

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

TWENTY-SIXTH MEETING OF THE
TECHNICAL ELECTRONIC PRODUCT RADIATION
SAFETY STANDARDS COMMITTEE

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Volume I

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1 electronic product radiation and safety standards.

2 The primary function of TEPRSSC is to provide
3 advice and consultation to the Commissioner of Food and
4 Drugs on the technical feasibility and reasonableness of
5 performance standards for electronic products, to control
6 the emission of electronic product radiation from such
7 products, and to review amendments to such standards before
8 being prescribed by the Commissioner. The committee is not
9 requested to review individual applications or particular
10 products of specific firms.

11 Public Law 90-602 and its legislative history
12 clearly indicated that the TEPRSSC members are expected to
13 represent a very wide range of interests with at least one-
14 third of the committee nominated by the regulated industry
15 itself and appointed on the basis of their being able to
16 represent industry-wide concerns.

17 Section 534 of the Federal Food, Drug, and
18 Cosmetic Act specifies that TEPRSSC members are not to be
19 considered officers or employees of the United States for
20 any purpose including conflict of interest determinations.

21 However, to be consistent with FDA's general
22 policies regarding advisory committees, the Agency believes
23 a public disclosure memorandum should be made a part of the
24 public record which identifies each member and provides
25 their employment affiliation.

1 Approved on March 20, 1996, September 15 and 22,
2 1998, and August 30, 1999, by the delegated authority of the
3 Commissioner of Food and Drugs, the members of the Technical
4 Electronic Product Radiation Safety Standards Committee are:

5 Representing the General Public are: David
6 LeGrande, Communication Workers of America; Marlene McKetty,
7 Howard University Hospital; Mary Marx, Los Angeles County
8 and University of Southern California Medical Center; John
9 Cardella, SUNY, Syracuse Health Science Center; William
10 Rice, American Radiology.

11 Representing Government are: Roland Fletcher,
12 Maryland Department of the Environment; Jill Lipoti, New
13 Jersey Department of Environmental Protection and Energy;
14 Kathleen Kaufman, Los Angeles County Department of Health
15 Services; Jerry Thomas, University Services University of
16 Health Sciences; William Gregory Lotz, National Institute
17 for Occupational Safety and Health.

18 Representing Industry are: Dennis Wilson, Heat
19 and Glo; Steve Szeglin, PTW New York Corporation; Quirino
20 Balzano, Motorola Florida Laboratories; John Sandrik,
21 General Electric Medical Systems; Alice Fahy-Elwood, Lucent
22 Technologies.

23 Thank you.

24 **Chairperson's Opening Remarks**

25 MR. FLETCHER: Good morning. It is once again my

1 pleasure to open this 26th meeting of TEPRSSC. This is my
2 fourth and final meeting as chair, and I will have more to
3 say about that tomorrow, but I am very pleased to see all of
4 you here, all of you who were able to make it. Thankfully,
5 most of us were not coming from the southeast this morning.

6 I look forward to a very enthusiastic, a very
7 fact-filled meeting, and I am not going to spend a lot of
8 time today, so I am going to turn the mike over to Orhan to
9 introduce Dr. Feigal.

10 DR. SULEIMAN: In trying to stick to the agenda
11 and keeping everything as brief as possible, I will keep my
12 introduction very simple, but I will say that the FDA and
13 the Center for Devices and Radiological Health is very
14 excited about the new center director, and we are very
15 pleased to have had the opportunity for him to take some
16 time from his very busy schedule this morning and come and
17 welcome you.

18 Dr. Feigal.

19 **Welcoming Address**

20 DR. FEIGAL: Thank you very much.

21 It really is a pleasure to welcome you to the
22 advisory committee. I was mentioning to someone this
23 morning that virtually my first introduction to the FDA was
24 the advisory committee process, and I was asked to come and
25 present some studies on behalf of an application for an

1 anti-infective product. One thing led to another and I
2 ended up employed here. So, you had better watch out. You
3 never know what is going to happen.

4 I also served on the committee that I presented
5 to, so I have both presented to a committee and sat as a
6 committee member, and then because the employment I first
7 had at FDA was a member of the division that was responsible
8 for that committee, I sat at the table.

9 Sometimes you count things. I was at that
10 committee for 39 consecutive meetings. It was a committee
11 that met about four or five times a year over an eight-year
12 period. But this committee actually has that record beat.
13 This committee, although none of the individual members, is
14 the oldest standing committee of the advisory committee
15 systems in the FDA, and although there was a time period
16 where this committee was appointed but didn't meet, this
17 committee still has the record of the longest continuous
18 operational FDA advisory committee.

19 It is a process that we really value quite a bit,
20 and we value because we need to have a forum to bring issues
21 before the public eye, to get feedback from the various
22 constituencies that have an interest in what we do, and this
23 is a committee that is composed in a way that it gives us a
24 vantage point from three different important sectors, both
25 the public, industry, and state and federal governments.

1 One of my concerns when I came to become the
2 center director here was raised when I was shown a graph of
3 the resources of the center. As you are probably aware,
4 there has been a gradual shrinkage in the size of the
5 federal work force over the last five or six years. It has
6 been kind of a slow, steady attrition of 5 to 7 percent per
7 year.

8 Overall, FDA, all of our operations, all of the
9 centers in the field, have shrunk from about 9,000 employees
10 to about 8,000. We have lost about 1,000 employees from our
11 work force. The center, being about 15 percent of the
12 resources of the FDA, has proportionately also lost about
13 100, 150 positions at that time.

14 The other competing force that was coming on was a
15 real explosion of device manufacturing. Part of this, I
16 think was the explosion of biotechnology. Part of that, if
17 you look over the last couple of decades, was the revolution
18 in computers, and if you think of what could be computerized
19 15 or 20 years ago and now, it is not unusual to have a
20 toothbrush with a computer in it, there was a doubling of
21 the number of device manufacturers and a rapid growth in the
22 number of applications.

23 When the two centers were merged, the radiation
24 health side of the program was actually the larger side of
25 the program. Then, there was a period of time when there

1 were able 800 employees in the device program and about 800
2 in radiation health and safety.

3 What concerned me was that with shrinking
4 resources and a growing device industry, and a very vocal
5 and politically active device industry, many of the
6 resources that had been in, in radiation health and safety,
7 were shifted over to the device program.

8 So, the device program shrank from about 400
9 positions in our direct work force down to under 100, and
10 that's 100 if we use our time accounting methods--which we
11 do a couple times a year to see what people are working on--
12 and we see that we have about 88 person years worth of
13 effort on the radiation program.

14 If we look at it another way and say how many
15 employees are solely involved, 100 percent of their job is
16 radiation health and don't do any device work, it is only 22
17 people. So, one of my concerns when I came in was to look
18 at this program and to see if there is a way that we can
19 address the needs of this program, and I think we have to
20 have it grow back, and we need to restore some of the
21 functions that have been getting a little thin, and we are
22 going to have to look at different ways for storing them
23 because you are not going to win the lottery and we are not
24 going to have Congress wake up and say, gee, the FDA ought
25 to double its budget, that would be great.

1 So, there have been some sort of hard times both
2 for the committee process where you all didn't meet, and
3 there have been the issues that we have, but there is
4 another interesting thing about radiation health and safety,
5 whether we take the efforts of this program, whether we take
6 some of the other activities of the center including the
7 mammography program, and that bright spot is our
8 partnerships with the State and other government agencies
9 that deal with this.

10 Really, I think a lot of our effectiveness has
11 been working through those partnerships, and that is an area
12 where although this is our meeting, and you are doing our
13 agenda items, we realize this cuts both ways, and I think we
14 need to look at how we address these issues.

15 Some of the things that we are doing inside the
16 center, one of the processes that has been going on in the
17 center that was a programs, actually, a series of programs,
18 started by Bruce Burlington, my predecessor, was a process
19 called reengineering where we took a look at our processes
20 and what we were doing, and how we could do them
21 differently, and where really were our priorities.

22 We have put together a radiation health
23 reengineering team. This team has already begun to map the
24 processes of how we do the radiation health, identify gaps
25 that have developed or probably some thin spots, as well as

1 gaps, areas where we are only maybe a person deep in
2 expertise, and the reengineering process begins by
3 developing pilot programs of trying to do things in a new
4 way and both internally and externally communicate on
5 radiation issues, how the pilots are working, and as I
6 mentioned before, continue to work with the outside
7 partnerships to see where we can leverage things.

8 Very recently, we have created a radiation council
9 within the center. That's Dr. Elizabeth Jacobs, who is a
10 long-time biologist/scientist who has served a couple of
11 stints as the Acting Director of the center, so she really
12 has a great overview of how the center operates, but she has
13 also a particular interest in this area and in the success
14 of this area.

15 So, I have asked her if she would head up a
16 radiation council that is composed of the deputy office
17 directors of the center. In our language, each federal
18 agency has a lot of different languages, but our office is
19 supervise the divisions or supervise the branches, so the
20 offices are sort of the bigger picture parts of the units.

21 This council will be asked to assist in the
22 reengineering issues and to internally address radiation
23 health policy issues and bring those to whatever level is
24 appropriate.

25 One of the ways that the center has dealt with the

1 shrinking resources is to really divide up the effort
2 between different parts of the agency. Much of the
3 radiation program is in the Office of Compliance, which is
4 our liaison with the field, and that is because so many of
5 the radiation health and safety efforts rely on inspectional
6 programs, rely on evaluation of imports and other types of
7 programs, and also that is an area where much of the
8 expertise has ended up.

9 But we also have strong radiation health expertise
10 in other areas, and so we are going to need to build a
11 matrix type operation to pull together and strengthen this
12 program.

13 We are enthusiastic about continuing our
14 engagement with the states with the conference on radiation
15 control program directors, and then this program, this
16 committee, TEPRSSC, will I think play perhaps an even
17 stronger role in the future. It will be one at your meeting
18 next year that we hope to bring back a progress report on
19 this new effort which is just starting.

20 This morning, I think what we are asking you to
21 turn to are a variety of issues that illustrate sort of the
22 diversity of the challenges of radiation safety, things
23 ranging from lasers to security scanning to ultraviolet
24 radiation, and other types of issues.

25 Radiation is something that is still very much on

1 the public's radar screen, if you will. They are very
2 concerned about radiated food and radiation and genetics are
3 a couple of those buzz words that, if they are involved, the
4 public is worried and thinks--our first reaction is they
5 think they don't like it.

6 So, there are many issues where we value your
7 help, not only with the policy and with the science, but
8 also with the public and the public health and the
9 perception of that which is necessary to carry out our
10 mission.

11 So, again, welcome, and I will thank you in
12 advance for your help with us today. I look forward this
13 being only the first time that I introduce you.

14 Thanks very much.

15 MR. FLETCHER: Thank yo, Dr. Feigal, for those
16 comments, and I certainly appreciate the items that you
17 covered, but I appreciate even more the fact that you stayed
18 so precisely on schedule, and I ask that all presenters
19 follow your example and also stay on schedule, so that we
20 might have a very informative, but timely, meeting.

21 Our next presenter will be Dr. Dennis, who will
22 present us with amendments to the laser standard.

23 **Amendments to the Laser Standard**

24 MR. DENNIS: Good morning. On a personal note,
25 Dr. Suleiman explained to the committee last night that

1 immediately after my presentation this morning, I am going
2 to have to leave due to family commitments.

3 On a more pleasant note, I want to thank Mr.
4 Fletcher and the organizing committee for the conferral of
5 the doctorate degree. I appreciate it very much. I presume
6 it's honorary. Usually, the conferral of such a degree is
7 deferred until the recipient is old enough no longer to be,
8 what, trouble? But, anyway, I appreciate it very much and
9 would like to set the record straight on that point.

10 [Slide.]

11 I am here this morning to talk to you about the
12 developing amendments to the CDRH Laser Standard. Since
13 many of you on the committee are new since when I last spoke
14 on this subject two years ago, I would like to give you some
15 of the background and summary, and bring you up to date, as
16 well as review the past.

17 [Slide.]

18 Why do we want to amend the standard? Well, first
19 of all, we would like to harmonize with the international
20 standard, which is the IEC 60825-1. The reasons for wanting
21 to harmonize are quite obvious. It makes no sense to have
22 one standard in the United and another standard in the rest
23 of the world. This invites noncompliance with both
24 standards, creates confusion on the part of the industry,
25 and for those of us who are supposed to be the experts in

1 the laser and optical radiation safety area, can't we get
2 our act together.

3 Secondly, our last amendments happened
4 approximately 15 years ago, and there have been new
5 developments in the science and photobiology since then. As
6 a result of the almost 25 years that we have had of our
7 standard being in effect, we have really begun to question
8 whether all of the requirements that we have in the standard
9 are really necessary from the standpoint of protecting the
10 public safety.

11 [Slide.]

12 A brief history of what we have been doing. In
13 1992, I met with industry, other U.S. Government industries,
14 academia, the laser product industry, professional
15 societies, and we agreed at that point it was very good for
16 us to embark upon a program to try to harmonize these two
17 standards.

18 In 1993, we published an Advanced Notice of
19 Proposed Rulemaking in which we outlined certain things we
20 were thinking about. I have to say the United States was
21 successful. In 1994, the international standard was amended
22 to bring that standard into complete agreement on two
23 critical areas.

24 One was the criteria for determining whether laser
25 radiation was accessible, and the second one was that the

1 criteria for the determination of the requirements of safety
2 interlocks was the same, and we are very happy to say we
3 were able to achieve harmonization on those two points.

