

# Myths and Facts About the National Toxicology Program Cell Phone Radiation Cancer Study Correcting the Misinformation

The National Toxicology Program (NTP) study found an association between cell phone radiation and cancer prompting an astonishing chorus of criticism from almost every prominent media outlet in the country.

Environmental Health Trust analyzed the media response and found a pattern of consistent inaccurate and misleading statements repeated over and over again in literally *hundreds* of news articles. Most of the criticisms levied at the NTP findings are inaccurate and simply do not hold up to scientific scrutiny.

# 23 Myths About the National Toxicology Program Cell Phone Radiation Study

Overarching Myth #1: The NTP study is just one rat study that is irrelevant to humans because the radiation exposures were far higher than humans get from cell phones.

Fact: This is the world's largest, most carefully done study on wireless radiation specifically designed to mimic human exposures in rodents. Every agent that is known to cause cancer in humans has been shown to be carcinogenic in animals when adequately tested.

Myth: The NTP rats radiation exposure was way too high to be relevant to human health.

Fact: The NTP study was designed to mimic long term human exposure to cell phone radiation and to test the adequacy of safety limits. It is standard practice for rodent studies to have experimental groups with higher exposure levels than average human exposure in carcinogenicity studies.

• This study was designed to test if government safety limits (which only protect us from thermal radiation levels) are protective. The results indicate that adverse carcinogenic effects occur at non-thermal (non-heating) levels which means that safety

is not assured even if one abides by government regulations. Government regulations for microwave radiation are based on the assumption that "if it does not heat you, it will not hurt you." To test the "no-heating" cut-off for harm, NTP animals were exposed up to almost the maximum dose they could tolerate with no increase in body temperature. The animals in this experiment never experienced an increase in body temperature over one degree Celsius, as this is considered the cut-off point for heating effects. Despite this limit, male rats developed increased cancers compared to controls and a dose response was observed with respect to the schwannoma rate. The most important thing to know about the NTP radiation exposures is that the radiation dose in the study did not cause a measurable increase in the animal's body temperature but still found a carcinogenic effect. This indicates that government safety need to be strengthened to include protection from biological effects found at non-thermal levels.

- The NTP study was specifically "designed specifically to mimic the human exposure scenario" and to account for the increased use of technology in the future. Listen to NIH scientists discuss the exposure set up stating, "Our studies are designed specifically to mimic the human exposure scenario. The NTP studies are looking at exposures for 10 hours a day. There's heavy cell phone users that may approach the 10 hour mark that may be excessive, but it allows us to fully investigate whether or not there is an effect of cell phone frequency radiation."
- The exposures of the brain in the NTP study were not very different from human exposures associated with use of cell phones. Lawyers and real estate agents are examples of many people who are on their cell phone for many hours every day. In the carefully designed NTP exposure system, animals were exposed to radiation in special reverberation chambers, with whole body specific absorption rates (SAR) values at 1.5, 3, and 6.0 W/kg. Specific absorption rates (SAR), are measures of the rate of RF energy absorbed per unit mass of tissue. With respect to exposures to the brain, SAR values in rats were similar to or slightly higher than human exposures from cell phones held next to the head. In the US, the localized FCC exposure limit for cell phones is 1.6 W/kg averaged over any one gram of tissue when considering the brain (in Europe it is higher at 2 W/kg) and for extremities such as the arms, legs and ears- the limit is 4.0 W/kg.
- It is standard practice for rodent studies to have higher exposure levels than average human exposure. Mice and rats have far shorter life spans than humans. Rodents only live up to 3 years whereas humans can live up to 100 years. To identify a hazardous agent, exposure levels in animal studies are often much higher than human exposures, while lower doses are included for analyses of dose-response relationships. The NTP study of RFR could not use exposure intensities much higher than that of cell phones in order to prevent any measurable increases in body temperature. Consequently, the duration of exposure was extended to nine hours a day for 106 weeks or less. The cumulative total exposure is comparable to thirty-six years of exposure (and children given a phone in middle school will have many more years of exposure than that) at a rate of 30 minutes per day, hardly excessive.
- People most commonly hold phones against their ears and are often exposed 24 hours to RF-EMF. The statement "Many people nowadays rarely hold their cellphones

up to their heads at all," is simply false. Many people have given up their landline and only use cell phones. All one has to do is stand outside in a public place such as a subway terminal and watch numerous people walk by with the cell phone up to their head. Real estate agents, lawyers, healthcare workers and even retail store employees are occupations where wireless technology is used for hours a day with devices carried on or against the body. It is a fact that many teenagers sleep with their phones at their pillow and carry their phones on their body all day long. Furthermore, cell tower and cell antennae placements are only increasing nationwide with the rollout of 5 G and newer technologies- exposing the population to higher levels and a variety of different frequencies.

#### Additional Info:

In the US, the localized exposure limit for cell phones is 1.6 W/kg averaged over any one gram of tissue. In Europe, it is 2 W/kg averaged over 10 grams of tissue. These exposure values, which are referred to as specific absorption rates (SAR), are measures of the rate of RF energy absorbed per unit mass of tissue. When an individual uses a cell phone and holds it next to his or her head, exposure to the brain will be much higher than exposures to other parts of the body. Body tissues located nearest to the cell phone antenna receive much higher exposures than tissues located distant from the antenna. When considering organ-specific risk (e.g., risk to the brain), the important measure of exposure is the 1.6 W/kg value in any gram of tissue in that organ. Individual manufacturers and the FCC provide SAR values for cell phone emissions. While some cell phones emit lower radiation levels, other phones emit radiation that can produce an SAR dose near or above 1.5 W/kg.

"Cellphones probably cause cancer if the exposure is close enough, long enough, and in sufficient magnitude. We don't yet know the risk for a given level of exposure in humans. We need more data in this area, not only for cellphones, but for bluetooth devices, wifi and all the other RF-EMF devices out there. Until then, reduce your exposure whenever possible."

- Christopher J. Portier and Wendy L. Leonard, Scientific American, June 13, 2016

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Myth: Rat research does not inform human health risk.

Fact: Rat research does inform human health risk.

• Rats are the preferred animal model for carcinogenicity studies. Carcinogenicity studies in rodents are important for several reasons: (1) animals and humans exhibit similarities in the biological processes of disease induction - this is why animal models are used in preclinical trials of new pharmaceutical agents, (2) it is unethical to intentionally expose humans to known hazardous agents, (3) every agent that is known to cause cancer in humans is carcinogenic in animals when adequately tested (IARC, preamble), and (4) almost one-third of human carcinogens were identified after carcinogenic effects were found in well-conducted animal studies (Huff, 1993, Chemicals

- and cancer in humans: first evidence in experimental animals, Environmental Health Perspectives 100:201-210). Read FDA guidance.
- Regulatory agencies currently rely on rodent carcinogenicity bioassay data to predict whether or not a given chemical poses a carcinogenic threat to humans. There are strong correlations of the carcinogenic potencies between rats and mice, and the upper limits on potencies in humans are consistent with rodent potencies for chemicals on which human exposure data are available. In 1999, the U.S. Food And Drug Administration (FDA) recommended that the National Toxicology Program initiate this large scale rodent study on radiofrequency and the 1999 FDA Report stated:

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- "Animal experiments are crucial because meaningful data will not be available from epidemiological studies for many years due to the long latency period between exposure to a carcinogen and the diagnosis of a tumor.
- There is currently insufficient scientific basis for concluding either that wireless communication technologies are safe or that they pose a risk to millions of users. A significant research effort, including well-planned animal experiments, is needed to provide the basis to assess the risk to human health of wireless communications devices."
- What happened in the NTP rats is happening in humans. The rodent cells which developed tumors in the NTP rats are the same cells that display elevated tumor risk in human studies of long-term, heavy cellphone users. This correlation cannot be ignored and is precisely why the NIEHS/NTP released the results. At the May 27, 2016 NIEHS press conference when the report was released, Dr. John Bucher (NTP) stated, "The reason that we're bringing these particular findings to the attention of the public today is the fact that they are in tumor sites, there's tumor sites and types that have been identified in human studies as I mentioned, the IARC human studies."

