

1           In the process of that review, there is  
2           some very rigorous scientific information that is  
3           required that is part and parcel of the entire  
4           documentation.

5           And then in the 510(k) process, a  
6           substantial equivalent determination is made. Now,  
7           granted that is a value judgment, but what is done is  
8           that you take this rigorous quantitative data, and you  
9           look at film screen, and you look at digital together,  
10          and you make a determination as to whether it is a  
11          substantial equivalent.

12          As part of that entire package our things  
13          like this. We would require that when they give the  
14          rigorous quantitative data that they operate a digital  
15          detector and they tell us what speed of film screen  
16          system are you intending to replace.

17          And so the comparison is done on an apples  
18          to apples basis. If you are intending to replace a  
19          200 speed system, the exposure to the detector has to  
20          be equivalent to what a 200 speed system would do for  
21          a particular exam.

22          And so there is this comparison going on

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1 between analog and digital devices within this center.  
2 I did not address any of that because we were talking  
3 specifically about the radiation protection and safety  
4 aspects under the Rad Health Act.

5 And maybe it was confusing a little bit,  
6 but under the Medical Device Act, there is a safety  
7 and effectiveness, and all of those aspects are  
8 brought in, including clinical trial data. In fact,  
9 very extensive clinical trial data on the PMA  
10 application, and some clinical trial data associated  
11 with the analog and the digital device for non-PMA.

12 CHAIRMAN ROTHENBERG: So you are saying we  
13 are already addressing some of Dr. Balzano's concerns?

14 DR. BALZANO: Those are the words that I  
15 said. Thank you very much.

16 DR. GAGNE: And so the exposure value of  
17 the detector, we ask them are you replacing a 200  
18 speed system, and for what. We know what a 200 speed  
19 system takes, in terms of exposure, to do a chest  
20 radiograph. Show us your quantitative data.

21 And this is data that includes resolution,  
22 noise, grade scale transfer, lots of things. But they

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1 are finally put together in terms of detective quantum  
2 efficiency as being the overall measure.

3 And then there is comparisons between the  
4 two of them, and when you look at that sort of data,  
5 what you see is that sometimes digital doesn't quite  
6 go out and perform as well at high spatial  
7 frequencies, but it has a longer and more dynamic  
8 range.

9 And so you have to make a value judgment,  
10 analog or digital, and how do you weigh these two  
11 aspects. I hope that helped.

12 CPT THOMAS: My motion on the floor is not  
13 that. My motion on the floor is to have an after  
14 exposure indication of what the dose detector  
15 procedure is.

16 CHAIRMAN ROTHENBERG: You said the dose to  
17 the detector, as opposed to the patient; is that  
18 correct?

19 CPT THOMAS: Either one. I will change it  
20 from detector to patient, but it is the dose delivered  
21 as a result of that examination, and I will change it  
22 from detector to patient. But what I am referring to

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1 is that there are different exposures for different  
2 examinations.

3 And in both CR and DR, we now are dealing  
4 with automatic exposure controls, and we do not have  
5 necessarily for these same procedures the same  
6 delivery to the patient. And there needs to be some  
7 indication of what that is in my opinion.

8 CHAIRMAN ROTHENBERG: Is there a second  
9 for that?

10 MS. KAUFMAN: I seconded the other one,  
11 and so I will second this one.

12 CHAIRMAN ROTHENBERG: John.

13 DR. SANDRIK: I have more perhaps of a  
14 comment than a question sort of thing. I think here  
15 we have to be more specific on just what dose we are  
16 talking about, because I think one of the things that  
17 distinguishes these CR and DR systems from CT systems  
18 is that they are not necessarily integrated systems  
19 from one manufacturer.

20 CR in particular can be cassettes that are  
21 totally separated from the x-ray source. So it is  
22 relatively simple to say that for the manufacturer of

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1 the x-ray source to give you some point of measure at  
2 a point in space.

3 But that manufacturer may not have any  
4 connection with the detector to know how much  
5 radiation actually reached that detector. Similarly,  
6 the detector manufacturer has his own information on  
7 what techniques were used to make the image.

8 So there is this disconnect between the  
9 source and the detector. So a source manufacturer can  
10 probably provide you a measure of dose delivered at  
11 some point.

12 The detector manufacturer may be able to  
13 give you some sort of measure of, say, of energy  
14 absorbed in that detector, but how well they could do  
15 that if they didn't now the techniques gets to the  
16 point of how useful a number is this supposed to be.

17 Is it just sort of a number value. You  
18 know, I reached a hundred points on my scale, as  
19 opposed you put in 10 ergs of energy. So I think it  
20 becomes necessary to define. Are we talking detector  
21 dose, patient dose, dose to a point in space, and that  
22 sort of thing.

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1 DR. LAMBERT: Are you suggesting that the  
2 medical community who is integrating these systems in  
3 to one unit?

4 DR. SANDRIK: In the CR essentially, yes.

5 CPT THOMAS: However, that's true and it  
6 is not true. Somebody integrates a CR or DR, and part  
7 of your comments were focused -- I took them more to  
8 be a DR comment, as opposed to a CR comment. I don't  
9 know if you necessarily want to separate those.

10 And in either one of those technologies,  
11 we have industry doing the integration, and industry  
12 provides an end for an end product that we use in CR,  
13 and I don't care if a CR reads the device, and from  
14 that reading of that device, it should be -- well,  
15 most CR systems that I know of are dose calibrated.

16 But there is not a clear indication of  
17 that dose equivalency number on those devices. Is a  
18 big number better than a small number, or is a small  
19 number better than a big number?

20 There is not meaning in those numbers  
21 today. DR, I think, again, there is not necessarily  
22 uniformity of meaning in the numbers, and the point

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1 really is somebody has to integrate the thing, and  
2 there should be able to be an indication of what the  
3 delivered dose is to the patient from that examination  
4 for either one of those receptors.

5 MS. KAUFMAN: Is that doable, Joe?

6 DR. SANDRIK: Well, as I said, I think the  
7 exposure at a point in space is not -- well, it is  
8 fairly straightforward from the source manufacturer,  
9 because that person knows what the KVP, the MA, the  
10 time, and the medical point was.

11 So basically it is millirads or grade per  
12 image at a point, which is relatively simple to do.  
13 Now, perhaps what the SID was, that kind of depends on  
14 what the source system is, or part of the detector  
15 system, to know where the patient really was, and how  
16 thick was the patient, and if you want a patient  
17 entrance exposure, then you have to have feedback to  
18 know where the entrance service of the patient was.

19 Is that part of the detector system or a  
20 part of the source system. You know, if they are not  
21 all integrated as one system, how to get that  
22 information may be difficult.

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1 MS. KAUFMAN: So I take it that it is --  
2 it sounds like it would be more effective to, as the  
3 amended motion does, to talk about patient exposures  
4 rather than detector? Just those two comparisons,  
5 detector versus -- well, let me rephrase that to some  
6 other measurement.

7 Like some other measurement would be  
8 better than detector, and as you said the detector  
9 might just be a cassette.

10 CHAIRMAN ROTHENBERG: I think it would be  
11 appropriate here -- it seems like there is interest in  
12 knowing something related to the patient dose, and to  
13 recommend that the Center investigate the best  
14 mechanism, and define in conjunction again with  
15 national and international bodies what might be the  
16 most appropriate indicator, and where it could be  
17 positioned.

18 DR. GAGNE: Well, I think I was trying to  
19 say that a lot of the details really have not been  
20 worked out.

21 CHAIRMAN ROTHENBERG: Right.

22 DR. GAGNE: But the fact of the matter is

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1 that the requirement would most probably fall on the  
2 x-ray control manufacturer.

3 MS. KAUFMAN: Larry, I would just like to  
4 comment that one reason why I think this is a good  
5 idea on these systems is that the digital units that  
6 we have seen -- and this has been true for the  
7 stereotype nano, in addition to just other  
8 radiography, is that we have seen some pretty  
9 significant increases in doses compared -- in skin  
10 entrance exposures compared to their film screen  
11 systems, even within the same facility that is using  
12 both systems.

13 And the problem -- and I don't think it is  
14 system performance. I think it is mostly operator  
15 use. And I am hoping that we are going to talk a  
16 little bit about training, because I think that is a  
17 big issue for both the operator and the application  
18 specialist.

19 But at least that kind of an indicator  
20 would help in that effort, and that people would at  
21 least know what kind of dose they were delivering, or  
22 at least what order of magnitude, if not with great

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1 specificity.

2 CHAIRMAN ROTHENBERG: So basically we are  
3 encouraging them to pursue this, but we are not giving  
4 them the specifics of how to do it.

5 MS. KAUFMAN: Yes, we have to figure that  
6 out.

7 DR. MARX: I have what may be a stupid  
8 question. It seems like the way to do -- it seems  
9 like doing dose calculations is relatively  
10 straightforward, although obviously complex in CT,  
11 because it is all integrated.

12 And then we are saying that these kinds of  
13 systems aren't integrated, and then the whole physics  
14 of it is more complicated, and getting these things to  
15 talk to each other is more complicated, and maybe it  
16 is not practical with current technology.

17 Is there any work being done on little  
18 radio lucent things that you just slap on the patient?  
19 Is there a way to do this directly without having to  
20 do all the math? I mean, is there a way to encourage  
21 R&D in that regard?

22 I don't know. Maybe like you put little

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1 temperature things on kids' foreheads, and a little  
2 number lights up as to what it is. I don't know.

3 DR. SHOPE: Yes, I think there are active  
4 vendor interests in these kinds of products. I am not  
5 sure that they have seen a great market for some of  
6 these.

7 DR. MARX: Well, if you made it a  
8 requirement.

9 DR. SHOPE: Well, that was not the point  
10 that I was going to make. We have to be very careful  
11 here when we are talking about making requirements.  
12 If we are doing that under the Radiation Control for  
13 Health and Safety Act, the product that we are  
14 regulating has to be electronic and emit radiation.

15 DR. MARX: Which the patient doesn't do we  
16 hope.

17 DR. SHOPE: Or the detector that we are  
18 talking about requiring it, and requiring things that  
19 the user does is a little different than having a  
20 product performance standard, which is another thing  
21 that we have to consider.

22 For instance, as I think Bob said, this

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1 kind of an indication requirement probably comes back  
2 to a feature that has to be on the generator, and it  
3 would apply to whether they are using film screen, or  
4 DR, or CR.

5 A manufacturer that is selling an  
6 integrated x-ray system, including the DR image  
7 receptor, maybe has a little easier task than the  
8 manufacturer who is going to just sell an x-ray  
9 generator type system, and have it be used either with  
10 film screening, which is not an electronic product.

11 And so we don't place performance  
12 standards on film screen systems. The same thinking  
13 would probably apply to CR systems, which are although  
14 electronic, they are not emitting radiation, and they  
15 weren't sold by the x-ray vendor, the manufacturer of  
16 the x-ray equipment typically.

17 So there are a little bit of legal issues  
18 that we haven't thought through completely. One of  
19 the reasons that we brought this was to get the  
20 discussion going to find out if there is on the part  
21 of the community any thought that there is value to  
22 this kind of a display.

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1 Technologically, it is probably clearly  
2 possible that we are about to require it on fluoro  
3 systems, and radiographic systems are a good bit  
4 simpler than that probably, at least in my thinking.

5 SECRETARY SULEIMAN: Thank you.

6 DR. SHOPE: And some sort of an indicator  
7 like this could be easily done. The question is if it  
8 is easily done, would it be useful and would it help  
9 solve the problem; are there other ways that we could  
10 attack this issue separate from a performance  
11 requirement on the generator manufacturers that might  
12 be a better way, i.e., education of the users, et  
13 cetera.

