

CHD v FCC

Transcript - Oral Arguments 1/25/2021

ORAL ARGUMENT REQUESTED

20-1025 (Lead); 20-1138 (Consolidated)

UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

ENVIRONMENTAL HEALTH TRUST; CONSUMERS FOR SAFE CELL
PHONES; ELIZABETH BARRIS; THEODORA SCARATO

CHILDREN'S HEALTH DEFENSE; MICHELE HERTZ; PETRA BROKKEN;
DR. DAVID O. CARPENTER; DR. PAUL DART; DR. TORIL H. JELTER; DR.
ANN LEE; VIRGINIA FARVER; JENNIFER BARAN; PAUL STANLEY, M.Ed.

Petitioners

v.

FEDERAL COMMUNICATIONS COMMISSION;
UNITED STATES OF AMERICA

Respondents

Typist's notes:

(??) = unknown word or unsure spelling

(ct) = cross-talk (more than one person is speaking)

Female voice:

Case number 20-1025 et(??) al.(??). Environmental Health Trust et al., Petitioners, vs. Federal Communications Commission and United States of America. Mr. McCollough for the Petitioners, Miss Boizelle for the Respondents.

Female voice:

Mr. McCollough, good morning. Please proceed.

Mr. McCollough:

Good morning. May it please the Court, I'm W. Scott McCollough, presenting argument on behalf of the 14 Petitioners in these consolidated cases. One of the Petitioners recently contacted the FCC to seek redress for injuries she attributes to RF exposures. The Commission representative said, "We don't deal with humans, only frequencies" and hung up. That conversation encapsulates the FCC's approach here. By closing the inquiry, the Commission failed its duty under the *Communications Act* to consider all potential health and safety impacts(??, 00:50) of radiofrequency emissions on humans. It ignored over 1,000 peer-reviewed studies showing that exposure to non-thermal radiation at authorized levels evokes a clear biological response beyond mere(??) tissue(??, 1:04) and it leads to multiple forms of harm. It ignored direct human evidence of current injury. It failed to comply with the APA and

NEPA for similar reasons. The Commission has a substantive duty under the *Act* to have and maintain adequate emission levels, beyond (inaudible, ct).

Male voice:

Can I ask you a question about standard of review? You say that we shouldn't give the Commission any heightened deference in this case—citing Fox Television among other cases—but can you, umm, point me to any instance where we or The Supreme Court have not given heightened deference to an agency decision involving scientific judgments?

Mr. McCollough:

Well, there are various levels of discretion that are given to agencies, depending on the circumstances. This Court, and The Supreme Court, has ruled that in the context of a Petition for Rulemaking there is very high discretion. The problem here is, this was not a Petition for Rulemaking. Indeed, if you look at what happening in the Inquiry, the Commission was... did engage in rulemaking functions. It established requirements. It extended its 1996 rules to situations, usage, and indeed even frequencies that were not covered by this. So it was functionally engaging in rulemaking here. And that's the level of deference that should be applied. But even under the highest level of deference, the Commission still has to engage in reasoned decision-making. It still has to address all the material issues. It still has to respond to, ah, to... to material comment(??, 2:48). It has to look at the entire record. (inaudible, ct).

Female voice:

That sounds like... that... that sounds a lot like a standard from if we were reviewing, after notice(??) and(??) comment(??, 2:58) rulemaking, where(??) everybody had sufficiently explained, ah, their final position and, you know, responded to substantial comments and concerns, and addressed the record as a whole. What I'm struggling with is we're not at that stage. We're at the should-they-engage-in-rulemaking-at-all. And I understand your argument is about things that they didn't, ah, respond to with much of any... much of any sufficiency, umm, but I'm... I'm searching for case law or precedent that says in *this* context how *much* they have to say about contrary evidence in the record.

Mr. McCollough:

Well, I... you know, my first point is that regardless, even if you are giving them the highest (inaudible, 3:48) that is given under any circumstances, which.... We think they were engaging... they were engaging in rulemaking here but (inaudible, ct).

Female voice:

Okay (inaudible, 3:55), let's assume I don't. Let's assume, just for these purposes, look at our.... We have a body of case law on Petitions for Rulemaking and how, ah, inaction or deniable of those is treating. So within that body of case law, can you explain to me what our(??) rule(??, 4:12) would be that they violated here?

Mr. McCollough:

This was not a Petition for Rulemaking. This was a proceeding...

Female voice:

I understand, but I (inaudible, ct)...

Mr. McCollough:

... the Commission guarded(??, 4:20) itself.

Female voice:

(inaudible, ct) most(??) analogy(??, 4:20) (inaudible) this(??) stage.

Mr. McCollough:

And it was, very much like in the Fox case, a Notice (inaudible, 4:26). And... and, you know, in that case this Court did not give the highest level of deference. Umm. But no matter how much deference you give them, the problem here is you just simply cannot say that the six paragraphs the Commission dedicated to addressing the inquiry can... can adequately deal with all of the evidence in this case. They... it did not mention all of the 1,000 peer-reviewed studies. It gave scant mention to only three items: the Razzamini[sic], the NTP, and the BioInitiative. Umm. And... and it dismisses (inaudible, ct).

Female voice:

(inaudible, ct) are the ones you sort of rely on most heavily, right?

Mr. McCollough:

Well, we rely on those but we also very much rely on the underlying science(??, 5:16) and the studies that were used for...

Female voice:

They don't have to address every submission. Can we agree on that? They don't have to respond to every (inaudible, ct).

Mr. McCollough:

They do not have to address every submission. They have to address every material submission. But even more important(??, 5:28) (inaudible, ct).

