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**Potential Hazards of Cellular Phone Radiation:
Responses to Fear and Uncertainty**

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ABSTRACT

In recent years, the public has become concerned that the electromagnetic radio-frequency radiation (“RF radiation”) emitted by cellular telephones may pose serious health risks, including the risk of cancer. There are over 110 million cell phone users in the United States and many of them may not know that cell phones actually send electromagnetic waves into the user’s brain. Depending on how close the cell phone antenna is to one’s head, as much as sixty percent of the microwave radiation from the phone is absorbed by, and actually penetrates the head, possibly reaching as far as an inch-and-a-half into the brain. The problem is that it is still unknown whether or not this RF radiation from cellular phones actually causes any sort of damage to the user. This paper will explore many aspects of the issue of cellular phone radiation. The first section of the paper will explain what RF radiation is and provide an overview of the various scientific studies which have examined the effects of RF radiation on health. The second section of the paper will discuss and critique the regulatory responses by the FDA and the FCC in the midst of this scientific uncertainty. The third section of the paper will provide an overview of the judicial treatment of cell phone radiation issues by exploring some of the recent case law in this area. Finally, the last section of the paper will provide policy recommendations for how the FDA and FCC *should* be responding to this potential health crisis.

I. Background and Studies on RF Radiation

In order to fully understand the fear and controversy surrounding the use of cellular telephones, it is helpful to describe some details of electromagnetic RF radiation and the mechanisms by which it may cause harmful effects. Electromagnetic radiation ranges from high frequency, ionizing forms of radiation, to lower frequency, non-ionizing forms of radiation.¹ Ionizing radiation, which has a frequency greater than approximately 1015

¹See Laura Grasso, Cellular Telephones and the Potential Hazards of RF Radiation: Responses to the Fear and Controversy, 3 Va. J.L. & Tech. 2, *6 (1998) (citing Sean T. Murray, Note, Comparative Approaches to the Regulation of the Electromagnetic Fields in the Workplace, 5 Transnat’l L. & Contemp. Probs. 177, 180 (1995)).

Hz, is capable of dislodging electrons from atoms or molecules and/or producing charged particles from the atoms and molecules with it interacts.² Because of this capability, ionizing radiation can cause damage to biologic systems when the products of the ionization react with other critical cellular components.³ Ionizing radiation exists as X-rays, gamma rays, and other forms of nuclear radiation.⁴ Electromagnetic fields (“EMF’s”)⁵ with frequencies less than 1015 Hz are known as non-ionizing radiation, because they lack the capacity to dislodge electrons as they pass through matter.⁶ The electromagnetic RF radiation emitted by cellular phones is a form of non-ionizing radiation.⁷ In fact, all other low-frequency, electromagnetic fields generated by electric power⁸, or occurring naturally, fall under this category of non-ionizing radiation.⁹

Non-ionizing radiation was once believed to be harmless and all attention focused on the harmful effects of ionizing radiation instead.¹⁰ Some studies have since revealed, however, that non-ionizing radiation may also present a danger to human health.¹¹ These studies caused the public and the scientific community to alter

²See Michael C. Anibogu, *The Future of Electromagnetic Field Litigation*, 15 *Pace Env'tl. L. Rev.* 527, 536 (1998) (citing National Research Council, *Committee on the Possible Effects of Electromagnetic Fields on Biologic Systems, Report on Possible Health Effects of Exposure to Residential Electric and Magnetic Fields* (National Academy Press, 1997), 12 [hereinafter, *NRC Report*]).

³See supra note 2 (citing *NRC Report* at 12).

⁴See supra note 1 (citing Roy W. Krieger, *On the Line*, 80 *A.B.A. J.* 40, 41 (1994)).

⁵For purposes of this paper, electromagnetic radiofrequency radiation (“RF radiation”) and electromagnetic fields (“EMF’s”) are used interchangeably.

⁶See supra note 2 (citing *NRC Report* at 12).

⁷See supra note 3.

⁸Common examples of EMF sources generated by electric power are power lines, distribution lines, hair dryers, baby monitors, pencil sharpeners, dishwashers, clocks, microwaves, vacuum cleaners, household wiring, computers, video display terminals, fans, and lighting fixtures. See Barbara Ann Aurecchione, *Note, EMF Regulation: Is Congress Riding the Wave of Paranoia?* 18 *Seton Hall Legis. J.* 261, 272-73 (1993).

⁹See supra note 1 (citing John Weiss, *The Power Line Controversy: Legal Responses to Potential Electromagnetic Field Health Hazards*, 15 *Colum. J. Env'tl. L.* 359, 361-363 (1990)).

¹⁰See supra note 1 (citing Rufus C. Young, Jr. et al., *Update: Electromagnetic Fields and Their Land Use Implications*, A.L.I.-A.B.A. *Course of Study*, Aug. 16, 1995, at 1051).

¹¹See supra note 1 (citing V. Korobkova et al., *Influence of the Electric Field in 500 and 750kv Switchyards on Maintenance Staff and Means for its Protection* (Presented at the International Conference on Large High-Tension Electric System in Paris, France, Aug. 28-Sept. 6, 1972). The Soviet Union issued the first report on the adverse health effects of exposure to non-ionizing radiation. Power line workers exposed to low-frequency EMFs were afflicted with symptoms of sleeplessness, headaches, and upper respiratory tract problems. The next major study to reveal hazards associated with exposure to low-frequency EMFs was conducted in Denver and published in 1979. The results of this study showed a link between exposure to EMF from power lines and increased incidence of childhood cancer. See Nancy Wertheimer & Ed Leeper, *Electrical Wiring Configurations and Childhood Cancer*, 109 *A.M. J. Epidemiology* 273 (1979)).

their view of non-ionizing radiation and to shift attention to questions concerning the effects of exposure to electromagnetic RF radiation, specifically from cell phones.¹² The next section of the paper will review some of the more current studies which have been undertaken to determine the health effects of cellular phone radiation.

A. Studies on the Effects of Electromagnetic RF Radiation

No scientific study has yet provided conclusive evidence to prove that the use of cellular telephones is hazardous to human health. The U.S. Food and Drug Administration's Center for Devices and Radiological Health Consumer Update on Mobile Phones states that, "the available science does not allow us to conclude that mobile phones are absolutely safe, or that they are unsafe. However, the available science does not demonstrate any adverse health effects associated with the use of mobile phones."¹³ This section will review some of the studies that have examined the link between RF radiation exposure and human health. These studies generally fall into one of two categories: biological studies and epidemiological studies. Each of these kinds of studies is subject to criticisms when they are offered as evidence that RF emissions pose significant risks to human health.

i. Biological Studies

Biological studies usually involve laboratory experiments that attempt to demonstrate the effects of EMF exposure on living things such as single cells, group cells, organs, and animals.¹⁴

¹²See U.S. General Accounting Office, 95-32, Report on the Status of Research on the Safety of Cellular Telephones 3-5 (Nov. 1994) [hereinafter, GAO Report], (reporting that available studies were inconclusive to determine whether handheld cellular telephones pose public health risks, and recommending that industry and federal agencies work together to develop research agenda).

¹³The U.S. Food and Drug Administration's Center for Devices and Radiological Health Consumer Update on Mobile Phones, February 2002 (This was included on a pamphlet which came with a cell phone that I recently purchased) [hereinafter, FDA Consumer Update].