14 What are the options that we need to  
15 explore, and I am not trying to get us away from a  
16 recommendation about a performance area, but we are  
17 trying to look at the broader picture here of how the  
18 FDA can be the most effective in dealing with what we  
19 see as a potential problem with this possibility of  
20 dose creep, and what is the best way to go about  
21 dealing with that with the tools that we have been  
22 given.

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1           So clearly there are other areas that  
2 aren't radiation emitting products that could come  
3 into the picture here. People are developing little  
4 detectors that are photodiodes that are transmitter  
5 type things.

6           But then you have to -- and for the  
7 radiographic system, that is not too hard, because you  
8 pretty much know where you are shooting. It is  
9 different from the fluro system.

10           Certainly you can calibrate an x-ray  
11 machine and know the output at a point in space, and  
12 provide that number, or you could have a complicated  
13 system where you have an x-ray generator that knows a  
14 point in space, and is also dialed in the kind of exam  
15 it is, and the patient size.

16           And the computer or part of the x-ray  
17 system could spit out the organ doses for you if you  
18 wanted. I mean, all that kind of thing is possible,  
19 but we have not thought through any of that. I don't  
20 know what is the correct approach.

21           One other thing that I do want to mention  
22 is that I think that one of the strengths of this idea

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1 is the idea that it would support the whole area of  
2 the reference value concept or the reference dose  
3 concept.

4 Facilities would be able to easily -- and  
5 more easily than they would now. How would you do  
6 that now if you were a facility that wanted to  
7 implement a reference dose kind of quality assurance  
8 program.

9 You would either have to, one, put TLVs on  
10 patients, and monitor a series of patients, and record  
11 their weight and size so that you know for the typical  
12 average patient what they get in this particular exam.

13 And so you have to get into a dose  
14 symmetry method, or you have dose area product meters  
15 on the systems, and then you correct for the field  
16 size to get what the dose was.

17 So there is two ways to go about  
18 collecting dose information. Both of them require  
19 additional expenditures perhaps by the facility in  
20 order to track those doses.

21 There is the potential here for a way to  
22 gather information and to provide information to the

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1 facilities for this kind of comparison if it is  
2 basically built into the machine.

3 So I think that is part of what we were  
4 hoping that we would get some feedback and discussion  
5 of as to what is the value of this, and how could it  
6 compliment some of these other things that we might be  
7 thinking about for the future. I'm sorry for  
8 expounding for too long.

9 CHAIRMAN ROTHENBERG: I think what this  
10 motion does is encourage you to pursue this. Are  
11 there any other comments? Yes.

12 DR. SANDRIK: Just to add to that, that  
13 that goes hand-in-hand with what is it that you want  
14 to display, and what are you going to do with it,  
15 because we can go through the expense, and add the  
16 complexity to put in some sort of display, and if it  
17 is ignored as timers on fluro units are now, and many  
18 other methods of trying to measure dose values, then  
19 it really has not accomplished anything.

20 So I think that you have to have the other  
21 side of this, which is how are you going to make  
22 people aware of what this value is, and what it means,

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1 and should they reduce it or not.

2 It has to be the other aspect of this, so  
3 that is what is provided really has some meaning and  
4 what benefit it can give.

5 MS. KAUFMAN: I am hoping that one thing  
6 we are going to talk about is training.

7 CHAIRMAN ROTHENBERG: I think that would  
8 be another item you might want to address. This will  
9 not be in the vacuum of an equipment item without  
10 appropriate training as well, or education. Are we  
11 ready to vote on this motion? All in favor?

12 (A raise of hands.)

13 CHAIRMAN ROTHENBERG: Opposed? Abstain?  
14 So again it is unanimous. Now, does anyone want to  
15 make a motion concerning education and training?

16 MS. KAUFMAN: Well, I need to ask a  
17 question first. The American Society of Radiologic  
18 Technologists is actively pursuing Congress to require  
19 certification of operators of x-ray equipment  
20 nationwide.

21 The FDA had come out with recommendations  
22 in the '70s that encouraged States to have

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1 certification, but it was voluntary. And currently I  
2 think on the order of 30 States have certification  
3 requirements for operators and the rest do not.

4 Has the FDA taken any kind of a position  
5 relative to the American Society of Radiologic  
6 Technologists' activities?

7 SECRETARY SULEIMAN: Congress passes laws.  
8 We try to obey. The Consumer Protection Act, which is  
9 what I think you are referring to, was passed 10 or 20  
10 years ago, and it was very voluntary. We are supposed  
11 to encourage States to do that sort of thing.

12 I know that there is a bill that keeps on  
13 being presented to Congress requiring MQSA type  
14 credentialing and whatever. I am not aware of the  
15 status. I don't think the Center or the Agency is  
16 actively lobbying for or against that.

17 MS. KAUFMAN: And so you could; is that  
18 right?

19 SECRETARY SULEIMAN: I'm not.

20 MS. KAUFMAN: The Center can't lobby or  
21 support that kind of activity?

22 SECRETARY SULEIMAN: I think it is good

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1 practice. We would probably encourage it, but in  
2 terms of lobbying for specific bills, I don't think  
3 so, unless somebody wants it.

4 DR. ELWOOD: Federal agencies cannot lobby  
5 for bills.

6 MS. KAUFMAN: Well, since they came out  
7 with a guidance back in '74, I thought that might be  
8 some kind of an entre to support that current effort.

9 SECRETARY SULEIMAN: I mean, the aims are  
10 similar, but we can't lobby for specific legislative  
11 bills.

12 MS. KAUFMAN: Well, I really don't know  
13 how FDA -- what they could do in the area of training,  
14 because as you say, you don't actually regulate the  
15 use of equipment.

16 It is clear that training is needed in  
17 this area for operators, and that there needs to be  
18 minimum standards for the operators and the  
19 application specialists. But I guess I am not clear  
20 on what FDA could do in that regard.

21 SECRETARY SULEIMAN: I think it is a real  
22 resource issue. I mean, if we had lots of money, we

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1 could say let's mount a national training program and  
2 educational program. We don't have those kinds of  
3 resources.

4 I think we have the law, the performance  
5 standard for all these electronic products, and that  
6 is a much more specific authority and control that we  
7 have. I think sort of a sentiment of the committee  
8 and encouraging us to do what we can, but we will do  
9 what we can.

10 CPT THOMAS: Let me make a comment if I  
11 could. These new technologies that we have been  
12 discussing kind of create a problem for us. We are  
13 collectively limited to electronic devices that emit  
14 radiation.

15 There are three compliments though in  
16 these systems that we are dealing with. We have got  
17 the acquisition, which we just finished discussing.  
18 Then we have display, and then we have manipulation of  
19 the required data for optimal display.

20 Part of the issue of training and training  
21 standards for technologists, medical physicists, and  
22 physicians using this technology is -- the broad focus

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1 is to improve the diagnostic process.

2 But that is outside the direct scope of  
3 what we are recommending. The training is the back  
4 door to the last two issues, and then it becomes a  
5 resource issue as Orhan has suggested.

6 Some of the most effective training in  
7 this nation in terms of improving public health and  
8 safety, and also the resulting quality of technology  
9 is that this has come out of the FDA in the '70s, '60s  
10 and '70s. It was absolutely superb.

11 I think that is a model that we might want  
12 to consider recommending that it be reinvestigated by  
13 the Center. And to that extent, I will try to throw  
14 out another motion if I may, and -- do you want to do  
15 it?

16 MS. KAUFMAN: No, you can do it. I will  
17 second it.

18 CPT THOMAS: Thanks. I get the verbal  
19 problems here. I would like to make a motion that  
20 this committee encourage the FDA to investigate  
21 educational programs for the physician, medical  
22 physicist, and technologist, in the application of

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1 these new technologies to medical practices.

2 MS. KAUFMAN: I will second it with one  
3 suggestion; that instead of maybe just saying  
4 investigate, but saying maybe investigate and prepare,  
5 because I am thinking about the QC books and stuff  
6 that FDA used to publish that were -- that they  
7 actually published them, and they were very  
8 educational. And they came out with like model QC  
9 programs, and stuff like that.

10 CPT THOMAS: That becomes a resource issue  
11 that we can't demand, and that they may not be able to  
12 do.

13 MS. KAUFMAN: Right. But I think if we  
14 don't make a recommendation that they may never get  
15 the resources. I mean, they are probably not going to  
16 get them anyway, but if we don't make the  
17 recommendations, then they probably really won't get  
18 them.

19 CHAIRMAN ROTHENBERG: Then I think we  
20 should make the recommendation if we feel it is  
21 important.

22 CPT THOMAS: I second that.

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1 CHAIRMAN ROTHENBERG: So we have a motion  
2 and a second regarding the educational material. Do  
3 we have any further discussion? All in favor?

4 (A show of hands.)

5 CHAIRMAN ROTHENBERG: Opposed. Abstain.

6 (A show of hands.)

7 CHAIRMAN ROTHENBERG: Two abstentions.  
8 All right. All right. Are there any other statements  
9 you want to make based on this one discussion, because  
10 we are approaching the time when we are going to get  
11 to this afternoon's discussion.

12 MS. KAUFMAN: I wanted to recommend or to  
13 make a motion that FDA require a post-exposure readout  
14 on automatic -- on regular radiographic units that use  
15 automatic control systems similar to what we currently  
16 require on mammography systems.

17 CHAIRMAN ROTHENBERG: Post-exposure MAS?

18 MS. KAUFMAN: If it is MAS or --

19 CPT THOMAS: A post-readout of the  
20 radiographic techniques?

21 MS. KAUFMAN: Correct.

22 DR. LOSCOCCO: Isn't that required?

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1 MS. KAUFMAN: No. You have to have an  
2 indication of what pre-exposure factors you select; is  
3 that right?

4 DR. LOSCOCCO: I thought you had to have  
5 it --

6 MS. KAUFMAN: Only on mammal.

7 DR. GAGNE: As far as I remember, the  
8 post-indication of MAS is not required on non-  
9 mammography equipment.

10 MS. KAUFMAN: That is my motion.

11 DR. GAGNE: When you use automatic  
12 exposure controls.

13 DR. LOSCOCCO: I guess it is on the  
14 machines that we have.

15 CHAIRMAN ROTHENBERG: It is on a lot of  
16 machines, but it is not required. Is there a second  
17 to that?

18 MS. KAUFMAN: It seems to me that the  
19 technology is there and readily available.

20 CPT THOMAS: So your motion is that you  
21 want to ask the FDA to require manufacturers to  
22 provide a post-exposure technique for a readout?

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1 MS. KAUFMAN: Right. Just like we  
2 currently do on mammography units.

3 CPT THOMAS: I second it.

4 DR. NELSON: What does that do?

5 MS. KAUFMAN: It tells the operator what  
6 the exposure actually was. It doesn't give patient  
7 dose, but for example if MAS is what the unit  
8 automatically selects, it tells you what the MAS is.

9 It is a very good indicator if something  
10 is going wrong. If you want to do a quick quality  
11 control test on whether the automatic exposure control  
12 is working, you can stick any kind of a fan in the  
13 beam.

14 And in fact that is what they do on  
15 mammography units, is that they use a fan on them, and  
16 they should get about the same mass readout every  
17 time. And my understanding is that it is pretty darn  
18 inexpensive. I think it is a few hundred bucks or so.

19 CHAIRMAN ROTHENBERG: Also, if you want to  
20 do any kind of dose calculation, you really can't do  
21 it without that. It is there. We have decided that  
22 it is important for mammography, and I don't see any

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1 reason why it is not just as important for many  
2 radiographic techniques as well. Any additional  
3 comment?

