in <u>Oral</u> <u>Contraceptives and Breast Cancer: The Implications of the Present Findings for Informed Consent and</u> <u>Informed Choice</u> ed. RD Mann. Parthenon Publishing Group Ltd. Lancs, UK, 1990.
<u>1991</u>	Wingo PA, Lee NC, <u>Ory HW</u> , Beral V, Peterson HB, Rhodes PH. Age-specific differences in the relationship between oral contraceptive use and breast cancer. Obstet Gynecol 1991;78:161-170.

OTHER PUBLICATIONS:

<u>1968</u>	Hopkins TF, <u>Ory H</u> , Despres E, et al. The effects of rat pituitary and hypothalamic tissue transplanted in super-ovulated immature rats. J Endocr 1968;40:363-369.
<u>1973</u>	The Boston Collaborative Drug Surveillance Program and Greenblatt DJ, <u>Ory HW</u> , Levy M. Oral contraceptives and venous thromboembolic disease, surgically confirmed gallbladder disease, and breast tumours. Lancet 1973; I:1399-1404.
<u>1974</u>	 The Boston Collaborative Drug Surveillance Program and <u>Ory HW</u>. Functional ovarian cysts and oral contraceptives. JAMA 1974;228:68-69. <u>Ory HW</u>, Conger B, Richart R, Barron B: Relation of type 2 herpesvirus antibodies to cervical neoplasia. Obstet Gynecol 1974;43:901-904. Munford RS, <u>Ory HW</u>, Brooks GF, Feldman RA: An analysis of factors contributing to death from diphtheria in the United States, 1959-1970. JAMA 1974;229:1890.
<u>1975</u>	 <u>Ory HW</u>, Jenkins R, Byrd JY, et al. Cervical neoplasia in residents of a low income housing project: An epidemiologic study. Am J Obstet Gynecol 1975;123:275-277. <u>Ory HW</u>, Allen DT, Conger SB, et al. The epidemiology and interrelationship of cervical dysplasia and type 2 herpes virus antibodies in a low income housing project. Am J Obstet Gynecol 1975;123:269-274.
<u>1976</u>	 Ory HW, Naib Z, Conger SB, et al. Contraceptive choice and prevalence of cervical dysplasia and carcinoma-in-situ. Am J Obstet Gynecol 1976;124:573-577. Ory HW, Cole PT, MacMahon B, Hoover R. Oral contraceptives and reduced risk of benign breast diseases. N Engl J Med 1976;294:419-422. Faulkner WL, Ory HW. Intrauterine devices and acute pelvic inflammatory disease. JAMA 1976;235:1851-1853. Cates W Jr., Ory HW, Rochat RW, Tyler CW Jr. The intrauterine device and deaths from spontaneous abortion. N Engl J Med 1976;295:1155-1159.
<u>1977</u>	 Ory HW, Conger SB, Naib Z, et al. A preliminary analysis of oral contraceptive use and risk of developing premalignant lesions of the uterine cervix. In: Garattini S and Berendes HW (eds). Pharmacology of steroid contraceptive use and breast diseases. In: Garattini S and Berendes HW (eds). Pharmacology of steroid contraceptive drugs. New York: Raven Press, 1977:211-218. Ory HW. Oral contraceptive use and breast diseases. In: Garattini S and Berendes HW (eds). Pharmacology of steroid contraceptive drugs. New York: Raven Press, 1977:179-183. Ory HW. The association of oral contraceptives and myocardial infarction: a review. JAMA 1977;237:2619-2622. Morisson A, Jick H, Ory HW. Oral contraceptives and hepatitis. Lancet 1977;2:1142-1143. Rochat RW, Morris L, Cates W Jr., Ory HW. Control de fecundidad y planificacion familiar en EEUU. Accepted for PAHO Bulletin. Ory HW, Rooks JPB. Oral contraceptives and benign tumors: a review. In: Colombo F, et al. (eds). Epidemiologic evaluation of drugs. Amsterdam: Elsevier, 1977:193-200. Cates W Jr, Grimes DA, Ory HW, Tyler CW Jr. Publicity and the public health: the elimination of IUD-related abortion deaths. Fam Plann Perspect 1977;9:138-140. White MK, Ory HW, Goldenberg LA. A case-control study of uterine perforations documented at laparoscopy. Am J Obstet Gynecol 1977;129:623-625. Rooks JB, Ory HW, Ishak KG, Strauss LT, Greenspan JR, Tyler CW Jr. The association between oral contraception and hepatocellular adenomaa preliminary report. Int J Gynaecol Obstet 1977;15:143-144.

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1980

<u>1981</u>

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- DeStefano F, Greenspan JR, <u>Ory HW</u>, et al. Demographic trends in tubal sterilization: United States, 1970-1978. Am J Public Health 1982;72:480-484.
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Testimony of the Maine Center for Disease Control and Prevention Maine Department of Health and Human Services

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Before the Joint Standing Committee on Health and Human Services

In Opposition to LD 1706 An Act to Create the Children's Wireless Protection Act

Sponsored by Representative Boland of Sanford March 2, 2010

Senator Brannigan, Representative Perry, and Members of the Joint Standing Committee on Health and Human Services, my name is Dr. Dora Anne Mills and I serve as the Director of the Maine CDC within the Department of Health and Human Services. I am testifying in opposition to LD 1706, An Act to Create the Children's Wireless Protection Act.

Although we appreciate the sponsor and other proponents raising some of these issues, we are opposing this bill for two main reasons. Our own reading of the research as well as of the opinions of the US Centers for Disease Control and Prevention (US CDC), the National Cancer Institute in the National Institutes of Health, the US Food and Drug Administration (FDA), Federal Communications Commission (FCC), the United Kingdom's Department of Health, Health Canada, the World Health Organization, and others do not indicate a defined brain cancer or other cancer risk that can be warned against.

We also believe the precautionary principle is already being applied. But, we do believe the situation warrants continued monitoring.

With me today are two Maine CDC professionals who assisted me with this testimony, and can also help answer any questions you may have: Molly Schwenn, MD, an oncologist who directs our Cancer Registry; and Jay Hyland, who is the Program Manager of our Radiation Control Program.

I will now clarify the two main reasons for our position.

First, to warn against something, there should be a defined risk. Our reading of the research, including numerous studies and analyses, does not indicate there is a defined cancer risk to warn against. We also rely on our federal sister agencies such as the US CDC, NIH's National Cancer Institute, the FDA, and the FCC for monitoring, supporting, and/or analyzing research on such complex topics, given their easier access to necessary resources. The US FDA has on their website the following, which we believe summarizes the research:

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Is there a connection between RF (radiofrequency) and certain health problems? The results of most studies conducted to date say no. In addition, attempts to replicate and confirm the few studies that have shown a connection have failed.

The scientific community at large therefore believes that the weight of scientific evidence does not show an association between exposure to radiofrequency (RF) from cell phones and adverse health outcomes. Still the scientific community does recommend conducting additional research to address gaps in knowledge. That research is being conducted around the world and FDA continues to monitor developments in this field.

A summary of the specific research on possible cancer risks and cell phone use is well articulated by the NIH's National Cancer Institute (NCI), and is included in the appendix of this testimony, pages 11 - 17. Below is an excerpt from this summary, with the bold-facing done by me:

What studies have been done, and what do they show?

Numerous studies have investigated the relationship between cellular telephone use and the risk of developing malignant and benign brain tumors, but results from long-term studies are still limited.

Several studies have investigated the risk of developing three types of brain tumors: Glioma, meningioma, and acoustic <u>neuroma</u>. Results from the majority of these studies have found no association between hand-held cellular telephone use and the risk of brain cancer (3-8); however, some, but not all, long-term studies have suggested slightly increased risks for certain types of brain tumors (9, 10). Further evaluation of long-term exposures (more than 10 years) is needed.

A series of multinational case-control studies (comparing individuals who have a disease or <u>condition</u> [case subjects] with a similar group of people who do not have the disease or condition [control subjects]), collectively known as the INTERPHONE study, are being coordinated by the International Agency for Research on Cancer (11). The primary objective of these studies is to assess whether RF energy exposure from cellular telephones is associated with an increased risk of malignant or benign brain tumors and other head and neck tumors. Participating countries include Australia, Canada, Denmark, Finland, France, Germany, Israel, Italy, Japan, New Zealand, Norway, Sweden, and the United Kingdom (12). Several reports describing data from individual countries have been published independently by researchers involved in the INTERPHONE study; however, these reports represent only a portion of the entire INTERPHONE dataset. The combined INTERPHONE <u>analysis</u> is under way and will provide more comprehensive and stable risk estimates than analyses from the individual countries.

Two reports published in November 2004 by researchers from individual countries that are participating in the INTERPHONE study described results of assessments of cellular telephone use and the risk of acoustic neuroma. One report described a Danish <u>case-control study</u> that showed no increased risk of acoustic neuroma in long-term (10 years or more) cellular telephone users compared with short-term users, and there was no increase in the <u>incidence</u> of tumors on the side of the head where the phone was usually held (<u>13</u>). The other report described a Swedish study that examined similar populations and found a slightly elevated risk of acoustic neuroma in long-term cellular telephone users (<u>14</u>).

A pooled analysis of data from Denmark, Finland, Norway, Sweden, and the United Kingdom did not find relationships between the risk of acoustic neuroma and the duration of cellular telephone use, cumulative hours of use, or number of calls; however, the risk of a tumor on the same side of the head as the reported phone use was higher among persons who had used a cellular telephone for 10 years or more. Some other studies have reported similar findings (15). However, there is concern that people with a tumor on one side of their heads might be more likely to report phone use on that side (2).

Other reports from the Danish and Swedish researchers who are collaborating in the INTERPHONE study investigated whether a relationship exists between cellular telephone use and the risk of meningioma or glioma. These studies compared individuals with meningioma or glioma with a control group of disease-free individuals and found no link between these conditions and cellular telephone use (<u>16</u>, <u>17</u>).

In addition, pooled analyses of data from four Nordic countries and the United Kingdom did not show overall associations between the risk of glioma or meningioma and the cumulative hours of cellular telephone use or the number of calls (18, 19). There was a slightly increased risk of glioma occurring on the same side of the head as the reported phone use among persons who used a cellular telephone for at least 10 years (18).

In an attempt to avoid the issue of <u>biases</u> associated with case-control studies, investigators defined a <u>cohort</u> of 420,095 persons in Denmark with cellular telephone subscriptions and linked this roster with the Danish Cancer Registry to identify brain tumors occurring in this population (<u>7</u>, <u>8</u>). Cellular telephone use was not associated with glioma, meningioma, or acoustic neuroma, even among persons who had been subscribers for 10 or more years. This type of <u>prospective</u> study has the advantage of not having to rely on people's ability to remember past cellular telephone use.

Incidence data from the Surveillance, Epidemiology and End Results (SEER) program of the <u>National Cancer Institute</u> showed no increase between 1987 and 2005 in the age-adjusted incidence of brain or other nervous system cancers despite the dramatic increase in use of cellular telephones (<u>20</u>).

There are very few studies of the possible relationship between cellular telephone use and tumors other than those of the brain and central nervous system (21-24).

We also checked on other countries' conclusions as well as the World Health Organization. We found their conclusions are quite similar, and some of them or links to them (WHO, UK, Finland, Canada) are also included in the appendix.

I would like to call your attention to the brochure the United Kingdom's Department of Health has issued. We have included a copy of it with this testimony. It is a good example of a comprehensive view toward cell phone use, focused on distractibility, especially related to driving, work-related issues, as well as potential radiofrequency issues. There is no mention in this brochure of risks from brain or other cancer.

In terms of our data here in Maine, we have not seen any statistically significant increases in malignant brain cancer. The appendix also includes a graph of malignant brain cancer data for Maine and the U.S.

At this point in time, we believe the preponderance of evidence does not suggest a defined brain cancer or other cancer risk associated with the use of cell phones. However, there is some uncertainty, especially regarding the health effects of long term use.

Although there are some uncertainties, there are challenges to issuing striking warnings every time there is an ill-defined risk or some uncertainty. The result can be an overwarned and turned-off public as well as a lack of credibility in the warnings themselves. We are glad to discuss and answer questions on any specific research studies.

Our second main reason for opposing this bill is that we believe the precautionary principle is already being applied. In essence, the precautionary principle provides a rationale for taking action against a practice or substance in the absence of scientific certainty rather than continuing the suspect practice while it is under study, or without study. Instead of asking what level of harm is acceptable, a precautionary approach asks: How much exposure can be avoided? What are the alternatives to this product or activity, and are they safer? Is this activity even necessary? The precautionary principle focuses on options and solutions rather than communicating about risks.

We believe the FDA is already using the precautionary principle by reducing this uncertainty through its promotion of reducing unnecessary exposure and of providing information to the public. From their website:

Although the existing scientific data do not justify FDA regulatory actions, FDA has urged the cell phone industry to take a number of steps, including the following:

- Support needed research on possible biological effects of RF for the type of signal emitted by cell phones;
- Design cell phones in a way that minimizes any RF exposure to the user; and
- Cooperate in providing users of cell phones with the current information on cell phone use and human health concerns.

FDA also is working with voluntary standard setting bodies such as the Institute of Electrical and Electronics Engineers (IEEE), the International Commission on Non-Ionizing Radiation Protection (ICNIRP) and others to assure that safety standards continue to adequately protect the public.

Also, from the FDA Website on Children and Cell Phones:

The scientific evidence does not show a danger to any users of cell phones from RF exposure, including children and teenagers. The steps adults can take to reduce RF exposure apply to children and teenagers as well.

- Reduce the amount of time spent on the cell phone
- Use speaker mode or a headset to place more distance between the head and the cell phone.

Some groups sponsored by other national governments have advised that children be discouraged from using cell phones at all. For example, The Stewart Report from the United Kingdom made such a recommendation in December 2000. In this report a group of independent experts noted that no evidence exists that using a cell phone causes brain tumors or other ill effects. Their recommendation to limit cell phone use by children was strictly precautionary; it was not based on scientific evidence that any health hazard exists.

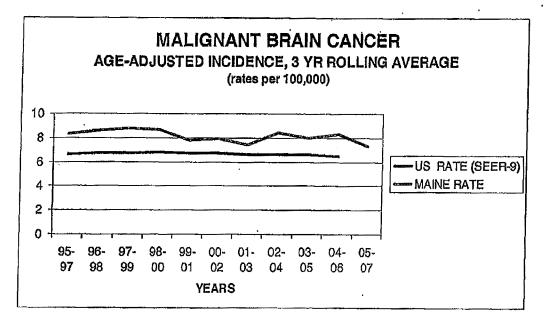
The brochure from the United Kingdom mentioned before is an example of the precautionary principle being applied.

What do we believe should occur, given some degree of uncertainty? We believe the CDC, the NIH's National Cancer Institute, the FDA, and the FCC are providing information, supporting research, and monitoring the situation related to possible associations between cell phone use and cancer. It should be noted that there is nearly <u>always</u> going to be some uncertainty when trying to prove a negative health risk.

However, we recognize there are many other factors that parents often must weigh when making decisions about cell phones and their children. These factors include costs (which can be considered high or low, in part depending on whether the family has a land line or not), the assurances of safety that this access to communication provides, as well as the challenges to a child's safety related to the distractibility that is associated with cell phone use.

At this point in time, we do not feel the scientific evidence warrants a specific warning placed on cell phones related to potential brain cancer risks among children or pregnant women.

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Appendices

INFORMATION ON PRECAUTIONARY PRINCIPLE

http://environmentalcommons.org/precaution-handbook.pdf

FDA WEBSITE ON RADIOFREQUENCY AND CELL PHONES

http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertain ment/CellPhones/ucm116335.htm

FDA QUESTIONS ON HEALTH AND CELL PHONES

http://www.fda.gov/Radiation-

EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/Cell

Excerpts:

Do cell phones pose a health hazard?

Many people are concerned that cell phone radiation will cause cancer or other serious health hazards. The weight of scientific evidence has not linked cell phones with any health problems.

Cell phones emit low levels of radiofrequency energy (RF). Over the past 15 years, scientists have conducted hundreds of studies looking at the biological effects of the radiofrequency energy emitted by cell phones. While some researchers have reported biological changes associated with RF energy, these studies have failed to be replicated. The majority of studies published have failed to show an association between exposure to radiofrequency from a cell phone and health problems.

