

**Maryland State Council on Cancer Control  
Indoor Tanning and Skin Cancer Discussion  
September 27, 2013**

**Transcription services for the discussion of indoor tanning and skin cancer were provided by Kennedy Services. [Note: The transcriptionist reported that there were a few incidents of people talking over one another wherein the wording was indecipherable. When this is the case, it is noted as “unclear comments”.]**

A meeting was held by the Maryland State Council on Cancer Control on September 27, 2013 from 8:30 – 11:30 a.m. The meeting was held at The Weinberg Building at the Johns Hopkins Kimmel Cancer Center, Weinberg Auditorium, 401 North Broadway, Baltimore, MD 21231

Council Attendees:

Carlessia A. Hussein, Dr.PH  
Minority Health & Health Disparities, Maryland DHMH

Jed Miller  
Maryland Department of the Environment

Paul B. Rothman, MD  
Johns Hopkins Medicine

Kevin Cullen, MD  
University of Maryland Greenebaum Cancer Center

Barbara Klein, MPH  
University of Maryland, Baltimore

William Nelson, MD  
Kimmel Cancer Center at Johns Hopkins

Roger Harrell, MHA  
Dorchester County Health Department

Kira Eyring  
American Cancer Society

Mark Gorman  
Cancer Survivor

Stanley P. Watkins, MD - CHAIR  
Anne Arundel Medical Center

Cathy Brady-Copertino, RN, MS, OCN  
Anne Arundel Medical Center

Kim Herman, MD, MSN  
Shore Health System

Mary Garza, PhD, MPH  
University of Maryland School of Public Health

Christine Marino, MD  
Johns Hopkins Community Physicians

Artie L. Shelton, MD  
Us TOO International; Prostate Health and Education Network

Yale Stenzler, Ed.D  
Oral Cancer Survivor

Carolyn Hendricks, MD  
Private Physician

Kala Visvanathan, MD, MHS  
Johns Hopkins Bloomberg School of Public Health

### **Welcome and Introduction**

Dr. Stanley Watkins: I would like to thank the council members and Dr. Paul Rothman and Dr. William Nelson of Johns Hopkins Medicine for providing the space for this meeting today. Before we begin, I would like to invite Dr. Rothman to say a few words of welcome. Dr. Rothman is the Dean of Johns Hopkins School of Medicine; he is also the Vice President of Medicine for Johns Hopkins University and CEO of Johns Hopkins Medicine.

Dr. Paul Rothman: I wanted to thank you all for coming here today and for service on this committee. Like many of us, my life is affected by someone dying of cancer when I was young. I have personally dedicated much of my life to cancer research which I was involved in and still an active researcher. As we evolved our understanding of cancer, when I began we didn't know what caused cancer and now we have such an evolved understanding of the causes of cancer it's groups like this that are so essential in assuring that we take the knowledge we have and utilize it for public purpose and ensure public policy helps us to stress those key issues to protect the citizens of the state of Maryland. I know many of you have busy lives but your

ability to participate in groups like this helps to advise the Maryland state of the best way for citizens to not get cancer or if they have cancers to be treated - is really essential for who we are as citizens. So thank you so much for your services and thanks for coming today to Hopkins.

Dr. Stanley Watkins: I would like to take a second to go through the agenda and the format of the meeting. It's important to note that this meeting is open to the public for observation but any discussion and questions are limited to the council members who are sitting around the table. In the agenda that is included in your packet of materials, this meeting is going to be divided up into two sections. The first part is going to be focusing on the issue of indoor tanning. The second section will focus on other council business. The intent of the discussion on indoor tanning is for the council to provide the Maryland Department of Health and Mental Hygiene the recommendations regarding scientific evidence on the relationship between indoor tanning and skin cancer, and what information regarding this relationship, if any, should be included in the Maryland indoor tanning devices parent guardian consent form? I would like to emphasize the scientific evidence on the relationship and that's where this discussion is going to be limited. The discussion will include a data presentation and two panel presentations. All guest speakers are limited to five minutes. There will be time for council members and only council members to ask questions to the speakers following the data presentations in each of the two panel discussions. I will invite council members to ask questions during these points on the agenda. Each presentation and question/answer segment will be timed by staff. Please be aware that the staff will hold up cards to signify when there is one minute remaining and when time is up. We ask council members and guest speakers to adhere to the time limit because this could go on for a long time. After presentations council members will engage in discussion based upon the list of questions that you received prior to this meeting. These three questions are listed in your packet. Those 3 questions are: Based on the available scientific evidence what is the relationship if any between indoor tanning and skin cancer? That's the first question. Based on the answer to question one, should the issue of cancer be included in the consent form for the use of tanning facilities by youth under the age of 18? And we are limiting this discussion to youth under the age of 18. The third question is A through F. And these are various exact wording that would go into the consent form. These go from no mention of cancer to indoor tanning causes skin cancers, skin cancer can be fatal, to reduce the risk of such cancer the American Academy of Pediatrics recommends that children under the age of 18 never use indoor tanning devices. From A to E it becomes more explicit. And F is an opportunity for the council to come up with additional wording. After the discussion each council member will be asked individually to provide a response to each of the 3 questions. For the purpose of accurate transcription please say your name before you vote on your three questions. The other item in the meeting packet is related to the discussions about public comment on this topic that have been received by DHMH. Public comment was also provided to council members in advance of this meeting. At this time I would like to invite Joshua Sharfstein, Secretary of Maryland Department of Health and Mental Hygiene, to provide an introduction regarding the recommendation being sought by the cancer council today.

Dr. Joshua Sharfstein: Thank you very much Dr. Watkins and thanks to everyone in the Cancer Council for your service. Thank you to Dr. Rothman for hosting this and his opening remarks.

And thanks for everyone from the public for coming and participating. I'm Josh Sharfstein, Secretary of Health and a pediatrician. I just want to give you a little bit of background on how we came to be here and about your recommendations and where they are in the process and how I will then use them. So basically, the background is that there is a law in Maryland that the owner and operator of a tanning facility may not allow a minor under the age of 18 to use a device unless the minor's parent or legal guardian provides written consent on the premises. Following that, there is a regulation that provided that the Department could specify the wording of the consent form. And there has been a consent form in use. Then I heard from Dr. Eric Seifter who is actually an Associate Professor of Medicine and Oncology here at Johns Hopkins in the Kimmel Cancer Center that the Oncology Society is interested in us looking at the accuracy of the consent form. In response to that, this was maybe a year and a half ago, we requested public comments about whether the current consent form should be changed and if so, how? We got more than fifty comments reflecting different viewpoints. From there, we got some input from the Children's Environmental Health and Protection Advisory Council where they looked at that first set of comments and provided some guidance including that the consent form to use language that is simple, clear, and appropriate for the reading level of those who will be using it. They felt that the previous language was too complex. I will try to give some of the things that are specific. One of the questions that came up in the comment period was whether there should be explicit photos. They advised against that. They also expressed considerable concern about the health risks of tanning for Minors and urged the Secretary (me) to consider those risks when evaluating the Council's recommendations. I'm reading from the summary by the chair of that Council. Earlier...my sense of time is distorted, but I think it was last week, I met with them again. I gave them a full update on where we were and they were completely comfortable with the process from here. So I got that advice from that Council and then we revised the form. We proposed the revision again for public comment. We didn't adopt it. We proposed it again for public comment. At that point, we basically looked at the comment and the scientific arguments that we received and the proposal that we made included the language "Indoor tanning causes skin cancer, skin cancer can be fatal. To reduce the risk of skin cancer, the American Academy of Pediatrics recommends children under 18 never use indoor tanning devices." We did not include graphic photos as the Council had advised. We tried to make the language clear as the Council had advised. This is for parents around the State. Then we got comments again. We heard from the medical community on one hand and we heard from the Indoor Tanning Association on the other hand. Let's just say they didn't have the same view of whether indoor tanning causes cancer and here we put out there that indoor tanning causes cancer. So that left me with a decision that I can make under the law. But I thought that we have a very clear disagreement and we have a Cancer Council. I would like the input of the Cancer Council before I make a final decision. I will just briefly note that there have been questions raised about the legal authority that I have to do this. The Attorney General's Office has reviewed all of those questions and is 100% behind our ability to do this. That's really why we are here. There is a full document written by the Attorney General's Office. Your meeting is not to address the legal issues. Those are for me but I feel completely confident in our authority under law and regulation. I explained the role of this committee to the Children's Environmental Health Council they are completely comfortable in hearing what you say. Here's my basic view, parents deserve to know the facts

about indoor tanning. They really do. They are going to be making decisions for their kids. Under the law, it's my responsibility that they get the facts. I want those facts to be clear, understandable, and the best we can do to be accurate. And I want your help so parents can get to know the facts of indoor tanning and make the best decisions for their children. I'm not going to be here staring at you. I have often been told that my next job is not going to be professional poker player. I have a very tough time of keeping a straight face. So I'm not going to be here. I think I have deep respect for each of you. I know that you are going to take this responsibility very seriously. This really matters. It is not your decision. I'll make the decision. But your input is going to be valuable. I just personally want to thank you, Dr. Watkins, members of the commission for taking this responsibility seriously, looking at the evidence and giving the best advice that you can. Thank you.

