

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,
Stephen.Hahn@fda.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about the risks of RF and ELF EMF exposure and to adopt much stronger exposure guidelines to protect humans than the outdated International Commission on Non-Ionizing Radiation Protection (ICNIRP) suggest.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 selective FDA 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.

Igor Belyaev, PhD, Dr.Sc.

Associate Professor

Head, Department of Radiobiology

Cancer Research Institute, Biomedical Research Center of the Slovak Academy of Science

Belpomme, D., Hardell, L., Belyaev, I., Burgio, E., & Carpenter, D. O. (2018). [Thermal and non-thermal health effects of low intensity non-ionizing radiation: An international perspective.](#) [Review]. Environ Pollut, 242(Pt A), 643-658. doi: 10.1016/j.envpol.2018.07.019

Belyaev, I. (2015a). [Biophysical Mechanisms for Nonthermal Microwave Effects.](#) In M. Markov (Ed.), Electromagnetic Fields in Biology and Medicine (pp. 49-68). Boca Raton, London, New York: CRC Press.

Belyaev, I. (2015b). Electromagnetic Field Effects On Cells And Cancer Risks From Mobile Communication. In P. J. Rosch (Ed.), Bioelectromagnetic and Subtle Energy Medicine (Vol. Second edition, pp. 517-539). Boca Raton, London, New York: CRC Press.

Belyaev, I. (2017). Duration of Exposure and Dose in Assessing Nonthermal Biological Effects of Microwaves. In M. Markov (Ed.), Dosimetry in Bioelectromagnetics (pp. 171-184). Boca Raton, London. New York: CRC Press.

Belyaev, I. (2019). Health effects of chronic exposure to radiation from mobile communication. In M. Markov (Ed.), Mobile Communications and Public Health (pp. 65-99). Boca Raton: CRC Press.

Belyaev, I., Dean, A., Eger, H., Hubmann, G., Jandrisovits, R., Kern, M., . . . Thill, R. (2016). [EUROPAEM EMF Guideline 2016 for the prevention, diagnosis and treatment of EMF-related health problems and illnesses.](#) [Review]. Rev Environ Health, 31(3), 363-397. doi: 10.1515/reveh-2016-0011

Carlberg, M., & Hardell, L. (2017). [Evaluation of Mobile Phone and Cordless Phone Use and Glioma Risk Using the Bradford Hill Viewpoints from 1965 on Association or Causation.](#) [Meta-Analysis Review]. Biomed Res Int, 2017, 9218486. doi: 10.1155/2017/9218486

EMFscientist.org. (2015). International EMF Scientist Appeal. Retrieved from <https://www.emfscientist.org/index.php/emf-scientist-appeal>

IARC. (2013). IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Non-ionizing Radiation, Part 2: Radiofrequency Electromagnetic Fields (Vol. 102). Lyon, France: IARC Press, <http://monographs.iarc.fr/ENG/Monographs/vol102/mono102.pdf>.

Lerchl, A., Klose, M., Grote, K., Wilhelm, A. F., Spathmann, O., Fiedler, T., . . . Clemens, M. (2015). [Tumor promotion by exposure to radiofrequency electromagnetic fields below exposure limits for humans.](#) [Research Support, Non-U.S. Gov't]. Biochem Biophys Res Commun, 459(4), 585-590. doi: 10.1016/j.bbrc.2015.02.151

Marques, M. M., Berrington de Gonzalez, A., Beland, F. A., Browne, P., Demers, P. A., Lachenmeier, D. W., . . . Guyton, K. Z. (2019). Advisory Group recommendations on priorities for the IARC Monographs. Lancet Oncol. doi: 10.1016/s1470-2045(19)30246-3

[Miller, A.B.](#), Morgan, L.L., Udasin, I, and Davis, DL, (2018) Cancer epidemiology update, following the 2011 IARC evaluation of radiofrequency electromagnetic fields (Monograph 102), [Volume 167](#), November 2018, Pages 673-683

NTP. (2018). National Toxicology Program, Peer Review of the Draft NTP Technical Reports on Cell Phone Radiofrequency Radiation, https://ntp.niehs.nih.gov/ntp/about_ntp/trpanel/2018/march/peerreview20180328_508.pdf. National Institute of Environmental Health Sciences Research Triangle Park, 1-48. Retrieved from https://ntp.niehs.nih.gov/ntp/about_ntp/trpanel/2018/march/peerreview20180328_508.pdf

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,
Stephen.Hahn@fda.hhs.gov, Secretary@HHS.gov,

Re: Call for Retraction of Flawed 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;

As experts in the field of bioelectromagnetics, we are writing to urge you to retract a recent flawed report entitled "[Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer](#)". Further, we ask you to remove and replace recent revisions to FDA websites that invoke this recent report as grounds for asserting that cellphone radiation has no known health effects, contrary to official reviews in other high-technology nations.

As many of us have detailed in letters sent to your offices, this report does not merit publication or posting on FDA's website as it represents a highly limited review of the literature, contains "numerous scientific errors" omitting important studies for review and including studies that have been rejected for their flawed methods, and fails to acknowledge official actions by governments in [France](#), [South Korea](#), [Belgium](#), [Cyprus](#), [European Parliament](#) and recommendations by the [American Academy of Pediatrics](#) and [California Department of Public Health](#) that have issued specific advice about why and how to reduce exposures to cellphones and other wireless radiation sources. By dismissing scientific evidence of adverse effects and downplaying the need for individuals to take precautionary measures when using cell phones, the FDA review does not comport with the Agency's mission of protecting and promoting public health.

Contrary to what the report and FDA website assert, there is no “scientific consensus” that cell phone radiation and 5G are safe as evidenced by the [official statements](#) of hundreds of scientists and medical organizations.

The FDA in collaboration with US health and environmental agencies should convene an interdisciplinary panel of independent experts to provide a systematic review of relevant literature on cell phones and wireless radiation and health to guide the agency in its policy recommendations. Further, any such review should also consider the growing evidence of environmental effects along with public health impacts of exposures as well as relevant policy developments.

Signed,

Ronald Melnick PhD, former National Institutes of Health Scientist

Lennart Hardell MD, PhD, Professor Department of Oncology, Faculty of Medicine and Health, Örebro University, SE-701 82 Örebro, Sweden (retired). The Environment and Cancer Research Foundation Örebro, Sweden

Samuel Miham MD, former Head of the Chronic Disease Epidemiology Section, Washington State Department of Health

David Carpenter MD, Director of the Institute for Health and Environment at University of Albany's School of Public Health, former director of the Wadsworth Laboratory of the New York State Department of Health.

Henry Lai, PhD, Professor Emeritus, University of Washington, Seattle, WA

Alfonso Balmori, BSc Biologist. Spain

Beatrice Golomb, MD PhD, Professor of Medicine, University of California, San Diego

Devra Davis, PhD, MPH President of Environmental Health Trust and Fellow American College of Epidemiology, former founding Executive Director, Board on Environmental Studies and Toxicology, National Academies of Sciences, Engineering and Medicine

Hillel Baldwin, MD, Fellow American Association of Neurological Surgeons

Dr. Anthony Miller, Professor Emeritus of University of Toronto and World Health Organization Senior Advisor to Environmental Health Trust

Prof. Tom Butler, University College, Cork, Ireland

Igor Belyaev, PhD, Dr.Sc.Head, Department of Radiobiology of the Cancer Research Institute, Biomedical Research Center of the Slovak Academy of Sciences

Magda Havas, Ph.D., Associate Professor, Trent University

Prof. Suleyman Dasdag, Department of Biophysics, Medical School of Istanbul Medeniyet University, Istanbul, Turkey

Don Maisch, PhD, Australia

Martin L. Pall, PhD, Professor Emeritus of Biochemistry and Basic Medical Sciences, Washington State University

Peter Hensinger M.A.

Hugo Schooneveld, PhD, Former senior researcher, Wageningen University, the Netherlands.

Dr. Monika Krout, Germany

Professor Elihu D. Richter MD, MPH at the Occupational and Environmental Medicine Department at the Hebrew University-Hadassah School of Public Health and Community Medicine

Marc Arazi MD of Phonegate Association, France

Marko S. Markov PhD, author of major medical textbooks in bioelectromagnetics.

