

29/02/2020

To: Jeffery Shuren, Director of the Center for Devices and Radiological Health, FDA.

Re: Response to FDA Center for Devices and Radiological Health (CDRH) Report: *Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer*

Dear Jeffery,

I wish to voice my concerns about the validity, reliability, and integrity of the report titled: *Review of Published Literature between 2008 and 2018 of Relevance to Radiofrequency Radiation and Cancer*.

To begin, I note that the mission of the FDA's Center for Devices and Radiological Health (CDRH) is as follows:

... the Center for Devices and Radiological Health (CDRH) is responsible for protecting and promoting the public health. We assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. We assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. We provide consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee. We facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

It is clear that the Center's central mission is to assess medical devices and radiation-emitting products in the field of medicine. Given the ongoing digital transformation of the healthcare industry focusing on the widespread use of wireless devices across hospitals and healthcare facilities, including the Internet of Things, enabled by 5G, there is an onus on the FDA to ensure the general safety of wireless technologies to patients and those with chronic illnesses and disabilities in the face of mounting scientific evidence of the risks posed by wireless technologies of all types.

The FDA seems unaware of, or is it simply ignoring, the overwhelming body of scientific evidence on non-thermal effects, and not just the carcinogenicity, of non-ionizing ionizing radiofrequency radiation (RFR). Take, for example, a recent research review by independent researchers on the health risks of microwave RFR concludes that "*the literature shows there is much valid reason for concern about potential adverse health effects from both 4G and 5G technology*" and that extant research "*should be*

viewed as extremely conservative, substantially underestimating the adverse impacts of this new technology."¹

The above review by US scientists reported that peer-reviewed studies find the following adverse health effects well below the safety limits set by the FCC and ICNIRP guidelines:

- *“carcinogenicity (brain tumors/glioma, breast cancer, acoustic neuromas, leukemia, parotid gland tumors),*
- *genotoxicity (DNA damage, DNA repair inhibition, chromatin structure), mutagenicity, teratogenicity,*
- *neurodegenerative diseases (Alzheimer’s Disease, Amyotrophic Lateral Sclerosis),*
- *neurobehavioral problems, autism, reproductive problems, pregnancy outcomes, excessive reactive oxygen species/oxidative stress, inflammation, apoptosis, blood-brain barrier disruption, pineal gland/melatonin production, sleep disturbance, headache, irritability, fatigue, concentration difficulties, depression, dizziness, tinnitus, burning and flushed skin, digestive disturbance, tremor, cardiac irregularities,*
- *adverse impacts on the neural, circulatory, immune, endocrine, and skeletal systems.”*

The above findings were independently verified by the research team using 5,400 studies in the MedLine database.

Given the foregoing, a question begs as to *whether the FDA had the required competencies to perform its recently published review?* Justification for this question arises from the thousands of relevant studies on the MedLine database identified by independent researchers, as opposed to the 282 studies referenced by the FDA, and the *“approximately 70 relevant epidemiological studies”* mentioned in the Executive Summary and which informed the FDA’s conclusions. The remaining peer-reviewed studies considered by the FDA appear to have been excluded on highly questionable grounds. All this gives the lie to the claim that *“[t]he Agency has taken a comprehensive approach to evaluating the available scientific evidence regarding the impact of radiofrequency radiation (RFR) exposure on human health.”* Furthermore, however limited the Center’s internal competencies may be, the FDA’s network of experts² are focused on medical practice and the use of various devices employed by health care professionals, and are not subject matter experts in 2-4G, Wifi and 5G telecommunications systems and devices. This is important, as 4G, Wifi and 5G technologies are now being employed across the healthcare industry and in general use across the population. The risks posed by such technologies deserve cross-agency attention and review by independent, competent experts across multiple disciplines, without a single conflict of interest.

Following on from the points made above, I accept that the FDA may call on physicians/scientists with relevant expertise to conduct its scientific reviews, however, the report is silent on which scientists, physicians or engineers conducted the review, the levels of expertise they possessed, and any conflicts of interest they had. This places the second question mark over the trustworthiness of the report—there are, however, several other critical questions that require to be answered in full.

Why were ceratin epidemiological studies excluded from the review?