Female voice:

Is that true? Is... is that true in this stage? Where have we said it in this stage, as opposed to again at the end of Notice and Comment rulemaking, that they have to respond to every material submission?

Mr. McCollough:

We are not contending that the Commission had to go by every single one of the thousand peer-reviewed studies.

Female voice:

I said "every material"... you just said to me every material one, so now I'm asking you where have we said that at this stage, this (inaudible, ct, 5:52) stage (inaudible, ct).

Mr. McCollough:

I... I think the Fox case. I apologize.

Female voice:

No, no. (inaudible).

Mr. McCollough:

I think the Fox case stands for that proposition. But no matter what scale of discretion (inaudible, ct)

Female voice:

And what... can you tell me which page on the Fox case you're relying on.

(silence)

Mr. McCollough:

At...

Female voice:

I'm sorry, I didn't mean to hold you up. (inaudible, ct).

Mr. McCollough:

Well, and I do apologize. The, umm. Of course, the... the Court addresses all of these things throughout the entire Fox case.

Female voice:

Right. If there's particular language or page you want us to focus on, maybe you could just tell us at rebuttal. I don't want to hold up your argument here. I'm sorry, I thought maybe you had something in particular in mind.

Mr. McCollough:

Well, I'll be happy to supply a post-submission on this. But, ah, you know, the... the real and fundamental point here is that the Commission does owe some(??) duty(??, 7:00) substantively. It recognized that it had a duty, when it opened the Inquiry, to give a full examination and explain its rationale and assure the public. In order to do that, it had to give some analysis to the... the evidence in this case. It did not mention a single one of these other studies. All that it did was mention The BioInitiative Report and then dismiss it because it did not solve the problem of being able to also still provide service. It did not get into the underlying science that shows the level at which there are adverse impacts from exposure.

Male voice:

Can we talk about the role of the FDA here? Because the Order said that no expert health agency expressed concern about the conditions radiofrequency exposure limits and that the FDA said no changes were warranted in that Congress tasked the FDA with evaluating the health effects of radiation. And that's something that... that the FCC also argues in their brief. So, umm. So what was wrong with the FCC relying on the FDA in this case?

Mr. McCollough:

It is permissible for an agency with jurisdiction to rely on agencies with expertise, but, ah, as was the case in the City of Boston, ah, the City of Boston case, the agency with jurisdiction, when it looks to the agency with expertise, what that does is require the agency to(??) expertise... with expertise to itself explain its rationale and how it went about this. If you compare the FDA response here to the, ah, analysis that the Court looked at in the City of Boston (inaudible, 9:02), you will find a magnificent difference(??, 9:04). The problem also is the FDA was concerned... its letters, its short missives here, looked only at cancer and only with cellphone. It did not look at all of the other adverse effects that the evidence shows occur here beyond just cancer. Umm. Finally, I... I need... do need to point out that the FDA is not necessarily the agency with expertise. The NTP Study was contracted by the FDA. It looked to another agency within the Department of Health and Human Services: the NTP. Presumably that's the agency with expertise. And so, you know, I think if you want to find the agency with expertise here, it would be the NTP. I will point out that the NIEHS—yet another DHHS agency—conducted a peer-review of the NTP Study in which the criticisms, as short as they were, by the FDA were considered. And that peer-review panel conducted by the NIHES[sic], another sister agency, rejected the FDA's concerns and... and in fact elevated some of the things that were found in the... in the NTP Study. So, you know....

Female voice:

Can I ask on the... so the agency, the F... sorry... the FCC here relied heavily on, ah, the FDA, ah...

Mr. McCollough:

(inaudible)

Female voice:

... in(??, 10:38) its analysis because of their medical expertise. Have you ever had an opportunity... did you have an opportunity... is there any procedure by which you could, umm, either challenge the FDA or go to the FDA and prompt them to look at your medical evidence and... and... and change their position? It's just it seems this is a very odd statute, in(??) that(??) they have the technological role but their... they don't have the medical knowledge, and you're asserting, ah, injuries that are medical injuries, ah, ah, physical injuries to bodies, ah, in which the FDA seem to have more expertise. And it just... it almost (laughs a little) seems like (inaudible) the one you should be talking to is the FDA.

Mr. McCollough:

(inaudible, ct)

Female voice:

Have you talked to the FDA? Have they... have you had... given(??) submissions to them? Did(??, 11:31) they look at these types of reports?

Mr. McCollough:

Umm. There is no information in the agency record here...

Female voice:

(inaudible)

Mr. McCollough:

... on that point. Ah, there were... there are... there is information in the record where people, near the end of this proceeding, responded to what the FDA, ah, Director said. But we... we do have a fascinating jurisdictional situation here. There is no direct way to challenge the FDA determination.

Female voice:

(inaudible)

Mr. McCollough:

But since the Commission was relying so heavily on the FDA, I think what that means is you now need to look at the FDA letter(??, 12:06) and see what it addressed, and whether the FDA letter(??) reflects some kind of reasoned decision-making. And we submit it does not. It is just as cursory as the F... as the FCC's six paragraphs here. (inaudible, ct).

Female voice:

(inaudible) I read the F... I read the FDA submission. It was focused exclusively on cellphones and didn't address (inaudible, ct, 12:28).

Mr. McCollough:

It was. It... it was, it was exclusively on cellphones and again exclusively on cancer. It did not address some of the other NTP findings on other adverse biological effects.

