

1 DR. CARDELLA: When I ask that question.  
2 Whenever something like that becomes more and more  
3 commonly used and the purpose of it is to look at it,  
4 particularly if it's a brake light or a traffic  
5 control light, I just want to make sure that everybody  
6 is still comfortable that the dispersion is enough  
7 that it's a safe issue and it should not be included  
8 in the laser standard regulation. I think they're  
9 going to become very ubiquitous, particularly given  
10 the durability and municipalities are very interested  
11 in cutting labor costs, replacing light bulbs in  
12 traffic signals. If an LED lasts 100 years instead of  
13 a 1000 hours, that's a good reason to use it even if  
14 it's a lot more expensive and the purpose is to look  
15 at it.

16 MR. DENNIS: I can tell you a funny story  
17 about that, but we're running low on time, but during  
18 the next break I'll be sure to tel you about it.

19 But on the other side of that, IEC has  
20 been addressing that. IEC has a large scope in that  
21 we include optimal radiation safety in general. IEC  
22 does have a technical specification on laser and LED

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1 products that are intended for visual transmission of  
2 information to the eye and they are recognizing that  
3 there are products which require a high degree of  
4 visibility such as in traffic and that kind of thing  
5 whereas up close or for extended periods, they could  
6 be hazardous, they could be hazardous to service  
7 personnel who are installing or replacing them. So  
8 that's being addressed in the IEC.

9 We have not addressed that specific issue.  
10 What we hope to do is keep, no pun intended, our eye  
11 on the technological developments and see. We're more  
12 concerned about the super-luminescent diode  
13 applications which haven't come along yet, but the  
14 super-luminescent diodes have. They're here. One  
15 other thing I'd say about the safety of the LED  
16 traffic signals, one of the auto manufacturers who  
17 capitalizes on advertising safety is saying that the  
18 time to illumination of these LED brake lights is  
19 sufficiently short enough compared to incandescent  
20 lights to be able to provide more reaction time to  
21 prevent accidents.

22 DR. ROTHENBERG: Okay, do we have further

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1 discussion?

2 Thank you very much, Mr. Dennis. I guess  
3 at this point we're a bit early, but it might be  
4 appropriate to take a longer break for lunch.

5 MS. KAUFMAN: Wasn't there a second issue  
6 you wanted the Committee to consider. The one issue  
7 had to do with FDA proceeding regardless of IEC. But  
8 I thought there was a second issue?

9 That was the only issue?

10 MR. DENNIS: According to your comments,  
11 yes.

12 DR. ROTHENBERG: Okay, so I at this point  
13 we'll break and we will resume probably at 1. We'd  
14 like everybody in the room and ready to go at 1  
15 o'clock. The next topic will be amendments to the  
16 sunlamp standard.

17 (Whereupon, at 11:16 a.m., the meeting was  
18 recessed, to reconvene at 1:00 p.m., Wednesday, June  
19 21, 2000.)

20

21

22



1 name is Howard Cyr. I'd like to talk about amendments  
2 to the sunlamp performance standard. This is work  
3 that's been done by the CDRH Working Group on  
4 Sunlamps. That's an ad hoc committee of about maybe  
5 10 to 12 people who were working part-time on this  
6 issue.

7 Next slide. I'm going to go into a bit of  
8 a review of why we published the advanced notice of  
9 proposed rule making and I described some of this at  
10 last year's meeting. We put out an advanced notice in  
11 February of 1999 and asked for data and comments on  
12 possible changes to sunlamp standard. One first  
13 reason we put this out was report of a melanoma  
14 epidemic and a melanoma sunlamp link. The melanoma  
15 epidemic is a large increase in the number of cases  
16 and deaths from melanoma over the last several  
17 decades. The exact reason not known in this country,  
18 particularly it's gone up. In some countries, there's  
19 some incidents actually flattening off, but not quite  
20 yet in the United States.

21 Report of the UVA Melanoma Association and  
22 this was work done in a model, a fish model of all

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1 things in which they showed that UVA was associated  
2 with more of melanoma than would be thought if you had  
3 looked at say erythemal action specter. This is an  
4 action specter of melanoma in this fish versus the  
5 wavelengths and they found an increase in the UVA  
6 region.

7 The next reason were petitions from the  
8 American Academy of Dermatology and a citizens  
9 petition from an individual who asked us to do  
10 something about our performance standard. In fact,  
11 the AAD at one time asked us to ban sunlamps.

12 Next, please. We had some reports that  
13 some salon owners, not all, not many, but some salon  
14 owners were not being attentive to regulations.

15 Next. And there were some specific  
16 considerations from CDRH that we make some changes on  
17 our own and the last reason was that we would like to  
18 get standards which are in harmony with those of other  
19 countries, particularly, Europe, for example, the  
20 standards of the International Electrotechnical  
21 Commission, the IEC.

22 Next slide. What we were considering in

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1 this advanced notice of proposed rulemaking, we were  
2 considering about 10 things, if I did my math here  
3 right. First of those was to make the exposure  
4 schedule part of the standard. What we have right now  
5 is the exposure schedule, recommended exposure  
6 schedule was in a policy letter. We were considering  
7 lower cumulative doses. This is on an annual basis.  
8 We were considering the use of a cancer action  
9 spectrum in addition to what is used now, the  
10 erythemal action spectrum. And also to extend the  
11 exposure schedule to different skin types.

12 Next slide. We were also considering  
13 making lamp product manufacturers, anyone who modifies  
14 a product, if somebody comes in and changes and puts  
15 in an incompatible bulb by definition they become a  
16 manufacturer.

17 Have a simpler warning label, include a  
18 melanoma warning, place warnings in catalogs,  
19 specification sheets and brochures and to have a  
20 biological efficacy rating scale for replacement  
21 lamps. These are all the things that we asked people  
22 to submit comments and data on.

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1                   Next slide. This one I went over last  
2 year. We got 27 responses from our advanced notice,  
3 four from the indoor tanning industry, about eight  
4 from the lamp and sunbed manufacturers, some from the  
5 dermatology community and academic, salon owners,  
6 state and county regulations and an insurance company.

7                   Next. Let me take an aside here. One of  
8 the considerations when we started doing this was a  
9 concern that perhaps we were on our way to banning  
10 sunlamps because for one thing the Academy had asked  
11 us to do that. Right now we have no plans to ban  
12 sunlamps. This has been our position for the last few  
13 years. It still is our position. One, it's an  
14 individual choice. You can get the same dose by going  
15 to the sun. Same effects or worse from going out to  
16 the beach and getting sun tans. The risks are fairly  
17 well understood by the public. This is not something  
18 that it comes as a surprise to people. I think most  
19 people know that they can get burns. Most people know  
20 that skin cancer may be associated with high does of  
21 UV.

22                   Next. And I'm pleased about this. There

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1 are already informed consent statements being used and  
2 more being proposed by the industry themselves so that  
3 people definitely understand what risks are involved  
4 with exposures.

5 And the last. So our emphasis will be on  
6 cooperation not on banning sunlamps.

7 Next slide. Here's our approach to the  
8 amendments. We got all the comments. We analyzed  
9 them and realized that some of these things were  
10 really going to be complex and controversial. We  
11 thought we were going to do them all at one time. In  
12 recent discussions we have come to the conclusion that  
13 maybe we should do this in stages, that some of them  
14 are just too hard to be handled right now. Let's not  
15 just sit around waiting for three or four years before  
16 we do anything and keep both the industry and  
17 everybody else in suspense. Let's go forward with  
18 some of the issues which are straight forward, easy to  
19 implement and noncontroversial. Some of the issues,  
20 some other ones may require more work, but are maybe  
21 noncontroversial. I'll describe what those are. And  
22 there are still others which are very complex and

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1 controversial and may require lots of additional data.

2           Next slide. So what I said essentially is  
3 therefore we will approach the amendments to sunlamp  
4 performance standard in at least two stages. The  
5 first stage will address the easiest, I say  
6 noncontroversial, maybe after today's hearing some of  
7 these will be, in fact, controversial. And then  
8 secondly, later on, the other stages which require  
9 more research will depend on more research and  
10 evaluation on more complex and controversial issues.

11           Next slide. So we are proposing that we  
12 will go forward with five amendments. By going  
13 forward I mean we are going to write a proposed rule.  
14 This is not a final rule. We have to go through this  
15 stage of proposed rule where we lay out what it is  
16 that we want to do, get comments back from people,  
17 analyze them and in addition to analyzing the comments  
18 on data and what have you, there's also provisions in  
19 a proposed rule where you address things such as  
20 economic impact.

21           The first amendment we want to make is to  
22 make the exposure schedule a part of the standard and

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1 this goes back to what I said just a few minutes ago  
2 and that is right now FDA has a recommended exposure  
3 schedule that is in a policy letter that was written  
4 back in 1986. There's been considerable  
5 misunderstanding and controversy, etcetera on the  
6 legal status of the policy letter and I probably have  
7 contributed to some of the chaos that has developed as  
8 to where, what the exposure schedule and how it really  
9 stands in terms of legality. So we want to make it a  
10 little more specific and include an exposure schedule  
11 as part of the standard.

12 Number two, use the cancer action  
13 spectrum, plus an erythematous action spectra. I'm going  
14 to go in more detail in all of these. Number three,  
15 emphasize that a manufacturer is anyone who modifies  
16 the product.

17 Next slide. The fourth is to place the  
18 warnings in catalogs, spec sheets and brochures. And  
19 the fifth is to have a simpler warning label.

20 And now I'll go into each of these.

21 Next slide. The amendment number one,  
22 make the exposure schedule a part of the standard. As

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1 I said, this is a current one is a policy latter of  
2 August 21, 1986 and we would like to update this  
3 current exposure schedule for skin type II and make it  
4 a requirement in the performance standard. Now I'd  
5 know you'd like to know all of you what we're going to  
6 say and do, what the final words are. We're not at  
7 there. What I wanted to tell you is what we're  
8 considering and what we're proposing to go forward  
9 with and it would be nice if I could tell you all the  
10 details. We don't have the details worked out yet.

11 Next slide. As I say, we're going to go  
12 forward to the one we have. We're used to it.  
13 There's some data in the literature saying that people  
14 can tan with this schedule and do not burn. So in  
15 that sense, it is safe. However, we are also aware  
16 that there are other exposure schedules out there and  
17 we're going to continue to evaluate those other ones  
18 so that we may use them later on, at a later date.  
19 And if we do do that, we want any future exposure  
20 schedules to be scientifically based and preferably be  
21 part of a national/international consensus.

22 Next slide. Amendment No. 2 is to use the

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1 cancer and erythemal action spectrum. Right now, we  
2 use the erythemal action spectra to weight all the  
3 doses. IEC is adopting the action spectra for  
4 squamous cell carcinoma to be used in conjunction with  
5 the erythemal action spectrum and we propose that we  
6 will take the lead of IEC and also use the SEC action  
7 spectrum. This is important when you're considering  
8 long term effects, cancer. So if you're going to talk  
9 about cancer effects and you want to do any  
10 calculations at all, then the doses should be weighted  
11 by the SEC action spectra, not by an erythemal action  
12 spectra. That's the approach IEC has and in terms of  
13 harmonization we would like to follow what IEC is  
14 doing.

15 Next slide. Manufacturer equals anyone  
16 who modifies the product. This is amendment 3. This  
17 is anyone who uses incompatible bulbs or changes an  
18 intended performance feature, becomes a manufacturer  
19 and they must recertify and identify the product. I  
20 think last year I mentioned that we got some comments  
21 back from the industry that they thought that this, in  
22 fact, was really good and in fact, make it strong.

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1 And that somebody who comes in and changes a sunbed,  
2 the original manufacturer doesn't want to be liable  
3 for the change that has been made. The liability  
4 should be passed on to whoever made that change, so  
5 this is what we're talking about in this amendment.

6 Next slide. That's what I just said.  
7 Many comments were, came about this, were strong and  
8 they were concerned about insurance coverage.