Dr. Watkins: Thank you, Dr. Sharfstein. I think one of the real points that we would like to reiterate is that this is really the scientific evidence of this. It has nothing to do with the politics and all the rest of it. It goes into Dr. Sharfstein's job on this. But this is just the science to see whether indoor tanning plays a role in skin cancer. To set the stage on that, Dr. Donald Shell from the Maryland Department of Health and Mental Hygiene has a presentation to give us the background on what the extent of the problem is. He is going to address the melanoma side of this and it should also be remembered that there are two other major forms of skin cancer, basal cell and squamous cell, that play a significant role in the health of our community. Dr. Shell.

## **Presentations**

Dr. Donald Shell: Good Morning everyone, thank you for being here today. I am Dr. Donald Shell. I have just a few quick slides. My purpose is to talk about the recent data from Maryland Cancer Registry about Melanoma and cancers of the skin. Maryland Cancer Registry collects and maintains reports on cancer incidence for the State of Maryland. Summary of what the slides will present – we'll talk about the fact that the rates are increasing for skin cancer in Maryland for whites. Secondly, the rates are increasing over time for whites of all ages, of both genders. We will talk about the fact that rates for white men are much higher than for white women who are 45 and above. Rates for white women are higher than for white men below the age of 40. The exposure to UV lights is a major risk factor however the Maryland Cancer Registry does not have any information on exposure to UV light or artificial tanning including commercial or home tanning beds. So in looking at the data slides we see that the rates for skin cancer have been increasing since 2000. The bottom on the left side starts to the recent data in 2010. We see that the rates are steadily increasing. If you focus on the bottom of this slide, where the red arrow is on the left side, you will see pointing to melanoma of the skin. Melanoma of the skin is one of the few cancers with rising mortality rates between 2006 and 2010. Next slide. For Melanoma rates and diagnosis, if you follow the colors, the top line is blue for white males; the second line is for white females. You see a gap between those two, a disparity. You see that melanoma skin cancer rates are much higher for white men than they are for white women. If you look down at the bottom of the slides, those lines down by the X-axis, you'll see the cancer rates for black men in green and for black women in purple. And you

see the distinctive gap between the rates of melanoma skin cancer between white men, white women, and then all the way down at the bottom for black men and for black women. Next slide. Looking particularly, specifically for whites in the State of Maryland, you see a significant gap or difference in the increase of rates and the incidents of skin cancer melanoma in white men which peaks up specifically at the age of 75. The rates are three times higher than for white women. But down on the left side, you will see that for women, which is the line with the squares on it, the rates are higher for women at the younger age groups. Looking more specifically, the previous slide was the top slide, but if we break up that younger age group, down in the bottom slide we see that when we look at rates per 100,000, specifically white women at a younger age have higher rates than for white men under the age of 40. Next slide. We look at this data and our series of data over time. The first series, 1994-1998, 1999-2003, 2004-2008, 2009-2010. In each one of those series we have incidence rates in Maryland where white females are higher than for white men in the younger age groups. That has been consistent over time. Looking then again at the series in each of the series and in each of the time periods we have in our cancer registry data base, in each of the series both male and female melanoma rates have been increasing in those four time periods. In those series, you may not be able to see the colors, but you can see in each one of those series 1994-1998, 1999-2003, 2004-2008, 2009-2010, in each one of the series based on the age group white male on the left side, white female on the right side. Their rates have been increasing over time. So finally, ending where we began with the summary, skin melanoma rates have been increasing in Maryland for whites, one of the few cancers that the rates are increasing. Rates are increasing over time for whites of all ages and for both genders. Rates for white men are much higher than for white women above the age of 45. Rates for white women are much higher than white men below the age of 40. Again, exposure to UV light is a major risk factor; however Maryland Cancer Registry does not have any information on exposure to UV light or artificial tanning including commercial or home tanning beds. Questions?

Question: Are there any data sets for the State, not that they could tell whether someone used a home tanning bed or a commercial tanning bed and then have got a reportable case of cancer, but are there data about the sales or utilization of tanning resources in the state that are even slightly reliable?

Dr. Shell: I don't think we have any source.

Question: Do we have the information whether or not how many children are using tanning devices below the age of 18?

Dr. Shell: I believe that information we could probably get access to if it is all sent to the Department.

Question: Do we have information that shows the women using these tanning devices that they are a higher rate at a young age?

Dr Shell: Well, based on the data that we have, we can't specifically, as we are talking about science today.

Question: Are the rates for basal cell cancers of the skin also increasing in Maryland?

Dr. Shell: Let's go back to that slide. What we are looking at from our data sets are melanoma of the skin, we don't have basal cell included. But we think particularly melanoma. But I don't have the other numbers with me today.

Dr. Watkins: For years the Registry has not collected data on basal cell.

Question: So I will just ask you in a different way, there was a CDC survey of tanning bed use among high school students and it was 30% of white adolescent girls and about 6% of white adolescent boys and less for other races. Is there any reason to believe that it's any different in Maryland?

Dr. Shell: No reason (further comment unclear)..

Dr. Watkins: At this time I would like to welcome panelist speakers from the Maryland Indoor Tanning Association. We remind you that each speaker will have five minutes. Council members will hold questions until all three speakers have served their presentation.

Joe Levy: Thank you Dr. Watkins and Cancer Council members. I am Joe Levy. I am a scientific advisor to the American Suntanning Association and Executive Director of a group called International Smart Tan Network which is the educational institute that trains tanning facilities. I have done that for 21 years and for 21 years I have developed all of the UV training materials for thousands of professionals in the tanning market. I have been a long-time member of the American Society for Photo Biology and have studied the science on this issue for two decades. I think we would all agree that we all need water in order to live. But I am told if we drank a gallon of this right now that no one would walk out of the room. It could be fatal. Similar type of situation with UV and risk. It's a dosage situation. Melanoma researcher and Professor of Dermatology, Dr. Jonathan Rees, from Newcastle University, once said that melanoma is an example of politics and science becoming tragically intertwined and that an amicable separation is required. Reason he is saying this, is because melanoma does not have a clear cut relationship with UV exposure. It's more common in indoor workers than it is in outdoor workers, who get 3 to 9 times more UV exposure. It is more common in men than it is in women. It's more common in parts of the body that do not get regular UV exposure. In African Americans it is most common the on the bottom of the foot. There is no study model that has ever isolated non burning UV exposure as an independent risk factor. No study model has looked at that independently. So the proponents of changing the informed consent forms in Maryland have ignored this and other important caveats about the message and aspects of UV science and photobiology. It's that nuance that we think is missing in this overall campaign. While we all agree that sunburn prevention is something that we all teach, this is the biggest source of our disagreement. That's the problem. That's what Dr. Rees was talking about. You

will find in the literature that research dermatologist, Dr. Bernard Ackerman, is the man who is largely credited with founding the field of dermatopathology, supports smart tan's position. He says that we are right and that the American Cancer Society and these other groups should reconsider their positions and emphasize sunburn prevention. That's what Dr. Sam Shuster, a British professor of dermatology, has written if you think a tan is damage, you should tell that to Charles Darwin. That a tan is an intended evolutionary device and that calling it damage would be like calling exercise damage to muscles tissues. Which on a micro level it is, but it's not the best way to describe it. That's why Dr. Sara Gandini from the International Agency of Research and Cancer has done a meta-analysis of 60 studies showing that the greatest risk factors of melanoma are actually having more than 40 moles, having red hair, having a family history of melanoma, and that these factors are greater than any UV and any environmental risk factors. In Dr. Shell's presentation, he talked about the greatest risk factor. UV is actually the greatest environmental risk factor but it's not the greatest risk factor. That's why Dr. Rhodes of Chicago and I attached part of a paper of his, he's a melanoma researcher. He has written that we need to teach those risk factors and not just concentrate on UV because the UV melanoma relationship is somewhat muddled by dosage. That's why research dermatologist Dr. Richard Weller is now getting worldwide press with research suggesting that the benefits of regular UV exposure may be 80 to 1 what the alleged risks are. He used a sunbed to prove that UVA light produces nitric oxide in the skin which can help lower blood pressure. That's why Boston University endocrinologist and research dermatologist, Dr. Michael Holick, has brought us hundreds of papers on the positive effects of Vitamin D and that it is best produced by UV exposure. There are more than 30,000 papers in literature today saying that Vitamin D deficiency is a major health issue. There is research on all ends of this topic. That's why we think that the present consent form in Maryland works fine. It promotes education and awareness and the dangers of over exposure. But it doesn't do so in a way that over states the risk. I think when you over state the risk, as a public health entity you lose your credibility. I have 1 minute left. Med Chi wrote in their comments that there are no benefits of indoor tanning. That's simply laughable. It's unsupportable. There are benefits of UV lights - sunbeds were created to harness those benefits in Europe. The people that come to us we market our service as a cosmetic service. But they understand that these benefits exist. That's why I think that public health messages should be crafted in a balanced way. We would like to be part of an intelligent discussion on how we harness that balance. But we can use the consent form as a tool in our salons instead of something that is ignored like when you go to a gym. When you go to a gym and sign up, they give you a consent form that tells you that exercise equipment can kill you. That over use is wrong. We don't want it to be that. We want the consent form to be a tool that we use to teach skin care properly. I have enclosed material on the U.S. Preventative Services Task Force, which has analyzed this topic; you will see that there is all sorts of nuance in their statement. The studies don't suggest a strong association between total or chronic sun exposure and squamous or basal cell. That occupational sun exposure is inversely associated with melanoma risk. Also, the World Health Organization's report on this topic implicates the use of home units but not commercial units and dermatology units have the highest risk factors on this. I'm happy to answer questions about all of that. Thank you very much.