The FDA report is significantly incomplete and therefore inaccurate, given the acknowledged timeframe and intention to include *“more recent, relevant peer-reviewed publications through August 2019.”* A simple example suffices to demonstrate this. The findings of 13 important epidemiological studies are presented below. Also below is a reference to a report that refutes the claims made by the Swedish Radiation Safety Authority cited in the FDA report. The 13 studies were ignored and omitted

¹ Kostoff, R. N., Heroux, P., Aschner, M., & Tsatsakis, A. (2020). Adverse health effects of 5G mobile networking technology under real-life conditions. Toxicology Letters.

²² <https://www.fda.gov/media/120990/download>

by those conducting the review. *Why did this omission take place?* The inclusion of the findings of this recent body of research would have made the report's conclusions untenable. A short review of the 13 studies will support my contention.

First, if the FDA team were using MedLine as indicated, they surely would have identified a study in The Lancet Neurology. The findings of this study places the FDA conclusions in serious doubt viz. *“CNS cancer is responsible for substantial morbidity and mortality worldwide, and the incidence increased between 1990 and 2016. Significant geographical and regional variation in the incidence of CNS cancer might be reflective of differences in diagnoses and reporting practices or unknown environmental and genetic risk factors. Future efforts are needed to analyze CNS cancer burden by subtype.”*³ Below is an excerpt from the findings of another relevant study which the FDA ignored.⁴

Table 1 The global death and incidence of all cancers and 29 specified cancer groups in 1990 and 2017

Tumor types	1990				2017			
	Death		Incidence		Death		Incidence	
	Number 10 ³ (95% UI)	Age-standardized per 100,000 (95% UI)	Number 10 ³ (95% UI)	Age-standardized per 100,000 (95% UI)	Number 10 ³ (95% UI)	Age-standardized per 100,000 (95% UI)	Number 10 ³ (95% UI)	Age-standardized per 100,000 (95% UI)
Brain and nervous system cancer	142 (171–117)	3.04 (3.58–2.56)	194 (234–159)	3.97 (4.71–3.33)	247 (265–213)	3.12 (3.34–2.68)	405 (443–351)	5.17 (5.64–4.46)
Thyroid cancer	22 (24–21)	0.55 (0.6–0.52)	95 (101–90)	2.11 (2.24–2.01)	41 (44–40)	0.52 (0.56–0.51)	255 (272–246)	3.15 (3.36–3.03)

While these studies did not link the significant increase in brain and CNS cancer to cellphone and RFR exposure, a recent study by US economists does.⁵ That study demonstrates *“that mobile phone subscription rates are positively and statistically significantly associated with death rates from brain cancer 15-20 years later. As a falsification test, we find few positive associations between mobile phone subscription rates and deaths from rectal, pancreatic, stomach, breast or lung cancer or ischemic heart disease.”* This 25-year cross country analysis provides solid evidence of the link between mobile phone use and cancer when positioned alongside epidemiological studies.

These trends are also evident in the findings of other studies. A research review of the incidence of glioblastoma multiforme tumours in England during 1995–2015 reported a *“a sustained and highly statistically significant ASR [(incidence rate)] rise in glioblastoma multiforme (GBM) across all ages. The ASR for GBM more than doubled from 2.4 to 5.0, with annual case numbers rising from 983 to 2531. Overall, this rise is mostly hidden in the overall data by a reduced incidence of lower-grade tumours.”*⁶ The study did not focus on RFR as the cause, so the findings must be considered ‘open to interpretation’ in this regard, as other environmental mechanisms cannot be ruled out. However, the following figures are clear and unambiguous. In the UK in 1995, 553 frontal lobe tumours were diagnosed in patients, while 1231 were found in 2015. Likewise, 334 temporal lobe tumours were reported in 1995, while 994 were diagnosed in 2015. The increase in these cancers of the CNS are clear and unambiguous. The authors of this study argue that:

³ Patel, A. P., Fisher, J. L., Nichols, E., Abd-Allah, F., Abdela, J., Abdelalim, A., ... & Allen, C. A. (2019).

Global, regional, and national burden of brain and other CNS cancer, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016. The Lancet Neurology, 18(4), 376-393.

⁴ Lin, L., Yan, L., Liu, Y., Yuan, F., Li, H., & Ni, J. (2019). Incidence and death in 29 cancer groups in 2017 and trend analysis from 1990 to 2017 from the Global Burden of Disease Study. Journal of hematology & oncology, 12(1), 96.

