From: theodorams <theodorams@aol.com>
To: [redacted]ol.com>
Subject: FDA response that I should file a Citizen Petition to the FDA Commissioner Fri, Nov 17, 2017 11:31 am
Date: Wed, Jan 9, 2019 12:57 pm

-----Original Message-----
From: theodorams <theodorams@aol.com>
To: CDRHOmbudsman <CDRHOmbudsman@fda.hhs.gov>
Sent: Fri, Nov 17, 2017 12:13 pm
Subject: Re: Difference of opinion on the scientific evidence the FDA relies upon to regulate radiofrequency energy emitting products such as cell phones

Dear Abiy Desta,
Thank you for your response. However I would like answers to my questions. The FDA answered some questions and I am asking for clarification. I would like a full response to the questions as my questions have been half answered.

I am asking for clarification on the answers I was given. I am glad to reword my letter to be specific to my questions, rather than asking the question. Citizens should have answers to these questions. Should I contact my elected officials to be engaged and support this? I was given answers that are not clear.

Thank you,
Theodora Scarato

FDA response that I should file a Citizen Petition to the FDA Commissioner Fri, Nov 17, 2017 11:31 am
After not getting a response

-----Original Message-----
From: CDRH Ombudsman <CDRHOmbudsman@fda.hhs.gov>
To: theodorams <theodorams@aol.com>
Cc: CDRH Ombudsman <CDRHOmbudsman@fda.hhs.gov>
Sent: Fri, Nov 17, 2017 11:31 am
Subject: Difference of opinion on the scientific evidence the FDA relies upon to regulate radiofrequency energy emitting products such as cell phones

Dear Ms. Scarato,

First, please allow me to introduce myself. My name is Abiy Desta and I am the Ombudsman for the Center for Devices and Radiological Health (CDRH) at the FDA. I have been monitoring the communications between you and CDRH regarding the scientific evidence the Agency relies upon to regulate radiofrequency energy emitting products such as cell phones. From reviewing the communications it is clear to me that you disagree with how the FDA is regulating these consumer products and I don't believe further informal engagements between you and the Center will resolve the differences of opinion that exist.

The appropriate method for requesting FDA change the way it regulates cell phones and similar radiofrequency energy emitting consumer products is by filing such a request via a Citizen Petition to the FDA Commissioner as described in the Code of Federal Regulations, Title 21, Section 10.30 (21 CFR 10.30). As mentioned in this regulation, a Citizen Petition must follow the format specified for petitions in 21 CFR 10.20. You can obtain further information on this matter on the FDA Web site at this location: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm.

Best regards
Abiy Desta

Abiy B. Desta
Ombudsman
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?O=100&D=140&B=140&E=&S=E

From: theodorams <theodorams@aol.com>

To: Daniel.Kassiday <Daniel.Kassiday@fda.hhs.gov>; Michael.OHara <Michael.OHara@fda.hhs.gov>; William.Jung <William.Jung@fda.hhs.gov>; Robert.Ochs <Robert.Ochs@fda.hhs.gov>; CDRHOmbudsman <CDRHOmbudsman@fda.hhs.gov>; Jeff.Shuren <Jeff.Shuren@fda.hhs.gov>; Mary.Pastel <Mary.Pastel@fda.hhs.gov>; Brian.Beard <Brian.Beard@fda.hhs.gov>; Bakul.Pa <Bakul.Patel@fda.hhs.gov>; theodorams <theodorams@aol.com>; Daniel.Kassiday <Daniel.Kassiday@fda.hhs.gov>; DICE <DICE@fda.hhs.gov>; stephanie.caccomo <stephanie.caccomo@fda.hhs.gov>

Cc: Michael.OHara <Michael.OHara@fda.hhs.gov>; William.Jung <William.Jung@fda.hhs.gov>; Robert.Ochs <Robert.Ochs@fda.hhs.gov>; CDRHOmbudsman <CDRHOmbudsman@fda.hhs.gov> michelle_altman <michelle_altman@lankford.senate.gov>; katherine_mayne <katherine_mayne@lankford.senate.gov>; dvora.lovinger <dvora.lovinger@mail.house.gov>; chris.meekins <chris.meekins@mail.house.gov>; karen.kudelko <karen.kudelko@mail.house.gov>; suzanne.owen <suzanne.owen@mail.house.gov>; keith.abouchar <keith.abouchar@mail.house.gov>

Subject: Letter to the FDA on the health and safety of wireless and 5G technology.

Date: Sat, Jun 2, 2018 7:06 am

Attachments: PDF Evaluation of Genotoxicity of Cell Phone Radiofrequency Radiation in Male and f the Genot d Female notoxicity e Rats and y Ce d Mice ell Ra e Following g Subchronic ncy c Exposure Po (266K), November 19, 2017 Letter to the FDA on french test reports and liability issues..pdf (16423K), Feb 3, 2018 Letter to the FDA on statement on the NTP Study.pdf (364K), The human skin as a sub-THz receiver – Does 5G pose a danger to it or not (1).pdf (1193K), 5G public health Cindy Russell 2018 first page .pdf (127K)

Dear Dr. Kassiday and Dr. Jeffrey Shuren

I am writing you in reference to FDA statements and stated opinion on the safety of wireless communications systems. My questions are in reference to the recent National Toxicology Program (NTP) Study that found "clear evidence of cancer" from radio frequency wireless radiation. (See details here).

Thank you in advance for answering these questions.

1. I am still in need of a response to my questions sent November 19, 2017, February 3, 2018, and April 5, 2018 by email. (See attached.) When will we be receiving the answers?

2. I have attached the presentation by the NTP on genotoxicity data. Is the FDA going to be doing a quantitative risk assessment on the DNA data?

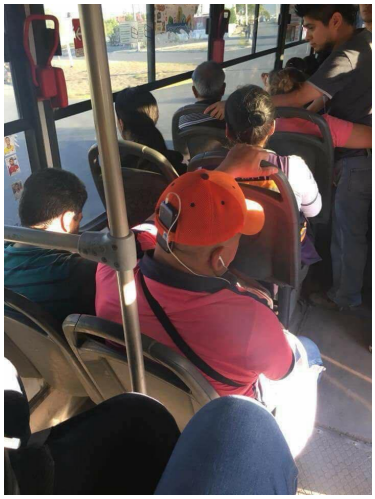
3. Is the FDA going to be doing a quantitative risk assessment on the findings of increased cancers from the NTP peer review? If so then when?

4. In a recent Congressional hearing the FCC Chair stated that "we have consulted with te FDA and others for determining what those limits should be and we are confident that our standards are ones that are healthy for consumers." See the video of that statement here https://www.youtube.com/watch?v=rk6Oy-Mw0bk&t=2s . Has the FCC consulted with the FDA since the NTP study to adress the issue of cell phone and wireless exposure radiation limits?

5. In light of the french ANFR tests showing excess radiation from phones at body contact, what steps is the FDA taking to adress the fact that cell phones and wireless devices have SARS that exceed FCC limits when devices are placed at body contact? In June and September 2017 I informed you of the results of the ANFR tests and of the ANSES scientific report. The FDA wrote back October 18, 2017 that "the information is interesting and we would like to see the experimentation in its entirety." The reports by ANFR are now posted in their entirety on the ANFR website. Will the FDA be addressing this issue of phones exceeding SAR limits when phones are used at body contact? We now have full documentation that a phone that meets SAR limits at 5 mm can fail at 0 mm distance from the body.
Note: In France several phones models are being removed from the market due to these excesses radiation issues. See a news report on the recalls here.

6. Will the FDA be updating their website with the scientific results *now peer reviewed* of the NTP finding "clear evidence of cancer"?

7. Is the FDA that children are holding wireless devices against their body such as in this video https://ehtrust.org/alert-virtual-assistant-radiation-exposure-linked-cancer-headaches-memory-unhealthy-impacts/ or in this image of a man with the phone in his hat.



8. The DNA and tumor findings of the NTP indicate non thermal effects from long term exposure as the animals were exposed at levels considered "non thermal. " What is the process by which the FDA is going to integrate this information into an opinion of the safety of exposure limits for RFR both occupational and for the public ?

9. In the NTP study heart damage was found at all exposure levels. Please see a video clip excerpt of this here https://www.youtube.com/watch?v=HtfXJFNOQFc . How is the FDA going to address this clear significant effect across all exposure groups? Will you do a quantitative risk assessment?

10. 5G technology will use millimeter waves that are known to have an effect to the skin. I attached research on this. Will their be any premarket safety testing for 5G technology? To understand the long term effect onto human health? If so please detail the research and who is performing it.

11. When did the FDA do a systematic review of the scientific evidence to evaluate impacts on human health?

12. Please See the literature review on 5G technology. What is the FDA response to this published paper?

13. What is the FDA response to the published paper on 5G and the skin?

Thank you so much for answering these questions. I have cced to Congressional staffers these questions and look forward to hearing back from you promptly.

Theodora Scarato

From: theodorams <theodorams@aol.com>

To: theodorams <theodorams@aol.com>; Daniel.Kassiday <Daniel.Kassiday@fda.hhs.gov>; Michael.OHara <Michael.OHara@fda.hhs.gov>; William.Jung <William.Jung@fda.hhs.gov>; Robert.Ochs <Robert.Ochs@fda.hhs.gov>; CDRHOmbudsman <CDRHOmbudsman@fda.hhs.gov>; Jeff.Shuren <Jeff.Shuren@fda.hhs.gov>; Mary.Pastel <Mary.Pastel@fda.hhs.gov>; Brian.Beard <Brian.Beard@fda.hhs.gov>; Bakul.Patel <Bakul.Patel@fda.hhs.gov>; DICE <DICE@fda.hhs.gov>; stephanie.caccomo <stephanie.caccomo@fda.hhs.gov>

Cc: michelle_altman <michelle_altman@lankford.senate.gov>; katherine_mayne <katherine_mayne@lankford.senate.gov>; dvora.lovinger <dvora.lovinger@mail.house.gov>; chris.meekins <chris.meekins@mail.house.gov>; karen.kudelko <karen.kudelko@mail.house.gov>; suzanne.owen <suzanne.owen@mail.house.gov>; keith.abouchar <keith.abouchar@mail.house.gov>

Subject: Re: Letter to the FDA on the health and safety of wireless and 5G technology.

Date: Mon, Jun 11, 2018 4:59 pm

Dear Dr. Kassiday and Dr. Jeffrey Shuren,

I have been informed my question was not clear enough so I added a few questions to be very clear about what I am asking in relation to allowable SAR exposures from cell phones.

Additional question 1: As the FDA stated to me there was a safety factor of 50 for whole body exposure- please answer this question for clarity. In terms of SAR for cell phones themselves- **What is the Safety factor that the FDA has determined to exist in terms of localized exposure?** Please be specific - for example- respond with a SAR something like "at 6.0 w/kg over 1 gram, the FDA considers a cell phone to be emitting RF that could be harmful." or if a cell phone SAR is measured at 10 w/kg then the FDA will take action.." In other words, **please specify the cell phone SAR level that the FDA believes is harmful and exceeds the safety factor to the degree that the FDA considers the SAR harmful.**

Additional question 2: What is the FDA's stated safety factor in terms of cell phone localized SAR? Please give me a number. Is it 2 times or 5 times or 50 times? What is the safety factor the FDA has determines exists for localized SAR from a cell phone?

Additional question 3: The FDA states there is a 50 times safety factor for whole body exposure. Does this mean that at 100w/kg the FDA will act?

Additional question 4: What is the FDA's determination of the safety factor in terms of cell phone localized SAR when considering exposure to the testes. Please also be specific the SAR threshold that the FDA will act on in terms of exposure to testes.

Additional question 5: What is the FDA's determination of the safety factor in terms of cell phone localized SAR when considering exposure to the eye. Also please specific the SAR threshold value that the FDA will act on in terms of exposure to eye tissue. Does the FDA have the same SAR for eye tissue that they use for localized tissue exposure? or does the FDA use another SAR threshold value- to determine at which time they will act?

Thank you so much,
Theodora Scarato

See below the full set of questions.

I am writing you in reference to FDA statements and stated opinion on the safety of wireless communications systems. My questions are in reference to the recent National Toxicology Program (NTP) Study that found "clear evidence of cancer" from radio frequency wireless radiation. (See details here).

Thank you in advance for answering these questions.

1. I am still in need of a response to my questions sent November 19, 2017, February 3, 2018, and April 5, 2018 by email. (See attached.) When will we be receiving the answers?

2. I have attached the presentation by the NTP on genotoxicity data. Is the FDA going to be doing a quantitative risk assessment on the DNA data?

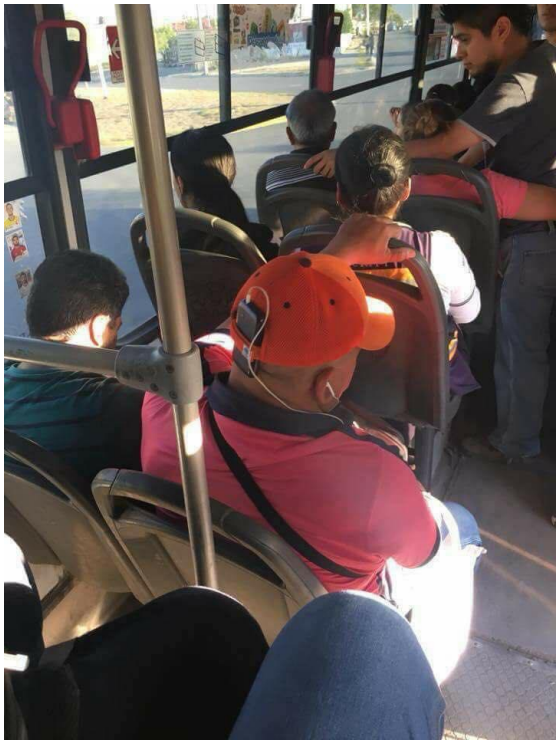
3. Is the FDA going to be doing a quantitative risk assessment on the findings of increased cancers from the NTP peer review? If so then when?

4. In a recent Congressional hearing the FCC Chair stated that "we have consulted with te FDA and others for determining what those limits should be and we are confident that our standards are ones that are healthy for consumers." See the video of that statement here https://www.youtube.com/watch?v=rk6Oy-Mw0bk&t=2s . Has the FCC consulted with the FDA since the NTP study to adress the issue of cell phone and wireless exposure radiation limits?

5. In light of the french ANFR tests showing excess radiation from phones at body contact, what steps is the FDA taking to adress the fact that cell phones and wireless devices have SARS that exceed FCC limits when devices are placed at body contact? In June and September 2017 I informed you of the results of the ANFR tests and of the ANSES scientific report. The FDA wrote back October 18, 2017 that "the information is interesting and we would like to see the experimentation in its entirety." The reports by ANFR are now posted in their entirety on the ANFR website. Will the FDA be addressing this issue of phones exceeding SAR limits when phones are used at body contact? We now have full documentation that a phone that meets SAR limits at 5 mm can fail at 0 mm distance from the body.
Note: In France several phones models are being removed from the market due to these excesses radiation issues. See a news report on the recalls here.

6. Will the FDA be updating their website with the scientific results *now peer reviewed* of the NTP finding "clear evidence of cancer"?

7. Is the FDA that children are holding wireless devices against their body such as in this video https://ehtrust.org/alert-virtual-assistant-radiation-exposure-linked-cancer-headaches-memory-unhealthy-impacts/ or in this image of a man with the phone in his hat.



8. The DNA and tumor findings of the NTP indicate non thermal effects from long term exposure as the animals were exposed at levels considered "non thermal. " What is the process by which the FDA is going to integrate this information into an opinion of the safety of exposure limits for RFR both occupational and for the public ?

9. In the NTP study heart damage was found at all exposure levels. Please see a video clip excerpt of this here https://www.youtube.com/watch?v=HtfXJFNOQFc . How is the FDA going to address this clear significant effect across all exposure groups? Will you do a quantitative risk assessment?

10. 5G technology will use millimeter waves that are known to have an effect to the skin. I attached research on this. Will their be any premarket safety testing for 5G technology? To understand the long term effect onto human health? If so please detail the research and who is performing it.

11. When did the FDA do a systematic review of the scientific evidence to evaluate impacts on human health?

12. Please See the literature review on 5G technology. What is the FDA response to this published paper?

13. What is the FDA response to the published paper on 5G and the skin?

14. **Additional question 1:** As the FDA stated to me there was a safety factor of 50 for whole body exposure- please answer this question for clarity. In terms of SAR for cell phones themselves- **What is the Safety factor that the FDA has determined to exist in terms of localized exposure?** Please be specific - for example- respond with a SAR something like "at 6.0 w/kg over 1 gram, the FDA considers a cell phone to be emitting RF that could be harmful." or if a cell phone SAR is measured at 10 w/kg then the FDA will take action.." In other words, **please specify the cell phone SAR level that the FDA believes is harmful and exceeds the safety factor to the degree that the FDA considers the SAR harmful.** Please state it in w/kg and specify ten or one gram averaging.

15. Additional question 2: What is the FDA's stated safety factor in terms of cell phone localized SAR? Please give me a number. Is it 2 times or 5 times or 50 times? What is the safety factor the FDA has determines exists for localized SAR from a cell phone? Please state the actual numerical number.

16. Additional question 3: The FDA states there is a 50 times safety factor for whole body exposure. Does this mean that at 100w/kg the FDA will act?

17. Additional question 4: What is the FDA's determination of the safety factor in terms of cell phone localized SAR when considering exposure to the testes. Please specific the SAR threshold that the FDA will act on in terms of exposure to testes. Either way please state the SAR limit the FDA uses to determine if they will act and please state the safety factor the FDA is applying from the FCC regulatory threshold.

18. Additional question 5: What is the FDA's determination of the safety factor in terms of cell phone localized SAR when considering exposure to the eye. Also please specific the SAR threshold that the FDA will act on in terms of exposure to eye tissue. Does the FDA have the same SAR for eye tissue that they use for localized tissue exposure? or does the FDA use another SAR threshold value- at which time they will act? Either way please state the SAR limit the FDA uses to determine if they will act and please state the safety factor the FDA is applying from the FCC regulatory threshold.

Thank you so much for answering these questions. I have cced to Congressional staffers these questions and look forward to hearing back from you promptly.

Theodora Scarato

From: theodorams <theodorams@aol.com>
To: theodorams <theodorams@aol.com>
Subject: Letter to Dr. Shuren: 11/2018 Questions for the FDA about the NTP study on cell phone radiation
Date: Mon, Dec 17, 2018 4:33 pm
Attachments: NTP clear cancer evidence James Lin 9-2018 Health Matters IEEE Microwave Magazine.pdf (1478K)

-----Original Message-----
From: theodorams <theodorams@aol.com>
To: Lindsay.Lloyd <Lindsay.Lloyd@fda.hhs.gov>
Sent: Tue, Nov 6, 2018 8:33 am
Subject: Re: Questions for the FDA about the NTP study on cell phone radiation

Dear Ms. Lloyd,

Thank you for getting back to me. I updated the questions for Dr. Shuren a bit and added two new ones. I would like an answer soon, being this is a timely issue. I hope to receive a response by the end of the week. The FDA has issued a statement widely cited in the media and I am asking for the documentation that underlies the statements made by the FDA . I am also asking for an explanation as to what seems to be a contradictory stance. The FCC limits are based thresholds for harm determined from animal studies from the 70's.

