

pharmacists planning service, inc.

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October 4, 2013

Documents Management Branch
Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane, Room 4-62
Rockville, MD 20852

Re: FDA Citizen's Petition For Public Hearings to establish standards on cellphone radiation adverse health effects that might be caused by specific absorption rates (SAR) and radio frequency radiation (RFR)/electromagnetic frequency (EMF)

The undersigned submits this Petition under Section 21 CFR 10.20 and 21 CFR 10.30 and other pertinent sections of the Federal Food, Drug and Cosmetic Act of any other statutory provision which authority has been delegated of the Commissioner of Food and Drug to request the FDA Citizen's Petition For Public Hearings to establish standards on cellphone radiation adverse health effects that might be caused by specific absorption rates (SAR) and radio frequency radiation (RFR)/electromagnetic frequency (EMF).

This Petition requests the FDA Commissioner to issue a Federal Regulation to augment FDA Citizen's Petition For Public Hearings to establish standards on cellphone radiation adverse health effects that might be caused by specific absorption rates (SAR) and radio frequency radiation (RFR)/electromagnetic frequency (EMF)

Some of the scientific facts which require immediate action on this Petition are:

- 1). Pharmacists Planning Services, Inc. (PPSI), a non-profit, public health, consumer, pharmacy professional organization is dedicated to the health, safety and well-being of the citizens of the United States and is the instigator of over 55 public health education and awareness campaigns in the US and internationally (see www.ppsinc.org). These campaigns include the Great American Smoke out (GAS), National Poison Prevention Month and Safety CAPS, Pregnant Man (Mr. Mom), National Condom Week, and 50 other campaigns.
- 2). PPSI is greatly concerned and encourages the Food and Drug Commissioner FDA to move forward with educating the American public on mobile phones and standards as they pertain to pregnant women, fetuses, unborn children, behavioral disorders, brain tumors and other adverse health impacts that could be caused by exposure to RFR/EMF.
- 3). One 2012 study from Sweden entitled 'Use of Mobile Phones' by Hardell et al claims that use of mobile phones and cordless phones is associated with increased risk for glioma and acoustic neuromas.
- 4) In a July 12, 2012 letter from the American Academy of Pediatrics (AAP), a non-profit organization of 60,000 primary care pediatricians dedicated to the health, safety and well-being of infants, children, adolescents and young adults requesting that the Federal Communication Commission (FCC) proposes that a formal inquiry into radiation standards for cellphones and other wireless products be instituted since standards for cellphone radiation has not been looked at since 1996.

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- 5). In May 2011, the World Health Organization (WHO) International Agency for Research on Cancer (IARC) classified radio frequency electromagnetic fields as possible carcinogenic to humans Category 2b.
- 6) The WHO/IARC reclassified RFR/EMF carcinogenic to humans group 2b based on the increased risk of glioma, a malignant type of brain cancer associated with wireless phone use.
- 7) The WHO/IARC working group included 33 scientists from 14 countries meeting at IARC in Lyon, France to assess the potential carcinogenic hazards from exposure to RFR/EMF fields.
- 8) The Chairman of the WHO/IA working group, Dr. Jonathan Samet University of Southern California has stated "THE EVIDENCE IS STRONG ENOUGH TO SUPPORT A CONCLUSION AND THE 2B CLASSIFICATION...The conclusion means that there could some risk and therefore we need to keep a close watch on cellphones and cancer risk."
- 9) In correspondence to the Los Angeles Unified School District (LAUSD), Martha Herbert PhD, MD a pediatric neurologist and a neuroscientist on the faculty of Harvard Medical School and on staff at the Massachusetts General Hospital, and a Board Certified in Neurology with Special Competency on Child Neurology and Subspecialty Certification in Neurodevelopmental Disorders wrote the following:
- "I recently accepted an invitation to review literature pertinent to a potential link between Autism Spectrum Disorders and Electromagnetic Frequencies (EMF) and Radiofrequency Radiation(RFR). I set out to write a paper of modest length, but found much more literature than I had anticipated to review. I ended up producing a 60 page single spaced paper with over 550 citations. It is available at http://www.bioinitiative.org/report/wp-content/uploads/pdfs/sec20 2012 Findings in Autism.pdf. "
- 10) Dr. Herbert also states: "In fact, there are thousands of papers that have accumulated over decades—and are now accumulating at an accelerating pace, as our ability to measure impacts become more sensitive—that document adverse health and neurological impacts of EMF/RFR. Children are more vulnerable than adults, and children with chronic illnesses and/or neurodevelopmental disabilities are even more vulnerable. Elderly or chronically ill adults are more vulnerable than healthy adults."
- 11). In an American study by Devra Lee Davis et al, January 2013, entitled 'Swedish Review strengthens grounds for concluding that radiation from cellular and cordless phones is a probable human carcinogen'.
- 12). On March, 2013 the FCC opened up a federal registry In the Matter of Reassessment of Federal Commission Radiofrequency Exposure Limits and Policies: ET Docket 13-84 calling for Proposed Changes in the Commission's Rules Regarding Human Exposure to Radiofrequency Electromagnetic Fields: ET Docket 03-137. PPSI is asking the FDA to include all the testimony, scientific papers and articles contained in the 145 page PPSI submission to FCC in the PPSI citizen's petition. http://apps.fcc.gov/ecfs/comment/view?id=6017467960
- 13). Included in an 1993 Internal FDA Memo animal studies show that RFR/EMF causes cancer growth. http://www.goaegis.com/fda0203.html
 In the spring of 1993 at the height of public concern over cell phone-brain tumor risks, Food and

