UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA,	.	
	.	
Plaintiff,	.	Docket No. CA CA99-02496
	.	
v.	.	
	.	
PHILIP MORRIS USA, et al.,	.	Washington, D.C.
	.	November 2, 2004
	.	
Defendants.	.	
. . . . .	.	

VOLUME 23
MORNING SESSION
TRANSCRIPT OF BENCH TRIAL PROCEEDINGS
BEFORE THE HONORABLE GLADYS KESSLER,
UNITED STATES DISTRICT JUDGE

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P R O C E E D I N G S

(9:30 a.m.)

THE COURT: Good morning, everybody. This is United States versus Philip Morris, CA 99-2496. Dr. Benowitz, would you please take the stand. You're still under oath this morning, of course.

And Mr. Wells, we're ready to begin.

MR. WELLS: Am I on?

THE COURT: Yes, but I don't think you have voice problems, Mr. Wells.

MR. WELLS: I just had an operation on my throat, so I'm coming back. Wait until you see me next year.

CONTINUED CROSS-EXAMINATION OF NEAL BENOWITZ, M.D.

BY MR. WELLS:

Q. Good morning, Dr. Benowitz.

A. Good morning.

Q. I want to turn this morning to the area of addiction, okay?

A. Yes.

Q. And you discuss in your direct testimony the term addiction and how that term has evolved over time, correct?

A. Yes.

Q. Now, I want to start out by focusing you on what the knowledge was within the scientific community about nicotine and addiction prior to 1964, okay?

A. Yes.
Q. Now, nicotine is a drug, correct?
A. Yes.
Q. And, scientists have known for over 100 years that nicotine was in tobacco, correct?
A. Yes.
Q. And, by the end of the 1800s or early 1900s, studies were being done that showed the effect of nicotine on nerve function, correct?
A. Yes.
Q. And, back in the 1930s, 1940s, and 1950s, the scientific community was aware that nicotine was driving tobacco use, correct?
A. Yes.
Q. And, in fact, in the 1940s and 1950s, there was some controversy about how to describe smoking, should it be described as an addiction or as an habituation or some other term?
A. Controversy among whom?
Q. Within the scientific community in terms of what the right terminology was. It was not clear as to whether it should be defined as an addiction or as an habituation or even some other term?
A. Perhaps -- I couldn't give you the people arguing on both sides, but I don't question that.

Q. You don't question that there was a debate and some confusion about what the right terminology was during that period, correct?
A. I don't recall a debate about the terminology until the time of the 1964 Surgeon General's Report.
Q. Okay. Could I see tab 168?
I'll show you a piece of your testimony from the Melman trial.
MR. McCABE: Is the witness going to be given a copy of that?
MR. WELLS: Where's Aaron?
BY MR. WELLS:
Q. Dr. Benowitz, the government doesn't want me to proceed until we find a copy of the transcript, but I'm trying to get you out of here today. My question is --
MR. McCABE: We would like to wait until he has a copy of the transcript in front of him.
MR. WELLS: If he doesn't need it for this --
THE COURT: This is an issue that I would think Dr. Benowitz could address. I understand the government's concern about taking things out of context, and actually, I think the problem is solved, which is good.
MR. McCABE: Thank you, Your Honor.
MR. WELLS: Thank you.
BY MR. WELLS:

Q. Dr. Benowitz, on the screen is a copy of some of your testimony from the Melman trial, and in that case you were asked the following question and gave the following answer. "Question: So back in 1930s and 40's and '50s, the scientific community was aware, wasn't it, that nicotine was addictive, weren't they?"

"Answer: Well, they certainly were aware that nicotine was driving tobacco use. The only question which I talked about before is the terminology. There was some controversy about what it should be called. But the importance of nicotine in driving tobacco use was -- there was a lot published about that." Did I read that correctly?

A. Yes.

MR. McCABE: Excuse me counsel, could we have a page number for that testimony?

MR. WELLS: Yes, sir. It's page 1543, lines 5 through 14.

BY MR. WELLS:

Q. And is it fair to say, Dr. Benowitz, that certainly by the 1940s scientists understood that nicotine in tobacco smoke could cause dependency or addiction?

A. Well, it certainly was known that it was sustaining tobacco use, and people called it different things, but yes, I would agree with certainly the spirit of what you're saying.

Q. Right. I mean, that was a problem -- that was the issue that I was trying to address in a prior question. The issue

focused more on terminology in terms of how you should describe it, but in terms of the consequences. There was no question that the scientific community had recognized that nicotine did have certain consequences that could be described as either addictive or habitual, correct?

A. Well, yes. What was clear was that nicotine was necessary for and maintained cigarette smoking.

Q. Okay. Now, there's a famous and often quoted article that was published in 1942, more than 20 years before the 1964 Surgeon General's Report, that said cigarette smokers are like nicotine addicts. Do you recall that?

A. Vaguely. Which article was it?

Q. Well, I want to show you the article. It's by Dr. Lenox Johnson, published in 1942, it's tab 143 JD 000972. And that is an article called Tobacco Smoking and Nicotine and it's published in a very well respected medical journal called the Lancet, correct?

A. Yes.

Q. And is it correct that Dr. Johnston wrote, "on the assumption that smoking tobacco is essentially a means of administering nicotine, just as smoking opium is a means of administering morphine. Nicotine was given hypodermically to 35 volunteers in known doses with a view of comparing its effects, and particularly its psychic effects, with those of tobacco smoking."

So it's clear that Dr. Johnson, as stated in 1942, that cigarettes are nicotine delivery systems, correct?

A. That's correct.

THE COURT: Dr. Benowitz, do you think that kind of experiment would be allowed today with IRBs?

THE WITNESS: Yes, if you give small doses, and if you monitor carefully, and if the people have given consent, studies like this can be done.

THE COURT: Okay.

BY MR. WELLS:

Q. Now, Dr. Benowitz, I want to focus your attention on a book published in 1991 called Tobacco Experimental and Classic Studies. First, you are familiar with that book, correct?

A. I think you have the title slightly wrong, but I think I know what book it is.

Q. Well, it's a book written by Larson, Haag and Silvette, correct?

A. But it's not classical studies it's clinical studies or something.

Q. So Tobacco Experimental and Clinical Studies, I apologize.

A. I am aware of that book.

Q. In fact, you have a copy of that book on your shelf, right?

A. I do.

Q. And Larson, Haag and Silvette were physicians and Ph.D.'s at the medical college in Virginia, correct?
A. I don't know their degrees, but they were at the medical college of Virginia.
Q. And this book is basically an encyclopedia of existing research on tobacco and tobacco related areas, right?
A. To that date, yes.
Q. Yeah. And this book includes all of the research about tobacco and nicotine that had occurred up to 1961, correct?
A. Yes.
Q. And at the time, this book was really the most comprehensive and thorough compilation of nicotine research that had ever been done, correct?
A. Yes.
Q. And this book -- and in this book there are entire chapters devoted to nicotine's affect on the nervous system, correct?
A. Yes.
Q. And this book summarized all of the pre-1961 research about people smoking for nicotine, that nicotine had pharmacological effects, and nicotine is addictive or habituate, correct?
A. That's correct.
Q. And this book was available in 1961, and thereafter, to both the public and the scientific community, correct?

A. Yes.
Q. And, in fact, the Surgeon General cited this book in his 1964 report on smoking and health, correct?
A. I believe so.
Q. And the Surgeon General considered this book to be an authoritative source, correct?
A. Well, I don't know what the Surgeon General said about it being an authoritative source, it was used. The term "authoritative source" is difficult for me to understand exactly, but it was cited.
Q. Okay. Now, I want to now focus your attention on JD 004658, which is an article by Dr. Peter Knapp. And this is an article that was published in the American Journal of Psychiatry, and it's called Addictive Aspects in Heavy Cigarette Smoking. And this article was published in 1963. Do you recall that?
A. Yes.
Q. And the article was supported by grants from the American Cancer Society and the Tobacco Industry Research Committee, correct?
A. That is correct.
Q. And on page 966, Dr. Knapp writes: "Nicotine is an active agent, though not necessarily the only noxious agent in tobacco. It appears to have certain addictive qualities. Tolerance develops to some of its effects, such as nausea, so

that it can be consumed in even greater amounts, but not to other effects, particularly those in the cardiovascular sphere."

So it's clear in 1969 Dr. Knapp has recognized that the concept of tolerance applied to nicotine and tobacco smoke, correct?

A. Yes.

Q. I want you to look now at the summary page on page 961, and the second point made by Dr. Knapp is that "heavy cigarette smokers thus appear to be true addicts, showing not only social habituation, but mild physiologic withdrawal effects." So it's also clear that in 1963, Dr. Knapp had recognized not only that smoking was addictive, but if someone tried to quit, they would experience physical withdrawal symptoms, correct?

A. Yes.

Q. Now, I want to ask you some questions about the criteria for defining what types of behavior should be classified as addictive, okay?

A. Yes.

Q. In 1964, the Surgeon General of the United States issued a report that declared that smoking was not an addiction and should be characterized as an habituation, correct?

A. That's correct.

Q. In 1988, 24 years later, the Surgeon General issued a report that concluded that smoking was an addiction and not an habituation?

A. It certainly said it was an addiction, I don't know that it says it was not habituation, because habituation was not just used anymore in the medical field to deal with characterizing drug use behaviors. But they certainly did say it was an addiction.

Q. Well, I want to ask you some questions about the circumstances surrounding the decision by the office of the Surgeon General to change its position after 24 years, okay?

A. Yes.

Q. Specifically, I want to examine with you to what extent that decision was influenced by social policy and political considerations, okay?

A. Okay.

Q. But before I turn to the issue of social policy and politics, I want to first ask you some background questions. Now, you would agree that over the last 50 or 60 years there has been an evolution in the way in which the medical and scientific communities have defined and described the habitual or repeated use of certain substances?

A. To some extent, yes.

Q. And the scientific community has sought to develop a set of criteria that will make a useful distinction between or among various substances?

A. Yes.

Q. And once the scientific community has selected the

appropriate set of criteria, the question of whether a particular substance or activity or behavior fits within that criteria is a separate issue, correct?

A. Separate from what?

Q. Separate from what the question of what the criteria should be in the first place.

A. Yes.

Q. The traditional approach is first, what is the correct criteria, correct?

A. Yes.

Q. And then after you have the correct criteria, the next question becomes what drugs fit within that criteria?

A. Yes.

Q. And that's the second question that follows after the criteria has been established, right?

A. Yes.

Q. Now, as of 1964, the most widely accepted criteria for defining what was and was not addictive was set forth by the World Health Organization; is that correct?

A. The World Health Organization developed criteria for drug dependence right after the Surgeon General's Report came up, and, in fact, those criteria for dependence were, and still are, sort of the main stay for understanding what drug dependence means.

Q. But, if we look at --

THE COURT: So the answer to Mr. Wells' question is yes, I think?

THE WITNESS: No, the World Health Organization did not use the term "addiction", they used "drug dependence".

THE COURT: I see.

THE WITNESS: And what happened later on in the Surgeon General's Report is that drug dependence was equated to addiction.

BY MR. WELLS:

Q. Let's take it one step at a time. In January of 1964, the Surgeon General came out with its 1964 report, correct?

A. Yes.

Q. And in the report issued in January of 1964, the Surgeon General relied on criteria for defining what was and was not addictive that had been set forth by the World Health Organization pre-1964 conference?

A. Yes.

Q. Following the issuance of the Surgeon General's Report in January of 1964, later that year, the World Health Organization changed its criteria with respect to the issue of how it would define certain substance abuses, correct?

