

NTP CELL PHONE RADIOFREQUENCY MEDIA TELEBRIEFING

**05/27/16
12:00 pm ET**

Operator: Good afternoon and welcome to today's briefing from the National Toxicology Program about their cell phone studies.

At this time, all participants are in a listen-only mode. Later, you will have the opportunity to ask questions during the question and answer session. You may register to ask a question at any time by pressing the star (*) and one (1) on your touchtone phone. Please note this call is being recorded.

It is now my pleasure to turn today's program over to Dr. John Bucher the Associate Director of the National Toxicology Program.

John Bucher: Thank you. Hello and thank you for joining the call. I'm Dr. John Bucher. I'm the Associate Director of the U.S. National Toxicology Program. I'm joined today by Dr. Michael Wyde, toxicologist for the NTP Cell Phone Radiofrequency Radiation Studies.

The National Toxicology Program is an interagency program headquartered at the National Institute of Environmental Health Sciences, which is part of the National Institutes of Health. The Food and Drug Administration and the National Institute for Occupational Safety and Health of the CDC are also participating agencies in the NTP. One of our charges is to perform comprehensive toxicology studies on agents of public health concern. These are typically done in response to nominations to our program from a variety of sources.

The FDA nominated radiofrequency radiation through our program for study. Today we posted a report of partial findings from studies on the

potential for health effects from radiofrequency radiation. These studies involve frequencies and modulations used in the United States telecommunications industry. These have been some of the most technically challenging studies that we've ever attempted and we've worked with experts from the National Institute of Standards and Technology here in the United States and the ITIF Foundation in Switzerland to design, engineer, build, test, and monitor our radiofrequency radiation exposure systems and facility.

The actual animal exposures were carried out at IITRI laboratories in Chicago. The studies were conducted in three phases. First, pilot studies were done to determine exposure levels that did not compromise the ability of the experimental animals to maintain normal body temperatures. As you may know, radiofrequency radiation generates heat when absorbed by the body. These studies were followed by short-term studies determining exposure levels that did not affect the normal growth and development of rats and mice. And finally, we performed studies in which pregnant rats and their offspring and young adult mice were exposed to radiofrequency radiation for the better part of their lifetimes.

Those of you who've been following this issue know that a working group for the International Agency for Research on Cancer concluded that radiofrequency radiation was a possible human carcinogen. Our report released today outlines small increases in tumors in male rats of types similar to those found in some of the human epidemiology studies that led to the IARC conclusions. There were no increases in tumors in our studies at these sites in female rats, and our studies in mice are still under review.

We are releasing these findings at this time because we believe they may contribute to the long-standing discussion over the potential for health

effects of radiofrequency radiation. We've provided this information to our federal regulatory agency partners and I'd emphasize that much work needs to be done to understand the implications, if any, of these findings for the rapidly changing cellular telephone technologies that are in use today.

Thank you and with that, Michael and I are happy to take your questions.

Operator: At this time if you would like to ask a question, please press the star (*) and one (1) on your touchtone phone. You may withdraw your question at any time by pressing the pound (#) key. Once again to ask a question, please press the star (*) and one (1) on your touchtone phone.

We will take our first question from Seth Borenstein, Associated Press. Please go ahead, your line is open.

Seth Borenstein: Yes, thank you for doing this. Oh, there are so many questions. Let's start with the control group here. Why did you not see any tumors among the control groups in the rats? If historical control incident in NTP studies for this is 2%, would the 3% that you see in male rats be statistically significant? Can you explain why the cell phone radiated rats lived longer than the control rats?

I guess this all brings up to sort of the thing that Dr. Lauer said in your review, false positive findings. There seem to be an awful lot of questions that your reviewers find in here, especially on this. Can you respond to these on why these seem significant to you?

John Bucher: So, many of the things that you've – all of the things, in fact, that you've mentioned have been the subject of very intense discussions here and as you can tell, among the reviewers of our studies.

The results of our studies are far from definitive at this point. We've had internal deliberations that have consistently led to groups of people having about a 70% to 80% of the people that look at this study feel that there is a significant association between radiofrequency radiation and the tumors and the outcomes that we see in the study.

This is not a universal conclusion, as you can tell by the reviewers' comments. Some of the specific aspects related to the control and the other experimental findings are at this point really not able to be determined, but we have, in fact, taken those into consideration in our finding that overall we feel that the tumors are, in fact, likely to be related to the exposures.

Seth Borenstein: And you don't think there are warning flags with the control issues?

John Bucher: I think these things all have to be taken into consideration when we decide how significant these findings are. These are unusual tumors in the brain. These are not particularly well-understood. In our studies, you'll notice that there were increases also in hyperplasias in these various tumor sites and these hyperplasias are, in fact, fairly rare and they also do sort of add to our conclusion that, in fact, these tumors are related.

Seth Borenstein: But would it be statistically significant if the control group had the 2% incidence?

John Bucher: I think that the statistical significance always diminishes when one adds tumors to the control groups. But in this particular study, there were no

tumors in the control groups in either the heart or the brain and this was using control groups that are usually – there are about twice the number of animals that are in our typical control groups.

Seth Borenstein: Thank you.

Operator: Our next question comes from Jeneen Interlandi with Consumer Reports. Please go ahead, your line is open.

