

Health Matters

The NTP Cell Phone RF Radiation Health Effects Project

■ James C. Lin

On 26 May 2016, a U.S.-government-led project reported occurrences of two types of rare cancers in laboratory rats exposed to RF radiation used for wireless cell phone operations [1].

This five-year project has been ongoing for more than ten years, with a currently estimated price tag of US$25 million or more of taxpayers' money (two to three times its original budget). That's huge! It is the largest health effects study ever undertaken by the National Toxicology Program (NTP) of the National Institute of Environmental Health Sciences (NIEHS).

The Findings and Their Implications

Observation of malignant gliomas in the brain and schwannomas of the heart from two-year (or lifelong, in most cases) RF-exposed rats represented partial findings from the project. Results reportedly were reviewed by expert peer reviewers selected by the NTP and the National Institutes of Health.

The NTP's announcement of animal results from their large RF health effects study is major; in 2011, the World Health Organization's International Agency for Research on Cancer (IARC) classified exposure to cell phone RF radiation as a possible carcinogen for humans. The classification was based on epidemiological studies reporting increased cancer risks among heavy or long-term users of cell phones.

The IARC had assessed available scientific papers and concluded that—while evidence was incomplete and limited, especially with regard to results from animal experiments—epidemiological studies reporting increased risks for gliomas (a type of malignant brain cancer) and acoustic neuromas (a nonmalignant tumor of Schwann-cells-sheathed auditory nerves) among heavy or long-term users of cell phones are sufficiently strong to support a Group 2B classification of possibly carcinogenic to humans for exposure to RF radiation.

This classification is third among the IARC's groupings of carcinogenic risk for humans. The highest category, Group 1, is reserved for agents that are "carcinogenic to humans," followed by Group 2A ("probably carcinogenic to humans") and Group 2B ("possibly carcinogenic to humans"), then Group 3 ("not classifiable as to its carcinogenicity to humans"), and, lastly, Group 4 ("probably not carcinogenic to humans").

Inevitable Controversy

Reactions have been swift, startling, and disconcerting. Some mainstream media opined that use of cell phones does not lead to cancer. The NTP report is just hype, pure and simple. In contrast, the American Cancer Society, among others, consider the NTP report as signifying a paradigm shift in the understanding of RF radiation and cancer, reversing its previous position.

How can this be?

To be sure, no new or any single study can be taken in isolation. Indeed, a large database of published research already exists. However, a number of published animal cancer studies on RF exposure have been equivocal and controversial. The inconsistencies have posed uncertainty as to assessments of health risks from RF exposure.

The NTP project was developed to challenge the limitations of previous animal studies on the potential of nonthermal RF exposure to cause chronic health effects such as cancer

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under controlled laboratory conditions. Its goal is to provide a major contribution of scientific knowledge on a very important public health issue. Complete results from the NTP studies have been promised belatedly, by the end of 2017.

The early offer of partial findings was prompted, according to the NTP, by (amid other factors) the widespread global use of cellular mobile devices among users of all ages, because a very small increase in the incidence of cancer resulting from exposure to cell phone RF radiation could have broad implications for public health. Also, there is a high level of public and media interest regarding the safety of cell phone RF radiation. Thus, early release of the results (ahead of their submission to, and publication in, a scientific journal) was seen, practically, as a public health obligation.

Some observers have decided, on that basis, that the findings would change the conversation and allow people to point to much more hard evidence to say that cell phone RF exposure does pose a health risk. Nevertheless, a number of questions may be raised about the reported study, even though the study is the single largest and most comprehensive of laboratory animals exposed to cell phone RF radiation.

Rhetoric aside, there are some rather puzzling issues surrounding the project.

A Sole-Sourced Study

Note that the cell phone RF exposure of rats and mice research project is the largest and most expensive animal health effects study ever undertaken by the NTP [2]. But it was sole-sourced through a contract to an industrial firm, with an estimated budget of US$12 million for a five-year duration. (The life spans of rats and mice are about two years.) Moreover, at the time, the contractor did not appear to have any prior experience in conducting research involving biological or health effects of laboratory animals exposed to RF radiation.