⁵ Mialon, H. M., & Nesson, E. T. (2019). The Association Between Mobile Phones and the Risk of Brain Cancer Mortality: A 25-year Cross-country Analysis. Contemporary Economic Policy. <https://doi.org/10.1111/coep.12456>.

⁶ Philips, A., Henshaw, D., L Lamburn, G. & M. O'Carroll, (2018). Brain tumours: rise in Glioblastoma Multiforme incidence in England 1995–2015 suggests an adverse environmental or lifestyle factor, Journal of Environmental and Public Health, vol. 2018, Article ID 7910754.

“The rise cannot be fully accounted for by promotion of lower-grade tumours, random chance or improvement in diagnostic techniques as it affects specific areas of the brain and only one type of brain tumour. Despite the large variation in case numbers by age, the percentage rise is similar across the age groups, which suggests widespread environmental or lifestyle factors may be responsible. This article reports incidence data trends and does not provide additional evidence for the role of any particular risk factor.”

It is significant that the frontal and temporal lobes receive the greatest exposure to RFR from smartphones and wireless devices.

A comprehensive review of the incidence of primary brain and other central nervous system tumors diagnosed in the United States during the period 2009–2013, found quite small, but statistically significant increases in some categories of CNS tumours and none in others.⁷ To be sure, in this study published in 2016, the increase in the incidence of tumours reported were not as alarming as those in the UK study. However, this is only the first in a series demonstrating an upward trend.

A related U.S. study echoed the previous findings, but found an *“an increasing medulloblastoma incidence in children aged 10–14 years.”*⁸ Another recent study on children found statistically-significant changes in several sub-types of CNS cancers, notably gliomas, in the period 1998-2013.⁹ The latter study concluded that *“Continued surveillance of pediatric CNS tumors should remain a priority given their significant contribution to pediatric cancer deaths.”*

In keeping with studies that provide compelling evidence for concern, a recent review study of epidemiological studies on brain and salivary gland tumours in relation to mobile phone use found the cumulative evidence to be inconclusive but indicated that such cancers may have a long latency (i.e. greater than 15 years) and clear evidence may emerge in the future. Nevertheless, scientists argue that childhood exposure to RFR devices is of significant concern.¹⁰ There is also evidence that RFR from cell phones may be triggering breast cancer in young women who carry their devices on or near their breasts.¹¹ In addition, while the extensive studies by the Hardell Group cited in the FDA review demonstrate increases in cancers of the CNS in Sweden, these findings have been recently replicated in Denmark.¹²

In a general context, the U.S. Center for Disease Control and related research finds that non-Hodgkin lymphomas, central nervous system tumors (including brain cancers), renal, hepatic and thyroid

⁷ Ostrom, Q. T., Gittleman, H., Xu, J., Kromer, C., Wolinsky, Y., Kruchko, C., & Barnholtz-Sloan, J. S. (2016). CBTRUS statistical report: primary brain and other central nervous system tumors diagnosed in the United States in 2009–2013. *Neuro-oncology*, 18(suppl_5), v1-v75.

⁸ Khanna, V., Achey, R. L., Ostrom, Q. T., Block-Beach, H., Kruchko, C., Barnholtz-Sloan, J. S., & de Blank, P. M. (2017). Incidence and survival trends for medulloblastomas in the United States from 2001 to 2013. *Journal of neuro-oncology*, 135(3), 433-441.

⁹ Withrow, D. R., de Gonzalez, A. B., Lam, C. J., Warren, K. E., & Shiels, M. S. (2018). Trends in pediatric central nervous system tumor incidence in the United States, 1998-2013. *Cancer Epidemiology and Prevention Biomarkers*, cebp-0784.

¹⁰ Rööslä, M., Lagorio, S., Schoemaker, M. J., Schüz, J., & Feychting, M. (2019). Brain and Salivary Gland Tumors and Mobile Phone Use: Evaluating the Evidence from Various Epidemiological Study Designs. *Annual review of public health*, 40.

¹¹ West, J. G., Kapoor, N. S., Liao, S. Y., Chen, J. W., Bailey, L., & Nagourney, R. A. (2013). Multifocal breast cancer in young women with prolonged contact between their breasts and their cellular phones. *Case reports in medicine*, 2013.