Jeneen Interlandi: Can you speak a bit why there's only a partial release of the results today? So why would we hold the rest of the results until 2017? And then also will there be any effort to replicate these studies with 3G or 4G technology?

John Bucher: Well, let me first answer the replication question. These were enormously time-consuming and expensive studies and it's – I can't say that there would never be a replication of these studies, but I think it would be unlikely in the near future that anybody would undertake this type of a program.

The studies are very large and that's one of the reasons that it's unlikely anybody would do this again. They have over 7,000 animals in these studies. Each animal generates about 40 tissues that are going to be evaluated, that have to be evaluated pathologically.

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 – and it's going to be a long time before we can

process and evaluate and confirm the findings from the rest of the studies. So this is why we're releasing this report of partial findings today.

Jeneen Interlandi: Thank you.

Operator: Thank you and we'll take our next question from Ryan Knutson with Wall Street Journal. Please go ahead, your line is open.

Ryan Knutson: Thank you. I wanted to clarify the amount of exposure that the rats were given. If you could put maybe sort of in layman's terms the amount of cell phone usage that would be equivalent in a person, 1.5 watts per kilogram is the ceiling limit, if I understand correctly that the FCC has, so what would 3 watts per kilogram and 6 watts per kilogram be equivalent to?

John Bucher: This is one of the issues that we are currently discussing with our federal agency partners. There are a number of differences in the way these studies were done with respect to the exposures to the animals versus the way a cell phone would be used. These exposures were done to whole body of the animals and that, of course, is somewhat different than the exposure that one would receive from a cell phone, which would be to a much smaller part of the head if you're using it next to the ear.

The cell phone regulations currently allow 1.6 watts per kilogram and that is in a small area of the head next to the ear when the phone is being held next to the ear. The equivalent, if you would, I guess of whole body exposures would be that the entire body would be receiving the 1.5 as in the low dose, the low exposure level in our studies. 3 and 6 watts per kilogram were chosen because we wanted to go higher than the current permitted level but we wanted to stay within the what we call the non-thermal region, which is a region in which the animals could still maintain

their body temperature within a degree, 1 degree centigrade of the normal temperature. So when one goes higher than the 6 watts per kilogram particularly in rats, then the body temperature start to rise and that would be unacceptable in this particular study.

Ryan Knutson: Great, thanks. And then if I could just reason one more, could you talk about the female rats and why there didn't seem to be a link [in] female rats but there was in male rats?

John Bucher: Well, it's very difficult to explain why something doesn't happen. [Laughter] The findings were, in fact, that we saw fewer tumors. There were a couple of tumors in the female rats in the organs that we're interested in in the male rats, in the brain and the heart but these were not statistically significant. These tumors occur usually at a lower level in control females than in males and that may have something to do with it, but we can't explain those findings at this time.

Operator: Our next question comes from Maggie Fox with NBC News. Please go ahead, your line is open.

Maggie Fox: Thanks. I'd just like to explore a bit more why you decided to release partial findings. Can it be expected that the full results and the full analysis of what you found will answer some of these questions, and can you also talk about the uncertainties of working with particular strains of lab rat? Thanks.

John Bucher: Well, again I'll start with the last question. There are many uncertainties with respect to dealing with certain strains of lab rats and lab mice. We do know that they have individual susceptibilities that differ across this frame. The Sprague Dawley rat is a typical strain that's used in many

toxicology evaluations and there's a long history of use of this animal in toxicology studies. So if one picks a strain, one needs to pick one that you have some familiarity with so that's why we did that.

With respect to the release of partial results, again we feel that these findings are potentially of interest to the discussion over the cell phone safety issues. One of the things that's been – and obviously a topic of concern for many, many years for many people is that non-ionizing radiation cannot cause biological effects at levels that do not also cause heating of tissues. And in this study, we did keep our exposures down to the levels that did not cause significant heating in tissues and we have the potential for findings that would contribute to the discussion of whether the human brain tumors and acoustic neuromas which are a form of schwannoma, also called vestibular schwannoma. So if there is some relationship to the schwannomas that we see in the heart in our studies. If in, in fact, that these results could contribute to that discussion, we felt it was important to get that word out.

Maggie Fox: Thank you.

Operator: Our next question comes from Carina Storrs with CNN Health. Please go ahead, your line is open.

Carina Storrs: Hi, thanks for taking my question. I wanted to revisit a bit the question of the finding that the results wherein you found statistically significant results in male rats but not female rats, and I am curious has this been suggested in epidemiological studies that females, there seems to be less of a link between females and males in people and these tumors for those studies that have found links?

John Bucher: I'm not aware if that has been evaluated and I've never seen a publication that has addressed that issue, so I can't say that that's the case or not the case. I will say that it's not uncommon at all in our toxicology and cancer studies to see such differences in responses to tumors, so this is not unusual. It's not often explainable but it's not unusual.

Carina Storrs: If I could ask one more question, I think you did see a suggestion that there is a link between the exposure and lower birth weights in the pups and I'm curious there if it suggests that at certain dosages there could be effects on the growth and development of the rats?

John Bucher: We didn't report an effect on the birth rates with the...

Carina Storrs: I'm sorry, birth weight.

John Bucher: Yes, the birth weight, yes. They were slightly lower and this sometimes happens in toxicology studies. We did note that and the important part of that, though, is that once the animals are born, even if they're at a lower birth weight, they tend to gain weight at the same rates as the other control animals and they just sort of maintain a body weight that's slightly lower than that of the controls throughout the study. Or sometimes they catch up.