4 DR. SANDRIK: Are we intending a  
5 retroactive implementation of this like MQSA did or a  
6 proactive --

7 MS. KAUFMAN: A proactive.

8 CPT THOMAS: It should be proactive.  
9 Actually, we want the machines made 25 years ago --

10 MS. KAUFMAN: Yes, G.E.s were made in  
11 1955.

12 CHAIRMAN ROTHENBERG: Okay. Any other  
13 discussion on that motion?

14 SECRETARY SULEIMAN: let me educate the  
15 committee a little since we are going on and it  
16 wouldn't hurt. When we propose rules, and let's say  
17 we go through the whole process, and we are there, it  
18 basically only impacts new equipment. So inherently  
19 the old equipment just either is grandfathered in  
20 until it is obsolete or is just discontinued. So it  
21 is not a retro.

22 CHAIRMAN ROTHENBERG: Okay. Any other

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1 discussion? Yes, John.

2 DR. CARDELLA: The motion that was made  
3 and voted upon this morning about the CT dose  
4 reduction for pediatric patients; it was brought to my  
5 attention over the lunch hour that there are adult  
6 patients that are pediatric size, little people.

7 And without making a huge discussion, if  
8 I could just make the point that maybe instead of it  
9 being pediatrically focused, it would be focused on  
10 small subjects.

11 You know, maybe instead of saying  
12 pediatric dosing, make it weight based, or thickness  
13 based in some way, so that you would include small  
14 adults.

15 CHAIRMAN ROTHENBERG: I don't think there  
16 is a problem with that if we expand that to include  
17 small subjects.

18 SECRETARY SULEIMAN: You are not  
19 suggesting the exclusion of pediatric?

20 DR. CARDELLA: No. By saying small  
21 subjects, you would include peds and little adults.

22 SECRETARY SULEIMAN: I don't see why that

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1 is a problem.

2 CHAIRMAN ROTHENBERG: Okay. Let's  
3 complete the discussion or the vote on this motion  
4 concerning the post-exposure technique indications.  
5 All in favor of that latest motion?

6 (A show of hands.)

7 CHAIRMAN ROTHENBERG: Opposed? Abstain?  
8 Okay. That was unanimous. Now, I think that  
9 completes most of the things, but does anyone have any  
10 other motions with regard to digital and CT  
11 discussions this morning?

12 (No audible response.)

13 CHAIRMAN ROTHENBERG: Okay. If not, I  
14 think we should move ahead in the interest of getting  
15 finished at a reasonable time. Any discussions for  
16 the afternoon concerning the -- well, we have two  
17 items. The first is performance standards for non-  
18 medical products, and Mr. Collin Figueroa will be  
19 presenting that.

20 SECRETARY SULEIMAN: You may want to enter  
21 for the open public hearing the --

22 CHAIRMAN ROTHENBERG: Oh, I'm sorry.

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1 There is one item at the point that we were supposed  
2 ot have the open public hearing, no one requested to  
3 speak, but we do have a letter concerning the  
4 reporting and compliance guide for television  
5 products, and some proposed changes from the Consumer  
6 Electronics Association, submitted by David Wilson,  
7 and we would like to enter that statement proposal  
8 into the record for this meeting.

9 SECRETARY SULEIMAN: And copies have been  
10 distributed to the committee, and there are copies  
11 outside available.

12 CHAIRMAN ROTHENBERG: Okay. Mr. Figueroa.

13 MR. FIGUEROA: First of all, it is a  
14 pleasure to be before this committee discussing  
15 performance standards and non-medical products areas.  
16 As indicated, my name is Collin Figueroa, and I am the  
17 electronic product branch chief in the Office of  
18 Compliance Center for Devices. Next slide.

19 And today I am going to be talking about  
20 electronic products and provide a history and summary  
21 of non-medical electronic products, and the  
22 surveillance [activities that are being done at the

1 Center for Devices.

2 This was requested during the 2000 meeting  
3 of TEPRSSC. I will be looking at radiation safety  
4 standards, changes in technology and use, adverse  
5 events, and safety investigations, and tools for  
6 surveillance and enforcement.

7 And before I do that, let me just kind of  
8 give you a kind of summary of some of the products  
9 that have performance standards. All the products  
10 that you see up here above the top of the line have  
11 performance standards; microwave ovens, televisions,  
12 receivers and monitors, laser products, x-rays,  
13 mercury vapor lamps.

14 The ones below do not have performance  
15 standards; mobile phones, and the like. Next slide,  
16 please.

17 Some of the activities that are done in  
18 the Center for Devices regarding non-medical products  
19 include maintenance of the performance standards.  
20 When performance standards need to be changed, we do  
21 that. We participate in consensus standards  
22 development, and we also provide technology and

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1 regulatory safety information, and information to  
2 users, as well as our FDA field operatives. Next  
3 slide.

4 We review radiation safety product  
5 reports, and what we look for in those reports are  
6 safety specifications, and we look for quality  
7 control, and to testing, and we try to make sure that  
8 those products are in conformance with the performance  
9 standard.

10 We also conduct reviews of post-market  
11 activities. We have individuals who actually do  
12 inspections of manufacturers. We look at complaint  
13 investigations. We have a facility in Massachusetts  
14 that does testing for us for lasers, and microwave  
15 ovens, and televisions. And we also look at import  
16 entries. Next slide.

17 We process requests for variances from the  
18 standards, and we approve corrective action plans for  
19 product recalls, and for future products as well. We  
20 grant exemptions, and we disapprove manufacturer's  
21 testing programs. We prepare legal cases, such as  
22 injunctions and civil money penalties.

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1 I like to think that this is where it all  
2 kind of started, and the three areas that I am going  
3 to be talking about today are televisions, microwaves,  
4 and lasers.

5 And when I talk to the people on my staff,  
6 they tell me this is where it began, right here in  
7 t.v.s, and it is pretty interesting when you really  
8 look at it.

9 There was a television x-ray problem in  
10 1966 when a t.v. manufacturer discovered that certain  
11 large screen color receiver models were emitting x-  
12 rays in excess of 45 milliroentgens per hour limit  
13 recommended by the National Council on Radiation  
14 Protection and Measurements.

15 The manufacturer's replacement of faulty  
16 tubes eliminated x-ray emissions from these sources.  
17 However, some receivers were found to leak x-rays from  
18 components common to other manufacturers. As a result  
19 of this, a survey was done to conduct and determine  
20 the problem, the scope of that whole problem.

21 The Bureau of Radiological Health, working  
22 with set manufacturers, checked home color receivers

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1 for x-ray images in 1967, and in 1968, in the  
2 Washington, D.C. area.

3 About 6 percent of the sets tested were  
4 found to emit leakage, x-ray leakage, above the .5  
5 milliroentgens per hour recommended standard. Local  
6 and State Health Agencies also participated in that  
7 survey, and found 6 to 20 percent of colored sets  
8 emitted x-rays above the recommended standard. Next  
9 slide.

10 As a result of that survey and testing, we  
11 have the Radiation Control for Health and Safety Act,  
12 and the purpose of that Act was to make sure that  
13 unnecessary radiation wasn't getting to the public.  
14 Next slide.

15 With that in mind, that Radiation Control  
16 for Health and Safety Act also gave us the authority  
17 to write standards, the first standard being the t.v.  
18 standard in 1970, which one of the elements of the  
19 standard was that x-ray emissions should not exceed  
20 the .5 milliroentgens per hour at 5 centimeters from  
21 the external surface. Next slide.

22 That standard has not changed since 1970.

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1 We did have a phase-in of worst component testing in  
2 1971, and basically that indicates that we required  
3 manufacturers to test components to the limit, plus  
4 one failure. This industry consists of approximately  
5 10 U.S. manufacturers, and 300 foreign manufacturers.  
6 This industry produces 70 million products per year.

7 Now and then. When I think about the  
8 history of this particular product, t.v.s and  
9 receivers, then t.v.s were filled with tubes that  
10 emitted x-rays, and also then I remember -- well, I  
11 don't remember the sets myself, but they were small  
12 boxes with round circles. You had small screens.

13 And I do remember my grandmother saying  
14 don't sit so close to the t.v. I do remember that.  
15 So the viewing distances have changed from where we  
16 are now, and I would say about half the households in  
17 the U.S. probably had t.v.s back then.

18 Right now the only x-ray tube that is  
19 emitting x-rays is the cathode ray tube. As I  
20 indicated, screen sizes are vastly different now. We  
21 have small screens, and so they vary, and the viewing  
22 distance has obviously changed, and most of us are

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1 right up on the monitors when we are either typing,  
2 and some of our children may be too close as well.

3 But the viewing distance has changed.  
4 Right now I would say at least three per household and  
5 some of us in this room may have four or five. You  
6 never know. But business is obviously in every office  
7 that there is and there is a monitor.

8 So times have changed, and technology has  
9 changed as well. What kinds of complaints do we get?  
10 First of all, when we get complaints, we investigate  
11 those complaints. But some of the things that we get,  
12 we have people who complain of chronic exposure, short  
13 distances.

14 And unfortunately when we do -- and I  
15 think last year we may have had two complaints, and  
16 when we investigated those complaints, we were not  
17 able to document that an actual exposure occurred.

18 So when we do investigate, we are in most  
19 cases not able to document that an actual exposure  
20 occurred from x-ray radiation. Next slide.

21 What do we find from surveillance  
22 activities? A lot of the overseas firms are lacking

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1 understanding of testing requirements and processes.  
2 Testing of whole down circuits and sealing of  
3 adjustable components, and identifying the worst case  
4 scenarios.

5 What do we do when we find these out?  
6 Basically, we find these out through reports, and we  
7 find these out through inspections, and we find these  
8 out through testing. We have a facility doing the  
9 testing.

10 We take regulatory action, and we send  
11 warning letters, and we stop these manufacturers from  
12 importing into the U.S. by program disapprovals. And  
13 we also do education. A lot of firms call us and we  
14 provide them insight and direction on what they should  
15 be doing. Next slide.

16 Microwave ovens. In 1968 through 1967  
17 (sic), it was estimated that half a million microwave  
18 ovens were being manufactured. Today, trillions of  
19 people use microwave ovens in their homes,  
20 restaurants, food vending service establishments, and  
21 the like. Next slide.

22 Prior to the microwave oven, the standard

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1 for uses of certain earlier models of microwave ovens  
2 may have been exposed to excess and unnecessary  
3 exposure to radiation leakage due to door or from the  
4 oven being turned on when the door was opened.

5 In the late '60s, a survey was performed  
6 to show that a significant percentage of microwave  
7 radiation leakage occurred, and that it was in  
8 violation of the voluntary standard. The survey  
9 resulted in the promulgation of the microwave standard  
10 in 1971.

11 As a result of the standard, an  
12 overwhelming improvement in oven design -- for  
13 example, door seals, safety interlocks, door hinges --  
14 were greatly superior than the 1971 models. Next  
15 slide.

16 Some of the elements of this standard.  
17 Before a microwave oven can leave the factory, it  
18 should not be emitting more than 1 milliwatts per  
19 centimeter square.

20 The microwaves that you have at your home,  
21 they should not emit more than 5 milliwatts per  
22 centimeter square. They also should have door

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1 interlocks. Next slide.

2 Amendments to this standard include added  
3 safety instructions and manuals, interlock  
4 concealment, and an interlock monitor in 1975, and in  
5 1981, changes in test instruments.

6 This industry consists of seven U.S.  
7 manufacturers, 16 foreign manufacturers, and this  
8 industry produces 14 million products per year. Next  
9 slide.