9 Amendment 4, warnings in catalogs,  
10 specification sheets and brochures and we would like  
11 to proceed with amendment to require these. The  
12 concern here is that for some units, particularly home  
13 units that the warning label isn't seen until you've  
14 actually bought the product. As I said, most people  
15 are familiar with the risk or what have you, but we  
16 would like to make it right up front that the label,  
17 what the warning label is included in the initial  
18 brochures that are handed out to customers.

19 Next slide. Simpler warning label. We'd  
20 like to proceed with a simpler warning label, other  
21 than all the words that are in the paragraph right  
22 now. The same information, but in a different format.

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1 The label will be identical or equivalent to the  
2 warning label of the IEC.

3 Next and here is their proposed, I think  
4 maybe even passed now, simpler warning label.  
5 "Danger, ultraviolet radiation. Follow instructions.  
6 Use protective eyewear. Overexposure causes skin and  
7 eye burns. Long term use may contribute to skin  
8 cancers, sometimes fatal, wrinkling and sagging of  
9 skin. Drugs and cosmetics may increase above  
10 effects." And I believe, as I said, most of these  
11 things are already in the current labeling, but in a  
12 different format that's not these bullets.

13 Next slide. One of the things we really  
14 seriously considered and would like to get into, but  
15 I think we need more data on and I've heard from  
16 people in the industry that this is a top priority  
17 that they'd like to see us do. I'm not sure we're  
18 ready to go with it right now, but the future  
19 amendment was to incorporate a new rating scale for  
20 replacement lamps, so that it was much easier to know  
21 which bulb is compatible for your bed. Right now it's  
22 somewhat of a slight mess. So if the data comes in.

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1 It's a little extra time. Maybe we, in fact, would  
2 get to this one and incorporate it in the first stage.  
3 Right now we're thinking that perhaps it would be  
4 another future amendment.

5 Next slide. As I said more effort is now  
6 needed to finalize this rating scale. There's almost  
7 universal agreement that it's needed and there is  
8 suggestion that we use the UV index as part of this  
9 rating system. You may be familiar with the UV index.  
10 This is what you hear on weather reports. Right now  
11 the index is 10 -- it's not right now, but sometimes  
12 you'll hear it's 10 which means the sun is really  
13 shining rather bright. I don't know what it would be  
14 right now, maybe about a 5, but it's the thing that  
15 you hear on weather reports that's been adopted by the  
16 EPA and the Weather Service and others.

17 Next. Other possible amendments down the  
18 road. Lower cumulative doses. The IEC is considering  
19 this. We have no immediate plans for that. If we  
20 did, however, that's where the action spectra for SCC  
21 would come into play.

22 We also are considering extending the

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1 schedules for different skin types. Here, we're a bit  
2 hindered right now and can't go forward at this time  
3 because we don't have the data for different skin  
4 types. And these amendments will be delayed because  
5 there's insufficient data to make a decision and we're  
6 going to have to wait for more research and  
7 evaluation.

8 Next. We will continue to work with  
9 industry and in the course of the last year, year and  
10 a half and upcoming we'll have further discussions on  
11 consent forms, exposure schedules, certainly on  
12 different skin types for future work on that. Work on  
13 the UV index in an attempt to get some sense maybe to  
14 the rating scale for replacement lamps and maybe even  
15 work on the benefits of UV weighing benefits with  
16 risk. We've had -- we will have a discussion of some  
17 of these at the upcoming workshop at the International  
18 Congress of Photobiology. This is going to be held in  
19 two weeks in San Francisco and this involves  
20 photobiologists, dermatologists, scientists, people  
21 from the industry who will be coming for a fairly  
22 large meeting that occurs only every four years.

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1 There's a two-day workshop on risk and benefits and  
2 quite a bit of it will be pertinent to this issue of  
3 sunlamps.

4 We have also talked about having specific  
5 FDA conferences where we may take an issue such as  
6 exposure schedules or rating scales and devote a  
7 conference just to that. This would help us in  
8 formulating language for future amendments and with  
9 on-going discussions and evaluations at -- in the  
10 normal course of doing business.

11 Next. There's tremendous work going on  
12 with the International Electrotechnical Commission,  
13 the IEC. They have finished several items. The  
14 finished items are on the left. They have a section  
15 done on timers. They have the warning level which I  
16 just read to you. They have incorporated protective  
17 eye wear language, their language differs a little bit  
18 from ours and now pretty much parallels what we have  
19 for protective eyewear where you can still be able to  
20 see the panic button. The panic button requirement is  
21 that there will be specifically a button where people  
22 can reach up and shut the machine off. One of the

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1 alternative was just to go up and turn the clock  
2 to zero, but they're making a specific requirement for  
3 a button which you could hit to shut the machine off.  
4 And a new definition of MED, minimal erythemal dose.  
5 The one that we had in our exposure schedule which  
6 we'll have to change was quite a bit lower than this,  
7 150 J/m<sup>2</sup>. The IEC is changing it and upping it to 250  
8 J/m<sup>2</sup> which is what the data now shows.

9 Things that they are considering and  
10 haven't finished are exposure schedules for different  
11 skin types and in the lab classification using the UV  
12 index. As I said, that's one of the reasons why we're  
13 putting those things on the second round is because  
14 we'd like to see what IEC is coming up with and by the  
15 way we work with IEC. One of our members of the  
16 radiation biology branch is a member of IEC and  
17 attends all their meetings and participates in their  
18 deliberations.

19 Next slide. So in conclusion, we will  
20 proceed with the proposed rule with these five  
21 amendments. I'd like to be able to tel you exactly  
22 what the words are, but we can't at this time. We're

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1 not at that stage.

2 Next. We will continue to work on the  
3 other issues for possible future amendments, probably  
4 quite a ways down the road.

5 Thank you. Do you want questions for me  
6 now or do you want to wait until after the speakers  
7 and then have questions all at one time?

8 DR. ROTHENBERG: Why don't we wait until  
9 the other speakers and then we can have a general  
10 discussion. Thank you.

11 Now we have four speakers scheduled,  
12 public hearing, the open public hearing. The first  
13 one is Mr. Don Smith.

14 Mr. Smith has also passed out a handout to  
15 the Committee.

16 Do you have a microphone? I just want to  
17 remind the speakers that we have originally scheduled  
18 20 minutes for the four speakers. But we are running  
19 a little bit ahead of schedule, so I'd like you to be  
20 concise, but we may have a few extra minutes.

21 MR. SMITH: High technology is handled by  
22 my son at home. My name is Donald L. Smith. I'm the

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1 Executive Director of the North American Alliance of  
2 Tanning Salon Owners and I should say at the outset  
3 that the constituencies that our organization  
4 represents and looks out for are the tanning salon  
5 owners and the clients that patronize us.

6 DR. ROTHENBERG: Can I just make one  
7 comment or clarification? When Dr. Cyr was  
8 presenting, when you spoke of the industry you were  
9 referring, I gather, most of the time to the  
10 manufacturers as opposed to the -- let's say the  
11 indoor tanning salons, is that correct or not?

12 DR. CYR: Actually, both. Some comments  
13 actually came from the indoor tanning industry.

14 MR. SMITH: Just to review, since last  
15 September, Dr. Cyr came to Chicago and talked to two  
16 meetings and that was very helpful to clarify the air  
17 and explain what had taken place.

18 Since then it would be helpful if the  
19 communications between us were better. I have yet to  
20 have a response from the ANPRM and other than what  
21 I've heard here, nor to the memos I've written and  
22 that's discouraging.

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1           Let's talk about the exposure schedule  
2           that Dr. Cyr mentioned. That becomes to salon owners  
3           a de facto ban. So make no bones about it because  
4           regulated states will mandate that and let's take a  
5           look at existing exposure schedule Dr. Cyr is talking  
6           about. For a typical 20 minute bed, first three  
7           sessions, 3 minutes, jumping to 7, 15 and 20. And  
8           I've not been able to find out where that came from,  
9           but it does not make sense to anything that anybody  
10          has -- would ever use or recommend.

11                 We have proposed what we call the neither  
12          nor which is to neither overexposure nor underexpose  
13          clients to UVR which takes a little different -- see,  
14          the FDA, what we believe is a more appropriate and the  
15          top line in the black is the point of erythema sunburn  
16          developing according to the typical calculations.

17                 To look at it just slightly different,  
18          standards call for the first three sessions, of .75  
19          MED and the question is how far under that do you want  
20          to be? FDA comes up to .38 and the one that I showed  
21          you, .64. So tanners have an obligation, they have a  
22          right to fair value for what they -- none of us argue

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1 that we should make sure that no one is overexposed.

2 We're concerned with the fact that this  
3 thing, as I mentioned is a de facto ban because  
4 tanning salon owners, the clients will not go for  
5 three minutes. And so you have a choice then of do  
6 you want to obey the law and lose your clients or not?  
7 And we have regulated states and nonregulated states.  
8 The problem comes in why it's a de facto ban is if  
9 someone didn't follow what Dr. Cyr has proposed to  
10 make mandatory, then your insurance will be null and  
11 void if you are ever sued. So it becomes a ban. It  
12 puts the tanning salon owners and tanners in a  
13 difficult place. All the tanners will do is go to two  
14 to three different salons every day or every other  
15 day. It won't change their behavior one iota.

16 You mentioned about the cancer action  
17 spectrum, at least clarified that as the SCUPH, the  
18 problem is as in talking to the optical experts  
19 there's a big jump from looking at an albino mouse and  
20 just arbitrarily saying and we've correlated to human  
21 skin. Mr. Dennis touched on that this morning.  
22 There's a big jump from that point.

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1 I'll just touch basically on melanoma  
2 warnings simply from the point of view that we're  
3 doing some work presented last year, the Christopher  
4 study that says it's skin temperature, not UVR that is  
5 the inducing factor for melanoma. A lot of exciting  
6 work being done with heat shock proteins and we need  
7 to remember that the peak in wave lengths is in the  
8 visible range. The peak in frequency photons is, in  
9 fact, in the infrared range.

10 Didn't mention until the last what we call  
11 the UBERSS, the Universal Biological Efficacy Rating  
12 Scale for Sunlamps. We need something that's  
13 traceable to NIST standards, to the manufacturer of  
14 the tanning salon because even if the lamp  
15 manufacturer and the sunbed manufacturer are in  
16 perfect compliance, if the electrical power coming  
17 into that salon is not right, you'll get higher or  
18 lower readings. So our proposal is we have to go from  
19 spectral radiometer to the hand held meter. We've  
20 bought an optronic 754 and we're in the process at our  
21 UVR Research Institute to look at all of these things.

22 I proposed last year that the UVI, the

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1 ultraviolet index scale was good. We're now finding  
2 that we need to look in terms of millijoules per  
3 centimeter square for some things and MED per hour and  
4 there's some nice conversion tables out. The real  
5 thing is MED per minute. And Dr. Cyr mentioned we  
6 need to look at cumulative things. I've been working  
7 with a software company so that we can sit down at the  
8 end of a month and a year and see the cumulative MEDs  
9 that a person has got. And for your information, as  
10 you look at this, it matters not which of the  
11 schedules you take, the FDA, that they intend to  
12 mandate or what we have proposed. Both deliver  
13 slightly under 25 MEDs in that 20 session time.

14 Skin typing. The FDA said very clearly in  
15 the 1986 letter Dr. Cyr referred to, since UV  
16 radiation dose causes a barely discernible pink  
17 coloration is not the same for different skin types.  
18 The exposure schedule for first time users will depend  
19 on the skin type of the user. We've been very active  
20 working on it. We don't believe that it should be  
21 guessed when they come in. We've had no response from  
22 our proposals. And so it would be helpful if we had

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1 responses from it and what Dr. Cyr said maybe it will  
2 be forthcoming. Same way with lamp compatibility. We  
3 had a conference at which the FDA was invited in  
4 April. We invited the state regulators and tanning  
5 salon owners from across the country and it was very  
6 beneficial. We both learned a lot about the problems  
7 of each other. FDA chose not to attend, but there it  
8 was clear, lamp compatibility is the number one  
9 problem we face.

