Congress of the United States Washington, DC 20515

July 18, 2019

Jeffrey Shuren, M.D., J.D., Director of the Center for Devices and Radiological Health Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, Maryland 20993 Edward Margerrison, Ph.D., Director of the Office of Science and Engineering Laboratories Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, Maryland 20993

Dear Dr. Shuren and Dr. Margerrison,

We're writing to request further information about the impact of radiofrequency (RF) exposure on human health. Specifically, we request a summary of the research that the Food and Drug Administration (FDA) has used to reach conclusions that the current safety limits for cell phone RF energy exposure is acceptable for protecting public health.

As you know, the Federal Food, Drug, and Cosmetic Act (FDCA) requires the Secretary of Health and Human Services to "establish and carry out an electronic product radiation control program," through which the Secretary shall "plan, conduct, coordinate, and support research, development, training, and operational activities to minimize the emissions of and the exposure of people to, unnecessary electronic product radiation." Additionally, the FDCA requires the Secretary to "prescribe performance standards for electronic products to control the emission of electronic product radiation from such products if he determines that such standards are necessary for the protection of the public health and safety." As such, FDA's public mission includes "ensuring the safety of…products that emit radiation," including cell phones.³

FDA's research of cell phone safety has three important uses. First, while FDA does not have pre-market review authorities for cell phones,⁴ its information is "used by the Federal Communications Commission (FCC) to set the standards for exposure limits of radiation from cell phones," which cell phone manufacturers must follow. Second, the public relies on conclusions published on FDA's website. Third, scientists and researchers use this information to assess methodologies and to inform their own research questions.

Director Jeffrey Shuren, who leads the Center for Devices and Radiological Health that is charged with overseeing radiation-emitting electronic products, has stated that FDA has "relied on decades of research and hundreds of studies to have the most complete evaluation of radiofrequency energy exposure," leading to the judgement that "the current safety limits for cell phone radiofrequency energy exposure remain acceptable for protecting the public health." In fact, FDA's website notes that "[t]he weight of scientific evidence has not linked cell phones with any health problems."

In addition to FDA, other agencies and scientists have reached similar conclusions. The FCC finds that, "currently no scientific evidence establishes a causal link between wireless device use and cancer or other illnesses." The Centers for Disease Control and Prevention finds that, "[a]t this time we do not have the science to link health problems to cell phone use." A study of over 300,000 Danish mobile phone users found that for mobile phone users, "there were no increased risks of tumours of the central nervous system, providing little evidence for a causal association." ¹⁰

While we respect the expertise, rigor, and independence that lead to the FDA's conclusions on the safety of cell phone use, we request that the agency make available a summary of the research and methodologies used to reach its conclusions as many in the public and scientific community raise questions about the health impacts of cell phones. Hundreds of constituents have contacted our offices and those of our colleagues to raise concerns about the impact of cell phone RF emissions on human health, especially as our country transitions to 5G. Recent National Toxicology Program studies, ¹¹ a Government Accountability Office report, ¹² many peer-reviewed studies, ¹³ and credible literature reviews ¹⁴ have also raised questions about the impact of RF exposure on human health and the state of scientific research on this topic.

Given that 95 percent of Americans own a cell phone, ¹⁵ having a better understanding of FDA's analysis on this issue and how the agency reached the conclusion that current safety limits for cell phone RF energy exposure protect public health is critical. To that end, we ask that the FDA share a summary of the research that the FDA has reviewed related to RF exposure in cell phones, including whether such research covers the RF ranges that may be used in 5G¹⁶ and the criteria used to include or exclude studies in the FDA's review of research.

Sincerely,

Anna G. Eshoo

Member of Congress

Jeff Merkley

United States Senator

ce: The Honorable Chairman and Commissioners of the FCC

The Honorable members of the Radiofrequency Interagency Work Group

¹ The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360ii(a) (1938).

² The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360kk(a)(1) (1938).

³ "What We Do," U.S. Food and Drug Administration, March 28, 2018, https://www.fda.gov/aboutfda/whatwedo/#mission.

⁴ "Cell Phones," U.S. Food and Drug Administration, August 29, 2018, https://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/homebusinessandentertainment/cellphones/defau lt.htm.

⁵ "Statement from Jeffrey Shuren, M.D., J.D., Director of the FDA's Center for Devices and Radiological Health on the National Toxicology Program's Report on Radiofrequency Energy Exposure" (U.S. Food and Drug Administration, November 1, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm624809.htm.

⁶ Id.

⁷ "Cell Phones - Health Issues," U.S. Food & Drug Administration, December 4, 2017, https://www.fda.gov/radiation-emittingproducts/ radiationemittingproductsandprocedures/homebusinessandentertainment/cellphones/ucm116282.htm.

⁸ "Wireless Devices and Health Concerns," Federal Communications Commission, August 6, 2018, https://www.fcc.gov/consumers/guides/wireless-devices-and-health-concerns.

⁹ "Radiation: FAQs about Cell Phones and Your Health," Centers for Disease Control and Prevention, June 9, 2014, https://www.cdc.gov/nceh/radiation/cell_phones._faq.html.

¹⁰ Patrizia Frei et al., "Use of Mobile Phones and Risk of Brain Tumours: Update of Danish Cohort Study," *BMJ* 343 (October 19, 2011): d6387, https://doi.org/10.1136/bmj.d6387.

¹¹ "Cell Phone Radio Frequency Radiation" (National Toxicology Program, November 2018), https://ntp.niehs.nih.gov/go/cellphone.

¹² "Exposure and Testing Requirements for Mobile Phones Should Be Reassessed" (U.S. Government Accountability Office, July 2012), https://www.gao.gov/assets/600/592901.pdf.

¹³ See, e.g., Lennart Hardell and Michael Carlberg, "Mobile Phone and Cordless Phone Use and the Risk for Glioma – Analysis of Pooled Case-Control Studies in Sweden, 1997–2003 and 2007–2009," *Pathophysiology* 22, no. 1 (March 1, 2015): 1–13, https://doi.org/10.1016/j.pathophys.2014.10.001; De-Kun Li et al., "Exposure to Magnetic Field Non-Ionizing Radiation and the Risk of Miscarriage: A Prospective Cohort Study," *Scientific Reports* 7, no. 1 (December 13, 2017): 17541, https://doi.org/10.1038/s41598-017-16623-8.

¹⁴ See, e.g., Igor Yakymenko et al., "Oxidative Mechanisms of Biological Activity of Low-Intensity Radiofrequency Radiation," *Electromagnetic Biology and Medicine* 35, no. 2 (April 2, 2016): 186–202, https://doi.org/10.3109/15368378.2015.1043557; Dominique Belpomme et al., "Thermal and Non-Thermal Health Effects of Low Intensity Non-Ionizing Radiation: An International Perspective," *Environmental Pollution* 242 (November 1, 2018): 643–58, https://doi.org/10.1016/j.envpol.2018.07.019.

¹⁵ "Mobile Fact Sheet" (Pew Research Center, February 5, 2018), https://www.pewinternet.org/fact-sheet/mobile/.

¹⁶ As defined by 3rd Generation Partnership Project's New Radio Release 15



The Honorable Anna G. Eshoo U.S. House of Representatives Washington, D.C. 20515-0518

SEP 0 9 2019

Dear Representative Eshoo:

Thank you for your letter of July 18, 2019, cosigned by Senator Jeff Merkley, regarding the impact of radiofrequency radiation (RFR) exposure on human health and requesting a summary of the research that the Food and Drug Administration (FDA or the Agency) has used to determine that current safety limits for cell phone RFR energy exposure is acceptable for protecting the public health. FDA takes any possible issues raised with respect to public health extremely seriously. We appreciate the opportunity to provide an overview of the substantial body of scientific evidence that has informed our determination that the current safety standard for RFR exposure remains appropriate.

The Agency has taken a comprehensive approach to evaluating the scientific evidence regarding the impact of RFR exposure on human health. In the attached summary, FDA explains the critical considerations that we have made in evaluating all available information on this and other related topics.

Please do not hesitate to contact us if you have additional questions. The same response has been sent to Senator Merkley.

Sincerely,

Jeffrey Sharen, M.D., J.D.

Director, Center for Devices and

Radiological Health

US Food and Drug Administration 10903 New Hampshire Avenue

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Summary of the Food and Drug Administration's (FDA) Review of the Scientific Evidence Regarding the Safety of Radio Frequency Radiation (RFR)

FDA's Findings.

FDA's conclusion that the current safety limits for cell phone RFR exposure remain acceptable for protecting the public health is supported by the considerable body of peer-reviewed scientific publications as well as public registries of, for example, cancer rates that show a slight decrease in brain tumors despite the enormous increase in cell phone use over the last two decades. Additionally, the Agency has not seen credible evidence that the roll out of 5G handsets will lead to additional risk for the population.

FDA considers all relevant scientific data on RFR and does not limit its considerations to any specific frequency or modulation due to the increasing use of, for example, Wi-Fi enabled medical devices. The Agency's ongoing evaluations include but are not limited to those frequencies currently being used by cell phones as well as those being considered for future uses (e.g., 5G).