Wenjun Sun PhD, Professor, Bioelectromagnetics Key Laboratory, Zhejiang University School of Medicine, China

Denis L Henshaw, Fellow Collegium Ramazzini, Emeritus Professor of Human Radiation Effects, Atmospheric Chemistry Group, School of Chemistry, University of Bristol

Christos D. Georgiou, Ph.D. Professor Emeritus of Biochemistry, Biology Department University of Patras, Greece

February 27, 2020

Jeffrey Shuren, M.D., J.D.
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Email: jeff.shuren@fda.hhs.gov

RE: FDA Literature Review on Radiofrequency Radiation and Cancer

Dear Dr. Shuren,

I am writing this letter to detail major incorrect statements and omissions of relevant data in the FDA document titled “Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer.” I led the design of the National Toxicology Program’s (NTP) toxicity and carcinogenicity studies on cell phone radiation and I strongly believe that the anonymously written FDA document misrepresents the utility of the NTP study for assessing human health risks. In addition, the report’s casual dismissal of both the mechanistic findings and the numerous results from epidemiological studies that have shown increased cancer risks associated with exposure to radiofrequency radiation (RFR) are inconsistent with the FDA’s stated core mission “to protect and promote the public health.”

Regarding the NTP studies on cell phone RFR, an expert peer-review panel discussed the results for 3 days and concluded ([NTP TR-595](#); [Peer-Review Report 2018](#)) that this carefully designed and conducted study provided “clear evidence of carcinogenic activity.” In contrast to the NTP and peer-review conclusions, the FDA claims that whole-body exposures used in the NTP study cannot be related to the local RFR exposures a human receives while using a cell phone. The dismissal of the NTP study results by the FDA is rather peculiar since it was the FDA’s Center for Device and Radiological Health that requested the toxicity and carcinogenicity of RFR in experimental animals ([CDRH nomination of RFR](#)) “to provide the basis to assess the risk to human health,” and FDA scientists were fully aware of the exposure methodology that was used in the NTP study long before those studies were begun.

The NTP study was designed to provide accurate organ-specific dosimetry that could be used to quantify risks for any adverse effect that might be identified. Most people who check on the RF emissions from their cell phones learn that the Federal Communication Commission (FCC) requires that local tissue exposures be lower than 1.6 W/kg averaged over any one gram of tissue. In the NTP study, the exposures to the brain of rats were approximately 1.5, 3.0, and 6.0 W/kg – close to the FCC’s local exposure limit. For experimental studies in small groups of laboratory animals, these values are unusually close to allowable local tissue exposures in humans and require minimal extrapolation to estimate human cancer risk.

The FDA report complains that the whole-body exposures in the NTP study at 6 W/kg was 75 times higher than the exposure limit for the general population (the lower doses were 38- and 19-times that limit for the general population, but only 8- and 4-times the exposure limit for workers). However, whole body exposures provide little information on organ-specific exposure levels. When an individual holds a cell phone next to their head, the important exposure for consideration of health risk is the local exposure. That is why the NTP study design focused on the local exposure intensities. If the animal studies had used the whole-body exposure limit of 0.08 W/kg, then the exposure to the brain of

exposed animals would have been 20-fold less than the FCC's local exposure limit for the general public, i.e., a useless study for assessing human risk. It is misleading for the FDA document to ignore the local exposure limit of 1.6 W/kg and its importance for assessing organ-specific cancer risk.

The FDA document criticizes studies that did not perform histopathology evaluations blinded to the dose group, including the NTP study. However, as was pointed out previously¹, the final diagnosis of lesions in the NTP study was done by a group of pathologists who did not know whether the slides they were examining came from an exposed or an unexposed animal. In addition, for anyone questioning the diagnosis of any tissue in this study, all of the slides from the NTP studies are available for examination at the NTP archives.

The FDA document also suggests without evidence that the carcinogenic effects in rats exposed to 6 W/kg were due to the loss of their ability to maintain their body temperatures during the exposures. However, measured body temperatures were within 1 °C of their normal body temperature, there were no differences in body weights between exposed and sham control rats in the 2-year study, there was no indication of tissue damage in the 28-day study, and there were no exposure-related clinical observations in the 2-year study ([NTP TR-595](#)). Thus, it is clear that animals tolerated the exposure levels used in the NTP study. The peer reviewers of the NTP studies were fully aware of all issues raised in the FDA document, yet still concluded that the results of those studies showed clear evidence of carcinogenic activity. FDA scientists had opportunity to offer criticisms of the NTP study prior to and during the 3-day peer-review, but did not. Did the FDA somehow have an epiphany regarding the human relevance of the NTP cancer data or was there some other factor influencing their decision to dismiss those results?

Lastly, the FDA document misstates the results of the genetic toxicology tests in animals from the NTP study. For example, the FDA document claims there were “no statistically significant increases in DNA damage in female rats or either mouse sex” and the increases in DNA damage in male rats “was not statistically significant,” when in fact there were significant increases and significant trends in DNA damage in the frontal cortex of male mice exposed to GSM or CDMA modulated RFR and in the frontal cortex and hippocampus of male rats exposed to CDMA ([NTP TR-595](#)).

The FDA document also claims there is a “lack of biological mechanistic plausibility,” while eight *in vivo* studies cited in that document provided evidence of increased oxidative stress associated with exposure to RFR and 15 studies provided evidence of genotoxicity. In addition, many relevant *in vivo* studies showing evidence of oxidative stress were not reported in the FDA document and there are many *in vitro* studies that have found oxidative stress associated with exposure to RFR². A true risk analysis should consider both *in vivo* and *in vitro* studies when ascertaining biological mechanistic plausibility. A characteristic of many human carcinogens is the induction of oxidative stress that can subsequently lead to mutations, chromosomal translocations, and genetic instability.³ Thus, there does exist a biologically plausible mechanism for the induction or progression of tumors associated with

1 Melnick RL (2019). Commentary on the utility of the National Toxicology Program study on cell phone radiofrequency radiation data for assessing human health risks despite unfounded criticisms aimed at minimizing the findings of adverse health effects. *Environ Res.* 168:1-6.

2 Yakymenko I, Tsybulin O, Sidorik E, et al. (2016). Oxidative mechanisms of biological activity of low-intensity radiofrequency radiation. *Electromagn Biol Med* 35: 186-202.

3 Smith MT, Guyton KZ, Gibbons CF, et al. (2016). Key characteristics of carcinogens as a basis for organizing data on mechanisms of carcinogenesis. *Environ Health Perspect.* 124:713-721.

exposure to RFR. For studies that did not show evidence of carcinogenicity or genotoxicity, the FDA document did not comment on whether or not those studies were adequately designed with respect to animal group size, exposure levels and duration of exposure.

Regarding human studies, the FDA document cites the study by Little (2012) in which it was reported that glioma trends in the US between 1997 and 2008 have remained relatively constant, but omitted the study by Philips et al. (2018)⁴ that reported a doubling in incidence of glioblastoma (frontal and temporal lobes) in England between 1995 and 2015. The latter study was published in June 2018, which is within the timeframe (August 2018) for epidemiological studies included in the FDA document.

The FDA document identified several human studies that reported risks of glioma, acoustic neuroma, and other tumor types that were increased among cell phone users. In each case, the document focused on limitations in those studies to raise doubt about their reliability for assessing cancer risk. Two limitations specified for most case-control studies included selection and recall bias. However, the FDA document neglected to discuss the impact of the study by Momoli et al.(2017),⁵ which re-analyzed the Canadian data that was included in the Interphone study and showed that there was no effect on the risk of glioma after adjustments were made for selection and recall biases; the odds ratios (OR) for glioma were significantly increased when comparing the highest quartile of use to those who were not regular users whether or not adjustments were made: OR = 2.0, 95% confidence interval 1.2–2.4 without adjustment; OR = 2.2 95% confidence interval 1.3–4.1 with adjustments. Evidently, selection and recall biases do not explain the elevated brain cancer risks associated with use of cell phones in that study.

