DA 08-1481
WT Docket No. 08-95

To: Office of the Secretary
Federal Communications Commission
Washington, DC 20554

Petition to Deny and
Comment Filed by:

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Introduction To Petition to Deny

The EMR Policy Institute (EMRPI) strenuously objects to and Petitions the FCC to Deny the proposed transfer of licenses, spectrum manager and *de facto* transfer leasing arrangements to Verizon Wireless and Atlantis Holdings LLC (VZW) until FCC updates its Guidelines for Evaluating the Environmental Effects of Radiofrequency Radiation (ET 93-62) in compliance with the National Environmental Policy Act (NEPA). Currently public health remains largely unprotected from the enormous amounts of electromagnetic radiation involved in this license transfer. The FCC has not addressed the impact of long-term exposure to this radiation on human health. Providing protection for human exposure to potentially unsafe levels of radio

frequency ("RF") radiation as required by the National Environmental Policy Act (NEPA) will not occur if the FCC approves this transfer before updating its present obsolete and inadequate guidelines.

In November 2004, EMRPI, Maria Gonzalez and other interested organizations, scientists, and individuals, submitted comments in response to the FCC's request for comment relating to the tentative conclusion set forth in the "RF Safety" section of the Notice of Proposed Rule Making adopted September 9, 2004 in Docket Nos. 04-356 and 02-353 (paragraph 114). That section sets a threshold for environmental review of 1000 watts of effective radiated power ("ERP") and asserts that this will prevent human exposure to potentially unsafe levels of radio frequency ("RF") radiation in compliance with the National Environmental Policy Act (NEPA). When FCC failed to respond to these timely-filed comments, Ms. Gonzalez sought a Writ of Mandamus in the United States Court of Appeals for the Second Circuit (See: No. 06-2139) to stop the August 2006 auction of licenses for the Advanced Wireless Services (AWS) frequencies at issue in those Dockets.

The Petition for Writ of Mandamus *In Re Gonzalez* (Docket No. 06-3129) is deemed attached hereto as Exhibit "A", along with the FCC's opposition papers. The full text is deemed a part hereof in its entirety by reference. At p. 17 of its 2006 Brief in Opposition to Petition for Writ *In re Gonzalez,* FCC stated that:

> *. . . winners must submit "long form" applications providing detailed information on their qualifications to hold the licenses. Id, at ¶¶248-249. At that point, the applications will be subject to petitions to deny, which can be filed by any interested party pursuant to 47 U.S.C. §309(d)(1). The Commission must resolve any petition to deny before it issues a license, 47 U.S.C. §§309(d)(20&(E), and any resulting order is subject to appeal to the D.C. Circuit Court of Appeals.*
>
> (Ex. A, FCC Brief p. 17) (Emphasis added.)

EMRPI now petitions FCC to deny the transfer of licenses from Alltel to VZW as sought in WT Docket No. 08-95.

* * *

On July 25, 2008 EMRPI made an inquiry by telephone to Ms. Erin McGrath at FCC's Mobility Division, Wireless Telecommunications Bureau as to whether any of the Alltel frequencies in this transaction came from the 2006 AWS auction, and her response was that

some were from that auction and had not yet been put to use by Alltel, making the transfer of licenses for the yet unused frequencies to VZW equivalent to licenses newly acquired in the 2006 AWS auction.

Grounds for EMRPI's Objection and Its Petition to Deny

The FCC's adoption of its "RF Safety" Guidelines was superficial, arbitrary and capricious, and EMRPI urges FCC to initiate or request thorough and comprehensive research and study of the rule's impact on human health using a biological approach including all six factors that operate in combination in high frequency transmissions to affect environmental exposure to RF radiation:

1. Frequencies that are resonant in human cells.
2. The effect of modulation of those frequencies on human cells.
3. The impact of different lengths of time of exposure.
4. Cumulative effects of repeated or continuous exposure.
5. Individual variation in susceptibility in population subgroups to RF radiation exposure.
6. The impact of different levels of radiated power (ERP) for the foregoing modulated frequencies.

Exposure of Workers

All wireless providers carry a non-delegable FCC license obligation to assure that no worker is overexposed to RF radiation regardless of employment category. This applies equally to communications and electrical workers, who have some training and protection against RF radiation workplace hazards, and to third-party workers in the building and maintenance occupations who have no RF safety training or equipment. These workers often encounter antenna sites that are camouflaged on rooftops or on the sides of buildings. This risk of exposure also applies to school and municipal maintenance workers and to students and teachers when antennas are sited on school or municipal properties and buildings.

FCC should deny the license transfer from Alltel to VZW until VWZ implements an RF safety solution that protects the public and all categories of workers whose workplaces are found near to VZW's antenna sites.

The 2008 National Academy of Sciences (NAS) Report

The NAS performs an unparalleled public service by bringing together committees of experts in all areas of scientific and technological endeavor. These experts serve *pro bono* to address critical national issues and give advice to the federal government and the public. Since its creation in 1863, the nation's leaders have often turned to the National Academies for advice on the scientific and technological issues that frequently pervade policy decisions. See: www.nationalacademies.org/about/history.html

In January 2008 NAS issued a report entitled: *Identification of Research Needs Relating to Potential Biological or Adverse Health Effects of Wireless Communication Devices* (NAS Report). For convenience, pages 1-17 of the NAS Report are attached here as Exhibit "B". The complete report is incorporated herein by reference (found at: http://www.nap.edu/catalog/12036.html.) The following excerpts from the NAS Report confirm and support EMRPI's objection that the research record upon which FCC's RF Safety Guidelines is based is deficient in the six factors listed above as applied to the adverse effects of RF radiation on the human environment:

> *Executive Summary*
>
> *The U. S. Food and Drug Administration (FDA) of the Department of Health and Human Services asked the National Academies to organize a workshop of national and international experts to identify research needs and gaps in knowledge of biological effects and adverse health outcomes of exposure to radiofrequency (RF) energy from wireless communications devices . . .*
>
> *For the purposes of this report, the committee defines research needs as research that will increase our understanding of the potential adverse effects of RF energy on humans. Research gaps are defined as areas of research where the committee judges that scientific data that have potential value are presently lacking, but that closing of these gaps is either ongoing and results should be awaited before judgments are made on further research needs, or the gaps are not judged by the committee to be of as high a priority with respect to directly addressing health concerns at this time.*
>
> (Ex. B, p.1)
>
> * * *
>
> *The committee judged that important research needs included, in order of appearance in the text, the following:*

- *Characterization of exposure to juveniles, children, pregnant women, and fetuses from personal wireless devices and RF fields from base station antennas.*

- *Characterization of radiated electromagnetic fields for typical multiple-element base station antennas and exposures to affected individuals.*

- *Characterization of the dosimetry of evolving antenna configurations for cell phones and text messaging devices.*

- *Prospective epidemiologic cohort studies of children and pregnant women.*

- *Epidemiologic case-control studies of childhood cancers, including brain cancer.*

- *Prospective epidemiologic cohort studies of adults in a general population and retrospective cohorts with medium to high occupational exposures.*

- *Human laboratory studies that focus on possible adverse effects on electroencephalography activity and that include a sufficient number of subjects.*

- *Investigation of the effect of RF electromagnetic fields on neural networks.*

- *Evaluation of doses occurring on the microscopic level.*

- *Additional experimental research focused on the identification of potential biophysical and biochemical/molecular mechanisms of RF action.*

(Ex. B, p. 2)

* * *

Summary

Dosimetry and Exposure

Research Needs

1. *There is a need to characterize exposure of juveniles, children, pregnant women, and fetuses, both for personal wireless devices (e.g., cell phones, wireless personal computers, [PCs]) and for RF fields from base station antennas including gradients and variability of exposures, the environment in which devices are used, and exposures from other sources, multilateral exposures, and multiple frequencies.*
2. *Wireless networks are being built very rapidly, and many more base station antennas are being installed. A crucial research need is to characterize radiated electromagnetic fields for typical multiple-element base station antennas and for the highest radiated power conditions with measurements conducted during peak hours of the day at locations close to the antennas as well as at ground level.*

3. *The use of evolving types of antennas for hand-held cell phones and text messaging devices need to be characterized for the Specific Absorption Rates (SARs) that they deliver to different parts of the body so that this data is available for use in future epidemiologic studies.*
4. *RF exposure of the operational personnel close to multi-element newer base station antennas is unknown and could be high. These exposures need to be characterized. Also needed are dosimetric absorbed power calculations using realistic anatomic models for both men and women of different heights.*

(Ex. B, p. 5)

* * *

Epidemiology

The committee identified significant research needs for a number of epidemiologic studies, particularly of children.

Adults

Research Needs

1. *Prospective Cohort Studies. A prospective cohort study will allow for the evaluation of diverse outcomes, but a very large sample size and extended follow-up is required for rare outcomes, but a very large sample size and extended follow-up is required for rare outcomes or those that occur only with very long latencies.*
2. *Occupational Cohorts with Medium to High Exposure. None of the occupational studies to date have been based on an adequate exposure assessment. Much work is needed to identify occupations with potentially high RF exposures and to characterize them.*

Children

1. *Prospective Cohort Studies of Pregnancy and Childhood. Children are potentially exposed from conception through maternal wireless device use and then postnatally when they themselves become users of mobile phones.*
2. *Case-control Study of Children Mobile Phone Users and Brain Cancer. Owing to widespread use of mobile phones among children and adolescents and the possibility of relatively high exposures to the brain, investigation of the potential effects of RF fields in the development of childhood brain tumors is warranted.*

(Ex. B, p. 6)

* * *

Mechanisms

1. *The effect of RF electromagnetic fields on neural networks is a topic needing further investigation. There are indications that neural networks are a sensitive biological target.*
2. *Evaluation of doses occurring on the microscopic level is a topic needing further investigation.*

In Vivo and In Vitro Studies in Experimental Model Systems

1. *Additional experimental research focused on the identification of potential biophysical and biochemical/molecular mechanisms of RF action is considered to be of the highest priority.*
2. *Evaluation of doses occurring on the microscopic level is a topic needing further investigations.*

(Ex. B, p. 8)

* * *

Introduction

The U. S. Food and Drug Administration (FDA) of the Department of Health and Human Services asked the National Academies to organize a workshop of national and international experts to discuss research needs and gaps in our knowledge of the biological effects and adverse health outcomes of exposure to radiofrequency (RF) energy from wireless communications devices. Although the sponsor's main interest centers on hand-held devices such as cell phones or portable home phones, base stations and antennas were also considered by the committee based on discussions with the sponsors indicating that consideration of these components would not be discouraged.

(Ex. B, p. 10)

* * *

The body of the full NAS Report (included herein by reference) identifies the following issues as not being covered by existing research:

. . . The purpose of the sixth session was to make sure that research needs that might reach across the disciplines were discussed and identified. The issues were thus designed to address current topics in RF research . . . The overarching issues were as follows:

- *Are there differences in health effects of short-term vs. long-term exposure?*
- *Are there differences between local vs. whole-body exposures?*
- *Can the knowledge of biological effects from current signal types and exposure patterns be extrapolated to emerging exposure scenarios?*
- *Are there any biological effects that are not caused by an increase in tissue temperature (nonthermal effects)?*
- *Does RF exposure alter (synergize, antagonize, or potentiate) the biological effects of other chemical or physical agents?*
- *Are there differences in risk to children?*
- *Are there differences in risk to other subpopulations such as the elderly and individuals with underlying disease states?*

(Ex. B, pp. 11-12.)

* * *

The NAS group specifically addressed problems presented by cell transmission antennas:

Base Stations

Wireless networks are being built very rapidly, and many more base station antennas are being installed. Maintenance personnel may be exposed to fairly high electromagnetic fields emanating from base station antennas unless all of the typically four to six antennas mounted on the base station are turned off. For all of the base station antennas, the radiated power is on the order of several tens of watts, with higher powers being radiated at peak hours of the day. Though not as well characterized, particularly for multiple co-located base station antennas, the radiated RF fields for rooftops near base stations may also be fairly high. The quantification of SAR distributions from base stations is fairly minimal and those distributions are of concern for professionals involved in maintenance of base stations, building/roof maintenance personnel, and member of the public that live in close proximity to the antennas. There are also subpopulations among the employees, which might be exposed to greater amounts of RF energy than the average population. The characterization of these subpopulations is important.

Thus, the interest in base station exposures close to the antennas is driven by the potential health effects on antenna repair professionals and building/roof maintenance workers from relatively high, acute exposures, but the interest in exposures for members of the public that live in close proximity to the antennas or for the public at the ground level at larger distances is motivated by the need to address public concern about very low level, chronic exposures that are in fact similar to those from existing TV and radio antennas albeit at different frequencies.

Most of the reported studies to date have involved one base station antenna and have used mostly homogeneous models, often of simplified circular or rectangular cross sections of the exposed human . . . In other words, the studies to date do not pertain to the commonly used multiple-element base station radiators. Also, unlike highly localized cell phone RF energy deposition, the base station exposures involve much, if not all, of the body and would have slightly different radiator origins (for multiple-element base stations) and may be multi-frequency as well, particularly if several different-frequency base station antennas are co-located. Furthermore, because of the whole-body resonance phenomenon, the SAR is likely to be higher for shorter individuals due to the closeness of the frequency/frequencies of exposure to the whole-body resonance frequency. In addition to the rapid growth in the number of base stations since 1990, there has also been growth in other sources of RF radiation from cordless phones, wireless computer communications, and other communications systems. The last general survey of RF levels in US cities was during the 1970s and an updated survey of RF intensities would be useful background for future epidemiologic studies. There are many indoor wireless systems as well as cell phones, which are used both indoors and outdoors. Measurements of the differences in the exposures generated by the use of these

devices in these environments will be of value in determining if there are any health effects resulting from exposures to low levels and intermittent sources of RF radiation.

(Ex. B, pp. 13-15)

* * *

Key Occupational Groups

Population groups that are required by law or by employment to spend significant time daily and throughout their lifetimes in locations where wireless antennas and transmitters are often sited are school children and school employees; and firefighters and first responders; communications and electrical workers; and third-party construction and maintenance workers**.** Their exposure scenarios relate directly to the typical base station antenna sites described in the "Base Stations" section of the NAS Report. They are examples of the thousands of people in the general public who are now exposed to RF radiation on a continuous basis in their workplaces as well as in residential neighborhoods where most schools and firehouses are located. The exposure schemes found in the research upon which FCC's RF Safety Guidelines are based are not parallel to the exposures these population groups encounter daily. The FCC Guidelines do not address the exposures of these population groups.

Presently, there is negligible or relatively little knowledge of local SAR concentration (and likely heating) in close proximity to metallic adornments and implanted medical devices for the human body. Examples include metal rim glasses, earrings, and various prostheses (e.g., hearing aids, cochlear implants, cardiac pacemakers). Research is therefore lacking to quantify the enhanced SARs close to metallic implants and external metallic adornments.

(Ex. B, p. 16) (Emphasis added.)

* * *

Laboratory Exposure Systems

There is need for improved exposure systems for human laboratory studies. Furthermore, location-dependent field strength needs to be accounted for in the characterization of exposures. Most of the present-day exposure systems used in laboratory studies focus on the exposure of the head. Though exposures to the head are relevant for most cell phone exposures, whole-body exposures due to base stations are a research need. The laboratory exposure systems also need to include ELF and pertinent modulation protocols.

(Ex. B, p. 17.) (Emphasis added.)

* * *

Toxicological Studies

In 1999 FDA nominated radiofrequency radiation emissions of wireless communication devices to the NTP for Toxicological Studies because of "widespread consumer

and worker exposure" and because "the available data is inadequate to properly assess safety." A copy of the pages from the Federal Register for this Request for Comment is attached hereto as Exhibit "C". FDA's "Nomination from FDA's Center for Devices and Radiological Health" is attached hereto as Exhibit "D." FDA explains its nomination entitled: "Radiofrequency Radiation Emissions of Wireless Communication Devices," with the following statements:

Executive Summary

Over 80 million Americans currently use wireless communications devices (e.g., cellular phones) with about 25 thousand news users daily. This translates into a potentially significant public health problem should the use of these devices even slightly increase the risk of adverse health effects. Currently cellular phones and other wireless communication devices are required to meet the radiofrequency radiation (RFR) exposure guidelines of the Federal Communications Commission (FCC), which were most recently revised in August 1996. The existing exposure guidelines are based on protection from acute injury from thermal effects of RFR exposure, and may not be protective against any non-thermal effects of chronic exposure. Animal exposure research reported in the literature suggests that low level exposures may increase the risk of cancer by mechanisms yet to be elucidated, but the data is conflicting and most of this research was not conducted with actual cellular phone radiation . . . There is currently insufficient scientific basis for concluding either that wireless communication technologies are safe or that they pose a risk to millions of users. A significant research effort, involving large well-planned animal experiments is needed to provide the basis to assess the risk to human health of wireless communications devices.