A. Yes.

Q. After January of 1964, the World Health Organization abandoned the use of the word "addiction" and went to the use of the word "dependence", correct?

A. Yes.
Q. But I want to talk to you now about the World Health Organization's definition that existed prior to January of 1964, okay?
A. Yes.
Q. Because that is the definition that the Surgeon General relied on when he issued his report in January of 1964, right?
A. Yes.
Q. And is it correct that as of January of 1964, the most widely accepted criteria for defining what was and was not addictive was set forth by the World Health Organization?
A. I believe so. I have to go back and look at the Surgeon General's Report to see exactly which criteria they cited, but I think it was the World Health Organization criteria.
Q. Is it your testimony today that you don't recall that he cited the World Health Organization criteria?
A. You know, again, I don't question it, but I just don't recall specifically -- I don't like to say something unless I'm absolutely positive about it, and I just -- I have to look at the report to see which -- how the criteria were cited.
Q. Well, do you recall your direct testimony that you gave under oath and affirmed in this case when you testified yesterday?
A. Yes, but this is like a fact cite check, very easy to just look at the report and see what was cited as the source of

the criteria.

Q. Okay. I don't want to waste time, we'll get to the report in a second and we can see what the report says, because that will tell exactly what happened and what the truth is, correct?

A. Yeah, I mean, it's not an issue. I don't question that those criteria were widely used and adopted by the Surgeon General, I just don't remember if they specifically came from the World Health Organization or some other organization.

Q. Okay. Let me see tab 10, which is your testimony in the Daniels case during deposition, page 14, line 8 through 17, and I think this is fairly clear and I'm just going to go ahead and read it.

At line 7, there's a question: "All right, in 1964 the Surgeon General's Report concluded that nicotine and cigarettes were not addictive, correct?"

"Answer: "Well, I don't know, they concluded that they were habituating by their classification."

"Question: Yes. And they used the World Health Organization standards from the '50s in order to reach that determination, right"?

"Answer: Yes."

Does that refresh your recollection that that is the definition that the Surgeon General relied on in the 1964 report?

A. I think so. I just wanted to be positive by checking it.

Q. Well, let's look at the Surgeon General's Report and dispense with any confusion or mystery. Could I see page 350, JE 05985. And this is a copy of the Surgeon General's Report of 1964. The title of the section is, Distinction Between Drug Addiction and Drug Habituation, and it is stated in the report: "In fact, to make this distinction, the World Health Organization expert committee on drugs liable to produce addiction, created the following definitions which are accepted throughout the world as the basis for control of potentially dangerous drugs."

Now, based on your review of the 1964 Surgeon General Report's comments that are on the screen, do you now agree that in 1964 the Surgeon General relied on the definitions being used by the World Health Organization?

A. Yes.

Q. Okay.

A. Yes.

Q. And the Surgeon General's comments that those definitions were accepted throughout the world, correct?

A. Yes.

Q. Now, after making that statement, on the next page, page 351, the Surgeon General set forth the World Health Organization's criteria, correct?

A. Yes.

Q. And there's a chart on page 351, and on the left-hand

side it said: "Drug addiction and Surgeon General sets forth the criteria under the WHO" -- I'm going refer to it as who -- "under the WHO definition", correct?

A. Yes.

Q. And on the right side it says "drug habituation and the Surgeon General sets forth the WHO criteria for drug habituation", correct?

A. Yes.

Q. And the first sentence under drug addiction states: "Drug addiction is a state of periodic or chronic intoxication produced by the repeated consumption of a drug, natural or synthetic", correct?

A. Yes.

Q. And, so it's clear that intoxication was a key factor in defining an addictive drug under the WHO definition as it existed in January of 1964, correct?

A. Yes.

Q. And another key factor was that there would be a link between the addictive drug and socially deviant behavior, correct?

A. Yes.

Q. And, in fact, in your direct testimony you testify about the need for there to be linkage between addiction and socially deviant behavior as addiction was viewed back in the pre-1964 period, correct?

A. Well, they were using a model for heroin, and so when they used heroin, there was a lot of criminality associated with it, antisocial behaviors and that was part of the idea of addiction.

Q. And, is it fair to say, that the Surgeon General in the 1964 report was trying to draw a clear line between addictive drugs which were linked with socially deviant behavior and smoking?

A. Yes.

Q. Now, the Surgeon General also made it clear in the report that labeling smoking as an habituation was not meant to imply that it was easy to quit smoking, correct?

A. That's correct.

Q. And I want to read that sentence also from page 351 where the Surgeon General writes: "Thus, correctly designating the chronic use of tobacco as habituation, rather than addiction, carries with it no implication that the habit may be broken easily."

And that was one of the messages in the report, correct?

A. Yes.

Q. So on one hand the Surgeon General is saying, smoking is hard to quit, correct?

A. Yes.

Q. But we are not going to define smoking the same way we define drugs like heroin, because to put the label of addiction

on smoking might suggest that it involves socially deviant behavior, correct?

A. I think they were just using those criteria that were used at the time.

Q. Right. But the criteria, as you just testified, and as you testified in your direct, was that addictive drugs would be associated with socially deviant behavior, correct?

A. There were several factors that was one factor, and another factor was severe withdrawal symptoms, the third factor was intoxication, so there were three factors.

Q. Right, but the Surgeon General goes on in depth in the Surgeon General's Report to talk about his concern that he not -- that he not create the impression that people who smoke are in some way socially deviant, correct?

A. Yes.

Q. Just so the Court can see, the next sentence continues: "It does, however, carry an implication concerning the basic nature of the user and this distinction should be a clear one."

So when the Surgeon General refers to the "basic nature of the user", he's talking about the individual who is engaged in the conduct of smoking, correct?

A. Yes.

Q. And then he goes on to write: "It is generally accepted among psychiatrists that addiction to potent drugs is based on serious personality defects from underlying psychologic or

psychiatric disorders which may become manifest in other ways if the drugs are removed." And I want to finish the last sentence. "Even the most energetic and emotional campaigner against smoking and nicotine could find little support for the view that all those who use tobacco" -- next page, please -- "coffee, tea and cocoa, are in need of mental care, even though it may, at some time in the future, be shown that smokers and nonsmokers have different psychologic characteristics."

So it's clear, as you testified, that the Surgeon General is trying to draw this distinction between smoking and socially deviant behavior, right?

A. Yes.

Q. Okay. Now, as you also testified, some time after January of 1964, WHO changes its definition of addiction, correct?

A. Yes, it really gets rid of addiction and habituation and talks about drug dependence.

Q. And you talked in your direct, on page 31, that WHO changed it definition of addiction because it was too narrow. Do you recall that testimony?

A. Yes.

Q. Now, the World Health Organization abandoned the term "addiction" all together because, in part, it thought there was confusion about what the term meant, correct?

A. Probably, but what they were doing is --

Q. Could you please answer my question yes or no?
A. Well, I don't recall exactly what their statement was or where they did it, but I know there was a lot of question about translating or transferring definitions to a scientific base that dealt with how drugs worked and commonalities of drugs of abuse, and so it was a much more scientifically developed definition rather than the prior ones, and I just don't recall what their rationale was exactly.
Q. Could we call up tab 24? I want to see your deposition from the Daniels case, page 18.
"Question" -- this is from your deposition in Daniels.
"Question: And the World Health Organization abandoned the term "addiction" all together because, in part, it thought there was confusion about what it meant, right?"
"Answer: Yes".
A. I would say --
Q. I didn't ask a question, sir.
A. Oh, sorry.
Q. Now, is it correct that WHO also abandoned the word "addiction" because it thought that addiction was a punitive and pejorative term, correct?
A. I think in part, yes.
Q. And is it correct that WHO does not state -- withdrawn. I want to make it clear. The questions I am posting to you, I think you understand, now relate to WHO's post 1964 changes,

correct?
A. Yes.
Q. Okay. And WHO does not state that dependence is synonymous with addiction, correct?
A. Correct.
Q. That -- the statement that dependence is synonymous with addiction cannot be found in any of the written materials published by WHO from 1964 until today, correct?
A. Well, certainly up until 2000. There has been a World Health Organization committee on tobacco meeting since 2000, and I have not carefully reviewed their documents to know whether these terms have been used interchangeably, but certainly before 2000 I would agree with you.
Q. Now, Dr. Benowitz, you are familiar with the diagnostic manuals published by the American Psychiatric Association, correct?
A. Yes.
Q. And those manuals are generally described as the DSMs?
A. Yes.
Q. And what does DSM stand for?
A. Diagnostic Statistical Manual.
Q. And the DSM is the definitive test, almost the Bible in this country, for the diagnosis of psychiatric disorders?
A. Yes.
Q. And the DSM does not use the word "addiction" in

connection with substance abuse and substance dependence, correct?

A. That is correct.

Q. And the DSM does not use the word "addiction" in connection with any drug related behavior, correct?

A. I believe that's correct.

Q. And the DSM does not state that addiction and dependence are synonymous, correct?

A. That's correct.

Q. And in 1980, the American Psychiatric Association created a diagnosis for tobacco dependence in its DSM-III, correct?

A. Yes.

Q. And the DSM-III marked the very first time that the APA included smoking behavior in its diagnostic manual, correct?

A. Yes.

Q. So, until 1980, the DSM specifically excluded tobacco and nicotine from its list of dependence producing substances, correct?

A. That's a funny way to put it, "specifically excluded". I don't know if it was excluded, it just was not included.

Q. I will accept that characterization. It had not been included, correct?

A. Yes.

Q. Right up until 1980, correct?

A. That's correct.

Q. And in creating a diagnosis for tobacco dependence, the APA described tobacco as a dependence producing drug, and, consistent with its practice, the APA did not use the word "addiction", correct?
A. Correct.
Q. And to this day, the APA refuses to use the term "addiction" for any drug, correct?
A. I'm again -- it's a funny way to phrase it. I don't know if they refused. They don't do it. I don't know if anyone asked them and they refused.
Q. Okay. So you agree that the APA, even as of today, does not use the term "addiction" for any drug, correct?
A. I do agree with that.
Q. And the APA does not state in its DSM, or anywhere else, that it views addiction and dependence as synonymous, correct?
A. That is correct.
Q. Now, at page 27 of your direct, you tell Judge Kessler that there are three scientific authorities that define addiction. Do you recall that?
A. Yes.
Q. I want to put that testimony up on the screen just for a second. It's page 27, line 3 to 5.
"Question: What are the scientific authorities that define drug addiction?"
"Answer: Drug addiction or dependence has been defined

by the World Health Organization, the U.S. Surgeon General, and the American Psychiatric Association."

Now, we have established that with respect to the term drug "addiction", the World Health Organization after 1964 does not use the term "addiction", correct?

A. Yes.

Q. And the American Psychiatric Association does not use the term "addiction", correct?

A. That's correct.

Q. Now, at page 26 of your testimony, I would like to put that on the screen, you tell the Court that the scientific and public health communities generally recognize addiction and dependence as synonymous, but let me just read what you stated.

THE COURT: What page are we on?

MR. WELLS: We are on page 26, line 7 to 12.

BY MR. WELLS:

Q. You state in your direct: "Question: Is there a distinction between the term drug addiction versus drug dependence?"

"Answer: I use those terms interchangeably, as was suggested in the 1988 Surgeon General's Report on nicotine addiction."

"Question: Do scientific and public health communities generally recognize these terms as synonymous?"

"Answer: Yes."