Dr. Watkins: The next speaker from the tanning group is Robin Eason.

Robin Eason: Good Morning Dr. Watkins and Council Members. Thank you for the opportunity to speak with you today. My name is Robin Eason and I am an independent indoor tanning salon owner established in 1983. I am also the President of the Maryland Indoor Tanning Association and representing 230 Maryland salons. In 2008, Maryland Indoor Tanning Association members participated in the negotiations with state legislators and state health department to create a balance law which requires the in person written parental consent to allow minors to tan. In assistance with writing of the parental consent form, we communicated the new law to Maryland tanning salons. Maryland tanning salons adhere to state and federal laws. To date there have been no complaints. We follow guidelines set by our own industry to responsibly promote controlled and moderate tanning practices. Yet we have been accused of everything from being baby killers to child abusers by the nation's largest medical associations. The World Health Organization's IARC report conducted by a working group of non scientists is the basis of the slanderous and brutal attacks waged against my industry and the sun. It has been 100% scientifically refuted on various levels. Refutations have been peer reviewed and published by scientists. The IARC report is the definition of junk science - research that has been poorly driven by political, ideological, financial or otherwise scientific motives. Med Chi has collected a number of news reports that quote the IARC's 75% increased risk if you ever tan before the age of 35, along with numerous studies that begin with that same statistic. But I am a little confused. When you use junk science as your starting point, doesn't that make all subsequent reports inconclusive? Med Chi says they are protecting our children, that parents are not smart enough to make a decision of whether or not their under-18 kid can get a tan. Med Chi says that they must put indoor tanning salons out of business. They dangerously engage in scare tactics to get the population to slop on toxic chemical sunscreen 24 hours a day, 7 days a week, indoors or out, rain or shine. They say that all UV light is evil, wear full spectrum sunscreen. This is the same sunscreen that includes carcinogenetic chemicals known to cause skin cancer including melanoma, DNA and cell damage, and disruption of normal hormones. I am concerned of the health of our nation when our largest medical associations can't seem to decipher a simple report like the IARC report conducted by non-scientists, and they ignore the science research proving the refutation of the IARC report, and ignore conclusive scientific research proving the benefits of UV induced Vitamin D3, whether from indoor tanning or the sun and how they far outweigh possible risk factors. I'm concerned for the health of our children when one of the nation's largest medical association's shouts "No, don't go to a tanning salon for \$4 a session where you have an insignificant 6% risk of developing melanoma. You must come to me for \$100 a session. Don't worry; we will bill your insurance company. Oh, did I mention that you have a 96% increased risk of developing melanoma by my skin treatments?" Why do they aggressively push propaganda and junk science? What do they stand to gain by pushing chemical sunscreen use 24 hours a day, 7 days a week inside and out, rain or shine? Did you know that 70% of Americans are vitamin D deficient? Did you know north at 37 degrees latitude is the point of which our sun's energy is not strong enough to cause our skin to create Vitamin D for months? Less the further north you go. Even in summer the sun is only strong enough to create Vitamin D between the hours of noon and 3pm. Did you know that Maryland's most southern tip is right at the 37 degree latitude line? Vitamin D3 deficiency diseases are reaching epidemic proportions. People are

sick. People are being maimed and crippled. People are dying from Vitamin D deficiency diseases. MS - sun light reduces the death rate by as much as 76%. Heart Disease which is the leading cause of death, 20 different cancers including breast, ovarian, colon, prostate, colorectal, lymphoma, lung, and melanoma skin cancer; several nervous system diseases, bipolar, autism, depression, and autoimmune disease such as crones and diabetes; rickets, rheumatoid arthritis, and osteoporosis – an estimated 25 million people are affected due to lack of vitamin D3. The nation's largest medical association not only turned a blind eye to the science but expects you to do so too. Why? Is the science incorrect? Could it be than more than 33,800 studies conducted on the health benefits of Vitamin D could all be wrong? I am beyond disappointment. I am outraged and you should be too. It is time to stop the lies. It is time to work together to come up with a common sense message with moderate sun exposure indoors and out. Thank You.

Bruce Bereano: Good Morning, Dr. Watkins and members of the Council and thank you very much for the opportunity to testify. My name is Bruce Bereano, I am a Juris Doctorate so maybe you can call me Dr. so I can fit in with the group. I am a registered lobbyist in the State of Maryland for the Maryland Indoor Tanning Association and American Suntan Association. I'm very proud of it. My clients are small mom and pop family-owned businesses. They are responsible people. Nobody wants cancer. Nobody wants melanoma. They have procedures. They turn a lot of people away because of their skin because they do skin testing. They don't tan recklessly at all. Respectfully, Dr. Watkins, it is terribly important as you listen to the science of this matter - that you really realize what this is all about. What Dr. Sharfstein did not tell you, is that since 2009 after the statute was passed, his Department, prior to him being Secretary and since, has been pushing aggressively to ban tanning by minors in the state of Maryland through law. It's not just providing the facts to the parents. They want to ban it. They want to tell parents that "we know better than you and we are going to take your parental consent and your right to raise your children." Which is really ridiculous because it just hurts my clients' businesses because they can go online and buy a tanning bed for \$300 up to \$1500 put it in their home and plug it into a regular socket that you have around the room here, and have a tanning party without any proper supervision or monitoring or anything whatsoever. So, we should be realistic about it. The Attorney General's office? This opinion is not an opinion of the Attorney General's office. It is the opinion of the Assistant Attorney General that lives at the Department of Mental Hygiene and uses the same coffee machine and the same water cooler. And, I do not agree with his logic whatsoever. Also, what unfortunately was not indicated to you which you have in your packet, and I'm not trying to get political, I went to these legislators, and these are legislators that have heard this issue for the past five years. You have 26 letters from significantly highly respected legislatures, Chairmen of the committees that have heard this issue. Chairmen of committees that consider the budget of the Department of Health and Mental Hygiene that think that the department is off course. This is a legislative policy issue. It is not a bureaucratic issue whatsoever. Very respectfully, I'm not trying to be mean, or rude or disrespectful, but the statute is very narrow, it's very clear. It is not an informational warning statute. It's a statute that says, and if you read the statue that's in the packet, it says that the tanning salons are supposed to exact a specific consent form from the parents and the parents determine the duration of the tanning. On their own, the Department

went ahead issued regulations. I think the legislation they're relying on does not have any statutory basis nor do the legislators that have sent in letters. There was one consent form that's in your packet. Then they went to another consent form, which is the second one. Already, the reference to the risk of the possibility of cancer is in these consent forms. But the draft consent form that the Department and Dr. Sharfstein want to use is politically motivated. It's an agenda to scare parents and have a ban which he can't get through the legislature. To scare them by saying "It's going to cause cancer", "your kids are going to come down with melanoma." There is no scientific evidence to support that. The FDA has been looking at this for years. I'm not saying they are better than you all. But they have all of the authority, if they haven't banned it I don't see how our scientists here in Maryland know more than the scientists that have gone before the FDA. If you look at the form #3, bureaucratically, they want to limit it to 6 months. Statute does not allow that. I spoke to the assistant attorney general and he said, "Well, the statute doesn't say we can't do that." The department, respectfully, is off course and pursuing an agenda. It's very unfair because these are reputable businesses. They are working very hard and acting responsibly. Not dealing with people that have stuff at home, or anything of this nature. In conclusion, I would say, in terms of the documents that you have I think the evidence is quite inconclusive as to the relationship between indoor tanning and skin cancer. There has been no controlled study that is just limited to indoor tanning without sun lamps, without tanning at home in a controlled fashion. Secondly, is the issue of skin cancer included in the consent form? It currently is, in number four. On the third question, very respectfully, the department has no authority to be doing what they are doing. I ask that you all see the political background that this is in and not conclude, because FDA hasn't concluded that there is a causal relationship between indoor tanning and melanoma. Thank you very much.

Dr. Watkins: What we would like to do is have a 10 minute discussion.

Question: One of the issues that you had described is the economic impact of a policy decision. Can you give us a sense of what fraction of the indoor tanning business is the delivery of tanning services to people under the age of 18 and how much money is that worth?

Joe Levy: It is a very small minority of the tanning business. Nationwide, it's around 3% of the net in dollars for tanning salons. On average maybe a higher percent of customers. It is not a huge impact on the business for minors. What we are concerned about is the correct issue for everyone, that there is nuance to the skin cancer issue. That it isn't just avoid every UV photon to prevent a skin cancer because there is no study anywhere that says that actually will reduce the risk of skin cancer. Again, I provided you references to that, that there is no study showing that regular sun screen usage lowers your risk of skin cancer for melanoma.