The low levels of RF cell phones emit while in use are in the microwave frequency range. They also emit RF at substantially reduced time intervals when in the stand-by mode. Whereas high levels of RF can produce health effects (by heating tissue), exposure to low level RF that does not produce heating effects causes no known adverse health effects.

The biological effects of radiofrequency energy should not be confused with the effects from other types of electromagnetic energy.

Very high levels of electromagnetic energy, such as is found in X-rays and gamma rays can ionize biological tissues. Ionization is a process where electrons are stripped away from their normal locations in atoms and molecules. It can permanently damage biological tissues including DNA, the genetic material.

The energy levels associated with radiofrequency energy, including both radio waves and microwaves, are not great enough to cause the ionization of atoms and molecules. Therefore, RF energy is a type of non-ionizing radiation. Other types of non-ionizing radiation include visible light, infrared radiation (heat) and other forms of electromagnetic radiation with relatively low frequencies.

While RP energy doesn't ionize particles, large amounts can increase body temperatures and cause tissue damage. Two areas of the body, the eyes and the testes, are particularly vulnerable to RP heating because there is relatively little blood flow in them to carry away excess heat.

Children and Cell Phones

The scientific evidence does not show a danger to any users of cell phones from RF exposure, including children and teenagers. The steps adults can take to reduce RF exposure apply to children and teenagers as well.

- Reduce the amount of time spent on the cell phone
- Use speaker mode or a headset to place more distance between the head and the cell phone.

Some groups sponsored by other national governments have advised that children be discouraged from using cell phones at all. For example, The Stewart Report from the United Kingdom made such a recommendation in December 2000. In this report a group of independent experts noted that no evidence exists that using a cell phone causes brain tumors or other ill effects. Their recommendation to limit cell phone use by children was strictly precautionary; it was not based on scientific evidence that any health hazard exists.

HEALTH CANADA

Has similar stance as US FDA: http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/prod/cell-eng.php

UK DEPT OF HEALTH

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4123979

Children and young people under 16

Mobile phones are very popular with young people and have obvious attractions for personal security and keeping in touch with others. Parents and young people should make their own informed choices about the use of mobile phones. The current balance of evidence does not show health problems caused by using mobile phones. However the research does show that using mobile phones affects brain activity. There are also significant gaps in our scientific knowledge. Because the head and nervous system are still developing into the teenage years, the expert group considered that if there are any unrecognised health risks from mobile phone use, then children and young people might be more vulnerable than adults.

The expert group has therefore recommended that in line with a precautionary approach, the wide spread use of mobile phones by children (under the age of16) should be discouraged for non-essential calls. In the light of this recommendation the UK Chief Medical Officers strongly advise that where children and young people do use mobile phones, they should be encouraged to: use mobile phones for essential purposes only keep all calls short - talking for long periods prolongs exposure and should be discouraged. The UK CMOs recommend that if parents want to avoid their children being subject to any possible risk that might be identified in the future, the way to do so is to exercise their choice not to let their children use mobile phones.

WORLD HEALTH ORGANIZATION

http://www.who.int/mediacentre/factsheets/fs193/en/

The World Health Organization (WHO) website reviews the research on RF and health issues. Their summary of this review is:

• Cancer: Current scientific evidence indicates that exposure to RF fields, such as those emitted by mobile phones and their base stations, is unlikely to induce or

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promote cancers. Several studies of animals exposed to RF fields similar to those emitted by mobile phones found no evidence that RF causes or promotes brain cancer. While one 1997 study found that RF fields increased the rate at which genetically engineered mice developed lymphoma, the health implications of this result is unclear. Several studies are underway to confirm this finding and determine any relevance of these results to cancer in human beings. Three recent epidemiological studies found no convincing evidence of increase in risk of cancer or any other disease with use of mobile phones.

- Other health risks: Scientists have reported other effects of using mobile phones including changes in brain activity, reaction times, and sleep patterns. These effects are small and have no apparent health significance. More studies are in progress to try to confirm these findings.
- Driving: Research has clearly shown an increased risk of traffic accidents when mobile phones (either handheld or with a "hands-free" kit) are used while driving.
- Electromagnetic interference: When mobile phones are used close to some medical devices (including pacemakers, implantable defibrillators, and certain hearing aids) there is the possibility of causing interference. There is also the potential of interference between mobile phones and aircraft electronics.

The WHO has the following recommendations:

Precautionary measures

Present scientific information does not indicate the need for any special precautions for use of mobile phones. If individuals are concerned, they might choose to limit their own or their children's' RF exposure by limiting the length of calls, or using "hands-free" devices to keep mobile phones away from the head and body.

FINNISH RADIATION AND NUCLEAR SAFETY ATHORITY

January, 2009 Statement http://www.stuk.fi/sateilytietoa/sateilyn_terveysvaikutukset/matkapuhelin_terveysvalkutus/en_GB/ stukin_matkapuhelinkannanotto/

Present knowledge on health effects of RF radiation

The biological effects of radio waves have been studied for decades. The known direct health effects of RF radiation are due to absorption of energy from the radio waves into the body causing warming-up of tissues. Health hazards emerge if the human temperature regulation cannot eliminate the excess heat. RF exposures of this magnitude occur, however, only in exceptional working conditions, like in mast operations, radar mounting and industrial high-frequency heating.

The effects of mobile phone radiation have been examined, for example, using cell studies. It has been observed that the RF radiation emitted by a mobile phone can temporarily change the activity of certain proteins in cell cultures and also in the human skin. The observed biological changes do not however indicate a health risk.

At Turku University in Finland, among others, the scientists have made neuropsychological studies to determine whether mobile phone radiation could have an influence on e.g. memory and deduction. In these studies, they have not found any reproducible evidence that mobile phone radiation would have any cognitive influence.

When examining the exposure of children, the calculations demonstrate that a mobile phone held against the ear causes an exposure on the brain surface double of that for adults. The difference is due to children's thinner skull bone and more elastic earlobe. The exposure is however focused to such a small area that the warming-up of children's brain tissue is not any heavier than with adults.

Approximately 20 general population studies concerning the causal relation of possible tumour risk and mobile phone use have been carried out. On the grounds of the studies to date, it is not possible to make such a conclusion that mobile phones would cause a health risk. Nevertheless, certain analyses that combine several earlier studies have reported an increased risk of brain tumour in people who have used a mobile phone for a long time (more than ten years). These studies however involve uncertainties. One source of error is a memory illusion related to the fact that mobile phone use and call durations that took place many years are ago are difficult to recall exactly.

Since it takes years to develop a cancer and mobile phones have been in common use only for about ten years, the possibility, that a link between mobile phone use and cancer might be found in later population studies, cannot be ruled out.

The health risks of mobile phones are continuously studied. There are many ongoing research projects in STUK at the moment, too. In 2009 an extensive follow-up study is launched as a part of a joint international venture. In the study, the occurrence of head and neck tumours and pathologies of nervous system and brain blood circulation of mobile phone users is intended to be followed for several years.

It would be good to restrict children's use of mobile phones

There is only scarce research evidence on children and mobile phones, and it is not easy to get more – in research ethical sense, children are a special group, which is why the intended study must be very well-founded. Research evidence is neither available on young people's using habits of mobile phones. Studies have been made with young test animals but these results are not directly applicable to humans.

Children nevertheless have a special status as mobile phone users, among others, because brains continue to develop even up to 20 years of age. It should also be taken into account that children will have much more time to use mobile phones than adults today who started their regular mobile phone use only about ten years ago. The risk of long-term use of mobile phones cannot however be assessed with certainty until mobiles phones have been in use for several decades. On the grounds of the above-mentioned facts, STUK states that it is reasonable to restrict children's use of mobile phones the following ways:

- Parents are recommended to advice their children to use rather SMS messages than mobile phone calls.
- Parents may restrict the number of their children's mobile phone calls and their duration.
- Parents are recommended to guide their children to use a hands-free that minimises the exposure of head significantly. When using a hands-free it is recommended to keep the mobile phone at least a few centimetres away from the body.
- It is not recommended to use mobile phones in weak fields.

STUK does not find it justifiable to totally prohibit children's use of mobile phones. Mobile phones also create safety because they make children's communication with parents easier.

If an adult person is concerned about his/her own exposure to RF radiation, it is possible to reduce the exposure accordingly as explained above in connection of children.

US FCC

Most Common Questions on Radiofrequency:

http://www.fcc.gov/oet/rfsafety/if-fags.html

US CDC

www.cdc.gov/nceh/radiation/factsheets/cellphone_facts.pdf

NATIONAL CANCER INSTITUTE

http://www.cancer.gov/cancertopics/factsheet/Risk/cellphones

Cellular Telephone Use and Cancer Risk

Key Points

- Cellular telephones emit radiofrequency (RF) energy, which is another name for radio waves (see <u>Questions 1</u> and <u>2</u>).
- Exposure to high levels of RF energy can heat body <u>tissue</u>, but RF energy exposures from cellular telephones are too low to cause significant tissue heating (see <u>Question 2</u>).
- Concerns have been raised that RF energy from cellular telephones may pose a <u>cancer</u> risk to users (see <u>Questions 1</u> and <u>2</u>).
- Researchers are studying <u>tumors</u> of the brain and <u>central nervous system</u> and other sites of the head and neck because cellular telephones are held next to the

head when used (see <u>Question 5</u>).

Studies have not shown any consistent link between cellular telephone use and cancer, but <u>scientists</u> feel that additional research is needed before firm conclusions can be drawn (see <u>Questions 6</u> and 7).

1. Why is there concern that cellular telephones may cause cancer?

There are three main reasons why people are concerned that cellular telephones (also known as "wireless" or "mobile" telephones) may cause certain types of cancer:

- Cellular telephones emit radiofrequency (RF) energy (radio waves), which is a form of <u>radiation</u> that is under investigation for its effects on the human body (1).
- Cellular telephone technology emerged in Europe in the 1980s but did not come into widespread use in the United States until the 1990s. The technology is rapidly changing, so there are few long-term studies of the effects of RF energy from cellular telephones on the human body (1).
- The number of cellular telephone users has increased rapidly. As of December 2008, there were more than 270 million subscribers to cellular telephone service in the United States, according to the Cellular Telecommunications and Internet Association. This is an increase from 110 million users in 2000 and 208 million users in 2005.

For these reasons, it is important to learn whether RF energy from cellular telephones affects human health.

2. What is RF energy and how can it affect the body?

RF energy is a form of <u>electromagnetic radiation</u>.

Electromagnetic radiation can be divided into two types: Ionizing (high-frequency) and non-ionizing (low-frequency) (2). RF energy is a form of nonionizing electromagnetic radiation. <u>Ionizing radiation</u>, such as that produced by <u>x-</u> ray machines, can pose a cancer risk at high levels of exposure. However, it is not known whether the non-ionizing radiation emitted by cellular telephones is associated with cancer risk (2).

Studies suggest that the amount of RF energy produced by cellular telephones is too low to produce significant tissue heating or an increase in body temperature. However, more research is needed to determine what effects, if any, low-level non-ionizing RF energy has on the body and whether it poses a health danger (2).

3. How is a cellular telephone user exposed to RF energy?

A cellular telephone's main source of RF energy is produced through its antenna. The antenna of a hand-held cellular telephone is in the handset, which is typically held against the side of the head when the telephone is in use. The closer the antenna is to the head, the greater a person's expected exposure to RF energy. The amount of RF energy absorbed by a person decreases significantly with increasing distance between the antenna and the user. The intensity of RF energy emitted by a cellular telephone depends on the level of the signal sent to or from the nearest base station (1).

When a call is placed from a cellular telephone, a signal is sent from the antenna of the phone to the nearest base station antenna. The base station routes the call through a switching center, where the call can be transferred to another cellular telephone, another base station, or the local land-line telephone system. The farther a cellular telephone is from the base station antenna, the higher the power level needed to maintain the connection. This distance determines, in part, the amount of RF energy exposure to the user.

4. What determines how much RF energy a cellular telephone user experiences?

A cellular telephone user's level of exposure to RF energy depends on several factors, including:

- The number and duration of calls.
- The amount of cellular telephone traffic at a given time.
- The distance from the nearest cellular base station.
- The quality of the cellular transmission.
- The size of the handset.
- How far the antenna is extended.
- Whether or not a hands-free <u>device</u> is used.

5. What parts of the body may be affected during cellular telephone use?

There is concern that RF energy produced by cellular phones may affect the brain and <u>nervous system</u> tissue in the head because hand-held cellular telephones are usually held close to the head. Researchers have focused on whether RF energy can cause <u>malignant</u> (cancerous) <u>brain tumors</u> such as <u>gliomas</u> (cancers of the brain that begin in <u>glial cells</u>, which surround and support the <u>nerve cells</u>), as well as <u>benign</u> (noncancerous) tumors, such as acoustic neuromas (tumors that arise in the cells of the <u>nerve</u> that supplies the ear) and <u>meningiomas</u> (tumors that occur in the <u>meninges</u>, which are the <u>membranes</u> that cover and protect the brain and <u>spinal cord</u>) (1). The <u>salivary glands</u> also may be exposed to RF energy from cellular telephones held close to the head.

6. What studies have been done, and what do they show?

Numerous studies have investigated the relationship between cellular telephone use and the risk of developing malignant and benign brain tumors, but results from long-term studies are still limited.

Several studies have investigated the risk of developing three types of brain tumors: Glioma, meningioma, and acoustic <u>neuroma</u>. Results from the majority of these studies have found no association between hand-held cellular telephone use and the risk of brain cancer (3-8); however, some, but not all, long-term studies have suggested slightly increased risks for certain types of brain tumors (9, 10). Further evaluation of long-term exposures (more than 10 years) is needed.

A series of multinational case-control studies (comparing individuals who have a disease or <u>condition</u> [case subjects] with a similar group of people who do not have the disease or condition [<u>control subjects</u>]), collectively known as the INTERPHONE study, are being coordinated by the International Agency for Research on Cancer (<u>11</u>). The primary objective of these studies is to assess whether RF energy exposure from cellular telephones is associated with an increased risk of malignant or benign brain tumors and other head and neck tumors. Participating countries include Australia, Canada, Denmark, Finland, France, Germany, Israel, Italy, Japan, New Zealand, Norway, Sweden, and the United Kingdom (<u>12</u>). Several reports describing data from individual countries have been published independently by researchers involved in the INTERPHONE study; however, these reports represent only a portion of the entire INTERPHONE dataset. The combined INTERPHONE <u>analysis</u> is under way and will provide more comprehensive and stable risk estimates than analyses from the individual countries.

Two reports published in November 2004 by researchers from individual countries that are participating in the INTERPHONE study described results of assessments of cellular telephone use and the risk of acoustic neuroma. One report described a Danish <u>case-control study</u> that showed no increased risk of acoustic neuroma in long-term (10 years or more) cellular telephone users compared with short-term users, and there was no increase in the <u>incidence</u> of tumors on the side of the head where the phone-was usually held (<u>13</u>). The other report described a Swedish study that examined similar populations and found a slightly elevated risk of acoustic neuroma in long-term cellular telephone users but not in short-term users (<u>14</u>).

A pooled analysis of data from Denmark, Finland, Norway, Sweden, and the United Kingdom did not find relationships between the risk of acoustic neuroma and the duration of cellular telephone use, cumulative hours of use, or number of calls; however, the risk of a tumor on the same side of the head as the reported phone use was higher among persons who had used a cellular telephone for 10 years or more. Some other studies have reported similar findings (<u>15</u>). However,

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there is concern that people with a tumor on one side of their heads might be more likely to report phone use on that side (9).

Other reports from the Danish and Swedish researchers who are collaborating in the INTERPHONE study investigated whether a relationship exists between cellular telephone use and the risk of meningioma or glioma. These studies compared individuals with meningioma or glioma with a control group of disease-free individuals and found no link between these conditions and cellular telephone use (16, 17).

In addition, pooled analyses of data from four Nordic countries and the United Kingdom did not show overall associations between the risk of glioma or meningioma and the cumulative hours of cellular telephone use or the number of calls (18, 19). There was a slightly increased risk of glioma occurring on the same side of the head as the reported phone use among persons who used a cellular telephone for at least 10 years (18).

In an attempt to avoid the issue of <u>biases</u> associated with case-control studies, investigators defined a <u>cohort</u> of 420,095 persons in Denmark with cellular telephone subscriptions and linked this roster with the Danish Cancer Registry to identify brain tumors occurring in this population (7, 8). Cellular telephone use was not associated with glioma, meningioma, or acoustic neuroma, even among persons who had been subscribers for 10 or more years. This type of <u>prospective</u> study has the advantage of not having to rely on people's ability to remember past cellular telephone use.

