Recommendations and Findings

DR. FREEMAN: Good afternoon, I am Dr. Harold Freeman. I am the chairman of the President's Cancer Panel. At the request of the Congress and the Federal Trade Commission, an ad hoc committee of the President's Cancer Panel has met over the last 2 days to consider the Federal Trade Commission test method for determining tar, nicotine, and carbon monoxide levels in cigarettes. Before I get into our statement, I would like to put the problem of tobacco into perspective. Tobacco use is the number one cause of preventable death in America. Cigarette smoking is responsible for more than 400,000 premature deaths every year in this country and causes one-third of cancer deaths and one-third of heart disease deaths.

Although smoking is declining among adults in the United States, it is discouraging that smoking is not declining among children, and in fact, smoking prevalence among adolescents has changed little for more than a decade.

I have with me Dr. Saul Shiffman of the Department of Psychology, University of Pittsburgh; Dr. Diana Petitti, director of the Division of Research and Evaluation, Kaiser Permanente; and Dr. William Rickert of Labstat, Inc.

This committee reviewed articles, studies, and other documents and heard presentations from a variety of experts, including tobacco industry scientists, on the subject of the FTC test method for determining tar, nicotine, and carbon monoxide levels in U.S. cigarettes. We have deliberated with the goals of answering questions and making recommendations. Our deliberations centered around the following three summary questions:

1. **Does the evidence presented clearly demonstrate that changes are needed in the current FTC protocol for measuring tar, nicotine, and carbon monoxide? If yes, what changes are required?**
2. **Should constituents other than tar, nicotine, and carbon monoxide be added to the protocol?**
3. **Does the FTC protocol provide information useful to smokers in making decisions about their health?**

I. The committee reached the following conclusions with respect to the first question.

A. The smoking of cigarettes with lower *machine-measured* yields has a small effect in reducing the risk of cancer caused by smoking, no effect on the risk of cardiovascular diseases, and an uncertain effect on the risk of pulmonary disease. A reduction in *machine-measured*

tar yield from 15 mg tar to 1 mg tar does not reduce relative risk from 15 to 1.

B. The FTC test protocol was based on cursory observations of human smoking behavior. Actual human smoking behavior is characterized by wide variations in smoking patterns, which result in wide variations in tar and nicotine exposure. Smokers who switch to lower tar and nicotine cigarettes frequently change their smoking behavior, which may negate potential health benefits.

C. Accordingly, the committee recommends the following changes to the FTC protocol:

1. This system should also measure and publish information on the range of tar, nicotine, and carbon monoxide yields that most smokers should expect from each cigarette sold in the United States.

2. This information should be clearly communicated to smokers.

3. A simple graphic representation should be provided with each pack of cigarettes sold in the United States and in all advertisements. The representation should not imply a one-to-one relationship between measurements and disease risk.

4. The system must be accompanied by public education to make smokers aware that individual exposure depends on how the cigarette is smoked and that the benefits of switching to lower yield cigarettes are small compared with quitting.

D. There should be Federal oversight of cigarette testing, but such testing should continue to be performed by the tobacco industry and at industry expense.

E. The questions involved in the purpose, methodology, and utility of the FTC protocol are complex medical and scientific issues that require the ongoing involvement of Federal health agencies, including the National Institutes of Health, Food and Drug Administration, and Centers for Disease Control and Prevention.

F. The system should be reexamined at least every 5 years to evaluate whether the protocol is maintaining its utility to the smoker.

G. When a cigarette manufacturer makes significant changes in cigarette design that affect yields, it should notify the appropriate Federal agency.

II. With regard to the second question, the committee recommends that to avoid confusing smokers, no smoke constituents other than tar, nicotine, and carbon monoxide be measured and published at the present time. Smokers should be informed of the presence of other hazardous smoke constituents with each package and with all

advertisements. These constituents should be classified by toxic effects.

III. In considering the third question, the committee reached the following conclusions:

A. Information from the testing system is useless to smokers unless they have ready access to it. The information from the testing system should be made available to all smokers, including those who smoke generic brands and other brands not widely advertised.

B. Brand names and brand classifications such as "light" and "ultralight" represent health claims and should be regulated and accompanied, in fair balance, with an appropriate disclaimer.

C. The available data suggest that smokers misunderstand the FTC test data. This underscores the need for an extensive public education effort.

I would like to underscore two major points: First, the health benefits of switching to low-tar and -nicotine cigarettes are minimal compared to quitting entirely, and finally, in effect, how you smoke is much more important than what you smoke.