Robin Eason: When it comes to children tanning under 18, in Maryland it is about 5%. I have been in this industry for 30 years and since our inception we have required parental consent. We have warning signs everywhere. Every piece of tanning equipment has a warning sign about the dangers of radiation. Every salon has a form that is called a skin typing form that everyone must fill out that lists the dangers of indoor tanning. There are signs in our store that are 1 foot square that list the possible dangers of tanning. In Maryland we have a code of conduct that is 2

pages about the procedure that we do whenever an under 18 age person comes in. If they don't have their parent with them, they can't tan. Not even once. They go through a vigorous training. We have lots of policies in place. We have lots of warnings in place. It's almost like what more can we do? Wrap caution tape around the salons? It kind of gets a little out of control.

Question: You mentioned the benefits of tanning. Do you think that these girls under 18 are coming in for vitamin D issues or for the cosmetics? They are not thinking of the medical issues, they are thinking about the cosmetics.

Joe Levy: Actually there are many reasons why people come in. This is widely being misunderstood. People do come in for the cosmetic benefits and that is what we advertise. But sun beds were invented for the therapeutic aspects. There recently was a very well publicized case in New Jersey. There is a young man who has to go to a salon every day referred by a doctor because there is no photo therapy unit anywhere nearby. It is a small percentage but people come in for many different reasons.

Bruce Bereano: But the other important thing Sir, and I say this respectfully, they are coming in with the permission of their parents.

Robin Eason: When the parents come into the salon they are involved in these conversations. They get a tour of the salon. They decide on how much tanning their child is going to do. If they want to give them permission to tan for 1 day, 1 week or 1 month, that's the parents' decision and we make sure of that. I also want to address something that Joe mentioned. There is a law, we are required by the FDA we cannot promote any benefits of tanning. No health benefits. We can only promote the cosmetic benefits. So that is a very important aspect that you all need to know as well.

Bruce Bereano: The notion by the opponents that the parents are ignorant, that they are dumb, and that we are pulling the wool over their eyes is so fallacious and disrespectful to these Marylanders that are running the business. These parents are very informed. They have agreed. Whether you agree with the parents or not, that is another issue. It's not kids coming in willy-nilly. Not only that sir, but they are computerized. If the minor leaves there and tries to bounce over to another place when you are not supposed to tan during a period of time, can't do it. We have policed ourselves for years and the legislators know that, which is why they have been killing the bill. But you get a different perspective from the Department, because respectively, they have a political agenda that they would like scientifically for you all to embrace so they can go back to the legislature and say that. Thank you.

Question: I think the warning signs are there for the reasons that we are all aware. I think we need to differentiate between the scientific points that we made here for just simple clarification. Clearly UV light in over 65% of the cases is associated with the risk of melanoma, artificial or natural light. So we realize that there is family history and genetic and environmental factors involved in the development of melanoma. But yes, UV light is,

regardless of the source, is overwhelmingly the cause of the majority of cases. So to suggest that Vitamin D can be changed with a healthy dietary supplement so that Vitamin D argument should not enter the equation. My concern is that you have these warning signs up for good reason. Because we know, it is a problem. To suggest that parents, that in some way that is protecting, we know this causes harm. So that they can give permission to have their child undergo a potentially harmful procedure is something that we need to address a little more carefully than we are.

Joe Levy: I think we do address that. In your packet, there is information that refutes what you have just claimed. Please go ahead and read it. It's from Dr. Arthur Rhodes a melanoma researcher from Chicago. He is not affiliated with the tanning industry. He is an independent researcher. He points out that the major risk factors of melanoma are not UV related and that concentrating on UV may be killing people who should know what their risk factors of melanoma are. He has written about the fact that he had a colleague was a Harvard trained physician, whose wife was a physician. Who had a lesion on his back and figured I don't ever go outdoors. I don't ever go outdoors, I never take my shirt off outside. I don't need to worry about this lesion. It was a melanoma. It progressed and he died of it. If a Harvard trained physician doesn't know what the risk factors are and his wife didn't know, how can we expect the public to understand there is nuance?

Comment: Well we all know that there are potential precursors to melanoma and that they do not require UV exposure. But that is not the majority of malignant melanoma cases. That is skewing the issue that UV light is one of the major causes. We are not suggesting because science does not support that it is the only cause, but we are here today to discuss the fact that it is a major risk factor for most types of melanoma.

Question: I have 2 questions. Have you ever participated in a study to follow your clients and if not would you ever be willing to work with the Cancer Council or university to really get at this issue and study your clients for the future to see if they are at a higher risk?

Joe Levy: I have been told in the past that Universities would not engage with us because they didn't feel like they could do a prospective study on this ethically. I would be happy to do it. I know if it was designed properly it would show that if you don't sunburn, that your risk doesn't increase. And that's what all of this data, if you look at it correctly, does. I didn't get the chance to talk about the fact that - and I provided the data to you from this allegation that we increase the risk of melanoma 75%. The data set for that is half home units and medical units. If you remove the home and medical units, the tanning salons did not increase the risks significantly. So this suggests that something else is going on here. That over exposure is probably the issue and not mere exposure. If you look at the biologic data - and nobody is out there promoting this because sunshine is free and there is no pharmaceutical company that sells sunshine. Melanocyte is not damaged by non burning UV exposure. Melanocyte only attempts to replicate and die off if it is cauterized or burned.

Question: Earlier I heard a comment about the intelligence level of parents. One of the things we should be concerned about is health literacy - an issue that we look at quite a bit in the State. As we talk to parents of all educational levels and income levels, literacy levels are very low across our populations, so we have to make sure that we draft materials to be sure that they are sure what they are coming into. I understand what you are saying about the parent comes in, but the parent has been body gripped by their child before they get there. I know I have been through that with my own family members and after a while you give in. We don't have the kind of controls we used to have over children. So that's going on. Just pay attention to health literacy levels of the parents and know what they are going through before they get to the tanning salon.

Robin Eason: I think that's a good point. A couple of things I want to say on that is that tanning is a luxury. So people that, predominately, have enough money to tan are going to tan. We are not opposed to saying that it's a risk factor. We are opposed to saying indoor tanning causes skin cancer. That's not true. That's not proven. So that's what we are opposed to.

Bruce Bereano: We are also opposed to saying the form is only good for 6 months. That is a blatant violation of the statute.

Question: One of the issues is dose. You made some distinctions between the use of tanning services in the tanning industry versus the home tanning beds. How are the machines of the industry calibrated? How often? And what are the standards for that?

Joe Levy: The system in the United States is the best in the world. The tanning unit's maximum exposure time in the U.S. delivers no more than 624 jewels of energy. A day at the beach in the summer would be an excessive 4,000. It is designed to be  $\frac{3}{4}$  or less of what would induce a sunburn in a fair skin type 2 person. And the gradual acclimation of time takes place as the person...

Question: But how are the machines calibrated? We do the same thing for x-ray doses but if you look across the country it's a 10 fold variation in what we say it delivers.

Joe Levy: The dosage is set by the counter, by the trained attendant. So the time is determined...

Question: So the machines aren't calibrated then?

Joe Levy: Absolutely. Because a new machine delivers  $\frac{3}{4}$  or less of what would induce a sun burn according to FDA schedules, and the amount of exposure that comes out of a machine will degrade overtime. So it is designed to be conservative in 2 ways. So it is calibrated that way. The equipment comes with a lamp intended for that piece of equipment that delivers no more than...(unclear comment)

Question: So it's calibrated from the start then it's less because of the lamp life?

Joe Levy: Yes.

Bruce Bereano: And when the person set the time period they can tan, the other person cannot set it any further.

Joe Levy: And that's the issue with home units. There is no control over that exposure time at home. And those are out there and available on the market. You can check craigslist and eBay. If you tell a minor that you can't go to a professional salon then they will end up in someone's home unit.

Dr. Watkins: Thank you all for answering the questions. We are going to move on to the second panel. Dr. Kirkorian. Again we'll have five minutes for each speaker and then we'll have a ten minute discussion.