Incidence data from the Surveillance, Epidemiology and End Results (SEER) program of the <u>National Cancer Institute</u> showed no increase between 1987 and 2005 in the age-adjusted incidence of brain or other nervous system cancers despite the dramatic increase in use of cellular telephones (20).

There are very few studies of the possible relationship between cellular telephone use and tumors other than those of the brain and central nervous system (21-24).

7. Why are the results of the studies inconsistent?

There are several reasons for the discrepancies between studies:

• Information about cellular telephone use, including the frequency of use and the duration of calls, has largely been assessed through questionnaires. The completeness and accuracy of the data collected during such interviews is dependent on the memory of the responding individuals. In case-control studies, individuals with brain tumors may remember cellular telephone use differently from healthy individuals, which can result in a problem known as *recall bias*.

- Cellular telephone use is relatively new in the United States (mostly since the 1990s), and cellular technology continues to change (1). Although older studies evaluated RF energy exposure from analog telephones, most cellular telephones today use digital technology, which operates at a different frequency and power level than analog phones.
- The interval between exposure to a <u>carcinogen</u> and the <u>clinical</u> onset of a tumor may be many years or decades. Scientists have been unable to <u>monitor</u> large cohorts of cellular telephone users for the length of time it might take for brain tumors to develop (1).
- Other limitations of current epidemiologic studies on cellular telephone use and brain cancer include a lack of verifiable data regarding cumulative RF energy exposure over time (the total amount of RF energy individuals have encountered) and potential errors in the exposure information reported by study participants after individuals are <u>diagnosed</u> with cancer, a problem known as *reporting bias* (25, 26). In addition, participation rates are frequently different between case subjects and control subjects in brain tumor studies, a problem known as *participation bias*. Some studies have indicated greater participation by individuals diagnosed with brain tumors compared with controls, and participation rates may be related to cellular telephone use.
- The use of "hands-free" wireless technology, such as Bluetooth®, is increasing and may contribute to variation in cellular telephone exposures.

Although research has not consistently demonstrated a link between cellular telephone use and cancer, scientists still caution that further <u>surveillance</u> is needed before conclusions can be drawn (1, 27).

8. Do children have a higher risk of developing cancer due to cellular telephone use than adults?

There are currently no data on cellular telephone use and risk of cancer in children because no published studies to date have included children. Cellular telephone use is increasing rapidly in children and adolescents, and they are likely to accumulate many years of exposure during their lives (1). In addition, children may be at greater risk because their nervous systems are still developing at the time of exposure. A large case-control study of childhood brain cancer in several Northern European countries is in progress.

9. What can cellular telephone users do to reduce their exposure to RF energy?

The <u>U.S. Food and Drug Administration</u> has suggested some steps that cellular telephone users can take if they are concerned about potential health risks from cellular telephones:

• Reserve the use of cellular telephones for shorter conversations, or for times when a conventional phone is not available.

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• Switch to a type of cellular telephone with a hands-free device that will place more distance between the antenna and the head of the phone user.

Hands-free kits reduce the amount of RF energy exposure to the head because the antenna, which is the source of RF energy, is not placed against the head (2). However, most studies conducted on cellular telephone use and cancer risk have focused on hand-held models not equipped with hands-free systems because they deliver the most RF energy to the user's head.

10. Where can I find more information about RF energy exposure?

The Federal Communications Commission (FCC), which regulates interstate and international communications, provides consumers with information about human exposure to RF energy from cellular telephones and other devices at http://www.fcc.gov/oet/rfsafety on the Internet. This Web page includes links to information about the specific absorption rate (SAR) of cellular telephones produced and marketed within the last 1 to 2 years. The SAR corresponds to the relative amount of RF energy absorbed into the head of a cellular telephone user. Consumers can access this information using the phone's FCC ID number, which is usually located on the case of the phone.

11. What are other sources of RF energy?

The most common use of RF energy is for telecommunications (2). In the United States, cellular telephones operate in a frequency range of about 1,800 to 2,200 megahertz (MHz) (1). In this range, the electromagnetic radiation produced is in the form of non-ionizing RF energy. AM/FM radios, VHF/UHF televisions, and cordless telephones (telephones that have a base unit connected to the telephone wiring in a house) operate at lower radio frequencies than cellular telephones. Other sources of RF energy, including radar, satellite stations, magnetic resonance imaging (MRI) devices, industrial equipment, and microwave ovens, operate at somewhat higher radio frequencies (2).

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Health Issues

Do cell phones pose a health hazard?

Many people are concerned that cell phone radiation will cause cancer or other serious health hazards. The weight of scientific evidence has not linked cell phones with any health problems.

Cell phones emit low levels of radiofrequency energy (RF). Over the past 15 years, scientists have conducted hundreds of studies looking at the biological effects of the radiofrequency energy emitted by cell phones. While some researchers have reported biological changes associated with RF energy, these studies have failed to be replicated. The majority of studies published have failed to show an association between exposure to radiofrequency from a cell phone and health problems.

The low levels of RF cell phones emit while in use are in the microwave frequency range. They also emit RF at substantially reduced time intervals when in the stand-by mode. Whereas high levels of RF can produce health effects (by heating tissue), exposure to low level RF that does not produce heating effects causes no known adverse health effects.

The biological effects of radiofrequency energy should not be confused with the effects from other types of electromagnetic energy

Very high levels of electromagnetic energy, such as is found in X-rays and gamma rays can ionize biological tissues. Ionization is a process where electrons are stripped away from their normal locations in atoms and molecules. It can permanently damage biological tissues including DNA, the genetic material.

The energy levels associated with radiofrequency energy, including both radio waves and microwaves, are not great enough to cause the ionization of atoms and molecules. Therefore, RF energy is a type of non-ionizing radiation. Other types of non-ionizing radiation include visible light, infrared radiation (heat) and other forms of electromagnetic radiation with relatively low frequencies.

While RF energy doesn't ionize particles, large amounts can increase body temperatures and cause tissue damage. Two areas of the body, the eyes and the testes, are particularly vulnerable to RF heating because there is relatively little blood flow in them to carry away excess heat.

Related Resources

- Current Research Results¹
- No Evidence Linking Cell Phone Use to Risk of Brain Tumors²

Page Last Updated: 08/08/2012

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Current Research Results

Is there a connection between certain health problems and exposure to radiofrequency fields via cell phone use?

The results of most studies conducted to date indicate that there is not. In addition, attempts to replicate and confirm the few studies that did show a connection have failed.

According to current data, the FDA believes that the weight of scientific evidence does not show an association between exposure to radiofrequency from cell phones and adverse health outcomes. Still, there is consensus that additional research is warranted to address gaps in knowledge, such as the effects of cell phone use over the long-term and on pediatric populations.

The World Health Organization's International Agency for Research on Cancer Classified Radiofrequency Fields as Possibly Carcinogenic to Humans on May 31, 2011.

The International Agency for Research on Cancer (IARC), through the *Monographs* program¹, seeks to identify environmental factors that can increase the risk of cancer in humans. IARC uses the following categories to classify environmental agents:

- Group 1 Carcinogenic to humans.
- Group 2A **Probably car**cinogenic to humans.
- Group 2B **Possibly carcinogenic** to humans.
- Group 3 Not classifiable as to its carcinogenicity to humans.
- Group 4 **Probably not** carcinogenic to humans.

IARC has classified radiofrequency fields in Group 2B, possibly carcinogenic to humans.

IARC interprets the 2B classification as meaning there is limited evidence showing radiofrequency carcinogenicity in humans and less than sufficient evidence of carcinogenicity in experimental animals.

For perspective, IARC has classified the following other agents as "possibly carcinogenic to humans":

- Coffee
- Extremely low frequency electromagnetic fields (power line frequency)
- Talc-based body powder

A complete list of agents classified by IARC Monographs Vol. 1 – 100 can be found at http://monographs.iarc.fr/ENG/Classification/ClassificationsGroupOrder.pdf²

The FDA continues to monitor research developments in exposure to radiofrequency fields.

Significant Ongoing Studies

International Cohort Study on Mobile Phone Users (COSMOS)

The COSMOS study aims to conduct long-term health monitoring of a large group of people to determine if there are any health issues linked with long-term exposure to radiofrequency energy from cell phone use. The COSMOS study will follow approximately 300,000 adult cell phone users in Europe for 20 to 30 years. Additional information about the COSMOS study can be found at http://www.ukcosmos.org/index.html³.

Risk of brain cancer from exposure to radiofrequency fields in childhood and adolescence (MOBI-KIDS)

MOBI-KIDS is an international study investigating the relationship between exposure to radiofrequency energy from communication technologies, including cell phones, and brain cancer in young people. This is an international, multi-center study involving 14 European and non-European countries. Additional information about MOBI-KIDS can be found at

http://www.creal.cat/programes-recerca/en_projectes-creal/view.php?ID=394

Surveillance, Epidemiology and End Results (SEER) program of the National Cancer Institute

The SEER Program of the National Cancer Institute (NCI) actively follows cancer statistics in the United States. If cell phones play a role in increasing the risk of brain cancer, rates would be expected to increase. However, between 1987 and 2008, SEER data shows that despite the sharp increase in heavy cell phone use in the U.S., the overall age-adjusted incidence of brain cancer did not increase. Additional information about SEER can be found at http://seer.cancer.gov/⁵.

Cell Phone Industry Actions

Although the existing scientific data do not support a change in FDA regulation of cell phones, the FDA has urged the cell phone industry to take a number of steps, including:

- Support additional research on possible biological effects of radiofrequency fields for the type
 of signal emitted by cell phones;
- Improve cell phone design by minimizing radiofrequency exposure to the user; and
- Cooperate in providing cell phone users with the latest scientific information on health concerns caused by radiofrequency exposure.

Safety Standards

The FDA also is working with voluntary standard setting bodies such as the Institute of Electrical and Electronics Engineers (IEEE), the International Commission on Non-Ionizing Radiation Protection (ICNIRP) and others to assure that safety standards continue to adequately protect the public.

Additional Resources

- NAS Report Identification of Research Needs Relating to Potential Biological or Adverse Health Effects of Wireless Communication Devices⁶⁶⁷
- World Health Organization: Electromagnetic Fields and Public Health: Mobile Phones $^{8}\kappa^{9}$

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WHO Fact Sheet



Media centre

Electromagnetic fields and public health: mobile phones

Fact sheet N°193 June 2011

Key facts

- Mobile phone use is ubiquitous with an estimated 4.6 billion subscriptions globally.
- The electromagnetic fields produced by mobile phones are classified by the International Agency for Research on Cancer as possibly carcinogenic to humans.
- Studies are ongoing to more fully assess potential long-term effects of mobile phone use.
- WHO will conduct a formal risk assessment of all studied health outcomes from radiofrequency fields exposure by 2012.

Mobile or cellular phones are now an integral part of modern telecommunications. In many countries, over half the population use mobile phones and the market is growing rapidly. At the end of 2009, there were an estimated 4.6 billion subscriptions globally. In some parts of the world, mobile phones are the most reliable or the only phones available.

Given the large number of mobile phone users, it is important to investigate, understand and monitor any potential public health impact.

Mobile phones communicate by transmitting radio waves through a network of fixed antennas called base stations. Radiofrequency waves are electromagnetic fields, and unlike ionizing radiation such as X-rays or gamma rays, can neither break chemical bonds nor cause ionization in the human body.

Exposure levels

Mobile phones are low-powered radiofrequency transmitters, operating at frequencies between 450 and 2700 MHz with peak powers in the range of 0.1 to 2 watts. The handset only transmits power when it is turned on. The power (and hence the radiofrequency exposure to a user) falls off rapidly with increasing distance from the handset. A person using a mobile phone 30–40 cm away from their body – for example when text messaging,

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Related link

Interphone study on mobile phone use and brain cancer risk

The International Electromagnetic Fields Project

Electromagnetic fields and public health: base stations and wireless technologies

Electromagnetic fields and public health: electromagnetic hypersensitivity

WHO research agenda for electromagnetic fields

accessing the Internet, or using a "hands free" device – will therefore have a much lower exposure to radiofrequency fields than someone holding the handset against their head.

In addition to using "hands-free" devices, which keep mobile phones away from the head and body during phone calls, exposure is also reduced by limiting the number and length of calls. Using the phone in areas of good reception also decreases exposure as it allows the phone to transmit at reduced power. The use of commercial devices for reducing radiofrequency field exposure has not been shown to be effective.

Mobile phones are often prohibited in hospitals and on airplanes, as the radiofrequency signals may interfere with certain electro-medical devices and navigation systems.

Are there any health effects?

A large number of studies have been performed over the last two decades to assess whether mobile phones pose a potential health risk. To date, no adverse health effects have been established as being caused by mobile phone use.

Short-term effects

Tissue heating is the principal mechanism of interaction between radiofrequency energy and the human body. At the frequencies used by mobile phones, most of the energy is absorbed by the skin and other superficial tissues, resulting in negligible temperature rise in the brain or any other organs of the body.

A number of studies have investigated the effects of radiofrequency fields on brain electrical activity, cognitive function, sleep, heart rate and blood pressure in volunteers. To date, research does not suggest any consistent evidence of adverse health effects from exposure to radiofrequency fields at levels below those that cause tissue heating. Further, research has not been able to provide support for a causal relationship between exposure to electromagnetic fields and self-reported symptoms, or "electromagnetic hypersensitivity".

Long-term effects

Epidemiological research examining potential long-term risks from radiofrequency exposure has mostly looked for an association between brain tumours and mobile phone use. However, because many cancers are not detectable until many years after the interactions that led to the tumour, and since mobile phones were not widely used until the early 1990s, epidemiological studies at present can only assess those cancers that become evident within shorter time periods. However, results of animal studies consistently show no increased cancer risk for long-term exposure to radiofrequency fields.

Several large multinational epidemiological studies have been completed or are ongoing, including case-control studies and prospective cohort studies

examining a number of health endpoints in adults. The largest retrospective case-control study to date on adults, Interphone, coordinated by the International Agency for Research on Cancer (IARC), was designed to determine whether there are links between use of mobile phones and head and neck cancers in adults. The international pooled analysis of data gathered from 13 participating countries found no increased risk of glioma or meningioma with mobile phone use of more than 10 years. There are some indications of an increased risk of glioma for those who reported the highest 10% of cumulative hours of cell phone use, although there was no consistent trend of increasing risk with greater duration of use. The researchers concluded that biases and errors limit the strength of these conclusions and prevent a causal interpretation. Based largely on these data, IARC has classified radiofrequency electromagnetic fields as possibly carcinogenic to humans (Group 2B), a category used when a causal association is considered credible, but when chance, bias or confounding cannot be ruled out with reasonable confidence.

While an increased risk of brain tumors is not established, the increasing use of mobile phones and the lack of data for mobile phone use over time periods longer than 15 years warrant further research of mobile phone use and brain cancer risk. In particular, with the recent popularity of mobile phone use among younger people, and therefore a potentially longer lifetime of exposure, WHO has promoted further research on this group. Several studies investigating potential health effects in children and adolescents are underway.

Exposure limit guidelines

Radiofrequency exposure limits for mobile phone users are given in terms of Specific Absorption Rate (SAR) – the rate of radiofrequency energy absorption per unit mass of the body. Currently, two international bodies ^{1,2} have developed exposure guidelines for workers and for the general public, except patients undergoing medical diagnosis or treatment. These guidelines are based on a detailed assessment of the available scientific evidence.

WHO'S response

In response to public and governmental concern, WHO established the International Electromagnetic Fields (EMF) Project in 1996 to assess the scientific evidence of possible adverse health effects from electromagnetic fields. WHO will conduct a formal risk assessment of all studied health outcomes from radiofrequency fields exposure by 2012. In addition, and as noted above, the International Agency for Research on Cancer (IARC), a WHO specialized agency, has reviewed the carcinogenic potential of radiofrequency fields, as from mobile phones in May 2011.

WHO also identifies and promotes research priorities for radiofrequency fields and health to fill gaps in knowledge through its research agendas.

WHO develops public information materials and promotes dialogue among scientists, governments, industry and the public to raise the level of understanding about potential adverse health risks of mobile phones.

¹ International Commission on Non-Ionizing Radiation Protection (ICNIRP). Statement on the "Guidelines for limiting exposure to time-varying electric, magnetic and electromagetic fields (up to 300 GHz)", 2009.