10 The source that emits microwave radiation  
11 is called the magnetron, and that has not changed.  
12 That still exists right now. Sizes of the microwave  
13 ovens have changed. Then they were larger, and the  
14 cavities were larger. Now we have smaller, and  
15 probably even very small cavity sizes for microwaves.

16 Back then the metal door was a wire mesh  
17 gasket, which at times would wear out, causing leakage  
18 around the doors. Now they are using chokes and the  
19 doors are more flexible; built in chokes, and they are  
20 not wearing out.

21 Back then houses, and restaurants, and  
22 convenience stores; now, vending machines, boats,

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1 cars. Microwave ovens are just about anywhere these  
2 days.

3 What kinds of complaints do we get?  
4 Apparent door operation, and users are concerned that  
5 the light is on, and they may hear a fan running.  
6 Therefore, they may think that the microwave is also  
7 emitting radiation.

8 We have not been able to document any of  
9 those. I think last year, we had three complaints,  
10 and we looked into those, and we were not able to  
11 document that an actual microwave radiation incident  
12 occurred. Next slide.

13 What do we find from surveillance  
14 activities. Some firms lack an understanding of  
15 interlocks; wire insertion, leakage testing, and door  
16 designs.

17 And we take seriously these problems, and  
18 in most cases shut the firms down until they get these  
19 problems right through program disapprovals and  
20 stopping them from importing into the U.S. Next  
21 slide.

22 Lasers. The FDA noted that serious

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1 accidents and injuries were known to occur as a result  
2 of the use of lasers. This standard was intended to  
3 establish a uniform hazard base set of criteria for  
4 the classification of laser products, and to prescribe  
5 class dependent controls, indicators, and warnings for  
6 products and their supporting instruction literature.  
7 Next slide.

8 When we first put this in, we were very  
9 conservative with this standard. Some of the elements  
10 of the standard are emission limits for different  
11 wavelengths and emission indicators. The accessible  
12 radiation determines the hazard classification --  
13 Class One, Class Two, Class Three, Class Four for  
14 lasers. Next slide.

15 Because we were so conservative, we began  
16 in 1978 to relax some of the aperture location  
17 requirements, and we also created a Class II laser  
18 class. In 1985, we relaxed the measurements and  
19 expanded the Class 3(a) to include visible laser  
20 products with outputs up to 5 milliwatts.

21 Lillian Gill may have mentioned earlier  
22 that we are in the process of revising the laser

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1 standard to harmonize with the international standard,  
2 and we are still doing that. Next slide.

3 This industry is our largest industry, and  
4 this is approximately 1,400 U.S. manufacturers, 60  
5 foreign manufacturers, and this industry is producing  
6 265 million products per year.

7 Some of the things for now and then is  
8 that they are still using Argon and CO2, and Yag  
9 lasers, but now we are having Green Yag, and we are  
10 going into different types of wavelengths.

11 So that is expanding and we have the micro  
12 machines now. Lab benches and sizes were the norm  
13 back then, but now it is changing, and we have smaller  
14 places where we are using laser pointers. I don't  
15 have one here, but someone in this office has a laser  
16 pointer, believe me.

17 But we have laser pointers just about  
18 everywhere. Science and industry has also changed,  
19 and now we use them for communication, for sports, for  
20 just about anything. Right now I am waiting for a  
21 laser pointer for cutting grass, and I know that  
22 someone out there is going to put that together and it

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1 will be faster. Next slide.

2 What kinds of problems are we finding?  
3 Flash blinding burns, retinal damage, and most of  
4 these occurrences -- I think we had three last year,  
5 and most of these occurrences are where people are  
6 inexperienced with the lasers, and in working with  
7 lasers, sometimes you have to get in there and get  
8 dirty, and sometimes you may get burned in doing that.

9 We investigate these to determine that it  
10 wasn't a manufacturing problem or a manufacturing  
11 design. So we are looking at these as well. Next  
12 slide.

13 Some problems that we have seen in the  
14 past is that laser pointer manufacturers overseas are  
15 having problems with testing and certification. For  
16 this industry, we have stopped a lot of them from  
17 coming into the U.S. because of that problem, with  
18 program disapprovals and warning letters. Next slide.

19 This slide here basically just gives you  
20 a kind of graphic picture of how the laser industry is  
21 expanding in relationship to the medical x-ray  
22 assemblers. So it is our largest industry that we

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1 handle, and you can see where t.v.s and microwaves  
2 fall into place. Next slide.

3 We already talked about how much products  
4 are in the market, and this just gives a depiction of  
5 that. Next slide. I talked a little bit about  
6 inspections, and lab tests, and field tests.

7 Last year, we did a hundred inspections of  
8 laser manufacturers, 120 field tests, and we did do  
9 some analysis on some laser pointers last year. We do  
10 more testing of microwave ovens, and we do a little  
11 bit of inspections, and most of the microwave ovens  
12 and t.v. manufacturers are foreign commerce, and we  
13 get out there when we are able to.

14 Basically, this talk is to basically give  
15 you a kind of summary and a history of what we do in  
16 non-medical electronic products. CDRH is not making  
17 or recommending any proposal to change any of the  
18 standards. This is just for your information only.  
19 Thank you.

20 CHAIRMAN ROTHENBERG: Okay. Thank you  
21 very much for a complete description of these three  
22 areas. Does anyone on the committee have any

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1 questions for Mr. Figueroa?

2 MS. KAUFMAN: I have a question. The  
3 manufacturers, and I have a question on manufacturers.  
4 The slide I think said for good cause.

5 MR. FIGUEROA: Right.

6 MS. KAUFMAN: So does that mean that there  
7 is no routine inspection of manufacturers?

8 MR. FIGUEROA: There are routine  
9 inspections, but the regulation actually says for good  
10 cause. But the 120 that I mentioned are basically  
11 routine, and we provide a list to the field  
12 investigators for possible problem firms that we have.

13 MS. KAUFMAN: The 120 were manufacturers  
14 or --

15 MR. FIGUEROA: Actually, it was a hundred.  
16 The 120 were field tests, and inspections.

17 MS. KAUFMAN: Was that necessarily of the  
18 manufacturer though?

19 MR. FIGUEROA: The manufacturers.

20 MS. KAUFMAN: These are only of  
21 manufacturers?

22 MR. FIGUEROA: The field tests are actual

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1 field tests. They actually go out and go to a person  
2 who purchased --

3 MS. KAUFMAN: That is what I was thinking,  
4 and so it is not necessarily at a manufacturer's?

5 MR. FIGUEROA: Correct.

6 MS. KAUFMAN: Okay. So getting back to  
7 the manufacturer, do you know about what percentage,  
8 or at what frequency a manufacturer might expect to be  
9 inspected by FDA?

10 MR. FIGUEROA: For -- well, I am not sure  
11 about what frequency. We are talking about -- we did  
12 a hundred firms last year. Maybe every five years  
13 just to take a guess. Anybody? Joanne Barron on my  
14 staff may have that.

15 MR. BARRON: I think to clarify first that  
16 routine, and routine in that we do a certain kind of  
17 activity when we do the inspection, but they are not  
18 routine in that we do a regular program.

19 Like we go to every company every so many  
20 years or whatever. They are not routine in that  
21 respect.

22 MS. KAUFMAN: There is no routine

1 inspection program; is that correct?

2 MR. BARRON: No. The program is for good  
3 cause, which means that we need to have some  
4 indication that there is a problem. We get reports  
5 from the manufacturers, and based on those reports, we  
6 may then test a product, whether it is a field test or  
7 a lab test.

8 Based on either the report or the product  
9 testing, we may then ask for an inspection. So they  
10 are routine in the fact that we have got a program  
11 where we look for a problem, and then once we find a  
12 problem, try to include the inspection process in the  
13 mix.

14 Sometimes, just based on the report or the  
15 inspection, we may just write a letter to the  
16 manufacturer disapproving their testing program, and  
17 we don't worry about the inspection until after  
18 everything gets cleared up, and then we might go in  
19 and look.

20 MS. KAUFMAN: So if no problem ever came  
21 to your attention, a manufacturer might never be  
22 inspected; is that correct?

1 MR. DENNIS: That is possible.

2 DR. ELWOOD: Can you tell me where in the  
3 process you are with the laser product performance  
4 standard?

5 MR. FIGUEROA: Right now it is still -- it  
6 is being updated, and it is still under review. And,  
7 Jerry, do you want to come up here and talk a little  
8 bit about that. Jerry Dennis is leading that.

9 MR. DENNIS: At your last meeting, I  
10 distributed a copy of an incomplete draft of the  
11 amendments. We have been continuing our work on  
12 completion of that document, completing the preamble,  
13 which would include the analysis of comments to the  
14 first proposed amendments.

15 As Lillian Gill said this morning, we had  
16 your advice last time to proceed, and we did proceed.  
17 Right now we are in the process of getting agency  
18 clearance so that we can publish a new proposal in the  
19 Federal Register for Public Comment. Does that answer  
20 the question?

21 DR. ELWOOD: Okay. And I have another one  
22 for you. I thought that I heard Ms. Gill say -- and

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1 maybe this is just wishful thinking on my part, but  
2 that if we are producing products in compliance with  
3 the new IEC standard -- for instance, we may now have  
4 a product that would now be considered one and under  
5 the IEC?

6 MR. DENNIS: That's correct. We have  
7 drafted a guidance document for the industry, which is  
8 also in the approval process at this point. I can't  
9 divulge the exact details of that at this moment, but  
10 it is in progress.

11 DR. ELWOOD: Can you estimate when it  
12 might be published?

13 MR. DENNIS: I really can't. I hope that  
14 it will be soon, but I can't give you a projected  
15 date.

16 DR. ELWOOD: Thank you.

17 CHAIRMAN ROTHENBERG: Any other questions  
18 or comments?

19 DR. LOTZ: I have a question with respect  
20 to LDTs, and that is have you done any testing in your  
21 Winchester lab to look at the larger monitors that are  
22 now produced?

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1           There was a lot of data produced by  
2 various parties in, say, the early '90s when monitors  
3 were typically a lot smaller, and there were some  
4 substantial epidemiologic studies going on.

5           And I just wondered if you had any or had  
6 actually done any checking to see whether -- well,  
7 actually I wasn't thinking so much of x-rays, but  
8 whether exposures around monitors that are now the  
9 larger 21 and even larger sizes, are any different  
10 than they are from the smaller ones?

11           MR. FIGUEROA: I would say no.

12           DR. LOTZ: No, you have not done any  
13 testing?

14           MR. FIGUEROA: That we have not done any  
15 testing, correct.

16           CHAIRMAN ROTHENBERG: Any other questions?  
17 Okay. Thank you very much.

18           MR. FIGUEROA: Thank you.

19           CHAIRMAN ROTHENBERG: Okay. We don't have  
20 any additional public hearing speakers. So we have a  
21 presentation that will take place shortly on cellular  
22 telephones, and maybe we should take a 5 minute

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1 stretch break, and then we will go ahead with the  
2 cellular telephones.

3 (Whereupon, at 2:35 p.m., the meeting was  
4 recessed, and was again called to order at 2:42 p.m.)

5 CHAIRMAN ROTHENBERG: Okay. Is everybody  
6 ready? We have a warmed up projector, and Dr. Owen is  
7 going to discuss wireless phones.

8 DR. OWEN: Thank you all for the slot on  
9 the agenda. I hope that you all are refreshed by  
10 today's events, and I am proud to have this piece of  
11 real estate in your agenda.

12 The slides that I am going to show are a  
13 little bit different from what you have gotten in your  
14 packet, but not drastically different. I am going to  
15 give an overview, and I am not planning on going into  
16 too much depth so that there will be time for  
17 questions.

