Transcript of Second-Day Discussion

DR. FREEMAN: Good morning, everyone. I would like to welcome all of the speakers and panel members and the audience back to these deliberations. We will continue to deliberate concerning the FTC test method, and we will begin this morning with continuation of the dialog that we were having with Dr. Townsend and Dr. deBethizy, who represent the tobacco industry.

DR. BENOWITZ: I would like to follow up with two questions on why the results from the study of 33 subjects relating the total nicotine recovery vs. the FTC yield from cotinine studies are so different. The first question is, since these results were so different, it would be very interesting to have measured cotinine levels in these smokers, as well as looking at urinary metabolites, and I would like to know if that was done and if we could see those data. The second thing I was wondering was, since this question of yield versus intake has been so important for so many years and since R.J. Reynolds has the capability of doing it, I wonder if they have ever done a study like the ones that I showed where they looked at cotinine levels vs. yields in a large population just to see if their own work would replicate the work of other people, and it seems like a very straightforward study that would be something they might have done.

DR. DEBETHIZY: The answer to your first question is no, we did not measure plasma cotinine in those studies. We were studying nicotine metabolism interindividual variation. That was how we got into that work, and we extended it then to ask the question across the tar categories. In the study that we are currently doing, we are actually measuring salivary cotinine. We made a conscious decision not to measure plasma cotinine because we did not want to interfere by taking a blood sample. So, we are doing salivary cotinine in that study to answer the exact question that you have raised. I think that is a good question to ask. In subjects where we see lower total nicotine output, are the plasma concentrations higher? That is a good question. And your second question was?

DR. BENOWITZ: There were data from Dr. Gori's work that I presented that were supported by Brown and Williamson, I believe. We basically looked at cotinine levels vs. yields for a large population, and I think those data were very important. I was wondering if R.J. Reynolds has ever done such a study, and if any data are available addressing that question?

DR. DEBETHIZY: We have not done a field study. There were so many field studies in the literature already, we just have never done a study like that.

DR. SHIFFMAN: Just to follow up on that study, a couple of us were pointing out that the relationship seemed to be very much driven by the extremes, and I took the liberty of computing what the correlation would be in those same data if one excluded the very extremes. I had to impute the data from

the graph, but if you look at the data above .13 and at or below 1.02 FTC yield, the correlation is .16. In other words, except for the extremes in your own data, there is no relationship.

DR. DEBETHIZY: Yes, it is interesting to me. I think what we have done is taken the best available technology, done what Jack Henningfield asked people to do, which is to take a look at things using modern techniques, and we have done a study that I think causes us to stop and think about what the previous data have shown. We can manipulate those data to get them to look like what the other data look like, or we can take them on their own merits, and I think that what we need to do is follow this study up with further work, and that is why we are doing that, and I have encouraged Dr. Benowitz to do the same thing. I have encouraged the Swedish Tobacco Company, which has the capability to do the same thing.

I think rather than doing some data selection on this particular study we should take it on its own merit. It is a 33-person study. It suggests that when smokers can freely do their activities, people consuming lower yielding cigarettes absorb less nicotine. Now, it also suggests that there is large interindividual variation, and I think lots of people have pointed that out.

When you do a study like this, you are going to get extremes because people smoke cigarettes across a wide range, and I think you have to include those people, and I think as we and others fill the data in over time we will find out whether this correlation or the slope of this line is as steep as it is now or whether it is shallower, and I just think we need to continue to do that work. We have worked hard to develop a state-of-the-art technique, and I think it has merit.

DR. SHIFFMAN: I think it has merit, too, and I applaud you for doing it. At the same time we ought to be clear on what the data show, and the data show that people smoking brands above 1.03 are getting more than people smoking brands at about .13 and that in the middle range there is no relationship to the FTC yield.

DR. FREEMAN: Dr. Benowitz, does that answer both of your questions?

DR. BENOWITZ: Yes.

DR. FREEMAN: Dr. Rickert?

DR. RICKERT: In the media recently, the cigarette Eclipse was described, and it is obvious from the media description that the cigarette is going to pose some challenges for the FTC methodology, in particular because it does not burn down to a fixed butt length. There are some other challenges that may be posed by that cigarette to the FTC methodology, and in particular I am wondering about the distribution of nicotine between the gas phase and the particulate phase. That is, in the current FTC methodology when testing the Eclipse cigarette, will the amount of nicotine that is being delivered by that cigarette be trapped using the traditional Cambridge Filter method?

DR. TOWNSEND: I do not think we really know the answer right now to the question of nicotine distribution between the gas and particulate phase. I do think we have confidence that the FTC method can provide useful data for Eclipse. Certainly the FTC method will have to be accommodated for that product in much the same way that the FTC considered accommodating the method for Barclay and the use of different holders. That proposal was certainly up for discussion. The FTC method as it stands with some modification, particularly for the fact that Eclipse does not burn down, can provide useful data for that.

DR. FREEMAN: Dr. Henningfield?

DR. HENNINGFIELD: In dealing with the smokeless tobacco issue, which has no labeling, and I think that is a problem, it struck me yesterday that I am not sure what is worse, having no labeling or having labeling that might be misleading to consumers about relative risks. In trying to deal with the relative risk issue yesterday, you spent a lot of time talking about your technologies that address health concerns and implying that there was some health benefit, and I would like to know what your estimate is as to the number of cancer deaths, for example, caused by standard cigarettes and how many lives, if any, would be saved if people were using cigarettes with these advanced technologies of filtration and so forth that you were talking about yesterday? In other words, how many people die of cancer in your estimation from the higher yield cigarettes, and how many fewer, if any, would die from the lower yield cigarettes?

DR. TOWNSEND: I think what you did was completely mischaracterize what I said yesterday. What I said was that the Surgeon General and the public health community called for the reduction in tar and nicotine yields from cigarettes, and I said that the industry and R.J. Reynolds responded to that consumer demand through major design changes to the product, and we successfully reduced the tar and nicotine yields from the very high 30's, as a sales-weighted average, down to currently about 12 mg.

DR. FREEMAN: To follow up on the question, do you think that fewer people die based on the changes that you have made?

DR. TOWNSEND: I am not an epidemiologist. The Surgeon General in 1981, in his report, did say that reduced-tar products pose a reduced health risk.

DR. HENNINGFIELD: I would like to follow this though because the words "light" and things like that are only used with foods when there is a health benefit. Your industry is using those terms relating them to FTC yields, and I would like to know what your estimate of the health benefit is. To know that, we have to know what your estimate of the death rates are with the different products.

DR. TOWNSEND: I just said that I was not an epidemiologist. I happen to be a chemist. I do know what the Surgeon General and epidemiologists have said. Many smokers have heard the same thing.

DR. FREEMAN: Dr. Hughes?

DR. HUGHES: I would like to ask your opinion about ordinal vs. cardinal scales because I think that was not made clear yesterday. You compared the FTC method to the EPA gas mileage. If I buy a car that has 38 miles per gallon and my sister buys a car with 19, I get twice what she gets. Now, even your own data show that is not true with tar and nicotine yields. When you have a tar yield that is twice another cigarette, you do not get twice the tar. So, I find those numbers misleading. I think the normal consumer when they see a cigarette that says, "1 milligram tar," and they see another cigarette that says, "8," they think they are getting one-eighth the tar, and that is not true. It seems to me if that is the case, and all you want is rankings, that we should do away with the numbers because they are misleading, and I would like to hear your thoughts about that.

DR. TOWNSEND: A relative ranking of cigarette yields is what is essential in the marketplace. To date we believe that the FTC method provides useful information for the consumer. Do you really believe that your car gets 19 miles per gallon when you drive it?

DR. HUGHES: I believe that my car that gets 19 gets half the mileage of somebody else's car that gets 38, and I think most consumers would believe that if they saw the numbers 19 and 38.

DR. DEBETHIZY: But what else is on that label? The other part that is on there is, "Your actual mileage may vary," and that is important because again this particular method was not set up to predict what an individual will get. It was set up for relative ranking, and I think it is really important to stick with that.

DR. HUGHES: I agree, and with relative ranking, when you have rankings and ordinal categories, you do not have numerals attached.

DR. DEBETHIZY: You just gave a good example of that when you gave EPA gas mileage.

DR. HUGHES: EPA gas mileage is a cardinal system. It is not a relative ranking. The EPA gas mileage, 38, cars that have 38 miles per gallon do, in fact, get twice the mileage as cars of 19.

DR. DEBETHIZY: Only if driven under standard conditions.

DR. HUGHES: No. You are confusing variability around the mean with ordinal vs. ranking.

DR. DEBETHIZY: I think I understand the difference, and I think that we could argue about this all day, but I think that the FTC method was intended as a machine-based standardized method to provide relative ranking, no more than that.

DR. FREEMAN: Dr. Henningfield?

DR. HENNINGFIELD: Then if we play by your rules, what is wrong with putting on the cigarettes, "Your intake may vary on a cigarette that is so-called an 'ultralow'" and put right on the cigarette, "You may get up to 3 mg of nicotine and 80 mg of tar from this, depending on how you smoke it"? What would be wrong with that? Wouldn't that just provide honest information to consumers so that they would know? Maybe even giving them a little bit of information that you folks know and we know about what pushes it up there, such as smoking harder and things like that; what is wrong with that?

DR. DEBETHIZY: As I said yesterday, we are quite willing to consider any reasonable proposal, and I suspect, Mr. Chairman, we are going to move into that mode eventually where we will discuss those proposals, and that is a proposal to put on the table and discuss.

DR. HENNINGFIELD: I am not sure that is an issue right now, but so, you would not object to that concept?

DR. DEBETHIZY: I would not object to putting that proposal on the table because my understanding of what this panel is supposed to do is to make recommendations like that for serious study and consideration.

DR. FREEMAN: Dr. Cohen?

DR. COHEN: Let me just say that a lot of the discussion proceeds from what experts know about the FTC method and what it was designed to do. I think the real question is what consumers think the numbers mean. So, the important issue is how do consumers understand these numbers, and I think it would come as a shock to them that these are only to be taken as rankings. That would come as a great shock, and I think we should keep that in mind.

DR. TOWNSEND: That is a point, Dr. Cohen, where we clearly disagree.

DR. COHEN: Do you have any data that show that consumers only think about these numbers as rankings?

DR. TOWNSEND: It is clear to us that consumers look at tar information; they also look at the category of cigarettes they smoke, whether it is a light or an ultralight or regular, and they make decisions in the marketplace. The actual fact is that in the market, sales-weighted tar and nicotine yields have declined dramatically over the years, and people have traded taste to do that.

DR. COHEN: Let me say, in response, that that is perfectly consistent with consumers believing that these are real numbers, not rankings. Your scenario fits a situation in which consumers think that by going down to a very-low-yield cigarette that these are cardinal numbers and real numbers. I am asking you whether your company or any cigarette company has data that indicate that consumers only think about these as rankings. The answer is either yes or no.

DR. TOWNSEND: It is clear to us from talking with consumers that they understand the notion of tar and nicotine yield, that they make choices in the marketplace. I am not about to talk about our consumer information at this point. I am not a marketing expert, but it is clear to us that consumers use the information from the FTC test method in one form or another, and even in your words, some use the numbers, and yes, those people who actually use the quantitative numbers may be more skewed to the ultralight category, but consumers do use the numbers or they use the category rankings of cigarettes, whether it be ultralight or regular.

DR. FREEMAN: Dr. Petitti?

DR. PETITTI: I am intrigued by the EPA mileage analogy and also by the water heater analogy, but I think the difference is one about consumer information. When you drive your 38-miles-per-gallon EPA-rated car, you know as you drive, based on measurements that you can make, whether or not you are, indeed, getting 38 miles per gallon or 19 miles per gallon based on your mileage, the way you actually use that car. Similarly for your water heater, you get your bill every month, and you can tell whether or not you are exceeding or not exceeding the conditions that are printed on your label. How does the cigarette consumer know whether or not they are or are not getting what is on the package?

