



September 24, 2020

The Honorable David Trone
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Trone:

Thank you for your inquiry of March 13, 2020, on behalf of your constituent, Ms. Theodora M. Scarato, regarding the impact of radiofrequency radiation (RFR) exposure on human health and requesting research information that the Food and Drug Administration (FDA or the Agency) has used to determine that current safety limits for cell phone RFR energy exposure are acceptable for protecting the public health.

FDA takes any possible issues raised with respect to public health extremely seriously. We appreciate the opportunity to provide an overview of the substantial body of scientific evidence that has informed our determination that the current safety standard for RFR exposure remains appropriate.

The Agency has taken a comprehensive approach to evaluating the scientific evidence regarding the impact of RFR exposure on human health. In the attached summary, FDA explains the critical considerations that we have made in evaluating all available information on this and other related topics.

Thank you for contacting us in this matter. Please do not hesitate to contact us if you have additional questions.

Sincerely,

Andrew Tantillo
Acting Associate Commissioner of
Legislative Affairs

Enclosure: RFR Summary

Summary of the Food and Drug Administration's (FDA) Review of the Scientific Evidence Regarding the Safety of Radio Frequency Radiation (RFR)

FDA's Findings.

FDA's conclusion that the current safety limits for cell phone RFR exposure remain acceptable for protecting the public health is supported by the considerable body of peer-reviewed scientific publications as well as public registries of, for example, cancer rates that show a slight decrease in brain tumors despite the enormous increase in cell phone use over the last two decades. Additionally, the Agency has not seen credible evidence that the roll out of 5G handsets will lead to additional risk for the population.

FDA considers all relevant scientific data on RFR and does not limit its considerations to any specific frequency or modulation due to the increasing use of, for example, Wi-Fi enabled medical devices. The Agency's ongoing evaluations include but are not limited to those frequencies currently being used by cell phones as well as those being considered for future uses (e.g., 5G).

FDA's standard for assessing risk to public health remains the data and information that is available for studying effects on humans. Animal and laboratory studies can provide useful supporting scientific information, but it is clear that the relevance of the data on human health is the most informative information where it is available. In the case of cell phone handsets, there is abundant evidence to support FDA's conclusion from epidemiological studies, public health surveillance data and supportive laboratory studies. The information on which FDA has based its conclusion is summarized below, together with a description of the methods that the Agency uses for undertaking risk analysis and other relevant scientific information.

Information Sources.

Peer-Reviewed Publications

Standard practice in scientific evaluation is to use the broadest set of credible information available and then to assess the significance of that information to the question at hand. The most commonly used source of information is the set of peer-reviewed publications that are indexed through Medline and typically retrieved through PubMed, which currently references over 29 million citations of biomedical literature. FDA uses this source as well as

more specific sources of information where appropriate. For the ongoing monitoring of possible effects of RFR, for example, the Agency also uses the Electromagnetic Frequency (EMF) Portal [1] as a potential source for peer-reviewed papers to ensure as wide a coverage as possible.

FDA also considers independent studies that are separately published, though the Agency often undertakes its own review of the papers analyzed in those reports. Recent examples of independent studies that FDA considered include the 2013 International Agency for Research on Cancer (IARC) study [6], the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR 2015, [11]), the Swedish Radiation Safety Authority's (SSM) Scientific Council reports on EMF [12-17], and the 2017 reports from the National Toxicology Program studies on the effects of whole body irradiation of rodents [7 and 8], as well as other reports [3-5,18].

The main health outcomes on which FDA focuses (for the current question) relate to tumorigenesis and cancer given the public health concerns that have been expressed about possible effects of RFR emissions specifically, though all public health concerns that are discerned from FDA's evaluation of scientific evidence are considered. The Agency examines evidence for any possible causal relationship between RFR exposure and tumorigenesis (cancer) based on both *in vivo* (animal) studies as well as available epidemiological evidence pertaining to RFR exposure.

Epidemiological Studies and Public Health Surveillance Data

Based on FDA's ongoing evaluation, the available epidemiological and cancer incidence data continues to support the Agency's position that there are no quantifiable adverse health effects in humans caused by exposures at or under the current cell phone exposure limits.

In the last decade, there have been approximately 70 relevant epidemiological studies that have been published as peer-reviewed scientific evidence. As part of our ongoing monitoring activities, we have analyzed these publications for specific outcomes including brain and other tumors as well as other potential adverse events, and while some studies suggest a possible link between, for example, "heavy" users of cell phones and some tumors, there is no clear and consistent pattern that has emerged from these studies. As an example of the complexity of the situation, a large cohort study on skin cancers [10] appeared to demonstrate a borderline increase for basal cell carcinoma among women with 5-9 years of mobile phone subscription. This slightly elevated risk, however, was not apparent in the population with longer subscriptions (10-12 years or over 13 years). Under

the principles of dose response, a higher dose or amount of a causative agent will lead to a higher or similar effect, but not a reduced effect. The findings briefly described above do not adhere to this principle (where longer cellphone use did not lead to a higher health risk) and therefore are likely to be the result of chance – a false positive.