The gold standard for the assessment of risk to public health remains the data and information that is available from studying effects on humans. Animal and laboratory studies can provide useful scientific information, but data on human health is the most informative where it is available. In the case of cell phone handsets, there is abundant evidence to support FDA's conclusion from epidemiological studies, public health surveillance data and supportive laboratory studies. The information on which FDA has based its conclusion is summarized below, together with a description of the methods that the Agency uses for undertaking risk analysis and other relevant scientific information.

Information Sources.

Peer-Reviewed Publications

Standard practice in scientific evaluation is to use the broadest set of credible information available and then to assess the significance of that information to the question at hand. The most commonly used source of information is the set of peer-reviewed publications that are indexed through Medline and typically retrieved through PubMed, which currently references over 29 million citations of biomedical literature. FDA uses this source as well as more specific sources of information where appropriate. For the ongoing monitoring of

possible effects of RFR, for example, the Agency also uses the Electromagnetic Frequency (EMF) Portal [1] as a potential source for peer-reviewed papers to ensure as wide a coverage as possible.

FDA also considers independent studies that are separately published, although the Agency often undertakes its own review of the papers analyzed in those reports in order to assess validity and applicability to the United States. Recent examples of independent studies that FDA considered include the 2013 International Agency for Research on Cancer (IARC) study [6], the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR 2015, [11]), the Swedish Radiation Safety Authority's (SSM) Scientific Council reports on EMF [12-17], and the 2017 reports from the National Toxicology Program studies on the effects of whole body irradiation of rodents [7 and 8], as well as other reports [3-5,18].

The main health outcome on which FDA focuses (for the current question regarding whether or not there are safety risks to patients from RFR emitted by cellphone handsets) relates to the onset of cancer formation, known as tumorigenesis. FDA focuses on this health outcome specifically because of public health concerns about possible effects of RFR emissions, although FDA considers all public health concerns that are discerned from FDA's evaluation of scientific evidence. The Agency examines evidence for any possible causal relationship between RFR exposure and tumorigenesis based on both *in vivo* (animal) studies as well as available epidemiological evidence pertaining to RFR exposure.

Epidemiological Studies and Public Health Surveillance Data

Based on FDA's ongoing evaluation, the available epidemiological and cancer incidence data continues to support the Agency's position that there are no quantifiable adverse health effects in humans caused by exposures at or under the current cell phone exposure limits.

In the last decade, there have been approximately 70 relevant epidemiological studies, mostly consisting of case-control studies and specifically excluding individual case reports, that have been published as peer-reviewed scientific evidence. As part of our ongoing monitoring activities, we have analyzed these publications for specific outcomes including brain tumors and other tumors as well as other potential adverse events. While some studies have suggested correlations between cellphone use and some tumors [20], there is no clear and consistent pattern that has emerged. As an example of the complexity of the situation, a large cohort study on skin cancers [10] appeared to demonstrate a borderline increase for basal cell carcinoma among women with 5-9 years of mobile phone

subscription. This slightly elevated risk, however, was not apparent in the population with longer subscriptions (10-12 years or over 13 years). Under the principles of dose response, a higher dose or amount of a causative agent will lead to a higher or similar effect, but not a reduced effect. The findings briefly described above do not adhere to this principle (where longer cellphone use did not lead to a higher health risk) and therefore are likely to be the result of chance – a false positive.

We also monitor the Surveillance, Epidemiology, and End Results (SEER) database maintained by the National Cancer Institute (NCI) at the National Institutes for Health (NIH), which continues to show that brain cancer rates are not increasing despite the significant uptake of cell phone usage. Ascribing changes in population-based health related outcomes to single causes is always challenging. Even so, there are highly reliable statistics on the current rates of cancer in the US population, and FDA continues to believe that studying the population rates of brain cancer is an appropriate marker for the assessment of risks to public health that may be associated with cell phone use. Data from the SEER database for brain and other nervous system cancer incidence rates shows that from 2000 to 2016 the rate of such cancers has gone down from a rate of 6.9 per 100,000 (confidence intervals 6.7 – 7.0) in 2000 to a rate of 5.9 cases per 100,000 (confidence interval 5.8 to 6.1) in 2016. NCI also estimates that from 1987 to 2016, the rate of such tumors has been dropping by approximately 0.2% per year. ¹

The NCI data clearly demonstrate that there is no widespread rise in brain and other nervous system cancers in the last (nearly) two decades despite the enormous increase in cell phone handsets use during this period. The Pew Research Center estimates that from 2002 to 2019, the percentage of the population owning a cell phone or smartphone has risen from 62% to 96%, and yet there is a small decrease in brain and other nervous tissue cancer rates. This is not a likely scenario if cell phones are causing cancer. ..

In Vivo Scientific Studies

There is no clear evidence that RFR exposure at levels experienced by the public from cell phone use leads to tumorigenesis in published *in vivo* studies.

Over the last decade, there have been approximately 125 articles relating to the study of RFR on animals; however, none have demonstrated convincing evidence that localized

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¹ seer.cancer.gov

exposure of RFR at levels that would be encountered by cell phone users can lead to adverse effects.

In vivo studies assessing possible adverse or other effects of RFR are extremely challenging studies to design and undertake for several reasons. These reasons include the engineering considerations of applying a RFR field to animals that may specifically simulate, for example, the localized exposure of tissue to a cell phone held to the ear. Many researchers therefore undertake whole body exposure of the animals to the RFR radiation to overcome the challenges noted above. However, the effects of whole body exposure data may not reflect what happens in the real-world situation of localized exposure around the ear from a handset.

There are also considerable difficulties in determining the specific absorption rate (SAR) RFR that animals may be exposed to in a study setting and relating that to human exposure. It is possible, for example, to determine the level of RFR that is generated, but equating that level to the amount that is absorbed in an animal cannot be done. Additionally, it is difficult to separate the effects of direct RFR exposure, if there are any that occurred, from the well-documented indirect effects of temperature rise (the only proven biological mechanism of RFR on tissue) and the stress encountered by experimental animals from whole body exposure even in the minority of scientific reports that suggest a link. Both increased body temperature and stress from any cause have been linked to an increase risk for developing tumors in animals.

Given the difficulties of conducting *in vivo* studies on the effects of RFR described above and the widespread use of cell phones, epidemiological and real-world evidence tend to provide more relevant and accurate information related to possible risk from RFR exposure caused by cell phone use. *In vivo* studies are clearly of immense value in medical science, but they are less useful than studying effects on the human population, where that is feasible.

FDA Review of NTP Reports

As we have stated in the past, the Agency disagrees with the conclusions of the rodent studies conducted by the National Toxicology Program (NTP) at the request of FDA [7 and 8]. These studies were conducted with high power levels of RFR over the whole body of the experimental rodents in intervals (10 minutes on 10 minutes off) for 2 years. FDA disagrees with the study's conclusions because the study design did not reflect the levels to which people are exposed to cell phone use and entailed the same problems as other whole body

in vivo animal exposure studies. In addition to the *in vivo* study concerns we noted earlier about extrapolating the results of such studies to local effects in the human body, the NTP studies also did not adequately account for other possible causes of health effects resulting from such indirect influences as temperature rises and stress to the animals. Furthermore, no effects were seen in mice of either sex or in female rats. As noted by the director of the NTP studies in the NIH Press Release accompanying the study results, "The levels and duration of exposure to RFR were much greater than what people experience with even the highest level of cell phone use, and exposed the rodents' whole bodies. So, these findings should not be directly extrapolated to human cell phone usage".

No New implications for 5G

As part of this summary of FDA's conclusions, it is important to address concerns about the implications of 5G technology. While many of the specifics of 5G remain ill-defined at this point in time, it is known that 5G cellphones will likely use higher frequencies than those currently in use [2]. The current body of scientific evidence covers these frequencies and the fundamental physics involved has been well understood for many years. The slightly higher frequencies are associated with correspondingly higher energy levels, but remain significantly lower than the energies associated with other forms of electromagnetic waves, including visible light. Additionally, these higher frequencies are known to penetrate less deeply into tissue compared with the frequencies currently in use for cellphones [19]. All frequencies used for communications (and visible light) are classified as non-ionizing (i.e. these frequencies do not carry sufficient energy to cause atoms or molecules to lose electrons and become ionized). This is in stark contrast to the energies associated with, for example, X-rays or gamma rays, which carry up to a billion times more energy than the radio wave frequencies in use by cell phones, and are well documented as a cause of cancer. Based on this information, the new 5G technologies are unlikely to pose additional risks to health for individuals. FDA will continue to monitor scientific information as it becomes available regarding the impacts of 5G.