18 After I give a little bit of background,  
19 I want to briefly go through some of the scientific  
20 literature on bio-effects of radio frequency exposure,  
21 and I am going to restrict my discussion to current  
22 issues and recent progress, with a focus on questions

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1 related to cancer.

2 And then finally I will talk about some of  
3 our activities to address the issue. Just a little  
4 background. Of course, for a long time we have had  
5 widespread radio frequency exposures from radio, from  
6 radar, from t.v., and there are current exposure  
7 standards.

8 Wireless phone exposures are generally in  
9 the .9 to 1.8 gigahertz ranges, which is sort of  
10 between t.v. and microwave ovens, just to get you  
11 oriented on the spectrum. What I am talking about  
12 today are the hand held devices, and not the base  
13 stations.

14 Just a regulatory note. The FDA does not  
15 regulate the bay stations. That belongs to the FCC.  
16 We do work with the Federal Communication Commission  
17 on RF matters, but they actually regulate the bay  
18 stations.

19 We have the potential for regulating the  
20 hand sets, and the FCC does regulate the hand sets in  
21 cooperation with us and other agencies. The wireless  
22 phone hand sets present to us an unprecedented

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1 exposure of the population by a couple of ways.

2 One is the type of RF exposure, and  
3 different sorts of modulation, very near to the body,  
4 and a relatively low level exposures, but chronic over  
5 a long period of time these low levels.

6 The other way that it is nominal is the  
7 scope. In about 20 years, we have gone to almost no  
8 users to right now roughly 114 million subscribers in  
9 the United States alone; and just for perspective, the  
10 subscribership or the penetration of the market in the  
11 U.S. is very low compared to several other countries.

12 Briefly, on the RF biological effects  
13 literature. Again, I am focusing on cancer, and I am  
14 looking at this in the context of additional research  
15 needs that would take us towards better assessments of  
16 possible adverse health effects.

17 And, of course, the literature can be  
18 grouped into three general areas; epidemiology  
19 studies, animal studies, and cellular studies, and I  
20 will begin with epidemiology studies.

21 There has been a rather few studies of  
22 human populations, but there have been a few studies

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1 that have been published recently that are relevant to  
2 this discussion.

3 Particularly lacking for us are studies of  
4 highly exposed, highly RF exposed populations. In all  
5 the studies in the past, and even in the recent ones,  
6 have big problems with exposure assessment.

7 And these problems remain to be resolved  
8 with additional work. The exposure assessment is  
9 difficult for a number of reasons. Sometimes studies  
10 depend on questionnaires, and so you have got issues  
11 of what people recall.

12 Sometimes they depend on billing records,  
13 and there is limited information available there.  
14 Then there are important factors of the actual phone  
15 use, and the position of the phone, and active control  
16 of the handset power during use has a very large  
17 impact on the actual RF exposure of a user.

18 So what has happened recently. In I think  
19 March of '98, Morgan and Co-Workers, an Office of  
20 Cohort Studies of employees of a large U.S. wireless  
21 manufacturer, they found no adverse health effects  
22 associated with RF exposures.

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1           There was little though in this study  
2 directly related to the use of wireless phones, and  
3 the RF exposures from that use. In '99, a  
4 Scandinavian study, a case control study from Hardell  
5 and Co-Workers again found no increase in brain  
6 cancers.

7           They did have a not statistically  
8 significant finding having to do with handedness of  
9 use of the phone, and I should back up one step. This  
10 portion on epidemiology, and questions on this, will  
11 really go to Ron Kaczmarek, who is in the room with  
12 us.

13           Again, the handedness issue, it is not  
14 statistically significantly, although on reanalysis of  
15 the data, which was published in a web article, there  
16 was some strengthening of this finding.

17           But it is a very complex issue, both for  
18 the exposure assessment, as well as the localization  
19 of where a tumor may have actually been initiated. A  
20 couple of other factors that figure into looking at  
21 that finding are that other types of analyses that  
22 could have been done were not published in the same

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1 sort of thoroughness and follow-up as this handedness.

2 And so that leaves open some questions  
3 about the finding, and in fact there was an apparent  
4 contralateral protection that suggests maybe recall  
5 bias played a role in this handedness finding or this  
6 laterality finding.

7 In December of last year, Muscat and Co-  
8 Workers published a hospital based multi-center case  
9 control study. They, too, found no association  
10 overall between wireless phone use and primary brain  
11 cancers.

12 They didn't find evidence of laterality.  
13 They did have some interesting findings when doing  
14 some subgroup analysis, subtypes or subgroups of types  
15 of brain cancers. They looked at about a couple of  
16 dozen different types, and found a positive  
17 association with neuroepithelioma tumors.

18 This may, however, have been a chance  
19 finding given that they were looking at the same data  
20 for a number of different factors. And in fact if  
21 that is a real finding, taken together, it suggests  
22 that the use of the phone could be protective for the

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1 other subgroupings of tumor.

2 But the primary question coming out of  
3 that would be whether you found it in subsequent  
4 studies. Another study done about the same time, and  
5 published in January of this year from the National  
6 Cancer Institute, looked at gliomas, meningiomas, and  
7 acoustic neuromas.

8 They found no association between wireless  
9 phone use and any of these neoplasms. They also did  
10 not find laterality and they didn't see the  
11 association with the particular subgroup, although the  
12 site was not designed to detect or to do that sort of  
13 subgroup analysis in any sort of detail.

14 Finally, on the epidemiology front, in  
15 February of this year, a nationwide cohort study from  
16 Denmark was published, looking back at use between  
17 1982 and 1995. This kind of study makes a nice  
18 compliment to the case control studies and does not  
19 have the same potential for recall by us.

20 They found no increase in brain or nervous  
21 system cancers, or any other number of cancers that  
22 they looked at. One of the difficulties in this type

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1 of study of course is that they were basing this study  
2 on billing records, and there can be some problems  
3 there in terms of not knowing from a billing record  
4 exactly who was using a phone.

5 And in the case of this study, I think the  
6 billing records logged only outgoing calls and not  
7 incoming calls. So you could ask how well that allows  
8 you to assess exposure.

9 So taken all together, one important thing  
10 to note about all these epidemiology studies is that  
11 the follow-up is only about three years of use for any  
12 of these studies.

13 So while they didn't find anything to  
14 suggest concern, a longer follow-up certainly would be  
15 needed to look at questions having to do with long  
16 latency diseases, like cancer, and also the  
17 possibility of any cumulative effects.

18 Right now there is beginning a multi-  
19 center study coordinated by the World Health  
20 Organization, International Agency for Research on  
21 Cancer, a large set of case control studies, and that  
22 is a step in this direction to seeing a little further

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1 down the road in terms of years of use.

2 And the study also incorporates some  
3 improvements in exposure assessment compared to  
4 earlier studies.

5 Animal and cellular studies can compliment  
6 the epidemiology work and can help out by providing  
7 controlled exposures, unlike those in the population,  
8 and can sometimes give quicker answers, and also give  
9 information about mechanisms for any possible  
10 association that you would see in epidemiology  
11 studies.

12 Animal studies up to now are really a  
13 mixed bag. I have shown here, and I am not really  
14 going to discuss a few examples -- a couple of  
15 positive studies, and a couple of negative studies.

16 More recently, high priority has been  
17 given to doing long term animal studies, and when I  
18 say long term animal studies, I mean taking normal  
19 animals, and exposing them for approximately their  
20 lifetime or much of their lifetime, so that you can  
21 see long latency -- long latency for the rodent anyway  
22 -- lifetime and cumulative effects.

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1                   And in such studies, you monitor the  
2 animals both during and after the study for a number  
3 of cancer and other toxicological end points. Several  
4 of the more recent studies of this type have not had  
5 any positive findings for the radio frequency  
6 exposure, but the design has not always been ideal,  
7 both in terms of the level of exposure that was looked  
8 at, and the number of dose rates, and usually only a  
9 single dose rate, looked at.

10                   In addition to work in normal animals,  
11 other model systems had been used to test the ability  
12 of radio frequency exposure to influence cancer  
13 development.

14                   I have just listed a few of them here, and  
15 they are used for a variety of reasons, and they have  
16 also given a mixture of results. And I will just  
17 focus on a couple of them.

18                   Looking at the induced rat brain tumors,  
19 the reason that this system was used is that there was  
20 an attempt to come up with a good model of brain  
21 cancers, since of course with one version of the  
22 technology the highest exposures are to the head for

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1 human users.

2 And in that study there was actually one  
3 isolated negative finding, and negative meaning an  
4 inverse association between the radio frequency  
5 exposure and the tumors. Another example from this  
6 list is the one on top, the PIM-1 mouse lymphoma  
7 studies.

8 This system was used I think because it  
9 was a convenient add-on to the study that was already  
10 being done on power frequency EMF. And in this case,  
11 they were using genetically modified animals that  
12 would have a higher tendency to have lymphomas because  
13 of this genetic modification.

14 And in this study the radio frequency  
15 exposures caused an approximate or were associated  
16 with an approximate doubling of the lymphoma  
17 formation.

18 The positive results from studies like  
19 these on this list are currently being addressed by  
20 ongoing studies. I would like to mention also some of  
21 the short term animal studies. Again, both positive  
22 studies and negative studies.

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1 For the positive studies, there tend to be  
2 some questions for anyone of these. For instance,  
3 efforts by several laboratories to verify the indirect  
4 DNA damage in rat brain reports have failed to confirm  
5 those results.

6 Finally, studies on isolated cells. The  
7 strength of course in those cellular studies is that  
8 they can tell us a lot about mechanisms of action,  
9 biological mechanisms. But of course by themselves,  
10 they can't really show a health effect or really any  
11 effect, much less a health effect.

12 Again, there have been several negative  
13 studies, but also several positive reports. However,  
14 none of these positive reports has provided convincing  
15 evidence of a reproducible biological effect from very  
16 low level exposures to RF.

17 A little more detail. The majority of the  
18 gene expression work that has been done has been  
19 negative, but there are a number of projects ongoing  
20 to address questions in gene expression.

21 Looking at ornithine decarboxylase, this  
22 is an enzyme that is used as tumor marker, there have

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1 been reports that this could be induced by RF  
2 exposure, but again other investigators have not  
3 confirmed these results.

4 In DNA damage, more recently there have  
5 been studies that have been completed suggesting that  
6 RF exposure can induce the formation of micronuclei  
7 which is a test associated with effects on the gene,  
8 and there is actually additional studies coming on  
9 line now to look at whether these results are  
10 reproducible, and what might be the cause of these  
11 findings.

12 So that completes what I have to say about  
13 a quick review of recent results. For wireless  
14 phones, current activities in science include not only  
15 engineering research, and animal research, and  
16 cellular research, and studies on humans, but also  
17 monitoring and critically reviewing all the available  
18 literature.

19 And an activity that is important to us is  
20 identifying the knowledge gaps for better risk  
21 assessments, and identifying and facilitating studies  
22 that will address these gaps.

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1                   Also important is work on testing and test  
2 method development, and of course finally the  
3 development of useable guidelines and standards. I  
4 gave a little bit more detail on some of these, but  
5 first I just wanted to point out our need for  
6 interagency and international collaboration to  
7 maximize the expertise that is brought to bear on  
8 these issues, and to maximize the benefit from the  
9 work, and to ensure coordinated responses to what is  
10 a set of global issues.

11                   And we are assisted immeasurably by our  
12 colleagues in other agencies and organizations. A  
13 little more specifically on FDA activities. As I  
14 said, there has been a priority on long term animal  
15 studies.

16                   In this area, we have proposed through the  
17 U.S. National Toxicology Program to do additional  
18 studies of RF exposures of the type and characteristic  
19 of wireless phone use. And that process is in its  
20 pre-study phases.