Drug Administration (FDA) biologists concluded that the available data "strongly suggest" that microwaves can "accelerate the development of cancer." "Of approximately eight chronic animal experiments known to us, five resulted in increased numbers of malignancies, accelerated progression of tumors, or both," wrote Drs. Mays Swicord and Larry Cress of FDA's Center for Devices and Radiological Health (CDRH) in Rockville, MD. They also pointed to other evidence from laboratory (in vitro) studies that supported a cancer risk."

Some of the pathologies and adverse health conditions coming to light, which are being linked associatively back to cellular radiation exposure include...glioma, acoustical neuronal, parotid gland tumors, strokes, autism, migraines, Alzheimers, dementia, sperm collapse, fetal damage, ADHD, infertility, DNA strand breakage and most recently, in a Kaiser Permanente Study by Dr. Li, asthma and COPD.

PPSI believes there is ample amount of scientific evidence and information available to request the FDA Commissioner to hold Public Hearings and open up a Federal Registry to establish standards on cellphone radiation adverse health effects that might be caused by specific absorption rates (SAR) and radio frequency radiation (RFR)/electromagnetic frequency (EMF)

There is no environmental impact associated with this Citizen's Petition and we wish to be excluded under 21 CFR Sec. 25.24.

There is no economic impact involved with this Citizen's Petition. We encourage the FDA to undertake this issue for public hearings immediately as the public has the right to know about cellphone safety and understanding the basic precautions that can be taken to reduce radiation exposure from cellphones. PPSI believes that people have a right to know about using cellphones more safely and that printed warning labels in 12 point font (California SB204) must be affixed to all wireless consumer devices such as cellphones that have been identified by WHO as a possible carcinogenic classification 2b.

PPSI is asking the FDA to do the following:

- 1) Consumers have a right to know the level of radiation their phones emit.
- 2) Latest science points to potential risk to children's health.
- 3) Federal standards for cell phone radiation need to be modernized from 1996.
- 4) What consumers can do to reduce exposures to cell phone radiation.
- 5) Education and awareness campaign to alert consumers of the WHO warnings.
- 6) Hold public hearings and open up a Federal Registry on the entire RFR/EMF health issues.
- 7) Print in 12 point font warning notices to consumers purchasing wireless devices.

The undersigned certified, that, to the best knowledge and belief of the undersigned this Petition includes all information and view on which the Petition relies, and that it includes representative data and information known to the petitioner which are uplayorable to the Petition (21 CFR Sec. 10.30b).

Signature

Name of Petitioner:

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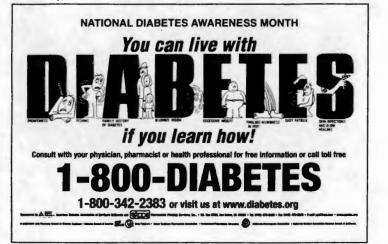
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