

1 but that is one of the things that you do.

2 [Slide.]

3 We have heard several discussions about
4 phototyping and subtyping as Dr. Cyr mentioned this morning.
5 We actually have broken it down into three subtypes of two
6 and two and three, and that is strictly so that we may be
7 especially cautious about the most sun-sensitive
8 individuals.

9 As Dr. Weinstock mentioned, tolerance to
10 ultraviolet light is a continuum, and certainly we all know
11 that a Phototype V and VI are much more tolerant to
12 ultraviolet light than are a II, so in over 1,000 people, we
13 have had like five II-A's, and they all tell us that whether
14 it is outside or inside, they have always had a history of
15 problems with tanning.

16 So, we think the first step is to identify them.
17 The first two questions, if you will notice, identify the
18 Phototype I, and where they are Phototype I, we recommend
19 that they use artificial devices and that they do not tan,
20 and then we are recommending an exposure schedule that is
21 based on these, that is appropriate to the individual
22 phototypes and subtypes.

23 So, we don't disagree with that in any way, shape,
24 or form.

25 [Slide.]

1 Just to cover this briefly, the red line at the
2 bottom is the existing FDA exposure schedule, and in a 20-
3 minute bed, that means that all phototypes and subtypes
4 currently get the same initial session of three minutes.

5 Obviously, when you get to a Phototype V, which we
6 have Hispanics, which we have a lot of in Tucson, that means
7 that that individual is only getting 13 percent of what
8 their tolerance would be. So, this is why we are
9 recommending a subtyping/phototyping system.

10 We are recommending an exposure schedule that is
11 based on the experience that the industry has had over the
12 last 10 years, and it is based on the premise that we want
13 neither to under-expose nor over-expose our clients.

14 Next, I just have a brief comment. Dr. Weinstock
15 mentions the psoralens, and psoralens are used in any
16 tanning accelerators used in the tanning industry. Those
17 are strictly used for PUVA studies by the medical community,
18 so they are not part of any formulation used by the tanning
19 industry.

20 The PUVA study that he mentioned, the Stern
21 article, that you should know is based on the fact that it
22 took 250 sessions and over 15 years. There were some other
23 caveats in there. Furthermore, it is a fascinating study if
24 you want to go back and look at some of the original work
25 with Parrish.

1 The 8-methoxy psoralen causes a photostimulation
2 effect of over eight times, and it is my belief that that is
3 what led us to some of these exposure schedules, because
4 they came from those early PUVA studies.

5 The Ontario study, a brief comment, that Dr.
6 Weinstock mentioned. In that study, it states that there
7 was no link with commercial tanning beds and melanoma. The
8 only reference to that point was for a home tanning bed, and
9 as I am sure all you understand, with a home tanning bed you
10 can tan as often or as long as you like, and you cannot do
11 that in a commercial.

12 One of the points that I would like to bring to
13 your attention is an article that was written by Dr. Allan
14 J. Christopher. He is a retired head of the Occupational
15 Medicine Section of the State of Victoria in Australia, a
16 medical doctor and who served on an Australian board.

17 His topic was Sunlight Does Not Cause Melanoma, a
18 very provocative title. I have written an article published
19 in one of the trade journals elaborating on that theme, and
20 I will give you my E-mail number if you are interested, and
21 I will be glad to send it to you.

22 Dr. Christopher's thesis was increased skin
23 temperature, that is, the climactic latitude dependent
24 factor involved in the induction of melanoma.

25 Now, I am no here to say whether his paper is

1 right or not, but what it does indicate to me at least, that
2 if this is true, then, this could be the first indication
3 that maybe global warming has a role in melanoma, so it
4 seems to me rather than rushing to a judgment to blame
5 everything on ultraviolet radiation, we ought to look at
6 these alternative factors.

7 For instance, not long ago it was believed that
8 ultraviolet radiation was killing the frogs. Now, we know
9 it was the trematode. So, we have to stay back and say is
10 there is a possibility that global warming could be playing
11 a role in this. It needs far more study.

12 The question was asked about the thinning of the
13 ozone layer. Dr. Cardella asked that question. Recently,
14 it was shown that in Australia, there was a 20 percent
15 increase in UV transmission, UVB, over the last--or 10
16 percent over the last 20 years. With that change, when you
17 use the UV index as a measuring tool, it changed the minutes
18 to erythema, the minutes to burn by one minute. So, it is
19 something that gives us a handy tool.

20 [Slide.]

21 Dr. Weinstock and I have exchanged some E-mails,
22 and I would like to just perhaps a postscript to his
23 presentation, because it touches on the disagreement I have
24 had with an article that was recently published.

25 In January of 1998, in the Journal of American

1 Academy of Dermatology, the conclusion from those 19 studies
2 was at this time, the published data are insufficient to
3 determine whether tanning lamps cause melanoma.

4 In the recent July 1999 Journal, the article which
5 addressed the question, do tanning lamps cause melanoma, it
6 was stated the evidence relevant to the association of
7 melanoma with tanning lamp exposure has recently has been
8 reviewed in detail in a footnote, but if you went to the
9 footnote, it went back to that original article, and my
10 point to Dr. Weinstock is I thought that article should have
11 stated that. His E-mail stated there is evidence to suggest
12 that tanning lamp exposure is a cause of melanoma, but the
13 available data is insufficient to prove this conclusion, and
14 we agree with that.

15 One thing that there was some discussion about the
16 fact that it is unlikely that a prospective study be
17 identified. The indoor tanning industry stands ready to
18 cooperate on a retrospective study, because after all, we
19 are the ones with the data in the computer databases. So,
20 this is something that we would like to explore because I
21 think this is a point that all of us would like to know.

22 MR. FLETCHER: Mr. Smith, could you come to a
23 conclusion in the next two minutes, please.

24 MR. SMITH: Yes. That ends my remarks. Thank you
25 very much.

1 MR. FLETCHER: Thank you.

2 Mr. Levy.

3 MR. LEVY: My name is Joseph Levy. I am the
4 Executive Director of an organization called the
5 International Smart Tan Network. We are an association
6 representing the tanning facility owners themselves. So,
7 that is our sole constituency.

8 I didn't prepare remarks for today, but I want to
9 thank the panel for allowing me to make a few comments.

10 I think what I would like you to realize is that
11 there is some tremendous excitement within the tanning
12 industry right now at the great opportunity that we have in
13 this process of reviewing the rules, and I do want to
14 commend both Dr. Cyr and Dr. Weinstock for what I felt was a
15 very balanced presentation of the research that it out
16 there.

17 One of the things that we, as an industry, as you
18 can imagine from a public relations standpoint, one of the
19 things that we are constantly faced with is the tremendous
20 amount of noise that is out there in discussing what the
21 research actually says on this topic, and Dr. Weinstock
22 showed an example of a tanning facility that, in its
23 advertising, was alluding to the fact that tanning was FDA
24 approved and safe, and certainly we don't condone the usage
25 of that terminology.

1 We know it is out there. On the other side, we
2 know that there are statements made in the medical community
3 that we feel very unfairly characterize what the
4 relationships are right now, and I think that is equally
5 responsible for the reaction of noise that we see from the
6 tanning facilities. There is a tremendous amount of
7 mistrust in what is going on.

8 What we right now is an opportunity for an
9 industry to work with the regulatory agency to develop a
10 better process, some better rules that can help to reduce
11 some of that misunderstanding.

12 I think you need to understand, and as Jerry
13 Thomas pointed out, this is a young industry. It is 20
14 years old in the United States. The modern evolution of it,
15 of the rules, really only existed since 1986. There are 26
16 states that regulate facilities, 24 that did not. Five
17 years ago, I thought that would be more like 45 states that
18 would be regulating the industry today.

19 What we are seeing from the state level is that
20 there isn't an interest in the departments of health to get
21 involved right now simply because it spreads the resources
22 of rather omnibus agencies even further, and they are not
23 seeing exactly what the benefit of getting involved would
24 be, nor the cost effectiveness of getting involved.

25 So, I think we are not going to see states getting

1 more involved in the near future, so this heightens the
2 importance of the process that we are undertaking right now,
3 and the tanning industry is taking that role very seriously
4 in cooperating with the government to accomplish something
5 that will maximize the efficacy of what goes on in the
6 field, where the rubber meets the road, as Don Smith is
7 always saying.

8 Noise. I talked about some of the noise. I
9 wanted to give you some examples. Don mentioned the fact
10 that the Steven Walter Canadian study refers only to risk
11 increase in home units rather than a risk increase in
12 commercial units. Obviously, there is an entirely different
13 set of circumstances involved with home units than there are
14 in commercial facilities.

15 There has been much said about the increasing
16 patterns of sun exposure among the population in the 20th
17 Century, and I would remind you that you could also
18 characterize that as the 20th Century being we obviously
19 have less free time. There have been a lot of studies on
20 the amount of free time that people spend outdoor, which
21 would tend to suggest that our exposure patterns are
22 actually getting more and more intermittent than more time
23 outdoors.

24 Obviously, in previous centuries, the society was
25 more agrarian and people spent time outdoors, so it could be

1 argued the other way, that we are spending more and more
2 time indoors. The time that we spend outdoors, the exposure
3 patterns are much different this century, but are different
4 phenomena going on out there. It is not just that we have
5 more exposure.

6 One interesting study--again, I didn't prepare my
7 remarks, so if anyone would like copies of this, please
8 contact me. I will leave my address, E-mail address, and I
9 know that FDA has that.

10 One example quite recently was a study done at
11 Thomas Jefferson University. The title of the study--I
12 don't remember the exact title--but it was something to the
13 effect that UVB causes melanoma in human skin.

14 The study was designed using 150 immunodeficient
15 mice and human skin grafts from newborn foreskin were
16 grafted onto the mice, and they were divided into three
17 subgroups. Two of the subgroups were exposed three times
18 weekly to a sunburn level dose of ultraviolet B light. The
19 other group, the control group, was not.

20 One of the groups that was exposed was also
21 treated with a type of skin accelerant, DNBA, I think is
22 the--I couldn't tell you what the acronym breaks down
23 totally as--but only one of the 150 mice, after I think 15
24 to 18 months of thrice weekly exposure, developed a
25 melanoma, and it was one of the mice in the group that was

1 treated with the skin accelerant that, as I understand it,
2 is potentially a carcinogen within itself.

3 The study was promoted by what I call the anti-
4 tanning lobby, some of the groups that are trying to
5 discourage people from tanning, as proof that ultraviolet B
6 causes melanoma.

7 The reason I feel that is an unfair
8 characterization of the study is that one very important
9 detail was omitted, that they didn't know the skin type of
10 the grafts, but that in the skin grafts that were able to
11 develop tans, the ones that did tan not only didn't develop
12 melanomas, they didn't develop any of the pre-melanomas nor
13 the actinic keratoses, no skin problems at all, which if
14 used by our industry to promote the study, it could have
15 been used to show evidence that those who can tan seem to
16 have decreased risk. Instead, it was used by the anti-
17 tanning lobby to show simply that UVB causes melanoma.

18 This is the type of thing--that is one example--
19 this is the type of thing that our industry is faced with.
20 It isn't just noise from tanning salons saying that tanning
21 is safe. By the way, that assessment dates back to the
22 early days when some people in the medical community
23 suggested that the technology used in tanning facilities at
24 that point was safe for use as tanning, and that
25 characterization is something we don't encourage anymore.

1 My organization is called the International Smart
2 Tan Network because we are educating both the facilities and
3 their customers that the word safe isn't a characterization
4 we like to use for tanning. We use the word smart because
5 it implies that someone has to think about what they are
6 doing, and we want to teach them based on their own set of
7 individual risk characteristics what their risks are, so
8 they can make intelligent decisions about this activity
9 rather than decisions based on misinformation.

10 One other comment I wanted to make, something I
11 jotted down, we talked about Vitamin D deficiency a little
12 bit in some of the presentations today and the role of
13 sunlight in Vitamin D. That depends greatly on who you talk
14 to. It is generally believed that sunlight is responsible
15 for 90 percent of the Vitamin D that you produce in the
16 body, and obviously, if Vitamin D is produced through diet,
17 the process is somewhat different than when it is produced
18 through exposure to ultraviolet B light.

19 Much like skin typing, which was discussed as
20 rather than six distinct types, it is a continuum, an
21 individual's--the time they need outdoors to develop the
22 Vitamin D through sun exposure is also continuum, and there
23 are several factors involved.

24 We know that as a person ages, it takes longer, so
25 it is very difficult to make a blanket recommendation on how

1 much time is needed, and there are some other factors
2 involved. I would encourage you to read some of the work of
3 Dr. Michael Hollick.

4 I want to thank you once again for allowing me the
5 opportunity to speak today, and if there are any questions,
6 I would be happy to answer them here or by my E-mail
7 address. Thank you.

8 MR. FLETCHER: Thank you.

9 Mr. Smith and Mr. Pipp, you may want to take seats
10 at the table, so that you will have direct access to a mike,
11 and Mr. Levy, if you would stay in that vicinity.

12 I am going to take the prerogative of throwing out
13 the first question myself.

14 Much of what I heard from everyone refers to
15 tanning salons, tanning centers, tanning facilities, et
16 cetera, and then I heard that there is some concern about
17 the fact that the study, which showed an increase in
18 melanomas, was based primarily on individual tanning beds in
19 homes. Now I will get to my concern.

20 Not every place where tanning goes on commercially
21 I would classify as a tanning facility, and I think there
22 needs to be some comment on how those locations, nail
23 centers, beauty parlors, even exercise facilities who happen
24 to have a tanning bed, how they differ so much from the
25 private beds where we have found an increase in melanomas,

1 and what can be done about it.