DR. TOWNSEND: I think the point of the analogy is not exactly where you are coming from. The point of the analogy is that consumers do not expect to get exactly that EPA gas mileage. I know I do not because yes, you are right, I can measure it, and I do not, but I do use the EPA gas mileage numbers to a degree in making choices in the marketplace in helping guide my purchases. I said yesterday that I recently bought a new hot water heater. I used the energy efficiency rating in helping me make that choice, and I actually paid more for a more efficient hot water heater, but that tag also said that the average price or the price you would expect to pay for running this hot water heater is $358 per year. Do I believe that is what it is costing me? No. So, it is a matter of providing me guidance for making choices and in no way do I believe that represents an absolute number that predicts my power bill.

DR. PETITTI: I think you already answered this question, but I do think that both for the EPA mileage example and your water heater, and perhaps also for cigarettes, that it would be useful to the consumer to know the specific range that they might expect under certain specified driving conditions and perhaps we are going to get to that in terms of the proposals that we consider.

DR. TOWNSEND: And I believe that is a question on the table because the FTC test method was not intended to do exactly that.

DR. PETITTI: Can you explain to me just once again your view of what the FTC method was meant to do in the context of health? You keep saying that it was not meant to do that. I am having a hard time understanding your view of what it was meant to do.

DR. TOWNSEND: Consumers responded to the calls for reduced-health-risk products for reduced-tar products that were made by the Surgeon General, Wynder and Hoffmann, and other members of the public health community. Consumers responded to that information, and they demanded of the industry a reduction in tar and nicotine yields from cigarettes. A standardized comparative, accurate, and reliable test method was required to accomplish that, and that was the purpose of the FTC method, to provide those comparative data.

DR. PETITTI: So they could make decisions about health?

DR. TOWNSEND: So they could make decisions about tar yields in the marketplace, which they were told by the public health community were related to health.

DR. KOZLOWSKI: I think there are great concerns about how many consumers are getting the information about tar and nicotine yields as they exist now. I think at the last testing, the Federal Trade Commission reported tar and nicotine yields on upward of 900 cigarettes. According to the rules, the tobacco industry is not required to print tar and nicotine yields on cigarette packs. They are only in ads. What, in fact, is the percentage of cigarettes that are not advertised at all so that there is, in fact, no way for the consumer to know? I think that may, indeed, vary from manufacturer to manufacturer, but also in a related point some data have shown that it is on the ultralow tars that people are most likely to know the yields. It is also the fact that it is on the ultralow tars that the yields themselves are likely to be printed on the packs. Does the FTC know what percentage of brands are unadvertised and therefore consumers have no access to information on yields?

MR. PEELER: We do not have those data, but we can get them for the panel if they like.

DR. FREEMAN: Dr. Shiffman?

DR. SHIFFMAN: I take it in a sense that we have a significant degree of consensus. I have heard the gentlemen from R.J. Reynolds say that they would be sympathetic to proposals that would provide more information for the consumer to make informed choices, and so, accordingly, I suggest that we shift from a mode of asking questions of them to a mode of considering proposals that would accomplish that goal on which we seem to have some consensus.

DR. DEBETHIZY: Mr. Chairman, it might help if Mr. Peeler would clarify what the purpose of the FTC method is. I think there has been some confusion here. I know I have been asked 10 times what the purpose is, and if you do not mind doing that, I think if you could do that concisely, that would help.

MR. PEELER: I would go back to the statement that I started with yesterday, and that is to say that the purpose of the FTC rankings when they were put

together was to establish a comparative basis for consumers choosing among cigarettes. The reason the Commission asked the National Cancer Institute to commence this review of the cigarette testing methodology was to review whether that approach is still the correct approach, and obviously we are very interested as an agency in the types of questions that Dr. Cohen's research raises, which is how consumers actually use and view these data.

DR. FREEMAN: Mr. Peeler, is it implied in what you said that the FTC was ultimately interested in what was happening to the American public in terms of health? Is that implied in what you say, or was it separate from that or were you as an agency concerned about what is happening to the American people?

MR. PEELER: If you look at the history of the establishment of the current tar and nicotine testing system, it was clearly driven by concerns about health. It was clearly driven by the Surgeon General's findings that were valid at that time, that lower tar, lower nicotine cigarettes had a health benefit for consumers. So, clearly one of the issues that the Commission asked this panel to address is whether those health considerations are still valid in light of research that has occurred since the 1981 Surgeon General's report reviewed those issues and reported them.

DR. FREEMAN: So, then we would conclude that there is a clear connection in the work of this committee, not only to measure appropriately what cigarettes contain, no matter what method is used, but the end result that we are looking for is how can we help people in America with respect to avoiding disease and death, which means we would have to communicate appropriately to them in order to accomplish that. Is that a fair statement?

MR. PEELER: Most of the data that I have looked at indicate that there is a large group of consumers who are concerned about tar and nicotine ratings because of health reasons. So, clearly if the tar and nicotine ratings are communicating that to consumers, the FTC would want to make sure that these numbers are accurately delivering that benefit to consumers.

DR. TOWNSEND: Mr. Chairman, I think I am confused at this point because what I just heard is different from what I heard in your opening statement, and so I pulled out the copy of your opening statement, which says, "The primary purpose of this meeting is not to redesign the FTC testing protocol but rather to examine the protocol and make suggestions for improvements, if warranted." Your opening statement does not really go to actual changes.

DR. FREEMAN: You failed to go far enough in the opening statement. We posed three questions, the third of which dealt with what I was just speaking of, in other words, how does this translate to the American public in terms of their perceptions in the opening statement.

DR. TOWNSEND: Thank you.

DR. DEBETHIZY: I have a question for Mr. Peeler on the relationship between the FTC and the Surgeon General's warnings. Could you clarify

that relationship for me? I was just curious about that because the questions that have been asked of me and that we have been getting into are the health implications of FTC numbers, and I was just curious about whether the FTC method is there to clarify the Surgeon General's warning, or is it related at all, or are they just two completely separate issues?

MR. PEELER: The FTC method as it was conceived and implemented was designed to provide consumers with comparative information about the relative tar and nicotine content of cigarettes. We know from the studies that we have seen that some groups of consumers look at those numbers as indicating a health benefit, which is why the Commission has asked the panel to look at the question of whether there is, for example, a dose-response relationship between the FTC tar and nicotine ratings and specific smoking-related diseases.

DR. SHIFFMAN: Let me come back to what I consider to be items of substantial consensus and maybe that will help us move on. I have not heard anyone speak against providing the consumer with more information, and so it seems to me that the appropriate education of the American smoking consumer is something we can all agree on, and that it is part of the intention of the FTC system, to give the consumer appropriate information. It seems to me that an important aspect is providing appropriate education to the consumer about the meaning of whatever information is conveyed in this labeling.

The second item on which I think we have considerable consensus is that in human smoking of particular cigarettes there is a considerable range or variability in what the consumer will actually extract from the cigarette. That was seen not only in some of the talks from past studies but also in the R.J. Reynolds study. So it seems to me the second item of substantial consensus is that no single number can completely represent the true human yield from a cigarette. Therefore, it seems to me that the direction in which we should be trying to move is to represent to the consumer the sense of that range in variability and to accompany that with appropriate educational measures so that we are providing the consumer with the kind of information on which to make informed choices, and I think that is the basis on which we ought to go forward.

DR. FREEMAN: Dr. Cohen?

DR. COHEN: Dr. Shiffman, could I ask if you would be willing to modify your view just a bit? I think that to start exactly at that point is not the right place to start because I think consumers want to know two things. They want to know if I smoke at all, how risky is it, and does that level of risk vary with the kind of cigarette I smoke. They want to know that. Now, that may be impossible to provide. That is not my field, but they do want it. We cannot finesse that issue.

DR. SHIFFMAN: I quite agree with you, and I think that part of what might go into an educational campaign would be about the meaning of these numbers or ranges in relation to health outcomes.

DR. COHEN: But it begs the question: Is there a way to provide two types of information, either in advertising or on the cigarette packages or both? The first type is the level of risk for that particular kind of cigarette or the level of harmfulness, and the second one is, can we give them a better sense of the relative magnitudes? I do not know the answer to either question, but I think that if we are going to wonder what we can do to help consumers, I think we should think long and hard about the need for those two different pieces of information.

DR. FREEMAN: At this point we are going to shift gears a little bit and get into the essence of the deliberations, and we thank the members of the tobacco industry for receiving those questions. We will go to the next phase of this discussion, which is the main phase and that is, as you remember from yesterday, we posed three questions that we were supposed to answer during these deliberations, and we are going to look at each of those three questions and get your comments on each one.

Question 1. Does the evidence presented clearly demonstrate that changes are needed in the current FTC protocol for measuring nicotine, tar, and carbon monoxide, and if so, what changes are required?

DR. GIOVINO: A lot has been made in this conference of the trends over time in the FTC yield in terms of tar and nicotine with a very large decline between the 1950's and 1980, roughly, and then a leveling off, and from the data that have been presented at this conference, I have to wonder, especially given Dr. Guerin's comments, what would that curve look like if consumer changes in puff frequency, puff volume, hole blocking, and vent blocking were incorporated? Dr. Guerin and Dr. Zacny have shown that the yields can be changed, given various factors, and I see that trend as a measure of yes, a standardized measure, but one that may not be as relevant now as it was 40 years ago.

So, I have to ask the panel to consider in its deliberations the issue of the usefulness of those trend data, given as was demonstrated yesterday the wide range of products now available and the different degrees of compensation that can happen with those products.

DR. TOWNSEND: May I respond to that? I believe that the trends that you saw yesterday in the chart are useful today as they always have been. One thing that I think there is consensus on within this panel is that if you change puffing conditions, what you do is shift the tar and nicotine yields up or down depending on to what level you change those puffing conditions. Even if you block the vents, you shift the tar and nicotine yields up, but in general the relative ranking does not change. If the relative ranking does not change, you are only changing the absolute values. Then that is going to have no substantive effect on the trend charts that showed nicotine and tar yield decreases over the years.

DR. GIOVINO: I have to wonder, given the situation 40 years ago when tar and nicotine levels were so high, if those behaviors would have been so

common. The relative rankings may be accurate for any given year, but the range was so different 40 years ago than it is now that the actual amount of some of the compensatory behaviors may have been much less frequent 40 years ago than now.

The range in tar values and nicotine values was so much higher in the 1950's and the 1960's given the FTC yield that people may not have had to perform the compensatory behaviors and wouldn't have even had the ability to hole block because it is my understanding that there were no holes then. So, my concern is that those trend data, while representing what the FTC has presented, are not representing even what the consumer is taking out of the cigarette, let alone getting into their lungs.

DR. GUERIN: I am not sure that was ever the case anyway. In trend data, what you are looking at are the characteristics of the average cigarette, not how the cigarette was used, and that is all those data mean.

DR. GIOVINO: Exactly. I think the panel understands this, that the trend data represent what the FTC method gives. The reality is that trends over time in terms of what the consumer is taking out are quite different.

DR. BOCK: At the very earliest time that yield data were collected, the standard deviations were given, which had big meaning for the analysts but obviously did not have much meaning for people out in the street. But the variability of smoking, which is part of the fact that people in the street really need to know, the range of values for each cigarette, has not been provided by the data. The labeling might have incorporated that type of information, which would in large part, I think, answer some of the criticisms.

DR. FREEMAN: Before you go on, let me follow up on that. Are you suggesting then that might be a change in this Question 1 concern?

DR. BOCK: It would indicate that maybe there should be a change in the protocol and the way the data are collected, and there should be provision made for a range.

DR. FREEMAN: Measuring the same elements but giving the range.

DR. BOCK: With different smoking parameters.

DR. FREEMAN: That is a point of discussion. Dr. Woosley?

DR. WOOSLEY: I think in answering that first one I have to agree with Dr. Giovino that things have changed over the years, and I think that is what the FTC is actually asking us. There was this huge range of difference 30 years ago or so, and the ability for this method to predict something was great then, but now that most of the tobacco products have come down to some very homogeneous group, the variance is quite tight, and the ability of this numerical ranking to have any meaningful information or carry any meaningful information to the public is gone, in my estimation. Data yesterday were very convincing for me that numerical ranking does not

really convey the exposure that occurs because of compensation. So, to me the answer to the first question is pretty clear. The current system must be changed in some way.