Thus, while there are reliable animal studies, mechanistic studies, and animal studies showing increased cancer risks associated with exposure to cell phone RFR, the FDA document dismisses nearly the entirety of those studies to enable the agency to conclude that there is insufficient evidence to support a causal association between RFR exposure and tumorigenesis. According to the FDA, animal studies are not useful for studying potential effects in humans (though animal studies are used in drug development) and the human studies “were subject to flaws and inaccuracies.” Yet, every known human carcinogen is carcinogenic in animals when adequately tested. Public health agencies including the NTP, US EPA, IARC, and the FDA have a long tradition of relying on the relevance of rodent toxicology/carcinogenicity studies to identify hazardous agents and assess human health risks in order to implement public health protective policies. The statement in the FDA report that “if any risk does exist, it is extremely low” is very misleading since the FDA has not performed a quantitative risk assessment on any of the available data sets and, because of the widespread use of cell phones in the US and world-wide, even a small increase in cancer risk would have a serious public health impact.

Based on the FDA review, which is not a risk analysis as stated in the document, the message for the general public appears to be that precautionary measures for use of cell phones are not necessary in spite of the fact that numerous studies have provided compelling evidence of increased cancer risk

4 Philips A, Henshaw DL, Lamburn G, O’Carroll MJ. (2018). Brain tumours: rise in glioblastoma multiforme incidence in England 1995-2015 suggests an adverse environmental or lifestyle factor. *J Environ Public Health*. Article ID 7910754,

5 Momoli F, Siemiatycki J, McBride ML, et al. (2017). Probabilistic multiple-bias modeling applied to the Canadian data from the Interphone study of mobile phone use and risk of glioma, meningioma, acoustic neuroma, and parotid gland tumors. *Am J Epidemiol*. 186:885-893.

associated with exposure to cell phone RFR. This is an irresponsible message for a government agency that claims its mission is to protect consumers and promote the public health.

The statement on the FDA website (<https://www.fda.gov/radiation-emitting-products/cell-phones/do-cell-phones-pose-health-hazard>) that there is a “scientific consensus on cell phone safety” is totally wrong and should be removed since there is no scientific consensus supporting this claim. In contrast, numerous experts in the field have reported evidence that current levels of cell phone radiation can be harmful to human health.

In conclusion, the FDA document has serious flaws and inaccuracies, as well as omissions of relevant data. Hence, in consideration of public health, it is important that FDA immediately retract their review on radiofrequency radiation and cancer.

Sincerely,

A handwritten signature in dark ink, reading "Ronald L. Melnick". The signature is written in a cursive, flowing style.

Ronald L. Melnick, Ph.D.
Retired toxicologist NTP, NIEHS

Press Statement from Dr. Albert Manville on the FDA Report

In a February 13, 2020, news release from MedPage Today, an anonymous, nonscientific review asserts that, according to the FDA, cellphones have ... "no quantifiable adverse health effects in humans," but FDA suggests that further research should be conducted in vulnerable individuals who may be more predisposed to tumors from "short but intense RF exposure" above current limits.

As a certified wildlife biologist and Ph.D. environmental scientist who has studied the impacts of radiation on migratory birds, other wildlife, and humans since the late 1990s, the statement credited to the FDA is preposterous, without any scientific credibility, and at a minimum deserves a retraction by the FDA.

There currently are well over 500 scientific, peer-reviewed papers addressing impacts of non-ionizing, non-thermal radiation on laboratory animals — many of the studies directly applicable to human health and safety. I'm coauthoring a detailed scientific paper on these impacts. When I worked as a wildlife biologist for the U.S. Fish & Wildlife Service for 17 years, I collaborated with the late Dr. Ted Litovitz in 2000. Dr. Litovitz and his colleagues studied the impacts of low-level, non-thermal radiation from the standard 915 MHz cell phone frequency on chicken embryos. In their laboratory studies, control/non-treated embryos suffered no effects, but some of the treated/irradiated embryos died — at levels as low as 1/10,000 the normal level of cell phone radiation exposure to humans. This was an eye-opener! The findings were published by DiCarlo and others in 2002 in the Journal of Cellular Biochemistry. Meanwhile, I worked closely with colleagues from Europe, including Balmori, Hallberg, Everaert, and Bauwens on the impacts of cell towers on wild migratory European birds. The results of their field research were equally astounding. Where healthy, breeding bird populations had persisted, once cell towers were installed and operating, nest and site abandonment, plumage deterioration, locomotion problems, reduced survivorship, and death were noted in House Sparrows, White Storks, Rock Doves, Magpies, Collared Doves, and other species. This was documentation in the field of some very troubling consequences of the impacts of cell tower radiation on wildlife.

With these scientific findings, I was instrumental in getting the Department of Interior to convince the First Responder Network Authority, National Telecommunications and Information Administration, Department of Commerce, to begin the process of an Environmental Impact Statement under the National Environmental Policy Act in early 2014. This was the first time one federal department had convinced another department to conduct such a review. While the NEPA review was ultimately scuttled, the results of previous studies clearly showed that radiation has impacts on wildlife, and therefore needed extensive further scientific and public review. The consequences to human health and safety were implicit.

The FDA needs to carefully review the existing and growing scientific record. The current FDA statement is irresponsible, unfounded, and sets a dangerous precedent — especially in this age of "fake news" and "alternative facts." It needs to be corrected or retracted.

Respectfully submitted.

Albert M. Manville, II, Ph.D.; Certified Wildlife Biologist (CWB), The Wildlife Society; Senior Lecturer and Adjunct Professor, Krieger School of Arts and Sciences, Advanced Academic Programs, Johns Hopkins University, Wash DC Campus; and retired Senior Wildlife Biologist, Division of Migratory Bird Management, U.S. Fish & Wildlife Service, Wash. DC HQ Office (17 years);

29/02/2020

To: Jeffery Shuren, Director of the Center for Devices and Radiological Health, FDA.

Re: Response to FDA Center for Devices and Radiological Health (CDRH) Report: *Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer*

Dear Jeffery,

I wish to voice my concerns about the validity, reliability, and integrity of the report titled: *Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer*.

To begin, I note that the mission of the FDA's Center for Devices and Radiological Health (CDRH) is as follows:

... the Center for Devices and Radiological Health (CDRH) is responsible for protecting and promoting the public health. We assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. We assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. We provide consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee. We facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

It is clear that the Center's central mission is to assess medical devices and radiation-emitting products in the field of medicine. Given the ongoing digital transformation of the healthcare industry focusing on the widespread use of wireless devices across hospitals and healthcare facilities, including the Internet of Things, enabled by 5G, there is an onus on the FDA to ensure the general safety of wireless technologies to patients and those with chronic illnesses and disabilities in the face of mounting scientific evidence of the risks posed by wireless technologies of all types.

The FDA seems unaware of, or is it simply ignoring, the overwhelming body of scientific evidence on non-thermal effects, and not just the carcinogenicity, of non-ionizing ionizing radiofrequency radiation (RFR). Take, for example, a recent research review by independent researchers on the health risks of microwave RFR concludes that "*the literature shows there is much valid reason for concern about potential adverse health effects from both 4G and 5G technology*" and that extant research "*should be*

viewed as extremely conservative, substantially underestimating the adverse impacts of this new technology."¹

The above review by US scientists reported that peer-reviewed studies find the following adverse health effects well below the safety limits set by the FCC and ICNIRP guidelines:

- *“carcinogenicity (brain tumors/glioma, breast cancer, acoustic neuromas, leukemia, parotid gland tumors),*
- *genotoxicity (DNA damage, DNA repair inhibition, chromatin structure), mutagenicity, teratogenicity,*
- *neurodegenerative diseases (Alzheimer’s Disease, Amyotrophic Lateral Sclerosis),*
- *neurobehavioral problems, autism, reproductive problems, pregnancy outcomes, excessive reactive oxygen species/oxidative stress, inflammation, apoptosis, blood-brain barrier disruption, pineal gland/melatonin production, sleep disturbance, headache, irritability, fatigue, concentration difficulties, depression, dizziness, tinnitus, burning and flushed skin, digestive disturbance, tremor, cardiac irregularities,*
- *adverse impacts on the neural, circulatory, immune, endocrine, and skeletal systems.”*

The above findings were independently verified by the research team using 5,400 studies in the MedLine database.