2 MR. LEVY: I will address that in two ways. One,
3 my illustration of that point was simply that we hadn't seen
4 from that study that there was an increase attributed to
5 commercial facilities.

6 As I mentioned, this is a 20-year-old industry in
7 the United States, and it evolved very quickly in the 1980s.
8 It was very easy to open a facility, it was very profitable
9 very early on because you simply opened the door, and it was
10 a turnstile type operation. There were few regulations. We
11 didn't understand a lot about the process, and we learned as
12 we went.

13 What we have seen since that point into the early
14 '90s, when there were states that developed the regulations,
15 and even the states that don't have regulations have been
16 influenced by the regulated states because we have now
17 developed what I call a professional tanning industry, and
18 this is a segment of the total tanning industry.

19 You are correct in identifying that. There are
20 operators out there that are not operating correctly.
21 However, what my organization is trying to do, and I believe
22 we have the cooperation of the manufacturer's group and
23 other groups, as well, is to educate the end consumer as to
24 what the protocol is in a tanning facility and what they
25 need to expect in terms of cleanliness, in terms of

1 adherence to the regulations and exposure schedules, in
2 terms of what types of lamps are used in that equipment and
3 are they appropriate for that equipment, so that the
4 consumer can be ensured they are going to get a tan, but
5 they are not going to get overexposed or an experience that
6 they didn't expect.

7 So, what we are trying to do now is to educate the
8 consumer, and I believe that this process and what we are
9 going to go through in the next several years is going to
10 give us a great opportunity to further that if this industry
11 can work with the government that regulates it to develop
12 rules and guidelines that maximize the efficacy of getting
13 that information to the consumer that wants to tan.

14 So, yes, there has been an evolution. There is a
15 segment of the market now--and it is a growing segment--that
16 we would classify as the professional tanning industry as
17 opposed to types of facilities out there that simply have
18 tanning units.

19 MR. SMITH: May I make a comment to Mr. Fletcher?
20 We speak of those as where tanning is a primary business or
21 a secondary, and it is my opinion that it is the 80-20 rule
22 in effect, that 20 percent of the salons where tanning is
23 strictly a primary endeavor account for perhaps 70 to 80
24 percent of the tans.

25 So, when Dr. Cyr comes to Chicago and addresses

1 the group, he will be talking to those 3- to 4,000 salons
2 who make up this bulk, so we can achieve some impact very
3 quickly. We are all searching for ways to get to that other
4 80 percent who tan a smaller amount.

5 MR. FLETCHER: I will start with Dr. Cardella,
6 then, Dr. Rice and Dr. Lipoti.

7 DR. CARDELLA: In the commercial or professional
8 tanning industry, how widespread do you think is the
9 phenomenon of upsizing the equipment when the units are re-
10 lamped to use so-called high-pressure tanning lamps, and if
11 that is widespread, do you think it is practical to engineer
12 tanning beds to have unique interlocks for the plug-ins of
13 the bulbs, similar to the way you can't get an 12-volt
14 automotive light bulb into a 120-volt socket?

15 MR. SMITH: That is an excellent idea, Dr.
16 Cardella. Let's start with the plain vanilla bed, which is
17 the mainstream. That is a 100-watt system. You cannot even
18 replace those bulbs with the new 100-watt reflector bulbs
19 and have them compliant. So, you have to use a lamp that is
20 compliant, so you can't just arbitrarily change lamps
21 because something new comes out. You have to stick with what
22 is compatible and approved for the lamps, and all the lamp
23 manufacturers put out schedules of whether or not their
24 lamps are compatible. So, you can't even change these
25 things.

1 One of the reasons we have recommended the
2 ultraviolet index concept is it gives us a tool whereby you
3 can directly relate that ultraviolet index to the minutes to
4 erythema, and it gives us a way of getting a better handle
5 on that.

6 DR. RICE: What kind of training does the
7 franchise owner get with your organization and what type of
8 formal training does the average worker receive prior to
9 doing the tanning procedures, and irrespective of the state
10 regulations and certifications, which vary from state to
11 state, is there a national industry standard of training
12 that you promulgate for your facilities?

13 MR. LEVY: There is in effect a national standard.
14 It doesn't exist formally, however, because the training
15 organizations that exist, such as ours, must adhere to
16 several of the states have standards. Our training is in
17 compliance with the highest state standards, and so every
18 person, even in a nonregulated state, is going to get that
19 experience.

20 Now, in order to be a member of our association,
21 the facility must be trained. They can't not be trained and
22 be members. We also require that they teach their customers
23 exactly what their protocol is, so that we are educating the
24 end consumer.

25 You asked more specifically about what the level

1 of training is. They are trained exactly how that equipment
2 works, how the schedules work, and how to operate it, how to
3 assess a client's skin type, and put the client in. So, the
4 operators are trained in the whole process, start to finish,
5 on how to properly put a person into a tanning unit to
6 minimize the risk of experiencing a sunburn.

7 DR. RICE: How long is the training?

8 MR. LEVY: The training varies from state to
9 state. There are some states where the training can be a
10 day-long experience. There are some states where it is
11 several hours. Some states allow the operators to train by
12 correspondence course, which is not always an easier
13 alternative because the testing is much more difficult with
14 the correspondence course.

15 MR. FLETCHER: Dr. Cardella had a followup.

16 DR. CARDELLA: I didn't quite get the answer to
17 the first part of my question or maybe I didn't understand
18 your answer. Are you saying that it is not possible to re-
19 lamp tanning beds with higher intensity bulbs, because my
20 understanding of it is that currently, it is a standard push
21 and twist fluorescent lamp fitting, so that the only
22 mechanism that assures replacement lamping to be compatible
23 with original equipment issued lamping is the honesty and
24 good faith of the owner, it is not a piece of the equipment
25 design, and I am aware of advertisements in my local area--I

1 am from one of the northern climates with very little
2 sunlight--where it is almost a macho portion of the
3 advertisement to say we now have high-pressure tanning beds.

4 I actually went to one of the guys and asked what
5 that meant, I called him up on the phone, and he said, well,
6 we have higher strength lamps that we are able to re-lamp
7 this equipment with.

8 Are you saying that he is telling me something
9 wrong or are you saying that yes, it is possible to re-lamp
10 units with higher intensity than intended lamps?

11 MR. LEVY: It is not possible to re-lamp a low-
12 pressure tanning system with a high-pressure lamp, if that
13 is what your question is. I think that is where you are
14 going. It is possible for some low-pressure tanning lamps
15 to be replaced with a lamp that has different
16 characteristics.

17 Now, what Don was talking about, and what we have
18 proposed to FDA in relation to using the UV index as a
19 guide, this would greatly simplify the procedure for re-
20 lamping a bed, and it would make the salon owner's job much
21 easier to know what lamp rating belongs in that bed.

22 It would also make it much easier for the state
23 inspectors because there is great confusion about what type
24 of replacement lamp can be used in a certain bed. That is a
25 source of tremendous confusion, and you can check with your

1 state regulators for that. That has been the number one
2 concern through the years.

3 It has been a concern that has greatly improved in
4 the last five years according to my conversations with state
5 regulators, but you need to realize also that if--I think a
6 lot of what you saw experience with marketing. If a salon
7 is going to re-lamp a unit with a light that is more
8 intense, the result would be a sunburned client, and the
9 salon does not want a sunburned client because a sunburned
10 client will not come back to that facility, cannot continue
11 his or her tanning regimen in the way it was designed.

12 MR. SMITH: Dr. Cardella, your point is--you are
13 exactly correct--it depends on the integrity of the person.
14 There is no fail/safe mechanism in there to prohibit
15 somebody from putting a higher UVB output bulb or a
16 reflective bulb in there.

17 I thought you were going to address my pet peeve,
18 when I go around and look at advertisements, that it will
19 say hot new bulbs, and our policy is, when we re-lamp with
20 compatible lamps, we cut back the maximum timer interval by
21 10 percent, and that is going to be a recommendation we will
22 make in Chicago, so that we offset for the first 100 hours.

23 The lamp manufacturers, Michael Step from Wolf
24 Technology, is here, if you have some other questions, but
25 in his submission to the FDA, he stated that new lamps turn

1 out a higher output until they burn in, so that is why we
2 cut it back. I thought that is what you were going to make.

3 MR. FLETCHER: Jill, you were next.

4 DR. LIPOTI: We have received from Howard a very
5 comprehensive summary of some of the comments that were made
6 to the Advanced Notice of Proposed Rulemaking, and some of
7 them are the complete antithesis of your comments. They say
8 FDA is biased against the tanning industry, FDA is only
9 catering to the dermatology sun-scare campaign, FDA didn't
10 consult industry.

11 So, I am really pleased to hear your complimentary
12 remarks about FDA at the beginning of each of your
13 statements, and since that is on the record, I think Howard
14 can probably use that in his response to comments.

15 But one of the things that is in here is that FDA
16 didn't have a balanced Notice of Proposed Rulemaking because
17 they didn't include benefits, so I was very carefully
18 reading the benefits statements, and some of them say that
19 UV leads to reduced incidence of breast and prostate cancer,
20 reduction in osteoporosis, and better school scores, as well
21 as a thermal protective effect of tans.

22 Don Smith, I believe that you referred to the
23 Christopher article in your statement. I would like to hear
24 more specifics about these benefits.

25 MR. SMITH: In the FDA submission, there was a

1 section on the published material on the beneficial effects
2 of ultraviolet radiation, and they cover a whole gamut of
3 substance, and some are epidemiological studies, and so I
4 wouldn't be able to comment on the whole thing. It was
5 many, many pages that are in that thing, and they are in the
6 published literature of benefits to ultraviolet radiation.

7 DR. LIPOTI: Could you summarize why a mechanism
8 for why UV radiation, for instance, might decrease breast or
9 prostate cancer or osteoporosis, or even improved school
10 scores?

11 MR. SMITH: The information, as I understand it,
12 tend to be based, for the various studies, whether it's a
13 SCAG study on reduction of coronary heart disease or the
14 Esther John study on breast cancer, all seem to come back to
15 below a certain level of Vitamin D, circulating Vitamin D in
16 animals per milliliter. Those below that level, they have
17 an increased relative risk and above it they do not, so it
18 all seems to come back to some of the information on the
19 cutaneous production of Vitamin D.

20 MR. LEVY: There is a paper by Dr. George
21 Studzinski that I think would explain the mechanism, and Dr.
22 Studzinski was a presenter last September when FDA and NIH
23 held a three-day conference on this topic, but it goes into
24 the mechanism of how Vitamin D induced through solar
25 exposure, I believe the terminology--I am not a doctor--is

1 the initiation of--what is the term--a receptor cell that is
2 activated by Vitamin D that can retard or prevent the growth
3 of certain types of tumors.

4 Again, what my organization believes is that there
5 is obviously a tremendous potential for great risk reduction
6 here. The research is not totally solid at this point, but
7 the potential for breast cancer, colon cancer, ovarian
8 cancer, we have even seen some studies written on reduced
9 risk of heart disease through regular exposure.

10 I don't think we can simply brush this aside and
11 say that the research isn't there. Certainly, the mechanism
12 exists whereby we could explain this. We need to do further
13 study. There is no industry that profits from promoting sun
14 exposure. I have often said that if the sun were owned by a
15 private corporation, we wouldn't probably be talking so much
16 about how terrible sun exposure is for us, we would hear an
17 awful lot about the benefits, but the fact is our industry
18 is probably the sole industry that would profit from sun
19 exposure. There are a lot of industries that profit from
20 keeping people out of the sun, and the research we have seen
21 has been directed that way.

22 What we would like to see is some balance. We are
23 not trying to make any outlandish claims at this point. We
24 believe that because the potential is so great for that type
25 of research, it deserves to be continued even if nobody

1 profits from it.

2 MR. FLETCHER: Jerry Thomas and then Dr. Weinstock
3 would like to make a comment.

4 MR. THOMAS: I have never actually been in a
5 tanning salon or seen a tanning salon bed, so maybe my
6 questions--I have got three or four regarding the piece of
7 equipment and how it is really used and operated. I think
8 that is what we are really looking at is issues of safety.

9 First of all, is there a standard type lamp, is
10 the lamp a UVA, a UVB, or is it a mixed spectrum lamp that
11 is used?

12 MR. LEVY: The most common type of lamp used in
13 the United States has a combination of UVA and UVB that is
14 somewhat similar to sun exposure. It's in the 95 to 97
15 percent UVA to 2 to 5 percent UVB in terms of the mixture of
16 the lamp.

17 MR. THOMAS: So, if you look at the sensitivity
18 spectrum of that light, that would be very similar to the UV
19 spectrum that we would find in normal sunlight, is that
20 correct?

21 MR. LEVY: I would imagine so.

22 MR. THOMAS: So, there is no particular lamp that
23 gives best results?

24 MR. LEVY: I think that you would get a lot of
25 different opinions on that.

1 MR. THOMAS: Well, you guys are the experts, I am
2 not, in your piece of equipment, so therefore, you wouldn't
3 say from a tanning salon we have a particular lamp, and
4 therefore, we get better results than the competition down
5 the street?

6 MR. LEVY: I don't think there is any subjective
7 on which lamp gives the best--excuse me--anything objective
8 right now on what lamp gives the best results.

9 MR. THOMAS: Three other questions regarding the
10 operation of the machine. Is there an internal dose
11 monitoring incorporated into a bed, so that you know the
12 energy of the particular wavelength delivered to the
13 patient?

14 MR. LEVY: The exposure schedule on the equipment
15 takes that into account.

16 MR. THOMAS: Is that an exposure schedule
17 developed by your organization?

18 MR. LEVY: No, that is developed by FDA and
19 followed by the facilities.

20 MR. THOMAS: The last two questions. Who has
21 control over the timer and is there a, let's call it for
22 lack of a better word, a chicken switch or an emergency exit
23 for the individual in the bed?