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October 18, 2019

The Honorable Anna Eshoo United States Representative for California 202 Cannon House Office Building Washington, D.C. 20515

The Honorable Jeff Merkley United States Senator for Oregon 313 Hart Senate Office Building Washington, DC 20510

Re: 1) FDA response to inquiry regarding RFR health and safety and 2) Congressional hearing

Dear Representative Eshoo and Senator Merkley,

I am writing to bring your attention to a number of serious errors and misleading statements made by Jeffrey Shuren and Edward Margarrison of the FDA in a September 9, 2019 letter to you in response to your request for information on the safety of 5G and cellphone and other wireless radiation.

I want to urge you to hold oversight hearings of the FDA and FCC to investigate how these agencies can ignore 1. the recent investigations by the Chicago Tribune and French government that find phones violate FCC limits when in the pocket¹² and 2. the results of a \$30 million National Toxicology Program (NTP) study design FDA previously had vetted that followed the gold standard for such research. It is important that Congress inquire as to what safety studies are underway to ensure public health and the environment do not face unreasonable risks from 5G.

Summary of Main Points:

- The FDA says cancer rates have not increased but the CDC has reported increases in pediatric
 cancers including brain, renal, hepatic and thyroid cancer. In addition, several studies show rises
 beginning when the studies investigated cellphone associated tumors such as salivary gland
 tumors and glioblastoma.
- The FDA states it is only focused on cancer as a health effect of cellphone radiation, but cancer is only one of many serious effects associated with radiofrequency radiation as research has found adverse effects to DNA, brain development, memory and reproduction.
- The FDA states that "the Agency has not seen credible evidence" whereas hundreds of studies
 have indeed found an effect from wireless frequencies and indicate that increased exposure
 could have serious consequences.

¹ Gandhi, Om P., (2019). <u>Microwave Emissions From Cell Phones Exceed Safety Limits in Europe and the US</u> When Touching the Body, IEEE Access

² Roe, Sam, (2019). We tested popular cellphones for radiofrequency radiation. Now the FCC is investigating, Chicago Tribune

- The FDA states that epidemiological data supports its position whereas, in fact, several published reviews of the epidemiological studies show the opposite: long-term use of cellphones is associated with increased cancer risk.
- The FDA dismisses the National Toxicology Program study on cellphone radiation with criticisms that are unfounded scientifically.
- The FDA letter lacks any comprehensive scientific report on the FDA's review of the research. Where are the studies they reviewed? How was the research evaluated? Scientists have repeatedly asked for the FDA's systematic review but never received a response to their request. Does the review even exist?

In summary, the FDA is not able to substantiate its opinion that RF limits remain acceptable to protect human health.

At the outset, I should note that their letter does not reference any specific public health, environmental or other human health effects studies conducted on 5G. This letter contains no research on the long term health effects to the public. Indeed, such research does not exist. This is why I and more than 240 other experts in the field have written to the United Nations seeking a moratorium on 5G until such testing can be carried out³. Over two hundred fifty scientists from 42 nations are calling for reductions in exposure to the current wireless systems in use today⁴.

In addition, it should be noted that none of the 5G handsets currently incorporate 5G for voice, but solely for enhancing downloads when connected to 5G networks in urban locations. Thus, these handsets must rely on 3G and 4G cellphones for voice for the foreseeable future.

In the meantime, it is instructive to consider what 5G entails at this time. So-called "small cells" infrastructure will require 3G, 4G and 5G wireless radiation-emitting antennas operating within them as the majority of devices available at this time rely on 3G and 4G. By bringing 3G and 4G antennas within a few feet of homes, schools and bedrooms, this effectively takes wireless signal generators generally sited at some distance from humans on mountain tops, tall buildings and the like and brings them into unprecedented close contact.

Wherever there are 80,000 or more people concentrated in a relatively small area as a football stadium, 5G signals operating at 27 GHz to 300 GHz (radar frequencies) will allow live streaming of videos and the use of social media, providing that individual users have the latest 5G phones. Of course, this presupposes that individuals value being able to attend a live sporting event while also broadcasting to social media, enabling an extraordinary level of multi-tasking. Does it also presuppose that individuals attending a live event are well-informed that they expose themselves and bystanders to firsthand and secondhand doses of biologically active radiation?

Most disconcerting to me, as a former member of the Scientific Review Board of the distinguished National Toxicology Program (NTP), is the FDA dismissal of the NTP bioassay on cellphone radiation.

³ Professor Em. Rainer Nyberg, Ass. professor Lennart Hardell, (2019) 5G Appeal https://www.5gappeal.eu/

⁴ Kelley, Elizabeth & Blank, Martin & Lai, Henry & Moskowitz, Joel & Havas, Magda. (2015). <u>International Appeal: Scientists call for protection from non-ionizing electromagnetic field exposure</u>. European Journal of Oncology, Volume 20, pp. 180-182.

This rejection is all the more surprising in light of the fact that throughout the decade-long process of creating this study, the FDA actively sought the original study in 1999, participated in review of proposed methodology in 2003 and provided oversight throughout the project, which followed well-established protocols for animal testing that form the backbone for evaluating potential toxic agents.

Exposure chambers were developed by Swiss engineers who also work closely with industry to provide exposures to rodents within their two-year lifespans comparable to those humans receive in their lifetimes. To reject the findings of the NTP that cellphone radiation at nonthermal levels (no measurable temperature change) can produce malignant rare tumors of the brain, malignant rare tumors of the heart nerve sheath, heart damage and DNA damage is a disservice to science and, frankly, endangers public health.

Specific errors or misleading statements of FDA are detailed below, with corrections immediately following:

FDA Letter states, "cancer rates ... show a slight decrease in brain tumors despite the enormous increase in cell phone use over the last two decades."

This is a misleading statement that has no relevance to the capacity of cellphones to cause glioblastoma multiforme (GBM)—a specific and highly aggressive form of brain tumor associated with long-term cell phone use. The research the FDA cites on brain tumors for the general population does not take into account data on malignant tumors specifically located in the temporal and frontal lobes. Nor does it account for the CDC research finding increases of brain, renal, hepatic, and thyroid cancers among individuals under 20 years old in the US⁵. In addition, Zada et al⁶ reported a very large increase in tumors located in the cerebellum. If all tumors are lumped together in any analysis with all age groups, this eliminates the ability to detect important patterns, especially in younger age groups. The incidence of glioblastoma multiforme more than doubled in England between 1995 and 2015, according to an analysis⁷ published in 2018. In fact, the types of tumors identified as being caused by cellphone radiation in epidemiological and toxicological studies include not only gliomas but also schwannomas (nerve tumors) and meningiomas⁸.

The specific types of tumors associated with long-term cellphone use are increasing, especially in the young in this country, as detailed in the following published account from a recent peer-reviewed article authored by several authorities in the field (including Anthony B. Miller, MD, who originally served as an expert editor for the International Agency for Research on Cancer monograph on cellphone radiation in 2011, and has written more than 600 peer-reviewed articles, and Colin Soskolne, Mark Oremus, myself

⁵ Siegel, David, et al., (2018). <u>INCIDENCE RATES AND TRENDS OF PEDIATRIC CANCER — UNITED STATES, 2001–2014</u>, Centers for Disease Control and Prevention, Atlanta, Georgia, United States ⁶ Gabriel Zada, Aaron E. Bond, Ya-Ping Wang, Steven L. Giannotta, Dennis Deapen, <u>Incidence Trends in the Anatomic Location of Primary Malignant Brain Tumors in the United States: 1992–2006</u>, World Neurosurgery, Volume 77, Issues 3–4, 2012, Pages 518-524, ISSN 1878-8750.

⁷ Philips, Alasdair, et al., (2018). <u>Brain Tumours: Rise in Glioblastoma Multiforme Incidence in England 1995–2015</u> <u>Suggests an Adverse Environmental or Lifestyle Factor</u>, Journal of Environmental and Public Health, vol. 2018, Article ID 7910754, 10 pages.

⁸ Hardell, L., & Hardell, L. (2019). <u>Comments on the US National Toxicology Program technical reports on toxicology and carcinogenesis study in rats exposed to whole-body radiofrequency radiation at 900 MHz and in mice exposed to whole-body radiofrequency radiation at 1,900 MHz. International Journal of Oncology, 54, 111-127.</u>

and other distinguished epidemiologists). It is critically important to note the location of the tumor within the brain when looking at associations with cellphone use.

"Although Karipidis et al. (12) and Nilsson et al. (13) found no evidence of an increased incidence of gliomas in recent years in Australia and Sweden, respectively, Karipidis et al. (12) only reported on brain tumor data for ages 20–59 and Nilsson et al. (13) failed to include data for high grade glioma, particularly GBMs. In contrast, others, including the Centers for Disease Control and Prevention, have reported increases in specific types of brain tumors associated with cellphone radiation in the National Toxicology Program and other laboratory studies in human populations of Britain and the US:

<u>Brain cancer</u> has replaced leukemia as the leading cause of cancer death among US children and adolescents aged 1 to 19 years, according to the Centers for Disease Control and Prevention (CDC)⁹. As Miller et al., 2019 have indicated:

- The incidence of neuro-epithelial brain cancers has significantly increased in all children, adolescents, and young adult age groupings from birth to 24 years in the United States (14, 15).
- A sustained and statistically significant rise in glioblastoma multiforme across all ages has been described in the UK (16), at the same time as there is no evident increase in all brain tumors combined.