Dr. Anna Kirkorian: Good Morning. My name is Anna Kirkorian. I will be talking about indoor tanning, skin cancer, and specifically the impact on pediatric patients, and that's because I'm a pediatric dermatologist fellow here at Johns Hopkins so I have a special interest in this population. So as we have all documented, skin cancers are rising in the U.S. We are focusing on melanoma but this also includes much common skin cancers such a basal cell and squamous cell. We focus rightly on malignant melanoma since this is the deadliest skin cancer. A few facts on skin cancer; this is the most common and rapidly increasing cancer in the U.S.. There are over a million new cases annually and of these about 50,000 are new cases of melanoma. And again, the reason we focus on melanoma is because it's the deadliest form of skin cancer and in about 20 % of patients when they arrive at the doctor it has already spread to other parts of the body and most of these patients will die. So this is a serious public health threat that we need to take on. This is not just an issue for adults; this is also an issue in children. There has been a 2% annual increase since 1973 in melanoma in children. People who are most at risk are actually young females 15 to 19. So as a pediatric dermatologist, I am particularly concerned about this increasing rate of melanoma. UV light is the major cause of skin cancer. Exposure in childhood and adolescence is particularly important since this may be the time of greatest risk for development of melanoma. Therefore UV light from indoor tanning is a preventable cause of skin cancer. That's something that when we talk about risk factors with patients, we can't control your genetics, but we can control your exposure and that's something that is important for us to do. Getting back to this issue of no such thing as a safe tan, how does tanning actually occur? Tanning occurs due to DNA damage from UV light. But what is UV light? UV light can be divided into 3 different sources. There is UVA, UVB, and UVC. UVC does not reach the earth so it's UVA and UVB that we are concerned about. UVB directly damages DNA and is classified as known carcinogen. UVA is important since that what is primarily delivered by tanning beds, indirectly damages DNA but that doesn't minimize what it does. It is damaging DNA and causing mutations that ultimately lead to skin cancer. Studies have shown that tanning beds emit higher doses of UV radiation than summer sun exposure. So it's important that we say that it's clear that saying that UVA light can be harmful doesn't mean that we recommend unrealistic ways of living like living like a hermit inside your house. In fact, we recommend healthy sun

behavior. Every day when I see children, and we want children to be participating in sports and outdoor activities, but what we recommend is wearing sun protective clothing, seeking shade, and avoiding mid-day sun. These are part of the healthy behaviors just like diet and exercise that it's important to recommend. We become concerned when the length or extent of sun exposure damages the skin. By definition that is always the case with UV exposure from indoor tanning. Therefore, indoor tanning is not part of a healthy life style behavior, this is important in our counseling to children. Many studies have shown that indoor tanning is a risk for the development for both non melanoma skin cancer and melanoma. I can point you to references in my paper or email them to you. This is particularly of interest in children again, my focus, because first exposure to indoor tanning before the age of 35 increases the risk in the development of melanoma and the risk of non-melanoma skin cancers. So again, just to emphasize this special population we are talking about today are increased risk for the development of melanoma from early exposure to UV light. So I can talk about prevalence, and statistics of prevalence in terms of use of tanning but I think it's more useful to see the kind of advertisements that have been targeting this populations and using events such as prom and homecoming that are important to young people. So it's clear that this is something that is important to the industry. We really want to go ahead and try to discourage children from using tanning for these special events. The American Academy of Pediatrics and the American Academy of Dermatology have recommended a ban on indoor tanning for individuals under 18 years of age. That was already mentioned. To conclude from my talk, rates of skin cancer, including melanoma, are rising in the U.S. This is particularly an issue among young people. Indoor tanning is a risk factor for the development of skin cancer including melanoma, again the deadliest skin cancer. Young people and adolescents are being targeted by the tanning industry and are frequent users of indoor tanning. Therefore regulating indoor tanning is needed especially in this population which is particularly vulnerable. I would be happy to take your questions and my references are here and I can provide them to you if you don't have them.

Dr. Watkins: Dr. Hornyak, from University of Maryland.

Dr. Thomas Hornyak: Thanks. I am Tom Hornyak. I'm Chief of Dermatology Service for the VA Maryland Health Care System. I'm also the Associate Professor of Dermatology and Biochemistry and Molecular Biology at the University Of Maryland School Of Medicine. My scientific and clinical interests focus upon understanding the biology in the melanocyte and melanoma. I'm pleased to be able build upon the previous talk to provide additional evidence linking indoor tanning and cancer risk. We heard earlier, about the report from the International Agency for Research on Cancer, reporting a positive association between tanning bed use and melanoma and squamous cell carcinoma. This report was the result of a meta-analysis conducted by a group of investigators. In fact, although it was suggested before that these investigators were not scientists, they in fact were one of the coauthors on this publication that was published in the International Journal on Cancer. It was Marty Weinstock; Marty is Chief of Dermatology at the Providence VA and a very well respected dermato-epidemiologist who was recently awarded the Lila Grubert award for his work in cancer epidemiology by the American Academy of Dermatology. That is normally not awarded to

dermatologists; in fact it one of the recent recipients was Burt Vogelstein of this institution. That publication reported a relative risk of melanoma development of 1.15, 15% higher with tanning bed use. Notably, if the first exposure to a tanning bed was prior to age 30 the relative risk was 1.775, 75% higher. This report then led to subsequent publication in Lancet Oncology in 2009 in which the agency classified UV radiation among other environmental agents from tanning beds as a human carcinogen. Peggy Tucker, who is a well known melanoma epidemiologist at the National Cancer Institute, who in fact did important work to define some of the other risk factors that were mentioned previously including dysplastic nevi as an independent risk factor for melanoma and germline mutations in the CDKN2A gene in coding the P16 tumor suppressor, was the lead author on a more recent study which showed the particular increase in incidence in melanoma among younger women beginning with women in the birth cohort of 1960-1965. This is one of a number of studies showing this particular increase in melanoma incidence among younger women. To correlate with that, in 2012, MMWR published the results of a survey conducted jointly by investigators at the NCI and Centers for Disease Control about the incidence of tanning bed use in both men and women and although there were many statistics in that report, one was that 32% of white women overall age 18-21 use tanning beds. Of those that used it, the mean number of sessions per year was 28. There was a question earlier about Maryland specific data, that wasn't in there, but Maryland was imbedded in data from the south in that study. Of the users in the south, 42.5% of the women tanned more than 10 times per year. And again, in the south cohort the mean number of tanning sessions was 20.4. I want to spend just a bit more time on the results of this study, the Nurse Health Study 2 cohort. This is a very well respected cohort which was organized initially to address particular problems in women's health. This is the iteration of the initial one and it's been used to survey incidences of cardiovascular disease and other illnesses in women. This is a single cohort study, not a meta-analysis. The investigators based out of Brigham and Women's Hospital and published in the Journal of Clinical Oncology last year, showed that there was for basal cell carcinoma an increased risk of 15% for tanning bed use 4 times a year occurring during high school to age 35 timeframe. There was an enhanced risk per use during the high school and college years compared to ages 25-35. In particular there was an increased risk for this cancers - 73% for usage more than 6 times a year during high school and college years. Separately, they found that squamous cell carcinoma was present at 15% increase risk for use 4 times a year, and in melanoma there was an 11% increased risk. Finally, just to wrap up, one strategy to perhaps confuse the distinctions between artificially induced UV radiation and natural sunlight - I think we heard a little bit about that before - this can be utilized to, at least cast a doubt, on some of the data that I presented but there was an interesting study The Swedish Women's lifestyle on health cohort study which effectively separated those issues. It found an increased all-cause and cancer related mortality for tanning bed use once a month or more over 2 or 3 decades. This was in distinction to lower mortality that was found with respect to natural sunlight and exposure. I think there is a difference here. Finally, some studies have shown the addictive properties of UV radiation. I can address those later if you'd like. I appreciate your attention.

Dr. Watkins: Mr. Ransom.

Ransom: Good Morning. I am Gene Ransom. I am the CEO of Med Chi. I am not a physician like the prior 2 panelists on our panel. I really want to focus on the science which is probably an odd thing someone who happens to be trained as a lawyer to do but that's what we are here to do today. We are not here to talk about all of the policy, lobbying and politics that the first panel spent the majority of their time on. The focus is on these 3 questions. That was the charge of the committee and that is where we need to focus our energy. Let me start by saying, nothing that we have gone through this process has been intended to specifically harm these businesses. They are good people. They are just trying to make a living, we understand that. We are sympathetic to their plight. It makes me think about maybe the kind of situation tobacco farmers might have been in, in southern Maryland 40 or 50 years ago as the world changed and things happened. Our focus has been the public health of Maryland which is one of our missions and the children of Maryland and making sure that they are safe. Every physician that I talked to, and we have over 7,500 physician members, and we talked to other non-members as well, not one of them has objected to our position over this in the last 5 years. I have gone to numerous hearings personally, and we have had numerous between the General Assembly and not one Maryland physician has come up and said that based on scientific evidence indoor tanning does not cause skin cancer. Indoor tanning causes skin cancer. The evidence is clear and two physicians presented it very clearly, much better than I ever could. There is no question about that. That's question one. The science is clear. There might be some parts of service studies that we can pull out or you might be able to find a paid expert to come in and tell you that it doesn't cause skin cancer, but it does. That's the first question. The second question is a little easier because even Mr. Bereano said it's in there so it sounded like he wasn't objecting to it. But should the issue of cancer be included in the consent form? Yes. It should be included. If there is something that is dangerous that folks are doing they should be warned about it. When I came in this morning my shoe was untied. Bruce said "Gene, your shoe is not tied." He warned me. That was helpful. I sat down and tied my shoe. I could have chosen to ignore him and maybe I would have fallen down when I walked up here and made a fool of myself or hurt myself. But luckily I was warned by Mr. Bereano and because of that warning I behaved differently. Now that doesn't mean that people might make a different decision when they learn about the risk of skin cancer. They might do that. They might say that having a nice tan for prom is more important than the risk that I am taking down the road. That's their right to do that and I understand that. But they should at least know what they are doing. Then the third question you guys were asked to talk about today, is which of the different warnings should we put on there or should we put something else on there? We like "E". We think what the Department of Health is proposing makes sense. Let's break down "E" and talk about it. The first sentence is "indoor tanning causes skin cancer." Well the science is clear, it does. That's logical and it's true. It makes sense. The second is "skin cancer can be fatal". I don't think there is anyone in the room who disagrees with that statement. That's true and it makes sense. It's logical. The third is "to reduce the risk of skin cancer the American Academy of Pediatrics recommends that children under age 18 never use indoor tanning devices." Well, we heard that from everybody. In fact they complained about our position in regards to that. So we have three true sentences that are clear and make sense. Parents should know the truth. That's all we are saying. The science is clear. You've heard it in detail. I gave you a bibliography of scientific background that we have turned into the Department. It's

attached to the letter we gave on the original consent form. I will reserve the rest of my time to ask questions to the two physicians who know much more about the science than I will ever understand. Thank you.