I want to take you now to a chart that lists the three major scientific authorities that you have mentioned. Could we put the chart on the board?

They can't find the chart right now. If they find it, I'll come back to it.

But again, when you tell the Court that the scientific and public health communities recognized the terms as synonymous, I want to make clear for this record, that the two scientific authorities who you identified in your direct, other than the Surgeon General, that is the WHO and the APA, neither of those scientific authorities state that the terms "drug addiction" and "drug dependence" are synonymous, correct?

A. Right, but that's not the same thing as all the scientific and public health communities.

Q. Well, the scientific and public health communities, in terms of what they view as scientifically accepted words for defining certain behavior, look to the scientific authorities; is that correct?

A. Well, the state of the art is really what is being used in current publications and current lectures, and you will see that "dependence" and "addiction" are widely interchanged in publications about smoking and other drugs for years. And at scientific meetings they're used interchangeably, and public health organizations, when they're speaking about the smoking problems, use both terms. So these terms are widely used

interchangeably.
Q. They're used in general conversation interchangeably, but if we go back to the period before 1988, is it not correct -- is it not correct that the scientifically accepted term for substance abuse was "dependence" and not "addiction"?
A. That was the term that was defined in approximately 1988 to characterize drug abuse.
Q. So, when you say to Judge Kessler that the scientific and public health communities generally recognize these terms as synonymous, you are not talking about the scientifically defined terms, but rather how people might talk in general over the dinner table or at their office?
A. No, I'm not talking about that. I'm talking about what they write in papers, what they present in meetings, what they talk about in public forum. These terms are widely used, and have been since 1988, by scientists in their formal communications.
Q. I want to go back to the period 1988 and before. Is it correct that before 1988 that the scientifically correct term for substance abuse was "dependence", correct?
A. I think that "drug dependence" was preferred before 1988.
Q. And when you state to Judge Kessler, again, that the scientific and public health communities generally recognize these terms as synonymous, were you talking about the period after 1988?

A. Yes.
Q. But you don't make that clear, correct?
A. That's correct.
Q. Now, you could not point to Judge Kessler any scientific organization or authority that makes the statement, other than the Surgeon General's Report, that the terms "drug dependence" and "drug addiction" are synonymous; is that correct?
A. Well, I -- prior to 1988 or up to the present?
Q. Up to today. Give me one scientific authority that you can point to that I can get and question you about and examine that makes the statement that "drug addiction" and "drug dependence" are synonymous other than the Surgeon General's Report.
A. I don't know that I can cite any written documents. I can certainly say that the Society for Research on Nicotine and Tobacco, which is the biggest research society in this area in the world, in its communications has used these terms interchangeably, but I don't know if there is any statement in a, you know, in a definitional sense that says they're interchangeable, but it's certainly used that way extensively.
Q. But, in terms of some scientific authority that has taken the time to decide what should we publish in terms of correct terminology, you cannot point to any written document or report that states that addiction and drug dependence are synonymous terms, correct?

A. I cannot think of one, that's correct.
Q. Now, in fact, -- withdrawn.
And it's also true that for the period 1964 through 1987, you are not aware of any scientific authority in the United States that had set forth a criteria for defining the term "addiction" for purposes of classifying substance abuse, correct?
A. That is correct.
Q. And, in fact, for a time, you yourself preferred not to use the term "addiction" when talking about smoking or nicotine to a lay audience, correct?
A. That's correct.
Q. You thought, at one time, that those terms were confusing or pejorative; is that correct?
A. That's correct.
Q. And one of the reasons you believe "addiction" was a loaded term was because you believe the general public associated the word addiction with attributes of mental illness or being a threat to society, correct?
A. That's correct.
Q. And those things had nothing to do with smoking, in terms of people being a threat to society, and you thought that the use of those terms would just prove confusing in that context, correct?
A. That is correct.

Q. And, in fact, you have testified that if smokers view themselves as addicted, they may be afraid that they cannot quit, correct?
A. Well, that's not my view now, that was testimony many years ago. I do not think that's correct today.
Q. You have a different view today?
A. That's correct.
Q. And when did that view change?
A. At least 15 years ago, I think. I don't know, it's -- it really has begun changing from the time of the 1988 Surgeon General's Report. I think now people understand addiction in a much different way, that addiction is not thought of as something that's associated as mental illness or antisocial behavior, and it does make some important points about the strength of behavioral impact of the drug, and that's what I think is understood by most people today.
Q. So, it's your testimony that today there's a movement towards making sure that the word "addiction" is not associated with antisocial behavior, correct?
A. I don't know if there's a movement toward that, but I think that's most people's understanding.
Q. Well, do you think that the way the Surgeon General used the term "addiction" in the 1988 Surgeon General's Report was designed so that smoking would not be viewed in a similar context to hard drugs like heroin?

A. It was designed to emphasize the commonality of the addiction process and the strength of the addiction -- well, if you want to call it "dependence", the strength of the dependence, the fact that there was a very detailed analysis in that Surgeon General's Report comparing nicotine and tobacco to other drugs of abuse, and aside from intoxication and severity of withdrawal symptoms and antisocial behavior, the other characteristics were very strikingly similar, including difficulty in quitting and changes in bringing hormone levels and we felt the similarities were so strong that the best term for all drugs that are abused in that way would be "addiction".

Q. Well, let's look at the Surgeon General's Report and see what Surgeon General Koop said about the relationship between addiction, hard drugs and smoking in the 1988 report. Put up tab 727.

MR. McCABE: Can you wait a minute for the witness to get a copy, please?

BY MR. WELLS:

Q. What Surgeon General Koop wrote in that 1988 report was that, "This report shows conclusively that cigarettes and other forms of tobacco are addicting in the same sense as are drugs such as heroin and cocaine. Most adults view illegal drugs with scorn and express disapproval, if not outrage, at their sale and use. This nation has mobilized enormous resources to wage a war on drugs -- illicit drugs. We should also give priority to the

one addiction that is killing more than 300 thousand Americans each year."

So it's clear, is it not, Dr. Benowitz, that in this statement Surgeon General Koop is emphasizing that illegal illicit drugs outrage people, people view illicit drugs with scorn, and that he is saying that smoking should be viewed in the same context as such illicit drugs? That's what he states, correct?

MR. McCABE: Objection, Your Honor, does the witness have a copy of this yet?

THE COURT: Well, let's make sure, although I suspect Dr. Benowitz is familiar with this. Do you need a copy of the report?

THE WITNESS: I would like to see it, especially since there are going to be more questions on it. But I don't really agree with your interpretation of what this says. And what this says is that "illegal drugs are viewed with scorn, and that this nation has mobilized enormous resources to wage a war on drugs." That's true.

BY MR. WELLS:

Q. Illicit drugs?

A. Illicit drugs. But when it says that "we should give priority to the one addiction that is killing more", that does not say that the reason we're calling smoking an addiction is to mobilize public resources. The reason why it's called addiction

is stated elsewhere, and those are the reasons that I said, it's because the processes involving and the nature of the drug dependence is very similar for those drugs. Now, this is also true, but this is not the reason why smoking was called an addiction or nicotine was called an addictive drug.

Q. Well, let me ask you this, Dr. Benowitz, why in the world would Surgeon General Koop, who is an educated person, who clearly knows the English language, why would he write a paragraph like that where the entire paragraph talks about illegal -- illicit drugs, waging a war on drugs, illegal drugs being viewed with scorn, if not outrage, and then have the concluding sentence say "we should give priority to the one addiction that is killing more than 300,000 Americans each year." Are you suggesting that in that paragraph he is not trying to connect smoking to illicit drugs and saying that we should have a war on smoking just like we had a war on illicit drugs?

MR. McCABE: Objection, Your Honor, lack of personal knowledge as to what the Surgeon General was thinking when it was drafted.

THE COURT: Objection is sustained. Also the question is so argumentative, it's a question of how one interprets that particular paragraph and I don't think Dr. Benowitz has any expertise in interpreting that particular paragraph, which doesn't use any medical or technical terms that are within his

area of expertise.

Let's move on, please.

BY MR. WELLS:

Q. Okay. One second, Your Honor, I lost my place.

Let's talk about the 1988, Surgeon General's Report. You were one of the senior scientific editors of the 1988 Surgeon General's Report, correct?

A. Yes.

Q. In fact, not only did that report state that smoking was an addiction, it adopted a new criteria for defining addiction, correct?

A. Yes, or at least a new set of criteria.

Q. And based on that new set of criteria, the report concluded that smoking was addictive, correct?

A. Yes.

Q. And you agree that, to the extent the Surgeon General is the chief spokesperson of the executive branch with respect to public health issues such as addiction, it was not until 1988 that the executive branch concluded that smoking was addictive?

A. Well, if I accept your definition of the executive branch, yes, I really don't know what the connotations are of the Surgeon General with respect to the executive branch bottling --

Q. Were you deposed in this case?

A. Pardon?

Q. Were you deposed in the case of United States of America versus Philip Morris?
A. Yes, -- well.
Q. Just say yes or no. Were you deposed?
A. Yes, but I'm just saying --
Q. Sir, I asked a very simple question. Were you deposed? You said yes.
A. Of course I was deposed.
Q. Could we bring up tab 44. This is a copy of your deposition in Philip Morris. You were asked this, "Question: When do you believe the government of the United States first determined that cigarette smoking was addictive?"
"MS. GLUCK: Objection."
"THE WITNESS: What do you mean by the government of the United States? Certainly the first sort of executive branch statement was probably the 1988 Surgeon General's Report."
Now, my next question is I want to talk about the new set of criteria for addiction. The new 1988 criteria for addiction eliminated certain elements for the criteria for addiction used by the Surgeon General in 1964, correct?
A. Yes.
Q. "Intoxication" was no longer part of the definition, correct?
A. Correct.
Q. The criteria that focused on the "detrimental effects on

society" was eliminated, correct?
A. Correct.
Q. Things like "severe medical withdrawal symptoms" were no longer part of the definition for addiction, correct?
A. Correct.
Q. And in doing away with the requirement in the 1964 Surgeon General's Report that drug addiction required intoxication, severe medical withdrawal symptoms and antisocial behavior, the 1988 Surgeon General's Report largely did away with the distinctions between smoking and drugs such as heroin, correct?
A. Distinctions with respect to this definition. No one thinks that smoking and heroin are the same thing, but it just made it clear that they are both addictive drugs in the sense that the World Health Organization redefined it as a loss of control of drug use, and similar mechanisms of that loss of control of drug use. But no one ever said that smoking is the same as heroin broadly. It's just that it's as hard to give one up as the other.
Q. Well, in the 1964 report, the criteria that separated smoking from drugs like heroin were the requirement that there be intoxication, that there be severe medical withdrawal symptoms, and there be antisocial behavior, correct?
A. Yes.
Q. And all of those criteria were eliminated in the 1988

report's new set of criteria, correct?
A. Yes.
Q. And you agree that the conclusion that smoking is addictive was one that occurred principally as a result of changes in the definition of addiction, correct?
A. Being called addictive, yes.
Q. Now, I want to compare the 1964 Surgeon General and the 1988 Surgeon General reports' criteria for addiction. The three main criteria for addiction under the definition in the 1988 Surgeon General's Report are drug reinforced behavior, psychoactive effects and highly controlled or compulsive use, correct?
A. That's correct.
Q. Now, it was known in 1964 that smoking was a reinforcing behavior, correct?
A. Yes, although this is talking about drug addiction, it's talking about nicotine. It was also known that nicotine was reinforcing, but I just want to make sure that what the Surgeon General's talking about was not smoking, he was talking about nicotine.
Q. It was known in 1964 that nicotine in smoke was a reinforcing behavior, correct?
A. Yes.
Q. And it was known in 1964 that nicotine had mood altering or psychoactive effects, correct?