(Ex. D, p. 1) (Emphasis added.)

* * *

B. Physical Properties of Wireless Telephone Radiation

. . . Thermal effects are well established and form the biological basis for restricting exposure to RF fields. In contrast, non-thermal effects are not well established and, currently, do not form a scientifically acceptable basis for restricting human exposure to microwave radiation at those frequencies used by hand-held cellular telephones. A large number of biological effects have been reported in cell cultures and in animals, often in response to exposure to relatively low-level fields, which are not well established but which may have health implications and are, hence, the subject of on-going research. It is not scientifically possible to guarantee those non-thermal levels of microwave radiation, which do not cause deleterious effects for relatively short exposure, will not cause long-term adverse health effects.

Ex. D, p. 2) (Emphasis added.)

* * *

D. Regulatory Status

. . . Currently cellular phones and other wireless communication devices are required to meet the RFR exposure guidelines of the Federal Communications Commission (FCC),

which were most recently revised in August 1996. Since the FCC is not a health agency, it sought and received guidance from the federal health agencies including the Environmental Protection Agency, the National Institute of Occupational Safety and Health, the Occupational Safety and Health Administration, and the FDA. These exposure guidelines incorporated the most recent exposure standards of the National Commission for Radiation Protection and the American National Standards institute, and are subject to continuing review and revision as new scientific information which could define a better basis for such exposure guidelines becomes available. As noted above, the existing exposure guidelines are based entirely on protection from acute injury from thermal effects of RF exposure, and may not be protective against any non-thermal effects of chronic exposures.

(Ex. D, p. 4) (Emphasis added.)

* * *

E. Toxicological Data

. . . There is currently insufficient scientific basis for concluding either that wireless communication technologies are safe or that they pose a risk to millions of users. A significant research effort, including well-planned animal experiments, is needed to provide the basis to assess the risk to human health of wireless communications devices.

(Ex. D, p. 6) (Emphasis added.)

* * *

National Toxicology Program Fact Sheet

NTP Fact Sheet describing the FDA nominated RF radiation study entitled: "Studies on Radiofrequency Radiation Emitted by Cellular Phones - Year 2005," is attached hereto as Exhibit E. It makes the following statements about the research upon which the current FCC Radiofrequency Radiation exposure guidelines as based:

. . . The existing exposure guidelines are based on protection from acute injury from thermal effects of RFR exposure. Current data are insufficient to draw definitive conclusions concerning the adequacy of these guidelines to be protective against any non-thermal effects of chronic exposures.

Studies in laboratory animals are considered crucial for understanding whether exposure to RFR is adverse to human health because meaningful data from epidemiological studies (human population studies) of cellular phone use will not be available for many years. This is due to the long latency period between exposure to a carcinogenic agent and the diagnosis of a tumor. Most scientific organizations that have reviewed the results from laboratory studies conducted to-date, however, have concluded that they are not sufficient to estimate potential human health cancer risks from low-level RFR exposures and long-term, multi-dose, animals studies are needed.

What is the NTP Doing?
The Food and Drug Administration (FDA) nominated RFR emissions of wireless communication devices to the [NTP] *for toxicology and carcinogenicity testing. The NTP has carefully evaluated the efforts underway and concluded that while they have an excellent probability of producing high quality results, additional studies may be warranted to more clearly define any potential hazards to the U.S. population.*

(Ex. E, p. 1) (Emphasis added.)

* * *

The BioInitiative Report

The August 2007 *Bioinitiative Report: A Rationale for a Biologically-based Public Exposure Standard for Electromagnetic Fields (ELF and RF)(The BioInitiative Report)* sets forth significant recent scientific evidence that public health is not protected by the "RF Safety" Guidelines relied upon by the FCC. The complete report is hereto incorporated by reference as Exhibit "F" and is found at www.bioinitiative.org .

In July 2008, the peer-reviewed journal *Reviews in Environmental Health* published a synopsis of *The BioInitiative Repor*t authored by its coeditors David O. Carpenter MD, and Cindy Sage MA entitled, "Setting Prudent Public Health Policy for Electromagnetic Field Exposures," and is incorporated hereto it its entirety by reference as Exhibit "G". Pages 110-112 are attached hereto as Exhibit "H" and are the passage in which the authors identify why the approach to protecting public health demonstrated by FCC and other regulatory agencies lags behind current scientific evidence:

The basis on which most standard setting agencies justify their failure to set new safety limits for ELF and RF is nearly always that no certain proof of harm from exposure and no known mechanism of action have been presented. A demand for a causal level of evidence and scientific certainty is implicit in nearly all discussion on what are the appropriate safely standards for ELF and RF. This demand, however, runs counter to both the existing scientific evidence and good public health practice.

Two obvious factors work against governments taking action to set exposure guidelines based on current scientific evidence of risk:

- *Contemporary societies are very dependent upon electricity usage and RF communications, and anything that restricts current and future usage potentially has serious economic consequences.*
- *Power and communications industries have enormous political clout, and even provide support for a significant fraction of the research done on EMF.*

This state of affairs results in legislation that protects the status quo and scientific publications whose conclusions are not always based only on the observations of the research. This situation also hinders wise public health policy actions and the implementation of prevention strategies because of the huge financial investments already made in these technologies. Huss et al. /120/ analyzed 59 studies of the health effects of cell phone use and found that studies funded exclusively by industry were least likely to report a statistically significant result . . .

Defining a new exposure standard for RF is complex, if we are to address properly new scientific results for chronic exposure to pulsed radiofrequency (for example from cell towers, cell phones, and other wireless technologies). Whereas the evidence of serious harm is strong, knowledge regarding the relation between cumulative exposure and risk of disease is inadequate. Uncertainty about how low such standards might have to go to be prudent from a public health standpoint should not prevent reasonable efforts to respond to the information at hand. No lower limits for bio-effects and adverse health effects from RF have been established, and no assertion of safety at any level of wireless exposure (chronic exposure) can be made at this time. A major concern is the exposure of children. We strongly recommend that wired alternatives to WI-FI be implemented particularly in schools and libraries so that children will not be subjected to elevated RF levels until more is understood about possible health impacts.

The Bioinitiative Report /121/ presents a much more extensive and exhaustive discussion of the literature on health effects of both ELF and RF EMF than can be presented here. The Report contains a recommendation of an RF standard of 0.1 μW/cm^2, but with the full knowledge that hazards may be associated with even lower exposures.

This review has focused on those diseases for which the evidence of increased risk with EMF exposure is the strongest. Other biological effects and potential health outcomes are presented in detail in the BioInitiative Report /121/. The effects that drive the need for immediate action in lowering exposure are cancer and neurodegenerative diseases. Leukemia appears the cancer of greatest concern when the exposure to either ELF or RF is over the whole body, as is the case with most ELF exposures and exposure from RF towers. When exposure is focused on a part of the human body, such as is the case of the head in cell phone use, one sees cancers of the brain, acoustic nerve, or parotid gland. For these diseases, the evidence is clearly sufficient to warrant regulatory changes in public safety limits now, at levels that are widely reported to be associated with increased risk of childhood leukemia and brain tumors. Exposure limits against these diseases will also likely be protective for other less-well-defined health impacts. The BioInitiative Report /121/ provides additional justification for the adoption of these levels to prevent the health hazards resulting from exposure to ELF and RF.

CONCLUSIONS

The evidence for hazards to human health from both ELF and RF EMF is sufficiently strong as to merit immediate steps to reduce exposure. Such a reduction can

best be achieved by setting exposure goals that are lower than levels known to be associated with disease, even while understanding that these exposure goals are significantly lower than many current exposures. A reasonable approach would be a 1 mG (0.1 T) planning limit for structures adjacent to all new or upgraded power lines, and for occupied space that affects sensitive receptors (homes, schools, day-care, pre-school, etc), and targets not to exceed 2 mG (0.2 T) for all other occupied new construction. Although reconstructing all existing electrical distributions systems is not realistic, steps to reduce exposure from these existing systems should be encouraged. For RF EMF, setting a level with certainty is difficult. A precautionary action level would reasonably be 0.1 µW/cm2.

The proposals presented here reflect the evidence that a positive assertion of safety cannot be made with respect to chronic exposure to low-intensity levels of ELF and RF radiation.

(Ex. H, pp.110-112) (Emphasis added.)

* * *

Germany's Federal Agency for Radiation Protection

The German Government's Federal Agency for Radiation Protection has adopted the approach that EMRPI asserts is imperative for FCC to follow. Wolfram König, President of Germany's Bundesamt für Strahlenschutz, put out a call to all doctors of medicine to collaborate actively in the assessment of the risk posed by the radiofrequency radiation employed in mobile phone transmissions. "The Influence of Being Physically Near to a Cell Phone Transmission Mast on the Incidence of Cancer," published by authors Horst Eger, Klaus Uwe Hagen, Birgitt Lucas, Peter Vogel, and Helmut Voit in *Umwelt·Medizin·Gesellschaft* 17,4 2004, in response to this call is attached hereto as Exhibit "I". In it these practicing physicians evaluated the personal data of almost 1,000 patients without any external financial support. The aim of the study was to examine whether people living close to mobile phone transmitter antennas were exposed to a heightened risk of taking ill with malignant tumors:

The result of the study shows that the proportion of newly developing cancer cases was significantly higher among those patients who had lived during the past ten years at a distance of up to 400 metres from the cellular transmitter site, which has been in operation since 1993, compared to those patients living further away, and that the patients fell ill on average 8 years earlier.

In the years 1999-2004, i.e., after five years' operation of the transmitting installation, the relative risk of getting cancer had trebled for the residents of the area in the proximity of the installation compared to the inhabitants of Naila [village studied] outside the area.

(Ex. I, p.1)

* * *

Biological Properties

FCC's examination of scientific data must include relevant biological properties and not simply the IEEE's physics approach. "A Biological Guide for Electromagnetic Safety: The Stress Response, " published by Martin Blank PhD and Reba Goodman PhD, both of Columbia University, in the journal *Bioelectromagnetics* 25:642-646, is attached hereto in its entirety as Exhibit "J". Professor Blank and Goodman assert:

> *The increase in RF broadcasting and communication devices, together with ELF power frequency devices, create an urgent need for realistic safety standards. The stress response is an appropriate biological guideline to evaluate cell safety in both thermal and non-thermal ranges, as well as the effects of long term and complex repeated exposures. It is also a natural biological bridge to the more complex mechanisms that affect human health.*
>
> (Ex. J, p. 645) (Emphasis added.)

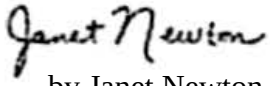
* * *

Conclusion

For these reasons EMRPI petitions FCC to deny VZW's proposed transfer of licenses, spectrum manager and *de facto* transfer leasing arrangements to Verizon Wireless and Atlantis Holdings LLC until:

1. FCC completes a thorough review of the research and studies cited above and the preparation of an EIS in full compliance with the National Environmental Policy Act.
2. VZW demonstrates that it has implemented an RF safety solution that protects the public and all categories of workers whose workplaces are found near to VZW's antenna sites.

The EMR Policy Institute



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recommendations from expert scientific bodies that the standards be changed. *EMR Network Petition*, 18 FCC Rcd 16822, 16824-16826 (2003). The Court found "nothing in those studies so strongly evidencing risk as to call into question the Commission's decision to maintain a stance of what appears to be watchful waiting." *EMR Network*, 391 F.3d at 274. In light of the decisions of both this Court and the D.C. Circuit, a claim of harm due to non-thermal effects cannot justify the stay of an auction.

Moreover, even if petitioners had shown some type of non-thermal effect, any harm is not sufficiently immediate to justify interfering with Auction 66. First, the spectrum at issue is already in use, and petitioners are thus exposed to RF energy at those frequencies in the absence of an auction. Second, the spectrum will not be put to use by the auction winners until considerable further administrative processing has taken place. As set forth in the *AWS Public Notice*, after the auction closes, the winners must submit "long form" applications providing detailed information on their qualifications to hold the licenses. *Id.* at ¶¶248-249. At that point, the applications will be subject to petitions to deny, which can be filed by any interested party pursuant to 47 U.S.C. § 309(d)(1). The Commission must resolve any petition to deny before it issues a license, 47 U.S.C. §§ 309(d)(2) & (e), and any resulting order is subject to appeal to the D.C. Circuit

EXHIBIT A

IDENTIFICATION OF RESEARCH NEEDS RELATING TO POTENTIAL BIOLOGICAL OR ADVERSE HEALTH EFFECTS OF WIRELESS COMMUNICATION DEVICES

Committee on Identification of Research Needs Relating to Potential Biological or Adverse Health Effects of Wireless Communications Devices

Nuclear and Radiation Studies Board

Division on Earth and Life Studies

NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES

THE NATIONAL ACADEMIES PRESS
Washington, D.C.
www.nap.edu

EXHIBIT B

Executive Summary

The U.S. Food and Drug Administration (FDA) of the Department of Health and Human Services asked the National Academies to organize a workshop of national and international experts to identify research needs and gaps in knowledge of biological effects and adverse health outcomes of exposure to radiofrequency (RF) energy from wireless communications devices. To accomplish this task, the National Academies appointed a seven member committee to plan the workshop.[1] Following the workshop, the committee was asked to issue a report based on the presentations and discussions at the workshop that identified research needs and current gaps in knowledge. The committee's task did not include the evaluation of health effects or the generation of recommendations relating to how the identified research needs should be met.

For the purposes of this report, the committee defines research needs as research that will increase our understanding of the potential adverse effects of RF energy on humans. Research gaps are defined as areas of research where the committee judges that scientific data that have potential value are presently lacking, but that closing of these gaps is either ongoing and results should be awaited before judgments are made on further research needs, or the gaps are not judged by the committee to be of as high a priority with respect to directly addressing health concerns at this time.

The research needs and gaps identified by the committee are presented in abbreviated form in the report Summary and in more detail in the text.

[1]Committee on Identification of Research Needs Relating to Potential Biological or Adverse Health Effects of Wireless Communications Devices.

These needs and gaps are committee judgments derived from the workshop presentations and discussions, and the report does not necessarily reflect the views of the FDA, individual workshop speakers, or other workshop participants.

The committee judged that important research needs included, in order of appearance in the text, the following:

- Characterization of exposure to juveniles, children, pregnant women, and fetuses from personal wireless devices and RF fields from base station antennas.
- Characterization of radiated electromagnetic fields for typical multiple-element base station antennas and exposures to affected individuals.
- Characterization of the dosimetry of evolving antenna configurations for cell phones and text messaging devices.
- Prospective epidemiologic cohort studies of children and pregnant women.
- Epidemiologic case-control studies and childhood cancers, including brain cancer.
- Prospective epidemiologic cohort studies of adults in a general population and retrospective cohorts with medium to high occupational exposures.
- Human laboratory studies that focus on possible adverse effects on electroencephalography[2] activity and that include a sufficient number of subjects.
- Investigation of the effect of RF electromagnetic fields on neural networks.
- Evaluation of doses occurring on the microscopic level.
- Additional experimental research focused on the identification of potential biophysical and biochemical/molecular mechanisms of RF action.

[2] *Electroencephalography* is a neurological diagnostic procedure that records the changes in electrical potentials (brain waves) in various parts of the brain.