However, available evidence shows that in due time—and prior to awarding the sole-sourced contract—the NIEHS/NTP officially received, from a team at a major research university, a 30-page written proposal presenting their interest and capability in response to NTP requirements. The submitted proposal indicated that they have a newly renovated and expanded animal facility, have in place essential features necessary to conduct good laboratory practice (or "GLP") studies on chronic toxicity/carcinogenicity of RF radiation in large groups of rats and mice (e.g., environmentally controlled animal rooms, a necropsy room, histology laboratories, a quality assessment group, etc.) and the expertise and staff to care for and process large numbers of animals (e.g., RF exposure and dosimetry engineers, toxicologists, pathologists, veterinarians, animal care technicians, pro-sectors, histologists, etc.).

The proposed principal investigator (PI) is a well-known leader with, at the time, more than 30 years experience conducting multidisciplinary research into the biological and health effects of RF and radiation. He listed 150 journal publications in that field.

In addition to the PI, the team includes toxicologists, chemists, engineers/exposure specialists, veterinarians, health and safety officers, and quality assurance unit officers on staff at the university (and can appoint more, if additional support is needed). The physical and organizational propinquity could greatly facilitate the daily interaction and constant coordination of efforts needed among the disciplinary areas throughout the in-life portion of the studies.

Nevertheless, the NIEHS/NTP decided against conducting a competitive procurement. The basis for this decision was, in summary, that "the capability statement submitted does not demonstrate capability nor sufficient experience to perform the project described in the NTP statement of work on the toxic and carcinogenic potential of cell phone RF radiation in laboratory animals."

The specific rationale concluded that "although the PI has many years of experience in RF radiation," there is no evidence "indicating that he has ever managed and coordinated a multidisciplinary health effects research project approaching the magnitude of that described in the NTP on studies to evaluate the chronic toxicity and carcinogenicity of cell phone RF radiation. An RF toxicology study led by the PI and highlighted in the capability statement because it was deemed to be 'similar to the NIEHS-NTP solicitation' was conducted 25 years ago." Moreover, "it is unclear how the PI will have adequate time to devote to all of his proposed roles in this project; he is proposed at 100% effort."

The bizarre and obvious paradox aside, this judgment is beyond perplexing if one recognizes that the sole-sourced contractor did not have any prior experience conducting research involving biological or health effects of RF radiation on laboratory animals at all.

Also, the verdicts on facilities include the following: "Most important, the laboratories that were proposed to participate in this project do not have a facility that could properly house the 14 reverberation chambers" required for these studies. The university proposed to "construct the RF reverberation exposure chambers in modular units" adjacent to TRL and BRL **<James, can you spell out "TRL/BRL"?>** and in the proposed RF exposure facility.

This is a non sequitur! It was patently clear: the unique NTP-required facility did not exist anywhere in the entire world, and the NTP knew it. If not newly constructed, extensive remodeling would be required of any comparable existing facility to accommodate the RF reverberation exposure chambers.

Facts speak louder, as always. It appears to have taken two or more years for the sole-sourced contractor to finish installing the reverberation chambers in their exposure facilities; this is likely one of the principal culprits for the huge budget overrun and excessive delay in project completion from five to more than ten years.

Foregone Conclusions?

Moreover, the NTP's reporting of occurrences of two types of cancers in RF-exposed rats (malignant gliomas in the brain and schwannomas of the heart) may have been something of a challenge or, perhaps, an extant dilemma. John Bucher, the associate director overseeing the NTP study,

shared with North Carolina's leading newspapers (the *Charlotte Observer* and *Raleigh News & Observer*) in January 2010) that he "doubts scientific research can demonstrate a link between cell phones and cancer." Bucher was quoted as saying, "I anticipate either no correlation or, if anything is seen at all, it won't be a strong signal" [3]. (The NIEHS and NTP are located in Durham, North Carolina).

Furthermore, Ronald Melnick spent the last decade of his career at NIEHS planning and designing the NTP cell phone animal exposure project. Before retiring in 2009, he had sole-sourced the massive project through a contract.

In a recent *Microwave News* article on the NTP cell phone cancer report [4], Melnick was quoted as saying, "The study had low power and was more likely to show no effect. The fact that it did makes the results more compelling."