"These results are particularly interesting in the light of the results of the INTERPHONE international study, which I had the opportunity to coordinate. The study included over 2,700 cases of glioma and 1,100 cases of schwannoma of the acoustic nerve and found evidence of an association between mobile phone use (as well as level of radiofrequency exposure) and increased risk of developing both types of tumours. "

Elisabeth Cardis May 27, 2016

GROWING EVIDENCE FOR THE LINK BETWEEN MOBILE PHONES AND CANCER

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Myth: The NTP study is just a small "single rat study." Fact:

This is the largest study ever done on wireless health risks. Thousands of rodents
were used in the NPT's three-phased study design to ensure accuracy in exposure.
 First, pilot studies and subchronic studies were conducted to determine the maximum
intensity of cellphone radiation that could be employed without inducing any heating

- effect. Then, the final two-year chronic studies exposed rodents prenatally and for the majority of their lifetime (up to 24 months), utilizing the information from the pilot and subchronic studies. Unlike prior studies in which rodents were exposed in tubes or using a ferris wheel design, the NTP rodents were allowed to be roam free in their cages during exposure. This was permitted due to the elaborate underground reverberation system built in Switzerland. (Click here for slides showing the exposure set up.)
- Double the usual number of rats were used. Usually 50 rodents are used per group in carcinogenicity studies but 90 were used for each group in the NTP study. As the American Cancer Society states, "The NTP was given the difficult task of trying to answer important questions about the potential cancer risk posed by cell phones, and the group did not shirk from its responsibility. NTP staff were clearly aware of the potential importance of this study and went the extra distance to ensure the best science is used. They used double the number of animals required for this type of study; they convened not one but three panels to look at abnormal tissues from treated animals to ensure that what was identified as a brain and heart tumor was indeed a brain and heart tumor; they solicited review from multiple scientists from outside the NTP to critically review all aspects of the data analysis and study findings, to ensure the findings would stand up to the critical assessment expected once these unexpected findings were released." Read the American Cancer Society Press Release here.

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Myth: The NTP study was underpowered and statistically unable to detect a true effect. Fact: A underpowered study is more likely to result in a false negative.

- Having low statistical power means that there is a greater chance for a false negative rather than a false positive result. That is, there is a high probability of accepting the no-effect hypothesis even when a true effect exists.
  - Or. Melnick responded to one of Dr Lauer's statements in the Hebrew University Press conference that "One comment was made that the study had low statistical power and that might lead to a false positive. I'm not sure if that was a misstatement by the reviewer because low statistical power means there's a high probability of accepting the null hypothesis even when a true effect may exist. That is, there is a greater chance for a false negative rather than a false positive if there is low statistical power."
- NTP scientists specifically addressed Dr. Lauer's concerns about the power in the NTP Report section entitled <u>NTP Comments on Statistical Issues Raised by the</u> <u>Reviewers page 67-74</u>, the NTP responded in full.
   On page 67:

"Although the NTP conducts statistical tests on multiple cancer endpoints in any given study, numerous authors have shown that the study-wide false positive rate does not greatly exceed 0.05 (Fears et al., 1977; Haseman, 1983; Office of Science and Technology Policy, 1985; Haseman, 1990; Haseman and Elwell, 1996; Lin and Rahman, 1998; Rahman and Lin, 2008; Kissling et al., 2014). One reason for this is that NTP's carcinogenicity decisions are not based

solely on statistics and in many instances statistically significant findings are not concluded to be due to the test agent. Many factors go into this determination including whether there were pre-neoplastic lesions, whether there was a dose-response relationship, biological plausibility, background rates and variability of the tumor, etc. Additionally, with rare tumors especially, the actual false positive rate of each individual test is well below 0.05, due to the discrete nature of the data, so the cumulative false positive rate from many such tests is less than person would expect by multiplying 0.05 by the number of tests conducted (Fears et al., 1977; Haseman, 1983; Kissling et al., 2015)."

On page 69 of NTP Comments on Statistical Issues Raised by the Reviewers the NTP states:

"Sample size calculations were conducted for this study. However, for detecting carcinogenesis, sample size and power will depend on the baseline (control) tumor rate and the expected magnitude of the increase in tumors. For example, at 80% power, sample size requirements will be quite different for detecting a 2-fold increase in a rare tumor having a spontaneous occurrence of 0.5% compared to 2-fold increase in a more common tumor having a spontaneous occurrence of 10%. Because many different tumor types having wide range of spontaneous occurrence are involved in these studies, there is no "one-size-fits-all" sample size; rather, the sample size is a compromise among several factors, including obtaining reasonable power to detect moderate to large increases for most tumor types, while staying within budgets of time, space, and funding. A sample of 90 animals per sex per group was selected as providing as much statistical power as possible across the spectrum of tumors, under the constraints imposed by the exposure system.

The NTP's carcinogenicity studies are similar in structure to the OECD's 45 Guideline for carcinogenicity studies and the FDA's guidance for rodent carcinogenicity studies of pharmaceuticals. These guidelines recommend at least 50 animals of each sex per group, but also mention that an increase in group size provides relatively little increase in statistical power. In the NTP's RFR studies, the group sizes were 90 animals of each sex per group, nearly twice as many as the minimum recommendation. Increasing the group sizes further provides diminishing returns, for which additional animals do not substantially increase power.

#### Page 70:

"It is true that the power is low for detecting moderate increases above a low background tumor rate of approximately – %, as was seen in the brain and heart tumors. However, this low power does not correspond to high risk of false positive findings. The paper by loannidis that was cited correctly states that when studies are small or effect sizes are small (i.e., statistical power is low), "the less likely the research findings are to be true." Research findings can be "not true" if the result is a false positive or a false negative. With low statistical power, false negatives are much more likely than false positives. Therefore, the vast majority of false research findings in a low power situation will result from the failure to detect an effect when it exists. The false positive rate on any properly constructed statistical test will not exceed its significance level,

alpha. By definition, the significance level of a statistical test is its false positive rate, and it is typically selected by the researcher, often at a low fixed value such as 0.05 or 5%."

On page 74 Dr. Bucher again addresses the issue:

"Although Mike referred to the example of positive findings in underpowered epidemiology studies that could not be replicated in larger follow up studies, there is a growing literature alluding to this problem with respect to experimental animal studies as well. An example is a relatively recent article by one of our collaborators in CAMARADES, Malcolm MacLeod.

http://www.nature.com/news/2011/110928/full/477511a.html

It's important to distinguish between low power to detect effects, and the constellation of other factors that often accompany low powered experimental animal studies in contributing to this problem. We've addressed this issue in a recent editorial, and these factors are captured in our published systematic review process for evaluating study quality in environmental health sciences (Rooney et al., 2014).

http://ehp.niehs.nih.gov/wp-content/uploads/122/7/ehp.1408671.pdf http://ehp.niehs.nih.gov/wp-content/uploads/122/7/ehp.1307972.pdf

Table 1 in the Rooney et al. report outlines risk of bias considerations that commonly plague studies carried out by academic researchers that are accounted for in NTP studies.

I provide these examples to assure you that we are completely cognizant of these issues and take them very seriously. Again, we appreciate the help you've provided in assuring that we appropriately interpret and communicate our findings.

Best	
John Bucher "	

Overarching Myth #2: The weak and unusual study results prove the risk to humans is small and likely nonexistent.

Fact: When scientifically reviewed and statistically analyzed, the findings of statistically significant increased cancers and precancers in the exposed rats remain valid *despite* the gender and survival differences. Furthermore, the analysis is strengthened by the

findings of *other adverse* effects from exposure such as lower birth rate and cardiac abnormalities.

Myth: Cancer rates were only increased in the male rats but were not equally increased in females so the findings are questionable.

Fact:

- It is extremely common for males to show different cancer rates from females in both laboratory and epidemiological studies with men usually having higher rates. Specifically, in previous NTP toxicology studies, male rats as compared to females had more than ten times the incidence of malignant gliomas (brain tumors) and more than twice the rate of malignant schwannoma of the heart. These statistics called "historical control incidence" are documented in the NTP report (Tables 1-6). As the American Cancer Society explains in their statement about the NTP results, "It's important to note that these sorts of gender differences often appear in carcinogenic studies, so the fact they show up here should not detract from the importance of the findings."
- While the tumor incidence was greater in exposed male rats than in female rats, these rare and uncommon tumors were observed only in RFR-exposed animals of both sexes while no tumors were observed in the control animals. In addition, pre-cancerous lesions (glial hyperplasia and Schwann cell hyperplasia) were observed only in RFR-exposed male and female rats. Numerical differences are commonly detected between the sexes in animal carcinogenicity studies as well as in human populations. For example, brain cancer mortality rates are approximately 50% higher in men than in women, and for many human cancers (e.g., colon-rectal, liver, soft tissue including heart, kidney, non-Hodgkin lymphoma, etc.) the incidence and mortality rates are much higher in men than in women.
- Female RFR-exposed animals did have higher rates than controls although it did not reach statistical signifigance. Seven exposed female rats had cancer or precancerous lesions in the glial cells and nine had cancer or precancerous lesions in their Schwann cells. Rates of cancer or precancerous lesions within the unexposed female rats were zero in the heart nerve and brain. Historically, female rats have much lower rates of both types of cancer. If we compare cancer rates among exposed female rats to historical controls (the average from studies of other exposures), RFR-exposed females developed 3.1 times the rate of gliomas and 1.9 times the rate of Schwannoma. It is essential to remember that not statistically significant does not equate to "no difference". Exposed groups in the NTP study had higher rates of disease in every one of these cases. However, the differences were not high enough to allow researchers to reject the notion that these were chance occurrences with 95% certainty.
- The different response rate between male and female rats in the RFR study does not alter the relevance of the cancer findings from this study.