Theodora Scarato

6 Hillside Road Unit S
Greenbelt MD 20770

Dear Mr. Jeffrey Shuren, M.D., J.D., Director of the FDA's Center for Devices and Radiological Health

1. Please send the technical report or full comments and explanation that explain that explain why the FDA disagrees with the findings of clear evidence of cancer regarding the schwannomas of the heart in male rats. The FDA says "After reviewing the study, we disagree, however, with the conclusions of their final report regarding "clear evidence" of carcinogenic activity in rodents exposed to radio frequency energy." The peer reviewers and scientists are listed on the NIH NTP report but there is no scientist names listed under the FDA statement nor is there a proper technical report with citations. We would like the FDA's technical scientific comments and the identification of which FDA scientists "disagree " as we were unaware there was a team of scientists at the FDA working on this issue.

2. Would the FDA agree with a determination that the schwannomas of the heart in male rats were "some evidence" or does the FDA say they are "no evidence"

3. Does the FDA agree with the determination of "some evidence" for the brain gliomas in the male rats?

4 The FDA stated of the March 2018 peer review "The FDA was not a participant in that process, but was invited to observe the panel discussions, which included an assessment of the study methods and data by a panel of 15 peer reviewers to determine the basis of evidence for the final report." So my question is this --as two FDA officials were in the room during the entire March peer review and had an opportunity to speak and offer comments (and one FDA staff did in fact make a statement and a rather astute statement that the exposure should consider dose over time as I recall) Did the FDA share their comments of disagreement with the NTP findings at any time? Including before and/or after the peer review?

4. Did the FDA inform the NIH/NTP at any time over the last twenty years that animal research would not be sufficient to determine risk to public health from cell phone radiation? And that the FDA would consider the NTP designed study to have findings irrelevant to humans?

5. The November 1, 2018 statement on the NTP final report says, "We have relied on decades of research and hundreds of studies to have the most complete evaluation of radiofrequency energy exposure. This information has informed the FDA's assessment of this important public health issue, and given us the confidence that the current safety limits for cell phone radiofrequency energy exposure remain acceptable for protecting the public health." **Please share with us this report or evaluation that shows the "complete evaluation of radiofrequency energy exposure" done by the FDA.**

6. **Why is the FDA centering on whole body exposure?**

The FDA states that "we only begin to observe effects to animal tissue at exposures that are 50 times higher than the current whole body safety limits set by the FCC for radiofrequency energy exposure." However, the NTP study was designed to look at localized tissue SARs --from the phone near the body- **so called near field exposure**. People certainly have areas of their bodies that will experience far higher levels than whole body SAR's. Clearly people's brains will get higher SARs than whole body exposure limits. **Why is the FDA centering on whole body exposure?** The study was designed to look at the SARs to tissue i**n the near field not far field.** As Dr. Lin who was a peer reviewer stated in his article attached to this email:

> "The current RF exposure guidelines of 1.6 or 2.0 W/kg are promulgated with a reduction factor of 50 as a safety margin for the general public and to provide protection against presumed hazardous biological effects in humans [5], [6]. The finding that RF exposure could lead to dose-dependent cancer development at levels that are the same or three times above current exposure guidelines is significant. This implies that the safety margin may be no more than a factor of three. In fact, one recommendation (IEEE C95.1-2005) has a set of guidelines under controlled environments that allows local SARs of the brain and heart to be as much as 10 W/kg [7]. An SAR of 10 W/kg is considerably higher than the 1.5, 3.0, and 6.0 W/kg used in the NTP study."
> (See full pdf online here, IEEE link here)

7. Why is the FDA not acknowledging that people can be exposed to localized SARs of well over 1.6 w/kg. The U.S. also has an "occupational" SAR limit, which is 8.0 W/kg averaged over any 1 gram of tissue for the head and body and 20.0 W/kg averaged over 10 grams of tissue for "extremities." Thus the NTP study used exposures UNDER FCC limits.

- I personally have repeatedly contacted the FDA with the French government research that establishes without a doubt that when cell phones are used at body contact, the SARs into localized tissue could reach far beyond FCC limits of 1.6. The French tests shows the SARs could be up to 5 times higher ! when people use phones at body contact in conditions of high power- for example, a phone streaming video in a room with a low signal.
-

- See a prime example of consumer use here (man with phone in hat in bus) and here (woman streaming video for child which changing baby's diaper.) In these two scenarios, the phone is directly to the skull without an ear to provide spacing. ***Why is the FDA maintaining a conversation about whole body exposure when this is about local exposures (as stated the NIEHS) and when French tests document that local tissue SARs can exceed the FCC limits and be as high as 14 to 22 w/kg (converting the ten gram to one gram average)?***

And finally
8. What is the FDA's opinion on the fact that short term animal studies were used as the basis of our FCC limits?

The FDA is stating that NTP animal data is not relevant to humans but the current FCC limits are based on animal studies *done in the 70's and 60's. Research primarily on small mammals- mice, rats and bunnies- are the basis for the determination of the threshold for the so called "thermal effect. Does the FDA also think that that the animal data that underpins our current FCC limits is not relevant to humans?*

Following the logic of the FDA that animal research cannot be directly correlated to human physiology (which I agree with by the way as you cannot directly apply the risk ratios and we need to do a quantitative risk assessment), this then means our FCC limits are irrelevant to humans as well.
NOTE: The animal studies referenced in the standards used by the FCC to define regulations on radiofrequency limits in place now were not performed as carefully controlled as the NTP's 30 Million dollar study. No study could ever come close to the NTP in terms of controlling the exposure.

- According to the FCC, "the FCC's guidelines are based on recommended exposure criteria issued by the NCRP and ANSI/IEEE". The current FCC exposure limit was adopted by the FCC in 1996- based substantially on the IEEE C95.1-1991 but officially ANSI/IEEE C95.1-1992 which is identical as the U.S. government's exposure limit regulation.
- This means that effectively the standards adopted in 1996 are really from 1991 documents and if you look at the standards document, ***you can see the research cited is on rats, mice and two with squirrel monkey for very short term exposure***. Go to table A1. The IEEE C95.1-1991 and ANSI/IEEE C95.1-1992 used to inform NCRP Report.
- According to the FCC, the exposure limits, adopted at the recommendation of the Environmental Protection Agency and other federal health agencies are primarily based on National Council on Radiation Protection and Measurement (NCRP) Report No. 86 "Biological Effects and Exposure Criteria for Radiofrequency Electromagnetic Fields" This report includes sections on developmental effects and considers children in deriving the exposure limits.
- Pg 286 of NCRP Report No. 86 "Exposure limits for RFEM radiation for the human population are based to a great extent on data obtained from exposures of small animals to

plane waves. Under such conditions, it is relatively easy to quantify the maximal rate of energy absorption by analytical or experimental means."

- NCRP Report No. 86 "The body of scientific knowledge of biological effects of RFEM
- irradiation, although containing several thousands of archival reports, is fragmented: it is preponderantly based on acute exposures at relatively few frequencies." In the absence of human data, it is necessary to turn to data on subhuman species… The carrier frequencies associated with behavioral disruption range from 400 MHz to 5.8 GHz. These studies were performed on species ranging from laboratory rats to rhesus monkeys, and involved nearfield, far-field, multipath, and plane-wave fields, both CW and modulated. In spite of marked differences in field parameters, thresholds of behavioral impairment were found within a relatively narrow range of whole-body-averaged SARs ranging from -3 to -9 W /kg."

Animal data was used to develop FCC limits as stated in IEEE C95.1-1991 (Revision of ANSI C95.1-1982) IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz :

- "The existing MPEs are based on the threshold for behavioral disruption with acute (short-term) exposures of experimental animals."

- "As was the case for ANSI C95.1- 1982 [B1], IEEE Subcommittee IV has had to turn to data collected on subhuman species, fully realizing that the small mass, limited physiological capacity, and unusual body dimensions of most furred laboratory animals strongly influence not only the SAR at any given frequency but also the character and magnitude of biological response. It is important to realize that not only is there an uncertainty inherent in measurements of the responses of animals, but extrapolation of these measurements to human beings may be difficult."

Putting it simply, **our FCC limits are based on data from short term exposures to animals.** The FDA asked the NTP to do animal studies to consider long term exposures. The NTP did just that. Now the FDA is rejecting the findings as irrelevant to thermal versus non thermal impacts on human health because it is an "animal study."

I am asking the FDA to explain these contradictory positions.

----Original Message-----

From: Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>
To: theodorams <theodorams@aol.com>
Sent: Tue, Nov 6, 2018 7:28 am
Subject: RE: Questions for the FDA

Thank you for taking time to write me. I will get this logged today.

Is there a name and mailing address for you that I can use for the official log of this question/email?

Lindsay

Lindsay Lloyd
Office of the Center Director
Center for Devices and Radiological Health

From: Kassiday, Daniel F. H. <Daniel.Kassiday@fda.hhs.gov>
To: 'theodorams@aol.com' <theodorams@aol.com>
Cc: O'Hara, Michael D <Michael.OHara@fda.hhs.gov>; Jung, William <William.Jung@fda.hhs.gov>; Ochs, Robert <Robert.Ochs@fda.hhs.gov>; CDRH Ombudsman <CDRHOmbudsman@fda.hhs.gov>
Subject: RE: Letter to FDA on FCC limits exceeded by cell phones at body contact and FDA's position that due to the "safety factor" it is ok if consumers use phones and exceed radiation limits.
Date: Wed, Oct 18, 2017 1:59 pm

Dear Ms. Scarato:

Thank you for bringing these issues, documents, and videos to our attention. We are responding to both your June 13, 2017 email and the additional questions submitted on September 8, 2017.

In your June 13 email you said:

> "I have attached below a press release regarding the data that the French government released testing data showing that cell phones violate cell phone radiation limits when tested directly against the body.
>
> This information from France is clear evidence that cell phone testing is inadequate to protect consumers from the radiation limits for cell phones we have in place. Children and pregnant women place these phones directly on their bodies, store them in bras took them into spandex pants and all of these positions are not tested by the manufacturers."

Response to the preceding text:

We have asked the French Agency for a discussion of their studies and findings and conclusions. However, they have not responded as of the writing of this response.

We would like to bring your attention to an opinion from the French Agency for Food, Environmental and Occupational Health and Safety (June 20, 2016). "According to the available studies on the health effects of radiofrequencies that were analyzed, the collective expert appraisal work group concluded as to a possible effect of radiofrequencies on: 1. cognitive functions: the results showing acute effects were based on experimental studies with well controlled methodologies. 2. Well-being: these effects may however be linked to the use of the mobile telephones rather than to the radiofrequency radiation they emit." In both cases the French working group concluded that there is limited evidence to conclude as to whether radiofrequencies have an effect on cognitive functions or well-being. SCENIHR (2015) has also looked at these kinds of studies and determined that there is not a great deal of evidence.

The working group for the French Agency for Food, Environmental and Occupational Health and Safety also concluded that "it is not possible to conclude from the current data as to whether or not radiofrequency radiation has an effect on children's: 1. behavior, 2. auditory function, 3. Teratogenic effects and development, 4. male and female reproductive systems, 5. carcinogenic effects, 6. Immune systems, and 7. systemic toxicity."

Below we will respond to the specific questions stated in both of your emails:

Question 1:

> I am writing to ask what the FDA's response is to information just released from France showing violations of SAR when phones are tested at body contact. The FDA is aware that people use cell phones resting on their legs or on chests and therefore the FDA needs to be aware that the American public is being exposed to radiation levels exceeding our government guidelines. Please see this picture taken at an airport just this week. Note the laptop resting on this man's chest.
>
> Please see these images from Maryland public Schools of students with devices on their body as well as how people typically wear their phones when they work out.
>
> I am writing to ask what the FDA's response is to information just released from France showing violations of SAR when phones are tested at body contact in light of the fact that Americans are placing radiating cell phones and wireless devices directly on their bodies in violation of the FCC instructions and therefore exceeding FCC SAR values in their body.

Response to Question 1:

The information is interesting and we would like to see the experimentation in its entirety. However, as mentioned above we have not discussed the experimentation with the French Agency for Food, Environmental and Occupational Health and Safety. The experimentation has not been commented on by expert review groups or by the Federal Communications Commission. At this time we have not formulated an opinion about the differences in the testing protocols used in France versus the United States. Currently we believe that the safety limits are adequate to protect the public.

Question 2:

> In a prior letter dated May 31, 2017 (see below) when I asked you about children and pregnant women placing cell phones directly against their bodies and abdomens, you responded with the statement, "There is a large safety factor included in the public exposure limit." If I understood your response it seemed like

you were saying that the FDA's position is that "it is OK" if this regulatory limit was exceeded because of this "large safety factor". Is that what you meant in your response?

Response to Question 2:

It is unclear what the SAR is when a phone or other electronic product is placed on the abdomen of pregnant women. The French Agency for Food, Environmental and Occupational Health and Safety experiment has not been fully reviewed so differences in their SAR values and SAR values generated from current testing methods are unknown. The 2015 expert review by SCENIHR provides a good summary of a large amount of data. According to the SCENIHR expert review group "Most recent studies investigating effects on pregnancy outcome and development of the offspring have been large and well conducted, and so can provide very useful information. These studies found that low level prenatal and early postnatal exposure to a variety of RF signals was not associated with any adverse outcome". Additionally, the Norwegian Mother and Child Cohort Study (Epidemiology July, 2015) concluded that there is no association between maternal prenatal or preconception cell phone exposure and any of the studied pregnancy outcomes. These studies suggest that the current safety limits are adequate to protect pregnant mothers and offspring.

Question 3:

So I am writing to ask if I understand correctly that the FDA believes that it is OK to exceed the regulatory limits because of this "large safety factor."?

Response to Question 3:

FDA is not saying that it is OK to exceed a regulatory limit. We stated that there is a large safety factor built into these regulatory limits. Please contact FCC regarding their compliance testing and enforcement policies regarding their regulatory limits.

Question 4:

And if the FDA believes that it is OK to exceed the regulatory limits because of this "large safety factor, *by how much* does the FDA allow the safety factor to be exceeded in excess of FCC limits? Could you please specify in terms of SAR as to the SAR at which the FDA will take action. For example is it a SAR of over 4 w/kg or 7 w/kg or 21 w/kg or more?

Response to Question 4:

The current safety limits established by the FCC are adequate to protect the public based on the peer reviewed literature. Please contact FCC regarding their compliance testing and enforcement policies regarding this regulatory limit.

Question 5:

What is the SAR limit at which time the public will be informed by the FDA that cell phones violate US regulatory SAR limits?

Response to Question 5:

At this time the FDA has no concerns about the regulatory safety limit set by the FCC. FDA has not established a performance standard for mobile phone products and thus we have not set any regulatory limits regarding RF emissions. Regarding notifications, the details of FDA's electronic product radiation control authorities are available on our FDA basics website at: https://www.fda.gov/AboutFDA/Transparency/Basics/ucm193950.htm.

Question 6:

I am included a chart so that you can see the cell phone, make and model and the SAR amount documenting how each phone violates SAR limits. Please see the document on this webpage but please note that the 0 mm SAR listed is per the European 10 gram averaging. Therefore the equivalent US FCC 1 gram averaging SAR is likely over 2 times the amount listed here.

I want to make you aware that Dr. Marc Arazi came to the United States and presented a lecture on these SAR violations. Please watch the lecture here. https://ehtrust.org/cell-phones-violate-radiation-limits-doctor-calls-urgent-action-update-cell-phone-radiation-tests/. I would like to ask if the FDA had watched this lecture?

Response to Question 6:

Yes, at least two FDA employees have watched that lecture video.

Question 7:

I continue to ask that the FDA update the out of date webpages. Please update these webpages. Cell Phones Health Issues. which states "No Evidence Linking Cell Phone Use to Risk of Brain Tumors." Why is the FDA still posting updated information?

Response to Question 7:

The webpage titled, Cell Phones Health Issues, links to an FDA Consumer Magazine article with the title, "No evidence linking cell phone use to risk of brain tumors". There have been several major epidemiology studies that add supporting evidence for that statement. The National Cancer Institute's Fact sheet on cell phones and cancer risk (https://www.cancer.gov/about-cancer/causes-prevention/risk/radiation/cell-phones-fact-sheet) discusses the scientific evidence regarding cancer risk and is attached for your convenience. FDA continues to believe that the preponderance of the evidence suggest that the existing safety standards for electromagnetic radiation are adequate to protect the general public.

We hope that our responses adequately address your concerns regarding the issues you raised.

Daniel Kassiday
SME: Electronic Product Radiation Control

Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-5865
daniel.kassiday@fda.hhs.gov

the agency to the view expressed.

For general information about electronic products, please visit the FDA website http://www.fda.gov/Radiation-EmittingProducts/default.htm. For Accession number status, please call (301) 796-6627. For assistance with eSubmitter please write to: esubmitter@fda.hhs.gov.

From: theodorams@aol.com [mailto:theodorams@aol.com]
Sent: Friday, September 08, 2017 10:19 AM
To: theodorams@aol.com; Kassiday, Daniel F. H.
Cc: O'Hara, Michael D; Jung, William; Ochs, Robert; CDRH Ombudsman; alonzo.washington@house.state.md.us; alonzo@alonzowashington.com; jamie.raskin@senate.state.md.us
Subject: Re: Letter to FDA on FCC limits exceeded by cell phones at body contact and FDA's position that due to the "safety factor" it is ok if consumers use phones and exceed radiation limits.

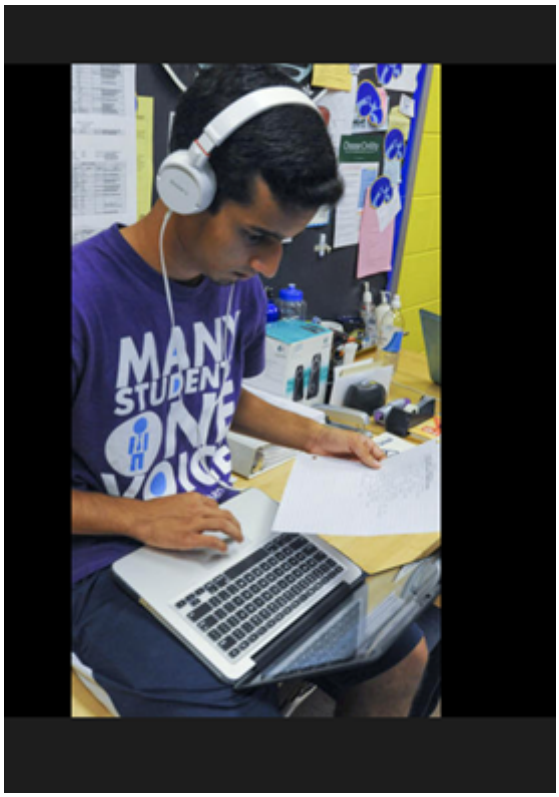
Dear Dr. Kassiday,

I have not received a response to the letter I sent Tue, Jun 13, 2017 9:09 am (see below this email the email I sent several months ago still unanswered).