DR. TOWNSEND: I do not understand your comment that cigarettes today are a more homogeneous group. From the data I showed yesterday the spread in tar deliveries in 1954 was really quite narrow. Cigarettes were really quite similar then. Today there is a huge range of products available to the consumer. I see that as less homogeneous.

DR. WOOSLEY: I was referring to the potential range of intake, not the range that the tobacco industry provided us.

DR. RICKERT: One of the things that people are concerned about is the fact that consumers tend to misinterpret the information. One of the ways of coming to grips with this problem is to deal with a range of potential values rather than specific numbers. This problem was first noted, I think, back in the 1981 Surgeon General's report when at that time there was a call for publishing maximal values in addition to the values that are obtained under FTC methodology. A more recent paper in 1994 has called for the same approach, and I think serious consideration should be given to this question of range, how one might express these upper limits, and if maximum were to be used, how that maximum would be determined.

DR. GUERIN: If one examines Question 1 that we are addressing, the question says, "Is there any evidence that changes are needed in the current FTC protocol for measuring tar and nicotine and CO?" I have not necessarily seen much evidence for changes in measuring it, but a lot of reasons for changes in how we communicate it. Do we have to change the testing protocol to achieve this, or do we have to have a better way of communicating?

DR. WOOSLEY: It says, "Constituent yields," and I think the yield from that method is probably inadequate. We need data on the yield to the smoker.

DR. ZACNY: I just want to go back to something that Dr. Townsend said about 5 minutes ago and that we spent some time on yesterday when he showed charts where you increase puff volume from, I guess 35 to 55 mL, and the relative rankings would not change if puff volume were increased across the different yields. I think things change when you talk about filter vent blocking and maybe altering parameters for extensive filter vent blocking because there is a fundamental difference between lower yield cigarettes and high-yield cigarettes.

The high-yield cigarettes do not have filter vents, and so you could, by manipulating this parameter, turn a low-yield cigarette into a high-yield cigarette; the relative rankings then would not be preserved.

DR. FREEMAN: Dr. Rickert?

DR. RICKERT: I think there is one issue that we have not really looked at, and that is, there is something else that happens when you move from standardized FTC testing conditions to other testing conditions. We always consider what happens to the quantity of particulates, like tar, for example; what should be also considered is what happens to the *quality* of that tar. For example, in the Brown and Williamson documents that I received, it seemed that moving from standard conditions to behaviorally defined conditions resulted in an increase in mutagenicity of the tar fraction on a gram-per-gram basis using the salmonella assay, and so I think focusing totally on the changes in the relative ranking misses the point that the biological activity on a per-gram basis may be changing as well.

DR. FREEMAN: Dr. Henningfield?

DR. HENNINGFIELD: I would like to follow up on a point that Dr. Woosley made. I agree. My impression is that what people want to know is what gets into people, not into machines. There is only one way to do that, and that is to do what you do with any other drug: Test what gets in people, and that is the only way that you can validate the upper range. There is no way you can do that with a machine. You have to put the system in people to see what they actually get.

Also, I think you need to do that because as we have seen, with almost any system you come up with, the industry might come up with a creative way to beat that machine. Testing in humans is essential. The question for Dr. deBethizy is, when we were discussing providing a wide range of values, and there seems to be some leaning that that would be a useful thing to do, you seemed to agree that was worth considering, but that the FTC method was not up to that task. I think that is what you said. If that is what you said, why is the FTC method not up to the task?

DR. DEBETHIZY: I did not say that. What I said was that it seemed like a reasonable proposal to put on the table. I did not say anything about not providing the FTC number. I think the FTC number is a good number. It has been a standardized number we have used for a long time to provide relative ranking. If somebody is proposing that a range also be determined, with a low and a high end, then let us discuss that.

DR. SHIFFMAN: Let us, indeed, discuss that. It seems to me that the FTC assay method may be adaptable to this goal in the sense that if one looked at a different set of parameters, if one included the potential vent blocking as part of a protocol for maximum extraction or maximum yield, perhaps it would be possible to use the machine testing method to adequately describe or estimate the range of human exposures from a particular cigarette, and that could well be more informative to smokers.

DR. FREEMAN: Before we get other comments, that seems to be a recurrent point of discussion about the range being an important point to consider as a possible suggestion, and I would like to zero in on that particular point and discuss it. Is there anyone who wants to discuss that point?

DR. KOZLOWSKI: A number of the studies in the literature argue that the rankings would be preserved if you had a heavy smoke setting on the machine. I think if you consider Zacny's data and other data, the idea of tuning every cigarette up to the same maximum puff volume or maximum puff rate is probably not a good model of human smoking behavior; the higher yield cigarettes may, in fact, be undersmoked relative to the lower yield cigarettes. Zacny's data on the puff volume show clearly that the puff volumes are bigger on the ultralights than on the higher yield cigarettes, so that when you have studies that just tune everything up, and you see the ranking preserved, the fact of the matter is that if the human behavior is more appropriately modeled you may well see that some of the higher yield brands go down, the lower yield brands go up, and it would get a lot flatter than simply jacking up all the settings of the machine regardless of what the strength of that cigarette is to begin with.

DR. FREEMAN: I think perhaps the question and my own opinion as I am posing it, given a particular cigarette, would be what is the range of possible exposure of that cigarette compared to any other cigarette? The question I would like some consideration of is, is that a reasonable thing to measure; is that a reasonable approach to take as to what we should measure? Dr. Benowitz?

DR. BENOWITZ: I think that is a reasonable approach. I think Dr. Kozlowski's point of view is very well taken, but I think in practical terms it really is impossible because you would have to study large numbers of people smoking every single brand of cigarettes to be able to get individual parameters. We know what he says occurs. It seems to me that the idea of having the standard condition and an intensive smoking condition with and without hole blocking would be very useful, but what it has to be coupled with is information for consumers about how their smoking of the cigarette will influence the yields. For example, if they block, this is what is going to happen, and if they puff intensively or take a lot of puffs, then this is what is going to happen, and I think that would be the best we could do to say, "If you smoke in this way, you are going to get the maximum yields." And that way we could pick what we think would be an intensive condition and say, "If you smoke in this way, this is what your yield is going to be."

DR. FREEMAN: With a given cigarette?

DR. BENOWITZ: With a given cigarette, because I do not think it is feasible, although I would like to, either to measure puffing parameters for every brand of cigarette or even, as Dr. Henningfield suggested, to do human exposure studies if you have 900 brands of cigarettes. I do not think that would be practical. I think we should test maybe some brands of cigarettes to see how well we are doing, but I do not think it is going to be feasible for all these brands to do anything other than a standardized testing.

DR. FREEMAN: Putting that forward as a point of discussion, does anyone disagree with what Dr. Benowitz has said, that we should perhaps

recommend that a given cigarette should be tested to see what its range of possible exposure would be using whatever techniques make sense; is there any disagreement with putting that forward? Dr. Hoffmann?

DR. HOFFMANN: I think that Dr. Benowitz' old studies concentrated on nicotine, but I think when we test on humans and try to see how they smoke, we should not limit it to nicotine. There are other carcinogenic toxic agents, and I think that the work done by Dr. Benowitz on nicotine is outstanding, but it is nicotine, and when we deal with cancer, at least, that is my area of expertise, there are agents that are just as important.

DR. FREEMAN: I did not understand that you were speaking only of nicotine. Were you not speaking of tar and the three things that are mentioned?

DR. BENOWITZ: Yes, in terms of the machine testing I was certainly speaking of all. In terms of human bioavailability testing, I think as Dr. Hoffmann says, if we have tools to measure tar exposure, we definitely should do that. Right now the only practical tools for large-scale studies are nicotine and CO, but when we get tar measurement tools where we can do it on hundreds of people, that should be included.

DR. TOWNSEND: If I could respond, my reaction to your proposal is that if we provide to the consumer an FTC number and a maximum deliverable number by hole blocking and a more intense puffing regimen, which I believe is your proposal, then from what I know about cigarette design those two are going to very closely parallel each other, and the ranking of cigarettes will be largely preserved. My question then is, does that provide additional and useful information to the consumer?

DR. BENOWITZ: I would like to respond to that. I do not believe that the ranking will be preserved. If you have the old-style cigarettes that are nonfilter cigarettes, no matter what you do, the ranking is going to be preserved, but if you are comparing a nonfilter cigarette and then a cigarette that has extensive ventilation and you block holes, you might see one surpass the other. I just do not believe that when you are dealing with a cigarette that has 90 percent ventilation in a standard test and people have the possibility of reducing that to zero percent ventilation, and you are comparing that to cigarettes with no ventilating filters, the ranking will be preserved.

DR. TOWNSEND: As a cigarette designer, I believe that it will be largely preserved, and I guess what I am hearing you say is that this is your suspicion, but I guess my question, is do you have data that support that, and I guess the obvious direction I am going in with this question is, should we collect data to see whether the ranking is largely preserved to convince you?

DR. FREEMAN: I think we have a question over here.

DR. HATSUKAMI: You mentioned changing the intensity of smoking. I would like to know how you determine those parameters; how do you determine the number of puffs that should be taken, the range of puffs that should be taken, or the volume that should be taken; what should that be based on?

DR. BENOWITZ: I have not looked at the current studies to see what is available, but I think you could do that on the basis of looking at observations, say in people who are smoking low-yield cigarettes and seeing what they do.

DR. HATSUKAMI: With the minimum and the maximum ranges in terms of number of puffs?

DR. BENOWITZ: I do not think a minimum is really necessary. I actually believe that we should continue to report the standard FTC method mostly because I would like to know how current cigarettes compare to cigarettes marketed 20 years ago so we could have that as sort of a minimum because in fact, you know, it is my belief, based on the evidence, that for the vast majority of cigarettes the FTC method underestimates exposure. So, we could still have that as a minimum exposure, and then we could have the test method to show what a smoker might get if they smoke in an intense way, which could then be specified.

DR. FREEMAN: Dr. Bock?

DR. BOCK: It does not make a lot of difference to me whether the ranking is changed or not. When you put down an average and a standard deviation, sophisticated people can understand whether the differences in the average are important, and a range will give that kind of information to unsophisticated people, and that is where I think the big advantage of a range is. Whether it changes the ranking, it will say that if the cigarettes are very closely ranked one above the other, it really does not matter very much which is the reality of the situation.

DR. FREEMAN: Dr. Hughes?

DR. HUGHES: You asked if there is any disagreement. I have a little bit of a disagreement, in that I am still worried about reporting numbers. I could go along with numbers if there were a disclaimer that says that 10 mg of tar does not cut your risk in half compared to 20 mg of tar. I am still very concerned that even if we give ranges that people are going to look at the averages and think that 10 gives you half the health risk of a 20, but it does not.

DR. FREEMAN: Dr. Hughes, what would you recommend in that case?

DR. HUGHES: You could go with either the nonnumerical system where you certainly had a band and put them in or numbers as long as there is a disclaimer that these are not cardinal numbers. That can be communicated fairly easily by doing that.

DR. FREEMAN: So, you favor going with numbers or not going with numbers?

DR. HUGHES: We have a long morning ahead of us; I can be persuaded either way. My only point is there must be some information to the consumer that 10 mg is not half the risk of 20. As long as that is in there, I am agreeable.

DR. FREEMAN: I think it is conceivable that whatever we decide here could also be accompanied by something in writing to explain and educate the public. I think we should assume that could be done.

DR. HUGHES: I would like to see if maybe Dr. Shiffman or Dr. Benowitz could give us a more concrete proposal here to make sure that we know what is going on because what I hear people saying, and I just want to make sure we are all saying the same thing, is that having a testing method that has a range of values, I do not know whether you want to call it the 95 percent vs. the 5 percent or something like that, some range of values based on doing different things, blocking holes and that sort of thing, but we are also talking about one thing (I was unclear), is still reporting a mean or not reporting a mean? That is what I am confused about.

DR. SHIFFMAN: You are suggesting that the current FTC system would represent a band?

DR. HUGHES: So, not a range. So, is it from the 50th to the 95th percentile?

DR. BENOWITZ: I do not think the current FTC is the 50th.

DR. DEBETHIZY: Yes, I do not think we want the current FTC method to be the bottom. I mean if you are talking about a range, the range has a low and a high, and the FTC number is in the middle. So, I think that is important. If you are going to talk about a range, you have to talk about the whole range.