24 MR. LEVY: The kill switches are mandatory, and
25 the timer is always controlled by the operator.

1 MR. FLETCHER: Dr. Weinstock.

2 DR. WEINSTOCK: I just wanted to give a brief
3 comment about the other cancers that were mentioned.
4 Science perceived by people putting forth all sorts of
5 hypotheses, and in the process of gathering evidence, and
6 the one decides whether the hypothesis is credible or not, I
7 would say these are basically in the hypothesis stage, and
8 people have put forward hypotheses, well, maybe prostate
9 cancer is related to sunlight, but there is no substantial
10 evidence to support that, the hypothesis was put forth on
11 the basis of geographic trends.

12 The same thing is true for breast cancer, and
13 indeed breast cancer, even the geographic trends don't
14 really support, for instance, it is just mortality, and that
15 strains the plausibility even more.

16 Who knows what will show up in the future in terms
17 of scientific evidence, but at the moment there is no
18 substantial scientific evidence for each of those.

19 The same thing for colon cancer with one
20 exemption, and that is for colon cancer, there is some
21 scientific evidence linking it to Vitamin D or something
22 related to Vitamin D, but there has been no relationship, to
23 the best of my knowledge, linking it to sun exposure.

24 So, I think that in the absence of future studies
25 that provides some substantial relationship, none of these

1 deserve to be given any credence from a public health point
2 of view at this point in time.

3 MR. FLETCHER: On that comment, I am going to
4 thank all three of you for your presentations, Dr. Cyr, Dr.
5 Weinstock.

6 We will adjourn for lunch. Please be back in
7 your seats by 1:15. At that time, we will have an open
8 discussion on all of the morning's presentations.

9 [Whereupon, at 12:10 p.m., the proceedings were
10 recessed, to be resumed at 1:20 p.m.]

1 AFTERNOON PROCEEDINGS

2 [1:20 p.m.]

3 **Committee Discussion**

4 MR. FLETCHER: We will now have a period of
5 committee discussion. During this period, we want to
6 provide to the FDA or to discuss amongst ourselves and
7 provide to the FDA what we feel are the main areas of
8 concern and whether or not we want to come forward with a
9 motion or a specific direction. So the floor is now open to
10 committee members to discuss the presentations from this
11 morning.

12 DR. McKETTY: I didn't get a chance to ask the
13 question, but the third speaker indicated, in terms of the
14 training, that in his group, all the people got the
15 training, but is there a feel for what percentage of the
16 industry--

17 MR. FLETCHER: Is trained?

18 DR. McKETTY: Yes.

19 MR. FLETCHER: Dr. Cyr, can you address that?

20 DR. CYR: The groups that were here, they had to
21 go and catch a plane. Not even a majority. Most of the
22 salon owners are not members, they don't participate,
23 although as Don Smith said, the bigger players are. You
24 have lots of little salons, the ones that he said are in the
25 nail parlors, and what have you, they are the ones that tend

1 not to be represented. I would think more probably the
2 bigger ones. But the answer is no, the majority of them do
3 not belong to these associations.

4 MR. FLETCHER: Dennis Wilson.

5 MR. WILSON: On that same subject, on the training
6 that they have, is there a certification program for that,
7 that shows that they actually did pass and that they were
8 qualified?

9 DR. CYR: I don't know the details of their
10 training programs. I have seen brochures and some
11 materials, but I have never been to one, and I don't know
12 how detailed it is.

13 MR. FLETCHER: I am going to ask Bill Pipp if he
14 has some information on the training and certification that
15 he can provide.

16 MR. PIPP: The two training associations that are
17 out there are SAE and International Smart Tan Network. They
18 do have certification courses. They do certify the people.
19 They give them materials, and so forth. Those two
20 organizations do certify the salons that do go through the
21 training.

22 MR. FLETCHER: I think one of the earlier
23 questions was do we know what percentage of those who are
24 operators are trained.

25 MR. PIPP: I couldn't give you an exact number,

1 but I would agree with Dr. Cyr that it is a very small
2 number at this time. That is one of the goals of the Indoor
3 Tanning Association, to expand that out significantly, but I
4 would say the number of maybe 5- to 6,000 of 30,000 salons
5 out there that have really been trained adequately and are
6 certified by the SAE or by the International Smart Tan
7 Network.

8 MR. FLETCHER: Thank you.

9 Jerry Thomas.

10 MR. THOMAS: The discussions we had this morning
11 were rather interesting, and I think if we change the word
12 tanning salons to tobacco, I have heard the same argument
13 used relating to the "causal" effect of tobacco and lung
14 cancer, as I have heard the arguments of the causal effect
15 of melanoma from tanning salons.

16 I am concerned that we have the ostrich in the
17 sand syndrome with our head in the sand, not looking at the
18 broad picture. I think that it is very clear that the
19 parenthetical evidence is that there is indeed a causal
20 relationship between tanning salon exposures and melanomas.

21 I state that because industry had come up and
22 said, well, we have a very active training and certification
23 program. Why, if there is no risk, is there a need for such
24 a program. If there is a need for such a program, then,
25 there is a need for regulation of the performance

1 characteristics of a tanning booth, both in terms of
2 wavelength, in terms of time. Instead of a count down
3 timer, maybe it should be a count up timer.

4 We don't know the biological effects, nor will we
5 probably ever have scientific evidence within our lifetimes.
6 If I am exposed at the age of 15, and that is about when I
7 expect to be wanting to that nice buff look, my teenage
8 years and my early 20s, that means that at the very
9 earliest, I am in my late 30s or early 40s before there is
10 an expression of the melanoma.

11 We all know that statistically that is probably
12 the earliest expected expression thereof, and therefore, how
13 do I differentiate my melanoma from a suntanning booth
14 versus the melanoma from the sun? You can't. They are both
15 melanomas, and they both have the same biological expression
16 and the biological endpoint.

17 It is very clear, though, that we are dealing with
18 the same wavelengths of radiation. It is unclear, though,
19 that we have defined what a tanning salon is. It is unclear
20 that we have defined who should be in possession of tanning
21 booth. Is that something that should be regulated and only
22 in industry? Is that something that should be eliminated
23 completely from our society?

24 There are members of our society who would like to
25 eliminate such products as tobacco, others would like to

1 eliminate such products as alcohol. We have a social
2 experience showing that eliminating any particular item that
3 is widely accepted and used by the public is difficult, if
4 not impossible, when there is a consumer desire for that.

5 So, I have great concerns. I cannot accept the
6 fact that we don't have credible scientific evidence showing
7 that causal relationship. I think the evidence is there. I
8 think the evidence, it's problematic within the short period
9 of time that we have really had tanning salons to see the
10 exact causal relationship, but it is not historically a
11 problem to identify same wavelengths from different sources
12 that have caused melanomas, i.e., the sun.

13 It is also very clear that in the tanning
14 industry, they want to have results, and those results are
15 darkening of your skin. I also reject as outright hogwash
16 the thermal discussions about thermal incidence being a
17 cause of melanoma.

18 If that is the case, you can put a person in a hot
19 room and keep them out of the sunlight, and we should have
20 tons of melanomas with the temperature differentials that
21 they are talking about. Those are very, very minimal
22 differentials in the public comments.

23 So, there are a number of things that toward the
24 end of this, I think we will probably come up with
25 resolutions of the group.

1 I would suggest, one, that we make suggestions
2 regarding timers. Second, I would make suggestions that we
3 make a recommendation regarding an integration or measure of
4 the dose from the particular UV spectra in the device. I
5 think the timer should be a count up timer versus a count
6 down timer.

7 I think we need to clearly define what is meant by
8 a tanning salon and what is meant by tanning. There is a
9 category of individuals that don't tan biologically. I
10 don't think that we should get into trying to differentiate
11 between phototypes.

12 There was a suggestion made by the industry on
13 phototypes and phototyping of patients. It appears to me
14 that that is far more complex than what should be looked at
15 in terms of regulation. What causes more difficulty in
16 establishing a regulation is that we don't know exactly what
17 the regulation should be because we have varying degrees of
18 sensitivity across the population.

19 The argument was made that the standards were too
20 low for this Hispanic population in the State of Arizona and
21 that they should be allowed to receive a higher tanning time
22 or higher dosage I guess is the best way of putting it
23 versus a fair-skinned redhead, light-eyed individual.

24 So, those are my thoughts. I want to be somewhat
25 controversial, but at the same time I don't think that we

1 can ignore the fact that I believe--my feeling is that there
2 is a causal relationship even though we don't have peer-
3 reviewed scientific evidence that states it overwhelmingly.

4 MR. FLETCHER: Thank you, Jerry.

5 I would like to add to that list that you gave
6 particularly as far as the rulemaking is concerned, the
7 definition of burning dose. I spoke with Dr. Cyr about it.
8 I am not sure I understand what that means, how you get it,
9 how you know you have got it, and who determines what it is,
10 so I think that needs to be clarified, so that we know what
11 we are dealing with.

12 Other comments?

13 DR. CYR: I am amplify a little bit. When it
14 comes to burning doses, you are right, whether they mean a
15 dose that gives just a slight redness, a slight erythema, or
16 are they speaking of doses which cause blistering burns.
17 Sometimes in studies it is the latter, but you are not
18 always sure what they are talking about when they talk about
19 burning doses.

20 DR. RICE: I am surprised at the short training
21 period for the people that operate these salons. I mean
22 from one hour to one day of training, I mean barbers have to
23 be trained and have to be certified, beauticians have to be
24 trained and certified, and they are just dealing with the
25 hair. We are dealing with the whole body, the skin

1 integument, and it seems to be a very loose area of concern,
2 and I am surprised.

3 MR. FLETCHER: Any other comments before I
4 entertain some directional comments?

5 DR. SZEGLIN: I agree. There should be something
6 with credentialing of the people that are actually running
7 these salons, the people that are actually applying the
8 timer settings and actually looking at the skin reactions,
9 et cetera. We should spend some time on that, at least be
10 able to review what they have.

11 MR. FLETCHER: Dr. Cardella.

12 DR. CARDELLA: I would like to advocate as a
13 recommendation, as well, that the tanning bed or the tanning
14 booth, whatever the style of tanning device is, that
15 although these things are carefully reported about, and
16 there is oversight at the time of their manufacture, I would
17 like to see in the recommendation measures employed that
18 would lessen the variability of what the unit can look like
19 two or three years down the road, when it is, for example,
20 re-lamped or re-timed or put the turbo charger on it, or
21 whatever it is that they are capable of doing.

22 I would like to see the idea of standardized bulb
23 replacements or even fittings that force standard
24 replacement of a dedicated lamp.

25 MR. FLETCHER: I think we are now ready to

1 entertain some kind of a directional comment. I am waiting
2 to call on my favorite motion giver.

3 Go ahead, Cass.

4 MS. KAUFMAN: I would like to make a motion that
5 at the minimum, that FDA pursue their proposals that were
6 published in the Federal Register on February 9 of '99. I
7 think the committee may well want to go beyond that, but as
8 a first motion I think I would like to propose that we
9 pursue what has already been proposed, that we encourage FDA
10 to pursue them.

11 MR. FLETCHER: Is there a second to that motion?

12 DR. CARDELLA: Second.

13 MR. FLETCHER: We have got a motion that the FDA
14 pursue the items in their rulemaking announcement of
15 February 9th.

16 Is there any further discussion?

17 All in favor just say aye.

18 [Chorus of ayes.]

19 MR. FLETCHER: Opposed?

20 [No response.]

21 MR. FLETCHER: The motion carries, and that is on
22 the record.

23 DR. LIPOTI: I was taking notes while people were
24 making recommendations, so let me see if I can summarize all
25 of the recommendations that were made, and then if I have

1 forgotten some, I will sure you will let me know.

2 First of all, I would like to speak to training.
3 I think one of the statements was made that the baseline
4 training is what is required by the most strict state
5 regulation. That sounds like a good baseline for the
6 training if you take what is the most strict state and put
7 in your regulation a specific curriculum and time frame for
8 covering each subject, I think you will have a good
9 curriculum. So, training was one of the recommendations.

10 Another recommendation was for warnings, and
11 warnings were constituted in two different ways. One was a
12 warning label, the other one was a warning in catalogs. One
13 of the things we haven't touched on in this last discussion
14 is the purchase of sunlamps for use in your own home.

15 We have talked about salons, we have talked about
16 tanning beds that aren't in salons, but people can buy them
17 and use them at home, and that seems to be essential that we
18 provide all of the warnings that would have been covered in
19 an informed consent in a salon, should certainly be there in
20 the catalog for someone who wishes to purchase the device.

21 Informed consent is the next one. There has to be
22 some right-to-know for the consumer that clearly identifies
23 the risks they are taking on when they subject themselves to
24 tanning and when they choose to participate in that.

25 As part of that, of course, it would help to

1 define what is a tanning salon, what is a tanning booth,
2 what constitutes tanning apparatus. We need to define
3 tanning and burning doses. We need to look carefully at the
4 piece of equipment. Dr. Cardella has very succinctly
5 described how you could lessen variability involved in re-
6 lamping and re-timing, standardizing bulb replacement,
7 standardizing sitting, some sort of efficacy rating for the
8 bulbs where the spectrum is defined. I think Jerry's point
9 about the spectrum is essential, so that you lessen
10 someone's variability when they go from one tanning
11 apparatus to another.

12 We might consider some sort of dose rating. I
13 mean we are considering that for fluoroscopy, couldn't there
14 be some kind of dose that would help for your informed
15 consent. The consumer would know what their dose was.

