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| Thursday, 2 April 2009 - Brussels | Provisional edition |
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| **Health concerns associated with electromagnetic fields** | P6_TA-PROV(2009)0216 A6-0089/2009 |

European Parliament resolution of 2 April 2009 on health concerns associated with electromagnetic fields (2008/2211(INI))

The European Parliament ,

– having regard to Articles 137, 152, and 174 of the EC Treaty, seeking to promote a high level of human health, environmental protection and workers' health and safety protection,

– having regard to Council Recommendation 1999/519/EC of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz)(1) and the related Commission implementation report of 1 September 2008 on the implementation of that recommendation (COM(2008)0532),

– having regard to Directive 2004/40/EC of the European Parliament and of the Council of 29 April 2004 on the minimum health and safety requirements regarding exposure of workers to the risks arising from physical agents (electromagnetic fields)(2) ,

– having regard to Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity(3) and to the respective harmonised safety standards for mobile phones and base stations,

- having regard to Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits(4) ,

**Exhibit B**

– having regard to its resolution of 4 September 2008 on the mid-term review of the European Environment and Health Action Plan 2004-2010(5) ,

– having regard to its resolution of 10 March 1999 on the proposal for a Council Recommendation on the limitation of exposure of the general public to electromagnetic fields 0 Hz – 300 GHz(6) ,

– having regard to Rule 45 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety (A6-0089/2009),

A. whereas electromagnetic fields (EMFs) exist in nature and have consequently always been present on earth; whereas, however, in recent decades, environmental exposure to man-made sources of EMFs has risen constantly, driven by demand for electricity, increasingly more specialised wireless technologies, and changes in the organisation of society; whereas the end effect is that every individual is now being exposed to a complex mixture of electric and magnetic fields of different frequencies, both at home and at work,

B. whereas wireless technology (mobile phones, Wi-Fi/WiMAX, Bluetooth, DECT landline telephones) emits EMFs that may have adverse effects on human health,

C. whereas most European citizens, especially young people aged from 10 to 20, use a mobile phone, an object serving a practical purpose and as a fashion accessory, and whereas there are continuing uncertainties about the possible health risks, particularly to young people whose brains are still developing,

D. whereas the dispute within the scientific community regarding the potential health risks arising from EMFs has intensified since 12 July 1999, when exposure limits for fields in the 0 Hz to 300 GHz range were laid down in Recommendation 1999/519/EC,

E. whereas the fact that the scientific community has reached no definite conclusions has not prevented some national or regional governments, in China, Switzerland, and Russia, as well as in at least nine EU Member States, from setting what are termed "preventive" exposure limits, that is to say, lower than those advocated by the Commission and its independent scientific committee, the Scientific Committee on Emerging and Newly Identified Health Risks(7) ,

F. whereas actions to limit the exposure of the general public to EMFs should be balanced against improvements to quality of life, in terms of safety and security, brought about by devices transmitting EMFs,

G. whereas among the scientific projects arousing both interest and controversy is the Interphone epidemiological study, financed by an EU contribution of EUR 3 800 000, primarily under the Fifth RTD Framework Programme(8) , the findings of which have been awaited since 2006,

H. whereas, however, there are some points that appear to be the subject of general

agreement, in particular the idea that reactions to microwave exposure vary from one person to another, the need, as a matter of priority, to conduct exposure tests under actual conditions in order to assess the non-thermal effects associated with radio-frequency (RF) fields, and the fact that children exposed to EMFs are especially vulnerable(9) ,

I. whereas the EU has laid down exposure limits to protect workers from the effects of EMFs; whereas on the basis of the precautionary principle such measures should also be taken for the sections of population concerned, such as residents and consumers,

J. whereas the Special Eurobarometer report on Electromagnetic Fields (No 272a of June 2007) indicates that the majority of citizens do not feel that the public authorities inform them adequately on measures to protect them from EMFs,

K. whereas it is necessary to continue investigations into intermediate and very low frequencies so that conclusions can be drawn as to their effects on health,

L. whereas the use of Magnetic Resonance Imaging (MRI) must not be threatened by Directive 2004/40/EC as MRI technology is at the cutting edge of research, diagnosis and treatment of life-threatening diseases for patients in Europe,

M. whereas the MRI safety standard IEC/EN 60601-2-33 establishes limit values for EMFs which have been set so that any danger to patients and workers is excluded.