DR. HUGHES: I think you have to have a range, but whether the FTC ends up in the middle I do not know. Let me suggest that I do not think that just getting an upper and a middle is fair to the consumer because there are consumers at the lower end who are getting more health benefit, if there is any, from the low-yield cigarettes than the average smoker, and I do not think it is fair to not portray that to them. So, I would like to see the full range. Everybody thinks they are the average. I would like to see it not have a mean.

DR. FREEMAN: Dr. Cohen?

DR. COHEN: I would guess that I am thinking ahead to what might happen in the marketplace, both competitively and with respect to smokers who are also consumers. I think that we have to understand that whatever analysis is done for internal purposes among specialists is one thing, but when information is presented to consumers in a form that they cannot handle, we cannot underrate the difficulty of educating them about that. It is not going to be easy to explain the idea of a range to consumers. I would ask the panel to consider a slightly different alternative, and that would be to

vary the test parameters and produce a range of reasonable smoking responses on say, tar, maybe using the machine and then to pick some number like the mean plus a standard deviation, let us say, just to throw something out for discussion, because this would represent a number that a reasonable number of smokers might really encounter. In other words, that would be the tar level that a substantial number of smokers would actually encounter in smoking a cigarette, and if that were presented to consumers, yes, it would err a little bit on the high side for some consumers, but I think our duty may be to give consumers information that serves to protect a reasonable number of those who are ingesting more.

I think that if that number were provided, I do not want to call it a maximum, you would find that firms would have an incentive to modify cigarettes. They have a lot of design features they can use to modify low-yield cigarettes to be sure that the mean plus one standard deviation would be as low as possible, and I do not think we should underestimate the importance of what is done here on the design of cigarettes in the future. I do not think we should underestimate that, and I think if we give them something along the lines of what we are talking about, they have the ability to see that their cigarettes come in at as low a number as possible.

DR. FREEMAN: May I ask you, Dr. Cohen, how would you reach the mean in such a method?

DR. COHEN: I am certainly not technically competent, but in listening to the discussions and reading the papers, if the FTC testing method were adjusted to deal with such things as puff number, puff interval, and puff volume and this were done based on an observation of how smokers smoke, just as it was done when the original Cambridge Filter method was set up in the first place, then you would be able to know what the magic number would be for two-thirds of the sample or some arbitrary number, and it would be greater than the mean. I think that number would probably be a lot easier to communicate than a range, and it would have the side benefit of better informing smokers as to what their potential risk might be, and it would also provide great incentives to the industry to make cigarettes that came in at as low a number as possible.

If one of the major problems with the low-tar cigarettes is where the filter holes are and how they work and the fact that they can be covered, then if this testing protocol were followed and the mean plus one standard deviation for that cigarette the way it was smoked were a fairly large range and if the company making that cigarette did not like that large a number, it has the capability of reducing that number by putting the filter holes in such a way that they are not going to be blocked.

I would say that it is very important to consider the impact of what is done here on what they do.

DR. FREEMAN: Dr. Shiffman?

DR. SHIFFMAN: I very much share your concern that we come up with a system that is communicative and that is grasped by the smokers whom we are trying to reach. Part of what is attractive about a range is that it also communicates, to borrow a phrase, that their "mileage" will vary. My concern about any one number, no matter where you put it on the spectrum, is that it does not communicate that and implies that this is exactly what this cigarette will deliver. So, I think it is a significant challenge to health education, public education, and advertising people to design a system that communicates this idea of range and the idea that range is to some degree under the control of the smoker and his or her behavior. Part of what is attractive to me about that range is communicating exactly that, that the human yield is variable and that it is variable to some degree according to the behavior of the smoker. That is something I would like to see communicated.

DR. FREEMAN: Dr. Stitzer?

DR. STITZER: I just want to support that point. I think that we are dealing with a situation where the public is very lacking in knowledge, and the one particular thing that is not understood by smokers, I believe, is that the way they smoke their cigarette determines the yield that they get from it. I think the basis of the system we design should be to convey a very basic piece of information, and some of these ideas about ranges and so forth are important. The fact of the matter is that, with low-yield cigarettes, these ranges are going to be very wide. They are going to be completely overlapping with the higher yield brands, but that is exactly the information that we want the consumers to know.

Now, the unfortunate part is that consumers do not have any good way of knowing where they in particular fit along any range that we might present, and that is a different problem.

DR. FREEMAN: Dr. Benowitz?

DR. BENOWITZ: I would also like to support Dr. Shiffman's comments and just say that we could be specific about this, and I think we should be. For example, we can say that if you block these ventilation holes, this is what your exposure will be, and if you do not, this is what your exposure will be, and we can also request that ventilation holes be marked to make them obvious to the smoker. Make them bright red or orange or something to minimize your exposure; I am all for ultralow-yield cigarettes if people will smoke them that way. I think that is great. You have to make it possible for them to do that, and we could with labeling.

DR. FREEMAN: Dr. Henningfield?

DR. HENNINGFIELD: I also agree that the range is basic, honest, accurate information, but it is clear that it has to be coupled with education on what factors may affect your intake: how consumers can change their behavior in ways that might be helpful. But a really important point of Dr. Cohen's I think should be considered, and that is the importance of providing an

incentive to the industry that may serve people. Drs. Benowitz and Kozlowski and I had this embedded in our *Journal of the American Medical Association* proposal: the notion that right now, in our estimation, virtually all cigarettes you throw into the regular category, but by providing the incentive to get that label of low, which could be a really nice selling point and may be of health benefit, you would have to work to redesign cigarettes in such a way that I think would be useful, and what you would have to do is redesign them in a way that would make sure that the upper level was lower. And that brings me again to the reason that I think we need some bioavailability testing. I agree with Dr. Benowitz, not necessarily on 900 brands, but you need to anchor it at some point to what people get, and you need an agency that can oversee that properly and also require it on demand; that is the only way you are going to prevent another Barclay cigarette type of scam, the notion that somebody comes up with a design that seems to meet the low category, and they have just done it by beating the machine. The only way you are going to check that is by seeing what people get.

DR. GUERIN: Dr. Henningfield, as a good example, the FTC test is what discovered the Barclay scheme. The FTC test has been successful in identifying those kinds of problems.

DR. SHIFFMAN: Dr. Henningfield, I take that perhaps as an additional proposal that you address a different issue than we have been talking about, which is the use of words like "light, low, ultralight" in advertising and the importance of making those accurate and not deceptive or confusing to the consumer, and that I think is something we ought to address. That the information that is presented to the public in advertising goes beyond the small numbers printed in the corner to the large "light," "ultralight," "low" printed in bold print, and I think that is something we ought to look at.

DR. HENNINGFIELD: Yes, I think those words should be banned.

DR. SHIFFMAN: I would disagree that they should be banned. They should be regulated so that they are accurate.

DR. FREEMAN: Dr. Rickert?

DR. RICKERT: I think it is obvious that many consumers choose their brands on the basis of some perceived risk to health, and it is also obvious that the FTC numbers do not and never were designed for that particular purpose. I share Dr. Hoffmann's concern in that our measure of dose is often based on nicotine, which may or may not tell us about other constituents in tobacco smoke. Specifically, at the level of molecular epidemiology, there are certain constituents that now can be tracked, and Dr. Hoffmann has mentioned NNK in urine. There is the constituent 4-amino-biphenyl, which is present in tobacco smoke and which in smokers ends up as a hemoglobin adduct. There is, also, benzo(*a*)pyrene, which in smokers ends up being bound to albumin. So, there are a number of traceable constituents in tobacco smoke that have known toxic or carcinogenic properties, which also then can be related to uptake in smokers and nonsmokers alike.

DR. FREEMAN: Dr. Cohen?

DR. COHEN: I would like to return to the point that Dr. Henningfield was just talking about and the point that I raised a few minutes ago. I think it is very important not to put the burden in the wrong place.

If we are going to put the burden on consumers to respond to whatever design changes industry makes and then educate them each time industry makes a clever change, as to where they put the holes or what kind of paper they use or whatever, we are fighting a losing battle. I think that the best approach here is really to allow the industry, which is able to modify its product, to modify it in order to obtain the maximum benefit to their sales from a low rating. They have an incentive to do that, and so, if the panel deems it appropriate, I would suggest that coming up with a rating system that reports to consumers a number within the range, which is not at the midpoint of the range but is tilted toward those who do compensate, is the smartest thing that can be done because that, in fact, will offer guidance to consumers who after all should not have the primary responsibility for outsmarting the designers of cigarettes, and I think that it would also provide the cigarette industry an opportunity to modify their design in order to achieve the numbers that are most beneficial for them.

DR. FREEMAN: Dr. Hoffmann?

DR. HOFFMANN: Before we got this upper limit and extreme, we should ask Dr. Guerin how far we can go. We have heard yesterday that the low-tar cigarette smoker may take up to 60 to 65 mL per puff and up to 6 or 7 puffs per minute; is that possible with our current equipment?

DR. GUERIN: Current instrumentation would have to be modified somewhat to reach some of the extremes in terms of volumes.

DR. HOFFMANN: You can do more than 50 mL?

DR. GUERIN: Right.

DR. HOFFMANN: With the machine?

DR. GUERIN: No, I said that you can, but it would require some modification.

DR. HOFFMANN: New machinery?

DR. GUERIN: To reach some of the extremes in terms of puff volumes, frequencies for a 20-port system would be too high. You can purchase systems of smaller capacity that have that flexibility.

DR. HOFFMANN: But the standard machine we have now cannot go through these extremes?

DR. GUERIN: It would not be able to go through all the extremes without some modifications.

DR. BOCK: The cost of the machine really is not something to use as a basis for this discussion. It is so small compared to the cost of labor that it is meaningless.

DR. FREEMAN: Dr. Hughes?

DR. HUGHES: We have been talking about these numbers and as scientists we like to talk about numbers, and maybe we will get to this with the third question. My major concern is conveying how much health benefit people get by these lower nicotine, lower tar cigarettes because what I saw in the 1981 Surgeon General's report and what I saw Dr. Samet present yesterday suggest to me that it is not great, and it is not very large, and I think when the normal consumer switches to a 1-mg cigarette, they think they are doing themselves a great benefit, and my concern is that the magnitude of that effect be conveyed to the consumer.

DR. FREEMAN: Dr. Rickert?

DR. RICKERT: At the present time, FTC methodology is providing us with information on tar and nicotine and CO; when we are talking about lower yield cigarettes, we tend to link tar and nicotine explicitly together, and while there is an obvious relationship between these variables, there is also extreme variation.

All one has to do is take the 933 brands that were just published recently in the FTC report and look at various plots of CO vs. nicotine or tar vs. nicotine, and you cannot help but be struck by the fact that there is a wide range of variation as far as specific nicotine level.

For example, if you look at that report and brands delivering .9 mg of nicotine, there were 54 brands with varying tar yields. So, I think, in addition to the issue of tar and nicotine, that the issue of how one communicates simultaneously changes in all three variables because you can have the situation where it could be high tar-low nicotine or low tar-high nicotine, and by constantly linking the two together, I think one is missing the point about the other two variables.

DR. FREEMAN: Yes, Dr. Stitzer?

DR. STITZER: I was going to pick up on Dr. Hughes' point because it is an important one, but I think it is very much intertwined with the whole discussion about reporting of the machine testing yields. If the smoker can visualize the fact that the actual yield from this low-yield cigarette is completely overlapping with the yield from this other high-yield cigarette, then I think that can more easily bring home the other health message, which is that switching to these cigarettes may not have any benefit whatsoever. I think that there is a dose-response problem there.

DR. FREEMAN: Dr. Benowitz?

DR. BENOWITZ: I think that it would be great if we could put something in about health risks. I think the data seem very clear that smoking any

cigarette is so much greater risk than smoking none that it will be impossible to quantitate it, and I think that should be communicated. But at the same time, even if there is a small difference in exposure from high- to low-yield cigarettes, if you are talking about a huge population of smokers, it is worthwhile to encourage as many possible to get as low a yield as possible, even though it is not going to have nearly the effect of stopping smoking. It still is of some benefit. So, I think we should warn people that switching to low-yield cigarettes is not going to remove the risk of smoking, but still try to encourage that somehow people do that.