² Institute of Electrical and Electronics Engineers (IEEE). *IEEE standard for* safety levels with respect to human exposure to radio frequency electromagnetic fields, 3 kHz to 300 GHz, IEEE Std C95.1, 2005.

GAO 2012 Study (first page is a Summary)



United States Government Accountability Office Report to Congressional Requesters

July 2012

TELECOMMUNICATIONS

Exposure and Testing Requirements for Mobile Phones Should Be Reassessed



GAO-12-771



July 2012

TELECOMMUNICATIONS

Exposure and Testing Requirements for Mobile Phones Should Be Reassessed

Highlights of GAO-12-771, a report to congressional requesters

Why GAO Did This Study

The rapid adoption of mobile phones has occurred amidst controversy over whether the technology poses a risk to human health as a result of long-term exposure to RF energy from mobile phone use. FCC and FDA share regulatory responsibilities for mobile phones. GAO was asked to examine several issues related to mobile phone health effects and regulation. Specifically, this report addresses (1) what is known about the health effects of RF energy from mobile phones and what are current research activities, (2) how FCC set the RF energy exposure limit for mobile phones, and (3) federal agency and industry actions to inform the public about health issues related to mobile phones, among other things. GAO reviewed scientific research; interviewed experts in fields such as public health and engineering, officials from federal agencies, and representatives of academic institutions, consumer groups, and the mobile phone industry; reviewed mobile phone testing and certification regulations and guidance; and reviewed relevant federal agency websites and mobile phone user manuals.

What GAO Recommends

FCC should formally reassess and, if appropriate, change its current RF energy exposure limit and mobile phone testing requirements related to likely usage configurations, particularly when phones are held against the body. FCC noted that a draft document currently under consideration by FCC has the potential to address GAO's recommendations.

View GAO-12-771. For more information, contact Mark Goldstein at (202) 512-2834 or goldsteinm@gao.gov, or Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

Scientific research to date has not demonstrated adverse human health effects of exposure to radio-frequency (RF) energy from mobile phone use, but research is ongoing that may increase understanding of any possible effects. In addition, officials from the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) as well as experts GAO interviewed have reached similar conclusions about the scientific research. Ongoing research examining the health effects of RF energy exposure is funded and supported by federal agencies, international organizations, and the mobile phone industry. NIH is the only federal agency GAO interviewed directly funding studies in this area, but other agencies support research under way by collaborating with NIH or other organizations to conduct studies and identify areas for additional research.

The Federal Communications Commission's (FCC) RF energy exposure limit may not reflect the latest research, and testing requirements may not identify maximum exposure in all possible usage conditions. FCC set an RF energy exposure limit for mobile phones in 1996, based on recommendations from federal health and safety agencies and international organizations. These international organizations have updated their exposure limit recommendation in recent years, based on new research, and this new limit has been widely adopted by other countries, including countries in the European Union. This new recommended limit could allow for more RF energy exposure, but actual exposure depends on a number of factors including how the phone is held during use. FCC has not adopted the new recommended limit. The Office of Management and Budget's instructions to federal agencies require the adoption of consensus standards when possible. FCC told GAO that it relies on the guidance of federal health and safety agencies when determining the RF energy exposure limit, and to date, none of these agencies have advised FCC to change the limit. However, FCC has not formally asked these agencies for a reassessment. By not formally reassessing its current limit, FCC cannot ensure it is using a limit that reflects the latest research on RF energy exposure. FCC has also not reassessed its testing requirements to ensure that they identify the maximum RF energy exposure a user could experience. Some consumers may use mobile phones against the body, which FCC does not currently test, and could result in RF energy exposure higher than the FCC limit.

Federal agencies and the mobile phone industry provide information on the health effects of mobile phone use and related issues to the public through their websites and mobile phone manuals. The types of information provided via federal agencies' websites on mobile phone health effects and related issues vary, in part because of the agencies' different missions, although agencies provide a broadly consistent message. Members of the mobile phone industry voluntarily provide information on their websites and in mobile-phone user manuals. There are no federal requirements that manufacturers provide information to consumers about the health effects of mobile phone use.

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Abbreviations

ANSI	American National Standards Institute
CDC	Centers for Disease Control and Prevention
DNA	deoxyribonucleic acid
EPA	Environmental Protection Agency
FCC	Federal Communications Commission
FDA	Food and Drug Administration
IARC	International Agency for Research on Cancer
IEEE	Institute of Electrical and Electronics Engineers
NIH	National Institutes of Health
OSHA	Occupational Safety and Health Administration
RF	radio frequency
RF SAR TCB	

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United States Government Accountability Office Washington, DC 20548

July 24, 2012

The Honorable Henry A. Waxman Ranking Member Committee on Energy and Commerce House of Representatives

The Honorable Anna G. Eshoo Ranking Member Subcommittee on Communications and Technology Committee on Energy and Commerce House of Representatives

The Honorable Edward J. Markey House of Representatives

Mobile phone use in the United States has risen dramatically over the last 20 years, and Americans increasingly rely on mobile phones as their sole or primary means of telephone communication.¹ The rapid adoption of mobile phones has occurred amidst controversy over whether the technology poses a risk to human health. Like other devices that transmit radio signals, mobile phones emit radio-frequency (RF) energy. At high power levels, RF energy can heat biological tissue and cause damage. Though mobile phones operate at power levels well below the level at which this thermal effect occurs, the question of whether long-term exposure to RF energy emitted from mobile phones can cause other types of adverse health effects, such as cancer, has been the subject of research and debate.

The Federal Communications Commission (FCC) and the Food and Drug Administration (FDA) share regulatory responsibilities for mobile phones. FCC, in compliance with the National Environmental Policy Act of 1969, regulates RF energy emitted from FCC-regulated transmitters, including mobile phones.² Toward that end, FCC has implemented a certification

²47 C.F.R. § 1.1307(b)(2).

¹In this report, we use the term "mobile phone" to refer to handheld (i.e., wireless) cellular telephones, including newer personal communication devices, such as "smart phones," that can deliver voice, data, and images.

program to ensure that all mobile phones sold in the United States comply with the agency's limit on RF energy exposure. This limit was designed to protect users from the thermal effects of acute exposure to RF energy. FDA is responsible for carrying out a program designed to protect public health and safety from electronic product radiation.³ FDA does not review the safety of all radiation-emitting electronic products, such as mobile phones, before they are marketed. However, FDA has the authority to take action, such as requiring manufacturers to replace or recall mobile phones that are shown to emit RF energy at a level that is hazardous.⁴ To date, FDA has not taken such action, but the agency regularly evaluates scientific studies on mobile phones and health to determine whether they raise public health questions.

In 2001, we reported on the status of scientific knowledge about potential health risks of RF energy exposure from mobile phones and the federal government's regulatory actions to ensure mobile phone safety.⁵ We found that FDA and others had concluded that the research did not show RF energy exposure from mobile phones had adverse health effects, but more studies were needed. We also found that FCC had not issued standardized procedures for testing mobile phones and that FCC's and FDA's consumer materials could be improved. Since 2001, FCC has issued revised guidance for mobile phone testing, and both FCC and FDA have provided updated information to consumers about the health effects of mobile phone use.

At your request, we are updating information related to mobile phone health effects and regulatory issues. Specifically, this report addresses:

- 1. What is known about the human health effects of RF energy exposure from mobile phone use, and what are the current research activities of federal agencies and other organizations?
- 2. How has FCC set the RF energy exposure limit for mobile phones and how does FCC ensure compliance with the limit?

³21 U.S.C. §§ 360hh--360ss.

⁴21 U.S.C. § 360II.

⁵GAO, *Telecommunications: Research and Regulatory Efforts on Mobile Phone Health Issues*, GAO-01-545 (Washington, D.C.: May 7, 2001).

3. What actions have federal agencies and the mobile phone industry taken to inform the public about issues related to mobile phone health effects?

To determine what is known about the human health effects of RF energy exposure from mobile phone use, we reviewed selected studies, including studies and reports that review and assess the scientific research as well as key individual studies. We identified these studies through literature searches in online databases, such as Embase and Medline, and interviews with officials from federal agencies, academic institutions, consumer groups, and industry associations. We also interviewed subject matter experts in a range of fields, such as public health and engineering. To determine the current research activities of federal agencies related to mobile phone use and health, we interviewed officials from FCC; the Department of Health and Human Services' FDA, Centers for Disease Control and Prevention (CDC), and National Institutes of Health (NIH); Department of Defense; Department of Labor's Occupational Safety and Health Administration (OSHA); and the Environmental Protection Agency (EPA). To determine the research activities of other organizations, we interviewed representatives of the International Agency for Research on Cancer (IARC), academic institutions, consumer groups, mobile phone industry associations, mobile phone manufacturers, and mobile phone providers. To determine how FCC set the RF energy exposure limit and ensures compliance with it, we reviewed FCC regulations and guidance. We also reviewed reports from international organizations that recommend RF energy exposure limits. We conducted interviews with officials from FCC and Telecommunication Certification Bodies (TCBs) to understand their role in certifying mobile phones. We also interviewed representatives of the mobile phone industry and consumer organizations, and experts in RF energy exposure limits to obtain their perspectives on the testing and certification of mobile phones. To determine the actions federal agencies and the mobile phone industry have taken to inform the public about issues related to mobile phone health effects, we reviewed information on the public websites of CDC. EPA, FCC, FDA, NIH, and OSHA. We also reviewed the user manuals for selected top-selling mobile phones of 2011 to identify the information manufacturers provided to consumers. (See app. I for more information on our scope and methodology and app. Il for a list of studies we reviewed.)

We conducted this performance audit from August 2011 through July 2012 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to

obtain sufficient, appropriate evidence to provide reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

The United States has experienced dramatic changes in mobile phone use since nationwide cellular service became available in the mid-1980s. For example, the number of estimated mobile phone subscribers has grown from about 3.5 million in 1989 to approximately 286 million by the end of 2009, according to the most recent data reported by FCC.⁶ Further, the number of Americans who rely exclusively on mobile phones for voice service has increased in recent years. For example, by the end of 2009 over 50 percent of young adults aged 25 to 29 relied exclusively on mobile phones, according to the most recent FCC data.⁷ The way individuals use mobile phones has also changed. For instance, while average minutes of use per mobile phone subscriber per month has declined in recent years, mobile text messaging traffic has increased.⁸ About 88 percent of teenage mobile phone users now send and receive text messages, which is a rise from the 51 percent of teenagers who texted in 2006.⁹

Mobile phones are low-powered radio transceivers—a combination transmitter and receiver—that use radio waves to communicate with fixed installations, called base stations or cell towers. The radio waves used by mobile phones are a form of electromagnetic radiation—energy moving through space as a series of electric and magnetic waves. The spectrum of electromagnetic radiation comprises a range of frequencies from very low, such as electrical power from power lines, through visible light, to extremely high, such as gamma rays, as shown in figure 1. The portion of

⁶Federal Communications Commission, *Annual Report and Analysis of Competitive Market Conditions With Respect to Mobile Wireless, Including Commercial Mobile Services*, Fifteenth Report (June 27, 2011).

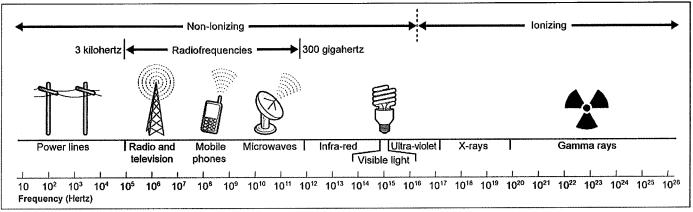
⁷Annual Report and Analysis of Competitive Market Conditions With Respect to Mobile Wireless, Including Commercial Mobile Services (2011).

⁸Annual Report and Analysis of Competitive Market Conditions With Respect to Mobile Wireless, Including Commercial Mobile Services (2011).

⁹Lenhart, A., et al, *Teens and Mobile Phones*, Pew Internet & American Life Project (April 20, 2010).

the electromagnetic spectrum used by mobile phones—as well as other telecommunications services, such as radio and television broadcasting— is referred to as the RF spectrum.

Figure 1: The Electromagnetic Spectrum



Source: FCC.

The electromagnetic spectrum includes ionizing and non-ionizing radiation. Ionizing radiation, such as gamma rays, has energy levels high enough to strip electrons from atoms and molecules, which can lead to serious biological damage, including the production of cancers. RF energy, on the other hand, is in the non-ionizing portion of the electromagnetic spectrum, which lacks the energy needed to cause ionization. However, RF energy can produce other types of biological effects. For example, it has been known for many years that exposure to high levels of RF energy, particularly at microwave frequencies, can rapidly heat biological tissue. This thermal effect can cause harm by increasing body temperature, disrupting behavior, and damaging biological tissue. The thermal effect has been successfully harnessed for household and industrial applications, such as cooking food and molding plastics. Since mobile phones are required to operate at power levels well below the threshold for known thermal effects, the mobile phone health issue has generally focused on whether there are any adverse health effects from long-term or frequent exposure to low-power RF energy emissions that are not caused by heating.

Research on RF Energy Exposure from Mobile Phones Has Not Demonstrated Adverse Health Effects, but More Studies Are Under Way	
Scientific Research	Scientific research to date has not demonstrated adverse human health effects from RF energy exposure from mobile phone use, but additional research may increase understanding of possible effects. In 2001, we reported that FDA and others had concluded that research had not shown RF energy emissions from mobile phones to have adverse health effects, but that insufficient information was available to conclude mobile phones posed no risk. ¹⁰ Following another decade of scientific research and hundreds of studies examining health effects of RF energy exposure from mobile phone use, FDA maintains this conclusion. FDA stated that while the overall body of research has not demonstrated adverse health effects, some individual studies suggest possible effects. Officials from NIH, experts we interviewed, and a working group commissioned by IARC— the World Health Organization's agency that promotes international collaboration in cancer research—have reached similar conclusions. For example, in May 2011 IARC classified RF energy as "possibly

¹⁰GAO-01-545.

carcinogenic to humans."¹¹ IARC determined that the evidence from the scientific research for gliomas, a type of cancerous brain tumor, was limited—meaning that an association has been observed between RF energy exposure and cancer for which a causal relationship is considered to be credible, but chance, bias, or confounding factors could not be ruled out with reasonable confidence.¹² With respect to other types of cancers, IARC determined that the evidence was inadequate—meaning that the available studies are of insufficient quality, consistency, or statistical power to permit a conclusion about the causal association. Additionally, in April 2012 an advisory group to the Health Protection Agency—an independent organization established by the United Kingdom government to protect the public from environmental hazards and infectious diseases—concluded that although there is substantial research on this topic, there is no convincing evidence that RF energy below guideline levels causes health effects in adults or children.¹³

A broad body of research is important for understanding the health effects of RF energy exposure from mobile phone use, because no single study can establish a cause-and-effect relationship and limitations associated with studies can make it difficult to draw conclusions. Two types of studies, epidemiological and laboratory, are used in combination to examine effects from mobile phones. Epidemiological studies investigate the association, if any, between health effects and the characteristics of people and their environment. Laboratory studies conducted on test subjects—including human volunteers, laboratory animals, biological

¹²IARC also determined that the evidence from the scientific research was limited for acoustic neuromas, a type of non-cancerous brain tumor.

¹¹IARC's classification of RF energy is based on conclusions of an IARC working group of more than 30 scientists from 14 countries who reviewed the scientific evidence on the exposure to RF energy from personal devices, such as mobile phones and other sources. IARC published a summary of this working group's findings, see Baan, R., et al, "Carcinogenicity of Radiofrequency Electromagnetic Fields," *The Lancet Oncology*, 2011, 12(7): 624-626. According to IARC officials, the IARC Monograph containing the complete assessments of the working group will be published in fall 2012. IARC has five groups for classifying factors: 1—carcinogenetic to humans, 2A—probably carcinogenic to humans, 2B—possibly carcinogenic to humans, 3—not classifiable as to its carcinogenicity to humans, and 4—probably not carcinogenic to humans. As of July 11, 2012, IARC had classified 952 factors, of which 779 have been classified in groups 2B or 3. Factors classified in the 2B group include coffee and gasoline.

¹³Health Protection Agency, *Health Effects from Radiofrequency Electromagnetic Fields*, RCE-20 (2012).

tissue samples, or isolated cells—are used to determine a causal relationship between possible risk factors and human health, and the possible mechanisms through which that relationship occurs.