Carina Storrs: Okay, thank you.

Operator: We'll take our next question from Warren Cornwall with Science. Please go ahead, your line is open.

Warren Cornwall: Hi, thank you for doing this. I have two questions. One is that the report notes that there was a pretty low survival rate for the rats in the control group and I'm wondering if you can explain whether there is something in

particular that might have led to that. And then I'll follow-up with my other question after that.

John Bucher: So the control rats, the control survival of the male rats was a little bit low in comparison with other studies that we've done with this particular strain. We have not yet finished the complete evaluation of all of the pathology findings from these studies and it's conceivable that we will find a potential cause of the earlier mortality in the controls. But at this point, we don't really have any indications as to why that happened. And [Crosstalk] the other question.

Female: [Wait, she didn't ask him yet.]

Warren Cornwall: Yes, so the other question was you were talking earlier about the amount of exposure that people might get when they're talking on a cell phone compared to the whole body exposure of these rats and I guess I'm wondering if you can talk a little bit about for purposes of a study looking at whether or not something is carcinogenic, how do you translate the results where you have whole body exposures for nine hours a day at radiation levels four times above what you might get next to your head with a cell phone? How do you translate that to humans?

John Bucher: So this is exactly the issues that are being discussed currently among the agencies who we share this information with. The whole body exposure as I indicated earlier gives the 1.5 or 1.6 watts per kilogram to all of the organs. One of the reasons for this is that we have no real sense of whether organs other than those that might have responded in this particular study may be more sensitive or less sensitive to radiofrequency radiation. Many people hold their cell phones at various places around their body. Women have been known to put their cell phone in their bra and exposures may not

always be to the head, so we wanted to do some studies that addressed all tissues, to the extent possible, and then of course that leaves the issues of relating the whole body exposure to the exposure next to the ear or in the head. So, sorry.

Warren Cornwall: True and I was – also the fact that they were exposed nine hours a day for their entire life, again how do you connect that with how humans are typically exposed, the amount of exposure they have?

John Bucher: Well, again we could easily do a study – alright, Europeans have also done some similar studies of this nature using a different technology. They did some studies earlier in starting around 2000 where they exposed animals in small tubes to hold them immobilized and had them arrayed around a central antenna in what's called a Ferris wheel type exposure system. To maintain exposures where the animals did not heat overly, their body temperature would not go up too much, that required the exposures to only 4 watts per kilogram and they could only expose the animals for two hours a day.

When you consider the amount of time that people are spending on cell phones and the way that they're using them, we couldn't predict that these particular studies were going to be an adequate assessment of the potential use of cell phones now and in the future. So we wanted to make sure that the studies that we did, considering how expensive and time-consuming they were, examined possibilities for exposures that were beyond that that were examined in the European studies.

Warren Cornwall: Okay, thank you.

Operator: We'll take our next question from Ike Swetlitz with STAT. Please go ahead, your line is open.

Ike Swetlitz: Hi. Hi, thank you. I had sort of a follow-up question about the radiation levels and then also a question with the powering of this study. For the radiation levels, the whole body as far as I'm aware, the safe maximum whole body exposure level for humans is 0.08 watts per kilogram, which is many magnitudes – and please correct me if I'm wrong about that – but that's orders of magnitude lower than any of the exposures given to the rats. I was just curious why either the rats were not exposed more locally or a much lower threshold was not used for this reason.

Second, I was hoping you could talk a little bit about the degree to which the study was powered to find results? I think that was brought up in some of the critiques in the reviewers' comments.

John Bucher: Sure. The whole body exposure limits that are set currently are quite a bit lower than were used in this study and that's correct. But I did mention before and I do repeat, though, that we were interested in trying to understand the sensitivity of all tissues in the body to radiofrequency radiation and it made sense to us to go ahead and use whole body exposures that the animals could still thermoregulate; they were not too high for that, but that exposed all of the tissues to the limits that are currently used for exposures to the head when you use a cell phone next to your ear. So that was the reason for that.

The power of the studies is a difficulty that we always run into with respect to toxicology studies. These studies required the construction and utilization of a large number of chambers to house the 7,000 animals in our study. We do know that the ability of increasing the power of an

animal study of this type much beyond the hundred animals per group, you run into the range of where you have quite diminishing returns and that the power levels that you gather by going up higher than 100 animals or so, incrementally fall off in relation to the time, money and effort that goes into a study of this type.

So, most guideline studies for carcinogenicity for drugs or for industrial chemicals suggest that one have 15 animals per group and that's the typical group size that we use in NTP studies, but we nearly double that for this particular study.

Ike Swetlitz: Okay and can you specify just what the rate was that the study was powered to detect? I didn't see that anywhere in the paper.

John Bucher: That is not an easy answer to come up with because it depends upon the background rates of the particular tumors that you're looking at and since were looking at animals, we're looking at tumors in tissues that typically range from almost zero as a background to, say, 20% to 30% in controls. The power to detect increases over that varies tremendously depending on the tumor type.

Ike Swetlitz: But for the tumor types that you report, I don't understand why you couldn't do that calculation?

John Bucher: I think we have done that calculation. The power to detect these tumors is probably in the range of between 10% and 20%, which also actually makes it more interesting that we have found statistically significant findings.

Ike Swetlitz: Okay, okay.