DR. DEBETHIZY: Dr. Benowitz, you are raising an important issue. It is that whatever change that gets recommended here today to the FTC, it is going to require some research and some study to make sure that some unintended things do not occur. For instance, if ranges were recommended, and put on in advertising, would that have the effect of discouraging people from switching down? As a scientist, I think it is important for us to understand the ramifications, and I am assuming that this is just the start of a process, that recommendations will be made, and that the FTC will consider those using research techniques.

DR. FREEMAN: Yes, Dr. Shiffman?

DR. SHIFFMAN: Just to proceed on the point that Dr. Hughes and Dr. Benowitz made, we have said a couple of times that the idea of educating smokers is very important. I think educating them not only about these numbers or ranges but also about the comparative benefit of not smoking at all vs. lowering the received yield is an important part, and I think it deserves some discussion, though perhaps not here, about the degree to which that can be done in this sort of labeling rating system or whether, in fact, we need other media as well. There is limited information we are going to get on a pack or in an ad, but I think there is a responsibility to educate smokers so that they do make those informed choices.

DR. FREEMAN: Dr. Woosley?

DR. WOOSLEY: I agree slightly with the representative from the tobacco industry that we have to make sure there are no adverse consequences from anything that we try to do in a meaningful way, and one of the most serious concerns I have is that we do not want to give a false impression about health risks. I think one of the most disturbing pieces of data that I saw yesterday was the indication that people who were on the ultralows had a lower cessation rate, and I am concerned that potential means that the recommendations that come out of this panel may encourage people to go to low yield instead of stopping smoking, and I think that overall will be a terribly adverse health risk or adverse effect on the overall health of the Nation.

DR. FREEMAN: Yes, Mr. Peeler?

MR. PEELER: In line with that discussion I just wanted to throw out two pieces of information for the panel's consideration. The first is from the time

the ban on tar and nicotine claims in advertising was lifted, the FTC basically prohibited any health claims in the advertising. So, what you are seeing is really what consumers are inferring from the low-tar and -nicotine systems. The other thing that we have focused on and thought about in this area is the fact that the Government's position for many, many years has been that people who are concerned about their health should stop smoking. There is actually a warning on the packages right now that says that. Stopping smoking now increases your health, but it is a very difficult communications conundrum, as Dr. Shiffman has indicated, about whether you can talk about relative risk from tar and nicotine and not send an unintended message that Dr. Woosley is talking about, that this is the better way to go.

DR. FREEMAN: Yes, Dr. Kozlowski?

DR. KOZLOWSKI: I think it is pretty clear that smokers currently are turning to so-called "light" and "ultralight" brands, believing that they are doing themselves a favor with respect to their health. I think there is a real concern about health-conscious smokers who want to try to do something. They now have the impression: How could a light cigarette kill anybody; how could an ultralight cigarette kill anybody, and there is no deadly connotation to the terms "light" or "ultralight." By providing better information the hope is that some of the people who out of health concerns are turning to lower yield cigarettes will see something of the risks of that, and they may be in a fool's paradise, and they maybe should stop altogether. The pamphlet that was passed out in an earlier version about 10 years ago was titled "Tar and Nicotine Ratings May Be Hazardous to Your Health: Information for Smokers Who Aren't Ready to Quit Yet." A smoker who is smoking a 1-mg tar cigarette and enjoying it may think, "My God, I am smoking the lowest yield cigarette on the market; how could that do me any harm? I have really done something." If that smoker then sees, "I blocked the vent holes," and so on and so on, the hope is that becomes an inducement to stop. I think you expressed some reservations about use of the term "consumers," but I think it is important that continuing smokers be treated in part as consumers and be given information similar to what consumers have expected about automobiles and things like that.

DR. COHEN: Could I follow up with some numbers? I have some evidence exactly on the point that you just made, and it may be useful to the panel to hear the evidence. I apologize, again, because you couldn't read the numbers so clearly yesterday. In my survey, *83 percent* of those smoking 1- to 5-mg tar cigarettes thought that switching from a 20-mg tar cigarette to a 5-mg tar cigarette would significantly lower that person's health risks due to smoking for someone who smokes a pack a day. More than 25 percent of those smoking cigarettes with 6 or more mg of tar thought that switching from a 20-mg tar cigarette to a 16-mg tar cigarette would significantly lower that person's health risk due to smoking for someone who smokes a pack a day.

DR. DEBETHIZY: I would not be surprised at that because the Surgeon General said in 1981 that if you reduced your tar intake, you reduce risk.

It has been communicated pretty clearly that if you cannot stop or are unwilling to stop, then reducing your tar intake is a good idea.

DR. GIOVINO: I would like the Surgeon General's comments to be put on the record so that they could be stated exactly and hopefully they will be used exactly as stated. The Surgeon General said:

> The Public Health Service policy on lower tar and nicotine cigarettes must remain unchanged. The health risks of cigarette smoking can only be eliminated by quitting. For those who continue to smoke, some risk reduction may result from a switch to a lower tar and nicotine cigarette provided that no compensatory changes in style of smoking occur.

I would ask that caveat be used when these types of statements are made.

I would also remind us that while the relative risk studies on lung cancer may have controlled for number of cigarettes a day, and I am not sure of the methodology on those, they certainly have not controlled for changes in puff frequency or puff volume. So, one point I want to make is, let us make sure that we provide in any statements we make about the Surgeon General's statements the caveats that the Surgeon General's report provides, and the second point I would like to make is that the categorization of light and ultralight cigarettes in advertising and promotion is not always consistent. There are many exceptions to those rules that Ron Davis pointed out in his article in the *American Journal of Public Health*, and the current system of light and ultralight seems not totally consistent at times with the tar and nicotine ratings.

DR. FREEMAN: Dr. Headen?

DR. HEADEN: I want to go on record in support of the color-coded representation of the FTC information for the consumer and to go on record in support of a range rather than a single number. I would ask us to consider the point that Dr. Cohen made. It is important to design this information in a way that would encourage the tobacco industry to redesign cigarettes to conform to whatever standard we adopt, but I do believe that if there is a range that there will be an incentive on the part of the industry to lessen the width of that range. A cigarette brand that has a very broad range gives a very clear message to the consumer that the yield is variable, particularly when they consider the upper limit, and that there would be a high incentive for the industry to narrow the range of whatever yield there is for each of the cigarettes.

DR. FREEMAN: Thank you very much. Because we have two other major elements to consider today, and it does not mean we cannot discuss more of this, we want to go to the second question, and you can continue to raise ideas on the first question as we go along because they do overlap a bit.

Question 2. Should constituents other than tar, nicotine, and carbon monoxide be added to the protocol?

Dr. Henningfield?

DR. HENNINGFIELD: I do not think we have the information to decide the entire list, but we probably have some ideas of things that should be added. I would suggest that the procedure be used as the FDA uses for food labeling, which is that substances that an organization or committee with specialty in toxicology agrees are of toxicological significance be added. And with foods, under the category of other flavorings and ingredients, industries are not free of listing things that are of toxicological significance just because they call it a flavoring, as occurs with cigarettes. Rather an outside body decides what is of toxicological significance. I do not know if they are of toxicological levels, but that should not be decided by the tobacco industry, in my opinion. That should be decided by a regulatory agency with toxicology experts.

DR. FREEMAN: Dr. Benowitz?

DR. BENOWITZ: I think Dr. Henningfield's comments are well taken, but I would just like to go on record in support of the sort of labeling that Dr. Harris showed us yesterday, which I thought is very informative to consumers when you see all the cyanide and arsenic and all those things in cigarettes. I think it just helps to provide more information to a consumer about the mix of what is in their tobacco smoke. I am sure they are not going to read every bit of it, but anytime they are interested in looking and they see a list of 30 cancer-causing compounds, I think it is useful for them to know that. So, I am in favor of having that sort of listing available.

DR. FREEMAN: May I try to understand what you said, that you would not present measurements in the way that we are measuring the three elements, but you would simply list them as carcinogenic or harmful to health? How would you do this?

DR. BENOWITZ: I think you could do it either way. It would be relatively straightforward to measure those and just list how many micrograms or whatever was there, or you could just list them. I do not have a very strong feeling about it just as long as it is made clear to people what the types and the mix of toxic chemicals they are taking in their smoke.

DR. FREEMAN: What I mean is, you would treat them differently from the way we are treating tar, nicotine, and carbon monoxide?

DR. BENOWITZ: Yes, I do not think we need to provide information about standard and maximum exposures, for example. I just think if we had one number or one list it would be adequate.

DR. FREEMAN: I see. Thank you. Dr. Rickert?

DR. RICKERT: I think there should be additional communication of information. I question whether or not it should be in the form of an absolute number. For example, it could be categorized in terms of

ciliatoxic agents and hydrogen cyanide, for example. It could be categorized as carcinogens and then certain carcinogens. I think, given all the discussion that we have had both yesterday and today about the potential misinterpretation of numbers, it would seem to me that to add to that confusion by a whole new set of numbers would not be serving the interests of the consumer.

DR. FREEMAN: Thank you, Dr. Rickert. Dr. Stitzer?

DR. STITZER: I am totally in favor of more information being given to the consumer, but I want to bring up priorities and to point out that cigarette packs are not very big, and personally I think it is more important to convey the information about the variability of yield in some prominent way on a cigarette package rather than using that space to list hundreds of chemicals.

Now, what I would be interested in seeing is a kind of package insert disclosure information that would be put in cigarette cartons. That might be a better format for delivering the information.

DR. FREEMAN: Dr. Petitti?

DR. PETITTI: I would like to provide support for both of the prior statements, particularly that perhaps cigarettes need to have prominently displayed the fact that they contain some list of selected carcinogens but not to portray that information in a quantitative fashion. I do not think we have the ability to decide which of the numerous carcinogens in cigarette smoke is the one or the ones that quantitatively are related to the various forms of cancer caused by cigarettes and that we would be further misleading the consumer by making them believe that, for example, a cigarette with low levels of chemical X is better for them than a cigarette with a higher level of chemical X. I do not think we will ever have the epidemiological database that will allow us to link these various carcinogens quantitatively with risk of any of the human cancers.

DR. FREEMAN: Yes, Dr. Guerin?

DR. GUERIN: If we had a list of common cigarette smoke toxins on packages, would that not discourage the industry from producing products that have undetectable quantities? Wouldn't we need some kind of a level of detection to determine when we are at basically nothing because there are advanced products that are being marketed or may be being marketed?

DR. FREEMAN: Let us go to Dr. Hughes first.

DR. HUGHES: People are interested in function. They do not care about the names. They care about what these things do. So, my proposal would be to get the word "cancer-forming" agents on there. That is the important thing, not whether it is this long name or that long name or whatever because that is the important thing that consumers need to know.

DR. FREEMAN: Yes, Dr. Townsend?

DR. TOWNSEND: Thank you, Mr. Chairman. In the U.S. market, cigarettes with comparable blends, in fact, show similar ratios of most smoke constituents per milligram of tar. What that means is, as you bring the tar level down in a cigarette, these constituents also come down more or less proportionately.

I guess the question then that leads me to is, are we providing really useful information for the consumer to use, or are we just giving them a lot of information that they are going to ignore, like I think Dr. Harris indicated that he did not read all the information on the food labeling. There is a lot of information there. Is it useful information? That is just a question I am proposing.

DR. FREEMAN: I understand. Dr. Rickert?

DR. RICKERT: I agree with what Dr. Guerin has said, in the sense that it would seem that if there are new products being developed that would have a zero yield of various carcinogens or ciliatoxic agents that must be allowed for, and I think for that, for the agent to appear on the package, there would have to be some consideration given to analytical detection limits and things of this nature. So, I do not think it should necessarily be a blanket piece of information that comes with every brand of cigarette, but there should be some differentiation based on the individual products of the cigarettes.

DR. FREEMAN: Yes, Dr. Henningfield?

DR. HENNINGFIELD: There always has to be a threshold for whether you list something, whether you are listing the lead in flour or rat droppings or whatever it is. So that is a basic concept, but I think the important thing is that an agency or panel with expertise, not the industry being regulated, make the decision. So if BHT is listed on flour or cookies, you know, we do not have to worry about how much of it is in there; I agree, that would be confusing, but another group decides if the cyanide should be listed as one of the "also contains" ingredients, for example, "also contains cyanide, formaldehyde, lead." You have somebody else decide what is of potential significance and therefore should be listed, and that is what is done with food labeling.

