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US Regulation of Exposure to Radiofrequency Radiation
for Cell Phone Emissions

Senator Branagan, Representative Perry and Honorable Members of the Health and Human Services Committee:

Thank you for the opportunity to speak. I am Janet Newton, President of The EMR Policy Institute. We continue to challenge the inadequacy of the US public health policy on cell phone safety by submitting official comment to key federal agencies as listed on the PowerPoint slide. No US agency policy protects children from cell phone radiation exposure. The federal record demonstrates this fact to be true.

The Federal Communications Commission (FCC) is a licensing and engineering agency that relies on other agencies and organizations to recommend and set safety standards for communications technology. It is not a health agency itself.

The Food and Drug Administration (FDA) regulates electronic devices that come in contact with the human body through its Center for Devices and Radiological Health (CDRH). This includes cell phones as they are held up to the side of the head in normal use.

The FCC has traditionally adopted safety recommendations from the American National Standards Institute (ANSI). ANSI is an industry-based organization comprised of numerous committees representing diverse business interests, such as automobile manufacturers, chemical/pharmaceutical companies, the electrical industries, and many others. To create standards for radiofrequency/microwave radiation (RF/MW) used in telecommunications and other RF/MW-related activities, ANSI looks to a subcommittee of the Institute of Electrical and Electronics Engineers (IEEE) called C95.1 that is responsible for making recommendations for RF/MW exposures. The standards are referred to as ANSI-IEEE C95.1-1992; the date refers to the last year in which revisions were made to the original standard, which was put out in 1966.

The model used for both the IEEE and the NCRP standards is an adult male of average height and weight. Though safety margins are factored in, the standards do not take women, pregnant women, or children into consideration – all of whom absorb radiation differently than this “average” model. Nor does it consider the elderly or the infirm who are more susceptible to adverse exposures.

The model, and all of the research it is drawn from, is based solely on the thermal effects these frequencies can create. It has been known for decades that microwaves, at sufficient power output, can create heating. That is what occurs in a microwave oven. The current FCC model presumes that nothing adverse other than heating occurs. Therefore, if heating does not occur, no other adverse biological effect does either. But a range of adverse non-thermal effects have been noted or decades as well – at levels significantly lower than the current FCC standard. This has been at the heart of the debate since the 1950's.

Timeline of U.S. Federal Activities Addressing Exposure to Mobile Phone Radiation

1996 - With passage of the Telecommunications Act of 1996 the FCC began to regulate the RF emissions of mobile phones. Prior to 1996 mobile phones were exempt from US federal RF regulation.

1999 – Federal Radiofrequency Interagency Work Group (RFAIWG) issued its June 17, 1999 letter to the radiofrequency (RF) standards setting subcommittee of the Institute of Electrical and Electronics Engineers (IEEE SCC28) that identified issues, “that we believe need to be addressed to provide a strong and credible rationale to support RF exposure guidelines.” The letter was issued “in response to previous requests for greater participation on our part in the SCC28 deliberations on RF guidelines.” See: www.emrpolicy.org/litigation/case_law/docs/exhibit_a.pdf

RFAIWG is comprised of experts in exposure to radiofrequency radiation (RF) from the Environmental Protection Agency, Federal Communications Commission, Food and Drug Administration, National Institute of Occupational Safety and Health, Occupational Safety and Health Administration, and the National Telecommunications Information Administration.

What happened – The IEEE committee has not responded.

To date the RFAIWG-identified issues have not been incorporated into any revision of IEEE Radiofrequency Exposure Standards. The current FCC human RF exposure guidelines are based on the IEEE RF exposure standards and the NCRP (National Council on Radiation Protection and Measurement) RF exposure guidelines. Going forward, the NCRP no longer works on RF exposure standards development. It reviews the RF standards development work of other bodies.

RFAIWG RF Guideline Issues Related to Mobile Phone Use

- **Biological basis for local SAR limit -**

... an effort should be made to base local SAR limits on the differential sensitivity of tissues to electric fields and temperature increases. For example, it seems intuitive that the local limits for the brain and bone marrow should be lower than those for muscle, fat and fascia; this is not the case with the current limits which implicitly assume that all tissues are equally sensitive (except for eye and testicle).

- **Selection of an adverse effect level -**

Since the adverse effect level for the 1991 guidelines was based on acute exposures, does the same approach apply for effects caused by chronic exposure to RF radiation, including exposures having a range of carrier frequencies, modulation characteristics, peak intensities, exposure duration, etc., that does not elevate tissue temperature on a macroscopic scale?

- **Acute and chronic exposures -**

. . . a clear rationale needs to be developed to support the exposure guideline for chronic as well as acute exposure.

- **Time averaging –**

If prolonged and chronic exposures are considered to be important, then there should be a reconsideration of the time-averaging practices that are incorporated into existing exposure guidelines.

- **Replication / Validation -**

Published peer-reviewed studies that have been independently replicated/validated should be used to establish the adverse effects level from which exposure guidelines are derived. The definition of "replicated/validated" should not be so restrictive to disallow the use of a set of reports that are scientifically valid but are not an exact replication/validation of specific experimental procedures and results.

Peer-reviewed, published studies that may not be considered to be replicated/validated, but are well done and show potentially important health impacts provide important information regarding uncertainties in the data base used to set the adverse effect level (e.g., incomplete data base).

- **Important Health Effects Literature Areas –**

Documentation should be provided that the literature review process included a comprehensive review of the following three areas:

- 1) long-term, low-level exposure studies (because of their importance to environmental and chronic occupational RFR exposure);*
- 2) neurological/behavioral effects (because of their importance in defining the adverse effect level in existing RFR guidelines); and*
- 3) micronucleus assay studies (because of their relevance to carcinogenesis).*

1999 - FDA nominated RF radiation emissions of wireless communication devices to the National Toxicology Program (NTP) for Toxicological Studies for research because of “widespread consumer and worker exposure” and because “the available data is inadequate to properly assess safety.”