Summary

In recent years there has been a rapid increase in the use of wireless communications devices, and a great deal of research has been carried out to investigate possible biological or human health effects resulting from the use of these devices. In a more focused initiative, the U.S. Food and Drug Administration (FDA) of the Department of Health and Human Services asked the National Academies to organize a workshop of national and international experts to identify research needs and gaps in knowledge of biological effects and adverse health outcomes of exposure to radiofrequency (RF) energy from wireless communications devices (for full statement of task see Appendix A). To accomplish this task, the National Academies appointed a seven member committee to plan the workshop (Appendix B).[1] Following the workshop, the committee was asked to issue a report based on the presentations and discussions at the workshop that identifies, in the committee's judgment, research needs and current gaps in knowledge. The committee's task did not include the evaluation of health effects or the generation of recommendations relating to how identified research needs should be met.

The requested workshop was held on August 7-9, 2007 (Appendix C). It was organized into five sessions to identify research needs and gaps in the following areas:

- dosimetry and exposure,
- epidemiology,

[1]Committee on Identification of Research Needs Relating to Potential Biological or Adverse Health Effects of Wireless Communications Devices.

- human laboratory studies,
- mechanisms, and
- animal and cell biology.

A sixth session, which was held on the morning of the third day of the workshop, introduced overarching issues and solicited research needs and gaps from workshop speakers and other interested parties.

The organizing committee invited experts from 9 countries (Appendix D) to speak on research needs and gaps relating to potential biological or adverse health effects of wireless communications devices. Written contributions relating to research needs and gaps were also solicited for consideration prior to and at the workshop (individuals who submitted written contributions are listed in Appendix E).

The report contains the committee's evaluation of the workshop presentation and discussion sessions followed by the committee's identification of research needs and gaps.

RESEARCH NEEDS AND GAPS

For the purposes of this report, the committee defines "research needs" as research that will increase our understanding of the potential adverse effects of RF energy on humans. "Research gaps" are defined as areas of research where the committee judges that scientific data that have potential value are presently lacking, but that closing of these gaps is ongoing, and results should be awaited before judgments are made on further research needs, or the gaps are not judged by the committee to be of as high a priority at this time.

To the extent possible, near-, mid-, and long-term research opportunities have been characterized as follows: the committee judged that "research needs" are near-term research opportunities. "Research gaps" that are currently being filled may result in mid-term research opportunities, depending on the outcome of the current research. "Research gaps" defined as being of lower priority with respect to directly addressing health concerns comprise possible long-term research opportunities.

Abbreviated versions of committee judgments on research needs and gaps are organized below in the Summary in order of the five sessions that comprised the first two days of the workshop. The reader is referred to the text of the report for details on research needs and gaps.

DOSIMETRY AND EXPOSURE

Research Needs

1. There is a need to characterize exposure of juveniles, children, pregnant women, and fetuses, both for personal wireless devices (e.g., cell phones, wireless personal computers [PCs]) and for RF fields from base station antennas including gradients and variability of exposures, the environment in which devices are used, and exposures from other sources, multilateral exposures, and multiple frequencies.

2. Wireless networks are being built very rapidly, and many more base station antennas are being installed. A crucial research need is to characterize radiated electromagnetic fields for typical multiple-element base station antennas and for the highest radiated power conditions with measurements conducted during peak hours of the day at locations close to the antennas as well as at ground level.

3. The use of evolving types of antennas for hand-held cell phones and text messaging devices need to be characterized for the Specific Absorption Rates (SARs) that they deliver to different parts of the body so that this data is available for use in future epidemiologic studies.

4. RF exposure of the operational personnel close to multi-element newer base station antennas is unknown and could be high. These exposures need to be characterized. Also needed are dosimetric absorbed power calculations using realistic anatomic models for both men and women of different heights.

Research Gaps

Research Ongoing

1. Although several dosimetric models are currently available for children and individuals of reduced stature, a research gap remains in the further development of models of several heights for men, women, and children of various ages for use in the characterization of SAR distributions for exposures characteristic of cell phones, wireless PCs, and base stations.

Judged to Be of Lower Priority

2. Presently, there is negligible or relatively little knowledge of local SAR concentration (and likely heating) in close proximity to metallic adornments and implanted medical devices for the human body.

3. There is a need for improved exposure systems for human laboratory studies including reliable and accurate exposure assessment for designs of next generation exposure systems for human laboratory studies. Furthermore, location-dependent field strength needs to be accounted for

in the characterization of exposures. A very important consideration is the validation of results by several independent investigators so that reliable and accurate exposure assessments are available for both comparisons between systems and between laboratories.

4. There is a need for an updated survey in a properly selected sample of the U.S. population to characterize and document rapidly changing exposures to electromagnetic field strengths that would improve our knowledge of the exposure levels for the population at large, taking into account the large number of new cell phones and base stations, radio and TV stations, and a wide array of other communications devices, including a survey of measured personal exposure with information on location and activity at the time of measurement including the difference between indoor and outdoor environments.

EPIDEMIOLOGY

The committee identified significant research needs for a number of epidemiologic studies, particularly of children.

Adults

Research Needs

1. Prospective Cohort Studies. A prospective cohort study will allow for the evaluation of diverse outcomes, but a very large sample size and extended follow-up is required for rare outcomes or those that occur only with very long latencies.

2. Occupational Cohorts with Medium to High Exposure. None of the occupational studies to date have been based on an adequate exposure assessment. Much work is needed to identify occupations with potentially high RF exposures and to characterize them.

Research Gaps

Judged to Be of Lower Priority

1. Nested case-control studies of rare diseases.
2. Observational studies on subjective outcomes.

Children

Research Needs

1. Prospective Cohort Studies of Pregnancy and Childhood. Children are potentially exposed from conception through maternal wireless device use and then postnatally when they themselves become users of mobile phones.

2. Case-control Study of Children Mobile Phone Users and Brain Cancer. Owing to widespread use of mobile phones among children and adolescents and the possibility of relatively high exposures to the brain, investigation of the potential effects of RF fields in the development of childhood brain tumors is warranted.

Research Gaps

Research Ongoing

1. Case-control studies of childhood cancer with improved exposure assessment taking into account all major fixed point sources of RF exposure (base stations, AM, FM, TV antennas, and other sources).

HUMAN LABORATORY STUDIES

Research Needs

There are some significant research needs for human laboratory studies. Due to the paucity of data from identically replicated experiments,

1. There is a need for experiments focusing on possible adverse RF effects identified by changes in electroencephalogram activity as well as a need to include an increased number of subjects.

Research Gaps

Research Ongoing

1. Little or no information is available on possible neurophysiological effects developing during long-term exposure to RF fields.
2. Risks of exposure to RF fields in elderly volunteers are not well explored.
3. There is a continuing need for experiments focusing on possible adverse RF effects identified by changes in cognitive performance functions.

Judged to Be of Lower Priority

4. There is a need to conduct human volunteer studies to investigate potential **health implications arising from interaction of cell phones with** hearing aids and cochlear implants.

MECHANISMS

Research Needs

1. The effect of RF electromagnetic fields on neural networks is a topic needing further investigation. There are indications that neural networks are a sensitive biological target.

2. Evaluation of doses occurring on the microscopic level is a topic needing further investigation.

Research Gaps

Research Ongoing

1. Mechanisms that can be modeled theoretically with the use of software-based nonlinear cell models that describe field-induced molecular changes. **It is currently unclear if a nonlinear biological mechanism exists** that could lead to demodulation effects. There is some research with respect to this question underway.

Judged to Be of Lower Priority

2. It is unclear whether low-level RF exposure can trigger effects through stimulation of cellular thermo-receptors.

3. Knowledge is lacking concerning the effects of electromagnetic fields on ion and molecular transport through the cell membrane.

IN VIVO AND IN VITRO STUDIES IN EXPERIMENTAL MODEL SYSTEMS

Research Needs

1. Additional experimental research focused on the identification of potential biophysical and biochemical/molecular mechanisms of RF action is considered to be of the highest priority.

Research Gaps

Research Ongoing

1. Following completion of several large ongoing studies, a "weight-of-the-evidence" analysis can be conducted to synthesize and evaluate the entire data set. At that time, rational, informed decisions can be made concerning the value of conducting additional oncogenicity[2] studies in standard-bred laboratory animals.

2. The use of genetically engineered animals may increase the sensitivity of laboratory studies to detect weak effects, and may be particularly suitable to evaluate the possible interactions between RF fields and other agents in disease causation.

3. The overall database for RF fields and cancer would be strengthened by additional studies using multi-stage model systems for cancer in tissues (such as the brain) that have been hypothesized to be targets of RF action.

4. Although genetic toxicology studies have failed to identify potential RF health effects, additional genetic toxicology studies may be warranted should evidence of oncogenicity be identified in any of the ongoing chronic toxicity/oncogenicity bioassays of RF fields in laboratory animals, or in any future studies to be performed using genetically engineered animal models.

5. A number of potentially critical cancer-related endpoints have received only very limited study and are identified in the report text.

6. In addition to cancer-related endpoints, data gaps exist in a number of other areas of toxicology in which knowledge is needed to support a complete evaluation of the possible health effects of RF exposure; these gaps are identified in the body of the report.

[2] *Oncogenicity* is the capacity to cause tumors.

Introduction

The U.S. Food and Drug Administration (FDA) of the Department of Health and Human Services asked the National Academies to organize a workshop of national and international experts to discuss research needs and gaps in our knowledge of the biological effects and adverse health outcomes of exposure to radiofrequency (RF) energy from wireless communications devices. Although the sponsor's main interest centers on handheld devices such as cell phones or portable home phones, base stations and antennas were also considered by the committee based on discussions with the sponsors indicating that consideration of these components would not be discouraged.

The workshop was announced on the National Academies' Current Projects site, and attendance was available to anyone interested in attending the workshop. This workshop announcement included instructions for submitting written comments for consideration at the workshop. A workshop announcement was also provided to the FDA and the Bioelectromagnetics Society for distribution as deemed appropriate, as well as to individuals who expressed an interest in the workshop.

It was clear from the presentations and discussions at the workshop that a great deal of research has been accomplished to date, but sometimes with inconsistent results. This workshop, however, was not intended to evaluate health effects, and the report based on a workshop does not assess health effects or make recommendations as to how the identified research needs should be met. The National Academies was asked to issue a report following the workshop that exclusively draws on the workshop

presentations and discussions to identify current research needs and gaps in knowledge. The committee was also asked to provide its consensus findings on near-, mid-, and long-term research opportunities. The report is a committee product and does not necessarily reflect the views of the FDA, individual workshop speakers, or other workshop participants.

To organize the workshop and to identify experts to address research needs and gaps relating to potential biological or adverse health effects of wireless communications devices, the committee (Appendix B) held a workshop planning meeting on July 9-10, 2007. As a result of this planning meeting, international experts from 9 countries were invited to speak at the workshop. Written contributions on research needs and gaps for the committee's consideration were also solicited for submission prior to the workshop, which was held on August 7-9, 2007. A total of 16 written contributions were received from individuals listed in Appendix E. The speakers' presentations, panel discussions, comments from interested workshop attendees, and written contributions were considered by the committee as it developed this report.

The workshop itself was organized into six sessions (Appendix C). The first five sessions consisted of invited participants and panel discussions that identified research needs and gaps in the following areas:

- exposure and dosimetry,
- epidemiology,
- human laboratory studies,
- mechanisms, and
- animal and cell biology.

A sixth session, which was held on the morning of the third day, introduced overarching issues and solicited research needs from speakers and other interested participants. Overarching issues were determined by the committee at the workshop planning meeting held in July 2007. The purpose of the sixth session was to make sure that research needs that might reach across the disciplines were discussed and identified. The issues were thus designed to address current topics in RF research. A short introduction of each subject was made by a committee member and unrestricted input was then invited from interested parties attending the workshop. The overarching issues were as follows:

- Are there differences in health effects of short-term vs. long-term exposure?
- Are there differences between local vs. whole-body exposures?
- Can the knowledge of biological effects from current signal types and exposure patterns be extrapolated to emerging exposure scenarios?

- Are there any biological effects that are not caused by an increase in tissue temperature (nonthermal effects)?
- Does RF exposure alter (synergize, antagonize, or potentiate)[1] the biological effects of other chemical or physical agents?
- Are there differences in risk to children?
- Are there differences in risk to other subpopulations such as the elderly and individuals with underlying disease states?

These overarching issues and the general discussions that followed were factored into the committee's deliberations in developing the report. From the presentations and discussions that took place at the workshop sessions, the committee identified research needs and gaps; the selection of these research needs and gaps are committee judgments.

For the purposes of this report, the committee defines research needs as research that will increase our understanding of the potential adverse effects of RF energy on humans. Research gaps are defined as areas of research where the committee judges that scientific data that have potential value are presently lacking, but that closing of these gaps is ongoing, and results should be awaited before judgments are made on further research needs, or the gaps are not judged by the committee to be of as high a priority at this time.

To the extent possible, near-, mid-, and long-term research opportunities have been characterized as follows: the committee judged that research needs are near-term research opportunities. Gaps that are currently being filled may result in mid-term research opportunities, depending on the outcome of the current research. Gaps defined as being of lower priority with respect to directly addressing health concerns comprise possible long-term research opportunities.

[1] *Synergize:* two or more agents or forces interacting so that their combined effect is greater than the sum of their individual effects. *Antagonize:* two or more agents or forces interacting so that one agent counteracts the effect of another agent. *Potentiate:* one agent promotes or strengthens a biochemical or physiological action or effect of another agent.

Dosimetry and Exposure

This section reports on the workshop session on radiofrequency (RF) energy,[1] dosimetry,[2] and exposure.[3]

As discussed by Dr. van Deventer at the workshop (van Deventer 2007) there is a need to characterize exposure of juveniles, children, pregnant women, and fetuses both for personal wireless devices (e.g., cell phones, wireless personal computers [PCs]) and for RF fields from base station antennas. This characterization includes taking into account gradients and variability of exposures due to the actual use of the device, the environment in which it is used, and exposures from other sources, multilateral exposures, and multiple frequencies. The data thus generated would help to define exposure ranges for various groups of exposed populations.

There is a need for reliable and accurate exposure assessment for designs of the next generation of epidemiologic studies, such as development of an index that integrates service technology and location of use (both

[1] *RF energy* includes waves with frequencies ranging from about 3000 waves per second (3 kHz) to 300 billion waves per second (300 GHz). Microwaves are a subset of radio waves that have frequencies ranging from around 300 million waves per second (300 MHz) to 300 billion waves per second (300 GHz).

[2] *RF dosimetry* is the science pertaining to coupling of RF waves, e.g., from cell phones to the human body. Because of the human anatomy, RF dosimetry must take into account the shape as well as the heterogeneity of the tissues. The unit for absorbed dose (i.e., rate of energy absorption per unit mass) is Watts/kg.

[3] *RF exposure* is the quantification of the absorbed RF energy and its distribution for the various parts of the body. The absorbed energy and its distribution within the exposed body is a function of the incident electromagnetic fields described in units of Watts/meter-squared and the spatial variation of these fields.

geographic location and whether a phone is primarily used indoors or outdoors). Towards this end, we need tissue-characterized models of children of different ages and of pregnant women for dosimetric calculations. Specific Absorbtion Rates (SARs)[4] for children are likely to be higher than for adults, both for cell phones and for base station exposures, due to the fact that the exposure frequency is closer to the whole-body resonance frequency for shorter individuals such as children (ANSI 1982; Gandhi 1979; Wang et al. 2006; Hirata et al. 2007). Better characterization of SARs for children of various age groups is, therefore, needed. Furthermore, models are not presently adequate for men and women of various heights and for children of various ages.

BASE STATIONS

Wireless networks are being built very rapidly, and many more base station antennas are being installed. Maintenance personnel may be exposed to fairly high electromagnetic fields emanating from base station antennas[5] unless all of the typically four to six antennas mounted on the base station are turned off. For all of the base station antennas, the radiated power is on the order of several tens of watts, with higher powers being radiated at peak hours of the day. Though not as well characterized, particularly for multiple co-located base station antennas, the radiated RF fields for rooftops near base stations may also be fairly high. The quantification of SAR distributions from base stations is fairly minimal and those distributions are of concern for professionals involved in maintenance of base stations, building/roof maintenance personnel, and members of the public that live in close proximity to the antennas. There are also subpopulations among the employees, which might be exposed to greater amounts of RF energy than the average population. The characterization of these subpopulations is important.