Female voice:

(inaudible)

Mr. McCollough:

And I do need to point out that the Commission's representation at all of the other sister agencies either did not object or agree. It is just belied by the record. The Interior Department has expressed concerns. Ah, the EPA has expressed concerns with the thermal-only approach. Obviously, the NIEHS doesn't agree. We had the Access Board finding. We have the CDC recognition of radiation sickness, as a disease. It is just simply not correct to say the federal government and all of its agencies is entirely aligned on this question.

Male voice:

But no one has proposed any specific change in standard, right? And you can't point to any international standard that is stricter or more restrictive than the U.S. standard.

Mr. McCollough:

There are.

Male voice:

Am I correct on both of those statements?

Mr. McCollough:

There are some more restrictive standards. Umm. And there's... there are some more all-compassing standards. Many other countries...

Male voice:

But what more restrictive standards did you cite in the Brief?

Mr. McCollough:

Well, for example... I... I can certainly cite to the Commission Order itself—although it is not in the Notice of Inquiry. As the Commission notes in paragraphs 122 through paragraphs 124, when it comes to some of the frequencies that the Commission applied its regulations to—which were not... which were not, in fact, covered by the 1996 specifically—under 100 kilohertz and over 100 gigahertz. Some of the international standards are more restrictive, especially at the lower end of the band, than the Commission's ones are here. If you take a look at, for example—and you may not have it in front of you but—Note 328, ah, when they're talking about neurostimular responses to low frequency, ah, emissions below 100 kilohertz, the Commission actually recognizes the very symptom that we recite(??, 15:03), what we call "radiation sickness." And the international organizations have made special provision for that. In the... the part of the Notice of Proposed Rulemaking, ah, the Commission proposes to make some changes to its regulations to more or less align itself with these international regulations. But it did not do so here in the Notice of (inaudible, 15:29). At present, under the rules, the, ah, (inaudible) for purposes of these regulations in(??, 15:37) these frequencies where the Commission had not heretofore applied its rules in 1996, it's... it's these rules now apply as a result of the Notice of (inaudible, 15:49). The Commission did indeed extend its 1996 rules to activities, frequencies, technologies that were not addressed in the 1996 Orders. And that is why we say this was functionally, although not in name, a rulemaking. It made new rules for all of these new things that were not contemplated in 1996(??, 16:15).

Male voice:

I understand that argument but... but what the FCC says is that basically in all of the comments there's a lot of sound and fury but there's no specific recommendation other than one, I guess, from The BioInitiative Report that says sets the limits, you know, a million times more restrictive or a billion times more restrictive. And they say that... that the technology can't work if those levels are that low. I didn't see any rebuttal to that point. And the only rebuttal I saw in

your Brief, in the Reply, was, “Well, The BioInitiative Report suggested a path forward.” Well, when I read that Report, the path forward I see is, well, there needs to be more study done. But there’s no... there’s no specific regulatory, umm, kind of, umm, limit change that it proposes. So (pause) do you disagree with anything that I’ve said there? And if not, umm, why isn’t that, umm, undermining your position?

Mr. McCollough:

I see that I’m somewhat over my opening time. May I still (inaudible, ct)?

Female voice:

Go ahead. Of course, go ahead.

Mr. McCollough:

The... the first step to solving a problem is recognizing that there is one. And the BioInitiative’s main point was there are these... these significant aspects of the problem that the thermal-based rules do not address. And that is that there are biological responses that... that are... that occur... there’s biological responses—many of which are adverse—when you are exposed to authorized emissions. The BioInitiative said, based on its analysis of the studies, here is the point at which there is a response. The BioInitiative was not necessarily recommending that emission limit be taken immediately all the way down to the point where there is a biological response. Their main point was you need to adjust your rules so that they are biologically based, not thermal-based. It then recommended collaboration between the scientists who understand biological responses, the Commission, and those who design networks to try to find the point where you could have services with less (inaudible, 19:01). And so the BioInitiative was not saying take limits down all the way to this level; it was saying recognize there is a biological response and let’s find a way to adjust standards so that we lessen the harm while still maintaining the ability to provide service. (inaudible, ct).

Male voice:

How does that translate into error by the Commission here?

Mr. McCollough:

It does because what the Commission demanded in the Inquiry and in the Order, it said, “We’re not going to pay attention to your science unless you also solve the service utility problem.” And the entire point is there’s two problems. The problem is the biological response; and then you have to figure out a way to address that within the context of being able to still provide service. This was a Notice (inaudible, 19:55). It... it... or at least it was supposed to be. In the actual rulemaking would be the time to find(??, 20:03) the actual emission levels that would serve both needs. And... and so the Commission just completely misconstrued and misapplied what the BioInitiative was saying. They were not saying take it down to this level. They were saying recognize biological (inaudible, ct).

Male voice:

Okay. Can I... can I just interrupt you for a second? Because there's something that I thought was very interesting about the Briefing here that I'm trying to get the take of both sides on. On page 37 of the FCC's Brief, they refer to 21 USC, Section 360ii, umm, and as part of their argument that the... that the FDA is really the... the kind of, umm, expert agency on human health impact of, ah, ah, radiation of this sort. Umm, and that particular statute, ah, references... says that the FDA is supposed to, ah, kind of get this advice and expertise, ah, from a Technical Electronic Product Radiation Safety Standards Committee, which is created a couple of Sections later in 360kk, sub-paragraph (f). And that Committee is supposed to have, you know, a diverse representation of people from industry and... and scientists and medical professionals etc. etc. to, ah, basically kind of do what you're saying that should... should, you know, undertake the sort of analysis that you say should be done. It's interesting to me, though, that you don't reference this Committee at all in your Briefing. It's also significant to me that the... that the FCC doesn't reference that, ah, Technical Electronic Product Radiation Safety Standards Committee in their Briefing, even though that Committee is supposed to take the lead on testing things like, ah, cellphones in the testing standards in the... in the standards that they're supposed to meet. Umm. Why is it that... that you don't seem to think that this statute has any relevance—or at least you don't talk about it in your Briefing?