10 Cellular telephone. There was recently a  
11 talk paper saying that FDA and CTIA to collaborate on  
12 cell phone research and here we're talking about a def  
13 factor banning of the indoor tanning industry. We  
14 requested information last year as part of the AMPRM  
15 process and the FDA was kind enough to send us 15  
16 years of complaints. There were 80, 8 - 0, attributed  
17 to the commercial tanning salons. There's been  
18 somewhere between -- whose numbers you like -- 12 to  
19 15 billion tanning session. I took 8 billion because  
20 it's easier for my math. So that's one complaint to  
21 every 100 million tanning sessions. We had 106,000  
22 deaths in hospitals alone from adverse drug reactions

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1 and 150,000 deaths from medical mistakes, so I think  
2 our priorities need to be looked at. The mandates  
3 need to be looked at.

4 I'd like to propose for your consideration  
5 the fact that we need a three-year collaborative  
6 program, not rushing into this de facto ban. We need  
7 -- the indoor tanning industry would fund the research  
8 the same way in the talking point. FDA would provide  
9 research recommendations and research oversight. You  
10 can't address lamp compatibility and you can't address  
11 exposure schedules until you get the universal  
12 biological efficacy rating scale. We have to all sing  
13 out of the same song book. You cannot have different  
14 units, so we have to resolve that. Then we can do  
15 lamp compatibility exposure schedules, skin typing and  
16 informed consent and we need to look at the risk  
17 versus the benefits of sensible, moderate and  
18 responsible exposure to ultraviolet radiation.

19 That's the question. What is the role of  
20 TEPRSSC? Is it analogous to a grand jury that the  
21 statement says they'll indict a ham sandwich? Is your  
22 job to rubber stamp what Dr. Cyr has provided or is it

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1 to take a look at it and say what is the right thing  
2 to do. And we think a collaborative study should come  
3 long before we go rushing into a de facto ban.

4 Thank you.

5 DR. ROTHENBERG: Thank you for your  
6 comments. The next person -- and again, we'll hold  
7 questions and discussion until after all the speakers.  
8 The next person will be Mr. Joe Levy.

9 MR. LEVY: I am Joe Levy. I am Executive  
10 Director of the International Smart Tan Network which  
11 is an association of about 4,000 indoor tanning  
12 facilities that are members and we provide educational  
13 materials that reach upwards to 12,000 facilities and  
14 publish a magazine that is received by about 20,000  
15 tanning facilities.

16 Like Mr. Smith's group, we are a salon  
17 group and in fact, Mr. Smith is a member of our group  
18 and has served on our advisory committee in the past  
19 and we cooperate with Mr. Smith. You're going to hear  
20 from the Indoor Tanning Association and I want to  
21 preface my remarks by saying that all three groups  
22 represent slightly different facets, but are

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1 cooperating together to work on what Dr. Cyr has  
2 presented this morning, excuse me, this afternoon.

3 My main concerns and I didn't prepare  
4 comments, I was waiting to hear and obviously this is  
5 the first we had heard of this proposal. Our main  
6 concern is on efficacy, the efficacy of what you're  
7 going to implement and I think there's reason to  
8 believe that perhaps the government doesn't really  
9 have the full realm of experience of what actually  
10 goes on in a tanning facility and what actually is  
11 happening with exposure schedules as they exist today.  
12 So I'd like to explain that a little bit.

13 Right now we have a recommended exposure  
14 schedule on each unit and Mr. Smith showed you a slide  
15 of how that works that leads up to a maximum exposure  
16 time. And the salons adhere to the maximum exposure  
17 time as an absolute, as a standard. And use the  
18 recommended exposure schedule as a tool and as a tool  
19 used by an educated tanning professional to assess  
20 when an individual comes into a salon, at what point  
21 should they be on that schedule that is going to  
22 minimize their risk of burning and then an educated

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1 salon employee can make the proper assessment on how  
2 to move that person through the schedule. Now that is  
3 a slightly subjective process. And what we're  
4 attempting to do with what Dr. Cyr I believe has  
5 suggested this morning, this afternoon and he didn't  
6 really give full details on how this exposure schedule  
7 as part of the standard would be implemented, but if  
8 he made it an absolute, I think you would end up not  
9 only with misapplied what happens where the rubber  
10 meets the road in the field, you would end up with  
11 abuse of the system and we have some evidence to  
12 suggest because we battled at this issue in the state  
13 of South Carolina working with the state government  
14 there on how to apply exposure schedules. South  
15 Carolina has one of the more aggressive regulatory  
16 programs for tanning facilities. And what we found  
17 out in conducting a survey of facilities and their  
18 customers because South Carolina was going to attempt  
19 to do what Dr. Cyr has suggested today, to make the  
20 schedule a mandatory, not a recommendation, but a  
21 mandatory regulation. What is going to happen is  
22 you're going to have tanning customers that if they

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1 cannot get the amount of exposure they want in their  
2 session, they're going to go to more than one facility  
3 in a single day and there's no way for us to regulate  
4 that. And that is as a facility, as a responsible  
5 industry, that is our single biggest frustration is  
6 that potential that we're going to lose control of  
7 applying these schedules in the correct way.

8 So I think you need to take that into  
9 consideration, that we have evidence that the consumer  
10 is simply going to abuse this system and in applying  
11 a too rigid a regulation that isn't based on proper  
12 assessment of each skin type and each person that  
13 comes into the facility, you're going to drive the  
14 industry, I guess, you'd say underground because  
15 consumers are going to go to more than one facility to  
16 get the level of exposure that they desire.

17 I am encouraged by the fact that this is  
18 a very initial part of this process of implementing  
19 this rule and would like to suggest that perhaps a  
20 conference committee consisting of both government, of  
21 FDA and our industry be put together to explore these  
22 issues and perhaps -- because I don't think industry's

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1 input -- I think it could have been more valuable to  
2 have these types of meetings before we got to this  
3 meeting today and I don't know that that process  
4 existed. I don't know that it did or didn't, but I  
5 would like to suggest that it should exist and that  
6 before we rush forward with something that we know in  
7 terms of efficacy in the field of what's going to  
8 happen in the salons, perhaps it's not going to be  
9 effective. We should explore this as a group so we  
10 can come up with a better solution in something  
11 because we're all looking for a better solution.  
12 We're all looking to do the right thing here. And I  
13 think it's very important at this juncture because  
14 there are some contradictions. This is a  
15 controversial industry, you all know that. There are  
16 so many contradictions floating around right now about  
17 ultraviolet light exposure. There's so many myths and  
18 misconceptions about UV exposure. Maybe I'm not sure  
19 if you folks realize this industry was developed in  
20 Europe, not as a cosmetic industry, but as a  
21 therapeutic industry and that the benefits of regular  
22 exposure had an interesting side effect of producing

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1 a tan and we've applied that in the United States, in  
2 North America, really, as a cosmetic industry and many  
3 of our customers, whether we are allowed to advertise  
4 this or not are coming to our facilities to accrue  
5 those benefits, whether we can suggest that they're  
6 getting them or not legally yet, that's irrelevant.  
7 That's why they're coming in. So before we rush ahead  
8 with applying the schedule, I think we need to take a  
9 look at what's going to actually happen in the field  
10 so that we can apply something properly.

11 Thank you.

12 DR. ROTHENBERG: Okay. The next speaker  
13 will be Mr. Jerry Deveney.

14 MR. DEVENEY: Good afternoon. My name is  
15 Jerry Deveney. I am representing Sun Industries.  
16 Recently, we were purchased by JK Ergoline of Germany  
17 and currently we represent the largest manufacturer  
18 of commercial tanning equipment in the world.

19 First, I want to make some things clear.  
20 We really appreciate what you guys have put together  
21 here today for us. Our main concerns are not so much  
22 with regulation. We agree there's a need for it. Our

1 concerns are more in the language that may be adapted  
2 in preparing these regulations or amendments. In  
3 particular, there's one regarding the sun lamp product  
4 manufacturer, that is identifying the person who  
5 adulterates or modifies its tanning unit in the field  
6 is now being labeled as a manufacturer. The problem  
7 with that is that as a manufacturer ourselves, we take  
8 a lot of steps in determining, putting a UL listing or  
9 ETL listing on a product. We put it through tests to  
10 determine the proper exposure schedule. We also  
11 maintain something called products liability insurance  
12 which costs my company about \$250,000 per year. What  
13 this does is insures the purchaser and the user that  
14 that unit is up to standard. It's safe, electrically,  
15 and so on. When you allow someone to come in  
16 arbitrarily from the field and start modifying or  
17 adulterating our product either with a new lamp or  
18 ripping the labels off and putting their labels on, if  
19 they in essence become the manufacturer, what happens  
20 is that we may no longer be responsible for that unit.  
21 That means the ETL listing which was the assurance to  
22 the local electrical and fire inspectors that unit is

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1 safe may no longer apply. Furthermore, our products  
2 liability insurance covers may be void because the  
3 unit was adulterated. Therefore, if you're going to  
4 adopt such strategies like that, you may want to  
5 inform the consumer who is going to use that unit that  
6 that unit has been modified and what implications or  
7 ramifications that may have in terms of safety,  
8 insurance and so on. If the local inspector issued a  
9 certificate of occupancy for that salon to open  
10 because a unit was ETL listed and now that no longer  
11 applies because the unit has been adulterated that  
12 salon may be shut down and by encouraging this the FDA  
13 may be actually encouraging people to modify a unit by  
14 putting this language in there.

15 What we ask at Sun Industries is that  
16 before you adopt such an amendment, you allow us to  
17 review what you're going to let someone do to our  
18 equipment in the field. We think it's only fair  
19 before you -- we have 14,000 locations across the  
20 country that feature our equipment. We have more than  
21 150,000 tanning units in the field. There's obviously  
22 a lot of people affected by this. To let people go

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1 out there and start messing around with our equipment,  
2 we like to be notified of who's doing it. We'd also  
3 like to be notified of how did they determine that the  
4 lamp that they want to use in that bed is truly  
5 compatible? What was the testing procedure they used?  
6 Did they use the same test we did? And again, that  
7 goes back to what the other gentlemen were speaking  
8 about today, about a more unified testing procedure  
9 for determining MED output. We submitted paperwork to  
10 the FDA on this about two years ago and one of the  
11 problems we see is that there is no clear definition  
12 on what an MED is.

13 Back in 1995, the National Weather Service  
14 put together a report where they determined the UV  
15 index. And what they said was basically that on a day  
16 rated as a 10, that meant you received 10 MED of  
17 ultraviolet light in one hour outside that day. And  
18 they used a very similar approach to how we determine  
19 MED.

20 Now what that also means though if you  
21 spend four or five hours in the outside sun on a hot  
22 afternoon in Florida or Virginia Beach, you could be

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1 getting 20, 30, 40 or 50 MED of ultraviolet light in  
2 one day. Yet, our tanning systems deliver 4 MED at  
3 most and must then shut off.

4 That brings about our next concern. That  
5 is, in the language that you use to adopt this  
6 amendment on the exposure schedule which is currently  
7 recommended, if in turn you then make it mandatory and  
8 you establish 4 MED precisely how it's delivered by  
9 that tanning unit as the maximum way to tan and it's  
10 mandatory, it's the only way to tan, as absurd as this  
11 may sound, you may be exposing yourselves to liability  
12 for people who work outside, in the outside sun. If  
13 4 MED becomes the standard and this is mandatory that  
14 the FDA says it can be no more and it must be  
15 delivered precisely as that unit does it, what does  
16 that say about the Florida Tourism Board? What does  
17 that say about highway workers, people who play golf?  
18 When does it stop? How much -- what next regulations  
19 will we have to impose? If 4 MED is the most and you  
20 can get 50 MED on a hot summer day, will in fact this  
21 regulation of indoor tanning have an effect on outdoor  
22 tanning? Again, this may sound absurd today, but

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1 think about where this could go and think about the  
2 potential liabilities that could be associated with  
3 such a statement. I mean will outdoor workers be  
4 required to wear sunscreen before they go out? Will  
5 they be required to only go out for three minutes at  
6 a time just like an indoor tanning bed? Because an  
7 MED indoors does not differentiate from an MED  
8 outdoors.