The incidence of several brain tumors is increasing at statistically significant rates, according to the 2010–2017 *Central Brain Tumor Registry of the U.S.* (CBTRUS) dataset (<u>17</u>).

- There was a significant increase in incidence of radiographically diagnosed tumors of the pituitary from 2006 to 2012 (APC¹⁰ = 7.3% [95% CI: 4.1%, 10.5%]), with no significant change in incidence from 2012 to 2015 (18).
- Meningioma rates have increased in all age groups from 15 through 85+ years.
- Nerve sheath tumor (Schwannoma) rates have increased in all age groups from age 20 through 84 years.
- Vestibular Schwannoma rates, as a percentage of nerve sheath tumors, have also increased from 58% in 2004 to 95% in 2010-2014.

In addition, salivary gland malignancies, especially parotid, have increased in the United States¹¹. Research studies have found associations between cellphone use and increased risk of these tumor types¹²¹³¹⁴.

The latency for glioma tied with cellphone use in a general population is estimated to be four or five decades, based on analyses of brain cancer data from survivors of the Hiroshima bombing and those who received therapeutic head radiation for *tinea capita*. No evidence of an increase in glioma occurred until 40 or more years after those bombings emitted ionizing radiation, or after radiation therapy had been

¹¹ Del Signore, Anthony G., et al., (2017). <u>The rising incidence of major salivary gland cancer in the United States</u>, ENT-Ear, Nose & Throat Journal.

⁹ Curtin, Sally C., et al., (2016). <u>Declines in Cancer Death Rates Among Children and Adolescents in the United States</u>, 1999–2014, NCHS Data Brief, Number 257.

¹⁰ Average Percent Change per year

¹² Bortkiewicz A et al., (2017). <u>Mobile **phone** use and risk for intracranial tumors and **salivary gland** tumors - A meta-analysis, Int J Occup Med Environ Health.</u>

¹³ Siegal Sadetzki, et al., (2008). <u>Cellular Phone Use and Risk of Benign and Malignant Parotid Gland Tumors—A</u>

<u>Nationwide Case-Control Study</u>, *American Journal of Epidemiology*, Volume 167, Issue 4, Pages 457–467.

¹⁴ de Siqueira EC et al., (2017), <u>Does cell phone use increases the chances of parotid gland tumor development? A systematic review and meta-analysis *J Oral Pathol Med*, 46: 480- 483.</u>

received. The increase in cellphone use is relatively recent and the way people use cellphones is changing rapidly, so it is not even reasonable to expect to see evidence of general increase in brain cancer at this time in the general population.

The FDA letter states: "The main health outcome on which FDA focuses for the current question (regarding whether or not there are safety risks to patients from RFR emitted by cellphone handsets) relates to the onset of cancer formation, known as tumorigenesis."

Cancer is only one of many serious effects associated with radiofrequency radiation. By focusing narrowly on cancer risks, the FDA ignores the fact that there are a number of human and experimental studies confirming damage to the reproductive¹⁵, immune¹⁶ and neurological systems from cellphone radiation. The Cleveland Clinic routinely advises men who wish to father healthy children to remove phones and other devices from their bodies due to their own research findings¹⁷¹⁸.

Replicated research has found memory damage in teens using cell phones to the head after just a year of use¹⁹. Research consistently finds alterations in the electroencephalogram (EEG) after exposure²⁰²¹²²²³ and researchers speculate that this could be related to the memory impacts found in the study of teenagers.

"It may be speculated that our results are related to relatively consistently observed alterations in the electroencephalogram (EEG) during sleep in randomized crossover studies of participants exposed to mobile phone radiation prior to sleep."²⁴

¹⁵ Singh R, Nath R, Mathur AK, Sharma RS., (2018). <u>Effect of radiofrequency radiation on reproductive health</u>. *Indian J Med Res.*,148 (Suppl):S92–S99.

¹⁶ Yakymenko, Igor, et al., (2016). Oxidative mechanisms of biological activity of low-intensity radiofrequency radiation. Electromagnetic Biology and Medicine, vol. 35, no. 2, pp. 186-202.

¹⁷ Hamada, Alaa & Singh, Aspinder & Agarwal, Ashok. (2010). <u>Cell Phones and their Impact on Male Fertility: Fact or Fiction</u>. The Open Reproductive Science Journal. 5.

¹⁸ Agarwal, Ashok, Fnu Deepinder, Rakesh K. Sharma, Geetha Ranga, and Jianbo Li. <u>Effect of Cell Phone Usage on Semen Analysis in Men Attending Infertility Clinic: An Observational Study</u>. *Fertility and Sterility* 89, no. 1 (January 1, 2008): 124–28.

¹⁹ Foerster Milena, Thielens Arno, Joseph Wout, Eeftens Marloes, and Röösli Martin. <u>A Prospective Cohort Study of Adolescents' Memory Performance and Individual Brain Dose of Microwave Radiation from Wireless Communication</u>. *Environmental Health Perspectives* 126, no. 7 (n.d.): 077007.

²⁰ Loughran, S. P., McKenzie, R. J., Jackson, M. L., Howard, M. E. and Croft, R. J. (2012), <u>Individual differences in</u> the effects of mobile phone exposure on human sleep: Rethinking the problem. Bioelectromagnetics, 33: 86-93.

²¹ Lustenberger, Caroline, Manuel Murbach, Roland Dürr, Marc Ralph Schmid, Niels Kuster, Peter Achermann, and Reto Huber. <u>Stimulation of the Brain With Radiofrequency Electromagnetic Field Pulses Affects Sleep-Dependent Performance Improvement</u>. *Brain Stimulation: Basic, Translational, and Clinical Research in Neuromodulation* 6, no. 5 (September 1, 2013): 805–11.

²² Regel, S. J., Tinguely, G., Schuderer, J., Adam, M., Kuster, N., Landolt, H. and Achermann, P. (2007), <u>Pulsed radio-frequency electromagnetic fields: dose-dependent effects on sleep, the sleep EEG and cognitive performance</u>. Journal of Sleep Research, 16: 253-258.

²³ Schmid, M. R., Loughran, S. P., Regel, S. J., Murbach, M., Bratic Grunauer, A., Rusterholz, T., Bersagliere, A., Kuster, N. and Achermann, P. (2012), <u>Sleep EEG alterations: effects of different pulse-modulated radio frequency electromagnetic fields</u>. Journal of Sleep Research, 21: 50-58.

²⁴ Foerster Milena, Thielens Arno, Joseph Wout, Eeftens Marloes, and Röösli Martin. <u>A Prospective Cohort Study of Adolescents' Memory Performance and Individual Brain Dose of Microwave Radiation from Wireless Communication</u>. *Environmental Health Perspectives* 126, no. 7 (n.d.): 077007.

Yet the FDA has not acted to inform parents about these findings. 95% of teens now report they have a smartphone,²⁵ 68% of teenagers reported that they keep their mobile devices within reach at night and nearly a third of teens sleep with smartphones, cellphones or tablets in their bed²⁶.

Replicated research finds behavioral problems associated with cellphone use (prenatally and postnatally) ²⁷²⁸²⁹. Experimental studies also indicate that exposures can cause a range of abnormalities in offspring ranging from testicular damage³⁰ to learning³¹ and memory problems³² to brain damage³³³⁴. When women rest a cellphone or wireless device on their pregnant abdomen, the developing brain of the developing baby absorbs the wireless radiation. Research finds higher levels in the final months of pregnancy³⁵. More than 200 doctors, educators and health professionals have signed onto an appeal calling for pregnant women to reduce cellphone and wireless exposure in order to protect the developing brain³⁶.

The American Academy of Pediatrics wrote the FDA calling for updated regulations:

"Children are not little adults and are disproportionately impacted by all environmental exposures, including cell phone radiation. Current FCC standards do not account for the unique vulnerability and use patterns specific to pregnant women and children...Pregnant women may carry their phones for many hours per day in a pocket that keeps the phone close to their uterus." ³⁷

Yet the FDA has not acted to recommend updating regulations nor to inform pregnant women about these research findings and what they can do to reduce exposure.

²⁵ Anderson, M., Jiang, Jingjing., (2018). Teens Social Media and Technology 2018. Pew Research Center.

²⁶ Robb, M. B. (2019). <u>The new normal: Parents, teens, screens, and sleep in the United States</u>. San Francisco, CA: Common Sense Media.

²⁷ Divan HA, Kheifets L, Obel C, *et al.*, (2012). <u>Cell phone use and behavioural problems in young children</u>, *J Epidemiol Community Health*, **66:**524-529.

²⁸ Divan, H., Kheifets, L., Obel, C., Olsen, J., (2008). <u>Prenatal and postnatal exposure to cell phone use and behavioral problems in children</u>. Epidemiology. 19(4):523-529.