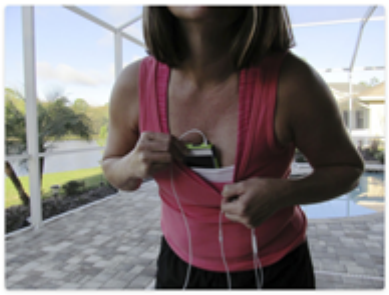
I will reiterate the questions and add a few more.

1. I am writing to ask what the FDA's response is to information just released from France showing violations of SAR when phones are tested at body contact. The FDA is aware that people use cell phones resting on their legs or on chests and therefore the FDA needs to be aware that the American public is being exposed to radiation levels exceeding our government guidelines. Please see this picture taken at an airport just this week. Note the laptop resting on this mans chest.

Please see these images from Maryland public Schools of students with devices on their body as well as how people typically wear their phones when they work out.


MANY
STUDENTS
ONE
VOICE

iPhone slips into cami bra pocket easily.



Closer view of the layers and iPhone in pocket.

I am writing to ask what the FDA's response is to information just released from France showing violations of SAR when phones are tested at body contact in light of the fact that Americans are placing radiating cell phones and wireless devices directly on their bodies in violation of the FCC instructions and therefore exceeding FCC SAR values in their body.

2. In a prior letter dated May 31, 2017 (see below) when I asked you about children and pregnant women placing cell phones directly against their bodies and abdomens, you responded with the statement "There is a large safety factor included in the public exposure limit." If I understood your response it seemed like you were saying that the FDA's position is that "it is OK" if this regulatory limit was exceeded because of this "large safety factor". Is that what you meant in your response?

3. So I am writing to ask if I understand correctly that the FDA believes that it is OK to exceed the regulatory limits because of this "large safety factor." ?

4. And if the FDA believes that it is OK to exceed the regulatory limits because of this "large safety factor., *by how much* does the FDA allow the safety factor to be exceeded in excess of FCC limits?

Could you please specify in terms of SAR as to the SAR at which the FDA will take action. For example is it a SAR of over 4w/kg or 7 w/kg or 21 w/kg? or more?

5. What is theSAR limit at which time the public will be informed by the FDA that cell phones violate US regulatory SAR limits?

6. I am included a chart so that you can see the cell phone, make and model and the SAR amount documenting how each phone violates SAR limits. Please see the document on this webpage but please note that the 0mm SAR listed is per the European 10 gram averaging. Therefore the equivalent US FCC 1 gram averaging SAR is likely over 2 times the amount listed here.

7. I want to make you aware that Dr. Marc Arazi came to the United States and presented a lecture on these SAR violations. Please watch the lecture here. https://ehtrust.org/cell-phones-violate-radiation-limits-doctor-calls-urgent-action-update-cell-phone-radiation-tests/ . I would like to ask if the FDA had watched this lecture?

8. I continue to ask that the FDA update the out of date webpages. Please update these webpages. Cell Phones Health Issues. which states "No Evidence Linking Cell Phone Use to Risk of Brain Tumors." Why is the FDA stil posting updated information?

Thank you so much. I would appreciate an answer to these questions. I am ccing my elected officials who are also interested in the answer to these questions.

Sincerely,

Theodora Scarato MSW

-----Original Message-----
From: theodorams <theodorams@aol.com>
To: Daniel.Kassiday <Daniel.Kassiday@fda.hhs.gov>
Cc: Michael.OHara <Michael.OHara@fda.hhs.gov>; William.Jung <William.Jung@fda.hhs.gov>; Robert.Ochs <Robert.Ochs@fda.hhs.gov>; CDRHOmbudsman <CDRHOmbudsman@fda.hhs.gov>
Sent: Tue, Jun 13, 2017 9:09 am
Subject: Letter to FDA on FCC limits exceeded by cell phones at body contact and FDA's position that due to the "safety factor" it is ok if consumers use phones and exceed radiation limits.

Dear Dr. Kassiday,

I have attached below a press release regarding the data that the French government released testing data showing that cell phones violate cell phone radiation limits when tested directly against the body.

This information from France is clear evidence that cell phone testing is inadequate to protect consumers from the radiation limits for cell phones we have in place. Children and pregnant women place these phones directly on their bodies, store them in bras took them into spandex pants and all of these positions are not tested by the manufacturers.

1. I am writing to ask what the FDA's response is to this information just released from France showing violations of SAR when phones are tested at body contact.

2. In a prior letter dated May 31, 2017 (see below) when I asked you about children and pregnant women placing cell phones directly against their bodies and abdomens, you responded with the statement "There is a large safety factor included in the public exposure limit." If I understood your response it seemed like you were saying that the FDA's position is that it is OK if this regulatory limit was exceeded because of this "large safety factor". So I am writing to ask if I understand correctly that the FDA believes that it is OK to exceed the regulatory limits because of this "large safety factor." And if so, *by how much* does the FDA allow the safety factor to be exceeded in excess of FCC limits? (SAR 4w/kg or 7 w/kg or 21 w/kg? or more?). What is the FDA limit at which time the public will be informed? Clearly most people use phones on their body and teens sleep with phones on their chests. Please respond to each question in this paragraph.

I appreciate your response in advance.

Thank you very much,

Theodora Scarato

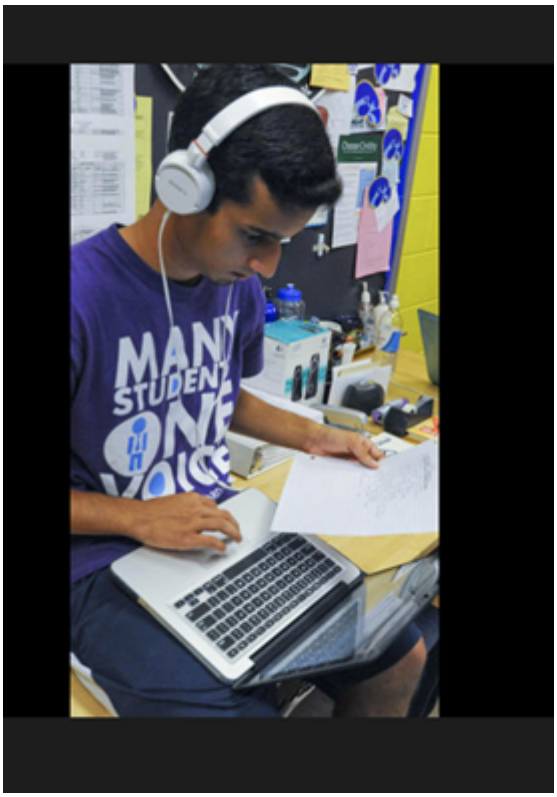
See press release on French data and prior communications below.

Cell Phone Radiation Scandal: More Exposure Than Manufacturers Claim

"PhoneGate" French government data reveals 9 out of 10 phones tested exceed regulatory limits

(Washington, DC) Under court order, the National Frequency Agency (ANFR) of France has just disclosed that most cell phones exceed government radiation limits when tested the way they are used, next to the body. Manufacturers are not required to test phones in shirt or pants pockets. French government tests on hundreds of cell phones reveal that in 2015, 9 out of 10 phones exceed the manufacturer's reported radiation test levels when re-tested in positions where the phone is in contact with the body. The government had refused to disclose these test results until the court order.

On June 1, 2017, ANFR



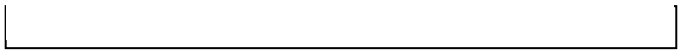
Children handed cell phones as toys.

posted the details of the make, model and test results for each phone that was tested, after months of legal action by French physician Dr. Marc Arazi. Arazi's request for the information was initially denied. Popular brands such as Apple, Motorola, Samsung and Nokia were among the cell phone models tested. When tested in contact with the body, some phones have test results as high as triple the manufacturer's previously reported radiation levels.
"As a physician, I am deeply concerned about what this means for our health and especially the health of our children. People have a right to know that when cell phones are tested in ways people commonly use phones – such as in direct contact with their body – the values exceed current regulatory limits. This is a first victory for transparency in this industry scandal," commented Arazi.

Ricocheting in headlines throughout France, Arazi and his colleagues have coined the situation as "PhoneGate" because of the parallels to "Diesel Gate" – the Volkswagen emissions saga. Devra Davis, PhD, President of Environmental Health Trust explained, "Volkswagen cars passed diesel emission tests when tested in laboratory conditions, but when the cars were driven on real roads, they emitted far more fumes. In the same way, every one of these cell phones 'passed' laboratory radiation SAR tests. These phones are legally considered compliant. However, when these phones are tested in the ways that people actually use them in real life, such as in your jeans pocket or bra, the amount of absorbed radiation emissions in our bodies violates the regulatory limits."

"This is an enormous international scandal. This is not only about France and Europe, as this applies to all persons who use cell phones in every country. If phones were tested in the ways we use them, they would be illegal," stated Dr. Davis, pointing out that these findings were replicated earlier by a US FCC certified laboratory as part of an investigation by the Canadian Broadcasting Corporation. Findings of higher radiation levels than expected (and even higher after phones are fixed) were also documented by the Holon Institute of Technology in

Israel and featured on Israeli news.



"Far more concerning is that the regulatory limits do not protect the public from adverse health effects related to long-term exposures," Davis commented, pointing to recently published research. A study in the American Journal of Epidemiology found cell phones associated with a doubled risk of glioma, a type of brain cancer. Studies performed by the US National Toxicology Program found glioma and DNA damage increased in rats exposed to long-term cell phone radiation.

"I see children cradling cell phones in their laps as their mothers do grocery shopping. Teenagers are sleeping with cell phones placed on their chest or directly beside their heads all night long. Pregnant women put cell phones and wireless devices on their abdomen. Parents have a right to know that when children use cell phones in these ways, their bodies are absorbing wireless radiation at levels that exceed limits set for adults 20 years ago," stated Theodora Scarato, Program Director at Environmental Health Trust, referring to how the American Academy of Pediatrics has repeatedly called on the US Government to update cell phone testing to reflect current use patterns. The American Academy of Pediatrics has issued clear recommendations to reduce cell phone radiation exposures to children.

The Public is Unaware

France's National Agency of Health Security of Food, Environment and Labour (ANSES) July 2016 report "Radiofrequency Exposure and the Health of Children" conceded that the public is largely unaware of instructions to keep a distance between cell phones and anyone's head and body. ANSES stated that it was "unlikely that people, especially children, are aware of the conditions of use close to the body, as defined by manufacturers."

The Canadian Broadcasting Corporation (CBC) independent survey of more than 11,000 Canadians found that more than 80 percent were unaware of manufacturers' recommended separation distance and 67 percent admitted they carry their phones against their bodies.

The newly released French data is also corroborated by the 2017 independently commissioned investigation by the Canadian Broadcasting Corporation that tested popular cell phones in a US government certified testing laboratory and found SAR values surpassed the US and Canadian allowable SAR values when the phones were tested in body contact positions. In response to the CBC report, manufacturers stated they were fully compliant.

The Wireless Industry Argues "No Evidence" To Update Testing Protocols

Read what Apple states here -and you can see in example of how the SAR looks different depending on the tissue averaging at this
link https://www.apple.com/legal/rfexposure/iphone5,1/en/

The CTIA, the wireless industry lobby group is opposed to mandatory disclosures about the manufacturer's instructions and also is opposed to updating cell phone radiation testing methods to include body contact positions ***such as were performed by the French government.*** The CTIA argued that "there is no reliable evidence proving that current testing protocols fail to ensure compliance with RF standards, " in their submission to the US Federal Communications Commission concerning the FCC Docket on Human Exposures to Radiofrequency Radiation. The CTIA stated that "a zero-measuring requirement would not accurately mimic real usage or increase safety."

In California, the City of Berkeley was sued by the CTIA, a wireless industry lobby group, when the City passed an ordinance mandating consumers are informed of these manufacturers' instructions by retail stores. The CTIA argued that the "Right To Know Ordinance" violated free speech rights and recently lost their case in court when the judges ruled that the Ordinance was "in the public interest".

After litigation by UC Berkeley public health professor Dr. Joel Moskowitz, the California Department of Public Health (CDPH) released cell phone guidance that the Department scientists had drafted, but withheld from publicly posting for seven years. The guidelines aimed inform the public from possible health impacts from cell phone radiation.

Litigation is moving forward involving more than a dozen people in the U.S. who claim their brain cancer is related to their cell phone use. In Italy, a recent court ruling recognized a link between cellphone use and brain tumors and granted lifetime compensation to a man who developed a brain tumor after 15 years of work related cell phone use.

"Why does the public have to sue to get this information?" Scarato asked. "And what about children in schools? The Maryland State Children's Environmental Health and Protection Advisory Council has recommended that schools reduce radiofrequency radiation exposures to children by installing wired networks rather than Wi-Fi, same as in Cyprus, France and Israel. Yet at the same time, schools are now allowing or even insisting children bring cell phones into classrooms. I am sure most of those children are carrying these phones from class to class in their pockets close to their body. They are not aware of the radiation exposures."

Specific Absorption Rate Testing

Before a cell phone model is permitted to go on the market for sale, its manufacturer performs Specific Absorption Rate (SAR) tests to evaluate the radiation levels. SAR values are expressed in terms of watts per kilogram (W/kg) and are intended to measure the amount of cell phone radiofrequency radiation absorbed by the body when using a wireless device. SAR tests are performed in laboratories by measuring the SAR in a test dummy filled with liquid. The European Union regulations allow a maximum of SAR 2.0 W/kg. The United States and Canada allow a maximum of SAR 1.6 W/kg. Every cell phone is rated with a specific SAR value, and many countries mandate that these SAR values be prominently displayed to consumers on cell phone packaging.

Current wireless device SAR compliance testing regulations allow manufacturers to put a separation distance (usually about 15 mm) between the phone and the test dummy. Cell phone manufacturers are not required to test cell phones for SARs in positions which mimic direct contact between the phone and the body.

ANSES reported the following findings: In 2015, 89 percent of tested cell phones had a SAR greater than the maximum limit value of 2 W/kg and 25 percent had a SAR greater than 4 W/kg.

See below the French government test data. It is in French so you can scroll to the right to see the column called "DAS tronc (au contact)" which refers to the testing done against the body at "contact" position.

This information is found online here and you can download a spreadsheet of the information.

Calls For Continued Policy Action

Since 2010, France law has ensured that SAR levels are placed prominently on cell phone packaging and the sale of cell phones was banned for young children. French legislation in 2015 included several new policies aimed at reducing exposure to radiofrequency radiation. Arazi called on the Health and Environment Ministers and Consumer Affairs and Fraud Prevention Agency to take immediate action on this new information by informing the public and issuing new protective policies.

Link to the French ANFR Website with full details on cell phones/make/model

ANFR Cell Phone SAR Measurements (PDF)

Link to France's National Agency of Health Security of Food, Environment and Labour Report on Radiofrequency and Children (In French)

English Translation of ANSES Report Section on Cell Phone Studies

NEWS REPORTS

Scandal about mobile radiation: Mobile Phones rays more than manufacturer's claim, Forskning.dk, June 7, 2017

Phones: Test bench or bench?, Journal of The Environment , June 7, 2017

Mobile phone: reassuring results that do not reassure everyone, Journal of Internal Medicine, Paris, June 7, 2017

Electromagnetic waves: Do mobile phones meet standards? Science Avenir, Paris France, June 7, 2017

France publishes the results of tests carried out on 379 GSM, Belgium News, June 3, 2017

Mobile phone: after the publication of ANFR data, Dr Marc Arazi points to irregularities, The Daily Health, June 2, 2017

Suspicions about Mobile Phones Le Monde , December 23, 2016

Phonegate: A first victory with the publication by the ANFR of the SAR, Press Release by French physician Marc Arazi, June 1, 2017

I apologize for the delay.

Your Follow up Questions To The FDA in blue

FDA answers to follow up questions are in red

I asked:**Will the FDA be updating it's website to include the NTP study results on radiofrequency radiation?**

The FDA answered:Our conclusion that current radiofrequency (RF) exposure limits adequately protect the public health has not changed based on the draft National Toxicology Program (NTP) report about a portion of NTP's study. We do not anticipate a website update on the NTP study before NTP publishes a final report regarding the complete study.

My Follow Up Question 1. : The results on the brain and heart cancers are final. They are not a draft In addition the research showing a genotoxic effect are now being added to the report. Even if all the other findings show "no effect" this is a significant finding. Why is the FDA waiting when children and pregnant women are actively exposing themselves to this radiation unaware that they could be racking up hours of exposure.

FDA answer to Follow-up Question 1: The results of the NTP study have not been published as a final document for the partial experiment discussed publically by the NTP nor have they been peer reviewed in the literature. Likewise, the genotoxicity experiments have also not been released publicly nor have they been peer reviewed. The data that has been released by the NTP is only a small subset of a much larger study. While the results add to the body of data on this topic they are not evidence that there is any risk of adverse health effects when exposures are at or below current exposure limits. When we have evidence of a public health hazard or significant risk, FDA has not hesitated to issue and disseminate appropriate safety notices. Our conclusion remains that the existing radiofrequency (RF) exposure limits adequately protects all members of the public including children and pregnant women.

My Follow Up Question 2. Please explain how the FDA arrived at that conclusion?

FDA Answer to Follow-up Question 2: While the experiments are interesting and well performed, the results are not clear and conclusive when compared to whole body or partial body RF exposures that comply with the existing safety limits. The lowest whole body RF exposures tested in the NTP experiment are much higher than the allowable whole body exposure limit. There are differences between the experimental controls and the historical controls that further limit the conclusions reached. Our conclusion that the current RF exposure limits adequately protect the public health is not altered by the available information related to the NTP study.

Why is the FDA not considering the evidence showing fertility damage from wireless and cellphones? Specifically the research on impacts on sperm DNA at non thermal levels, impacts on the ovaries and the fact that the NTP study found the exposed group had offspring with lower birth weight. See research study found here in the drop down:http://ehtrust.org/science/research-on-wireless-health-effects/

We have looked at the papers you identified. Those studies suffer from many confounding factors that significantly limit or eliminate their impact. There is insufficient evidence available to establish adverse health effects, including when these studies are taken into account.

My Follow Up Question 3. So you are stating that all these studies are insufficient. On what grounds?

FDA Answer to Follow-up Question 3 part 1: Peer-reviewed papers are evaluated for any adverse effects reported to be caused by RF exposure. The relative strength of those papers' conclusions must be considered. Examples of factors that may weaken the utility of a paper include: the study design, study protocol violations, RF exposure sources, the dosimetric methods, SAR determination, thermometry, reproducibility of RF emissions, reproducibility of all environmental factors (temperature, air flow, vibration, etc.), differences with historical controls and recall bias. Based on the individual papers and analysis by expert review panels we conclude that the current RF exposure limits adequately protect the public health. This includes reproductive health.