¹⁴See supra note 2, at 546 (citing Greg LaBar, Electromagnetic Fields: the Problem with Power, 52 Occupational Hazards 90, 96 (Oct. 1990)).

a. Genetic and Cellular Studies

Starting at the most basic level, researchers (supported by the mobile phone industry), have conducted numerous laboratory tests to assess the effects of mobile phone RF exposure on genetic material.¹⁵ These tests sought to determine whether RF exposure has a role in creating several kinds of genetic abnormalities such as mutations, chromosomal aberrations, DNA strand breaks, and structural changes in the genetic material of lymphocyte blood cells.¹⁶ None of the tests demonstrated any effect of the RF exposure on genetic material except for one micronucleus assay.¹⁷ In this assay, the genetic material of the cells did show structural changes after exposure to simulated cell phone radiation; however, this was only after a full 24 hours of exposure.¹⁸ One weakness of this assay is the possibility that exposing the test cells to radiation for this extreme length of time resulted in the heating of these heat-sensitive cells.¹⁹ Therefore, heat alone could have caused the abnormalities to occur.²⁰ Other available data on the effect of RF radiation on genetic material is conflicting; hence, follow-up research is necessary.²¹

In addition, some research has been done to examine the effect of RF radiation on intracellular activities. According to a series of studies, low-level, low frequency electromagnetic radiation may affect the intracellular activity of enzymes involved in tumor promotion.²² For instance, a 1991 study found that low-power RF radiation may facilitate the development of cancer in the presence of other substances known to cause

¹⁵See supra note 13 (citing Tice et. al. Tests of mobile phone signals for activity in genotoxicity and other laboratory assays. In: Annual Meeting of the Environmental Mutagen Society; March 29, 1999, Washington, D.C.; and personal communication, unpublished results).

¹⁶See id.

¹⁷See id.

¹⁸See id.

¹⁹See id.

²⁰See id.

²¹See id.

²²See FDA Nomination for National Toxicology Program (NTP) Study of Radiofrequency Radiation (link can be found at <http://www.fda.gov/cdrh/phones/index.html>) (citing E.K. Balcer-Kubiczek and G.H. Harrison, Neoplastic Transformation of C3H/I OT Cells Following Exposure to 120 Hz Modulated 2.45 GHz Microwaves and Phorbol Ester Tumor Promoter, 126 Radiation Res. 65 (1991), AW Guy, C-K Chou, LL Kunz, J Crowley, J Krupp, Effects of Long-Term Low-Level Radiofrequency Radiation Exposure on Rats, Vol 9: Summary. Texas, Brooks Air Force Base, USAF School of Aerospace Medicine: ASAFSAM-TR-85-11 (1985), S. Sznurkielski, A. Szudzinski, A. Pietraszek, M. Bielec, JK Wrembel, Accelerated Development of Spontaneous and Benzo(a)pyrene-induced Skin Cancer in Mice Exposed to 2450 MHz Microwave Radiation, 3 Bioelectromagnetics 179 (1982), LG Salford, A Brun, BRR Persson, J Eberhardt, Experimental Studies of Brain Tumor Development During Exposure with Continuous and Pulsed 915 MHz Radiofrequency Radiation, 30 Bioelectrochem Bioenerget 313-8 (1993)).

cancer.²³ According to this study, when cells were exposed for 24 hours to low-level, pulsed radio-frequency alone, there was no effect on the cells' survival or transformation into tumor cells.²⁴ However, when the cells were treated with a tumor-producing chemical, exposure to RF radiation significantly enhanced the transformation of the cells into tumor cells.²⁵ To date, the significance of these results is unclear as there are some inconsistencies with prior studies.²⁶ Again, further studies need to be done in order to determine the importance of these results.

Other studies at the cellular level tend to show that exposure to low levels of RF emissions can produce changes in the cell membrane under certain conditions²⁷ as well as diminish the effectiveness of the immune system.²⁸ The immune system study found that certain immune system cells, responsible for fighting off tumor cells, had temporary diminished effectiveness after only 4 hours of exposure to low-power, pulsed RF signals.²⁹ The researchers also found that the effectiveness of the immune system cells was diminished the most when the RF radiation was pulse-modulated at 60 times per second, slightly more than the 50 times per second that digital cellular telephones' signals "pulse."³⁰ The weakness of all of these cellular studies lies in the fact that results observed under these artificial conditions may not necessarily be duplicated in comparable exposure to a whole organism, and the effect on humans will be even less predictable.³¹

b. Whole Animal Studies

There have been a number of whole animal experiments done to evaluate the health effects of exposure to RF

²³See Balcer-Kubiczek, *supra* note 22, at 17.

²⁴See *id.*

²⁵See *id.*

²⁶See *supra* note 23. In addition, since this was an *in vitro* experiment, the significance of these results in terms of *in vivo* carcinogenesis is not clear.

²⁷See Carol R. Goforth, *A Bad Call: Preemption of State and Local Authority to Regulate Wireless Communication Facilities on the Basis of Radiofrequency Emissions*, 44 N.Y.L. Sch. L. Rev. 311, 338-39 (2001) (citing Dean J. Donatello, Note, *Locating Cellular Telephone Facilities: How Should Communities Answer When Cellular Telephone Companies Call?* 27 Rutgers L.J. 447, 474 (1996)).

²⁸See *supra* note 13 (citing D.B. Lyle, et al., *Suppression of T-Lymphocyte Cytotoxicity Following Exposure to Sinusoidally Amplitude-Modulated Fields*, 4 *Bioelectromagnetics* 281 (1993)).

²⁹See *id.*

³⁰See *id.*

³¹See *id.* (citing Sherry Young, *Regulatory and Judicial Responses to the Possibility of Biological Hazards from Electromagnetic Fields Generated by Power Lines*, 36 Vill. L. Rev. 129, 139 n. 37 (1991)).

radiation. These studies involve the scientific observation of living animals (and sometimes human beings), exposed to low levels of RF radiation.³² Animal experiments which have investigated the effects of low levels of RF emissions, similar to those of mobile phones, have yielded conflicting results.³³ A few of these studies are discussed below.

A few animal studies have suggested that low levels of RF radiation can accelerate the development of cancer in laboratory animals.³⁴ For instance, “[I]n one study, mice genetically altered to be predisposed to developing one type of cancer developed more than twice as many such cancers when they were exposed to RF energy compared to controls.”³⁵ However, there is much uncertainty among scientists about whether results obtained from animal studies such as this one, apply to the use of mobile phones.³⁶ First, there is uncertainty on how to translate results obtained in rats and mice to effects on humans.³⁷ Second, many of these studies have methodological flaws. For instance, similar to the mouse experiment discussed above, many of the other studies that also showed increased tumor development, used animals that had already been treated with cancer-causing chemicals.³⁸ Furthermore, some of the studies exposed the test animals to continuous RF radiation, up to 22 hours per day.³⁹ Because these conditions are not similar to the conditions under which people normally use wireless phones, results from these studies do not provide clear evidence as to the long-term effects of low-level RF exposure from cell phones on humans.⁴⁰

There have also been a number of animal studies suggesting that RF exposure may have various negative health impacts. For instance, one study found that permanent damage occurred to the eyes of test animals when they were exposed to low-level radiation.⁴¹ This damaging effect was enhanced when the test animals

³²See supra note 25, at 339.

³³See supra note 13.

³⁴See id.

³⁵Id.

³⁶See id.

³⁷See id.

³⁸See id.

³⁹See id.

⁴⁰See supra note 28, at 339.

⁴¹See GAO Report, supra note 12, at 17.

were treated with drugs used in glaucoma treatment and exposed to RF radiation at frequency levels lower than those emitted by cell phones.⁴² In addition, another study has suggested that exposure to low-level radiation could adversely affect the central nervous system.⁴³ Researchers at the University of Washington found that rats had difficulty learning a maze after 45 minutes of exposure to low-level, pulsed radio-frequency radiation, similar to cell phone frequencies.⁴⁴ The researchers concluded that exposure to low-level RF radiation decreases certain chemical agents in the rodents' central nervous system which are essential for spatial learning.⁴⁵ However, a study on humans did not illustrate any negative impact on cognitive functions. In this 1999 study, two groups of 18 people were exposed to simulated mobile phone signals under laboratory conditions while they performed cognitive function tests.⁴⁶ No changes were observed in the subjects' ability to recall words, numbers, or pictures, or in their spatial memory.⁴⁷ Interestingly, subjects that were exposed to simulated mobile phone signals were able to make choices more quickly in one visual test.⁴⁸ This was the only change noted among more than 20 variables compared.⁴⁹ Again, further tests need to be done in all of these areas to determine if RF radiation really does have a detrimental effect on the health of humans.

ii. Epidemiological Studies

Epidemiological studies use statistics to chart the associations between death or disease with other factors, such as exposure to RF radiation.⁵⁰ This section will review some of the epidemiological studies that have explored the possible association between the use of wireless phones and various cancers.