9 So again, all we're asking is that we need  
10 regulation. We absolutely believe in it. Hey, it  
11 protects us too. At the same time we'd just like to  
12 have set before any amendments are adopted some real  
13 world scenarios of what may come of this from  
14 potential liability and litigation. I mean it  
15 wouldn't take a third year law student too hard to  
16 figure this one out. Okay?

17 Thank you.

18 DR. ROTHENBERG: Thank you. Our last  
19 speaker in the public presentation is Jack Riley.

20 MR. RILEY: Good afternoon. My name is  
21 Jack Riley. I'm Executive Director of an organization  
22 known as ITA, the Indoor Tanning Association. ITA was

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1 founded, incorporated on July 15th of last year, 1999.  
2 And for purposes of this discussion, when you've been  
3 approached by people who represent the industry, we  
4 also represent the industry. ITA covers all segments  
5 of the industry from the salons to the manufacturers.  
6 Included in our membership are 95 percent of the  
7 manufacturers of sunbed products, as you define them,  
8 100 percent of manufacturers of UV lamps or sunlamps  
9 as we prefer to call them.

10 Among the objectives, ITA is looking to  
11 accelerate or advance the level of professionalism in  
12 our industry and are working hard to do that. ITA has  
13 formed a Regulatory Affairs Committee and right now  
14 are working on exposure schedule data.

15 Earlier in the presentations, Dr. Cyr  
16 mentioned on slide 20, I believe, he was interested in  
17 working with industry. We had Mr. Levy indicate that  
18 also we'd like to work together as an industry to form  
19 a joint committee to determine appropriate and  
20 practical exposure schedules. ITA is extending an  
21 invitation or would accept an invitation to join with  
22 FDA any joint committee to marshal and focus the

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1 resources of our industry and its membership to forge  
2 appropriate and practical exposure schedules.

3 Thank you very much.

4 DR. ROTHENBERG: Thank you. I would like  
5 to thank all of the speakers for keeping to their time  
6 schedule and now let possibly Dr. Cyr would want to  
7 make a few comments in reply to the previous four  
8 comments?

9 DR. CYR: I guess maybe one of the things  
10 I wanted to make clear and didn't in my original  
11 presentation was another reason why we wanted to make  
12 the exposure schedule part of the standard and it  
13 wasn't so much a debate between the FDA exposure  
14 schedule versus Mr. Smith's exposure schedule, both of  
15 which may not cause burning, but it was more to the  
16 point of somebody saying that our recommended policy  
17 which is in a letter doesn't carry the weight of any  
18 law and can be ignored and you can do anything you  
19 please, including anything. That was probably the  
20 point we really wanted to address and why we needed to  
21 put something stronger into the standard that yes, you  
22 must have an exposure schedule which is based on

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1 science and it must consider frankly burning people  
2 and things like that. You cannot get away with doing  
3 anything you please. And that's maybe a point I  
4 didn't address.

5 One of the good things about the FDA  
6 exposure schedule happened recently and that was a  
7 published study showing the effects that you got and  
8 they had two measurements, actually, people looking at  
9 the skin of individuals and grading the tan and there  
10 was another dosimetry machine that looked at the skin  
11 and gave a similar measurement and the two agreed  
12 fairly well. And what that study showed was that you  
13 can, in fact, get tans following the exposure schedule  
14 of the FDA and not produce any significant burns or  
15 erythema. However, you do get what Mr. Smith has  
16 talked about and that is that you can go for about 5  
17 to initial sessions before anything starts showing up.  
18 And so this study did show that there was that problem  
19 that maybe there are people who would go out and pay  
20 good money to produce an effect in the first five or  
21 six sessions and not come -- and come home not feeling  
22 that they got anything. So there is a significant,

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1 maybe a problem in there that we could work on in  
2 terms of the initial doses.

3 But I want to make the point that it  
4 wasn't just our schedule versus his. It was totally  
5 ignoring all exposure schedules that I wanted to make  
6 a point about.

7 If we have the time and resources I would  
8 love to have a conference to iron these things out  
9 before we put pen to paper for final words. Certainly  
10 would save an awful lot of effort after the fact  
11 because these same comments, you know, are going to  
12 come back after we publish them. If we can iron some  
13 of these out before we did that, that would make great  
14 sense, so if that can be done and we have the money to  
15 do it. But that's not my decision.

16 I guess I have some clarifications of  
17 Jerry Deveney's suggestion about manufacturers. And  
18 I guess he's not disagreeing with me that anybody who  
19 modifies this becomes, in fact, a manufacturer, but  
20 what he wants, if I'm interpreting his comments right  
21 is that he'd rather really have stronger things in  
22 there to keep the original manufacturer and that if

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1 somebody wants to go in there and do a replacement  
2 that at least you notify the original manufacturer  
3 that it's been done and also notify the customers that  
4 something has been done. So he's actually, I think,  
5 in a sense going beyond what I had even suggested in  
6 my presentation.

7 DR. ROTHENBERG: Maybe he could just make  
8 a quick comment. Microphone, please, since everything  
9 is being recorded for the minutes, etcetera.

10 MR. DEVENEY: Yes. We absolutely agree  
11 that if someone -- if there's a need to modify a  
12 product, I think that the original manufacturer, if  
13 they're still in business, that is, and so on, should  
14 be notified of exactly what someone is doing to their  
15 system, how they're doing it, why they're doing it  
16 because if they start peeling labels off and so on it  
17 opens up a lot of liability and we can't identify the  
18 unit and if we get sued and we say wait a minute, the  
19 FDA said it was okay to do this and this guy says  
20 well, it opens up a can of worms for us. So we  
21 definitely want to expand upon that.

22 DR. CYR: And I also would like to say

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1 that I am in agreement with Mr. Smith and Joe Levy  
2 that we wouldn't want to get in a situation where  
3 people would feel cheated, let's say, in their initial  
4 exposures and run off across the street to another  
5 salon to get something that they felt that they were  
6 not getting. That is certainly not the purpose of us  
7 proposing the amendments.

8 Am I missing something here? I'll let you  
9 ask questions.

10 DR. ROTHENBERG: A brief comment, Mr.  
11 Smith?

12 MR. SMITH: The study Dr. Cyr refers to  
13 is a so-called Caswell Report and it addressed 11  
14 subjects, 9 have completed it. All type III and type  
15 IV skin types. There were no type IIs, especially the  
16 ones we're most concerned with, what we call the IIAs,  
17 the most sensitive and that study does not show  
18 anything about the safety and effectiveness of the FDA  
19 schedule pertaining to these most sensitive skin  
20 types. I have the paper with me so --

21 DR. CYR: Don, do you have the  
22 measurements of tanning? I know your schedule for

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1 Type IIa and b comes from the questionnaire, but do  
2 you have the follow-up data actually showing the tans  
3 or the burns that occur following your schedule?

4 MR. SMITH: That's what we want to sit  
5 down and discuss. We need an agreed upon study that  
6 we all set up and say here's what we're going to do.  
7 We can get enough people around the country to do it.  
8 We're completely in agreement with you. And we  
9 appreciate your offer to have a conference. We'd like  
10 to schedule one in four to six weeks where we lay out  
11 all these things. Thank you.

12 DR. ROTHENBERG: Do you have any further  
13 comments or should we -- maybe we can open it up to  
14 the Committee now for some questions and comments.

15 Jerry?

16 MR. THOMAS: I have four or five questions  
17 that came up during the discussion that I'd like some  
18 clarification on.

19 You talked about making U.S. standards  
20 follow IEC standards and one of the speakers talked  
21 about the fact that tanning booths were initially  
22 designed for medical benefits.

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1 Does the IEC have a currently adhered to  
2 or published tanning schedule?

3 DR. CYR: I'm not sure about the initial  
4 doses. I know they have an annual limit and they have  
5 a different definition of MED.

6 The build up schedule, I'm not sure. I  
7 have not seen that.

8 MR. THOMAS: Okay. That might be  
9 something if we have different definitions of MED  
10 internationally that that I think probably needs to be  
11 considered as to what is the definition of an MED.

12 DR. CYR: That was one the proposals that  
13 we adopted, 250, because that's what the science now  
14 tells us, too.

15 MR. THOMAS: Mr. Deveney was expressing  
16 some concerns I don't think is what I heard from you.  
17 If we have somebody that changes a lamp in a tanning  
18 booth, the definition of making that individual a  
19 manufacturer makes some sense to me because they're  
20 modifying the piece of equipment that has absolutely  
21 nothing to do with what I heard stated by him in that  
22 it impacts -- that individual is changing that piece

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1 of equipment so therefore they are a manufacturer,  
2 they are not the original manufacturer. Is that your  
3 interpretation of what you mean by more clearly  
4 defining the role of an individual who modifies a  
5 piece of equipment as a manufacturer?

6 DR. CYR: That's my understanding, but I'm  
7 not the true expert on this.

8 Jerry, are you here? Do you want to add  
9 in on this? Jerry Dennis.

10 MR. DENNIS: Hello. This is Jerry Dennis  
11 again. The idea is that if someone owns a piece of  
12 equipment, they can fairly well do whatever they want  
13 with it. If I have my watch, I can throw it on the  
14 floor, I can throw it out the window or I can do  
15 whatever I want. I'm the owner of it. The question  
16 is when you have a product such as this which is used  
17 in commerce to deliver a tanning exposure to a  
18 customer and the piece of equipment is subject to a  
19 safety standard and the owner of the equipment now  
20 installs the lamps, installs the timers, installs  
21 other equipment that modifies the way in which the  
22 piece of equipment would no longer comply with the

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1 standard, we would want to believe that person to be  
2 responsible for what they do and as a manufacturer  
3 because they are essentially remanufacturing that  
4 product as far as its compliance with the standard is  
5 concerned.

6 I think that's where we're going.

7 DR. CARDELLA: If anything, that  
8 definition to me makes good sense because it will take  
9 the original equipment manufacturer off the hook. I  
10 mean I would think, I would think that the notion that  
11 it's going to drive your insurance premiums up or  
12 something is far fetched at best. Is that the point  
13 you were trying to make?

14 MR. DENNIS: While Jerry is coming up, the  
15 idea is if a salon were to replace lamps, lamps of the  
16 same type or a type which is equivalent, then they  
17 wouldn't be modifying it at all.

18 MR. DEVENNEY: That's correct. But what is  
19 the test to determine equivalency? It's based on some  
20 guy who does it in his lab and he says oh yes, it's  
21 equivalent and here's my letter. Is there any  
22 follow-up? Have you guys ever tested it? When they

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1 say that this lamp is compatible, does the FDA ever  
2 come back and say yes, we've tested it?

3 The people who make these compatibility  
4 claims today, I guarantee you, do not test a lamp in  
5 my unit before they make that claim. All right? And  
6 that's where we're getting at. And it does drive up  
7 our insurance premiums because if there's an accident  
8 or something what happens is and this again is the  
9 real world, the salon owner may say oh, I saved the  
10 original lamps in the closet. Let me change those  
11 lamps and put the other ones back in and now Sun  
12 Industries who has deep pockets are back on the hook  
13 for this. And changing or adulterating product does  
14 modify the ETL or UL listing regardless of what  
15 anybody says because we test it as a complete unit for  
16 UL or ETL with every component in there. And it says  
17 it was tested with this lamp on this date and so on.  
18 If you modify that, then again, all we're asking  
19 though is that we'd like to be informed of such  
20 modifications of someone intending to adulterate our  
21 product. It's kind of like if you have brakes on a  
22 car. And someone sells bad replacement brakes. You'd

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1 want those recalled in a minute and again, it's just  
2 a question of who enforces such a thing.

3 DR. CARDELLA: What is the motivation for  
4 a salon owner to switch away from the originally  
5 installed bulb? Let's say you've got an XB28 bulb in  
6 the thing is the way it comes from the factory and  
7 when you relamp it, if you put a XB28 bulb from any  
8 manufacturer you should be in good shape. What is the  
9 motivation to put an XB30 in it? Are they cheaper?

10 MR. DEVENNEY: It could be in some  
11 instances, it could be a marketing strategy that  
12 someone says that we've altered the wavelength so it  
13 delivers a different type of tan. There's maybe more  
14 bronzing. There's different UVA/UVB ratio and as long  
15 as it's within 10 percent of the original lamp it can  
16 be replaced at this point.