16 Timers were mentioned and measurement of dose, I
17 covered that. So, that is all the ones that I wrote down.

18 DR. SZEGLIN: Count-up timer.

19 DR. LIPOTI: Count-up timer, not a count-down
20 timer, yes.

21 I will make that a motion as the summary of
22 recommendations that I heard from TEPRSSC.

23 MR. FLETCHER: Is there a second?

24 DR. SZEGLIN: Second.

25 MR. FLETCHER: Discussion? Dr. Lotz.

1 DR. LOTZ: I just had one point, and that was
2 there was one other note that I made, I think, that was not
3 in your motion, and that was the question of whether FDA had
4 proposed dealing with phototypes. The comment was made
5 earlier of not being in favor of them dealing with
6 phototypes.

7 It seemed to me that dealing with phototypes is
8 somewhat problematic, and I am inclined to follow the
9 suggestion that it not be at least a central element. There
10 is obviously some merit to taking that into account,
11 particularly for the people who can't tan, but the problems
12 of determining the phototype, especially in a population of
13 operators who aren't even trained very well to begin with
14 and things like that, make me a little uneasy about FDA
15 basing much on phototype.

16 MR. FLETCHER: Just for point of clarification,
17 your motion is that the FDA review and further clarify or
18 better define these areas?

19 DR. LIPOTI: And consider them in their rule
20 proposal.

21 MR. FLETCHER: Alice and then Dr. Cyr.

22 MS. FAHY-ELWOOD: I just wanted some clarification
23 on the count-up timer. I understand the reason for it was
24 so you could get an idea of what the cumulative dose would
25 be during the tanning session, but it would seem to me--I

1 don't know if it is that important for this motion--but a
2 count-down timer, so it does the same thing as long as the
3 timer is set appropriately or so that by the end of the
4 schedule, you know you have got that cumulative dose.

5 I just wanted a little clarification on what you
6 meant I guess by that.

7 DR. SZEGLIN: I will answer that if I can. With a
8 count-down timer, after it is all done, you don't know how
9 long the person has been in there; with the count-up timer
10 you do. We have that problem with cobalt 60 machines that
11 had count-down timers. You never knew if it was a one-
12 minute treatment or a 1.2 minute treatment or a 2.1 or a 21,
13 so if you had a count-up timer, you would.

14 MS. FAHY-ELWOOD: So, the idea behind the timer is
15 not when the time is over the system shuts down?

16 DR. SZEGLIN: No, no. What would happen is you
17 would set it--let's say the treatment is one minute--you
18 would set it for one minute, and as the minute elapsed, or I
19 could display what actually count up to one minute, so when
20 it was all done, you would still have a minute showing.

21 MR. FLETCHER: Any other discussion? Dr. Cyr
22 wanted to make a point.

23 DR. CYR: No, that was my question.

24 MR. FLETCHER: Go ahead, John.

25 DR. CARDELLA: The other point that I would like

1 to have considered--I don't know if it should be as a
2 friendly amendment or how you want to do that--but for the
3 warning labels, if a warning label is to be placed, I would
4 suggest that the IEC version be used, in other words,
5 association with skin cancer (sometimes fatal), rather than
6 specifying melanoma, basal cell, squamous cell, because the
7 information to support those specific inclusions is a little
8 soft.

9 MR. FLETCHER: I will not consult the
10 parliamentarian and just ask will you accept that as a
11 friendly amendment.

12 DR. LIPOTI: Yes, I think the IEC, it also gets to
13 harmonization, and I think we want to do that.

14 MR. FLETCHER: Any other discussion?

15 DR. LIPOTI: Just as a point of clarification, do
16 you want to take the phototypes question as a separate
17 question or do you want to consider it all in one? That has
18 a lot of gray areas, and I am not sure how even I would vote
19 on that one.

20 MR. FLETCHER: My reading of the motion is that we
21 are more or less directing FDA as a part of this rulemaking
22 to review, evaluate or reevaluate all of these areas with
23 the guidance of our comments. So, I am not sure we can say
24 that we want to take this out or not take it out. I think
25 we want them to take into account the comments that we have

1 made, but if I am not saying that properly, please let me
2 know.

3 DR. LIPOTI: That's fine then.

4 MR. THOMAS: There may actually be a way of
5 handling phototypes that those of use on the committee don't
6 understand, Mr. Smith, when he presented what they were
7 doing in Tucson, had something that was pseudophototype
8 typing form, that you had a cumulative score that resulted
9 in self-classification of the patient or I should say of the
10 individual, it is not a patient, it is a client I guess, and
11 in terms of what their phototype might be.

12 I don't know what phototypes really are going to
13 do in a regulation other than bring to people's attention
14 that there is different sensitivities that are individually
15 based. I concur with Jill in terms of I am not sure how to
16 handle phototypes in the basic discussion that we have had.

17 MR. FLETCHER: Cass.

18 MS. KAUFMAN: Dr. Cyr, it is my understanding that
19 the current exposure guidelines are based on a Phototype II
20 individual, is that?

21 DR. CYR: That is my understanding.

22 MS. KAUFMAN: So, that is where I think it comes
23 in, and they do talk about it relative to the first motion
24 in the Federal Register, about taking a look at that, but I
25 believe that the current recommended guidelines, which

1 apparently few are following according to this, are based on
2 a Phototype Type II.

3 I am inclined to think that it has some relevancy
4 and even though there are considerable problems with it, at
5 least it offers some reference point of guidance and ought
6 not to just be completely disregarded.

7 MR. FLETCHER: Let me try as best I can to
8 highlight the main parts of the motion. What we are voting
9 on is that the FDA review, evaluate, or reevaluate and
10 reanalyze, as a part of rulemaking, comments, concerns, and
11 perhaps different approaches for the suntanning in the areas
12 of training, warning labels particularly reviewing the IEC
13 warning, purchase, informed consent, identification of risk,
14 definitions of the tanning devices, booths, salons, et
15 cetera, definitions of what is tanning and what is burning,
16 efficacy, a clear delineation of the spectra, and consider
17 dose rating, phototypes, the timer, the count-up timer, and
18 I think that is a complete list. So, that is what we are
19 voting on.

20 All those in favor of this motion, please just say
21 aye.

22 [Chorus of ayes.]

23 MR. FLETCHER: Any opposed?

24 [No response.]

25 MR. FLETCHER: The motion carries. Thank you.

1 Cass.

2 MS. KAUFMAN: I talked a little bit with Dr.
3 Weinstock right before lunch about the issue of the
4 percentage of the bulbs that are UVA versus UVB, and I am
5 not sure that this is something that this committee can do,
6 but it seems like it would be helpful if FDA could encourage
7 research in the area of might it be safer if there was a
8 higher percentage of UVA relative to UVB or something like
9 that.

10 Can this committee make that kind of
11 recommendation that we encourage FDA to support and
12 encourage that kind of research?

13 MR. FLETCHER: If that is the feeling of the
14 committee, we can make that recommendation.

15 MS. KAUFMAN: I am going to make that motion then
16 that we encourage FDA to encourage and support additional
17 research in the area of UVA versus UVB, and if bulbs might
18 be modified that might result in safer exposures.

19 MR. FLETCHER: Is there a second?

20 MS. FAHY-ELWOOD: Can I get clarification on what
21 you mean on the motion, you mean research into the bio
22 effects of one versus the other or whether some bulbs put
23 out more A than B?

24 MS. KAUFMAN: Bio effects.

25 MR. FLETCHER: I am still looking for a second.

1 [No response.]

2 MR. FLETCHER: I am afraid your motion dies for
3 lack of a second.

4 Are there any other comments regarding?

5 DR. LIPOTI: Yes, on your research, you mentioned
6 that CDRH is currently doing some research, and I am
7 interested in finding out what research it is that you are
8 doing here at CDRH, and then what research recommendations
9 you might have perhaps for a cancer study, a National Cancer
10 Institute study, or some other research that we might
11 endorse.

12 DR. CYR: The one project I was referring to
13 involved people of different skin types, and again it was
14 just the amount of dosage it took to reach minimal erythema
15 doses.

16 DR. LIPOTI: Are these people at CDRH?

17 DR. CYR: They are volunteers at CDRH and other
18 centers. It's an intercenter project. It's just getting
19 started.

20 MR. THOMAS: Regarding research, is NCI funding
21 any research in this area, do you know?

22 DR. CYR: I suspect they must be when there is an
23 awful lot of research. You are talking about relative roles
24 of UVA and UVB.

25 MR. THOMAS: Yes.

1 DR. CYR: There is lots of research.

2 MR. THOMAS: I am trying to think of a study
3 section that might be doing that, and I am unaware of one is
4 why I am asking.

5 MS. KAUFMAN: I wonder if we could ask Dr.
6 Weinstock.

7 DR. CYR: There is another agency involved with
8 skin diseases, allergies and skin diseases, an agency that
9 takes care of that. So, it may not come out of NCI.

10 DR. WEINSTOCK: There is a variety of research
11 going on, and I don't have a comprehensive view of all of
12 it. A lot of it is laboratory research looking at the
13 differential effects of different wavelengths of light on
14 immune function and skin of rats and mice, and so on.

15 It's part of the whole field of photoimmunology
16 which is an area of active research. There are some
17 epidemiologic studies going on, as well. Those tend to be
18 fewer in number, but there are some going on.

19 Many of these aren't, I would say almost all of
20 these are not specifically looking at UVA versus UVB, but
21 they may be looking at, say, one wavelength and looking at
22 the effect of that wavelength on DNA or on some other
23 molecule in the cell which presumably has biologic effects.

24 So, there is such research being funded by the NIH
25 and other agencies. I don't think it is geared to

1 specifically tanning booths, but it is more general.

2 One thing that has inhibited epidemiology research
3 is that people don't know what the booths are emitting. I
4 mean when you go into a booth, you don't know, is it these
5 or they, is this neither or both, or what proportion, and no
6 one knows, so a consumer is in the dark.

7 The owners, I think in general, are in the--or at
8 least the operators in general, I believe Don knows for a
9 fact, that is my impression, that they are in the dark about
10 exactly what their bulbs are emitting, as well, so it is not
11 widely disseminated what people are actually getting.

12 MR. FLETCHER: Any further discussion? Cass
13 Kaufman.

14 MS. KAUFMAN: I think that is where I was trying
15 to go was to try and have more research into what the bulbs
16 are emitting, and might we be able to produce a safer bulb.
17 I think right now there is just a great deal of variability
18 just relative to that one issue of UVA versus UVB, and it
19 might really be helpful if we could get more research going
20 and in terms of both measuring spectra of the bulbs and what
21 impact that might have on humans.

22 DR. SANDRIK: To pose a question and perhaps
23 somebody might have some information, but what is the state
24 of the dosimetry capabilities for this kind of radiation in
25 terms of does it all limit dose effect kind of studies, are

1 there field portable kind of units, so that it is simple to
2 go into a tanning facility and get an indication of
3 spectrum, is the state of dosimetry satisfactory to provide
4 reasonable sort of information on these systems.

5 MR. FLETCHER: Dr. Cyr?

6 DR. CYR: I am not a great expert on dosimetry.
7 There is all kinds of dosimeters. You can get some fairly
8 inexpensive ones to take some measurements, and then there
9 are some complicated ones that our engineers use, which hook
10 up to scopes and things like that, which are quite expensive
11 and take time to set up, and are not quite so easy.

12 You can do cheap dosimetry or expensive dosimetry.

13 DR. SANDRIK: Just to follow up, has there been
14 any sort of standardization in this regard that is applied
15 to any of these other studies that are done, so that one
16 study could in any way be compared to any other study, or is
17 it every one is sort of a unique incident?

18 DR. CYR: It depends on what dosimetry they use,
19 yes. Those using the expensive stuff, it is probably kind
20 of hard to compare them to what somebody used as a simple
21 tool.

22 MR. FLETCHER: I hope you will consider the
23 dosimetry as a part of the dose rating that I included in
24 our motion.

25 Jerry.

1 MR. WILSON: The information we were provided in
2 the comments, somebody said this is a \$5 billion a year
3 industry. If there is that much money, and industry is
4 interacting with the FDA, I would strongly encourage the FDA
5 to interact with industry.

6 It is in their best interests to, one, find a
7 wavelength that gives maximal return for the exposure that
8 the individual is receiving, i.e., tanning, if that is what
9 the client desires; and, secondly, to deliver that result at
10 the lowest potential risk to the client.

11 I think that is really what Cass was asking when
12 she was encouraging or asking the group to have a motion. I
13 will try to reword what she said, and say I would like to
14 move that we encourage the FDA to strengthen the industrial
15 relationships and encourage the industry, with the amount of
16 money that they claim they have in this industry per year,
17 to actively fund research that would promote the benefits if
18 they see a benefit of this technology for mankind.

19 MR. FLETCHER: Is there a second to the motion?

20 MS. KAUFMAN: I am sorry, I didn't quite hear the
21 end of the motion, promote the benefits?

22 MR. THOMAS: I will make it simple. The motion is
23 that we would encourage the FDA to be proactive in their
24 interaction with industry to investigate the tanning benefit
25 of UVA versus UVB or other components of the electromagnetic

1 spectrum that they are using.

