

March 14, 2019

Ron Melnick, PhD Senior Toxicologist and Director of Special Programs in the Environmental Toxicology Program at the National Institute of Environmental Health Sciences (NIEHS) National Institutes of Health (retired)

Dear Dr. Melnick et al:

Thank you for your letter, dated December 17, 2018.

The Food and Drug Administration (FDA) is charged with ensuring cell phones—as a radiation-emitting electronic product—are safe for the public to use. Our scientific expertise and input, along with other health agencies, are used by the Federal Communications Commission (FCC) to set the standards for exposure limits of radiation from cell phones, called radiofrequency (RF) energy.

Animal studies, like the one done by the National Toxicology Program (NTP), contribute to our discussions on this topic. However, this study was not designed to test the safety of cell phone use in humans, so we cannot draw conclusions about the risks of cell phone use to people from it. We also must thoroughly evaluate and take into consideration the totality of the data, and do so within the context of the complete body of available evidence rather than drawing conclusions from the results of a single study.

As part of our commitment to protecting the public health, the FDA has reviewed, and will continue to review, many sources of scientific and medical evidence related to the possibility of adverse health effects from radiofrequency energy exposure in both humans and animals and will continue to do so as new scientific data are published. As scientists, we welcome new studies.

As our colleagues at NTP noted in a <u>statement</u> earlier this year about their draft final report, "the levels and duration of exposure to radiofrequency radiation 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."

We reviewed the recently finalized research conducted by our colleagues at NTP on RF energy exposure. After reviewing the study, we disagree, however, with the conclusions of their final report regarding "clear evidence" of carcinogenic activity in rodents exposed to radiofrequency energy. The FDA discussed its concerns regarding the draft and final reports with NTP representatives.

In the NTP study, researchers looked at the effects of exposing rodents to extremely high levels of radiofrequency throughout the entire body. This is commonly done in these types of hazard identification studies and means that the study tested levels of radiofrequency energy exposures considerably above the current whole body safety limits for cell phones. Doing this was intended to help contribute to what we

already understand about the effects of radiofrequency energy on animal tissue. In fact, we only begin to observe effects to animal tissue at exposures that are 50 times higher than the current whole body safety limits set by the FCC for radiofrequency energy exposure.

Cell phones emit low levels of RF energy. Over the past 15 years, scientists have conducted hundreds of studies looking at the biological effects of the RF energy emitted by cell phones. While some researchers have reported biological changes associated with RF energy, these studies have failed to be replicated. The majority of studies published have failed to show an association between exposure to radiofrequency from a cell phone and health problems.

The low levels of RF energy cell phones emit while in use are in the microwave frequency range. They also emit RF energy at substantially reduced time intervals when in the stand-by mode. Whereas high levels of RF energy can produce health effects (by heating tissue), exposure to low level RF energy that does not produce heating effects causes no known adverse health effects.

As has been stated by the NIH, prior human, observational data collected in earlier, large-scale population-based studies have found no conclusive evidence of an increased risk for developing cancer from cell phone use. Additionally, it is important to note that the results of the majority of scientific studies conducted to date have not linked RF energy exposure from using cell phones with any health problems.

Thank you again for your inquiry and your attention to this matter.

Sincerely.

Jeffrey Shuren, M.D., J.D.

Center Director

Center for Devices and Radiological Health

Food and Drug Administration