

From: theodorams@aol.com,

To: Daniel.Kassiday@fda.hhs.gov,

Cc: Michael.OHara@fda.hhs.gov, William.Jung@fda.hhs.gov, Robert.Ochs@fda.hhs.gov, CDRHOmbudsman@fda.hhs.gov, marc@arazi.fr,

Bcc: ryan.knutson@wsj.com,

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: Mon, Mar 19, 2018 9:12 am

Attachments:

Dear Dr. Kassiday and FDA officials,

The French ANSES Reports are now posted "in their entirety" as you asked. They show cell phones exceed SAR Limits at body contact. This means that the way people use phones can allow them to absorb radiation at levels that far exceed FCC limits.

See the ANSES test reports and information here <https://ehtrust.org/france-cell-phone-radiation-tests-make-model-sar-radiation-measurements-379-phones/>

This email is to confirm that you now have access to the reports showing cell phones violate US SAR limits.

Again I ask, **at what SAR level will the FDA act?** How much in excess does the SAR need to be for the FDA to act? The FDA seems to be stating in prior email exchanges that *even if FCC limits are violated*, they do not need to do anything.

Thus the FDA has still not responded to my question: What SAR level does a phone need to measure in order for the FDA to act. If phones violate FCC limits the FDA is not taking action. Thus, it seems there is a SAR number at which the FDA believes is safe and one that is not safe?

What is the cell phone SAR measurement that the FDA has identified that would trigger the FDA to act?
Note: the ANSES SAR tests indicate localized exposures are possible that will exceed National Toxicology Program exposures.

Thank you so much,
Theodora Scarato

-----Original Message-----

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>

Sent: Wed, Oct 18, 2017 1:59 pm

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 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



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<https://www.research.net/s/cdrhcustomerservice?O=500&D=560&B=564&E=&S=E>.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit 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,

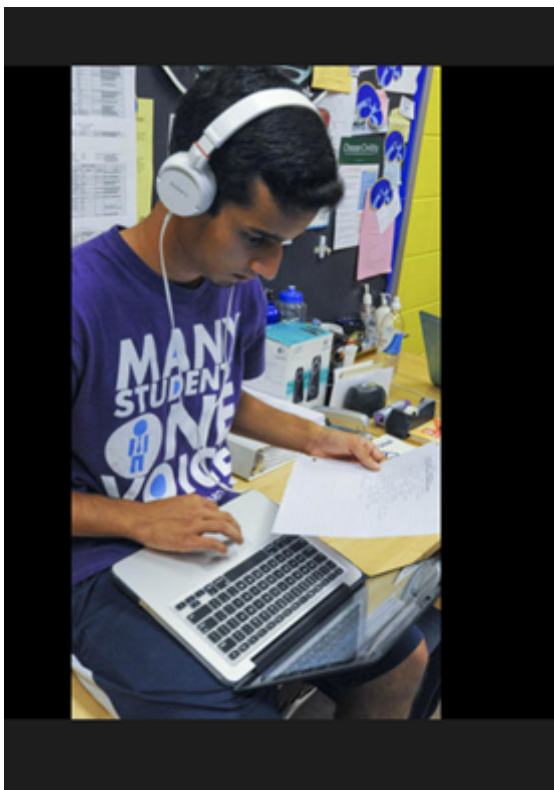
I have not received a response to the letter I sent Tue, Jun 13, 2017 9:09 am (see below this email the email I sent several months ago still unanswered).

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.



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.

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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 the SAR 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.

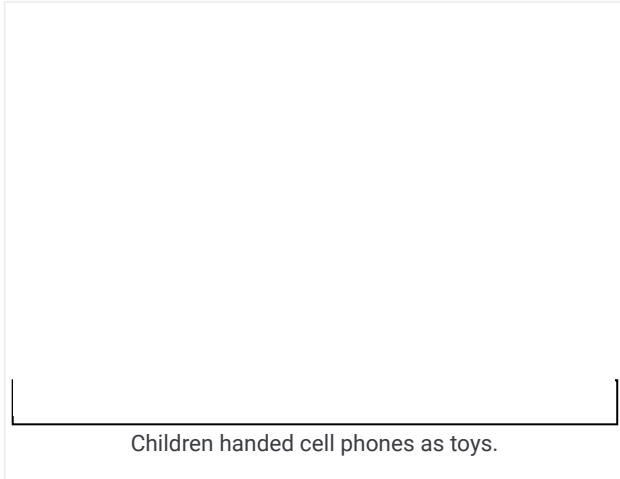
Thank you very much,
Theodora Scarato

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



[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.

[REDACTED]

"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

[Suspicious about Mobile Phones](#) Le Monde, December 23, 2016

[Phonagate: 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 GE.\(2012\). 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 too 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 Verschaeve 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 time 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 operate 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 RFIAGW 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 (RFIAGW) 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 (RFIAGW) 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 RFIAGW 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 rationale 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.

TS Note- sometimes the antenna is on the bottom. Tablets have antennas all over and they are in contact with the body.

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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