We have deliberated for 2 days. We believe these findings are very important to the health of the American public. We are dealing with a product that is lethal, that needs to be controlled, and we believe that these recommendations will lead to some control. I would open it up for questions to my colleagues or to myself.

PARTICIPANT: Dr. Freeman, what do you expect to be the next step in the educational process for consumers?

DR. FREEMAN: The findings from the deliberations of this committee will be reported to the Director of the National Cancer Institute, who will then formulate a report that will be passed on with the help of the President's Cancer Panel to the appropriate agencies and the Congress.

PARTICIPANT: That is a lot of reporting. Can you predict what might happen next?

DR. FREEMAN: I do not think we can predict what is going to happen in the future, but our hope is that since the FTC methodology has been in effect from 1967 and was based on findings that relate to 1936, and since in the last 25 years there has been a considerable change in our knowledge through research, as well as in the type of cigarettes that are being smoked, we now believe that these changes are very essential and should be put into effect very soon.

No one can predict because we are dealing with the FTC, possibly other agencies of the Government, and the Congress, and no one on this committee can predict how rapidly these changes may take place, but we believe they are very important.

PARTICIPANT: Are you saying that you are recommending keeping the current FTC testing method and expanding it in some way or are you talking about a whole new testing system?

DR. FREEMAN: Let me reemphasize that we are recommending the keeping of the basic parts of the FTC testing methodology with the exception that we want to expand testing to show the ranges of possible effects of the three substances that are being measured. The reason that we believe this is important is that the research has shown that people who smoke cigarettes that, for example, are labeled as having low tar can get a much higher dose from that cigarette than the label may indicate. For example, if you have a low-yield cigarette, the way you smoke it, the rapidity of the puffing, the depth of the puffing, whether you block the ventilation holes, etc., can have an extraordinary effect on the real dose to the patient. Disease, we believe, is related to the dose of carcinogens and other toxins.

PARTICIPANT: The impetus for this effort came from Congressman Waxman, a Democrat in the Congress. Now the Congress is primarily Republican. What effect do you think this is going to have on your recommendations?

DR. FREEMAN: It is conceivable that people in power who have philosophies that are different from Congressman Waxman's could present barriers to our recommendations. We are hopeful though that even with these changes that the logic of what we are saying will make sense even to people who may disagree with what we are recommending in principle. There are people, for example, who may wish to diminish the fight against tobacco, and I am sure you are referring to them. I am hopeful that even such people will listen to the logic of reporting to the American public the truth of a finding that is responsible for 400,000 deaths a year and give the public the chance of making an intelligent decision. We are not saying, "Eliminate cigarettes." We are not saying, "Stop using the methodology that has been present for 25 years." We are saying, "Give an honest report to the American public and show them the range of the risk that they are subjected to." I hope that everybody, Democrat, Republican, conservative, or liberal, will follow that logic.

PARTICIPANT: You are suggesting, in addition, putting the CO on cigarettes and also putting other ingredients?

DR. FREEMAN: One of the recommendations that I read to you indicates that we believe that in addition to putting the ranges of the tar, nicotine, and carbon monoxide that are now being measured with one number, we want to change that to a range because that is a more truthful statement. This committee is also recommending that certain key harmful substances known to be in cigarettes (we are not saying which ones should be listed) should be given as information to everyone who buys a package of cigarettes. We believe that if this is done in food, which does not apparently have the toxic effect of tobacco, then we believe it should be done in this lethal product.

PARTICIPANT: Could you explain the graphics that you would put on the package?

DR. FREEMAN: I am going to refer this question to Dr. Rickert.

DR. RICKERT: There are a number of different ways of looking at that particular problem. The graphics could involve a number of different issues; for example, it could involve a color representation of the cigarette filter. It could represent some icon that illustrates putting all of this information together. A number of different possibilities were discussed, and I do not think that the committee recommended any specific procedure. I think the feeling was that there should be some way of communicating the information to smokers without total reliance on numbers themselves.

PARTICIPANT: What would be the purpose? I do not understand the purpose of the graphics overall.

DR. RICKERT: The graphics would make several points. First of all, the point that yields to smokers depend on how the cigarette is used; that is, if you have a graphic, it gets away from the idea that there is a fixed amount of whatever the constituent happens to be. The purpose of the graphic is to illustrate the variable nature of the smoking characteristics.

DR. SHIFFMAN: If I may add, we thought it was very important to communicate to American smokers that what you get depends on how you smoke and that any system that simply gives one number is, therefore, inherently misleading. So, we envisioned a graph that would show you a band within which your particular exposure might lie and that will give smokers information on which they can make more accurate, more reasonable comparisons among brands. We think they will find that there is a good deal of overlap among brands that they now consider to be different.