A. Yes.
Q. And, in fact, the Surgeon General's advisory committee made that very clear in the 1964 report, correct?
A. Yes.
Q. And it was also known in 1964 that nicotine use could be highly controlled or compulsive, correct?
A. Yes.
Q. And again, the Surgeon General advisory committee made that clear in the report, correct?
A. Yes.
Q. And so the scientific evidence regarding nicotine in smoke that was known as of 1964 was, in fact, sufficient to satisfy the new criteria for addiction set forth in the 1988 Surgeon General's Report, correct?
A. That is correct.
Q. And if someone today stated that in his or her opinion that smoking is not addictive as defined by the definition of addiction, as used in the 1964 Surgeon General's Report, that statement would be scientifically truthful and accurate, correct?
A. That would be a correct statement.
Q. Now, I want to ask you some questions concerning how politics and policy considerations influence the decision to conclude that smoking was addictive in the 1988 report.
Now, you talk in your direct about the 1988 report in

which you played a role, correct?
A. Yes.
Q. And it's fair to say that looking at your direct and it's fair to say that you had substantial involvement in putting together the 1988 report?
A. That's correct.
Q. And "Surgeon General" was the Surgeon General at the time the report was issued?
A. Yes.
Q. And Surgeon General Koop's goals had already been stated that he wanted to achieve a smoke free society, correct?
A. Probably. I don't remember exactly when he said that, but it's -- knowing Surgeon General Koop, I would say he did say that.
Q. Now, I want to start, really, at the beginning of the process of drafting the 1988 Surgeon General's Report. You would agree that in January of 1987, Dr. Juan Davis was appointed director of the office of smoking and health, correct?
A. Probably. I don't -- I don't consider myself an authority on the dates on which these things occurred, but he was the person in charge.
Q. Okay. And he was the person in charge, not only of the office of smoking and health, he was the person who over saw the 1988 reports' preparation, correct?
A. That is correct.

Q. To the extent you were one of the editors, he was the senior person who you reported to, correct?
A. That is correct.
Q. And isn't it a fact that prior to his appointment, Dr. Davis was on record as saying that smoking was addictive?
A. Probably. I can't cite you when he said that, but it wouldn't surprise me.
Q. Well, let's look at tab -- I'll move on, because I want to save time.
Now, not long after Dr. Davis was appointed, he appointed Dr. Henningfield as a senior scientific editor, correct?
A. Yes.
Q. And there were eventually three more senior scientific editors appointed, including yourself, correct?
A. Yes.
Q. And the other editors, in addition to you and Dr. Henningfield, were Neil Grunberg and Harry Lando, right?
A. Correct.
Q. And you were the last scientific editor to be added, correct?
A. Yes.
Q. And, in fact, it was Dr. Henningfield who recommended you and the other scientific editors, correct?
A. I believe so.
Q. Now, at the time that you were asked to serve as

scientific editor, several of the others involved with the report were already on record as saying that nicotine in cigarette smoking are addictive; is that right?

A. It could be. I really don't know what the record is, but it wouldn't surprise me.

Q. Well, you know Dr. Henningfield was already on record?

A. I know that he has believed that nicotine is addictive for a long time. I don't know when the first time was that he said it.

Q. And do you recollect that Dr. Grunberg had also written articles that he took the position that nicotine was addictive?

A. I don't have specific recollection. It's quite possible.

Q. Is it fair to say that unlike the situation with the 1964 Surgeon General's Report, when the Surgeon General took pains to include only people who had not spoken out publicly on the issues to be examined, that the people selected as senior scientific editors of the 1988 report did not have a history of impartiality on smoking and health issues?

A. Well, I have to say it is difficult to find any public health scientist who is not partial about smoking and health, since we've all been educated from the very beginning of our training that smoking is a major cause of disease. So how can you be a physician or public health person and be impartial about tobacco?

Q. Is it fair to say that everyone of the senior editors had

a long history participating with the public health community with respect to attempts to combat problems arising from smoking?

A. Every health professional who studies smoking comes to that conclusion, that it's an important priority to reduce smoking because it causes so much disease. Who could you find who would not be partial in that way who is a physician or healthcare worker? I mean what -- from the beginning of my medical school training I was taught that smoking is a major cause of disease and patients should stop smoking. How could you fine someone who's neutral about that?

Q. Well, Dr. Benowitz, some people go to medical school, they get taught about the health effects of smoking, and they go out and they open up a private practice, right?

A. Yes.

Q. And they may have their views about smoking, but they spend their time treating patients day-to-day, or engaging in other activities, right?

A. Right.

Q. You, Dr. Benowitz, and Dr. Henningfield, you go to medical school, and by the time you had been appointed as a senior editor in 1988, you had spent significant time participating as a member of that segment of the public health community that was involved in addressing what you saw as the problems arising from smoking, right?

A. Yes.
Q. And every person who was appointed as a senior editor had been doing the same thing, correct?
A. Well, they were appointed because they were experts in studying smoking, and anyone studying smoking is studying it because it's a health problem.
Q. Well, you didn't see anybody from Philip Morris who has been studying smoking appointed as a senior editor, right?
A. No.
Q. And, you know, all the tobacco companies, they've got people who study smoking all the time, right?
A. I don't know any tobacco companies people who are studying smoking and health issues.
Q. You know no -- never mind. Your testimony is you know no one connected with any tobacco company who's involved in smoking and health issues?
A. Well, they're doing smoking research, but I don't know people who are studying the question of how to reduce smoking to improve health.
Q. Okay. Let's move on.
I want to look at the time period immediately surrounding your appointment as a senior scientific editor to the 1988 report. And, first, I want to show you a letter dated April 13, 1987 from Ron Davis to John Pinny, P-I-N-N-Y, executive director of the Institute for the Study of Smoking Behavior and Policy at

Harvard's Kennedy School, and that's tab 700. Would you please give the witness a copy of the document?

Now, this letter is dated April 13, 1987, and it's from Ron Davis, and I'll show you the signature in a minute. And it says: "Dear Mr. Pinny, as you know, I was appointed director of the Office on Smoking and Health in January, 1987, approximately four months after the office was transferred administratively to the Centers for Disease Control." So the letter indicates that he was appointed in January of '87, correct.

A. Yes.

Q. And he then says in the yellow highlighted part: "I plan to update you on many new developments within the office. The purpose of this letter is to bring you up-to-date on the 1987 Surgeon General's Report."

"Since my appointment, I have discussed possible topics for the report with numerous individuals, including the Surgeon General, editors of previous Surgeon General's reports, and representatives of the voluntary agencies. Based on these discussions, we have decided that the focus of the 1987 report will be the pharmacologic aspects of cigarette smoking" -- and just so the record is clear, the report actually ended up coming out in 1988, right?

A. Yes.

Q. So you understand when he refers to the "1987 report", he was actually referring to the report that ultimately became

known as the 1988 Surgeon General's Report, correct?
A. Yes.
Q. And it goes on, "the report will examine in detail the drug dependency nature of smoking, and will review interrelated behavioral aspects of smoking as well."
So, at least an as of April 13, 1987, there's no mention of the word "addiction," but, rather, the letter states that the report will look at the drug dependency nature of smoking, correct?
A. That's correct.
Q. And then the letter says: "The editors for the 1987 report are Jack Henningfield, Harry Lando and Neil Grunberg, correct?
A. Correct.
Q. And then he says, "Enclosed is a preliminary outline of the report. Please let me know if you have comments on the outline by April 22nd, if possible."
Now, you are appointed as an editor some time between April 13th and April 27th, do you recall that?
A. I don't remember the exact date, but that sounds right.
Q. Some time shortly after this letter is written?
A. Yes.
Q. Now, let me show you an outline. I want to put up on the screen tab 711, it's Exhibit JD 066099.
And this is a copy of an outline for what became the 1987

Surgeon General's Report dated April 14, 1987, a day after the April 13th letter that I just showed you. And that outline says: "Outline of 1987 Surgeon General's Report on tobacco use (4/14/78)", and it says introduction -- II talks about overview, III talks about epidemiology, and IV says chemical dependence, excluding tobacco products, that's like nicotine gum and things like that, right, that's not smoking, correct?

A. This is just something that's talking about chemical dependence broadly not --

Q. I understand, and the exclusion is not to exclude other tobacco products, you understand that, correct?

A. Well, I don't recall what the -- I think this was just to talk about what chemical dependence means in a broad sense rather than specifically tobacco.

Q. Okay. So it says, "chemical dependence, determinants of acquisition maintenance and relapse." And when it says "C: Dependence producing chemicals," and just so -- while we're on this page, there's some handwritten notes, and this document comes from the files of HHS and was produced to us by the government.

The handwritten notes read: "It is quite urgent to explore the chemical dependency in tobacco use." And then it says: "The choice of terms is good, better than addiction or habituation."

Now, can we see the next page of the outline? Is there a

second page? Tab 711.

And the outline goes on. It says, "V, characteristics of tobacco that contribute to habitual use," so the word "addiction" does not appear in V, correct?

A. Correct.

Q. And then it says, "VI, nicotine as a behavior modifying chemical" and under C it says, "physiologic dependence produced by nicotine administration," and you would agree that the word "addiction" does not appear either on page 1 or page 2 of the outline; is that correct?

A. Yes.

Q. Is there some more handwriting on that document at the bottom? Could you move it up? Is there a third page?

Now, the third page -- I'm going to review the third page with the Court and the witness, and it's clear, there is no mention of the word "addiction" on the third page, correct?

A. Correct.

Q. And then the handwritten notes state: "I would assume that somewhere in this rather thorough review there will be a summary comparison of the clinical features of dependency on tobacco with those of other drug dependency. This comparison may be important to litigative approaches by plaintiffs in actions against tobacco companies."

So the handwritten notes do not use the word "addiction", they use the word drug "dependency", correct?

A. Yes.
Q. And they also talk about how the report would compare tobacco with other drugs that might help plaintiffs in lawsuits against tobacco companies, correct?
A. That's what it says.
Q. Now, I want to now go -- is it correct that as of April 14, 1987, the date of this outline, it was still your personal opinion that the choice of the word "dependence" was better than "addiction"?
A. Well, I think when I began working on this report that's what I thought, but as I worked on the report, and interacted with the other people, I decided that there was some very good reasons to change.
Q. I just want Judge Kessler to know that it was your position as of April 14, 1987 that the choice of the word "dependence" was better than "addiction", correct?
A. You know, I don't -- well, I think that was my general sentiment. I don't recall that I specifically thought about that question at this time. We weren't -- in the beginning the report was just compiling the science.
Q. But you hadn't walked into the meeting that I'm going to get to in a few minutes where you and Mr. Henningfield, and others, talked about the pros and cons of what word to use, right?
A. No, I have not thought about that issue.