Michael Wyde: This is Mike Wyde. I'd like to add a little bit to John's answer on the first part of your question. You had asked about the 0.08 regulatory limit. If you look at the limit, there's also a separate limit for the hands, the wrists, the arms, the legs and the ankles and that is 4 watts per kilogram.

Ike Swetlitz: Sorry, I didn't catch that number you said. That's how many?

Michael Wyde: That is 4 watts per kilogram.

Ike Swetlitz: Right.

Operator: We'll take our next question from Sara Reardon with Nature. Please go ahead, your line is open.

Sara Reardon: Yes, hi, I just had one question. I know there's a forthcoming mouse study. With what's known about the tumor risk in that strain of mice and with the strain of rats, would you expect to see anything different in those animals? Or I guess...

John Bucher: Well, I guess as I said, we haven't finished the evaluation of the mouse study. Typically we use rats and mice in studies because we want to try to cover a little bit more biological space than just having all of our eggs in one basket, if you will, with respect to having we know that there are species and strain sensitivities and if you do studies with rats and mice, you're more likely to find something that might in fact potentially indicate a public health issue. So, I can't really answer the question about mice until we finish those studies.

Sara Reardon: Okay. I guess I was just asking about the basal rate of tumors that these develop anyway. Are there any plans by this group or others that you're aware of to do this in larger animals?

John Bucher: I'm not aware of any plans and in large – for studies in larger animals, no.

Sara Reardon: Okay, thank you.

Operator: Our next question comes from Mario Trujillo with Hill Newspaper. Please go ahead, your line is open.

Mario Trujillo: Hi, thanks. I noticed that the conclusions focused on hyperplastic lesions and glial cell neoplasms, are those cancerous or are they precancerous? Can you just give a little background on that in particular?

John Bucher: Sure. So we've had a number of pathology groups evaluate those particular small lesions, the small hyperplastic lesions. They have come to the conclusion that they resemble in almost all respects except size, the neoplasms, the glial cell neoplasms and the schwannomas.

The pathology opinion is that they represent pre-neoplastic lesions that have the potential to progress to neoplasia. So for our purposes, we would consider them part of a continuum of tumor formation.

And I will say that we have – if you notice, you can go back into the appendices, there's been extensive involvement of outside pathologists in reviewing these studies and including some pathologists with extensive experience in human brain tumors.

Operator: Our next question comes from Heather Tesoriero with CBS News. Please go ahead, your line is open.

Heather Tesoriero: Hi, thanks for taking my question. Just wanted to ask whether or not you observed a dose response, did the rates go up? Did the rates of tumors increase as the radiation exposure increased?

John Bucher: With respect to the tumors in the heart, the schwannomas, yes, there was dose response. There were less weaker indications of dose response in the brain tumors, but there were some statistical significance among the trends exhibited.

Heather Tesoriero: Thank you.

Operator: Our next question comes from Michelle Cortez with Bloomberg News. Please go ahead, your line is open.

Michelle Cortez: Thanks so much. I'm wondering if you can tell us the difference between the death rates of the radiated rats and the control rats. And also in the paper itself, you talk about vestibular schwannoma and the risks there in humans, but the study breaks out the heart schwannoma. So I'm wondering why you pulled out those numbers and what you saw with the ones that have been epidemiologically linked to humans? And perhaps most importantly, I mean, you guys must be aware that people read these kind of stories, the stories that we're all writing and wonder what it means for humans, I'm wondering if you can speak to that at all whether it has any kind of larger significance that people should be aware of, or if it's just that we need more study at this point?

Sorry to go with all these questions. But my last question would be what was your hypothesis going into the trial itself? Was there something that you guys could have gotten out of it that would have been like, 'Oh yes, we know for sure there seems to be no risk here' or 'Oh my word, this is very concerning, we need to ramp up our efforts'? So I'm just wondering what the hope was from the study going into it? Thanks.

John Bucher: So we always design studies going to it with an objective view towards simply trying to evaluate whether, in fact, an agent that we're studying has the potential to cause cancer in the animals that we're evaluating and then that sort of enters into the larger discussion about human relevance.

I'm sorry, but I didn't quite get all of the questions that you asked. So you mentioned what were the death rates, we mentioned in the report that the control animals in the male rats actually lived less long. They had on average shorter lifespan than the exposed animals and as I indicated earlier, we don't really yet have a reason for that.

What were your other questions, I'm sorry? What does...?

Michelle Cortez: I'm sorry, I'm actually asking for the actual numbers. I think that it was like 27% of the radiated rats were live at the end of the study and I looked but I couldn't find a comparison for the control rats. It looked like for some groups, it was about twice as many survived.

John Bucher: I'm sorry. I don't have those numbers right in front of me. But we can look at those and see if we can come up with them.

Michelle Cortez: Because that seems like the most statistically significant finding of the study itself, right? I mean, the differences there are dramatically different than the differences you're seeing in cancer rate.

John Bucher: That could be. I will say, though, that the statistics that we generate take survival into account. So the fact that we did see slightly shorter survival in the control animals was evaluated, taken into consideration in evaluating the tumor incidences. I'm sorry, was there...?

Michelle Cortez: I really think that you guys need to give us those numbers. I mean, you're saying that you found slightly less survival rates, but the only number I could find and I looked specifically for it was not at all slightly less, it looked significantly less.