"It is not surprising that the exposed males had more tumors than the females given what we have seen in the historical controls. But we can go one step further, the fact that

we saw any of these tumors in the exposed females but none in the concurrent controls adds support to the conclusion that cell phone radiation leads to cancer among rats."

-Ron Melnick in Microwave News

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Myth: If the control group had developed cancer at the usual rate (historical controls), there would be no statistically significant difference.

Fact:

- The concurrent controls are the best controls and the most important to consider in any given study. The fundamental concept behind a controlled experimental study is that the control group matches the exposed group as closely as possible as every detail of feed, housing and environment are truly identical. If all groups of rats are treated the same in the same experiment and only the exposed group has a statistically significant effect, then the statistical analysis calculates the probability that chance caused the observed differences by making the control rates artificially low or the exposed rates artificially high.
- NTP scientists carefully considered the issue of historical controls and factored it into their analysis. Please listen to Dr. Michael Wyde, lead investigator of the National Toxicology Program study and Dr. Birnbaum, director of the National Institute of Environmental Health Sciences (NIEHS) of the National Institutes of Health specifically explain how this concern is invalid and does not detract from the findings in a video of a June 15, 2016 presentation of the NTP study. Dr. Birnbaum explains how the historical data was considered in the final analysis and she also points out that prior studies with this rat strain are limited and were under different conditions than in the NTP study. The NTP study on RFR was unique in that no other chronic study housed rats in individual cages (including controls) in reverberation chambers and only one other NTP study (but in a different strain of rats) was conducted in the laboratory where the RFR studies were performed. The reverberation chambers used in the NTP study were fully shielded from external electromagnetic fields. No data are available to evaluate the impact of these unique circumstances on tumor rates in control animals.
- An analysis comparing all controls—historic and present—with all exposed
  animals in the present study still shows a consistently increased probability of
  developing cancer. The argument that "if the control group had developed these
  cancers at the normal levels, there wouldn't have been much to report here at all" simply
  does not hold up to scientific scrutiny.
- https://www.youtube.com/watch?v=mGbssctlJWQ&feature=youtu.be

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Myth: Since only the rats exposed to super high radiation levels had increased cancer, it must be perfectly safe to use our cell phones which emit a "safe" level of radiation.

# Fact:

- Testing for the absence of an effect requires a completely different study design
  and uses different methods of statistical analysis than were employed in the NTP
  study. Moreover, any discussion of safe exposure levels is not supported by the data.
  Such safety inferences have no scientific basis. The NTP study was not designed to
  determine a safe exposure level, but rather was setup to determine if non-heating levels
  could induce cancer and/or a toxic effect.
- Adequate research to determine a safe level of radiofrequency has not been
  performed by the US Government as of yet. As of today, not a single US health and
  safety agency has determined a "safe" level of wireless radiation. Decades ago, the EPA
  initiated research and was set to issue standards when it was abruptly defunded in 1996
  (see timeline below). Contrary to a widely held belief that premarket safety testing was
  done, in fact, long term safety testing for cell phones and wireless devices was never
  done. The NTP study was initiated for this very reason.
- Timeline showing how the US EPA raised concerns and was defunded from setting safety standards.
  - 1971 U.S. Naval Medical Research Institute, Bibliography of Reported Biological Phenomena (Effects) and Clinical Manifestations Attributed to Microwave and Radio-Frequency Radiation
  - 1984: US Science Advisory Board Recommendation to the EPA: The Board recommends that the EPA develop radiation protection guidance to protect the public. In 1983 The EPA published <u>Biological Effects Of RadioFrequency Radiation</u> and in 1981 The EPA published an <u>Index of Publications on Biological Effects of Electromagnetic Radiation</u>. <u>Read the US Science Advisory Board Letter</u>.
  - 1990 draft report, Evaluation of the Potential Carcinogenicity of
     Electromagnetic Fields, contains information regarding the potential
     carcinogenicity of radiofrequency fields as well as electrical power frequency
     fields. The EPA Science Advisory Board (SAB) reviewed this draft document in a
     series of public meetings in 1991 and 1992. This draft document was not finalized
     after the SAB reported its findings but was leaked.
  - 1993, Environmental Protection Agency Letter Criticizes the Federal Communication Commission's (FCC's) proposed RF/MW radiation limits: The Letter states that certain subgroups are more at risk (pregnant women, children and the elderly) and calls for an updated, comprehensive review that considers the biological effects of RF, specifically pointing to the need to update the NCRP Report 86 (Note: NCRP 86 is still the basis for US regulations according to the FCC and has not been updated to include biological effects). Read the Letter here.
  - 1994 (U.S.) Air Force Material Command, Rome Laboratory Radiofrequency / Microwave Radiation Biological Effects and Safety Standards: A Review "It was

- recognized that the SAR does not encompass all of the important factors necessary to determine safe exposure levels. The modulation frequency and peak power of the incident EM field should also be considered. Some of the investigators warned that extra care should be taken by persons that are subjected to pulsed EM fields or by fields that are modulated near the whole-body resonance frequency."
- June 1995, the EPA announced to the FCC that the EPA would be releasing its own RF/MW radiation safety limits by early 1996. In March 1995 the EPA briefed the FCC and NTIA on the development of their guidelines on thermal and non-thermal RF/MW radiation effects. Read the 1995 EPA letter.
- September 1996 EPA Radiation Research De-Funded: The EPA Radiation
  Division that drafted the regulations to protect the public from harmful EMF was
  de-funded by the Senate Appropriations Committee, which wrote, "The
  Committee believes EPA should not engage in EMF activities".
- 1996 Federal Communications Commission (FCC) Limits Adopted:
   IEEE/ANSI C95.1 1992 were the basis of the FCC regulated exposure limits with some minor points coming from the NCRP Report 86 (1986).
- 1999: Gregory Lotz (NIOSH) Radio -Frequency Interagency Workgroup (RFIW) Letter to Richard Tell: The members of the federal RFIW identity several critical issues with the RF exposure guidelines. Their concerns include the need for a biological basis for SAR limit and they point out that the limits for brain and bone marrow should be lower than those from muscles and fat as tissues are not equally sensitive. They question the selection criteria for the adverse effect and state there is extensive data on acute effects but that the lower-level non-thermal chronic exposure effects may be very different and chronic effects need to be accounted for. They state the uncertainties in the data should be addressed. "These studies have resulted in concern that exposure guidelines based on thermal effects, and using information and concepts (time-averaged dosimetry, uncertainty factors) that mask any differences between intensity-modulated RF radiation exposure and CW exposure, do not directly address public exposures, and therefore may not adequately protect the public." Read the Letter.
- 2001:Industry Tied Scientist Becomes Whistleblower: Martin Schram and George Carlo (the scientist who lead 27 million research funded by wireless industry) publish the book *Cell Phones: Invisible Hazards In the Wireless Age* which alleges that research findings showing cell phone radiation was harmful was then "suppressed" by the Wireless Industry. Watch the C-Span Interview.
- 2002 Letter from Norbert Hankin of the EPA about the inadequacy of the FCC guidelines. His letter states that children, pregnant women and the elderly were not considered in the regulations and that the regulations were to protect against hearing damage only and did not consider long-term chronic exposure. Read it here.