4 One other thing that I will say in these
5 amendments, what happened was that the international
6 standard was also amended in its scope to include light-
7 emitting diode, LED devices, and that has caused no end of
8 problem, which I will get to later.

9 In 1996, we circulated an informal draft to the
10 industry for their comments. We received lots of comments
11 on that, and we took them into consideration in developing
12 our Proposed Rule, which was published in March of this
13 year. The comment period closed at the end of June, and one
14 of the things that we have brought to you this morning is
15 what those comments were all about.

16 [Slide.]

17 The proposed highlights or the highlights of our
18 proposed amendments are to adopt the classification limit
19 tables from the international standard, so that we would be
20 the same in that area, and we wanted to redefine our hazard
21 classifications to be in agreement with those in the
22 international standard, and we would like to introduce
23 correction factors to increase the limits for radiant energy
24 and power from sources that are larger than the minimal
25 resolvable angular subtense.

1 As you may know, prior to now we have a criteria
2 or radiance and integrated radiance, which is fundamentally
3 a property of any optical source. The other standards,
4 namely, the IEC and the ANSI Z136, have gone to
5 consideration of angular subtense of a source rather than
6 radiance.

7 So, if we are going to harmonize, we have got to
8 harmonize on that, as well.

9 [Slide.]

10 One of the things that we didn't do in our last
11 amendments, but ANSI and IEC have done, and that is to
12 reduce the limits for repetitive pulses. The photobiology
13 seems to support that, and we are proposing at this point to
14 introduce the same downward correction factor for repetitive
15 pulses.

16 We also would like to reduce the maximum emission
17 duration to be used for classification to be better in
18 accord with reasonable exposure times. Right now our
19 exposure time for classification is 10,000 seconds, which is
20 essentially an eight-hour workday. For most laser
21 applications, we believe that that is an excessive time,
22 however, there are certain products for which a very long
23 classification time remains appropriate.

24 [Slide.]

25 We would like to delete the requirements for beam

1 shutters and emission indicators for low power laser
2 products, such as this one. We would like to simplify the
3 requirement for a scan failure safeguard.

4 Right now the way the requirement is written, it
5 is too difficult for the industry and for most people who
6 are applying the standard to understand. What we would like
7 to do is just have that requirement applicable to situations
8 where a product's radiation class would jump to a higher
9 class if a scanning device failed.

10 We would like to recognize--and we have also
11 already done this unofficially--is to recognize the geometry
12 of the design for the warning logo type labels for laser
13 products.

14 [Slide.]

15 We would like to make some significant changes in
16 the area of requirements for high power medical laser
17 systems. These are laser systems that are used for
18 radiation of the body for surgery, diagnosis, or therapy.

19 Our basic principle over the years has been that
20 there be a means of measurement. The requirement of the IEC
21 Standard, which is in the 601 series, and now it is 60601-2-
22 22--I missed that when I was preparing the slide--they want
23 the output to be accurate. I believe that is a very good
24 idea.

25 Now what we are proposing is the output be

1 accurate to plus or minus 20 percent of a preset value. If
2 the output should deviate from the preset value by more than
3 plus or minus 20 percent, that there be some indication of
4 that; that there be a means of shutting down--which we don't
5 have now in case of emergency--and an indication of when
6 emission is actually occurring or if you have a pulse laser
7 that requires the charging to the capacitor bank, a warning
8 when the capacitor isn't charged and the system is ready to
9 fire.

10 [Slide.]

11 Now, this all sounds so good, what has been
12 holding us up, what is a stumbling block to harmonization
13 with the IEC Standard?

14 [Slide.]

15 There, we get into the optical radiometry
16 questions. This is what we have now in the CDRH Standard.
17 For the purposes of measuring radiant energy or radiant
18 power for the purpose of hazard classification, we use a 7-
19 millimeter aperture placed 200 millimeters from the apparent
20 source, which in this case I have shown to be the laser
21 product.

22 That means that we are collecting a cone of 35
23 milliradiance plane angle projection. For those laser
24 products that are likely to be used in environments where
25 one will encounter collecting optics, such as for surveying

1 instruments, laser light shows in large stadia where you
2 will find people using binoculars, that type of situation,
3 then, we would use a 50-mm aperture to account for the
4 increased hazard provided by the collecting optics, and in
5 that case, we are collecting 250 milliradiance.

6 [Slide.]

7 What is the IEC doing? Here is the stumbling
8 block. They use a 50-millimeter collecting aperture placed
9 100 millimeters from the source. We think the 100
10 millimeter is reasonable. It accounts for the fact that
11 certain people are myopic and children can accommodate at
12 much closer distances than can adults.

13 However, who has seen in casual use an optic
14 having 50-millimeter collection aperture that can
15 accommodate a source at a distance of only 100 millimeters
16 away. That is an F2 optical system, it is extremely fast.
17 Where do you find F2 optics? Well, you find them on some
18 high-priced cameras, but people don't look at things like
19 this through that kind of optics. It is just not a
20 realistic thing.

21 [Slide.]

22 So, what are we proposing as an alternative? We
23 are proposing to use either a 7-mm aperture placed 100
24 millimeters from the source and 100 millimeters--that's
25 again our looking out for the myopic people--and also to

1 make a measurement using a 50-millimeter aperture placed 2
2 meters from the source.

3 Where do the 2 meters come from? That is about 6
4 feet. That is usually your minimum focusing distance for a
5 binocular, a telescope, a camera, or anything like that.
6 What we would do is we would make an evaluation under both
7 conditions, the 50-millimeter aperture and the 7-millimeter
8 aperture, and we would use whichever is worse for product
9 classification.

10 Now, if we classified using the 7-mm aperture,
11 then, we would require a warning in the user instructions,
12 pointing out that the use of collecting optics could
13 increase the hazard.

14 [Slide.]

15 So, that is the problem. The measurements, the
16 hazard classification that the IEC is using exaggerates the
17 hazard for diverging sources, and it is an unrealistic
18 collection of radiation.

19 When IEC put that requirement into effect, there
20 was a very loud scream from the infrared data communications
21 industry worldwide. As a result, what the IEC has had to do
22 was to publish two, let me call them vertical standards.

23 Let me explain first vertical standards, I will
24 start with horizontal standard.

25 A horizontal standard is a standard that applies

1 across the board to a whole family of products, and then
2 from that comes vertical standards which impose relaxed or
3 additional requirements for specific product applications.

4 So, as a result of the amendments, including LEDs
5 and imposing their measurement conditions for
6 classification, the IEC Committee has had to publish two now
7 interim vertical standards, has a third one out for vote
8 right now to correct this situation.

9 In the view of the experts in the United States,
10 present company included, we would like to see them fix the
11 base standard. The proposal that we are making is something
12 that was worked out in the IEC Working Group in 1995, and
13 was almost approved. Unfortunately, it missed by one vote.
14 We haven't given up on that. I will talk a little bit more
15 about that in a little while.

16 [Slide.]

17 The other thing I will say relative to the IEC, in
18 addition to honorary doctorate which the organizing
19 committee gave me, I have received another very great honor,
20 and that in June to have been appointed, not honorary this
21 time, but I am now the chairman of the IEC Technical
22 Committee 76, which is responsible for optical radiation and
23 safety and laser equipment.

24 To our proposal in the Federal Register, we
25 received only 15 comments. Seven of those were from

1 manufacturers, five were from consultants, two trade
2 associations, and one from the U.S. Department of Defense.

3 [Slide.]

4 What did they have to say? Basically, they
5 supported our goal of harmonization with the international
6 standard, but they were very astute. Some of them said we
7 should delay publication of a Final Rule pending present
8 amendments that are out for vote in the IEC Committee.

9 Another extremely astute comment said, well, if
10 the IEC does not approve their present amendments, CDRH
11 should publish what they have already proposed.

12 Another comment said adjust the effect of dates of
13 the Final Rule to give industry more time to make
14 adjustments that are necessary.

15 We had one comment that has me extremely
16 concerned, and that was from a manufacturer of a laser
17 product that is used by the police for speed measurement.
18 It's an optical radar. They did an analysis whereby they
19 calculated that their product which is now under the CDRH
20 standards be Class 1, no recognized hazard, to be Class 3B,
21 and they anticipate terrible market resistance to that, and
22 it may be very detrimental to that kind of product.

23 I haven't had the opportunity to go over their
24 numbers very carefully, but it's a comment that I take very
25 seriously. If that product was not hazardous up to this

1 point, if it is suddenly going to become hazardous or do we
2 need to make some other adjustments in what we are
3 proposing.

4 [Slide.]

5 I have to make several editorial corrections, I am
6 sorry to say. Another comment recommended that we develop a
7 vertical standard for fiber optic communications products
8 that are going to be used in the home. This is a
9 conservative type of outlook that we are going to have to
10 examine more closely.

11 The Navy recommended that we adopt the vertical
12 standard for laser products intended for combat, combat
13 training, or that are classified in national security
14 interests.

15 We, in 1976, issues a blanket exemption from the
16 CDRH Standard to the Department of Defense for such
17 products, however, some factions in the Department of
18 Defense feel that that exemption doesn't have adequate
19 control, doesn't have adequate legal basis, and would like
20 us to make that more formal.

21 [Slide.]

22 I spoke a little about or mentioned that the IEC
23 has out now for vote a proposed amendment to one of the most
24 significant portion of which is to redefine their
25 classification system. Right now they have 1, 2, 3A, 3B,

1 and 4, similar to what we have in CDRH.

2 What they are proposing to do is to have 1, 1M, 2,
3 2M, 3R, 3B, and 4.

4 What does all that mean? Class 1 is not hazardous
5 under any conditions. Class 1M, although not hazardous with
6 unaided vision, would be recognized as being hazardous if
7 collecting optics were used.

8 Class 2 is what we have today. These are laser
9 products that are hazardous if one stares into them for more
10 than a quarter of a second, in other words, low power
11 continuous wave lasers.

12 2M is analogous to 1M, that these would be more
13 hazardous if someone were to view them with collecting
14 optics. 3R, that is something new. Right now they have 3A.
15 We have 3A also. We differ on what 3A means. To us, 3A
16 includes low power visible lasers, such as these things.
17 This is a 3A laser.

18 In the IEC, they have a transition where they have
19 3A at invisible wavelengths, as such. What we are proposing
20 is a 3R, which would be the low end of Class 3 both in the
21 visible and in the invisible wavelength ranges. The R means
22 relaxed requirements.

23 Class 3B is essentially the same as it is today.
24 Products that are hazardous for direct ocular exposure and
25 at the high end for skin exposure, and, of course, Class 4

1 is anything above that where the sky is the limit.

2 Before I get to that one, where are we in the IEC?
3 We now have that proposal out for vote, as what is called
4 the CDV, a Committee Draft for Vote. If that draft is
5 approved, it will then go to what is called an FDIS, Final
6 Draft international standard .

7 At that point, the nations will have to vote yea
8 or nay, no new issues, no new issues now, we are beyond that
9 point. We will either approve this or we will disapprove
10 that.

11 My closing date for submitting the U.S. vote
12 recommendation to the U.S. National Committee is this very
13 day, September 15th. The National Committee, which is ANSI
14 in New York, must submit the formal United States vote to
15 the IEC in Geneva by the end of the month.

16 The committee will be meeting in Milano the second
17 week of November. We will see what the comments are now.
18 We, the United States, are very supportive of this new
19 classification scheme. We hope it will be approved.

20 [Slide.]

21 So, what are our options at this point? We can
22 delay publication of a Final Rule until we wait to see how
23 the IEC vote turned out. If the IEC amendments are
24 approved, then, we could repropose, or if the IEC amendments
25 are not approved, then, we can go and polish up what we have

1 now and publish that as a Final Rule.

2 Another option to us is that we can publish
3 amendments to the CDRH standard in two phases - one, to give
4 the relaxations that we would like to see now in those
5 things that are not controversial, and then wait and see on
6 the others.

7 A third option is to propose a new vertical
8 standard for toy and novelty laser products under 1040.11,
9 limiting those things to levels that are not recognized to
10 be hazardous, and I want to give credit to Frank Mackison of
11 our staff who came up with that idea.

12 This is the kind of product that we are talking
13 about. This product, we believe is perfectly safe when
14 used by lecturers as pointers, by teachers in that
15 environment. We have been in close contact with the leading
16 photobiological and ophthalmic people in the United States
17 and abroad.

18 Just about everybody agrees that the risk of the
19 direct ocular injury from one of these devices is very, very
20 small, if present at all, unless somebody were to
21 deliberately stare into the thing for more than 10 seconds,
22 however, the other sides of that coin are this. There is a
23 huge public outrage about these things.

24 Many states have passed ordinances against them,
25 prohibiting sales to people under 18 years old. What is the

1 hazard? The hazard primarily is one of distraction to
2 someone driving a car. Airline interests are very
3 interested in what could happen as a result if one should
4 shine in the cockpit of an aircraft.

5 They have been used to disrupt sporting events
6 where people have been arrested for trying to flash a
7 basketball player about to make a foul shot. The police are
8 upset about them. The police are trained to use laser
9 pointing devices on their weapons. What is the policeman
10 going to think or a policewoman going to think if he or she
11 sees a red spot, and what is the reaction going to be?

12 We thank our stars that nothing has happened yet,
13 but these things are all over the place.

14 What can we do? We have been trying to make sure
15 that they at least comply with our labeling requirements,
16 that say avoid direct eye exposure, and it's as simple as
17 that, but we are having large problems.

