Jeffrey Shuren, MD, JD,
Director of the FDA's Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Sent August 26, 2019

Questions RE: FDA's Statement on RF limits and FDA's Rejection of the Cancer Association Found in the National Toxicology Program Radiofrequency Cell Phone Research Studies

Dear Dr. Jeffrey Shuren;

In December 2018, and April 2019 we sent you a letter inquiring as to why the FDA rejected the National Toxicology Program cell phone radio frequency radiation (RFR) study findings of clear evidence of cancer and also why the FDA has put forth a statement that RF limits do not need to be changed. On August 13, 2019 you responded with a letter dated March 12, 2019. In addition, you sent a letter to the FCC regarding RF. Both letters state RF limits do not need to be changed to protect public health. However, almost all of our questions as to how the FDA came to this determination remain unanswered and we have not been provided any documentation. Thus, we are writing for clarifications. In light of the billions of cell phone users, including children, babies and pregnant women, we hope that the FDA can provide answers to our questions as soon as possible.

1. The FCC issued an August 8, 2019 press release stating RF limits do not need to be changed as "The FCC sets radiofrequency limits in close consultation with the FDA and other health agencies. After a thorough review of the record and consultation with these agencies, we find it appropriate to maintain the existing radiofrequency limits, which are among the most stringent in the world for cell phones."

Can you please provide us the FDA reports and documentation regarding the FDA/FCC "consultation" referenced by the FCC in the FCC release.

2. The FDA stated to the FCC they are engaged in "ongoing monitoring activities" and research reviews related to radiofrequency radiation.

Please provide us with reports or documentation of your monitoring and research reviews of the health impacts of RF. (i.e., What studies have you reviewed? Which staff is engaged ? What is the budget? How many hours are dedicated to this monitoring?)

3. In your August letter to us you stated that "exposure to low level RF energy that does not produce heating effects causes no known adverse health effects." This statement is simply untrue. However, the NTP studies were carefully controlled to minimize any potential heating/thermal effects of RF on exposed animals, yet clear evidence of cancers and other adverse health effects were found at non

heating levels. The tumor and genotoxicity data (DNA strand breaks), as well as the induction of cardiomyopathy of the right ventricle in male and female rats from the NTP study clearly show that the null hypothesis (i.e., low-level cell phone radiation at thermally insignificant exposures cannot cause adverse health effects) has been disproved. Furthermore the studies done by the Ramazzini Institute in Italy showed the very same cancers occurring in rodents exposed to even lower intensities of RF. The scientific evidence simply does not support the position of the FDA.

On what basis is the FDA stating that non heating levels do not cause adverse health effects? As the NTP study exposures were non thermal, and effects were found, does the FDA fully reject the findings in totality?

4. The August 2019 Letter stated, "While some researchers have reported biological changes associated with RF energy, these studies have failed to be replicated." However several important studies show replication and various biological changes from EMF are well recognized. For example, Lerchl et al. 2015 replicated Tillmann et al. 2010 findings of tumor promotion in mice, Foerster et al. 2018 replicated the Schoeni et al. 2015 findings of memory impairments in teens and Divan et al. 2012 replicated Divan et al. 2008 finding behavioral issues in children. Research consistently finds alterations in the electroencephalogram (EEG) (Loughran et al. 2012; Lustenberger et al. 2013; Regel et al. 2007; Schmid et al. 2011). Perhaps most important, independent, case-control studies have found that long-term use of cell phones increases risk for specific tumor types also found in the NTP study (Interphone Study Group. 2010; Hardell et al, 2013; Coureau et a. 2014, Carlberg and Hardell 2017). Which important studies are you referring to that "failed to be replicated?

5. In our December 2019 letter, we asked for the following but did not receive an answer in your 2019 response. We can only assume they do not exist or are not publicly available.

We respectfully ask for these documents again.

1. Technical comments by the FDA that substantiate the FDA's conclusions that NTP's study did not find "clear evidence" of carcinogenicity for RF-EMF.
2. FDA's conclusions of evidence from the FDA in regards to the NTP data regarding the schwannomas of the heart in male rats, the brain gliomas in the male rats, the DNA damage, and the cardiomyopathy of the heart.
3. *Documentation on the* FDA's review process for the NTP study (which scientists, agendas for meetings and notes)
4. Statements by FDA on their criticisms of the NTP study design at any time over the last twenty years since the FDA first asked the NTP for animal toxicity and carcinogenicity studies on cell phone radiofrequency radiation because of FDA's concerns at that time that existing exposure guidelines "may not be protective against non-thermal effects of chronic exposures.".
5. A decision as to whether the FDA will be performing a quantitative risk assessment based on the NTP data.

6. You stated in your letter that "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." However, the NTP was specifically designed to look at localized exposures (not full body limits), comparable to absorption levels when the phone is held next to the head. In fact, all NTP exposures are lower than US cell phone localized radiation SAR absorption limits for public and workers.The Ramazzini Institute used exposures even lower than the NTP and also found tumor increases. The animal study results on schwannoma and glioma are of particular concern since they corroborate human epidemiological findings. Scientists have submitted comprehensive testimony to the FCC and in published reports on the fact that the safety factor is non existent. Perhaps most importantly, the NTP study exposure system was carefully designed to test for adverse effects at levels that did not create significant heating.

Please explain why the FDA believes there is a safety factor. As the Chicago Tribune tests indicate, the localized SARs could be at levels that exceed 6 W/kg (the highests SAR in the NTP) when the phone is at body contact. Please also explain why the FDA is not considering that the NTP exposure levels were just near to localized public SAR limits and all of them were within occupational localized SAR limits. Your misleading statement does not preclude the need for a quantitative risk assessment of the NTP data.

7. As highlighted by investigations of the Chicago Tribune and CBC, a recently published study finds the ANFR cell phone tests of the French government indicate cell phone radiation can exceed US limits *up to 11 times* when tested in accordance with FCC standards in positions mimicking a phone touching the body. When Theodora Scarato sent the ANFR test data to the FDA years ago (along with copious documentation on adverse effects of cell phone radiation), informing the FDA about this new documentation on how cell phones exceed legal limits, the FDA asked for the full test reports. These cell phone test results were sent to the FDA, yet no FDA action has been taken to inform the public. The FDA has a responsibility to protect the public. The FDA could ensure cell phones are compliant with radiation limits in any use condition and could immediately inform the American people that cell phones in body contact positions can result in radiation absorption that violates US limits.

We would like to know why the FDA has not taken action to inform the public about the separation distances in light of this published analysis. We also would like to know if the FDA has a specific SAR level that will trigger a FDA action as the FDA has been aware of SAR violations for years.

8. We note that Senator Blumenthal has also asked the FDA and FCC questions about the safety of new wireless technologies such as 5G. In a February 2019 Senate Commerce hearing Blumenthal stated, "if you go to the FDA website, there basically is a cursory and superficial citation to existing scientific data" on the health and safety of wireless and 5G. He concluded that, "We're kind of flying blind here, as far as health and safety is concerned."

If you have provided any scientific information to Senator Blumenthal documenting why the FDA is of the opinion that RF limits do not need to be updated (research or reports), could you please share it with us and with the public.

Sincerely,

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, now retired.

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