- 2002: EPA States FCC limits are thermally based and do not apply to long term exposure. EPA's Norbert Hankin writes Janet Newton of the EMR Network at letter explaining the limitations of FCC RF exposure standards and states that, "the generalization by many that the guidelines protect human beings from harm by any or all mechanisms is not justified." Read the letter here.
- 2003: EPA's Norbert Hankin Letter to CK Chou from the Interagency Radio Frequency Workgroup on Additional Concerns about US RF Exposure Guidelines. The federal RFIWG writes a second letter with three additional concerns about the exposure limits. To our knowledge neither the 2003 or 1999 letter were ever responded to. Read the Letter here.
- January 2008: National Research Council Report "The Identification of Research Needs Relating to Potential Biological or Adverse Health Effects of Wireless Communications Devices" called for the critical need to increase our understanding of any potential adverse effects of long term chronic exposure to RF/microwave energy on children and pregnant woman.
- September 2008 Congressional Hearing: Health Effects of Cell Phone Use
   Please watch the C-Span Video of these hearings here.
- January 2009, The President's Cancer Panel Presented on Cell Phone Radiation: Raad the <u>PRESIDENT'S CANCER PANEL MEETING SUMMARY</u>, <u>ENVIRONMENTAL FACTORS IN CANCER</u> and <u>Dr Carpenter's testimony</u> to the President's panel was published in <u>Reviews in Environmental Health 2009</u>.
- September 2009 US Senate Hearings on Health Effects of Cell Phone
   Wireless Radiation. Please watch the video of the testimony at the C-SPAN link
   HERE.
- 2012 Government Accountability Office (GAO) Report: "Exposure and Testing Requirements for Mobile Phones Should Be Reassessed" calls on the FCC to "formally reassess and, if appropriate, change its current RF energy (microwave) exposure limit and mobile phone testing requirements related to likely usage configurations, particularly when phones are held against the body," because without such a reassessment, the "FCC cannot ensure it is using a limit that reflects the latest research on RF energy exposure."
- 2012: FCC opens Inquiry Into Human Exposure Guidelines: In response to the GAO Report, the FCC opened a proceeding to explore whether it should modify its radiofrequency exposure standards stating, "we specifically seek comment as to whether our current limits are appropriate as they relate to device use by children." Over 900 submissions have been made to the FCC. To access these papers go to the FCC's web site for Proceeding Number 13-84. To date no actions have been taken by the FCC or any other Federal agency on this docket.
- 2014: U.S. Department of the Interior Letter States FCC Guidelines are
   Outdated: "However, the electromagnetic radiation standards used by the
   Federal Communications Commission (FCC) continue to be based on thermal
   heating, a criterion now nearly 30 years out of date and inapplicable today". Read
   the 2014 U.S. Department of the Interior Letter

• Biological effects from wireless radiation are found at radiation levels thousands of times lower than government safety limits and some studies also report adverse effects even after very short time periods of exposure. For example, after only 50 minutes of cell phone radiation exposure, cell phone radiation caused an increase in glucose metabolism in the human brain in a 2011 NIH US government study. In a series of studies performed by Dr. Suleyman Kaplan's team, damage to brain cells occurred after cell phone radiation exposures of one hour a day for one month. A research review published in Electromagnetic Biology and Medicine found that among 100 peer-reviewed papers "93 confirmed that RFR induces oxidative effects in biological systems". Long term oxidative stress is known to be related to immune and inflammatory responses, carcinogenesis and metastasis, reproductive damage and even neurological diseases.

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Myth: The lower survival rate of the control group skewed the results because the control group did not live long enough to develop tumors.

# Fact:

- There was no statistical difference in survival between control male rats and the exposed group of male rats with the highest incidence of gliomas and heart schwannomas. At week- 93 of the 2-year study, survival was exactly the same in that exposure group and in control male rats. Second, no glial cell hyperplasias (potential precancerous lesions in the brain) or heart schwannomas were observed in any control rat, even though glial cell hyperplasia was detected as early as week 58 and heart schwannomas were detected as early as week 70 in exposed rats. Thus, survival was sufficient to detect tumors or precancerous lesions in control male rats
- NTP scientists carefully considered this question in their analysis. If the control rats were going to develop tumors, these precancerous lesions and tumors would have already been present. Yet not a single control had any evidence of an effect.

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Myth: The other effects found in the exposed rats such as decreased birthweight are trivial and irrelevant.

Fact: Low birth weight is *not* a trivial effect.

- If birthweight was stunted then what other developmental processes were
  stunted? Significant experimental research has shown that radio frequency exposure at
  legal levels damages brain neurons in prenatally exposed rats. The NTP study was not
  set up to investigate impacts on nervous system development so this information is not
  available from the NTP study. When it comes to the lower birthweight of NTP rodents,
  this effect constitutes an important signal that non thermal radiation levels can impair
  development.
- https://www.youtube.com/watch?v=VpwcF3Malj8

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Myth: The results are weak and confounding.

Fact:

- A doubling or tripling of risk would never be considered "weak". In his statement, Foster has misused the term "confounding". Lets consider the potential impact on humans. There are almost as many cell-phone subscriptions (6.8 billion) as there are people on this earth (7 billion). Even a small risk could eventually result in a considerable number of these lethal tumours. Studies carried out in Sweden indicate that those who begin using either cordless or mobile phones regularly before age 20 have greater than a 4-fold increased risk of ipsilateral glioma. If current young users of mobile phones face the risks shown in these case control studies, then several thousand new cases could develop annually in the U.S. alone.
- The results are strong, especially for the heart schwannomas. In the heart,
  exposure to RFR in male rats resulted in a statistically significant, positive trend in the
  incidence of schwannomas. Positive trends for a greater number of tumors at higher
  doses were observed for both tumor types. Significantly more gliomas were seen in
  males exposed to CDMA (95% confidence level). Both the trends and the replication
  make these very strong results.
- DNA damage was induced with both modulations of radiofrequency radiation (RFR) in brains of both rats and mice. In the frontal cortex of rats (CDMA) and mice (GSM and CDMA) the comet assay showed a genotoxic effect with a statistically significant trend and pairwise SAR-dependent increase. How is DNA damage "weak"?
- Yes, a "low incidence" of tumors were found, but since these are *rare* tumors, the findings are quite significant. <u>Dr. Moskowitz cites these statistics</u> which help to put it in perspective.:
  - Overall, one in 18 male rats exposed to cell phone radiation developed cancer- thirty of 540 (5.5%).
  - One in 12 male rats exposed to cell phone radiation developed cancer (glioma, schwannomas of the heart) or precancerous cells as compared to none of the 90 unexposed male rats- 46 of 540. Remember that 16 precancerous hyperplasias were diagnosed and these are known to develop into cancer in time. Had the study been a lifetime study, rather than a two year study, we likely

- would have marked these as cancers in the older rats. Rodents can live up to three years.
- o In the group exposed to the lowest intensity of cell phone radiation (1.5 W/kg), 12 of 180, or **one in 15 male rats** developed cancer or precancerous cells. In the highest exposure group (6 W/kg), 24 of 180, or **one in 8 male rats** developed cancer or precancerous cells.

Bottom line: The results provide significant *animal* evidence that cell phone radiation can cause cancer and DNA damage.

"Given the extremely large number of people who use wireless communication devices, even a very small increase in the incidence of disease resulting from exposure to the RFR generated by those devices could have broad implications for public health."

-National Toxicology Program Report

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# Response:

- It is scientifically understood that different modulations could have different biological effects. Cellular communication signals are very complex. Radiofrequency radiation with different modulations and characteristics can produce different effects even though they may produce the same pattern of SAR distribution and tissue heating. For example, there are two mechanistic studies which consider the effects of 2G and 3G signals. Statistical analysis in a study on human stem cells revealed that UMTS exposure had a stronger effect than GSM exposure (Markova et. al., 2010). In an earlier study, an analysis of impacts on the formation of DNA repair foci showed that effects were depend on carrier frequency (Belyaev et.al., 2009. These results are in line with the hypothesis that some signals may have higher biological impacts and possibly larger health risk effects than others.
- Such findings are consistent with the recent analysis by Swedish cancer researchers which found differences in human gliomas associated with different modulations of cell phone radiation. They found the lower power3G UMTS phones had a higher glioma (a type of brain cancer) risk than the higher power 2G GSM phones. More recent technologies appear to have more a more dramatic biological effect. Modulations are evolving to transmit more data faster at a given frequency, and this results in higher peak to average power ratios. In the lab, it is notable that experiments using real-life devices are much more likely to find significant effects.
- The US Federal Interagency Workgroup raised this issue in a 1999 letter citing how
  research shows different biological responses to modulated RF radiation exposures as
  compared to unmodulated exposures. Read the Letter. Currently different modulations
  are in use that were never imagined decades ago when the original research was done
  to understand human health risk.
- Decades of research has pointed to the importance of modulation in impacting human health. For example in 1994 a (U.S.) Air Force "Material Command, Rome

Laboratory Radiofrequency / Microwave Radiation Biological Effects and Safety Standards: A Review" stated "It was recognized that the SAR does not encompass all of the important factors necessary to determine safe exposure levels. The modulation frequency and peak power of the incident EM field should also be considered. Some of the investigators warned that extra care should be taken by persons that are subjected to pulsed EM fields or by fields that are modulated near the whole-body resonance frequency."

