May 13, 2020

Comments on the FCC's Proposed Rule (Docket No. 19-226):

"Human Exposure to Radiofrequency Electromagnetic Fields"

Submitted by

Ronald Melnick, PhD

Senior Toxicologist, National Toxicology Program,
National Institute of Environmental Health Sciences, now retired

I am submitting these comments to the FCC because I find that the proposed rule titled "Human Exposure to Radiofrequency Electromagnetic Fields," which was published in the Federal Register (Vol. 85) on April 6, 2020, does not address adverse health effects that might occur at the radiofrequency (RF) exposure limits and at the expanded range of frequencies specified in the proposed rule. In my search of that document, I found no mention of 'health effects', 'toxicity', or 'carcinogenicity' associated with exposure to RF radiation despite the extensive scientific literature on these topics. With respect to public health considerations, I find it shocking that the FCC document lacks any discussion on how health effects of RF radiation, other than tissue heating, impacted the proposed rule. Surely, the FCC is aware of the numerous health effects studies at frequencies and modulations that have been used for wireless communication and that there are no adequate long-term health effects studies at frequencies above 6 GHz, which are included in the proposed rule.

The apparent basis for the FCC's decision to ignore the health effects literature on RF radiation is the document "Commission's Notice of Proposed Rulemaking" (NPRM) (Docket No. 19–226, adopted November 27, 2019 and released December 4, 2019) that was referenced in the section on Supplementary Information of the proposed rule. Interestingly, the December 4th release of the latter document indicated that the FCC would accept comments for "60 days from [its] publication in the Federal Register". Since the NPRM was never published in the Federal Register and because it appears that that document served as the basis for the FCC's decision to ignore concerns about potential health effects of RF radiation in the proposed rule, my comments provided below focus on the unreliable nature of the December 4th document.

The NPRM appears to have been written to support the FCC's decision to retain the more than 20-year old standards for radiofrequency (RF) emissions; however, it is clear from the NPRM that the FCC has relied on a faulty narrative from the Food and Drug Administration (FDA) concerning health effects of RF radiation and in particular the utility of the National Toxicology Program (NTP) studies on cell phone radiation for assessing human health risks. Because I led the design of the NTP's toxicity and carcinogenicity studies on cell phone RF radiation and was a senior toxicologist in the

NTP for more than 28 years, I feel compelled to address these issues so that the FCC will take into account potential health effects in their proposed rule on human exposure to RF radiation.

The FCC states in paragraph 11 of the NPRM that "no evidence has moved our sister health and safety agencies to issue substantive policy recommendations for strengthening RF exposure regulation. Indeed, the FDA maintains that "[t]he weight of scientific evidence has not linked cell phones with any health problems" and that "the current safety limits for cell phones are acceptable for protecting the public health." "Accordingly, it is imprudent to revise these scientifically accepted recommendations….. especially when the FDA itself has found no evidence to support any revisions." Without the FDA performing a quantitative risk assessment on available cancer data on cell phone radiation, it is inappropriate for the FCC to accept the FDA's conclusion that "current safety limits for cell phones are acceptable for protecting the public health."

Some background is needed to understand why it is wrong for the FCC to rely on the invalid comments by FDA. Ironically, it was the FDA that nominated [1] cell phone RF radiation emitted from wireless communication devices to the NTP. The FDA requested toxicity and carcinogenicity studies in experimental animals "to provide the basis to assess the risk to human health." In making this nomination, the FDA was concerned that "existing exposure guidelines are based on protection from acute injury from thermal effects of RF radiation exposure, and may not be protective against any non-thermal effects of chronic exposures." Thus, it is clear that FDA at that time believed that the NTP could conduct a reliable evaluation of potential health effects of RF radiation through animal experiments and that if any adverse effects were observed, then those data would be suitable to assess human health risks. To address the FDA's request, the NTP conducted the largest and most expensive study on an agent ever nominated to this program.

Results from health effects studies in experimental animals are used by national and international health agencies (including the FDA) to assess human cancer risk for the following reasons; similar biological process of disease induction in animals and humans, exposures are well controlled in experimental studies thereby eliminating potential confounders, every known human carcinogen is carcinogenic in animals when adequately tested, and animal studies can eliminate the need to wait for sufficient human cancer data before implementing public health protective strategies. At the time that the NTP was developing its exposure methodology and experimental design, NTP scientists regarded previous and ongoing studies on cell phone RF radiation to be inadequate to test the prevailing assumption that cell phone RF radiation at non- or minimally thermal exposure intensities was incapable of inducing adverse health effects. For example, in most of these studies exposure durations were 2 hours or less

[1] Nomination Background: Wireless Communication Devices (CASRN: WIRELESSDEV, CELLPRADGSM, CELLPRADCDMA)

per day, animal movement was restricted, and/or animals were not provided access to drinking water during exposures.

