Scientific Evidence for Cell Phone Safety

The state of scientific knowledge continues to demonstrate that:

- The current limit on radio frequency (RF) energy set by the Federal Communications Commission remains acceptable for protecting (https://www.fcc.gov/general/radio-frequency-safety-o) the public health. The FDA recently provided an updated assessment of the current limits based on the currently available scientific evidence (see Letter from the FDA to the FCC on Radiofrequency Exposure (/media/135022/download) PDF 74KB).
- To date, there is no consistent or credible scientific evidence of health problems caused by the exposure to radio frequency energy emitted by cell phones (see Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer (/media/135043/download) – PDF 1.3MB).

The FDA's doctors, scientists and engineers continually monitor the scientific studies and public health data for evidence that radio frequency energy from cell phones could cause adverse health effects. If a credible risk is detected, the FDA will work closely with other federal partners to mitigate the risk.

The gold standard for the assessment of risk to public health remains the data and information that is available from studying effects on humans. The currently available epidemiological studies, public health surveillance data, and supportive laboratory studies on cell phone radiation provide abundant evidence to support the FDA's determination.

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Epidemiological Studies and Public Health Surveillance Data

As part of ongoing monitoring activities, the FDA analyzes published epidemiological studies for specific outcomes including brain and other tumors as well as for any evidence of other adverse events. No clear and consistent pattern has emerged from epidemiological studies. Based on the evaluation of the currently available information, the FDA believes that the weight of the scientific evidence does not support an increase in health risks from radio frequency exposure from cell phone use at or below the radio frequency exposure limits set by the FCC.

The FDA also monitors the Surveillance, Epidemiology, and End Results (SEER) (https://seer.cancer.gov/) database maintained by the National Cancer Institute (NCI) at the National Institutes for Health (NIH). The SEER data show that brain cancer rates are not increasing in the United States despite the significant increase in the number of cell phone users.

Ascribing changes in population-based health related outcomes to single causes is always challenging. Even so, the SEER data provide highly reliable statistics on the current rates of cancer in the U.S. population. As a highly relevant example, 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) in 2000 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 no widespread rise in brain and other nervous system cancers in the last (nearly) three decades despite the enormous increase in cell phone 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 percent to 96 percent, and yet there is a small *decrease* in brain and other nervous tissue cancer rates.

In Vivo Scientific Studies

Published *in vivo* studies have yielded no clear evidence that radio frequency energy exposure at levels experienced by the public from cell phone use leads to tumorigenesis.

Over the last decade or so, many scientific articles have been published on the effects of radio frequency energy on animals. None of these articles have produced convincing evidence that localized exposure of radio frequency radiation (RFR) at levels that would be encountered by cell phone users can lead to health problems. Although some researchers have reported adverse biological changes associated with RF energy, these studies have not been replicated. Most published studies have failed to show an association between exposure to RF energy from a cell phone and health problems.

In vivo animal studies assessing possible adverse or other effects of radio frequency energy are extremely challenging studies to design and undertake due to numerous confounding factors. The methodological flaws and weaknesses in many radio frequency energy exposure studies include:

Failure to accurately determine the specific absorption

rate (SAR) of exposures to radio frequency energy

- Failure to use a reproducible source of radio frequency energy
- Failure to verify the subject animal's core temperature did not increase during exposure
- The use of too few animals
- Failure to include adequate controls (e.g., sham exposures that do not account for vibration or high frequency sound that accompany radio frequency exposure, lack of positive controls, etc.)
- Incomplete reporting
- Improper interpretation of results

In addition, the results from studies on whole-body exposures are not comparable to real world local exposures as occurs with cell phone use. In a whole-body exposure, the animal's temperature will rise until exposure is stopped. By contrast, in a local exposure, blood flow cools the area of exposure.

The FDA's Review of the National Toxicology Program's Studies on High Dose Radio Frequency Radiation

In 2018, the National Toxicology Program (NTP) published the results of two hazard identification studies conducted at the request of the FDA. The studies were conducted with high power levels of RFR over the whole body of experimental rodents. The radio frequency energy was delivered in intervals of 10 minutes on and 10 minutes off for 18 hours and 20 minutes a day, every day for 2 years.

The conclusions relating to public health risks reached by the FDA's scientists differ from those of the NTP, and the FDA determination is that the study did not demonstrate that cell phones cause cancer.

5 Facts About the Rat Study

1. Rats received radiation over their *entire bodies*.

- Rats received this whole-body radiation for *9 hours per day* for their *entire lives*.
- Rats received levels of radiation that were up to 75
 times higher than the whole-body exposure limit
 for people.
- 4. The study found **no health effects** on female rats or mice (both male and female) exposed to these extreme conditions that passed a test for statistical significance.
- 5. Exposed rats *lived longer* than the control group rats.

The design did not reflect the partial-body radio frequency exposure people receive from cell phone use and as noted by the NTP in their February 2018 press release (https://www.nih.gov/news-events/news-releases/high-exposure-radiofrequency-radiation-linked-tumor-activity-male-rats):

"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."