We also monitor the Surveillance, Epidemiology, and End Results (SEER) database maintained by the National Cancer Institute (NCI) at the National Institutes for Health (NIH), which continues to demonstrate that brain cancer rates are not increasing despite the significant uptake of cell phone usage. Ascribing changes in population-based health related outcomes to single causes is always challenging. Even so, there are highly reliable statistics on the current rates of cancer in the US population, and FDA continues to believe that studying the population rates of brain cancer is an appropriate marker for the assessment of risks to public health that may be associated with cell phone use. Data from the SEER database for brain and other nervous system cancer incidence rates shows that from 2000 to 2016 the rate of such cancers has gone down from a rate of 6.9 per 100,000 (confidence intervals 6.7 – 7.0) to a rate of 5.9 cases per 100,000 (confidence interval 5.8 to 6.1) in 2016. NCI also estimates that from 1987 to 2016, the rate of such tumors has been dropping by approximately 0.2% per year.

The NCI data clearly demonstrate that there is no widespread rise in brain and other nervous system cancers in the last (nearly) two decades despite the enormous increase in cell phone handset use during this period. The Pew Research Center estimates that from 2002 to 2019, the percentage of the population owning a cell phone or smartphone has risen from 62% to 96%, and yet there is a small decrease in brain and other nervous tissue cancer rates. This is not a likely scenario if cell phones are causing cancer.

***In Vivo* Scientific Studies**

There is no clear evidence that RFR exposure at levels experienced by the public from cell phone use leads to tumorigenesis in published *in vivo* studies.

Over the last decade, there have been approximately 125 articles that are most relevant for the study of RFR on animals. However, none have demonstrated convincing evidence that localized exposure of RFR at levels that would be encountered by cell phone users can lead to adverse effects.

In vivo studies assessing possible adverse or other effects of RFR are extremely challenging studies to design and undertake for several reasons. These reasons include the engineering considerations of applying a RFR field to animals that may specifically simulate, for example, the localized exposure of tissue to a cell phone held to the ear. Many researchers therefore undertake whole body exposure of the animals to the RFR radiation to overcome the challenges noted above. However, the effects of whole body exposure data may not reflect what happens in the real-world situation of localized exposure around the ear from a handset.

There are also considerable difficulties in determining the specific absorption rate (SAR) RFR that animals may be exposed to in a study setting and relating that to human exposure. Additionally, it is difficult to separate the effects of direct RFR exposure, if there are any that occurred, from the well-documented indirect effects of temperature rise (the only proven biological mechanism of RFR on tissue) and the stress encountered by experimental animals from whole body exposure even in the minority of scientific reports that suggest a link. Both increased body temperature and stress from any cause have been linked to an increase risk for developing tumors in animals.

Given the difficulties of conducting *in vivo* studies on the effects of RFR described above and the widespread use of cell phones, epidemiological and real-world evidence tend to provide more relevant and accurate information related to possible risk from RFR exposure caused by cell phone use. *In vivo* studies are clearly of immense value in medical science, but they are less useful than studying effects on the human population, where that is feasible.

FDA Review of NTP Reports

As we have stated in the past, the Agency disagrees with the conclusions of the rodent studies conducted by the National Toxicology Program (NTP) at the request of FDA [7 and 8]. These studies were conducted with high power levels of RFR over the whole body of the experimental rodents in intervals (10 minutes on 10 minutes off) for 2 years that do not reflect the levels to which people are exposed from cell phone use and entail the same problems as other whole body animal exposure studies. In addition to the concerns we noted earlier about extrapolating the results of such studies to local effects in the human body, the NTP studies did not adequately account for other possible causes of effects seen including temperature rises and stress to the animals. Furthermore, no effects were seen in mice of either sex or in female rats. As noted by the director of the NTP studies in the NIH Press Release accompanying the study results, "The levels and duration of exposure to RFR

were much greater than what people experience with even the highest level of cell phone use, and exposed the rodents' whole bodies. So, these findings should not be directly extrapolated to human cell phone usage."

No New implications for 5G

As part of this summary of FDA's conclusions, it is important to address concerns about the implications for 5G technology. While many of the specifics of 5G remain ill-defined at this point in time, it is known that 5G cellphones will likely use higher frequencies than those currently in use [2]. The current body of scientific evidence covers these frequencies and the fundamental physics involved has been well understood for many years. The slightly higher frequencies are associated with correspondingly higher energy levels, but remain significantly lower than the energies associated with other forms of electromagnetic waves, including visible light. Additionally, these higher frequencies are known to penetrate less deeply into tissue compared with the frequencies currently in use for cellphones [19]. All frequencies used for communications (and visible light) are classified as non-ionizing (i.e. these frequencies do not carry sufficient energy to cause atoms or molecules to lose electrons and become ionized). This is in stark contrast to the energies associated with, for example, X-rays or gamma rays, which carry up to a billion times more energy than the radio wave frequencies in use by cell phones, and are well documented as a cause of cancer. Based on this information, the new 5G technologies are unlikely to pose additional risks to health for individuals. FDA will continue to monitor scientific information as it becomes available regarding the impacts of 5G.

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