¹² Swedish Radiation Protection Foundation (2017). Brain tumors are increasing in Denmark https://www.stralskyddsstiftelsen.se/wp-content/uploads/2017/01/denmark_cnstumorrising_2017-01-20.pdf

tumours have increased recently among adolescent Americans.^{13, 14} When comparing the Annual Average Total and Average Annual Age-Adjusted Incidence Rates for Children and Adolescents of Brain and Other Central Nervous System Tumors from 2009-2013⁴ and 2012-2016¹² an increase in total cases of 0-19 year olds from 23,522 to 24,931 is found, with the annual average increasing from a rate of 5.70 in 2012 to 6.06 to 2016. Thus, many scientists conclude that microwave radio frequency radiation has a significant role to play in the increasing rates of particular types of CNS cancers being reported.

A senior epidemiologist at US healthcare provider Kaiser Permanente, Dr. De-Kun Li, believes that while the increase in brain tumors is worrisome, increases in colorectal cancer is even more troubling, particularly as he believes RFR is implicated due to the manner in which people carry their smartphones in the front and back pockets of their pants and jeans. Take, for example, in 2019, the journal *Cancer* described a rising incidence of colorectal cancer among young Americans, with rectal cancers being slightly higher than colon cancers.¹⁵ Another contemporary study found significant increases in colorectal cancer among people under 50 in Denmark, New Zealand, and the UK since 2009.¹⁶ Yet another study of colorectal cancer in young adults in 20 European countries over the last 25 years found that over the last 10 years, the incidence of colorectal cancer increased 8% per year among people in their 20s, by 5% for people in their 30s, and by 1.6% for those in their 40s.¹⁷ Dr. De-Kun Li maintains that *“When placed in trouser pockets, the phones are in the vicinity of the rectum and the distal colon and these are the sites of the largest increases in cancer.”* While phones go into standby mode where telephone calls are concerned, most young people have WiFi, Bluetooth and 4G data enabled. This increases the level and incidence of exposure, as their apps keep their smartphones active on a continuous basis. Thus, other environmental, diet and lifestyle factors aside, wireless microwave radio frequency radiation is strongly implicated as a direct or indirect (e.g. co-carcinogen) in this latest ‘uptick’ in cancers.

Again the weight of the scientific evidence is considerable. If the findings of the above studies are accurate and generalizable, then the rates for frontal and temporal lobe tumours may increase significantly, as they more than doubled over a 20-year period in the UK, or increase in line with high RFR exposure, as RFR is now accepted as either a causal or a contributory mechanism in the occurrence of brain tumours and other cancers.

Serious questions on the trustworthiness of the report

Focusing on the report itself, and in regard to the probable deficiencies in scientific expertise among the authors of the review, the FDA has questions to answer in regard to the report’s...

(a) scientific accuracy and integrity;

¹³ Siegel, D. Li, S J., Henley, J., Wilson, R., Buchanan Lunsford, N., Tai, E. Van Dyne, E. (2018) Incidence rates and trends of pediatric cancer — United States, 2001–2014, American Society of Pediatric Hematology Oncology Conference, Centers for Disease Control and Prevention, Atlanta, Georgia, United States http://aspho.org/uploads/meetings/2018annualmeeting/Abstracts_for_Website.pdf

¹⁴ Ostrom, Q. T., Gittleman, H., Truitt, G., Boscia, A., Kruchko, C., & Barnholtz-Sloan, J. S. (2018). CBTRUS statistical report: primary brain and other central nervous system tumors diagnosed in the United States in 2011–2015. *Neuro-oncology*, 20(suppl_4), iv1-iv86.

¹⁵ Virostko, J., Capasso, A., Yankeelov, T. E., & Goodgame, B. (2019). Recent trends in the age at diagnosis of colorectal cancer in the US National Cancer Data Base, 2004-2015. *Cancer*.

¹⁶ Araghi, M., Soerjomataram, I., Bardot, A., Ferlay, J., Cabasag, C. J., Morrison, D. S., ... & Engholm, G. (2019). Changes in colorectal cancer incidence in seven high-income countries: a population-based study. *The Lancet Gastroenterology & Hepatology*, 4(7), 511-518.