John Bucher: We can continue to look for those numbers. If we can find them, I will announce them at the end of this call.

Michelle Cortez: Perfect. I'm sorry [Audio Gap] I'm wondering thereabout with some of the people raised in the – some of the reviewers said that maybe there's an issue of false positives here. So if you're looking at a whole bunch of different possible endpoints, I'm wondering what the vestibular schwannoma rate was.

John Bucher: So again the vestibular schwannoma is of interest to us because that's the human schwannoma that is formed in the nerve that is most irradiated, most affected, most exposed during the use of a cell phone, that's the acoustic nerve going from the ear to the brain. Our animals were exposed in whole body format so we felt that the increase in the schwannomas of the heart was of significance. It's an analogous tumor type in an analogous cell type.

Female: Next one.

Operator: We will take our next question from Matthew Herper with Forbes. Please go ahead, your line is open.

Matthew Herper: Hey, so I mean, this is kind of a follow-up on a lot of the discussion we're having. The two things that I'm hearing being asked a lot but I'm not hearing answers to are really concerns of multiplicity and concerns of a mortal time bias, right? There are a lot of comparisons, multiple comparisons and as your reviewers noted, you're not showing us what the other comparison stuff.

So how do we – I mean, aside from just waving at the specifics, I think a lot of the reporters in the call have some comfort with statistics, can you give us a little bit more of an argument about why this isn't finding as a result of multiplicity? You guys looked at a lot of things. Or of a mortal time bias that the control rats didn't live as long. That can be very hard to deal with as I understand it with statistical methods, because if the cancer is age-related, you can't always correct for that.

Also when you talk about homeostasis here, do we have any knowledge over whether forcing increased homeostasis, even if you don't increase the body temperature of the animals, has any effect on cancer incidence?

And just to those two prior questions, I really am concerned about the control group having potentially acted strangely and whether maybe there was anything in the experimental set up that actually decreased the risk of cancer for the control group and is that a possibility?

John Bucher: So, that's a good question. We have considered that as a possibility. We don't have any conclusions about that at this time.

I would say that with respect to the survival-adjusted statistics, that is an issue that is difficult but we run into that all the time. We generally tend to look at how the tumors fall in a study, whether they occur late in a study or they occur early in a study and we make adjustments to the statistical methodology based on late-occurring or early-occurring tumors.

This is based on historical survival-adjusted statistics for tumor onset from our control animals, and it is a complicated issue but our program has been doing these studies for almost 40 years and we've run into this situation in many times in the past and have developed I think good statistical methods to be able to accommodate those differences. And I'm sorry, you may want to repeat some of your earlier part of your question.

Matthew Herper: Well, it was the middle part that we didn't ask which is do we know that inducing homeostasis in the Harlan rats doesn't have some kind of pro-carcinogenic? Obviously heat does, right, which is why you wanted to make sure they don't heat up, but if you're forcing one strain of rats half or a third to half of their day to lower their body temperature, does that have a biological effect, right?

I don't know how rats lower their body temperature, but if you're making a dog pant twice as much and his body temperature's coming the same, there might be a biological effect. If you're making me sweat twice as much, there might be biological effect. Does stimulating a raise of body temperature that the animal can control have an effect versus not doing so?

John Bucher: So let me take some of your questions. First, we don't have any evidence that heat increases cancer rates. Second thing is that we have evaluated the – sorry, I'm not catching this question again.

Female: [Unintelligible]

John Bucher: Oh, the homeostasis. The issue of homeostasis is one that we really need to consider as we go forward in the evaluation of these studies. I would say, though, that the localized homeostatic mechanisms that would have to occur in the brain when one uses a cell phone may well be similar to those that happen in other tissues in a whole body exposure to radiofrequency radiation. So I don't know yet as to whether this is a whole organism effect or could conceivably be an effect on tissues that would be irradiated during the use of a cell phone. So these issues are all under active consideration when we take these findings forward to see if they have public health significance.

Matthew Herper: Can I just ask one quick follow-up?

John Bucher: Sure.

Matthew Herper: Can we exclude – so the concern is that these are the epidemiologically increased tumors but they're very rare. But they're matching up between this study and the other. That's the principal argument for why we should think this might matter, right? So, can we say anything about the tumors that weren't found? Given the amount of study you've done and given the epidemiology, are we really only worried about glioma and schwannoma here?

John Bucher: We've brought these findings to the attention of the scientific community and the public for the reasons that I indicated earlier that we do have a suspicion that in the human studies, there are increases in gliomas and schwannomas. The fact that these are the same tumors sites that we're seeing these small increases is of interest to us and we feel that it contributes to the conversation. That's basically our position at this point.

Operator: We'll take our next question from Anne Thompson with NBC News. Please go ahead, your line is open.

Anne Thompson: Thanks so much. My first question is just so that I understand it, these rats were exposed every day for two years, is that correct?

John Bucher: That's correct.

Anne Thompson: Okay and how would you describe their daily radiation exposure? Would you call it heavy? Would you call it extreme? What is the adjective you would use?

John Bucher: Well, these animals were exposed at levels that were heavy – certainly I would guess they would be considered heavy exposure in relation to that cell phone use in the United States, but that was the intention of the exposure systems was to provide a rigorous evaluation of the exposure scenario, so, yes.

Anne Thompson: The exposure that the rats saw, what is that supposed to mimic in humans? What's the human equivalent of that? Is there a human equivalent of that?