From the Executive Summary of the FDA’s Nomination:

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.

. . . 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.

2000 - Senator Joe Lieberman and Congressman Ed Markey request GAO (Government Accounting Office) to investigate US research on and regulation of mobile phone health issues.

2001 – GAO issued Report 01-545 Research and Regulatory Efforts on Mobile Phone Health Issues. See: www.gao.gov/new.items/d01545.pdf

One section of the GAO Report addresses “shortcomings” of the FDA and FCC. In particular it underscored a brochure produced by FCC’s Consumer Information Bureau that “puts the statement ‘Cell Phones Cause Medical Problems’ into the category of ‘fiction,’ noting that ‘there is no scientific evidence that proves wireless phone usage can cause cancer, increased blood pressure, memory loss, or other health problems,’ though research is continuing.” Officials in the FCC’s Office of Engineering and Technology were asked to comment on that statement. They concurred with the GAO that “this characterization could be misleading, because it implies that the health issue is settled.”

GAO Report Conclusions –

Scientific research to date does not demonstrate that the radiofrequency energy emitted from mobile phones has adverse health effects, but the findings of some studies have raised questions indicating the need for further investigations . . . Given the long-term nature of much of the research being conducted – particularly the epidemiological and animal studies – it will likely be many more years before a definitive conclusion can be reached on whether mobile phone emissions pose any risk to humans health . . .

Given the prominence of the mobile phone health issue, FDA and FCC need to provide the public with clear, accurate, and timely information so that they can make informed decisions.

2003 - RFIAWG sent another letter to Chou at IEEE with three more RF concerns:

- **Exclusion of pinna** [ear lobe]. IEEE proposed to reclassify the earlobe as an “extremity” as if it is not part of the head.

If the pinna is to be considered an extremity and subjected to exposure limit of 20 W/Kg over 10 g of tissue, then a clear rationale for treating the pinna as an extremity should be presented. This rationale should include biological properties of the pinna that qualifies it for this exclusion. If thermal effects would be the basis for the ICES standard, then the thermophysiology of the pinna and the skin, bone and other head tissues adjacent to the pinna should be discussed.

- **Rationale for relaxation of current limits**

Federal agencies, as well as the general public and the public health community, are very concerned about a relaxation of exposure guidelines that may result in increased exposure in the future. A rationale should be presented for relaxation of standards. The rationale should include a clear explanation of the impact of the exposures that may result, i.e., the description of the exposures and the effects on critical tissues and organs. An explanation should be given as to why the current standard should be relaxed. The issue of safety factors should be also be addressed as part of the rationale for relaxation of current limits.

- **Sensitivity of different tissues**

A clear explanation on how the revision has taken into account sensitivity of different tissues to temperature. Effects of acute and chronic exposure to elevated temperature should be revised standard a description of the risk analysis that was done.

What happened? The IEEE committee has not responded.

Frequently noted in the 2001 GAO Report is the CRADA (Cooperative Research and Development Agreement) between FDA and CTIA (Cellular Telecommunications and Internet Association). Outcomes of that CRADA at NTP and The National Academies of Science are:

2005 – NTP issues a Fact Sheet describing the FDA-nominated RF radiation study entitled: “Studies on Radiofrequency Radiation Emitted by Cellular Phones - Year 2005.” It makes the following statements about the research upon which the current FCC Radiofrequency Radiation exposure guidelines are 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.

2007 – As negotiated in the FDA / CTIA CRADA, the National Academies of Science (NAS) convened a Workshop on Identification of Research Needs Relating to Potential Biological or Adverse Health Effects of Wireless Communication Devices. 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 NAS for advice on the scientific and technological issues that frequently pervade policy decisions. See:

www.nationalacademies.org/about/history.html

2008 - NAS issued its Report entitled: *Identification of Research Needs Relating to Potential Biological or Adverse Health Effects of Wireless Communication Devices*, which states that the FCC's RF Safety Guidelines do not take into account a number of factors needed to protect public health. See: www.nap.edu/catalog.php?record_id=12036

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.

(p. 2)(Emphasis added.)

* * *

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.

(p.2)(Emphasis added.)

* * *

The body of the full NAS Report identifies the following issues as not being covered by existing research and therefore are not addressed in current RF safety policy: (Emphasis added.)

- 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?

(pp. 11-12.)(Emphasis added.)

* * *

Laboratory Exposure Systems

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.

(p. 17.) (Emphasis added.)

2009 – FDA’s Center for Devices and Radiological Health asked for a private briefing on *The BioInitiative Report* in April of 2009. It was provided by *The Report’s* co-editors David O. Carpenter MD, MPH, and Cindy Sage, MA. See: www.bioinitiative.org

What happened? The FDA has taken no action to protect children since the NAS Report was issued.

It is clear from the statements of the NAS Report as well as from the statements of federal experts in the RFIWG and from the statements of the FDA and the NTP, all cited herein, that to date the question of adverse health effects from long-term exposure to cell phones to all subgroups of the American public has not been answered in the research record. Our US RF safety guidelines are based on this incomplete research record. Precaution for reducing the exposure of our most vulnerable citizens, i.e., children, pregnant women and the unborn, is warranted.

Children have no voice about their cell phone exposure. Adults in their lives along with policy makers make those decisions for them. I’m very unhappy that my three young grandchildren have no choice about what phone they are given to use. We need warning labels on cell phones so that parents make responsible, informed decisions about their children’s future health.