¹⁷ Vuik, F. E., Nieuwenburg, S. A., Bardou, M., Lansdorp-Vogelaar, I., Dinis-Ribeiro, M., Bento, M. J., ... & Suchanek, S. (2019). Increasing incidence of colorectal cancer in young adults in Europe over the last 25 years. *Gut*, gutjnl-2018.

- (b) systematic distortion and misrepresentation of the findings of peer-reviewed studies in reputable journals;
- (c) dismissal of scientific evidence on spurious “limitations” grounds;
- (d) bias and systematic omission of studies;
- (e) incorrect and misleading statements;
- (f) lack of transparency.

In the round, and in my view as a scientist, this review fails to meet the basic criteria set for valid and reliable scientific research. You might ask where is the objective proof of my assertion? In answering this, I contend that if a truly independent group of scientists conducted an equally rigorous review of the same literature and came to different conclusions then this would support my argument as to the trustworthiness of your report. Was there such a review? Yes, there was. I now discuss this.

The WHO’s IARC Advisory Group comes to different conclusions using the same body of evidence

In March 2019, based on what was similar laboratory and epidemiological research evidence, an Advisory Group of 29 scientists from 18 countries recommended that non-ionizing radiofrequency radiation (RFR) receive High Priority from by the WHO’s International Agency for Research on Cancer (IARC) Monographs programme during 2020–24. In doing so, the Advisory Group voiced concern about the health risks identified by the research they reviewed over the past 8 years, since non-ionizing radiofrequency radiation was classified as Class 2B carcinogen (see below¹⁸). Above I identified recent epidemiological studies on the incidence of primary brain and other central nervous system tumors and colorectal cancers in young adults, which would only serve to strengthen their recommendations, had they been available at the time of the review. These studies indicate clear risks to adolescents and young adults from smartphone use and the global practice of carrying smartphones in front and back pants/jeans pockets, all things considered.

In addition, there is an increasing body of independent analyses of peer-reviewed scientific research, which concludes that non-ionizing RFR should be reclassified as a Class 1 carcinogen.^{19, 20, 21, 22} It is more likely, however, that the IARC Advisory Group recommendation will result in RFR achieving at least a Class 2A probable carcinogen status. However, former ICNIRP scientist James C. Lin²³ argues in relation to the NTP and Ramazini Institute peer-reviewed findings in 2018: *“The time is right for the IARC to upgrade its previous epidemiology based classification of RF exposure to higher levels in terms of the carcinogenicity of RF radiation for humans. Recently, two relatively well-conducted RF and microwave exposure studies employing the Sprague–Dawley strain of rats—without, however, using any cancer-promoting agents (or cocarcinogens)—showed consistent results in significantly increased*

¹⁸¹⁸ <https://www.iarc.fr/news-events/report-of-the-advisory-group-to-recommend-priorities-for-the-iarc-monographs-during-2020-2024/>

https://monographs.iarc.fr/wp-content/uploads/2019/10/IARCMonographs-AGReport-Priorities_2020-2024.pdf.

¹⁹Kostoff, R. N., Heroux, P., Aschner, M., & Tsatsakis, A. (2020). Adverse health effects of 5G mobile networking technology under real-life conditions. *Toxicology Letters*.

²⁰ Miller, A. B., Morgan, L. L., Udasin, I., & Davis, D. L. (2018). Cancer epidemiology update, following the 2011 IARC evaluation of radiofrequency electromagnetic fields (Monograph 102). *Environmental research*, 167, 673-683.: [//www.sciencedirect.com/science/article/pii/S0013935118303475](https://www.sciencedirect.com/science/article/pii/S0013935118303475)

²¹Belpomme, D., Hardell, L., Belyaev, I., Burgio, E., & Carpenter, D. O. (2018). Thermal and non-thermal health effects of low intensity non-ionizing radiation: An international perspective. *Environmental Pollution*, 242, 643-658.

²² Kostoff, R. N., Heroux, P., Aschner, M., & Tsatsakis, A. (2020). Adverse health effects of 5G mobile networking technology under real-life conditions. *Toxicology Letters*.

²³ James C. Lin is Professor of Physiology and Biophysics University of Illinois, Chicago.

total primary cancer or overall tumor rates in animals exposed to RF radiation.”²⁴ Thus, for all intents and purposes, respected independent scientists are of the strong opinion that RFR is at least a Class 2A probable carcinogen and, given the recent experimental and epidemiological evidence, almost certainly a Class 1 carcinogen. It is also noteworthy that Professor Lin’s assessment of the validity and reliability of the NTP and Ramazzini studies also calls into question the conclusions of the report by your Center.