DR. FREEMAN: So, in principle what are you saying that we should do?

DR. HENNINGFIELD: Of course there is a threshold, but that threshold does not necessarily affect the labeling on the pack in the sense of the number because you are not putting any numbers in the same way that for potato chips you are not putting how much BHT is in there. You are listing the milligrams of things that groups decide are very important to list by milligrams like cholesterol and sodium, and then you have the list of other ingredients as Dr. Harris showed on his label, and what the thresholds are; to merit listing, another group decides that—a group with toxicology background.

DR. FREEMAN: Dr. Rickert?

DR. RICKERT: I am not really quite sure whether it is a toxicological consideration or whether it is a chemistry consideration. If you take cholesterol, for example, in order to earn a label of cholesterol-free, there has to be a certain level. I mean in the instrument you can measure this level, but it is cholesterol-free if it is less than that level. So, I think the issue, from my point of view anyway is more of a chemical issue, rather than a toxicological issue.

DR. FREEMAN: Dr. Shiffman?

DR. SHIFFMAN: I would like to come back to an issue that I think we discussed but perhaps had not gotten closure on, which is the consumer information or misinformation that is conveyed outside the formal label in the form of brand names like "light" and "ultralight," and I guess what I was hearing from several people was a proposal that the use of those terms be regulated in a manner parallel to the FDA's recent regulations of such labels on foods. That is my own view—that those labels ought to be allowed. They have the potential to provide a smoker with meaningful information, but they should be regulated so that they represent a particular number or range in the ratings and so that they have a common meaning across brands and across manufacturers. I would like to hear other people address that issue.

DR. FREEMAN: Dr. Hughes?

DR. HUGHES: I think that is a good comment, Dr. Shiffman. Where I keep seeing the break is at .5. The ones less than .5 are different from those above .5. So I would like to see the categories only be on those that are less than .5 mg of nicotine with the comparable tar.

DR. FREEMAN: I think the general question here is, should constituents other than tar, nicotine, and carbon monoxide be added to the protocol for testing? It sounds to me as though you have said that they should not be added for testing or, if testing is done, it should be done by either chemists or toxicologists but not in the same way as for the other three major substances. There is a question of whether certain substances should be listed in some way on the tobacco pack or in some other way, so the American public would know that there are harmful ingredients in tobacco other than the three elements.

Let us try to get closure on that particular point before we go on.

DR. GUERIN: I think that tar and nicotine and CO in terms of quantitative measurements are adequate. I have one question for Dr. Hoffmann. Of all of the constituents that might not necessarily correlate very well with tar, the N-nitrosamines stand out. Should we consider an N-nitrosamine measurement?

DR. HOFFMANN: When you find another HCN, benzo(*a*)pyrene, you will always get from our friends of the tobacco industry, "Yes, but this can come from air pollution." Carcinogens that derive from nicotine can come only from tobacco, and I think that should be cited. Benzo(*a*)pyrene comes from

every combustion. Hydrogen cyanide comes from every combustion of a protein-containing component. Phenol comes from any combustion. The tobacco-specific nicotine-derived nitrosamines, which are strong carcinogens, come only from tobacco. I think the consumer should know that.

DR. GUERIN: To my knowledge that is the one class of chemicals that might be considered in addition, although it would be very difficult to do, relative to tar and nicotine and CO measurements.

DR. HOFFMANN: I personally do not think we confuse the smoker. I think we can let them know on the package that cigarette smoke contains toxic agents: hydrogen cyanide and known carcinogens, chloraminobiphenyls, benzo(*a*)pyrene, and the nicotine-derived nitrosamines. We should say that, though not quantitatively. Giving numbers is only confusing here.

DR. FREEMAN: Before we entertain other questions, I would like to have the committee's sense of whether you support what Dr. Hoffmann has just said, which seems to be a good summary of what we have said so far? Is there any disagreement with what Dr. Hoffmann has just said?

[NO RESPONSE]

Then we will take that as a consensus, and we will go on to consider it further in the latter part of the day.

You had another comment, Dr. Petitti?

DR. PETITTI: Just to emphasize that this information should not be quantitatively presented to the consumer because of the potential for misinformation.

DR. FREEMAN: My understanding relative to Question 2 is that there are certain elements that are proven to be harmful to human beings that are within tobacco that should be listed, though this panel is not recommending which specific compounds; that they should not be listed according to quantity; and that they should not undergo the same testing that we are recommending for tar, nicotine, and CO. I will take that as a consensus at this point.

If that is sufficient for that question, I would like to go on now to the third question that we have been asked to consider.

Question 3. Does the FTC protocol provide information useful to consumers in making decisions about their health?

Yes, Dr. Petitti?

DR. PETITTI: I think that in the context of the purpose of the FTC protocol, which is to provide information that allows consumers to choose cigarettes that reduce their risk of disease, the current FTC protocol is misleading in at least two important ways. First, it presents the consumer with a single number, thus implying that the consumer will receive exactly that exposure. Second, I think that the numbers when presented as numbers implicitly

suggest that there is a ratio-scaled relationship between machine-measured yield and disease risk. I think that these numbers could be made more useful by remedying these misleading aspects of the current FTC protocol in ways that we have been discussing throughout the morning.

DR. FREEMAN: Specifically what do you recommend?

DR. PETITTI: First, present a range of numbers, thereby correcting the problem of a single number implying that the consumer will receive exactly that amount of exposure; and, second, provide some kind of graphic presentation of this information to the consumer in a way that takes away the numerical aspect of "9 is 9 times higher than 1 and 20 is 20 times higher than 1."

DR. FREEMAN: Dr. Rickert and then Dr. Hughes.

DR. RICKERT: I agree. I think the issue is, *can* the FTC protocol provide useful information rather than *does* it? In other words, are there ways that we can take this kind of information and convey it? One of the options that has been discussed and also appears in the literature is this idea of using the color of tar to communicate the range of variation that one can get in tar yields and, also, to allow individual smokers to gauge what they are receiving from the cigarette. I think a lot of us feel that if it were possible for low-yield smokers, that is those who are smoking the less-than-5-mg cigarettes, to achieve a low-yield smoke from that cigarette, there may be an accompanying health benefit to that achievement. At the present time, however, there is no means for the smoker to ascertain what the yield is. If there were some sort of graphic technique for them to visualize this process, then that may confer a health advantage to them.

DR. FREEMAN: Dr. Hughes?

DR. HUGHES: I have a question for Mr. Peeler. I was struck by the remark that talking about health benefits implies a health claim, which I understand the tobacco industry has not made with this product. Therefore my question to you is, can the FTC require such health education to come from the tobacco manufacturers when they have not made that health claim?

MR. PEELER: The numbers clearly communicate some health benefit to some portion of consumers. If we were able to determine that a significant number of consumers were being misled by that, we could require some corrective information or provide some corrective information. I think the concern has always been the one that we started out with in 1960, that as a result of that position, there basically were not any tar and nicotine numbers being made available to consumers.

In terms of our present status right now, our jurisdiction is simply to require that claims made in advertising be substantiated. Currently, there is not an FTC rule, an FTC case, or any legislation requiring the disclosure of tar and nicotine data either on labels or in advertising.

DR. HUGHES: If some surveys or several surveys showed that most consumers inferred a claim of health benefits from these cigarettes, would that be important information for the FTC to know when considering whether to force the tobacco companies to put in health information?

MR. PEELER: Consumer survey information is absolutely vital to everything the FTC does in the regulation of advertising and labeling. Therefore, the answer to the first question is yes. The next question is this point that we raised earlier: whether there would be the ability to compel disclosure of tar and nicotine information absent a health claim. You do get back to the tension between having no information out there at all and having just the accurate tar and nicotine.

DR. HUGHES: I think you are misunderstanding, because I am not talking about whether they report the numbers or not. Suppose there was a proposal that the FTC would require all cigarette advertisements that state anything about tar to have a statement that reads something like, "Switching to a low-tar cigarette is a very small health improvement compared to stopping smoking."

MR. PEELER: There is a legal analysis under the Commission's unfairness authority that could be used to require disclosure of that information, assuming the correct factual predicate could be established.

DR. HATSUKAMI: Regarding health benefits, it seems that based on Dr. Cohen's presentation there are significant numbers of people who believe that there are benefits to switching to a lower tar and nicotine cigarette, and yet some of the data do not show this relationship between tar yield and health benefits, with the exception possibly of lung cancer. Therefore, I agree with Dr. Hughes in requiring some kind of label on the package explaining that switching to a low-tar and -nicotine cigarette may or may not provide health benefits, thereby hopefully correcting an apparent misconception.

DR. FREEMAN: Dr. Benowitz?

DR. BENOWITZ: I would just like to emphasize that such language has to be stated very carefully; I believe for an individual there is very little benefit to switching. For the society of all smokers there may be benefit, and I would not want to lose that benefit. We have to walk that line of warning individuals that this is not going to help you very much, but still encourage the whole society of smokers to reduce their tar and nicotine intake. We need to find language that will serve both purposes.

DR. FREEMAN: Dr. Kozlowski?

DR. KOZLOWSKI: I would like to encourage the panel to note in the report that there is a fundamental deficiency in that the current procedures are linked to cigarette advertising. A number of presenters mentioned that currently one-third of cigarette brands are generics. There is no requirement that a cigarette brand be advertised. There is no law that says that you must

advertise a cigarette, and, if it is not advertised, there is no option for any kind of brand-yield information or any kind of FTC method. I think one might see the linking of consumer information solely to advertising as a loophole in the system. I would encourage the panel to ask the FTC to try to provide some estimate of what percentage of brands are not advertised at all.

DR. FREEMAN: Mr. Peeler, can you address that question?

MR. PEELER: As I said earlier, we do not have that information today. We could certainly get that for the panel, if the panel would like it.

DR. FREEMAN: Are there a significant number of brands that are out in the market but are not being advertised?

MR. PEELER: There has been a very large increase in the number of brands that we have been reporting because of the increased number of generic brands, which are frequently not advertised.

DR. FREEMAN: And is it true that the FTC does not require that those brands undergo the same analysis?

MR. PEELER: Again, we have to go back to the beginning. The disclosure of tar and nicotine is provided for under the FTC's general authority to regulate advertising and to require substantiation of claims in advertising. At one point there was an FTC proposal to require the disclosure of tar and nicotine content in all cigarette advertising. Cigarette labeling is largely regulated by separate Federal statute called the Federal Cigarette Labeling Act. The rulemaking was suspended when the cigarette industry voluntarily agreed to put this information in all their cigarette advertising. So that is the current status of disclosure. Many companies do put that information on their packs, particularly with respect to their lower yield cigarettes. I do not have an estimate of how many packs that is.

DR. FREEMAN: Then it is conceivable that there could be cigarettes sold that do not have this labeling?

MR. PEELER: I believe it is likely that there are many cigarettes, particularly generics, that do not have these labels.

DR. FREEMAN: I think that is a very significant point. If the FTC does not regulate that, who does?

MR. PEELER: The content of the cigarette label is largely regulated by the Federal Cigarette Labeling Act, which is a Federal statute that requires a certain number of disclosures, for example, the Surgeon General's disclosure, and then basically says that, for other statements relating to smoking and health, only Congress can impose those additional statements.

DR. FREEMAN: Thank you. Dr. Hughes?

DR. HUGHES: I think we have a model with the recent food pyramid. That labeling change was accompanied by a massive educational campaign, and I do not know who did that, but it seems to me that we need a similar effort

with tar and nicotine. I want my patients to know about nicotine yield much more than I want them to know about riboflavin and cholesterol and that sort of thing. My question is, why have we not had the same public education campaign around nicotine yield, spending at least as much money as we did on the food pyramid?

DR. KOZLOWSKI: To respond to that, there is a question of in whose jurisdiction does that campaign fall. I think it is not within the FTC brief in any explicit sense to do an extensive education campaign on it, and you have just heard that cigarette labeling falls under quite a different procedure.

DR. FREEMAN: Dr. Townsend?