²⁹ Sudan, Madhuri, Jorn Olsen, Oyebuchi A Arah, Carsten Obel, and Leeka Kheifets. <u>Prospective Cohort Analysis of Cellphone Use and Emotional and Behavioural Difficulties in Children</u>. *Journal of Epidemiology and Community Health* 70, no. 12 (December 1, 2016): 1207.

³⁰ Atasoy, Halil I., et al. <u>Immunohistopathologic demonstration of deleterious effects on growing rat testes of radiofrequency waves emitted from conventional Wi-Fi devices.</u> Journal of Pediatric Urology, vol. 9, no. 2, 2013, pp. 223-9.

³¹ Kishore, GK, Venkateshu, KV, Sridevi, NS. (2019). <u>Effect of 1800-2100 MHz electromagnetic radiation on learning-memory and hippocampal morphology in Swiss albino mice.</u> J Clinical and Diagnostic Research. 13(2).

³² Aldad, Tamir S., et al. <u>Fetal radiofrequency radiation exposure from 800-1900 Mhz-rated cellular telephones affects neurodevelopment and behavior in mice.</u> Scientific Reports, vol. 2, no. 312, 2012.

³³ Bas, O., et al. "900 MHz electromagnetic field exposure affects qualitative and quantitative features of hippocampal pyramidal cells in adult rat." Brain Research, no. 1265, 2009, pp. 178–85.

³⁴ Dasdag et al. "<u>Effects Of 2.4 Ghz Radiofrequency Radiation Emitted From Wi-Fi Equipment On microRna Expression In Brain Tissue.</u>" International Journal of Radiation Biology, vol. 16, 2015, pp. 1-26.

³⁵ Cabot, E., Christ, A., Bühlmann, B., Zefferer, M., Chavannes, N., Bakker, J., van Rhoon, G., Kuster, N., Quantification of RF-exposure of the fetus using anatomical CAD-models in three different gestational stages, Health Physics. 107(5):369–381.

³⁶ Signatories on The Joint Statement on Pregnancy and Wireless Radiation.

³⁷ Letter from the American Academy of Pediatrics to the FCC and the FDA, <u>Comment on the Proposed Rule</u> "Reassessment of Exposure to Radiofrequency Electromagnetic Fields Limits and Policies" published in the Federal Register on June 4, 2013.

The FDA letter says, "the Agency has not seen credible evidence that the roll-out of 5G handsets will lead to additional risk for the population."

This statement does not even indicate what "credible" evidence of safety the FDA has reviewed that it deems relevant. Where is the FDA report with scientific citations? Scientists have been requesting the FDA evaluation but so far have not been sent any evidence such a report even exists. Furthermore, what does "additional risk" mean? Is the FDA saying that the risk is the same as it would be for current 3G and 4G technology? 5G phones will not operate solely with 5G signals but will rely on 3G and 4G signals for voice for the foreseeable future, according to industry experts. 3G and 4G signals have been associated with increased cancer³⁸ and reproductive³⁹⁴⁰⁴¹, neurological⁴² and DNA damage⁴³ in experimental studies, plus a number of studies of humans have associated exposure with serious health risks, ranging from sperm damage⁴⁴ to brain cancer⁴⁵, as indicated in a number of publications⁴⁶⁴⁷.

In addition, this FDA statement fails to take into account new discoveries on the vulnerabilities of the skin—the organ always first exposed to 5G signals. Industry states that they will use millimeter waves for 5G, in addition to the lower frequencies. Millimeter waves do not penetrate the body as deeply as current 3G and 4G wireless frequencies. However, they do not simply bounce off the skin; they are absorbed into the skin⁴⁸. Research by physicists finds that 5G signals have been shown to reach just under the skin where they resonate with helical shaped sweat ducts and are highly absorbed⁴⁹⁵⁰. This resonance could

³⁸ Lerchl, Alexander, Melanie Klose, Karen Grote, Adalbert F.X. Wilhelm, Oliver Spathmann, Thomas Fiedler, Joachim Streckert, Volkert Hansen, and Markus Clemens. <u>Tumor Promotion by Exposure to Radiofrequency Electromagnetic Fields below Exposure Limits for Humans</u>. *Biochemical and Biophysical Research Communications* 459, no. 4 (April 17, 2015): 585–90.

³⁹ Singh R, Nath R, Mathur AK, Sharma RS. <u>Effect of radiofrequency radiation on reproductive health</u>. *Indian J Med Res.* 2018;148(Suppl):S92–S99.

⁴⁰ Houston, B.J., et al. <u>The effects of radiofrequency electromagnetic radiation on sperm function.</u> Reproduction, vol. 152, no. 2, 2016, pp. R263-76.

⁴¹ Avendano, Conrado, et al. <u>Use of laptop computers connected to internet through Wi-Fi decreases human sperm</u> motility and increases sperm DNA fragmentation. Fertility and Sterility, vol. 97, no. 1, 2012, pp. 39-45.

⁴² Aldad, Tamir S., Geliang Gan, Xiao-Bing Gao, and Hugh S. Taylor. <u>Fetal Radiofrequency Radiation Exposure From 800-1900 Mhz-Rated Cellular Telephones Affects Neurodevelopment and Behavior in Mice</u>. *Scientific Reports* 2 (March 15, 2012): 312.

⁴³ Panagopoulos, Dimitris J. <u>Comparing DNA Damage Induced by Mobile Telephony and Other Types of Man-Made Electromagnetic Fields</u>. *Mutation Research/Reviews in Mutation Research* 781 (July 1, 2019): 53–62.

⁴⁴ Kesari, Kavindra Kumar, Ashok Agarwal, and Ralf Henkel. <u>Radiations and Male Fertility</u>. *Reproductive Biology and Endocrinology* 16, no. 1 (December 9, 2018): 118.

⁴⁵ Miller, Anthony B., L. Lloyd Morgan, Iris Udasin, and Devra Lee Davis. <u>Cancer Epidemiology Update</u>, <u>Following the 2011 IARC Evaluation of Radiofrequency Electromagnetic Fields (Monograph 102)</u>. *Environmental Research* 167 (November 1, 2018): 673–83.

⁴⁶ Bandara, Priyanka, and David O Carpenter. <u>Planetary Electromagnetic Pollution: It Is Time to Assess Its Impact</u>. *The Lancet Planetary Health* 2, no. 12 (December 1, 2018): e512–14.

⁴⁷ Lerchl, Alexander, Melanie Klose, Karen Grote, Adalbert F.X. Wilhelm, Oliver Spathmann, Thomas Fiedler, Joachim Streckert, Volkert Hansen, and Markus Clemens. <u>Tumor Promotion by Exposure to Radiofrequency Electromagnetic Fields below Exposure Limits for Humans</u>. *Biochemical and Biophysical Research Communications* 459, no. 4 (April 17, 2015): 585–90.

⁴⁸ Di Ciaula, Agostino. <u>Towards 5G Communication Systems: Are There Health Implications</u>? *International Journal of Hygiene and Environmental Health* 221, no. 3 (April 1, 2018): 367–75.

⁴⁹ N. Betzalel, Y. Feldman, and P. B. Ishai. <u>The Modeling of the Absorbance of Sub-THz Radiation by Human Skin</u>. *IEEE Transactions on Terahertz Science and Technology* 7, no. 5 (September 2017): 521–28.

theoretically activate pre-cancerous cells just under the surface, effectively transforming them into melanoma or other malignancies or other proliferative responses. The researchers have cautioned about the need to restrict 5G exposures, noting:

"One must consider the implications of human immersion in the electromagnetic noise, caused by devices working at the very same frequencies as those, to which the sweat duct (as a helical antenna) is most attuned. We are raising a warning flag against the unrestricted use of sub-THz technologies for communication, before the possible consequences for public health are explored."

Several additional new developments in scientific understanding of the skin are also not considered by the FDA. Specifically, the old paradigm held that the skin was a barrier, effectively sponge-like and relatively inert. The new evolving paradigm indicates that the skin plays a major systemic role possibly involving the immune system, with extensions from the surface throughout the body⁵¹. In *Science* magazine, the skin has recently been found to have a complex of glial sensors that exist just under the surface—that may well be considered a new organ with broad implications for sensation and communication⁵². These glial cells are the same types of cells that can be transformed by cellphone radiation to produce gliomas in the brain, in the NTP study and in epidemiological studies. Called the nociceptive-glio-neural complex, this proposed new organ of the skin may account for the capacity to perceive pain and is believed to extend and have influence throughout the body.

This ability to resonate with the skin may also explain why the skin feels like it is on fire when targeted by the Active Denial System, a non-lethal Department of Defense weapon that works with a high-powered beam of millimeter waves at 95GHz⁵³.

The mechanisms of this new organ are being uncovered by scientists now but are believed to tap into unmyelinated glial nerves located just below the skin surface that form a mesh-like structure between the skin's outer and inner layers. It is not known how deeply the new structures may extend with filament-like protrusions. Note that these glial cells are not protected by myelin—the fatty protective sheath that affords some protection to more mature brain cells as compared with those of infants, toddlers and children.