18 We have detained and refused entry into the United
19 States of tens of thousands of these devices. They are
20 tying up our resources, they are tying up the resources of
21 the FDA field organization. They are keeping the state and
22 municipal legislatures very busy.

23 Are they likely to directly hurt somebody? No,
24 but there is a huge public outrage. The press has been very
25 interested in them. So, Frank came up with a brilliant idea

1 of let's have a new vertical standard for toy and novelty
2 laser.

3 Then years ago, these things were selling for \$100
4 apiece. Now, they are under 10.

5 Frank, in his pocket, has a green one. Frank,
6 would you shine one up on the ceiling? Now we have green
7 ones. The green ones now cost over \$100 apiece. Where will
8 they be in 10 year? The other photobiological thing is
9 spectral response. Green light produces 20 times the visual
10 response of red light. For the same power, therefore, you
11 are going to get 20 times the distraction, 20 times the
12 disruption.

13 So, maybe these are not being sold primarily as
14 pointers. Maybe they are being sold as toys and novelties.
15 Pet toys, if you see the promotional literature on the
16 internet, what are they being used for? In discos, at
17 sporting events, and we try to get after them, but our
18 resources are very limited. Custom Service is helping us,
19 the districts are helping us, but it has been very costly to
20 us. So, something to think about.

21 The other option that we have is to consider the
22 proposal of a new vertical standard under 1040.11 for laser
23 products for the Department of Defense, for combat, combat
24 training, or that have security classifications, and we
25 can't talk or even know about them.

1 So, that concludes what I wanted to say to you
2 this morning, and I believe I have some time for questions,
3 if you have any questions.

4 MR. FLETCHER: Do any members of the committee
5 have questions? Cass.

6 MS. KAUFMAN: I guess I am a little still confused
7 about the two different standards for measuring. There is
8 the 7 millimeters at 100 centimeters and 50 millimeters at a
9 meter, I think it was.

10 And you said that the Europeans were only using
11 the one standard. What are the prospects of them going to
12 the two standards that FDA is proposing of measurements?

13 MR. DENNIS: Well, our standard was around a long
14 time before theirs, and they decided to go a different
15 route. I do have to admit in all honesty that I have
16 simplified. The IEC standard also permits the use of a 50-
17 mm aperture at 2 meters for products that are collimated,
18 such that the divergence is less than 5 milliradiance, so
19 they do permit for very well collimated lasers the use of
20 the large aperture at 2 meters.

21 The problem really doesn't impact until you have
22 laser products that have diverging outputs. These would be
23 primarily used in surveying and construction areas. We have
24 laser products that project fan-shape beams. They are used
25 quite extensively in the construction and sawmill

1 applications to get maximum yield from sawmill operations.

2 Also, the other thing that we have use in optical
3 disk readers where you have fairly large angles of
4 convergence to converge on a compact disk, and then if the
5 disk weren't there, it would diverge at the same angle, and
6 these angles typically are the order of 60 degrees.

7 So, with the 60-degree cone, you can compare that
8 to the geometry that I showed on the screen. They collect
9 just much more of the radiation than would be reasonably
10 hazardous.

11 MS. KAUFMAN: So, is that discrepancy, I mean
12 going to prohibit us from ever being completely in alignment
13 with the IEC?

14 MR. DENNIS: Well, I cannot commit the Agency at
15 this point, but we think--I sit on a number of committees, I
16 also sit on the Executive Committee of the ANSI-Z136, and we
17 are all poised to go along with--if I can go back--the
18 experts in the United States generally believe that this is
19 a good idea if it is approved.

20 So, if that happens, then, there is a clear road,
21 but we have a real stumbling block in the United States as
22 far as very unrealistic, 50-millimeter aperture at 7
23 millimeters.

24 Does that answer it?

25 MS. KAUFMAN: I think so.

1 MR. DENNIS: Thank you.

2 DR. RICE: Is there any consideration for using
3 child-proof locks on these lasers, because inquisitive
4 children, they are going to look, it is a fascinating tool,
5 and they might look at it for more than 10 seconds, and they
6 will have permanent eye damage?

7 MR. DENNIS: On this kind of thing?

8 DR. RICE: Yes.

9 MR. DENNIS: We hadn't considered that. My
10 experience, at least with my grandchildren, is they are
11 pretty inventive. I don't know what an adequate child-proof
12 lock would be unless it was some combination that you punch
13 in. That would drive that back up over \$100 perhaps.

14 MR. FLETCHER: Dr. Cardella and Dr. McKetty.

15 DR. CARDELLA: I had two questions. The first is
16 the optical collecting devices, do prescription glasses or
17 prescription contacts qualify or are they in the definition
18 of optical collecting devices?

19 MR. DENNIS: Definitely not.

20 DR. CARDELLA: They are not. Okay.

21 The second question is in your early comments, you
22 mentioned the furor that was caused by inclusion of light-
23 emitting diodes, and later in the talk you didn't say too
24 much about that for the CDRH or the U.S. proposal.

25 What is the inclusion or exclusion of LEDs?

1 MR. DENNIS: Thank you for your comment. It is a
2 very good one.

3 When we published our Advanced Notice and in the
4 draft that we sent around for informal comments, we had
5 included LEDs and LED products for the purposes of
6 harmonization. They were not in our Proposed Rule.

7 The reason is we are concerned about the impact on
8 the industry. We know of no injuries from LED devices that
9 have ever occurred. We are concerned about the impacts on
10 the industry. Most LED devices are surface-emitting devices
11 that we encounter today.

12 New in the technology are super luminescent LEDs,
13 which have a much higher radiance associated with them. At
14 this point, I am not familiar with too many of these things
15 that are in the marketplace, and if they do appear in the
16 marketplace, and they do appear to be a hazard, then, we
17 would reevaluate the situation.

18 MR. FLETCHER: Dr. McKetty.

19 DR. MCKETTY: Yes. What was the rationale used by
20 IEC versus CDRH that you came up with sort of different
21 methods?

22 MR. DENNIS: I am sorry, I didn't quite get it.

23 DR. MCKETTY: What rationale was used by IEC
24 versus CDRH that you would end up with?

25 MR. DENNIS: Well, the CDRH standard was last

1 amended in 1985, so those were proposals that were developed
2 over 1983 and '84. Having sat on a number of standards
3 committees, it is very interesting to try to observe what
4 determines the dynamics within that committee.

5 We find that there are some very, very
6 conservative factions primarily in the UK and Germany. I
7 can't comment on what is driving these particular factions.

8 Obviously, we can make any product super safe. We
9 can also drive it out of the marketplace. What is
10 reasonable, do we have to have zero risk or should we be
11 taking prudent risks?

12 The other thing we have to do at FDA is we have to
13 consider the economic impact of whatever we propose. We
14 have to not only address risk, we have to address cost, and
15 if you consider the costs and the impact on the industry of
16 inclusion of LED devices, and taking a zero risk approach,
17 whoa. So, we have to take everything into consideration,
18 and that is one reason I think we are apart.

19 MS. FAHY-ELWOOD: One question. You talked about
20 the vertical standard for toys.

21 MR. DENNIS: Yes.

22 MS. FAHY-ELWOOD: Can you give us some idea of
23 what requirements you are thinking about for that vertical
24 standard?

25 MR. DENNIS: We haven't developed any really yet

1 that we can talk about, but just it is an approach to
2 addressing this particular problem that has such large
3 public outrage.

4 MS. FAHY-ELWOOD: And one more question. This
5 classification scheme, it seems a little confusing. Do you
6 think it would be possibly confusing for consumers and laser
7 users?

8 MR. DENNIS: That is a wonderful question and a
9 wonderful comment. The reason is the User Safety Committee
10 or the User Safety Standard in the United States is the
11 ANSI-Z136.1. The control measures for users, medical
12 surveillance, the requirement for laser safety officers, all
13 that stuff is dependent upon the class of the product, and,
14 yes, there is going to have to be a rather significant
15 educational effort.

16 MR. FLETCHER: Dr. Lipoti.

17 DR. LIPOTI: I have two comments. The first one
18 is a nice comment. Congratulations on being Chair of the
19 IEC Committee. I am really pleased that FDA is taking a
20 leadership role. For those of us in states, we really have
21 no budget or opportunity to participate on an international
22 standard committee, so we look to the Federal Government for
23 doing this, and I am pleased that you are taking that role.

24 Now, the other comment. I was concerned by one of
25 the comments about the police laser being reclassified from

1 a Class 1 to a Class 3. To me, it raised the question about
2 whether your measurement regime was correct, and if police
3 lasers, which has caused no harm, can be reclassified from
4 Class 1 to a Class 3, are you classifying these properly?

5 MR. DENNIS: Well, what I wanted to say--I may not
6 have said it clearly enough--because I want to look at their
7 analysis very carefully. I want to make sure that their
8 analysis is correct, and then I want to look at the impact
9 and see exactly how that is going to happen.

10 I don't have the answer to that yet, but I am
11 taking it very seriously.

12 MR. FLETCHER: Dr. Cardella.

13 DR. CARDELLA: Another question about the
14 Department of Defense proposed vertical standard. The
15 lasers that they are asking for special consideration of,
16 are they strictly targeting lasers or are they destructive
17 lasers? I mean are they powerful enough that they are being
18 used as the laser is the actual weapon.

19 MR. DENNIS: I don't know. When a standard came
20 into effect in 1976, we gave the Department of Defense an
21 exemption, and that exemption is not only from those
22 portions of the standard that is specifically inappropriate
23 to a particular type of military product, but it is also an
24 exemption from reporting.

25 So, at that point, your speculation is as good as

1 mine as to just what the entire compass of these exempted
2 laser products would be.

3 MR. FLETCHER: Dennis.

4 MR. WILSON: One of the proposals that you had as
5 far as the standard was delaying it until there is the IEC
6 decision on the amendment. Within your committee, what is
7 the time frame for the CDV and going through the FDIS?

8 MR. DENNIS: The vote from several nations on the
9 present committee draft for vote is the end of this month.
10 We will be meeting in Milan in November. The working group
11 then will be working on resolving the comments that came in
12 with the votes, and I would hope that they would have a
13 final draft international standard out early next year, and
14 that would be voted upon before the year 2000 meeting which
15 is scheduled for September, October--we haven't come down
16 with a specific month yet, but it will be in the fall of
17 2000 in Japan.

18 MR. WILSON: So, then, what we are seeing here is
19 practically two years, in that neighborhood, before the U.S.
20 standard could be changed then? It would be delayed until
21 that time?

22 MR. DENNIS: We will have a pretty good view next
23 month as to whether it looks like this proposal is going to
24 fly. But we have been waited, you know, we have been in
25 this process now for seven years, so what is another year.

1 MR. FLETCHER: Are there any other questions from
2 member of the committee? For the benefit of those who are
3 recording, everyone on the committee, when you speak, speak
4 directly into the mike. These are being recorded and we
5 need to identify who is speaking.

6 Jerry, we thank you very much for your
7 presentation. You have exceeded our expectations and
8 finished well ahead of schedule. We also thank you very
9 much for the work that you are doing and presenting to us.
10 As Joe said, this is reassuring for those of us in state
11 organizations, but I think for us to be at least working to
12 be consistent with international standards, as long as they
13 are appropriate standards, is beneficial.

14 So, we thank you very much for the presentation
15 and the information.

16 MR. DENNIS: One thing I forgot to mention, and I
17 apologize for that, is that although I have to leave now,
18 Corey Toker will be here if things come up in discussion.

19 MR. FLETCHER: As you note, though, we are
20 approximately 30 minutes ahead of schedule. I will
21 therefore rearrange the agenda slightly and have Dr. Cyr
22 present at this time and we will take a break thereafter.

23 **Proposed Amendments to the Sunlamp**

24 **Products Performance Standard**

25 DR. CYR: Thank you very much.

1 This is the first time that we have done this
2 computerized projection system here, and it takes a while to
3 get used to the technology.

4 A little out of sequence. We had hoped that Dr.
5 Weinstock from Brown University would be here. We had
6 invited him to come and talk about some of the epidemiology
7 studies that have been done directly on sunlamps and skin
8 cancer. He is flying in from Providence, supposed to have
9 landed around 8:15 on U.S. Air, and hopefully, will still
10 show up, but given all the flight delays because of Floyd
11 and what have you, we are not sure.

12 Anyway, I will proceed without him. It would have
13 made more sense to have him go first, but I will proceed
14 without him and give my talk.

15 [Slide.]

16 I am going to talk about the ANPRM - Summary of
17 Comments and Data. Last year, before TEPRSSC, we told you
18 that we were in the process of writing an Advanced Notice of
19 Proposed Rulemaking, considering some changes, some
20 amendments to the sunlamp standard.

21 I am here today to tell you that that process has
22 been completed. We did publish the ANPRM. It went out in
23 February, we got the comments back in. We actually had an
24 extension, comments came in, oh, I guess around the end of
25 July. We have had a chance to look at them, collate them,

1 and summarize them.

2 We have not had a chance to evaluate them in full.
3 It is just only a couple of months, actually more like a
4 month, so I don't have the complete story for you. This is
5 still an ongoing process in terms of the evaluation. I
6 wanted to tell you a little bit about where we stand.

7 [Slide.]

8 Our objectives. I want to explain a little bit
9 about rulemaking because there was some misunderstanding
10 about what we are doing with this ANPRM.