⁴²See id.

⁴³See supra note 1, at *7 (citing H. Lai, et al., Department of Pharmacology and Center for Bioengineering, University of Washington, Neural Mechanisms Involved in Microwave-Induced Deficit in Radial-Arm Maze Performance, (presented at the Bioelectromagnetics Society Meeting, Feb. 1993)).

⁴⁴See id.

⁴⁵See id.

⁴⁶See supra note 13 (citing AW Preece, G Iwi, A Smith-Davies, K Wesnes, S Butler, E Lim, and A Varey, Effect of 915-MHz simulated mobile phone signal on cognitive functions in man, *Int. J. Radiat. Biol.* (1999)).

⁴⁷See id.

⁴⁸See id.

⁴⁹See id.

⁵⁰See supra note 2, at 546.

In a hospital-based, case-control study, completed in 1999, researchers looked for an association between mobile phone use and either glioma (a type of brain cancer) or acoustic neuroma (a benign tumor of the nerve sheath).⁵¹ No statistically significant association was found between mobile phone use and gliomas when all types of gliomas were considered together.⁵² However, when 20 types of glioma were considered separately, an association was found between mobile phone use and one rare type of glioma, neuroepitheliomatous tumors.⁵³ It is possible that this association occurred by chance because the risk did not increase with how often the mobile phone was used.⁵⁴ In fact, the risk actually decreased as cumulative hours of mobile phone use increased, which seems inconsistent with carcinogenic behavior.⁵⁵ An ongoing study by the National Cancer Institute is expected to bear on the accuracy and repeatability of these results.⁵⁶ Another weakness of this study is that the average length of mobile phone exposure in these subjects was less than three years.⁵⁷ Therefore, these results reveal very little about the long-term effects of RF exposure.

Another recent study of 209 brain tumor cases and 425 matched controls, found that there was no increased risk of brain tumors associated with mobile phone use.⁵⁸ “When tumors did exist in certain locations, however, they were more likely to be on the side of the head where the mobile phone was used. Because this occurred in only a small number of cases, the increased likelihood was too small to be statistically significant.”⁵⁹

iii. Overall Status of the Science

⁵¹See supra note 13 (citing Muscat et al., Epidemiological Study of Cellular Telephone Use and Malignant Brain Tumors, State of the Science Symposium, 1999 June 20; Long Beach, California).

⁵²See id.

⁵³See id.

⁵⁴See id.

⁵⁵See id.

⁵⁶See id.

⁵⁷See id.

⁵⁸See id (citing L Hardell, A Nasman, A Pahlson, A Hallquist, and KH Mild, Use of Cellular Telephones and the Risk for Brain Tumors: A Case-Control Study, 15 Int. J. Oncol. 113-116 (1999)).

⁵⁹Id.

Overall, there is not enough evidence at this point to determine whether or not cell phone use causes any health problems.⁶⁰ The studies which suggest that exposure to RF radiation may cause adverse health consequences have raised important questions but have not provided conclusive evidence.⁶¹ Further laboratory and epidemiological studies need to be done in order to supplement the data already received. Many of the studies mentioned above fail to rise to the level of probative value due to a number of methodological problems, which may have prevented scientists from reaching accurate results.⁶²

For instance, biological studies, which attempt to examine the effects of exposure to RF radiation, will not likely produce consistent, replicable results until the scientific community has reached a consensus on which aspects of exposure are relevant and important.⁶³ For example, there is inconsistency among the studies as to the appropriate level of RF frequency, intensity, consistency, duration, and direction of field.⁶⁴ These are all aspects of exposure which affect scientific research and can dramatically alter results.⁶⁵ Some studies are conducted on the premise that biological effects occur only at certain levels, or “windows” of frequency and intensity.⁶⁶ On the other hand, “[o]ther studies suggest that the ‘transient effect’ of a very rapid change in magnetic field strength, caused simply by turning an electrical device off, can cause cancer.”⁶⁷ The manner in which scientists treat and prioritize these aspects of exposure is, therefore, a vital and determinative feature of any study assessing the health risks posed by RF radiation.⁶⁸ A further problem with whole animal studies is that a very large number of animals would be needed to provide reliable proof of a cancer

⁶⁰See *id.*

⁶¹See GAO Report, *supra* note 12, at 16-17. A major problem is that some of these studies are based on the effects of radio waves outside of the cellular frequency or on exposure levels different from those of cellular users and may not be helpful in determining the potential hazards of cellular telephone use.

⁶²See *supra* note 1, at *8 (citing James H. Stilwell, *Straddling the Wire: Electromagnetic Fields and Personal Injury Suits*, 14 *Rev. Litig.* 545, 552 (1995)).

⁶³See *id.* (citing Murray, at 180).

⁶⁴See *id.*

⁶⁵See *id.*

⁶⁶See *id.* (citing Office of Technology Assessment, U.S. Congress, *Biological Effects of Power Frequency Electric and Magnetic Fields*, OTA-BP-E-53, at 37 (May 1989)).

⁶⁷*Supra* note 4, at 55.

⁶⁸See *supra* note 1, at *9.

promoting effect if it does exist.⁶⁹ Unfortunately, such experiments could take many years to pursue.

While epidemiological studies do provide some useful information about human populations, 10 or more years' of follow-up may be necessary to provide answers about some of the long-term health effects of cell phone usage, including cancer.⁷⁰ This span of time is critical because the interval between the time of exposure to a cancer-causing agent and the time a tumor develops (if it does), may be many years.⁷¹ Furthermore, the interpretation of epidemiological studies is hampered by difficulties in measuring actual RF exposure during day-to-day use of wireless phones.⁷² There are many factors which affect this measurement such as the angle at which the phone is held and/or which model of phone is used.⁷³

The only thing that is clear right now is the fact that it is still unknown whether or not cell phone use can be deleterious to one's health. It also seems as if conclusive scientific data on this topic may not be available for another several years. The next section of the paper will discuss the manner in which regulatory agencies, especially the FDA, have responded to this emerging public health concern amidst all the scientific uncertainty.

II. Regulatory Responses to Cellular Phone Radiation Issues

According to some commentators, during the late 1960s, administrative agencies in the United States began to play an active role in regulating technologies that could potentially pose threats to the public health, safety, and environment.⁷⁴ According to these commentators, “[t]his movement toward preventative policy making, driven by a perceived need to control the processes of scientific and technological change, represented a dramatic shift in regulatory thinking.”⁷⁵ This shift in thinking caused agencies to be expected to go

⁶⁹See U.S. Food and Drug Administration's Center for Devices and Radiological Health: Consumer Update on Wireless Phones, July 18, 2001 (found at <http://www.fda.gov/cdrh/ocd/mobilephone.html>).

⁷⁰See id.

⁷¹See id.

⁷²See id.

⁷³See id.

⁷⁴See supra note 1, at *10 (citing Sheila Jasanoff, *Science at the Bar: Law, Science and Technology in America* 71 (1995)).

⁷⁵Id (citing Jasanoff, at 4).

beyond regulating hazards which were known to be harmful, to guarding against risks.⁷⁶ However, risk-based regulation is a complex discipline because it places regulators in an uncomfortable position where they are subject to pressure from Congress and the public to enact safety standards even when there may be insufficient scientific evidence to support such actions.⁷⁷ In these situations, the agencies may also be vulnerable to charges that they have misinterpreted or misused scientific findings.⁷⁸

The issue of cellular phone radiation regulation is a perfect example of this struggle to deal with outside pressures amidst a backdrop of scientific uncertainty. This section will explore the roles of government agencies in the regulation of this area. It should be noted that there are various government agencies that are responsible for different aspects of mobile phone safety. These agencies include the Food and Drug Administration (“FDA”), Federal Communications Commission (“FCC”), National Institute for Occupational Safety and Health, Environmental Protection Agency, Occupational Health and Safety Administration, National Telecommunications and Information Administration, and the National Institutes of Health.⁷⁹ The following section will focus on the two agencies with the most responsibility in this area: the FDA and the FCC.