Dr Watkins: Now we have 10 minutes to question the three panelists.

Question: I have a question for Dr. Hornyack. One of the arguments that our tanning friends have generated is that you can suffer with a fatal melanoma that is not caused by the sun, and you know that's true because you have mucosal melanoma of the intestine and it's hard to imagine that UV light was the source of it. The people on this panel are well aware of my bias to turn almost everything into a DNA sequencing problem. When those melanomas have been sequenced they do not show evidence of the same kind of genome alterations that ones on the skin show which is pretty smoking gun related to the source of the carcinogen. It's a very characteristic play on the mutations in a very large number that are related to UV exposure. Is that your understanding of the sequencing? Could you mention that or your views on it?

Dr. Hornyack: Yes. The point you are making is true, there's been a lot of great work done over the past decade on the genetics of melanomas - not talking about the genes that you're born with but the actual types of genes and genetic rearrangements that occur within the tumor itself that are important for the tumor's behavior. What Bill mentioned is that there is evidence that those melanomas that are occurring inside the mouth, on other mucosal surfaces of the skin, even melanomas occurring on the palms and soles. These are melanomas that are as frequent in more highly pigmented individuals as Caucasians. But these are distinctly genetically different. They tend not to have these very specific mutations that we find more predominantly in melanomas occurring on Caucasians, on skin that gets intermittent high intensity sun exposure. Those mucosa melanomas tend to have more of a wide genetic rearrangement. A mutation that is found is a mutation in a gene called B-RAF and you can actually trace back photo chemically what causes that mutation. It's the result of an (unclear comment) adduct at a particular nucleotide in the B-RAF gene that is an oxidated change most likely caused by the ultraviolet A radiation that is most prominent in the artificially administered ultraviolet lighting.

Question: Obviously there has been a lot of discussion that certain melanomas are not associated with sun exposure but in the literature and in your practice, what percentage of non melanoma skin cancers, particularly squamous cell cancers are sun exposed or due to sun exposure?

Dr Hornyack: Regarding non melanoma skin cancers, the strongest association that we've really known about for decades is that squamous cell carcinoma is the most highly correlated with cumulative sun exposure, or UV light exposure. That's a very strong association. In fact the study that I reported for The Journal of Clinical Oncology, the one cancer that was more frequent in the higher age group versus the younger age group was the squamous cell carcinoma, consistent with that additional scientific evidence that we have regarding that. It's important to know that melanoma is not the only fatal skin cancer. There are 8,000 deaths out of 50,000 cases each year in the U.S. from melanoma. But 2,000 people died from squamous

cell carcinoma. So, even if the argument is made that the data regarding melanoma from UV light exposure is equivocal, 20% of all skin cancer deaths are from squamous cell carcinoma where there's this very high association with cumulative exposure due to ultra violet light .

Comment: I would just make a point that I have an unusual practice but in the last year alone I have lost five patients to non-melanoma skin cancer. Those patients were subjected to repetitive mutilating surgeries and when the tumors become metastatic there is no effective therapy for them. I have a young guy who I saw this week, who is in his 40's, who is dying from a non melanoma skin cancer with widespread metastasis. It's a preventable disease.

Question: This question is for Dr. Hornyack again. And I'm just going to play devil's advocate here but it seems to me like this question of language so everyone agrees from a medical perspective I think that there is an increased risk of skin cancer conversed by this UV exposure. So what about causation? So when does a risk factor have such magnitude that you can say with certainty "that's causing those skin cancers"? Is there data to really use that causation? I think the risk factor is established. And the second question is, when you use that data in support of this as important risk factor for skin cancer, is there also that concern of underreporting, are there data that does not represent UV as a risk factor for skin cancer? So the first question is about do we have enough to show that this is causing the cancer, we know it's a risk factor. And then are there studies that do not establish that relationship that are beyond the scope of this material that's been presented?

Dr. Hornyack: Well, I might be able to handle the first question better than the second. I think the essence of the answer resides in statistics. Are the data sets that have been examined large enough, robust enough to provide a statistically significant conclusion? Going back to that Journal on Clinical Oncology article, where the nurses in that large cohort of 70,000 persons who participated in this survey over two years were queried. The associations with basal cell carcinoma and squamous cell carcinoma were highly significant, according to the established statistical criteria. You have to look closely at the data. Absolutely. But, those two conclusions were very highly significant statistically. The second question?

Question: Are there studies that do not show the association of UV light and skin cancer?

Dr. Hornyack: I believe there are some older studies that were part of the meta analysis that was conducted by the International Agency for Research on Cancer. If you look at the one figure in that paper in which the results of individual studies, even though a statistical assessment of all of the studies showed that association, there were some that individually did not. But what was also notable about that paper was the final figure in which those studies that looked specifically at younger women and their use was reported. All seven of the studies that comprised that portion of the paper showed that positive association with melanoma development.

Question: So I have a question for Dr. Kirkorian. I really don't know the answer to this question, ok? Other than sort of the general hypothesis which I think is correct. So your interest is in

pediatrics, and it's true that children and adolescents are not physiologically just small adults. Their systems are not mature. So, is there some aspect of that not-maturity, biologically, that could be contributing to increased risk for exposure during the adolescent years or younger?

Dr. Kirkorian: I think that is a very important question. Are children different in some way in terms of their skin than adults? The literature that I can point to that I read about was actually studies in mice where skin grafting from a young person onto a mouse, so a human skin graft onto a mouse, so the young person can induce skin cancer in that skin as opposed to skin grafted from an adult. So I couldn't tell you what specifically on a molecular level is different but clearly there is evidence that supports that there is a physiological difference between the skin of pediatric patients versus the skin of adults. It may be just as you are developing in terms of your height, and weight and so forth, your systems are also developing in terms of your melanocytes. They are present since in utero time so you have the melanocytes that you are going to have, the pigments that you are going to have, since you were in utero - but most likely as developments occurring, as with other systems, it is a time of change that makes you uniquely vulnerable. I think that's really important for people to continue to focus on because if you could tease out the true physiologic differences then you have even more of a smoking gun to suggest that this is a time that is uniquely vulnerable and that what we should be focusing on in terms of not having UV exposure.

Question: So as a follow up, is that also true about the development of the human immune system?

Dr. Kirkorian: I'm not an immunologist so I couldn't tell you that much about that. But certainly the human immune system is developing from early childhood when you are educating your t-cells and so on. So most likely, we talk about allergies and how allergies develop. Most likely there are these important events that occur both in utero and in the early years of life that teach your immune system how to act. You could make that argument (if you are talking about the immune system in general) that there is a period of time where you can capture a child and make differences in the immune system opposed to an adult.

Comment: But the issue there would be if the immune system is not as mature as its going to be or you get later, with these skin cancers and especially with melanoma, immune surveillance is a big deal.

Dr. Kirkorian: It is a big deal. The medications that we now use to treat melanoma are promoting the immune system to try to fight the melanoma. That is something important. I will definitely look into it further to see if there is an actual paper on it.

Dr. Paul Rothman: It's actually totally matured at about 15 to 17 years old, your immune system's totally mature when you're 15-17 years old.

Question: You get into discussions in epidemiology and medically; relative risk is a very hard concept to base policy on. What you really would like to know are two things. I've only found

an estimate on one so would like to ask if anyone has any estimates. So, what is the attributable risk for non-melanoma skin cancer? You had a number of 170,000 cases, that's on a denominator of over 3.5 million so that means 5% of the cases can be attributed to indoor tanning. That's the best estimate. What I was wondering, is there an estimate of lifetime risk that if you do this, what is your life time risk? For cigarette smoking, we know what it is, it's exactly 16%. If you are a cigarette smoker that is your life time risk of getting cancer. What is the best estimate of lifetime risk for tanning use in adolescents for non melanoma skin cancer?

Dr. Hornyack: I also have seen that 170,000 risk figure. I think that was a figure that came from a study that did not look specifically at any premature age. Given the fact that several studies support a higher relative risk for earlier exposure versus later, I think I presented some of that evidence, one would expect that that would.