11 Why did we publish it in the first place? What
12 led us to this process? Did we get the answers to our
13 concerns? Is the data that we got sufficient for us to
14 proceed to doing a published amendment?

15 [Slide.]

16 Why did we publish the ANPRM? First, there was
17 reports in the literature of a melanoma "epidemic." This is
18 true in the United States and elsewhere that since the turn
19 of the century, the number of cases of melanoma have been
20 going up and rather sharply.

21 Deaths have been less steep an incline. This rise
22 in the United States has in some ways not been paralleled in
23 other countries. I think in Canada, it has actually
24 flattened out and maybe starting to come down, so the
25 question of is this a continuing epidemic or not is

1 uncertain.

2 Another aspect of it is that there is some debate
3 that--here is Dr. Weinstock, we will put him on when I get
4 done. Greetings. I just started.

5 There is some debate that the epidemic in some
6 sense is maybe due to increased surveillance and maybe
7 removal of thin lesions. That is controversial, but there
8 is some evidence that perhaps an epidemic is due to those
9 factors.

10 The second reason was reports in the literature of
11 an actual melanoma-sunlamp connection. In particular, about
12 five years ago, there was one that came out of Sweden that
13 got lots of publicity in press and excited people, and
14 caused the American Academy of Dermatology to contact us and
15 say do something.

16 Again this study has limitations and Dr. Weinstock
17 will talk about those. As with every epidemiology study,
18 they are small sample size, the relative risk had enormous
19 error bars on it, and he will tell you a little bit more
20 about that.

21 There was also a report in the literature of an
22 action spectrum showing that UVA was more efficient in
23 producing melanoma than it was in producing erythema, and
24 this is of concern because sunlamps have a large component
25 of the emissions as UVA, lesser than UVB. So, this was of

1 concern to us.

2 On the other side, however, is that this study was
3 done in the laboratory, was not a human study, was done on
4 animals, and, in fact, was done on a fish, a small, little
5 fish. There are very few animals that get melanoma, this
6 little fish one of them.

7 So, you have a problem in extrapolating from fish
8 to man, so that is one of the limitations of that particular
9 study.

10 Nevertheless, all of these reports caused great
11 concern in the scientific community, and as I said, the
12 Academy of Dermatology actually contacted us and said do
13 something about our concerns here. So, those are the
14 reasons that we got involved with thinking about an ANPRM.

15 [Slide.]

16 The process of rulemaking. The first step was the
17 Advanced Notice of Proposed Rulemaking. All we were doing
18 here was asking for comments and data, give us the stuff
19 that you know of that is in the scientific literature that
20 might be useful for us in considering proposed amendments.

21 The second step is after we have done this
22 evaluation, we would go on to a Proposed Rule. The
23 difference between a Proposed Rule and the first one is at
24 this particular stage, we are giving specific amendments.

25 Two other things. We must address all written

1 statements that come in on a Proposed Rule. We don't need
2 to do this at the stage of the ANPRM, we will try, but we
3 don't have to give a specific answer, one for one, for each
4 of the things that came in, in the ANPRM, whereas, in the
5 Proposed Rule, we do have to give specific answers to
6 everybody that submits comments.

7 The other thing is when we do a Proposed Rule, we
8 will have to do economic impact statements, which we did not
9 have to do in the ANPRM.

10 Then, finally, after you have done all of this,
11 you will end with a Final Rule. While all of this is going
12 on obviously in all these stages, you will have scientific
13 evaluation, we come to TEPRSSC for advice, and, as I said,
14 we do have to address specific responses to the Proposed
15 Rule.

16 [Slide.]

17 We got 27 submissions from the tanning industry,
18 lamp manufacturers, dermatology organizations, academia,
19 salon owners, State and County regulatory agencies, and even
20 one insurance company, hundreds and hundreds of comments.
21 Obviously, I am not going to be able to cover hundreds of
22 comments, so I am only going to give you a few, hopefully,
23 main points and telling you some of the agreements and some
24 of the disagreements.

25 [Slide.]

1 First of all, we maintain that our standards are
2 based on science, good science, and so there were some
3 comments on the biological basis for our standards.

4 Everyone agreed that Phototype I should not be
5 exposed to UV. There are different classifications of skin.
6 One that is commonly used right now breaks it down into six
7 different phototypes. Phototype I red hair, freckles, the
8 typical Celtic Irish skin which burns all the time and
9 rarely tans, doesn't tan, mostly burns.

10 Type II can tan somewhat, but easily burns. You
11 go all the way up to V, which is brown skin, and Type VI,
12 which is black skin.

13 Now, other people have proposed different schemes.
14 This is the one that most people are familiar with right
15 now.

16 There was disagreement on Phototype II. The
17 dermatologists said be very careful on Phototype II's, they
18 could easily burn. Some of them recommended that they
19 shouldn't go to tanning salons.

20 The indoor tanning industry has said yes,
21 Phototype II's can tan. They agree they could easily burn,
22 so be careful, and there is a proposal that Type II's are so
23 important that we need to break it down maybe even into two
24 subtypes, because it doesn't take much of the Type II to go
25 over the edge.

1 All people agreed that we should avoid burning
2 doses. Let me tell you there is tanning doses and burning
3 doses. Tanning produces melanin and doesn't give you the
4 erythema or the redness. You can get sub-erythema doses
5 that do not burn, but can lead to a tan. Everybody agreed
6 that if you get burns, that is bad.

7 [Slide.]

8 There is agreement that tanning is
9 photoprotective. By that, I mean if you get a tan, your
10 next exposure to the tan or to a tanning lamp, you are a
11 little bit more protected, you can take more dose the second
12 time around.

13 There is some disagreement over the degree of
14 protection. Some people say it is not quite as much as
15 other people.

16 The biggest area of disagreement was over
17 benefits, and these benefits, other benefits other than
18 photoprotection. There are reports in the literature of
19 lower cancer risk, things even like breast cancer. People
20 who have more UV exposure have lower breast cancer rates and
21 other cancers. This is linked with the production of
22 Vitamin D.

23 So, there is debate on these particular benefits.
24 The dermatology community says that some of these can be
25 explained with confounding factors, the studies are not so

1 good. Other people said the studies are great. So, what I
2 point out is that the debate on benefits is probably one of
3 the more controversial areas.

4 Dosage needed to produce adequate Vitamin D is a
5 major consideration, how much Vitamin D. We know how much
6 Vitamin D is really necessary to get these effects in the
7 reported effects.

8 [Slide.]

9 Exposure schedules. An exposure schedule is a
10 couple parts - how much dose do you get to produce the
11 desire tan, and the second component is how much dose does
12 it take to build up. When you are first start off, when you
13 have got previously unexposed skin, you have lower doses to
14 give you the tolerance before you can get the full dose.
15 So, it's the build-up dose and then the maintenance dose, so
16 there is two aspects of an exposure schedule.

17 A third aspect is skin type. If you are a Type
18 II, you would probably have lower doses than if you were
19 Type III or IV. Most of our exposure schedules right now
20 have been based on Type II. We haven't done much about the
21 other ones, and I will address that.

22 I was hoping that we might get some data on
23 exposure schedules based on cancer risk. There are a couple
24 of published reports about this, one by deGruijl in the
25 Netherlands and one by Diffey. I was hoping to get comments

1 on those studies in particular and maybe even some new ones.
2 We didn't get anything on that.

3 We did get lots of comments on exposure schedules
4 based on erythema, based on tanning and burning, but nothing
5 on cancer risk.

6 The biggest comments were that we should include
7 the other phototypes. As I said, most of the stuff has been
8 done on Phototype II. We need to have schedules for
9 Phototypes III, IV, even V and VI, which we don't really
10 have well-developed schedules for.

11 We actually got some new data. One study in the
12 comments did the FDA exposure schedule on people who were
13 not previously tanned and found a couple of things. One,
14 the FDA schedule, if you follow it rigorously, you do not
15 get burned. You end up getting tanned, but you do not get
16 burned.

17 However, he maintained that it was so conservative
18 in the initial stages that you could go to a salon several
19 times, maybe even six to eight times, before you see the
20 desired effect of a tan. He thought this was bad marketing.
21 I could see why it might be. You know, you pay for
22 something, you want an effect, and you don't want to go six
23 or eight times before you start seeing something, so this is
24 a concern on the industry side.

25 [Slide.]

1 Training. An area of total agreement. Nobody
2 disagrees with training. Training is necessary for the
3 people, the clients and for the operators. It is important
4 to inform customers particularly about drug interactions.
5 There are some photosensitive drugs that can really mess
6 things up, psoralens in particular.

7 A trained operator should cover the topics in
8 FDA's warning labels with first-time tanners, and there was
9 a comment that actually, the salon is an excellent place to
10 do training. You can have the brochures and the information
11 right there.

12 Particularly, the comment was made do it in the
13 room before you get into the--not in the room where the
14 tanning takes place, but in the front office area where you
15 have time to talk to people. The comment was made by
16 several people that once you get into the room where the
17 lamps are, it is too late. They are preparing to undress
18 and get the tanning doses, and they don't want to read stuff
19 there. Do it beforehand.

20 [Slide.]

21 The other area of great concern was, as I said,
22 the melanoma-sunlamp connection. We had asked for comments
23 on this connection. We had also asked for comments on a
24 possible melanoma warning - should we include the word
25 melanoma in our warnings on lamps per se.

1 Back in 1994, the Academy of Dermatology asked us
2 to consider a ban on sunlamps mainly because of this
3 melanoma association. We looked at the data at that time
4 and came to the conclusion that--again, the study from
5 Sweden--things were suggestive, but not really conclusive,
6 and we came back and said no, it is not rigorous enough
7 right now for us to do a ban. So, we told the Academy that.

8 Four years have passed. We have gotten the
9 comments from the ANPRM. We have had many scientific
10 meetings, a really big one at NIH a year or so ago. There
11 have been some recent reviews, which Dr. Weinstock will talk
12 about. I think that statement still holds. The evidence is
13 suggestive, but not conclusive.

14 As I say, some studies show a positive
15 association, some show negative, others show no association
16 at all. The data is not strong.

17 We also asked for comments about putting these
18 warning labels, these warning statements in catalogs,
19 specification sheets, and brochures. We only got two
20 comment on that - one agreed, and the other one said we have
21 a problem with that. This was a manufacturer who did home
22 units, and we have a problem with that because we don't give
23 a whole lot of materials out, and we just want to know what
24 it is that you want us to do. We don't want to have a large
25 expense in this operation.

1 [Slide.]

2 Informed consent. There was remarkable agreement
3 on that, and that is, that people who come into salons
4 should know the risk that they are encountering, and perhaps
5 should even have a signed consent statement, and efforts are
6 actually underway right now by the indoor tanning industry
7 to require written consent statements even for particularly
8 young clients. By "young," I am not sure, I think 18 or 16,
9 I forget the age, but there are some efforts underway right
10 now to actually suggest and implement this.

11 [Slide.]

12 Other comments. Sometimes you get unexpected
13 comments. Somebody said on timers, that right now one way
14 to--there is a panic button sort of thing--and one of the
15 ways you can have this panic button is just to turn the
16 timer off. One comment came in and said no, separate that,
17 have a separate emergency switch, a separate shut-off
18 switch.

19 Eyewear. There are requirements for protective
20 goggles, and one person wanted to add something to the
21 warning label saying, "If you see light, do something,
22 change your protective eyewear." If you see light,
23 something is wrong.

24 This one was totally unexpected. Make some
25 requirements for sanitary pillows. I am not even sure that

1 is our standard, but it was a fun comment.

2 [Slide.]

3 Efficacy ratings for bulbs. The issue here is
4 replacement bulbs, replacement lamp. I said "bulbs," I
5 think the proper term is lamps, a bulb is an electric bulb.
6 Efficacy rating for lamps. When a lamp burns out, you have
7 to find a suitable compatible lamp to replace it with, and
8 right now we apparently have a very long list of lamps which
9 are suitable for replacement.

10 We wanted to simplify that, and one way of doing
11 that was to have a rating system and putting similar lamps
12 into a particular classification. Actually, there was fair
13 agreement that this was needed.

14 There was one suggestion that we take this
15 approach and use something called a UV index as part of the
16 rating system, actually use the UV index for doses that
17 people get in the tanning salon. UV index is the index that
18 has been developed by NOAA and EPA.

19 You probably hear it on weather reports, takes in
20 cloud cover, the fact that it is summer versus winter, the
21 index today is 9. It is a system that many people
22 understand and it might be very useful for people to be
23 dealing with a system that they understand.

24 I also understand that actually, the IEC, the
25 International Electrical Technical Commission, has been

1 considering the use of this index, so I think we need to
2 spend some time and effort and really evaluating the
3 usefulness of the UV index.

4 There was disagreement as to whether testing of
5 lamps is needed or testing of the whole sunlamp system is
6 needed. One person said that all you really needed to do
7 was to know the characteristics of the lamp and a tanning
8 bed, which has 10, 12, as many lamps, is nothing more than
9 the sum of the individual lamps, whereas, another person
10 said no, no, no, you really need to know the system. You
11 need to know the reflective characteristics of the material
12 behind the lamps in addition to just the lamp itself.

13 I may be missing something in the comments, and I
14 have got to get back to these people and find out what they
15 are talking about here. This seems to be an engineering
16 problem that could be easily solved, and what appears to be
17 a disagreement, I think probably has a solution here, but I
18 wanted to point out that even on this simple engineering
19 thing, there was some disagreement.

20 [Slide.]