17 Again, we're not looking at this from the  
18 standpoint that we just want the replacement lamps  
19 because we want to make all the money in the  
20 replacement lamps. We're concerned about if somebody  
21 puts a lamp in that's too strong for the 20-minute  
22 schedule on that bed and they have not done the proper

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1 testing and instead of getting 4 MED, they're getting  
2 8 MED in 20 minutes, we're the guys, no matter whose  
3 name is on there, it's manufactured by Sun Industries,  
4 believe me, they come after us. It happens all the  
5 time.

6 DR. CARDELLA: It seems to me then, maybe  
7 I'm not understanding what the maintenance is like on  
8 these things, but for a piece of x-ray equipment let's  
9 say I buy from Vendor X. Typically, what happens is  
10 Vendor X comes and services that machine and they put  
11 original equipment back in it. An analogy would be if  
12 the brakes go bad on my car, I can take them back to  
13 Ford or I can take them to Midas. Brakes are brakes,  
14 near as I can figure. Ford would have me believe that  
15 the only way my vehicle will stop is with Ford brakes.  
16 And Midas will have me believe that the only way to  
17 stop my car is with Midas brakes. And I'm not 100  
18 percent sure I understand the fine fractionation of  
19 lamp bulbs.

20 It seems to me that lamps ought to be  
21 rated. My solution to it would be stipulate that  
22 tanning beds have to be serviced by the original

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1 equipment manufacturer period and don't allow the  
2 option for clever low cost substitute, after market  
3 bulbs to be put in. Would you --

4 MR. DEVENEY: I agree with that.

5 DR. CARDELLA: Would you like that?

6 (Laughter.)

7 MR. DEVENEY: I think we can stop right  
8 there. I'm very happy now.

9 (Laughter.)

10 Again, I don't mind replacement market --  
11 as long as they submit the same tests and  
12 documentation that we do. As long as they give us the  
13 paperwork saying look, we took that unit. We tested  
14 it as a complete unit and it's compatible. And we can  
15 verify it ourselves. We don't have a problem.

16 MR. THOMAS: We're going away from my  
17 original question. I'm going to step in because I  
18 have a couple more.

19 MR. DEVENEY: I like that idea.

20 MR. THOMAS: Can you give us -- it's  
21 impossible to do in two sentences, but tell us about  
22 the cancer action spectrum. There appears to be some

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1 objection to using as a metric and you've implied that  
2 you think that's something we need to consider.

3 DR. CYR: I think what I heard was -- it  
4 wasn't really an objection about using it, but that  
5 there may be expressing difficulty in translating an  
6 action spectrum that was developed on an albino mice  
7 to what humans -- to something that's useful for  
8 humans. Now that has been done and there were  
9 calculations made taking into account the skin  
10 thickness differences between the mouse and the human.  
11 So there has been developed a cancer action spectrum  
12 for humans. And the IEC has chosen to say that this  
13 one is the one that we will be using as cancer action  
14 spectrum.

15 Don will clarify.

16 MR. SMITH: I will be brief. The  
17 so-called SCUP cancer action spectrum relies on the  
18 measurement of cyclobutane pyrimidine dimer, CPDs. It  
19 is a HPLC, high pressure liquid chromatography  
20 measurement off of biopsy. That's a long way from the  
21 wave length analysis we've been doing with erythemat  
22 action spectrum and don't underestimate that. That's

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1 the problem.

2 MR. THOMAS: Okay, shifting to the  
3 material that you handed out to us that you didn't  
4 have in the overhead, you gave us a handout called  
5 solar radiation exposure to sunlamps or sunbeds.  
6 That's this multiple page document.

7 DR. CYR: Oh yes.

8 MR. THOMAS: Which looks like it's a  
9 report of the NINTH on carcinogenesis. In that report  
10 the language is fairly strong about sunlamps and  
11 sunbeds being known to be human carcinogens and there  
12 are references in there, but the references are not  
13 provided in a bibliography. Would it be possible to  
14 provide the Committee the bibliography for those  
15 references?

16 DR. CYR: I have those papers. I can give  
17 them to you, yes.

18 MR. THOMAS: Okay, I don't need the  
19 papers. Just what journals they were in. I have no  
20 feeling for the credibility of the citations. I'm  
21 sure that the citations are very credible. I don't  
22 know whether these are photobiology journals or

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1 whether they're sun tanning publications. Completely  
2 different in terms of their scientific merit.

3 DR. MURDOCH NELSON: I can speak to that  
4 to some degree. I've reviewed these articles myself.  
5 I don't really remember what journals they're  
6 published and I do know they're peer reviewed. I can  
7 say that they're methodologically concerning. One of  
8 the problems is how they measured cumulative exposure  
9 to either sunlight or to the sunlamps. There is also  
10 -- there is concern about how they define cases and  
11 controls and the way they were defined is the cases  
12 and controls were selected in such a way that there  
13 was a greater likelihood of finding an association  
14 which may or may not be clinically significant.

15 Let's see what else? I would say that the  
16 jury is still out on whether there's an association.

17 MR. THOMAS: Okay, so what you're really  
18 saying is the science is not as sound as it might be.

19 DR. MURDOCH NELSON: I would agree with  
20 that.

21 DR. CYR: Likewise. I think I'm slightly  
22 at odds with NTP on the final conclusion there. We're

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1 in the process of contacting NTP and trying to see if  
2 we can make a resolution here.

3 I attended a meeting of the Federal  
4 Council on Skin Cancer Prevention last week which had  
5 representatives from all federal agencies, CDC and  
6 EPA, Weather Service and all that and they likewise  
7 had some reservations about how NTP came to this very  
8 strong conclusion.

9 MR. THOMAS: Another and final question  
10 from me and we can go where the Chairman wants us to  
11 go with recommendations.

12 Are these issues issues in your opinion we  
13 need to proceed forward with action or a three year  
14 collaborative study program to me is a block and parry  
15 to slow down the process, not necessarily a drive to  
16 move forward with what appears to be areas that are of  
17 concern to the FDA. Am I missing something with the  
18 five proposals that you -- five amendments that you  
19 listed? Versus a three year study because that's a  
20 long period of time before any regulatory actions  
21 might be taken.

22 DR. CYR: I think some of them will not

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1 require a three year study. I think the exposure  
2 schedule, at least getting something into the standard  
3 saying that you have to pay attention to doses which  
4 don't burn people, doses which are safe to cover my  
5 concern that you can do anything that you darn well  
6 please.

7 That wouldn't require much, a three year  
8 study. Putting a modified FDA exposure schedule in I  
9 don't think would require a 3-year study. Trying to  
10 get an exposure schedule for different skin types  
11 might because I don't think that data is there.

12 MR. THOMAS: Do you feel that the schedule  
13 is going to be a de facto pin?

14 DR. CYR: I understand their concerns  
15 about people going across the street and getting --  
16 trying to get an effect for those first six sessions.  
17 I don't think it's an effective ban, but I am  
18 sympathetic to their concerns that maybe the customer  
19 is not getting bang for the buck, so to speak, for  
20 those initial sessions. And maybe that is something  
21 we could address in a shorter time period, certainly,  
22 than three years.

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1 MR. THOMAS: Although there's nothing to  
2 preclude me going across the street today is there?

3 DR. CYR: Absolutely not, no.

4 DR. CARDELLA: The only thing that would  
5 preclude going across the street is that typically  
6 there's a front end load to attending a tanning salon.  
7 I mean I have personal experience with three tanning  
8 salons in three different cities in the Mid-Atlantic  
9 and Northeastern regions of the country and you don't  
10 just walk in and plot down your \$5 for your 20 minute  
11 or 15 minute or 10 minute session. They're frequently  
12 loaded with \$50 to \$100 up front membership fees and  
13 I was going to make the comment that I take exception  
14 to that going across the street thing. I don't think  
15 people would do that in a heartbeat. I mean I  
16 personally wouldn't do it with that kind of a front  
17 load on it, so I don't know that that's a legitimate  
18 concern.

19 DR. ROTHENBERG: Yes, Cass?

20 MS. KAUFMAN: Dr. Cyr, Mr. Levy mentioned  
21 the educated salon employee using the current exposure  
22 schedule as a tool and I was wondering, are there

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1 currently any minimum training standards for salon  
2 employees and have there been any studies that  
3 indicated how much training those educated salon  
4 employees get?

5 DR. CYR: This depends state by state.  
6 There are some states that have a requirement for  
7 education and have good programs. I believe other  
8 states have absolutely nothing. Anybody want to  
9 comment on that?

10 MR. LEVY: There are currently, I think 27  
11 states, if memory serves correctly that have some sort  
12 of regulation, but are really only a handful that  
13 mandate less than a dozen that mandate standards for  
14 education. However, what we found is that salons,  
15 even in unregulated states today in order to stay  
16 competitive, education is a marketing tool and so I'd  
17 say that the majority of what I call tanning salon qua  
18 tanning salon where tanning is the primary business  
19 and it's the reason for existence and you identify it  
20 as a tanning salon as opposed to a type of facility  
21 that also offers tanning, but the majority of tanning  
22 salons where that is their business and their

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1 livelihood are educated regardless of rules requiring  
2 it.

3 MR. THOMAS: Mr. Chairman, we had five  
4 amendments. Do we need to provide Committee feedback  
5 to the FDA on each of these proposed amendments or as  
6 a group? What is your direction?

7 DR. ROTHENBERG: I'd like to get a little  
8 more sense from the Committee, their feelings on  
9 whether they'd like to look at this as a group or  
10 individually.

11 We could certainly look at them as a  
12 group.

13 MR. THOMAS: We have 20 minutes left on  
14 your schedule to keep on time.

15 I would recommend that we look at them as  
16 a single group as opposed to an individual motion on  
17 each one of the amendments would be my proposal to the  
18 Committee.

19 DR. ROTHENBERG: Okay. Any -- yes.

20 MS. KAUFMAN: I guess I really am  
21 concerned about this education of salon employees  
22 issue and while we can look at the five, I would like

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1 to suggest that perhaps the regulations include  
2 something about educating employees who are actually  
3 providing the immediate interaction with clients.

4 MR. THOMAS: Why don't we just go down the  
5 numbers, Cass. You and I are good at motions and  
6 start at the top and go through. Start with that  
7 right now and then we'll go into the amendments.

8 DR. MURDOCH NELSON: I wonder -- I'm  
9 sorry, I did have one more question before we go to  
10 the amendments, if that's all right. And my question  
11 has to do with -- again, this concern that people  
12 might cross the street and go to another tanning booth  
13 to get more doses. My question is whether they  
14 actually do that or not and whether or not we adopt  
15 some sort of standard. It sounds to me that if  
16 they're going to one tanning both and they're getting  
17 a certain amount of doses and they go to another  
18 tanning booth and get the same scheduled from another  
19 group how will these regulations protect the consumer  
20 because they're getting twice the amount of exposure.  
21 I'm asking you.

22 DR. CYR: I'm not sure what we can do

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1 about that. You could probably get a lot more than  
2 that by going to Rehobeth Beach on Saturday.

3 DR. MURDOCH NELSON: Right.

4 DR. CYR: And we don't do anything about  
5 that either.

6 DR. MURDOCH NELSON: Right. Well, I guess  
7 I'm wondering -- if it makes sense to have a  
8 regulation like that when there is no check point to  
9 make sure they're not getting more doses.

10 DR. CYR: I think the point of a  
11 recommended exposure schedule was in the original  
12 policy letter and that was to assure that you didn't  
13 come out with burns, significant erythema so you  
14 wanted to make sure that you set up a schedule that  
15 didn't cause people to be burned and that is a  
16 function of whether you have originally got some tan  
17 in you or were you coming out from a winter's  
18 whiteness and going to a first session. So you do  
19 have to have a build up time and a different schedule  
20 for people who are just coming to get their first dose  
21 and for those who have built up a tan.