Thus, the interest in base station exposures close to the antennas is driven by the potential health effects on antenna repair professionals and building/roof maintenance workers from relatively high, acute exposures, but the interest in exposures for members of the public that live in close proximity to the antennas or for the public at the ground level at larger distances is motivated by the need to address public concern about very low

[4]*Specific Absorption Rate* (SAR) is a measure of the rate at which radiofrequency (RF) energy is absorbed by the body when exposed to an RF electromagnetic field. The most common use is in relation to cellular telephones.

[5]Base station antennas mounted on rooftops, on poles, or other elevated positions are the important intermediaries for cell phone communications.

level, chronic exposures that are in fact similar to those from existing TV and radio antennas albeit at different frequencies.

Most of the reported studies to date have involved one base station antenna and have used mostly homogeneous models, often of simplified circular or rectangular cross sections of the exposed human. One study involving a heterogeneous, anatomically based model consisting of diverse constituents, but still assuming a single antenna rather than typical arrangements of four to six antennas, is given in Gandhi and Lam (2003). In other words, the studies to date do not pertain to the commonly used multiple-element base station radiators. Also, unlike highly localized cell phone RF energy deposition, the base station exposures involve much, if not all, of the body and would have slightly different radiator origins (for multi-element base stations) and may be multi-frequency as well, particularly if several different-frequency base station antennas are co-located. Furthermore, because of the whole-body resonance[6] phenomenon, the SAR is likely to be higher for shorter individuals due to the closeness of the frequency/frequencies of exposure to the whole-body resonance frequency. In addition to the rapid growth in the number of base stations since 1990, there has also been growth in other sources of RF radiation from cordless phones, wireless computer communications, and other communications systems. The last general survey of RF levels in U.S. cities was during the 1970s, and an updated survey of RF intensities would be useful background for future epidemiologic studies. There are many indoor wireless systems as well as cell phones, which are used both indoors and outdoors. Measurements of the differences in the exposures generated by the use of these devices in these environments will be of value in determining if there are any health effects resulting from exposures to low levels and intermittent sources of RF radiation.

MOBILE PHONES

The use of evolving types of antennas for cell phones and text messaging devices needs to be characterized for the SARs that they deliver to different parts of the body so that this data is available for use in future epidemiologic studies. A great deal of research has been done by many laboratories worldwide to understand coupling of RF energy irradiation from cell phone antennas to the human head. For most of these studies, the

[6] *Whole-body resonance*: It has been shown that each individual absorbs maximum energy from incident RF fields at frequencies that are higher for shorter individuals. Furthermore the SAR at this resonance frequency is increasingly higher for shorter individuals (Gandhi 1979). As the absorbed energy diminishes inversely with frequency in the post-resonance region, it is still quite high for the shorter individuals at base station frequencies because of the relative proximity of these frequencies to the resonance frequencies.

researchers have assumed that cell phones are held against one of the ears, and studies have used a variety of anatomically based models. Cell phones were assumed to have pull-out linear rod antennas with dimensions on the order of several centimeters. However, most of the recent telephones use built-in antennas of various shapes for which additional published information is needed.

The published results on pull-out linear rod antennas are generally in agreement in that the RF energy coupled to the human head is the highest for the ear and for a limited volume (approximately 3 × 3 × 3 cm) of the brain proximal to the cell phone (IEEE 1996). As expected, the penetration of the coupled electromagnetic fields[7] into the brain is shallow (approximately 2 cm) at higher frequencies (i.e., 1800-1900 MHz). For cell phones held against the ear, the SAR drops off rapidly for the regions of the brain away from the antenna and is negligible for the rest of the human body except for the hand.

Wireless technology is leading to devices such as wireless PCs, handheld devices used for video calls, and other handheld devices for text messaging. In their typical usage, the antennas are closer to the hand or other parts of the body. SAR distributions for these newer devices have been obtained using homogeneous liquid-filled flat phantom models. Though these models are reasonably accurate to get the 1 or 10 Watts/kg average SAR needed for safety compliance testing, they are incapable of providing detailed SAR distributions because of lack of detailed anatomical features, e.g., for the hand or the human lap or parts of the body close to the devices. Additionally, such models cannot resolve the detailed RF field distribution at the cellular and subcellular levels. Given a set of anatomical data, the RF field distributions can be modeled and estimates can be made of the effects of various wave forms and carrier frequencies. An important research gap is the lack of models of several heights for men, women, and children of various ages for use in the characterization of SAR distributions for exposures characteristic of cell phones, wireless PCs, and base stations.

Presently, there is negligible or relatively little knowledge of local SAR concentration (and likely heating) in close proximity to metallic adornments and implanted medical devices for the human body. Examples include metal rim glasses, earrings, and various prostheses (e.g., hearing aids, cochlear implants, cardiac pacemakers). Research is therefore lacking to quantify the enhanced SARs close to metallic implants and external metallic adornments.

[7]If either the electric or magnetic field has a time dependence, then both fields must be considered together as a coupled electromagnetic field using Maxwell's equations.

LABORATORY EXPOSURE SYSTEMS

There is a need for improved exposure systems for human laboratory studies. Furthermore, location-dependent field strength needs to be accounted for in the characterization of exposures. Most of the present-day exposure systems used in laboratory studies focus on the exposure of the head. Though exposures to the head are relevant for most cell phone exposures, whole-body exposures due to base stations are a research need. The laboratory exposure systems also need to include ELF[8] and pertinent modulation protocols.[9]

There is a need for reliable and accurate exposure assessment for designing the next generation of epidemiologic studies, such as development of an index that integrates service technology and location of use (both geographic location and whether a phone is primarily used indoors or outdoors). For human laboratory studies there has been considerable effort to quantify the uncertainties of the different methods used in dosimetry. However, there is little information about the overall accuracy of the dosimetric approaches with respect to reality and variability. The accuracy of dosimetric approaches is particularly important as well as the validation of results by several independent investigators to establish SAR variability.

The committee's evaluation of presentations and discussions at the workshop has resulted in the identification of the following research needs and gaps.

Research Needs

1. There is a need to characterize exposure of juveniles, children, pregnant women, and fetuses both for personal wireless devices (e.g., cell phones, wireless PCs) and for RF fields from base station antennas including gradients and variability of exposures, the environment in which devices are used, and exposures from other sources, multilateral exposures, and multiple frequencies. The data thus generated would help to define exposure ranges for various groups of exposed populations.

2. Wireless networks are being built very rapidly, and many more base station antennas are being installed. A crucial research need is to characterize radiated electromagnetic fields for typical multiple-element (four to six elements) base station antennas for the highest radiated power conditions and with measurements conducted during peak hours of the day at locations close to the antennas as well as at ground level. A study of the wire-

[8] *ELF:* Extremely low frequency fields, such as the 50 and 60 Hz power frequency fields used in Europe and the United States, respectively.

[9] Some commonly used modulation protocols are TDMA (time division multiple access) and CDMA (code division multiple access).

National Institute of Environmental Health Sciences, National Toxicology Program; Request for Comments on Substances Nominated to the National Toxicology Program (NTP) for Toxicological Studies and on the Testing Recommendations Made by the NTP Interagency Committee for Chemical Evaluation and Coordination (ICCEC); Solicitation of Information on Nominated Substances

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institute of Environmental Health Sciences, National Toxicology Program; Request for Comments on Substances Nominated to the National Toxicology Program (NTP) for Toxicological Studies and on the Testing Recommendations Made by the NTP Interagency Committee for Chemical Evaluation and Coordination (ICCEC); Solicitation of Information on Nominated Substances

Summary

The National Toxicology Program (NTP) routinely solicits, accepts and reviews for consideration nominations for toxicological studies to be undertaken by the Program on substances of potential human health concern. Nominations are received from Federal agencies, industry, the public, and other interested parties and undergo several levels of review before toxicological studies are designed and implemented. The NTP Interagency Committee for Chemical Evaluation and Coordination (ICCEC) serves as the first level of review for NTP nominations.

EXHIBIT C

At the December 13, 1999 meeting of the ICCEC, 12 new nominations were reviewed and testing recommendations made. As part of an effort to inform the public and to obtain input about the selection of chemicals for evaluation, the NTP routinely seeks public comment on (1) substances nominated to the Program for toxicological studies and (2) the testing recommendations made by the ICCEC. This announcement outlines briefly the process for nomination and selection of substances for NTP study, presents the testing recommendations made by the ICCEC at the December 13, 1999 meeting, requests comment on those nominations and recommendations, and solicits the submission of additional information for consideration by the NTP in its subsequent evaluation of the nominations.

Background

1. Nomination and Selection of Substances for NTP Studies

The nomination and selection for study of chemicals and agents with the highest potential for adversely impacting public health are essential to the success of the NTP's testing program. The nomination process is open and nominations are solicited from academia, Federal and State regulatory and health agencies, industry, and labor unions, as well as from environmental groups and the general public. Particular assistance is sought for the nomination of studies to be undertaken by the NTP that permit the testing of hypotheses to enhance the predictive ability of future NTP studies, address mechanisms of toxicity, or fill significant gaps in the knowledge of the toxicity of chemicals or classes of chemicals. Substances selected for study generally fall into two broad overlapping categories: (1) Those substances of greatest concern for public or occupational health and (2) chemicals for which toxicological data is needed to reduce uncertainty in risk assessment by aiding species-to-species extrapolation and understanding dose-response relationships. Substances may be studied for a variety of health-related effects, including but not limited to, reproductive and developmental toxicity, genotoxicity, immunotoxicity, metabolism and disposition, as well as carcinogenicity. The possible public health consequences of exposure remain the over-riding factor in the decision to study a particular chemical or agent. Selections for government testing are based on the principle that responsible manufacturers will evaluate their own chemicals or agents for health and environmental effects as mandated by Congress under legislative authorities. Increased efforts continue to be focused on: (1) Improving the quality of the nominations of chemicals, environmental agents, or issues for study so that public health and regulatory needs are addressed; (2) broadening the base and diversity of nominating organizations and individuals; and (3) increasing nominations for studying toxicological endpoints in addition to carcinogenesis.

II. Review Process for Substances Nominated for NTP Studies

Nominations are first reviewed by a multi-disciplinary NIEHS committee to determine whether the nominated agent has undergone adequate toxicological testing or has been previously considered by the NTP. For nominations not eliminated from consideration or deferred at this stage, the available literature is examined in detail to prepare Toxicological Summaries that describe and summarize relevant

information for each nominated substance. Included in each Toxicological Summary are information on chemical and physical properties, production levels, use, human exposure, regulatory status, toxicological effects, and rationale for the nomination. The Toxicological Summaries are distributed to the NTP Interagency Committee for Chemical Evaluation and Coordination (ICCEC), which is composed of representatives from the Agency for Toxic Substances and Disease Registry, Consumer Product Safety Commission, Department of Defense, Environmental Protection Agency, Food and Drug Administration's National Center for Toxicological Research, Occupational Safety and Health Administration, National Cancer Institute, National Institute of Environmental Health Sciences, National Institute for Occupational Safety and Health, and the National Library of Medicine. ICCEC members are assigned as reviewers for each substance after consideration of the nature of its uses and exposure so that, to the extent possible, appropriate regulatory concerns will be addressed. Members are requested to identify their agency's interests, if any, in the chemical and to provide any relevant information from their respective agencies regarding the nominated chemicals or structurally related substances. During the evaluation process, the NTP works actively with regulatory agencies and interested parties to supplement the information about nominated substances and to ensure that the nomination and selection process meets regulatory and public health needs.

At its meeting to consider the nominated substances, the ICCEC makes testing recommendations including testing priorities and also may make recommendations for studies in addition to those requested by the nominator. Summaries of the ICCEC recommendations and any public comments received on these nominations are then presented to the NTP Board of Scientific Counselors (the Program's external scientific advisory committee) for review and comment in an open public session. The ICCEC's recommendations, NTP Board of Scientific Counselors' recommendations, and public comments are incorporated into recommendations that are then submitted to the NTP Executive Committee, the Federal interagency policy oversight body. For each substance nominated for the various types of studies, the NTP Executive Committee reviews and approves action to move forward to test, defer testing, or remove from testing consideration, and recommends testing priorities. The selection of a substance by the Executive Committee does not automatically commit the NTP to its evaluation. The priority of the nominations and the proposed studies are assessed during the nomination and

selection process and reassessed during the study design process. During any of these stages, a chemical or study may be withdrawn if applicable research data or higher priority studies are identified, or if a study proves impractical. A broad range of regulatory and toxicological concerns is addressed during the nomination and selection process through the participation of representatives from Federal agencies concerned with public health issues. In addition, representatives from non-government organizations including academia, industry, labor, and public interest sit on the NTP Board of Scientific Counselors, and thus have input into chemical selection decisions.

Nominated Substances and ICCEC Review

At its meeting on December 13, 1999, the ICCEC reviewed 12 nominations for NTP studies. For six of these nominations, metabolism, toxicity, or carcinogenicity studies were recommended. No studies were recommended at this time for two nominations, and a testing recommendation for four chemicals was deferred pending receipt of (1) additional data from other organizations on related studies completed, anticipated, or in progress or (2) information on production, exposure, and use patterns. The nominated substances with CAS numbers, nomination source, types of studies recommended, study rationale, and other information are given in the attached tables.

Request for Comment

Interested parties are encouraged to provide comments or supplementary information on the nominated substances and recommendations that appear in this announcement. The Program would welcome receiving toxicology and carcinogenesis information from completed, ongoing, or planned studies, as well as information on current production levels, human exposure, use patterns, or environmental occurrence for any of the substances listed in the attached tables. To provide comments or information, please contact Dr. William Eastin at the address given below within 60 days of the publication date of this announcement. Persons submitting comments or additional information are asked to include their name, affiliation, mailing address, phone, fax, e-mail and sponsoring organization (if any) with the submission. An electronic copy of this announcement as well as further information on the NTP and the NTP Chemical Nomination and Selection Process can be accessed through the NTP web site. The URL for the NTP homepage is http://ntp-server.niehs.nih.gov.

Contact may be made by mail to Dr. William Eastin, NIEHS/NTP, P. O. Box 12233, Research Triangle Park, North Carolina 27709; by telephone at (919) 541-7941; by FAX at (919) 558-7057; or by email at eastin@niehs.nih.gov.

Dated: February 17, 2000.
Samuel H. Wilson,
Deputy Director, National Institute of Environmental Health Sciences.

Attachment--Substances Nominated to the NTP for Study and Testing Recommendations Made by the ICCEC on December 13

[Excerpt of attachment specific to Radiofrequency Radiation Nomination]

Radio frequency radiation emissions of wireless communication devices.	FDA	establish interagency program to design studies assessing cancer and non-cancer health effects to fulfill regulatory needs	Widespread consumer and worker exposure; available data is inadequate to properly assess safety.

Nominations from FDA's Center from Device and Radiological Health

Radio Frequency Radiation Emissions of Wireless Communication Devices (CDRH)

Executive Summary

Over 80 million Americans currently use wireless communications devices (e.g., cellular phones) with about 25 thousand new users daily. This translates into a potentially significant public health problem should the use of these devices even slightly increase the risk of adverse health effects. Currently cellular phones and other wireless communication devices are required to meet the radio frequency radiation (RFR) exposure guidelines of the Federal Communications Commission (FCC), which were most recently revised in August 1996. The existing exposure guidelines are based on protection from acute injury from thermal effects of RFR exposure, and may not be protective against any non-thermal effects of chronic exposures. Animal exposure research reported in the literature suggests that low level exposures may increase the risk of cancer by mechanisms yet to be elucidated, but the data is conflicting and most of this research was not conducted with actual cellular phone radiation. In one study transgenic mice exposed to a digital phone signal developed more than twice as many non-lymphoblastic lymphomas as the unexposed control group, a statistically significant increase. These results suggest a potential carcinogenic effect from the digital phone signal using this animal model. There is wide agreement within the international scientific community regarding the types of research needed to assess whether RFR from wireless communications poses a health risk to users. Research needs have been articulated by a number of groups, including the European Commission and the World Health Organization International EMF Project. Animal experiments are crucial because meaningful data will not be available from epidemiological studies for many years due to the long latency period between exposure to a carcinogen and the diagnosis of a tumor. Studies must also be performed in animals that are genetically predisposed to cancer and endpoints other than cancer, such as ocular damage and neurological effects, must also be examined. High priority must be given to replication of prior studies that indicate adverse effects, such as the transgenic mice model mentioned above. There is currently insufficient scientific basis for concluding either that wireless communication technologies are safe or that they pose a risk to millions of users. A significant research effort, involving large well-planned animal experiments is needed to provide the basis to assess the risk to human health of wireless communications devices.