Q. Right, you didn't think about it until you got into a meeting and people started taking positions that the right word that should be used is "addiction", right?
A. Well, we did talk about the pros and cons, that's correct.
Q. But when you walked into the meeting, you still thought the word "dependence" was the better term?
A. That was a term that I used at that time, correct.
Q. And after you went into the meeting and Mr. Henningfield and others started talking, they convinced you that you should adopt going forward the word "addiction", right?
A. Well, we had an extensive conversation and what they said made a lot of sense. I was convinced.
Q. And so, you got on board with Mr. Henningfield's position, that's what happened, right?
A. Well, I don't know if it was Dr. Henningfield's position or the group position, but I did agree with the group.
Q. And I just want to be clear, as you said, before you went into the meeting you had a different view and when you came out of the meeting you had decided that their position made sense, right?
A. Yes.
Q. Now, you attended a meeting on April 27th during which you, Mr. Henningfield and others discussed the pros and cons of whether you should use the word "dependence" or "addiction",

correct?
A. Again, I don't know the dates. There was a meeting that occurred. I have no idea what date it was.
Q. I would like to put up on the screen a memo dated April 29th, and it's tab 706 and it's JD 054316.
Now, this memo is dated April 29, 1987, the heading is Department of Health and Human Services, and it says "note to Jack Henningfield, Neil Benowitz, Neil Grunberg, Harry Lando: Attached is an updated version of the outline of the Surgeon General's Report. It reflects changes from our meeting on April 27th, as well as minor changes from discussions among Jack, Henry and myself the following day. If there are no changes from you, or as a result of late comments from the consultants receiving the earlier version, I will send this one out to the latter group of people in about a week."
Now, he refers also to an attachment concerning appendix A. Now you recall receiving this memo, correct?
A. I'm sure I did.
Q. And the people in the meeting that, according to the memo, took place April 27th, were Henningfield, yourself, Grunberg, Harry Lando and Ron Davis, right?
A. Yes.
Q. So the five of you are in the meeting, and one of the issues, as you've already indicated, is what are the pros and cons of using the word "addiction" rather than "dependence",

right?
A. Yes.
Q. And as you've testified in other -- on other occasions, some people had very strong views, correct?
A. Yes.
Q. And other people, like yourself, were more neutral, right?
A. Yes.
Q. And it's fair to say that the people with the stronger views ultimately convinced the people who were more neutral that going forward the focus of the report should be on the word "addiction" rather than "dependence"?
A. Well, this was a draft stage, but certainly at this draft stage, yes. I think this was discussed again later on as well.
Q. The draft stage and the final stage both ended up using the term "addiction", correct?
A. Yes.
Q. Now, I want to show you the attached outline -- well, before I get to the outline, just a couple other questions.
You've already said there was a lot of discussion about the pros and cons of using the "addiction" label, right?
A. Yes.
Q. And you agree that there was a debate at this meeting over whether to use the word "addiction", correct?
A. Yes.

Q. And the meeting was held to decide what to name the report and whether to use "addiction" in the title and in the report, correct?
A. Yes, although this was still early, so it was still subject to change later on.
Q. Okay. But you had previously testified under oath that the meeting was held to decide what to name the report and whether to use "addiction" in the title and in the report, correct?
A. Yes.
Q. And you had only been appointed as a scientific director on this committee within days of the meeting, right?
A. Yes.
Q. Because we know from the April 13th letter that lists the scientific directors, you had not even been appointed yet, right?
A. That's correct.
Q. And you know by the time you're in the room on April 27th you had been appointed, right?
A. Yes.
Q. So within days of your appointment, you are in a room with the other scientific directors where the issue is, what are you going to name the report, correct?
A. Yes.
Q. And whether to use the word "addiction" not only in the

title but also in the report, correct?
A. Yes.
Q. Now, let's go back to the outline that was attached to the April 29th memo. Could we see tab 721. It's JD 054316.
Now, you would agree, that outline is totally different from the outline that was dated April 14th?
A. Yes, it is different.
Q. Let's put the April 14th outline next to the April 29th outline, if we can.
So, the April 14th outline, which is to the left, you have already testified does not use the word "addiction" at all, correct?
A. Correct.
Q. Now, April -- by April 29th, the outline now states: "II: Tobacco use as an addiction", correct?
A. Yes.
Q. And if we go to the second page. Let's go to the third page. And under VII, it talked about tobacco use compared to other addictions, general concepts of drug addiction, B, relationship among the use of tobacco and other addicting substances.
So, it's clear by the time -- withdrawn. So, at least by April 29th, the word "addiction" has been added to the outline, correct?
A. Yes.

Q. And is it correct that you reached the conclusion to use the term "addiction" in the outline before you selected the criteria?
A. It may be. Because I don't think we selected the criteria until the end.
Q. Well, you recollect you've testified under oath that you used -- you reached a conclusion to use the term "addiction" before you selected the criteria. You don't dispute that, do you?
A. No, I don't.
Q. And when you just said you didn't select the criteria until the end, you don't mean at the end of the meeting, you mean at the end of the report being drafted, right?
A. Well, yeah, in part of the drafting of the report, that's right.
Q. The criteria, you had made the decision in the meeting on April the 27th, to use the term "addiction". Months and months went by, drafting was done, and only at the end of the drafting period did you develop the final criteria that was ultimately used in the report, correct?
A. I believe that's correct.
THE COURT: Are you changing topics at this point?
MR. WELLS: No, Your Honor.
THE COURT: Go ahead. Or, is this a good time the take a break, since you did take a breath, Mr. Wells?

All right, the witness may step down. We'll take a 15-minute break, please.

(Thereupon, a break was had from 11:00 a.m. until 11:17 a.m.)

THE COURT: All right. Mr. Wells, please.

BY MR. WELLS:

Q. Dr. Benowitz, you personally recognized that: "If smoking was described in the 1988 Surgeon General's Report just as a bad habit, then the public health community might not be able to propose certain antismoking legislation," correct?

A. I don't know. I'm not sure.

Q. You're not sure about what? You're not sure --

A. About the terminology that you used, if it's a "bad habit." I think clearly that regulation was needed, based on smoking behaviors. Is your question whether I ever used those terms, if it's called a "bad habit"?

Q. My question to you is just what I asked: Did you recognize that: "If smoking was described in the 1988 Surgeon General's Report just as a bad habit, then the public health community might not be able to propose certain antismoking legislation"? Right or wrong?

MR. McCABE: Objection, Your Honor, calls for speculation.

THE COURT: No. The question was simply whether he ever made the statement or advocated it.

MR. WELLS: Did he recognize?

THE COURT: So overruled. If you can remember. If you can't remember, Dr. Benowitz, we'll move on.

THE WITNESS: I clearly think that it should be addressed by the public health community and should be regulated. Whether I used those exact words, I don't remember.

BY MR. WELLS:

Q. Well, as you sit here today, do you agree with the statement that: "If smoking was just described as a bad habit, then the public health community might not be able to propose certain antismoking legislation"? Right or wrong?

A. I don't know. It is not just a bad habit, so I don't know -- it's hard for me to answer that question. I think it's -- what smoking is clearly warrants public intervention and whether I said that in terms of a bad habit, I just don't recall.

Q. Do you think it's a possibility you said it?

A. It's possible.

Q. Let's look at JD 054314, which is a copy of a 1988 U.S. News and World Report article.

So U.S. News. So on the front of the exhibit is a picture of Surgeon General Koop; at the top, it's dated May 1988. U.S. News: "America's Number One Doctor: His Advice on Everything From Acupuncture to Sex Education."

And could we go to the next page.

And at the bottom of that page, there's a box and at the

top, it says: "The Surgeon General's Latest Word on Smoking." It shows "A New Addictive Drug: Nicotine."

You see the word "new" in the article, don't you, Dr. Benowitz?

A. I'm looking for it.

Q. Right here. Right here in the box, it says "New."

A. Which line?

Q. It's in the title, sir.

A. Oh, yes, sure, I see it.

Q. It doesn't say "an addictive drug, nicotine"; it says "a new addictive drug, nicotine," correct?

A. Yes, I see it.

Q. And then the article goes on to read: "Last week's declaration from the Surgeon General that cigarettes are as addictive as heroin or cocaine was quintessential Koop. Sidestepping pressure to tone down his antismoking campaign, the Surgeon General released a 618 page report that lays the groundwork for a new offensive in his effort to achieve a smoke free society by the year 2000.

Scientifically, the conclusions of the report may be nothing new. Denials of tobacco manufacturers notwithstanding, researchers have known for decades that nicotine is addicting, as has any smoker who has tried to quit. But officially labeling nicotine an addictive drug could help push through tough new restrictions on cigarette sales and advertising,

stronger warning labels, the banishment of cigarettes from vending machines, an end to the distribution of free samples and penalties for selling cigarettes to minors."

Then there's a quotation and the sentence in quotes states: "'If it's just a bad habit, you might not want to propose these things,' end of quote, says Dr. Neal Benowitz, Professor of Medicine at the University of California, San Francisco, and a scientific editor of the report."

And then it says in quotes: "'But once you say it's addictive, it puts the whole thing in a different perspective.'" And then it says: "The report may also help out the plaintiffs in more than 100 liability suits nationwide that charge tobacco companies with responsibility for causing lung cancer and other smoking related diseases."

My question to you, yes or no, is: Do you now recollect, having reviewed the statement in Newsweek (sic), that in fact you made that statement?

A. Well, I don't recall saying it, but I'm sure if it's there, I did say it.

Q. Now, just one last question in this area: Is it also correct that Dr. Ron Davis, the person who was ultimately responsible for overseeing the 1988 Surgeon General's Report, has stated publicly that while Director at the U.S. Office on Smoking and Health, he sought to keep the word "habit" out of three Surgeon Generals' Reports and to use the term "addiction"

because it was designed to turn the industry green?

Is that a true statement?

A. I can't tell you.

Q. Let's look at tab 464, exhibit JD 054318.

And it's in an article, at the top it says: "The Language of Nicotine Addiction: Purging the Word 'Habit' From Our Lexicon." It's an editorial in Tobacco Control, volume 1, page 163 to 164, 1992.

Could I see the whole paragraph. Go up to -- it says "When I served." It's right above that. Yellow that piece.

And this is by Dr. Davis, the person who oversaw the report. And he says, quote: "When I served as director of the U.S. Office on Smoking and Health from 1987 to 1991, I sought to keep 'habit' out of three Surgeon Generals reports and other publications of the office. I am now working to keep the word out of this journal. The entrenchment of the word in our verbal discourse and writing will make efforts to purge it slow and difficult. A similar effort to replace the term 'passive smoking,' in parens, many nonsmokers are hardly passive, close paren, with 'involuntary smoking' has largely failed. Nevertheless, I will carry on with my obsession and I hope others will join me.

"Simon Chapman, Deputy Editor of Tobacco Control, once wrote that '"addiction" is a highly evocative word and the industry turn green when it is applied to smoking.' I believe

we should use language that is clearly understood, scientifically accurate and designed to turn the industry green."

Is it your testimony, Dr. Benowitz, that you have no recollection of Dr. Davis making that statement?

A. I have not read this article before, but that's exactly what it says.

Q. Let's go to a different area.

Dr. Benowitz, I have promised my colleagues, and I'm trying to be of assistance to you, to try to get you out of here today --

A. I appreciate it.

Q. -- to try to cut some things short, and I'm going to.

I have an entire section dealing with the significant differences between nicotine and drugs like heroin, alcohol and cocaine.

Now, you agree that there are significant differences between nicotine and drugs like heroin, alcohol and cocaine, correct?

A. Yes.

Q. And while you have already testified in the record about similarities, I want to put in the record the differences. And I have prepared a chart, based on your testimony in other cases, that I would like to show to you and see if you can review the chart and tell me if it's a fair and accurate representation of

the differences between alcohol, cocaine, heroin and nicotine. I have --

You can put the chart up on the screen.

And I have --

MR. McCABE: Excuse me, Your Honor. The United States needs a copy of the chart.