Consequently, the NTP study was designed to challenge the assumption that RFR could not cause adverse health effects other than by tissue heating and to provide data on tissue dose and incidence of response that could be used to assess potential human health risks for any identified effects.

For the NTP chronic study, an exposure system was developed that enabled whole body exposures while animals were free roaming, had access to water during exposures, and that provided RF dosimetry in the brain at three levels: SAR = 1.5, 3.0, or 6 W/kg. These levels were selected based on results from preliminary thermal pilot and toxicity studies to ensure that these doses would not cause thermal injury. Because measured body temperatures were within 1 ^{O}C of their normal body temperature, there were no differences in body weights between exposed and sham control rats in the 2-year study, there was no indication of tissue damage in the 28-day study, and there were no exposure-related clinical observations in the 2-year study (NTP TR-595)[2], it is clear that animals in the NTP study tolerated these exposure levels.

The NTP SAR exposure levels are similar to FCC's local exposure limit for cell phone usage by the general population (SAR = 1.6 W/kg averaged over any one gram of tissue). The NTP levels are lower than FCC's local limit for occupational exposures to RF radiation (SAR = 8 W/kg). If exposures to RF radiation in the NTP study had been limited to the FCC's whole body exposure limit of 0.08 W/kg, then the brain and other organs would have been exposed to levels far below the FCC's local exposure limit; data at that exposure level would be useless for assessing organ-specific human cancer risk because exposure to the brain of rats would have been 20-fold less than the FCC's local limit for exposure to tissues such as the human brain.

The criticism that the RF levels were excessive is unfounded. Because of the limited power of an experimental study using 50 - 100 animals per exposure group to assess risk in the general population, it is unusual for such a study to only use doses in the range of permissible human exposures. In fact, exposures used in experimental carcinogenicity studies conducted by the NTP always include exposures that are greater than what most humans experience, and regulatory agencies including the FDA have used such data for nearly 40 years to extrapolate to 'acceptable' levels of human risk. Also, because animals were free roaming and had access to drinking water throughout the study, it was possible to increase the daily duration of exposure to 9 hr/day. While some may opine that this design does not represent most human exposures to RF radiation from use of cell phones (though most people carry their phones in the on-position on different parts of their bodies throughout the day), this comment is irrelevant since human risk assessments are based on the combination of exposure levels and duration of exposure.

[2] NTP Toxicology and Carcinogenicity Studies of Cell Phone RF Radiation in Rats

The NTP study found increased incidences of cancers and preneoplastic lesions in the heart and brain of rats, proliferative lesions in the rat prostate gland, DNA damage in brain cells of rats and mice (Smith-Roe et al., 2019)[3], heart muscle disease in rats, and reduced rat birth weights. The results of the NTP study underwent an extensive (3-day) external peer review,[4] and the peer-review panel concluded that the well-designed and well-conducted NTP study provided *clear evidence of carcinogenic activity* for heart schwannomas in male rats exposed to GSM and CDMA modulated RF radiation and *some evidence of carcinogenic activity* for brain gliomas in **male** rats. There were also small numbers of gliomas and heart schwannomas in exposed female rats but none in controls; the peer review panel concluded that there was *equivocal evidence of carcinogenic activity* for those tumors. The FCC's current and proposed limits for RF radiation are based on the assumption that heating is the only way in which such exposures can cause adverse health effects. The results from the NTP studies demonstrate that this assumption is wrong.

It is also important to note that the cancers identified in the NTP study (heart schwannoma and brain glioma) involved the same cell types (Schwann cell and glial cell) for which an International Agency for Research on Cancer (IARC) expert working group found evidence of increased cancer risk among cell phone users and which served as the basis for the IARC conclusion in 2011that RF radiation was *possibly carcinogenic to humans* (https://www.ncbi.nlm.nih.gov/books/NBK304630/).