Mr. McCollough:

We do not talk about that in our Briefing because it has no relevance to this proceeding. We are dealing with the *Communications Act*, which has given to the Commission the exclusive right to set emission levels for all point sources. The FDA's jurisdiction over some radiation-emitting devices is far more limited than(??) that(??, 22:29). And while it is true that the FDA itself would have jurisdiction to establish rules upon proper petition, that would be the Secretary of the FDA, not necessarily the division that handles these ma... that... that Dr. Shuren is with. And so we have not only a procedural and jurisdictional problem, there's also just(??, 23:24) nobody seems to have invoked or sought a rulemaking from the FDA that would have set in process the committees and such like that are described in the statute you cite. We are dealing with (inaudible, ct) federal (inaudible, ct).

Female voice:

Does that Committee exist or not?

Mr. McCollough:

I beg your pardon?

Female voice:

Does that FDA Committee exist or not?

Mr. McCollough:

There is no evidence in the record on that, as far as I know (inaudible, ct).

Female voice:

Do you just know whether it exists?

Mr. McCollough:
I do not know. I apologize.

Female voice:
(inaudible)

Mr. McCollough:
Remember, in this context, in... in looking at it more or less a NEPA(??, 24:01) perspective, that the Commission is trying to rely on the FDA as an agency with expertise, where the Commission is the agency with jurisdiction. And the problem is, the FDA is not necessarily properly considered an agency with expertise under the environmental laws. It deals with human health, not the environment. And so, you know, I... I truly do think that the Commission needed to look to far more than, and rely on far more than, a couple of letters from an FDA Director. And... and once you look at those letters, to begin with they simply do not pass any kind of muster, umm, or reasoned decision-making if this is what the entire case turns on. It does not at all, compared to what... what this Court approved in the City of Boston case—to again cite that example.

Female voice:
All right. If there are no more questions then we'll hear from... we'll give you some time in reply... we'll hear from Miss Boizelle.

(25:05)

Miss Boizelle:
Good morning. May it please the Court, Ashley Boizelle, for the Federal Communications Commission. As I think the Panel recognizes, the FCC was not writing on a blank slate in this case. Instead, it was seeking scientific evidence and recommendations on the effectiveness of radiofrequency emission limits that it adopted in 1996 and that have been upheld against judicial challenge twice before. As both this Court and the Second Circuit have approved, in making this evaluation the FCC reasonably relied on the views of federal agencies with primary jurisdiction in public health, as well as recognized standards bodies. The FCC relied on substantial evidence...

Female voice:
(inaudible, ct), I mean, (inaudible) first of all I guess I should back up. Do you know (inaudible) this Committee that Judge Wilkins referenced within the FDA even exists and whether it has spoken on this issue?

Miss Boizelle:
I'm not familiar with the Committee or what its status is.

Female voice:

(inaudible). So, in the Notice of Inquiry, FDA... sorry... FCC flagged that it wanted to get input, including from these expert federal agencies, sister agencies—information on what had changed since 1996, and that is the ubiquity, ah, of the devices, the different types of devices, the (inaudible, 26:21) sheer volume of them, and intervening developments in analysis of medical consequences. And... and in both the introduction and then in... even in your final decision in your second Report and Order, there's lots of discussion about how there's so many new devices, and people are using multiple devices, and they're using them way... way more people are using them and way more people are using them all the time or for extension periods. This was even before the pandemic when we're now living on the stuff. But even before that, the amount of usage, ah, the number of devices used—often simultaneously—the age range of people who are using these, and how long they're using them. That was all, quite sensibly, what the FCC asked for. The FDA came back and talked about cellphones and cancer. How was that reasonable for the FCC to rely so heavily on a response from the FDA that there's no indication relied on this specialized Committee and did not address the very things you asked for information on: other devices, the use of multiple devices, and physical harms other than cancer? How was that reasonable—even with the super-deference you get at this stage?

Miss Boizelle:

Well, first of all, we didn't rely exclusively on the FDA's representations about the state of the science. You're right. But their statements spoke specifically about cellphones, although (inaudible, ct).

Female voice:

(inaudible, ct, 27:55) rely on that at all?

Miss Boizelle:

I think it...

Female voice:

Other(??) than(??) what's(??, ct, 27:59) being said about cellphones, (inaudible) simply didn't answer the question asked. So how was it reasonable to rely on it? I don't want to hear... I just want to know how it was reasonable to rely on something that was not responsive to the Inquiry.

Miss Boizelle:

Sure. For two reasons. One: cellphones are used in close proximity to the body, and the power of an emission decreases exponentially with distance. So cellphones are the device that is creating a... the... the most radiofrequency emission, umm, when compared to other devices and other base facilities. Umm. Second: we have aggregate limits that apply to, ah, fixed facilities. Those are set forth at 1.1307(b)(3). And they require that (inaudible, ct).

Female voice:

I'm not talking about fixed facilities. I'm talking about watches. I'm talking about iPads.

Miss Boizelle:

Okay

Female voice:

Those are not fixed facilities. So.

Miss Boizelle:

Sure

Female voice:

And then I'm also not talking about just using a phone and holding it up to your ear. People don't use their phones... hardly use them for phone calls anymore. They are constantly in the hand—not two centimeters away, they're constantly in the hand. And the fingers are constantly on them. And so I'm just trying to understand how the FDA coming back and talking about cellphones that are in a holster—where nobody keeps them anymore—or in a purse when they're not being used is at all... and looking only at cancer is at all relevant to an Inquiry, again, into the effect of this radiation frequency from multiple devices that are used in entirely different ways now, in entirely different volume, and throughout the population, including children who live on iPads.