A. Summary of Biological Effects - Wireless Telephone Radiation

As noted above, the use of wireless communications devices (e.g., cellular phones) is increasing rapidly. FDA concluded over five years ago that little was known about the possible health effects of repeated or long-term exposure to low levels of RFR of the types emitted by such devices. However, some scientific articles suggest a potential cancer risk may exist. While some other studies did not find evidence of carcinogenicity for RFR, data from long-term animal studies with a multi-dose exposure paradigm are unavailable. Properly conducted scientific research is needed to address these issues and

EXHIBIT D

fill in the gaps in our understanding of the biological effects of exposure to RFR.

B. Physical Properties of Wireless Telephone Radiation

Personal (cellular) telecommunications is a rapidly evolving technology that uses microwave radiation to communicate between a fixed base station and a mobile user. Presently, most systems employ analog technology, where the low frequency speech signals are directly modulated on to a high frequency carrier in a manner similar to a frequency-modulated (FM) radio. The power level is effectively constant during the modulation, although some power control may occur. However, the recently introduced second-generation systems in Europe, USA and Japan employ digital technology, where the low frequency speech is digitally coded prior to modulation. There is a strong trend towards hand-held cellular telephones, which means that the radiating antenna is close to the head of the user. In the relatively near future the use of digital systems will predominate.

The electric and magnetic fields surrounding a cellular telephone handset near a person's head are complicated functions of the design and operating characteristics of the handset and its antenna and the electric and magnetic fields vary considerably from point to point.

Microwave radiation absorption occurs at the molecular, cellular, tissue and whole-body levels. The dominant factor for net energy absorption by an entire organism is related to the dielectric properties of bulk water, which ultimately causes transduction of electromagnetic energy into heat. For laboratory experiments, exposure conditions can be classified as thermal or non-thermal. There are no strict boundaries for these different exposure regimens because a number of factors may influence the characteristics of exposure. Thermal effects are well established and form the biological basis for restricting exposure to RF fields. In contrast, non-thermal effects are not well established and, currently, do not form a scientifically acceptable basis for restricting human exposure to microwave radiation at those frequencies used by hand-held cellular telephones. A large number of biological effects have been reported in cell cultures and in animals, often in response to exposure to relatively low-level fields, which are not well established but which may have health implications and are, hence, the subject of on-going research. It is not scientifically possible to guarantee those non-thermal levels of microwave radiation, which do not cause deleterious effects for relatively short exposures, will not cause long-term adverse health effects.

C. Human Exposure

For the purpose of radiation protection, dosimetric quantities are needed to estimate the absorbed energy and its distribution inside the body. A dosimetric quantity that is widely adopted for microwaves is the Specific Absorption Rate (SAR). SAR is defined as the time derivative of the incremental energy, absorbed by or dissipated in an incremental mass contained in a volume element of a given density. SAR is expressed in the unit watt per kilogram ($W\ kg^{-1}$). Numerical calculations, based upon coupling from handsets to an anatomically realistic numerical phantom of the head have been performed. Such

calculations have shown that, during normal operation, a radiated power of 1 W gives rise to a maximum SAR of 2.1 W kg^{-1} at 900 MHz and 3.0 W kg^{-1} at 1.8 GHz averaged over any 10 g of tissue. Typical handset powers are 0.6 W. To enable communication with locations not easily reachable with land networks, satellite communication systems have been recently designed and implemented. New systems will involve small portable units and hand-held sets similar to current cellular telephones. In these special cases, higher power classes can be envisioned.

Digital cellular telephones transmit information in bursts of power. The power is turned on and off, and the equipment transmits for a fraction of the time only and then is silent for the remaining part of the burst period. The basic repetition frequency is 217 Hz for GSM and DCS 1800 systems and 100 Hz for DECT; however, the spectrum also contains a number of higher harmonics due to the narrow pulse, so there are also frequencies in the kilohertz region. Owing to the complexity of these communications systems, there are also 2 and 8 Hz components in the signal, apart from multiples of 100 and 217 Hz.

D. Regulatory Status

As described previously, when tissues are exposed to microwave fields strong enough to raise the temperature, the resulting biological effects are said to be thermal. There is currently a general consensus in the scientific and standards community that the most significant parameter, in terms of biologically relevant effects of human exposure to RF electromagnetic fields, is the SAR in tissue. SAR values are of key importance when validating possible health hazards and in setting standards.

Possible thermal effects in the eye are also important. The latter is regarded as potentially sensitive to heating because of the limited cooling ability of the lens caused by the lack of a blood supply and the tendency to accumulate damage and cellular debris. Effects of electromagnetic radiation on the three major eye components essential for vision, the cornea, lens and retina, have been investigated, the largest number of studies being concerned with cataracts. It has been established that lens opacities can form after exposure to microwave radiation above 800 MHz; however, below about 10 GHz cataract induction requires long exposures at an incident power density exceeding 10^3 Wm^{-2}. SARs in the lens large enough to produce temperatures in the lens greater than 41 ^{o} C are required. Effects on the retina have been associated with levels of microwave radiation above 500 Wm^{-2}. All these data suggest that thermal effects will probably only occur in people subjected to whole body or localized heating sufficient to increase tissue temperatures by more than 1 ^{o}C. These various effects are well-established and form the biological basis for restricting exposure to RF fields. In contrast, non-thermal effects are not well-established and, currently, do not form a scientifically acceptable basis for restricting human exposure to microwave radiation at those frequencies used by handheld cellular telephones and base stations.

The setting of safety limits for human exposure to RF electromagnetic fields is currently performed in two steps. First, basic limits (or restrictions) for SARs inside the body are specified from biological considerations in terms of whole-body SAR and SAR averaged

over a small mass of tissue. Then relationships between SAR values and unperturbed field strengths are used to set derived limits (or reference or investigation levels) for field strengths and power density to be used in assessing compliance with the adopted standard. Studies to relate core temperature rise with whole-body averaged SARs (Elder and Cahill, 1984) suggested that the 1-4 W Kg^{-1} range is the threshold at which significant core temperature rise occurs. Another approach to identify thresholds of whole body thermal effects is based on the change in animal behavior exposed to RF fields. A review of animal data indicates a threshold for behavioral responses in the same 1-4 W kg^{-1} range. Another review of animal data also concluded that the threshold of RF exposure in terms of the whole body SAR is 4 W kg^{-1} (IEEE, 1991). Based on the estimated threshold and a safety factor of 10, the whole body averaged SAR of 0.4 W kg^{-1} has been widely accepted as the basic restriction for occupational exposures under controlled environmental conditions (IEEE, 1991). For the general public under uncontrolled environmental conditions, a five times smaller value of 0.08 W kg^{-1} has often been adopted as the basic restriction. In order to avoid excessive local exposures, maximum local SARs are limited as one of the basic restrictions in safety guidelines.

Basic restrictions for partial body exposure are given in terms of maximum local SARS. Local SAR values change spatially within the body depending on the depth of penetration, shape of the body part, and tissue homogeneity. It is therefore important to define the mass of tissue taken to evaluate average local body SARS. The limit values of local SARs have not been unified between various standards or guidelines. However, a local SAR limit of 8 W kg^{-1} averaged over a mass of 1g has also been adopted (IEEE, 1991).

Currently cellular phones and other wireless communication devices are required to meet the RFR exposure guidelines of the Federal Communications Commission (FCC), which were most recently revised in August 1996. Since the FCC is not a health agency, it sought and received guidance from the federal health agencies including the Environmental Protection Agency, the National Institute of Occupational Health and Safety, the Occupational Safety and Health Administration, and the FDA. These exposure guidelines incorporated the most recent exposure standards of the National Commission for Radiation Protection and the American National Standards Institute, and are subject to continuing review and revision as new scientific information which could define a better basis for such exposure guidelines becomes available. As noted above, the existing exposure guidelines are based entirely on protection from acute injury from thermal effects of RF exposure, and may not be protective against any non-thermal effects of chronic exposures.

E. Toxicological Data

The evidence for a clastogenic (chromosome breaking) or genetic effect of microwave radiation exposure is contradictory and, overall, it may be concluded that RF/microwave radiation is not genotoxic. Therefore, it may also be concluded that RF/microwave radiation is not a tumor initiator and that, if it is somehow related to carcinogenicity, this has to be by some other mechanism (e.g., by influencing tumor promotion). Tumor

promotion may be influenced by increases in cell proliferation rate via effects mediated through changes in proliferative signaling pathways, leading to enhanced transcription and DNA synthesis.

According to a series of papers, low level, low frequency, amplitude-modulated microwave radiation may affect intracellular activities of enzymes involved in neoplastic promotion without measurable influence on overall DNA synthesis. For example, a number of investigations showed some evidence of an effect on intracellular levels of ornithine decarboxylase (ODC) an enzyme implicated in tumor promotion. Tumor promoters increase ODC synthesis. Where such effects have been observed with microwave exposure, they have been much weaker and have occurred only for certain modulations of the carrier wave.

Assays of cell transformation were performed in order to detect changes consistent with carcinogenesis. For example, Balcer-Kubiczek and Harrison (1991) exposed cells to 120 Hz modulated microwave radiation followed by treatment with a phorbol ester tumor promoter. Cell transformation was induced in a dose-dependent way (increase with increasing SAR value). Overall, these results are in agreement with those from earlier studies, although there are also some inconsistencies. To date, the significance of these results is not clear in terms of *in vivo* carcinogenesis.

Along with investigations carried out *in vitro,* a number of *in vivo* investigations have also been performed. Of particular interest is, for example, the study conducted by Szmigielski et al (1983), who observed faster development of benzo(a)pyrene-induced skin tumors in mice that were exposed for some months to sub-thermal 2450 MHz microwave radiation.

Also of interest is a study where 100 rats were exposed from 2 to 27 months of age to pulsed microwave radiation (0.4 W kg^{-1}) (Guy et al, 1985). The exposed group had a significant increase in primary malignant lesions compared with the control group when lesions were pooled regardless of their location in the body, but no single type of malignant tumor was enhanced. Overall the incidence of primary malignancies was similar to that reported elsewhere in rats of this type. If the incidence of primary malignant lesions was pooled without regard to site or cause of death, however, the exposed group had a significantly higher incidence compared with the control group. Also, primary malignancies occurred early in the exposed group compared with the sham exposed group. While interesting, these data do not provide clear evidence of an increase in tumor incidence as result of microwave exposure. The incidence of benign tumors did not appear enhanced in the exposed group compared with the controls, nor was any particular type of neoplasm in the exposed group significantly elevated compared with the values reported in stock rats of this strain. Yet, overall, there was no clear evidence of an increase in tumor incidence as a result of exposure to microwave radiation.

In another study, the effects of exposure to electromagnetic fields were investigated in a rat brain glioma model. The exposure consisted of 915 MHz microwave radiation, both as continuous wave and ELF-modulated radiation (Salford, *et al*, 1993). The extensive

daily exposure did not cause tumor promotion. However, the experimental model has sometimes been questioned as the experimental animals had a high rate of spontaneous tumors. In another investigation in which cancer cells (B 16 melanoma) were injected into animals, a lack of effect of exposure to continuous wave and pulsed RFR on tumor progression was observed (Santini et al, 1988). Overall, evidence for a co-carcinogenic effect of microwave radiation on tumor progression is not substantiated. The few positive results which do exist are, however, sufficiently indicative to merit further investigation.

Repacholi et al (Repacholi, et al 1997) using Pim-l transgenic mice that are moderately predisposed to develop lymphoma spontaneously, conducted a more recent study of the co-carcinogenic potential of RFR. One hundred mice were exposed for two thirty-minute periods per day for up to 18 months to 900 MHz RFR with modulation characteristics and SAR similar to those of some wireless telephones. The mice exposed to RFR developed over twice as many lymphomas as the sham-exposed group of mice. A study of 50 Hz magnetic fields in these same transgenic mice conducted by the same investigators (Repacholi et al, 1998) did not result in greater numbers of lymphomas in the exposed mice, suggesting that the earlier positive result in RFR exposed mice is unlikely to be artifactual.

There is wide agreement within the international scientific community regarding the types of research needed to assess whether RFR from wireless communications poses a health risk to users. Research needs have been articulated by a number of groups, including the European Commission and the World Health Organization International EMF Project. Animal experiments are crucial because meaningful data will not be available from epidemiological studies for many years due to the long latency period between exposure to a carcinogen and the diagnosis of a tumor. Studies must also be performed in animals that are genetically predisposed to cancer and endpoints other than cancer, such as ocular damage and neurological effects, must also be examined. High priority must be given to replication of prior studies that indicate adverse effects, such as the transgenic mice model mentioned above. These research needs are similar to those identified by the *VVEO* EMF Project.

There is currently insufficient scientific basis for concluding either that wireless communication technologies are safe or that they pose a risk to millions of users. A significant research effort, including well-planned animal experiments, is needed to provide the basis to assess the risk to human health of wireless communications devices.

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NATIONAL TOXICOLOGY PROGRAM

FACT SHEET

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STUDIES ON RADIOFREQUENCY RADIATION EMITTED BY CELLULAR PHONES

Year 2005

Personal (cellular) telecommunications is a rapidly evolving technology that uses microwave radiation to communicate between a fixed base station and a mobile user. Until recently, most systems employed analog technology where low frequency speech signals are directly modulated onto a high frequency carrier in a manner similar to a frequency-modulated (FM) radio. These second-generation systems, widely used in Europe, USA and Japan, employ digital technology where the low frequency speech is digitally coded prior to modulation. Most systems employ hand-held cellular telephones where the radiating antenna is close to the head of the user.

Over 100 million Americans currently use wireless communication devices with over 50 thousand new users daily. This translates into a potentially significant public health problem should the use of these devices even slightly increase the risk of adverse health effects. Cellular phones and other wireless communication devices are required to meet the *radiofrequency radiation* (RFR) exposure guidelines of the Federal Communications Commission (FCC, August 1996)[1]. The existing exposure guidelines are based on protection from acute injury from thermal effects of RFR exposure. Current data are insufficient to draw definitive conclusions concerning the adequacy of these guidelines to be protective against any non-thermal effects of chronic exposures.

Studies in laboratory animals are considered crucial for understanding whether exposure to RFR is adverse to human health because meaningful data from epidemiological studies (human population studies) of cellular phone use will not be available for many years. This is due to the long latency period between exposure to a carcinogenic agent and the diagnosis of a tumor. Most scientific organizations that have reviewed the results from laboratory studies conducted to-date, however, have concluded that they are not sufficient to estimate potential human cancer risks from low-level RFR exposures and long-term, multi-dose, animal studies are needed.

Currently there is an international effort underway to develop and conduct long-term toxicology studies on the potential health effects associated with cellular phone RFR emissions. This effort includes studies by a consortium of European investigators and cellular phone manufacturers under the auspices of the European Union (PERFORM-A), and by investigators at the Cancer Research Center of the European Ramazzini Foundation of Oncology and Environmental Sciences Commission in Bologna, Italy.

What is the NTP Doing?

The Food and Drug Administration (FDA) nominated RFR emissions of wireless communication devices to the National Toxicology Program (NTP) for toxicology and carcinogenicity testing. The NTP has carefully evaluated the efforts already underway and concluded that while they have an excellent probability of producing high quality research results, additional studies may be warranted to more clearly define any potential health hazard to the U.S. population.