A. FDA’s Role

The FDA is empowered by Congress to directly regulate electronic products that emit radiation with regard to public health and safety. Therefore, the FDA has the primary responsibility to respond to the concern over cellular telephones. The FDA receives this enforcement authority through the Electronic Product Radiation Control Provisions of the Federal Food, Drug, and Cosmetic Act. The Radiation Control Provisions, originally enacted as the Radiation Control for Health and Safety Act of 1968, are located in Sections 531

⁷⁶See id.

⁷⁷See id (citing Jasanoff, at 72).

⁷⁸See id.

⁷⁹See supra note 13.

through 542 of the Act. These provisions apply to any “electronic product” which is defined as:

Any manufactured or assembled product (or component, part, or accessory of such product) which, when in operation,

- (i) contains or acts as part of an electronic circuit and
- (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation.⁸⁰

“Electronic product radiation” is defined as:

- (A) any ionizing or non-ionizing electromagnetic or particulate radiation, or
- (B) any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product.⁸¹

Under the Electronic Product Radiation Control provision, the FDA Secretary shall:

... by regulation prescribe performance standards for electronic products to control the emission of electronic product radiation from such products if he determines that such standards are necessary for the protection of the public health and safety. Such standards may include provisions for the testing of such products and the measurement of their electronic product radiation emissions, may require the attachment of warning signs and labels, and may require the provision of instructions for the installation, operation, and use of such products.⁸²

Currently, the FDA does not review the safety of radiation-emitting consumer products such as mobile phones before marketing, as it does with new drugs or medical devices.⁸³ However, the agency does have the authority to take action if mobile phones are shown to emit radiation at a level that is hazardous to the user.⁸⁴ “In such a case, the FDA could require the manufacturers of mobile phones to notify users of the health hazard and to repair, replace or recall the phones so that the hazard no longer exists.”⁸⁵

B. FDA’s Response

⁸³See supra note 13.

⁸⁴See id.

⁸⁵Id.

For many years it seemed as if the FDA refrained from exercising the full extent of its powers over the cell phone industry. Instead, the FDA chose to take limited actions until the scientific community could confirm the presence of hazards associated with exposure to RF radiation.⁸⁶ The FDA first took action in 1993, when it met with representatives of the cellular telephone industry to discuss the potential health problems associated with cell phones and possible solutions.⁸⁷ Since then, the FDA has worked with manufacturers in order to seek ways to minimize human exposure to RF radiation.⁸⁸ For example, the FDA and manufacturers have discussed the advantages and disadvantages of redesigning the placement of the antenna so that the source of radiation is further away from the user's head.⁸⁹

In recent years, the FDA has also become more active in overseeing and supporting research on the effect of RF radiation exposure on human health. For instance, the FDA is working with the U.S. National Toxicology Program as well as with groups of investigators around the world to ensure that high priority animal studies are conducted to address important questions about the effects of RF exposure.⁹⁰ The FDA has also urged the mobile phone industry to cooperate in providing mobile phone users with the best possible information on what is known about the possible effects of mobile phone use on human health.⁹¹ The FDA also participates in the World Health Organization International Electromagnetic Fields ("EMF") Project which began in 1996.⁹² As a result of this work, a detailed agenda of research needs was developed which has driven the establishment of new research programs worldwide.⁹³ This Project has also helped develop a series of public information documents on EMF issues.⁹⁴

Most notably, in June 2000, the FDA and the Cellular Telecommunications & Internet Association ("CTIA")

⁸⁶See supra note 1, at *20 (citing Update on Cellular Phones, FDA Talk Paper No. T93-7, 3-4 (Feb. 4, 1993)).

⁸⁷See GAO Report, supra note 12, at 21.

⁸⁸See supra note 1, at *21 (citing Telephone Interview with Joanne Barron, Representative of the FDA Science Advisory Board (Nov. 1, 1996)).

⁸⁹See id.

⁹⁰See supra note 69.

⁹¹See supra note 13.

⁹²See supra note 69.

⁹³See id.

⁹⁴See id.

launched a formal Cooperative Research and Development Agreement (“CRADA”) to conduct research on wireless phone safety.⁹⁵ The CRADA will be a three to five year study on cell phones to determine if they pose a health danger, including whether they increase the risk of brain cancer or genetic mutations.⁹⁶ Under the agreement, CTIA will fund about \$1 million in safety studies while the FDA will oversee the research.⁹⁷ Specifically, the FDA will gather a panel of international experts to choose what to study, pick independent scientists to do the work, and oversee that the science is done properly.⁹⁸

The first experiments conducted under the CRADA will study the ability (or inability), of cell phone radiation in causing genetic toxicity at various levels.⁹⁹ These genotoxicity assays will follow up on the findings of studies previously conducted by Wireless Technology Research, L.L.C. (“WTR”), which was funded by CTIA.¹⁰⁰ The previous genotoxicity assays, conducted by WTR, had conflicting results and warrant these follow-up studies.¹⁰¹ The new studies, therefore, will address the accuracy and reproducibility of previous results, the critical parameters upon which these results depend, and exposure dosimetry.¹⁰²

The second portion of the research will follow up on the findings of some epidemiology studies previously performed by WTR.¹⁰³ The CRADA states that the initial goal of this portion is to identify the type of research that may be warranted and to establish relative priority of those studies.¹⁰⁴ Also, “potential issues to be addressed include the type of follow up studies required to address pertinent unanswered questions,

⁹⁵See “FDA to Participate in Study on Mobile Phones,” CNN.com, June 9, 2000 (found at <http://www.cnn.com/2000/TECH/ptech/06/09/fda.cellphones/index.html>).

⁹⁶See id.

⁹⁷See id.

⁹⁸See id.

⁹⁹See U.S. Food and Drug Administration – Center for Devices and Radiological Health, “Cooperative Research and Development Agreement (CRADA) – Health Effects of RF Emissions from Wireless Phones (Mobile Unites for Commercial Radio Services),” (found at <http://www.fda.gov/cdrh/ocd/wlessphonocrada.html>).

¹⁰⁰See U.S. Food and Drug Administration – Center for Devices and Radiological Health, “Letter of Intent for a Proposed Collaboration on Mobile Phone Research between the Food and Drug Administration and the Cellular Telecommunications Industry Association,” October 20, 1999 (found at <http://www.fda.gov/cdrh/ocd/cradamobilephone.html>).

¹⁰¹See id.

¹⁰²See supra note 99.

¹⁰³See id.

¹⁰⁴See id.

whether additional information is necessary to perform such an evaluation, and whether an additional case control study is required.”¹⁰⁵ The FDA will also evaluate the need for participation in a multi-center case control study as well as the need for an additional cohort study.¹⁰⁶ Results from the first of these studies should be out in the near future.

C. Evaluation of FDA's Response

Although the FDA's more recent actions have been somewhat proactive, this was not the case for many years. In fact, until the formation of the CRADA in 2000, the FDA seemed content with waiting for the scientific results from WTR's research on the health effects of mobile phones. However, WTR was funded by the cellular telephone industry itself. Certainly it seems as if there is a conflict of interest problem which arises from the fact that the industry was allowed to do its own scientific testing with little or no oversight.¹⁰⁷ By reading the Electronic Product Radiation Control (“EPRC”) provision of the Federal Food, Drug, and Cosmetic Act, it seems as if the FDA has the authority to do much more. In fact, in reading these provisions it seems as if the FDA had the *duty* to do much more, especially at an earlier stage.

For instance, the EPRC provision states that the “Secretary shall establish and carry out an electronic product radiation control program designed to protect the public health and safety from electronic product radiation.”¹⁰⁸ As part of this program the Secretary is to:

¹⁰⁵Id.