 The NTP study was designed to study both modulations precisely because the researchers wanted to understand potential effects from the different modulations.

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Overarching Myth #3: Because we don't fully understand the biology behind these results we can ignore them.

Fact: The NTP study confirms the existence of a non-thermal effect. For almost every well established carcinogen ever identified, from cigarettes to asbestos, the evidence of risk preceded our understanding of the mechanism by many years, if not decades.

Myth: There is no well understood *mechanism* by which cell phone radiation induces cancer so - *regardless of the findings*- there must be a lack of risk.

Fact: A proven mechanism is not necessary to understand data showing increased risk.

- The study indicates that a non-thermal mechanism clearly exists. The NTP study controlled for heating effects by making sure that the body temperatures of exposed rats did not increase by more than 1° C (1.9° F), suggesting that the cancers were triggered by some other mechanism.
- It could take decades before the mechanism is considered "proven". For almost
  every well established carcinogen ever identified, from cigarettes to asbestos, the
  evidence of risk preceded our understanding of the mechanism by many years, if not
  decades. The mechanisms by which smoking, for example, causes lung cancer were not
  established until the 1980's decades after the surgeon general began to warn of the
  massive cancer risks associated with smoking.
- There is now sufficient evidence that radiofrequency radiation could result in biochemical changes that alter how our cells functions and increase the oxidative stress (increasing free radicals) in our bodies leading to chronic inflammation and cancer. Several prominent scientists have published (with full documentation) on the possible mechanisms by which cell phone/wireless radiation could result in increased cancer. They explain how long-term exposure to extremely low power levels of radiofrequency fields could initiate a series of biological effects with the end result of an increased risk for cancer and a myriad of other serious health effects.

- For example, a 2016 article published in IEEE Power Electronics Magazine, scientists propose a hypothesis that long-term exposure to weak magnetic fields can lead to elevated radical concentrations and an association with aging, cancer, and Alzheimer's.
- The review article "Microwave frequency electromagnetic fields (EMFs) produce widespread neuropsychiatric effects including depression" looks at the literature over the last half-decade, concluding "in summary, then, the mechanism of action of microwave EMFs, the role of the VGCCs in the brain, the impact of non-thermal EMFs on the brain, extensive epidemiological studies performed over the past 50 years, and five criteria testing for causality, all collectively show that various non-thermal microwave EMF exposures produce diverse neuropsychiatric effects."
- A 2016 published analysis concludes "Our analysis supports a linkage between RF EMF exposure to human cells and changes in the pathways associated with apoptosis, cellular regulation, and cytoskeleton maintenance. There is weaker support for linkage to metabolic pathways and neurological pathways. Based on these linkages alone, there is reason to believe that RF EMF could play a role in carcinogenesis, metabolic disorders, and neurological development and function." (Parham et al. 2016)
- A <u>2016 published paper</u> by Dr. Magda Havas <u>When Theory and Observation</u>
   <u>Collide: Can Non-ionizing Radiation Cause Cancer?</u> states;

"Evidence of free-radical damage has been repeatedly documented among humans, animals, plants and microorganisms for both extremely low frequency (ELF) electromagnetic fields (EMF) and for radio frequency (RF) radiation, neither of which is ionizing. While IR directly damages DNA, NIR interferes with the oxidative repair mechanisms resulting in oxidative stress, damage to cellular components including DNA, and damage to cellular processes leading to cancer. Furthermore, free radical damage explains the increased cancer risks associated with mobile phone use, occupational exposure to NIR (ELF EMF and RFR), and residential exposure to power lines and RF transmitters including mobile phones, cell phone base stations, broadcast antennas, and radar installations".

 A 2016 published study Mechanism of low-level microwave radiation effect on nervous system (Hinrikus et al. 2016) aimed to explain the mechanism of the effect of low-level modulated microwave radiation on brain bioelectrical oscillations.

"The proposed model of excitation by low-level microwave radiation bases on the influence of water polarization on hydrogen bonding forces between water molecules, caused by this the enhancement of diffusion and consequences on neurotransmitters transit time and neuron resting potential. Modulated microwave radiation causes periodic alteration of the neurophysiologic parameters and parametric excitation of brain bioelectric oscillations. The experiments to detect logical outcome of the mechanism on physiological level were carried out on 15 human volunteers."

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Overarching Myth #4: Existing research invalidates the NTP findings of increased cancer and genotoxicity.

Fact: The NTP study substantiates previous research findings from human and animal research indicating increased cancer risk and DNA impacts.

Myth: Previous animal research has not shown a link between cell phone radiation and cancer.

Fact: Previous animal research has shown a link between cell phone radiation and cancer.

- In fact, previous animal studies are now replicated that indicate a carcinogenic effect, specifically cancer promotion. A 2015 study, which replicated a study done in 2010, found that weak cell phone signals can promote the growth of lymphomas, lung and liver tumors in mice. In 2013, the World Health Organization International Agency for the Research on Cancer specifically noted that "Four of six co-carcinogenesis studies showed increased cancer incidence after exposure to RF-EMF in combination with a known carcinogen".
- The two small-scale studies cited in the CNN article are incomparable to the NTP study. The 2006 "six hour a day" study cited by CNN was funded by Motorola and had an unusual set up in that the mice were sacrificed starting at 171 days (about 5.5 months) and the mice did not even live an entire year in the study. The "one hour a day" study cited was, well one hour a day and only followed animals for one and a half years. The life span of a rodent is approximately three years and the NTP study followed mice for a full two years to allow for a more adequate long term exposure. Importantly, the NTP study trumps all previous animal studies because no other animal study was as well designed and used such an elaborate set up.
- A 5 year, \$5 Million <u>U.S. Air Force study conducted in the early 1980's</u> found that significantly higher numbers of male rats exposed to low-intensity microwave radiation developed cancer in comparison to those not exposed. The Chou study exposed experimental animals to 2450 MHz, which is similar to the frequencies used for WiFi, whereas the NTP study exposed rodents to 900 MHz and 1800 MHz microwave radiation. However in the Air Force Study, the rats' average exposure was about 4-10 times *lower* than in the NTP study. Read more about this study in Dr. Moskowitz analysis. It is notable that in this study the researchers state, "Only male rats were used to minimize statistical variation, i.e., to avoid the hormonal variations characteristic of female rats. Use of female rats would have required a substantial increase in the number of animals."

• In the 1990's, Henry Lai and V.J. Singh demonstrated that low levels of microwave radiation (2.45 GHz) well below that of cell phone radiation levels could increase the frequency of single-strand DNA breaks in the brain cells of live rats. The in-vitro studies of the \$15 Million dollar REFLEX project lead by Franz Adlkofer also indicated a genotoxic effect of RF-EMFs at levels below proposed radiation safety levels. In an June 2016 interview, Professor Adlkofer commented that the NTP and Reflex study complement each other, and "intensify in their significance."

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Myth: There is no human evidence linking brain and heart tumors to cell phones.

Fact: There is human evidence linking brain and heart tumors to cell phones.

