The Honorable Alex Azar Secretary of Health and Human Services U.S. Department of Health & Human Services 200 Independence Avenue, S.W. Washington, D.C. 20201

The Honorable Stephen Hahn MD Commissioner of Food and Drugs Administration

Jeffrey Shuren, M.D., J.D. Director, Center for Devices and Radiological Health

Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20857

Sent electronically to ombuds@oc.fda.gov, DICE@fda.hhs.gov, jeff.shuren@fda.hhs.gov, Secretary@HHS.gov, Secretary@HHS.gov,

Re: FDA Literature Review on Cell Phones

Dear Honorable Commissioner Hahn, Honorable Secretary of Health and Human Services Alex Azar and

Dr. Shuren Director of the FDA Center for Devices and Radiological Health;

The selective FDA review is not in line with the majority of the scientific community on the issue of RF EMF health effects. I and more than 220 scientists from 41 countries, many of them EMF-active, have signed the International EMF Scientist Appeal (EMFscientist.org, 2015), which calls on the World Health Organization (WHO), the United Nations, and all member nations to issue health warnings about the risks of RF and ELF EMF exposure and to adopt much stronger exposure guidelines to protect humans than the outdated International Commission on Non-Ionizing Radiation Protection (ICNIRP) suggest. Please be aware that ICNIRP standards, while slightly different from the FCC standards, are also based on avoiding thermal RF effects for short periods of time -- acute (not chronic) exposures. In this regard, ICNIRP guidance ignores thousands of studies showing non-thermal RF effects.

Multiple studies (not referred to in the selectiveFDA review) have appeared since the classification of RF as possible human carcinogen, Group 2B, by the International Agency for

Research on Cancer (IARC) in 2011 (IARC, 2013). These studies from our laboratory and many others demonstrate carcinogenic potential of non-thermal RF exposures and preferential primary mechanism through induction of reactive oxygen species (ROS), see for review (Belpomme, Hardell, Belyaev, Burgio, & Carpenter, 2018; Belyaev, 2015a, 2015b, 2017, 2019; Belyaev et al., 2016).

The National Toxicology Program (NTP) findings along with recent replicated animal studies from Germany (Lerchl et al., 2015), supplemented other animal studies and provided sufficient evidence for carcinogenicity of cellphone exposure in animals. The NTP results on schwannoma and glioma are of special concern since they corroborate human epidemiology findings on human use of cell phones where similar tumors were found. Studies with chronic exposures have also provided evidence for possible mechanisms of RF non-thermal effects, which involve production of reactive oxygen/nitrogen species. According to the unanimous opinion of the 19-member peer review panel that examined NTP study (NTP, 2018), its results provide "clear evidence"—the highest standard of proof—that RF fields cause schwannomas (malignant tumors of the Schwann cells that sheath all myelinated nerves) in the hearts of male rats.

Taking into account the evidence from human epidemiological studies, I concur with a number of experts in the field that evidence at this time supports the classification of RF exposure from cell phones as human carcinogen according to the generally accepted Bradford Hill criteria (Carlberg & Hardell, 2017; Miller et al., 2018). The NTP study also reported less clear evidence that RF causes various other tumors (gliomas in the brain, pheochromocytomas in the adrenal gland, and tumors of the prostate and pancreas) (NTP, 2018). In contrast to the selective FDA review, the IARC advisory group of 29 scientists from 18 countries has recently stated that the new bioassay and mechanistic evidence warrants high-priority re-evaluating the RF-induced carcinogenesis (Marques et al., 2019).

Based on these considerations, I urge the FDA to withdraw their selective report from publication, convene an independent expert group to evaluate all the evidence including mechanistical and in vitro studies, which were omitted by the FDA report, and take steps to advise the public on how to reduce exposures to radiation at this time.

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