2 MR. FLETCHER: Is there a second?

3 DR. CARDELLA: Second.

4 MR. FLETCHER: It has been properly moved and
5 seconded that the committee encourage the FDA to be
6 proactive in its interactions with industry to investigate
7 the benefit of UVA versus UVB and other--I didn't get what
8 came after other--

9 MR. THOMAS: The other comments of the
10 electromagnetic--

11 MR. FLETCHER: -- and other components of the
12 electromagnetic spectrum.

13 Comments?

14 MS. KAUFMAN: May I offer an amendment to that, or
15 what is called, an alteration?

16 MR. FLETCHER: Amendment is fine.

17 MS. KAUFMAN: Instead of using the word benefits,
18 could we change it to something like impact?

19 MR. FLETCHER: Okay. You accept the amendment, so
20 it is now impact, because I am not going to repeat it.

21 Any other comments? Dr. Lipoti.

22 DR. LIPOTI: It is the intent of your motion to
23 support unbiased research although it is funded by the
24 industry.

25 MR. THOMAS: But of course.

1 MR. FLETCHER: Do we need to make that statement
2 in the recommendation?

3 Please speak into the mike, so I know what you are
4 saying.

5 MR. THOMAS: One of the committee members
6 whispered in my ear yes, and I agree with that.

7 MR. FLETCHER: Any other comments?

8 The motion we are voting on is that we are going
9 to encourage the FDA to be proactive in its interaction with
10 this industry to investigate on an unbiased basis the impact
11 of UVA versus UVB and other components of the
12 electromagnetic spectrum. Did I get it?

13 All those in favor say aye.

14 [Chorus of ayes.]

15 MR. FLETCHER: Opposed?

16 [No response.]

17 MR. FLETCHER: The motion carries.

18 We are now five minutes of our original schedule.
19 Is there any further discussion?

20 If not, I would ask Joanne Barron--

21 MS. BARRON: Joanne Barron with the FDA. We would
22 like the committee to comment on the proposal for the laser
23 standard.

24 MR. FLETCHER: Okay. There has been a request
25 that we make a comment or even a recommendation motion on

1 the proposal or the laser standard.

2 Dennis.

3 MR. WILSON: I think from what I seen and heard
4 this morning, and I commend the FDA on the work that they
5 have done on the laser standard and the efforts to harmonize
6 it with the IEC standards.

7 I would recommend or make a motion that they do
8 hold off on changing the standard until the IEC has
9 completed their work on their work on their current CDV, so
10 they can stay in harmonization with the later standards.

11 MR. FLETCHER: Is there a second?

12 MS. FAHY-ELWOOD: Second.

13 MR. FLETCHER: It has been moved and seconded that
14 this committee, first of all, commend FDA for the work that
15 they have done, but recommend that they hold off on approval
16 of the laser standard until their efforts can be harmonized
17 with that of the IEC.

18 Discussion?

19 MS. KAUFMAN: I have a question. If we didn't
20 hold off, if we went ahead and went with our own standard,
21 is it possible that that might be taking more of a
22 leadership position and that that might encourage the
23 international community to come along with us and perhaps
24 move a little more quickly?

25 MR. WILSON: I can comment on that. Being

1 involved in the international standards area for about 12,
2 13 years, I would say no. Each country has a single vote in
3 the process, and although we have some expertise in certain
4 areas, it still depends on who is on a committee and who is
5 controlling the committee, too.

6 So, I would say that there really isn't a reason
7 for us to hold off or to go ahead earlier because that will
8 not affect the voting that will go on in that current
9 process in the IEC.

10 MR. FLETCHER: Any further discussion?

11 DR. LIPOTI: I guess I had a question on exactly
12 the timing, and the way Roland restated the motion, the way
13 you made the motion gave me a little bit of doubt.

14 It seemed to me when Jerry Dennis made his
15 presentation, that he said that by November, you will have a
16 pretty good idea of which way the IEC is going, and the real
17 proposal was March of '99. So, it seemed to me that by
18 November, the FDA could move forward if it appears that IEC
19 is approving the way that they are going.

20 I don't think we should wait until the IEC has
21 gotten all their formal votes in, and so forth, because that
22 will be in another two years. I think once we know the
23 direction of the IEC, then, FDA can proceed.

24 So, it's just a little bit of the timing of the
25 schedule. We will have a pretty good idea the November-

1 December time frame?

2 MR. FLETCHER: Dennis.

3 MR. WILSON: Well, I think that depends on the
4 comments they get back on their CDV. If there is a lot of
5 controversy over it, then, it could go back to another
6 draft, another CDV. It depends just how much change, again,
7 how many substantive comments that will come out of the
8 particular document.

9 The FDIS, it is clear that whatever comments are
10 taken into account, they create the FDIS, and then that is
11 at the point where you can't really comment on it. At that
12 point, you just say yea or nay, and the majority rule
13 affects on whether it is implemented or not.

14 You would almost have to wait until after the
15 comments came through and they create the FDIS before you
16 really know the direction they will head in. If there are
17 very few comments that come through that would impact it,
18 then, you would pretty much know that you can incorporate
19 that and go with it at that point.

20 MR. FLETCHER: Jerry.

21 MR. THOMAS: Dennis, would you be willing to amend
22 your motion to encourage the FDA to move forward with
23 rulemaking if there are few comments? My concern is, it has
24 been what, 14, 15 years since anything has been done, and I
25 think if we look at the technology, it has changed

1 dramatically. There were some very sound recommendations
2 made this morning, especially the school kids' lasers, the
3 reclassification of lasers, the measurement techniques.

4 I am uncomfortable waiting another two years, and
5 that is probably what the rulemaking would be, so I am
6 asking really would you entertain amending your motion to
7 encourage them to move forward if there appears to be a
8 consensus in the November time frame.

9 MR. WILSON: Yes, I would agree. I think my
10 feeling is that we need to have a standard as soon as
11 possible that stays in harmony with the IEC standard, and if
12 we get to a point where we recognize what will happen in the
13 IEC standard, we can keep the U.S. standard at least pretty
14 close in harmony with it, then, we ought to move forward
15 with it as soon as possible.

16 MR. FLETCHER: Okay. He has accepted that
17 amendment.

18 DR. CARDELLA: I want to make sure that I am clear
19 on the specifics of the measurement methodology. My
20 recommendation would be that if it appears that the IEC
21 standard will stick with the 50-millimeter aperture at 100-
22 millimeter distance, that doesn't make much sense to me, and
23 if that is the direction that IEC goes, then, I would
24 recommend FDA write a non-harmonized standard that suggests
25 either 7 millimeters at 100 millimeters or the 50

1 millimeters at 2,000 millimeters or 2 meters.

2 I don't think that that measurement methodology
3 necessarily needs to be harmonized, and what my
4 understanding of optic is, that the 50 millimeters at 100
5 millimeters doesn't make much sense.

6 I would further like to encourage the FDA to
7 exempt light-emitting diodes from any standard, and I think
8 that is the intent, but I would echo the idea that we should
9 move forward with some sort of a standard, you know, a
10 shorter time frame than 14 years, and if it necessitates
11 disharmony with IEC on that testing point, then, I would go
12 forward with that.

13 MR. FLETCHER: Is there any part of your comments
14 that need to be incorporated in the basic motion? If so, do
15 you accept those changes?

16 MR. WILSON: Yes, I do.

17 MS. FAHY-ELWOOD: I just had one other comment,
18 Roland, I am sorry.

19 I think from my point of view, the more important
20 disharmony would be in the classification schemes, because
21 the IEC is changing there so drastically from what we use
22 now, what they use now. So, I just wanted to point that
23 out, I guess, to the committee, that that to me is really
24 the most important disharmonization, and that if we move
25 forward with the current CDRH recommendation, and the IEC

1 goes ahead with our new classification scheme, that is going
2 to be a big gap again. Am I being clear with that?

3 So, that is my concern, but I think it would be
4 good that if we could, as people have suggested, maybe wait
5 until we get a better feeling for what IEC is going, how
6 they are going to vote in November, just some thoughts.

7 MR. FLETCHER: Dennis, I am going to do something
8 to you. I am going to ask you to restate your motion as
9 best you can, incorporating the comments that have been
10 given to you.

11 MR. WILSON: All right. I may have to take some
12 notes from Jill on this. Have you got any notes?

13 [Laughter.]

14 I think my motion would be for the FDA to stay in
15 touch or stay informed, which I know they are, on the IEC
16 changes that come up this October, to stay on track with the
17 differences they have from the harmonized standard,
18 particularly in the light-emitting diodes and I think on the
19 aperture question that we have, but on the rest of the
20 standard is to try to look at the harmonization with the
21 IEC, the 60825-1.

22 MR. FLETCHER: I need another second.

23 DR. CARDELLA: Second.

24 MS. KAUFMAN: I am not sure that that motion does
25 say what we were talking about.

1 MR. FLETCHER: There was one area that I didn't
2 hear, and that was to have them move ahead if there were
3 fewer comments.

4 MS. KAUFMAN: Right, if there weren't a lot, if
5 there were not very many, and not too significant comments
6 in IEC in October and November, that we encourage FDA to
7 move forward, and that if the only difference had to do with
8 the measurement criteria, we feel that the FDA's criteria
9 probably makes a lot more sense.

10 MR. FLETCHER: He didn't mention measurement.

11 MS. KAUFMAN: Even if there is disharmony in that
12 one area.

13 MR. FLETCHER: So, we are going to add the fact
14 that they move ahead if there are few comments.

15 DR. CARDELLA: Also, Alice's--

16 MS. FAHY-ELWOOD: Well, for them to move ahead if
17 there are few comments, and they were to adopt their
18 rulemaking, and then the IEC were to adopt their new
19 standard, again, the classification schemes would be
20 completely different.

21 I guess I don't understand what you mean by move
22 ahead. Maybe I am missing something. I probably am.

23 MR. FLETCHER: Jerry, you brought that up.

24 MR. THOMAS: My concern is, and I need your help
25 on this, is that it has been a long time since we have

1 modified anything in the CFR and laser standards in the
2 United States.

3 Harmonization is an ideal, but quite frankly, we
4 have got countries that are incredibly conservative, that
5 came up with an unreasonable measurement criteria that is
6 part of their standard now.

7 I think that we have leaders in this area in the
8 world in the FDA, and frankly, I think the FDA should move
9 forward, and if this is disharmony, that's tough in my
10 feeling. We have people that are setting the standards, and
11 I think maybe it's time that our country stand up and say
12 here is the standard, world, follow it in this particular
13 area.

14 Now, that is fairly strong with what I have just
15 said, but my concern is that even if there is disharmony
16 between the classification schema, between the FDA proposal
17 and the international proposal, maybe I am wrong, but that
18 doesn't bother me, because if really appears that the folks
19 that have presented to us, that are in the FDA, fully
20 understand what is needed in the United States to regulate
21 this.

22 Consequently, I would like to see us move forward.
23 I feel even stronger than what I said. I think we should
24 move forward independent of the IEC, but to restate what I
25 have just said quickly, I think what Dennis' concern is, is

1 that we have--with moving forward we have disharmonization.

2 Your concern is, is that if we are not consistent
3 in classification, we are going to continue to have a
4 disharmonious standard. Maybe there isn't a solution.
5 Probably the better thing to do is to recommend to the FDA
6 that they develop something that meets the United States'
7 standards requirements, which may or may not be in harmony
8 with the international standard, but not to wait for another
9 two years to move forward.

10 MS. FAHY-ELWOOD: I would just comment that I
11 understand it has been a long time for this rulemaking, but
12 as one of your objectives for that to be harmonization, and
13 then to not wait maybe another year or so to ensure there is
14 harmonization across the board, I think, you know, I think
15 it would be a shame - after waiting all this time, maybe not
16 waiting another year.

17 MR. FLETCHER: I am going to limit final comments
18 to two, and then we need to either vote yea or nay on this.

19 Dr. Lotz and Cass, and then we are going to vote.

20 DR. LOTZ: I had a question about your comments
21 about the classification, not the difference, but would you
22 rather see, if the IEC were to adopt their current proposal
23 for classification, would you rather see the FDA go to that
24 in the interest of harmonization or stay with the other
25 regardless? Clearly, there is a difference. What were you

1 saying about that difference, do we need to be harmonized or
2 do we need to stay the course with the FDA proposal?

3 MS. FAHY-ELWOOD: I think that the IEC
4 classification scheme, from what I know about it, is the
5 more realistic classification scheme as far as giving people
6 an idea--you know, the idea of classification is to let
7 people know, you know, this broad category of lasers has
8 this potential danger, and so the IEC classification scheme,
9 my understanding is that it does a better job of that, and
10 so that would probably be a better classification scheme for
11 the United States. That is my understanding of it. Maybe
12 people have a different understanding of it.

13 MR. FLETCHER: Final comment from Cass.

14 MS. KAUFMAN: I generally agree with what Jerry
15 had said, again, going back to my original statement that I
16 think maybe we just need to take a leadership position on
17 this, and I guess what concerns me is that it so often works
18 out where we think it is only going to be one year, and then
19 a year goes by, and, well, we think maybe it is only going
20 to be one more year after that, and the next thing you know,
21 another five years have gone by.

22 So, I would like to see us just move on forward.
23 I certainly feel it prudent to wait another month or two and
24 kind of see the direction that IEC is going in, but
25 thereafter I think we pretty much need to do what we think

1 needs to be done.

2 MR. FLETCHER: We are now going to vote on the
3 motion, which essentially is that the FDA stand firm, but
4 hold off on the laser amendment at least until November when
5 they can see what the comments are that the IEC has, and
6 provided those comments are minimal, to move ahead with
7 their own amendments.

8 That is essentially what I got out of the
9 discussion.

10 All in favor say aye.

11 [Ayes.]

12 MR. FLETCHER: All opposed say no.

13 [Chorus of no's.]

14 MR. FLETCHER: Okay. The motion dies.

15 Now, what are we giving to the FDA?

16 MS. KAUFMAN: Can we do another roll on that? I
17 only heard one name.

18 MR. FLETCHER: I didn't hear any ayes. I didn't
19 hear any ayes, I heard all no's. That is the motion.

20 We have to move on, on the schedule. We have
21 another open discussion. I am reluctant to reopen anything.

22 MS. KAUFMAN: Just have a hand vote just to make
23 sure, though.

24 MR. FLETCHER: Okay. We will do a hand vote.

25 All in favor of this motion, please raise your

1 hand.