After the FDA nominated cell phone RF radiation to the NTP for toxicity and carcinogenicity studies in experimental animals that could be used to provide the basis to assess the risk to human health and the NTP conducted a large and comprehensive study on cell phone RFR that an external peer-review panel concluded provided clear evidence of carcinogenic activity, Dr. Jeffrey Shuren, director of the FDA's Center for Devices and Radiological Health stated that the FDA disagrees with the conclusions of this carefully conducted, peer-reviewed study and that "these findings should not be applied to human cell phone usage." At the time of the posting of the NPRM (December 4, 2019), the FDA had only provided online statements that lacked scientific documentation. In February 2020, the FDA released an anonymously written report titled "Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer." On February 27, 2020, I wrote a letter to Dr. Shuren (provided as an addendum to these comments) in which I noted numerous and serious flaws and inaccuracies in the FDA document, as well as omissions of relevant data from both mechanistic and epidemiological studies that indicate increased cancer risks associated with exposure to RF radiation. In an earlier publication, I addressed unfounded criticisms of the NTP study results (Melnick, 2019).[5]

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[3] Smith-Roe et al., Genotoxicity of Cell Phone Radiation in Rats and Mice

[4] Peer Review of NTP Report on Cell Phone RF Radiation

[5] Melnick 2019, Utility of NTP Study on Cell Phone Radiation for Assessing Human Health Risks

The FDA needs to fulfill the intent of their nomination to the NTP and conduct a quantitative risk assessment so that the FCC can provide health-protective exposure standards. However, rather than providing a quantitative risk assessment of the NTP results, the FDA has dismissed the NTP findings, and without assessing human risk, arbitrarily claimed that "current safety limits for cell phones are acceptable for protecting the public health." This recommendation by the FDA lacks scientific merit. It is certainly unusual for an agency such as the FDA to claim it is "committed to protecting public health," when it chooses to ignore adverse health effects data that run counter to their preconceived notions.

Consequently, for the FCC to rely on the unfounded claims of the FDA shows a lack of commitment by the FCC to protecting public health. I urge the FCC to reevaluate their RF exposure standards with full consideration of potential adverse health effects for the general population and for occupational exposures. At the expanded range of frequencies included in the proposed rule (i.e., above 2.5 GHz) there are no adequate long-term health effects studies. Thus, once again considerations for human safety are based on untested assumptions, yet we know from studies and experience with cell phone RF frequencies and modulations that assumptions of safety can be wrong. The general population and workers are entitled to know if there are potential health risks associated with exposures to these higher frequencies prior to the installation of 5G antennas in neighborhoods throughout the country. The determination of potential health risks or adequate safety can best be determined from properly conducted experimental studies. The alternative of waiting 20 to 30 years to learn whether exposures to 5G radiation increased disease rates in exposed human populations is not a wise public health strategy.

ADDENDUM

Letter from Ronald Melnick to Jeffrey Shuren concerning the flaws, inaccuracies, and omissions in the FDA document "Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer"

February 27, 2020

Jeffrey Shuren, M.D., J.D.
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Email: jeff.shuren@fda.hhs.gov

RE: FDA Literature Review on Radiofrequency Radiation and Cancer

Dear Dr. Shuren,

I am writing this letter to detail major incorrect statements and omissions of relevant data in the FDA document titled "Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer." I led the design of the National Toxicology Program's (NTP) toxicity and carcinogenicity studies on cell phone radiation and I strongly believe that the anonymously written FDA document misrepresents the utility of the NTP study for assessing human health risks. In addition, the report's casual dismissal of both the mechanistic findings and the numerous results from epidemiological studies that have shown increased cancer risks associated with exposure to radiofrequency radiation (RFR) are inconsistent with the FDA's stated core mission "to protect and promote the public health."

Regarding the NTP studies on cell phone RFR, an expert peer-review panel discussed the results for 3 days and concluded (NTP TR-595; Peer-Review Report 2018) that this carefully designed and conducted study provided "clear evidence of carcinogenic activity." In contrast to the NTP and peer-review conclusions, the FDA claims that whole-body exposures used in the NTP study cannot be related to the local RFR exposures a human receives while using a cell phone. The dismissal of the NTP study results by the FDA is rather peculiar since it was the FDA's Center for Device and Radiological Health that requested the toxicity and carcinogenicity of RFR in experimental animals (CDRH nomination of RFR) "to provide the basis to assess the risk to human health," and FDA scientists were fully aware of the exposure methodology that was used in the NTP study long before those studies were begun.