(Discussion had off the record.)

BY MR. WELLS:

Q. And do you have a copy?

A. I can see it on the screen.

Q. Okay. And just to speed this up, I want you to review it. I have at the bottom testimony that you've given in other trials, but in terms of the issue of intoxication, is it correct that alcohol, cocaine and heroin are intoxicating drugs?

A. Yes.

Q. Nicotine is not, correct?

A. That's correct.

Q. In terms of withdrawal, does the chart fairly set forth the differences between nicotine, heroin, cocaine, and alcohol with respect to the issue of withdrawal?

MR. McCABE: Objection, Your Honor. This is referring to the Engle trial, which is not before the Court.

THE COURT: I'm sorry. What is the objection?

MR. McCABE: This refers to the Engle trial, which is not before the Court, Your Honor.

THE COURT: Well, I think -- what Mr. Wells is doing is simply identifying for the witness where he gave testimony to this effect, to the effect of what is contained in the diagram on the screen. So the objection's overruled.

BY MR. WELLS:

Q. Is that a fair presentation of the differences with respect to the issue of withdrawal?

A. Yes.

Q. And finally, with respect to the issue of impaired thinking, the diagram shows that alcohol, cocaine and heroin may cause impaired thinking and nicotine does not. Is that a fair presentation of the chart with respect to that -- is that a fair presentation of the differences with respect to that item?

A. In terms of when the drug is present, because clearly in withdrawal, you can have impaired -- of cognitive function from smoking. But in terms of when a person is using the drug, this is correct.

Q. Okay. Just so we can move on, this chart is a fair and accurate representation of the behavioral comparisons between alcohol, cocaine, heroin and nicotine, as you have testified in other trials?

A. I'd say insofar as you've chosen these elements, they are. Now, there are other things that are much more in common, but for these three elements, what you say here is correct.

Q. Right. Okay. I want to move on.

Now, I want to ask you questions about the difficulty with which smokers may have in quitting. And you devote some of your direct testimony to that subject, right?
A. Yes.
Q. Now, in your direct testimony, you refer to cigarette smoking as an "addiction" and sometimes you refer to it as a "dependence," correct?
A. Yes.
Q. And to you, those terms are pretty much interchangeable, correct?
A. Yes.
Q. And you would agree that whatever term you use, be it "addiction," "dependence" or "habituation," the real issue is the control that people have over their own behavior, correct?
A. Over their use of a drug, yes.
Q. And what we're really saying in using any of these terms to describe smoking, be it "habituation," "addiction" or "dependence," is that smoking can be hard to quit, correct?
A. Yes. Hard to quit and disruptive and often requiring multiple attempts before one succeeds.
Q. Now, the scientific community has known of the fact that smoking can be hard to quit for decades, correct?
A. Yes.
Q. And for several -- for at least 200 years, the public has known it, correct?

A. For how many?
Q. 200 years.
A. They've known for a long time. I don't know how many hundreds of years.
Q. A hundred years?
A. Okay.
Q. Now, the difficulties in quitting smoking have been a part of our popular culture for a very long time, correct?
A. Yes.
Q. And people have talked about being "hooked on cigarettes," correct?
A. Yes.
Q. And in the mid-1800s, Mark Twain even made a joke about how hard it was to quit smoking, correct?
A. He said it's easy.
Q. "I've done it a hundred times"?
A. Right.
Q. And indeed, you testified in your written direct that the public has known for a long time that cigarette smoking could be addictive and extremely difficult to quit, right?
A. Yes.
Q. But no matter what the word you use to describe cigarette smoking, whether you call it an "addiction," a "habit," "dependence" or something else, it does not mean that people cannot quit, correct?

A. People can quit any drug addiction or drug dependency.
Q. And you are not aware of any tobacco company statement in which they disagree with the idea that smoking can be hard to quit, correct?
MR. McCABE: Objection, Your Honor. It's beyond the scope of his direct testimony. He's referring to statements by the tobacco companies.
MR. WELLS: He's an expert on addiction.
THE COURT: I'm going to overrule the objection.
You may answer.
THE WITNESS: Well, I do believe there have been statements by tobacco companies that have tended to minimize the difficulty. I've never seen them say it's easy to quit, but some statements say that it's a habit and if you just put your mind to it, you can quit. I think it's been minimized, but never denied, so far as I know.
BY MR. WELLS:
Q. Well, don't you -- you just stated that anybody, if they put their mind to it, can quit. That was your testimony?
A. Right. But it's -- the question is whether it's a trivial issue of just putting some willpower to it or whether it's something that is a very powerful force, such that half the people even after heart attacks can't even quit. I think that's quite different.
Q. Have you testified under oath in the past that you are

not aware of any tobacco company statement in which they disagree with the idea that smoking can be hard to quit?

Have you said that in the past under oath?

A. Most likely, yes.

Q. You agree that smokers can and do quit every day, correct?

A. Yes.

Q. And you testified in your written direct that approximately 1.2 million smokers quit smoking every year, correct?

A. Yes.

Q. You have also testified previously that it is 1.3 million smokers who quit every year -- withdrawn. I'll withdraw the question.

And when you use those figures, what you're talking about are people who quit smoking for good or at least for one year; is that right?

A. Yes.

Q. And you know that about 50 million people living in this country, more or less, have permanently quit smoking, correct?

A. Yes.

Q. And that is about half of everybody who has ever smoked, correct?

A. I think it's half of everyone who has been a regular smoker.

THE COURT: Do you know what percentage that is of people who have tried to quit smoking?

THE WITNESS: Well, that's an important point. I'm just trying to think of the best way to address that question, because it's kind of a rolling thing. People are starting to smoke all the time; people are quitting all the time; people are dying all the time.

I don't remember the exact number of the percentage of average smokers who have quit. Maybe 35 percent, 50 percent. I'm just not sure.

BY MR. WELLS:

Q. Is it true that today in the United States, there are more former smokers than current smokers?

A. Probably true.

Q. And is it correct that the overwhelming number of people who have quit smoking did it without any help?

A. Yes.

Q. And in fact, in the 1988 Surgeon General's Report, which you helped write, it indicates that approximately 90 percent of the people who have quit smoking did it on their own, correct?

A. Yes.

Q. And these people, they've quit without going to see doctors, correct?

A. Yes.

Q. And they've quit without getting counseling, correct?

A. Yes.

THE COURT: Does that include marital counseling?

THE WITNESS: Good question.

THE COURT: I don't mean it only facetiously, just in part facetiously.

MR. WELLS: Judge, if you give us these two extra days for Christmas, you will save some of us from marriage counseling.

THE COURT: That may be. That may be. Go ahead, please.

BY MR. WELLS:

Q. You will agree that the motivation to quit is the single biggest factor in quitting, correct?

A. Well, it's necessary. You can't quit unless you're motivated, so that's -- it's not sufficient, but it's necessary to quit. So yes, it's an important factor because you won't quit without that.

MR. WELLS: Let me see tab 469, deposition testimony in Leucer.

BY MR. WELLS:

Q. I'm going to show you your deposition testimony in the Leucer case, February 18th, 2000 to -- I'm trying to speed things up. In that case, you were asked: "Question: For someone who wants to quit, motivation is the most single important -- is the single most important factor; is that correct?

"Answer: Well, yes. That's been found in several

studies."

Now in fact, being motivated to quit is essential for quitting successfully, correct?

A. Yes.

Q. And motivation is more important than patches and inhalers, clinics or anything else, correct?

A. Well, as I said before, it's necessary -- it's the first thing that's necessary. No matter how you quit, you have to be motivated first and then you can try different ways, but motivation is necessary as a first step.

Q. Now, you talk in your written direct about -- is it pronounced "agonists"? How do you pronounce it?

A. "Agonist."

Q. Okay. You talk in your written direct about agonist, like nicotine gum. But nicotine gum or patches can't replace motivation to quit, correct?

A. Correct.

Q. So just giving someone a drug is not going to make them stop smoking if they do not really want to stop, correct?

A. Yes.

Q. Now, you would agree that sometimes people say they want to quit and do not really mean it, correct?

A. That can happen, yes.

Q. And some people will say, "Yes, I'll try to quit," even though they have no real intention of quitting, correct?

A. I'm sure that happens. It's hard to distinguish because some people sort of want to quit and don't want to quit and they're willing to try and if you can motivate them and treat them, they may be successful. So sometimes people really don't know for sure when they make that first step.

Q. And is it correct that persistence is another factor that has a tremendous impact on a smokers' ability to quit smoking?

A. Yes.

Q. And that is because many former smokers were not successful in their first attempt, but ultimately were successful after a few attempts, right?

A. On average, it does take several attempts and persistence is critically important.

THE COURT: Do you understand why that is the case? I certainly think I understand the basic outlines of your testimony on the strength of the addiction and what it means, but why is it that people are often able to quit after several tries? It's almost counterintuitive since in other areas, when people fail, they often give up. And I wonder if there's some special reason in terms of smoking that you suggest that it's almost necessary to fail a few times before you succeed.

I'm overstating what you said.

THE WITNESS: Well, the process of quitting is sort of a balance of factors that keep you smoking, which is the use of nicotine to help deal with mood problems and arousal, and also

the withdrawal symptoms, which can be quite disruptive in terms of not being able to concentrate on your work, causing irritability, family problems.

So there are other reasons why you keep on smoking. The reasons not to smoke include health concerns, family concerns, economic concerns. And a person stops smoking when the balance shifts. What a person sometimes finds -- the first time is they try to quit smoking and then they have a fight with a spouse and they start smoking again or they go to a bar and they drink with friends and that triggers smoking again.

And what people learn, certainly with counseling, is what to do when these different stimuli to smoke again occur, so you develop alternative strategies. Or if your withdrawal symptoms are severe, you can take medication for that.

So once you understand why a person fails the first time, there are some specific ways that you can deal with those issues the second time.

THE COURT: Okay.

THE WITNESS: And sometimes motivation just gets stronger. Someone gets sick. The biggest impetus to quit smoking, unfortunately, is having a heart attack. 50 percent of people do quit and 50 percent still smoke, which to me is astounding, but at least 50 percent quit. So that's because the motivation for health is very strong.

THE COURT: All right, Mr. Wells.

BY MR. WELLS:

Q. Dr. Benowitz, it is a fact that there are some smokers who successfully quit smoking the first time they try, correct?

A. Yes.

Q. And you testified that on average, it takes somewhere between three and five tries before quitting for good, right?

A. Yes.

Q. I just have three more questions. I want to ask you a brief question concerning Monograph 13, which Mr. Biersteker is going to talk to you about in a minute. But you have testified previously that it is very important in determining the weight to be given to a scientific work to know the affiliation or personal interest or sponsorship of the authors, correct?

A. Yes.

Q. And Dr. Burns, who is an expert witness in this case, is also an author and co co-editor of Monograph 13, correct?

A. Yes.

Q. And Lynn Kozlowski wrote a chapter for Monograph 13 as well?

A. Yes.

Q. And Neil Weinstein also wrote a chapter?

A. Yes.

Q. And the reviewers for Monograph 13 included John Hughes, Jonathan Samet, Jesse Steinfeld, Kenneth Warner and Joel Cohen, correct?

