September 26, 2019

Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Attention: Dr. Jeffrey Shuren, MD, JD, Director
Center for Devices and Radiological Health
Subject: Rescind Opinion to FCC on Radiofrequency Exposure Limits

Dear Dr. Shuren,

We urge you to rescind your recent endorsement of the adequacy of current FCC public safety limits for electromagnetic radiation. The FCC Press Release dated August 8, 2019 specifies that Ajit Pai, Chairman of the FCC is relying on your agency's endorsement of current safety limits in order to justify 'no change'.

> *"As Jeffrey Shuren, Director of the Food and Drug Administration's Center for Devices and Radiological Health, wrote to the FCC, "[t]he available scientific evidence to date does not support adverse health effects in humans due to exposures at or under the current limits..." and "[n]o changes to the current standards are warranted at this time."*

There is no indication that CDRH has updated its assessment of scientific publications and conducted a thoughtful, independent scientific evaluation of the strong evidence for carcinogenicity of EMR. The FDA can reasonably be expected to show how it is taking into account the recent scientific evidence and how it is modifying the FDAs advice to other agencies, including the FCC on the adequacy of current RF public safety standards.

The FDA presents grossly outdated and incomplete information on its website regarding what is known today about cell phone radiation health risks. A complete update of the FDA website is urgently needed to reflect the last 5-10 years of scientific studies showing statistically significant risk of cancer and neurological disease from RF at what are today legal exposure levels. It is inconceivable that the recent publication of the National Toxicology Program results reporting

statistically significant cancer risk from cell phone radiation is omitted (the animal toxicity studies which tool 16 years to complete at a cost of $30 million). This US Government sponsored study was conducted for the specific purpose of testing animal toxicity of EMR to complete the picture emerging from human epidemiological studies and *in vivo* and in vitro studies that preceded it. Animal studies are of course performed to test carcinogenicity and are accepted to be applicable to human cancer risk, or there would be no point in doing them.

The FDA cannot reasonably give a positive assertion of safety for the FCCs cell phone radiation safety standards in 2019 given the extensive scientific basis now available for review and assessment. The available scientific evidence to date does support adverse health effects in humans due to exposures at and under the current limits. Changes to the current FCC public safety standards for electromagnetic radiation are clearly warranted at this time.

We urge you to address this issue quickly, before the FCC completes its reassessment of health risks from EMR. If the FCC is relying on your agency, and your agency is not able or willing to provide a adequate health review using the currently available information, the public health consequences will be enormous.

Submitted on behalf of the BioInitiative Working Group by;

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FDA Website Links

1) https://www.fda.gov/radiation-emitting-products/home-business-and-entertainment-products/cell-phones

This webpage says current as of 8/29/18. The information is seriously outdated and therefore distorts and minimizes health risks that are already sufficiently demonstrated to warrant public health warnings and new, tighter safety limits. The standard of evidence for judging this evidence should not be based on absolute certainty of risk, but the sufficiency of evidence to trigger public health warnings. It is grossly deficient.

Citing the Interagency Radiofrequency Working Group as a show of involvement is preposterous. This group indicated in 1999 the need for more research on pulsed RF given the scientific evidence for biological effects at that time, twenty years ago.

This page also notes "*the FCC relies on the FDA and other health agencies on health and safety related questions about cell phones*" yet there is no indication that the FDA is aware of current scientific evidence documenting human health risks on which other agencies rely (most importantly the FCC at this time).

2) https://www.fda.gov/radiation-emitting-products/cell-phones/children-and-cell-phones This webpage says current as of 12/4/2017

"*The scientific evidence does not show a danger to any users of cell phones from RF exposure, including children and teenagers. The steps adults can take to reduce RF exposure apply to children and teenagers as well.*"

This conclusion is outdated, unwarranted and poses a direct risk to children whose parents are misguided by faulty FDA advice which essentially gives a positive assertion of safety.