EXHIBIT E

[1] FCC, Guidelines for Evaluating the Environmental Effects of Radiofrequency Radiation, 61FR41006 available at http://www.fcc.gov/oet/dockets/et93-62/

ADDRESS P.O. Box 12233, Maildrop A3-01, Research Triangle Park, NC 27709-2233 *WEB SITE* http://ntp-server.niehs.nih.gov/
NTP LIAISON & SCIENTIFIC REVIEW OFFICE 919-541-0530 *E-MAIL* liaison@starbase.niehs.nih.gov

Because of the technical complexity of such studies, NTP staff is working with RFR experts from the National Institute of Standards and Technology (NIST). With support from the National Institute of Environmental Health Sciences of the National Institutes of Health, scientists at NIST have been testing the suitability of various RFR exposure systems for use in these studies. The studies at NIST have demonstrated the feasibility of using specially designed reverberation chambers as the exposure system to evaluate potential long-term health effects, including carcinogenicity, of cellular phone RFR in unrestrained laboratory animals. Based on the findings from NIST, the NTP designed studies to evaluate the potential toxicity and carcinogenicity of cell phone RFR in rats and mice exposed in reverberation chambers at the two frequencies (~900 and 1900 MHz) that are at the centers of the primary cellular bands used in the United States. In addition, these exposures will include the most common coding strategies for carrying information by cellular telephone communication technology in the United States: the Global System for Mobile Communications (GSM) and Code Division Multiple Access (CDMA) signal modulations. These studies will be conducted at multiple power levels and will include special emphasis on potential adverse effects in the brain. In addition to histopathological evaluations for toxic or neoplastic lesions, special studies will examine effects on the blood brain barrier, neonatal cell migration patterns in the brain, and DNA strand breaks in brain cells.

For further information, contact:
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BioInitiative Report:

A Rationale for a Biologically-based Public Exposure Standard for Electromagnetic Fields (ELF and RF)

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EXHIBIT F

Setting Prudent Public Health Policy for Electromagnetic Field Exposures

David O. Carpenter[1] and Cindy Sage[2]

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Abstract: Electromagnetic fields (EMF) permeate our environment, coming both from such natural sources as the sun and from manmade sources like electricity, communication technologies and medical devices. Although life on earth would not be possible without sunlight, increasing evidence indicates that exposures to the magnetic fields associated with electricity and to communication frequencies associated with radio, television, WiFi technology, and mobile cellular phones pose significant hazards to human health. The evidence is strongest for leukemia from electricity-frequency fields and for brain tumors from communication-frequency fields, yet evidence is emerging for an association with other diseases as well, including neurodegenerative diseases. Some uncertainty remains as to the mechanism(s) responsible for these biological effects, and as to which components of the fields are of greatest importance. Nevertheless, regardless of whether the associations are causal, the strengths of the associations are sufficiently strong that in the opinion of the authors, taking action to reduce exposures is imperative, especially for the fetus and children. Inaction is not compatible with the Precautionary Principle, as enunciated by the Rio Declaration. Because of ubiquitous exposure, the rapidly expanding development of new EMF technologies and the long latency for the development of such serious diseases as brain cancers, the failure to take immediate action risks epidemics of potentially fatal diseases in the future.

Keywords: leukemia, brain cancer, electricity, radiofrequency, cell phones, neurodegenerative diseases

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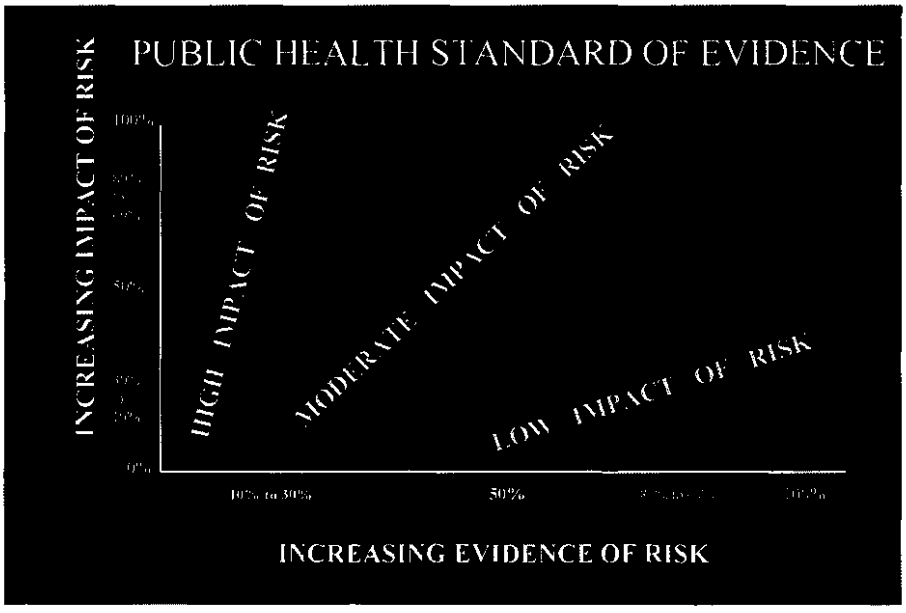

Fig. 4: A public health-based response must be relative to the magnitude of the potential impact of inaction. When the potential impact is high, action should be taken even when the evidence of risk is low.

DEFINING NEW EXPOSURE STANDARDS FOR ELF AND RF ELECTROMAGNETIIC FIELDS BASED ON THE PRECAUTIONARY PRINCIPLE

The most contentious issue regarding public and occupational exposures to ELF involves the resolute adherence by many countries to the existing International Commission on Non-Ionizing Radiation Protection (ICNIRP) standards /119/ of 1,000 mG (100 μT), in face of the growing scientific evidence of health risks at far lower levels. The basis on which most standard setting agencies justify their failure to set new safety limits for ELF and RF is nearly always that no certain proof of harm from exposure and no known mechanism of action have been presented. A demand for a causal level of evidence and scientific certainty is implicit in nearly all discussion on what are the appropriate safely standards for ELF and RF. This demand, however, runs counter to both the existing scientific evidence and good public health practice.

Two obvious factors work against governments taking action to set exposure guidelines based on current scientific evidence of risk:

- Contemporary societies are very dependent upon electricity usage and RF communications, and anything that restricts current and future usage potentially has serious economic consequences.
- Power and communications industries have enormous political clout, and even provide support for a significant fraction of the research done on EMF.

This state of affairs results in legislation that protects the status quo and scientific publications whose conclusions are not always based only on the observations of the research. This situation also hinders wise public health policy actions and the implementation of prevention strategies because of the huge financial investments already made in these technologies. Huss et al. /120/ analyzed 59 studies of the health effects of cell phone use and found that studies funded exclusively by industry

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were least likely to report a statistically significant result.

Substantial evidence indicates that ELF is carcinogenic at levels of exposure in the 2 mG to 5 mG (0.2-0.5 μT) range and above. ICNIRP and other standards that place public exposure limits as high as 1,000 mG (100 μT) are outdated and should be replaced, based on the evidence presented above. New standards are warranted now, based on the totality of scientific evidence, the risks of taking no-action, the large population at risk, the costs associated with ignoring the problem in new and upgraded site selection and construction, and the loss of public trust by ignoring the problem. New exposure limits must be developed for ELF-EMF based on the clear sufficiency of evidence for carcinogenicity to humans at levels that are routinely approved today for occupancy by children, pregnant women, and others. To wait any longer to adopt new public safety limits for ELF is not prudent public health policy. Such limits should reflect the exposures that are commonly associated with increased risk of childhood leukemia (in the 2 to 5 mG (0.2-0.5 μT) range for all children, and over 1.4 mG (0.14 μT) for children age 6 and younger.

Defining a new exposure standard for RF is complex, if we are to address properly new scientific results for chronic exposure to pulsed radiofrequency (for example from cell towers, cell phones, and other wireless technologies). Whereas the evidence of serious harm is strong, knowledge regarding the relation between cumulative exposure and risk of disease is inadequate. Uncertainty about how low such standards might have to go to be prudent from a public health standpoint should not prevent reasonable efforts to respond to the information at hand. No lower limit for bio-effects and adverse health effects from RF have been established, and no assertion of safety at any level of wireless exposure (chronic exposure) can be made at this time. A major concern is the exposure of children. We strongly recommend that wired alternatives to WI-FI be implemented particularly in schools and libraries so that children will not be subjected to elevated RF levels until more is understood about possible health impacts.

The Bioinitiative Report /121/ presents a much more extensive and exhaustive discussion of the literature on health effects of both ELF and RF EMF than can be presented here. The Report contains a recommendation of an RF standard of 0.1 $\mu W/cm^2$, but with the full knowledge that hazards may be associated with even lower exposures.

This review has focused on those diseases for which the evidence of increased risk with EMF exposure is the strongest. Other biological effects and potential health outcomes are presented in detail in the Bioinitiative Report /121/. The effects that drive the need for immediate action in lowering exposure are cancer and neurodegenerative diseases. Leukemia appears the cancer of greatest concern when the exposure to either ELF or RF is over the whole body, as is the case with most ELF exposures and exposure from RF towers. When exposure is focused on a part of the human body, such as is the case of the head in cell phone use, one sees cancers of the brain, acoustic nerve, or parotid gland. For these diseases, the evidence is clearly sufficient to warrant regulatory changes in public safety limits now, at levels that are widely reported to be associated with increased risk of childhood leukemia and brain tumors. Exposure limits against these diseases will also likely be protective for other less-well-defined health impacts. The BioInitiative Report /121/ provides additional justification for the adoption of these levels to prevent the health hazards resulting from exposure to ELF and RF.

CONCLUSIONS

The evidence for hazards to human health from both ELF and RF EMF is sufficiently strong as to merit immediate steps to reduce exposure. Such a reduction can best be achieved by setting exposure goals that are lower than levels known to be

associated with disease, even while understanding that these exposure goals are significantly lower than many current exposures. A reasonable approach would be a 1 mG (0.1 μT) planning limit for structures adjacent to all new or upgraded power lines, and for occupied space that affects sensitive receptors (homes, schools, day-care, pre-school, etc), and targets not to exceed 2 mG (0.2 μT) for all other occupied new construction. Although reconstructing all existing electrical distributions systems is not realistic, steps to reduce exposure from these existing systems should be encouraged. For RF EMF, setting a level with certainty is difficult. A precautionary action level would reasonably be 0.1 μW/cm2.

The proposals presented here reflect the evidence that a positive assertion of safety cannot be made with respect to chronic exposure to low-intensity levels of ELF and RF radiation.

As with many other standards for environmental exposures, even these proposed limits may not be completely protective, but more-stringent standards are not realistic at the present time.

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The Influence of Being Physically Near to a Cell Phone Transmission Mast on the Incidence of Cancer

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'Einfluss der räumlichen Nähe von Mobilfunksendeanlagen auf die Krebsinzidenz'

Summary

Following the call by Wolfram König, President of the Bundesamt für Strahlenschutz (Federal Agency for radiation protection), to all doctors of medicine to collaborate actively in the assessment of the risk posed by cellular radiation, the aim of our study was to examine whether people living close to cellular transmitter antennas were exposed to a heightened risk of taking ill with malignant tumors.

The basis of the data used for the survey were PC files of the case histories of patients between the years 1994 and 2004. While adhering to data protection, the personal data of almost 1,000 patients were evaluated for this study, which was completed without any external financial support. It is intended to continue the project in the form of a register.

The result of the study shows that the proportion of newly developing cancer cases was significantly higher among those patients who had lived during the past ten years at a distance of up to 400 metres from the cellular transmitter site, which has been in operation since 1993, compared to those patients living further away, and that the patients fell ill on average 8 years earlier.

In the years 1999-2004, *ie* after five years' operation of the transmitting installation, the relative risk of getting cancer had trebled for the residents of the area in the proximity of the installation compared to the inhabitants of Naila outside the area.

Key words: cellular radiation, cellular transmitter antennas, malignant tumours

The rapid increase in the use of mobile telephony in the last few years has led to an increasing number of cell phone transmission masts being positioned in or near to residential areas. With this in mind, the president of the German governmental department for protection against electromagnetic radiation (Bundesamtes für Strahlenschutz) Wolfram König, has challenged all doctors to actively help in the work to estimate the risks from such cell phone masts. The goal of this investigation was therefore to prove whether on not people living near to cell phone masts have a higher risk of developing cancerous tumours.

The basic data was taken from the medical records held by the local medical authority (Krankenkasse) for the years 1994 to 2004. This material is stored on computer. In this voluntary study the records of roughly 1,000 patients from Naila (Oberfranken) were used, respecting the associated data protection laws. The results from this study show a significantly increased likelihood of developing cancer for the patients that have lived within 400 metres of the cell phone transmission mast (active since 1993) over the last ten years, in comparison to those patients that live further away. In addition, the patients that live within 400 metres tend to develop the cancers at a younger age. For the years 1999 to 2004 (*ie* after five or more years of living with the cell phone transmission mast), the risk of developing cancer for those living within 400 metres of the mast in comparison to those living outside this area, was three times as high.

Introduction

A series of studies available before this investigation provided strong evidence of health risks and increased cancer risk associated with physical proximity to radio transmission masts. Haider *et al.* reported in 1993 in the Moosbrunn study frequent psychovegetive symptoms below the current safety limit for electromagnetic waves (1). In 1995, Abelin *et al.* in the Swiss- Schwarzenburg study found dose dependent sleep problems (5:1) and depression (4:1) at a shortwave transmitter station that has been in operation since 1939 (2).

In many studies an increased risk of developing leukaemia has been found; in children near transmitter antennas for Radio and Television in Hawaii (3); increased cancer cases and general mortality in the area of Radio and Television transmitter antennas in Australia (4); and in England, 9 times more leukaemia cases were diagnosed in people who live in a nearby

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area to the Sutton Coldfield transmitter antennas (5). In a second study, concentrating on 20 transmitter antennas in England, a significant increased leukaemia risk was found (6). The Cherry study (7) indicates an association between an increase in cancer and living in proximity to a transmitter station. According to a study of the transmitter station of Radio Vatican, there were 2.2 times more leukaemia cases in children within a radius of 6 km, and adult mortality from leukaemia also increased (8).

In 1997 Goldsmith published the Lilienfeld-study that indicated 4 times more cancer cases in the staff of the American Embassy in Moscow following microwave radiation during the cold war. The dose was low and below the German limit (9).

The three studies of symptoms indicated a significant correlation between illness and physical proximity to radio transmission masts. A study by Santini *et al.* in France resulted in an association between irritability, depression, dizziness (within 100m) and tiredness within 300m of a cell phone transmitter station (10).

In Austria there was an association between field strength and cardiovascular symptoms (11) and in Spain a study indicates an association between radiation, headache, nausea, loss of appetite, unwellness, sleep disturbance, depression, lack of concentration and dizziness (12).

The human body physically absorbs microwaves. This leads to rotation of dipole molecules and to inversion transitions (13), causing a warming effect. The fact that the human body transmits microwave radiation at a very low intensity means that since every transmitter represents a receiver and transmitter at the same time, we know the human body also acts as a receiver.

In Germany, the maximum safe limit for high frequency microwave radiation is based on purely thermal effects. These limits are one thousand billion times higher than the natural radiation in these frequencies that reaches us from the sun.

The following study examines whether there is also an increased cancer risk close to cellular transmitter antennas in the frequency range 900 to 1800 MHz. Prior to this study there were no published results for long-term exposure (10 years) for this frequency range and its associated effects to be revealed. So far, no follow-up monitoring of the state of health of such a residential population has been systematically undertaken.

Materials and Methods

Study area

In June 1993, cellular transmitter antennas were permitted by the Federal Postal Administration in the Southern German city of Naila and became operational in September 1993.

The GSM transmitter antenna has a power of 15 dbW per channel in the 935MHz frequency range. The total transmission time for the study period is ca. 90,000 hours. In December 1997 there followed an additional installation from another company. The details are found in an unpublished report, appendix page 1-3 (14).