- Human data does show the same type of tumor increases. The NTP finding of increased gliomas and schwann cell tumors of the heart in rats exposed to RFR is consistent with epidemiological reports of increases in gliomas and acoustic neuromas (schwann cell tumors) among humans exposed to cell phone radiation. Research studies that examined long term heavy cellphone users have found a statistically significant increase in glioblastomas (Coureau et. al., 2014, Hardell et al., 2014, Morgan et al., 2015,) The multi-country Interphone study published findings in 2010 and 2011 with results stating higher glioma risks in heavy users. In 2016 re-analysis of Interphone data found stronger positive associations to glioma risk among long term users and heavy users (Turner et al. 2016) and a statistically significant association between the intracranial distribution of gliomas and the self-reported (possible bias) location of the phone (Grell et al. 2016).
- The <u>Swedish studies</u> and the <u>Interphone study</u> not only found elevated glioblastomas, but also higher acoustic neuromas, schwann cell tumors at the highest level of cumulative call time. The acoustic neuroma is also known as vestibular schwannoma, and it is a nonmalignant tumor of the 8th cranial nerve in humans. The NTP rats developed schwannomas- tumors of the nerve sheath but of the heart. Famous individuals diagnosed with an acoustic neuroma include <u>Mark Ruffalo</u>, <u>Tara Subkoff</u>, and <u>Lucille Lewin</u>.
- "Human evidence" was a large part of the basis for the International Agency for Research on Cancer (IARC) classification of the cancer risk of radiofrequency radiation as a Class 2B "possible" carcinogen in 2011. The IARC expert working group noted research studies which indicated brain cancer risks were increased significantly after 10 years of cellphone use, and risk levels were greatest on the side of the head on which users held their cell phones. The Class 2B classification was based on "positive associations observed between exposure to radiofrequency radiation from wireless phones and glioma, and acoustic neuroma," and for which a causal relationship was considered to be credible. Those associations were not considered to represent

- "sufficient evidence of carcinogenicity" at that time in 2011 because recall bias in the case-control studies could not be fully ruled out as a possible contributing factor.
- NIEHS/NTP presented the results at the June 8, 2016 BioEM2016 Meeting, in Ghent, Belgium stating, "Tumor types observed in this study are similar type to those observed in some epidemiology studies of cell phone users" and the study "Supports IARC conclusions of potential carcinogenic potential of RFR." (NTP BIOEM 2016 Powerpoint 27 of 32)

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Myth: Large studies such as the Million Women study and Danish study and petri dish studies reassure us there is no problem because they show no evidence.

# Fact:

- Epidemiological cohort studies, like the Danish Cohort or Million Women study, are of poor quality and it is not possible to draw any scientifically reliable conclusions from them.
- The Danish Cohort Study has been heavily criticized by scientists worldwide and was originally funded by Danish Telecom. Many scientists state that the design flaws invalidate the study's conclusions. Why? Because the heavy cell phone users, more than 200,000 corporate subscribers, who used cell phones as part of their job, were placed in the control group. The study authors state, "Because we excluded corporate subscriptions, mobile phone users who do not have a subscription in their own name will have been misclassified as unexposed." This bias explains why the 2011 World Health Organization IARC panel put less weight on the Danish study than on the Interphone and Hardell efforts. The International Agency for the Research on Cancer's Robert Bann wrote that the exclusion of the corporate subscribers for the Danish Studies "seems remarkable" and "could have resulted in considerable misclassification in exposure assessment."
- The Million Women Study has been criticised for a short observation period, bias and crude exposure assessment. The researchers did not assess how much time the women spent on a cell phone either before or during the course of the study, so women who spent merely a few minutes almost every day at baseline would be lumped together with women who used their phone one half hour or more per day. Despite these major shortcomings, the study actually reported a statistically significant doubling of risk of acoustic neuroma, a tumor on the nerve from the ear to the brain, among those who had used their cell phone for 10 or more years.
- Cohort cancer studies are only reliable if they adequately capture the long latency
  period for cancer development as well as the actual characteristic of cell phone
  use by individuals in these studies (e.g., use of speakers, head sets, frequency and
  duration of calls, type of phone, etc.). Exposure misclassifications in cohort studies such
  as those found in the Danish Cohort and Million Women study tend to increase the
  chances of a negative result.

• The four year <u>REFLEX studies</u>, involving 12 groups from 7 European countries, studied the effects of radiation on animal and human cells in Petri dishes. They found GMS-modulated mobile phone radiation caused DNA strand breaks in isolated human fibroblasts and granulosa cells from rats and proved the presence of damage with the Comet Assay. Similar results were obtained with UMTS-modulated mobile phone radiation, the genotoxicity of which seems to be even higher than that of GSM. The NTP study used the same assay tests and found similar DNA damages in specific organs of the exposed male and female rats and mice.

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Myth: The lack of an epidemic of brain cancer demonstrates that cell phones pose no risk of brain cancer.

### Fact:

- It will take decades to see an epidemic of brain cancer in the general population because brain tumors have a very long latency period. While cell phones have been around for decades, the majority of cellphone users have only recently become heavy users, so it is not likely that a large overall increase in incidence rates will have appeared yet.
- In fact, the most aggressive types of brain cancers and those types specifically associated with cell phone use (the types which NTP rats developed) are rising. According to the American Brain Tumor Association's largest, most comprehensive analysis to date, the incidence of the most aggressive gliomas (a category of brain tumors) are rising in adolescents and young adults within the US. The ABTA study shows increased yearly incidence of the following brain tumors: anaplastic astrocytoma, tumors of the meninges, tumors of the sellar region and unclassified tumors. Glioblastomas, the type of brain cancer found to be linked to cell phone radiation in the NTP study and in human studies, are increasing in those aged 15-39 in the United States. International registries have also indicated an increase (Zada et al. 2012, Danish Cancer Society Press Release, Ho et .al., 2014 and Dobes 2011). These increases are not evident in population based research studies when the incidence of all brain cancers "overall" are considered. These increases are only evident when you break down the statistics into specific tumor type.
- Case control research is a more useful study design than population trends at this time and these studies do show an association between cancer and cell phone use. Population wide based studies are not the best way to assess the link between cellphones and cancer until at least another decade from now (cell phones and wireless have only fully saturated society for a little over a decade). Research looking at high-risk groups using case-control designs are more suited to showing cancer risk from cell phones and they have found an association. All independent research using case control

design examining long term (greater than ten years) cell phone use have showed increases in brain cancer associated with long term cell phone use.

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Myth: A recent Australian study showed there is no rise in brain cancer so this NTP study must be bogus.

#### Fact:

- The widely publicized article claiming that cell phones are safe by the Australian sociologist Simon Chapman has been critiqued by a series of published articles. Scientists are calling for a retraction of the Australian study because of a number of errors, false assumptions and cherry-picked data. Newly published appraisals (Bandara 2016, Morgan 2016, Wojcik 2016) debunk the claim by Chapman et. al. that "After nearly 30 years of mobile phone in Australia among millions of people, there is no evidence of any rise in any age-group that could be plausibly attributed to mobile phones."
- Examples of concerns raised about the study:
  - The paper referred to an Australian paper but failed to report the full statement that found a significant increasing incidence in glioblastoma.
  - The scientists also point out that Chapman does not analyze information on actual minutes of mobile phone use by a person, but rather estimates this based only on the number of mobile phone subscriptions.
  - Clinical director and forensic expert Damian Wojcik of New Zealand wrote that the Chapman study fails to take into account evidence that the locations of brain tumors that are increasing in the young are precisely those locations associated with mobile phones.

"By showing only that part of the data that supports his view, Chapman is playing fast and loose with science and putting us all at grave risk," stated Devra Lee Davis, "He basically ignores rising brain cancer rates in the U.S. and Australia that have grown rapidly in those under age 65 that have incurred the greatest use of phones for the longest time. Instead he points to the lack of an overall population increase in the disease as proof phones have no effect."

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Overarching Myth #5: Experts overwhelmingly have discredited the study results and conclude it to be irrelevant.

Fact: The <u>majority</u> of NIH scientific reviewers to the NTP dataset believe the findings are valid and that the radiation exposure is related to the cancer.

Myth: NIH's own reviewers could not accept the study conclusions.

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Fact: The majority of NIH scientists who reviewed the data agreed with the study conclusions.

- Dr. Lauer's comments are incorrectly presented as representing the general tone of scientific reception to the study. In fact, Dr. Lauer's review comments were comprehensively and scientifically rebutted in the NTP report itself (in the section entitled NTP Responses to NIH Reviewer's Comments, page 67-74). It is standard process to solicit peer reviews, then to explain the analysis or make changes if necessary in response to the critiques and this process is fully documented in the NTP report. The repeated presentation of Dr. Lauer's review statements without explaining the review process and NTPs later response to the statements paints an inaccurate depiction of the scientific discourse on the study.
- The <u>majority</u> of NIH scientific reviewers to the NTP dataset believe the findings are valid and that the radiation exposure is related to the cancer. The NTP study had three panels of reviewers rather than the usual one panel. Dr. John Bucher, Director of the National Toxicology Program Division, has repeatedly stated in his presentations of the NTP study that "the majority" of reviewers agreed with the analysis. <u>Watch the NIEHS video presentation in June 2016.</u>
- Dr. Michael Lauer's criticisms have been invalidated by not only the NTP (in their response to his statements) but also by experts.
  - Or. Melnick responded to one of Dr Lauer's statements in the Hebrew University Press conference that "One comment was made that the study had low statistical power and that might lead to a false positive. I'm not sure if that was a misstatement by the reviewer because low statistical power means there's a high probability of accepting the null hypothesis even when a true effect may exist. That is, there is a greater chance for a false negative rather than a false positive if there is low statistical power."
- Despite these facts, Dr. Michael Lauer's comments have repeatedly and incorrectly been presented as evidence of a flawed study. The New York News article headline misleadingly states, "National Institutes of Health expert reviewers are finding flaws in the agency's new study that connects heavy cell phone radiation to a slight increase in brain tumors in male rats."