Given the foregoing, a question begs as to *whether the FDA had the required competencies to perform its recently published review?* Justification for this question arises from the thousands of relevant studies on the MedLine database identified by independent researchers, as opposed to the 282 studies referenced by the FDA, and the *“approximately 70 relevant epidemiological studies”* mentioned in the Executive Summary and which informed the FDA’s conclusions. The remaining peer-reviewed studies considered by the FDA appear to have been excluded on highly questionable grounds. All this gives the lie to the claim that *“[t]he Agency has taken a comprehensive approach to evaluating the available scientific evidence regarding the impact of radiofrequency radiation (RFR) exposure on human health.”* Furthermore, however limited the Center’s internal competencies may be, the FDA’s network of experts² are focused on medical practice and the use of various devices employed by health care professionals, and are not subject matter experts in 2-4G, Wifi and 5G telecommunications systems and devices. This is important, as 4G, Wifi and 5G technologies are now being employed across the healthcare industry and in general use across the population. The risks posed by such technologies deserve cross-agency attention and review by independent, competent experts across multiple disciplines, without a single conflict of interest.

Following on from the points made above, I accept that the FDA may call on physicians/scientists with relevant expertise to conduct its scientific reviews, however, the report is silent on which scientists, physicians or engineers conducted the review, the levels of expertise they possessed, and any conflicts of interest they had. This places the second question mark over the trustworthiness of the report—there are, however, several other critical questions that require to be answered in full.

Why were ceratin epidemiological studies excluded from the review?

The FDA report is significantly incomplete and therefore inaccurate, given the acknowledged timeframe and intention to include *“more recent, relevant peer-reviewed publications through August 2019.”* A simple example suffices to demonstrate this. The findings of 13 important epidemiological studies are presented below. Also below is a reference to a report that refutes the claims made by the Swedish Radiation Safety Authority cited in the FDA report. The 13 studies were ignored and omitted

¹ Kostoff, R. N., Heroux, P., Aschner, M., & Tsatsakis, A. (2020). Adverse health effects of 5G mobile networking technology under real-life conditions. Toxicology Letters.

²² <https://www.fda.gov/media/120990/download>

by those conducting the review. *Why did this omission take place?* The inclusion of the findings of this recent body of research would have made the report's conclusions untenable. A short review of the 13 studies will support my contention.

First, if the FDA team were using MedLine as indicated, they surely would have identified a study in The Lancet Neurology. The findings of this study places the FDA conclusions in serious doubt viz. *"CNS cancer is responsible for substantial morbidity and mortality worldwide, and the incidence increased between 1990 and 2016. Significant geographical and regional variation in the incidence of CNS cancer might be reflective of differences in diagnoses and reporting practices or unknown environmental and genetic risk factors. Future efforts are needed to analyze CNS cancer burden by subtype."*³ Below is an excerpt from the findings of another relevant study which the FDA ignored.⁴

Table 1 The global death and incidence of all cancers and 29 specified cancer groups in 1990 and 2017

Tumor types	1990				2017			
	Death		Incidence		Death		Incidence	
	Number 10 ³ (95% UI)	Age-standardized per 100,000 (95% UI)	Number 10 ³ (95% UI)	Age-standardized per 100,000 (95% UI)	Number 10 ³ (95% UI)	Age-standardized per 100,000 (95% UI)	Number 10 ³ (95% UI)	Age-standardized per 100,000 (95% UI)
Brain and nervous system cancer	142 (171–117)	3.04 (3.58–2.56)	194 (234–159)	3.97 (4.71–3.33)	247 (265–213)	3.12 (3.34–2.68)	405 (443–351)	5.17 (5.64–4.46)
Thyroid cancer	22 (24–21)	0.55 (0.6–0.52)	95 (101–90)	2.11 (2.24–2.01)	41 (44–40)	0.52 (0.56–0.51)	255 (272–246)	3.15 (3.36–3.03)

While these studies did not link the significant increase in brain and CNS cancer to cellphone and RFR exposure, a recent study by US economists does.⁵ That study demonstrates *"that mobile phone subscription rates are positively and statistically significantly associated with death rates from brain cancer 15-20 years later. As a falsification test, we find few positive associations between mobile phone subscription rates and deaths from rectal, pancreatic, stomach, breast or lung cancer or ischemic heart disease."* This 25-year cross country analysis provides solid evidence of the link between mobile phone use and cancer when positioned alongside epidemiological studies.

These trends are also evident in the findings of other studies. A research review of the incidence of glioblastoma multiforme tumours in England during 1995–2015 reported a *"a sustained and highly statistically significant ASR [(incidence rate)] rise in glioblastoma multiforme (GBM) across all ages. The ASR for GBM more than doubled from 2.4 to 5.0, with annual case numbers rising from 983 to 2531. Overall, this rise is mostly hidden in the overall data by a reduced incidence of lower-grade tumours."*⁶ The study did not focus on RFR as the cause, so the findings must be considered 'open to interpretation' in this regard, as other environmental mechanisms cannot be ruled out. However, the following figures are clear and unambiguous. In the UK in 1995, 553 frontal lobe tumours were diagnosed in patients, while 1231 were found in 2015. Likewise, 334 temporal lobe tumours were reported in 1995, while 994 were diagnosed in 2015. The increase in these cancers of the CNS are clear and unambiguous. The authors of this study argue that:

³ Patel, A. P., Fisher, J. L., Nichols, E., Abd-Allah, F., Abdela, J., Abdelalim, A., ... & Allen, C. A. (2019).

Global, regional, and national burden of brain and other CNS cancer, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016. The Lancet Neurology, 18(4), 376-393.

⁴ Lin, L., Yan, L., Liu, Y., Yuan, F., Li, H., & Ni, J. (2019). Incidence and death in 29 cancer groups in 2017 and trend analysis from 1990 to 2017 from the Global Burden of Disease Study. Journal of hematology & oncology, 12(1), 96.

⁵ Mialon, H. M., & Nesson, E. T. (2019). The Association Between Mobile Phones and the Risk of Brain Cancer Mortality: A 25-year Cross-country Analysis. Contemporary Economic Policy. <https://doi.org/10.1111/coep.12456>.

⁶ Philips, A., Henshaw, D., L Lamburn, G. & M. O'Carroll, (2018). Brain tumours: rise in Glioblastoma Multiforme incidence in England 1995–2015 suggests an adverse environmental or lifestyle factor, Journal of Environmental and Public Health, vol. 2018, Article ID 7910754.

“The rise cannot be fully accounted for by promotion of lower-grade tumours, random chance or improvement in diagnostic techniques as it affects specific areas of the brain and only one type of brain tumour. Despite the large variation in case numbers by age, the percentage rise is similar across the age groups, which suggests widespread environmental or lifestyle factors may be responsible. This article reports incidence data trends and does not provide additional evidence for the role of any particular risk factor.”

It is significant that the frontal and temporal lobes receive the greatest exposure to RFR from smartphones and wireless devices.

A comprehensive review of the incidence of primary brain and other central nervous system tumors diagnosed in the United States during the period 2009–2013, found quite small, but statistically significant increases in some categories of CNS tumours and none in others.⁷ To be sure, in this study published in 2016, the increase in the incidence of tumours reported were not as alarming as those in the UK study. However, this is only the first in a series demonstrating an upward trend.

A related U.S. study echoed the previous findings, but found an *“an increasing medulloblastoma incidence in children aged 10–14 years.”*⁸ Another recent study on children found statistically-significant changes in several sub-types of CNS cancers, notably gliomas, in the period 1998-2013.⁹ The latter study concluded that *“Continued surveillance of pediatric CNS tumors should remain a priority given their significant contribution to pediatric cancer deaths.”*

In keeping with studies that provide compelling evidence for concern, a recent review study of epidemiological studies on brain and salivary gland tumours in relation to mobile phone use found the cumulative evidence to be inconclusive but indicated that such cancers may have a long latency (i.e. greater than 15 years) and clear evidence may emerge in the future. Nevertheless, scientists argue that childhood exposure to RFR devices is of significant concern.¹⁰ There is also evidence that RFR from cell phones may be triggering breast cancer in young women who carry their devices on or near their breasts.¹¹ In addition, while the extensive studies by the Hardell Group cited in the FDA review demonstrate increases in cancers of the CNS in Sweden, these findings have been recently replicated in Denmark.¹²

In a general context, the U.S. Center for Disease Control and related research finds that non-Hodgkin lymphomas, central nervous system tumors (including brain cancers), renal, hepatic and thyroid

⁷ Ostrom, Q. T., Gittleman, H., Xu, J., Kromer, C., Wolinsky, Y., Kruchko, C., & Barnholtz-Sloan, J. S. (2016). CBTRUS statistical report: primary brain and other central nervous system tumors diagnosed in the United States in 2009–2013. *Neuro-oncology*, 18(suppl_5), v1-v75.