What do you think of this study please in particular as the majority of studies showed an effect.

Houston B., et al. "The effects of radiofrequency electromagnetic radiation on sperm function." Reproduction, 2016.

- Among a total of 27 studies investigating the effects of RF-EMR on the male reproductive system, negative consequences of exposure were reported in 21. Within these 21 studies, 11 of the 15 that investigated sperm motility reported significant declines, 7 of 7 that measured the production of reactive oxygen species documented elevated levels and 4 of 5 studies that probed for DNA damage highlighted increased damage, due to RF-EMR exposure. Associated with this, RF-EMR treatment reduced antioxidant levels in 6 of 6 studies that studied this phenomenon, while consequences of RF-EMR were successfully ameliorated with the supplementation of antioxidants in all 3 studies that carried out these experiments.

FDA Answer to Follow-up Question 3 part 2 – re: Houston et al: Thank you for directing us to the Houston et al. "The effects of radiofrequency electromagnetic radiation on sperm function" review paper. We find this scientific opinion of this review paper to be interesting and the tabulation of the available data from the cited references useful. The paper does not extensively cover the confounding factors present in the papers reviewed. This appears to be because it is a review article that's purpose is the development of a possible mechanism of action. The authors stated that, "we explored the documented impact of RF-EMR on the male reproductive system and considered any common observations that could provide insights on a potential mechanism". The authors also acknowledge that research to date is not conclusive. In their conclusion, they say, "to date, contradictory studies surrounding the impact of RF-EMR on biological systems maintain controversy over this subject". The review's authors' proposed two-step mechanism of action and their call for further laboratory research are interesting. While the opinion of the authors contributes to the body of knowledge on this topic it alone does not change the current understanding of mechanism of RF action nor does it prove there is an adverse effect of RF exposure that complies with the limits on male reproduction. The current RF exposure limit adequately protects the public health.

Additionally, a recent paper by Lewis adds some epidemiological evidence that there is no adverse effect from RF exposures from cell phones. Please see, Lewis, R. C., et al. (2017). "Self-reported mobile phone use and semen parameters among men from a fertility clinic." Reprod Toxicol 67: 42-47. Lewis et al concluded, "The present study found that within the range of self-reported mobile phone use there was no evidence for a relationship with semen quality."

What are the confounding factors on this study please.

Avendaño C, Mata A, Sanchez Sarmiento CA, Doncel GF.(2012). Use of laptop computers connected to internet through Wi-Fi decreases human sperm motility and increases sperm DNA fragmentation.Fertility Sterility. 97(1), 39-45.

FDA Answer to Follow-up question 3 part 3: The paper Avendano et al. examines the impact of radiofrequency radiation from an internet-connected laptop on human sperm in vitro. The authors test an interesting hypothesis with inventive methods. The experiment suffers from a lack of radiofrequency field homogeneity, inadequate information regarding occurrence of temperature change, ambiguity regarding if the control was handled the same as the exposed samples, and some of the semen samples were teratozoospermic which may have impacted the conclusions. The use of a reproducible source of RF exposure is essential to assure that reproduction of an experiment is possible. Cell phones, Wi-Fi routers, and laptops are not reproducible sources of RF exposure thus should not be used for experimentation.

This conclusion is consistent with recent expert reports on radiofrequency. For example, Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) in 2015 concluded, "The previous SCENIHR Opinion concluded that there were no adverse effects on reproduction and development from RF fields at non-thermal exposure levels. The inclusion of more recent human and animal data does not change that assessment. Therefore, it is concluded that there is a strong overall weight of evidence against an effect of low-level RF fields on reproduction or development."[2]

My Follow Up Question 4. Is the FDA's stance to consider the SCENIHR opinion as the FDA's opinion?

FDA answer to Follow-Up Question 4: No, the SCENIHR expert working group is composed of expert scientists that have reviewed, reported on, and collated a large amount of information on RF radiation and FDA values their contribution. However, the FDA comes to its own conclusions.

My Follow Up Question 5. What review has the FDA done on fertility research. Please document and share this analysis.

Regarding your particular concern related to body weight, the NTP's draft report states, "Throughout the remainder of the chronic study, no RFR exposure-related effects on body weights were observed in male and female rats exposed to RFR, regardless of modulation.[3]"

FDA Answer to Follow-Up Question 5: We follow the potential radiofrequency bioeffects literature. We are not actively engaged in laboratory or clinical fertility research. However, there may be other parts of the FDA that does research fertility.

My Follow Up Question 6. Please see on Page 8 the following:

- RESULTS
- In pregnant rats exposed to 900 MHz GSM- or CDMA-modulated RFR, no exposure-related effects were observed on the percent of dams littering, litter size, or sex distribution of pups.Small, exposure-level-dependent reductions (up to 7%) in body weights compared to controls were observed throughout gestation and lactation in dams exposed to GSM- or CDMA- modulated RFR. In the offspring, litter weights tended to be lower (up to 9%) in GSM and CDMA RFR-exposed groups compared to controls. Early in the lactation phase, body weights of male and female pups were lower in the GSM-modulated (8%) and CDMA-modulated (15%) RFR groups at 6 W/kg compared to controls. These weight differences in the offspring for both GSM and CDMA exposures tended to lessen (6% and 10%, respectively) as lactation progressed. Throughout the remainder of the chronic study, no RFR exposure-related effects on body weights were observed in male and female rats exposed to RFR, regardless of modulation n in all groups of male rats exposed to GSM-modulated RFR

The quote you sent me is not adequate to address the concern I raised. As you can see from this paragraph, the weights were lower (see my yellow highlighted areas above) after prenatal exposure. You sent me details that pertain to the animals later in the study. (My daughter was a low birth weight when she was born and has caught up now.) The fact is that an effect of lower birth weight was found at non thermal levels. This indicates an important non thermal effect. (Smoking caused babies to be smaller as well and the industry stated this was good for mothers and doctors recommended that women smoke if they were gaining to much weight during

pregnancy.) Please explain why the FDA is not considering this effect and investigating the issue. Clearly non-thermal effects are evident from this study. Please explain the FDA's analysis on the issue of these lower body weights.

FDA Answer to Follow-up question 6: FDA is sorry that our quote was not adequate to address your concern. However, our quote is still accurate. The observation of a birth weight difference between exposed and control-animals is an important observation. The excerpted discussion above does say that pregnant rats gave birth to normal litters, pup were smaller early in lactation and lessened as lactation proceeded and no differences were noted in weight during the remainder of the chronic study. The very next paragraph discussed in the study said that control male rat survival was lower than RF exposed rat survival. This survival advantage for RF exposed male rats also may suggest that the lower birth weight at birth was not significant in the exposed group. We do not believe that this is a non-thermal effect of radiofrequency exposure. The study also said that thermal regulation was more difficult in pregnant or geriatric rats. It is possible that temperature elevation and thermal regulation was still an issue in these whole body irradiation experiments.

3.

Is it still the FDA's position that the weight of evidence does not show health effects? If so, please provide the documentation that supports this position by the FDA in light of the NTP results. In a prior email dated February 5, 2016 Email RE-Question about the FDA and radiofrequency radiation this is what you told me. Please provide the scientific research that shows safety.

The FDA's position has not changed. Based on the available scientific evidence, including published literature and published expert reports, the Agency has concluded that the current RF exposure limits provide adequate protection for use of RF consumer communication electronic products like cell phones.

My Follow Up Question 7. Please send me the "the available scientific evidence, including published literature and published expert reports" the FDA specifically looked at to state that "the Agency has concluded that the current RF exposure limits"

FDA Answer to Follow-up question 7: Copyright infringement is a problem with this request. What you are asking for is already on line at the WHO website, SCENIHR website, in the bibliographies of the documents noted in our original response and through PubMed literature searches.

Many expert reports have been released that discuss the strengths and weaknesses of the published literature. There have also been formal analyses and reviews of published expert reports.

You cite two reviews but is this how the FDA investigates ? by citing two reviews well cited by industry funded scientists? It is notable that this review "International and national expert group evaluations: biological/health effects of radiofrequency fields." not only cites industry linked reports but the authors state: "We thank Chung-Kwang Chou (chairman, SC-95 of the international committee on electromagnetic safety, Institute of Electrical and Electronic Engineers) for critical reading of the manuscript and helpful suggestions." CKChou is former Chief Motorola Scientist.

My Follow Up Question 8. Are these reviews that you refer to from organization that the FDA then is taking on as it's own opinion? How does the FDA determine that these reviews are scientifically sound and unduly influenced by industry?

FDA Answer to Follow-up Question 8: The FDA has been following RF exposure potential bioeffects since at least the early 1990s. We have met with and listened to numerous organizations on the topic, including your organization. The FDA reviews all published papers and reviews that are brought to our attention or that we identify through literature searches. Our answers were meant to guide you to scientific reviews that cover a large amount of literature in a systematic fashion. The expert review groups that have reviewed the RF literature have guidance policies and procedures in place to prevent undue influence from outside. FDA knows that Chung-Kwang Chou is an internationally recognized expert on RF radiation and we know that we also know that he

worked for industry. The weight of the evidence from the literature and expert opinions are what lead us to believe that the current exposure limits adequately protect the general public.

We note that Vershaeve 2012 specifically evaluated expert reports to assess bias. Verschaeve says, "**Evaluation of expert group reports based on 10 criteria**

An evaluation of the different reports should take into account a great number of aspects. Amongst them the composition of the working group, the topics that were taken into account and the methods that were used are certainly some of the important aspects. We therefore tried to identify the members or participants in the working group activities and tried to see whether they constituted a *multidisciplinary* and *independent* group of experts. Did they evaluate all scientific (peer reviewed) publications, or did they make a selection of papers, and if so, what was the rationale for doing so? Was this satisfactory? Was the report a consensus report? Where minority opinions mentioned?" Similarly, Vijayalaxmi and Scarfi 2014 included comments on negative and positive aspects of the expert groups and their reports.

4. Does the FDA consider oxidative stress a health effect? I sent you a review article last year about this and it seems important to share with the American people
(http://nebula.wsimg.com/107f00a88ae36803a132e3ca6c222157?AccessKeyId=045114F8E0676B9465FB&disposition=0&alloworigin=1**)**

Thank you for the review article on oxidative stress. We have reviewed it, and it contains opinions that have added to our understanding of the topic.

In the World Health Organization (WHO) International Agency for Research on Cancer (IARC) monograph 102 (2013), the IARC expert working group concluded that there was only weak evidence that adverse health effects could be caused by RF due to oxidative stress. We do not believe that the available scientific evidence shows a link between the magnitude of oxidative stress attributable to RF exposures from cell phones (or similar electronic products) and adverse health effects.

My Follow Up Question 9. How do you substantiate such a statement ?

"We do not believe that the available scientific evidence shows a link between the magnitude of oxidative stress attributable to RF exposures from cell phones (or similar electronic products) and adverse health effects."

FDA Answer to Follow-up Question 9: From the totality of the scientific literature available and expert opinions.

My Follow Up Question 10. Does the FDA think that oxidative stress can impact health.

the research study here states that constant oxidative stress over tome can lead to health problems. Please review and explain why this has not impacted the view of the FDA.

FDA Answer to Follow-up question 10: Oxidation is a normal component of metabolism and cells have redundant systems to deal with the consequences of oxidative stress. We are aware that approximately 70% of the damage done by ionizing radiation is due to oxidative stress. We follow the RF literature on potential mechanisms of action. Our opinion at this time is that the totality of the scientific literature does not support that hazardous levels of oxidative stress can be induced by radiofrequency radiation exposure that does not also cause hazardous temperature elevation.

5.

If the FDA is supposed to protect the public then they need to inform the public of the fine print instructions the manual related to RF. Why is the FDA not acting on this and informing people of the fine print instructions on RF on cell phones and wireless devices? Children are carrying phones on their bodies, tucked in spandex pants and in bras and jeans in school classrooms. Can you please explain why the FDA is not ensuring the public is aware of the fine print warnings?

There is a large safety factor included in the public exposure limit (see IEEE Std. C95.1-2005 Annex C, *Rationale*, for more information regarding this safety factor).

My Follow Up Question 11. What does the FDA think the safety factor is for SAR exposure limits. Please state it.

FDA Answer to Follow-Up Question 11: Wireless communication devices are required to meet radiofrequency (RF) energy exposure guidelines set forth by the Federal Communication Commission (FCC). These guidelines were last revised on August 1st, 1996 when the FCC adopted local body RF energy specific absorption rate (SAR) limits for devices operating within close proximity to the body as recommended by ANSI/IEEE C95.1-1992 guideline. The ANSI/IEEE C95.1 guidelines are based on protection from thermal effects of whole body RF energy exposure. RF exposure in the 1– 4W/kg SAR range was shown to induce behavioral changes in several animal species, including non-human primates. The observed behavioral change was accompanied by an increase in core temperature of ~1°C. ANSI/IEEE C95.1-1992 guideline derives the local body exposure limit in two steps. First the threshold for behavioral responses was set at 4W/kg SAR, and then a safety factor of 10 was put in place for exposure under controlled environmental conditions (occupational exposure). An additional safety factor of 5 was put in place for the general public exposure setting the whole body exposure limit at 0.08 W/kg. Thus the public whole body exposure limit is approximately 50 times lower than the threshold for heat related adverse health effects. Based on the general public whole body exposure limit a spatial peak limit on 1.6 W/kg averaged over one gram of tissue was set for local body exposure. Before adopting the ANSI/IEEE C95.1-1992 limits the FCC consulted with the Food and Drug Administration (FDA) and other health agencies.

We note that Federal Communications Commission (FCC) guidance on general RF exposure procedures and equipment authorization policies for mobile and portable devices explains that for devices designed to operate in contact with the body, the specific absorption rate (SAR) compliance tests should be conducted a separation distance of 5 mm or less (FCC KDB 447498 D01 section 4.2.2).

My Follow Up Question 12. Why does the FDA not share this information with the public? Why are these separation distances not stated on the FDA website so that te American people are aware of it. I have a teenage daughter and her friends do the following: They place the cell phone in their spandex pants against their skin. They lay the phone on their lap as they watch music videos or stream and facetime. They also sleep with the phone next to their head. They easily can roll over and sleep on the cell phone. Women carry cell phones in their bra all the time. The public is unaware. Again- Why does the FDA not share this information with the public on their website? So far it is a secret.

FDA Answer to Follow-up question 12: As you yourself noted, the FCC shares this information with the public. The FDA website on Cell Phones (https://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/homebusinessandentertainment/cellphones/default.htm) has links to the FCC.

Additionally, that FCC guidance explains that mobile and portable devices designed to be used with a body-worn accessory must be tested for body-worn accessory SAR compliance. According to the guidance, a conservative minimum test separation distance should be used for such testing, at worst case using no more than a 25 mm separation distance. The same FCC guidance states that operating manuals must include specific information to allow users to select body-worn accessories that meet the compliance test separation distance requirements, and all supported body-worn accessory operating configurations must be clearly disclosed to users, through conspicuous instructions in the user guide and user manual, to ensure unsupported operations are avoided.

My Follow Up Question 13. Everyone I have spoken to to is 100% unaware of this information buried in manuals. Please explain how the FDA has decided it is not their responsibility to inform the public on this. Has the FDA done a survey?

FDA Answer to Follow-up Question 13: The FDA website on Cell Phones (https://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/homebusinessandentertainment/cellphones/default.htm) has links to the FCC. As any web search for "usability of user manuals" will reveal, there is a lot of concern and research on

why most consumers ignore manuals and instructions. So it is not surprising that consumers are unaware of one particular fact in a manual when most consumers don't read anything in user manuals. The FDA has not done a survey and we are not aware if the FCC has.

Additionally, cell phone RF exposure compliance testing must be determined at the maximum average power level.

My Follow Up Question 14. Well actually you will use your cell phone at maximum power under several conditions such as if you are far from a tower with lower bars- or in an elevator, in a moving car far from a tower and video streaming- as you are aware. So it is possible. Is the FDA saying that although it is possible to be at maximum power, it is not necessary for the public to be aware because it does not happen often? There are many moments when people use phones in maximum power conditions- especially when they have a lot of applications on at once far from a base station. Please explain why the FDA is rationalizing not telling people about this.

FDA Answer to Follow-up Question 14: As you state, these are *moments* when a cell phone needs to operate at maximum power. Cell phones will always attempt to operate at the minimum power necessary in order to prolong battery life. Over the course of a day the average exposure is considerably lower. You mention using a cell phone in a moving car far from a tower; because of factors unrelated to RF exposure this is indeed a dangerous situation. The safety factors set in place for RF exposure adequately protect the general public.

However, the National Safety Council estimates cell phone use to be involved in 26 percent of all motor vehicle crashes – 5 percent of crashes involve texting, while 21 percent involve drivers talking on handheld or hands-free cell phones. (http://www.nsc.org/NewsDocuments/2014-Press-Release-Archive/3-25-2014-Injury-Facts-release.pdf) Clearly the greatest risk to public safety posed by cell phones is the risk of death or injury resulting from vehicular accidents due to distracted driving.

In order to conserve battery life, cell phones seldom actually operate at maximum power, which reduces the SAR proportionately.

My Follow Up Question 15. Can you tell me what data you have on how "cell phones seldom actually operate at maximum power" How often do they opeate at maximum power.

FDA Answer to Follow-Up Question 15: There has been considerable research on cell phone power consumption related to energy management and battery life. Actually transmitted RF power can be a minor part of the power consumption in smartphones which use a lot of power for the processor and display. Unfortunately these research efforts consider total transmit power over one battery charge and do not look at a typical time history of transmission power. Actual transmit power will be dependent on many factors unique to individuals, such as: where they live and work in relation to cell phone towers and usage patterns.

There is some relevant information in IARC Monograph 102 at the bottom of page 76 and top of page 77. There are also papers regarding exposure assessments that attempt to quantify dose for use in epidemiology assessments.

6.

I understand that the RFIAWG was given a presentation of these findings. What is the FDA perspective on the findings now that you have reviewed them please? Please detail the next steps for the FDA with a timeline.

The U.S. Radiofrequency Interagency Working Group (RFIAWG) has not had a presentation on findings from the NTP study.

My Follow Up Question 16. Why hasn't the U.S. Radiofrequency Interagency Working Group (RFIAWG) had a presentation on these findings? I thought the Groups role was to provide some sort of oversight? Why are they

not given a full presentation?

FDA Answer to Follow-up Question 16: The RFIAWG allows staff to discuss RF research and any concerns. It does not have a management or oversight role. The remainder of this question has already been answered. No further information is available.

My Follow Up Question 17. Has the FDA been given a presentation on the NTP findings of increased brain cancer, increased heart nerve sheath tumors and genotoxicity?

FDA Answer to Follow-up Question 17: The FDA has been briefed on the partial findings of the NTP study.

FDA's conclusion that current RF exposure limits adequately protect the public health has not changed based on the information in the draft NTP report about a portion of NTP's study.

My Follow Up Question 18. How did you determine that conclusion? What is the rationale for FDA's conclusions?