Another recently discovered property of the skin is also relevant in understanding why skin exposures are relevant. A new mesh-like organ—the interstitium—was first identified last year in a study published in the journal *Scientific Reports*, by researchers from New York University's School of Medicine⁵⁴. This organ appears to weave together surrounding arteries and veins, casing the fibrous tissue between muscles, and lining our digestive tracts, lungs and urinary systems. The discoverer of this new fluid, NYU Professor of Medicine Neil Theise, observed that 70% of the body consists of fluid, 2/3 of which is found within cells. The remaining one-third may well consist of this interstitial fluid that runs throughout the body connecting the lymph system. Thus, the assertion that because 5G only reaches just below the skin surface therefore it is unlikely to have any biological effect does not take into account these important new discoveries

⁵⁰ Betzalel, Noa, Paul Ben Ishai, and Yuri Feldman. <u>The Human Skin as a Sub-THz Receiver – Does 5G Pose a</u> Danger to It or Not? *Environmental Research* 163 (May 1, 2018): 208–16.

⁵¹ Richmond JM, Harris JE. <u>Immunology and skin in health and disease</u>. *Cold Spring Harb Perspect Med*. 2014;4(12):a015339. Published 2014 Dec 1.

⁵² Karolinska Institutet. (2019, August 15). New pain organ discovered in the skin. ScienceDaily.

⁵³ Non-Lethal Weapons Program, Active Denial System FAQs, U.S. Department of Defense.

⁵⁴ PUBLIC RELEASE: 27-MAR-2018, Newfound 'organ' had been missed by standard method for visualizing anatomy, NYU LANGONE HEALTH / NYU SCHOOL OF MEDICINE.

indicating that what lies just beneath the surface does not remain there in living bodies. In fact, it is entirely conceivable that the skin plays a major function for our immune system that in turn affects the chances that disease can arise.

The FDA letter concludes:

"Based on FDA's ongoing evaluation, the available epidemiological and cancer incidence data continues to support the Agency's position that there are no quantifiable adverse health effects in humans caused by exposures at or under the current cell phone exposure limits."

In making this broad assertion, the agency fails to provide detailed references and makes a fundamental methodological error by combining case control studies with so-called cohort studies of human populations. The latter type of study is notoriously inappropriate for evaluating brain cancer tied with cellphone use, for reasons that have been well-articulated by a number of serious experts in the field⁵⁵. These include the fact that when studying a very rare event, such as brain tumors, with rapidly changing exposures, population statistics cannot provide definitive information. Moreover, the largest cohort studied so far consists of fewer than one million persons. As the rate of glioma is less than 7 per 100,000, in this entire population one would expect a baseline rate of no more than 70 gliomas. The capacity to follow such a population over decades to determine whether or not there are significant changes in rates that could be due to cellphone use is obviously limited, given the fast-changing nature of phones, users, and other wireless technology today. Those who find the absence of evidence from cohort studies reassuring confuse this with evidence of absence of an effect. It is not.

FDA Dismissal of the National Toxicology Program

The FDA dismisses the findings of the National Toxicology Program studies on cellphone radiation by putting forth multiple unsubstantiated and unfounded criticisms.

The FDA letter states, "FDA disagrees with the study's conclusions because the study design did not reflect the levels to which people are exposed to cell phone use and entailed the same problems as other whole body in vivo animal exposure studies."

In fact, the study design was developed in close consultation with experts to provide as much exposure in rodents' two-year lifetimes as humans get in theirs. As the former National Institutes of Health Senior Study Director of the NTP project, Ronald Melnick, PhD, has explained in a peer-reviewed <u>publication</u>:

"Fact: While the exposure limit to RFR for the general population in the US is 0.08 W/kg averaged over the whole body, the localized exposure limit is 1.6 W/kg averaged over any one gram of tissue (FCC, 1997); for occupational exposures, the limit is five times higher (0.4 W/kg and 8 W/kg, respectively). Thus, the whole-body exposure levels in the NTP study were higher than the FCC's whole-body exposure limits. Whole-body SAR, however, provides little information about organ-specific exposure levels (IARC, 2013). When an individual uses a cell phone and holds it next to his or her head, body tissues located nearest to the cell phone antenna receive much higher exposures than parts of the body that are located distant from the antenna. Consequently, the localized exposure level is more important for understanding and

⁵⁵ Miller, Anthony B., L. Lloyd Morgan, Iris Udasin, and Devra Lee Davis. <u>Cancer Epidemiology Update</u>, <u>Following the 2011 IARC Evaluation of Radiofrequency Electromagnetic Fields (Monograph 102)</u>. *Environmental Research* 167 (November 1, 2018): 673–83.

assessing human health risks from cell phone RFR. When considering organ-specific risk (e.g., risk to the brain) from cell phone RFR, the important measure of potential human exposure is the local SAR value of 1.6 W/kg (the FCC's SAR limit for portable RF transmitters in the US, FCC, 1997) averaged over any gram of tissue. In the NTP study in which animals were exposed to whole-body RFR at SARs of 1.5, 3, and 6.0 W/kg, exposures in the brain were within 10% of the whole-body exposure levels. Consider the converse scenario. If the brain and whole-body exposures were limited to 0.08 W/kg, then localized exposures in humans from use of cell phones held next to the ear could be 20 times greater than exposures to the brain of rats in the NTP study. Under this condition, a negative study would be uninformative for evaluating organ-specific human health risks associated with exposure to RFR. Therefore, exposure intensities in the brains of rats in the NTP study were similar to or only slightly higher than potential, localized human exposures resulting from cell phones held next to the head."56

The FDA letter says: "These studies were conducted with high power levels of RFR over the whole body of the experimental rodents in intervals (10 minutes on 10 minutes off) for 2 years."

Contrary to the FDA assertion that exposure was 10 minutes off and on for 24 hours a day, exposures were limited to a time period of 18 hours a day (or a total of 9 hours a day), a level that certainly is comparable to what humans may encounter now given the widespread use of wireless radiation. Levels were set that did not measurably increase body temperature of the animals. In fact, the experimental chambers were designed with FDA approval in collaboration with scientists from the RF fields group at the U.S. National Institute of Standards and Technology (NIST) in Boulder, Colorado and the Swiss national institute for engineering, headed by Niels Kuster⁵⁷.

What makes the dismissal of the NTP study results especially strange is the fact that the FDA nominated the NTP to perform large scale animal studies⁵⁸ and FDA expert scientists were originally part of the Federal Interagency Workgroup that reviewed and approved the proposed NTP experimental study design (including FDA, EPA, FCC, NIOSH, and OSHA), as part of the Toxicology Forum (2003), and at the 25th annual meeting of the Bioelectromagnetics Society (2003). As the Bioelectromagnetics Society 2003 abstract states, the objective of the study is "To evaluate health effects, including carcinogenicity, in laboratory animals exposed for near lifetime to `non-thermal' levels of RF radiation emissions of wireless communication devices." ⁵⁹

Before the findings were announced, NIH scientists repeatedly⁶⁰ discussed the exposure set up as mimicking human exposure to cell phones stating, "Our studies are designed specifically to mimic the human exposure scenario. The NTP studies are looking at exposures for 10 hours a day. There's heavy

Melnick, Ronald L. 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. Environmental Research 168 (January 1, 2019): 1–6.

⁵⁷ Wyde, Michael, (2016). <u>Toxicology and Carcinogenicity Studies of Cell Phone Radiofrequency Radiation</u>, National Toxicology Program.

⁵⁸ Nominations from FDA's Center from Device and Radiological Health, <u>Radio Frequency Radiation Emissions of</u> Wireless Communication Devices (CDRH), Executive Summary.

⁵⁹ Abstracts for the Bioelectromagnetics Society Annual Meeting June 22-27, 2003 Wailea, Maui, Hawaii; <u>The Bioelectromagnetics Society gratefully acknowledges the following for their generous financial support for the 25th Annual Meeting.</u>

⁶⁰ Michael Wyde Ph.D., D.A.B.T., <u>Presentation on the National Toxicology Program Radiofrequency Research Study</u>, 2009.

cell phone users that may approach the 10 hour mark – that may be excessive, but it allows us to fully investigate whether or not there is an effect of cell phone frequency radiation."⁶¹

The NTP put out a factsheet in 2012 that stated "The NTP is conducting toxicology and carcinogenicity studies in laboratory animals that are designed to simulate the exposure of cell phone users in the United States." 62

The FDA letter says: Furthermore, no effects were seen in mice of either sex or in female rats."

The FDA's statement is inaccurate as the NTP found several other statistically significant effects in female rats and in the mice. Most important, were the findings of DNA damage and heart damage. As Dr. Melnick has noted, "DNA damage (strand breaks detected with the comet assay) was significantly increased in the brains of rats and mice exposed to GSM- and CDMA-modulated RFR (Wyde, 2016)⁶³.