¹⁰⁶See id.

¹⁰⁷In fact, there are currently allegations and potential evidence that CTIA intentionally and/or negligently, concealed evidence and research of WTC. These allegations will be discussed in the section on judicial treatment of RF radiation cases. Dr. George Carlo, the epidemiologist who headed up WTC's six-year, \$28 million program has made similar allegations of cover-ups by the cellular phone industry. See Jeffrey Silva, “Litigation Frenzy Hits Wireless,” Arrowheadhealthworks.com (January 22, 2001) (found at <http://www.arrowheadhealthworks.com/Verizon.htm>).

¹⁰⁸21 U.S.C.A. § 360ii (a) (West. Supp. 2002).

(4)

study and evaluate emissions of, and conditions of exposure to, electronic product radiation and intense magnetic fields;

(5) develop, test, and evaluate the effectiveness of procedures and techniques for minimizing exposure to electronic product radiation...¹⁰⁹

As stated above, the Secretary is then supposed to “prescribe performance standards for electronic products to control the emission of electronic product radiation...”¹¹⁰

At this point, the FDA has not prescribed *any* standards for the cell phone industry. While it is true that the FDA needs to become aware of the health effects of cell phone radiation before any standards can be promulgated, up until June of 2000, the FDA took virtually no steps towards advancing this research. Due to the conflict of interest problem, reliance on the cell phone industry to do their own scientific research was insufficient. It is true that the FDA has limited resources and cannot devote research money to every product which has some infinitely small possibility of posing a threat to human health. However, as soon as it was apparent that cell phone radiation might pose a credible health risk, the FDA should have become more active in pursuing research in this area. As shown in the scientific studies discussed above, there was evidence as early as the 1970’s that exposure to EMF’s could have a detrimental impact on one’s health.¹¹¹ Certainly by the early 1990’s there was increasing evidence that cell phone radiation could be harmful.¹¹² The CRADA with the mobile phone industry should have been established years earlier. The CRADA arrangement is an efficient usage of the FDA’s limited resources because the mobile phone industry funds the studies while the FDA oversees the research programs, chooses the studies to be performed, and picks

¹⁰⁹Id.

¹¹⁰21 U.S.C.A. § 360kk (a) (1) (West Supp. 2002).

¹¹¹See supra note 11.

¹¹²See supra note 22.

the scientists, thereby eliminating any potential biases.

At this point, the FDA is pursuing the correct path in order to enhance the scientific knowledge in this area. However, since the EPRC provision puts the FDA in the lead role of protecting the public health from cell phone radiation, the FDA simply acted too slowly in reacting to this potential health concern. The last section of this paper will make some additional suggestions as to what other measures the FDA should currently take to ensure public knowledge and safety in this area.

D. FCC's Role and Response

The FCC is required by the National Environmental Policy Act of 1969 to evaluate the effect of emissions from FCC-regulated transmitters on the quality of the human environment.¹¹³ On August 1, 1996, under intense Congressional pressure to act, the FCC adopted and issued a new set of RF radiation exposure guidelines that were applicable to cellular telephones for the first time.¹¹⁴ Because the FCC does not consider itself a health agency with the expertise to determine what levels of radiation are safe, it turned to health experts (such as the FDA), and radiation experts outside of the FCC for guidance on these regulations.¹¹⁵ The FCC adopted exposure limits based on industry standards established by the American National Standards Institute (“ANSI”), the Institute of Electrical and Electronic Engineers (“IEEE”), and the National Council on Radiation Protection and Measurements (“NCRP”).¹¹⁶ These limits for cellular telephones are based on exposure criteria quantified in terms of specific absorption rate (“SAR”), which is a measure of the rate of RF absorption into the body.¹¹⁷ Cellular telephones must be below the SAR limit of 1.6 watts/kg as

¹¹³See Federal Communications Commission’s Radio Frequency (RF) Safety Page (found at <http://www.fcc.gov/oet/rfsafety>).

¹¹⁴See supra note 1, at *13 (citing Guidelines for Evaluating Environmental Effects of Radiofrequency Radiation, 61 Fed. Reg. 41, 006 (1996) (codified at 47 C.F.R. pts. 1, 2, 15, 24, 97)) [hereinafter FCC Guidelines].

¹¹⁵See GAO Report, supra note 12, at 5.

¹¹⁶See supra note 1, at *14.

¹¹⁷See FCC Guidelines, supra note 113, at 41,006. The EPA was pressing the FCC to adopt the NCRP guidelines while the cell phone industry was lobbying for the adoption of the ANSI standard. The FCC ended up adopting portions of both standards.

averaged over one gram of tissue.¹¹⁸

All cellular phones sold in the United States must comply with the FCC safety guidelines that limit RF exposure.¹¹⁹ All current phones on the market should be labeled with FCC identification numbers.¹²⁰ The consumer can then use this number to determine his or her phone's maximum SAR level by visiting the FCC's website.¹²¹

E. Evaluation of FCC's Response

There are many scientists and commentators who argue that the FCC's guidelines are an ineffective and/or inadequate measure to guard against any of the potential risks of RF radiation.¹²² According to some scientists, the FCC's guidelines are flawed because they do not take into account the possibility that weaker levels of RF radiation are just as harmful to human health as stronger levels.¹²³ As mentioned before, some studies indicate that biological effects occur at certain windows of exposure or through a transient effect of a very rapid change in power strength.¹²⁴ This suggests that the FCC's adoption of RF radiation exposure standards may be an ineffective means of reducing the potential health risks from cell phone use.¹²⁵ Others argue that the FCC's exposure standards are inadequate because they are limited to providing protection from thermal effects and fail to address potential non-thermal effects.¹²⁶ Furthermore, there have been criticisms that the FCC's requirements are so vague that a cell phone can pass the guidelines when tested

¹¹⁸See supra note 1, at *14 (citing Robert F. Cleveland, Office of Engineering and Technology, FCC, New FCC Policies and Guidelines for Evaluating Human Exposure to Radiofrequency Electromagnetic Fields, Remarks at the International Business Communications (IBC) Conference Cellular Phones – Is There a Health Risk? (June 23-24, 1997)).

¹¹⁹See supra note 69.

¹²⁰See supra note 113.

¹²¹See id. The website on which you can find a particular cell phone's SAR levels is: www.fcc.gov/oet/fccid.

¹²²See supra note 1, at *16.

¹²³See supra note 66, at 2-3 (suggesting that weaker electromagnetic fields may pose a health risk).

¹²⁴See id.

¹²⁵See supra note 1, at *17.

¹²⁶See id (citing Ex Parte Comments Pertaining to ET-Docket 93-62 Regarding Petitions for Reconsideration of Commission Rule & Order FCC 96-326, and First Memorandum of Opinion and Order FCC 96-487, submitted by the Ad-hoc Association of Parties Concerned about the FCC's RF Health and Safety Rules, 11 (June 10, 1997)). "Thermal effects" are biological effects which occur when tissues are exposed to RF or microwave fields strong enough to raise the temperature. "Non-thermal" effects describe biological responses to microwave fields at SARs too low to involve any response to heating.

in one position and exceed maximum allowable levels when held in another position.¹²⁷

As stated above, the FCC's expertise does not lie in health issues; therefore, it relies on the FDA and other health agencies to provide assistance in establishing radiation guidelines. Hence, these guidelines can only be as effective as the scientific evidence behind them. Unfortunately, the FCC's radiation emission guidelines were established in 1996, four years before the FDA became actively involved in the research process. This fact underscores the need for further research on the effect of radiation at various levels. To reiterate, such research is currently underway; however, it would have been more helpful had the research begun at an earlier date.

III. Judicial Treatment of Cellular Phone Radiation Cases

This section will explore the basic legal doctrines that plaintiffs have attempted to use against the cellular phone industry. This review of some of the recent case law illustrates the different claims that can be brought against cellular phone companies and assesses the viability of each of these claims. The cases below also demonstrate the many hurdles which plaintiffs must overcome when bringing these suits. Some of these obstacles are discussed below.