International Agency for Research on Cancer (IARC) Monograph

In 2013, the **International Agency for Research on Cancer (IARC)** published a monograph
(https://publications.iarc.fr/Book-And-Report-Series/Iarc-Monographs-On-The-Identification-Of-Carcinogenic-Hazards-To-Humans/Non-ionizing-Radiation-Part-2-Radiofrequency-Electromagnetic-Fields-2013) (http://www.fda.gov/about-fda/website-disclaimer) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) that classified radio frequency fields as possibly carcinogenic to humans (class 2B). This

classification is an indication that more research is probably justified. The 2013 IARC classification was based on limited evidence in humans which were from a few case-control epidemiological studies.

The IARC committee acknowledged that those studies were susceptible to certain limitations such as recall errors by the participants and the selection criteria for participation. The classification was also based on a few animal studies which had only weak mechanistic evidence relevant to carcinogenic action. The determination that the IARC committee made was that the evidence in humans could not be dismissed as only due to bias for the group that received the highest exposures.

In the monograph, the IARC committee stated that, "Time trends in cancer of the brain have not shown evidence of a trend that would indicate a promptly acting and powerful carcinogenic effect of mobile-phone use."

There are several more time trend papers that have been published since the 2013 IARC monograph. These newer time trend studies further demonstrate that while use of cell phones has risen rapidly, the incidence of brain cancer has not risen.

No New implications for 5G

The FDA is responsible for, among other things, ensuring cell phones – and any radiation-emitting electronic product – are safe for the public to use. This includes, understanding the health risks (if any) of new electronic products that emit radiation as they become widely available to the U.S. public, such as 5G cell phones. While many of the specifics of 5G remain ill-defined, it is known that 5G cell phones will use frequencies covered by the current FCC exposure guidelines (https://docs.fcc.gov/public/attachments/DOC-358968A1.pdf) (300 kHz-100 GHz), and the conclusions reached based on the current body of scientific evidence covers these frequencies. The FDA will continue to monitor scientific information as it becomes available regarding the potential impacts of 5G.

Electromagnetic Hypersensitivity: Idiopathic

Environmental Intolerance to Electromagnetic Fields

To date, the scientific evidence indicates symptoms experienced by people who self-identify as having electromagnetic hypersensitivity occur when the individual believes they are being exposed to radio frequency energy. Based on the available scientific evidence, their very real symptoms are not the result of radio frequency exposures. Many studies have been done to determine if participants can determine if they are being exposed to RF or a sham exposure. The results indicate people cannot sense when they are being exposed to RF. The World Health Organization has a fact sheet on this subject: Electromagnetic Hypersensitivity (https://www.who.int/peh-emf/publications/facts/fs296/en/) (http://www.fda.gov/about-fda/website-policies/websitedisclaimer) (http://www.fda.gov/about-fda/websitepolicies/website-disclaimer). The FDA continues to monitor all scientific publications in this area.

Scientific Information About Radio Frequency Exposure

Other sources of scientific information about RF exposure and safety is available from these U.S. and international organizations:

- Federal Communications Commission (FCC):
 Wireless Devices and Health Concerns
 (https://www.fcc.gov/consumers/guides/wireless-devices-and-health-concerns)
- National Cancer Institute (NCI):
 Cell Phones and Cancer Risk
 (https://www.cancer.gov/about-cancer/causes-prevention/risk/radiation/cell-phones-fact-sheet)
- Center for Disease Control and Prevention (CDC):
 Frequently Asked Questions about Cell Phones and Your
 Health
 (https://www.cdc.gov/nceh/radiation/cell_phones._faq.html)
- World Health Organization (WHO):
 Electromagnetic fields and public health: mobile phones
 (https://www.who.int/en/news-room/fact-

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sheets/detail/electromagnetic-fields-and-public-health-mobile-phones) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
What are the health risks associated with mobile phones and their base stations?
(https://www.who.int/features/qa/3o/en/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
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- International Agency for Research on Cancer (IARC):
 IARC Monographs on the Evaluation of Carcinogenic
 Risks to Humans Volume 102: Non-ionizing Radiation,
 Part 2: Radiofrequency Electromagnetic Fields
 (https://publications.iarc.fr/126)
 (http://www.fda.gov/about-fda/websitepolicies/website-disclaimer)
 (http://www.fda.gov/about-fda/websitepolicies/website-disclaimer)
 - International Commission on Non-Ionizing Radiation
 Protection (ICNIRP):
 Mobile Phones, Brain Tumours and The Interphone
 Study: Where Are We Now?
 (https://www.icnirp.org/cms/upload/publications/ICNIRPSCIreview2011.pdf
 (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
 (http://www.fda.gov/about-fda/website-policies/website-disclaimer) (PDF)
 Mobile Phones
 (https://www.icnirp.org/en/applications/mobile-

(https://www.icnirp.org/en/applications/mobile-phones/index.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)