⁸ Khanna, V., Achey, R. L., Ostrom, Q. T., Block-Beach, H., Kruchko, C., Barnholtz-Sloan, J. S., & de Blank, P. M. (2017). Incidence and survival trends for medulloblastomas in the United States from 2001 to 2013. *Journal of neuro-oncology*, 135(3), 433-441.

⁹ Withrow, D. R., de Gonzalez, A. B., Lam, C. J., Warren, K. E., & Shiels, M. S. (2018). Trends in pediatric central nervous system tumor incidence in the United States, 1998-2013. *Cancer Epidemiology and Prevention Biomarkers*, cebp-0784.

¹⁰ Rööslä, M., Lagorio, S., Schoemaker, M. J., Schüz, J., & Feychting, M. (2019). Brain and Salivary Gland Tumors and Mobile Phone Use: Evaluating the Evidence from Various Epidemiological Study Designs. *Annual review of public health*, 40.

¹¹ West, J. G., Kapoor, N. S., Liao, S. Y., Chen, J. W., Bailey, L., & Nagourney, R. A. (2013). Multifocal breast cancer in young women with prolonged contact between their breasts and their cellular phones. *Case reports in medicine*, 2013.

¹² Swedish Radiation Protection Foundation (2017). Brain tumors are increasing in Denmark https://www.stralskyddsstiftelsen.se/wp-content/uploads/2017/01/denmark_cnstumorrising_2017-01-20.pdf

tumours have increased recently among adolescent Americans.^{13, 14} When comparing the Annual Average Total and Average Annual Age-Adjusted Incidence Rates for Children and Adolescents of Brain and Other Central Nervous System Tumors from 2009-2013⁴ and 2012-2016¹² an increase in total cases of 0-19 year olds from 23,522 to 24,931 is found, with the annual average increasing from a rate of 5.70 in 2012 to 6.06 to 2016. Thus, many scientists conclude that microwave radio frequency radiation has a significant role to play in the increasing rates of particular types of CNS cancers being reported.

A senior epidemiologist at US healthcare provider Kaiser Permanente, Dr. De-Kun Li, believes that while the increase in brain tumors is worrisome, increases in colorectal cancer is even more troubling, particularly as he believes RFR is implicated due to the manner in which people carry their smartphones in the front and back pockets of their pants and jeans. Take, for example, in 2019, the journal *Cancer* described a rising incidence of colorectal cancer among young Americans, with rectal cancers being slightly higher than colon cancers.¹⁵ Another contemporary study found significant increases in colorectal cancer among people under 50 in Denmark, New Zealand, and the UK since 2009.¹⁶ Yet another study of colorectal cancer in young adults in 20 European countries over the last 25 years found that over the last 10 years, the incidence of colorectal cancer increased 8% per year among people in their 20s, by 5% for people in their 30s, and by 1.6% for those in their 40s.¹⁷ Dr. De-Kun Li maintains that *“When placed in trouser pockets, the phones are in the vicinity of the rectum and the distal colon and these are the sites of the largest increases in cancer.”* While phones go into standby mode where telephone calls are concerned, most young people have WiFi, Bluetooth and 4G data enabled. This increases the level and incidence of exposure, as their apps keep their smartphones active on a continuous basis. Thus, other environmental, diet and lifestyle factors aside, wireless microwave radio frequency radiation is strongly implicated as a direct or indirect (e.g. co-carcinogen) in this latest ‘uptick’ in cancers.

Again the weight of the scientific evidence is considerable. If the findings of the above studies are accurate and generalizable, then the rates for frontal and temporal lobe tumours may increase significantly, as they more than doubled over a 20-year period in the UK, or increase in line with high RFR exposure, as RFR is now accepted as either a causal or a contributory mechanism in the occurrence of brain tumours and other cancers.

Serious questions on the trustworthiness of the report

Focusing on the report itself, and in regard to the probable deficiencies in scientific expertise among the authors of the review, the FDA has questions to answer in regard to the report’s...

(a) scientific accuracy and integrity;

¹³ Siegel, D. Li, S J., Henley, J., Wilson, R., Buchanan Lunsford, N., Tai, E. Van Dyne, E. (2018) Incidence rates and trends of pediatric cancer — United States, 2001–2014, American Society of Pediatric Hematology Oncology Conference, Centers for Disease Control and Prevention, Atlanta, Georgia, United States http://aspho.org/uploads/meetings/2018annualmeeting/Abstracts_for_Website.pdf

¹⁴ Ostrom, Q. T., Gittleman, H., Truitt, G., Boscia, A., Kruchko, C., & Barnholtz-Sloan, J. S. (2018). CBTRUS statistical report: primary brain and other central nervous system tumors diagnosed in the United States in 2011–2015. *Neuro-oncology*, 20(suppl_4), iv1-iv86.

¹⁵ Virostko, J., Capasso, A., Yankeelov, T. E., & Goodgame, B. (2019). Recent trends in the age at diagnosis of colorectal cancer in the US National Cancer Data Base, 2004-2015. *Cancer*.

¹⁶ Araghi, M., Soerjomataram, I., Bardot, A., Ferlay, J., Cabasag, C. J., Morrison, D. S., ... & Engholm, G. (2019). Changes in colorectal cancer incidence in seven high-income countries: a population-based study. *The Lancet Gastroenterology & Hepatology*, 4(7), 511-518.

¹⁷ Vuik, F. E., Nieuwenburg, S. A., Bardou, M., Lansdorp-Vogelaar, I., Dinis-Ribeiro, M., Bento, M. J., ... & Suchanek, S. (2019). Increasing incidence of colorectal cancer in young adults in Europe over the last 25 years. *Gut*, gutjnl-2018.

- (b) systematic distortion and misrepresentation of the findings of peer-reviewed studies in reputable journals;
- (c) dismissal of scientific evidence on spurious “limitations” grounds;
- (d) bias and systematic omission of studies;
- (e) incorrect and misleading statements;
- (f) lack of transparency.

In the round, and in my view as a scientist, this review fails to meet the basic criteria set for valid and reliable scientific research. You might ask where is the objective proof of my assertion? In answering this, I contend that if a truly independent group of scientists conducted an equally rigorous review of the same literature and came to different conclusions then this would support my argument as to the trustworthiness of your report. Was there such a review? Yes, there was. I now discuss this.

The WHO’s IARC Advisory Group comes to different conclusions using the same body of evidence

In March 2019, based on what was similar laboratory and epidemiological research evidence, an Advisory Group of 29 scientists from 18 countries recommended that non-ionizing radiofrequency radiation (RFR) receive High Priority from by the WHO’s International Agency for Research on Cancer (IARC) Monographs programme during 2020–24. In doing so, the Advisory Group voiced concern about the health risks identified by the research they reviewed over the past 8 years, since non-ionizing radiofrequency radiation was classified as Class 2B carcinogen (see below¹⁸). Above I identified recent epidemiological studies on the incidence of primary brain and other central nervous system tumors and colorectal cancers in young adults, which would only serve to strengthen their recommendations, had they been available at the time of the review. These studies indicate clear risks to adolescents and young adults from smartphone use and the global practice of carrying smartphones in front and back pants/jeans pockets, all things considered.