Studies we reviewed suggested and experts we interviewed stated that **Epidemiological Studies** epidemiological research has not demonstrated adverse health effects from RF energy exposure from mobile phone use, but the research is not conclusive because findings from some studies have suggested a possible association with certain types of tumors, including cancerous tumors. Findings from one such study, the INTERPHONE study, were published in 2010.14 This retrospective case-control study with more than 5,000 cases examined the association between mobile phone use and certain types of brain tumors, including cancerous tumors, in individuals aged 30-59 years in 13 countries.¹⁵ Overall study findings did not show an increased risk of brain tumors from mobile phone use, but at the highest level of exposure, findings suggested a possible increased risk of glioma.¹⁶ Other epidemiological studies have not found associations between mobile phone use and tumors, including cancerous tumors. For example, findings from a nationwide cohort study conducted in Denmark that originally followed 420,095 individuals did not show an association between increased risk for certain types of tumors, including cancerous

¹⁴This study was conducted at 16 research sites. Several publications are available on study findings from the individual research sites. Findings discussed here are the primary study findings published by the INTERPHONE Study Group. See The INTERPHONE Study Group, "Brain Tumour Risk In Relation To Mobile Telephone Use: Results of the INTERPHONE International Case-Control Study," *International Journal of Epidemiology*, 2010, 39: 675-694.

¹⁵A "case-control" study is a study that compares individuals with a particular disease or outcome—cases—to individuals without that disease or outcome—controls—to investigate if the outcome is associated with exposure to a specific factor. Case-control studies are sometimes called retrospective studies, because the outcome occurred before the study began.

¹⁶RF energy exposure levels from mobile phone use were measured in terms of (1) the number of years since first use, (2) cumulative number of calls, and (3) cumulative duration of calls. Analysis of the relationship between RF energy exposure and risk of four types of tumors—tumors of the brain including glioma and meningioma, acoustic nerve, and parotid gland—were done using these three measures. Individuals that fell into the highest level of exposure are those that reported 1,640 or more cumulative lifetime hours of mobile phone use, which ranged from less than 1 year to more than 10 years of use.

tumors, and mobile phone use.¹⁷ Additionally, findings from a subset of the cohort—56,648 individuals with 10 or more years since their first mobile phone subscription—did not show an increased risk for brain and nervous system tumors.¹⁸ Further, these findings did not change for individuals in the cohort with 13 or more years since their first mobile phone subscription.¹⁹ Also, the CEFALO study—an international case-control study that compared children aged 7 to 19 diagnosed with certain types of brain tumors, including brain cancers, to similar children who were not diagnosed with brain tumors—found no relationship between mobile phone use and risk for brain tumors.²⁰ Findings from another study, which was conducted by NIH and examined trends in brain cancer incidence rates in the United States using national cancer registry data collected from 1992 to 2006, did not find an increase in new cases of brain cancer, despite a dramatic increase in mobile phone use during this time period.²¹

Limitations associated with epidemiological studies can make it difficult to draw definitive conclusions about whether adverse health effects are linked to RF energy exposure from mobile phone use. One such limitation is that it is difficult to measure and control for all variables that may affect results. For example, it can be difficult to accurately measure RF energy exposure from mobile phone use because humans are exposed to RF energy from many sources within their environments and mobile phone technology and user patterns frequently change. Also, epidemiological studies to date have been limited in their ability to provide information about possible effects of long-term RF energy exposure because the

¹⁹Frei, P., et al, "Use of Mobile Phones and Risk of Brain Tumours: Update of Danish Cohort Study," *British Medicine Journal*, 2011, 343: d6387.

²⁰Aydin, D., et al, "Mobile Phone Use and Brain Tumors in Children and Adolescents: A Multicenter Case-Control Study," *Journal of the National Cancer Institute*, 2011, 103: 1-13.

²¹Inskip, P.D., Hoover, R.N., Devesa, S.S., "Brain Cancer Incidence Trends In Relation To Cellular Telephone Use In the United States," *Neuro-Oncology*, 2010, 12(11): 1147-1151.

¹⁷A "cohort" study is a study that follows a defined group of people—the cohort—over time. Outcomes of the people in subsets of the cohort are compared to examine if a particular intervention or factor is associated with a particular outcome. Cohort studies are sometimes called prospective studies, although they can be performed either retrospectively from historical records or prospectively.

¹⁸Schüz, J., et al, "Cellular Telephone Use and Cancer Risk: Update of a Nationwide Danish Cohort," *Journal of the National Cancer Institute*, 2006, 98(23):1707-1713.

prevalence of long-term mobile phone use is still relatively limited and some tumors, including some cancerous tumors, do not develop until many years after exposure. In addition, epidemiological studies, specifically cohort studies, are sometimes limited in their ability to provide information about increased risks for rare outcomes, such as certain types of brain tumors. To address challenges with assessing rare outcomes, case-control studies, which collect information about past mobile phone use among study participants, may be undertaken with large numbers of cases and controls. While these studies can potentially provide information on long-term use, and include enough cancer cases to examine whether this use is associated with rare diseases, collecting data in this way can introduce bias, such as recall bias, into study data and further limit findings. To mitigate this potential bias, some epidemiological studies, specifically cohort studies, follow large populations over time and collect data about mobile phone use before participants develop a certain outcome. In spite of these limitations, experts we spoke with told us that epidemiological studies are a key component of the body of research used for assessing the health effects of mobile phones.

Laboratory Studies Studies We reviewed suggested and experts we interviewed stated that laboratory research has not demonstrated adverse human health effects from RF energy exposure from mobile phone use, but the research is not conclusive because findings from some studies have observed effects on test subjects. Some laboratory studies have examined whether RF energy has harmful effects by exposing samples of human and animal cells to RF energy over a range of dose rates, durations, and conditions to detect any changes in cellular structures and functions. For example, some studies have examined the effects of RF energy on deoxyribonucleic acid (DNA) in rodent and human cells. While some of these studies found that RF energy exposure damaged DNA,²² others

²²For example see Nikolova, T., et al, "Electromagnetic Fields Affect Transcript Levels of Apoptosis-Related Genes In Embryonic Stem Cell-Derived Neural Progenitor Cells," *The FASEB Journal*, 2005, 12: 1686-1688 and Diem, E., et al, "Non-Thermal DNA Breakage by Mobile-Phone Radiation (1800 MHz) In Human Fibroblasts and In Transformed GFSH-R17 Rat Granulosa Cells In Vitro," *Mutation Research*, 2005, 583(2): 178-183.

failed to replicate such an effect using similar experimental conditions.²³ Other studies have exposed laboratory animals to RF energy, examined the animals for changes, and compared outcomes with a control group. For example, some studies have measured the behavior or cognitive functioning of rats to assess the neurological effects of RF energy.²⁴ According to some studies we reviewed, while some of these studies have observed changes in behavior and cognitive function, overall, these studies have not consistently found adverse effects from RF energy levels emitted from mobile phones. Laboratory studies also have exposed human volunteers to RF energy to investigate possible effects, such as effects on the neurological system or blood pressure. According to studies we reviewed, some studies on human volunteers have observed changes in brain activity, but the implications of these physiological changes in relation to adverse effects on human health are unknown.²⁵

Limitations associated with laboratory studies can make it difficult to draw conclusions about adverse human health effects from RF energy exposure from mobile phone use. For example, studies conducted on laboratory animals allow researchers to examine the effects of RF energy exposure on animal systems, but this type of research is limited because effects on laboratory animals may not be the same on humans. Additionally, studies on test subjects may observe biological or physiological changes, but in some circumstances it is unclear how or even if these changes affect human health. Further, to increase the strength of the evidence that observed changes in laboratory studies are

²³For example see Speit, G., Schütz, P., Hoffmann, H., "Genotoxic Effects of Exposure To Radiofrequency Electromagnetic Fields (RF-EMF) In Cultured Mammalian Cells Are Not Independently Reproducible," *Mutation Research*, 2007, 626(1-2): 42-47 and Hook, G.J., et al, "Measurement of DNA Damage and Apoptosis In Molt-4 Cells After In Vitro Exposure To Radiofrequency Radiation," *Radiation Research*, 2004, 161(2):193-200.

²⁴For example see Kumlin T., et al, "Mobile Phone Radiation and the Developing Brain: Behavioral and Morphological Effects in Juvenile Rats," *Radiation Research*, 2007, 168(4): 471-479 and Nittby, H., et al, "Cognitive Impairment in Rats After Long-Term Exposure to GSM-900 Mobile Phone Radiation," *Bioelectromagnetics*, 2008, 29(3): 219-232.

²⁵For example see Volkow, N.D., et al, "Effects of Cell Phone Radiofrequency Signal Exposure on Brain Glucose Metabolism," *Journal of the American Medical Association*, 2011, 305(8): 808-813 and Regel, S.J., et al, "Pulsed Radio-Frequency Electromagnetic Fields: Dose-Dependent Effects on Sleep, the Sleep EEG and Cognitive Performance," *Journal of Sleep Research*, 2007, 16: 253-258.

	the effect of RF energy exposure, studies must be replicated and confirmed with additional research using different dose rates, durations, and conditions of RF energy while observing similar effects. To date, according to FDA officials and some experts we interviewed, only a few laboratory studies that have shown effects from RF energy have been replicated, and some replicated studies have not confirmed earlier results.
Areas for Additional Research	Studies we reviewed and experts we interviewed identified key areas for additional epidemiological and laboratory studies, and according to experts, additional research may increase understanding of any possible effects. For example, additional epidemiological studies, particularly large long-term prospective cohort studies and case-control studies on children, could increase knowledge on potential risks of cancer from mobile phone use. Also, studies and experts identified several areas for additional laboratory studies. For example, additional studies on laboratory animals as well as human and animal cells examining the possible toxic or harmful effects of RF energy exposure could increase knowledge on potential biological and health effects of RF energy. Further, additional laboratory studies on human and animal cells to examine non-thermal effects of RF energy could increase knowledge of how, if at all, RF energy interacts with biological systems. However, some experts we spoke to noted that, absent clear evidence for adverse health effects, it is difficult to justify investing significant resources in research examining non- thermal effects of RF energy from mobile phone use. Another area identified for additional laboratory research is studies on human volunteers examining the effect of changes in the neurological system, which could help determine if these possible observed changes in neurological functioning from RF energy are adverse effects. In addition to conducting additional research, experts we interviewed reported that the broader body of evidence on RF energy should be re-evaluated when findings from key studies become available, to determine whether additional research in certain areas is still warranted.
Current Research Activities	Current research activities of federal agencies, international organizations, and the mobile phone industry include funding and supporting ongoing research on the health effects of RF energy exposure from mobile phones. NIH is the only federal agency we interviewed that is directly funding ongoing studies on health effects of RF energy from mobile phone use. NIH officials reported that the agency has provided about \$35 million for research in this area from 2001 to 2011. (See table 1 for more information on ongoing studies funded by NIH.) Although other federal agencies are not directly funding research in this area, some

agencies are providing support for ongoing studies. For example, FDA officials reported that FDA's National Center for Toxicological Research, with funding provided by NIH as part of the National Toxicology Program, is conducting studies on rat and bovine brain cells to examine whether RF energy emitted from mobile phones is toxic.²⁶ Also, CDC officials reported that the agency is collaborating with others to conduct ongoing studies in this area. For example, CDC officials reported that one of the agency's staff is collaborating with researchers in seven countries to conduct additional analyses on data collected through the INTERPHONE study to determine whether occupational exposure to RF energy and chemicals was a risk factor for brain cancer.

²⁶The National Toxicology Program is an interagency program that evaluates factors, such as RF energy, that could affect public health for the federal government. The three core federal agencies that make-up this program are NIH's National Institute of Environmental Health Sciences, CDC's National Institute for Occupational Safety and Health, and FDA's National Center for Toxicological Research. The National Toxicology Program is conducting comprehensive carcinogenicity studies on laboratory animals. Collectively these studies will provide information about potential human health effects of RF energy exposure.

Table 1: Ongoing NIH-Funded Studies on Health Effects of RF Energy Exposure from Mobile Phone Use

Description	NIH institute funding the study	Totai NIH funding	Estimated year of completion
Examining environmental and genetic factors for meningioma, a type of brain tumor, at research sites in five states	National Cancer Institute	\$8,779,998	2012
Evaluating brain cancer incidence trends in the United States using cancer registry data to determine if trends are consistent with reported epidemiological associations of mobile phone use and certain types of cancer	National Cancer Institute	Not applicable ^a	Not applicable ^a
Examining effects of mobile phones on brain glucose	National Institute on Alcohol Abuse and Alcoholism	\$595,700	2012
Examining effects of exposure to mobile phones in childhood on the central nervous system using children in the Danish National Birth Cohort ^b	National Institute of Environmental Health Sciences	\$423,500	2012
Examining toxicology and carcinogenic effects of RF energy in laboratory animals as part of the National Toxicology Program ^e	National Institute of Environmental Health Sciences	\$25,600,000	2015

Source: GAO analysis of NIH information.

^aThe National Cancer Institute regularly monitors and evaluates the U.S. brain cancer incidence trends using Surveillance Epidemiology and End Result data. According to NIH officials, the National Cancer Institute does not separately track funding associated with performing this task. The most recent publication of data from this surveillance activity was published in 2012. See Little, M.P., et al, "Mobile Phone Use and Glioma Risk: Comparison of Epidemiological Study Results With Incident Trends In the United States," *British Medical Journal*, 2012, 344: e1147.

^bThe Danish National Birth Cohort consists of over 100,000 Danish children who were born from 1996 to 2002. Data on lifestyle factors, dietary habits, and environmental exposures have been collected on these children, and data on current mobile phone use by children have been collected since these children reached the age of seven.

^cThe National Toxicology Program is an interagency program that evaluates factors, such as RF energy, that could affect public health for the federal government. The three core federal agencies that make-up this program are NIH's National Institute of Environmental Health Sciences, CDC's National Institute for Occupational Safety and Health, and FDA's National Center for Toxicological Research. The National Toxicology Program is conducting comprehensive carcinogenicity studies on laboratory animals. According to FDA officials, FDA is conducting one of these National Toxicology Program studies in its National Center for Toxicological Research laboratory.

Federal agencies are also engaged in other activities to support research on the health effects of mobile phone use. For example, FDA collaborates with other organizations on research-related projects. According to FDA officials, the agency helped the World Health Organization develop its *WHO Research Agenda for Radiofrequency Fields* in 2001 and has provided comments to the World Health Organization on updates to this research agenda.²⁷ Also, officials from federal agencies that have responsibility for different aspects of RF energy safety and work—CDC, EPA, FCC, FDA, NIH, the National Telecommunications and Information Administration, and OSHA—are members of the Radiofrequency Interagency Work Group, which works to share information on RF energy related projects at the staff level. According to FCC and FDA officials, this group periodically meets to discuss RF energy related issues, including recently published and ongoing research on the health effects of RF energy exposure.

International organizations also support research on health effects of RF energy exposure from mobile phone use. Officials from IARC told us that the organization is currently supporting research activities for ongoing studies examining health effects of mobile phone use with respect to cancer. For example, IARC is involved in the identification of research sites for and implementation of the COSMOS study-a large international, prospective, cohort study that will follow individuals for 25 or more years to examine possible long-term health effects of using mobile phones, such as brain tumors, including cancers, and other health outcomes. IARC is also coordinating additional data analyses on previously published studies examining mobile phone health effects. For example, IARC is coordinating additional analyses of data collected for the INTERPHONE study. Additionally, the European Commission-the European Union's executive body that represents the interest of Europe as a whole----is supporting research in this field. Under its research program-the Seventh Framework Programme-the European Commission has provided funds for the MOBI-KIDS study, an international case-control study examining the possible association between communication technology, including mobile phones and other environmental exposures, and the risk of brain tumors in people aged 10 to 24 years.