21 Recertification. After you have replaced a lamp,
22 this now becomes a new tanning bed, and essentially become a
23 manufacturer, and we wanted to make some changes in the
24 standard to show that anybody who makes changes to tanning
25 systems in effect becomes the manufacturer, and they should

1 know the laws and the regulations as a manufacturer.

2 There were many comments about this requirement,
3 and people said make it a strong requirement because we are
4 concerned. The biggest concern was insurance coverage. We
5 want to make sure that whatever changes you have, don't
6 change the characteristics of the lamp and people aren't
7 going to be accidentally burned or something like that
8 because then you have got insurance considerations.

9 So, many, many people commented that whatever you
10 do, don't mess up our insurance coverage.

11 [Slide.]

12 I want to address two important issues. The first
13 one is the call for banning of sunlamps, which was done, as
14 I said, in 1994, and again when the Academy of Dermatology
15 sent their comments in, they said maybe ban these things.

16 Right now we never had plans on banning of it. It
17 was the Academy of Dermatology that asked us to do that. I
18 said there are no immediate plans to ban sunlamps. The
19 connection between melanoma and sunlamp is not well
20 established. The science is not rigorous.

21 The second this is going to a salon or going to
22 the sun and getting a tan is a choice issue. You are free
23 to do it.

24 The third thing is the risks are actually fairly
25 well understood by the public. You have had millennia to

1 understand how much sun you can take before you burn or tan,
2 the thing there being--and I think people say they expect,
3 if they are going to a tanning salon, that the risk would be
4 about the same, certainly not more dangerous.

5 So, risks are understood and it is a choice issue,
6 they can do it.

7 [Slide.]

8 The other issue that evolved as being major was
9 this melanoma warning. There are three ways we could deal
10 with that, that have been suggested - yes, put one in. Even
11 though the science is not rigorous, err on the side of
12 public health and include the words melanoma in your
13 warning.

14 The second way we could deal with it is no, the
15 science is not that rigorous, so don't put something into a
16 warning label that you really can't solidly defend, don't
17 put it in there. This still gives you the option of
18 discussing it in scientific literature and your supporting
19 materials, your public health statements that you have on
20 web sites and things like that, where you can talk about the
21 data, the good points and the bad points, the pros and the
22 cons, but don't put it in the warning label per se.

23 There is actually a third way we could deal with
24 it, and that is way that the International
25 Electrical/Technical Commission has dealt with it, and we

1 are part of that. We have one member of our staff who is
2 actually on that commission.

3 They have come up with this in their warning -
4 Skin cancer (sometimes fatal).

5 It does two things - doesn't single out melanoma,
6 but it does admit that sometimes there are fatal cancers,
7 and these fatal cancers could be either squamous or basal,
8 too. In most cases, even with melanoma, fatality of skin
9 cancer is usually due to people who totally neglect it.

10 These are surface lesions, and it is unfortunate,
11 but the fatality is for people who ignore lesions.

12 Another advantage of the IEC warnings is that it
13 is an international standard, and one of our reasons for
14 proposing new amendments was to be in conformity with
15 international standards.

16 [Slide.]

17 Where do we go? Well, as I said, we got all this
18 data. It is not all analyzed. We haven't come to
19 decisions. We still need to continue to evaluate the data
20 and comments for the ANPRM.

21 We need to work with the people who submitted
22 these comments. We still have questions. I told you about
23 is it just the lamps or the system. We need to get back
24 with these people and clarify these things, can't make a
25 decision without all the full information, and I need to

1 have time to work on that.

2 Let me back up a bit. One of the things was this
3 melanoma business. This was so important that maybe we
4 needed to drop everything and put all of our resources and
5 do something immediately and put out proposed amendment
6 within a matter of months.

7 We are not in that situation. All the comments
8 and stuff came back and said, no, we don't need to drop
9 everything and do this in a couple months. I think we have
10 got time to do what I am talking about here - continue to
11 evaluate, continue to work with the people.

12 Also, FDA, and I think the industry too, should
13 start working with consensus organizations. As I say, the
14 Modernization Act of FDA 1997 says that, "If you can use a
15 recognized national or international standard, (approval) of
16 your product would be easier."

17 This is the way that we are headed, is to use
18 standards, and I think using a standard, such as the IEC, is
19 the way to go.

20 [Slide.]

21 There is still research going on. Even last week,
22 and this is a changing situation, even last week, another
23 report came out in P&P, Photobiology and Photochemistry, on
24 again this melanoma business with the fish. There is a
25 report by Moan and Setlow. They have a theory as to maybe

1 why UVA is connected.

2 It is a changing situation. We need to continue
3 to monitor this research. We even have research ongoing
4 right now in CDRH on sensitivity of different skin types.
5 It is just getting started. It is a great project. I hope
6 it gets finished, and we can have the data from it.

7 I am going to brief the tanning industry in
8 November, going to Chicago, telling them essentially what I
9 am telling you and perhaps a little bit more. There is
10 probably going to be changes between what I say now and
11 November, just a couple of months, but I am going to go to
12 the tanning industry and explain to them the process.

13 As I said, many of them were very nervous because
14 they didn't understand the process, why didn't you consider
15 economics, why aren't you addressing all of my questions in
16 a real-time situation, and I need to tone them down and tell
17 them this is just the initial stage, here is what the
18 process is, and there is still plenty of time for everybody
19 to submit more comments in this process.

20 Then, after all the evaluation, we can draft
21 proposed rules, bring it back to you, TEPRSSC, for advice,
22 and then possibly go on and publish a Proposed Rule. That
23 is where we stand. Lots of comments. The evaluation is
24 still ongoing

25 I am open for questions.

1 MR. FLETCHER: Dr. Cyr, let me ask. Are you going
2 to be around for the remainder of the morning?

3 DR. CYR: Yes.

4 MR. FLETCHER: What I suggest, since you have
5 referred to Dr. Weinstock's presentation many times, that we
6 go ahead with our break now, have Dr. Weinstock present, and
7 then reserve questions.

8 DR. CYR: I will not be here this afternoon. I am
9 meeting with the industry folks to talk about this morning
10 in Chicago.

11 MR. FLETCHER: We will get back to you this
12 morning, because we only have one more presentation. If the
13 committee agrees, I think that is the way we should proceed.

14 We will now take a 15-minute break. Please be
15 back by 10:20.

16 [Recess.]

17 MR. FLETCHER: Before we call upon Dr. Weinstock,
18 there is something we didn't do this morning, and I want to
19 do briefly now, is I would like for each member of the
20 committee to just give a short introduction, who they are,
21 et cetera, beginning with Dr. Rice.

22 DR. RICE: I am Bill Rice. I am a radiologist. I
23 work in Baltimore for American Radiology.

24 DR. CARDELLA: Good morning. My name is John
25 Cardella. I am the Chairman of the Department of Radiology

1 at State University of New York, Syracuse Health Science
2 Center.

3 DR. MCKETTY: I am Marlene McKetty. I am a
4 medical physicist at Howard University Hospital.

5 DR. LIPOTI: I am Jill Lipoti. I am in charge of
6 the New Jersey Radiation Protection Program in the
7 Department of Environmental Protection.

8 MR. THOMAS: I am Jerry Thomas. I am a medical
9 physicist and assigned to the Uniformed University of the
10 Health Sciences.

11 MR. SZEGLIN: Steve Szeglin, medical physicist,
12 PTW New York Corporation.

13 DR. SULEIMAN: I am Orhan Suleiman. I am
14 Executive Secretary for the committee.

15 MR. FLETCHER: I am Roland Fletcher. I am the
16 manager of the Maryland Radiological Health Program, and I
17 am the Chairman of the committee.

18 MS. FAHY-ELWOOD: Alice Fahy-Elwood. I am a
19 health physicist at Lucent Technologies.

20 DR. SANDRIK: John Sandrik, imaging physicist at
21 GE Medical Systems.

22 MS. KAUFMAN: Cass Kaufman, Director, Los Angeles
23 County Radiation Management.

24 DR. LOTZ: Greg Lotz. I have a background in
25 physiology and biophysics, and I am the Chief of the

1 Physical Agents Effects Branch at NIOSH, the National
2 Institute for Occupational Safety and Health, in Cincinnati.

3 MR. FLETCHER: And Dennis?

4 MR. WILSON: I am Dennis Wilson. I am the VP of
5 Engineering for Heat and Glo. My background is microwave
6 ovens for about 20 years.

7 MR. FLETCHER: Thank you very much. I would like
8 to remind the committee--and you all did it that time--to
9 please remember to speak directly into the mike, so that
10 your comments can be recorded.

11 I will now call upon Dr. Weinstock to give us a
12 presentation. I guess Dr. Cyr is going to do an
13 introduction.

14 DR. CYR: Dr. Martin Weinstock has a dual
15 association. He is with the Veterans Hospital up in
16 Providence, Rhode Island. He also is in the Medical College
17 at Brown University, Department of Dermatology.

18 I know him from our association in the American
19 Society for Photobiology, of which both of us are members.
20 He is co-author of a paper which has looked at the Epi
21 studies, the epidemiology studies on sunlamp and skin
22 cancer.

23 **Guest Speaker/UV Radiation**

24 DR. WEINSTOCK: Thank you all for inviting me.
25 This is an honor to be able to share my thoughts with this

1 group. I think part of the reason why I am here is because
2 of my background in epidemiology in addition to being a
3 dermatologist who sees patients with melanoma and other
4 sorts of skin cancers, and who clinically specializes in
5 that. I also do research, which is epidemiology research,
6 which is the basis for much of what I will be saying. That
7 is what my Ph.D. is in and that is what my grants are in,
8 and much of that epidemiology research relates to melanoma,
9 and what doesn't relate to melanoma, for the most part
10 relates to non-melanoma and skin cancer, such as basal and
11 squamous cell.

12 [Slide.]

13 With that introduction to who I am, and I do
14 indeed work at the VA Medical Center and at Brown
15 University, Rhode Island Hospital, and various other
16 institutions around Rhode Island, I will just move right on
17 to the main topic, which is the relationship between tanning
18 lamp use and melanoma.

19 [Slide.]

20 The main I think message with melanoma is too much
21 sun, and the reason why melanoma has increased so
22 dramatically in the past 60 years since we have records of
23 incidence rates, where it has gone from 1 per 100,000 to
24 about 15 to 20 per 100,000. So, that is about a 2,000-fold
25 increase in melanoma over 60 years since the late 1930s.

1 The primary reason for that I believe is that our
2 attitude and habits with respect to sun exposure have
3 changed, and we have gone from a very sun-protected
4 lifestyle where people would go to the beach with parasols
5 and clothing that would cover their legs and cover almost
6 all their skin 100 years ago to our current lifestyle now
7 that describes how exposed people are when they engage in
8 recreational activities.

9 [Slide.]

10 So, that is the main story with melanoma.
11 Melanoma is a huge public health problem. The leading sites
12 of cancer is increasing more rapidly than any other in this
13 decade according to published reports, and it kills over
14 7,000 people a year. It is a major public health concern
15 particularly because of the potential for prevention and
16 early detection.

17 Now, in terms of tanning facilities, this is my
18 understanding. None of this is based on my own research,
19 but just gathered from literature. About 12 million persons
20 per year, visits per year to commercial tanning facilities
21 in the U.S. Children are allowed in general, although
22 regulations vary from state to state.

23 One survey found 8 percent were age 16 to 19, 8
24 percent of the visits to the commercial tanning facilities,
25 and 42 percent in their 20s, and 71 percent female. I

1 should just point out that among women in their 20s, of all
2 the cancer sites in the SEER registry, which is the main
3 cancer registration system for the United States, melanoma
4 is the most common. So, even though melanoma is not the
5 most common cancer overall, that is one particular
6 demographic group in which it is the most common.

7 [Slide.]

8 I am from Rhode Island. I don't know how many of
9 you have been to Rhode Island. This is Rhode Island right
10 there. Not very big, but it is a very important state, at
11 least for me.

12 [Slide.]

13 I am going to share with you one--it's an old
14 slide, about two years old or so--it is a flyer that I got
15 in Rhode Island, and this aroused a lot of concern in me and
16 many others. I guess we need to get the lights down a
17 little bit to read this.

18 I will read it for you. It is here in Rhode
19 Island. It is, of course, a new tanning salon. One of
20 things it says to which I want to draw your particular
21 attention, brand-new, state-of-the-art, blah-blah-blah.

22 One of the things it says right here is UVA and
23 UVB safe, FDA approved, and then it goes how you get five
24 tans for 20 bucks, and so on, and so forth.

25 Clearly, this type of advertising is disturbing.

1 I think it is disturbing to individuals in industry who are
2 trying to set a reasonable standard for industry, as well as
3 for regulators. I don't know how common this is. This was just
4 one flyer that was handed to me, anecdotal report there.

5 [Slide.]

6 I have listed here some of the biologic effects
7 that are attributable to tanning lamp exposure according to
8 generally accepted understanding of these devices. Number
9 one is acute sunburn, which occurs actually in a mild form
10 in a substantial proportion of patrons according to
11 published surveys.

12 Reaction to medication. There have been severe
13 burns in people on photosensitizing medications, and
14 undoubtedly much more common mild phototoxicity in others.
15 Polymorphous light eruptions, exacerbation of systemic lupus
16 or porphyria, sunbed lentigines, which is a type of
17 pigmented lesion, atypical melanocytic lesions in the
18 setting of UVA and PUVA particularly. It is less clear how
19 closely they are related to tanning booths in the absence of
20 a photosensitizing medication.