This statement begs several questions. Given the NTP contract stipulation that these studies be conducted in accordance with the current "Specifications for the Conduct of Studies to Evaluate the Toxic and Carcinogenic Potential of Chemical, Biological and Physical Agents in Laboratory Animals for the National Toxicology Program," does it mean that all NTP health effects studies are designed to have low statistical power, or had Melnick designed and planned for the NTP cell phone cancer study to have low statistical power? Worse, should anyone trust the NTP's reputation on identification of chemical and other environmental carcinogens, based on such low statistical power in their experimental design?

Also, are 90 to 100 animals per exposure group small in toxicology and cancer studies involving thousands of animals in total? Typically, these kinds of projects are regarded as large animal studies.

In a written response to a *New York Times'* article on the NTP cell phone health effects study [5], Melnick [6] stated that the author of the *Times* article is "probably unaware that the design of this study was presented at an annual meeting of the Bioelectromagnetics Society prior to the start of these studies." It should be noted that, while meeting participants consider a comprehensive study of animals exposed to cell phone radiation as important, the vast majority of opinion expressed was that use of reverberation chambers for RF exposure is inappropriate. It is fraught with potential complications in terms of maintaining RF field uniformity: the number, mass, and movement of animals vary over time and space; uncertainties exist in terms of animal housing, feeding, watering, and waste disposal; and changes can occur in environmental conditions including mechanical factors, among others, inside the chambers. There may even be better ways to do it. Obviously, the NTP paid no attention to them and proceeded anyway.

Limited Reporting

Another intriguing aspect of this NTP investigation (which, as I noted earlier, was initiated in 2005 as a five-year project with a budget of US$12 million) is that it quickly became very guarded. Everyone involved was mum about it. The NIEHS had refused to release any progress reports or project documents [7]. The lack of transparency is palpable.

In contrast to scientific norms, there were no presentations of any results at any scientific meetings. At a minimum, one would expect the NTP to have presented and discussed, years ago, such topics as design, performance, and measurement of exposure fields in the unique reverberation chambers and the dosimetric characterization of specific RF absorption rates in exposed animals.

But none was forthcoming until the sudden announcement in May. Meanwhile, the five-year project has carried on for more than ten years, and the US$12 million sole-sourced contract has ballooned to a budget exceeding US$25 million so far.

Is it possible that, right or wrong, the NIEHS/NTP appear to have determined to do their own thing and draw their own conclusions as to the "Studies to Evaluate the Toxic and Carcinogenic Potential of Cell Phone Radio Frequency Radiation"?

References

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[2] NIEHS. The NIEHS intends to solicit and negotiate on a sole source basis under the authority of FAR 6.302-1 with IIT Research Institute. [Online]. Available: http://www1.eps.gov/spg/HHS/NIH/NIEHS/NIH%2DES%2D04%2D13/SynopsisP.html **<AU: Please provide the year.>**

[3] J.C. Lin, "The curious case of the IARC Working Group on Radio Frequency Electromagnetic Fields and Cell Phones,"*IEEE Microwave Mag.*, vol. 12, no. 6, pp. 32–34, 2011.

[4] J.C. Lin, "Reply to Letter to the Editor regarding a column by Dr. J. C. Lin," *IEEE Antennas Propagat. Mag.*, vol. 53, no. 5, pp. 162–163, 2011. **<AU: Please note that ganged references are not allowed per magazine style. Therefore, we have renumbered the second part of Ref. 3 as Ref. 4.>**

[5]"News Media Nix NTP Cancer Study,"*Microwave News,* May 2016. **<AU: Please provide the author names, volume number, and complete page range.>**

[6] A. E. Carroll, "Why it's not time to panic about cellphones and cancer," *The New Health Care, New York Times*, May 2016 **<AU: Please provide the volume number and complete page range.>**.

[7] R. Melnick, "Correcting misinformation about health effects studies on cell phone radiation," *Microwave News*, June 2016 **<AU: Please provide the volume number and complete page range.>**.

[8]"Institute of environmental health secrets: NIEHS mum on $25 million RF animal project," *Microwave News*, Nov. 2015 **<AU: Please provide the author names, volume number, and complete page range.>**

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