The NTP study was designed to provide accurate organ-specific dosimetry that could be used to quantify risks for any adverse effect that might be identified. Most people who check on the RF emissions from their cell phones learn that the Federal Communication Commission (FCC) requires that local tissue exposures be lower than 1.6 W/kg averaged over any one gram of tissue. In the NTP study, the exposures to the brain of rats were approximately 1.5, 3.0, and 6.0 W/kg – close to the FCC's local exposure limit. For experimental studies in small groups of laboratory animals, these values are unusually close to allowable local tissue exposures in humans and require minimal extrapolation to estimate human cancer risk.

The FDA report complains that the whole-body exposures in the NTP study at 6 W/kg was 75 times higher than the exposure limit for the general population (the lower doses were 38- and 19-times that limit for the general population, but only 8- and 4-times the exposure limit for

workers). However, whole body exposures provide little information on organ-specific exposure levels. When an individual holds a cell phone next to their head, the important exposure for consideration of health risk is the local exposure. That is why the NTP study design focused on the local exposure intensities. If the animal studies had used the whole-body exposure limit of 0.08 W/kg, then the exposure to the brain of exposed animals would have been 20-fold less than the FCC's local exposure limit for the general public, i.e., a useless study for assessing human risk. It is misleading for the FDA document to ignore the local exposure limit of 1.6 W/kg and its importance for assessing organ-specific cancer risk.

The FDA document criticizes studies that did not perform histopathology evaluations blinded to the dose group, including the NTP study. However, as was pointed out previously[2], the final diagnosis of lesions in the NTP study was done by a group of pathologists who did not know whether the slides they were examining came from an exposed or an unexposed animal. In addition, for anyone questioning the diagnosis of any tissue in this study, all of the slides from the NTP studies are available for examination at the NTP archives.

The FDA document also suggests without evidence that the carcinogenic effects in rats exposed to 6 W/kg were due to the loss of their ability to maintain their body temperatures during the exposures. However, measured body temperatures were within 1 ^{O}C of their normal body temperature, there were no differences in body weights between exposed and sham control rats in the 2-year study, there was no indication of tissue damage in the 28-day study, and there were no exposure-related clinical observations in the 2-year study (NTP TR-595). Thus, it is clear that animals tolerated the exposure levels used in the NTP study. The peer reviewers of the NTP studies were fully aware of all issues raised in the FDA document, yet still concluded that the results of those studies showed clear evidence of carcinogenic activity. FDA scientists had opportunity to offer criticisms of the NTP study prior to and during the 3-day peer-review, but did not. Did the FDA somehow have an epiphany regarding the human relevance of the NTP cancer data or was there some other factor influencing their decision to dismiss those results?

Lastly, the FDA document misstates the results of the genetic toxicology tests in animals from the NTP study. For example, the FDA document claims there were "no statistically significant increases in DNA damage in female rats or either mouse sex" and the increases in DNA damage in male rats "was not statistically significant," when in fact there were significant increases and significant trends in DNA damage in the frontal cortex of male mice exposed to GSM or CDMA modulated RFR and in the frontal cortex and hippocampus of male rats exposed to CDMA (NTP TR-595).

The FDA document also claims there is a "lack of biological mechanistic plausibility," while eight *in vivo* studies cited in that document provided evidence of increased oxidative stress associated with exposure to RFR and 15 studies provided evidence of genotoxicity. In addition,

[2] Melnick RL (2019). Commentary on the utility of the National Toxicology Program study on cell phone radiofrequency radiation data for assessing human health risks despite unfounded criticisms aimed at minimizing the findings of adverse health effects. *Environ Res.* 168:1-6.

many relevant *in vivo* studies showing evidence of oxidative stress were not reported in the FDA document and there are many *in vitro* studies that have found oxidative stress associated with exposure to RFR[2]. A true risk analysis should consider both *in vivo* and *in vitro* studies when ascertaining biological mechanistic plausibility. A characteristic of many human carcinogens is the induction of oxidative stress that can subsequently lead to mutations, chromosomal translocations, and genetic instability.[3] Thus, there does exist a biologically plausible mechanism for the induction or progression of tumors associated with exposure to RFR. For studies that did not show evidence of carcinogenicity or genotoxicity, the FDA document did not comment on whether or not those studies were adequately designed with respect to animal group size, exposure levels and duration of exposure.