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Background: Aaron Carroll, a pediatrician at the Indiana University School, authored a New York Times column titled "Why It's Not Time to Panic About Cell Phones and Cancer." Following his publication in the New York Times, his column has been cited numerous times as "proof" by an "expert" that the NTP study is fundamentally flawed. However, he presented multiple inaccurate and misleading statements regarding the NTP study results and when concerns were raised by experts, the New York Times refused to publish the concerns nor correct the false statements.

Myth: The New York Times review of the NTP study proves the study is bad.

Fact: Dr. Carroll's column contained 8 serious false and misleading statements prompting a response from Dr. Ronald Melnick, who led the NTP study' design team. Dr. Melnick sent the New York Times a letter going point by point through Carroll's column pointing out each of the false and misleading statements. The New York Times responded that "We do not see anything in the article that needs to be corrected" and did not print Dr. Melnick's letter. The full email exchange between Dr. Melnick and the New York Times is available to read.

Read the Letter by Ronald Melnick PhD sent to the New York Times Correcting New York Times Misinformation About the NTP Cell Phone Radiation Study.

I am compelled to write this letter because of the numerous incorrect and misleading statements made by Aaron Carroll, a pediatric professor at Indiana University School of Medicine (<u>Upshot</u>, <u>New York Times</u>, <u>May 31, 2016</u>) in his critique of the cell phone study conducted by the National Toxicology Program (NTP).

- 1) The statement that the NTP report had been "shopped for review, but had not been accepted by any editors" is blatantly wrong and makes one wonder where Carroll obtained such false information or did he simply decide to make up his own facts.
- 2) While Carroll notes that this was a study in rats, he neglects to note that every known human carcinogen induced tumors in animals when adequately tested. Animals are used as models in toxicity and carcinogenicity studies because it is unethical to intentionally expose humans to agents that might cause an adverse health effect such as cancer that has a long latency period between exposure and manifestation of disease.
- 3) The finding of significant increases of cancer in male rats but not in female rats is presented as contempt of the data; however, Carroll neglects to note that such findings are common in animal studies especially at sites that have higher background rates in male rats than females. This gender difference might be a consequence of low statistical power, an issue that I comment on below.
- 4) Carroll claims that control rats "dying early could be responsible for all the significant results of the study." This statement is wrong for at least two reasons: First, there was no statistical difference in survival between control male rats and those exposed to CDMA at 6 W/Kg (the group with the highest rate of gliomas and heart schwannomas); at week 94, survival of rats in these two groups were the same. Second, no glial cell hyperplasias (potential pre-cancerous lesions) or heart

schwannomas were observed in any control rat, even though glial cell hyperplasia was detected in a CDMA-exposed rat as early at week 58 and heart schwannomas were detected as early as week 70 in exposed rats.

- 5) Carroll seems to endorse the incorrect view that because the study had low statistical power, it is likely to have "an increased risk of being a false positive." However, having low statistical power means that there is a greater chance for a false negative rather than a false positive result. That is, there is a high probability of accepting the no-effect hypothesis even when a true effect exists.
- 6) Carroll warns against accepting results from the NTP study, which he refers to as an "imperfect rat study." He is probably unaware that the design of this study was presented at an annual meeting of the Bioelectromagnetics Society prior to the start of these studies. The overwhelming opinion expressed by the meeting participants was that this would be the largest and most comprehensive study in animals exposed to cell phone radiation, and that the results from this study would trump all other animal carcinogenicity studies of this agent.
- 7) Carroll criticizes the usefulness of human case-control studies while praising cohort studies. Actually both types of studies are important, though each has its own limitations. Carroll neglects to note that cohort cancer studies are reliable if they adequately capture the long latency period for cancer development as well as the actual characteristic of cell phone use by individuals in these studies (e.g., use of speakers, head sets, frequency and duration of calls, type of phone, etc.). Exposure misclassifications in cohort studies tend to increase the chances of a negative result.
- 8) While Carroll argues against a relationship between brain cancer and cell phone use because the incidence of brain cancers have not increased in the United States since the late 1980s, he neglects to note that unfortunately the incidence of highly lethal glioblastomas has increased during that same time period.

In my view, a pediatrician would be acting irresponsibly if he or she knew and understood the implications of the human and animal cancer data on cell phone radiation and did not offer precautionary advice to the parents of his or her patients.

# —Ronald L Melnick, PhD

Ronald L Melnick, PhD, led the design of the NTP/NIEHS Rodent Study. Melnick was a Senior Toxicologist and Director of Special Programs in the Environmental Toxicology Program at the National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health, and is now retired.

In response to Dr. Melnick's letter the New York Times editor wrote this response Jun 8, 2016, at 11:24 PM, Darlin, Damon wrote:

Mr. Melnick,

Aaron Carroll forwarded your letter to me. I was one of the editors who worked on the piece with Aaron. Thank you for taking the time to write to us about it. We read through your concerns carefully and discussed each point with Aaron. We do not see anything in the article that needs to be corrected.

I see you have also submitted this to our letters editor. We at The Upshot have no role in their decisions to print the letter or not.

All the best.

Damon Darlin
Editor, The Upshot
The New York Times

#### Ronald Melnick PhD then sent a letter to Damon Darlin of the New York Times

Mr. Darlin

I find it appalling that the NY Times printed the op-Ed by Aaron Carroll on health effects of cell phone radiation that had numerous inaccurate and misleading assertions, while denying my submission that attempted to correct many of the incorrect statements in that article. The fact that you allowed the author of that op-Ed (who obviously has no background in toxicology) to reject my comments because you and he did not see anything in his article that needed to be corrected is not only absurd, but is also a disservice to the readers of the NY Times.

Sincerely,

Ronald Melnick, PhD, Retired Senior Scientist, National Toxicology Program, National Institute of Environmental Health Sciences, National Institutes of Health

• Dr. Carroll has no expertise in electromagnetic fields or understanding rat bioassays, and his misleading and non factual New York Times article was not peer reviewed science. Yet it is being presented as an "expert" opinion. In fact,

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Carroll's research instead focuses on integrating information technology into health care. For example, he has published on the use of <a href="mobile">mobile</a> phones in diabetes management, and issues in adopting <a href="health information technology">health information technology</a> and integrating <a href="health-information technology">computerized</a> clinical decision <a href="mailto:support systems">support systems</a> into clinical practice.

Caroll again cites the NTP study in a <u>JAMA Forum opinion piece</u> stating, "This is how we can have <u>headlines proclaiming that cell phones cause cancer</u> because of a new small study, regardless of how much data and evidence that we already have that don't fit with those findings." Such a statement seems to be referring to the NTP as a "new small study" yet again perpetuating myths about the study being small.

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Myth: The NTP study has been fully discredited by scientists and experts due to major flaws.

#### Fact:

• The National Toxicology Program (NTP) of The National Institutes of Health animal toxicology research is considered the "gold standard". The NTP, established by Congress in 1978 is internationally renowned for its research and toxicological studies, which are used by federal and state regulatory agencies to protect the public from exposure to toxic and carcinogenic substances. Worldwide experts were brought in to validate the exposure setup. Statements that the NTP work is "poor quality" and "failing to meet basic principles of toxicology" are unfounded at best.

"This report from the National Toxicology Program is good science... they convened not one but three panels to look at abnormal tissues from treated animals to ensure that what was identified as a brain and heart tumor was indeed a brain and heart tumor; they solicited review from multiple scientists from outside the NTP to critically review all aspects of the data analysis and study findings, to ensure the findings would stand up to the critical assessment expected once these unexpected findings were released." - Otis W. Brawley, M.D., American Cancer Society Chief Medical Officer

- There is not "overwhelming epidemiology data which contradicts these findings" but quite the contrary. The findings of brain tumors (gliomas) and malignant schwann cell tumors of the heart in the NTP study present a major public health concern because these tumors occurred in the same types of cells in rodents that had been reported to develop into tumors in humans in several epidemiological studies of long term cell phone users.
- A generalization that the NTP study is "discredited by scientists" is false and
  misleading. For example, the <u>Bloomberg</u> article was cited in the Linked-In post as proof
  of this despite the article being penned by Faye Flam, a columnist (not a scientist) who
  focuses on sex and evolution and her <u>review of the NTP</u> where she describes it as "just
  another study" with "just a few rats" propagates most of the myths addressed about the

NTP study on this very page. The majority of NIH reviewers to the NTP study data agreed with the study conclusion.