21                   We also have been working with  
22 investigators elsewhere who are doing studies, long

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1 term animal studies, such as those done under what is  
2 called the fifth framework program of the European  
3 Commission.

4 Additional work is being done in exposure  
5 assessment, both in testing and modeling, and in test  
6 method development. For instance, for compliance  
7 testing of wireless hand sets, as well as figuring out  
8 new ways to adapt more or less conventional toxicology  
9 testing for looking at the physical agent at hand.

10 Finally, we have a small amount of work in  
11 our own laboratories. We cooperate and contribute to  
12 assessments leading to the development of new or  
13 updated revised guidelines and standards. We have  
14 some activities to promote public information, and we  
15 are involved in a cooperative research program with  
16 the industry.

17 A little bit more on those last two  
18 points. We have some or a few documents up on the web  
19 right now, including consumer update on wireless  
20 phones. This update was put out in October of '99,  
21 and actually many in the wireless phone industry have  
22 actually been printing this out and putting it in the

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1 box with new phones.

2 This document includes an overview of the  
3 whole issue, and includes a section that addresses  
4 ways in which individuals that are concerned can  
5 reduce their exposure to RF from wireless phone use.

6 Right now we are working on revising this  
7 document and other information that we have on the web  
8 so as to make sure that it is up to date, and so that  
9 it is evident to the viewers that it is up to date.

10 The cooperative research program that I  
11 mentioned mostly pertains to future activity in this  
12 area, and this supplements the other activities that  
13 I have referred to.

14 This is a cooperative research and  
15 development agreement, and it is the particular  
16 mechanism here. It is with the Cellular  
17 Telecommunications and Internet Association that was  
18 signed last June.

19 And under this agreement the FDA provides  
20 a scientific and a technical oversight for a program  
21 of research contracts that will be let by the CTIA.  
22 Basically, there is three parts to this agreement of

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1 CTIA if you go by the abbreviation, if you go by the  
2 acronym.

3 The first part is to focus on the  
4 micronucleus assay results that I mentioned briefly  
5 earlier; and the second part is epidemiology studies;  
6 and the third part I just listed here and it is other  
7 topics.

8 The reason for this focus is that this  
9 agreement was the outcome of earlier work funded by  
10 the CTIA, and they wanted to follow up some of the  
11 results from that earlier program of research, and  
12 came to FDA asking us to help them as they followed up  
13 this work.

14 And we arrived at the CTIA as a mechanism  
15 to go forward with this. And in the earlier program  
16 of research had positive results using the  
17 micronucleus assay, and some questions also on work  
18 that they had funded in epidemiology.

19 And so that is again the reason for the  
20 structure of the CTIA and to focus on these three  
21 parts. The third part that I have listed here is  
22 other topics, and that is to step back and identify

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1 whether there are other specific topics that are of  
2 mutual interest for further investigation.

3 On the micronucleus assay work we had a  
4 meeting in this room last August, and brought some  
5 people in to get scientific input on what gaps there  
6 were, and what scientific questions came out of that  
7 earlier work, and what kind of new studies could be  
8 done to address these questions.

9 We wrote up some recommendations not long  
10 after that meeting that we sent to the CTIA. CTIA led  
11 an advertising request for proposals, and then once  
12 they got the proposals in, they sent them to us to  
13 review them for scientific and tactical merit, and  
14 responsiveness to the initial recommendations.

15 And right now they are in the midst of  
16 negotiating a collection of contracts to carry out  
17 research on this part of the project. Moving on to  
18 the epidemiology section.

19 At the end of last month and the beginning  
20 of this month, we had two meetings actually again to  
21 gather input from topic experts on RF studies and  
22 epidemiology, and we will in the not too distant

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1 future be communicating recommendations to the CTIA  
2 for follow-up research needs in this area.

3 The plan right now is to maybe down the  
4 road, and maybe in the spring, to have a meeting to  
5 take a broader look at all the research questions that  
6 maybe open questions from the literature that relates  
7 to RF exposures from wireless phones, and to include  
8 in this overview studies that are getting started or  
9 that are in process right now for which we don't yet  
10 have the results, but anticipate having results in the  
11 not too distant future.

12 And again as I said, through this meeting  
13 and follow-up to that meeting to identify possible  
14 other specific topics of mutual interest between FDA  
15 and CTIA for a more detailed follow-up research.

16 I will summarize here and say that really  
17 what we have in that consumer update piece on the web  
18 is that although the weight of the evidence suggests  
19 that if there is a health effect that it may be a  
20 subtle one associated with radio frequency exposures  
21 from wireless phones.

22 But most importantly we are continuing to

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1 work toward obtaining a more complete set of data that  
2 will allow us to do a better assessment of the  
3 technology so that appropriate action can be taken if  
4 scientific evidence demonstrating hazard is found.

5 The only other thing that I have to point  
6 out is that right now we are awaiting the publication  
7 or publicity of a report from the General Accounting  
8 Office on wireless phone issues.

9 The General Accounting Office communicated  
10 to Senator Lieberman and Congressman Markey their  
11 report, and sometime in the next month we expect that  
12 to be publicly available. And that concludes my  
13 prepared remarks. I would like to answer any  
14 questions that you have.

15 CHAIRMAN ROTHENBERG: I have just one  
16 general question. You titled this wireless phones,  
17 and I wanted to know about the cordless phones, or the  
18 phones that we use in the house, and particularly the  
19 new higher frequency ones. Where do they fit in this?

20 DR. OWEN: Well, historically the  
21 exposures, both in magnitude and type, have been a lot  
22 different from those phones compared to cellular type

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1 phones.

2 As you were alluding to with newer  
3 cordless phones the technologies are becoming more  
4 similar to conventional cellular phones. But they are  
5 still operating and giving lower level exposure,  
6 considerable lower level exposures compared to  
7 conventional cellular phones.

8 We anticipate that anything we can find  
9 out that would pertain to regular cellular phones --  
10 PCS phones and so on -- would be useful in assessing  
11 those. But right now because those are getting such  
12 lower exposures compared to cellular phones that they  
13 are not an area of direct investigation.

14 CHAIRMAN ROTHENBERG: Do you have any  
15 other questions or comments you would wish to make?

16 CPT THOMAS: The literature shows --

17 DR. OWEN: That would be a little bit too  
18 broad to say. I said taken together, yes, nothing has  
19 indicated that any adverse health effects exists.  
20 Exceptions. For instance, there was a paper in  
21 February, I believe, reporting an epidemiology study  
22 associating phone use and glioma melanoma.

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1           But there were some serious questions that  
2 actually -- if you want to know more about that study,  
3 I am sure that Ron would be glad to give you the  
4 lowdown on it.

5           But, yes, taken as a whole the available  
6 literature doesn't demonstrate any adverse health  
7 effects. In the recent literature, there were a  
8 number of epi studies that I mentioned, and again the  
9 important thing to remember with those studies is that  
10 for any of them, they were really only looking at  
11 about three years of use of the phone.

12           And if you are looking at questions like  
13 cancer, where long latency for the development of  
14 disease is an issue, three years post-exposure to an  
15 agent is not very long after to look.

16           DR. CARDELLA: On a couple of the slides  
17 there was the designation of laterality and  
18 handedness, and I didn't quite understand the point  
19 that you were making there. Was the assumption that  
20 a left-handed person would listen on their left ear,  
21 and a right-handed person on their right ear?

22           DR. OWEN: And that in the Hardell study

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1 they had a non-statistically significant increase of  
2 tumors on the same side of the head as they would  
3 normally be using the phone.

4 MS. KAUFMAN: It is my understanding that,  
5 and especially in some other countries, and somehow I  
6 am thinking that maybe Israel is one of them, more and  
7 more younger children are using cell phones with  
8 greater frequency. Are any studies focusing in on  
9 children's use?

10 DR. OWEN: There are no studies that I am  
11 aware of right now that are focusing on children's use  
12 in particular. There are people asking questions  
13 about are there differences in the exposures. Of  
14 course, right now there is also no evidence to suggest  
15 that there would be a biological difference of the  
16 effects of the RF exposures because of the lack of  
17 demonstrated effect. Do you know anything different  
18 from that?

19 DR. LOTZ: The only thing I was going to  
20 say is that the U.K. and France have each had study  
21 panels that came out and recommended caution in  
22 children using phones, primarily because of the

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1 dosimetry differences, although they didn't really  
2 clarify that those generally have to do only with very  
3 young children, like under 10 years of age, where you  
4 have differences in the bone density of the skull and  
5 things like that.

6 And the other thing is that they  
7 acknowledged that it was basically just a  
8 precautionary idea, and that we don't know whether  
9 there is any long term effects here. So maybe we just  
10 ought to be cautious about children using them.

11 But you are right. There are other  
12 countries where the use among adolescents is much  
13 higher than in this country.

14 DR. OWEN: And that reminds me to point  
15 out that I did refer to some studies being funded by  
16 the IEC, and there was also recently announced in the  
17 U.K. a program of research that would address  
18 wireless phone issues, and they are just in the  
19 beginning stages of looking at proposals.

20 CHAIRMAN ROTHENBERG: Michele.

21 DR. LOSCOCCO: At the beginning, you gave  
22 us a range of use. Is there any FDA regulation that

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1 regulates what that is or is that just the industry  
2 standard?

3 DR. OWEN: There are no FDA regulations  
4 that pertain to wireless phones. There is, however,  
5 an FCC safety guideline that all phones are required  
6 to comply with before they can be marketed, and this  
7 guideline was put into effect in August of '96, I  
8 think.

9 And it was -- they came up with it based  
10 on the advice of FDA and the Environmental Protection  
11 Agency, NIOSH, because the FCC has pointed out  
12 repeatedly that they are not a health agency, and so  
13 they relied on these other health agencies for input  
14 in developing those safety guidelines. And  
15 essentially those guidelines are identical to existing  
16 consensus standards.

17 DR. LOSCOCCO: So do all manufacturers  
18 pretty much regulate all around the same thing, or is  
19 there some outline?

20 DR. OWEN: They have to, to sell in the  
21 U.S. It is a requirement from the FCC. 1.6 watts per  
22 kilogram SAR.

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1 CHAIRMAN ROTHENBERG: Dr. Marx.

2 DR. MARX: And how is it that the RF  
3 energy is supposed to cause brain cancer? Do they  
4 think it heats your brain up? The reason that I am  
5 asking the question is because your skin is closer to  
6 the phone than your brain, and the cells turn over  
7 faster. So is there any association? Do they look at  
8 anything besides brain cancer?

9 DR. OWEN: Yes, they look at things  
10 besides brain cancer. No, there is not any  
11 established mechanism there. There have been  
12 theories, but none yet borne out with laboratory data.

13 CHAIRMAN ROTHENBERG: Dr. Nelson.

14 DR. NELSON: My question sort of goes  
15 along the same lines. There are studies in rats where  
16 they have shown that there are behavioral effects in  
17 rats that were exposed to radiation doses along the  
18 lines of cellular phones and that the children or  
19 offspring rather of those rats also had some neuro  
20 behavioral changes.

21 And so I am wondering if it might not be  
22 reasonable to look at something besides cancer in your

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1 outcomes of evaluating safety.

2 DR. OWEN: I didn't remember those being  
3 in utero exposures. Do you remember those studies?  
4 Do you remember those studies? I am looking to Dr.  
5 Lotz because he is --

6 DR. LOTZ: Well, I was thinking of the  
7 lining effect studies, in terms of mature rats, but I  
8 am not sure of the in utero for neuro behavioral along  
9 the lines of cell phones. There have been some higher  
10 intensity RF studies that have looked at neuro  
11 behavioral effects. So they are in the RF literature,  
12 more on the acute phase.