Miss Boizelle:

So as I said, the FDA said in its letter, at J 81/87, that it was engaged in an ongoing review of the evidence in this area. And then, as you say, it represented a specific conclusion with respect to the National Toxicology Program's, ah, research on cellphones. But that was coupled with representations in... in our termination of the Notice of Inquiry, at J 8/12, that the World Health Organization had found no substantiated adverse effects from fixed facilities. So this wasn't an inquiry that was limited (inaudible, ct, 30:07).

Female voice:

(inaudible, ct), I'm sorry, maybe... I... I... you are way more expert than me. Is an iPad a fixed facility?

Miss Boizelle:

No. An iPad is (inaudible, ct, 30:13).

Female voice:

(inaudible, ct). Is a watch a fixed facility?

Miss Boizelle:

No

(inaudible, ct)

Female voice:

Is a wireless laptop a fixed facility?

Miss Boizelle:
No (inaudible, ct).

Female voice:
When they talked about... when the Notice of Inquiry talked about the ubiquitous uses of devices, was it talking about fixed facilities?

Miss Boizelle:
No, not exclusively. But I was going to (inaudible, ct).

Female voice:
No, no, no, but I don't think that was.... Okay. (inaudible, ct).

Miss Boizelle:
I apologize.

(inaudible, ct)

Female voice:
(inaudible, ct) fixed facility stuff, I don't... to me, at least, doesn't feel responsive unless I'm misunderstanding it. I'm really curious about all these other devices.

Miss Boizelle:
Absolutely. (inaudible, ct).

(inaudible, ct)

Miss Boizelle:
So with respect to mobile and portable devices, we said, at paragraph 143 of the Notice of Inquiry and paragraph 67 of, ah, the Order on review here, that there didn't need to be aggregate limits—that we didn't have a concern about the aggregate effect of transmissions from these mobile and portable devices, because they tend to be used....

Female voice:
I'm sorry (inaudible). Sorry, I'm sorry.

Miss Boizelle:
It's okay. It's 67.

Female voice:
(inaudible, 31:07) JA(??) 67 or 67 (inaudible, 31:10)?

Miss Boizelle:
It's paragraph 67.

Female voice:
Sorry

Miss Boizelle:
It's JA, ah, thirty... 35 to 36.

Female voice:
Okay

Miss Boizelle:
So, we explained in that paragraph that exposure from mobile and portable devices tends to be a more localized exposure when they're held close to the body. That would cover things like a watch, or a tablet held in the hand, or a cellphone. And that exposure, because it's more localized, umm, tends to... to, ah... doesn't need to be aggregated because the whole-body exposure is much more diffuse. Umm. So we addressed the... the fact that, umm, (inaudible, ct).

Female voice:
What expert agency... what other expert agency was the one that addressed that for you?

Miss Boizelle:
We were making that judgment in our own technical expertise—that the effect of these emissions was not, umm, significant in the aggregate and that therefore there didn't need to be any kind of aggregate limit. But with respect to our reliance...

Female voice:
(inaudible, ct)

Miss Boizelle:
Pardon me?

Female voice:
(inaudible, 32:10) you decide? I mean, like(??) these things are strapped onto the arms and in the hands a significant part of the day. How was it that you decided that that was not a significant change from what you had looked at in 1996?

Miss Boizelle:
Well, there are no substantial adverse effects from exposures, umm, at... at the existing levels. So the fact that they're strapped (inaudible, ct).

Female voice:
(inaudible, ct) and how did you find that? Was this your... your 2.5-centimeter test?

Miss Boizelle:

Well, n-no. I... what I'm... what I'm doing is referring to our explanation of why the existing limits continue to be sufficient. And what we said in terminating the Notice of Inquiry is that the scientific evidence—and we relied on the FDA but we also referred to other expert organizations and bodies—that the scientific consensus had not changed. And... and I think it's a mistake to characterize what we did as if relying exclusively on the FDA's conclusion, because that's not what we did here. We also looked to, ah, the views of, as I said, the World Health Organization, at JA 12, umm, the International Commission on Non-ionizing Radiation Protection. Umm, the... the National Toxicology Program, umm, scientists themselves said, "Don't rely on this rat study and extrapolate to humans." So it... it was a broader, umm, Inquiry. And... and we engaged more broadly with the experts in this area in drawing the conclusion that there were no substantiated adverse effects. Umm, and... and your question, I think, (inaudible, ct).

Female voice:

Sorry. I'm in... I see what you're talk... (inaudible, 33:44) section you say that(??) (inaudible, 33:47) worry about cumulative ones, exposure from fixed RF sources will vary. But we're not talking about fixed RF sources. And so where do you say for non-fixed ones? I'm sorry, I'm not reading the paragraph, maybe, the way... I'm not reading it with your expertise; I'm missing something. Where are you talking about non-fixed? In paragraph 67?

Miss Boizelle:

Umm, we say that the location.... Let's see, sorry. Umm. When the RF are sources to the body...

Female voice:

(inaudible)

Miss Boizelle:

... they will be exposing smaller areas of the body—just at the end of that paragraph—and separated sources will accordingly expose different areas of the body without overlap.

Female voice:

That's just (inaudible, 34:24).

Miss Boizelle:

Apologies(??). If you keep reading. So it's... it's 67 leads into paragraph 68. We note that the exposure from each portable or mobile device near a person will generally involve low total power absorption while being highly localized and will not result in significant contributions to whole-body average (inaudible, ct, 34:41).