FDA Answer to Follow-up Question 18: From the totality of the scientific literature available and expert opinions.

When NTP completes its analysis and a full report is available, we will review it and consider what, if any, effect it has on the agency's thinking regarding risks associated with RF exposure from cell phones.

My Follow Up Question 19. Can you please explain the review process for the FDA and the transparency that will be involved in the review.

FDA Answer to Question 19: The NTP has briefed FDA on the partial result already. We believe that the NTP will also brief FDA on the completed total study when it is complete. FDA will review the entire study and decide if the results impact our understanding of its impact on RF safety.

Who is the point person at the FDA for this issue and what are they doing in regards to this issue. What questions are being asked and of whom? What other FDA staff are involved in the process. Are any consultants working with the FDA? Who are they?

The Center for Devices and Radiological Health (CDRH) is the FDA center that regulates electronic products under the Electronic Product Radiation Control (EPRC) provisions of the Federal Food, Drug, and Cosmetic Act. Note: EPRC may also be referred to as "Radiological Health." Questions or concerns can be sent to the FDA document mail center:

U.S. Food & Drug Administration

Center for Devices and Radiological Health

Office of In Vitro Diagnostics and Radiological Health

10903 New Hampshire Avenue

WO66-5521

Silver Spring, MD 20993-0002

Marking the documents, "Attn: Division of Radiological Health" can help expedite routing to the Division of Radiological Health for review and appropriate follow-up. The staff in other divisions and offices who have the required expertise to answer specific questions are called upon for assistance when a need occurs. If necessary, we could call on expertise from other government (international, national, state, etc.) agencies, concerned consumer groups, or industry.

My Follow Up Question 20. You did not answer my questions so here they are again.

Who is the point person at the FDA for this issue and what are they doing in regards to this issue?

What questions are being asked and of whom?

What other FDA staff are involved in the process.

Are any consultants working with the FDA? If so- Who are they?

FDA Answer to Question 20: These questions have been asked and answered.

8. The NTP study found DNA damage in the brain; please detail the FDA response to these findings and the next steps in terms of protecting the people.

We assume your question is referring to the draft supplemental NTP document that covers experiments looking for DNA damage. Our conclusion that current RF exposure limits adequately protect the public health has not changed based on our review of the draft NTP supplemental papers.

The NTP comet assay, indicated DNA damage (see the table).

My Follow Up Question 21. Please explain how this DNA damage found in the comet assay - not change the FDA opinion?

FDA Answer to Follow-up Question 21: The table you included is a variant of the table the NTP used in its briefings and is a summary of all of the Comet assay data. FDA does not agree with this summary table and how it reflects the data. Unfortunately, this paper has not been published and FDA is not at liberty to discuss the data further.

My Follow Up Question 22. What would change the FDA opinion? How much evidence is necessary?

FDA Answer to Follow-up Question 22: FDA believes that the current exposure standard is adequate to protect public health. In order to change that belief we would need to see well controlled studies that have reproducible results, we would also consider opinions from other expert organizations and the rational for or against changes by standard setting organizations that collectively say that the current exposure standards need to change to protect people.

9. Is the FDA preparing a response to inform the FCC of the official recommendations to the issue of cell phones and wireless? Please give specifics on the timelines.

As a general policy, the FDA does not comment on pending matters that are under review. If FDA had concerns regarding the current RF exposure limits, the agency would communicate those concerns to FCC.

My Follow Up Question 23. I thought that a transparent process was underway and that all comments would be available. The FCC states they are looking to their federal partners for guidance as they are not a health and safety agency. If the FDA does not give any comments then I wonder who will. Will the FDA be commenting at all to the FCC in their Proceeding Number 13-84? Have they ever commented?

FDA Answer to Follow-up Question 23: Question was asked and answered.

10.

The FDA has received reports of people who develop headaches, nerve damage and rashes from cell phone and wireless use. What is being done by the FDA to monitor these side effects?

The FDA has received anecdotal reports from individuals that attribute their symptoms to RF exposure from cordless phones and cell phones. The anecdotal reports are reviewed to determine if they contain new information indicating that RF radiation from an electronic product caused the adverse health effects described. No such evidence has been revealed through our review of those reports. We also monitor literature regarding experiments intended to prove or disprove a causal link between RF exposure and adverse health effects as well as literature regarding the most effective treatments for individuals suffering from these symptoms.

Where can these reports be accessed online?

Currently, these reports cannot be publicly accessed online.

My Follow Up Question 24. Why not, Can you please make them available.

FDA Answer to Follow-up Question 24: These records can contain patient specific medical information that we cannot make public. Redacted copies are probably available via Freedom of Information requests.

My Follow Up Question 25. Are you keeping track? Can you please make publicly available the amount of complaints that you have received

FDA Answer to Follow-up Question 25: The FDA does keep track. We can look into making the amount of complaints publically available.

What is the timeline for response to these concerns and reports?

The agency reviews these reports within one month. We only contact the responder if further information or clarification appears to be needed.

My Follow Up Question 26. Then what do you do with the information?

What is the procedure for reporting and what reports are the FDA generating on the issue?

To report a problem that appears to be related to electronic product radiation, please see our website at: https://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ *ReportaProblem/default.htm*. FDA has not generated a report on reports it has received from individuals attributing their symptoms to RF exposure from consumer communications products.

FDA Answer to Follow-Up Question 26: An accidental radiation occurrence means a single event or series of events that has/have resulted in injurious or potentially injurious exposure of any person to electronic product radiation as a result of the manufacturing, testing, or use of an electronic product. The reports are required from manufacturers if the regulatory definition and criteria for requiring a report are met. Reports can come from consumers or occupational product user. The FDA reviews the reports to determine if the information indicates a defect could be present in a specific product or generally in a product type. To complete that evaluation we occasionally find we need to request more information from the manufacturer, report submitter or other relevant source.is necessary. For this product area the literature indicates that RF exposure is not a plausible cause of the problem described.

My Follow Up Question 27. Can you please generate an annual report on this. It seems important.

FDA Answer to Question 27: The FDA has not generated annual reports on cell phone complaints.

11. Will the FDA be recommending that the NTP now do a systematic review of radiofrequency considering the research results? If so when? If not, please explain why not-considering the widespread proliferation of cell phones. Please see where the FDA can nominate this issue for systematic review here – The NTP Office of Health Assessment and Translation (OHAT) develops literature-based evaluations to reach conclusions about potential human health hazards and to examine the state of the science. https://ntp.niehs.nih.gov/pubhealth/hat/noms/index-2.html**.**

We have not asked NTP to perform a systematic review for several reasons, including the fact that there are already numerous high quality expert reports, formal reviews, and meta-analyses related to the safety of use of RF consumer communication products.

My Follow Up Question 28. Please list those you are referring to. As far as I know, there are no systematic reviews that have been done and the US has not looked at this for over 20 years.

FDA Answer to Follow-Up Question 28: The IEEE International Committee on Electromagnetic Safety has posted a list of statements from governments and expert panels concerning research and conclusions about the possibility of health effects and safe exposure levels of radiofrequency energy. Many of these organizations have further analysis at their own web sites. Many of these organizations go into great detail on their analysis and have extensive bibliographies. The link to the IEEE website is attached. http://www.ices-emfsafety.org/expert-reviews/

In addition, the WHO EMF Project is currently updating the relevant Environmental Health Criteria.

My Follow Up Question 29: The WHO EMF Project was started with industry funded and is lead by an engineer and the group members are also connected to ICNIRP. It is not the same as the IARC. Is the FDA going to go with the results of the WHO EMF Project Environmental Health Criteria rather than do an independent review?

FDA Answer to Follow-up Question 29: FDA has answered this concern above. We have worked closely with the US National Academy of Science and we follow the work of expert review groups like IARC, the WHO EMF project, ICNIRP and SCENIHR. All of these expert review organizations have vetting processes for their expert scientific review panels. In addition, our scientists have been following the RF science at national and international meetings as well as via Pubmed since at least the early 1990s.

Thank you for the link. FDA has no plan to nominate this issue for systematic review at the NTP Office of Health Assessment and Translation at this time.

My Follow Up Question 30: Why not? . Please I would think a systematic review is in order considering the exposure to babies and children for a lifetime.

FDA Answer to Follow-up Question 30: There is no need for NTP to do this work for the FDA. This can be done by the FDA if necessary. Also, there are already many systematic reviews available.

Additional Questions:

My Follow Up Question 31.

Children are handed wireless laptops in classrooms across the USA. Please explain why the FDA is not informing the parents that many laptops have minimum separation distance of 20cm or 8 inches that the device should be from the body to ensure FCC compliance. The FDA should be informing the public about this distance. Why aren't they.

See this http://news.arubanetworks.com/press-release/prince-georges-county-public-schools-creates-one-nations-largest-k-12-wi-fi-deployment

FDA Answer to Follow-up Question 31: The antenna in laptop computers is usually located along the top edge of monitor of the laptop. Opening the laptop to use it puts the antenna approximately 8-10 inches away from the viewer. Our current conclusion remains that the existing radiofrequency (RF) exposure limits adequately protects all members of the public including children and pregnant women.

My Follow Up Question 32.

What proof of safety is there that pregnant women are protected when it comes to this radiation. They are placing laptops on their bellies. Has the FDA looked at research on impacts on pregnancy? If so, please share what studies have been reviewed.

FDA Answer to Follow-Up Question 32: The FDA has been reviewing RF published reports since the early 1990's. FDA has meetings with interested organizations and working with the National Academy of Sciences, and conducted PubMed literature searches over this time period. In addition, the FDA has followed the work of expert review groups like SCENIHR, ICNIRP and the WHO on this topic. For the most up to date review of this specific topic a PubMed search will provide an excellent background. A review of the SCENIHR document entitled "Potential Health Effects of Exposure to Electromagnetic Fields (EMF) section 3.6.4.1 Reproductive Effects is also a good place to start a review.

My Follow Up Question 33.

Send me documentation that children adequately covered by the current US guidelines. Children absorb the radiation deeper into their brain and body. Please explain why the FDA states "The scientific evidence does not show a danger to any users of cell phones from RF exposure, including children and teenagers."

Why does the FDA clarify that long term effects are still being researched and children are more vulnerable to this radiation? They will have more impacts as they will have a lifetime of exposure. Why doesn't the FDA state this clearly for parents?

FDA Answer to Follow-Up Question 33: Our current conclusion remains that the existing radiofrequency (RF) exposure limits adequately protects all members of the public including children and pregnant women. The FDA has been reviewing RF published reports since the early 1990's. FDA has meetings with interested organizations and working with the National Academy of Sciences, and conducted PubMed literature searches over this time period. In addition, the FDA has followed the work of expert review groups like SCENIHR, ICNIRP and the WHO on this topic. For the most up to date review of this specific topic a PubMed search will provide an excellent background. A review of the SCENIHR document entitled "Potential Health Effects of Exposure to Electromagnetic Fields (EMF) is also a good place to get a compilation of published reports.

My Follow Up Question 34.

The FDA has outdated information (highlighting Interphone 2010 results) on a webpage under the cellphones section entitled Cell Phones Health Issues. which states "No Evidence Linking Cell Phone Use to Risk of Brain Tumors."

https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm212273.htm

FDA Senior staff have been asked to update these webpages 4 times over the last two years *and have not done so*. Please explain why this outdated material is being left on the FDA website.

FDA Answer to Follow-up Question 34: Thank you for your review of the FDA website on this topic. Your concern regarding the information is noted. The information is still useful.

Daniel Kassiday

SME: Electronic Product Radiation Control

Center for Devices and Radiological Health

Office of In Vitro Diagnostics and Radiological Health

U.S. Food and Drug Administration

Tel: 301-796-5865

daniel.kassiday@fda.hhs.gov

From: theodorams <theodorams@aol.com>
To: CDRHOmbudsman <CDRHOmbudsman@fda.hhs.gov>
Subject: Fwd: Letter to FDA on FCC limits exceeded by cell phones at body contact and FDA's position that due to the "safety factor" it is ok if consumers use phones and exceed radiation limits.
Date: Fri, Sep 8, 2017 10:19 am
Attachments: Screen Shot 2017-09-08 at 9.52.01 AM.png (917K), Screen Shot 2017-09-08 at 9.51.40 AM.png (401K), Screen Shot 2017-09-08 at 9.51.40 AM.png (401K)

Dear Ombudsban,
Please help me to receive an answer to my questions.
Thank you , Theodora Scarato

-----Original Message-----
From: theodorams <theodorams@aol.com>
To: theodorams <theodorams@aol.com>; Daniel.Kassiday <Daniel.Kassiday@fda.hhs.gov>
Cc: Michael.OHara <Michael.OHara@fda.hhs.gov>; William.Jung <William.Jung@fda.hhs.gov>; Robert.Ochs <Robert.Ochs@fda.hhs.gov>; CDRHOmbudsman <CDRHOmbudsman@fda.hhs.gov>; alonzo.washington <alonzo.washington@house.state.md.us>; alonzo <alonzo@alonzowashington.com>; jamie.raskin <jamie.raskin@senate.state.md.us>
Sent: Fri, Sep 8, 2017 10:18 am
Subject: Re: Letter to FDA on FCC limits exceeded by cell phones at body contact and FDA's position that due to the "safety factor" it is ok if consumers use phones and exceed radiation limits.

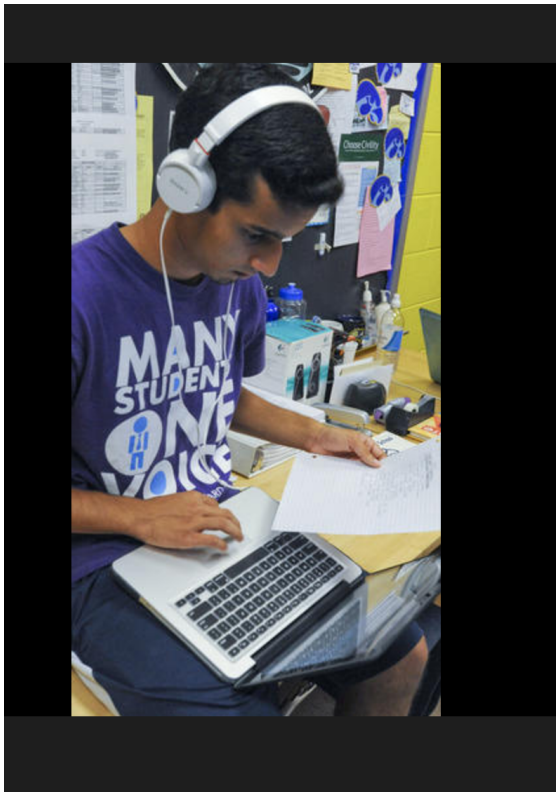
Dear Dr. Kassiday,

I have not received a response to the letter I sent Tue, Jun 13, 2017 9:09 am (see below this email the email I sent several months ago still unanswered).

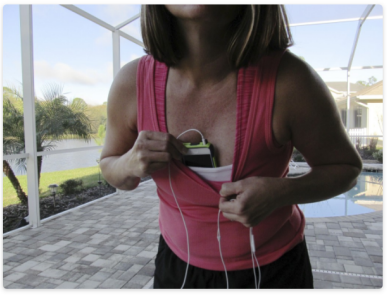
I will reiterate the questions and add a few more.

1. I am writing to ask what the FDA's response is to information just released from France showing violations of SAR when phones are tested at body contact. The FDA is aware that people use cell phones resting on their legs or on chests and therefore the FDA needs to be aware that the American public is being exposed to radiation levels exceeding our government guidelines. Please see this picture taken at an airport just this week. Note the laptop resting on this mans chest.

Please see these images from Maryland public Schools of students with devices on their body as well as how people typically wear their phones when they work out.


MANY
STUDENT
ONE
VOICE

iPhone slips into cami bra pocket easily.



Closer view of the layers and iPhone in pocket.

I am writing to ask what the FDA's response is to information just released from France showing violations of SAR when phones are tested at body contact in light of the fact that Americans are placing radiating cell phones and wireless devices directly on their bodies in violation of the FCC instructions and therefore exceeding FCC SAR values in their body.

2. In a prior letter dated May 31, 2017 (see below) when I asked you about children and pregnant women placing cell phones directly against their bodies and abdomens, you responded with the statement "There is a large safety factor included in the public exposure limit." If I understood your response it seemed like you were saying that the FDA's position is that "it is OK" if this regulatory limit was exceeded because of this "large safety factor". Is that what you meant in your response?

3. So I am writing to ask if I understand correctly that the FDA believes that it is OK to exceed the regulatory limits because of this "large safety factor." ?

4. And if the FDA believes that it is OK to exceed the regulatory limits because of this "large safety factor., *by how much* does the FDA allow the safety factor to be exceeded in excess of FCC limits? Could you please specify in terms of SAR as to the SAR at which the FDA will take action. For example is it a SAR of over 4w/kg or 7 w/kg or 21 w/kg? or more?

5. What is theSAR limit at which time the public will be informed by the FDA that cell phones violate US regulatory SAR limits?

6. I am included a chart so that you can see the cell phone, make and model and the SAR amount documenting how each phone violates SAR limits. Please see the document on this webpage but please note that the 0mm SAR listed is per the European 10 gram averaging. Therefore the equivalent US FCC 1 gram averaging SAR is likely over 2 times the amount listed here.

7. I want to make you aware that Dr. Marc Arazi came to the United States and presented a lecture on these SAR violations. Please watch the lecture here. https://ehtrust.org/cell-phones-violate-radiation-limits-doctor-calls-urgent-action-update-cell-phone-radiation-tests/ . I would like to ask if the FDA had watched this lecture?

8. I continue to ask that the FDA update the out of date webpages. Please update these webpages. Cell Phones Health Issues. which states "No Evidence Linking Cell Phone Use to Risk of Brain Tumors." Why is the FDA stil posting updated information?

Thank you so much. I would appreciate an answer to these questions. I am ccing my elected officials who are also interested in the answer to these questions.

Sincerely,
Theodora Scarato MSW

-----Original Message-----
From: theodorams <theodorams@aol.com>
To: Daniel.Kassiday <Daniel.Kassiday@fda.hhs.gov>
Cc: Michael.OHara <Michael.OHara@fda.hhs.gov>; William.Jung <William.Jung@fda.hhs.gov>; Robert.Ochs <Robert.Ochs@fda.hhs.gov>; CDRHOmbudsman <CDRHOmbudsman@fda.hhs.gov>
Sent: Tue, Jun 13, 2017 9:09 am
Subject: Letter to FDA on FCC limits exceeded by cell phones at body contact and FDA's position that due to the "safety factor" it is ok if consumers use phones and exceed radiation limits.

Dear Dr. Kassiday,

I have attached below a press release regarding the data that the French government released testing data showing that cell phones violate cell phone radiation limits when tested directly against the body.

This information from France is clear evidence that cell phone testing is inadequate to protect consumers from the radiation limits for cell phones we have in place. Children and pregnant women place these phones directly on their bodies, store them in bras took them into spandex pants and all of these positions are not tested by the manufacturers.

1. I am writing to ask what the FDA's response is to this information just released from France showing violations of SAR when phones are tested at body contact.