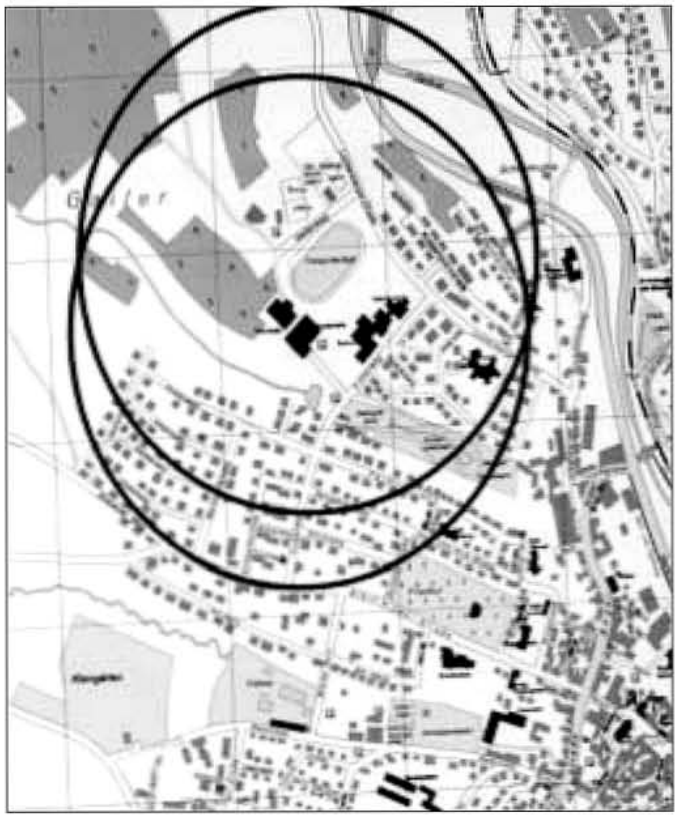

Fig. 1: Schematic plan of the antenna sites

To compare results an 'inner' and 'outer' area were defined. The inner area covered the land that was within a distance of 400 metres from the cellular transmitter site. The outer area covered the land beyond 400 metres. The average distance of roads surveyed in the inner area (nearer than 400m) was 266m and in the outer area (further than 400m) 1,026m. Fig. 1 shows the position of the cellular transmitter sites I and 2, surrounded by circle of radius 400 metres. The geographical situation shows the transmitter sites (560m) are the highest point of the landscape, which falls away to 525m at a distance of 450m. From the height and tilt angle of the transmitter it is possible to calculate the distance where the transmitter's beam of greatest intensity strikes the ground (see Fig. 2).

The highest radiation values are in areas of the main

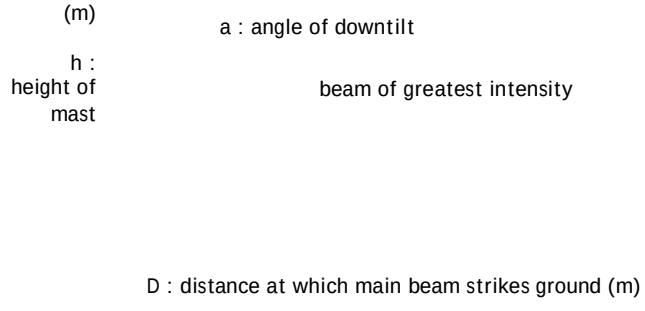

Fig. 2: From the mast height h and the downtilt angle a, the distance D at which the main beam reaches ground is given by D = tan(90-a) × h

beam where it hits the ground and from the expected associated local reflection; from this point the intensity of radiation falls off with the square of the distance from the transmitter.

In Naila the main beam hits the ground at 350m with a beam angle of 6 degrees (15). In the inner area, additional emissions are caused by the secondary lobes of the transmitter; this means in comparison that from purely mathematical calculations the outer area has significantly reduced radiation intensity.

The calculations from computer simulations and the measurements from the Bavaria agency for the environmental protection, both found that the intensity of radiation was a factor of 100 higher in the inner area as compared to the outer area. The measurements of all transmitter stations show that the intensity of radiation from the cell phone transmitter station in Naila in the inner area was higher than the other measurement shown in the previous studies of electromagnetic fields from radio, television or radar (14).

The study StSch 4314 from the ECOLOG Institute indicates an association between a vertical and horizontal distance from the transmitter station and expected radiation intensity on the local people (16). The reason for setting a distance of 400m for the differentiation point is partly due to physical considerations, and partly due to the study of Santini *et al.* who chose 300m (10).

Data Gathering

Similar residential streets in the inner area and outer areas were selected at random. The large old people's home in the inner area was excluded from the study because of the age of the inhabitants. Data gathering covered nearly 90% of the local residents, because all four GPs in Naila took part in this study over 10 years. Every team researched the names of the patients from the selected streets that had been ill with tumours since 1994. The condition was that all patients had been living during the entire observation time of 10 years at the same address.

The data from patients was handled according to data protection in an anonymous way. The data was evaluated for gender, age, tumour type and start of illness. All cases in the study were based on concrete results from tissue analysis. The selection of patents for the study was always done in exactly the same way. Self-selection was not allowed. Also the subjective opinion of patients that the radio mast detrimentally affected their health has not affected this study. Since patients with cancer do not keep this secret from GPs, it was possible to gain a complete data set.

Population study

In the areas where data was collected 1,045 residents were registered in 31.12.2003. The registration statistics for Naila at the beginning of the study (1.1.1994) show the number of old people in the inner and outer areas, as shown in Table 1. The average age at the beginning of the study (1.1.1994) in both the inner and outer areas was 40.2 years. In the study period between 1994-2004, 34 new cases of cancer where documented out of 967 patients (Table 3). The study covered nearly 90% of local residents.

	female	male	total
Inner area	41.48	38.70	40.21
Outer area	41.93	38.12	40.20
Naila total	43.55	39.13	41.45

Table 1 : Overview of average ages at the beginning of the study in 1994

1994	inner 22.4%	outer 2.8%	Naila total 24.8%
2004	inner 26.3%	outer 26.7%	

Table 2 : Proportion of patients aged over 60

The average age of the residents in Naila is one year more than that of the study due to the effects of the old people's home. From the 9,472 residents who are registered in Naila, 4,979 (52.6%) are women and 4,493 (47.4%) are men. According to the register office, in 1.1.1994 in the outer area, the percentage was 45.4% male and 54.5% female, and in the inner area 45.3% male and 54.6% female. The number of people who are over 60 years old is shown in Table 2.

The social differences in Naila are small. Big social differences like in the USA do not exist here. There is also no ethnic diversity. In 1994 in Naila the percentage of foreigners was 4%. Naila has no heavy industry, and in the inner area there are neither high voltage cable nor electric trains.

Results

Results are first shown for the entire 10 year period from 1994 until 2004. Secondly, the last five-year period 1999 to 2004 is considered separately.

Period 1994 to 2004

As a null hypothesis it was checked to see if the physical distance from the mobile transmission mast had no effect on the number cancer cases in the selected population, *ie* that for both the group nearer than 400 metres and the group further than 400 metres the chance of developing cancer was the same. The relative frequencies of cancer in the form of a matrix are shown in Table 3. The statistical test method used on this data was the chi-squared test with Yates's correction. Using this method we obtained the value of 6.27, which is over the critical value of 3.84 for a

Period 1994-2004	**Inner area**	**Outer area**	**total**
new cases of cancers	18	16	34
with no new cancer	302	631	933
total	320	647	967

Table 3 : numbers of patients with and without cancers, 1994-2004

statistical significance of 0.05).

This means the null hypothesis that both groups within the 400-metre radius of the mast and beyond the 400 metre radius, have the same chance of developing cancer, can be rejected with a 95% level of confidence. With a statistical significance of 0.05, an even more significant difference was observed in the rate of new cancer cases between the two groups.

Calculating over the entire study period of 1994 until 2004, based on the incidence matrix (Table 3) we arrive at a relative risk factor of 2.27 (quotient of proportion for each group, *eg* 18/320 in the strongly exposed inner area, against 16/647 in the lower exposed comparison group). If expressed as an odds ratio, the relationship of the chance of getting cancer between strongly exposed and the less exposed is 2.35.

The following results show clearly that inhabitants who live close to transmitter antennas compared to inhabitants who live outside the 400m zone, double their risk of developing cancer. In addition, the average age of developing cancer was 64.1 years in the inner area whereas in the outer area the average age was 72.6 years, a difference of 8.5 years. That means during the 10 year study that in the inner area (within 400 metres of the radio mast) tumours appear at a younger age.

In Germany the average age of developing cancer is approximately 66.5 years, among men it is approximately 66 and among women, 67 (18).

Over the years of the study the time trend for new cancer cases shows a high annual constant value (Table 4). It should be noted that the number of people in the inner area is only half that of the outer area, and therefore the absolute numbers of cases is smaller.

Table 7 shows the types of tumour that have developed in the cases of the inner area.

Period 1994 to 1999

No. of cases of tumours per year of study	inner area: of the 320 people		outer area: of the 647 people	
	total cases	per 1,000	total cases	per 1,000
1994	—	—	I	1.5
1995	—	—	—	—
1996	II	6.3	I	1.5
1997	I	3.1	III	4.6
1998	II	6.3	III	4.6
1999	II	6.3	I	1.5
2000	IIIII	15.6	I	1.5
2001	II	6.3	II	3.1
2002	II	6.3	II	3.1
2003-3/2004	II	6.3	II	3.1

Table 4 : Summary of the total tumours occurring per year (no. and per thousand)

Period 1994-1999	Inner area	Outer area	total
new cases of cancers	5	8	13
with no new cancer	315	639	954
total	320	647	967

Table 5 : numbers of patients with and without cancers, 1994-1999

For the first five years of the radio transmission mast operation (1994-1998) there was no significant increased risk of getting cancer within the inner area as compared to the outer area (Table 5).

Period 1999 to 2004

Under the biologically plausible assumption that cancer caused by detrimental external factors will require a time of several years before it will be diagnosed, we now concentrate on the last five years of the study between 1999 and 2004. At the start of this period the transmitter had been in operation for 5 years. The results for this period are shown in Table 6. The chi-squared test result for this data (with Yates's correction) is 6.77 and is over the critical value of 6.67 (statistical significance 0.01). This means, with 99% level of confidence, that there is a statistically proven difference between development of cancer between the inner group and outer group. The relative risk of 3.29 revealed that there was 3 times more risk of developing cancer in the inner area than the outer area during this time period.

Period 1999-2004	Inner area	Outer area	total
new cases of cancers	13	8	31
with no new cancer	307	639	946
total	320	647	967

Table 6 : numbers of patients with and without cancers, 1999-2004

The odds-ratio 3.38 (VI 95% 1.39-8.25, 99% 1.05-10.91) allows us with 99% confidence to say that the difference observed here is not due to some random statistical effect.

Discussion

Exactly the same system was used to gather data in the inner area and outer areas. The medical chip card, which has been in use for 10 years, enables the data to be processed easily. The four participating GPs examined the illness of 90% of Naila's inhabitants over the last 10 years. The basic data for this study were based on direct examination results of patients extracted from the medical chip cards, which record also the diagnosis and treatment. The study population is (in regards to age, sex and cancer risk) comparable, and therefore statistically neutral. The study deals only with people who have been living permanently at the same address for the entire study period and therefore

Type of tumour (organ)	no. of tumours found	total expected	incidence per 100,000	ratio inner: outer
breast	8	5.6	112	5:3
ovary	1	1.1	23	0:1
prostate	5	4.6	101	2:3
pancreas	m 3 f 2	0.6 0.9	14 18	2:1 1:1
bowel	m 4 f 0	3.7 4.0	81 81	2:2 0:0
skin melanoma	m 1 f 0	0.6 0.7	13 14	1:0 0:0
lung	m 3 f 0	3.6 1.2	79 24	2:1 0:0
kidney	m 2 f 1	1.0 0.7	22 15	1:1 1:0
stomach	m 1 f 1	1.2 1.1	27 23	0:1 0:1
bladder	m 1 f 0	2.0 0.8	44 16	0:1 0:0
blood	m 0 f 1	0.6 0.7	14 15	0:0 1:0

Table 7 : Summary of tumours occurring in Naila, compared with incidence expected from the Saarland cancer register

have the same duration of exposure regardless of whether they are in the inner area or outer area.

The result of the study shows that the proportion of newly developing cancer cases was significantly higher ($p<0.05$) among those patients who had lived during the past ten years within a distance of 400 metres from the cellular transmitter site, which has been in operation since 1993, in comparison to people who live further away. Compared to those patients living further away, the patients developed cancer on average 8.5 years earlier. This means the doubled risk of cancer in the inner area cannot be explained by an average age difference between the two groups. That the transmitter has the effect that speeds up the clinical manifestations of the illness and general development of the cancer cannot be ruled out.

In the years 1999-2004, *ie* after five years and more of transmitter operation, the relative risk of getting cancer had trebled for the residents of the area in the proximity of the mast compared to the inhabitants of Naila in the outer area ($p>0.01$). The division into inner area and outer area groups was clearly defined at the beginning of the study by the distance to the cell phone transmission mast. According to physical considerations people living close to cellular transmitter antennas were exposed to heightened transmitted radiation intensity.

Both calculated and empirical measurements revealed that the intensity of radiation is 100 times higher in the inner area compared to the outer area. According to the research StSch 4314 the horizontal and vertical position in regards to the transmitter antenna is the most important criterion in defining the radiation intensity area on inhabitants (16).

The layered epidemiological assessment method used in this study is also used in assessment of possible chemical environmental effects. In this case the layering is performed in regards to the distance from the cell phone transmitter station. Using this method it has been shown that there is a significant difference in probability of developing new cancers depending on the exposure intensity.

The number of patients examined was high enough according to statistical rules that the effects of other factors (such as use of DECT phones) should be normalised across the inner area and outer area groups. From experience the disruption caused by a statistical confounding factor is in the range between 20% and 30%. Such a factor could therefore in no way explain the 300% increase in new cancer cases. If structural factors such as smoking or excessive alcohol consumption are unevenly distributed between the different groups this should be visible from the specific type of cancers to have developed (*ie* lung, pharyngeal or oesophageal). In the study inner area there were two lung cancers (one smoker, one non-smoker), and one in the outer area (a smoker), but no oesophageal cancers. This rate of lung cancer is twice what is statistically to be expected and cannot be explained by a confounding factor alone. None of the patients who developed cancer was from a family with such a genetic propensity.

Through the many years experience of the GPs involved in this study, the social structures in Naila are well known. Through this experience we can say there was no significant social difference in the examined groups that might explain the increased risk of cancer.

The type and number of the diagnosed cancers are shown in Table 7. In the inner area the number of cancers associated with blood formation and tumour-controlling endocrine systems (pancreas), were more frequent than in the outer area (77% inner area and 69% outer area).

From Table 7, the relative risk of getting breast cancer is significantly increased to 3.4. The average age of patients that developed breast cancer in the inner area was 50.8 years. In comparison, in the outer area the average age was 69.9 years, approximately 20 years less. In Germany the average age for developing breast cancer is about 63 years. The incidence of breast cancer has increased from 80 per 100,000 in the year 1970 to 112 per 100,000 in the year 2000. A possible question for future research is whether breast cancer can be used as a 'marker cancer' for areas where there is high contamination from electromagnetic radiation. The report of Tynes *et al.* described an increased risk of breast cancer in Norwegian female radio and telegraph operators (20).

To further validate the results the data gathered were compared with the Saarland cancer register (21). In this register all newly developed cancers cases since 1970 are recorded for each Bundesland. These data are accessible via the Internet. Patents that suffer two separate tumours were registered twice, which increases the overall incidence up to 10%. In this

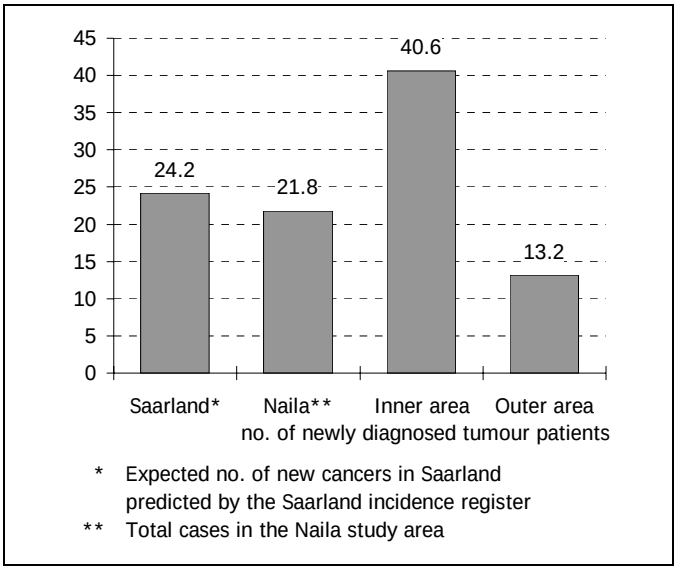

Fig. 3 : Number of new cancer cases 1999 to 2004, adjusted for age and gender, calculated for the 5,000 patient years

register there is no location-specific information, for instance proximity to cell phone transmission masts. The data in the cancer register therefore reflect no real control group but rather the effect of the average radiation on the total population.