21 Skin fragility, phototoxicity, suppression of DNA
22 repair in the skin, cutaneous immune functioning. These are
23 laboratory markers. The practical significance of those is
24 uncertain, I would say, or unproven, a variety of ocular
25 effects, squamous cell carcinoma of the skin. I think we

1 have good evidence that tanning lamp exposure is capable of
2 inducing that. The action of squamous cell carcinoma of the
3 skin is fairly well worked out, and there is other evidence
4 that supports the presumption that tanning lamp exposure can
5 give rise to those.

6 Melanoma and basal cell carcinoma are question
7 marks, and the main thing that I wanted to talk about for
8 the rest of this, about 15 minutes, will be melanoma,
9 because melanoma is the leading cause of death among skin
10 conditions, and hence, is the greatest public health
11 concern.

12 I just want to have one more mention about
13 photosensitizing medications. This is a partial list of
14 medications that may cause phototoxicity. I was thinking
15 about the practical aspects of having the tanning booth
16 operators, who may be high school students or other people
17 without extensive medical training finding out whether all
18 their patrons are exposed to any of these medications.

19 Now, it is not quite as bad as it looks because
20 even though this is only a partial list, and there are more,
21 and to compound it, the list keeps changing as new
22 medications are approved and other medications are withdrawn
23 from the market, but there are a smaller number of these
24 that are responsible for the bulk of photosensitivity, and
25 the one that has been responsible for the most serious

1 reactions that I have heard about in tanning booths is
2 psoralens. A lot of these give photosensitivity reaction
3 sometimes, but not frequently.

4 So, that is sort of one of the complexities of
5 this whole issue.

6 [Slide.]

7 Now, I just want to make this statement.
8 Ultraviolet radiation cause melanoma. There are some people
9 who have, in some quarters, been referred as "full-mooners,"
10 who dispute this, but there have been prestigious
11 international bodies that have concluded this, the evidence
12 is very strong, it's multifaceted, it comes from many
13 different types of research, and I think it is fairly
14 conclusive that ultraviolet radiation, primarily from the
15 sun, which is the major source of ultraviolet radiation, is
16 a major cause of melanoma. It is certainly not the only
17 cause, and there are other cause which are important.

18 If someone cares to dispute this, I would be happy
19 to discuss it further, but I think it is generally accepted
20 in the scientific community at this point. The
21 International Agency for Research on Cancer published a
22 detailed review in 1992 that reached that conclusion.

23 [Slide.]

24 The relationship between ultraviolet exposure and
25 melanoma risk, however, is not completely straightforward,

1 and the ultraviolet is most effective in inducing melanoma
2 with intense exposures and with intermittent exposures, and
3 with early exposures meaning early in life exposures, and
4 that has given rise to this whole concept of sunburns to
5 melanoma, and so on, because that is the intense
6 intermittent exposure that has been closely linked to
7 melanoma.

8 It is not proven that sunburns cause melanoma.
9 What can be inferred from the existing epidemiologic
10 literature is at least in temperate climates, the type of UV
11 exposure that is most closely linked to melanoma is the
12 intense intermittent exposure, such as the types of exposure
13 that give rise to sunburns, which tend to be intense and
14 intermittent.

15 Early exposure meaning exposure early in life has
16 been particularly related to melanoma. The lag period for
17 melanoma is thought to be on the order of 20 years or more
18 between exposure and the actual onset of the condition.

19 [Slide.]

20 The relation to commercial tanning facilities is a
21 little bit less clear. There is a proportion of users in
22 commercial tanning facilities who sustain UV injury in the
23 form of erythema or other types of UV injury, and the
24 pattern of use of commercial tanning facilities is not well
25 documented.

1 There is certainly a subgroup of people who use
2 commercial tanning facilities to get intense intermittent
3 exposures. That happens in two ways. Either they get
4 intense intermittent exposures in the commercial tanning
5 facilities where they expose themselves to the point of
6 erythema, and they do it over a fairly short period of time,
7 so they can get their tan quickly, or another group is the
8 group of people preparing for a vacation.

9 It used to be that those people who live near me
10 in Rhode Island, who are preparing to go to Florida for
11 spring break or something, they would just go down to
12 Florida, and they would be a little careful when they were
13 down in Florida because they knew if they weren't, they
14 would get a blistering sunburn and then they would be
15 miserable for their whole break.

16 Now, what they do, sometimes anyway, is instead of
17 doing that, they go to one of these commercial tanning
18 facilities and they get their ultraviolet exposure there, so
19 that when they go to Florida, they can be completely
20 uninhibited and really fry.

21 So, that is a real potential concern in terms of
22 intermittent exposure. Now, how common that is compared to
23 a more consistent pattern of tanning lamp use, I don't know.
24 That is not documented to the best of my knowledge.

25 [Slide.]

1 Now, the action spectrum. It is important to talk
2 about action spectrum in all this, and I don't have to
3 convince this group, there is quite a number of physicists
4 among you, but the action spectrum for melanoma
5 unfortunately is unknown.

6 What we do know, however, is action spectrum for a
7 number of other outcomes. We know the action spectrum for
8 erythema in human beings. The action spectrum of erythema
9 is heavily weighted in the UVB, meaning the UVB rays are
10 more efficient at inducing erythema in human beings than UVA
11 rays.

12 We know the action spectrum for squamous cell
13 carcinoma induction in rodents, which is a good animal model
14 for squamous cell carcinoma in humans, and that is very
15 similar to the erythema action spectrum, heavily weighted in
16 the UVB range. UVA can induce squamous cell carcinoma, but
17 is less efficient at doing so.

18 We don't know the action spectrum for melanoma, as
19 I mentioned. We have one animal model of melanoma for which
20 an action spectrum has been derived, and that is this
21 platyfish sword-tail back-cross hybrid, which is a little
22 black fish that it is so small, it can swim around its
23 cuvette, and what Dr. Setlow actually did was he put a bunch
24 of them in a cuvette, had them swimming around in his lab,
25 and exposed them to different wavelengths of monochromatic

1 light to see how frequently they get their melanomas, and
2 they do get melanomas.

3 The relevance of this fish model, which is
4 extraordinarily susceptible to melanoma from UVB light, UVA
5 light, and visible light, as well, which induces melanoma in
6 this model, the relevance of this to the human condition
7 where the people who get melanoma most are not the ones that
8 are heavily pigmented, they are the ones that are very
9 lightly pigmented. I mean we are a little different than
10 fish in a few other ways anyway.

11 So, there has been a lot of controversy about what
12 is the relation between the fish data and humans. There is
13 a possum model of melanoma where melanoma has been induced
14 by ultraviolet light. Ron Ley, who is the one who has done
15 that model, has tried to now expose the possums to UVA only
16 and see if he can get melanoma that way, and so far, he told
17 me the last time I spoke with him a few months ago, none of
18 his possums have gotten melanoma. They have gotten
19 melanocytic hyperplasia, which he believes to be a
20 precursor, but none of them have actually gotten melanoma.

21 There is one other thing that is relevant to
22 action spectrum, and that is xeroderma pigmentosum, which is
23 a human condition. It's a genetic defect of DNA repair
24 where these people are particularly unable to repair the
25 type of DNA damage that is induced by ultraviolet B

1 radiation.

2 They have extraordinarily high rates of basal
3 cell, squamous cell, and melanoma, like 1,000-fold excess
4 over the general population. So, if that is, in fact, due
5 to the UVB that they are extraordinarily sensitive to, then,
6 that suggests that UVB is important for melanoma.

7 But these are all very indirect forms of evidence.
8 We don't have direct evidence of an action spectrum for
9 melanoma in humans.

10 Now, the emission spectrum for tanning beds, how
11 well does that correspond to the action spectrum for
12 melanoma? Well, obviously, we don't know the action
13 spectrum for melanoma, but we also know that the emission
14 spectra of the lamps in commercial tanning booths are
15 variable. They are knowable in any one given booth, but the
16 user is almost uniformly without a clue. So, the consumer
17 doesn't know.

18 Even if the consumer were capable of understanding
19 action spectrum and all the concepts associated, the
20 consumer has no way of knowing when they go into the tanning
21 booth whether these lamps have very little UVB and they are
22 almost all UVA, whether they have a lot of UVB, what the
23 mixture ratio is. So, it makes it very difficult for
24 consumers.

25 [Slide.]

1 Now, PUVA therapy is important. That is where a
2 patient takes a psoralen pill--psoralen is a
3 photosensitizer--and then gets exposed for therapeutic
4 purposes for certain types of skin conditions to ultraviolet
5 A radiation.

6 There has been an article published now showing
7 that people who have a lot of these exposures, a lot of
8 these PUVA treatments, have a higher risk of melanoma. I
9 won't go into tremendous detail.

10 [Slide.]

11 This gives some of those details. There is a lot
12 of question about that article because it's just one study,
13 it hasn't yet been confirmed, but anyway there is evidence
14 in the literature linking PUVA therapy to melanomas.

15 [Slide.]

16 This is the type of study that has been published
17 that links tanning lamp use to melanoma. This is one from
18 Ontario. You see relative risks here. It is an
19 epidemiologic case-controlled study of melanoma among men
20 according to duration of use of tanning booth, relative
21 going from 1.0 in the reference group of those people who
22 never used one, up to about 2.0, and in women, going from
23 1.0 up to about 3.0. These were significant trends.

24 This is one case-controlled study. This is the
25 type of thing that has led to the concern about tanning

1 booths and melanoma.

2 [Slide.]

3 Overall, we reviewed, as Dr. Cyr mentioned, 19
4 published case-controlled studies which we believe to be, at
5 least as of last year, all of the published case-controlled
6 studies relating to tanning lamps and melanoma risk.

7 Six of those 19 studies showed a direct relation,
8 the more tanning lamp exposure or tanning lamp exposure was
9 associated with melanoma risk; 13 showed no association.
10 None of them showed an inverse association, in other words,
11 none of them showed that tanning lamp exposure protected you
12 or reduced your risk for melanoma of these 19 studies.

13 Several of them noted dose or duration-response
14 relationships, others just noted an overall association.

15 [Slide.]

16 As was alluded to already, there were significant
17 limitations. The intensity and spectra of the devices were
18 in general unknown because consumers have no idea what they
19 are getting when they are going into a tanning booth other
20 than there is ultraviolet radiation.

21 There was concern about recall bias and recall
22 inaccuracy in stating how often you used the tanning lamp or
23 how often you were exposed to a tanning lamp many years
24 past. Many exposures were minimal, and so they really
25 shouldn't be included with the people who had heavy exposure

1 if you are looking for a relative risk associated with it.

2 Many exposures were too recent if you believe, in
3 fact, the 20-year lag period for melanoma, which I do, and
4 there is evidence to support that. Many of the analyses
5 were poorly described, particularly those that found no
6 association. As you might expect, there is a bit of
7 publication bias there because if you find an association,
8 then, that becomes the headline of your article and you
9 describe your analyses in more detail.

10 If the main point of your article is that you are
11 looking at how many times you went to the beach in
12 relationship to melanoma, and you asked about tanning lamps,
13 and you didn't see an association, that merits one sentence,
14 you don't get a lot of details in that analysis. These were
15 all limitations of that group of studies.

16 [Slide.]

17 There were also confounding variables.
18 Recreational sun exposure can be a confounding variable,
19 such as the people who expose themselves to tanning booths
20 prior to recreational sun exposure on a holiday, as I
21 mentioned.

22 Socioeconomic status, we believe is a confounding
23 variable because people who have more money, more disposable
24 income are more likely to use tanning booths and also are at
25 a higher risk of melanoma. On the other hand, sun

1 sensitivity people are more sun sensitive. That can be a
2 confounding variable, as well.

3 [Slide.]

4 So, all these things sometimes were taken into
5 consideration in some of these studies, but certainly not
6 consistently, and frequently they were not even measured.

7 I mentioned the issue of publication bias.
8 Probably the most important issue with these studies is
9 statistical power because these studies in general did not
10 have, in my opinion, sufficient statistical power to detect
11 a real association.

12 A lot of the exposures were too recent given the
13 lag period for melanoma to have had enough exposures far
14 enough in the past to have had a plausible effect on
15 melanoma incidence at the time that the study was conducted.

16 Many people who were included in the exposed
17 groups had too few exposures to have a plausible effect.
18 The effect is more likely to be seen among those who had
19 intense exposures. Many had very few users of tanning booth
20 because they are asking about exposures in the past, and
21 tanning booths have become more popular in recent years.

22 [Slide.]

23 So, to conclude here, I would say that there is
24 reason to suspect that exposure to tanning lamps would
25 increase melanoma risk, but the existing data are

1 insufficient in my view to prove or disprove the link
2 between tanning lamps and melanoma.

3 So, it must remain at this point a hypothesis that
4 has some evidence behind it, but that is not proven.

5 I had a personal suggestion based on my background
6 as a researcher. Now, if I was to do a research study, say,
7 a randomized trial of tanning booth exposure, and followed
8 people for 20 years to see if they are going to get melanoma
9 at the end, one thing I would have to do before I enrolled
10 the first person is to get an informed consent form, make
11 sure the person signs it. That informed consent form would
12 have to list all the known and likely risks of participation
13 in the study including being exposed to tanning booths.

14 Now, if I had to do it to get an answer to the
15 question, certainly the public which is being exposed to
16 this vast experiment with this technology, I think it is
17 reasonable to require that they get informed consent, as
18 well, and that they be informed of the risks that are proven
19 and the risks that are likely, and being told what the
20 probabilities are.