1. Urges the Commission to review the scientific basis and adequacy of the EMF limits as laid down in Recommendation 1999/519/EC and report to the Parliament; calls for the review to be undertaken by the Scientific Committee on Emerging and Newly Identified Health Risks;

2. Calls for particular consideration of biological effects when assessing the potential health impact of electromagnetic radiation, especially given that some studies have found the most harmful effects at lowest levels; calls for active research to address potential health problems by developing solutions that negate or reduce the pulsating and amplitude modulation of the frequencies used for transmission;

3. Maintains that as well as, or as an alternative to, amending European EMFs limits, the Commission, working in coordination with experts from Member States and the industries concerned (electricity companies, telephone operators and manufacturers of electrical appliances including mobile phones), should draw up a guide to available technology options serving to reduce exposure to EMFs;

4. Notes that industry stakeholders as well as relevant infrastructure managers and competent authorities can already influence certain factors, for example setting provisions with regards to the distance between a given site and the transmitters, the height of the site in relation to the height of the base station, or the direction of a transmitting antenna in relation to living environments, and, indeed, should obviously do so in order to reassure, and afford better protection to, the people living close to such facilities; calls for optimal placement of masts and transmitters and further calls for the sharing of masts and transmitters placed in this way by providers so as to limit the

proliferation of poorly positioned masts and transmitters; calls on the Commission and Member States to draw up appropriate guidance;

5. Invites the Member States and local and regional authorities to create a one-stop shop for authorisation to install antennas and repeaters, and to include among their urban development plans a regional antenna plan

6. Urges the authorities responsible for authorising the siting of mobile telephony antennas to reach agreement, jointly with the operators in that sector, on the sharing of infrastructure, in order to reduce the volume thereof and the exposure of the public to EMFs;

7. Acknowledges the efforts of mobile communications and other EMF-transmitting wireless technologies to avoid damaging the environment, and in particular to address climate change;

8. Considers that, given the increasing numbers of legal actions and measures by public authorities having the effect of a moratorium on the installation of new EMF-transmitting equipment, it is in the general interest to encourage solutions based on negotiations involving industry stakeholders, public authorities, military authorities and residents" associations to determine the criteria for setting up new GSM antennas or high-voltage power lines, and to ensure at least that schools, crèches, retirement homes, and health care institutions are kept clear, within a specific distance determined by scientific criteria, of facilities of this type;

9. Calls on the Member States to make available to the public, jointly with the operators in the sector, maps showing exposure to high-voltage power lines, radio frequencies and microwaves, and especially those generated by telecommunications masts, radio repeaters and telephone antennas. Calls for that information to be displayed on an internet page so that it can easily be consulted by the public, and for it to be disseminated in the media;

10. Proposes that the Commission consider the possibility of using funding from the Trans-European Energy Networks to investigate the effects of EMFs at very low frequencies, and particularly in electrical power lines,

11. Calls on the Commission, during the 2009-2014 parliamentary term, to launch an ambitious programme to gauge the electromagnetic compatibility between waves created artificially and those emitted naturally by the human body with a view to determining whether microwaves might ultimately have undesirable consequences for human health;

12. Calls on the Commission to present a yearly report on the level of electromagnetic radiation in the EU, its sources, and actions taken in the EU to better protect human health and the environment;

13. Calls on the Commission to find a solution enabling Directive 2004/40/EC to be implemented more rapidly and thus ensure that workers are properly protected against EMFs, just as they are already protected under two other Community acts against

noise(10) and vibration(11) and to introduce a derogation for MRI under Article 1 of that Directive.

14. Deplores the fact that, as a result of repeated postponements since 2006, the findings of the Interphone study have yet to be published, the purpose of this international epidemiological study being to establish whether there is a link between use of mobile phones and certain types of cancer, including brain, auditory nerve, and parotid gland tumours;

15. Draws attention in this context to the appeal for caution from the coordinator of the Interphone study, Elisabeth Cardis, who, in the light of existing knowledge, recommends, as far as children are concerned, that mobile phones should not be used beyond reasonable limits and that landlines should be preferred;

16. Believes in any event that it is up to the Commission, which has an important contribution to the financing of this global study, to ask those in charge of the project why no definitive findings have been published and, should it receive an answer, to inform Parliament and the Member States without delay;

17. Also suggests to the Commission, to make for efficiency in policy and budget terms, that the Community funding earmarked for studies on EMFs be partly switched to finance a wide-ranging awareness campaign to familiarise young Europeans with good mobile phone techniques, such as the use of hands-free kits, keeping calls short, switching off phones when not in use (such as when in classes) and using phones in areas that have good reception;

18. Considers that such awareness-raising campaigns should also familiarise young Europeans with the health risks associated with household devices and the importance of switching off devices rather than leaving them on stand-by;

19. Calls on the Commission and Member States to increase research and development funding for the evaluation of potential long-term adverse effects of mobile telephony radio frequencies; calls also for an increase in public calls for proposals for investigation of the harmful effects of multiple exposure to different sources of EMFs, particularly where children are concerned;

20. Proposes that the European Group on Ethics in Science and New Technologies be given the additional task of assessing scientific integrity in order to help the Commission forestall possible cases of risk, conflict of interests, or even fraud that might arise now that competition for researchers has become keener;

21. Calls on the Commission, in recognition of the public concern in many Member States, to work with all relevant stakeholders, such as national experts, non-governmental organisations and industrial sectors, to improve the availability of, and access to, up-to-date information understandable to non-specialists on wireless technology and protection standards;

22. Calls on the International Commission on Non-Ionising Radiation Protection and the World Health Organisation (WHO) to be more transparent and open to dialogue with all

stakeholders in standard setting;