PARTICIPANT: You said "light" and "ultralight." Some people say that those words represent health claims. Could you explain a little bit more about that? How does that represent a health claim, and what kind of disclaimer would be used?

DR. FREEMAN: It is the committee's belief that the public infers health claim meanings from these labels, whether they be light, ultralight or whether they be the numbers in tar and nicotine. It is anecdotal, and also studied, that people look at these numbers and these claims and translate them into what it means for their own destiny. The information gathered at this meeting indicates that smokers should not be making these predictions, first of all, and second, if the labeling by the cigarette industry of ultralight implies that you are better off according to health, if that is so, and we believe that this is so, then that represents a health claim on the part of the advertiser. If it is a health claim, it should be followed by a disclaimer saying that it is not a health claim, if it is inferred to be a health claim.

DR. SHIFFMAN: I think, again, specifically we want to be sure that the smoker understands that smoking a cigarette that is labeled as light or ultralight does not necessarily protect them from the health risks of smoking and that, in that sense, cutting down in this way may not keep people from being cut down eventually by their smoking habit. We do think that the public perceives those labels as implicit health claims.

DR. FREEMAN: It is even conceivable that a low-tar cigarette smoked in a certain way may have the same health risk as a regular cigarette, and we have pointed out in what I have already said that there is no scientific evidence that any level of tar in cigarettes protects one against death due to coronary heart disease.

PARTICIPANT: The other substances that you referred to, are you going to talk about numbers?

DR. RICKERT: I think that what the committee felt in that area was that at the present time, since there is evidence that consumers tend to misinterpret the existing numbers, that to add additional numbers may add to that confusion. At the same time there was the concern that there are additional agents, other than tar, nicotine, and carbon monoxide, that have definite implications for health. It was anticipated that these compounds would be classified in various ways, for example, "carcinogens," and then there may be a list of several carcinogens. There would be a list based on toxicological effects but not including any numerical measurement.

PARTICIPANT: Can the machinery that is currently used to test cigarettes be used?

DR. FREEMAN: We were told by an expert today that there may be some fine tuning that will be necessary to use the current equipment to do this kind of testing.

PARTICIPANT: Who would determine what that range was and how many times the machine smoked or how long the puffs?

DR. FREEMAN: This committee did not go into that kind of detail. We are talking about the principle, and the principle is that we know that human smokers smoke in different patterns. Some smokers puff many times in a minute, and some smokers may puff once a minute. Some smokers puff deeply, and there are other factors that I could mention. While we are not trying to micromanage how this should be done, the principle is that we would like the machine measurement to more closely mimic the variation that humans evidence in their patterns of smoking to give a more honest range of what a given milligram of tar really represents in range. We do not believe it is accurate at all; in fact, it is misleading to give one number when the pattern of smoking can change that number radically with respect to dose.

DR. SHIFFMAN: What the panel intended was that the range represent the range of human smoking of particular brands so that the machine would

model that under different parameters, which might include things that are now not dealt with in the FTC protocol, such as the blocking of ventilation holes that are used to dilute the smoke in some brands that now list as being low yield, but in fact can become high yield when a human finger or a human lip blocks those vents.

PARTICIPANT: Can you tell us what the role of other Federal agencies is going to be?

DR. FREEMAN: I am not an expert on the bureaucracy of America. However, we did get somewhat of a description of the FTC role in our meeting here today, which is a role that I understand deals with truth in advertising as one of its major roles. And to make a personal statement here, I think that is a limited role with respect to what we are trying to accomplish for the American public.

We found out today that 40 percent of cigarettes smoked in America are generics, and these for the most part are not advertised. However, the FTC in most of its role is limited to making statements about cigarettes that are advertised. So that if nearly half the cigarettes smoked in America are not advertised, it diminishes the FTC's role. Yet, the American public needs to know about the lethal nature of all cigarettes.

Now, as far as the FDA is concerned, again, I am not an expert on what they do, but I think their role is different from the FTC and may get more into the range of health concerns, hopefully. So, I cannot give you a finite answer. Perhaps my colleagues can help me out.

DR. SHIFFMAN: I would just add that the current FTC system operates under a voluntary agreement with the tobacco industry and cigarette manufacturers, and the representatives of that industry who addressed us during this meeting expressed an interest on the part of the industry of keeping consumers and smokers informed. We expect that they would follow through on that then in taking this step to make sure that accurate, useful information is available to smokers.