A. Causation

For those claims which try to establish a link between cell phones and medical problems, the issue of causation is going to be a tough battle. In the absence of sufficient scientific evidence to support the claim that cell phone radiation is hazardous to human health, and under the current tort law system, the causation element will continue to represent the most difficult legal hurdle for plaintiffs to overcome when bringing personal injury or product liability claim against cellular telephone manufacturers. A plaintiff claiming personal

¹²⁷See Brian Ross, "Wireless Worries?" ABCNEWS.com, October 20, 1999 (found at http://abcnews.com/onair/2020/2020_991020cellphones.html). After an ABC news show revealed this flaw, the FCC issued a statement that they were going to conduct their own examination to see if this was true. See FCC's Unofficial Announcement of Commission Action: Safety Guidelines for Hand-Held Cellular Telephones, October 21, 1999 (found at http://www.fcc.gov/Bureaus/Wireless/News_Releases/1999/nrw19044.html).

injury as a result of exposure to cell phone radiation must show: 1) that the substance to which he or she was exposed is capable of causing harm (general causation), and 2) that it is more likely than not that the exposure caused by the defendant's actions was the actual cause of the injury (specific or individual causation).¹²⁸ These factors will be difficult to prove in cell phone cases because of long latency periods, a lack of understanding of casual mechanisms of disease, diverse patterns of exposure, and the possibility of exposure with other causal agents.¹²⁹

For instance, in *Reynard v. NEC Corp*, one of the first cases attempting to link RF radiation from cellular telephones to cancer, the issue of causation was a salient and determinative factor in influencing the outcome of the case on summary judgment.¹³⁰ In *Reynard*, the plaintiff claimed that exposure to RF radiation initiated, or aggravated and accelerated, the growth of a brain tumor which eventually killed his wife.¹³¹ The plaintiff presented an affidavit by a medical expert which stated, "It is my opinion, within a reasonable degree of certainty, that the use of the hand-held cellular telephone did in fact accelerate the growth of Susan Reynard's brain tumor."¹³² The court reviewed this affidavit, along with two medical journal articles, and found that none of the evidence established a genuine issue of material fact with regard to medical causation.¹³³

The court stated that the plaintiff failed the but-for test of causation because even the plaintiff's medical expert stated that Susan Reynard developed the brain tumor before she began using the cellular phone.¹³⁴

¹²⁸See supra note 1, at *33 (citing Jeffrey D. Cutler, Implications for Strict Scrutiny of Scientific Evidence: Does Daubert Deal a Death Blow to Toxic Tort Plaintiffs? 10 J. Envtl. L. & Litig. 189, 197 (1996)).

¹²⁹See id.

¹³⁰See *Reynard v. NEC Corp.*, 887 F. Supp. 1500 (M.D. Fl. 1995).

¹³¹See id at 1502.

¹³²Id at 1505. However, the plaintiff's medical expert also agreed with portions of an affidavit by the defendant's medical expert that "no scientific or medical studies have shown that exposure to emissions deposited at the brain from a source such as a portable cellular telephone operating at a power level and frequency of the portable cellular phone alleged to have been used by Susan Reynard is associated with any adverse biological effects, including initiation of brain cancer or promotion of brain cancer growth." Id.

¹³³See id at 1506.

¹³⁴See id.

The plaintiff also failed to meet Florida law’s “more likely than not” standard for evidence of causation, because they did not present any evidence suggesting that, but for Susan Reynard’s use of the cellular telephone, it was more likely than not that she would have survived.¹³⁵ Likewise, in *Motorola v. Ward*, a case presenting similar claims, the court held that the issue of causation had not been established.¹³⁶

Due to the current amount of scientific uncertainty in this area, it seems very unlikely that any plaintiff alleging medical problems due to cell phone use will be able to present enough evidence to withstand summary judgment on the causation issue. A somewhat related problem of expert testimony is discussed next.

B. Expert Testimony

Closely tied to the issue of causation in cell phone radiation cases is the issue of admissibility of scientific evidence and expert testimony. Generally, in cases where there is a high level of scientific uncertainty, courts have stated that the dangers of allowing unreliable or untested science in the courtroom can be significant. Therefore, courts have developed a strict standard for determining the admissibility of the types and quality of scientific evidence and expert testimony. In *Daubert v. Merrell Dow Pharmaceuticals*, the Supreme Court established the criteria for admissibility of scientific evidence at trial.¹³⁷ In *Daubert*, the Court held that the trial judge must assume the “task of ensuring that an expert’s testimony rests on both a reliable foundation and is relevant to the task at hand.”¹³⁸ The Court also provided some questions which were appropriate

¹³⁵See *id.*

¹³⁶See *Motorola v. Ward*, 478 S.E.2d 465 (Ga. App. 1997). In this case, the district court’s orders denying the defendants’ motions for summary judgment were reversed in a strict liability action brought against the manufacturer and seller of a cell phone which the plaintiff used for an average of approximately 25 hours per month. The plaintiff used the phone mostly by holding it to his right ear and was subsequently diagnosed with a malignant brain tumor above and forward of his right ear. The plaintiff produced affidavits of two physicians, both researchers who studies the effects of electromagnetic fields, stating that they had studied the plaintiff’s medical records and phone use records and concluded, to a “reasonable degree” of certainty, that his phone use caused or exacerbated his cancer. The court found that neither affidavit explained a mechanism by which the electromagnetic field could cause cancer; set out any statistical correlation between electromagnetic field exposure and cancer; or otherwise explained how the affiant reached his conclusion. The court stated that on evidence such as this, a jury would have had to speculate about whether a causal connection existed. Such mere conclusory allegations were insufficient to create a genuine issue of material fact regarding the plaintiff’s injury. See *id.*

¹³⁷See *Daubert v. Merrell Dow Pharmaceuticals*, 113 S.Ct. 2786 (1993).

¹³⁸*Id.* at 2799.

to this inquiry: “(1) whether the theory or technique has been or can be tested; (2) whether the theory or technique has been subjected to peer review; (3) whether there is a known or potential rate of error in the technique; and (4) whether the theory or technique is generally accepted in the scientific community.”¹³⁹

The Ninth Circuit of Appeals clarified the Supreme Court’s *Daubert* decision and emphasized that judges should carefully examine whether the experts are proposing to testify about matters growing directly out of research they have conducted independent of the litigation, or whether they have developed their testimony expressly for the purposes of testimony.¹⁴⁰

Consequently, in *Reynard*, the court found that the affidavit from the plaintiff’s medical expert failed to satisfy the admissibility criteria under *Daubert* because the affidavit contained no reference to any scientific or medical research by the physician independent of the litigation.¹⁴¹ There was also no proffered evidence that the studies and conclusions of the plaintiff’s physician had been subjected to scientific scrutiny through peer review or publication.¹⁴² Additionally, the conclusions of the affidavit were not supported by any objective source, such as a treatise or a published article in a reputable scientific journal.¹⁴³

Although there have been more scientific studies on the effects of cell phone radiation on health in recent years, we have already seen that the results are *still* inconclusive. Due to the uncertainty of the current science, it seems unlikely that any expert testifying to the fact that a cell phone caused a particular plaintiff’s health problems will be able to satisfy the strict *Daubert* standard of admissibility. Hence, plaintiffs alleging personal injury due to cell phone radiation certainly do have many difficult hurdles to overcome. In fact, until the scientific studies provide more conclusive answers, these hurdles will be virtually insurmountable.

When suing cell phone companies, however, plaintiffs may have more success with different types of claims.

¹³⁹Id at 2796-2797.

¹⁴⁰See *Daubert v. Merrell Dow Pharamaceuticals, Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995).

¹⁴¹See *Reynard*, 887 F.Supp. at 1508.

¹⁴²See *id.*

¹⁴³See *id.*

Some of these alternative causes of action, along with their own obstacles, are reviewed below.

