



FDA U.S. FOOD & DRUG
ADMINISTRATION

May 23, 2019

Cindy L. Russell, M.D.
Executive Director
Beatrice A. Golomb, MD, PhD
Scientific Advisory Board
Physicians for Safe Technology
P.O. Box 7443
Menlo Park, CA 94026

Dear Dr. Russell and Dr. Golomb:

Thank you for sharing your concerns and references about radiofrequency (RF) exposures in your letter on behalf of Physicians for Safe Technology dated December 9, 2018. The Food and Drug Administration (FDA) has the responsibility¹ to establish and carry out an electronic product radiation control program designed to assure the safety of electronic product radiation exposure to people. FDA's Center for Devices and Radiological Health (CDRH) is active in this mission. CDRH plans, conducts, coordinates, and supports research, development, training, and operational activities to minimize the emissions of and the exposure of people to, unnecessary electronic product radiation. As part of this mission CDRH staff began monitoring developments in the scientific literature regarding RF exposure from wireless technologies, such as cell phones, in the early 1990s. We continue to monitor new scientific publications as they become available to review, including the references that you cited.

FDA's initial review of summaries provided by the National Toxicology Program (NTP) to the FDA contributes to our current conclusion that the weight of all available scientific evidence shows no association between RF exposure at levels at or below FCC limits and any adverse health outcomes. Our preliminary understanding of the NTP results is that the study found only equivocal (ambiguous) evidence that high levels of whole body RF exposures causes cancer in rats or mice. The study tested levels of RF exposure well above the current safety limits for cell phone RF exposure and which further demonstrates that the results are consistent with decades of evidence from other studies that support the current safety limits for cell phone RF exposure. FDA has the authority to take action if cell phones are shown to emit RF energy at a level that is hazardous.

Although bias based on funding can be a possible confounding factor in the absence of appropriate safeguards, there are many possible confounding factors that could weaken the relative strength of a research result. In the field of RF exposure and the search for possible adverse health effects possible confounding factors also include, but are not limited to: inadequate dosimetry, unreproducible exposures,

¹ Information about the Electronic Product Radiation Control (EPRC) provisions of the Federal Food, Drug and Cosmetic Act (FD&C Act) and its implementing regulations can be found at <https://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/LawsandRegulations/default.htm>.



lack of thermal monitoring, animal stresses caused by other factors (e.g., high frequency sound, vibration, different animal handling), and inadequate blinding of research results before analysis. Mitigation of as many confounding factors as possible is necessary to produce a meaningful and repeatable experimental result. In our review of scientific literature, we carefully consider the strength of the evidence given the quality of the study design, methods, and analysis. Our literature sources and conclusions are consistent with other non-industry national and international organizations. The references FDA used for benchmarking our conclusions include, but are not limited to, those found at the end of this letter.

We reviewed your discussion of effect modification and its referenced sources. From that material it appears that for effect modification to be a valid concern there must first be an established adverse effect from an exposure. Causation of an adverse effect from RF exposures at or below FCC safety limits has not been established. Similarly, the work on oxidative stress you referenced is not sufficient to establish causality of carcinogenesis or other adverse effect as a direct effect of small increases in production of reactive oxygen species.

The NTP study will be considered by FDA as one part of the larger body of scientific evidence on RF exposure. The study was designed to identify and assess potential hazard levels associated with RF at exposure levels significantly above current FCC limits for human exposure levels. FDA intended this hazard analysis to provide a basis to assess the risk to human health of RF emitted from wireless communications devices. The study was not designed to assess whether cell phones cause cancer in humans, rather, it was designed to assess the effects of whole body RF exposure in rodents at levels significantly higher than are encountered as a result of typical cellphone use. Testing at higher RF exposures helps contribute to what we already understand about the effects of radiation frequency on animal tissue, which is important for understanding how well the current safety limits protect public health.