Female voice:

And what are you citing for that conclusion? I don't see any authority cited, or any study, or any base... any explanation of how you came to that conclusion—other than that just conclusory statement? The footnote (inaudible, 34:53).

Miss Boizelle:
You're correct.

(inaudible, ct)

Miss Boizelle:
How did we decide that the localized exposure didn't... would be absorbed (inaudible, ct)?

Female voice:
Multiple localized exposures for prolonged periods of time.

Miss Boizelle:
How that would not be harmful?

Female voice:
Yes, how did you (inaudible, 35:10)?

Miss Boizelle:
Ah, well, again I think you have to link the observations here with the observations we made in concluding the Notice of Inquiry. You're correct. There is no footnote here. But if you go back to the Resolution terminating the Notice of Inquiry, we said repeatedly that there was no evidence of any effect—not just cancer, any illness—from, ah, radiofrequency emissions below our existing levels. And in fact we said, at... below, at, and sometimes even above our existing levels.

Female voice:
And that one said.... Sorry, can you point me to that paragraph where it said... where it was addressing cumulative impacts?

Miss Boizelle:
Umm

(inaudible, ct)

Miss Boizelle:
Again I apologize that I'm not being responsive...

Female voice:
(inaudible)

Miss Boizelle:

... to your question, but the cumulative effects are addressed here, in addition to (inaudible, ct).

Female voice:

(inaudible, ct, 35:56) you're referring back to findings that were not themselves cumulative.

Miss Boizelle:

I... No. The scientific conclusions here are cumulative. They... the... the scientific studies that the FDA and others have... have looked at and... and...

Female voice:

No, the FDA didn't. The FDA was only talking about cellphones. That's my point. That's why I'm.... There could well be—it's a very big (inaudible, and laughs a little, 36:17) better than me—there could very well be something where it was clear that you were relying on either your own determinations, rather than just conclusions, or... or there's another... FDA somewhere else or another agency talked about cumulative exposures from multiple devices over a prolonged period of time for physical impacts other than cancer. And is that... you're telling me that's at... that was made at the beginning cumulative?

Miss Boizelle:

I don't know that... that we used the word "cumulative" in terminating the Notice of Inquiry. But the statements that we made....

Female voice:

(inaudible, ct, 36:56) that's what you meant.

Miss Boizelle:

(inaudible)

Female voice:

What paragraph are you talking about? Did the FDA ever talk about anything other than the cellphones?

Miss Boizelle:

In its public statements it makes... it makes broader statements about the science. Umm.

Female voice:

(inaudible, ct, 37:12) talked about cellphones. That was the only science that backed up... had to back it up, right?

Miss Boizelle:

I... I think that most of the FDA statements were about cellphones. But again...

Female voice:

(inaudible, ct)

Miss Boizelle:

... those were supplemented by representations by other, ah, entities...

Female voice:

What other entities?

Miss Boizelle:

... that the state of the science.... The World Health Organization, the International Commission for Non-ionizing Radiation Protection, which also...

Female voice:

(inaudible)

Miss Boizelle:

Pardon me?

Female voice:

(inaudible, ct, 37:33). And they talked specifically about cumulative exposure (inaudible) use of multiple devices, umm, for prolonged periods of time. As you've noticed. This was the whole reason you had your Notice of Inquiry—these changes. And they talked about this(??, 37:45) specifically.

Miss Boizelle:

Umm. The studies that were conducted... or... the scientific conclusions reflect the conclusion that even the cumulative effects are not harmful to human health.

Female voice:

(inaudible, ct, 37:57) devices... (inaudible) wireless devices, not of fixed devices.

Miss Boizelle:

Yes. Because the only substantiated harm is a thermal harm, at this point in time. And... and what we know is that at four Watts per kilogram, we start to observe thermal changes. Umm. There are... there are no substantiated adverse effects below that level. And, as it is, our standards incorporate a substantial safety margin: they're 50 times, umm, safer than that four Watts per kilogram.

Female voice:

(inaudible, ct, 38:27) thermal effects but non-thermal... that wasn't for non-thermal effects, right?

Miss Boizelle:

We're not... the limits address both kinds of effects, because the only substantiated adverse effects are thermal ones. And... and we acknowledged evidence on the other side. We acknowledge that, ah, much of the record was not scientific. That which supported to constitute research evidence lacked any persuasive case as to its value or significance. Ah, we acknowledged three of the four major studies that Petitioners rely on in their Brief, umm, and explained why they didn't provide any basis to re-evaluate our limits. Umm, and... and again going back to the Panel's questions at the start of opposing Counsel's presentation, the standard the review is quite high here. This is not the kind of case that presents the rarest or most compelling of circumstances in which reversal is required. We... we based our decision on substantial evidence, as the Second Circuit, and Cellular Phone Task Force, and this Court, and EMR Network held, umm. It was reasonable for us to rely on (inaudible, ct).

Male voice:

Can I explain my problem? I'm just(??) going to be very upfront with why I am inclined to rule against you. So I want you to... to... to tell me why, ah, I shouldn't have the concern that I do. So, I misstated earlier when I said, ah, you referenced on page 37 of your Brief, 21 USC 360ii; it was page 23 of your Brief.