John Bucher: The equivalency of this is and from the design standpoint of these studies, we wanted to use exposure levels where the rats would not overheat, obviously.

Anne Thompson: Right.

John Bucher: We also wanted to use an exposure level that was at the top end of the current exposure that is allowed to occur to the area of the head that is within the range of the antenna of the cell phone when one is using that, which is 1.6 watts per kilogram. The lowest exposure level in our study was 1.5 watts per kilogram and that was to all tissues in the body not just the head.

Anne Thompson: Right. So I guess and because one of the questions will be when people hear that the rats were exposed to radiation for nine hours a day everyday for two years, they'll be like, "Well, I don't use my cell phone for nine hours a day, so why do I have to care about this?" And I think that's my question is how do I translate this [Laughter] into human usage?

John Bucher: So I think that the translation to human usage is part of the evaluation of these studies that has to go on when the Food and Drug Administration and the Federal Communications Commission evaluate the information to see if it has an effect on the current exposure limits, or recommendations that they put forward with respect to how one actually uses cellular telephone communication systems.

Anne Thompson: Do you use a cell phone?

John Bucher: Yes.

Anne Thompson: You do and have these findings changed the way you use a cell phone?

John Bucher: No.

Anne Thompson: No, okay. So for the average person out there that's going to see this story on NBC Nightly News tonight or read it in the New York Times tomorrow, what is the takeaway that the average person should get from this study?

John Bucher: So this is a study that is looking at the plausibility, biological plausibility of carcinogenic effect due to cell phone radiation. The direct translation of these findings to the way humans are using cell telephones is not currently completely worked out and that's part of the evaluation that's going forward. This may have relevance, it may have no relevance.

Anne Thompson: Thank you very much. Appreciate it.

Operator: Our next question comes from Cindy Sage with BioInitiative Working Group. Please go ahead, your line is open.

Cindy Sage: Yes, thank you. Well, given that the U.S. now has a gold standard animal toxicology study that's taken 16 years and \$25 million and it is reporting increased cancer risks at exposure levels that are illegal today in the United States under FCC public safety limits, what changes do you intend to recommend to the FCC in terms of perhaps halting its current procedure to relax public safety standards under a 1339 and other proceedings?

John Bucher: I think the recommendation or the question really is directed more at the regulatory agencies than at us. I will say that the Food and Drug Administration has some very nice guidelines for cell phone use on their

website. There are other agencies that have put out recommendations to limit exposures to radiofrequency radiation during the use of cell phones. So I think that, if anything, there may be some tweaks to these recommendations. We don't know at this point.

Cindy Sage: So you're not calling for tighter standards and you're not commenting on the fact that the FCC is very close to promulgating new rules that would actually relax the current safety standards which are going to make more exposure possible?

John Bucher: We are simply sharing the results that we have found in our studies and the Food and Drug Administration and FCC will be evaluating this information and I'm sure they'll take it in advisement.

Cindy Sage: Okay and last question. In the absence of study here on lower RF exposure levels that would apply to tablets, wireless computers and so on, are you going to make any precautionary recommendations or comment?

John Bucher: No, we don't make those kind of recommendations.

Cindy Sage: Will you be commenting on the exposure levels in relation to those found in this study if asked by other agencies for guidance on their website advice to consumers?

John Bucher: I think that the issue came up earlier. The guidelines for whole body exposures from radiofrequency radiation are fairly strict already, the 0.08 watts per kilogram, and it's been pointed out that our studies were at higher levels than that for the reasons that I gave earlier which was to look at the sensitivity of various tissues to radiofrequency radiation.

Cindy Sage: Thank you.

Operator: We'll go next to Paul Tadich with Motherboard. Please go ahead, your line is open.

Paul Tadich: Hi, thanks for taking my question. The pathways to tumorigenicity on a molecular level in many different species are very similar. I know this is probably pretty advanced at this point, but are you looking for some sort of molecular mechanism?

John Bucher: We have a variety of studies that we are either haven't planned or proposed that might get at some of the molecular issues that cell phone radiation or radiofrequency radiation has been studied for many, many years in a variety of different exposure scenarios with respect to generating information about mechanisms, potential mechanisms of carcinogenesis. This is far from a settled area, but the new technologies that we are able to apply to these kind of studies now and in the future I think will help us understand the mechanistic underpinnings if in fact these tumors are related to radiofrequency radiation.

Paul Tadich: Just one more quick follow-up. A lot of people, as previous callers have mentioned, are going to see the results of this study. Even though the results are partial, are you at all concerned that there will be a misunderstanding of these results leading to people making unnecessary steps to reduce their exposure to cell phone radiation?

John Bucher: I think that is always a concern about this. You have to balance the potential for public health benefits and public health harms and each time we put forward information that is at this stage in particular where we're simply beginning the process of evaluating the human health effects, if

any – or implications, if any – that there are some fairly simple steps that one can take if one is concerned about radiofrequency radiation to reduce that during the use of cell phones. And in fact, these are included in the FDA website, these are included in the inserts that go along with the cell phones that are put out by the manufacturer. So I think that one always has differences in their perception of hazards and risks and one has to make their own decisions.

Paul Tadich: Thank you.

Operator: Our next question comes from Marvin Lipman with Consumer Reports. Please go ahead, your line is open.