The mobile phone industry supports research by providing funding for studies. According to representatives from mobile phone manufacturers, service providers, and industry associations, most industry funding for scientific research is provided by the Mobile Manufacturers Forum—an international not-for-profit association that is largely comprised of wireless

²⁷The World Health Organization most recently updated this research agenda in 2010. See The World Health Organization, *WHO Research Agenda for Radiofrequency Fields*, Geneva, Switzerland (2010).

	device manufacturers. According to representatives from the Mobile Manufacturers Forum, the association has provided about \$46 million for RF energy research since 2000 and is currently providing support for epidemiological and laboratory studies. Although representatives from all four mobile phone manufacturers that we interviewed reported that their companies support research through their industry associations, representatives from one manufacturer reported that it is also funding two studies examining the effects of RF energy emitted from mobile phones on human hands and the head.
FCC's RF Energy Exposure Limit May Not Reflect Latest Evidence on Thermal Effects, and Mobile Phone Testing Requirements May Not Identify Maximum Exposure	· ·
RF Energy Exposure Limit	In 1996, FCC adopted the RF energy exposure limit for mobile phones of 1.6 watts per kilogram, averaged over one gram of tissue, a measurement of the amount of RF energy absorbed into the body. ²⁸ FCC developed its limit based on input from federal health and safety agencies as well as the 1991 recommendation by the Institute of Electrical and Electronics Engineers (IEEE) that was subsequently approved and issued in 1992 by the American National Standards Institute (ANSI). ²⁹ This recommended limit was based on evidence related to the thermal effects
	²⁸ 61 Fed. Reg. 41017, August, 7, 1996. This measurement is called the specific absorption rate (SAR) and is the widely accepted measurement of RF energy absorbed into the body in watts per kilogram, averaged over an amount of tissue ranging from the entire body to one gram. ²⁹ See IEEE Std. C95.1-1991 and 47 CFR Sec. 2.1093(d)(2).

of RF energy exposure³⁰—the only proven health effects of RF energy exposure—and was set at a level well below the threshold for such effects. FCC noted that the limit provided a proper balance between protecting the public from exposure to potentially harmful RF energy and allowing industry to provide telecommunications services to the public in the most efficient and practical manner possible.

In 2006, IEEE published its updated recommendation for an RF energy exposure limit of 2.0 watts per kilogram, averaged over 10 grams of tissue.³¹ This new recommended limit could allow for more RF energy exposure from mobile phone use, although actual exposure depends on a number of factors, including the operating power of the phone, how the phone is held during use, and where it is used in proximity to a mobile phone base station.³² According to IEEE, improved RF energy research and a better understanding of the thermal effects of RF energy exposure on animals and humans, as well as a review of the available scientific research, led to the change in recommended RF energy exposure limit. IEEE's new recommended limit was harmonized with a 1998 recommendation of the International Commission on Non-Ionizing Radiation Protection, which has been adopted by more than 40 countries, including the European Union countries.³³ Both of these recommendations call for an exposure limit of 2.0 watts per kilogram averaged over 10 grams of tissue, which according to IEEE represents a scientific consensus on RF energy exposure limits.

³¹See IEEE Std. C95.1-2005.

³²The output power of a phone is variable, using the minimum necessary for successful communication, and at any time will be a function of distance to the nearest mobile phone antenna and the presence of obstructions.

³⁰In scientific tests, animals had adverse behavioral effects once they absorbed enough RF energy to increase their body temperature by 1 degree Celsius. IEEE incorporated a safety factor into its standards for general human exposure by setting them at one-fiftieth the exposure shown to cause adverse effects in animals. Because this limit is based on whole-body exposure, it was further adjusted to account for the fact that mobile phones expose only a part of the body to RF energy.

³³See International Commission on Non-Ionizing Radiation Protection, *Guidelines for Limiting Exposure to Time-Varying Electric, Magnetic, and Electromagnetic Fields (Up to 300 GHz)* (1998). The International Commission on Non-Ionizing Radiation Protection is an independent scientific organization that provides guidance and advice on the health hazards of non-ionizing radiation exposure. Its recommended exposure limit is for frequencies up to 10 gigahertz. The IEEE recommendation was made for frequencies between 100 kilohertz and 3 gigahertz.

According to senior FCC officials, the agency has not adopted any newer limit because federal health and safety agencies have not advised them to do so. FCC officials told us that they rely heavily on the guidance and recommendations of federal health and safety agencies when determining the appropriate RF energy exposure limit and that, to date, none of these agencies have advised FCC that its current RF energy limit needs to be revised. Officials from FDA and EPA told us that FCC has not formally asked either agency for an opinion on the RF energy limit. FDA officials noted, though, that if they had a concern with the current RF energy exposure limit, then they would bring it to the attention of FCC.

Although federal guidance states that agencies should generally use consensus standards, FCC officials provided reasons why they did not have current plans to change the RF energy exposure limit. Office of Management and Budget Circular A-119 concerning federal use of technical standards states that federal agencies must use "consensus standards in lieu of government-unique standards," except where inconsistent with law or otherwise impractical. FCC officials noted that no determination has been made that the new recommended RF energy exposure limit is inconsistent with law or impractical. FCC has recognized that research on RF energy exposure is ongoing and pledged to monitor the science to ensure that its guidelines continue to be appropriate.34 FCC officials noted that an assessment of the current limit and the new recommended limit could be accomplished through a formal rulemaking process, which would include a solicitation of information and opinions from federal health and safety agencies.³⁵ FCC could alternatively release a Notice of Inquiry to gather information on this issue without formally initiating rulemaking.

Stakeholders we spoke with varied on whether the current U.S. RF energy exposure limit should be changed to reflect the new recommended limit. For instance, a few experts and consumer groups we spoke with said FCC should not adopt the new recommended exposure

³⁴In re Guidelines for Evaluating the Environmental Effects of Radiofrequency Radiation, 11 FCC Rcd 15123, 15125 (1996).

³⁵FCC's rulemaking process includes multiple steps as outlined by law, with several opportunities for public participation. FCC generally begins the process by releasing a Notice of Proposed Rulemaking and establishing a docket to gather information submitted by the public or developed within FCC to support the proposed rule. FCC analyzes information in the docket and drafts a final rule.

limit because of the relative uncertainty of scientific research on adverse health effects from mobile phone use. An official from one consumer group told us that adopting the 2.0 watts per kilogram exposure limit would be a step back, since it could allow users to be exposed to higher radiation levels. Conversely, some experts we spoke with maintained that both the 1.6- and 2.0-watts-per-kilogram limits protect users from the thermal effects of RF energy exposure—which the experts maintained are the only conclusively demonstrated effects of exposure—since a safety factor of fifty was applied to obtain the limits, meaning that the maximum permitted exposure is a fiftieth of what was determined to be the exposure at which potentially deleterious thermal effects are likely to occur.

Nevertheless, by not formally reassessing its current RF energy exposure limit, FCC cannot ensure that it is using a limit that reflects the latest evidence on thermal effects from RF energy exposure, and may impose additional costs on manufacturers and limitations on mobile phone design. FCC's current limit was established based on recommendations made more than 20 years ago. According to IEEE, the new recommended limit it developed is based on significantly improved RF research and therefore a better understanding of the thermal effects of RF energy exposure. Additionally, three of the four mobile phone manufacturers we spoke with favored harmonization of RF energy exposure limits, telling us that maintaining the separate standards can result in additional costs and may affect phone design in a way that could limit performance and functionality. According to some manufacturers we spoke with, many of their phones are sold in multiple countries. As a result, the manufacturers have to develop and test phones based on different exposure limits, which can require additional resources and slow the time it takes to get new phones into the market. Additionally, one manufacturer indicated that some features are not enabled on phones sold in the United States that are available in other countries to comply with FCC's current limit. A reassessment by FCC would help it to determine if any changes to the limit are appropriate.

Mobile Phone Certification FCC ensures compliance with its RF energy exposure limit by certifying all mobile phones sold in the United States. In its application for certification, manufacturers must provide evidence that their mobile phones meet FCC's RF energy exposure limit. FCC has authorized 23 TCBs in the United States and other countries to review applications that involve evaluation of RF exposure test data and issue certifications on behalf of the agency. TCBs are private organizations that have been accredited to perform these functions.³⁶ TCBs now perform the majority of mobile phone certifications, with FCC generally only handling the more complex certifications, such as mobile phones with multiple transmitters using third generation and fourth generation technology.³⁷ Figure 2 illustrates the mobile phone certification process.

Figure 2: U.S. Mobile Phone Certification Process

Phone manufactured

Manufacturers develop and introduce new models of mobile phones with new features and designs.

Phone tested

Manufacturers must test their mobile phones for compliance with FCC's RF energy exposure limit. Manufacturers may conduct the tests themselves at their own facilities or have the testing done for them by testing laboratories.

Source; GAO.

Phone reviewed

Manufacturers must submit an application for certification that their phone meets FCC's RF energy exposure limit. Either FCC or a TCB reviews the application, a process which may involve repeated inquiries to the manufacturer. Phone certified

A written certification, which allows the mobile phone to be put on the U.S. market, is issued by FCC, or by a TCB on behalf of FCC, once it is determined that applicable requirements, including the RF energy exposure limit, have been met.

Representatives from mobile phone manufacturers we spoke with were generally satisfied with how TCBs review and certify mobile phones, but noted that complex certifications handled by FCC can take a long time to process. For instance, since there are generally no established test procedures for new technologies, FCC must work with the manufacturer to develop appropriate procedures by which the agency can determine if the device meets the RF energy exposure limit. According to FCC, part of this review may result in changes to testing guidance. For example, representatives from one manufacturer told us that FCC may take many months to process an application for a newer product. FCC officials told us that over the last 10 years, the average time to review an application

³⁷According to FCC, third and fourth generation mobile phone technologies allow consumers to access a variety of different services and functionalities, such as Web browsing, e-mail, access to application stores, video conference or chat, mapping and navigation systems, mobile commerce, and the downloading of content.

³⁶In 1999, FCC established a TCB program and requested that the National Institute of Standards and Technology accredit entities to perform TCB functions. The National Institute of Standards and Technology determined, in accordance with its procedures and in consultation with the FCC, that it would recognize qualified accreditation bodies to accredit TCBs. Subsequently, the National Institute of Standards and Technology approved ANSI in May 2000 and the American Association for Laboratory Accreditation in April 2007 as accreditation organizations for TCBs. These accreditation bodies assess new and current TCBs to ensure they comply with relevant requirements.

	submitted directly to the agency has ranged from 45 to 60 days. Representatives from one TCB we spoke with noted that the TCB review can be as short as a week, though FCC does not collect data on how long it takes TCBs to process applications.
Mobile Phone Testing	To ensure that mobile phones comply with FCC's RF energy exposure limit, manufacturers conduct tests at their own laboratories or have the testing conducted for them by private laboratories. Laboratories must follow standardized FCC testing procedures or work with FCC to develop acceptable alternatives in some complex cases. These procedures require that the SAR be measured to ensure the mobile phone's compliance with the FCC exposure limit, which was designed to ensure that mobile phones do not expose the public to levels of RF energy that could be potentially harmful. FCC periodically updates the testing procedures as new mobile phone technology is introduced. A typical testing set-up is shown in figure 3.

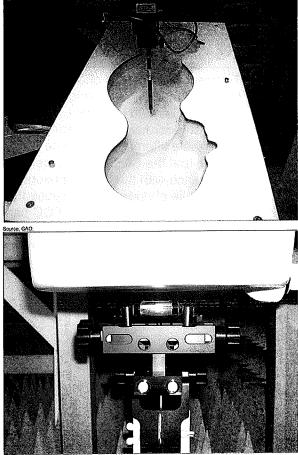


Figure 3: Photographs of Mobile Phone Testing near the Body

Source. GAD

Note: To test mobile phones, a mold in the shape of an adult torso and head is filled with fluid mixture designed to simulate the electrical properties of human tissue. A phone is placed near the head or torso (the torso, or body, testing is illustrated above) and operated at maximum power. A probe attached to a computer-controlled mechanical arm is inserted into the mixture at various locations to measure SAR. This procedure is repeated for a number of closely specified phone positions and operating frequencies. To receive FCC certification, none of the SAR measurements can exceed FCC's exposure limit of 1.6 watts per kilogram.

FCC has implemented standardized testing procedures requiring mobile phones to be tested for compliance with the RF energy exposure limit when in use against the ear and against the body while in body-worn accessories, such as holsters, but these requirements may not identify the maximum exposure under other conditions.³⁸ The specific minimum separation distance from the body is determined by the manufacturer (never to exceed 2.5 centimeters), based on the way in which the mobile phone is designed to be used.³⁹ The results of these testing requirements are two different values: a maximum SAR value for the head and a maximum SAR value for the body. However, these testing procedures may not identify the maximum SAR for the body, since some consumers use mobile phones with only a slight distance, or no distance, between the device and the body, such as placing the phone in a pocket while using an ear piece. Using a mobile phone in this manner could result in RF energy exposure above the maximum body-worn SAR determined during testing, although that may not necessarily be in excess of the FCC's limit. In such a case, exposure in excess of FCC's limit could occur if the device were to transmit continuously and at maximum power.

FCC has not reassessed its testing requirements to ensure that testing identifies the maximum RF energy exposure for the other usage conditions a user could experience when mobile phones are in use without body-worn accessories or as advised by the manufacturer's instructions, rather than the head. Although FCC officials said that they provide case-by-case guidance for many mobile phones operating with new technologies, they do not require testing of mobile phones when used without body-worn accessories unless such conditions are specifically identified by the manufacturer's operating instructions. Representatives of some consumer groups we spoke with expressed concern about the exposure to RF energy that can come with such use. Officials from IEEE, though, told us that the average power and resultant radiation level of mobile phones while in use is very low, such that even when a mobile phone is used against the body it is unlikely that the RF energy exposure would exceed the FCC limit. Nevertheless, FCC has not

³⁸These procedures were based on IEEE Std. 1528-2003. Because mobile phones are not tested when in use directly against the body, FCC recommends that mobile phone user manuals note that a minimum separation distance must be maintained between the user's body and the phone to comply with RF exposure limits.

³⁹FCC guidance states that mobile phone body-worn tests should be conducted with beltclips and holsters attached to the phone and positioned against the flat surface of the mold in normal use configurations. If the manufacturer does not supply these accessories, a predetermined distance from the back of the mobile device to the flat surface of the mold is recommended.

reassessed its testing requirements to ensure that mobile phones do not exceed the RF energy exposure limit in all possible usage conditions.

Beyond the testing required for certification, FCC also ensures that mobile phones meet its RF energy exposure limit by reviewing information collected as part of routine surveillance of mobile phones on the market. FCC requires TCBs to carry out this post-market surveillance program, through which each TCB tests one percent of the mobile phones they have certified for RF energy exposure, to ensure that the phones continue to meet FCC's RF energy exposure limit⁴⁰ According to FCC, no mobile phone tested under this surveillance program has been found in violation of the RF energy exposure limit.

Federal Agencies and Mobile Phone Industry Provide Information to the Public through Websites and User Manuals	
Information Provided by Federal Agencies	Federal agencies provide information to the public on the health effects of mobile phone use and related issues primarily through their websites. This information includes summaries of research, and agencies' conclusions about the health effects of mobile phone use, as well as suggestions for how mobile phone users can reduce their exposure to RF energy. Table 2 summarizes selected information on mobile phones and health provided by six federal agencies on their websites.

⁴⁰Testing may be performed at either the TCB's testing facilities or at a subcontracted test facility.

Types of information provided	Agency	
What RF energy or radiation is	CDC, EPA, FCC, FDA, NIH, OSHA	
Current mobile phone RF energy exposure limits	CDC, FCC, OSHA	
How mobile phones are tested or certified	FCC	
Thermal effects of RF energy exposure	CDC, FCC, NIH, OSHA	
Non-thermal effects of RF energy exposure	CDC, FCC, OSHA	
Health issues and research related to mobile phones	CDC, FCC, FDA, NIH, OSHA	
Summaries or links to ongoing studies	CDC, FDA, NIH	
Information on how to minimize or reduce RF energy exposure from mobile phone use	CDC, EPA, FCC, FDA, NIH, OSHA	

Table 2: Federal Agency Website Information on Mobile Phones and Health as of June 2012

Source: GAO analysis of federal agency websites.

Note: Some federal agency websites include additional information on mobile phones and health beyond the major topics listed above.

The types of information that federal agencies' websites provide on mobile phone health effects and related issues vary, in part because of the agencies' different missions, though the websites provide a broadly consistent message. For instance, NIH primarily provides information about the research on health effects of RF energy exposure from mobile phone use, while FCC provides information on how mobile phones are tested and certified. Nevertheless, the concluding statements about whether RF energy exposure from mobile phone use poses a risk to human health are generally consistent across selected federal agencies' websites that we reviewed, though the specific wording of these concluding statements varies.