The tumor and genotoxicity data (DNA strand breaks), as well as the findings of reduced pup birth weights when pregnant dams were exposed to GSM- or CDMA-modulated RFR and the induction of cardiomyopathy of the right ventricle in male and female rats, were also noted in both sexes.

The cited research in this letter is just a sampling of the research indicating serious harm to humans from wireless radiation. I also have attached a list of scientific research studies. If the FDA is of the opinion that these cited studies are not significant to human health then the FDA should share its full report, if it exists at all, documenting the FDA's research review on cellphone radiation.

In closing, the Chicago Tribune recently published an exposé of the exposure limits measurement of cellphones by testing facilities approved by the FCC. The Tribune found that all phones they tested exceeded current test guidelines when tested in positions mimicking a phone in the pocket (as if 2 mm distant from a person's body), some by as much as 5-fold⁶⁴. Importantly, previous investigations by the Canadian Broadcasting Corporation (CBC) and the government of France have found the same results. The French government tests on hundreds of cellphones found radiation excesses that are equivalent up to 11 times the FCC legal limit⁶⁵. The FDA has repeatedly been informed but has taken no action to inform the public. Children and babies are using phones in positions of body contact every day. Yet the FDA has neglected to inform the public that phones can violate legal limits at body contact.

The FDA only has the authority to consider effects from cellphones and consumer devices, but not human and environmental effects from cell towers, and not cell antennas in so-called "small cells." The 5G network is not just about phones, but also intends to install more than 800,000 new telecommunication towers in the US and operation of literally millions of wirelessly connected devices and machines. No US health and safety agency has jurisdiction to evaluate the human health and environmental effects from

⁶¹ Cell Phone Radiation Cancer Study Was Designed To Mimic Human Exposure (2016).

⁶² Cell Phone Radiofrequency Radiation Studies (2011), National Toxicology Program.

⁶³ Wyde, M., (2016). NTP toxicology and carcinogenicity studies of cell phone radiofrequency radiation. BioEM2016 Meeting, Ghent, Belgium.

⁶⁴ https://www.chicagotribune.com/investigations/ct-cell-phone-radiation-testing-20190821-72qgu4nzlfda5k yuhteiieh4da-story.html

⁶⁵ O. P. Gandhi, (2019). <u>Microwave Emissions From Cell Phones Exceed Safety Limits in Europe and the US When Touching the Body</u>, in IEEE Access, vol. 7, pp. 47050-47052, 2019. doi:10.1109/ACCESS.2019.2906017

these networks. What about the impacts to the birds, bees and trees within all the signal coverage areas of these new and proposed microwave antennas that industry proposes to build for 5G?

In light of the lack of a systematic research review on human health and environmental effects, Environmental Health Trust is calling for an oversight hearing that will include staff from the FDA, FCC and EPA plus expert scientists to address health and environmental effects of 5G, cellphone and wireless radiation and, most importantly, the issue of accountability in our federal agencies.

Our scientists are always available to answer any questions.

Thank you for your consideration.

Devra Davis, PhD, MPH

Devra Davis

President, Environmental Health Trust

Fellow, American College of Epidemiology

Visiting Prof. Hebrew Univ. Hadassah Medical Center & Ondokuz Mayis Univ. Medical School

Associate Editor, Frontiers in Radiation and Health



October 1, 2019

P.O. Box 7443 Menlo Park, CA 94026

Honorable Representative Anna Eshoo 241 Cannon Building Washington, DC 20515

Executive Director Cindy L. Russell, MD Re: 1) FDA response to inquiry regarding current safety limits for RFR energy exposure and acceptability to protect human health 2) Congressional hearing

Scientific Advisory Board

Dear Honorable Congresswoman Eshoo:

David E Blask, PhD, MD Tulane University School of Medicine, Professor of Chrono-Neuroendocrine Oncology

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Jerry L. Phillips, PhD University of Colorado Professor of Chemistry and Biochemistry

Cindy Sage, MA Editor, BioIntiative Reports

John G West, MD Breast Health Awareness Foundation Thank you for your continued efforts to shed light and transparency on the issue of safety of radiofrequency (RF) radiation we are increasingly exposed to. As you know on August 8, 2019, FCC Chairman Ajit Pai proposed that the FCC maintain its current RFR exposure limits. We have read with interest the letter of response to you, from Dr. Jeffrey Shuren and Edward Margerrison, PhD of the FDA, dated Sept 9, 2019, regarding their determination that the current safety limits for RFR energy exposure are acceptable to protect human health. You requested the agency make available a summary of the research and methodologies used to reach its conclusions.

We believe that there are a number of inconsistencies, misstatements and flaws in the research summaries the FDA provided which we would like to comment on. We request:

- That you ask for a full list of research papers that the agency considered as well as their deliberation. When they state they used "all relevant data", we would like to see exactly what data they consider relevant, and
- Request documentation that the Secretary of Health and Human Services has established and is carrying out an "electronic product radiation control program" and is prescribing "performance standards for electronic product radiation" through the FDCA, as stated in your prior letter, and
- Consider holding a Congressional hearing on the matter of radiofrequency and cell phone radiation exposures
 - 1) What is the FDA's "comprehensive approach"?: The public and non-governmental scientists deserve to know and have access to all of the information used, not just a summary of research. This is critical in light of the FCC proposal for a massive increase in radiation with small cell towers every 200 to 300 feet and much closer proximity. Even a small increase in risk in those exposed translates into a large number of people affected. This is not just a moral issue, it is an economic issue, as health care costs continue to rise from chronic illness. In addition, an abundance of newer literature has emerged providing a significant body of evidence that non-thermal levels of RF radiation are a biologic toxin. None of this research is currently considered as guidelines continue to look at only heat effects of RFR. In addition, the RFR standards widely used are based on those of ICNIRP, which is based on selective data and have serious flaws. (Hardell June 25, 2019)

- 2) Conclusions of scientific research can be entirely reversed or questioned by the addition or omission of key data as well as subjective interpretation. We need to see all the detailed research papers and analysis, not just cite a website with studies or a few studies. We note,
 - A) The European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR 2015), claims that there are no established non-thermal EMF effects but the agency has ignored at least 20 robust reviews. Pall (2018) in "5G: Great Risk for EU..." points out the omissions, flaws and falsehoods in this report.
 - B) The Swedish Radiation Safety Authority's (SSM) Scientific Council report on EMF 2018, states that no new health effects have been identified, results were inconsistent and "some studies" indicate oxidative stress. Yakymenko showed at least 93 of 100 studies cause oxidative stress. Dr. Henry Lai in his research summary at BioInitiative identified 203 of 225 studies on RF oxidation to show a positive effect (89%), in addition 222 of 305 scientific abstracts on neurologic effects showed a positive finding (72%).
 - C) The European Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) 2018 lists electromagnetic radiation as an emerging risk.
 - D) NTP Study: Dr. Melnick notes that the NIEHS NTP study (2018) was designed to test the null hypothesis that long term exposure to non-thermal levels of RF radiation is a risk factor for brain tumors. The study showed a health risk for brain tumors and heart tumors as well as DNA damage, cardiomyopathy and clear evidence of carcinogenicity.
 - E) Ramazzani Study: This large well-controlled independent Italian study corroborated the NTP study. It also found increased incidences of heart schwannomas and Schwann cell hyperplasia at even lower RF intensities.
- 3) **The Mechanism of harm is confirmed** to be oxidative and through calcium channel membrane effects that are non-thermal and non-ionizing (Bioinitiaitye 2019, Pall 2018, Yakymenko 2016).
- 4) **Brain tumors are rising**: Research from the Interphone Study Group (2010), Hardell (2013, 2015, 2017) and Coueau (2013) have demonstrated a statistically significant increase in brain tumors with cell phone use over 10 years. Their research indicates a doubling of risk with 10 years of cell phone use and a tripling of risk with 25 years of use. According to the American Brain Tumor Association (ABTA) brain tumors are now the most common cancer in youth ages 0-14, followed by testes and leukemia. (Ostrom et al, 2015) A recent study by Dr. Alasdair Philips (2018) revealed a "sustained and highly statistically significant ASR rise in glioblastoma multiforme (GBM) across all ages." in England.
- 5) Risk assessment is not just based on human studies: The full body of research must be considered in reaching a conclusion that an exposure is safe for the public. This includes basic science laboratory research, controlled animal studies, clinical studies, case reports, as well as epidemiologic studies. According to the National Academy of Science report on Assessment of Toxicity, "Data used in hazard identification typically are derived from animal studies and other types of experimental work, but can also come from epidemiologic studies." They go on to state, "in the case of chemicals suspected of causing cancer in humans, expert groups ("working groups") are regularly convened by the International Agency for Research on Cancer (IARC) to consider and evaluate epidemiologic evidence." As well as to determine "a consistent pattern of responses". Consensus is not easy to achieve and industry influence must be weighed as part of their conclusions. Note that IARC has listed RF radiation to be a Class 2B Possible Carcinogen based on careful research. Independent EMR scientists who have published new research feel the weight of scientific evidence has shifted enough to classify RF radiation as a Class 1 Known Carcinogen.
- 6) **Non-linearity of effects** is a common phenomenon found with other toxic exposures such as endocrine disruptors. This effect is also seen in EMF research, due to complex cellular interactions, as well as different characteristics of the radiofrequency radiation emitted, including pulsation form, frequency, power and wave mix, as well as individual health, biological and cellular differences, and cumulative effects. Just because a study shows non-linearity does not mean the study is invalid. (Levitt and Lai 2010)