23. Condemns certain particularly aggressive marketing campaigns by telephone operators in the run-up to Christmas and other special occasions, including for example the sale of mobile phones designed solely for children or free call time packages aimed at teenagers;

24. Proposes that the EU's indoor air quality policy should encompass the study of "wireless" domestic appliances, which, like Wi-Fi for Internet access and digital enhanced cordless telecommunications (DECT) telephones, have been widely adopted in recent years in public places and in the home, with the result that citizens are being continuously exposed to microwave emissions;

25. Calls, given its constant concern to improve consumer information, for the technical standards of the European Committee for Electrotechnical Standardisation to be amended with a view to imposing labelling requirements whereby the transmitting power would have to be specified and every wireless-operated device accompanied by an indication that it emitted microwaves;

26. Calls on the Council and Commission, in coordination with the Member States and the Committee of the Regions, to encourage the introduction of a single standard designed to ensure that local residents are subjected to as low a degree of exposure as possible when high-voltage grids are extended;

27. Is greatly concerned about the fact that insurance companies are tending to exclude coverage for the risks associated with EMFs from the scope of liability insurance policies, the implication clearly being that European insurers are already enforcing their version of the precautionary principle;

28. Calls on Member States to follow the example of Sweden and to recognise persons that suffer from electrohypersensitivity as being disabled so as to grant them adequate protection as well as equal opportunities;

29. Instructs its President to forward this resolution to the Council, the Commission, the governments and parliaments of the Member States, the Committee of the Regions, and the WHO.

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(1) OJ L 199, 30.7.1999, p. 59.

(2) OJ L 159, 30.4.2004, p. 1.

(3) OJ L 91, 7.4.1999, p. 10.

(4) OJ L 374, 27.12.2006, p. 10.

(5) Texts adopted, P6_TA(2008)0410.

(6) OJ C 175, 21.6.1999, p. 129.

(7) Opinion of 21 March 2007 adopted at the 16th plenary meeting of the Committee.

(8) Quality of life programme, contract No QLK4-1999-01563.

(9) March 2001 STOA study on "The physiological and environmental effects of non-ionising EMR", PE297.574.

(10) Directive 2003/10/EC of the European Parliament and of the Council of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise) (OJ L 42, 15.2.2003, p. 38).

(11) Directive 2002/44/EC of the European Parliament and of the Council of 25 June 2002 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (vibration) (OJ L 177, 6.7.2002, p. 13).

Last updated: 6 April 2009.

# 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
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Exhibit C

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# 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.



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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.

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# 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,

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- 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.

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## 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

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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.

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### 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.

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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.**

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## *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.

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# 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



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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?

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- 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.

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# 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.



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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.

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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.

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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.

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## 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).

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## 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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## 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 **F**ood and **D**rug **A**dministration (FDA) nominated RFR emissions of wireless communication devices to the **N**ational **T**oxicology **P**rogram (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.

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# BioInitiative Report:

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

www.bioinitiative.org


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# Setting Prudent Public Health Policy for Electromagnetic Field Exposures

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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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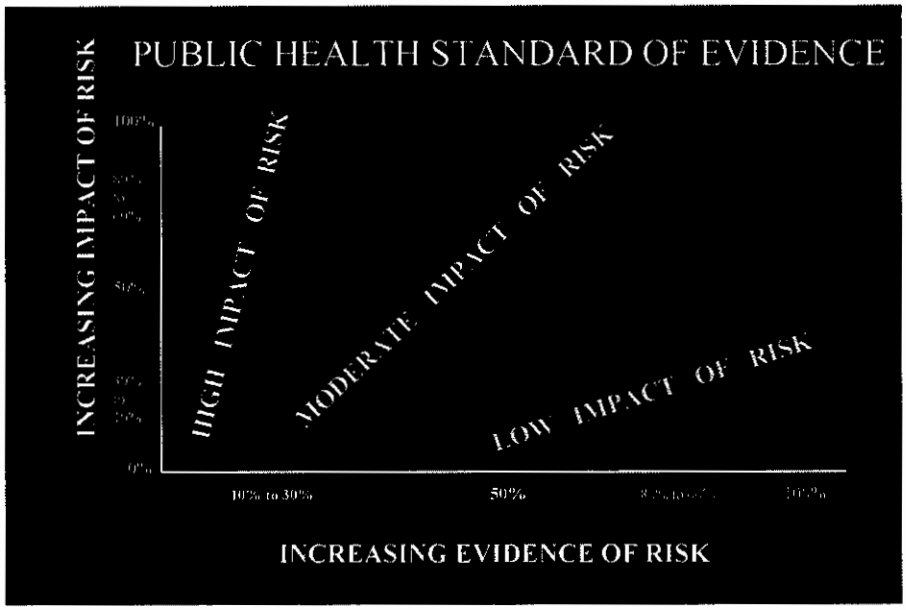


**Fig. 4:** A public health-based response must be relative to the magnitude of the potential impact of inaction. When the potential impact is high, action should be taken even when the evidence of risk is low.

## 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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