A. Yes.
Q. And Jeffrey Wigard, who's also going to be a witness in this case, was also a reviewer?
A. Wigand?
Q. Wigand.
A. Yes.
Q. And is it correct that each one of the people I just named has been a witness on behalf of plaintiffs in cigarette litigation?
A. I don't have personal knowledge of that, but it may well be true. I have personal knowledge of many of them, not all of them, but I don't doubt it.
Q. But you certainly know that -- who are the ones who you have personal knowledge of?
A. Dr. Burns, Dr. Samet, Dr. Weinstein, Dr. Hughes, Dr. Wigand. I forget who else was on there.
Q. Kozlowski?
A. I don't know about Kozlowski.
Q. Okay. Now, you know that each of those persons has not only been a witness, but that they have obtained a portion of their income from testifying as expert witnesses in cigarette litigation, correct?
A. Yes.
Q. They have not testified for free; they have been paid by the plaintiffs bringing the lawsuits, correct?

A. So far as I know, yes.
Q. And you yourself over the years, you have made hundreds of thousands of dollars testifying as an expert witness for plaintiffs in tobacco litigation, correct?
A. I don't know how much money, but yes, I made substantial income over the years, yes.
Q. And it is in the hundreds of thousands of dollars; you would agree with that, though you can't give me an exact number, correct?
A. It could be. I just don't know. I haven't counted it.
Q. And is it fair to say that the connection to the plaintiffs' tobacco litigation bar that you and Dr. Burns and the others you named, was not disclosed anywhere in Monograph 13?
A. Yes. And I stated that I didn't think about that at the time, but I think that we should have stated that.
Q. You now recognize, in light of having been challenged in various tobacco cases, that the right thing, the fair thing to do would have been to have disclosed your affiliations, correct?
A. Not just in tobacco cases. I think -- I -- the other part of my life involves medicinal pharmaceuticals and the same issue comes up when you publish articles in support of a drug company. I think that there should be full disclosure whenever you write anything.
Q. Well, in fact, some of the medicinal pharmaceuticals you

are involved with are drugs that are being sold to assist people to quit smoking, right?

A. Well, in that part of my life, yes, but I'm also involved with other sort of pharmaceuticals in terms of my job on pharmacy committees and dealing with pharmacy issues broadly. But the bottom line is I do agree that full disclosure is appropriate.

Q. But in terms of drugs designed to help people stop smoking, I want the record clear. You have earned hundreds of thousands of dollars from such companies, correct?

MR. McCABE: Objection, asked and answered.

THE COURT: No. The objection's overruled.

THE WITNESS: No, that's not correct. I have consulted with them on advisory boards and ordinary advisory boards pay an honorarium of a few thousand dollars.

BY MR. WELLS:

Q. What about research? Have you gotten maybe $400,000 from drug companies to do research on products that might assist people in quitting smoking?

A. Over the years, I have had several hundred thousand dollars of research support. That's not personal income. That's to fund the science.

Q. In fact, do you recall when the 1988 Surgeon General's Report was being critiqued by outside reviewers, one of the critiques that many of the reviewers made was that there was an

overemphasis on products like nicotine gum? Do you recall that?
A. Not specifically.
Q. Is it a fact that Dr. Henningfield earns hundreds of thousands of dollars with respect to his connections to people who sold nicotine gum?
MR. McCABE: Objection, beyond the personal knowledge of this witness.
MR. WELLS: If he knows.
THE COURT: If you know, you may answer.
THE WITNESS: He works currently with a consulting company that does do a lot of work for one of the manufacturers of smoking cessation products, so I think that at least a substantial portion of his income over the years has come from pharmaceutical companies.
BY MR. WELLS:
Q. Just a final question, Doctor. When you failed in Monograph 13 and hundreds of other -- well, many other research articles that you have written to disclose your connection to plaintiffs bringing lawsuits against the tobacco industry, you were not trying by such nondisclosure to commit any type of fraud, correct?
A. No. I think it was an oversight that I'm sorry occurred because I think it should have been stated.
Q. Right. And is it fair to say that over time, there's been an evolving concept within the scientific community with

respect to the issue of attribution?
A. Yes. There's been a lot of emphasis in recent years, mostly stemming from pharmaceutical company-supported trials.
Q. Right. But the concept that exists -- that has come to exist within the last five or six years is quite different than what people thought was proper and accepted in the early '90s and going back? A fair comment?
A. I think it's getting stronger now. The idea to do it is becoming stronger. More journals are requiring extensive disclosures, although I have to say many journals, even back in the early '90s, were requiring it, but now I think more journals are.
Q. But back in the '80s and '70s, people just didn't have the same sensitivity to the issues; fair comment?
A. Probably true, yes.
MR. WELLS: No further questions.
THE COURT: All right. Mr. Biersteker.
Mr. Biersteker, give me a very rough idea of what you anticipate.
MR. BIERSTEKER: I anticipate probably about two hours. As I said from the beginning, I'm trying to stick to it. There are two broad topic areas. The first is whether or not compensation is complete in light of Monograph 13 today, with today's science.
And the second broad issue is the doctor advanced some

proxies for what would be reasonable to say a person is addicted if they smoked every day, or if they smoked five cigarettes or more than five cigarettes a day. And I want to address that issue, too. So those are the two broad areas.

THE COURT: Okay.

MR. BIERSTEKER: If I could have your indulgence for a minute while we get situated.

THE COURT: Yes.

CROSS-EXAMINATION OF NEAL BENOWITZ, M.D.

BY MR. BIERSTEKER:

Q. Dr. Benowitz, I would like to start by just talking about the idea of youth first to make sure we have a clear idea of what it means. The minimum age to purchase cigarettes in most states is 18 years old; is that correct?

A. Yes.

Q. And 18-year-olds will be voting today? Fighting in Iraq? Right?

A. Yes.

Q. In your direct examination, when you talk about youth, you cited a number of different data. And I can go through the list of different things you cite, but isn't it true that most of the data that you cite concern people as young as age 11 up to about age 17 or 18, high school seniors, when you're referring to youth?

A. Most of the research has been done on individuals up

through high school.
Q. And indeed, you generally use the age 18 to distinguish adults from youth, do you not?
A. I have, although some reports have dealt with aged below 20, so 18 or 19.
Q. Well, let's talk about the difference between physical dependence and seeking pharmacological effects from nicotine. Would you agree with me that there's a difference between seeking the pharmacological effects of nicotine and actually being physically dependent on nicotine?
A. Yes.
Q. And indeed, you mentioned in your direct examination coffee and caffeine and you say, well, it has a stimulating effect and that's because it has pharmacologic action, correct?
A. Yes.
Q. And you go on to say that only about 10 percent of coffee drinkers, though, are addicted to caffeine, right?
A. Yes.
Q. And the reason is -- the difference between seeking the pharmacological effects of a particular drug, whether it be caffeine or nicotine or whatever, and physical dependence is for physical dependence, you have to be taking the substance to avoid withdrawal effects; is that fair?
A. Right, but that's not the reason why I talk about addiction. Addiction also includes compulsive behavior or

compulsive use of the drug. Some people who even drink just one or two cups of coffee a day can have physical dependence and if they skip a day, they'll have a headache. That doesn't necessarily mean they are addicted; it means they have physical dependence.

Q. So I thought you equated the terms "dependence" and "addiction"?

A. No. Drug dependence -- this is a really important distinction: Drug dependence is the global phenomenon. Physical dependence is a specific aspect of drug dependence, which means when you stop a drug, you have withdrawal symptoms. But they are a little bit confusing because physical dependence is not the same thing as drug dependence.

Q. Let me make sure I understand the distinction you just articulated.

In order to be physically dependent upon a particular substance, a person has to have withdrawal effects when they stop using it?

A. Correct.

Q. But you're saying somebody could be generally dependent upon a substance if they take it compulsively, such as the coffee drinker?

A. No. Physical dependence is often part of it, but it's not necessary. For example, you could be a binge alcoholic and you don't drink every day; you don't have physical dependence.

But once you start, you can't control your use. So that can be compulsive use, but you don't have to have of physical dependence as the reason for why you're drinking.

Q. But again, physical dependence is taking a substance to avoid withdrawal effects, correct?

A. No. Physical dependence just means that once you stop using a drug, you experience withdrawal effects.

Q. All right. That's fair enough, I'll take that. And that's what you refer to as smoking for negative reinforcement; for example, smoking to avoid withdrawal effects, right?

A. Exactly.

Q. And whether a person is an adult or a minor, your definition of "addiction" requires the person to be at a point with respect to smoking where they can't properly function without nicotine; is that right?

A. No, not that they can't properly function. It's just that there is a compelling need to have cigarettes. Now, it could be because they need to modulate their mood; it could be because of withdrawal symptoms.

And there are both kinds of smokers. Some people have relatively few withdrawal symptoms, but need cigarettes because they can't deal with stress or anxiety or whatever. And some people have very little of that, but have severe withdrawal symptoms. So there's a spectrum of how much positive and negative enforcements people seek.

Q. I understand that, but if somebody is smoking solely for positive reinforcement because it makes them feel calmer, for example, in that particular situation, that person is not physically dependent, correct?
A. Right.
Q. Okay, thank you. And what gives rise to physical dependence, these withdrawal symptoms, is the process of what you termed in your direct examination, I believe, neuroadaptation, correct?
A. Yes.
Q. And that process of neuroadaptation is one that takes a fair amount of time from the time that somebody becomes a daily smoker until that process is fully complete, correct?
A. Well, there is progressive neuroadaptation because smokers could take years before they reach their ultimate level of smoking, but it begins very quickly.
Q. It takes about seven years to complete it, correct?
A. That's when it plateaus, yes.
Q. All right. Now let's talk about the different proxies for addiction that you use, and I want to start with adults. In your direct testimony I believe you said something to the effect that smoking more than five cigarettes per day was a conservative proxy for addiction among individuals age 20 or 21. Do you remember that?
A. Yes.

Q. Okay. And I want to talk about that proxy and the different scientific standards briefly.

The DSM-IV that you talked about with Mr. Wells briefly is the only medically accepted criteria for diagnosing a smoker as nicotine dependent, isn't it?

A. What do you mean by medically -- what was the term again you used?

Q. Medically accepted. It's the approved definition of --

A. Well, it certainly is one that has been put forth by the American Psychiatric Association. There are other definitions, but that's the only thing that's been put forth by a medical organization for the diagnosis.

Q. And in that sense it's the only medically accepted definition, correct?

A. No, I think you could say that the Surgeon General's definition is also a relevant definition.

Q. I meant for diagnosing an individual, and I know --

A. If we're --

Q. Let me rephrase the question just so the record is clear. Would you agree with me that the only medically accepted definition of addiction for diagnosing somebody as nicotine dependent is the standards set forth by the American Psychiatric Association in the DSM-IV?

A. I think that's the one that has been sort of written out, yes.

Q. And to be addicted under the DSM-IV criteria, to be physically dependent under the DSM-IV criteria --
A. It's actually "dependent"; not "physically dependent".
Q. Well, but there's a difference under the DSM-IV, is there not, between dependence and physical dependence, and physical dependence requires that you have three or more withdrawal symptoms within the last 12 months?
A. Right. I thought you -- you're going back to the diagnosing of addiction dependence which is different from physical dependence. They are two separate categories.
Q. I'm asking you about physical dependence, Doctor, in the question. Physical dependence under the DSM-IV criteria requires that you have three or more withdrawal symptoms within I believe it's the last 12 months; is that correct?
A. I think so. I haven't looked at those criteria recently.
Q. And diagnosing an individual as physically dependent on nicotine using those criteria is a highly individualized determination, right?
A. You mean for each person?
Q. Yeah, for each person. To diagnose a person, you have to sit down and talk to them, right?
A. Yes.
Q. And simply knowing how many cigarettes per day a person smokes isn't enough to diagnose them as physically dependent on nicotine using the DSM-IV criteria, correct?