FDA’s confused and contradictory approach to regulating carcinogens

During the second half of 2019, the FDA investigated “*the detection of a contaminant known as N-Nitrosodimethylamine (NDMA) in ranitidine medications, commonly known by the brand name Zantac.*”²⁵ In an update to its previous announcement, the FDA “*advised companies to recall their ranitidine if testing shows levels of NDMA above the acceptable daily intake (96 nanograms per day or 0.32 parts per million for ranitidine).*” N-nitrosodimethylamine (NDMA) is an IARC Class 2A probable carcinogen. That FDA recall affects Zantac and all medications containing ranitidine as NDMA was found in these over-the-counter indigestion drugs. In October, *Scientific American* published an article titled: *What We Know about the Possible Carcinogen Found in Zantac*. *Scientific American* reported that the NDMA found in this medication is classified as a probable human carcinogen based on results from laboratory tests on rats. There is little evidence that it causes cancer in humans, despite the WHO’s IARC classification of it as a Class 2A carcinogen. Please note that the majority of Class 2A/B carcinogens are linked with an increased risk of cancer in individuals that are periodically exposed to them. That is, the frequent ingestion of NDMA over a particular period of time increases the risk, but not the certainty of developing cancer. Digestion remedies such as Zantac were nevertheless withdrawn because of “*fears it contains traces*” of NDMA.

To reiterate, while currently a Class 2B carcinogen as indicated above, scientific evidence and expert opinion currently places RFR in the Class 2A category and probably in the Class 1 category. The WHO/IARC is expected to reclassify it as such soon. With the proliferation of 4G, WiFi and 5G, adults and children are exposed to a scientifically recognized toxin and carcinogen, 24 hours a day, 7 days a week, from multiple sources in the home, school, the workplace, and society. The FCC and ICNIRP thermal safety levels do not protect adults or children from exposure to this carcinogen and the risks it poses. Risks much greater than that which NDMA poses in Zantac. Note that the risk here from RFR is systemic and individual, not just individual as in the case of Zantac, and is one that must be mitigated by minimizing or eliminating exposure, where possible. Thus, the FDA has demonstrated that it does not really understand the risks that carcinogens such as RFR pose to humans.

Why were the authors of the FDA review not named?

As indicated previously, it is most troubling that this report has no authors. On the FDA website on the scientific integrity page, the following text appears.

*“Our scientific experts may hold differing views on what they conclude from data. There may be multiple options that can be considered during policy development or regulatory decision-making. However, in reaching our conclusions through a deliberative scientific process, FDA strives to present an evaluation and analysis of the data—including uncertainties—in an unbiased manner.”*²⁶

²⁴ Lin, J. C. (2019). The Significance of Primary Tumors in the NTP Study of Chronic Rat Exposure to Cell Phone Radiation [Health Matters]. IEEE Microwave Magazine, 20(11), 18-21.

²⁵ <https://www.fda.gov/news-events/press-announcements/statement-new-testing-results-including-low-levels-impurities-ranitidine-drugs>

²⁶²⁶ <https://www.fda.gov/science-research/about-science-research-fda/scientific-integrity-fda>

In light of the report's provenance and lack of transparency in its authorship and conduct, the following questions require attention.

- Did the in-house scientific experts at the FDA's Center for Devices and Radiological Health (CDRH) refuse to be associated with the published conclusions?
- How can the scientific community accept the validity and reliability of an anonymous report, given its mysterious provenance?
- How are we to evaluate any conflicts of interest among the authors of the report?

It is notable that as Director of the Center for Devices and Radiological Health, you have not put your name to this report nor signed off on it, as one would have expected. *Why is this?*

There are too many question marks over this report for it to be accepted as valid and reliable by any reasonable person, let alone a member of the scientific community. Thus, one may ask if the FDA has failed in its statutory duty to protect public health by promulgating the falsehood that RFR is not a carcinogen? Has it, therefore, put the health of US citizens, and children in particular, at significant risk, the very antithesis to its overall mission to "*protect the public health*"?

Yours Sincerely,



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