### **Discussion/Voting on Questions**

Dr. Watkins: In order to keep things on an absolute even keel, we are two minutes over on this but we were two minutes over on the prior discussion so we have to cut this off. As Chairman, I'll take a prerogative, on the 170,000 cases that was written in the British Medical Journal and I have a reference for that. So let's move on. At this point I am going to thank the presenters for their efforts and their direction at keeping this on the science. At this point the council members will have a discussion directed at each one of these questions. I think initially we have 3 questions to solve and to potentially vote on but we can continue the general discussion among the council members. Are there questions we would like to bounce against each other on this relationship with skin cancer and tanning? Are there any general questions from the council members for council members before we address the first question?

Comment: I would just like to say the discussion today is not to ban tanning salons. It is only to focus on the approval from parents if you're under 18 years of age and that's what it is. I don't want to - it's not as if we are trying to change the law. (further comments unclear)

Dr. Watkins: And to refine that - what is the science that says that indoor tanning below the age of 18 has been a factor in incidents of skin cancer? Clearly, melanoma is sort of a cardinal skin cancer and has the highest death rate but the general practice of oncology, the number of basal cells and squamous cells that an oncologist or a primary care physician sees, way outnumber the number of melanomas that you see. Melanomas very much stick in your mind because the death rate is remarkably high. So, questions among the council members?

Comment: I think the point raised by Dr. Hendricks is a very crucial point. One of the questions we have to ask is what is the strength of the evidence? Because we can conclude something individually or as a group - is a question of increasing the risk versus saying something causes is a very fundamental question here. I think that question is one question, and I also think beyond that, what is going to be on this form is not intended for people who have a background in medicine or science. So, there are two questions about how do we feel about things? But also how is it best communicated? For instance, one of my questions is for choice

“E” on the proposed language, would saying indoor tanning can cause skin cancer, rather than saying it does cause skin cancer. Does that change things? Is it an ethical obligation of us to make sure that we don’t say something that is technically accurate, but that can come across as and have unintended consequences. For instance, I can imagine some people seeing something saying, “This increases the risk for this” as sounding like “oh, this sounds like propaganda, I don’t know what that really means, and I’m not going to care about that”. Versus someone reading something and saying, “Indoor tanning can cause skin cancer” and then saying “Oh OK, I understand that”. I hope I am getting my point across and I’m articulating it but that I think that we have to think about things from our perspective but we also have to think about how they come across on the consent form. I think that there is nuanced language here that we have to be very mindful of.

Dr. Watkins: Are there further thoughts on that?

Comment: I think that that is a very good response to the concept. The caveat that I have as I evaluate this evidence that has been presented is that it isn’t very good quality. That is the real issue. You have so much evidence for example, in smoking and association with lung cancer, I’m a breast cancer oncologist and am frequently inundated with questions about the risk factors for breast cancer and women are taking away the message that that is what caused their breast cancer. This is something I have to deal with essentially every day. So I do think that the scientific evidence is weaker than we would like. Probably because of the lag time and complexity of this disease at the genetic level and the coexistence of multiple risk factors. It’s just a complex issue, medically and scientifically. And we don’t have good evidence. Not nearly as good as we have on lung cancer or breast cancer. I do think the message is very challenging to convey these issues of risks and causations to patients with cancer. It’s very difficult.

Paul Rothman: In many association studies we don’t have a mechanistic understanding of why an associated environmental factor could actually cause the cancer. In contrast with UV light we actually have a pretty good mechanism of why UV light actually causes mutagenesis. So I am going to ask Bill again, until the last 5 or 10 years although we could cause cancer in a dish with UV light, the data is zero. Utilizing genetic sequencing has given us a further insight to causations of environmental factors. So Bill, how strong when they have done the sequencing of these melanomas, or other skin cancers, is the evidence that they actually were caused by a UV damaging agent such as UV light?

Bill Nelson: Well, it’s extremely strong and it also offers a partial answer to one of the things that has been difficult which is, if you look at sun exposure, the epidemiologists and the dermatologists will tell you this, the evidence that you are causing sun exposed areas the basal and squamous carcinomas and melanomas, you can’t get around it. You are definitely causing it. The issue is can you get a fatal melanoma in something that doesn’t involve this mechanism? The answer is that you clearly can. So the fraction of those, fortunately many of these melanomas are treatable, mutilated treatment but treatable. Some of them are still fatal. But the evidence that the UV light causes these things from the DNA sequencing is overwhelming. It

is actually better than it was for cigarette smoking. Because of the very specifics of the damage that is caused by UV light.

Paul Rothman: So there are melanomas that aren't caused by UV light?

Bill Nelson: Yes.

Paul Rothman: But, certainly a lot of these are. You can tell by the sequencing of the genomes of cancers that they were caused by UV light. So that argument is causation versus association.

Bill Nelson: Causation is much stronger than anything we know about breast cancer.

Comment: To follow up on that Dr. Nelson, it's actually not just UV. There is the particular wave length that has been identified and linked to the particular type of damage. Isn't that correct?

Bill Nelson: You are exactly correct. You have been reading ahead.

Comment: What I think the epidemiological evidence does here, is supports UV trigger and identifies populations that we think that this association is stronger, as in young woman for example. When you think about it you have to think in combination with what you were just saying as well as all the data that is presented in these large epidemiological studies. What that does, is it actually tells us particular groups where the relationship between indoor tanning and skin cancer might be useful.

Paul Rothman: So can I follow up with something? So stem cells, for those of you that don't know stem cells seem to be a target that causes cancer. Actually it is a mutation of stem cells rather than other cells. So is there evidence in this age group that the stemness of the skin is different from an adult? I think that is what someone was asking before and I couldn't quite understand the answer. So is that a more vulnerable time in someone's life because it's a difference in the proliferation or growth of the stem cells in the skin at that age? Do we know that?

Bill Nelson: There are lots of studies of skin exposure in epithelial stem cells in skin regions, and dermatologists will correct me if I am wrong on this, that aren't neoplastic and you can see evidence of the previous UV exposure in the stem cell population so it does live forever in a precancerous field effect state so that is...

Comment: Can I just respond, just to play a little more devil's advocate. If it is so clear cut on a scientific level or a medical level, then why just for the purpose of everyone around this table, then why are we seeing this battle kind of play out in the literature? How can we resolve this? What are we seeing in the medical references that are disputing what we are discussing. Why isn't it more clear cut? What is lacking there?

Comment: I'm not sure that it is a battle. Is it a battle? Oh sorry, we can't ask that. (laughing) We don't care what you say. (laughing). I am not sure that it is a battle. The idea that IARC is two standard deviations beyond conservatism is a preposterous notion. I think just yesterday they decided cigarette smoking was bad. IARC is not a bunch of crazy people. They are very conservative. They are levels above.

Dr. Watkins: So let's move on and address the three specific questions that we have. The first question is based on the best available scientific evidence, what is the relationship between indoor tanning and skin cancer. And I think what we will do is go around the table and ask everybody to vote or give their opinion on how they feel about this first question.

Kevin Cullen: I would say that the scientific evidence shows that indoor tanning increases the number of skin cancers.

Mark Gorman: I agree with Dr. Cullen. So I would say yes to that question.

Jed Miller: I first want to thank Dr. Rothman for his comment. I think this is a different scenario, thinking about having a mechanism, and how epidemiological or other evidence can support that. I think that is a very important thing to note. And I appreciate that. My vote or perspective on this is that based upon the evidence there is a relationship between indoor tanning and skin cancer.

Yale Stenzler: I agree that there is evidence showing their relationship between indoor tanning and cancer.

Barbara Klein: I think the way Dr. Cullen stated it makes it clear that there is a relationship.

Roger Harrell: I concur with Dr. Cullen

Kira Eyring: I believe there is scientific evidence showing the relationship.

Bill Nelson: Yes

Kala Visvanathan: Yes

Cathy Copertino: I believe the evidence does show a clear relationship between indoor tanning and skin cancer.

Mary Garza: I also agree there is a relation.

Carolyn Hendricks: I also agree.

Artie Shelton: I also agree.

Christine Marino: I also agree.

Carlessia Hussein: With the evidence and the discussion of both causation and risk, I think the evidence is clear that there is a relationship.

Kim Herman: I agree.

Paul Rothman: I agree.

Stan Watkins: I agree. Next we will go onto question number 2. Based on the answer to Question 1, should the issue of cancer be included in the consent form for the use of tanning by youth under the age of 18?

Comment: I have a question. Do you have a consent form for adults?

Dr Watkins: We are isolating questions to the committee.

Comment: Sorry. Is there a consent form for adults?

Comment: No there is not.

Comment: Does the Association of Tanning Salons and or the Department of Health and Mental Hygiene have any brochures that are directly targeted for those under the age of 18, with photographs of different types of skin cancers that they make available obviously?

Dr. Watkins: I am not privy to that.

Sarah Hokenmaier: I don't believe the department has a brochure of that nature. I'm not sure about the tanning association.

Dr. Watkins: There are brochures out about what melanoma looks like. But it doesn't show the end stage of melanoma or the end stage of squamous cell cancer.

Comment: As an oral cancer survivor, I have been involved in a lot of oral cancer literature and they have graphic pictures of what's happening. That to me, is one thing we should think about.

Dr. Watkins: That is sort of out of the spectrum of what we are addressing here today. So to go back to, should we include the issue of cancer in the consent form for tanning facilities for people under the age of 18?