In addition, there is an increasing body of independent analyses of peer-reviewed scientific research, which concludes that non-ionizing RFR should be reclassified as a Class 1 carcinogen.^{19, 20, 21, 22} It is more likely, however, that the IARC Advisory Group recommendation will result in RFR achieving at least a Class 2A probable carcinogen status. However, former ICNIRP scientist James C. Lin²³ argues in relation to the NTP and Ramazini Institute peer-reviewed findings in 2018: *“The time is right for the IARC to upgrade its previous epidemiology based classification of RF exposure to higher levels in terms of the carcinogenicity of RF radiation for humans. Recently, two relatively well-conducted RF and microwave exposure studies employing the Sprague–Dawley strain of rats—without, however, using any cancer-promoting agents (or cocarcinogens)—showed consistent results in significantly increased*

¹⁸<https://www.iarc.fr/news-events/report-of-the-advisory-group-to-recommend-priorities-for-the-iarc-monographs-during-2020-2024/>

https://monographs.iarc.fr/wp-content/uploads/2019/10/IARCMonographs-AGReport-Priorities_2020-2024.pdf.

¹⁹Kostoff, R. N., Heroux, P., Aschner, M., & Tsatsakis, A. (2020). Adverse health effects of 5G mobile networking technology under real-life conditions. *Toxicology Letters*.

²⁰Miller, A. B., Morgan, L. L., Udasin, I., & Davis, D. L. (2018). Cancer epidemiology update, following the 2011 IARC evaluation of radiofrequency electromagnetic fields (Monograph 102). *Environmental research*, 167, 673-683.: [//www.sciencedirect.com/science/article/pii/S0013935118303475](https://www.sciencedirect.com/science/article/pii/S0013935118303475)

²¹Belpomme, D., Hardell, L., Belyaev, I., Burgio, E., & Carpenter, D. O. (2018). Thermal and non-thermal health effects of low intensity non-ionizing radiation: An international perspective. *Environmental Pollution*, 242, 643-658.

²² Kostoff, R. N., Heroux, P., Aschner, M., & Tsatsakis, A. (2020). Adverse health effects of 5G mobile networking technology under real-life conditions. *Toxicology Letters*.

²³ James C. Lin is Professor of Physiology and Biophysics University of Illinois, Chicago.

total primary cancer or overall tumor rates in animals exposed to RF radiation.”²⁴ Thus, for all intents and purposes, respected independent scientists are of the strong opinion that RFR is at least a Class 2A probable carcinogen and, given the recent experimental and epidemiological evidence, almost certainly a Class 1 carcinogen. It is also noteworthy that Professor Lin’s assessment of the validity and reliability of the NTP and Ramazzini studies also calls into question the conclusions of the report by your Center.

FDA’s confused and contradictory approach to regulating carcinogens

During the second half of 2019, the FDA investigated “*the detection of a contaminant known as N-Nitrosodimethylamine (NDMA) in ranitidine medications, commonly known by the brand name Zantac.*”²⁵ In an update to its previous announcement, the FDA “*advised companies to recall their ranitidine if testing shows levels of NDMA above the acceptable daily intake (96 nanograms per day or 0.32 parts per million for ranitidine).*” N-nitrosodimethylamine (NDMA) is an IARC Class 2A probable carcinogen. That FDA recall affects Zantac and all medications containing ranitidine as NDMA was found in these over-the-counter indigestion drugs. In October, *Scientific American* published an article titled: *What We Know about the Possible Carcinogen Found in Zantac*. *Scientific American* reported that the NDMA found in this medication is classified as a probable human carcinogen based on results from laboratory tests on rats. There is little evidence that it causes cancer in humans, despite the WHO’s IARC classification of it as a Class 2A carcinogen. Please note that the majority of Class 2A/B carcinogens are linked with an increased risk of cancer in individuals that are periodically exposed to them. That is, the frequent ingestion of NDMA over a particular period of time increases the risk, but not the certainty of developing cancer. Digestion remedies such as Zantac were nevertheless withdrawn because of “*fears it contains traces*” of NDMA.

To reiterate, while currently a Class 2B carcinogen as indicated above, scientific evidence and expert opinion currently places RFR in the Class 2A category and probably in the Class 1 category. The WHO/IARC is expected to reclassify it as such soon. With the proliferation of 4G, WiFi and 5G, adults and children are exposed to a scientifically recognized toxin and carcinogen, 24 hours a day, 7 days a week, from multiple sources in the home, school, the workplace, and society. The FCC and ICNIRP thermal safety levels do not protect adults or children from exposure to this carcinogen and the risks it poses. Risks much greater than that which NDMA poses in Zantac. Note that the risk here from RFR is systemic and individual, not just individual as in the case of Zantac, and is one that must be mitigated by minimizing or eliminating exposure, where possible. Thus, the FDA has demonstrated that it does not really understand the risks that carcinogens such as RFR pose to humans.

Why were the authors of the FDA review not named?

As indicated previously, it is most troubling that this report has no authors. On the FDA website on the scientific integrity page, the following text appears.

*“Our scientific experts may hold differing views on what they conclude from data. There may be multiple options that can be considered during policy development or regulatory decision-making. However, in reaching our conclusions through a deliberative scientific process, FDA strives to present an evaluation and analysis of the data—including uncertainties—in an unbiased manner.”*²⁶

²⁴ Lin, J. C. (2019). The Significance of Primary Tumors in the NTP Study of Chronic Rat Exposure to Cell Phone Radiation [Health Matters]. IEEE Microwave Magazine, 20(11), 18-21.

²⁵ <https://www.fda.gov/news-events/press-announcements/statement-new-testing-results-including-low-levels-impurities-ranitidine-drugs>

²⁶²⁶ <https://www.fda.gov/science-research/about-science-research-fda/scientific-integrity-fda>

In light of the report's provenance and lack of transparency in its authorship and conduct, the following questions require attention.

- Did the in-house scientific experts at the FDA's Center for Devices and Radiological Health (CDRH) refuse to be associated with the published conclusions?
- How can the scientific community accept the validity and reliability of an anonymous report, given its mysterious provenance?
- How are we to evaluate any conflicts of interest among the authors of the report?

It is notable that as Director of the Center for Devices and Radiological Health, you have not put your name to this report nor signed off on it, as one would have expected. *Why is this?*

There are too many question marks over this report for it to be accepted as valid and reliable by any reasonable person, let alone a member of the scientific community. Thus, one may ask if the FDA has failed in its statutory duty to protect public health by promulgating the falsehood that RFR is not a carcinogen? Has it, therefore, put the health of US citizens, and children in particular, at significant risk, the very antithesis to its overall mission to "*protect the public health*"?

Yours Sincerely,



Professor Tom Butler
University College Cork
e: tbutler@ucc.ie
m: 0879865629

Statements to the FDA by Alfonso Balmori, BSc, Lennart Hardell MD, Paul Heroux PhD, Devra Davis PhD, Elihu D. Richter MD, MPH, Alvaro de Salles, PhD, Dr. Marc Arazi, Marko S. Markov PhD, Martin L. Pall, PhD, Hiie Hinrikus, PhD, DSc, David O. Carpenter MD, Suleyman Dasdag PhD.

Statement by Wildlife Biologist Alfonso Balmori, BSc on the FDA Review of Cell Phone Radiation and Cancer

The FDA review omits an evaluation of the science on wireless radiation impacts to trees and wildlife. Electromagnetic radiation is a form of environmental pollution which may hurt wildlife. I am providing examples of my published research below as examples of this scientific evidence.