From the Saarland cancer register for the year 2000 the incidence of new cancer cases was 498 per 100,000 for men and 462 per 100,000 for women. When adjusted for age and sex one would expect a rate of between 480 and 500 per 100,000 in Naila. For the years 1999 to 2004 there were 21 new cases of cancer among 967 patients. The expected number was 24 cases per 1,000 patients.

The results of the study are shown graphically in Fig. 3. The bars of the chart represent the number of new cancer cases per 1,000 patients in the separate areas, over the five years (bars 2 to 4). The first bar represents the expected number from the Saarland cancer register.

In spite of a possible underestimation, the number of newly developed cancer cases in the inner area is more than the expected number taken from the cancer register, which represents the total population being irradiated. The group who had lived during the past five years within a distance of 400 m from the cellular transmitter have a two times higher risk of developing cancer than that of the average population. The relative risk of getting cancer in the inner area compared with the Saarland cancer register is 1.7 (see to Table 7).

Conclusion

The result of this retrospective study in Naila shows that the risk of newly developing cancer was three times higher among those patients who had lived during past ten years (1994-2004), within a distance of 400m from the cellular transmitter, in comparison to those who had lived further away.

Cross-sectional studies can be used to provide the decisive empirical information to identify real problems. In the 1960s just three observations of birth deformities were enough to uncover what is today an academically indisputable Thalidomide problem.

This study, which was completed without any external financial support is a pilot project. Measurements of individual exposure as well as the focused search for further side effects would provide a useful extension to this work, however such research would need the appropriate financial support.

The concept of this study is simple and can be used everywhere, where there it a long-term electromagnetic radiation from a transmitting station.

The results presented are a first concrete epidemiological sign of a temporal and spatial connection between exposure to GSM base station radiation and cancer disease.

These results are, according to the literature relating to high frequency electromagnetic fields, not only plausible and possible, but also likely.

From both an ethical and legal standpoint it is necessary to immediately start to monitor the health of the residents living in areas of high radio frequency emissions from mobile telephone base stations with epidemiological studies. This is necessary because this study has shown that it is no longer safely possible to assume that there is no causal link between radio frequency transmissions and increased cancer rates.

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Footnotes

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Bioelectromagnetics 25:642–646 (2004)

Editor's Note

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This Comment-Reply pair departs from our published Instructions for Authors in that the comment is longer and introduces more ideas than usual. It has been published as a rare exception to the Instructions because it raises a broad viewpoint concerning the totality of the Journal's recent Supplement, as well as the authors' specific suggested mechanism. This viewpoint is held by a number of readers, while the Reply presents the contrasting viewpoint of the committee members, as well as other readers. As usual, the thoughts of the customary peer reviewers were shared with authors and considered by the Editor before acceptance.

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Comment: A Biological Guide for Electromagnetic Safety: The Stress Response

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Questions of safety of electromagnetic (EM) fields should be based on relevant biological properties, i.e., specific cellular reactions to potentially harmful stimuli. The stress response is a well documented protective reaction of plant and animal cells to a variety of environmental threats, and it is stimulated by both extremely low frequency (ELF) and radio frequency (RF) EM fields. It involves activation of DNA to initiate synthesis of stress proteins. Thermal and non-thermal stimuli affect different segments of DNA and utilize different biochemical pathways. However, both ELF and RF stimulate the same non-thermal pathway. Since the same biochemical reactions are stimulated in different frequency ranges with very different specific absorption rates (SARs), SAR level is not a valid basis for safety standards. Studies of EM field interactions with DNA and with model systems provide insight into a plausible mechanism that can be effective in ELF and RF ranges. Bioelectromagnetics 25:642–646, 2004.

Key words: electromagnetic fields; DNA; frequency; electrons; H-bonds; EMRE (electromagnetic response element)

INTRODUCTION

Supplement #6 of the Bioelectromagnetics Journal [2003], entitled "Reviews of Effects of RF Energy on Human Health," has stimulated much discussion about differences between thermal and non-thermal processes and the biological mechanisms that could provide a rational basis for electromagnetic (EM) field safety standards. We feel that recent advances in biology have not been adequately considered in the

Abbreviations: EM, electromagnetic; ELF, extremely low frequency; RF, radio frequency; SAR, specific absorption rate; EMRE, electromagnetic response element.

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EXHIBIT J

search for EM safety standards, and that a biological perspective is essential if the process is to be realistic. This article is a more detailed discussion of the ideas in letters published in the January/February BEMS Newsletter [2004] (Number 176).

Safety Problem in a Biology Context

The EM spectrum is continuous, and its division into frequency ranges, like extremely low frequency (ELF) and radio frequency (RF), is based on physics and engineering criteria related to instrumentation and physical descriptors of the energy, rather than biology. The divisions reflect differences in absorption depth and fractional absorption/reflection of all materials, due to changes in dielectric constant, and are not specifically related to living tissues. The distinction between ionizing and non-ionizing ranges based on chemical reactivity also has limited utility, since the dividing line is within the UV range and chemical reactions are stimulated in ELF and RF ranges. Except for the visible range with its connection to vision, there is no relation between divisions in the EM spectrum and biological properties, and there is no reason to expect responses of living systems to follow the arbitrary classification based on frequency. Despite attempts to alert engineers to developments in biology [e.g., Kasevich, 2002], there is little biological input in formulating the safety problem. As discussed below, new information clarifies the biology of thermal and non-thermal responses, and shows that specific absorption rates (SARs) are not a valid criterion to evaluate biological response.

Thermal and Non-Thermal Responses in Biological Cells

Living cells have mechanisms to maintain homeostasis (constancy of the internal environment in the face of external changes). The stress response mechanism is activated in reaction to many environmental stimuli, i.e., changes in temperature, pH, osmotic pressure, toxic ions, alcohol, etc. In the classic thermal stress response, originally called ''heat shock,'' stress proteins (originally ''heat shock proteins'') are synthesized via the biochemical heat shock pathway [Lindquist and Craig, 1988]. Stress protein synthesis also occurs in the non-thermal response to EM fields [Blank et al., 1994; Goodman et al., 1994; Goodman and Blank, 1998, 2002]. The same stress proteins are synthesized in both thermal and non-thermal processes, but via two different biochemical pathways that involve different segments of DNA and that have very different thresholds [Blank et al., 1994; Blank and Goodman, 2000].

An important insight into the EM induced non-thermal response comes from similarities in stress protein synthesis stimulated in ELF and RF frequency ranges [Goodman and Blank, 1998; dePomerai et al., 2000; Kwee et al., 2001; Leszczynski et al., 2002; Shallom et al., 2002; Weisbrot et al., 2003]. The biochemical mechanism activated, the MAPK signaling pathway, is the same non-thermal pathway in both ELF and RF. Several points immediately come to mind:

- Since quantum energies of EM fields in ELF and RF ranges are very different, the responses must be triggered by a mechanism that does not depend on total energy or one for which the threshold energy is independent of frequency.
- A standard based on biological response should apply in all ranges. Since SAR does not apply for both ELF and RF, it cannot and should not be a criterion for evaluating safety.
- The same biological response in ELF and RF ranges suggests that the effects of a wide range of EM field frequencies could be additive and perhaps synergistic. The cumulative effects of all frequencies in the environment and summation in long term exposures need to be considered in setting safety standards.

Approximate calculations point up the magnitude of the problem [Blank and Goodman, 2004]. In the RF range, the accepted safe occupational exposure SAR level is 0.4 W/kg and the public exposure level is 0.08 W/kg, based on a SAR of 4 W/kg as the level at which ''adverse effects'' are said to be detected. A SAR of 4 W/kg (power density/mass) can be compared to the measured threshold for stress protein synthesis in the ELF range, 2.6×10^{-7} J/m^3 (energy density/volume) by first converting to a per mass basis using an approximate tissue density of water, 10^3 kg/m^3, the major constituent of cells. In these units, the threshold for stress protein synthesis is 2.6×10^{-10} J/kg.

Since a Joule is a Watt-second, the threshold is 2.6×10^{-10} W-s/kg. Changes in protein synthesis were observed by 300 s [Lin et al., 1996], an upper limit for response time. If we assume 300 s is needed, the ELF threshold is $\sim 10^{-12}$ W/kg, and it is $\sim 10^{-10}$ W/kg if only 3 s are needed, a duration considered too short for protein synthesis. This means the accepted safe level in the RF range, $\sim 10^{-1}$ W/kg, and the measured threshold for cellular changes in the ELF range differ by $\sim 10^9$–10^{11}, a factor of over a billion. The accepted SAR standard bears no relation to the threshold for the biological response to environmental threats.

Elements of a Plausible EM Field Interaction Mechanism

A plausible mechanism for EM interactions is needed in developing a safety standard, especially for

evaluating long term exposures and exposure to many frequencies. Experiments with models and the stress response itself have provided insights into mechanism.

Interaction of EM fields with DNA. Stress protein synthesis indicates that EM fields have stimulated transcription from the separated DNA chains that encode these proteins. Direct evidence for interaction with DNA comes from experiments identifying a segment of DNA, an electromagnetic response element (EMRE), associated with and essential for an EM field response [Lin et al., 1999, 2001].

Interaction of EM fields with electrons. Studies of model systems indicate that weak EM fields accelerate electron transfer from cytochrome C to cytochrome oxidase and in the catalyzed oxidation of malonic acid, the Belousov–Zhabotinski reaction [Blank and Soo, 2001b, 2003]. The Na,K-ATPase is also accelerated, and the calculated speed of the charge suggests that it is an electron. Interaction with electrons could perturb H-bonds that hold DNA together and initiate protein synthesis.

Need for repeated interactions involving many cycles. The Na,K-ATPase is accelerated at ELF frequencies, but not by DC fields of the same and larger magnitudes [Blank and Soo, 1997], so the enzyme must only react to regular repetitions of the alternating field. EM sensitive biological reactions have optimal accelerations at frequencies that coincide with natural rhythms [Blank and Soo, 2001a; Blank and Goodman, 2004]. Optima for Na,K-ATPase and cytochrome oxidase are close to the turnover numbers (i.e., rates) of the reactions. Since the interactions wax and wane in each cycle, the need for repetition suggests that the oscillations in each cycle build up to the threshold.

Energetics of Interaction With Electrons

The very low energy level in the ELF range is sufficient to trigger gene expression. This suggests that EM interaction with DNA can stimulate chain separation, at least in the segment of the chain needed to start the process [Young et al., 2004]. Destabilization of H-bonds when electrons oscillate in the EM field is consistent with the low electron affinity of nCTCTn bases in the EMREs needed for interaction with DNA. The force (in N) on an electron,

$$F = q\,v\,B,$$

where $q = 1.6 \times 10^{-19}$ coulombs, $v =$ velocity (in m/s), and the magnetic flux density, B, is approximately 10 μT (100 mG) in our experiments. The electron velocity, $v = 10^3$ m/s, calculated from electric and magnetic field thresholds of the Na,K-ATPase [Blank and Soo, 1992, 1996], is comparable to electron velocities measured in DNA [Wan et al., 1999] and also to expected velocities if electrons move at the ∼nanometer/picosescond flicker rate of protons in H-bonded networks [Fecko et al., 2003]. The assumed value for v leads to $F \sim 10^{-21}$ N and an acceleration of $\sim 10^9$ m/s^2 for an electron of mass 9.1×10^{-31} kg. This acceleration can move an electron 1 nm in 1 ns, a displacement greater than the ∼0.3 nm average length of H-bonds [Blank and Goodman, 2004]. ELF fields appear to have sufficient energy to perturb electrons.

Electric fields have a comparable effect on DNA, and in vivo and in vitro stimulation of biosynthesis by electric fields occurs with forces on electrons comparable to those generated by EM fields [Blank and Goodman, 2004]. The in vivo studies show that field stimulation of DNA is a natural mechanism to relate muscle composition to function [Blank, 1995].

Effect of Frequency

The fact that the same non-thermal mechanism (and biochemical pathway) is activated in ELF and RF ranges shows that total energy of the field is not critical, but rather the regular oscillations of the stimulating force. The energy associated with each wave (i.e., energy/cycle) is probably more or less independent of the frequency. In the ELF range, a typical frequency is 10^2 cycles/s, and a cycle lasts 10^{-2} s. In the RF range, a typical frequency is 10^9 cycles/s and a cycle lasts 10^{-9} s. If same energy is needed to reach threshold in RF, the effect in a single cycle must be the same as in ELF. If we assume the energy is approximately proportional to frequency (energy = Planck's constant × frequency), the energy associated with an RF cycle is $\sim 10^7$ fold greater than in the ELF range. Since durations are in the inverse ratio, the energy transferred in each cycle is about the same (see Table 1). However, because of many repetitions at the higher frequency, the non-thermal threshold is reached in a shorter time. This should apply until there are interactions with normal vibration frequencies of chemical bonds in the IR range.

The threshold energy/cycle is essentially frequency independent, but total energy absorbed over time (energy/s in Table 1) increases with frequency and contributes to the thermal process. In the RF range, the EM non-thermal stress response pathway is activated first, and at longer times, the thermal pathway is stimulated due to heating. The biological responses are complicated by negative feedback involving stress proteins [Lin et al., 1996] and longer term habituation effects [Shallom et al., 2002]. Even in the ELF range, where SAR levels are very low, the stress response is

TABLE 1. Energy per Cycle and per Second in Extremely Low Frequency (ELF) and Radio Frequency (RF) Ranges (Relative Energy in ELF Units)

Range	Frequency (f) Hz	Cycle duration (t) s	Relative energy (E)	$E \times t$ [a] E/cycle	$E \times t \times f$ [b] E/s
ELF	10^2	10^{-2}	1	10^{-2}	10^2
RF	10^9	10^{-9}	10^7	10^{-2}	10^7

[a]Energy/cycle associated with electromagnetic (EM) non-thermal mechanism.
[b]Energy/second associated with thermal (''heat shock'') mechanism.

activated by short exposures to fields of 10 mG (0.1 μT), while single and double strand breaks in DNA have been reported at longer exposures to higher field strengths ~1 G (0.1 mT) [Lai and Singh, 2004]. The two mechanisms may be related in that breaks in DNA appear to result from free radical mechanisms that also involve electron transfer reactions.

Stress Response in a Practical Context

The increase in RF broadcasting and communication devices, together with ELF power frequency devices, create an urgent need for realistic safety standards. The stress response is an appropriate biological guideline to evaluate cell safety in both thermal and non-thermal ranges, as well as the effects of long term and complex repeated exposures. It is also a natural biological bridge to the more complex mechanisms that affect human health.

The ubiquity and low threshold of the stress response, and the wide range of frequencies that interact with DNA and affect electron transfer reactions, has prompted us to ask why biological effects do not occur with greater frequency. Several factors may contribute to this:

- EM field interactions require special alignment of field with reactants, and a small fraction of reactants is properly oriented to maximize the effect. The alignment problem is pronounced in DNA, where adjacent base pairs would have to react simultaneously to create an opening for RNA polymerase. The fact that the stress response is induced at relatively short exposures indicates the ubiquity and sensitivity of stress genes.
- Cells and organisms do not sit idly by when interactions occur. In addition to the stress response, various protective mechanisms are activated to mitigate the effects. However, DNA repair mechanisms may themselves be compromised by exposure to EM fields.
- Effects occur on opposing reactions, as in cytochrome oxidase [Blank and Soo, 1998], where forward and backward reactions are accelerated and equilibrium is reached faster.
- Cellular damage may not be detected, and diseases, such as cancers, may take years to develop. Because of the long induction period, other factors may contribute to the development of the disease and confound the analysis.

By focusing on biological mechanisms, we have linked thermal and non-thermal effects to a protective cellular mechanism that appears to be independent of frequency over a large part of the spectrum. Further insights should result from utilizing the stress response and specific markers in the biochemical pathway to evaluate effects of complex and repeated exposures. We cannot overemphasize the importance of focusing on biological mechanisms in assessing risk.

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