• Read responses to the NTP study by experts:

<u>Dr. Otis W. Brawley</u>, Chief Medical Officer of the American Cancer Society "For years, the understanding of the potential risk of radiation from cell phones has been hampered by a lack of good science. This report from the National Toxicology Program (NTP) is good science."

<u>Dr. Jennifer A. Lowry</u>, Chair of the American Academy of Pediatrics Council on Environmental Health Executive Committee

Dr. Elisabeth Cardis, the Barcelona Institute for Global Health

Dr. Franz Adlkofer, the Pandora Foundation

Dr. Joel Moskowitz , University of California at Berkeley

Dr. Gautam Khurana, CNS Neurosurgery

Dr. Dariusz Leszczynski, Chief Editor of 'Radiation and Health'

<u>Dr. Chris Portier</u>, former Director of the Environmental Toxicology Program (ETP) at the NIEHS and Associate Director of the NTP

EMF Scientists Appeal, 223 scientists that have published in the field

Dr. Eitan Kerem, Chair of Pediatrics, Hadassah Hebrew University Hospital

 The <u>majority</u> of NIH scientific reviewers to the NTP dataset believe the findings are valid and that the radiation exposure is related to the cancer. The NTP study had three panels of reviewers rather than the usual one panel. Dr. John Bucher, Director of the National Toxicology Program Division, has repeatedly stated in his presentations of the NTP study that "the majority" of reviewers agreed with the analysis. <u>Watch this</u> <u>stated in the NIEHS video presentation in June 2016.</u>

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Overarching Myth #6: This study still needs to be replicated before it will have an impact on federal regulations or health recommendations to the public.

Fact: This \$25 Million dollar study one of the most elaborate studies of any potentially hazardous exposure ever conducted. The concordance between the NTP study and human epidemiological studies is stunning and should guide federal agencies to issue protective policy and strong recommendations to reduce exposure.

Myth: This study needs to be replicated first- until then, it will not have an impact. Fact: This \$25 Million dollar study one of the most elaborate and expensive studies of any potentially hazardous exposure ever conducted. It will likely not be repeated as the exposure equipment has been dismantled. The concordance between the NTP study and human epidemiological studies is stunning. In addition, NTP also reported statistically significant evidence of DNA damage in mice as well as in rats.

- This is one of the most elaborate and expensive studies of any potentially hazardous exposure ever conducted. It will likely not be repeated and there is little scientific reason to do so. The history of science is rich with single studies that have changed our way of thinking. Most importantly, the concordance between the NTP study and human epidemiological studies that have found evidence of a cancer risk (with the same types of cancers shown in the NTP rats) is stunning. The NTP study cost \$25 million dollars. There is nothing small about it. It is the largest, most thorough and meticulously conducted animal study ever conducted. The design of the NTP study was presented at an annual meeting of the Bioelectromagnetics Society prior to the start of the NTP study and Ron Melnick PhD states of that day, "the overwhelming opinion expressed by the meeting participants was that this would be the largest and most comprehensive study in animals exposed to cell phone radiation, and that the results from this study would trump all other animal carcinogenicity studies of this agent."
- The results show a significant effect of DNA damage. Not only did cancer rates
  significantly increase in male rats, the NTP also reported statistically significant evidence
  of DNA damage from nonthermal exposure to cellphone radiation in mice as well as in
  rats. (male rats: frontal cortex, hippocampus, liver, blood; male mice: frontal cortex;
  female rats: frontal cortex; female mice: liver, blood.)
- The NTP study will never be replicated as the exposure equipment no longer exists. The reverberation chambers have been dismantled. The NTP equipment, design and costs associated with validating the radiofrequency exposures cost roughly 10 million dollars alone.

"Based on this new information, regulatory agencies should make strong recommendations for consumers to take precautionary measures and avoid close contact with their cell phones (use speaker, headset, text —not while driving), and especially avoid use of cell phones by children. The recommendation to take precautions "if you are concerned" is inadequate."

- Ronald Melnick, Ph.D. senior toxicologist in the Environmental Toxicology Program at the National Institute of Environmental Health Sciences when he led the design of the NTP studies on cell phone RFR. He is now retired.

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Myth: The NTP study is not groundbreaking and will have little impact on federal health agency recommendations.

Fact: The NTP report marks a paradigm shift in our understanding of radiation and cancer risk.

• The NTP report will have an impact on federal health and safety agency recommendations because it shows that federal radiation exposure limits are based on a flawed assumption.

The NTP findings indicate our federal exposure limits are not protective of human health. If cell phone radiation were safe then we should have seen *no effect* from these exposures. The NTP tested the hypothesis that low level cell phone radiation -at non thermal levels- could *not* cause health effects. Yet a health effect was shown. This is groundbreaking because US government exposure limits are based on the now disproved hypothesis that non-thermal effects are benign. The study results clearly show that cell phone radiation can cause adverse health effects at nonthermal levels. In order to adequately protect the public, federal agencies should now reassess federal exposure limits to protect the public from non thermal effects.

"The NTP report linking radiofrequency radiation (RFR) to two types of cancer marks a paradigm shift in our understanding of radiation and cancer risk" and "This new evidence will undoubtedly factor into ongoing assessments by regulators to determine the potential cancer risk posed by cell phones. The American Cancer Society eagerly awaits guidance from government agencies, like the U.S. Food and Drug Administration (FDA) and the Federal Communications Commission (FCC), about the safety of cell phone use."

- The American Cancer Institute Press Release

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#### Facts:

- The NTP findings were reviewed by expert peer reviewers selected by NTP and the National Institutes of Health. These expert reviewers gave comments included as appendices to the NTP report, and as a result revisions to the current document incorporated and addressed these comments. Page 32 of the NTP Report lists the reviewers:
  - o Diana C. Haines, D.V.M., Frederick National Laboratory
  - o Michael S. Lauer, M.D., Office of Extramural Research, NIH
  - o Maxwell P. Lee, Ph.D., Laboratory of Cancer Biology and Genetics, NCI,
  - Aleksandra M. Michalowski, M.Sc., Ph.D., Laboratory of Cancer Biology and Genetics, NCI
  - R. Mark Simpson, D.V.M., Ph.D., Laboratory of Cancer Biology and Genetics, NCI
  - Sixth reviewer's name and comments are withheld.
- The NTP also clearly states the charge of these reviewers is to peer review:
  - "Charge: To peer review the draft report, statistical analyses, and pathology data and comment on whether the scientific evidence supports NTP's conclusions) for the study findings."
- The NTP also extensively involved outside pathologists including pathologists with extensive experience in human brain tumors.

They solicited review from multiple scientists from outside the NTP to critically review all aspects of the data analysis and study findings, to ensure the findings would stand up to the critical assessment expected once these unexpected

findings were released." - Otis W. Brawley, M.D., American Cancer Society Chief Medical Officer

- The NTP typically publishes results of toxicology studies in detailed technical reports. These reports are available on the NIEHS site.
- The NTP study will likely result in numerous published papers in medical journals and several manuscripts are being prepared for publication. The NTP Report states:

"These manuscripts describe in detail the designs and performance of the RFR exposure system, the dosimetry of RFR exposures in rats and mice, the results to a series of pilot studies establishing the ability of the animals to thermoregulate during RFR exposures, and studies of DNA damage."

Capstick M, Kuster N, Kühn S, Berdinas-Torres V, Wilson P, Ladbury J, Koepke G, McCormick D, Gauger J, Melnick R. A radio frequency radiation reverberation chamber exposure system for rodents.

Yijian G, Capstick M, McCormick D, Gauger J, Horn T, Wilson P, Melnick RL and Kuster N. Life time dosimetric assessment for mice and rats exposed to cell phone radiation.

Wyde ME, Horn TL, Capstick M, Ladbury J, Koepke G, Wilson P, Stout MD, Kuster N, Melnick R, Bucher JR, and McCormick D. Pilot studies of the National Toxicology Program's cell phone radiofrequency radiation reverberation chamber exposure system.

Smith-Roe SL, Wyde ME, Stout MD, Winters J, Hobbs CA, Shepard KG, Green A, Kissling GE, Tice RR, Bucher JR, Witt KL. Evaluation of the genotoxicity of cell phone radiofrequency radiation in male and female rats and mice following subchronic exposure.

(Page 2 of the NTP Report)