Marvin Lipman: Is any attempt made to study the offspring of the irradiated rats both male and female?

John Bucher: I'm sorry, could you repeat that question?

Marvin Lipman: Is any attempt made to study the offspring of the irradiated rats both male and female?

John Bucher: No. We didn't do the study that I think you're referring to, but the rats were in fact exposed during gestation and throughout their lifetime in this particular study. We did not take rats that were exposed during gestation and then breed those animals when they were of breeding age to see if there were effects on the offspring. We did not do that study, no.

Marvin Lipman: Thank you.

Operator: Our next question comes from Lloyd Morgan with Environmental Health Trust. Please go ahead, your line is open.

Lloyd Morgan: You have found a significant risk for CDMA and the GSM modulation, are you going to repeat this study with UMTS and LTE modulations? And I have additional questions.

John Bucher: We don't have any plans to repeat these studies at this time with different modulations. One of the problems with the whole area is that the technologies advanced so rapidly and the time that it takes to do these studies makes it difficult to keep up.

Lloyd Morgan: Well, the additional question would be before the fifth generation is released, is should that be tested prior to release for carcinogenicity in animals?

John Bucher: Well, that's not a decision for us to make. I will say, though, that if we can get a better handle on the mechanisms of potential carcinogenicity, that there might be ways to shortcut the time that it takes to make an evaluation of this type for the different technologies and that's really the goal of moving toxicology to a much more onto the molecular level than a tissue pathology level.

Lloyd Morgan: You also mentioned earlier that women keep cell phones in their bras, do you think it's reasonable to put out a warning that women should not do that?

John Bucher: Again I think this is going to be up to the regulatory agencies to make a decision as to whether [those would be] potential health hazards.

Lloyd Morgan: And last question, now that there are these animal studies showing carcinogenicity, would you expect IARC to increase their classification from a Group 2B “possible carcinogen” to a Group A or possibly a Group 1 which is a human carcinogen?

John Bucher: I really can’t speculate on that at this time, sorry.

Lloyd Morgan: Thank you.

Female: [Unintelligible]

John Bucher: If there are no further questions, we do have the actual survival percentages. Oh, we have more questions? Sorry.

Female: You can go ahead and look at [Crosstalk].

John Bucher: Well, alright. I can read these off for you. The final survivals of the GSM male rats were 28% in control, 50% in 1.5 watts per kilogram, 56% at 3 watts per kilogram, and 60% at six watts per kilogram. In CDMA, again this was a common control group so it’s also 28%; it was in 1.5 watts per kilogram, 48%; 3 watts per kilogram, 61%; and 6 watts per kilogram, 48%.

I’ll take other questions then.

Operator: Our next question comes from John Boockvar with Northwell Health, Lennox Hill, Neurosurgery. Please go ahead, your line is open.

Amanda: Hi, it’s actually Amanda on behalf of Dr. Boockvar. He had to go see a patient, but he didn’t have a question.

Female: Next question.

John Bucher: Was there another...?

Female: Is there another question?

Operator: We'll move on to Ian Evans with Undark Magazine. Please go ahead, your line is open.

Ian Evans: Hi, thank you for taking my questions. I just wondered if you could specify what exactly the sample size was that you used here and if you could, I know you've touched on this already, but talk a little bit more about why if you're really seeing partial research now in order to continue the discussion, how confident are you that other researchers will be able to accurately use this research to use the discussion with only partial data?

John Bucher: So I will say that the findings that we're releasing today have been completely verified and we know that those numbers for those particular tumor sites will not change, so we feel confident that that is not going to be affected by the completion of the rest of the studies. The group sizes are 90 animals per group and those are spelled out in the report.

Ian Evans: One last question. So if cell phones do cause – if there is this effect but U.S. cancer rates have dropped since 2003 despite an increase in the number of people who have cell phones, I was wondering if you have any idea what might have led to that.

John Bucher: [Aye.] We are aware of the fact that there is certainly not an increase in brain cancer rates in the United States over the course of time. We do not

know if the latency period for tumors had been sufficiently long for tumors to actually begin to show up in the human population, but it is very reassuring in fact that there has been no dramatic increase and it may well be that current cell phone use is safe. This is an issue that we continue to look at.

Ian Evans: Thank you.

Operator: Our next question comes from Joel Moskowitz with the University of California, Berkeley. Please go ahead, your line is open. Joel Moskowitz, your line is open.

Joel Moskowitz: Thank you for taking my question. I noticed in the report that you mentioned low incidence tumors, but if one were to look at overall tumor [incidences] are tied. One would see because there doesn't seem to be any duplication in terms of [data] that 1 in 18 of the male rats were diagnosed with one of these tumors. If you also included the hyperplasia for 16 of those and add to the 30, I'm not sure if those were unduplicated. But then there would be 446 of 540 or essentially 1 in 12 of the rats, the male rats were diagnosed with one of these two types of tumors and there may be other tumors that emerge [if you] report more of the pathology. This does not seem to me to be low incidence. I would imagine most breeders if they were exposed to these numbers are not considered to be low incidence, I'd like [a] comment.

John Bucher: So they are low incidence because of increases in tumors. That's simply our statement of our view of the effects. I will say that there is no duplication of counting, if you will, between hyperplasias and tumors. If an animal is diagnosed with the hyperplasia and a tumor, it's only counted as a tumor, it's not counted as both. So those tumors and hyperplasias

occur in different animals, so it is conceivable that one might want to group those if one wants to look at proliferative lesions.