C. Preemption Cases

Another hurdle for plaintiffs in cases against the cellular phone industry will be to successfully present claims that will not be preempted by regulations of the FDA. For instance, in *Verb v. Motorola*, a class of plaintiffs who had purchased cellular telephones filed a class action suit against manufacturers of these phones.¹⁴⁴ The plaintiffs filed an eight-count complaint which included claims of breach of implied warranty of merchantability, breach of implied warranty of fitness for a particular purpose, breach of express warranty, violation of the Magnuson-Moss Warranty Act, negligence, strict liability, consumer fraud and deceptive trade practices.¹⁴⁵ These claims were based on the plaintiffs' allegations that a specific design of cellular telephone manufactured by the defendants may cause an increase in health risks to the users.¹⁴⁶ The plaintiffs also alleged that the defendants' cellular telephones operated over a high frequency electromagnetic radio wave at a low power level that scientific research had shown to have negative "biological effects."¹⁴⁷ The plaintiffs further alleged that the defendants "failed to adequately warn the plaintiffs that (1) the defendants had not conducted tests to discern whether use of the cellular phones posed any health risk to users, and that (2) use of cellular phones may be hazardous to the user's health."¹⁴⁸ The claimed damages included a reduction in value of the cellular phones by lessening their use to limit exposure to the harmful or the potentially harmful radio waves; increased risk of exposure to harmful or potentially harmful radio waves; and increased risk of personal injury, whether manifested or not.¹⁴⁹

The Appellate Court of Illinois first found that preemption was not applicable under the statutes or regula-

¹⁴⁴See *Verb v. Motorola*, 672 N.E. 2d 1287, 1288 (Ill. App. 1996).

¹⁴⁵See *id.* at 1289.

¹⁴⁶See *id.*

¹⁴⁷*Id.*

¹⁴⁸*Id.*

¹⁴⁹See *id.*

tions of the FCC because the parties had not directed the court to any specific statute governing the FCC's regulation of the cell phone industry with regard to their health effects.¹⁵⁰ Therefore, there was no direct conflict between federal and state law and there could be no preemption on the grounds that an FCC law directly overrode state law.¹⁵¹ However, the court did find that the FDA preempted a state's power over the issues raised in the plaintiffs' complaint because the FDA, pursuant to the Electronic Product Radiation Control Act, 21 U.S.C.A. § 360kk (a)(1), directly regulates electronic products that emit radiation with regard to public health.¹⁵² The court stated that it was irrelevant whether the FDA had set any standards because the power to do so still resided with the FDA.¹⁵³ The court stated further, "Any determination by the trial court as to whether the cellular telephones are unsafe and what warnings and labels must be made would require the court to establish standards of safety and warnings, which would usurp the FDA's exclusive power to do so with respect to electronic products that emit radiation."¹⁵⁴ Furthermore, the plaintiffs failed, at a minimum, to properly allege a compensable injury and/or damages. The plaintiffs only showed a possibility that somebody may be injured down the road, which constituted conjecture and speculation.¹⁵⁵ Similarly, in *Schiffner v. Motorola*, a case very similar to *Verb*, the appellate court also held that the Electronic Product Radiation Control Act preempted the plaintiffs' state law claims against the cellular phone company defendants.¹⁵⁶ Since the allegations in the *Schiffner* complaint were virtually the same as those in *Verb* for purposes of the preemption issue, the court found the *Verb* decision persuasive and dispositive.¹⁵⁷ Responding to the argument that the FDA had not set any standards, the court stated, "The absence of an affirmative regulation by an agency that is authorized to make such regulations does not discharge its power to do so and does not extinguish Congress' intent to relegate the authority to a federal agency to

¹⁵⁰See id at 1292-93.

¹⁵¹See id.

¹⁵²See id.

¹⁵³See id.

¹⁵⁴Id at 1293-94.

¹⁵⁵See id.

¹⁵⁶See *Schiffner v. Motorola*, 697 N.E.2d 868, 872-3 (Ill. App. 1998).

¹⁵⁷See id at 870.

enact, where appropriate and approved, uniform national standards.¹⁵⁸ However, unlike *Verb*, the *Schiffner* court found that the plaintiffs had alleged a compensable injury in this case based on the diminished value of their cellular phones resulting from defects associated with the product.¹⁵⁹ The court found this to be a compensable injury in consumer fraud and breach of warranty causes of action.¹⁶⁰ The court stated that claims for diminished value of an allegedly defective product without any pleading of actual damage to the product or person are valid.¹⁶¹

However, in *Naquin v. Nokia Mobile Phones*, a similar and more recent case, a district court judge in Louisiana refused to dismiss the plaintiffs' complaints on grounds of preemption.¹⁶² The plaintiffs' complaint asserts that the inherent design of the defendants' cellular phone exposes plaintiffs to risk of damage and injury to their health and well-being.¹⁶³ It adds that phone manufacturers have known about the potential risks of cellular phones, and that there is an economically feasible, reasonable and safer design which they have failed to incorporate into their phones.¹⁶⁴ Instead, in order to make their phones safe, plaintiffs are required to make the additional purchase of a remote headset.¹⁶⁵ Plaintiffs were deceived to believe, at the time of their initial phone purchase, that all the necessary and complete costs for a safe phone and services has been paid.¹⁶⁶ The suit alleges that the failure to incorporate the remote headset along with the cell phone, renders the cell phone a defective product, which constitutes a breach of warranty; negligent or intentional misrepresentation; and/or an unfair trade practice.¹⁶⁷ The suit asks that the cell phone industry supply headsets to present and future consumers and reimburse those who have already purchased

¹⁵⁸Id at 873 (citing *Ray v. Atlantic Richfield Co.*, 435 U.S. 151, 178 (1978)).

¹⁵⁹See id at 870.

¹⁶⁰See id at 874.

¹⁶¹See id at 875.

¹⁶²See *Naquin v. Nokia Mobile Phones*, WL 1242140, *1 (E.D. La. 2001).

¹⁶³See *Plaintiffs Win First Round in Suit Challenging Safety of Cell Phones*, 4 No. 13 *Andrews Telecomm. Indus. Litig. Rep.* 9 (March 1, 2001).

¹⁶⁴See id.

¹⁶⁵See id.

¹⁶⁶See id.

¹⁶⁷See id.

headsets.¹⁶⁸

The defendants unsuccessfully argued that the issues raised in the plaintiffs' complaint came within the exclusive jurisdiction of the FDA.¹⁶⁹ Motorola argued that the case law in favor of preemption reaches back to 1993 and that the FDA has twice examined the issue of radio frequency and concluded "that there is no basis for issuing any additional performance standards beyond the FCC's regulations."¹⁷⁰ Motorola also argued that in order for the plaintiffs' claims to be successful, it would require the court to find that cellular telephones are unsafe, which would conflict with the FDA's expression to the contrary.¹⁷¹ The judge found, however, that FDA statements about the safety of cellular phones are contradictory and do not conflict with applicable state law.¹⁷²

This is a significant ruling, because after this loss in court, it will be difficult for cell phone industry lawyers to make the preemption argument in future cases. It is also important because the plaintiffs are now one step closer to actually presenting their case in court. The *Naquin* case has since been consolidated with three other pending actions involving cell phones and transferred to the District of Maryland.¹⁷³ According

¹⁶⁸See G. Patrick Pawling, "Cell Phone Suit Will Get its Day in Court," CNN.com (January 22, 2001) (found at <http://www.cnn.com/2001/TECH/computing/01/22/cellphone.suit.idg/index.html>).

¹⁶⁹See *supra* note 163.

¹⁷⁰FDA Cell Phone Statements Found Inconsistent by Judge Hearing Preemption Argument, 9 No. 21 Mealy's Emerging Toxic Torts 4 (February 2, 2001).

¹⁷¹See *id.*

¹⁷²See *id.* Judge Lemelle found three scenarios in interpreting the FDA position – "They don't know there is a risk or the risk is very small or that data right now doesn't demonstrate that mobile phones are harmful."