Kevin Cullen: Yes

Mark Gorman: Yes

Jed Miller: Yes

Yale Stenzler: Yes

Barbara Klein: Yes

Roger Harrell: Yes

Kira Eyring: Yes

Bill Nelson: I just wanted to comment that I was impressed with the desire of the industry to securely consent the parents for children under the age of 18 which they mentioned that they do. So yes I believe informed consent is the best way to do it. So yes.

Kala Visvanathan: Yes

Cathy Copertino: Yes

Mary Garza: Yes

Carolyn Hendricks: Yes

Artie Shelton: Yes

Christine Marino: Yes

Carlessia Hussein: Yes

Kim Herman: Yes

Paul Rothman: I actually agree with Bill. I am impressed that the industry is really trying to do the right thing here but I also agree that informed consent is important for us. So I agree.

Stan Watkins: Yes - and I would like to reinforce that the fact that the tanning group has a computer that tells us if a child is running from one tanning salon to another that you can pick that up. The heart is in the right spot on that one. We are dealing with the science. The third question is, sort of a question of degree, and how emphatic do we want to state this recommendation and how emphatic do we want to state this relationship, and how you can imagine a parent looking at this and being able to understand this breadth of data short of having a seminar on DNA damage.

Other Comments: (unclear)

Stan Watkins: Yes – and the variety of things that they expose themselves to from seatbelts to alcohol and cigarettes. So let's have a discussion about how specific.

[Following taken from meeting materials:

Based upon the above answers; please recommend text of relating to the issue of cancer in the consent form for the use of tanning facilities by youth under age 18.

- A.) No mention of cancer
- B.) Indoor tanning may increase the risk of skin cancer but scientists do not agree on whether indoor tanning actually causes skin cancer.
- C.) Some scientists believe that indoor tanning causes skin cancer. To reduce the risk of cancer the American Academy of Pediatrics recommends that children under 18 never use indoor tanning devices.
- D.) Indoor tanning increases the risk for skin cancer. To reduce the risk of skin cancer, the American Academy of Pediatrics recommends that children under age 18 never use indoor tanning devices.
- E.) Indoor tanning cause skin cancer. Skin cancer can be fatal. To reduce the risk of skin cancer, the American Academy of Pediatrics recommends that children under age 18 never use indoor tanning devices. (current statement on the draft *Indoor Tanning Devices Parent/Guardian Consent Form*).
- F.) OTHER-to be drafted by committee during meeting.]

Comment: I would like to know what happened that the department felt they need to change the form to the new form. What has occurred in the last 3 years or so? (further comments unclear)

Dr. Watkins: That's not quite related to the questions we are answering today. We want to state how emphatic or how clear or how strongly the group feels that there is a relationship between UV tanning and cancer.

Comment: But the current form does state that. The question is what has happened and why do we need to change this? It's like cigarette smoking is related to tobacco (further statement unclear). Then it changed. It continued with other evidence. That's what I'm trying to understand, why does it need to change now?

Dr. Watkins: The thought is that the difference is between draft two and the current draft.

Dr. Rothman: I guess Yale's point is, is it thought to be ineffective or not effectively informing the people?

Comment: Yes, if they need to change something, why are we changing it? (further comments unclear)

Dr. Watkins: It's on how specific it is. Some of the language in this is less specific than what we have in the current form. Then we have other language that is way more specific.

Comment: Yes, but there is no choice to stay with what we have.

Dr. Watkins: You do have option "F" to come up with another thought.

Comment: Is the current form number 2? If you read the current form, and talk about literacy, it's all in medical terms. What does photo allergy and photo toxicity mean to the parent? So, I am thinking that regardless of what we decided in terms about what we should say about skin cancer, I think the new form gives you better information about using protective eyewear not sunglasses, etc. These are particular things you need to be careful of.

Comment: I am looking at it where it says overexposure. How much is overexposure? How many sessions are we talking about? 6 sessions? 10, 48?

Dr. Watkins: You could argue about that on whether the person has red hair or fair skin.

[further comments unclear]

Comment: I have a suggestion. We could look at the consent form but we are not the Maryland Panel of Photo Allergy, we are experts on cancer, so we should probably restrict our opinion on cancer. Obviously, we are trying to balance clarity with the information. My wiser and younger colleague here has suggested that in number E if you had Indoor tanning CAN cause skin cancer, skin cancer CAN be fatal, to reduce a melanoma that's pretty much the facts and the summary of what we just did. Rather than the way it's phrased, this would be an F choice. Indoor tanning CAN cause skin cancer and skin cancer CAN be fatal. To reduce the risk of skin cancer, the American Academy of Pediatrics recommends that children under 18 never use indoor tanning devices.

Comment: We are changing "causes" to "can". I think the bottom line is the attributable risk is reasonable and I think that that muddles the research - every time you switch on this thing you know it can cause cancer.

Comment: We are not trying to create fear. We are trying to present facts.

Dr. Watkins: Any other thoughts on this?

Comment: Would it be in our purview as a council to look at the readability of it as we do other informed consents? To put it in more 6<sup>th</sup> grade or 8<sup>th</sup> grade level reading?

Multiple Comments: That is outside our council.

Comment: I know we said we didn't want to discuss the law but each of you has spun around the term "informed consent". This law does not say "informed consent". I think we as a body that represents the Governor, who has to get legislation passed, has to have a keen understanding of what is in the law. I would like to see informed consent but if I am correct, Mr. Bereano it does not say informed consent, does it? [Mr. Bereano: It has nothing to do with it.] That's where we should be but we are not there. I think we as a recommending body as we look at the language for the consent form needs to bear that in mind.

Dr. Watkins: The secretary of the DHMH is asking us to decide if there is a relationship and how strongly we want to word it. We will go around and have a vote. So we now have A, B, C, D, E, and F. "F" we will say is "E" modified with the wording "Indoor tanning can cause skin cancer" instead of saying "indoor tanning causes skin cancer". So that's the difference between E and F. I think the best way to do it is to just ask everyone around the table what language they would prefer to see on the consent form.

Kevin Cullen: I support the revised language supplied by Dr Nelson. That would be F.

Mark Gorman: I think that actually makes it clearer than what is in E which is what the Department is proposing. So I support the Nelson modifications as well. F

Dr. Watkins: I'm not sure that the -- these questions were put together as a way of sort of focusing the answers so we don't come up with 49 pages of various opinions. These are not necessarily what the Department wants. We are asking your thoughts on this.

Comment: I understand that but E is what is in the proposed.

Dr. Watkins: Yes, but that does not limit us.

Jed Miller: F

Yale Stenzler: F

Barbara Klein: F

Roger Harrell: F

Kira Eyring: F

Bill Nelson: F

Kala Visvanathan: F

Cathy Copertino: F

Mary Garza: F

Carolyn Hendricks: F

Artie Shelton: F

Christine Marino: F

Carlessia Hussein: F

Kim Herman: F - Can I just make a comment though? I guess when we talk about the American Academy of Pediatrics, could we not have room in this to add, maybe not the multitude of other national, medical associations and groups but some germane ones. American Academy and Physicians, the dermatology groups, I don't know. At 17 maybe I don't want to listen to what the American Academy of Pediatrics has to say.

Comment: But isn't the Academy of Pediatrics specific to this age group?

Kim Herman: There are others that are too, dermatology groups.

Dr. Watkins: And should we put the Maryland State Council of Cancer Control on there?  
(Laughing)

Paul Rothman: F

Stan Watkins: F. Good. This concludes the discussion. I thank you all for participating in this.

Comment: Due to the fact that the tanning industry has a computer program, to register or supply a form for under the age of 18. Why can't that be sent to the Department of Health and Mental and Hygiene? So that in fact we know how many under age 18 years olds are using this. Second, we should have this association to prepare some brochures that show more informative information of the cause and effect and let them see what they are doing.

Comment: I guess my response would be, while on some levels I can understand the reason why we would want to track that, without a longitudinal epidemiology study that information is not in the long run going to be very helpful. And that's in a properly designed epidemiology study and would be complicated and costly and if that is something that could be funded on some level it would be a worthwhile study but I think going to the regulatory burden of tracking the numbers without the long term follow up data, to me, doesn't necessarily provide us with a lot of useful information.

Comment: And one of the things that you heard from the industry representatives, is that if you were to do a study is to be able to do it with the right design, and have it be large enough,

and also explore potential health benefits, if we would do a study that looks at all of those things, I suspect that would be expensive. You really want to look at both.

Comment: Just one other issue. I am wondering if we as a council also ought to take a position on an issue that Mr. Bereano I think raised in many of the letters from legislators that relates to the 6 month time frame on the form - whether the council supports having a such a statement, such a limitation on the form that wasn't specified in the statute but it is something the Department is recommending to be included in the form. The prior forms have no limitation for the duration of the consent.

Dr. Watkins: What we asked our panel to address did not cover that. So I think we would be sort of sticking our uninformed necks out to address that. It's a good suggestion. It also goes along with the epidemiological study. I thank you all very much for your effort. The transcript of this will be available very shortly.

We'll take a 5 minute break. All these meetings are open so people can stay.