22 DR. ROTHENBERG: I must confess to being

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1 a little confused. We were talking about possibly  
2 looking at the five amendments. The first one seems  
3 to be the more -- 1 and 2 seem to be more  
4 controversial than 3, 4 and 5, particularly as to what  
5 the schedule would be that would be listed. I think  
6 that's a problem. I'd like to look at 3, 4 and 5 as  
7 one group and 1 and 2, discuss 1 and 2 a little bit  
8 more.

9 MR. THOMAS: I agree with you and so to  
10 start out the discussion, if I might, I make the  
11 motion that the Committee recommends the FDA move  
12 forward with making an exposure schedule as part of  
13 the standard.

14 DR. CARDELLA: Second.

15 DR. ROTHENBERG: Discussion. Yes?

16 MS. KAUFMAN: Regarding No. 4 which is  
17 warnings in catalogs and spec sheets and that kind of  
18 stuff, would there be some discussion of that exposure  
19 schedule within that within those warnings? In other  
20 words, I guess I always feel really strongly that what  
21 we need to do is educate consumers and then what they  
22 do thereafter is kind of what they want to do. If

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1 there was an exposure schedule, would it be explained  
2 what that is and how it works in those warnings which  
3 I presume would be given to consumers if they were in  
4 catalogs and spec sheets and that kind of thing. Or  
5 would that spec sheet only be required to be used by  
6 the tanning facility. The spec sheet and brochures  
7 and all that come from the manufacturer of the sun  
8 lamps and sun lamp products, the beds and it would be  
9 included in the materials that they give to people  
10 buying their products. We were considering the  
11 warning itself, the simple warning with just a few  
12 bullets. That's all that we were considering. We had  
13 not considered anything about including a recommended  
14 exposure schedule in that.

15 MS. KAUFMAN: So regarding amendment No.  
16 4, which is warnings, FDA wouldn't have any say in  
17 what would be in those warnings. It would just be  
18 that kind of a vague statement that there would be  
19 warnings.

20 DR. CYR: No, no, no. We were saying that  
21 the warning label which --

22 MS. KAUFMAN: Which is No. 5.

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1 DR. CYR: Which is danger, ultraviolet  
2 radiation bullet.

3 MS. KAUFMAN: Right.

4 DR. CYR: Follow instructions, provide,  
5 use protective eyewear. Overexposure causes skin and  
6 -- that's the warning.

7 MS. KAUFMAN: I'm talking about amendment  
8 No. 4 which is warnings in catalog spec sheets and  
9 brochures.

10 DR. CYR: That's the same warning that  
11 would be included. It's much in the same way that  
12 every little pack of cigarettes has a little warning  
13 down in the corner and if you have a brochure  
14 describing your product that the warning label would  
15 be included as part of that brochure.

16 MR. THOMAS: Cass, it's my understanding  
17 from what was presented that the answer to your  
18 question is no.

19 MS. KAUFMAN: I think you're right. I  
20 know and it would seem to me that if we want to  
21 include an exposure schedule, that it would be much  
22 more effective if it were included in terms of being

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1 provided to the consumer, what that schedule was for  
2 and what it was supposed to do. And that might assist  
3 in terms of people going across the street.

4 MR. THOMAS: Yes, but I think the issue is  
5 that this is a 14 year old letter that's being  
6 ignored. What I'm hearing is that this industry is  
7 flaunting their -- they're essentially ignoring the  
8 FDA's guidance that's 14 years old and that bothers  
9 me. That's what was indicated in the discussions  
10 earlier today.

11 I think that we need a standard. We need  
12 a standard that's clear, that has the force of  
13 regulation, not the force of an advisory policy  
14 letter. And I'm very concerned that what I've heard  
15 today is on the part of some people within this  
16 industry an overt effort to ignore policy guidance.

17 MR. LEVY: I think there's a  
18 misunderstanding. The industry is not ignoring that  
19 14 year old recommendation. That is a recommended  
20 exposure schedule that leads to a maximum exposure  
21 time. We are definitely adhering to the maximum  
22 exposure time and we are using the recommended,

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1 recommended being the key word, exposure schedule as  
2 a tool to lead an individual to the maximum exposure  
3 time because we know and that is one of the things  
4 that Mr. Smith pointed out, we know that the  
5 recommended exposure schedule as an absolute, each of  
6 those steps in the schedule, several of them there are  
7 problems with. They are not realistic nor appropriate  
8 and the science behind developing that and I'm not the  
9 right person to be speaking on that, but I know for a  
10 fact, it was not developed specifically with the  
11 tanning industry in mind. And so what we're saying is  
12 if we're to revamp that recommended exposure schedule  
13 and I'm not certain -- I don't know what you've  
14 suggested, Howard, is to put the recommended exposure  
15 schedule into your rules or to make a mandatory step  
16 by step schedule as part of your rules and I think  
17 maybe there's some misunderstanding about that.

18 DR. CYR: Repeat again, because I got lost  
19 in that.

20 MR. LEVY: Okay.

21 MS. KAUFMAN: I think the question is is  
22 the recommended -- when you say you're going to put in

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1 an exposure schedule into regulations are we talking  
2 about the guidance letter or are we talking  
3 generically an exposure schedule which will be  
4 determined at some point in the future in terms of  
5 individual steps? We're not clear what exposure  
6 schedule we're referring to. Is that right?

7 DR. CYR: Our initial --

8 MS. KAUFMAN: That's my question.

9 DR. CYR: Our initial consideration was  
10 pretty much to follow what was in the policy letter of  
11 1986, updating it with modern definitions of MED.

12 MR. LEVY: And that, as exists, is a  
13 recommendation leading to a maximum exposure time and  
14 the salons today are using that recommendation as a  
15 tool, as a guideline so that they can make proper  
16 assessments because people come in into salons.  
17 They're not all at the first step of the schedule when  
18 they step in the salon and so it requires some  
19 education on the part of the salon as to where is  
20 appropriate to begin that person in their tanning  
21 regimen.

22 DR. CYR: Back to brochures, etcetera. I

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1 want to make another point here that I was reminded  
2 of. What we're talking about is the material that the  
3 manufacturer generates because we do not per se  
4 regulate the day to day operation of the salons.  
5 That's the state and local operation.

6 MS. KAUFMAN: So if FDA makes amendment  
7 No. 1 regulatory, that means that if someone comes in  
8 and they've already been down to Bermuda for three  
9 weeks and has a really dark tan, they still have to  
10 follow that guidance, otherwise they would be in  
11 violation of the law, of the regulation?

12 I'm not clear.

13 DR. CYR: I guess you've gotten into  
14 details that we haven't considered yet.

15 MS. KAUFMAN: That makes me reluctant to  
16 vote on it.

17 MR. THOMAS: You know, probably what we've  
18 got is maybe something that needs to be modified.  
19 We've got a motion o the floor and we may want to  
20 withdraw it and restate it. It's clear that an  
21 exposure schedule, to me at least, it's clear that an  
22 exposure schedule is required which strengthens the

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1 policy guidance that's 14 years old. Photobiology has  
2 made significant discoveries and advancements in that  
3 area of study. They have a better understanding of  
4 carcinogenesis of UV radiation and it's clear to me  
5 that a risk exists from a device. I could care less  
6 about the sun and the reason I could care less is it's  
7 not a device that we can regulate.

8 The tanning salons are devices and tanning  
9 booths are devices that can be regulated. And they  
10 potentially have medical benefits, but the fact that  
11 we do understand photobiology better and the risks of  
12 the exposure to this wave length radiation, I feel  
13 that if there's additional study that needs to be done  
14 then let's get with it. If there are existing  
15 standards, the tanning industry stood up and said  
16 we're already using a maximum exposure standard that's  
17 in accordance with these guidelines, so what's the  
18 problem? If we are already doing everything, then  
19 let's put it into regulations so it's very clear that  
20 it's no longer a recommendation, but a requirement.

21 MS. KAUFMAN: Now the exposure schedule  
22 though wouldn't just be a maximum, right? It would be

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1 the first day you can get this?

2 DR. LOTZ: But isn't that what we're  
3 saying that all that has to be determined yet, so  
4 we're kicking around things that don't -- aren't even  
5 defined at this point.

6 MS. KAUFMAN: But Dr. Cyr had said what  
7 they were going to use is the guidance letter as the  
8 exposure schedule.

9 DR. CYR: Initially, that's exactly what  
10 we were doing. We were going to include what was in  
11 the FDA policy letter which does spell out the  
12 incremental schedules on the first few days. They do  
13 differ from what --

14 DR. LOTZ: I guess I have a little concern  
15 with that in the sense that we are 14 years down the  
16 road in terms of the science and it would seem to me  
17 that unless the science confirms that that letter was  
18 accurate, using that letter as it currently exists is  
19 not a good first step because we're stepping back to  
20 that point in time.

21 But I do think we had a motion on the  
22 floor about amendments 4, 5 and -- or 3, 4 and 5?

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1 MS. KAUFMAN: We're still on number 1.

2 DR. ROTHENBERG: I think just to  
3 summarize. Everyone that I've heard speak at the  
4 table at least feels that there should be at some  
5 point an exposure schedule. The question is should it  
6 be the exposure schedule that's in the 14 year old  
7 document and it seems like the consensus there is we  
8 don't think so or at least we need to look at that a  
9 lot more carefully. So it seems to me maybe what we  
10 should do is put forth our feeling that there should  
11 be an exposure schedule, but I don't think we can say  
12 necessarily it has to be the one that's step by step  
13 the one that's in the document of 14 years ago.

14 MR. THOMAS: I agree with that. Now do  
15 you want me to withdraw the motion and restate it? Or  
16 do we want to modify what was stated? It's your call.

17 MS. KAUFMAN: I'd like to see it withdrawn  
18 and resubmitted, but if I could mention one thing  
19 because I'm not sure that it needs to be an exposure  
20 schedule rather than maybe several exposure schedules.  
21 I'm not sure that one size is going to fit all.

22 MR. THOMAS: Let me do this. John, do you

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1 want to say something?

2 DR. SANDRIK: Yes, I just want to say that  
3 I think that's the direction -- I think what I see  
4 here is that we want to say that there must be an  
5 exposure schedule, some exposure schedule in place.  
6 There's not just a willy-nilly expose people to  
7 anything, but a specific exposure schedule, I still  
8 question whether there is scientific merit to the one  
9 that's 14 years old. Is there scientific merit to any  
10 one that might be in use at this point.

11 So I think an exposure schedule, perhaps  
12 the next step is that maximum exposure level where  
13 there seems to be perhaps some consensus. But I think  
14 the problem, if you actually put an exposure schedule  
15 into the regulation then it makes it just that much  
16 more difficult when new scientific evidence comes in  
17 to ever try to change it again. So I think there's  
18 agreement on an exposure schedule, whether it's more  
19 than one, I don't think it's that -- but some exposure  
20 schedule must be in place and perhaps the next element  
21 is the maximum.

22 MS. KAUFMAN: I'd like to also comment and

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1 reiterate that it should be defined as for the device  
2 and that could not be construed as Mr. Deveney  
3 mentioned somehow to equate to the sun's exposure. So  
4 it has to be very specifically targeted to the  
5 sunlamps.

6 DR. CYR: The comment I just got the  
7 exposure schedule is something that comes with the  
8 device itself. It's from the product manufacturers.  
9 It's not directions to the salon, it's something  
10 that's on the product itself.

11 MR. THOMAS: Okay, withdraw the motion and  
12 I'll resubmit the following. Move that the FDA make  
13 the scientifically value exposure schedule part of the  
14 standard and that this exposure standard should be  
15 validated through photobiology science.

16 MS. LOSCOCCO: I'll second that.

17 DR. ROTHENBERG: Any further discussion?

18 DR. MURDOCH NELSON: It's still not clear  
19 to me that this is enforceable and I go back to my  
20 original point. It's just not clear to me that you  
21 can --

22 DR. CYR: What we'll -- as I said what we

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1 do here at CDRH is enforce what's on the product.  
2 That part we can enforce. What comes on the product  
3 -- here's the recommended exposure schedule or here's  
4 the exposure schedule and it's a label that goes right  
5 onto the product. Whether the salons use it or not is  
6 out of our hands. That would be something that the  
7 state or a locality whichever regulates the salon  
8 would look at and say yes, we want to adopt this or  
9 no, we want to -- that's up to the states as to how  
10 they want to regulate salons. We don't regulate the  
11 salons.