Representatives from some consumer groups and experts we spoke with raised concerns that the information on federal agency websites about mobile phone health effects is not precautionary enough, among other things. In particular, these representatives and experts said that federal agencies should include stronger precautionary information about mobile phones because of the uncertain state of scientific research on mobile phone health effects as well as the fact that current testing requirements may not identify the maximum possible RF energy exposure. Representatives from one consumer group also said that federal agency websites should provide more consumer information, such as the impact of different mobile phone technologies on RF energy exposure. Officials from FCC and NIH maintained that the information on their websites reflects the latest scientific evidence and provides sufficient information for consumers concerned about potential health effects related to mobile phones.

	Some consumer groups noted that they would like FCC to mention IARC's recent classification of RF energy exposure as "possibly carcinogenic" on FCC's website. FCC noted that it generally defers to the health and safety agencies for reporting on new research, though FCC's website did include information on the recent INTERPHONE study when we reviewed the site in June 2012. FCC does provide links to CDC, EPA, FDA, and other websites, some of which have information about the IARC's classification. ⁴¹ FDA notes on its website that the IARC classification means there is limited evidence showing RF carcinogenicity in humans and insufficient evidence of carcinogenicity in experimental animals.
	Some local governments are taking steps to provide precautionary information to consumers. For example, the city of San Francisco has developed a Web page on mobile phone health issues, including steps to reduce RF energy exposure from mobile phone use, and has passed an ordinance requiring local mobile phone retailers to distribute a flyer on ways that consumers can reduce their exposure. ⁴²
Information Provided by Mobile Phone Industry	The mobile phone industry provides information to consumers on the health effects of mobile phone use and related issues through user manuals and websites. The information provided in user manuals by manufacturers is voluntary, as there are no federal requirements that manufacturers provide any specific information to consumers about the health effects of mobile phone use. ⁴³ Most manuals we reviewed provide information about how the device was tested and certified, as well as the highest energy exposure measurement associated with the device. Some manufacturers also provide suggestions, often based on information from FDA, to consumers about how to minimize their exposure, among other things.
	⁴¹ FCC's links to the EPA and FDA websites were not functional when we reviewed them in April 2012. After we provided our draft report to FCC these links were fixed and were functional as of July 2012.
	⁴² The ordinance has been challenged in federal court. The case is currently being considered by the U.S. Court of Appeals for the 9 th Circuit.
	43 ECC does require a statement that the mobile phone complies with the agency's RF

 ^{43}FCC does require a statement that the mobile phone complies with the agency's RF energy exposure limit, among other things. 47 CFR § 2.1077.

All manuals we reviewed, except one, include a statement that, when used on the body, as opposed to against the ear, a minimum distance between the body and the mobile phone should be maintained. These distances ranged from 1.5 to 2.5 centimeters. Since all mobile phones are tested for RF energy exposure compliance at a distance from the body, as discussed previously in this report, these instructions are consistent with how the devices were tested and certified by FCC. Some consumer groups and experts we spoke with noted that consumers could be unaware of these instructions if they do not read the entire user manual.

Conclusions

FCC's current RF energy exposure limit for mobile phones, established in 1996, may not reflect the latest evidence on the thermal effects of RF energy exposure and may impose additional costs on manufacturers and limitations on mobile phone design. FCC regulates RF energy emitted from mobile phones and relies on federal health and safety agencies to help determine the appropriate RF energy exposure limit. However, FCC has not formally asked FDA or EPA for their assessment of the limit since 1996, during which time there have been significant improvements in RF energy research and therefore a better understanding of the thermal effects of RF energy exposure. This evidence has led to a new RF energy exposure limit recommendation from international organizations. Additionally, maintaining the current U.S. limit may result in additional costs for manufacturers and impact phone design in a way that could limit performance and functionality. Reassessing its current RF energy exposure limit would ensure that FCC's limit protects the public from exposure to RF energy while allowing industry to provide telecommunications services in the most efficient and practical manner possible.

The current testing requirements for mobile phones may not identify the maximum RF energy exposure when tested against the body. FCC testing requirements state that mobile phone tests should be conducted with belt-clips and holsters attached to the phone or at a predetermined distance from the body. These requirements were developed by FCC to identify the maximum RF energy exposure a user could experience when using a mobile phone, to ensure that the mobile phone meets the agency's RF energy exposure limit. This limit was designed to ensure that mobile phones do not expose the public to levels of RF energy that could be potentially harmful. By testing mobile phones only when at a distance from the body, FCC may not be identifying the maximum exposure, since some users may hold a mobile phone directly against the body while in use. Using a mobile phone in this manner could result in RF energy

	exposure above the maximum body-worn SAR determined during testing, although that may not necessarily be in excess of FCC's limit. Reassessing its testing requirements would allow FCC to ensure that phones used by consumers in the United States do not result in RF energy exposure in excess of FCC's limit.
Recommendations for Executive Action	 We recommend that the Chairman of the FCC take the following two actions: Formally reassess the current RF energy exposure limit, including its effects on human health, the costs and benefits associated with keeping the current limit, and the opinions of relevant health and safety agencies, and change the limit if determined appropriate. Reassess whether mobile phone testing requirements result in the identification of maximum RF energy exposure in likely usage configurations, particularly when mobile phones are held against the body, and update testing requirements as appropriate.
Agency Comments and Our Evaluation	We provided a draft of this report to the Department of Commerce, Department of Defense, Department of Health and Human Services, Department of Labor, EPA, and FCC for review and comment. FCC provided comments in a letter from the Chief, Office of Engineering and Technology. (See app. III.) In this letter, FCC noted that FCC's staff has independently arrived at the same conclusions about the RF exposure guidelines as GAO. FCC also noted that a draft Order and Further Notice of Proposed Rulemaking, along with a new Notice of Inquiry, which has been submitted by FCC staff to the Commission for their consideration, has the potential to address the recommendations made in this report. We agree that FCC's planned actions may address our recommendations. However, since FCC has not yet initiated a review of the RF energy exposure limit or mobile phone testing requirements, our recommendations are still relevant. FCC and the Departments of Commerce, Defense, and Health and Human Services also provided technical comments, which were incorporated as appropriate. The Department of Labor and EPA did not provide comments on the draft.
	As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the appropriate congressional committees, the Chairman of the FCC, the

Administrator of the EPA, as well as the Secretaries of the Departments of Commerce, Defense, Health and Human Services, and Labor. The report will also be available at no charge on GAO's website at http://www.gao.gov.

If you or your staff have any questions or would like to discuss this work, please contact Mark Goldstein at (202) 512-2834 or goldsteinm@gao.gov or Marcia Crosse at (202) 512-7114 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Individuals making key contributions to this report are listed in appendix IV.

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Appendix I: Scope and Methodology

To determine what is known about the human health effects of radiofrequency (RF) energy exposure from mobile phone use, we reviewed selected studies including studies and reports that review and assess the scientific research, such as meta-analyses and government reports, as well as key individual epidemiological and laboratory studies.¹ We identified 384 studies that examine the health effects of RF energy emitted from mobile phone use through literature searches and interviews. We conducted literature searches in six online databases with health and engineering content—Embase, Inspec, Medline, National Technical Information Service Bibliographic, SciSearch, and SocialSciSearch—containing peer-reviewed publications and government reports to identify studies published from January 2006 through September 2011 using health-, mobile phone-, and RF energy-related search terms. Additionally, we interviewed officials from federal agencies and representatives of academic institutions, consumer groups, and industry associations to identify studies published through December 2011. To select studies for our review, we conducted a preliminary review of the 384 studies and included those that met the following criteria: (1) reviewed and assessed the scientific research in a systematic way, such as meta-analyses, and discussed their methods for identifying, selecting, and assessing the scientific research that were used to draw conclusions or (2) were key reports that identify areas for additional research in these fields, such as the 2008 National Research Council's Identification of Research Needs Relating to Potential Biological or Adverse Health Effects of Wireless Communication.² We selected 38 studies that met these criteria. (See app. II for a list of the 38 studies we reviewed.)

To collect information on the 38 selected studies, we developed a data collection instrument that contained 16 open- and closed-ended questions about the entity or entities that published and funded the study; the study methods, key findings, and limitations; and additional research needs. To apply this data collection instrument, one analyst reviewed each study

¹Epidemiological studies investigate the association, if any, between health effects and the characteristics of people and their environment. Laboratory studies conducted on test subjects—including human volunteers, laboratory animals, biological tissue samples, or isolated cells—are used to determine a causal relationship between possible risk factors and human health, and the possible mechanisms through which that relationship occurs.

²See National Research Council, *Identification of Research Needs Relating to Potential Biological or Adverse Health Effects of Wireless Communication* (Washington, D.C.: 2008).

and recorded information in the data collection instrument. A second analyst then reviewed each completed data collection instrument to verify the accuracy of the information recorded. We summarized the findings and limitations of studies based on the completed data collection instruments, as well as areas for additional research identified in the studies. Additionally, we used this analysis to identify key, individual, epidemiological and laboratory studies.

We also interviewed subject matter experts to determine what is known about the human health effects of RF energy exposure from mobile phone use. First, we identified 123 potential subject matter experts to interview through the following sources: (1) interviews with officials from federal agencies and representatives of academic institutions, consumer groups, and industry associations and (2) participant lists of recent expert panels and workgroups on this topic. These panels and workgroups included:

- The National Research Council's Committee on Identification of Research Needs Relating to Potential Biological or Adverse Health Effects of Wireless Communications Devices,³
- The International Agency for Research on Cancer's (IARC) Monograph Working Group on RF electromagnetic fields,⁴
- The INTERPHONE Study Group,⁵ and
- The European Commission's Scientific Committee on Emerging and Newly Identified Health Risks.⁶

Second, we assigned each expert to one or more broad categories that captured his or her general area of expertise. Next, we e-mailed those experts who, based on our initial review, (1) were identified through at

⁵The INTERPHONE study is a retrospective case-control study that examined effects of mobile phone use on certain types of brain cancers or tumors in more than 5,000 cases aged 30-59 years in 13 countries. See Cardis, E, et al, "Brain Tumor Risk in Relation to Mobile Telephone Use: Results of the INTERPHONE International Case-Control Study," *International Journal of Epidemiology*, 2010, 39: 675-694.

⁶European Commission, Health Effects of Exposure to EMF, 2009.

³National Research Council, *Identification of Research Needs Relating to Potential Biological or Adverse Health Effects of Wireless Communication* (Washington, D.C.: 2008).

⁴Baan, R., et al, "Carcinogenicity of Radiofrequency Electromagnetic Fields," *Lancet Oncology*, 2011, 12(7): 624-626.

least one source and we had information on their general area of expertise or (2) were identified through at least two sources regardless of whether we had information on their general area of expertise. We received responses from 42 experts agreeing to help us with our study. Based on these responses, we selected a judgmental sample of 11 experts who represented a range of expertise and professional backgrounds including public health and policy; biology and medicine; biostatistics; epidemiology; engineering, including bioelectrical engineering; and RF energy standards. (See table 3 for the list of individuals interviewed.) These experts were interviewed as individuals, not as representatives of any institution. Further, all of the experts completed a form stating that they had no conflicts of interest that would affect their ability to provide us with their perspectives on what is known about the human health effects of RF energy exposure from mobile phone use and related issues.

Name	Title	Institution ^a
Carl Blackman	a founder and former President (1990-91)	Bioelectromagnetics Society
Linda Erdreich	Senior Managing Scientist	Center for Epidemiology and Computational Biology, Exponent
Jukka Juutilainen	Professor of Radiation Biology and Radiation Epidemiology	Department of Environmental Science, University of Eastern Finland
Leeka Kheifets	Professor of Epidemiology	Department of Epidemiology, School of Public Health, University of California, Los Angeles
Henry Lai	Research Professor	Department of Bioengineering, University of Washington
James Lin	Professor of Electrical Engineering, Bioengineering, Physiology, and Biophysics	University of Illinois, Chicago
David McCormick	Senior Vice President and Director	IIT Research Institute
Martin Röösli	Assistant Professor	Unit for Environmental Exposures and Health, Swiss Tropical and Public Health Institute, Basel
Siegal Sadetzki	Head	Cancer and Radiation Epidemiology Unit, The Gertner
J		Institute, Chaim Sheba Medical Center, Israel
	Associate Professor	Sackler School of Medicine, Tel-Aviv University, Israel
Jonathan Samet	Professor and Flora L. Thornton Chair	Department of Preventive Medicine, Keck School of Medicine, University of Southern California
Bernard Veyret	Senior Scientist	National Center for Scientific Research, Bordeaux University, France

Table 3: Subject Matter Experts Interviewed

Source: GAO.

[®]We interviewed experts as individuals, not as representatives of any institution. We provide information on institutions to help readers identify experts.

To determine the current research activities of federal agencies and other organizations related to mobile phone use and health, we interviewed representatives from various agencies and organizations. We identified agencies and organizations by reviewing information on their websites on RF energy and conducting interviews with officials from federal agencies and representatives of organizations familiar with research on health effects of mobile phone use. To determine the current research activities of federal agencies related to mobile phone use and health, we interviewed officials from the Department of Defense; Department of Health and Human Services' Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and National Institutes of Health (NIH); Department of Labor's Occupational Safety and Health Administration (OSHA); Environmental Protection Agency (EPA); and Federal Communications Commission (FCC). To determine the research activities of other organizations, we interviewed representatives from IARC, academic institutions, consumer groups, mobile phone industry associations, mobile phone manufacturers, and mobile phone providers.

To determine how FCC set the RF energy exposure limit and ensures compliance with it, we reviewed and summarized FCC regulations and guidance as well as reports from international organizations that recommend RF energy exposure limits. We also reviewed and summarized FCC testing and certification regulations and guidance for mobile phones. We conducted interviews with officials from FCC and representatives from selected Telecommunication Certification Bodies (TCBs). We selected the four TCBs that approved the most mobile phone certification applications for fiscal years 2000-2011 according to FCC: PCTEST Engineering Laboratory, Inc.; ACB, Inc.; CETECOM ICT Services GmbH; and Timco Engineering, Inc. These four TCBs have approved 69 percent of all U.S. mobile phone applications since 2000. We interviewed representatives from National Institute of Standards and Technology, American National Standards Institute, and American Association for Laboratory Accreditation to discuss their role in accrediting entities as TCBs and monitoring the activities of current TCBs. We also conducted interviews with representatives of the mobile phone industry and consumer groups for their perspectives on RF energy exposure limits as well as the testing and certification of mobile phones. Representatives of the mobile phone industry we spoke with included industry associations (CTIA-The Wireless Association and Mobile Manufacturers Forum) as well as the top four mobile phone service providers (AT&T, Sprint, T-Mobile, and Verizon) that represent about 90 percent of U.S. mobile phone service subscribers. We also spoke with

representatives from four mobile phone manufacturers that represent over 70 percent of the U.S. market (LG, Motorola, Nokia, and Samsung).

To determine the actions federal agencies and the industry take to inform the public about issues related to mobile phone health effects, we reviewed the information on federal agency websites. We identified six federal agencies that have information about mobile phones and healthrelated issues on their websites: CDC, EPA, FCC, FDA, NIH, and OSHA. We conducted interviews with officials from those federal agencies to learn how they developed and update their websites. We spoke with representatives of the mobile phone industry noted above and consumer groups to obtain perspectives on the strengths and limitations of federal agency public-information-sharing efforts. We also spoke with the representatives of the mobile phone industry about how and why manufacturers include warnings or specific usage guidelines in their user manuals. Finally, we reviewed the user manuals of selected mobile phones (see table 4) to identify the usage and health information being provided to consumers, including any instructions to hold the mobile phone away from the body during use. The specific mobile phone models were identified by the manufacturers we spoke with as their top selling models in 2011.

Manufacturer	Phone model	-
Apple ^a	iPhone 4	
LG	Octane	
	Optimus	
Motorola	Bionic	
	Razr	
Nokia	1616	
	6350	
	X2-01	
Samsung	GoPhone	
	Gusto	
	TracFone	

Table 4: Mobile Phone User Manuals Reviewed

Source: GAO

^aWe included the Apple iPhone because of its prominence in the industry. Representatives from Apple declined to speak with us for this report.

Appendix II: Studies GAO Reviewed

Ahlbom, Anders, Maria Feychting, Adele Green, Leeka Kheifets, David A. Savitz, and Anthony J. Swerdlow. "Epidemiological Evidence on Mobile Phones and Tumor Risk: A Review." *Epidemiology*, vol. 20, no. 5 (2009): 639-652.

Balbani, Aracy Pereira Silveira, and Jair Cortez Montovani. "Mobile Phones: Influence on Auditory and Vestibular Systems." *Brazilian Journal of Otorhinolaryngology*, vol 74, no. 1 (2008): 125-131.