2. In a prior letter dated May 31, 2017 (see below) when I asked you about children and pregnant women placing cell phones directly against their bodies and abdomens, you responded with the statement "There is a large safety factor included in the public exposure limit." If I understood your response it seemed like you were saying that the FDA's position is that it is OK if this regulatory limit was exceeded because of this "large safety factor". So I am writing to ask if I understand correctly that the FDA believes that it is OK to exceed the regulatory limits because of this "large safety factor." And if so, *by how much* does the FDA allow the safety factor to be exceeded in excess of FCC limits? (SAR 4w/kg or 7 w/kg or 21 w/kg? or more?). What is the FDA limit at which time the public will be informed? Clearly most people use phones on their body and teens sleep with phones on their chests. Please respond to each question in this paragraph.

I appreciate your response in advance.

Thank you very much,
Theodora Scarato

See press release on French data and prior communications below.

Cell Phone Radiation Scandal: More Exposure Than Manufacturers Claim

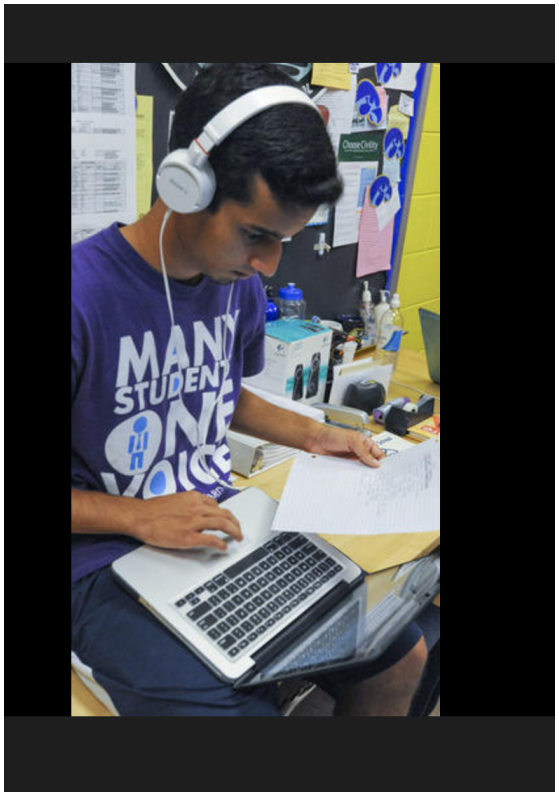
"PhoneGate" French government data reveals 9 out of 10 phones tested exceed regulatory limits

(Washington, DC) Under court order, the National Frequency Agency (ANFR) of France has just disclosed that most cell phones exceed government radiation limits when tested the way they

are used, next to the body. Manufacturers are not required to test phones in shirt or pants pockets. French government tests on hundreds of cell phones reveal that in 2015, 9 out of 10 phones exceed the manufacturer's reported radiation test levels when re-tested in positions where the phone is in contact with the body. The government had refused to disclose these test results until the court order.

Children handed cell phones as toys.

On June 1, 2017, ANFR

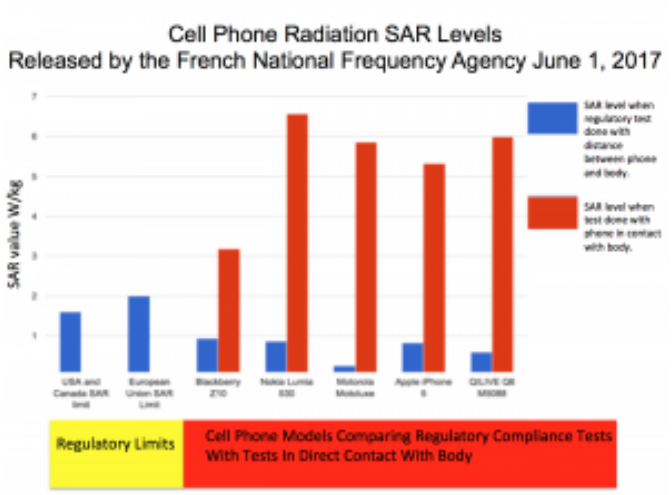


posted the details of the make, model and test results for each phone that was tested, after months of legal action by French physician Dr. Marc Arazi. Arazi's request for the information was initially denied. Popular brands such as Apple, Motorola, Samsung and Nokia were among the cell phone models tested. When tested in contact with the body, some phones have test results as high as triple the manufacturer's previously reported radiation levels.
"As a physician, I am deeply concerned about what this means for our health and especially the health of our children. People have a right to know that when cell phones are tested in ways people commonly use phones – such as in direct contact with their body – the values exceed current regulatory limits. This is a first victory for transparency in this industry scandal," commented Arazi.

Ricocheting in headlines throughout France, Arazi and his colleagues have coined the situation as "PhoneGate" because of the parallels to "Diesel Gate" – the Volkswagen emissions saga. Devra Davis, PhD, President of Environmental Health Trust explained, "Volkswagen cars passed diesel emission tests when tested in laboratory conditions, but when the cars were driven on real roads, they emitted far more fumes. In the same way, every one of these cell phones 'passed' laboratory radiation SAR tests. These phones are legally considered compliant. However, when these phones are tested in the ways that people actually use them in real life, such as in your jeans pocket or bra, the amount of absorbed radiation emissions in our bodies violates the regulatory limits."

"This is an enormous international scandal. This is not only about France and Europe, as this applies to all persons who use cell phones in every country. If phones were tested in the ways

we use them, they would be illegal," stated Dr. Davis, pointing out that these findings were replicated earlier by a US FCC certified laboratory as part of an investigation by the Canadian Broadcasting Corporation. Findings of higher radiation levels than expected (and even higher after phones are fixed) were also documented by the Holon Institute of Technology in Israel and featured on Israeli news.



"Far more concerning is that the regulatory limits do not protect the public from adverse health effects related to long-term exposures," Davis commented, pointing to recently published research. A study in the American Journal of Epidemiology found cell phones associated with a doubled risk of glioma, a type of brain cancer. Studies performed by the US National Toxicology Program found glioma and DNA damage increased in rats exposed to long-term cell phone radiation.

"I see children cradling cell phones in their laps as their mothers do grocery shopping. Teenagers are sleeping with cell phones placed on their chest or directly beside their heads all night long. Pregnant women put cell phones and wireless devices on their abdomen. Parents have a right to know that when children use cell phones in these ways, their bodies are absorbing wireless radiation at levels that exceed limits set for adults 20 years ago," stated Theodora Scarato, Program Director at Environmental Health Trust, referring to how the American Academy of Pediatrics has repeatedly called on the US Government to update cell phone testing to reflect current use patterns. The American Academy of Pediatrics has issued clear recommendations to reduce cell phone radiation exposures to children.

The Public is Unaware

France's National Agency of Health Security of Food, Environment and Labour (ANSES) July 2016 report "Radiofrequency Exposure and the Health of Children" conceded that the public is largely unaware of instructions to keep a distance between cell phones and anyone's head and body. ANSES stated that it was "unlikely that people, especially children, are aware of the conditions of use close to the body, as defined by manufacturers."

The Canadian Broadcasting Corporation (CBC) independent survey of more than 11,000 Canadians found that more than 80 percent were unaware of manufacturers' recommended separation distance and 67 percent admitted they carry their phones against their bodies.

The newly released French data is also corroborated by the 2017 independently commissioned investigation by the Canadian Broadcasting Corporation that tested popular cell phones in a US government certified testing laboratory and found SAR values surpassed the US and Canadian allowable SAR values when the phones were tested in body contact positions. In response to the CBC report, manufacturers stated they were fully compliant.

The Wireless Industry Argues "No Evidence" To Update Testing Protocols

Read what Apple states here -and you can see in example of how the SAR looks different depending on the tissue averaging at this

link https://www.apple.com/legal/rfexposure/iphone5,1/en/

The CTIA, the wireless industry lobby group is opposed to mandatory disclosures about the manufacturer's instructions and also is opposed to updating cell phone radiation testing methods to include body contact positions ***such as were performed by the French government.*** The CTIA argued that "there is no reliable evidence proving that current testing protocols fail to ensure compliance with RF standards, " in their submission to the US Federal Communications Commission concerning the FCC Docket on Human Exposures to Radiofrequency Radiation. The CTIA stated that "a zero-measuring requirement would not accurately mimic real usage or increase safety."

In California, the City of Berkeley was sued by the CTIA, a wireless industry lobby group, when the City passed an ordinance mandating consumers are informed of these manufacturers' instructions by retail stores. The CTIA argued that the "Right To Know Ordinance" violated free speech rights and recently lost their case in court when the judges ruled that the Ordinance was "in the public interest".

After litigation by UC Berkeley public health professor Dr. Joel Moskowitz, the California Department of Public Health (CDPH) released cell phone guidance that the Department scientists had drafted, but withheld from publicly posting for seven years. The guidelines aimed inform the public from possible health impacts from cell phone radiation.

Litigation is moving forward involving more than a dozen people in the U.S. who claim their brain cancer is related to their cell phone use. In Italy, a recent court ruling recognized a link between cellphone use and brain tumors and granted lifetime compensation to a man who developed a brain tumor after 15 years of work related cell phone use.

"Why does the public have to sue to get this information?" Scarato asked. "And what about children in schools? The Maryland State Children's Environmental Health and Protection Advisory Council has recommended that schools reduce radiofrequency radiation exposures to children by installing wired networks rather than Wi-Fi, same as in Cyprus, France and Israel. Yet at the same time, schools are now allowing or even insisting children bring cell phones into classrooms. I am sure most of those children are carrying these phones from class to class in their pockets close to their body. They are not aware of the radiation exposures."

Specific Absorption Rate Testing

Before a cell phone model is permitted to go on the market for sale, its manufacturer performs Specific Absorption Rate (SAR) tests to evaluate the radiation levels. SAR values are expressed in terms of watts per kilogram (W/kg) and are intended to measure the amount of cell phone radiofrequency radiation absorbed by the body when using a wireless device. SAR tests are performed in laboratories by measuring the SAR in a test dummy filled with liquid. The European Union regulations allow a maximum of SAR 2.0 W/kg. The United States and Canada allow a maximum of SAR 1.6 W/kg. Every cell phone is rated with a specific SAR value, and many countries mandate that these SAR values be prominently displayed to consumers on cell phone packaging.

Current wireless device SAR compliance testing regulations allow manufacturers to put a separation distance (usually about 15 mm) between the phone and the test dummy. Cell phone manufacturers are not required to test cell phones for SARs in positions which mimic direct contact between the phone and the body.

ANSES reported the following findings: In 2015, 89 percent of tested cell phones had a SAR greater than the maximum limit value of 2 W/kg and 25 percent had a SAR greater than 4 W/kg.

See below the French government test data. It is in French so you can scroll to the right to see the column called "DAS tronc (au contact)" which refers to the testing done against the body at "contact" position.

This information is found online here and you can download a spreadsheet of the information.

Calls For Continued Policy Action

Since 2010, France law has ensured that SAR levels are placed prominently on cell phone packaging and the sale of cell phones was banned for young children. French legislation in 2015 included several new policies aimed at reducing exposure to radiofrequency radiation. Arazi called on the Health and Environment Ministers and Consumer Affairs and Fraud Prevention Agency to take immediate action on this new information by informing the public and issuing new protective policies.

Link to the French ANFR Website with full details on cell phones/make/model

ANFR Cell Phone SAR Measurements (PDF)

Link to France's National Agency of Health Security of Food, Environment and Labour Report on Radiofrequency and Children (In French)

English Translation of ANSES Report Section on Cell Phone Studies

NEWS REPORTS

Scandal about mobile radiation: Mobile Phones rays more than manufacturer's claim, Forskning.dk, June 7, 2017

Phones: Test bench or bench?, Journal of The Environment , June 7, 2017

Mobile phone: reassuring results that do not reassure everyone, Journal of Internal Medicine, Paris, June 7, 2017

Electromagnetic waves: Do mobile phones meet standards? Science Avenir, Paris France, June 7, 2017

France publishes the results of tests carried out on 379 GSM, Belgium News, June 3, 2017

Mobile phone: after the publication of ANFR data, Dr Marc Arazi points to irregularities, The Daily Health, June 2, 2017

Suspicions about Mobile Phones Le Monde , December 23, 2016

Phonegate: A first victory with the publication by the ANFR of the SAR, Press Release by French physician Marc Arazi, June 1, 2017

I apologize for the delay.

Your Follow up Questions To The FDA in blue

FDA answers to follow up questions are in red
I asked:Will the FDA be updating it's website to include the NTP study results on radiofrequency radiation?
The FDA answered:Our conclusion that current radiofrequency (RF) exposure limits adequately protect the public health has not changed based on the draft National Toxicology Program (NTP) report about a portion of NTP's study. We do not anticipate a website update on the NTP study before NTP publishes a final report regarding the complete study.
My Follow Up Question 1. : The results on the brain and heart cancers are final. They are not a draft In addition the research showing a genotoxic effect are now being added to the report. Even if all the other findings show "no effect" this is a significant finding. Why is the FDA waiting when children and pregnant women are actively exposing themselves to this radiation unaware that they could be racking up hours of exposure.

FDA answer to Follow-up Question 1: The results of the NTP study have not been published as a final document for the partial experiment discussed publically by the NTP nor have they been peer reviewed in the literature. Likewise, the genotoxicity experiments have also not been released publicly nor have they been peer reviewed. The data that has been released by the NTP is only a small subset of a much larger study. While the results add to the body of data on this topic they are not evidence that there is any risk of adverse health effects when exposures are at or below current exposure limits. When we have evidence of a public health hazard or significant risk, FDA has not hesitated to issue and disseminate appropriate safety notices. Our conclusion remains that the existing radiofrequency (RF) exposure limits adequately protects all members of the public including children and pregnant women.

My Follow Up Question 2. Please explain how the FDA arrived at that conclusion?
FDA Answer to Follow-up Question 2: While the experiments are interesting and well performed, the results are not clear and conclusive when compared to whole body or partial body RF exposures that comply with the existing safety limits. The lowest whole body RF exposures tested in the NTP experiment are much higher than the allowable whole body exposure limit. There are differences between the experimental controls and the historical controls that further limit the conclusions reached. Our conclusion that the current RF exposure limits adequately protect the public health is not altered by the available information related to the NTP study.
Why is the FDA not considering the evidence showing fertility damage from wireless and cellphones? Specifically the research on impacts on sperm DNA at non thermal levels, impacts on the ovaries and the fact that the NTP study found the exposed group had offspring with lower birth weight. See research study found here in the drop down:http://ehtrust.org/science/research-on-wireless-health-effects/
We have looked at the papers you identified. Those studies suffer from many confounding factors that significantly limit or eliminate their impact. There is insufficient evidence available to establish adverse health effects, including when these studies are taken into account.
My Follow Up Question 3. So you are stating that all these studies are insufficient. On what grounds?
FDA Answer to Follow-up Question 3 part 1: Peer-reviewed papers are evaluated for any adverse effects reported to be caused by RF exposure. The relative strength of those papers' conclusions must be considered. Examples of factors that may weaken the utility of a paper include: the study design, study protocol violations, RF exposure sources, the dosimetric methods, SAR determination, thermometry, reproducibility of RF emissions, reproducibility of all environmental factors (temperature,

air flow, vibration, etc.), differences with historical controls and recall bias. Based on the individual papers and analysis by expert review panels we conclude that the current RF exposure limits adequately protect the public health. This includes reproductive health.

What do you think of this study please in particular as the majority of studies showed an effect.

Houston B., et al. "The effects of radiofrequency electromagnetic radiation on sperm function." Reproduction, 2016.

- Among a total of 27 studies investigating the effects of RF-EMR on the male reproductive system, negative consequences of exposure were reported in 21. Within these 21 studies, 11 of the 15 that investigated sperm motility reported significant declines, 7 of 7 that measured the production of reactive oxygen species documented elevated levels and 4 of 5 studies that probed for DNA damage highlighted increased damage, due to RF-EMR exposure. Associated with this, RF-EMR treatment reduced antioxidant levels in 6 of 6 studies that studied this phenomenon, while consequences of RF-EMR were successfully ameliorated with the supplementation of antioxidants in all 3 studies that carried out these experiments.

FDA Answer to Follow-up Question 3 part 2 – re: Houston et al: Thank you for directing us to the Houston et al. "The effects of radiofrequency electromagnetic radiation on sperm function" review paper. We find this scientific opinion of this review paper to be interesting and the tabulation of the available data from the cited references useful. The paper does not extensively cover the confounding factors present in the papers reviewed. This appears to be because it is a review article that's purpose is the development of a possible mechanism of action. The authors stated that, "we explored the documented impact of RF-EMR on the male reproductive system and considered any common observations that could provide insights on a potential mechanism". The authors also acknowledge that research to date is not conclusive. In their conclusion, they say, "to date, contradictory studies surrounding the impact of RF-EMR on biological systems maintain controversy over this subject". The review's authors' proposed two-step mechanism of action and their call for further laboratory research are interesting. While the opinion of the authors contributes to the body of knowledge on this topic it alone does not change the current understanding of mechanism of RF action nor does it prove there is an adverse effect of RF exposure that complies with the limits on male reproduction. The current RF exposure limit adequately protects the public health.

Additionally, a recent paper by Lewis adds some epidemiological evidence that there is no adverse effect from RF exposures from cell phones. Please see, Lewis, R. C., et al. (2017). "Self-reported mobile phone use and semen parameters among men from a fertility clinic." Reprod Toxicol 67: 42-47. Lewis et al concluded, "The present study found that within the range of self-reported mobile phone use there was no evidence for a relationship with semen quality."

What are the confounding factors on this study please.

Avendaño C, Mata A, Sanchez Sarmiento CA, Doncel GF.(2012). Use of laptop computers connected to internet through Wi-Fi decreases human sperm motility and increases sperm DNA fragmentation.Fertility Sterility. 97(1), 39-45.

FDA Answer to Follow-up question 3 part 3: The paper Avendano et al. examines the impact of radiofrequency radiation from an internet-connected laptop on human sperm in vitro. The authors test an interesting hypothesis with inventive methods. The experiment suffers from a lack of radiofrequency field homogeneity, inadequate information regarding occurrence of temperature change, ambiguity regarding if the control was handled the same as the exposed samples, and some

of the semen samples were teratozoospermic which may have impacted the conclusions. The use of a reproducible source of RF exposure is essential to assure that reproduction of an experiment is possible. Cell phones, Wi-Fi routers, and laptops are not reproducible sources of RF exposure thus should not be used for experimentation.

This conclusion is consistent with recent expert reports on radiofrequency. For example, Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) in 2015 concluded, "The previous SCENIHR Opinion concluded that there were no adverse effects on reproduction and development from RF fields at non-thermal exposure levels. The inclusion of more recent human and animal data does not change that assessment. Therefore, it is concluded that there is a strong overall weight of evidence against an effect of low-level RF fields on reproduction or development."[2]

My Follow Up Question 4. Is the FDA's stance to consider the SCENIHR opinion as the FDA's opinion?