DR. TOWNSEND: In response to Dr. Kozlowski's concern and your obvious concern about generics or unadvertised cigarettes being out there in the marketplace without any information, that really is not true. While the specific numbers are not advertised, the generic products are broken into categories of tar deliveries, the same as other brands. For example, you can find a generic sold as regular, lights or ultralights. There is information out there, even if there is no advertising that carries with it specific absolute FTC tar numbers.

DR. FREEMAN: Would you clarify this point because I am a little confused. What would be the difference on the labeling of the generic product vs. the one that is advertised?

DR. TOWNSEND: Let me take one example with the generic cigarette brand Doral. The packages are in different colors, the same as other brands, with dark green for the regular, light green for the lights, and a real light green or a white for the ultralights; and their tar category is stated on the package. That is a comparative measure of the FTC tar yield for those cigarettes even though there is no advertising that carries the FTC number with it.

DR. FREEMAN: That is how they are similar. How do they differ?

DR. TOWNSEND: What I am saying is that there is a distinction in the marketplace by virtue of what is written on the pack, that it is a light or an ultralight or a regular.

DR. FREEMAN: I understand.

DR. TOWNSEND: And by the color of the pack.

DR. FREEMAN: But other than that, the numbers are not there?

DR. TOWNSEND: Because many of these products are not advertised, the numbers in some cases are not available to consumers.

DR. FREEMAN: You have clarified my point. Dr. Benowitz?

DR. BENOWITZ: One of the central recommendations of this panel should be that cigarette labeling include these warnings. The other issue that concerns all of us is consumer information, and even though it is not a

direct charge, I think we should make a strong recommendation that there be labeling about yields and the other issues we have been talking about.

DR. FREEMAN: Are you speaking also on the generic cigarettes?

DR. BENOWITZ: Yes, on all cigarettes.

DR. FREEMAN: That is your recommendation?

DR. BENOWITZ: Yes, because the FTC can regulate advertising, but what we are really talking about is labeling on the cigarette packs. If there is no vehicle for doing that now, I think we should recommend there be one.

DR. FREEMAN: Yes, Dr. Rickert?

DR. RICKERT: I would certainly support what Dr. Benowitz is saying, particularly given the amount of confusion that sometimes arises over the use of the terms "light," "ultralight," and so on. Unless these terms have been defined with some specific tar range associated with them, the use of the terms without that tar information is certainly open to the potential for misleading consumers.

DR. FREEMAN: Dr. Woosley?

DR. WOOSLEY: I agree with both of those statements wholeheartedly, but I am concerned by the reality of labeling being proscribed by legislation so that it is not to be touched by anyone but Congress. If I am interpreting that correctly, that is a terrible situation to be in. Let me just go on to say that I believe the use of the terms "light" and "ultralight" in advertising are perceived as a claim. I think there needs to be a very strong message from this committee that those are perceived claims, and they carry with it the impression of improved health, and I think that is a form of advertising.

DR. FREEMAN: Dr. Townsend, can you give the committee any sense of what percentage of cigarettes sold in America are in the generic category as opposed to the advertised category?

DR. TOWNSEND: No, I really cannot. There are some generic products or low-cost products that are advertised; most, however, are not. I cannot give you an exact percentage right now.

DR. FREEMAN: Thank you. Dr. Cohen?

DR. COHEN: Dr. Townsend, are you asserting that for cigarettes the color of the package is intended to convey the tar level of the cigarette?

DR. TOWNSEND: In practice, if you look at products that are in the market currently, in addition to having the category defined as regular, lights, or ultralights on the pack and in the advertising, in many cases the packs are different colors. If you look within one brand family, particular brands within that brand family that are in the different tar categories do have different pack colors.

DR. COHEN: Is there an intention on the part of cigarette manufacturers to convey information about tar yields by using color on packages, as well as terms such as "light" and other descriptive adjectives?

DR. TOWNSEND: There is an intention, in my opinion, by the cigarette industry in general to convey tar information to the consumer so that they can make choices. In some brands the different colors are intended to convey the different tar category in which they fall, and that category is stated explicitly in the advertising.

DR. FREEMAN: I have been informed by staff that approximately 40 percent of cigarettes sold in America are of the generic category. If that is true, then I think this is a major issue to be considered here.

DR. KOZLOWSKI: It appears that Dr. Townsend is indicating that the designations light and ultralight are in a sense being used as surrogates in a broad sense for tar and nicotine ratings and that they are carrying tar and nicotine rating information. My question is, are there industry standards or R.J. Reynolds standards for what numbers are required before a cigarette is called light or ultralight or is there variance across the industry and in what products get the label "light"?

DR. TOWNSEND: It is my understanding that the definition, of course, has changed a little bit over the years, but today the definition is really quite consistent. Cigarettes under 6 mg constitute ultralights, those from 6 to 15 are lights, and above 15 are regulars.

DR. FREEMAN: Dr. Henningfield?

DR. HENNINGFIELD: I have a recommendation and a question for Mr. Peeler. The recommendation is that, on discovering that FTC does not have the means to put on the labeling this information that we are saying is so important, I recommend that the FTC use all means at its disposal to get this information and make it readily available to consumers. My question for Mr. Peeler is, what kinds of things can you do? For example, could you put your tar report information at all points of sale, or do people just have to write for the catalog?

MR. PEELER: Let me clarify about the labeling. The place where we are preempted on cigarette labeling and where everyone is preempted on cigarette labeling is on statements relating to smoking and health, and there is a question about exactly where that is. I would think if there were a misrepresentation, for example, on a label of the tar content, and that is all that there was, that would be something on which the FTC could take action. The question of exactly how much information the FTC can affirmatively require to be disclosed absent a representation by the company is a whole other issue that we would have to look at in light of the panel's recommendations. For example, in the 1970's when the FTC required that health warnings start appearing in advertising, these requirements were based on allegations that the advertising at that point was making

representations about the cigarette's healthfulness. The FTC's actions resulted in settlements between the FTC and a number of companies that provided for the health warnings in advertising, which ultimately became required by statute in 1984.

The FTC does not have the FDA-type of regulatory power over the cigarette industry. We have the power to prevent deceptive statements, and we have the power to require the disclosure of certain types of information when a failure to disclose that information would be unfair.

DR. HENNINGFIELD: Can you only regulate what appears in a magazine ad? How do we get it to the consumers who do not read the magazine ads or for the cigarettes that are not advertised?

MR. PEELER: If you are talking about information about the relationship of cigarettes to health, then the advertising and the labeling right now contain warnings, and our authority to require additional warnings or descriptions would be triggered by what representations are made.

DR. HENNINGFIELD: So you could not require that a label like the one Dr. Harris showed be put on cigarette packages?

MR. PEELER: Again, what we are here for is to hear the committee's recommendations and take those back to the five commissioners who run the agency. I think what you ought to be doing is making those recommendations that you think are right, and then it will be up to the five commissioners to sort through them in terms of what is within the FTC's authority and what is not within the FTC's authority. Clearly the focus of our concern and the reason that we are here is there has been a lot of concern that the current tar and nicotine labeling system is not serving its intended purpose, and because we are putting those numbers out every year, that is going to be the first thing that we focus on.

DR. FREEMAN: Yes, you have a comment?

MS. WILKENFELD: In the seventies and early eighties when the Commission published its number, the Office on Smoking and Health made a large chart that was available at point of purchase in pharmacies and other places where cigarettes were sold so that there was educational information at the point of sale. Whether you call that labeling or the Commission would call it advertising, I do not know. But the money ran out and that stopped.

DR. FREEMAN: I would like to just express a personal concern here. I think all of us here should be concerned with the effect of a lethal product on the American public with respect to morbidity and mortality. On the other hand, this meeting has been called by the FTC along with the Congress. My concern is that our human concerns do not become engulfed in bureaucratic problems. The 40 percent of people in America who are smoking cigarettes that you do not oversee still are smoking cigarettes and still have the same lethality for those 40 percent. I hope that although we are governed by the bureaucracy in a certain way, and you have limits, and we certainly respect

that—we do have a Congress that can rule one way or another. I think we should speak to the general problem while we are giving you direction.

MR. PEELER: I would certainly agree with that.

DR. FREEMAN: Thank you. Dr. Cohen?

DR. COHEN: Consumers want information that they can use to make meaningful decisions. Assume the consumer wants to make the meaningful decision as to whether switching to a particular kind of cigarette, say a 1- to 5-mg tar cigarette, would lead to a significant reduction in health risks. Can this panel, given the state of the art, attempt to provide information that would be helpful to the consumer as to the relative risk of smoking different kinds of cigarettes? If the answer is no, then it is no, but I think that is more important information than the information currently available through tar numbers because tar numbers do not tell consumers information that is meaningful.

DR. FREEMAN: Dr. Benowitz?

DR. BENOWITZ: If you tell people that if they take in less tar, there is a small benefit, it is not one that should be denied, but I think it is misleading. I do not think we can tell people that *you* are going to reduce *your* hazard; *you* are going to live longer if *you* shift to low-yield cigarettes. So, we are caught in a bind. We want to encourage people to minimize the risk, but we cannot really tell them it is going to make a huge difference.

DR. COHEN: I think frankly that this is a subject that ought to command the attention of the panel because consumers, like it or not, are using these numbers as if they had absolute significance as numbers. The numbers mean almost nothing. The panel has to address the question of is there a way of informing consumers as to the relative risk, and perhaps the answer is to let us inform them that there is not a lot of gain; doing that, frankly, would be very useful and maybe more useful than telling them exactly what the tar differences are.

DR. FREEMAN: Dr. Rickert?

DR. RICKERT: I think the committee has thought about that to a large extent, and I think there is a consensus that what is really needed is a rather large public health education campaign to try to communicate that very information to consumers.

You are also asking for information about risk, and generally this comes from epidemiological studies, which by their very nature are extremely long and do not provide information that we can use immediately. The information that we have today has been gleaned over a number of years with respect to relative risk, and as we have seen, there is not much change.

Now, if one is going to ask what is the effect with today's cigarettes, then we are talking about a period of time that will be measured in tens of years.

Unfortunately, we have to come to grips with the problem today, and we cannot wait for tens of years to pass to obtain accurate information about today's cigarettes.

DR. FREEMAN: Dr. Hughes?

DR. HUGHES: I would like to respond very concretely to what you said, Dr. Cohen, and it is my opinion that if there is not information that you suggest about the health benefits of switching, the whole system should be junked. My concern is that we are going to say, "Yes, there should be this big public health campaign," and nothing will happen. NCI says, "We don't have money for it." FTC says, "We don't have the bureaucracy to do it." The FDA says, "We have other more important things to do," and this whole education campaign does not get done. We come up with a range of values that still has numbers on them, and people still think that they are doing themselves a big benefit, and I would rather junk the entire system than to have that happen.

The only way around it I can see is that the FTC decides that all claims of light and ultralight imply a health claim and therefore require a disclaimer. That is the only way out of it I can see, to make sure that that happens.

DR. FREEMAN: What form of disclaimer?

DR. HUGHES: I do not want to micromanage with the wording. Whether we say, "You may get a small benefit" or "You will get very little benefit compared to stopping smoking," is a tough question, and I do not think we need to decide on that wording. My point, again, is to reiterate what Dr. Cohen said, which is that the system is bankrupt unless there is some statement about the magnitude of health benefit that you will receive by switching to a low-tar and -nicotine cigarette.

DR. FREEMAN: Dr. Stitzer?

DR. STITZER: I want to return to a point I made earlier. It seems to me that we would be doing a great service if we could implement a new testing technique that involved ranges that could display and convince smokers that light cigarettes are the same or can be exactly the same as a regular cigarette. I think the data show us that all the cigarettes from .4 mg up can look exactly the same. They basically are occupying the same place in space. The range of variability is the same, and that there is no health benefit for switching to light cigarettes because of this dose variation, but there are also some data suggesting that the ultralight cigarettes, those .1 mg and below, do produce a different level of exposure.

Now, those cigarettes are not popular. They capture a very, very tiny segment of the market, but they may make a difference. We do not have the health data, but if there is a dose effect for health, those are the only cigarettes that are going to make a difference, and it seems to me that a new labeling system could potentially convey that kind of information.