"Some groups sponsored by other national governments have advised that children be discouraged from using cell phones at all. For example, the Stewart Report from the United Kingdom made such a recommendation in December 2000. In this report a group of independent experts noted that no evidence exists that using a cell phone causes brain tumors or other ill effects."

This is a 2002 statement which is largely nullified by scientific research published since 2002, where some studies report that children who use cell phones are five times more likely to suffer brain tumors (adults only twice as likely) as those with low or no cell phone use. Children are more susceptible to the harmful effects of cell phone radiation for many reasons established now by scientific studies.

3) https://www.fda.gov/radiation-emitting-products/cell-phones/current-research-results This webpage says current as of 5/2/2019.

This FDA webpage was updated just four months ago, yet inexplicably ignores the NTP results. The FDA could not possibly be unaware of the most significant research study ever undertaken in the United States, completed in 2018 by the National Toxicology Program (NTP), under the US Department of Health and Human Services (DHHS), National Institutes of Health (NIH) yet it is omitted. There is no reference to (and by implication, no consideration) of the results of this landmark study. The report results demonstrated that RF causes cancer in animals. It is also associated with cardiomyopathy (heart tissue damage) and pre-cancerous lesions in the Schwann cells that produce the kind of tumors widely reported in brain cancers from cell phone radiation.

Baan et al (2011) report on the IARC Working Group proceedings in Lyon, France during May 24-31, 2011. The IARC Working Group included about 30 international scientists and RF-EMF experts who did a comprehensive scientific assessment of the relevant literature. IARC concludes:

"In view of the limited evidence in humans and in experimental animals, the Working Group classified RF- EMF as "possibly carcinogenic to humans" (Group 2B) . This evaluation was supported by a large majority of Working Group members."

"(T)he Working Group concluded that the (Interphone Final Report) findings could not be dismissed as reflecting bias alone, and that a causal interpretation between mobile phone RF-EMF exposure and glioma is possible."

In light of the WHO IARC classification of radiofrequency electromagnetic fields on May 31, 2011 as a possible human carcinogen, the FDA is urged to take these immediate steps in response.

1) UPDATE FDA WEBSITE TO REFLECT THIS NEW CLASSIFICATION 2) ADVISE FCC OF NEED TO RE-ASSESS SAFETY LIMITS

1) Rationale: The FDA serves as a primary source of health information to the public and decision-makers. The FDA website needs to be updated to inform consumers that the World Health Organization International Agency for Cancer Research (IARC) has classified radiofrequency electromagnetic fields as a possible human carcinogen (a 2B or Possible Human Carcinogen). This is consistent with the FDA responsibility for public

health and clear communication of risks, and for advising consumers and organizations about ways to minimize exposures to such risks.

2) Rationale: Your agency has the authority and responsibility to advise the FCC on health issues related to radiofrequency electromagnetic fields. The FCC has jurisdiction to develop and enforce public safety limits but claims no health expertise on its own. That burden is directly on the FDA.

The FDA needs to inform the FCC that the WHO IARC classification is a significant development warranting the FCC to re-assess public safety limits and to update its own website advisory on radiofrequency electromagnetic fields. This is consistent with the FDA responsibility to facilitate the development of safety standards, and to maintain oversight and work with other agencies that rely on the FDA for health advice.

Taking steps now to highlight for consumers what risks may be present with radiofrequency electromagnetic fields is in keeping with public health principles, and is based on good science (the WHO Interphone 13-country glioma and acoustic neuroma study, and the WHO IARC Working Group scientific assessment and
classification of RF-EMF as a possible human carcinogen). It would also reflect the primary recommendation of the President's Cancer Panel Report that:

"a precautionary, prevention-oriented approach should replace current reactionary approaches to environmental contaminants in which human harm must be proven before action can be taken to reduce or eliminate exposure."

Thank you for your consideration.

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Baan et al, June 22, 2011, The Lance Oncology, published on-line at DOI:10.1016/S147-2045 (11)70140-4