2 [Show of hands.]

3 MR. FLETCHER: I see five.

4 It is the motion that Dennis originally made that
5 people kept commenting on, about giving the FDA guidance on
6 how to proceed on the amendment, to wait at least until the
7 IEC receives their comments, and provided these comments
8 don't have--I don't really know how to put it--but aren't of
9 the significance to really cause us to question our own
10 amendments, to proceed as quickly as possible.

11 That is my understanding of the discussion.

12 Okay. Now, I will ask again.

13 All those in favor please raise your hand.

14 [Show of hands.]

15 MR. FLETCHER: Eight.

16 All those opposed?

17 [Show of hands.]

18 MR. FLETCHER: Three. Okay. The ayes have it. I
19 don't know where they were when I called for it before, but
20 the ayes have it.

21 We will now move on to our next item on the
22 agenda, and I thank the committee for this period of
23 discussion. I think it was very good.

24 We will now have a presentation on CDRH Radiation
25 Program Reengineering by Joanne Barron from the FDA.

1 **CDRH Radiation Program Reengineering**

2 MS. BARRON: I am going to give you a short
3 update. Hopefully, I can get you closer back on schedule.

4 [Slide.]

5 For those of you who were not here last year, I
6 will give you a little bit of background, so you understand
7 what this is about.

8 [Slide.]

9 We started reengineering because our resources had
10 declined so much that we were having difficulty finding all
11 the pieces of the program, and therefore, trying to figure
12 out whether we wanted to keep some of the processes or
13 reengineer them or do something else.

14 The management was particularly concerned that we
15 had lost the coordination across the center and that we
16 weren't documenting things that we had already resolved, so
17 we were going back and doing things again.

18 The team itself was concerned about new
19 technologies, that we weren't getting to them, and that
20 there was a priority balance issue in the center between the
21 medical device issues and the radiation issues.

22 From the reengineering principles, basically, we
23 keep asking the question should somebody else be doing it,
24 and so we are looking at partnerships and leveraging, and
25 what happens if we stop, are there certain parts that if we

1 just stop doing it, would someone else pick it up or would
2 anybody even miss it.

3 [Slide.]

4 Dr. Feigal talked to you a little bit about our
5 resource picture. This is basically how it worked.

6 [Slide.]

7 Just to give you a perspective, we are talking
8 about original equipment production running about \$75
9 billion for consumer products, 52 billion for industrial
10 products, and the original component equipment for medical
11 devices running about 17 billion. That is not counting the
12 systems, nor the assemblers, nor the refurbishers, nor all
13 the rest of the group.

14 [Slide.]

15 In reengineering, we are following a business
16 process improvement methodology. We have worked at
17 understanding the customer, understanding the process,
18 assessing those processes, and we are now at the stage of
19 improving, so we are looking at benchmarking, who is doing
20 things that are better than what we are doing, see if we can
21 model what they are doing, or looking for just a complete
22 reengineering, if we can throw out some and start all over,
23 we are looking at that option, as well.

24 [Slide.]

25 We went to many stakeholders in various venues,

1 questionnaires, and so forth, and these are the bottom line
2 of the kinds of comments that we are getting from the user
3 perspective, the health professionals and the consumers.

4 Their biggest issues are that we maximize benefit
5 and risk for that particular use, that we provide guidelines
6 for use and manufacturing, that the consumers have some way
7 of knowing how to balance that risk, what kind of
8 perspective to put on it, consistent messages, of course,
9 and input into the process.

10 From the industry and academia, their issues are a
11 little bit different, but not a whole lot different, of
12 course, looking for reliable data and analysis, and I think
13 that is a pretty good indicator of where they want the
14 center to be as a leader. Appropriate regulatory burden,
15 communication issues, of course.

16 The one that is interesting is down at the bottom,
17 test methodology, came out higher from the stakeholder
18 questionnaire than we expected it to be, and it turns out it
19 is because there are not too many other organizations that
20 do that kind of work, so they are looking to us to do that,
21 some of the dosimetry in particular.

22 [Slide.]

23 From this group right here, this is a summary of
24 what I heard last year, that we provide national uniformity
25 and consistency, and this is mostly so the states can be

1 able to follow, that we conduct in-depth radiation
2 characterizations of products, again, so that people can
3 build on that, they need what these things are emitting, so
4 then we can go out and do research or whatever; that we
5 analyze trends, and this is where we are having a big
6 problem, we have lost that expertise, and we have lost the
7 processes to even be able to do this; that we give those
8 characterizations and trends to the states, so that they can
9 do some follow-up work and add onto what we are doing; that
10 we provide training to the states and to industry and to
11 third parties, and we used to have a big training operation
12 at the center, and have lost that, so people are asking that
13 as part of that leadership role develops again, that we
14 consider putting that back in.

15 And this is not the only group, TEPRSSC was not
16 the only group that made that comment. The other
17 interesting one that came out of this group last year was
18 that instead of collecting paper from the industry, that we
19 consider other methods, such as conferencing to get that
20 data, so that is one of the things that I really haven't
21 explored a whole lot yet, but I think that is something we
22 are interested in.

23 [Slide.]

24 In terms of maintaining expertise, because most of
25 the folks are eligible to retire, we have had very few hires

1 in this program for probably 15 or 18 years. These were the
2 kinds of suggestions again that we got from this group -
3 bioeffects analysis rather than actually doing research,
4 that we kind of direct the research of others; that we keep
5 up with new technologies, that we use focused panels of
6 experts, this group, and similar things to the National
7 Academy of Sciences, and that we again provide training, but
8 in this case, to multiplier groups, in other words, get
9 other people to do the continuing training.

10 [Slide.]

11 We asked a lot of other stakeholders what they
12 were interested in, and basically, it comes down to
13 communication in the first two, knowing what the exposures
14 are in the second group, that we look at electronic exchange
15 of data, both the industry to us and amongst FDA.

16 We don't share our data very well from our field
17 force to our headquarters, and so forth; that we actively
18 work on standards. We have got standards that are very old
19 and need amending, and the consensus process that we need to
20 financially support that. And then that we have a risk base
21 process for allocating our resources.

22 [Slide.]

23 We went through and did some mapping of the major
24 processes. We determined there were 28 major processes
25 within the center that were still ongoing, and we decided

1 that we needed to fit them within some kind of functional
2 model rather than tools.

3 [Slide.]

4 We tend to look at product testing as what the law
5 says to do or the law says to collect reports from the
6 industry. Those are all tools, and we wanted to make sure
7 that we were looking at our processes from a functionality
8 point of view.

9 This was the model that was decided upon for the
10 medical device reengineering, and we just decided to adopt
11 it. It turned out that it didn't matter as long as it was
12 some kind of functional model.

13 [Slide.]

14 So, we looked at those and came up with the
15 relationships in the radiation program and the resources
16 that were being allocated to those particular sections.
17 Part of what we want to do is to figure out if some of these
18 boxes need to be different sizes - are we putting the
19 resources in the wrong box.

20 You will notice that disseminating information is
21 running at about 7 FTEs. That is person years in government
22 lingo. Policing conformance, the legal actions, the recalls
23 of products is running very low, about 3 FTEs, and we don't
24 think that is insufficient.

25 When we looked at those processes, they were very

1 good, they were consistent, they were being utilized across
2 the board, and they are working. We are primarily getting
3 voluntary compliance from the industry, so that we didn't
4 see a need to make a change there, but the others all had
5 issues.

6 [Slide.]

7 When we looked at the individual processes, trying
8 to figure out what was wrong, where the gaps are, these were
9 the issues that came up. We don't have consistent criteria
10 for when we do product testing or how we do product testing
11 or which products are included, and so forth, or how old are
12 the products. We thought that something needed to be done
13 in that area.

14 The processes have conflicts in whether we are
15 being proactive or reactive, and that caused some
16 inconsistencies. We found that trend analysis was literally
17 not being done. It is an area that we have got data, we
18 have got information, and except for the next data that is
19 being done, it essentially doesn't exist.

20 We have difficulty knowing who the people are who
21 have the expertise. When we trying to shuffle resources and
22 figure out how to restaff the program, we have got to figure
23 out what we have got, and we are having difficulty doing
24 that.

25 Our database management is old. It's in dire need

1 of revamping, so that is an issue. The reports that come in
2 from industry, we are having difficulty managing the volume
3 of reports, and we are having difficulty keeping up with the
4 reviews. We always have backlogs.

5 We are not looking at new technologies, we are not
6 looking at combined technologies, that is, the intended use
7 changed or they have taken two technologies and put them
8 together, and now it does a third application, and we have
9 got some difficulties with that.

10 We have lost our direction on setting research
11 priority.

12 [Slide.]

13 All of those, we think need to have some
14 reengineering done on them, but we decided that that was
15 going to be phase two of this particular project, because we
16 thought that there were so many cross-cutting issues that we
17 needed to deal with first. We needed to put the foundations
18 back on the program.

19 So, we looked at if we had an ideal program and we
20 had ideal functional processes, what would we need.

21 [Slide.]

22 Basically, we want safe products going on the
23 market, we want unsafe products coming off the market. We
24 want products that do what they say they are going to do,
25 they are effective, and that they do something that has a

1 benefit. That's the effectiveness.

2 We also, because the law is different from so many
3 that FDA deals with, look at the efficacious use conditions,
4 that is, that the health practitioner knows what they are
5 doing, knows how to use the product, and that they are
6 actually using it that way, and that requires education.

7 So, with those in mind, we wanted to look at how
8 would we put together an ideal program.

9 [Slide.]

10 We started out with a vision statement, and this
11 is tentative, but at least it is getting everybody talking.
12 The concept is we have become a leader again, we get back
13 into that role, that it be for national radiation control,
14 which is basically straight out of the law, to protect and
15 promote the public health.

16 This law's intent is to control exposures. It
17 turns out that the source of those exposures is from
18 electronic products that emit radiation. So, we are not
19 trying to control the product, we are trying to control the
20 exposures, but from the product, the source, rather than how
21 it is necessarily used. That would be one thing we would
22 take into consideration, but not what we are trying to do.

23 Again, that is a difficult issue for FDA to deal
24 with because they are so used to dealing with assuring
25 safety and effectiveness of a particular product, whether it

1 is a drug or a medical device or even the foods in our
2 supply.

3 [Slide.]

4 The basic gaps when we looked at the entire
5 system, these 28 major processes, was that we needed to do
6 some drastic changing in the management of this program,
7 that it needs to be centralized and dedicated.

8 We need resources that match what we are trying to
9 do, and sometimes the resources are a little bit skewed and
10 sometimes there just aren't enough resources to go around.

11 We found out that we don't know enough about what
12 is going on in the outside world. The electronic products
13 are exploding and new technologies, and we are not keeping
14 up, and if we are going to do our job, we have got to get
15 back on track with that, and we need prioritization.

16 [Slide.]

17 So, we came up with a group of the initial pilot
18 ideas. Now, remember I said this is foundational. There
19 was a list of all the problems with the individual
20 processes, but we looked the whole first, and so these are
21 the pilot ideas that we have come up with.

22 The first one we are calling a skinny rabbit
23 because we think we can implement this pretty easily, and it
24 is something that is not very drastically wrong anyway.
25 It's a quick fix, something that we can do. Unfortunately,

1 it turns out we have got to go to our attorneys to be able
2 to get this to work, so until we get our attorneys' blessing
3 on this, it is going to be difficult.

4 The concept that we get nonconforming products
5 corrected by the industry in an even quicker method than we
6 are doing now, and basically, it is to let us take advantage
7 of that voluntary correction that we get from the industry.

8 If we get voluntary correction with 98 percent of
9 our industry, then, why not do it in a simpler fashion, so
10 that is the concept behind this, and then all we would have
11 to do is maintain a tickler system that if they didn't
12 correct, then, we would go through the official procedures.

13 [Slide.]

14 The first full-fledged pilot that we would like to
15 implement is one on information surveillance and exchange,
16 and this gets at the problem of not knowing enough about the
17 product performance, exposures, and risks, in other words,
18 to get up to speed on what is going on in the world.

19 We would have to determine what kinds of
20 information we need that would define the product
21 performance and exposures. We would have to find where that
22 information is available, and then figure out do we actually
23 collect it or do we just use somebody else's database or
24 what, how do we deal with that.

25 We think we have got the availability of a lot of

1 partners to help us with this one. We think states have got
2 information, and we think other federal agencies have got
3 information, and we are sure the industry has got
4 information, that if we put our heads together and found a
5 system that would work, we could solve a lot of problems,
6 and that is why this one is so foundational.

7 The problem then would be how do we exchange all
8 that data, and our biggest problem we thought was to start
9 within our center. So, we want to reestablish the
10 connections within the center for exchanging data.

11 So, we have got the idea. Now, nothing is set in
12 concrete, these are still ideas, that we would have an
13 information council within the center that would meet on a
14 regular basis. They would develop an expertise list, so we
15 would find where that expertise is across the center.

16 They would find out who our stakeholders, our
17 participants would be to help us, and that they would
18 actually work on a particular product, that is, pick a
19 product and actually go through the motions of figuring out
20 how we would collect the information, how we would share it,
21 and so forth.

22 [Slide.]

23 Basically, they would be the information gatherers
24 and the information analyzers, and then to make sure if it
25 was disseminated, how it was going to be disseminated.

1 They would also, in the outputs here, you would
2 see recommendations to the managers, and any reports or
3 responses to something, for example, if this committee had
4 asked for a particular piece of information, and we didn't
5 have it, this group would be the one responsible to go find
6 it and report back.

7 [Slide.]

8 The second one is prioritization. The entire
9 center has struggled with this, not only for radiation
10 control, but for medical devices, and there are lots of
11 models out there. We have looked at several. We need to
12 look at several more. But the concept is that we want to
13 prioritize which products we look at, which issues of those
14 products do we really need to tackle first, and which
15 processes need to be prioritized.

