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Dr. Jeffrey Shuren, M.D., J.D.,
Director, Center for Devices and Radiological Health
U.S. Food and Drug Administration
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

December 9, 2018

Dear Dr. Shuren:

We read with dismay your statement in the FDA's press release dated November 1, 2018, stating that "the totality of the available scientific evidence continues to not support adverse health effects in humans caused by exposures at or under the current radiofrequency energy exposure limits."³⁹

The results of the recent cell phone radiation studies completed by the National Toxicology Program⁴¹ and the Ramazzini Institute⁴² reaffirm the concerns raised by the scientific community in the International EMF Scientist Appeal about the harm caused by chronic exposure to low-intensity, non-ionizing electromagnetic fields (EMF), including DNA damage. The Appeal, which has been signed by more than 240 EMF scientists who have published over 2,000 papers on EMF and biology or health in professional journals, calls for warning the public and strengthening EMF exposure guidelines, especially to protect children and pregnant women.⁴⁰

The Appeal states:

"Numerous recent scientific publications have shown that EMF affects living organisms at levels well below most international and national guidelines. Effects include increased cancer risk, cellular stress, increase in harmful free radicals, genetic damages, structural and functional changes of the reproductive system, learning and memory deficits, neurological disorders, and negative impacts on general well-being in humans. Damage goes well beyond the human race, as there is growing evidence of harmful effects to both plant and animal life."

"The totality of the available scientific evidence" includes evidence on the large and inimical impact of conflict of interest on research results¹⁻⁵. It includes evidence of the pervasive relevance of effect modification. Based on the latter, individual vulnerability factors must be identified, and safety must be assured in the most vulnerable prior to declaring an exposure acceptably "safe." This is particularly true for an exposure to which all will be exposed, without their consent, and in some cases against their objection, and irrespective of past evidence of injury. It is particularly true for an exposure for which many studies report problems – and many patients report being affected. {Seldom do we force those who have had serious adverse effects to a drug to be continually exposed to it.}

continued

We urge that you also consider that oxidatively mediated injury can be cumulative: Ultraviolet radiation injury leads to DNA damage, photoaging and cataracts through cumulative effects mediated by oxidative stress and free radical formation.⁴³⁻⁴⁶ Far ultraviolet radiation and X-ray imaging are considered lower energy ionizing radiation, but that is largely irrelevant to the injury it causes. Ionizing radiation primarily mediates injury through oxidative stress – a mechanism of harm also well supported for radiofrequency (RF/EMF) radiation⁸. Excess cumulative exposure to UV radiation or X-ray imaging (CT scans, fluoroscopy and nuclear medicine scans) results in DNA strand breaks and increases the risk of cancer.⁴⁸ Moreover, there is also evidence of cumulative injury and DNA damage with low level non-ionizing radiofrequency radiation¹⁵, including evidence that health problems will be progressive with re-exposure in those whose injury is of at least moderate severity.¹⁶ RF radiation can cause cataracts and because it penetrates more deeply, can also affect much more than skin and eyes.¹⁷⁻²² Please see the extensive reference list in Cleary 1988, with scores of citations, dating as far back as 1948, and documentation of non-thermal as well as thermal mechanisms¹⁸. Many of the studies are older, but science is meant to build on older work, not let knowledge fall by the wayside.

A. We request that you provide the following:

1. Provide the list of references you have considered in determining the “totality of scientific evidence”. How were these identified, and/or from whom were these supplied? How was the evidence analyzed?
2. Have you segregated evidence that is not influenced by industry conflict of interest (whether industry funding or industry conflicts of investigators) and viewed that separately? The “totality of scientific evidence” includes extensive evidence of a massive relationship of conflict of interest to results –in this¹ as in other fields.²⁻⁵ As evidence makes clear, a search should be made for industry conflicts that are undisclosed.³
3. With what processes have you considered the impact of “effect modification,” the phenomenon by which individual differences in vulnerability (risk of harm) can be vast.⁴⁹ This can lead to non-linear and at times even opposite direction effects – especially for exposures for which mechanisms are on the oxidant-antioxidant spectrum^{6,7} a mechanism common to RF radiation⁸. Effect modification is a pervasive if not universal theme in medicine⁹⁻¹². Because of this, average or typical effects, are not acceptable in designations of potential harm. Findings like those of De Luca et al (2014), showing that those experiencing health effects from accepted levels of radiation are significantly more likely to have polymorphisms adverse to oxidative stress defense.¹³ In addition, Belpomme (2015) showed that levels of a key antioxidant known to protect against radiation injury are consistently low in those citing health effects of accepted levels of radiation.¹⁴ These studies underscore not only that effects are real and causally mediated by expected mechanisms of oxidative stress but that understanding of health effects *must* consider vulnerable subsets.

Illustrating the magnitude of impact of effect modification, based on just a few features, risk of hospitalized rhabdomyolysis on statins can be increased by 2300-fold (from one case per 22,727 treated for a year, to one case in ~10 treated with statin for a year)¹² – making a problem transition from very rare to frankly common in the identified vulnerable group. And this considers only a few factors that are measurable, measured, and readily available (age, diabetes, whether on a fibrate – and which statin): more comprehensive assessment would doubtless expand this range, identifying individuals at even higher risk.

4. Please also advise us-are the utilities required to maintain records of adverse event reports e.g. from smart meters (Quite obviously they should be.) Have you requested adverse effects reported to the utilities following introduction of smart meters? Which utilities? How have these been analyzed?

B. We request that the FDA set up a Radiation Adverse Event Reporting System (RAERS), like the Vaccine Adverse Event Reporting system (VAERS) for wireless devices and infrastructure including smart meters, Wi-Fi routers, cell phones, wireless wearable devices and driverless cars. How can the FDA

declare a product safe with neither premarketing phase I, II, III trials, nor post-marketing surveillance? There needs to be a central repository to which people can report; and it needs to be well advertised, so that both patients and physicians are familiar with it.

C. RF devices, especially smart meters and cell towers, provide exposure to everyone. When people are not able to escape the exposure, a radically more stringent standard is required to protect the vulnerable, including those already injured. Many millions may now be experiencing health effects based on estimates from epidemiological studies. Many cases describe compelling evidence for causality, with dechallenge- rechallenge support²³⁻²⁶. The “intervention” of removing a cell tower improved health in a study in Japan, a group level dechallenge²⁷. There is distance to source evidence²⁸⁻³⁰ (a form of dose response – as is evidence of a tie to polymorphisms adverse for oxidative stress detoxification¹³). There is evidence that mechanisms involved are tied to conditions like dementia, metabolic illness, and autism – all conditions whose rise cannot be attributed merely to aging of the population (or parents), or better diagnosis, and there is mounting and increasingly powerful evidence of a tie to cancer, particularly glioblastoma^{31, 32} and hemolymphatic cancers (please read this article)³³, but also suggestive evidence for breast cancer^{34, 35} and melanoma and particularly uveal melanoma^{36, 37}.

D. We also direct your attention to the evidence that the health effects reported by individuals who cite health effects from low level RF radiation), comport in detail to those reported in US diplomats in Cuba, in which evidence for the so-called microwave auditory effect essentially compels the case for a causal role of radiofrequency radiation³⁸. Please read the evidence in this carefully.

E. We are in an era in which some will pay close attention to who *failed* in their duty to protect, when evidence – viewed without the palliating lens of industry conflict – was already overwhelming. This is your chance to be on the right side of history, at the critical juncture.

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Physicians for Safe Technology

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