The FDA has reviewed reports we received from individuals that attribute their symptoms to RF exposure from microwave communication, data transmittal, and measurement products (e.g., cell phones, WiFi routers, smart meters, etc.). These reports have not provided information that supports reported RF exposure as causing the adverse health effects described. We also have monitored literature regarding experiments intended to prove or disprove a causal link between RF exposure and adverse health effects as well as literature regarding the most effective treatments for individuals suffering from these symptoms. In addition, we reviewed the references you provided regarding identification of genetic markers that could be related to idiopathic environmental intolerances (IEI). Although we are not questioning the symptoms that some individuals report, the research on idiopathic environmental intolerance attributed to electromagnetic fields (IEI-EMF) does not support a finding that EMF exposure is the cause of those symptoms. For example, the evidence indicates that electromagnetic fields (EMFs) are not detectable by individuals, and the presence or absence of RF exposure does not appear to affect the timing of symptoms occurring or worsening.

A dedicated adverse reporting system is not required because CDRH already has a means for consumers to submit this type of report and those reports are received and reviewed. Instructions on how to report a problem that appears to be related to exposure to electronic product radiation is on FDA's website at: <https://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ReportaProblem/default.htm>.



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Additionally, many of the reports we have received were initially reported to the Consumer Product Safety Commission (CPSC). CPSC routinely refers complaints that appear to include electronic product radiation issues to the FDA.

Again, thank you for sharing your concerns and references about RF exposures. We share your concerns for protecting the public and take our responsibilities seriously to establish and carry out an electronic product radiation control program to protect the public health. We continue to believe existing radiofrequency energy exposure limits are sufficient to protect the public and will continue to monitor the scientific literature, adverse event reports, and other sources to evaluate the adequacy of existing safety limits.

Sincerely,

Jeffrey Shuren, M.D., J.D.
Center Director
Center for Devices and Radiological Health
Food and Drug Administration

Encl.



List of Selected References FDA Has Used as Benchmarks

The references used as benchmarks include, but are not limited to:

- SCENIHR (2015). Scientific Committee on Emerging and Newly Identified Health Risks report on Potential health effects of exposure to electromagnetic fields (EMF) European Commission Report.
- Health Canada (2015, 6/3/2015). "Safety Code 6: Health Canada's Radiofrequency Exposure Guidelines." and related documents such as the Royal Society of Canada Review and 2014 Public Consultation. – from <https://www.canada.ca/en/health-canada/services/environmental-workplace-health/reports-publications/radiation/safety-code-6-health-canada-radiofrequency-exposure-guidelines-environmental-workplace-health-health-canada.html>.
- New Zealand Interagency Committee on the Health Effects of Non-ionising Fields (2015). Interagency Committee on the Health Effects of Non-ionising Fields: Report to Ministers 2015. Wellington: Ministry of Health.
- Swedish Radiation Safety Authority (SSM)'s Scientific Council on Electromagnetic Fields (SCEF) (2018) – and the previous reports. Recent Research on EMF and Health Risk Twelfth report from SSM's Scientific Council on Electromagnetic Fields, 2017, Swedish Radiation Safety Authority (SSM). 2018.
- Health Council of the Netherlands (2014). "Mobile phones and cancer Part 2 - Animal studies on carcinogenesis 2014." Report.
- Health Council of the Netherlands (2016). "Mobile phones and cancer Part 3 Update and overall conclusions from epidemiological and animal studies." Report
- Public Health England (PHE) (2017, 6/28/2017). "Smart meters: radio waves and health." Retrieved 10/4/2017, 2017, from <https://www.gov.uk/government/publications/smart-meters-radio-waves-and-health/smart-meters-radio-waves-and-health>.
- National Cancer Institute (NCI) (2016, 5-27-2016). "Cell Phones and Cancer Risk". National Cancer Institute fact sheet. Retrieved 11-21-2016, 2016, from <https://www.cancer.gov/about-cancer/causes-prevention/risk/radiation/cell-phones-fact-sheet>.
- National Council on Radiation Protection and Measurements (NCRP) (1986). NCRP Report No. 86, Biological Effects and Exposure Criteria for Radiofrequency Electromagnetic Fields.
- National Council on Radiation Protection and Measurements (NCRP) (2005). NCRP Commentary No. 18, Biological Effects of Modulated Radiofrequency Fields.
- The publications of the International Commission on Non-ionizing radiation protection (ICNIRP) - <https://www.icnirp.org/>
- The publications of the World Health Organization's "The International EMF Project" - <https://www.who.int/peh-emf/project/en/>