Another interesting fact about this case is that the plaintiffs' lawyer, Allweiss, claims that a letter written by Dr. David Feigel, director of the FDA's Center for Devices of Radiological Health ("CDRH"), included in CDRH's annual report, states that the FDA does not have the time or the resources to devote to setting standards. Allweiss claims that this is an extraordinarily powerful confession of FDA inaction and the inability to do its job under the law, and stands as evidence that the plaintiffs' arguments in this case are not preempted by federal law.

¹⁷³See *In re Wireless Telephone Radio Frequency Emissions Products Liability Litigation*, 170 F.Supp.2d 1356 (2001). The other cases consolidated were: *J. Douglas Pinney, M.D., et al. v. Nokia Inc., et al.*, C.A. No. 1:01-1456 (District of Maryland); *Crystal Giliam, et al., v. Nokia Inc., et al.*, C.A. No. 1:01-4275 (Southern District of New York); *Francis J. Farina v. Nokia Inc, et al.*, C.A. No. 2:01-2477 (Eastern District of Pennsylvania).

It is worth noting that the Maryland case of *Pinney v. Nokia*, has gotten a fair amount of publicity ever since wealthy, Baltimore super-lawyer, Peter Angelos, took over the case for the plaintiff. Angelos has litigated against asbestos, tobacco and lead paint manufacturers and has won more than \$1 billion in personal injury lawsuits. See Dr. Gary Brown, "Litigation Frenzy Hits Wireless," Arrowheadhealthworks.com (2001) (found at <http://www.arrowheadhealthworks.com/Verizon.htm>).

to the Judicial Panel on Multidistrict Litigation, which made the consolidation decision, the actions in all four litigations involve common questions of fact arising out of allegations that defendants misrepresented and concealed alleged adverse health risks of wireless telephone use that could be eliminated by use of a telephone headset.¹⁷⁴

This overview of cell phone radiation case law demonstrates the difficulties that the plaintiffs in these cases must overcome. It also shows us which claims are more likely to be successful as compared to others. For instance, due to the current state of scientific uncertainty on this issue, plaintiffs who bring products liability or personal injury claims based on injury from cell phone radiation, will most likely fail to establish causation and their expert witnesses' testimony will, similarly, be inadmissible under *Daubert*. On the other hand, according to *Schiffner* and *Naquin*, it appears as if consumer protection claims of consumer fraud, breach of warranty, negligent or intentional misrepresentation, and/or unfair trade practices, have a better chance of success (assuming that preemption is not an issue). These claims are based on allegations that cell phones are defective products and/or have diminished value due to alleged defects. Some of these claims also seem to rest on the allegation that cell phone companies misrepresented and/or concealed adverse health consequences of which they were aware.

The next stage of the litigation is to decide whether or not these products really are defective. In coming to this conclusion, however, the courts will have to explore the issue of RF radiation and its effects on health. Will it be enough that the FDA's Consumer Update recommends the use of headsets for those who are concerned about avoiding even potential risks? Will it be enough that some studies, though methodologically flawed, have shown that cell phone radiation *could* cause negative health effects? Will the plaintiffs really be able to show that the cell phone industry manipulated research and intentionally concealed evidence of the harms of cell phone radiation? The consolidated cases in the district of Maryland will, most likely, provide

¹⁷⁴See *id.*

answers to many of these questions.¹⁷⁵

IV. Proposed Policy on Cellular Phone Radiation Issues

As mentioned in the section on regulatory responses, the FDA is currently on the right path in promoting further research on cell phone radiation and its effects on human health. However, I submit that the FDA could and should do more. For instance, the FDA should require that all cellular phones currently on the market must include inserts on the FDA's Consumer Update on Mobile Phones. Currently, the addition of these inserts is voluntary. The FDA has complete authority to require the inclusion of these inserts under 21 U.S.C. § 360kk (a)(1), in which the Secretary may "require the attachment of warning signs and labels..."¹⁷⁶ on such products. In addition, the FDA should require that all cell phone companies' web pages have links to this consumer update, in an effort to notify users of previously purchased cellular phones. This requirement of including the FDA's Consumer Update on websites and with all new phones, will allow cell phone purchasers to be fully aware of the potential hazards of cell phone use.

Furthermore, the FDA should require that all cellular phones on the market include an external headset. Once again, the FDA has the power to impose this requirement under 21 U.S.C. § 360kk (a)(1), as the Secretary can "prescribe performance standards for electronic products to control the emission of electronic product radiation from such products..."¹⁷⁷ There is no question that use of an external headset greatly reduces the amount of RF radiation that penetrates inside the cell phone user's head. Since there are studies which suggest that this RF radiation may be dangerous to human health, requiring inclusion of a headset with all new cell phones is a relatively small price to pay for the prevention of possible negative health effects.

These headsets only cost about \$5 - \$10 and will not be a major expense for the cell phone industry.¹⁷⁸

¹⁷⁵

¹⁷⁶21 U.S.C.A. § 360kk (a)(1) (West. Supp. 2002).

¹⁷⁷21 U.S.C.A. § 360kk (a)(1) (West. Supp. 2002).

¹⁷⁸In fact, requiring inclusion of headsets may actually help cell phone companies in the future by preventing additional lawsuits, such as *Naquin*, which allege that cell phones are defective due to the lack of head set inclusion.

FCC standards also need to be improved. Although it is useful for each phone to have a FCC identification number which can be used to obtain information about that particular cell phone's radiation levels, it is currently a somewhat obscure and difficult process. For instance, the FCC number on many cell phones can only be viewed by removing the cell phone battery. In addition, cell phone consumers are probably not even aware that they can find this information unless they log on to the FCC's website. The FDA, in accordance with its powers under the EPRC provision should require that radiation levels of each cell phone model are more clearly displayed on all phones, along with a brief description of what these levels mean. Again, by providing this information, cell phone purchasers will become more aware of the properties and potential dangers of their particular phone. In addition, FCC standards should be revised as more knowledge about the effects of differing levels of RF radiation becomes available. Currently, as discussed earlier, the FCC's standards seem somewhat arbitrary in relation to human health.

The case law in this area shows us that there is consumer demand for more information about the harms of cell phone use. There is also a demand for increased safety precautions such as inclusion of headsets. The *Naquin* case, and its lack of a preemption finding, illustrates the belief by many that the FDA is not doing its job in providing this information and/or precautions. If left to the courts, it is possible that each state could prescribe its own standards for cell phones. However, a national standard is much more desirable and efficient. This is precisely why the FDA needs to impose the further regulations suggested here, so that all Americans have access to the same information and are able to take the same precautions to safeguard their health.

Clearly it is difficult for regulatory agencies and courts to take much action amidst all the scientific uncertainty surrounding cell phone radiation. Policy makers must make difficult choices and balance conflicting interests in deciding a course of action which adequately protects the public from potential harm, without running the risk of driving a useful product out of the market. A failure by regulatory agencies and courts to effectively

act on this unresolved issue could lead to serious, if not catastrophic, consequences. There are over 110 million cell phone users in the United States and industry forecasters predict that the demand for cellular services will grow dramatically, to the point where nearly all Americans will have a cellular phone.¹⁷⁹ These facts drive home the point that courts and agencies should take appropriate steps to avoid the possibility of a public health crisis by acting aggressively now. At the same time, there is also a danger that courts and agencies could unnecessarily and unreasonably cause harm to the cellular telecommunications industry, a multi-billion dollar industry that plays a role in advancing the general welfare of citizens and business through improved telephonic communications. Cellular technology enhances the ability of police, fire, and other rescue personnel to provide emergency services, increases business productivity and efficiency, and facilitates the exchange of information. Certainly policy makers must consider these benefits whenever they propose any regulations in this area.

The policy recommendations proposed above correctly balance these two competing goals of 1) informing consumers and preventing potentially detrimental health effects, and 2) preventing unreasonable harm to the cellular telecommunications industry. All of the policy recommendations proposed above are relatively easy and cheap to implement. By combining these actions, along with continued scientific research, the FDA will be providing effective regulation in this area of uncertainty and fear.

¹⁷⁹See supra note 168.