I have co-published research entitled "[Radiofrequency radiation injures trees around mobile phone base stations](https://www.ncbi.nlm.nih.gov/pubmed/27552133)" finding harm to trees near base stations (cell antennas) in a long term field monitoring study in two cities. We measured the radiofrequency radiation levels and found significant differences between the damaged side facing the cell phone mast and the opposite side. Our statistical analysis demonstrated that electromagnetic radiation from mobile phone masts was harmful to the trees. The damage usually starts on one side of the tree, then extends to the whole tree over time. <https://www.ncbi.nlm.nih.gov/pubmed/27552133>

I have also published an [experimental study](https://www.ncbi.nlm.nih.gov/pubmed/20560769) where we exposed eggs and tadpoles of the common frog (*Rana temporaria*) to the electromagnetic radiation from mobile (cell) phone antennas located at a distance of 140 meters. The experiment lasted two months, from the egg phase until an advanced phase of tadpole prior to metamorphosis. In this study, we found the exposed group had altered development and a higher mortality rate in comparison to the unexposed frogs. <https://www.ncbi.nlm.nih.gov/pubmed/20560769>

In addition, my [research](https://www.ncbi.nlm.nih.gov/pubmed/25747364) has documented anthropogenic radiofrequency electromagnetic fields as an emerging threat to wildlife orientation. For example, exposure at levels that are found in the environment (in urban areas and near base stations) may particularly alter the receptor organs to orient in the magnetic field of the earth. These results could have important implications for migratory birds and insects, especially in urban areas, but could also apply to birds and insects in natural and protected areas where there are powerful base station emitters of radio frequencies. Therefore, more research on the effects of electromagnetic radiation in nature is urgently needed to investigate this emerging threat. At the present time, there are reasonable grounds based on scientific evidence for believing that microwave radiation constitutes an environmental and health hazard. Existing guidelines are not protective. The paper "Anthropogenic radiofrequency electromagnetic fields as an emerging threat to wildlife orientation" is online at <https://www.ncbi.nlm.nih.gov/pubmed/25747364>

Another research study I co-published in the journal Electromagnetic Biology and Medicine is entitled "[The urban decline of the house sparrow \(*Passer domesticus*\): a possible link with](https://www.ncbi.nlm.nih.gov/pubmed/25747364)

[electromagnetic radiation.](#)” Between October 2002 and May 2006, point transect sampling was performed at 30 points during 40 visits in Valladolid, Spain. At each point, we carried out counts of sparrows and measured the mean electric field strength (radio frequencies and microwaves: 1 MHz–3 GHz range). Significant declines ($P = 0.0037$) were observed in the mean bird density over time, and significantly low bird density was observed in areas with high electric field strength. The logarithmic regression of the mean bird density vs. field strength groups (considering field strength in 0.1 V/m increments) was $R = -0.87$ ($P = 0.0001$). The results of this article support the hypothesis that electromagnetic signals are associated with the observed decline in the sparrow population. We conclude that electromagnetic pollution may be responsible, either by itself or in combination with other factors, for the observed decline of the species in European cities during recent years. The apparently strong dependence between bird density and field strength according to this work could be used for a more controlled study to test the hypothesis. <https://www.ncbi.nlm.nih.gov/pubmed/17613041>

In another study, monitoring of a white stork population in the vicinity of Cellular Phone Base Stations was carried out, with the objective of detecting possible effects. The total productivity, in the nests located within 200 meters of antennae, was 0.86 ± 0.16 . For those located further than 300m, the result was practically doubled, with an average of 1.6 ± 0.14 . Very significant differences among the total productivity were found ($U = 240$, $p = 0.001$, Mann-Whitney test). Twelve nests (40%) located within than 200m of antennae never had chicks, while only one (3.3%) located further than 300m had no chicks. The electric field intensity was higher on nests within 200m (2.36 ± 0.82 V/m) than on nests further than 300m (0.53 ± 0.82 V/m). The study concludes that, “these results are compatible with the possibility that microwaves are interfering with the reproduction of white storks and would corroborate the results of laboratory research by other authors”. <https://www.tandfonline.com/doi/abs/10.1080/15368370500205472>

A review on the impact of radiofrequency radiation from wireless telecommunications on wildlife is presented in [“Electromagnetic pollution from phone masts. Effects on wildlife”](#) published in the journal Pathophysiology. Electromagnetic radiation is a form of environmental pollution which may hurt wildlife. Phone masts located in their living areas are irradiating continuously some species that could suffer long-term effects, like reduction of their natural defenses, deterioration of their health, problems in reproduction and reduction of their useful territory through habitat deterioration. Electromagnetic radiation can exert an aversive behavioral response in rats, bats and birds such as sparrows. Therefore microwave and radiofrequency pollution constitutes a potential cause for the decline of animal populations and deterioration of health of plants living near phone masts. To measure these effects urgent specific studies are necessary. <https://www.ncbi.nlm.nih.gov/pubmed/?term=Electromagnetic+pollution+from+phone+masts.+Effects+on+wildlife>

Despite the widespread use of wireless telephone networks around the world, authorities and researchers have paid little attention to the potential harmful effects of mobile phone radiation on wildlife. This paper briefly reviews the available scientific information on this topic and recommends further studies and specific lines of research to confirm or refute the experimental

results to date. Controls must be introduced and technology rendered safe for the environment, particularly, threatened species. <https://www.ncbi.nlm.nih.gov/pubmed/25089692>

Atmospheric electrical discharges during thunderstorms, and the related electromagnetic fields (EMFs)/waves called sferics, can be sensed by humans at long distances through a variety of symptoms, mainly headache, fatigue, etc. Up to today there is no explanation for this association. Sferics consist of partially polarized electromagnetic pulses with an oscillating carrier signal in the very low frequency (VLF) band and a pulse repetition frequency in the extremely low frequency (ELF) band. Their ELF intensity may reach ~5 mV/m at global ranges, and ~0.5 V/m at ~1000 km from the lightning. The health symptoms associated with sferics are also associated with antennas of mobile telephony base stations and handsets, which emit radio frequency (RF) radiation pulsed on ELF, and expose humans at similar or stronger electric field intensities with sferics. According to the Ion Forced-Oscillation mechanism, polarized ELF EMFs of intensities down to 0.1–1 mV/m are able to disrupt any living cell's electrochemical balance and function by irregular gating of electro-sensitive ion channels on the cell membranes, and thus initiate a variety of health symptoms, while VLF EMFs need to be thousands of times stronger in order to be able to initiate health effects. We examine EMFs from sferics in terms of their bioactivity on the basis of this mechanism. We introduce the hypothesis that stronger atmospheric discharges may reasonably be considered to be ~70% along a straight line, and thus the associated EMFs (sferics) ~70% polarized. We find that sferics mainly in the ELF band have adequate intensity and polarization to cause biological/health effects.

We provide explanation for the effects of sferics on human/animal health on the basis of this mechanism. <https://www.ncbi.nlm.nih.gov/pubmed/28558424>

It is documented that a few days or weeks before major Earthquakes (EQs) there are changes in animal behavior within distances up to 500 km from the seismic epicenter. At the same time Seismic Electric Signals (SES), geomagnetic and ionospheric perturbations, are detected within similar distances. SES consist of single unipolar pulses, and/or groups of such pulses called "SES activities" with an average frequency between successive pulses on the order of ~0.01 Hz and electric field intensity on the order of ~10⁻⁵-10⁻⁴ V/m (Frazer-Smith et al., 1990; Rikitake, 1998; Varotsos et al., 1993, 2011, 2019; Hayakawa et al., 2013; Grant et al., 2015). We show that the SES activities can be sensed by living organisms through the "Ion Forced-Oscillation Mechanism" for the action of Electromagnetic Fields (EMFs) on cells, according to which polarized EMFs can cause irregular gating of electro-sensitive ion channels on the cell membranes with consequent disruption of the cell electrochemical balance (Panagopoulos et al., 2000, 2002, 2015). This can be sensed by sensitive animals as discomfort in cases of weak and transient exposures, and may even lead to DNA damage and serious health implications in cases of intense exposure conditions (as in certain cases of man-made EMF exposures). Moreover, we show that the geomagnetic and ionospheric perturbations cannot be sensed through this mechanism. The same mechanism has explained meteoropathy, the sensing of upcoming thunderstorms by sensitive individuals, through the action of the EMFs of lightning discharges (Panagopoulos and Balmori, 2017). The present study shows that centuries-long anecdotal rumors of animals sensing intense upcoming EQs and displaying unusual behavior, lately documented by systematic studies, are now explained for the first time on the basis of the

electromagnetic nature of all living organisms, and the electromagnetic signals emitted prior to EQs. <https://www.ncbi.nlm.nih.gov/pubmed/28558424>

Signed, Alfonso Balmori, BSc Biologist. Spain
[Alfonso Balmori on researchgate.](#)

Paul Heroux PhD Statement in Response to the FDA Report on Cell Phone Radiation

The FDA Report stated, "We do not know if there is a causal effect or if these results are due to weakening of the immune response due to animal stress from cyclic heating and thermoregulation decline in aging animals leading to whole-body temperature increase, possible sleep disruption due to the cyclic heating, or due to an RF-specific effect that has not been identified and has an adverse effect before heating becomes the dominant safety issue."