FDA answer to Follow-Up Question 4: No, the SCENIHR expert working group is composed of expert scientists that have reviewed, reported on, and collated a large amount of information on RF radiation and FDA values their contribution. However, the FDA comes to its own conclusions.

My Follow Up Question 5. What review has the FDA done on fertility research. Please document and share this analysis.

Regarding your particular concern related to body weight, the NTP's draft report states, "Throughout the remainder of the chronic study, no RFR exposure-related effects on body weights were observed in male and female rats exposed to RFR, regardless of modulation.[3]"

FDA Answer to Follow-Up Question 5: We follow the potential radiofrequency bioeffects literature. We are not actively engaged in laboratory or clinical fertility research. However, there may be other parts of the FDA that does research fertility.

My Follow Up Question 6. Please see on Page 8 the following:

- RESULTS
- In pregnant rats exposed to 900 MHz GSM- or CDMA-modulated RFR, no exposure-related effects were observed on the percent of dams littering, litter size, or sex distribution of pups.Small, exposure-level-dependent reductions (up to 7%) in body weights compared to controls were observed throughout gestation and lactation in dams exposed to GSM- or CDMA-modulated RFR. In the offspring, litter weights tended to be lower (up to 9%) in GSM and CDMA RFR-exposed groups compared to controls. Early in the lactation phase, body weights of male and female pups were lower in the GSM-modulated (8%) and CDMA-modulated (15%) RFR groups at 6 W/kg compared to controls. These weight differences in the offspring for both GSM and CDMA exposures tended to lessen (6% and 10%, respectively) as lactation progressed. Throughout the remainder of the chronic study, no RFR exposure-related effects on body weights were observed in male and female rats exposed to RFR, regardless of modulation n in all groups of male rats exposed to GSM-modulated RFR

The quote you sent me is not adequate to address the concern I raised. As you can see from this paragraph, the weights were lower (see my yellow highlighted areas above) after prenatal exposure. You sent me details that pertain to the animals later in the study. (My daughter was a low birth weight when she was born and has caught up now.) The fact is that an effect of lower birth weight was found at non thermal levels. This indicates an important non thermal effect. (Smoking caused babies to be smaller as well and the industry stated this was good for mothers and doctors recommended that women smoke if they were gaining to much weight during pregnancy.) Please explain why the FDA is

not considering this effect and investigating the issue. Clearly non- thermal effects are evident from this study. Please explain the FDA's analysis on the issue of these lower body weights.

FDA Answer to Follow-up question 6: FDA is sorry that our quote was not adequate to address your concern. However, our quote is still accurate. The observation of a birth weight difference between exposed and control-animals is an important observation. The excerpted discussion above does say that pregnant rats gave birth to normal litters, pup were smaller early in lactation and lessened as lactation proceeded and no differences were noted in weight during the remainder of the chronic study. The very next paragraph discussed in the study said that control male rat survival was lower than RF exposed rat survival. This survival advantage for RF exposed male rats also may suggest that the lower birth weight at birth was not significant in the exposed group. We do not believe that this is a non-thermal effect of radiofrequency exposure. The study also said that thermal regulation was more difficult in pregnant or geriatric rats. It is possible that temperature elevation and thermal regulation was still an issue in these whole body irradiation experiments.

3.

Is it still the FDA's position that the weight of evidence does not show health effects? If so, please provide the documentation that supports this position by the FDA in light of the NTP results. In a prior email dated February 5, 2016 Email RE-Question about the FDA and radiofrequency radiation this is what you told me. Please provide the scientific research that shows safety.

The FDA's position has not changed. Based on the available scientific evidence, including published literature and published expert reports, the Agency has concluded that the current RF exposure limits provide adequate protection for use of RF consumer communication electronic products like cell phones.

My Follow Up Question 7. Please send me the "the available scientific evidence, including published literature and published expert reports" the FDA specifically looked at to state that "the Agency has concluded that the current RF exposure limits"

FDA Answer to Follow-up question 7: Copyright infringement is a problem with this request. What you are asking for is already on line at the WHO website, SCENIHR website, in the bibliographies of the documents noted in our original response and through PubMed literature searches.

Many expert reports have been released that discuss the strengths and weaknesses of the published literature. There have also been formal analyses and reviews of published expert reports.

You cite two reviews but is this how the FDA investigates ? by citing two reviews well cited by industry funded scientists? It is notable that this review "International and national expert group evaluations: biological/health effects of radiofrequency fields." not only cites industry linked reports but the authors state: "We thank Chung-Kwang Chou (chairman, SC-95 of the international committee on electromagnetic safety, Institute of Electrical and Electronic Engineers) for critical reading of the manuscript and helpful suggestions." CKChou is former Chief Motorola Scientist.

My Follow Up Question 8. Are these reviews that you refer to from organization that the FDA then is taking on as it's own opinion? How does the FDA determine that these reviews are scientifically sound and unduly influenced by industry?

FDA Answer to Follow-up Question 8: The FDA has been following RF exposure potential bioeffects since at least the early 1990s. We have met with and listened to numerous organizations on the topic, including your organization. The FDA reviews all published papers and reviews that are brought to our attention or that we identify through literature searches. Our answers were meant to guide you to

scientific reviews that cover a large amount of literature in a systematic fashion. The expert review groups that have reviewed the RF literature have guidance policies and procedures in place to prevent undue influence from outside. FDA knows that Chung-Kwang Chou is an internationally recognized expert on RF radiation and we know that we also know that he worked for industry. The weight of the evidence from the literature and expert opinions are what lead us to believe that the current exposure limits adequately protect the general public.

We note that Vershaeve 2012 specifically evaluated expert reports to assess bias. Verschaeve says,

"Evaluation of expert group reports based on 10 criteria

An evaluation of the different reports should take into account a great number of aspects. Amongst them the composition of the working group, the topics that were taken into account and the methods that were used are certainly some of the important aspects. We therefore tried to identify the members or participants in the working group activities and tried to see whether they constituted a multidisciplinary and independent group of experts. Did they evaluate all scientific (peer reviewed) publications, or did they make a selection of papers, and if so, what was the rationale for doing so? Was this satisfactory? Was the report a consensus report? Where minority opinions mentioned?" Similarly, Vijayalaxmi and Scarfi 2014 included comments on negative and positive aspects of the expert groups and their reports.

4. Does the FDA consider oxidative stress a health effect? I sent you a review article last year about this and it seems important to share with the American people (http://nebula.wsimg.com/107f00a88ae36803a132e3ca6c222157?AccessKeyId=045114F8E0676B9465FB&disposition=0&alloworigin=1)

Thank you for the review article on oxidative stress. We have reviewed it, and it contains opinions that have added to our understanding of the topic.

In the World Health Organization (WHO) International Agency for Research on Cancer (IARC) monograph 102 (2013), the IARC expert working group concluded that there was only weak evidence that adverse health effects could be caused by RF due to oxidative stress. We do not believe that the available scientific evidence shows a link between the magnitude of oxidative stress attributable to RF exposures from cell phones (or similar electronic products) and adverse health effects.

My Follow Up Question 9. How do you substantiate such a statement ?

"We do not believe that the available scientific evidence shows a link between the magnitude of oxidative stress attributable to RF exposures from cell phones (or similar electronic products) and adverse health effects."

FDA Answer to Follow-up Question 9: From the totality of the scientific literature available and expert opinions.

My Follow Up Question 10. Does the FDA think that oxidative stress can impact health.

the research study here states that constant oxidative stress over tome can lead to health problems. Please review and explain why this has not impacted the view of the FDA.

FDA Answer to Follow-up question 10: Oxidation is a normal component of metabolism and cells have redundant systems to deal with the consequences of oxidative stress. We are aware that approximately 70% of the damage done by ionizing radiation is due to oxidative stress. We follow the RF literature on potential mechanisms of action. Our opinion at this time is that the totality of the scientific literature does not support that hazardous levels of oxidative stress can be induced by radiofrequency radiation exposure that does not also cause hazardous temperature elevation.

5.

If the FDA is supposed to protect the public then they need to inform the public of the fine print instructions the manual related to RF. Why is the FDA not acting on this and informing people of the fine print instructions on RF on cell phones and wireless devices? Children are carrying phones on

their bodies, tucked in spandex pants and in bras and jeans in school classrooms. Can you please explain why the FDA is not ensuring the public is aware of the fine print warnings?

There is a large safety factor included in the public exposure limit (see IEEE Std. C95.1-2005 Annex C, Rationale, for more information regarding this safety factor).

My Follow Up Question 11. What does the FDA think the safety factor is for SAR exposure limits. Please state it.

FDA Answer to Follow-Up Question 11: Wireless communication devices are required to meet radiofrequency (RF) energy exposure guidelines set forth by the Federal Communication Commission (FCC). These guidelines were last revised on August 1st, 1996 when the FCC adopted local body RF energy specific absorption rate (SAR) limits for devices operating within close proximity to the body as recommended by ANSI/IEEE C95.1-1992 guideline. The ANSI/IEEE C95.1 guidelines are based on protection from thermal effects of whole body RF energy exposure. RF exposure in the 1– 4W/kg SAR range was shown to induce behavioral changes in several animal species, including non-human primates. The observed behavioral change was accompanied by an increase in core temperature of ~1°C. ANSI/IEEE C95.1-1992 guideline derives the local body exposure limit in two steps. First the threshold for behavioral responses was set at 4W/kg SAR, and then a safety factor of 10 was put in place for exposure under controlled environmental conditions (occupational exposure). An additional safety factor of 5 was put in place for the general public exposure setting the whole body exposure limit at 0.08 W/kg. Thus the public whole body exposure limit is approximately 50 times lower than the threshold for heat related adverse health effects. Based on the general public whole body exposure limit a spatial peak limit on 1.6 W/kg averaged over one gram of tissue was set for local body exposure. Before adopting the ANSI/IEEE C95.1-1992 limits the FCC consulted with the Food and Drug Administration (FDA) and other health agencies.

We note that Federal Communications Commission (FCC) guidance on general RF exposure procedures and equipment authorization policies for mobile and portable devices explains that for devices designed to operate in contact with the body, the specific absorption rate (SAR) compliance tests should be conducted a separation distance of 5 mm or less (FCC KDB 447498 D01 section 4.2.2).

My Follow Up Question 12. Why does the FDA not share this information with the public? Why are these separation distances not stated on the FDA website so that te American people are aware of it. I have a teenage daughter and her friends do the following: They place the cell phone in their spandex pants against their skin. They lay the phone on their lap as they watch music videos or stream and facetime. They also sleep with the phone next to their head. They easily can roll over and sleep on the cell phone. Women carry cell phones in their bra all the time. The public is unaware. Again- Why does the FDA not share this information with the public on their website? So far it is a secret.

FDA Answer to Follow-up question 12: As you yourself noted, the FCC shares this information with the public. The FDA website on Cell Phones (https://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/homebusinessandentertainment/cellphones/default.htm) has links to the FCC.

Additionally, that FCC guidance explains that mobile and portable devices designed to be used with a body-worn accessory must be tested for body-worn accessory SAR compliance. According to the guidance, a conservative minimum test separation distance should be used for such testing, at worst case using no more than a 25 mm separation distance. The same FCC guidance states that operating manuals must include specific information to allow users to select body-worn accessories that meet

the compliance test separation distance requirements, and all supported body-worn accessory operating configurations must be clearly disclosed to users, through conspicuous instructions in the user guide and user manual, to ensure unsupported operations are avoided.

My Follow Up Question 13. Everyone I have spoken to to is 100% unaware of this information buried in manuals. Please explain how the FDA has decided it is not their responsibility to inform the public on this. Has the FDA done a survey?

FDA Answer to Follow-up Question 13: The FDA website on Cell Phones (https://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/homebusinessandentertainment/cellphones/default.htm) has links to the FCC. As any web search for "usability of user manuals" will reveal, there is a lot of concern and research on why most consumers ignore manuals and instructions. So it is not surprising that consumers are unaware of one particular fact in a manual when most consumers don't read anything in user manuals. The FDA has not done a survey and we are not aware if the FCC has. Additionally, cell phone RF exposure compliance testing must be determined at the maximum average power level.

My Follow Up Question 14. Well actually you will use your cell phone at maximum power under several conditions such as if you are far from a tower with lower bars- or in an elevator, in a moving car far from a tower and video streaming- as you are aware. So it is possible. Is the FDA saying that although it is possible to be at maximum power, it is not necessary for the public to be aware because it does not happen often? There are many moments when people use phones in maximum power conditions- especially when they have a lot of applications on at once far from a base station. Please explain why the FDA is rationalizing not telling people about this.

FDA Answer to Follow-up Question 14: As you state, these are moments when a cell phone needs to operate at maximum power. Cell phones will always attempt to operate at the minimum power necessary in order to prolong battery life. Over the course of a day the average exposure is considerably lower. You mention using a cell phone in a moving car far from a tower; because of factors unrelated to RF exposure this is indeed a dangerous situation. The safety factors set in place for RF exposure adequately protect the general public.

However, the National Safety Council estimates cell phone use to be involved in 26 percent of all motor vehicle crashes – 5 percent of crashes involve texting, while 21 percent involve drivers talking on handheld or hands-free cell phones. (http://www.nsc.org/NewsDocuments/2014-Press-Release-Archive/3-25-2014-Injury-Facts-release.pdf) Clearly the greatest risk to public safety posed by cell phones is the risk of death or injury resulting from vehicular accidents due to distracted driving.

In order to conserve battery life, cell phones seldom actually operate at maximum power, which reduces the SAR proportionately.

My Follow Up Question 15. Can you tell me what data you have on how "cell phones seldom actually operate at maximum power" How often do they opeate at maximum power.

FDA Answer to Follow-Up Question 15: There has been considerable research on cell phone power consumption related to energy management and battery life. Actually transmitted RF power can be a minor part of the power consumption in smartphones which use a lot of power for the processor and display. Unfortunately these research efforts consider total transmit power over one battery charge and do not look at a typical time history of transmission power. Actual transmit power will be dependent on many factors unique to individuals, such as: where they live and work in relation to cell phone towers and usage patterns.

There is some relevant information in IARC Monograph 102 at the bottom of page 76 and top of page 77. There are also papers regarding exposure assessments that attempt to quantify dose for use in epidemiology assessments.

6.

I understand that the RFIAWG was given a presentation of these findings. What is the FDA perspective on the findings now that you have reviewed them please? Please detail the next steps for the FDA with a timeline.

The U.S. Radiofrequency Interagency Working Group (RFIAWG) has not had a presentation on findings from the NTP study.

My Follow Up Question 16. Why hasn't the U.S. Radiofrequency Interagency Working Group (RFIAWG) had a presentation on these findings? I thought the Groups role was to provide some sort of oversight? Why are they not given a full presentation?

FDA Answer to Follow-up Question 16: The RFIAWG allows staff to discuss RF research and any concerns. It does not have a management or oversight role. The remainder of this question has already been answered. No further information is available.

My Follow Up Question 17. Has the FDA been given a presentation on the NTP findings of increased brain cancer, increased heart nerve sheath tumors and genotoxicity?

FDA Answer to Follow-up Question 17: The FDA has been briefed on the partial findings of the NTP study.

FDA's conclusion that current RF exposure limits adequately protect the public health has not changed based on the information in the draft NTP report about a portion of NTP's study.

My Follow Up Question 18. How did you determine that conclusion? What is the rationale for FDA's conclusions?

FDA Answer to Follow-up Question 18: From the totality of the scientific literature available and expert opinions.

When NTP completes its analysis and a full report is available, we will review it and consider what, if any, effect it has on the agency's thinking regarding risks associated with RF exposure from cell phones.

My Follow Up Question 19. Can you please explain the review process for the FDA and the transparency that will be involved in the review.

FDA Answer to Question 19: The NTP has briefed FDA on the partial result already. We believe that the NTP will also brief FDA on the completed total study when it is complete. FDA will review the entire study and decide if the results impact our understanding of its impact on RF safety.

Who is the point person at the FDA for this issue and what are they doing in regards to this issue. What questions are being asked and of whom? What other FDA staff are involved in the process. Are any consultants working with the FDA? Who are they?

The Center for Devices and Radiological Health (CDRH) is the FDA center that regulates electronic products under the Electronic Product Radiation Control (EPRC) provisions of the Federal Food, Drug, and Cosmetic Act. Note: EPRC may also be referred to as "Radiological Health." Questions or concerns can be sent to the FDA document mail center:

U.S. Food & Drug Administration
Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health
10903 New Hampshire Avenue

WO66-5521
Silver Spring, MD 20993-0002
Marking the documents, “Attn: Division of Radiological Health” can help expedite routing to the Division of Radiological Health for review and appropriate follow-up. The staff in other divisions and offices who have the required expertise to answer specific questions are called upon for assistance when a need occurs. If necessary, we could call on expertise from other government (international, national, state, etc.) agencies, concerned consumer groups, or industry.
My Follow Up Question 20. You did not answer my questions so here they are again.
Who is the point person at the FDA for this issue and what are they doing in regards to this issue?
What questions are being asked and of whom?
What other FDA staff are involved in the process.
Are any consultants working with the FDA? If so- Who are they?
FDA Answer to Question 20: These questions have been asked and answered.
8. The NTP study found DNA damage in the brain; please detail the FDA response to these findings and the next steps in terms of protecting the people.
We assume your question is referring to the draft supplemental NTP document that covers experiments looking for DNA damage. Our conclusion that current RF exposure limits adequately protect the public health has not changed based on our review of the draft NTP supplemental papers.

The NTP comet assay, indicated DNA damage (see the table).
My Follow Up Question 21. Please explain how this DNA damage found in the comet assay - not change the FDA opinion?
FDA Answer to Follow-up Question 21: The table you included is a variant of the table the NTP used in its briefings and is a summary of all of the Comet assay data. FDA does not agree with this summary table and how it reflects the data. Unfortunately, this paper has not been published and FDA is not at liberty to discuss the data further.
My Follow Up Question 22. What would change the FDA opinion? How much evidence is necessary?
FDA Answer to Follow-up Question 22: FDA believes that the current exposure standard is adequate to protect public health. In order to change that belief we would need to see well controlled studies that have reproducible results, we would also consider opinions from other expert organizations and the rational for or against changes by standard setting organizations that collectively say that the current exposure standards need to change to protect people.
9. Is the FDA preparing a response to inform the FCC of the official recommendations to the issue of cell phones and wireless? Please give specifics on the timelines.
As a general policy, the FDA does not comment on pending matters that are under review. If FDA had concerns regarding the current RF exposure limits, the agency would communicate those concerns to FCC.
My Follow Up Question 23. I thought that a transparent process was underway and that all comments would be available. The FCC states they are looking to their federal partners for guidance as they are not a health and safety agency. If the FDA does not give any comments then I wonder who will. Will the FDA be commenting at all to the FCC in their Proceeding Number 13-84? Have they ever commented?
FDA Answer to Follow-up Question 23: Question was asked and answered.
10.