21 Certainly, for minors, I think parents should be
22 involved in the consent process, so it should be required to
23 sign consent from the parents because, as the parent of two
24 teenagers, I can tell you that I would really appreciate it
25 if society were more supportive of parents trying to guide

1 their teenagers who tend to do risky behaviors without any
2 thought of possible consequences.

3 So, having said that, I am done with my slides,
4 but I did want to make a few comments that were triggered by
5 Dr. Cyr's presentation. There were a few points I just
6 wanted to make.

7 One, he did talk a lot about phototypes in his
8 discussion, Phototype I, Phototype II, et cetera. It is
9 important for this committee to be aware that there is a lot
10 of difficulty in defining phototypes, and while Dr.
11 Fitzpatrick, who trained me and who developed this system,
12 he knows what a skin Type I, Type II, Type III, and Type IV
13 are, and Type V and Type VI, when other people have tried to
14 obtain that same knowledge for particular individuals, what
15 has been observed is that their knowledge of a person's
16 phototype is somewhat unreliable from one observer to
17 another. These are among even expert observers. Dr.
18 Fitzpatrick is excluded, of course.

19 So, if you are going to hang your hat on
20 phototypes for any of your regulations, you just have to be
21 careful about how you are defining them. Obviously, it is a
22 continuum of sun sensitivity from the very sensitive to the
23 very insensitive to the adverse effects of UV light.

24 The second thing I wanted to mention which is not
25 part of this talk is the issue of benefits from tanning

1 lamps, does it benefit you with breast cancer, prostate
2 cancer, colon cancer, Vitamin D, et cetera.

3 There is a few points to make about that. Number
4 one, Vitamin D deficiency is not a problem in the population
5 that goes to tanning salons or in the population from which
6 the tanning salon patrons are derived.

7 Vitamin D in our society is primarily an issue
8 among the elderly where their Vitamin D absorption from
9 dietary sources decreases, and they have risk of hip
10 fractures, and so on, and so forth, which can be quite
11 serious.

12 I have spoken with some endocrinologists about the
13 amount of sun exposure that you need to get Vitamin D,
14 adequate Vitamin D, and so this is not based on my own
15 research, but rather based on my conversations for things I
16 think would be useful to you as background.

17 First of all, you take some people, such as those
18 patients with xeroderma pigmentosum that I mentioned, the
19 people who get all these skin cancers when they are
20 children. They get lots of basals and squames and
21 melanomas, hundreds in childhood they are so sensitive to
22 the ultraviolet light.

23 Some people who take care of these particular
24 individuals with this genetic defect rigorously sun-protect
25 them, and I mean very rigorously sun-protect these

1 individuals, much more than any rational person would submit
2 themselves to because of their particular problem.

3 Recently, there was a study published looking at
4 the Vitamin D status of these individuals, and they all had
5 normal Vitamin D status. None of them were Vitamin D
6 deficient. So, that is one thing.

7 There was a randomized trial of sunscreen use in
8 relation to actinic keratoses, which are a skin cancer
9 precursor in human beings, and that randomized trial found
10 that, in fact, sunscreens were effective in reducing the
11 incidence and increasing the rate of spontaneous regression
12 of actinic keratoses. So, these people were sun-protecting
13 themselves with sunscreens. Their Vitamin D levels were
14 also examined, and they were found not to be Vitamin D
15 deficient.

16 My understanding is that for a person in the
17 Boston area, which is not the sunniest area of the country,
18 to get more than adequate Vitamin D from sunlight
19 synthesizing their skin, they need to expose themselves,
20 face and arms, for five minutes a day, three days a week,
21 for the six months when the sun is the strongest, and that
22 will give them more than enough Vitamin D. That is for a
23 typical Bostonian.

24 For people with dark skin, such as people with
25 medium brown or dark brown skin, that probably has to be

1 increased to about 15 minutes or so was what I was told.
2 For people in the southern part of the country, that would
3 be decreased, so the five minutes would become maybe two
4 minutes.

5 So, we are talking about brief exposures, these
6 are noontime exposures. It is important to realize in terms
7 of action spectrum that it is the ultraviolet B that results
8 in the endogenous Vitamin D synthesis in the skin, not the
9 ultraviolet A. So, the ultraviolet A rays are pretty
10 useless in that regard. It is the ultraviolet B that does
11 it. Those are the same rays that give rise to the burns and
12 the squamous cell carcinomas.

13 There was a comment made about the public's
14 understanding of the risks of tanning booths. All I have is
15 anecdotal evidence, but I certainly have lots of people who
16 come up to me and say aren't tanning booths safe, isn't that
17 the safe ultraviolet radiation.

18 So, I think that there is a lot of
19 misunderstanding about tanning booths. People don't
20 understand that this is the same ultraviolet radiation that
21 they get from the sun. There is some feeling on people's
22 part that this is really safe and ignorance about these
23 potential hazards even among people who are aware of hazards
24 of intensive sun exposure.

25 I want to mention two research articles about

1 sunscreens that have come out--well, one has come out
2 recently, one has only been presented and has not yet been
3 published--that suggests that sunscreens are efficacious at
4 preventing skin cancer.

5 One relates to melanoma where it was found that
6 sunscreens were efficacious in a randomized trial in
7 reducing the multiplicity of moles, which is a melanoma
8 precursor in children. That was a randomized trial, and
9 that confirms the importance of sunscreens.

10 Another one was just published in Lancet by Adele
11 Green, which found again, in a randomized trial, sunscreen
12 seems to be effective in preventing squamous cell carcinoma
13 even if only used for about four or five years.

14 The final comment I want to make is about deaths
15 due to melanoma. Deaths due to melanoma are not necessarily
16 due to neglect by the patient of an obvious lesion. The
17 case fatality rate for melanoma is on the order of about 15
18 to 20 percent. Some of these people are physicians. I have
19 case stories I can tell you about physicians who just
20 ignored spots on their skin or just weren't aware because it
21 was a place they don't look, and like on their back, they
22 can't see it well, and then it turned out to be a melanoma
23 that killed them.

24 Some melanomas grow more rapidly than others.
25 Some people are more aware of their skin than others. It is

1 not necessarily gross neglect of an obvious lesion that
2 gives rise to death from melanoma.

3 So, that is the final thought I wanted to leave
4 you with, and that is all I have to say. Thank you very
5 much for your attention, and I welcome your questions.

6 MR. FLETCHER: Thank you very much, Dr. Weinstock.
7 Member of the committee? Cass.

8 MS. KAUFMAN: When we talk about different
9 phototypes, is it possible and is it likely for a person to
10 have more than one phototype on different parts of their
11 body, or is it generally they are just, for example,
12 Phototype II all over, or might they be Phototype II except
13 on their chest, for example, that might be Phototype I?

14 DR. WEINSTOCK: The definition of phototype,
15 according to Fitzpatrick, who defined the term, describes
16 the person, not a particular region of the body. People
17 have measured experimentally the sensitivity of different
18 regions of the body to ultraviolet radiation, and some
19 regions get red sooner from ultraviolet radiation, others
20 are more resistant to that. So, there is variation across
21 the body, but that doesn't specifically apply to the term
22 phototype.

23 DR. LOTZ: When you were talking about the
24 epidemiology with respect to socioeconomic status, and so
25 forth, and you at least referred there to the likelihood of

1 people with higher socioeconomic status having the resources
2 to take more vacations and get more sun or go to the tanning
3 booth more, and so forth.

4 Have there been studies of people who
5 occupationally would be exposure more just to sunlight, not
6 to the tanning, such as construction workers or people like
7 that?

8 DR. WEINSTOCK: Yes. People who are
9 occupationally exposed to a consistent pattern of sun
10 exposure have lower melanoma risk than people who are not so
11 exposed, and that is one of the pieces of evidence that has
12 been used to support the intermittent exposure hypothesis.
13 It is more the stockbroker who works on Wall Street during
14 the week, never sees the sun except on Saturday and Sunday
15 when he goes to the Hamptons and gets fried. That person is
16 the type of person who gets melanoma as opposed to the
17 construction worker, working on Wall Street outside, who
18 gets exposed to the sun every day.

19 DR. CARDELLA: You read a lot about changes in the
20 atmosphere. Whether you believe about holes in the ozone
21 layer or not is not so much my question, but assume for a
22 minute that that might be true.

23 Is it conceivable that the 25 million tanning
24 salon users in a world of billions of people in which we
25 have now a swiss cheese ozone layer, let's say, would that

1 not be a more likely explanation for the rise in melanoma
2 incidence than the relatively small segment of the
3 population that uses the tanning beds?

4 DR. WEINSTOCK: I want to be clear about one thing
5 in preface to my answer, and that is that my best inference
6 from the available data is that the primary cause of the
7 rise in melanoma over the past 60 years is exposure to
8 sunlight and our patterns and attitudes towards exposure to
9 sunlight and our consequent behaviors with respect to
10 sunlight.

11 So, those trends that we see I believe are due to
12 the sun, not due to tanning exposures. Tanning lamp use has
13 become very popular more recently, and given the 20-year lag
14 time to melanoma, I don't think that any of our statistics
15 really reflect much of a bump from tanning lamp use.

16 As I said, I don't think the relationship is
17 proven, but even if tanning lamp use were to be proven to
18 cause melanoma, I would be extremely skeptical of anyone who
19 claimed that the increases we are seeing now are due to
20 that.

21 Now, going forward, it becomes more of an issue
22 because as these booths have now been popular for a longer
23 period of time, soon we will get beyond that lag period, and
24 then we may see an effect.

25 So, I would say unequivocally to your question, I

1 see no reason to suspect that tanning lamp exposure to date
2 has had a significant impact on melanoma incidence that we
3 have observed to date.

4 DR. CARDELLA: Just as a followup. So, you are
5 saying that the increased incidence in your mind is more
6 related to behavioral aspects or attitudes about being
7 tanned as equivalent to healthiness or you look buffed as an
8 example.

9 DR. WEINSTOCK: Exactly.

10 DR. CARDELLA: And not so much the changes in any
11 atmospheric filtration or anything like that.

12 DR. WEINSTOCK: In terms of the ozone hole, there
13 has been depletion of ozone, there has been some increase in
14 ultraviolet, particular ultraviolet B reaching the surface
15 of the earth due to that.

16 There are many other factors that affect those
17 things, and I guess none of you are atmospheric chemists,
18 but having talked to one about these, and actually having a
19 whole series of conversations, it gets very complicated very
20 quickly, but the fact of the matter is that more UV is
21 getting through because of the ozone hole, but the magnitude
22 of that in temperate climates is modest. We are talking
23 about maybe 20 percent more over the last decade, and
24 compared to a 2,000 percent increase in melanoma, and
25 compared to the vast changes in behavior, it is unlikely to

1 have played a major role to date.

2 Again, the ozone depletion is an issue going
3 forward. We have now the Montreal protocol, and so on, and
4 hopefully, the ozone layer will repopulate itself and so it
5 won't be too much of an issue going forward, but the
6 potential is there for significant impact going forward, but
7 to date I don't think it has been a major factor.

8 MR. FLETCHER: Jerry Thomas.

9 MR. THOMAS: I am concerned in what I have heard
10 both you and Dr. Cyr say regarding that there is no evidence
11 in the literature regarding a causal relationship between UV
12 exposure from tanning booths and melanomas.

13 With a latent period of 20 years, tanning booths
14 have not been around for 20 years obviously. To do an
15 appropriately controlled study requires a very large "n" and
16 also requires deliberate exposure under controlled
17 conditions, I don't think we are ever going to see that. I
18 don't think the NCI or the NIH is going to fund that type of
19 a study.

20 What are your thoughts about really us ever seeing
21 sound causal relationships in the scientific literature to
22 support the claim that is being made that there is a
23 relationship, but you can't prove it?

24 DR. WEINSTOCK: I agree with your statement
25 entirely. I don't think we will ever see a randomized

1 trial. I think a randomized trial would be almost
2 impossible to get past an institutional review board,
3 because it would be viewed as unethical, and I think that
4 the types of evidence that will accumulate over time is the
5 observational evidence, the epidemiologic data.

6 I have talked about briefly, but I mentioned some
7 of the flaws in that observational data.

8 I think if we see--I don't know what the magnitude
9 of the association is going to be--if we see a powerful
10 association, then, these flaws may sort of become less
11 important, and we may be able to make some reasonable
12 inferences based on epidemiologic data, but having to wait a
13 long period of time, unfortunately, that is what
14 epidemiology is. I mean we observe the diseases people get.
15 They have to get sick or die before we can make an inference
16 about it.

17 So, that is a sort of dismal way of going about
18 things, but that is the most likely type of evidence I think
19 that is going to be convincing for human populations.

20 MR. THOMAS: I would like to follow up. Based
21 upon--I am sitting here forgetting my thought process--let
22 me come back.

23 MR. FLETCHER: Dr. Lotz, go ahead.

24 DR. LOTZ: I am aware of a study of police
25 officers in Canada that showed just an association with the

1 occupation and an increase in melanoma.

2 The question I had was does the melanoma
3 necessarily, is it necessarily associated with the area of
4 the skin that is exposed, or do people have apparently an
5 initial melanoma lesion in areas that are not exposed, and
6 what does that tell us about the cause and effect type
7 relationship?