Clapp, Richard W., Molly M. Jacobs, and Edward L. Loechler. "Environmental and Occupational Causes of Cancer: New Evidence 2005-2007." *Reviews on Environmental Health*, vol. 23, no. 1 (2008): 1-37.

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European Health Risk Assessment Network on Electromagnetic Fields Exposure. "D3 – Report on the analysis of risks associated to exposure to EMF: in vitro and in vivo (animals) studies." July 2010.

French Environmental Health and Safety Agency. "AFSSE Statement on Mobile Phones and Health." AFSSE. April 16, 2003.

German Mobile Telecommunication Research Programme. "Health Risk Assessment of Mobile Communications." Department Radiation Protection and Health. Germany: 2008. Habash, Riadh W.Y., J. Mark Elwood, Daniel Krewski, W. Gregory Lotz, James P. McNamee, and Frank S. Prato. "Recent Advances in Research On Radiofrequency Fields and Health: 2004-2007." *Journal of Toxicology and Environmental Health*, Part B, vol. 12 (2009): 250-288.

Han, Yueh-Ying, Hideyuki Kano, Devra L. Davis, Ajay Niranjan, and L. Dade Lunsford. "Cell Phone Use and Acoustic Neuroma: The Need for Standardized Questionnaires and Access to Industry Data." *Surgical Neurology*, vol. 72 (2009): 216-222.

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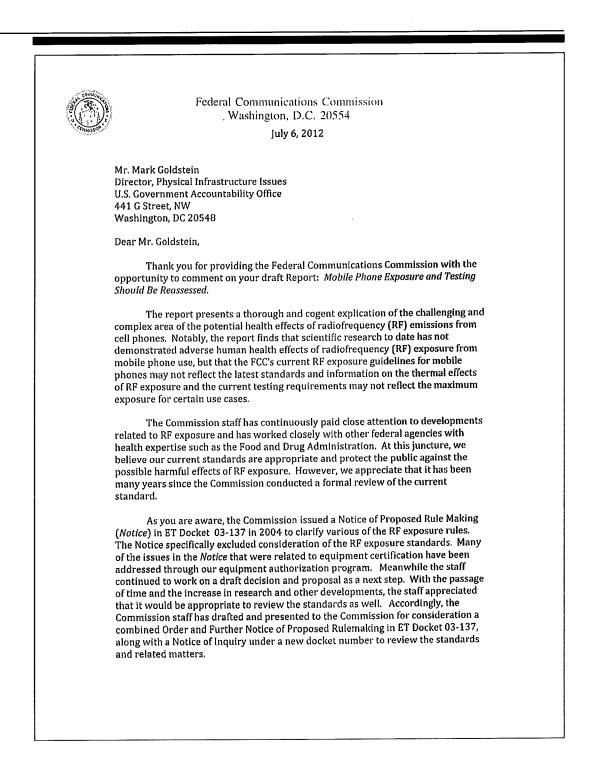
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Appendix III: Comments from the Federal Communications Commission



In short, the Commission's staff had independently arrived at the same conclusions as are reflected in the GAO report. We believe that the draft document currently under consideration by the Commission has the potential to address and even expand on the recommendations in the GAO report to thoroughly review our RF safety rules. In discussing our referral of consumers to other agencies' websites for information about research in this area, you note that our weblinks to the websites of the Food and Drug Administration and the Environmental Protection Agency were not functional when you tried to use them in April of this year. We can advise you that those weblinks are currently functioning properly. Thank you again for the opportunity to provide comments and further information with respect to this GAO Report. If you have any questions, please contact Bruce Romano at 202-418-2124 or bruce.romano@fcc.gov. Sincerely, Julius P. Knapp Chief Office of Engineering and Technology Federal Communications Commission

Appendix IV: GAO Contacts and Staff Acknowledgments

GAO Contacts	Mark L. Goldstein, (202) 512-2834 or goldsteinm@gao.gov
	Marcia Crosse, (202) 512-7114 or crossem@gao.gov
Staff Acknowledgments	In addition to the contacts named above, Janina Austin and Teresa Spisak, Assistant Directors, as well as Kyle Browning, Owen Bruce, Marquita Campbell, Leia Dickerson, Kristin Ekelund, Lorraine Ettaro, Colin Fallon, David Hooper, Rosa Leung, and Maria Stattel made key contributions to this report.

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Inskip (NIH) study (abstract)

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Brain cancer incidence trends in relation to cellular telephone use in the United States

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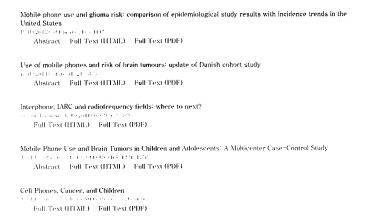
Abstract

The use of cellular telephones has grown explosively during the past two decades, and there are now more than 279 million wireless subscribers in the United States. If cellular phone use causes brain cancer, as some suggest, the potential public health implications could be considerable. One might expect the effects of such a prevalent exposure to be reflected in general population incidence rates, unless the induction period is very long or confined to very long-term users. To address this issue, we examined temporal trends in brain cancer Incidence rates in the United States, using data collected by the Surveillance, Epidemiology, and End Results (SEER) Program. Log-linear models were used to estimate the annual percent change in rates among whites. With the exception of the 20-29-year age group, the trends for 1992-2006 were downward or flat. Among those aged 20-29 years, there was a statistically significant increasing trend between 1992 and 2006 among females but not among males. The recent trend in 20-29-year-old women was driven by a rising incidence of frontal lobe cancers. No increases were apparent for temporal or parietal lobe cancers, or cancers of the cerebellum, which involve the parts of the brain that would be more highly exposed to radiofrequency radiation from cellular phones. Frontal lobe cancer rates also rose among 20-29-year-old males, but the increase began earlier than among females and before cell phone use was highly prevalent. Overall, these incidence data do not provide support to the view that cellular phone use causes brain cancer.

Key words brain cancer cellular telephones epidemiology SEER

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Cell Phones, Cancer, and Children

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We live in a high-tech world of electronics, constantly strolling through invisible fields of radio waves, television waves, microwaves, radar, and Wi-Fi networks. In the 1980s in the Nordic countries and in the 1990s in the United States, a new source of radio frequency waves came into widespread use: The cell phone, which emits nonionizing radio waves through an antenna commonly held close to the head. By 2009, the cell phone had become an integral part of everyday life, with more than 285 million subscribers to cell phone service in the United States (91% of the population) and more than 5 billion worldwide. This ubiquitous exposure to an emerging technology prompted the initiation of large-scale health studies (some started over 20 years ago) in the United States (1,2) and throughout the world (3,4). The results of these epidemiological investigations have been largely consistent and reassuring, with the World Health Organization (WHO) and the US National Cancer Institute concluding that there is no conclusive or consistent evidence that nonionizing radiation emitted by cell phones is associated with cancer risk (5,6).

Amid this encouraging evidence from human observational studies, coupled with the negative findings from virtually all experimental animal and in vitro studies and the absence of any known biological mechanism by which weak nonionizing radio waves emitted from cell phones could damage DNA and lead to cancer (7-9), it may therefore seem surprising that a monograph committee of the International Agency for Research on Cancer (IARC), an agency of the WHO, recently announced that cell phones may be "possibly carcinogenic to humans" (10). The change from "no conclusive evidence" to "possibly carcinogenic" was not new research (11), and it has understandably led to widespread public as well as media concern and confusion (12). The footnote accompanying the IARC press release (10) is often missed----that a "possibly carcinogenic to humans" (2B) classification by IARC is based on "limited evidence of carcinogenicity" and that "chance, bias, or confounding could not be ruled out with reasonable confidence" for the few positive associations reported in the literature. A published summary of the IARC Working Group conclusions (13) noted that some members found the epidemiologic evidence to be inadequate to support the 28 classification. Viewed in this context, "possibly carcinogenic" is not a signal to abandon mobile phones and return to landline phones. Rather, it is a signal that there is very little scientific evidence as to the carcinogenicity of cell phone use. This assessment is reflected in a recent paper by the International Commission on Non-lonizing Radiation Protection (14) which concluded: "Although there remains some uncertainty, the trend in the accumulating evidence is increasingly against the hypothesis that mobile phone use can cause brain tumours in adults".

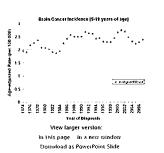
Although evidence that children may be especially sensitive to nonionizing radio waves when compared with adults is not at all clear (15), there is genuine concern for the obvious reasons that children are young, growing, and have many years of life remaining (16). In this issue of the Journal, Aydin et al. (17) provide results from the first study specifically designed to address cell phone use among children and adolescents diagnosed with brain tumors (primarily glioma). They conducted an international case-control study of children and adolescents between 7 and 19 years of age in Denmark, Norway, Sweden, and Switzerland. Children who were diagnosed in 2004–2008 with a brain tumor (n = 352) were identified from various clinic- and population-based registry records, and controls (n = 646) were randomly selected from the general population. Cell phone use was estimated based on face-to-face interviews with a parent present and from cell phone subscriber records when available.

Consistent with virtually all studies of adults exposed to radio frequency waves (4,11,14,18), no convincing evidence was found that children who use cell phones are at higher risk of developing a brain tumor than children who do not regularly use cell phones. There were no consistent exposure-response relations for any of the metrics evaluated, whether by time since first phone use, cumulative duration of calls, cumulative number of calls, or location of the brain tumor with respect to ear (side of the head) most often used during calls. Over 100 odds ratios were computed to cover multiple combinations of cell phone use and brain tumor risk, and the authors concluded that the few statistically significant findings were likely due to bias, confounding, or chance. For example, risk was lowest in areas of the brain having the highest energy absorption to emltted radio waves; statistically significant positive trends were seen for cell phone use when the tumor occurred on the opposite side of the head (contralateral use) and statistically significant negative trends were seen for cell phone use when the tumor occurred in the center of the brain. These results parallel those from the 13-country Interphone study on adult brain tumors of which the summary article (4) reads like a textbook on how the biases and flaws that may creep into cell phone exse-control interview studies may render results virtually uninterpretable. Potential sources of error abound and include exposure misclassification, recall blas, selection bias, and a variation of confounding by indication (or reverse causality) in cases in which developing a brain disorder prompts the increased use of the exposure of interest [eg, prodromal symptoms before the diagnosis of childhood cancer may have caused parents to provide their child with a cell phone in response to the developing ill-health and the perceived need for emergency contact (17)]. The case-control methodology based on personal interview to obtain information on cell phone use, even when exec

Aydin et al. (17) also evaluated brain tumor incidence rates over the years 1990-2008 among Swedish children and adolescents aged 5-19 years—and found that the rates appeared to decrease in the presence of increasing and now substantial regular usage of cell phones by children and adolescents, over 50% in the current study, and approaching 100% by age 20 years in many countries (20). In the United States, we find similarly that the incidence of brain cancer among American children, adolescents, and teenagers has not increased over the past 20 years (1986-2007) based on data from the National Cancer Institute's population-based Surveillance, Epidemiology, and End Results Program registries (Figure 1).

Figure 1

Annual age-adjusted incidence rates (3-year moving average) of brain cancer among children in the United States aged 5-19 years (1974-2007). Cell phone use in the United States was not widespread until the early 1990s. The increase in brain cancer rates in the mid-1980s has been attributed to



Improved diagnoses of brain tumors due to advances in medical imaging and computerized tomography scanning (21). Data are from the National Cancer Institute Surveillance, Epidemiology, and End Results Program (nine original registries).

There have been other recent studies presenting brain tumor incidence trends among adults and children over the last 20 years in the United States (21,22); the United Kingdom (23); New Zealand (24); and Denmark, Norway, Sweden, and Finland (14,25,26). It is especially encouraging that these nationwide time-trend studies are uniformly and remarkably consistent in showing no evidence of increases in brain tumors over recent calendar years, up to and including 2009 in Sweden (14). Increases would have been expected if radio frequency waves were causally associated with brain cancer, given the steady and marked rise in the use of cell phones throughout the world since the 1980s. In an instructive exercise, Aydin et al. (17) asked if radio waves from cell phones do cause brain cancer, what trends in brain cancer rates would we have observed by now among Swedish children? They assumed two scenarios based on their empirical findings that regular use is associated with a doubling of risk (OR = 2.15) with a 3-year latency period, and that regular use is associated with a moderate increase In risk (OR = 1.36) with no latency period. The hypothetical rising trends assuming a cell phone risk diverged substantially from the actual, and slightly decreasing, observed time trend in the rates of brain tumor in the Swedish population. If Aydin et al. (17) had assumed an odds ratio of 5.2 after a 1-year latency as reported in a previous Swedish study for first use of a cell phone under age 20 years (27), the discrepancy would have been even more striking. Overall, the trend data in Sweden do not support the possibility that cell phones increase the risk of brain tumor in children or adults nor do they support case-control studies that report large or even moderate risk ratios. Consistent with the time-trend data, the one large nationwide cohort study of over 420000 cell phone subscribers also found no evidence for an association between cell phone use and brain cancer (28).

Although Aydin et al. (17) have filled an important gap in knowledge by showing no increased risk of brain tumors among children and adolescents who are regular cell phone users, it is impossible to prove a non-effect, and it will be debated whether and at what level additional research funds should be spent in assessing health effects associated with nonionizing radiation especially in times of limited resources. Ongoing research includes a large-scale study of rodents exposed to cell phone frequencies that is being conducted by the National Toxicology Program (29), a prospective study that is recruiting 250000 cell phone users in five European countries (30), and a case-control study of 2000 young people who were diagnosed with brain tumor aged between 10 and 24 years and an equal number of control subjects from 13 countries (31). The IARC announcement, however, has led to the usual call for "more research," especially among long-term cell phone users (a constantly moving goal post because "long" appears to be defined as a few years beyond what the last study was able to evaluate) and among young users [the latter addressed in the current investigation (17)]. So what, if anything, should be don? We concur with Aydin et al. (17) that the incidence rates of brain cancer in the general population should continue to be monitored. This descriptive epidemiological approach might be the most viable, informative, timely, and relatively unbiased method available to researchers, given that the population use of cell phones is well over 90% in most developed data, there is no known biologically plausible mechanism by which nonionizing radio waves of low energy can disrupt DNA and lead to cancer. The photoelectric effect is not a matter of opinion; radio frequency energy absorption cannot break DNA molecules (7), and carcinogenicity studies in animals are rather consistent in showing no increases in cancer following radio frequency energy absorption (8,9).

Nonetheless, if an individual is still concerned about remote possibilities, he or she might consider keeping calls short and using an earpiece or speaker option on the cell phone. And, heeding what is known about real risks, one should avoid using a cell phone while driving a car, because such distractions have been clearly documented to increase the risk of accidents and serious injuries (32,33).

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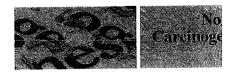
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Mobile Phone Use and Brain Tumors in Children and Adolescents: A Multicenter Case-Control Study

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Abstract

Background It has been hypothesized that children and adolescents might be more vulnerable to possible health effects from mobile phone exposure than adults. We investigated whether mobile phone use is associated with brain tumor risk among children and adolescents.

Methods CEFALO is a multicenter case-control study conducted in Denmark, Sweden, Norway, and Switzerland that includes all children and adolescents aged 7-19 years who were diagnosed with a brain tumor between 2004 and 2008. We conducted interviews, in person, with 352 case patients (participation rate: 83%) and 646 control subjects (participation rate: 71%) and their parents. Control subjects were randomly selected from population registries and matched by age, sex, and geographical region. We asked about mobile phone use and included mobile phone operator records when available. Odds ratios (ORs) for brain tumor risk and 95% confidence intervals (CIs) were calculated using conditional logistic regression models.

Results Regular users of mobile phones were not statistically significantly more likely to have been diagnosed with brain tumors compared with nonusers (OR = 1.36; 95% CI = 0.92 to 2.02). Children who started to use mobile phones at least 5 years ago were not at increased risk compared with those who had never regularly used mobile phones (OR = 1.26, 95% CI = 0.70 to 2.28). In a subset of study participants for whom operator recorded data were available, brain tumor risk was related to the time elapsed since the mobile phone subscription was started but not to amount of use. No increased risk of brain tumors was observed for brain areas receiving the highest amount of exposure.

Conclusion The absence of an exposure-response relationship either in terms of the amount of mobile phone use or by localization of the brain tumor argues against a causal association.

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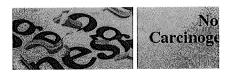
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