DR. FREEMAN: To play devil's advocate, there seems to be a point on the other side that, if the American public becomes confused about the value of low dose vs. high dose, would it defeat the purpose of encouraging people to switch, assuming there is a benefit to low-dose cigarettes? I think I am hearing those two arguments. Yes, Dr. Giovino?

DR. GIOVINO: I think part of any disclaimer that would be given if you decided to do that would include the statement that I read earlier from the Surgeon General's report that any cigarette smoking is dangerous, that quitting is absolutely the best thing a person could do to protect his or her health, and that reducing to these brands "may." And that is exactly what the Surgeon General's report says, "May pose reduced risk, provided that no compensation occurs." I think those two caveats are absolutely essential, that quitting is better than switching and that provided no compensation there may be reduced risk.

DR. FREEMAN: Dr. Benowitz?

DR. BENOWITZ: I think there is a second function that the FTC testing does perform, and that is to mold what the tobacco companies provide. I do think that there has been a reduction in lung cancer if you compare 1950's cigarettes to modern cigarettes, and I would not want to lose that pressure to keep yields as low as possible. I think whatever we do, we do not want to lose that by saying that it does not matter at all. The other argument is if there is a 10-percent reduction of health hazard—which would be very difficult to measure by epidemiological means—if you are applying it to about 40 million smokers, that can be substantial. And I would not want to lose that for the population either.

I do not want to be misleading. I certainly appreciate Dr. Hughes' point of view, but I think we somehow should not let things slide the other way.

DR. FREEMAN: Is there any way that you can bring the two points of view together? I think this is a very important point. We need to settle it here.

DR. STITZER: There is just one other thing. The only way that this information can be relevant to the individual consumer is if there is a way for that individual to judge where he or she falls along the dose continuum. Now, that could be accomplished with a lovely sophisticated method like Dr. Rickert has described with the color coding. I do not know whether that technology is sufficiently available to incorporate into our recommendations, but it could be part of our recommendation that we try to develop a system that allows the individual smoker to know where they fall on the exposure and dose continuum.

DR. FREEMAN: Yes, Dr. Hughes?

DR. HUGHES: I disagree a little bit with you, Dr. Stitzer. Even if people could tell exactly where they were on the dose continuum, that does not solve the problem of the dose response-health benefits curve being so shallow. Also, I want to respond to your comment. I am not saying that

there is no benefit, and I do not think we should say that there is no benefit because I agree the public health argument is there. But the physician in me says, "Always oversell your case," because people do not change very much. Again, I do not care what kind of disclaimer or how it is worded, but there has to be, again, something about health benefits to the consumer in all of this.

DR. FREEMAN: Dr. Shiffman?

DR. SHIFFMAN: I think the two issues we have struggled with most recently are related. While the system as now constituted has its focus on advertising and on showing a single number for an FTC measure of tar and nicotine values, in fact there are implicit claims being made both in advertising proper and in brand names, which are a form of advertising that imply a health claim. Therefore, it seems to me we ought very strongly to recommend both that the use of those terms, like "light" and "ultralight," be regulated and that when they are used, they be accompanied in fair balance by a disclosure of the sort that Dr. Hughes has suggested.

I think there is a middle ground that allows us to proceed based on what we know and based, I think, on regulatory authority that already exists.

DR. FREEMAN: Yes, Dr. Zacny?

DR. ZACNY: Based on Dr. Rickert's point about state-of-the-art epidemiological studies not being done at this time where you can say with any degree of certainty what the relationship is between nicotine dose and risk of disease with the brand of cigarettes we are dealing with now—the low-yield cigarettes and the ultralow-yield cigarettes—I disagree slightly with Dr. Hughes when he says that the relationship may be very shallow. As scientists, in any claims we make we can just say that we do not know at this time what the relationship is because it takes 10 or 20 years, but based on what we know, it would be best not to block vent holes, to take smaller puffs, etc.

DR. FREEMAN: That would be an educational campaign?

DR. ZACNY: Yes. Maybe I am wrong, but it seems that there may be a dose-response relationship between risk of lung cancer and how much smoke people take into their system, and they may realize a substantial benefit with the ultralow-yield cigarette. I do not think we know with certainty, and in the absence of that, I think the formulations that we are putting forth with bands and ranges are a good idea.

DR. FREEMAN: Dr. Kozlowski?

DR. KOZLOWSKI: I would like to draw an analogy to the FDA nutritional labeling. For a lot of the items on those labels, there is not persuasive epidemiological research to show the dose-response curves for a lot of the things that are listed as of interest. I think we do not want to be held to a higher standard. Epidemiology takes time. It has its limitations, and the

basic point is there is a lot of labeling that pertains to risks that are only approximately known.

DR. FREEMAN: Dr. Benowitz?

DR. BENOWITZ: To follow up on Dr. Zacny's comments, what we really would like to know is not brands vs. risk; we would like to know actual exposure level. If we were able to measure cotinine or adducts of different compounds or whatever in smokers vs. their yields, then we would have the basis for recommending that individuals should reduce their exposure. Since there is such an overlap with the yields as marketed now, I do not think we are ever going to see a difference by yield—that does not mean that the rationale for an individual reducing their intake is not valid, and so at this point in time we may have to go forward based on scientific rationale and plausibility for reducing exposure to toxic materials.

DR. FREEMAN: Dr. Hoffmann?

DR. HOFFMANN: I think there is a misunderstanding. It has been shown in *dozens* of studies that there is a dose response with respect to cancer of the lungs and the upper respiratory tract by number of cigarettes smoked per day, length of time smoking, and groups of cigarettes. This continues for ultralow, low, and average cigarettes. There is a dose response with respect to cancer but not with respect to coronary artery disease. Any cigarette is harmful. But ultralow cigarettes have a lower risk than nonfiltered regular cigarettes when you smoke them for 10 or more years. We should not say that there is no dose response.

DR. FREEMAN: Dr. Hoffmann, just to follow up on what you said, as far as the science is concerned, you indicated that in there is no apparent dose response for coronary heart disease?

DR. HOFFMANN: We do not know from the literature any benefit with respect to coronary heart disease.

DR. STITZER: Dr. Benowitz can speak to this. Is there a dose effect based on light vs. heavy smoking for coronary disease?

DR. BENOWITZ: No, there is not. I would like to add that I agree with Dr. Hoffmann that this dose response would provide a rationale for what we are doing here today. There are data in pregnancy showing the dose response between cotinine level and the weight reduction of the newborn, and therefore that is another rationale for another disease that there is a dose-response relationship, and therefore, even though we cannot say that a particular brand is going to be less hazardous than some other brand, we can say that lowering your exposure in general will be beneficial, and then we just have to help people to do that.

DR. FREEMAN: Didn't Dr. Samet state yesterday that there is no evidence that coronary heart disease is reduced by lowering the nicotine or tar content in cigarettes?

DR. BENOWITZ: He said that there was no evidence.

DR. HOFFMANN: That may be the case, but that we have no evidence.

DR. FREEMAN: I think we should respect those data because I think more than 100,000 people die each year from cardiac death due to smoking. I do not know the exact numbers, and that is a very significant point to argue that even smoking low-nicotine, low-tar cigarettes will not protect you as far as we know from dying from coronary heart disease. Is that a fair statement, Dr. Hoffmann?

DR. HOFFMANN: No, I think we do not know.

DR. FREEMAN: Let me narrow down the point. Are you saying that there is no distinction between the low-tar and -nicotine smokers and the high with respect to death from coronary disease?

DR. HOFFMANN: There is no evidence.

DR. FREEMAN: No evidence that there is a difference?

DR. HOFFMANN: No evidence that I am aware of. We discussed it last night, and nobody came up with any, but there may be. I am not aware of it.

DR. PETITTI: Since we are relying so heavily on the 1981 Surgeon General's report, and very few data have come out since then, I would like to read the statement specifically about cardiovascular disease:

> The overall changes in the composition of cigarettes that occurred during the last 10 or 15 years have not produced a clearly demonstrated effect on cardiovascular disease, and some studies suggest that a decreased risk of CHD may not have occurred. Evidence on the association between CHD and filter cigarettes is somewhat conflicting. One major study showed a reduction of 10 to 20 percent of coronary deaths among persons smoking lower tar and nicotine cigarettes as compared with those smoking higher yield cigarettes.

That was the CPS-I study, but other surveys have shown a slightly increased risk of coronary mortality in people who smoke filter cigarettes or those who smoke nonfilter cigarettes. Recent unpublished data from the Framingham study that were ultimately published do not show a lower CHD risk among smokers of filter cigarettes. It is not that there are no data. The data that exist show no association of smoking lower yield cigarettes with reduction in coronary heart disease morbidity and mortality.

DR. FREEMAN: I think that is a very, very important point that ought to be factored into this discussion. Dr. Cohen?

DR. COHEN: I was very pleased, Dr. Hoffmann, to hear you clarify an issue for me. I heard you say that we can inform people about lung cancer, at least. Now, lung cancer is a major issue for people, and what I am wondering is, since people use tar as a surrogate for relative harmfulness, might it make

some sense to restrict their usage of tar by maybe getting rid of tar and talking about cancer-causing compounds or some other component and let these numbers communicate meaningful information about something we do know something about, rather than where we do not know anything about it that is conclusive? Would it be possible, in other words, to indicate people's relative risk with respect to lung cancer for smoking these different yield cigarettes?

DR. HOFFMANN: As I see it, the public associates tar with cancer.

DR. COHEN: I think they do it more broadly and associate it with overall safety.

DR. HOFFMANN: They are not well informed. The American Cancer Society did a fantastic job, publishing this over and over again, and the public is well informed with respect to smoking and lung cancer. There has not been the same level of information communicated about coronary risk.

DR. COHEN: In your view though, is it possible to relate the differences in tar yield in cigarettes to a reduction in cancer risk? If the answer is yes, it seems to me that one of the things the panel might consider doing is trying to convey that or recommending that be conveyed.

DR. FREEMAN: Dr. Rickert?

DR. RICKERT: I would be somewhat reluctant to do that for several reasons. First of all, the information with respect to lung cancer and risk reduction is from the 1981 Surgeon General's report that relates to cigarettes that were consumed 10 to 20 years prior to that date. My other concern is in terms of "tar is tar is tar," that is, is the quality of the tar from today's ultralow-yield cigarette the same as the quality or the carcinogenic potential of tar from a cigarette from many years ago? I do not think we know that the tar of today's cigarette is the same as the tar of the cigarette many years ago that was being related to lung cancer.

DR. HOFFMANN: With respect to your first point, Dr. Rickert, there was an International Agency for Research on Cancer monograph in 1986 that presented 15 studies that all show between a 13- and 30-percent reduction. There are also reports from the World Health Organization, and there is the European study by the National Cancer Institute. It did not end with 1981.

DR. RICKERT: I am not uncomfortable with the idea that there is a risk reduction. What I am suggesting is that we really do not have enough information about the tar characteristics of today's cigarettes to directly compare them.

DR. HOFFMANN: You can do only risk biomarkers. Otherwise you cannot do it.

DR. RICKERT: I agree.

DR. FREEMAN: Yes, Dr. Hoffmann.

DR. HOFFMANN: I believe that we should do better education. I do not think that including whether it is plus or minus 3 mg or 5 mg helps the public. The public has to be much better informed.

DR. FREEMAN: It appears from what I have heard here on the question of does the FTC protocol provide information useful to consumers in making decisions about their health, that the answer seems to be not sufficiently so, and we have had an interesting discussion and debate here this morning concerning various aspects of that decision.

Things that stand out in my mind are what do the numbers mean to the public? Dr. Cohen has been eloquent in raising that issue. What is the value of projecting a range per type of cigarette to the public? What is the value of any kind of color coding to the public? What would be the value of presenting a graph to the public so a person could see by graph form what the differences in cigarettes are? We also have heard this morning, unknown to me before, that approximately 40 percent of cigarettes are not looked at by the Federal Trade Commission because they are not advertised.

MR. PEELER: They are looked at, and they are tested. The results are reported, but unless the manufacturer either voluntarily puts that information on the label or unless they advertise, those numbers aren't necessarily communicated directly to consumers.

DR. FREEMAN: Thank you for that correction. The bottom line is the public does not know those numbers.