8 DR. WEINSTOCK: That is actually a complicated
9 question, and the evidence isn't absolutely definitive.
10 There has been some speculation in the literature about a
11 so-called solar circulating factor that may affect melanoma
12 risk in sites that are not exposed.

13 My reading of the literature is that the risk of
14 melanoma is at least primarily, if not entirely, in the
15 areas that are exposed, but now let me add a caveat to that,
16 and I am talking about melanomas that are induced by
17 ultraviolet light.

18 Ultraviolet light is not the only cause of
19 melanoma, and in some circumstances, including particularly
20 people who, for example, have dysplastic nevus syndrome,
21 which depending on your estimate is between 2 and 10 percent
22 of the population, they not too infrequently get melanomas
23 on sites that you wouldn't think of as exposed even
24 intermittently.

25 So, it is a bit of a complex question.

1 MR. FLETCHER: Dr. Rice.

2 DR. RICE: What was the patient population in the
3 Ontario study, the numbers?

4 DR. WEINSTOCK: That was a study by Steven Walter
5 in the American Journal of Epidemiology 1990. I am
6 guessing, I don't remember exactly, I think the numbers were
7 around 500 cases, 500 controls, but I am not really sure, I
8 would have to pull it to give you a certain answer, but if
9 someone is checking the literature, Walter is the first
10 author. It is the American Journal of Epidemiology 1990.

11 DR. LIPOTI: In ionizing radiation, we have
12 something we call the linear non-threshold hypothesis, and
13 some people believe it, some people don't, but there is a
14 group of people who have suggested that there is indeed a
15 threshold for exposure to radiation which is safe, and, in
16 fact, they believe in hormesis, which says that you can
17 stimulate the repair mechanism by being exposed to
18 radiation.

19 Now, I am curious about that effect for non-
20 ionizing exposure, in particular UV. One of the things that
21 you listed in your list of health effects was suppression of
22 DNA repair in skin and cutaneous immune functioning.

23 What does that say about stimulation of the repair
24 mechanism, and what does it say about a threshold?

25 DR. WEINSTOCK: Those are very good questions. I

1 am afraid my answer won't be as good as the questions. In
2 UV photobiology, there has been I would say probably a lot
3 more work in the laboratory than epidemiology work, and so a
4 lot of known about laboratory phenomena, such as DNA repair,
5 such as various indices of immune suppression, whether you
6 are talking about contact hypersensitivity or whatever.

7 These can be profoundly perturbed by laboratory
8 exposure to ultraviolet radiation in rodents, as well as in
9 humans, and the experiments have been done both ways. I
10 don't know what the relevance of those is to human disease.
11 There have been many theories put forward, such as, for
12 example, the importance of having intact immune system to
13 reject incipient skin cancers before they become clinically
14 noticeable, but that is a theory. I mean maybe it's true,
15 maybe it is not. It sounds good.

16 In terms of inducing protective mechanisms, we do
17 know something about that. One of the responses of skin to
18 injury, not just ultraviolet-induced injury, but its
19 particular response to ultraviolet radiation is
20 melanization. There is an immediate tanning response, there
21 is a delayed tanning response, and so there is a
22 proliferation of melanocytes that can be induced by
23 ultraviolet, increased melanization of those melanocytes
24 that can be induced by ultraviolet, hyperkeratosis of the
25 skin that can be induced by ultraviolet, so the skin becomes

1 thicker, and since all the keratinocytes in the skin, which
2 is the main cell in the skin, have melanin in them, then,
3 that confers increased protection from the ultraviolet to
4 the deeper layers of the skin.

5 So, there are those sort of mechanisms that are
6 induced. There is some epidemiologic evidence that people
7 who tan well may get some degree of protection from
8 subsequent melanoma due to frequent ultraviolet exposure
9 relative to people who tan poorly, but that is very
10 controversial, and I would say the evidence there is weak.

11 So, there is a lot there that is not known, so I
12 am afraid your question was a lot better than my answer, but
13 that is what information I can give you.

14 MR. FLETCHER: Jerry Thomas.

15 MR. THOMAS: You gave an incredibly well balanced
16 presentation of the case-controlled studies, but in the six
17 studies that showed a relationship between melanoma and UV
18 exposure versus the 13 that did not, did you find a
19 difference in terms of the scientific approach to the
20 results that were reported between those two groupings?

21 In other words, what I am really trying to probe
22 is were the 13 studies so weak that they shouldn't stand on
23 their own in terms of coming up with a sound scientific
24 conclusion that there is a causal relationship versus the 6
25 that said there was indeed a causal relationship.

1 DR. WEINSTOCK: I don't think I can draw that
2 conclusion. Now, it is a little bit confounded, and even
3 answering your question is confounded, by the fact that
4 there is a little bit of a publication bias there, and that
5 studies, as I mentioned, that were focused on something else
6 and just mentioned that--well, they asked about tanning
7 booths, and there was no relation, there was a lot less
8 detail there, and the less detail you have, the less you can
9 evaluate the scientific quality of what was done, the less
10 attention was paid to those analyses, and so on.

11 The studies that had positive conclusions, that
12 had it as a headline, you know, sunlamps associated with
13 melanoma risk, such as that Ontario study, and so on, they
14 tended to have more detailed analyses, so it seemed like
15 they were--they were certainly better analyzed and better
16 described, but that doesn't necessarily mean that they were
17 better studies. They were certainly better reported
18 studies. The reporting of those studies was better is what
19 I meant to say.

20 The other thing that seemed to be in common among
21 those studies that showed a positive relationship was that
22 they tended to be in more northerly climates, in like Sweden
23 and Scotland and Ontario. I wouldn't say that was an
24 absolute rule, but there was a tendency towards that, and
25 those are climates where I mean one can draw all sorts of

1 hypotheses.

2 Maybe they have less natural sunlight, maybe more
3 of the natural sunlight is on vacations when they go from
4 Norway to Spain, and before that, maybe they get all their
5 ultraviolet exposure, and so they have that sort of
6 scenario, so you can speculate a lot of ways, but they did
7 tend to be more northerly locations.

8 MR. FLETCHER: Now that we are back on schedule, I
9 am going to allow one more question, and that is from Dr.
10 Sandrik, and then we need to continue.

11 DR. SANDRIK: You mentioned the difficulty in
12 determining phototype, I guess particularly by somebody who
13 is just observing or whatever. Do you think there is a
14 possibility of an objective test where you could give some
15 sort of a test exposure and see some sort of a response to
16 that, that might alleviate some of the difficulty in
17 determining what a phototype is?

18 DR. WEINSTOCK: There are objective tests. One is
19 the determination of the MED, or the minimum erythema dose,
20 which is the dose each person requires of ultraviolet light
21 to turn red, the first sign of acute phototoxicity, and that
22 can be determined experimentally by exposing different
23 squares on their back, say, to different intensities of
24 ultraviolet light, and then waiting 24 hours, and seeing
25 which was the lowest dose that turned that area of the skin

1 red.

2 That is used. It is not clear to me how reliable
3 that is, but it is more reliable than phototype I think, and
4 that is just an impression. I don't know of formal tests of
5 reliability of that. Maybe they exist, and I am just not
6 aware of them.

7 There are other means that have been used to
8 estimate sun sensitivity, such as measuring the amount of
9 melanin in untanned skin. That has not been as successful
10 as one would think it should be, but that can be done
11 photometrically and non-invasively.

12 The way I tend to do it in my own research studies
13 is to ask a series of questions, not just one phototype
14 question, but a series of questions - what is the tone of
15 your untanned skin, what is your hair color, how readily do
16 you tan, how deep a tan do you get, do you burn easily in
17 the sun, and by asking those questions and taking index of
18 the answers, you can get a strong corollary skin cancer risk
19 in terms of phototype.

20 MR. FLETCHER: Than you once again, Weinstock.

21 DR. WEINSTOCK: My pleasure. Thank you.

22 **Open Public Hearing**

23 MR. FLETCHER: At this point, we enter our public
24 hearing. We have three public speakers who will be allowed
25 to speak for 10 minutes each - Bill Pipp, Don Smith, and Joe

1 Levy. Bill Pipp, I guess will begin.

2 MR. PIPP: Good morning and thank you for allowing
3 me to have a few moments of your time here. My name is Bill
4 Pipp. I represent the Indoor Tanning Association. I serve
5 as the President. I also am a board member and Vice
6 President of ETS, Inc., the leading distributor of tanning
7 beds and lotions in the United States.

8 My purpose for reserving this time was to just
9 give you a little bit of an idea of what our organization is
10 doing, trying to accomplish.

11 The intent of the organization when developing the
12 Articles of Incorporation and the Bylaws was to have an
13 organization that represented all segments of the industry.
14 The industry is made up of tanning salons, tanning equipment
15 and lotion distributors, allied suppliers that represent
16 lotion suppliers, protective eyewear, associated products in
17 the cleaning of the units in the salons, the tanning trade
18 magazines, as well as the tanning training organizations,
19 such as SAE, Smart Tan, and various other ones that have
20 been evolving over the years.

21 The board of directors of ITA consist of 19
22 members, consists of 4 members from the salon segment of the
23 industry, 4 members from the distributor segment of the
24 industry, 4 members from the allied supplier segment of the
25 industry, and 7 members from the actual manufacturers of

1 tanning equipment.

2 We also provide for open board membership for
3 professionals, from the scientific community that do
4 research, the medical community, as well as the
5 dermatological community. We welcome those type of board
6 members because they serve as advisers to what I would say
7 is non-Ph.D., M.D. type people that would like to have that
8 advice and understanding of what is going on within our
9 industry as it relates to UV radiation.

10 The primary focus of the Indoor Tanning
11 Association was to ensure uniform education and training for
12 all segments of the industry as it relates to responsible
13 use of tanning equipment and related products.

14 In an effort to keep the ITA and the regulatory
15 agencies governing our industry ahead of the curve as it
16 relates to UV radiation and its effects on the skin, the ITA
17 is designating the majority of its funds, revenues produced,
18 to give to research for further information as it relates to
19 UV radiation and its effects on the skin, so that we all
20 have good information to make our decisions on how to
21 regulate this industry and to be more responsible.

22 Additionally, the ITA hopes to work hand in hand
23 with regulatory agencies as we move forward with
24 understanding UV radiation, our professional board members
25 should provide us with good advice as to how to better

1 understand UV radiation and interpret the information from
2 our research studies.

3 Ultimately, the ITA will work to develop a uniform
4 education and training program by which we can endorse
5 salons as certified and responsible in the way they run them
6 and the way they disperse UV radiation to the consuming
7 public.

8 As an industry, we have already begun funding a
9 couple of projects which will give more scientific data to
10 both the agencies and our industry as to what the real
11 effects of UV radiation are.

12 As you noticed from several presentations prior to
13 me, there is a lot of data. It is confounding, it is not
14 all specific. It is not well documented in some cases, and
15 in several cases, we believe it may be a little bit biased
16 because it came out of secondary parts of a study as opposed
17 to the primary purpose for the study.

18 The ITA welcomes and looks forward to working with
19 the agencies, the regulatory agencies of our industry, as
20 well as our advisory board and the training segments within
21 our industry to try and truly understand the effects of UV
22 radiation on the consuming public and how we can better and
23 more responsibly disperse UV radiation as we move forward in
24 the coming years and as we understand more about it.

25 We wanted to be here today to let you know that as

1 a group of people that are truly organized now, we want to
2 work and understand more about UV radiation and how to
3 responsibly disperse it in a commercial tanning environment.

4 I thank you for your time and I welcome any
5 questions.

6 MR. FLETCHER: Will you be around for the next few
7 minutes?

8 MR. PIPP: Yes, I will.

9 MR. FLETCHER: What I would like to do is have all
10 of the public presenters present and then we direct the
11 questions at the three of you.

12 MR. PIPP: Thank you very much.

13 MR. FLETCHER: Mr. Smith.

14 MR. SMITH: While they are getting the overhead
15 ready, I will make a couple of preliminary remarks. My name
16 is Donald L. Smith from Tucson, Arizona. I have retired
17 after a career in the medical laboratory business. My wife
18 owns and operates tanning salons.

19 I got interested because of some of the
20 misinformation about the field. I commend Dr. Cyr for a
21 very balanced presentation this morning, and we look forward
22 as an industry to him speaking in Chicago.

23 There are certain things that Dr. Weinstock spoke
24 about that I agree with wholeheartedly. We will start with
25 those.

1 [Slide.]

2 This is a client release form that we use and will
3 be recommended at the meeting in Chicago for adoption
4 throughout the industry. You can see we cover a number of
5 points, talking about that we recommend sensible, moderate,
6 appropriate, responsible tanning.

7 The second point covers that we don't allow Type
8 I's, Phototype I's to tan. We recommend that they avoid
9 overexposure, warn them about photosensitive items, wear
10 protective eyewear, and we allow them to sign a medical
11 condition. There is a signature form and a witness for
12 handicapped people and a modified parental consent form. We
13 have a complete one, and I can tell you that we do turn down
14 people that do not have it. We require it to be done and
15 without exception the parents commend us for sending home a
16 parental consent form.

17 We do not--in our particular thing it is not a
18 federal or a state law--but we do not allow under anyone
19 under 16 to participate no matter their parental consent.

20 Now, that brings up an issue of principle versus
21 practice. The parents will say I think I should have the
22 right to decide whether my child tans at age 15, because we
23 think that they need to develop a tan, we are going to
24 Hawaii. I agree with them in principle, but not in
25 practice, so we do not allow it and we lose some customers,