PARTICIPANT: Is it your understanding that if the regulatory agencies wanted to do this, that legislation would be necessary?

DR. FREEMAN: To do exactly what?

PARTICIPANT: To carry out your recommendations?

DR. FREEMAN: It is our belief that most of what we have recommended could be carried out by the FTC without congressional change. Our worry is that 40 percent of cigarettes are not regulated in a similar manner. Our concern is about the health of the American public and that the bureaucracy that we must go through to accomplish some of these things sometimes is a barrier to that. The FTC has regulations; the FDA has regulations, but sometimes what must be done or what should be done to save lives is beyond the confines of a certain agency, and this is somewhat of a problem.

PARTICIPANT: You said that this information would be useless unless smokers had ready access to information, including smokers of generic brands. In view of what you said about the FTC's jurisdiction, how do you anticipate getting that?

DR. FREEMAN: This came up very honestly today. We have not had time to think in depth about it. This was probably a surprise, even to this committee, that that problem is so large, that 40 percent of cigarettes are of the generic type, and honestly I do not have a good answer to that question. It may be that the FDA and other agencies could help in some respects, but I will refer this question to my colleagues to see if there is an answer to that.

DR. PETITTI: I could only repeat, I think, what we heard this morning, which is that some of these changes might, in fact, require congressional action, particularly if they resulted in changes in the labeling law. We are saying that there may be the need to put things on cigarette packs in order to adequately inform the American public about the FTC protocol.

PARTICIPANT: Looking ahead to the next 5-year review, do you see any gaps in research areas that need to be addressed?

DR. FREEMAN: Yes, we do. First of all, we have this paper. Where we are now with respect to our current knowledge, of course, is based on research, not perfect research, but we know a lot more now than we knew in 1950, when Ernst Wynder and others showed that tobacco is associated with death. So, research is a critical element and at any time I think we must act on what we know, but we must always move forward to finer knowledge. For example, further research is needed to determine the extent to which smokers of lower tar and nicotine cigarettes are less likely to attempt to quit smoking. There is some preliminary evidence, for example, that low-tar smokers may have less tendency to quit smoking. This would be very bad if it turns out to be true. It needs further research.

Next, to adequately understand and evaluate the impact of what is called compensation, research is required to assess the extent to which other biomarkers are correlated with machine-measured yields of the same substance. By compensation we refer to the point that low-tar smokers frequently smoke more cigarettes apparently to get the physiological dose of nicotine, which of course is an addictive substance. Compensation needs to be studied further to see what effect it may have, and certain biomarkers may come in handy to help us. Third, the differences in smoking patterns in different ethnic groups should be studied for the implications for health education and consumer information. We know, for example, that African-Americans tend to smoke cigarettes that are higher in tar and tend to smoke mentholated cigarettes. Other examples could be given. Poor Americans tend to smoke higher tar cigarettes. Educated Americans tend to smoke lower tar cigarettes. These are all very important questions that we only have preliminary information on, and these things need to be studied much more deeply. Finally, a system should be developed to help smokers gauge

where their individual smoking behavior places them on a dose continuum. What diseases you develop, whether it be cancer or anything else, is often associated with the dose that you receive, and individuals need to know what dose they are receiving. There may be other research questions, and I will open it up for Dr. Rickert and Dr. Shiffman to comment.

DR. SHIFFMAN: I would add only that in addition to refining our knowledge in these areas that there may be some very different products for smokers on the horizon. We heard some indication of those in the press, and the system would have to be very carefully considered in order to properly evaluate new kinds of products aimed at smokers.

DR. FREEMAN: I think using research in a different way, we need to better understand the way the people in power deal with tobacco in America. It is a substance that is high in the economy.

If cigarettes were invented today, they probably would be outlawed since they kill 400,000 people a year. However, it is deeply integrated into our economy. It affects policymaking. Sometimes there is a conflict, in my opinion, between making regulations and trying to balance the budget.

America in one of its Government roles is saying that tobacco kills 400,000 American people. Other parts of Government are selling it overseas and growing it in America. These are deep problems. They require further research and knowledge and action.

Are there other questions?

If not, I would like to conclude by expressing my privilege of chairing this committee. We brought together the best experts in America on the subject. Dr. Dietrich Hoffmann, for example, is one of the pioneers in the study of tobacco, and there were others, and it is a privilege to chair this committee. It is our hope that these deliberations will have an effect on the American public with respect to saving lives and preventing disease.

Thank you very much.