Operator: Our next question comes from Elizabeth St. Philip with CTV National News. Please go ahead, your line is open.

Elizabeth St. Philip: Thank you. My question actually has already been answered but I do have another. You mentioned that you use a cell phone and the findings have not changed the way you use one, can you expand on that? How many hours a day do you use a cell phone and how do you use it? Do you hold it next to your head or do you use hand free?

John Bucher: I don't use a cell phone very often. People don't seem to call me much. [Laughter] Maybe they will after this call, [Laughter] I don't know. I use a cell phone next to my head or with earbuds depending upon what I'm doing.

Elizabeth St. Philip: When you say you don't use it much, can you quantify that? Like an hour a day?

John Bucher: No, probably not that much, no.

Elizabeth St. Philip: Okay, thank you.

Operator: Thank you and our next question comes from Ryan Knutson with Wall Street Journal. Please go ahead, your line is open.

Ryan Knutson: Thank you. I just wanted to follow-up on this comment that Joel Moskowitz of Berkeley made about this study effectively finding that 1 in 12 of the rats had either a tumor or something that would be on the

continuum of a lesion that could potentially lead to a tumor, is that an accurate way of phrasing this result?

John Bucher: I haven't actually done that calculation. I assume that he is doing it correctly, but you probably should contact him for the exact calculations.

Ryan Knutson: Okay and then, well, just to follow-up, I guess is there any other way to explain like what is the significance or what is the increase by any particular measure? I know you have the table on page nine, is it fair to say that like in the 1.5 watts per kilogram exposure level for malignant gliomas, that there was 3.3% of the rats had that, or what's sort of like a number, if any, we could put on this?

John Bucher: I'm not sure that there is any other way of expressing this information. If you have some suggestions, we'd be happy to consider those.

Ryan Knutson: Or could you say how many total rats out of what total? Like...?

John Bucher: Yes. If you look at the table, the number examined in each group is above the columns. So it's 90 animals per group, three tumors which is 3.3%.

Ryan Knutson: So it's 3 tumors out of 90 animals...

John Bucher: That's correct.

Ryan ...in that group, okay, [nice].

John Bucher: And all of the tables have the same format.

Ryan Knutson: Got it, thank you. One follow-up if I may, your study would seem to indicate that there is potentially another mechanism other than heating effectively, right? Which is the only thing that people sort of widely agreed upon now, but this may indicate that there is another mechanism. We still don't know what it may be but it potentially could be something else.

John Bucher: I guess we haven't really examined that. There is a potential that a number of mechanisms may be in play. Lots of studies in the literature have indicated that a large number of potential mechanisms, but there has been no association in solid terms at all with any particular tumor outcome.

Operator: We'll go next to Jane Derenowski with NBC News. Please go ahead, your line is open. Jane Derenowski, your line is open.

Female: [Move on.]

Operator: We'll go next to Seth Borenstein with Associated Press. Please go ahead.

Seth Borenstein: Yes, thank you. Two questions here. First, when I look at the reviewers, you have four pretty negative, one fairly neutral but still raises question, and then one that is not included nor is the person. Can you explain what that sixth person said and why it wasn't included and if you're at all concerned that the reviews were mostly negative? I mean, I am when I send out for outside reviews and they're mostly negative.

Secondly, once again to try to put the risk here in perspective, is there in other NTP studies an analogous risk level that you can point this too? Obviously it's not cigarettes, but I mean something on the same level.

Whether it is charcoal, burned meats from grilling, or something else, is there a good analogous risk that you could use?

John Bucher: No, I don't know of any way of associating risks or comparing risks across these kinds of results. I would comment, though, on with respect to the reviewers. I think that those reviewers who are very familiar with the way these kinds of studies have been done have been very complementary in their performance. They have indicated that we have applied the criteria that we typically use for evaluating these studies appropriately and they've had in general agreed with our findings.

Remember, our findings are that these tumors are likely related to radiofrequency radiation. There is a great deal of uncertainty. We have acknowledged that and we've tried to point out the areas of uncertainty and why it is a very difficult decision and that's one of the reasons that so many reviewers have actually been looking at this information and it's also one of the reasons that we put this information on a website that allows one to collect comments.

We'll be looking at the comments that come in because this is really, in essence, a way of crowdsourcing the scientific evaluations and I think that's really one of the strengths of putting this on a website and it's really one of the ways that I think we need to evaluate science in the future.

Seth Borenstein: So you're saying that you found them complementary? I guess I'm trying to understand. I mean, for example, Dr. Lauer was really blunt there. Can you explain to me how this weren't the alarm bells to you? I guess I don't understand, and are there ones that you have not shared that are complimentary?

John Bucher: One reviewer who requested anonymity, I don't remember what their outcome was. I don't believe that they wanted – if their name was not to be used, they could not be included on the particular website that we posted this information. So that's the only reason that you don't see that other review.

Again I think that in my experience the people that have looked at these studies that are very experienced in evaluating these kinds of studies have, in general, agreed with our findings that there is – it's nothing. That's certainly the outcome that we're hearing.

Female: Thank you. Thank you.

John Bucher: I think that concludes our time and I will turn it back over to the moderator.

Operator: Ladies and gentlemen, this does conclude today's program. Thank you for your participation. You may disconnect at any time.

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