The FDA has received reports of people who develop headaches, nerve damage and rashes from cell phone and wireless use. What is being done by the FDA to monitor these side effects?
The FDA has received anecdotal reports from individuals that attribute their symptoms to RF exposure from cordless phones and cell phones. The anecdotal reports are reviewed to determine if they contain new information indicating that RF radiation from an electronic product caused the adverse health effects described. No such evidence has been revealed through our review of those reports. We also monitor literature regarding experiments intended to prove or disprove a causal link between RF exposure and adverse health effects as well as literature regarding the most effective treatments for individuals suffering from these symptoms.
Where can these reports be accessed online?
Currently, these reports cannot be publicly accessed online.
My Follow Up Question 24. Why not, Can you please make them available.
FDA Answer to Follow-up Question 24: These records can contain patient specific medical information that we cannot make public. Redacted copies are probably available via Freedom of Information requests.
My Follow Up Question 25. Are you keeping track? Can you please make publicly available the amount of complaints that you have received
FDA Answer to Follow-up Question 25: The FDA does keep track. We can look into making the amount of complaints publically available.
What is the timeline for response to these concerns and reports?
The agency reviews these reports within one month. We only contact the responder if further information or clarification appears to be needed.
My Follow Up Question 26. Then what do you do with the information?
What is the procedure for reporting and what reports are the FDA generating on the issue?
To report a problem that appears to be related to electronic product radiation, please see our website at: https://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ ReportaProblem/default.htm. FDA has not generated a report on reports it has received from individuals attributing their symptoms to RF exposure from consumer communications products.
FDA Answer to Follow-Up Question 26: An accidental radiation occurrence means a single event or series of events that has/have resulted in injurious or potentially injurious exposure of any person to electronic product radiation as a result of the manufacturing, testing, or use of an electronic product. The reports are required from manufacturers if the regulatory definition and criteria for requiring a report are met. Reports can come from consumers or occupational product user. The FDA reviews the reports to determine if the information indicates a defect could be present in a specific product or generally in a product type. To complete that evaluation we occasionally find we need to request more information from the manufacturer, report submitter or other relevant source.is necessary. For this product area the literature indicates that RF exposure is not a plausible cause of the problem described.
My Follow Up Question 27. Can you please generate an annual report on this. It seems important.
FDA Answer to Question 27: The FDA has not generated annual reports on cell phone complaints.
11. Will the FDA be recommending that the NTP now do a systematic review of radiofrequency considering the research results? If so when? If not, please explain why not-considering the widespread proliferation of cell phones. Please see where the FDA can nominate this issue for systematic review here – The NTP Office of Health Assessment and Translation (OHAT) develops

literature-based evaluations to reach conclusions about potential human health hazards and to examine the state of the science. https://ntp.niehs.nih.gov/pubhealth/hat/noms/index-2.html.

We have not asked NTP to perform a systematic review for several reasons, including the fact that there are already numerous high quality expert reports, formal reviews, and meta-analyses related to the safety of use of RF consumer communication products.

My Follow Up Question 28. Please list those you are referring to. As far as I know, there are no systematic reviews that have been done and the US has not looked at this for over 20 years.

FDA Answer to Follow-Up Question 28: The IEEE International Committee on Electromagnetic Safety has posted a list of statements from governments and expert panels concerning research and conclusions about the possibility of health effects and safe exposure levels of radiofrequency energy. Many of these organizations have further analysis at their own web sites. Many of these organizations go into great detail on their analysis and have extensive bibliographies. The link to the IEEE website is attached. http://www.ices-emfsafety.org/expert-reviews/

In addition, the WHO EMF Project is currently updating the relevant Environmental Health Criteria.

My Follow Up Question 29: The WHO EMF Project was started with industry funded and is lead by an engineer and the group members are also connected to ICNIRP. It is not the same as the IARC. Is the FDA going to go with the results of the WHO EMF Project Environmental Health Criteria rather than do an independent review?

FDA Answer to Follow-up Question 29: FDA has answered this concern above. We have worked closely with the US National Academy of Science and we follow the work of expert review groups like IARC, the WHO EMF project, ICNIRP and SCENIHR. All of these expert review organizations have vetting processes for their expert scientific review panels. In addition, our scientists have been following the RF science at national and international meetings as well as via Pubmed since at least the early 1990s.

Thank you for the link. FDA has no plan to nominate this issue for systematic review at the NTP Office of Health Assessment and Translation at this time.

My Follow Up Question 30: Why not? . Please I would think a systematic review is in order considering the exposure to babies and children for a lifetime.

FDA Answer to Follow-up Question 30: There is no need for NTP to do this work for the FDA. This can be done by the FDA if necessary. Also, there are already many systematic reviews available.

Additional Questions:

My Follow Up Question 31.

Children are handed wireless laptops in classrooms across the USA. Please explain why the FDA is not informing the parents that many laptops have minimum separation distance of 20cm or 8 inches that the device should be from the body to ensure FCC compliance. The FDA should be informing the public about this distance. Why aren't they.

See this http://news.arubanetworks.com/press-release/prince-georges-county-public-schools-creates-one-nations-largest-k-12-wi-fi-deployment

FDA Answer to Follow-up Question 31: The antenna in laptop computers is usually located along the top edge of monitor of the laptop. Opening the laptop to use it puts the antenna approximately 8-10 inches away from the viewer. Our current conclusion remains that the existing radiofrequency (RF) exposure limits adequately protects all members of the public including children and pregnant women.

My Follow Up Question 32.

What proof of safety is there that pregnant women are protected when it comes to this radiation. They are placing laptops on their bellies. Has the FDA looked at research on impacts on pregnancy? If so, please share what studies have been reviewed.
FDA Answer to Follow-Up Question 32: The FDA has been reviewing RF published reports since the early 1990's. FDA has meetings with interested organizations and working with the National Academy of Sciences, and conducted PubMed literature searches over this time period. In addition, the FDA has followed the work of expert review groups like SCENIHR, ICNIRP and the WHO on this topic. For the most up to date review of this specific topic a PubMed search will provide an excellent background. A review of the SCENIHR document entitled "Potential Health Effects of Exposure to Electromagnetic Fields (EMF) section 3.6.4.1 Reproductive Effects is also a good place to start a review.
My Follow Up Question 33.
Send me documentation that children adequately covered by the current US guidelines. Children absorb the radiation deeper into their brain and body. Please explain why the FDA states "The scientific evidence does not show a danger to any users of cell phones from RF exposure, including children and teenagers."
Why does the FDA clarify that long term effects are still being researched and children are more vulnerable to this radiation? They will have more impacts as they will have a lifetime of exposure. Why doesn't the FDA state this clearly for parents?

FDA Answer to Follow-Up Question 33: Our current conclusion remains that the existing radiofrequency (RF) exposure limits adequately protects all members of the public including children and pregnant women. The FDA has been reviewing RF published reports since the early 1990's. FDA has meetings with interested organizations and working with the National Academy of Sciences, and conducted PubMed literature searches over this time period. In addition, the FDA has followed the work of expert review groups like SCENIHR, ICNIRP and the WHO on this topic. For the most up to date review of this specific topic a PubMed search will provide an excellent background. A review of the SCENIHR document entitled "Potential Health Effects of Exposure to Electromagnetic Fields (EMF) is also a good place to get a compilation of published reports.

My Follow Up Question 34.
The FDA has outdated information (highlighting Interphone 2010 results) on a webpage under the cellphones section entitled Cell Phones Health Issues. which states "No Evidence Linking Cell Phone Use to Risk of Brain Tumors."
https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm212273.htm
FDA Senior staff have been asked to update these webpages 4 times over the last two years and have not done so. Please explain why this outdated material is being left on the FDA website.

FDA Answer to Follow-up Question 34: Thank you for your review of the FDA website on this topic. Your concern regarding the information is noted. The information is still useful.

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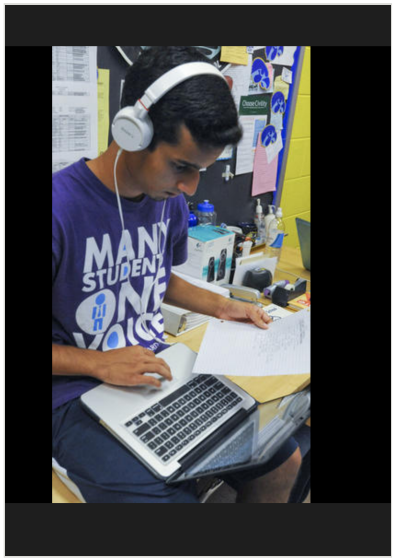
3Attached Images



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Microwave Emissions From Cell Phones Exceed Safety Limits in Europe and the US When Touching the Body

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ABSTRACT In our publications, we have shown both from measurements and computer modeling that the specific absorption rate (SAR) reduces by 10%–15% for every millimeter separation of the cell phone on account of rapidly diminishing EM fields in the near-field region of the cell phone antenna. This rapid reduction of SAR depending on the antenna and its location on the handset has been shown, both computationally and experimentally, regardless of the phantom model such as a flat phantom suggested for SAR compliance testing of devices in contact with the body, for a sphere phantom, and for head-shaped models used for SAR compliance testing of cell phones. Unfortunately, our observations in the past were based on SARs of only three cell phones. Expecting that the SARs for cell phones may exceed the safety limits for body contact, cell phone manufacturers have started to recommend that the devices can be used at 5–25 mm from the body even though it is difficult to see how to maintain this distance correctly under mobile conditions. The National Agency ANFR of France recently released the cell phone SAR test data for 450 cell phones that measure 10-g SARs reducing by 10%–30% for each millimeter distal placement from the planar body phantom. Their data corroborate our findings that most cell phones will exceed the safety guidelines when held against the body by factors of 1.6–3.7 times for the European/ICNIRP standard or by factors as high as 11 if 1-g SAR values were to be measured as required by the U.S. FCC.

INDEX TERMS XXXXX.

I. INTRODUCTION

Safety guidelines for radiofrequency (RF) microwave radiation have been proposed by the expert committees in the United States (Institute of Electrical and Electronics Engineers, IEEE) and by the International Committee for non-ionizing radiation protection (ICNIRP) of World Health Organization (WHO) [1], [2] as well as expert committees in Canada, Japan, Australia, etc. While the guidelines suggested by IEEE are followed by the U.S. Federal Communications Commission [FCC] in Washington, DC, the ICNIRP Standard is followed in Europe and many other countries in the world.

The IEEE safety guidelines followed by the FCC prescribe that the microwave emissions of a personal wireless device be limited to ensure that the mass-normalized power absorbed in any part of the body except limbs (specific absorption rate or SAR) does not exceed 1.6 W/kg for any 1 g of tissue in the shape of a cube [3]. The ICNIRP guideline is more lax and prescribes that the microwave radiation for such wireless devices not create an SAR in any part of the body of more than 2.0 W/kg for any 10 g of tissue. In published literature it has been reported that because of a larger volume for 10 g of tissue the ICNIRP standard will permit radiated powers of cell phones to be 2.5 to 3 times higher than those allowed by the IEEE/FCC standard [4]. The regulatory agency FCC requires that the personal wireless devices marketed in the U.S. meet the IEEE C95.1-1992 standard, thereby requiring lower radiated powers so as not to exceed SAR of 1.6 W/kg in any 1 g of tissue in the shape of a cube for all parts of the body except the limbs (''extremities'' such as hands, pinna, or the legs).

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II. RECENTLY SUGGESTED CHANGES BY INDUSTRY

Whereas the cell phones are often used held against the ear canal or against the body in shirt or pant pockets and are therefore very close to the body, the cell phone manufacturers

TABLE 1. SARs in W/kg measured for some representative telephones held against the flat phantom model of the body at manufacturer-suggested distances D and at distances of 5 and 0 mm as for actual use by consumers (taken from ANFR Test Report [10]).

Make	MODEL	SAR at Mfr. Suggested Distance D	SAR (5mm)	SAR (0mm)	Percent increase in SAR for	
					From D to 0mm	From 5 to 0mm
POLAROID	PRO 881A	1.05 (15 mm)	3.63	7.42	13.90%	15.40%
HTC	ONE SV	0.366 (15 mm)	2.256	7.183	22.00%	26.10%
BLACKBERRY	Z 10	0.934 (15 mm)	3.18	6.8	14.20%	16.40%
MOTOROLA	MOTOLUXE	0.254 (25 mm)	2.96	5.86	13.40%	14.60%
ORANGE	NEVA 80 (ZTE BLADE V770)	1.39 (15 mm)	3.62	5.79	10.00%	9.90%
HUAWEI	P9 (EVA-L09)	1.32 (15 mm)	3.18	5.6	10.10%	12.00%
MOTOROLA	RAZR I	0.507 (25mm)	2.27	5.51	10.00%	19.30%
SONY	XPERIA S CITIZY LT26i	0.748 (15 mm)	2.253	5.45	14.20%	19.30%
APPLE	iPHONE 5	0.825 (10 mm)	1.453	5.321	20.50%	29.60%
SAMSUNG	GALAXY S 5 SM-G900 F	0.545 (15 mm)	1.55	3.55	13.30%	18.00%
ECHO	NOTE	1.35 (5 mm)	1.35	4.15	25.20%	25.20%
APPLE	iPHONE 5C	1.11 (5 mm)	1.11	3.11	22.90%	22.95%
SAMSUNG	GALAXY J7 (SM-J710FN)	1.29 (5 mm)	1.29	3.56	22.50%	22.50%

in the last 5-10 years have started to recommend that they be held 5, 10, or 15 up to 25 millimeters from the body. We assume this additional spacing between the cell phone and the body was recommended because of our past publications that these wireless devices will not pass the safety standards when held against the body on account of the very rapidly diminishing EM fields close to radiating antennas [4]–[7], [10]. In spite of the manufacturer recommendations, we find it hard to believe that one can carry out a conversation when the telephone is held up to 25 millimeters away from the ear canal particularly in crowded noisy environments or that these recommended distances can be maintained consistently under mobile conditions without use of a spacer to maintain the suggested distances of 5 to 25 millimeters.

III. RECENT ANFR (FRANCE) CELL PHONE TEST MEASUREMENTS

On June 1, 2017, the National Agency (ANFR) of France released the cell phone SAR test results on hundreds of cell phones that they had been testing at accredited laboratories since January 2012 [9] using a two-sided version of the IEEE-recommended SAM model or a flat body-simulant model. The ANFR tests differed from regulatory tests in that they measured SARs with separation distances D recommended by individual manufacturers as well as placements that were closer at 5 and 0 millimeter to mimic actual use conditions by consumers holding the wireless device against the body, e.g. in their pockets where SARs higher than the safety limits have also been previously reported by us in peer reviewed published literature [10].

The ANFR test program measured the 10 g SAR called for in the European/ICNIRP standard at three positions of use: the manufacturer-suggested distance D (5, 10, 15, or 25mm) and 5 and 0 mm as for most likely use close to the body (5 mm presumably because of thickness of clothing). A strength of the ANFR results is they have tested 450 cell phones as against our very limited data based on 3 telephones [6], [10]. As the ANFR had tested a large number of cell phones resulting in a very large report [9], we decided to select a limited number of 13 telephones for this paper to illustrate the results. The SARs measured for these 13 selected cell phones are given in Table 1. Shown in this Table is that the telephones give SARs that are within ICNIRP guideline of 2.0 W/kg for manufacturer-suggested distances D (5, 10, 15, or 25 mm), but give SARs that are considerably higher than those of ICNIRP guidelines (by factors of 1.6 to 3.7 times) when the telephones are held against the body to mimic likely actual use conditions. In this context it should be mentioned that the SARs would be even higher by an additional multiplier of 2.5 to 3 or a factor of up to 11 times higher if 1 g values required by the IEEE/FCC standard were measured. All of the 13 selected ANFR-tested devices of Table 1 will not pass the US/FCC safety compliance requirement of 1.6 W/kg for any 1 g of tissue [3]. In the last column of Table 1 we give the calculated increase of SAR per millimeter of reduced spacing for each of the wireless devices from manufacturer-recommended distance D to zero and from 5 mm to zero, respectively. The increase in SAR for each millimeter of proximal placement of the wireless device varies from 10 to 30% which is higher than our previously reported results of 10-15% based on a very limited number—only three cell phones. However the ANFR results do reinforce our additional previously published observations [5] that Standard Anthropomorphic Mannequin (SAM) with tapered plastic

spacer that creates an artificial separation of the wireless device by 6-10 mm will reduce the measured SAR and cannot be trusted as a method for SAR compliance testing. Another thing to observe from the data in columns 4 and 5 is that the SAR is higher by a factor of 2 to 3 for a 5-millimeter closer placement of the wireless device. In [6] we have also proposed this as the reason for a higher SAR for children and for women and men with thinner pinna and skulls resulting in radiating wireless devices being placed closer to the brain in stronger radiated EM fields.

IV. INTERPRETATION OF THE ANFR TEST RESULTS OF TABLE 1

All 13 of the selected telephones of Table 1 fail the SAR requirements mandated by the ICNIRP/European Standard and the US FCC Standard because of the following considerations:

1) The ICNIRP guidelines state that the 10-g SAR for conditions of actual use be no more than 2 W/kg and FCC requires compliance with IEEE Standard C95.1-1991 [1] which is set in terms of 1 g SAR of 1.6 W/kg. It has been shown in peer-reviewed published literature [4], [6] that because of the fairly shallow penetration of RF energy coupled to the tissues, the 1 g SAR is typically 2.5-3 times the 10-g SAR.
2) For cell phones held against the pinna, the measured 1 or 10 g SAR will also be much higher if SAM had not used the lossless artificial plastic spacer in lieu of the tissue-simulant human pinna. As pointed out in [5] and [6], the tapered plastic spacer artificially separates the radiating cell phone antenna by up by up to 10 mm additional spacing for the RF coupled regions of the head resulting in underestimation the 1 g and 10 g SAR by a factor to 2-4. This factor of 2-4 higher SAR is also borne out by the ANFR the ANFR measured results in Table 1 where higher values of SAR are reported in columns 3 and 4 that are for separation distances of 15 and 5 mm respectively.

V. CONCLUSIONS

It is important that safety compliance testing be done under realistic conditions of actual use of the cell phones by the present day users. This should include telephones held close to the body at 0 millimeter spacing and against the tissue-simulant pinna rather than a pinna simulated by a tapered plastic spacer. For the latter, phantom models of the actual users such as children and women and men of smaller head sizes should be used rather than the large head size of Army Recruits used for SAM. The children and women are known to have thinner pinna and skulls which results in closer placements by several millimeters of the radiating antennas to the brain. It is not sufficient for manufacturers to start recommending that the microwave radiating devices be held at distances of 5 to 25 millimeters away from the body to reduce measured SAR to meet the safety standards since these suggested distances cannot be maintained correctly without use of properly attached spacers. Even though ANFR of France has to date released the higher SAR data that does not meet the safety compliance standards when the telephones are held against the body, similar results have also been obtained by independent testing in Canada [11].

Because of the increasing popularity of wireless phones all over the world with use by over 90-95% of populations, it is important that the regulatory agencies in various countries define correct conditions for SAR testing that will cover a majority of users including children.

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