Response by Paul Heroux PhD

"FDA is pushing red herrings to avoid the inevitable conclusion that electromagnetic fields have important carcinogenic effects on animals below thermal levels.

This is an apparent attempt to confuse the discussion by invoking an "immune" mechanism driven by heat and sleep disturbances, and other ghost mechanisms that would inevitably turn out to be dead ends.

These surprising comments should not distract us from (1) at least four previous spectacular animal experiments linking fields to cancer, from (2) the drastic action of fields on human cancer cells at field intensities nowhere near the thermal limit, as well as (3) the literature linking fields to reactive oxygen species and mutations.

An institution (FDA) displaying such a fundamental reluctance to acknowledge evidence should abstain from commenting on the NTP study.

The FDA Report stated, "It is possible that any form (ambient, IR, ultrasound) of cyclic whole-body heating of this magnitude may cause similar findings, but no such studies have been conducted to date."

Response by Paul Heroux PhD

"This is a way to extend the lie about health impacts of electromagnetic fields by directing attention to some form of further investigation that would allow industry to proceed with increases in human exposures, while we await the results of yet another waste of time."

Paul Héroux, PhD
Professor of Toxicology and Health Effects of Electromagnetism
McGill University Medicine

Department of Surgery, McGill University Health Center

Statement by Christos D. Georgiou, Ph.D.

The issued by FDA "literature review" conclusion that there are no connections between cell phones and cancer is not valid, as it is contradicted, at least, by the classification, by IARC-WHO, of cell phone-emitted EMF as possibly carcinogenic to humans (Group 2B). The numerous research studies IARC reviewed to base the Group 2B classification also included a study of mine (cited in the IARC-WHO 2013 report; https://www.ncbi.nlm.nih.gov/books/NBK304630/pdf/Bookshelf_NBK304630.pdf, pages 101,103,121), which advances the free radical pair mechanism of non thermal induction of carcinogenic oxidative stress by exposure to low-intensity RF radiation.

Christos D. Georgiou, Ph.D.
Professor Emeritus of Biochemistry
Biology Department
University of Patras, Greece

Statement by Anthony B. Miller MD

“Radiofrequency is an established carcinogen. Cell phones held close to the head will substantially increase the risk of a type of brain cancer—glioblastoma,” stated Dr. Anthony B. Miller, Professor Emeritus at the Dalla Lana School of Public Health, University of Toronto and former Director of the Epidemiology Unit of the National Cancer Institute of Canada. Miller also served as a Senior Epidemiologist, International Agency for Research on Cancer and published a major [research review](#) in 2018, concluding that “based on the evidence reviewed it is our opinion that IARC's current categorization of RFR as a Possible Human Carcinogen (Group 2B) should be upgraded to Carcinogenic to Humans (Group 1). Miller recommends people use safer wired technology rather than wireless technology, “We should do all we can to reduce exposure.”

Statement by Devra Davis PhD

“This astonishing report from an agency charged with protecting public health should be retracted. It does not meet minimum standards of scientific reporting or review, as it takes a skewed look at science, lists neither authors nor reviewers. It ignores the recent [Yale study](#) supported by the American Cancer Society linking cell phone use to thyroid cancer. It does not consider that antiquated phone test methods [do not protect](#) anyone from microwave radiation emitted by phones or other devices. It ignores [repeated calls](#) from the American Academy of Pediatrics and numerous experts in the field of child health to take into account the [unique vulnerability](#) of children, pregnant women and young adults. No reference is made to a growing [body](#) of [research](#) showing [brain damage](#) and [headache](#) and [replicated research](#) showing

memory damage in teens after just one year of cell phone use,” stated [Devra Davis PhD, MPH](#), President of the Environmental Health Trust.

Prof. Suleyman Dasdag, Department of Biophysics, Medical School of Istanbul Medeniyet University, Istanbul, Turkey, also noted: “Mobile phones are not as innocent as they seem. In [my studies to date](#), I have found that wireless radiofrequency (RF) does not affect every organ in the same way and very different parameters are important in the emergence of effects. In our two studies on RF and the brain in 2015 and our study published this year, we found that RFs may affect key molecules. In addition, we observed in our brain study that RF radiation can affect the death of brain cells. I also want cell phones not to cause brain tumors, but our studies and the published studies we have reviewed are in the direction that the risk will increase even more after 5G.”

Martin L. Pall, PhD, Professor Emeritus of Biochemistry and Basic Medical Sciences, Washington State University who has published [extensively](#) on how EMFs activate Voltage-Gated Calcium Channels which can lead to tumor promotion, disputed the report’s conclusions that cellphones are safe, noting that, “EMFs produce double strand DNA breaks which cause cancer via chromosomal rearrangements, copy number mutations and gene-amplification. EMFs also cause oxidized bases including 8-OHdG, which produce transition and transversion mutations such that when these occur in oncogenes or tumor suppressor genes, these mutations have important roles in causing cancer.”

“This report is pure nonsense! It is as though the author didn’t read any of the literature they cite,” stated David O. Carpenter MD, Director, Institute for Health and the Environment, University at Albany who has repeatedly documented adverse effects over 4 decades of [published research](#).

“Radiofrequency radiation should be regarded as a human carcinogen causing glioma,” stated Lennart Hardell MD, an advisor to the World Health Organization’s International Agency for Research on Cancer, who has published several studies finding associations between cancer and people who use cell phones regularly. He referred to one of his [published research](#) reviews concluding that radiofrequency is a carcinogen.

“The latest report by the National Toxicology Program is a game changer. We also should not ignore [case series reports](#) on cancer in military workers with whole body exposure to RF/MW, stated Professor Elihu D. Richter MD, MPH at the Occupational and Environmental Medicine Department at the Hebrew University-Hadassah School of Public Health and Community Medicine.

“Due to the recent results described in many peer reviewed scientific papers published in the international literature showing significant human health risks (including cancer) at levels of EMF exposures well below the available recommended limits (e.g., ICNIRP, FCC/IEEE/ANSI). We believe that the Precautionary Principle should be urgently adopted and the population

should be fully informed on the best ways to reduce their exposure and health impacts, “ stated Alvaro de Salles, Ph. D. Professor at Federal University of Rio Grande do Sul, Porto Alegre, Brazil whose [research studies](#) have found children are more exposed to RF from cell phones.

"The FDA's position is totally incomprehensible especially since the findings of the Phonegate scandal have revealed the deception by cell phone manufacturers who have knowingly overexposed all cell phone users to excessive radiation for decades," stated Dr. Marc Arazi of [Phonegate Association](#).

"Mankind is being forced to participate in a giant "experiment" without protocol, without collection of data and without adequate evaluation of the cocktail of EMF humankind is exposed to every day. The engineering community needs to recognize the fact that there is a difference between experimental exposure and continuous exposure to multiple frequencies and modulations. The FDA as well as ICNIRP have failed to investigate this to assure public safety, " stated Marko S. Markov PhD, [author](#) of major medical textbooks in bioelectromagnetics.

“Tissue heating is certainly not the only effect caused by radiofrequency radiation.,” stated Hiie Hinrikus, PhD, DSc, Professor Emeritus Centre for Biomedical Engineering at the Tallinn University of Technology who has published several [research studies](#) on microwave radiation. “Hundreds of studies performed by independent researchers have convincingly approved biological effects caused by low-level radiofrequency radiation in animals and humans at constant temperature. The reason is coherent nature of radiofrequency radiation. During billions years, living nature has been adapted to natural solar radiation, radiofrequency radiation is in principle different from solar radiation. Sun emits irregular incoherent radiation in wide frequency spectrum whereas technical radiofrequency sources emit regular coherent single-frequency radiation. The impact of irregular random and regular coherent electromagnetic radiation on living systems is different. Irregular radiation causes random forces and movement in tissues and can create only tissue heating. Coherent radiation causes regular forces and synchronous movement affecting simultaneously large amounts of molecules and cells in tissues. Therefore, the impact of radiofrequency radiation is much stronger than the heating effect only. This is convincingly approved also in microwave chemistry.”