13 And interestingly enough there have been  
14 a couple of human laboratory provocation studies that  
15 have shown some measurable differences in reaction  
16 time and actually favorable in terms of being faster.

17 But those were with cell phone type  
18 exposures, and so there is some question there about  
19 whether there may truly be some interaction with neuro  
20 tissue. But that is about as far as the research has  
21 gone to sort of raise those questions.

22 DR. OWEN: The U.K. program that I

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1 mentioned that is just starting to consider proposals,  
2 in the discussions leading up to that program, they  
3 have announced an interest and emphasis on non-cancer  
4 studies. So I expect that there will be a good bit  
5 more data in that area in the not too distant future.

6 DR. NELSON: It might be reasonable to  
7 also consider focusing on pregnant women.

8 CHAIRMAN ROTHENBERG: Any other questions?

9 MR. PLEASURE: This is just a very general  
10 question about the responsibility and the charter of  
11 TEPRSSC, and the advisory committee. Is it  
12 permissible for someone to introduce a device that  
13 exposes the population to let's say harmful or  
14 potentially harmful radiation without testing the  
15 safety of it in advance? Is that a different process  
16 than the process in using drugs?

17 SECRETARY SULEIMAN: Okay. Let me answer  
18 that. We have different cultures, and the FDA  
19 basically has a pre-market and post-market culture.  
20 And that term has now crept into the authority of the  
21 Radiation Control Act.

22 Basically, it is a gate. Any product, any

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1 drug that has got to be or is going to be used  
2 medically has got to be approved, or reviewed, or  
3 undergo some sort of exercise before it is allowed to  
4 be marketed.

5 Some of the controls are very, very loose,  
6 but that is the pre-market, post-market. The  
7 Radiation Control Act has no pre-market, post-market.  
8 Basically, it is a much broader safety radiation  
9 hazard authority that basically says that if there is  
10 a electronic product that appears to be causing harm  
11 to the public from radiation emissions, then we have  
12 the authority to look into that and mandate emission  
13 standards essentially for that broad class of  
14 electronic products.

15 The other differentiation is that it is  
16 not limited to medical. It covers consumer products  
17 that are non-medical. So there is those two  
18 distinctions that are very, very important in the  
19 approach.

20 It means that we have to be more vigilant  
21 because there are products out there that may be  
22 causing harm that are being used. They can't come to

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1 us and say how did you let that get out there in the  
2 first place. We have to catch it sort of as it gets  
3 out there.

4 And there is the public health. I think  
5 you have heard some of the discussion today regarding  
6 the short term effects of fluoro burns or whatever with  
7 some of the x-ray procedures, versus the longer term  
8 stacastic and probablistic. You may get a cancer and  
9 you may not get a cancer, but you are not going to see  
10 it with somebody right now.

11 But if you radiate enough millions of  
12 people, you will see some of it, and that is the issue  
13 with cell phones, and all these other products, where  
14 the effects may be subtle, and they may not happen.  
15 So the studies may be years away.

16 MR. LEASURE: A follow-up question is, is  
17 there consideration that these exposures may be  
18 cumulative from multiple products? You are just  
19 focusing on one particular product in this case, but  
20 introducing or exposing the population to radiation  
21 unnecessarily?

22 Let us say, for example, that a shield for

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1 very little cost can be introduced to virtually  
2 eliminate this exposure. Do we take into account the  
3 cost benefit of looking at that kind of shielding?

4 Do we also take into account the possible  
5 cumulative exposures of multiple products when we are  
6 looking at a judgmental question?

7 SECRETARY SULEIMAN: Okay. You are going  
8 to get a very simplistic, but an honest answer. Yes,  
9 we live with that burden all the time. I think --  
10 what is it in medicine? Adjunct therapies, where you  
11 do different types of therapies at the same time,  
12 drug, radiation, or whatever.

13 I don't think we have reached that level  
14 of sophistication, in terms of long term subtle  
15 effects. Greg, you correct me if I am wrong, but I  
16 think we have not gotten there, and maybe in 50 years  
17 or somewhere down the line we will have a better  
18 understanding of that.

19 The other thing that you have picked on,  
20 Mr. Pleasure, is the fact that there is a concept in  
21 radiation that says that as long as reasonably  
22 achievable. And the debate goes on about what is

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1 reasonable, in terms of economic costs, and in terms  
2 of eliminating risk to zero, or what is negligible, or  
3 is it a background level if we have it in the  
4 background.

5 So those are concepts, but I think we live  
6 with them every day, but the debate -- there have been  
7 terms in the professional societies of de minimis, and  
8 insignificant. There are lots of concepts, but the  
9 objective is not to reduce some of these hazards down  
10 to zero. But to what level do you reduce them? I  
11 don't know.

12 DR. OWEN: I would like to add to that  
13 about the question of the combined exposures. From  
14 more of a scientific perspective, certainly in the  
15 design of epidemiology studies, and animal studies,  
16 and other types of studies, investigators often do try  
17 to incorporate that, and, for instance, epidemiology  
18 studies look at a lot of different non-ionizing  
19 exposure and consider them.

20 Frequently, you will see a paper that  
21 looks that it is in favor of cell phones, but it was  
22 a study about a number of different agents. Likewise,

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1 with designing animal studies, frequently there is  
2 attempts to combine or to come up with very complex  
3 sorts of exposures that perhaps address some of those  
4 combined exposure condition issues to try and come up  
5 with this whole mix of exposures to be tested.

6 DR. LOTZ: I was going to comment with  
7 respect to Orhan's earlier description or response to  
8 your question about the whole radiation question of  
9 pre-market and post-market, and that comment.

10 I think an example in the cell phone arena  
11 that shows the FDA sort of in action on that was the  
12 question of interference with pacemakers. About six  
13 years ago or so there were a couple of quality  
14 articles published demonstrating that when a digital  
15 phone was held in close proximity to an implanted  
16 cardiac pacemaker that there could be interference  
17 with the signal of that.

18 And I think actually it was an industry  
19 FDA cooperative effort, but FDA people were very  
20 heavily involved in studies, rather quick studies to  
21 show that while that was a real phenomena, it was also  
22 one that could be controlled or engineered, and

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1 engineering developments could be done to overcome it.

2 And I think it has really kind of quieted  
3 the issue, in terms of that interference problem, by  
4 virtue of a response. But it was as Orhan was saying,  
5 it was a case of vigilance, and not of looking at  
6 something ahead of time. But rather vigilance of  
7 watching what was going on and then trying to respond.

8 MR. PLEASURE: Well, it does answer my  
9 question in part, but it makes me wonder why when we  
10 consider an issue like this that we don't also as a  
11 group consider the costs of virtually eliminating the  
12 exposures.

13 We happen to have an expert on our panel  
14 who knows some perfunctory knowledge. Why is it that  
15 we don't -- well, I am repeating myself.

16 DR. ELWOOD: Can I comment on that? I  
17 think one of the distinctions that hasn't been made  
18 yet is that for non-ionizing radiation, the consensus  
19 of the scientific community is that bio-effects are  
20 threshold effects.

21 So we don't have the ALARA concept in non-  
22 ionizing necessarily, and as long as you are below the

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1 limits or below the threshold, then it is accepted  
2 generally I guess that statement.

3 So when you don't have that, it is called  
4 the ALARA concept; that as low as reasonably  
5 achievable and cost benefit type thing, I think you  
6 could comment on it.

7 DR. LOTZ: I think there has been a lot  
8 of debate about what is appropriate that way. The  
9 hole that we have in the non-ionizing area basically  
10 is a question of whether there are any long term  
11 effects.

12 And as Russ indicated earlier in response  
13 to Mary's question, there is not an identified  
14 mechanism that would explain a latent or long term  
15 delayed effect.

16 Yet, there are some studies out there that  
17 are reputable, in terms of where they have been  
18 published and how they have been done, that raise  
19 questions, and there is a relative paucity of data at  
20 all whether epidemiologic or long term animal, to deal  
21 with the question. There just has not been very many  
22 studies.

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1           It as only been in the last few years that  
2           there has been much of an attempt to look at long term  
3           effects. You could probably say that before 1990  
4           nobody even really addressed the question at all  
5           whether there was long term latent effects of RF  
6           exposure of any kind.

7           DR. OWEN: You mean from phones?

8           DR. LOTZ: From any RF really. I mean,  
9           there were a few isolated studies of past radar  
10          workers and that kind of thing, but generally there  
11          was no concerted effort to say let's look at the  
12          populations of people, or let's design a number of  
13          animal studies.

14          Let's do animal studies with multiple  
15          doses so that we can look for some kind of dose  
16          response. It just didn't exist. And part of that was  
17          exactly what Alice was referring to. There was an  
18          acceptance that there was no mechanism there. So we  
19          didn't have to study it you might say.

20          But as the change in population use has  
21          come about, to where now it is practically a  
22          ubiquitous agent in society, which RF was not before

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1 to any appreciable extent, it raises those questions  
2 that if we have not studied it, then how do we know,  
3 and that is where we are, I think.

4 MS. KAUFMAN: I guess I am not clear that  
5 the question has actually been answered. I guess is  
6 it impossible to shield the phones, and/or is it  
7 extremely costly to do so?

8 DR. BALZANO: It is very difficult and  
9 costly to do it. Again, it is a question of how much.  
10 We already bring it down to a factor of acutely of  
11 four, it is already costly, and to bring it down by a  
12 factor of 100 is extremely costly, and we will end up  
13 with something so bulky that nobody would use it.

14 So in terms of impact, considering the  
15 fact that there has been no proven effect other than  
16 hitting, there has not been an effort to actually  
17 shield the user.

18 Let me add one more parameter though. The  
19 emission from the device is kept to a minimum over  
20 time, because the system is around the business of not  
21 interfering. So the system makes sure that you have  
22 a voice quality and a minimum level of emission by the

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1 device.

2 So there is a self-limiting cost and there  
3 is a self-limiting process that keeps exposure as low  
4 as possible while the user gets a good voice quality  
5 of communication. So there is control in the sense  
6 that exposure is kept to a minimum in order to provide  
7 the service.

8 As a matter of fact, as the systems are  
9 right now, the level of exposure drops to a level  
10 where -- most of the time, and sometimes not, but the  
11 level of exposure is dropping.

12 DR. ELWOOD: And additionally I would just  
13 comment that the reason that the phone is dynamically  
14 controlled has really nothing -- and the fact that  
15 exposures are reduced most of the time, really has  
16 nothing to do with safety, per se, and more to do with  
17 the battery life of the phone.

18 So some people are confused about that,  
19 and trying to design it to be an ALARA kind of device.  
20 But in reality, it is just to save the battery. And  
21 also I understand that some of those shields actually  
22 increase people's exposure.

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1 DR. BALZANO: Well, there is a shield  
2 issue, yes, but actually all they do is match the  
3 level, and you match the overall level of radio to  
4 battery, and as it is with the technology that we have  
5 right now, within the limitation of space and weight  
6 that the customers seem to accept, I think we have a  
7 system that indeed brings the exposure below that  
8 accepted level of safety.

9 And not only that, but there is a  
10 continuous decrease of the overall exposure because  
11 there has been a very proliferation of the usage. So  
12 as more stations are being installed around towns, and  
13 so people are always closer to these stations and so  
14 the power necessary to have communication has dropped  
15 substantially in the last 5 or 6 years.

16 MR. PLEASURE: I understood from our last  
17 discussion on whether or not some consumers would  
18 purchase it or not that the industry has in the past  
19 -- and that police officers carry around very heavy  
20 telephones, for whatever reason, and whether or not my  
21 teenager would purchase it is not necessarily the  
22 issue for all consumers -- and that eliminated the

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1 exposure. So is that possible?