Female voice:

(inaudible)

Male voice:

And you say that Congress directed the FDA to establish an Electronic Product Radiation Control Program designed to protect the public health and safety from electronic product radiation. The statute that you cite there is Section, you know, it's 21 USC, Section 360ii. When I read that, it says that basically the way that that is done is that a committee that is established in a cross-reference to 360kk will be established that will review these standards for testing an(??, 40:39) emissions level. Okay? But you don't reference that committee anywhere. And I don't see anything about that committee mentioned in the administrative record. Then, later on in your Brief, at page 37, you say not to worry because the FCC stands ready to consider changing exposure limits in... in appropriate circumstances. And you refer to a radiofrequency interagency working group that maintains a(??) continuing dialog between the FCC and the FDA about these issues. And that's referred to in a letter. Or you say that it's referred to in a letter. But when I read that letter, I don't see any, ah, mention of that working group. And... and I don't see anything in the record that says that that working group actually, ah, exists or looked at any of the evidence in this case. So the problem that I have is that you say that you're relying on the expertise of the FDA, but the entity that Congress specifically said to review this—this committee—you've given us no evidence that this committee has looked at any of this. And then you say that in the future, to the extent anything needs to be looked at, it's going to be looked at by this working group. But I don't see any evidence that the working group looked at anything this time. So why shouldn't I send it back for the... the relevant working groups and the FDA to look at this record? Tell me what... why... why... why I shouldn't... my vote shouldn't be to do that.

Miss Boizelle:

So with respect to the working group, it does exist and... and it is an ongoing project. Umm. With respect to the omission of any reference to this committee in the Order terminating the Notice of Inquiry, we did formally solicit the views of all expert agencies in the Notice of Inquiry. Umm, at JA 165, we made very clear that we intended to rely on them. Umm. We... we were very interested to hear their views. Umm, and the views that we received we took into account. And... and I think that that's all that's required here. We explained why our conclusions were what they were, based on the representations that we received.

Male voice:

Is there anything in the record that says that the FDA asked this radiofrequency interagency workgroup to review this and they weighed in, or anything in the record that says that the Technical Standards etc. Committee that was created by statute reviewed any of this and weighed in?

Miss Boizelle:

There's nothing that says that specifically.

Male voice:

(inaudible, ct)

Miss Boizelle:

Pardon me?

Male voice:

Is the answer "no"?

Miss Boizelle:

The answer is "no" on that specific question. But I would just point your attention to JA 81/87, where the FDA says, explicitly, they acknowledge 5G specifically—which goes to Judge Millett's questions about the proliferation and ubiquity of personal devices—but they say, "FDA is responsible for the collection and analysis of scientific information that may relate to the safety of cellphones and other electronic products." (inaudible, ct).

Male voice:

So why shouldn't we, as a court reviewing this, say that, at a minimum, FDA should tell FCC—and by extension tell the public and any Court reviewing this—that the expert bodies within it reviewed the materials that were submitted in response to the Notice of Inquiry? I.e., if we want to say this... this interagency workgroup is the... the right body, or if we want to say that the committee that Congress required the FDA to establish is the right body. But one of them, why shouldn't we, at a minimum, say, "Before we believe that... that... that the... we can allow kind of any sort of deference to the FCC relying on the FDA, we need to know that the right people at the FDA actually looked at the materials"?

Miss Boizelle:

Well, I think that there's nothing in the statute that suggests that the committee has to speak through the committee. I think that the FDA, umm, as the agency charged with keeping abreast of the science in this area, can speak to the state of the science. And it does refer to its ongoing monitoring activities, in its letter to the FCC, at JA 81/87. Umm, and... and this is extra-record material and we're not relying on it for you to uphold the agency's decision. But the FDA did release a review of the scientific evidence in 2020. And its conclusions were consistent with the conclusions, umm, that the FCC (inaudible, ct, 45:39).

Male voice:

But we can't consider that.

Miss Boizelle:

No. I... we're not arguing....

Male voice:

(inaudible, ct, 45:41) we can't consider that.

Miss Boizelle:

That's absolutely right. And we're not suggesting that you need to consider it to uphold the agency's decision. But I think it does confirm the centrality of the FDA to this area.

Female voice:

The FDA, it's not just that we don't know that they asked their experts, we don't know what they asked them. Because all we got from the FDA is cellphones and cancer. (inaudible, 46:02) we know whether... was... is it unreas... it is reasonable for the FCC to take the FDA's representations at face-value without verifying that the relevant experts have looked at the questions that the FCC actually asked—when they get a report back that only talks about cellphones and cancer?

Miss Boizelle:

I think it is reasonable for the agency to do so. And I think that's what the Court in(??) Cellular Phone Task Force (inaudible, ct, 46:25).

Female voice:

(inaudible, ct) in our EMR case, we specifically noted that, ah, what could make a difference is if circumstances change. We have that in there. And that circumstances could change over time, then it would need to be another look. And that was, (inaudible) flagged in your Notice of Inquiry. Your Notice of Inquiry was things have changed, including the ubiquity and multiplicity of devices. And then when the FCC gets an answer back that simply isn't answering those questions and then, as Judge Wilkins is pointing out, doesn't even say, "We consulted the people who are in charge of studying these things," that just seems to be.... I'm not.... You get a long leash but as some point that leash goes too far and becomes unreasonable without a little

bit of followup by the FCC—to make... to verify... just to pin down that the information is responsive.

Miss Boizelle:

Well, I hear your concern again about the cumulative effects here. But I think the predicate question to any assessment of the cumulative effects is whether there's any adverse effect at all from... from a single device. And, as I said, the only substantiated adverse effects are thermal—which would mean that cumulative effects wouldn't be... wouldn't be something that... that could cause injury, at least under the substantiated credible scientific evidence as it stands now. And... and (inaudible, ct).