12 DR. ROTHENBERG: But is the question we're  
13 putting it on each manufacturer to develop their own  
14 exposure schedule?

15 DR. CYR: No. Our recommended exposure  
16 schedule was to manufacturers, and this is what we  
17 told them they should put on. And you go to a sunbed  
18 right now and you will see a label on there with a  
19 recommended exposure schedule.

20 DR. MURDOCH NELSON: I'm very committed to  
21 sort of making these safer and making sure that every  
22 person who goes and uses one of these is getting a

1 safe tan and isn't burning. I'm just not clear that  
2 this is the way to accomplish that and do you have a  
3 sense that this will help?

4 DR. CYR: Well, I think one of the  
5 speakers said that if we take that step that probably  
6 the states will follow that. That's the sense, I  
7 think I have on it.

8 DR. ROTHENBERG: We've got a motion on the  
9 floor. If there's no further discussion.

10 DR. BALZANO: I have a question. This is  
11 Quirino Balzano. How long will it take to come up  
12 with a scientifically based exposure schedule?

13 MR. THOMAS: I'm not a photobiologist and  
14 I don't know the literature that well.

15 DR. CYR: Well, as I said, I think the FDA  
16 one has been validated, but it's also -- it shows that  
17 you can get a tan safely without burning. You're  
18 still stuck with the problem we talked about before of  
19 not -- it's -- you build it up slower than what some  
20 people in the industry would like. They would like to  
21 have the initial steps be a little higher. That's the  
22 debate that we're having.

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1 DR. BALZANO: From what I understand from  
2 the objection is that you will force the same schedule  
3 on someone who has never been exposed to substantial  
4 sunlight and someone who has been for a few weeks in  
5 Bermuda.

6 DR. CYR: We have not addressed that.

7 DR. BALZANO: So that's what I thought  
8 would be a rational exposure schedule because this  
9 might turn out to be what do you call the bed of  
10 Procrustes, if you remember from mythology, Greek,  
11 people were put in a bed and if the bed was too short  
12 they were cut off and if the bed was too long they  
13 were stretched.

14 (Laughter.)

15 I was wondering if indeed there were other  
16 ways to address the issue.

17 MR. FRAPPAOLO: My name is Phil Frappaolo  
18 and I'm the Deputy Director of the Office of  
19 Compliance.

20 Howard, let me ask you a question and it's  
21 for point of clarification. We're not enforcing a  
22 schedule on anyone, right?

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1 DR. CYR: Not now.

2 MR. FRAPPAOLO: The schedule that's  
3 provided by the manufacturer is specifically for their  
4 product?

5 DR. CYR: I believe that's -- I'm not in  
6 the compliance end of things.

7 MR. FRAPPAOLO: That's what I'm trying to  
8 figure out. So specific for your product.

9 Our recommendation is what, somewhat more  
10 generic in terms of what we're asking people to do or  
11 is it specific?

12 DR. CYR: Very basically, again back to  
13 what I wanted, I wanted something in there which said  
14 that you must consider the safety of the person, the  
15 customer, so that they can tan and not burn.

16 MR. FRAPPAOLO: Right.

17 DR. CYR: And one way of doing that is to  
18 pay attention to the manufacturer's recommended  
19 exposure schedule.

20 MR. FRAPPAOLO: Okay.

21 DR. CYR: As opposed to that this is only  
22 a recommendation and you can do what you darn well

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1 please.

2 MR. FRAPPAOLO: All right.

3 DR. CYR: It was more of an attitude  
4 thing. Make it a little more stronger there which  
5 says that you can't totally ignore safety.

6 DR. ROTHENBERG: Yes.

7 MR. PLEASURE: I have a concern of voting  
8 for adoption of any particular schedule in a situation  
9 where the clients may differ in their capacity to  
10 withstand a particular schedule. I went through the  
11 same process with commercial diving regulation where  
12 decompression schedules were initially being  
13 considered for adoption by OSHA and it was -- OSHA  
14 moved in the direction instead at first of adopting  
15 protocols for the development of the schedules to see  
16 whether the protocols would be a way of approaching it  
17 with an outcome of not producing first level bends.  
18 And eventually, unfortunately to my way of thinking,  
19 they decided not to regulate at all.

20 It seems to me that there's something in  
21 between requiring manufacturers to give, to follow a  
22 protocol for its recommendations and acknowledging

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1 that clients differ, both in their experience and in  
2 their physiology, on the one end and not doing  
3 anything at all, but giving general advice and counsel  
4 when the process itself may carry some inherent  
5 dangers.

6 So it seems to me that what we've been  
7 wrestling with is whether or not we're comfortable  
8 with recommending a precise schedule with a science  
9 being such that we know people differ and we know that  
10 their experience as they walk into the salon have  
11 differed, but there may still be some responsibility  
12 on the part of the manufacturer to give required --  
13 information that may be required and appropriate for  
14 the use of the product in a way that will be  
15 reasonably safe. And it seems to me that the staff  
16 could move in that direction rather than asking us to  
17 adopt a specific schedule which we know may be  
18 inappropriate for a certain fraction of the  
19 population.

20 DR. CARDELLA: Could you get around the  
21 issue by saying that what <sup>\*\*</sup> is needed is a tanning  
22 schedule that facilitates tanning and prevents burning

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1 in the most sensitive group of skin type, recognizing  
2 that that's a very conservative approach. I mean  
3 nobody would burn under those circumstances and the  
4 objection would be that there are some unexperienced  
5 individuals who would be penalized with that type of  
6 a schedule because they would not be able to ramp  
7 their tan up as fast. But if you're looking for  
8 safety, if it is believed that burning of the skin is  
9 the problem, not the tanning of the skin, then I would  
10 think the smart money would be to structure a schedule  
11 that burns no one or that does not burn the most  
12 sensitive skin and work from there. I mean that ought  
13 to be your base and then if you want to get creative  
14 and have four or five tiers of schedule, then you can  
15 say southern Mediterraneans will be on a different  
16 schedule, you know, people -- darker and darker skin  
17 types would be on a more accelerated schedule. I mean  
18 if you want to get very complex -- but at a first cut,  
19 I think from a safety standpoint you ought to avoid  
20 burn.

21 MR. THOMAS: That make sense. You may  
22 want to propose an amendment to the motion.

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1 MS. KAUFMAN: Isn't that what the current  
2 scheduled -- it's for Type II skin.

3 DR. CYR: For Type II, right. But it does  
4 say in the standard, it says taking into account the  
5 different skin sensitivities, so that can be taken --  
6 the difference between Type I and Type IV is rather  
7 large.

8 DR. ROTHENBERG: We've got two problems  
9 here. This whole scheduling I think is very confusing  
10 at this point because of all the variation that could  
11 be possible and we're also running way off schedule  
12 with this discussion.

13 It seems clear that nobody is happy with  
14 the current schedule. The idea would be just to have  
15 a schedule, but it seems that because it's not  
16 necessarily based on the best timing. It could  
17 present significant problems as well. I would  
18 personally like to see us just make recommendation  
19 that schedules be developed rather than to put up what  
20 we think is a flawed schedule into the standard.

21 MR. THOMAS: I think that was the intent  
22 of the motion was to do exactly that. It wasn't as

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1 worded as well as you've just stated.

2 DR. ROTHENBERG: I guess we don't have it  
3 exactly written. Is there any way we can get it read  
4 back what we're voting on?

5 If we say that's the intent, why don't we  
6 now vote on that? But it seems clear we're not voting  
7 to put the 14-year-old schedule --

8 MR. THOMAS: No, no. That was never the  
9 intent.

10 DR. ROTHENBERG: It could be interpreted  
11 that way.

12 MR. THOMAS: Yes, I understand. Help me,  
13 we'll word it so that it's precise and then it will  
14 come back. The motion is for the FDA to develop an  
15 appropriate exposure schedule for various skin types  
16 based upon science, based upon the current scientific  
17 understanding of the photobiological effects of UV  
18 radiation.

19 Well, that's got a -- I did not say it's  
20 part of a standard? I mean as part of a standard.

21 To develop a standard to do what I just  
22 said.

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1 DR. ROTHENBERG: Do we have a second?

2 MS. LOSCOCCO: I'll re-second.

3 DR. ROTHENBERG: I think we've had a lot  
4 of discussion. I think we can vote on that at this  
5 point. So would all those who are in favor of that  
6 raise your hand?

7 (Vote taken.)

8 Opposed? Steve?

9 MR. SZEGLIN: My hand was raised.

10 DR. ROTHENBERG: So again that's  
11 unanimous.

12 Now amendment 2.

13 MR. THOMAS: I don't know enough about  
14 cancer action spectrums to make an intelligent comment  
15 on that.

16 John, do you? We really need a  
17 dermatologist to address us on that particular issue.  
18 I'm very, very uncomfortable that I didn't see anybody  
19 here from AAD.

20 DR. CARDELLA: It's way afield from what  
21 I do.

22 MR. THOMAS: I, for one can't comment on

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1 the second one because I don't have the scientific  
2 skill sets to understand the details of the  
3 photobiology in that area.

4 DR. CARDELLA: I would move that the  
5 TEPRSSC Advisory Panel recommend to the FDA that  
6 amendment 3 be added into the proposed --

7 DR. ROTHENBERG: Are we skipping 2?

8 MR. THOMAS: Why don't we address 2 in a  
9 way that says we need more information and make a  
10 motion that FDA provide the TEPRSSC at a future  
11 meeting more detail on cancer action spectrum and  
12 erythemal action spectrum from the scientific and  
13 clinical community.

14 DR. ROTHENBERG: Do we have a --

15 (Seconded.)

16 DR. ROTHENBERG: Discussion?

17 MS. KAUFMAN: Does that mean that these  
18 would be all delayed by a year? Because we only meet  
19 once a year. Can it be provided outside of the  
20 Committee?

21 MR. THOMAS: They can go forward as far as  
22 I'm concerned on what we say, but in that particular

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1 area we need more information. We either meet more  
2 frequently than annually or be provided the  
3 information outside the Committee formal deliberation.

4 MS. KAUFMAN: If we vote in favor of that  
5 is that going to preclude FDA from moving forward on  
6 that number two amendment?

7 MR. THOMAS: Yes. They shouldn't move  
8 forward until we know what we're talking about.

9 DR. SULEIMAN: Cass, let me clarify. I  
10 think Howard's presentation was for five  
11 noncontroversial issues.

12 (Laughter.)

13 I think that the deliberations that have  
14 gone on are clearly being heard by IFDA so and you can  
15 see how quickly we move as well so the -- what will  
16 eventually get published as a notice of proposed  
17 rulemaking will be a first draft for public comment  
18 and at that point if we've ignored the Committee you  
19 guys can come down pretty heavily, but I think we want  
20 to hear your concerns and I think we are hearing them,  
21 so I don't think we're going to move so quickly and  
22 get this stuff out of the way. It just doesn't happen

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1 that fast.

2 DR. CYR: I can tell you that when you  
3 look at the two curves between erythematous and squamous  
4 cell carcinoma and normalized action spectrum, there's  
5 not tremendous difference. I also must say that the  
6 person who was championing this who was our member of  
7 IEC is not here and not able to give a better  
8 explanation than I can give you.

9 DR. ROTHENBERG: I think we've discussed  
10 this one and I think we can vote at this point.

11 All in favor of the motion which is that  
12 we need to be provided with more information on these  
13 two spectrums is -- all in favor?

14 (Vote taken.)

15 Opposed? Steve?

16 MR. SZEGLIN: My hand was up.

17 DR. ROTHENBERG: I didn't quite see it.  
18 So again we're unanimous on that one.

19 Now should we -- well, let's take a crack  
20 at doing the last three together since we're kind of  
21 short on time. Hopefully, are less controversial.

22 Someone want to propose? Jerry's good at

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1 proposing.

2 MR. THOMAS: I'm good at proposing, I  
3 guess. You may want to take the last two and third  
4 one independently, but it was the way I would  
5 recommend it.

6 I make a motion that the definition of  
7 manufacturer be expanded to include anyone who makes  
8 any modification to a tanning bed or a tanning device.