- 7) **Main Health Outcome is not just cancer.** The FDA letter references only cancer as a health effect, ignoring a large and growing body of evidence on RFR and harm to reproduction, the nervous system, immune system, endocrine system, prenatal development as well as DNA and protein damage. (EMF Portal, Oceania Radiofrequency Scientific Advisory Association Committee, BioIntiative Report)
- 8) The assumption of safety of 5G is not based on science. There is every indication that incoming 5G, and the broad mix of 2G, 3G and 4G frequencies we will still be exposed to, will be increasingly harmful to humans and the environment. (Russell 2018) The 2019 Danish Legal Opinion on Whether it Would be in Contravention of Human Rights and Environmental Law to Establish the 5G-System in Denmark, by attorney Christian Jensen, stated that, "activating the 5G-network, as it is currently described, would be in contravention of current human and environmental laws enshrined in the European Convention on Human Rights, the UN Convention on the Rights of the Child, EU regulations, and the Bern- and Bonn-conventions. The reason is the very significant body of scientific documentation available, showing that radiofrequency electromagnetic radiation is harmful and dangerous to the health of humans (particularly children), animals and plants. This also applies when the radiation remains within the limits recommended by ICNIRP and currently used in Denmark as well as broadly within the EU.

Despite the FDA letter stating that there is "no convincing evidence", "no clear evidence", and no "consistent pattern" that current standards are unsafe, scientific research proves otherwise. This inconvenient truth needs to be widely recognized and action taken to reduce our exposures, allow health considerations, base standards of RF emissions on biologic effects and use a cautionary approach to protect human health and the environment we all depend upon.

Sincerely,

Cindy Lee Russell, MD Executive Director Physicians for Safe Technology MDSafeTech.org



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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 <u>in vitro</u> 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;

Cindy Sage, MA, Co-Editor, BioInitiative Reports

Lennart Hardell, MD, PhD, The Environment and Cancer Research Foundation, Sweden

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.

Cindy Sage, MA David O. Carpenter, MD Sage Associates Director, Center for Health and the Environment

University at Albany Rensslaer, New York

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



Ellen Marks 2 Theatre Square, #215 Orinda, CA 94563 925-285-5437

September 30, 2019

U.S. Rep. Anna Eshoo 202 Cannon House Building Washington, DC 20515

RE: FDA response to your inquiry to Dr. Shuren and Dr. Margerrison

Dear Honorable Rep. Eshoo,

Thank you for your continued concern and actions concerning the oversight of radio-frequency (RF) testing and the guidelines for human safety. I work closely with Leonard Shen and Dr. Cindy Russell, both of whom are your constituents, and I am in receipt of the letter you received from Dr. Shuren and Dr. Margerrison.

I am attaching a Legislative Briefing Book which I developed to help educate local, state and federal legislators. My letter will reference the "book" and I will direct you to the corresponding page.

I have been quite involved in the cell phone and health effects issue for over a decade. I testified to the United States Congress Oversight Committee in 2008 on this topic. That hearing resulted in the introduction of a federal cell phone right to know bill which had little traction at that time.

Dr. Shuren states "The available scientific evidence to date does not support adverse health effects in humans due to exposures at or under the current limits". That statement is absolutely false and the information he provided in his letter is insufficient. Apparently, the FDA's Center for Devices and Radiological Health has not performed a systematic review of recent science and thus should not be advising the FCC to maintain the current RF guidelines. Also, Drs. Shuren and Margerrison failed to answer you about the important FDCA issue. In addition, it should be mandatory that the FDA and FCC perform a Quantitative Risk Assessment in regard to this issue.

The FDA states they have "taken a comprehensive approach to evaluating the scientific evidence regarding the impact of RFR exposure on human health". Instead they have done cherry picked studies, most of which have ties to industry, and have eliminated many excellent studies that demonstrate a link. Even industry funded studies, such as the 2002 T-Mobile Ecolog study, found a link between cell phone

radiation and cancer. https://www.emfresearch.com/ecolog-study/ "This review of over 220 peer-reviewed and published papers found strong indications for the cancer-initiating and cancer-promoting effects of high frequency electromagnetic fields used by mobile telephone technology."

Dr. Shuren states that brain tumor rates have not increased. Studies have shown that gliomas (lethal brain tumors) have increased in the areas of the brain closest to where the phone is held, while tumors are down in other parts of the brain thus skewing the data. There is often a long latency period for brain tumors thus users may not be diagnosed for decades after exposure. Brain tumors are on the rise in Scandinavian countries where cell phones have been used longer then in the United States. (pg 17).

Their letter focuses on brain tumors. The antennas of the phone are now at the bottom of the phone. Thyroid cancer is on the rise across the globe. (pg 26) There is excellent science from Harvard and Cleveland Clinic showing sperm death and damage from cell phones that are kept on in a pocket. (pgs. 20-21) There is also science showing a large spike in salivary gland tumors. (pg. 28) Other science shows cell phone radiation linked to testicular cancer, miscarriages, infertility, bone cancer and more. The FDA letter also fails to mention the CDC findings that brain, renal, hepatic and thyroid tumors have increased in children. https://ehtrust.org/cdc-finds-brain-liver-and-thyroid-cancers-increasing-among-us-children-2001-2014/

The FDA letter states "the gold standard for the assessment of risk..... is available from studying effects on humans". This statement drastically contradicts the FDA and FCC's own guidelines and the research which they nominated. In regard to the US NTP study the FDA has stated "Animal studies like this one contribute to our discussions on this topic, but we must remember the study was not designed to test the safety of cell phone use in humans, so we cannot draw conclusions about the risks of cell phone use from it."

If it was not intended to test safety for humans, what was the intent? They certainly did not spend \$30 million of taxpayer money to determine if rats get cancer from cell phone use.

Additionally, the U.S. guidelines (SAR) for radio-frequency exposure that the FDA upholds were established by the Institute of Electrical and Electronics Engineers (IEEE) and based on research conducted in the 1980s on animals. If we can't draw conclusions about the NTP study because it was performed on rats, why is this earlier animal research still the basis of our safety limits?

In their attempt to discredit the US NTP study they fail to mention that the renowned Ramazzini Institute in Italy replicated the exact findings in rodents exposed to less RFR than in the US NTP study. I personally visited the Ramazzini Institute last April and learned firsthand that the study conducted by them is similar to the NTP study with one major difference – while the NTP study used levels of radiation similar to those emitted from a cell phone, the Ramazzini used levels of radiation many times lower. The cancer results from the Ramazzini research replicated the US NTP study almost exactly. Both studies proved that non thermal exposure causes cancer.

The American Cancer Society responded to the US NTP results: "For years, the understanding of the potential risk of radiation from cell phones has been hampered by a lack of good science. This report from the National Toxicology Program (NTP) is good science. The NTP report linking radiofrequency radiation (RFR) to two types of cancer marks a paradigm shift in our understanding of radiation and cancer risk. The findings are unexpected; we wouldn't reasonably expect non-ionizing radiation to cause these tumors. This is a striking example of why serious study is so important in evaluating cancer risk. It's interesting to note that early studies on the link between lung cancer and smoking had similar resistance, since theoretical arguments at the time suggested that there could not be a link."

Dr. Shuren mentions the Interphone study but fails to mention that this partially industry funded study hid the truth in the appendix- with 10 years or more of use just 30 minutes a day one has a doubled increased risk of a brain tumor to the side of the head to which they held the phone. He also mentions Danish Cohort study which was deeply flawed and industry funded. https://ehtrust.org/science/danish-cohort-cell-phone-and-cancer-study/ (pg 7)

Recently the Chicago Tribune investigated the testing of the phones and found that iPhones and Samsung phones emitted RF up to 5 times the allowable absorption levels. This is serious. There are already wrongful death and personal injury cases against the industry in the DC courts regarding cell phone use and cancer. The Italian Supreme Court ruled in favor of plaintiffs whose brain tumors were caused by cell phone use.

I am requesting Congress hold a hearing on the lack of proper oversight by the FDA and FCC on cell phone radio-frequency radiation. The FDA and FCC should also be investigated about their collusion with industry.

I greatly appreciate your attention to this serious issue. As Director of the California Brain Tumor Association I am witnessing the devastation firsthand. I have watched many young people die, more likely than not, from exposure to cell phone radiation. This is a needless travesty.

Respectfully Submitted,

Ellen Marks