Regarding human studies, the FDA document cites the study by Little (2012) in which it was reported that glioma trends in the US between 1997 and 2008 have remained relatively constant, but omitted the study by Philips et al. (2018)[4] that reported a doubling in incidence of glioblastoma (frontal and temporal lobes) in England between 1995 and 2015. The latter study was published in June 2018, which is within the timeframe (August 2018) for epidemiological studies included in the FDA document.

The FDA document identified several human studies that reported risks of glioma, acoustic neuroma, and other tumor types that were increased among cell phone users. In each case, the document focused on limitations in those studies to raise doubt about their reliability for assessing cancer risk. Two limitations specified for most case-control studies included selection and recall bias. However, the FDA document neglected to discuss the impact of the study by Momoli et al.(2017),[5] which re-analyzed the Canadian data that was included in the Interphone study and showed that there was no effect on the risk of glioma after adjustments were made for selection and recall biases; the odds ratios (OR) for glioma were significantly increased when comparing the highest quartile of use to those who were not regular users whether or not adjustments were made: OR = 2.0, 95% confidence interval 1.2–2.4 without adjustment; OR = 2.2 95% confidence interval 1.3–4.1 with adjustments. Evidently, selection and recall biases do not explain the elevated brain cancer risks associated with use of cell phones in that study.

Thus, while there are reliable animal studies, mechanistic studies, and animal studies showing increased cancer risks associated with exposure to cell phone RFR, the FDA document dismisses nearly the entirety of those studies to enable the agency to conclude that there is insufficient

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[2] Yakymenko I, Tsybulin O, Sidorik E, et al. (2016). Oxidative mechanisms of biological activity of low-intensity radiofrequency radiation. *Electromagn Biol* Med 35: 186-202.

[3] Smith MT, Guyton KZ, Gibbons CF, et al. (2016). Key characteristics of carcinogens as a basis for organizing data on mechanisms of carcinogenesis. *Environ Health Perspect*. 124:713-721.

[4] Philips A, Henshaw DL, Lamburn G, O'Carroll MJ. (2018). Brain tumours: rise in glioblastoma multiforme incidence in England 1995-2015 suggests an adverse environmental or lifestyle factor. *J Environ Public Health*. Article ID 7910754,

[5] Momoli F, Siemiatycki J, McBride ML, et al. (2017). Probabilistic multiple-bias modeling applied to the Canadian data from the Interphone study of mobile phone use and risk of glioma, meningioma, acoustic neuroma, and parotid gland tumors. *Am J Epidemol*. 186:885-893.

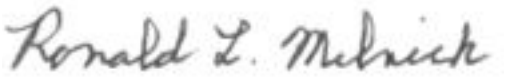
evidence to support a causal association between RFR exposure and tumorigenesis. According to the FDA, animal studies are not useful for studying potential effects in humans (though animal studies are used in drug development) and the human studies "were subject to flaws and inaccuracies." Yet, every known human carcinogen is carcinogenic in animals when adequately tested. Public health agencies including the NTP, US EPA, IARC, and the FDA have a long tradition of relying on the relevance of rodent toxicology/carcinogenicity studies to identify hazardous agents and assess human health risks in order to implement public health protective policies. The statement in the FDA report that "if any risk does exist, it is extremely low" is very misleading since the FDA has not performed a quantitative risk assessment on any of the available data sets and, because of the widespread use of cell phones in the US and world-wide, even a small increase in cancer risk would have a serious public health impact.

Based on the FDA review, which is not a risk analysis as stated in the document, the message for the general public appears to be that precautionary measures for use of cell phones are not necessary in spite of the fact that numerous studies have provided compelling evidence of increased cancer risk associated with exposure to cell phone RFR. This is an irresponsible message for a government agency that claims its mission is to protect consumers and promote the public health.

The statement on the FDA website (https://www.fda.gov/radiation-emitting-products/cell-phones/do-cell-phones-pose-health-hazard) that there is a "scientific consensus on cell phone safety" is totally wrong and should be removed since there is no scientific consensus supporting this claim. In contrast, numerous experts in the field have reported evidence that current levels of cell phone radiation can be harmful to human health.

In conclusion, the FDA document has serious flaws and inaccuracies, as well as omissions of relevant data. Hence, in consideration of public health, it is important that FDA immediately retract their review on radiofrequency radiation and cancer.

Sincerely,



Ronald L. Melnick, Ph.D.
Retired toxicologist NTP, NIEHS