9 DR. SANDRIK: Second.

10 DR. ROTHENBERG: I gather the discussion  
11 was that that person must -- the gist of this was to  
12 provide that that person who becomes the manufacturer  
13 provides some type of report on that action of  
14 changing the unit, modifying the unit.

15 MR. THOMAS: I'm not sure that the issue  
16 of reporting was involved as much as manufacturing and  
17 responsibility and all of the tenets of being a  
18 manufacturer. That includes a report, absolutely.  
19 But if it doesn't then -- if reporting -- if  
20 modification of device doesn't currently include  
21 reporting requirement, reporting wouldn't be included  
22 in there. But if modification includes an appropriate

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1 report to the FDA, then absolutely.

2 DR. ROTHENBERG: Did we have a second on  
3 that?

4 DR. SANDRIK: Yes, I did.

5 DR. ROTHENBERG: Okay, are we ready to  
6 vote on that one?

7 All in favor. Steve?

8 MR. SZEGLIN: Yes.

9 DR. ROTHENBERG: Opposed.

10 (Vote taken.)

11 That one also carries unanimously.

12 MS. KAUFMAN: Larry, number 4 and 5, I'm  
13 going to presume those aren't very controversial. I'm  
14 going to make a motion that we suggest FDA proceed  
15 with amendments No. 4 and 5.

16 (Seconded.)

17 MR. SZEGLIN: I didn't hear that.

18 DR. CARDELLA: Could we -- as a point of  
19 clarification, at amendment 4 you're talking about  
20 placing the warning label in the catalog spec sheet  
21 and brochures. Is that correct? Not generic  
22 warnings. You would actually put the text --

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1 DR. CYR: The text of the label, right.

2 DR. CARDELLA: I might suggest that  
3 amendment 4 be reworked a little bit or that we put  
4 together something that says have a simpler warning  
5 label and include it in catalog spec sheets and  
6 brochures.

7 DR. CYR: Combining the two.

8 DR. CARDELLA: Yes, I think that captures  
9 the essence of it.

10 DR. ROTHENBERG: Since we're voting on  
11 them together I think that would be acceptable.

12 MR. THOMAS: Did you want to put any  
13 education in that one too?

14 MS. KAUFMAN: Yes. I was going to make  
15 another motion on that.

16 DR. ROTHENBERG: As a separate?

17 MS. KAUFMAN: Yes, as a separate.

18 DR. ROTHENBERG: Okay, so let's just vote  
19 then on the combined 4 and 5 as stated by John. All  
20 in favor? Steve?

21 MR. SZEGLIN: Aye.

22 DR. ROTHENBERG: Opposed?

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1 (Vote taken.)

2 Okay, that one also carries unanimously.

3 Now, Cass.

4 MS. KAUFMAN: I'd like to make a motion  
5 that FDA consider including some kind of a  
6 training/educational component for salon employee  
7 operators. Actually, let me take out the word  
8 "salon". And just say for operators.

9 MR. THOMAS: Of what?

10 MS. KAUFMAN: I guess I'm thinking that --  
11 well, I'm kind of wondering if maybe people who buy  
12 one for their own home ought to have some kind of  
13 training themselves on how to use it. So that's why  
14 I was thinking about taking out the word salon.

15 DR. CYR: I think we could work in  
16 conjunction with states and the industry itself, but  
17 I don't think that's part of our law to --

18 MS. KAUFMAN: Well, we require training in  
19 other areas. I mean I don't know -- it bothers me a  
20 lot if these people have -- here's how you turn it on,  
21 you push that button and that's the extent of their  
22 training and they're the ones who are making -- who

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1 are offering guidance to clients to consumers on how  
2 long they should stay under and what their frequency  
3 ought to be and that kind of thing. It just seems to  
4 me that that's kind of the critical component in terms  
5 of consumer safety is how much education those  
6 operators have.

7 DR. SULEIMAN: Let me just clarify because  
8 I seem some angst among our Center staff and the  
9 audience as well. The analogy is with a car. You  
10 know you have pollution emission requirements. We  
11 don't regulate the driver and so trying to address  
12 regulations for the user is the issue here. I think  
13 we'll do whatever we can, I think, regarding the  
14 educational aspect, but I think clearly we're strapped  
15 from a regulatory point of view about what we can say  
16 that will be binding or enforceable.

17 MS. KAUFMAN: I guess I don't see that as  
18 a good analogy at all because a pollution control  
19 device on your car, you just buy the car and you get  
20 it. This is a service that's delivered and it's  
21 easily modifiable by the operator and is especially  
22 modifiable in terms of their instructions to

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1 consumers. We certainly have other areas where FDA  
2 has mandated training and my motion was that FDA  
3 consider, not that they actually do it, but that they  
4 consider adding a training or educational component to  
5 operators of the unit.

6 DR. ROTHENBERG: Do we have a second?

7 MS. KAUFMAN: We don't have a second.

8 MS. LOSCOCCO: Actually, I'll second that.  
9 Because I equate it more to the driver's license of  
10 the car than to just owning the car. You have to be  
11 able to hold that license to get on the road with.

12 DR. ROTHENBERG: Any further discussion?

13 DR. CARDELLA: Cass, for clarification now  
14 are you talking about a face to face education or is  
15 this going to be literature education?

16 MS. KAUFMAN: It could be either or.

17 DR. CARDELLA: Either or.

18 MS. KAUFMAN: In other words, my motion  
19 doesn't go into that level of specificity at all. It  
20 just says that FDA consider adding some kind of a  
21 training component to the regulations for operators.

22 DR. ROTHENBERG: Bob?

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1 MR. PLEASURE: Just a point of  
2 information, whether TEPRSSC has ever taken up this  
3 kind of training or certification. I'm not suggesting  
4 a certification was also proposed, but that training  
5 be undertaken, whether this has come up before and  
6 whether, in fact, you have mandated training as part  
7 of these performance standards. Just a point of  
8 information.

9 DR. ROTHENBERG: Bob? Bob Gagne from our  
10 Office of Science of Technology.

11 DR. GAGNE: Hi. Maybe I can make a couple  
12 of comments with respect to that. I think there's a  
13 distinction between the different laws. MQSA, for  
14 example, has some very specific requirements  
15 associated with users, but in this particular area  
16 under the Rad Health Act it really deals mainly with  
17 equipment manufacturers and you don't get to the  
18 individuals that are users, for example, diagnostic  
19 x-ray equipment. It's the equipment. It's not the  
20 user of the equipment. It's left to the states.

21 The closest thing that we've come to, I  
22 think in terms of performance requirements is in the

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1 CT regs. There are some requirements in there,  
2 quality assurance programs and training materials that  
3 they have to give to the users. But it doesn't --  
4 it's not a regulation on users themselves. I don't  
5 know if that helps to clarify.

6 MS. LOSCOCCO: Actually, that's kind of  
7 what I would like to see is that the manufacturer be  
8 at least required to provide training materials and  
9 that's kind of where it stops. If the user then wants  
10 to just put it on five times before they get out,  
11 that's their responsibility, but they've had to  
12 provide them.

13 DR. ROTHENBERG: Do you have a quick  
14 comment?

15 MR. DEVENEY: Fifteen seconds. In  
16 response to this about eight years ago we developed an  
17 educational poster. It's 24 by 36 inches. One goes  
18 inside every tanning unit we sell. It was edited by  
19 Dr. Isaac Willis. It contains information on how the  
20 schedule is determined, why you should only go 3  
21 minutes the first time, why you shouldn't exceed the  
22 schedule, why you should have eyewear and why you

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1 shouldn't tan more than once within a 48 hour, 24 hour  
2 period. It's all in there right now. We'll gladly  
3 give you copies and you can look at it and edit it and  
4 do what you need to do.

5 DR. ROTHENBERG: I think given the timing  
6 and the fact that this is encouraging them to look  
7 into this we don't need a lot more discussion. I'd  
8 like to vote on this now. Unless there's strong  
9 objection. Could we have a vote on this proposal?

10 All in favor? Steve?

11 MR. SZEGLIN: Aye.

12 DR. ROTHENBERG: Opposed.

13 (Vote taken.)

14 Well, it carries and again it is vague, so  
15 it's an encouragement to proceed.

16 Okay, I think that concludes that item of  
17 our agenda. Thank you for your participation, all of  
18 you.

19 Unfortunately, we're at the break period,  
20 but we didn't do one of the topics, so we'll try to --  
21 let's take a 10 minute break, try to start at -- I  
22 have about 2:55. Let's start at 5 after 3 and

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1 hopefully we can get through the next two items  
2 without going much over schedule.

3 (Off the record.)

4 DR. ROTHENBERG: Could I ask you all to  
5 reassemble? We're missing -- Steve, are you back?  
6 Can't tell.

7 (Pause.)

8 Okay, Steve, are you there? We lost him.  
9 We can start.

10 I think we'll go ahead. Most of the  
11 people are here.

12 Our next item of business is about a half  
13 hour before on the schedule, Ionizing Radiation  
14 Security Systems, and Mr. Frank Cerra.

15 MR. CERRA: Good afternoon. I will be  
16 giving you a very short briefing or update on the  
17 status of ANSI N43.17 which is a standard on radiation  
18 safety for personnel security screening systems  
19 utilizing ionizing radiation, also known as people  
20 scanners.

21 I will give you a <sup>\*\*</sup>short background on the  
22 matter and then go over some of the membership of the

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1 task group charged with this project and go over some  
2 of the discussions that have taken place and the  
3 discussions that are going on right now and finally  
4 conclude with our goals for the future.

5 This is a slide that I stole from Dan  
6 Kassiday. It illustrates how these things work. This  
7 slide was presented at the last year's meeting.  
8 Basically, the subject stands in front of a cabinet  
9 and there is a source of x-rays and a narrow beam  
10 which comes out and scans back and forth and the  
11 information is fed into a computer an image comes out.  
12 Then normally the subject will turn around. It will  
13 scan again and again you get the image. It's used to  
14 look for contraband or weapons hidden under clothing.

15 This technology is relatively new. It was  
16 applied to scanning of people in the mid-1990s and it  
17 utilizes this back scatter or the radiation bounces  
18 off the subject in order to form the image so the  
19 doses are quite low. Since we have no performance  
20 standards there was some concern that these devices  
21 would go to market without being sufficiently  
22 regulated, so the issue was brought up at the 1998

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1 meeting of this Committee and there were several  
2 recommendations, one of which was for a mandatory  
3 standard. FDA considered the recommendation and  
4 decided that for the time being the best way to  
5 proceed would be to promote the development of a  
6 consensus standard for several reasons. One reason  
7 was the priorities of the Center and also the time  
8 required to -- for completion of a standard. And also  
9 going back to some of the things that were talked  
10 about before, a consensus standard can address the use  
11 of the device also, not just the manufacturer and the  
12 Center only has jurisdiction over the manufacturer of  
13 the device.

14 In April of last year we submitted a  
15 proposal to the ANSI N43 Committee for a new standard  
16 and the proposal as approved in June and in November  
17 we convened a task group.

18 You can see the task group membership  
19 consists of representatives from all the task holders,  
20 three regulatory bodies are represented including FDA  
21 and two states, also for the Canadian government. We  
22 also have the two U.S. manufacturers represented and

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1 all the major users in this country.

2 The very first item on the agenda for a  
3 meeting was the scope of the standard. We considered  
4 not only these people scanners, but also systems  
5 similar to these where people walk through them and  
6 these are available overseas.

7 Also, systems that are envisioned to scan  
8 a moving vehicle including their driver, for example,  
9 a vehicle going through a border checkpoint, we  
10 consider systems that are also available in Europe to  
11 detect swallowed contraband and those emit more  
12 radiation by maybe a factor of 100 and also the large  
13 cargo scanners.

14 We decided to only include the first two.  
15 The others are so different that we thought it would  
16 really slow down the development of the standard and  
17 we think it's important to come to publication as soon  
18 as possible so that there is some guidance on these  
19 devices.

20 The topics that were discussed at the  
21 first meeting, the first -- we talked about how  
22 important it is that the standard be consistent with

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