2 DR. BALZANO: The initial exposure I don't  
3 think is possible, and elimination and bringing it  
4 down to zero photons are vague, and I don't think it  
5 is possible. By decreasing the weight and the size of  
6 the device, you can bring it down by a factor of 10 or  
7 a factor of 100, and when you get to the factor of  
8 100, you really are talking about a minimum amount.

9 DR. OWEN: You are leaving out distance.

10 DR. BALZANO: By the wavelength --

11 DR. OWEN: Like a hand squeeze.

12 DR. BALZANO: And are on either side, and  
13 the point is using it, and that's why there has been  
14 a substantial research on this angle, and the  
15 companies who actually increase the efficiency,  
16 because whatever is deposited into the user is -- and  
17 the stated purpose of the device is to get a signal  
18 from a station to a station, and there is no other  
19 purpose of the device.

20 So the industry has done a concerted  
21 effort to minimize the time of exposure for the user  
22 because of engineering, but they realize why there are

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1 reasons around that way. But actually there is  
2 minimum exposure, and by decreasing the pocket weight  
3 you bring it down.

4 DR. CARDELLA: I have watched for a couple  
5 of years now the discussion about the wireless phones,  
6 and I have often thought about this, but I am going to  
7 ask the question because I may be rotating off the  
8 committee.

9 As we walk around in our lives, there are  
10 100 or 150 radio stations broadcasting radio shows all  
11 around us, and nobody says anything about that. My  
12 question is what is the relative power to which your  
13 brain is subjected; a cell phone versus living in a  
14 large metropolitan area with a hundred FM radio  
15 stations, let's say?

16 DR. OWEN: Actually, it is a pretty big  
17 difference. I couldn't tell you the factor, but maybe  
18 on the order of a thousand or something, because your  
19 wireless phone is right here, and the exposure is in  
20 this case impacted more by the distance from the  
21 source to the tissue than by just the power.

22 And that is why a bay station -- a

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1 cellular phone bay station, which is weak compared to  
2 a t.v. station, but it is many times more powerful in  
3 terms of energy consumption compared to the handset,  
4 but the exposures are much higher from the handset.

5 And approaching immeasurable with field  
6 devices from the bay stations because of the distance  
7 between the tissue and the source.

8 DR. LOTZ: Russ, I think -- and we were  
9 just sort of comparing notes here, but we would  
10 probably go as high as 10 to the 5th, given the one  
11 difference between what you get from sort of the  
12 general environmental from radio and t.v. stations, or  
13 bay stations.

14 But with one caveat, that the handset is  
15 only going to expose the tissue right there, whether  
16 that be at your head or at your waist if you have got  
17 it on your belt, with an ear piece of something like  
18 that.

19 So the handset itself only produces a very  
20 localized exposure; whereas, the other is whole body.  
21 But the order of magnitude of how much energy is there  
22 is probably maybe something along the order of 10 to

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1 the 5th.

2 DR. OWEN: Actually, one analysis I did  
3 see, and it may have been somewhat of a back of the  
4 envelope, but it said that the dose rate from a hand  
5 held is equivalent to the dose rate from a radio  
6 station if you are standing at the fence line of the  
7 FCC regs. You know, the little fence that is around  
8 the transmitter. So that is pretty close.

9 DR. BALZANO: Another way to look at it,  
10 most bay stations give exposure of microwatt, and you  
11 cannot measure correctly from a cellular phone the  
12 power density, because you cannot exactly define it.  
13 You are so close to the source that you cannot define  
14 power density -- and if you go to a t.v. station that  
15 is emitting hundreds of kilowatts, you get --

16 CHAIRMAN ROTHENBERG: Thank you very much.  
17 We have one additional item for discussion, and if  
18 there are others. But one is possible meeting dates  
19 for next year, and Orhan has identified some possible  
20 dates to consider, which would be May and Wednesday  
21 and Thursday dates; May 15th, 22nd, and 29th.

22 So if you are aware of conflicts, please

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1 let Orhan know, and we will decide among those three  
2 dates.

3 SECRETARY SULEIMAN: I have checked with  
4 our first round of conflicts, and that's why we have  
5 selected those three dates. Like we did this past  
6 year, we selected two dates for this meeting.

7 And then I think a couple of months ago it  
8 looked like it was going to be a one day meeting, and  
9 then we sort of polled the committee and it was almost  
10 consensus or it was consensus, and I forget if it was  
11 unanimous, but everybody wanted to come today rather  
12 than yesterday.

13 So, E-mail me and we will take care of it.  
14 I mean, it is fun to manage when you know well ahead  
15 of time what you are supposed to be doing. And it is  
16 difficult to get everybody's schedules worked out. If  
17 you know now that there is a conflict, let me know.  
18 Otherwise, I will query electronically in the next  
19 couple of days or weeks.

20 It is the 3rd, 4th, and 5th Wednesday-  
21 Thursdays of May, 2002.

22 MS. KAUFMAN: Larry, Dr. Lotz and I do

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1 have a question. In Mr. Wilson's letter on t.v.s, he  
2 says back in 1968 there were -- or somewhere in the  
3 '60s, there was some set that generated radiation in  
4 excess of 8,000 m/r per hour. Is that a typo or is  
5 that right?

6 DR. OWEN: That's correct.

7 MS. KAUFMAN: 8,000? Wow.

8 CPT THOMAS: On this letter of Dr. Wilson,  
9 it was -- and he has got a reasonable suggestion here,  
10 and I am not sure whether it is appropriate to discuss  
11 it.

12 SECRETARY SULEIMAN: You could discuss it.  
13 We will take it under consideration.

14 CPT THOMAS: Well, they were going to look  
15 into it.

16 CHAIRMAN ROTHENBERG: Are you asking or  
17 saying is it reasonable to look at it?

18 CPT THOMAS: Well, there were two items  
19 that were written into the minutes in the meeting,  
20 neither of which the committee has discussed, and  
21 there is no background information on either one of  
22 those to the committee.

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1                   So maybe it is not appropriate to discuss.  
2           But what Mr. Wilson is saying essentially is  
3           manufacturing practices have changed since this  
4           regulation was implemented, and that based upon our  
5           members' experiences, we would like to seek relief  
6           from this testing requirement.

7                   I don't know what the implications of that  
8           relief are, but it certainly sounds like a legitimate  
9           request on their part as to what has been submitted  
10          here, but I am not sure that they have enough  
11          information to make a recommendation without further  
12          input from both the CEA, as well as the FDA on what  
13          this really means.

14                   SECRETARY SULEIMAN: We have guidance  
15          regarding testing of t.v. receivers, and I think that  
16          is what the CEA letter was, and they are asking us to  
17          change some of that guidance.

18                   We have a process by which we review  
19          guidance periodically, and make changes and so on.  
20          The guidance is a recommendation for what the  
21          manufacturers may do. It is not a requirement, and  
22          they are just making a suggestion based on their

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1 experience.

2 So the next time we review the guidance,  
3 we will have the staff look at it and consider it. We  
4 won't ignore it, but both submitters were given -- I  
5 said were you coming to the meeting, and did you want  
6 time to make verbal presentations, and both people  
7 said no. Our statements should be submitted for the  
8 public record and that is the extent of it.

9 CPT THOMAS: And the other submission, I  
10 don't understand.

11 SECRETARY SULEIMAN: Well, if you can  
12 figure it out and explain it to me, I would appreciate  
13 that as well.

14 DR. LAMBERT: I think Jerry has a  
15 legitimate point. This is a very coherent letter, and  
16 I think it is a very legitimate request, and it is  
17 asking that we take some form of action on this and  
18 saying that we should study it and consider the  
19 request.

20 CPT THOMAS: That is exactly what I am  
21 asking. I don't want to see -- and this I feel is a  
22 legitimate request, and that I think has been well

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1       staffed from the way that the letter has been  
2       presented. And from CEA's standpoint, it appears to  
3       be well stated.

4               SECRETARY SULEIMAN: Well, I think it is  
5       the prerogative of the committee to comment on it.  
6       You can vote and say we agree with it, and we think  
7       the FDA should consider it. If you want to discuss  
8       it, it is your prerogative. Larry.

9               CHAIRMAN ROTHENBERG: It seems reasonable,  
10       but I don't know.

11              MS. KAUFMAN: Do we have anyone here who  
12       has information on how many sets exceed the .5  
13       milliram and .5 centimeter standard or when the last  
14       time one was?

15              CPT THOMAS: He claims a hundred percent  
16       of them pass.

17              MS. KAUFMAN: Well, I know that there was  
18       some problem with some t.v. set imported from Japan,  
19       I think, some years ago. This was like 10 or 12 years  
20       ago.

21              SECRETARY SULEIMAN: My understanding, and  
22       we have got staff here, but my understanding is that

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1 we have not found any sets that emit in excess of the  
2 standard. There are three types of -- come on up.

3 CPT DAWSON: I am Ed Dawson with the  
4 Office of Compliance, CDRH. I work with t.v.s and we  
5 do occasionally find a set when tested under the Phase  
6 III test conditions, which involves introducing a  
7 fault and misadjusting all the controls to maximize x-  
8 radiation, we do occasionally find one that will emit  
9 more than .5 m/r per hour.

10 And in fact we have a case right now which  
11 has not been totally settled, where we found that in  
12 testing where they can do this Phase III testing -- it  
13 is not something that you can do in the field though,  
14 or that you would do in a consumers' home.

15 And under normal operating conditions, you  
16 would not find it, but they do happen on occasion when  
17 you do subject them to this severe, worst case Phase  
18 III testing.

19 DR. LAMBERT: And that is because or is  
20 that the test that you are talking about for shift?

21 CPT DAWSON: The factories are supposed to  
22 do the Phase III testing. Right now our policy is a

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1 minimum of one set per production lot per shift per  
2 day.

3 They say that a hundred percent pass, but  
4 that is not totally accurate. I don't know what they  
5 found, because I don't think that we have found that  
6 their records showing failed tests that they didn't  
7 report to us.

8 We don't get reports from them that they  
9 found sets that failed, but in our tests we sometimes  
10 find worst conditions than they are doing.

11 DR. LAMBERT: I don't really understand  
12 this test, this Phase III test, and where you say all  
13 the controls are mis-set. Would I watch television  
14 under those circumstances? Can I visually see a set  
15 that --

16 CPT DAWSON: Well, it requires a useable  
17 picture, and that has long been a subject of debate  
18 and discussion as to what is a useable picture, and  
19 the old definition in VRH was that if your team or  
20 your football team was in the championship game and it  
21 was the last part of the game, and they are ready to  
22 score would you still watch the picture.

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1 DR. LAMBERT: Well, would that three  
2 minutes of exposure --

3 CPT DAWSON: You probably would. Well,  
4 today, you might be -- you have an urgent job you have  
5 to do, and would you work at your computer monitor if  
6 you could still read something on the screen and be  
7 able to do it.

8 Would a utility monitor person, a security  
9 person or something, would he continue to leave the  
10 video monitor on if it appeared to be an extremely  
11 bright picture, but it still showed something on the  
12 screen.

13 So that is a point of contention  
14 occasionally with manufacturers, but we stretch the  
15 test to where you can just barely see an image on the  
16 screen, and we think manufacturers should, too.

17 DR. LAMBERT: And so what we don't have is  
18 a feel for what fraction of the t.v. sets might  
19 actually be in a that situation.

20 CPT DAWSON: Well, I don't think that very  
21 often anybody would actually watch it that way, no.  
22 I think that is a very conservative examination.

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