16 As we have found over the years, some product
17 areas are better managed with, say, product testing and
18 report reviews from the manufacturers, and another product
19 area may be managed better through inspections of the firm
20 and, oh, I don't know, telephone calls.

21 Each area seems to have its best method, and that
22 is one of the things we want to look at is to make sure our
23 prioritization is getting to that issue, as well.

24 We want to make sure that if we put things at a
25 low priority, that we are not impacting something adversely.

1 The point of prioritizing is to allow a method of saying we
2 only have enough resources to cover the top 10 on the list,
3 and everything else has to wait until we get rid of the
4 first two or three, but even so, even putting something on a
5 wait list rather than never getting to it may have an
6 adverse impact we would have to look at, and we want a
7 method to update this from time to time.

8 [Slide.]

9 We want to make sure that we are going to look at
10 ionizing and non-ionizing products. We have an idea that
11 what we could do is put together a panel of seven people,
12 called the evaluators, and they would go through a consensus
13 process of determining how the products would all into these
14 categories.

15 The concept would be a decision tree followed by a
16 matrix, followed by a decision tree. So, you could do
17 something very, very quickly with a simple decision tree,
18 and then only the complex ones would actually go through
19 some kind of a full-blown model for a matrix of priorities.

20 [Slide.]

21 The other option, of course, is to stop, that if
22 it is so drastic that we know we have to do something, you
23 don't go through the prioritization, you just go do it, or
24 it is so nonsensical, you just put it on the bottom of the
25 list.

1 [Slide.]

2 The third pilot idea is what we are calling policy
3 response to emerging issues. The concept here is that we
4 can get more of our stakeholders to participate with us if
5 they know what our decision criteria is, it is visible, it
6 is repeatable, and it is updated as we go.

7 [Slide.]

8 If we have a system for keeping track of new
9 issues that need response, how we would handle that, who
10 within the center would deal with it, do we need decisions
11 to be made or is it something that is routine and already
12 been done before.

13 Sometimes capturing the "what we have done before"
14 and just making it a model will take care of a lot of
15 problems, and then we can put our resources into dealing
16 with the new issues.

17 [Slide.]

18 The concept here is that we would have some
19 gatekeepers, one at the center level and one at each of the
20 offices. This group would form a council that would make
21 sure that they were being consistent, but they would have
22 developed or they would develop a set of canned procedures
23 and canned responses to take care of the routine stuff, and
24 that would allow the managers and the scientific staff to be
25 able to handle the ones through what we are calling a multi-

1 office, ad-hoc process of resolving issues and actually
2 developing policy.

3 [Slide.]

4 They would take the prioritization process or the
5 hazard, and take that into consideration along with what we
6 are calling heat, that is, political pressure or the outrage
7 from the outside world, the consumers or health
8 professionals, whatever, and also, in this process, having
9 the decision based on whether we have sufficient
10 information. Sometimes not having information stymies us,
11 but this process would make sure that even when we don't
12 have information, we have got a process that can go through.

13 [Slide.]

14 The fourth pilot didn't turn out to be a pilot, it
15 was just an outflow of the various process inconsistencies
16 that we found, but we mentioned to the managers that we were
17 having some difficulties with getting this program back on
18 track, and we needed their help.

19 So, basically, as Dr. Feigal mentioned this
20 morning, they have started what they are calling the
21 radiological health council made up the deputy office
22 directors, and they basically have already started this
23 pilot. So, this one is not just ideas, this one has
24 actually started.

25 They have decided that they are going to take on a

1 very active role. They will take over the oversight
2 concerns of this committee. They will be the contact for
3 liaison with CRCPD, the Conference of Radiation Control
4 Program Directorate, and they are going to be the central
5 place for making sure that policies get resolved and defined
6 within the center in this area.

7 So, this is going to be exciting. I am looking
8 forward to this one actually working.

9 [Slide.]

10 When we were trying to develop some metrics for
11 these new pilots, we wanted a baseline measure before we
12 implement anything so we can see if any of the pilots
13 actually make improvement.

14 We went around to our office directors and asked
15 them what do they need to be able to manage the program.
16 Some of the things they came up with were that we need a
17 balance between the perspective of the outside world and the
18 realities of what is a detriment, what is a problem
19 exposure, what is a problem use and so forth, and that we
20 need to sell our role.

21 People don't know who we are, what we do, where we
22 are or anything and we need to make sure that that gets
23 resolved. Then we can get good partnerships and they will
24 better be able to manage the program. So this is kind of
25 making sure that the outside world and we are connected,

1 that we be able to measure and evaluate health effects, that
2 we have priorities and we do trends analysis and that we
3 share that knowledge, providing training mostly to our own
4 selves as well as the outside world and that we have some
5 kind of feedback, a quality system that gets things working.

6 So you can see the managers didn't disagree with
7 most of what we got from the various stakeholders.

8 [Slide.]

9 Our time line; we have done the planning for these
10 pilots. We are in the process of developing them. These
11 ideas are going to be taken to a workshop that we are hoping
12 to have the latter part of October that will actually
13 develop the concepts more fully with these pilots and, I
14 suspect there will be more.

15 I think when the industry gets a chance to take a
16 look at these processes, they are going to say, "I want
17 electronic filing or I want less reporting," or whatever.
18 So I suspect there are going to be more pilots than these.
19 If you remember from the list of problems, the key findings
20 from those processes, I suspect a lot of those are going to
21 trigger some ideas.

22 Thank you, Mr. Chairman. I will take questions.

23 MR. FLETCHER: Any questions?

24 MS. KAUFMAN: You were talking about the policing
25 part role. I think the total FTEs were, like, 66 or 67 and

1 only three FTEs were on the policing part. And then you
2 mentioned that voluntary compliance seemed to be working. I
3 guess I wanted some understanding of how you came to that
4 conclusion without policing.

5 In other words, if you are not looking at these
6 folks, what makes you think they are in compliance? How did
7 you determine that?

8 MS. BARRON: The assessment of conformance is one
9 of the largest boxes in there. And that is where we do the
10 checking to see if people are complying. We will do product
11 testing. We will do report reviews. We will do
12 inspections. We will do data from the industry, however we
13 can get it. And that assessment is what is telling us do
14 they comply or don't they.

15 The policing is simply the enforcement of going to
16 them and saying, "You did something wrong. Now, recall the
17 product," or, "You did something wrong and you are not
18 fixing it, therefore, we are taking you to court." So those
19 legal actions are the ones that are in that policing.

20 MS. KAUFMAN: So policing does not include
21 inspections.

22 MS. BARRON: Correct.

23 MR. FLETCHER: Any other questions by the
24 committee?

25 DR. LIPOTI: You mentioned that your vision was to

1 have FDA lead the National Radiation Control Program to
2 protect and promote public health. And then you mentioned
3 that one of the pilots was a management pilot, No. 4, the
4 management pilot, and had a radiation council. I would like
5 to suggest to you that you take a more leadership role on
6 the Interagency Steering Committee for Radiation Standards,
7 ISCORS, because that group is to coordinate all of the
8 federal agencies that are involved in radiation control.

9 Up until now, I have not seen FDA take a
10 leadership role, but that is one place where you could make
11 a difference. Perhaps one of the members of this radiation
12 council might participate in ISCORS and determine its value.

13 MS. BARRON: Thank you. That is a good comment.

14 MR. FLETCHER: Thank you very much.

15 Our next presenter is going to give us a
16 presentation on an update on medical telemetry, Mr. Witters.

17 **Update on Medical Telemetry**

18 MR. WITTERS: Good afternoon, Mr. Chairman and
19 members of the committee.

20 [Slide.]

21 I don't know if any if you remember the
22 presentation I made last year, but how many of you actually
23 recall what electromagnetic compatibility really is. Not
24 many. Okay. Let me go through this as quickly as I can.
25 It shouldn't be very long.

1 [Slide.]

2 But I want to make sure that at least the message
3 that I am bringing you today which is to follow up on what
4 we did last year is that electromagnetic interference with
5 medical telemetry, specifically wireless medical telemetry,
6 is going to challenge these devices from now into the future
7 as devices get more into using wireless communication.

8 But, with communication cooperation with other
9 agencies, manufacturers, users, as you will see as I go
10 through, this is improving. We are making strides. I will
11 explain a number of these things. This ultimately reduces
12 the risk to the people that interference can lead to.

13 [Slide.]

14 The world that we are subjecting medical devices
15 to is become more populated with sources of electromagnetic
16 energy; radios, computers, radars, cell phones. I don't
17 know if any of you have cell phones today but, certainly,
18 they do put out signals that can interfere with medical
19 devices. The power quality is a large concern.

20 Lightning, which we will certainly see with the
21 storm coming through, does have problematic implications for
22 many medical devices. The medical devices that we are
23 talking about are central to things like heart monitoring,
24 physiological monitoring, and send these signals via the air
25 waves to a central processing station.

1 [Slide.]

2 What I am going to go over today, and my real
3 purpose, is to update the TEPRSSC committee on what has
4 happened in this area since we met last September. Several
5 things are well underway to helping this situation. The
6 problems and concerns that we have center around
7 interference with the new digital t.v. and the mobile radio
8 service.

9 These are changing and these changes are coming
10 about because we have been working with several interested
11 parties here. I will also go over the proposals for the new
12 spectrum. These are the proposals that are before the FCC
13 right now. The closed period for the comments is actually
14 tomorrow, but we are in the process of getting our comments
15 into that, too and the actions that we have taken in regard
16 to this.

17 Under tab 7 you will see much of the information
18 that has been developed as a result of work in this area.
19 You will see the FCC Notice of Proposed Rulemaking which is
20 out now, the FDA letters to the users, our letter from Dr.
21 Jacobson to FCC supporting the recommendations that were
22 made by the American Hospital Association Task Group on
23 telemetry and those recommendations in detail which I
24 encourage you to look at closer because you will understand
25 more about the concerns and types of efforts that are being

1 made to deal with these concerns.

2 [Slide.]

3 Just to give you a little bit of background so we
4 are all at least familiar with the basis, wireless medical
5 telemetry is basically a device connected to the patient,
6 usually measuring and monitoring heart rate, respiration,
7 other physiological measures.

8 This is the wireless link. It is a radiofrequency
9 transmission back to a central unit where a clinician is
10 monitoring a patient. Usually, these are on step-down units
11 monitoring, in many cases, heart patients.

12 They work primarily in two areas but not all of
13 them are in this area. And they work on a secondary basis.
14 In the FCC's grand scheme of things, medical telemetry has
15 not really met the criteria to become separately licensed or
16 really primary users of the spectrum. They are relegated to
17 secondary users.

18 This means that if they are interfered with, they
19 have to deal with it. If they cause interference to the
20 licensed users, then it is medical telemetry's problem to do
21 something to change that. They are now operating, and have
22 been for many years, on vacant t.v. channels or the mobile
23 radio services.

24 About 60 percent of them are operating in the
25 mobile radio service and about 40 percent in t.v. channels

1 but there are a few in the industrial, scientific and
2 medical bands that are around--not many, but they are there.
3 And, as I said, the users of these are really secondary.
4 This is part of the problem. They don't have any real right
5 to use the airwaves up to this point up until the
6 regulations are changed by FCC.

7 [Slide.]

8 Just to give you an idea, the spectrum that is
9 used for sending information, communications, is very
10 crowded. It has many things; television, both UHF and VHF.
11 It has mobile radio services which are down just between
12 these two, in some cases, emergency radios for police, fire,
13 emergency ambulances. Radar, cell phones are actually in
14 two or three places.

15 You have microwave ovens, fm radios, very crowded.
16 This is just a very simple view of that. The Mobile Radio
17 Service, which operates from 450 to 470 megahertz is
18 undergoing dramatic changes now because of the demand for
19 spectrum and use by mobile radio users. These are the
20 taxicab dispatchers, the business users that do get licensed
21 for using channels.

22 At this point in time, medical telemetry is
23 relegated to a secondary status. It is between these
24 channels in a low-power mode. The changes that are being
25 proposed to go over to digital radio which would allow a

1 larger of users would, basically, preclude much of the
2 medical telemetry from use in that band if there is one of
3 these mobile users nearby. And it is likely in urban
4 settings that that will happen.

5 Also, in the t.v. bands, as I mentioned, unvacant
6 television channels are available to telemetry and, for many
7 years, have been used. Who has heard of digital t.v.?
8 Digital t.v. now is coming on-line. It has since last
9 March. The first one that came on caused a problem. I will
10 talk to that in a second but, basically, analogue and
11 digital t.v.s are working now hand-in-hand.

12 Television stations now have an analogue channel
13 that they are allowed to broadcast on and a digital channel.
14 So that means two channels where there previously was one,
15 consequently less vacant channels and less for the medical
16 telemetry to use.

17 [Slide.]

18 Let me go into what we have seen as a problem in
19 this area because this actually happened last year and,
20 actually, again this year, unfortunately. The first
21 digital-t.v. broadcast to come on in the country was in
22 Dallas last March. They began testing and immediately
23 affected two hospitals in the Dallas region a mile or more
24 away.

25 The nature of the digital t.v. signal basically

1 takes up the whole channel. There is no room for any other
2 broadcast in that channel. The old analogue t.v. signals
3 didn't take up quite the whole channel but still had some
4 overflow and, consequently, all analogue t.v. channels, no
5 matter what they look like on your dial, are really spaced
6 at least one channel apart in their frequency use.

7 That is where the telemetry was working very
8 happily until last year. In Dallas, this television station
9 began broadcasting and, because of that, basically took a
10 vacant channel that the telemetry was operating on for a
11 number of years and took down that whole unit in two
12 hospitals, over 50 patients, as we understand it.