Male voice:

How do I know that the... that the radiofrequency interagency work group, ah, doesn't believe that there are non-thermal effects that should be regulated? How do I know that the, ah, committee that Congress told the FDA to create—this Technical Electronic Product Radiation Safety Standards Committee—doesn't believe that there are non-thermal, ah, effects that need to be, ah, regulated or concern?

Miss Boizelle:

(inaudible)

Male voice:

I mean, my point is that you're asking me to infer a negative and you... and... but without there being anything in the record that the agencies... the agency that Congress said should look at this—the Committee that Congress said should look at this—even looked at it. And then you refer to an interagency work group that you say looks at these things, ah, even though there's nothing in the record about that work group or what they've looked at or haven't looked at.

Miss Boizelle:

I... I... again I think that, umm, the... we formally solicited the views of other entities with expertise in this area. We made very clear that we wanted to rely on them. We relied on the views of expert agencies in adopting these limits in the first place. And no federal agency or body...

Female voice:

Did you solicit these committees, or did you just solicit the FDA?

Miss Boizelle:

We... we... in... in... at JA 165 of the Notice of Inquiry, we said we formally seek the input of all of the... the... the expert bodies in this area. Umm. And we... we left the docket open for seven years, giving... giving ample opportunity to weigh in. And not one of these bodies said, "You need to change your standards." And... and we don't... we're not arguing that silence should be construed as endorsement, but it shouldn't be construed as disapproval of the... of the agency's

existing limits. I think even if you construe it as neutral, umm, all of the representations that we did receive—and again, the FDA has... it's undisputed that the FDA (inaudible, ct, 49:58).

Male voice:

You want us to construe, as deliberation, that silence should be construed as... as these... that these relevance committees actually deliberated, actually reviewed, umm, the record and studies. So you are asking us to infer something that's significant.

Miss Boizelle:

Well, all that we're asking you to infer is what the Second Circuit in Cellular Phone Task Force said was reasonable, which was for us to presume that the agencies and bodies charged with staying on top of this area, and regulating in this area, and... and paying attention to the science in this area have done so. Umm. And... and... yes, we're asking that you presume that the agencies with responsibility in this area....

Male voice:

Even... even... even when the report that they send back doesn't reference, you know, ah, lots of relevant studies and lots of relevant issues, we still presume that they reviewed those studies and those issues.

Miss Boizelle:

Yes. I think it's reasonable for the... for the FCC to presume that they did. As I said, the FDA referred to its ongoing monitoring activities, umm, and... and... and confirmed its responsibility in this area. Umm, and... and I don't think that there's any requirement that the... that the FCC, umm, wait for the... this Committee to speak as a committee, ah, that it can't rely on the FDA's representations about the state of the science. Umm, again, this Committee is created in the FDA's, you know, operating statute and... and appears in the section right after FDA has been anointed the agency with responsibility in this area. Umm, and... and under the (inaudible, ct).

Male voice:

You can't tell me whether that Committee even exists, or whether the Committee reviewed anything having to do with this Petition.

Miss Boizelle:

I can't, sitting here. I... I don't... I don't have any personal knowledge about that Committee. I do know, as I said...

Male voice:

Then why shouldn't that bother... bother the Court?

Miss Boizelle:

Well, again, because the FDA weighed in. It's statutorily directed to be the responsible agency in this area. And I think the FDA, we know it does have primary jurisdiction over public health. I don't know that every other member of that Committee does. But they are certainly well

equipped to evaluate the science and make a representation about the sufficiency of the radiofrequency emission limits. I mean, one other point: the FDA regulates in this area. Umm, they are responsible for promulgating the radiofrequency emission levels for devices that the FCC doesn't regulate. So again this is an important part of their mandate. Umm, and... and just as we relied on expert agencies in adopting the limits, it was reasonable to do so here. I just... one more point on this. As I said at the outset, we weren't writing on a blank slate here. In 1996 we adopted these limits, and we had the input of the FDA, the EPA, OSHA, NIOSH. So these limits don't reflect, umm, the views exclusively of the FDA. Umm, it was a considered and... and, umm, and lengthly, umm, deliberative rulemaking. And none of them weighed in to say that they needed to be changed. I'd be happy to answer other questions of the Panel.

Female voice:

I do have one. How difficult would it be to determine whether these committees and working groups exist? (inaudible, ct).

Miss Boizelle:

I can easily....

Female voice:

Well, I mean, are they set up by regulation or... or...? That's my question. Is it....

Miss Boizelle:

Sure

Female voice:

Answer... is it a question you can answer with a... some sort of supplemental, ah, submission?

Miss Boizelle:

Yes. It is a factual question. And ah, it's certainly one that we can answer in a supplement if the Panel is interested.

Female voice:

All right.

Female voice:

Are there any more questions?

Male voice:

None from me.

Female voice:

All right. Judge Millett?

Female voice:

(inaudible)

Miss Boizelle:

If there are no further questions, we ask that the Petitions for Review be denied.

Female voice:

All right. Ah, Mr. McCollough, why don't you take a couple minutes and reply.

Mr. McCollough:

Thank you. I would like to try to make about five or six really quick points. First of all to follow up from a question made(??) about Fox. If you could take a look at 780(f)3rd(??, 54:28) at 1024 to 1047. That's where the Court discusses, ah, the matter that we were... we were addressing. You might also take a look at the American Forest(??, 54:38) decision that we cited in our Brief. It says that even at the high level of deference, the agency has to...

Female voice:

I'm sorry, which pages in Fox specifically are you talking about?

Mr. McCollough:

1024 to 1047. Umm. I... I...

Female voice:

Wait, I have... sorry... Fox starts on 1027, doesn't it? I'm so sorry. (54:58)