13 Fortunately, no patient was hurt. Fortunately, no
14 patient suffered a heart attack during this period of time.
15 The clinical people got them back on wire telemetry very
16 quickly and were able to make the appropriate adjustments,
17 call the t.v. station when they recognized this and dealt
18 with it that way.

19 But one hospital changed out its complete system
20 which cost several hundred thousand dollars. The other
21 hospital had to make adjustments to equipment which was
22 rather expensive, also.

23 We learned about that and, very quickly, worked
24 with the FCC and the hospital involved, the two hospitals
25 involved. We wrote a public-health advisory. You had that

1 in your brochure last year. If you need copies, I have an
2 original I can have copied.

3 We also have sent letters to the device
4 manufacturers and talked to many of the larger ones about
5 this. FCC contacted the broadcasters directly, asked them
6 to make sure that before they go on with their new digital
7 t.v. that they coordinate with hospitals and clinics in
8 their area. They also worked with device manufacturers to
9 see where they were, what was going on. But, even to this
10 day, we still don't have a good picture of what telemetry is
11 working and what frequencies, and we are working on that
12 through the AHA and the manufacturers to get a better
13 picture.

14 They also have information on their website which
15 we were coordinated with and a joint statement. However,
16 even with all of this, we thought that this was relatively
17 taken care of. Unfortunately, we learned that in July, in
18 Miami, when another d.t.v station began broadcasting, it did
19 the same thing at at least two hospitals that were ten or
20 more miles away.

21 Unfortunately, though, it appears that this was
22 something that was really a mixup in communication. The
23 television station took great pains to notify the hospitals.
24 The hospitals, unfortunately, didn't get the word down to
25 where it needed to get to in one case and, in the other

1 case, they mistakenly thought that they were able to change
2 frequencies, but it was only within the t.v. station that
3 they were operating on so that did little good.

4 FCC investigated that and some adjustments have
5 been made. That is the only other incident that we are
6 aware of.

7 [Slide.]

8 Let me talk a little bit about the concerns and
9 how they are being addressed right now and have been since
10 last year. I mentioned the crowding and competition for the
11 spectrum. I mentioned about the d.t.v and the incidences
12 involved and what has been going on but let me just take a
13 second and mention that there is such competition in the
14 public-land mobile, the mobile radio service now, that the
15 users of that, the commercial users, are really far past the
16 point that they need more channels. They have backup people
17 who are waiting for channels in many urban settings so there
18 is quite a push from that direction to get some solution to
19 this problem.

20 We have been working with the American Hospital
21 Association Telemetry Task Group. This is a group that the
22 American Hospital Association gathered together. We
23 suggested, and have been working with them directly, to
24 develop recommendations and put these forth to the FCC and
25 the appropriate parties.

1 This includes FDA, FCC, the manufacturers, users
2 from the AHA. These are hospital users which includes the
3 VA and a number of other organizations and we have developed
4 recommendations, that you will find again, in your tab 7, in
5 four areas. First and foremost, to many of the clinical
6 users, is to educate people like clinicians about the
7 concerns and the problems that they might see and,
8 hopefully, avoid.

9 Second was to look at the use of the actual
10 telemetry in hospitals now. What is it used for? How many
11 patients? How many leads? How many things is it measuring,
12 not only now but what the use will be in the future.

13 The third group was looking at developing a real
14 definition that the FCC particularly needs to develop its
15 regulation. What is wireless medical telemetry?

16 The fourth group was looking at specifically
17 recommendations for frequency spectra. Candidates were
18 developed and solicited from the FCC and an exhaustive
19 analysis was done of these various frequency options to come
20 up with what would be the best for at least the purposes of
21 the medical telemetry.

22 This is short term. It goes not very far, a
23 couple hundred yards at the most. It is not meant to be
24 high powered. It is meant to be low power, very clearly, so
25 that if a patient did have a problem and you needed to get

1 to them, you could do that. They are not going to be
2 wandering a mile away. It is usually within the ward or
3 somewhere close.

4 As a use of the recommendations, they were sent
5 earlier this year to the FCC who developed a notice for
6 proposed rulemaking which is their process for regulatory
7 process to get new regulations and change what they do.

8 These, really, are based primarily on the
9 recommendations that the American Hospital Association gave
10 them. There are some changes. We are in the process of
11 commenting with the AHA on the recommendations and they were
12 soliciting comments about various parts of this. But,
13 primarily, it goes into recommending new spectrum and a new
14 wireless medical-telemetry service.

15 This is new in this country. This is the first
16 time it has ever been done for medical and we think this is
17 a leap forward for the medical industry to reduce that EMI
18 risk that patients can be part to. We have also contacted
19 the medical-device manufacturers, kept them abreast. You
20 will see in your package three letters that have been sent
21 just this year and a little late last year to keep
22 manufacturers up to date and encourage them to participate
23 in both the AHA Task Group and with comments to the FCC so
24 that they are part of the process and encouraged to be as
25 much part of the process as possible.

1 [Slide.]

2 Let me mention a few things that we have done a
3 little bit more specifically. I mentioned the letters. We
4 have also made a great deal of effort in developing public
5 forums that we can discuss this with manufacturers, with
6 users, with any other interested parties. We, at the
7 Association for the Advancement of Medical Instrumentation
8 annual conference in Boston in June had two sessions.

9 One was presentations by people on the task group
10 from AHA and the other was a panel discussion of this. We
11 had a very lively and full group and there was a lot of
12 positive feedback, especially from some of the designers and
13 manufacturers. They wanted to understand what was going on
14 and become part of the process and that really was what we
15 were searching for.

16 Also, as recent as last month, at the
17 International Union of Radio Scientists at their general
18 congress held in Toronto, I co-chaired a session and I
19 organized it. It did deal with medical telemetry in an area
20 that is mostly of scientists and engineers working with
21 radio signals and electromagnetic interference and
22 compatibility.

23 I mentioned a letter to FCC. We also are
24 developing a guidance for the manufacturers and reviewers to
25 help them and encourage them to make the change in migration

1 to the new frequencies. This we see, and most of the
2 manufacturers seem to agree with this, as a vast improvement
3 to help reduce the risk of interference from various sources
4 around for wireless medical telemetry and, actually, a very
5 large opportunity for them to make a new spectrum with new
6 uses and, perhaps, enlarge those uses that are being made of
7 this already.

8 [Slide.]

9 Let me get into a little bit more specifically
10 about the FCC proposal. I just am summarizing a few of the
11 major points here. The definition that they are
12 recommending, and this is really for their regulatory
13 purposes, but it helps, us, too, so we can come to a sort of
14 consensus on what this really is.

15 It is essentially the measurement and recording of
16 patient information, generally physiological information,
17 both one directly and, potentially, two directions using RF
18 signals. In the future and, in some cases, in development
19 now, is a bidirectional type of system where you are not
20 only recording information but, perhaps, delivering therapy.

21 These are all possible with the new spectrum. The
22 proposal for the actual spectrum is 608 to 614 megahertz,
23 Channel 37. Channel 37 is available to telemetry on a
24 secondary basis now, but they generally don't encourage it
25 because this is set aside across the country for

1 radioastronomy. It is basically clear all the way across
2 the country.

3 Radioastronomers have been coordinated with and,
4 in general, agree that this is something that they could
5 live with, that they could cooperate with, on a co-primary
6 channel. Since medical telemetry is low power, most of the
7 big radiotelescopes are in isolated areas and away from
8 urban areas and probably won't be affected too much and,
9 generally, they are pointing up to the sky and not to the
10 horizon. But not in all cases.

11 The other part of the spectrum is 1395 to
12 1400 megahertz and 1429 and 1432, or 1391 to 1400. The
13 American Hospital Association Task Group looked at what was
14 needed and, right now, there is a need for at least
15 6 megahertz--that is a full t.v. channel--because hospital
16 facilities can be, in urban areas, very close to each other.

17 In the Boston area, there are three major
18 hospitals within a mile or so, that do have this kind of
19 equipment. They can be, potentially, interfering with each
20 other.

21 Also, looking at the future, they estimated that,
22 at least in the immediate future, the next five to ten
23 years, they could need as much as twice that, perhaps 12 to
24 14 megahertz worth of spectrum. Both of these give at least
25 12 megahertz worth. The advantage of dividing it up, for

1 the bidirectional, is it is generally the case that systems
2 are designed with one frequency spectrum used to go one way
3 and another used to go the other way.

4 You don't have to have it that way, but some of
5 the manufacturers have thought that this would be a little
6 bit more advantageous.

7 It would be licensed by rule. That means,
8 basically, that you do not have to have an individual
9 license. You, the hospital, may want to be registered but
10 you wouldn't necessarily have to have a license for each
11 individual telemetry unit. They are also designating it,
12 FCC, now, as something that would be necessarily in a
13 24-hour healthcare facility, not in these very short-term
14 facilities or outpatient clinics but basically where people
15 can take care of the patients and the equipment, if
16 necessary, can be dealt with on an immediate basis.

17 They also have a key point of having a frequency
18 coordinator. At this point in time, as I mentioned, many
19 hospitals are not really aware of what frequencies they are
20 using for this telemetry. Some of them are, but most of
21 them are really not. They buy equipment. They have it set
22 up by the manufacturer. They use it.

23 The frequency coordinator's job would be to
24 collect and disseminate information in a database, who has
25 what equipment and where is it located, provide early

1 warnings for potential conflicts, coordinate with the users
2 in those geographic areas and continue to monitor the
3 situation as best they can and provide information to
4 whoever is needing it in those areas.

5 This also becomes particularly important because
6 these higher frequencies are, right now, used by the
7 military. But they are being phased out of military use in
8 the Year 2009. But, up until then, manufacturers or users
9 in certain areas of the country would not be able to use
10 some of these frequencies even now, if this was in place
11 today. But that can be dealt with on an individual basis.

12 That is the essence of what the proposal is. We
13 support it, in general. We do have some comments on some
14 specific portions of it, but we think this is definitely
15 going to improve and we have certainly been pushing for a
16 separate spectrum for many years for telemetry because of
17 what we have seen as the challenges and the concern for
18 electromagnetic interference.

19 [Slide.]

20 In the longer term, a separate spectrum is
21 definitely needed. And it will lead, I think, to definite
22 improvements in reduction of risk to patients. That is our
23 ultimate concern here. Also, there are various regulatory
24 options that we have in the postmarket arena, particularly,
25 what to do with the equipment that is installed now and how

1 do we migrate that in a reasonable way. The FCC proposal
2 does have some words on that.

3 Optimizing technology; this will open up, as we
4 have heard from several manufacturers, opportunities that
5 they are very eager to exploit. The first few manufacturers
6 that have this spectrum will, of course, exploit that and
7 probably really take a large portion of that particular
8 potential community.

9 [Slide.]

10 So, with that, I am going to finish up now and
11 just really reiterate what is the basic message here. EMI
12 will continue to challenge wireless medical telemetry.
13 There is no way of absolutely guaranteeing that you won't
14 but the concerns are being addressed with the FCC Notice of
15 Proposed Rulemaking with the coordination with the
16 manufacturers through and in the American Hospital
17 Association Telemetry Task Group and the users, of course,
18 play a large portion in how they need to see this and how
19 long it will take them to make the migration.

20 I hope that is helpful and I will answer any
21 questions. Thank you very much for allowing me to have this
22 time.

23 MR. FLETCHER: Thank you.

24 Questions?

25 DR. RICE: What kind of teeth will the program

1 coordinator have to get the hospitals to comply with their
2 suggestions?

3 MR. WITTERS: Under the FCC proposal, he is not an
4 enforcement body. That is not the goal of that. We have,
5 through the guidance and other methods, encouraged
6 manufacturers to look at this. Some of them are already
7 exploring it and a few have indicated, privately, that they
8 are well on their way to producing product.

9 It isn't clear how we can force anybody to make
10 that change. The hospitals, in particular, are hard pressed
11 with many different kinds of needs on their resources. This
12 does represent a rather major change.

13 The FCC proposal allows a two-year transition
14 period and then proposes to basically disallow licenses for
15 any medical telemetry that doesn't operate in the new
16 spectrum, in essence, really pushing people towards that.

17 I don't know if that addresses it, but--

18 DR. LIPOTI: I guess I am concerned about is this
19 allocation of frequency bands enough. You talked about
20 there being three hospitals in Boston. Well, in New York
21 City, they have something like Bedpan Alley where there are
22 seven hospitals in a three-block area.

23 Are these frequencies really going to be enough to
24 handle the telemetry with the increase in patients that
25 might occur over the next ten years?

1 MR. WITTERS: That is what the American Hospital
2 Association group of people came up with, at last 12
3 megahertz. Yes; it could be more but I think with the
4 technology available, at least today, if you think about how
5 many users are on the cell-phone frequencies, with that kind
6 of technology, you begin to see the capabilities that are
7 potential there.

8 The particular intention of the AHA
9 recommendations and the FCC Notice of Proposed Rulemaking is
10 to allow the freedom to the manufacturers to come up with
11 things that will address that. Remember, these are not long
12 range. They are short range. It would be unlikely that,
13 unless you are really in the same room and on the same basic
14 frequency, that you would have that interference but that is
15 a good point.

16 In the competition, we have the backing of the
17 Chairman of the FCC. This was unanimously voted for by the
18 FCC commissioners and is going forward. Now, there are
19 other dynamics that I didn't go into that allow us to see
20 how much competition there really is. 12 megahertz to
21 14 megahertz is, really, very good.

22 MR. WILSON: In the AHA information that we have
23 got, it talks about telemetry needs today and a case study
24 on 14 hospitals, and it has a chart showing how many
25 patients, number of concurrent patients. I am a little