A. Well, not a person, but you can certainly correlate research that's been done looking at the number of cigarettes versus behaviors to make a prediction, although you can't say for every individual.

Q. Well, we'll get there in just a second. Let me just wrap up this minor piece, and that is the DSM-IV criteria -- there's I think seven major criteria that are listed; is that correct?

A. For dependence, yes.

Q. Yes. And none of those criteria are the number of cigarettes you smoke per day, correct?

A. Correct.

Q. All right. Now let's talk about what you're talking about, the correlation between the number of cigarettes you smoke and a diagnosis of nicotine dependence. And the DSM-IV criteria have been applied, have they not, to survey data to estimate the proportion of people in the population who are dependent on nicotine?

A. Yes.

Q. And in fact, one of those articles was a study by Denise Kandel and Kevin Chen that you cited in your September 29th, 2003 declaration in this case, correct?

A. Yes.

Q. All right. But what Kandel and Chen did was there was a survey that was administered that asked questions that were designed to get at basically the DSM-IV criteria, right?

A. Well, I believe they took information that they had and they tried to extract relevant answers based on DSM-IV criteria, so those are like proxy questions.
Q. Proxy questions to try to match up with the DSM-IV criteria, correct?
A. Right, but I don't know that they prospectively asked the DSM-IV questions; I think they took information they were collecting and tried to use those to address the DSM-IV criteria.
Q. Do you recall or do you need to see the study that Kandel and Chen estimated that about 28 and a half percent of current smokers are nicotine dependent?
A. I need to see that, but I don't think that refers to daily smokers. I think that refers to smokers who have smoked any cigarettes in the last 30 days.
Q. If I could have JD 063755.
All right, if you'll look at page 266 of the article, Doctor -- I'll see if I can do this. I seem to have a hard time getting it the right way. There we go. Do you see the highlighted bit on page 266 under "Results"?
A. Yes.
Q. And that's the 28 and a half percent of the current smokers who they found were addicted?
A. Yeah, that's not daily smokers. That's all --
Q. Well, in fact, what they found was, if you look down a

little bit further, more than half the smokers who participated in this particular survey smoked at least one pack of cigarettes a day, didn't they?

A. Yes.

Q. Doesn't that suggest that Kandel and Chen at least reported that not even all smokers who smoke at least one pack of cigarettes a day are nicotine dependent?

A. Well, there are other studies that have specifically -- that's what this says, but there are other studies that have specifically used the DSM in a more direct way than Dr. Kandel has and finds that 60 to 70 percent of people who smoke daily meet these DSM-IV criteria.

Q. As a reality check, using your more than five cigarettes a day standard that you've suggested as a proxy, do you happen to know what percentage of smokers, current smokers smoke more than -- adult smokers smoke more than five cigarettes a day?

A. Probably 85 percent.

Q. Do you think it's higher, maybe 95 percent?

A. Pardon?

Q. Have you looked at the data? Do you think it's more than -- closer to 95 percent, 95?

A. Are you talking about all smokers? Again, it's all smokers versus daily smokers.

Q. Current adult smokers.

A. Talking about daily smokers, people who smoke every

single day, then I think you're right it's probably 95 percent. But if you're talking all smokers including some percentage that don't smoke every day, that's currently about 15 percent.

Q. If you turn to figure 3 in this particular article -- I'll see if I can get it up there. Kandel and Chen present a chart that correlates how many cigarettes you smoke per day with the percentage of people who are nicotine dependent. Do you see that?

A. Yes.

Q. And they break it out by race in this chart, that's why there are three graphs, right?

A. Yes.

Q. And just sort of eyeballing it because they don't actually present the data in tabular form, it appears to me just looking at it that at one to five cigarettes per day maybe about 15 percent of the people were believed to be nicotine dependent. Does that look about right to you?

A. According to this graph?

Q. Yes.

A. Yes.

Q. And if you get up to ten cigarettes a day, that's the half pack, right?

A. Yes.

Q. The number jumps to about 25 or 30 percent?

A. Yes.

Q. And if you turn back a page in the article, let's see if I can find that, too, to figure 2, Kandel and Chen actually present some data on adolescence, and the 12 to 17-year old line consistent with your testimony is the heavy line on the top, right?
A. Yes.
Q. And as I kind of eyeball this chart for the 12 to 17-year olds, it looks to me that among those who smoked one to five cigarettes a day, about 25 percent were nicotine dependent according to this study?
A. Yes.
Q. And about -- I don't know, between 30 and 35 percent who smoked ten cigarettes a day?
A. Yes. And again, you need to keep in mind that this is not the DSM-IV administered the way that it's supposed to be administered. This is proxy information that they collected that they thought addressed the DSM-IV criteria.
Q. Right, and your testimony in this case is proxy information, too, is it not?
A. I don't follow that question.
Q. Well, when you say it's reasonable to say that somebody who smokes more than -- an adult who smokes -- in fact, "conservative to say that an adult who smokes more than five cigarettes per day is nicotine dependent", that's a proxy, that's not a medical diagnosis, is it?

A. Right, but what I'm validating it against is not DSM-IV, it's against the future smoking behavior. It's a more direct issue, how difficult is it for people to quit and whether they're smoking as an adult which is --

Q. I understand, but I want to compare what you have done with the medically accepted criteria as applied through the survey instrument here and then we can talk about another survey next.

Let me just ask one more question about this figure: Is it not true that in no group of the 12 to 17-year old people in the particular study does the percentage who are nicotine dependent exceed 50 percent even for those who are smoking more than two packs per day?

A. No, but I have to say that there are studies that have used the DSM-IV as intended to and found 60 percent of daily youth smokers meets criteria.

Q. Doctor, you cited this study in your declaration in this case, correct?

A. Yes, but I'm saying that there are some other studies that show 60 percent that use --

Q. Let's talk about another one, let's talk about Breslau, that's a study that was done that went about this in a similar way, it looked at survey data and applied the DSM, I think it was III, criteria at that time, or maybe III-R, to ascertain nicotine dependence. You're familiar with that article, aren't

you?
A. Yes.
Q. Okay. If I could have JD 067814, please.
Isn't it true that Breslau et al. estimated what they call "lifetime dependence"?
A. Yes, they also use proxy measure. They did not collect specific DSM-IV responses, they took information that was collected for another purpose and they tried to answer the DSM-IV questions using those data.
Q. And they estimate, at least on a lifetime basis, if you turn to page 812, that about half of the folks were at some point during their lifetime, about half of the current smokers were nicotine dependent, correct?
A. That's what they state, that's correct.
Q. And this study has information also, does it not, about the onset of nicotine dependence?
A. Yeah, they do provide data to address that question.
Q. And they found that nicotine dependence is a distinctly later stage than daily smoking, didn't they?
A. That's what they report using their measures.
Q. In fact, I think they reported that 95 percent of nicotine dependent smokers didn't become nicotine dependent until at least a year after they started smoking on a daily basis, right?
A. Yes.

Q. And, in fact, the highest rate of becoming nicotine dependent was observed within the first 16 years after somebody started smoking on a daily basis; is that correct?
A. That's what they report.
Q. Now, there's another test for nicotine dependence that you, at least sometimes, use with your patients called the Fagerstrom Test for Nicotine Dependence, right?
A. Yes, it focuses more on the severity of dependence rather than the diagnosis yes or no.
Q. And the -- but you have used it to ascertain -- to determine whether or not somebody is nicotine dependent at all, as supposed to severity, correct?
A. It's not used that way -- it has been used that way, but it's intended to look at severity.
Q. Now, the Fagerstrom Test for nicotine dependence has six questions, right?
A. Yes.
Q. And one of those questions is how many cigarettes does a smoker smoke per day, right?
A. Yes.
Q. And if somebody says I smoke ten cigarettes a day or nine or anything less than 10, their score on that test, if that's all you know about them, is zero, isn't it?
A. For that question.
Q. For that -- if that's all you know about them, that would

be for the entire test as well.
A. Well, it's -- I'm not sure how to answer the question. If you only have one question of that test, you wouldn't have the test. That test is really meant to look at severity of dependence among smokers, and it's got a number of other questions that are very relevant to smoking behavior, so you would never use one question to define that test.
Q. Would you ever use the answer to one question as a proxy for nicotine dependence in the population as a whole and declare it to be conservative or reasonable?
A. It depends on what you are -- what data you have that correlates with it, and smoking per day, cigarettes per day, we have good data predicting future smoking. We have good data on difficulty with quit attempts, and the essence of addiction or dependence or whatever we want to call it, is really how difficult is it for someone to quit. Will they keep on smoking, and how does it predict for youth? How does it predict what happens as an adult? And we have pretty good data to say that smoking five cigarettes a day predicts adult smoking, and that's the bottom line for addiction.
Q. And you just assume that it predicts adult smoking because people are nicotine dependent, right?
A. Yes.
Q. Have you validated that assumption, sir?
A. Well, there are a number of studies that have looked, on

recent years, at things like withdrawal symptoms, looked at pharmacologic reasons for smoking, looking at autonomy of smoking, and when you look at those measures, you find that, for example, loss of autonomy is reported about 90 percent of daily smokers, withdrawal symptoms are reported about 80 percent of daily smokers as youth. So when you begin to breakdown and look at the elements that are involved in dependence, you do find very strong effects of daily smoking.

Q. Let me ask this question: Isn't it true that the number of cigarettes a person smokes per day hasn't been adopted by any medical organization, or anybody else for that matter, as sufficient to diagnose somebody as being nicotine dependent?

A. It's not part of a medical organization, but it certainly is a good predictor of future behavior, which is the reason why you want to use the test based on scientific research. It's not part of any questionnaire, but it's well validated by research.

Q. In fact, the number of cigarettes smoked per day is not used by the United States government when it attempts to assess nicotine dependence among smokers is it?

A. I don't know what assessment you're talking about, but --

Q. Do you know whether or not the Department of Human Health and Services through the Substance Abuse Mental Health Administration has since, maybe 2001, maybe 2002, undertaken an effort to measure the extent of nicotine dependence among current cigarette smokers?

A. I'm not aware of what instrument they use for that.
Q. Let's take a look at JD 067884, please.
Are you familiar with the document that you've been handed, the results from 2003 national survey on drug use and health, national findings.
A. Well, I am familiar with this survey that's done on an annual basis, but I -- I'm not sure I've looked at this particular year in its full form. But what I need to do is to find what instrument they used to determine dependence.
Q. Well, why don't we take a look at page 103 of this exhibit doctor.
Do you see that, first of all, they basically use the conceptual roots of what they're trying to do here are rooted in the American Medical Association's -- excuse me, the American Psychiatric Association's DSM-IV?
A. Yes.
THE COURT: I want to be very clear. What is this document, please?
MR. BIERSTEKER: It's a final --
THE COURT: No, no.
MR. BIERSTEKER: I'm sorry.
THE WITNESS: There is a survey at a Health and Human Services performs each year through the population to try to assess drug use broadly, so they ask about alcohol use, smoking, heroin, cocaine, a number of drugs. They try to survey what the

prevalence is in the population of youths, and they also try to ask some specific questions to look at behavioral characteristics as well.

BY MR. BIERSTEKER:

Q. And, in any event, Doctor, would you agree with me that this government agency has attempted to measure nicotine dependence upon current cigarette smokers based upon 19 questions in a survey that have their conceptual roots in the American Psychiatric Association's DSM-IV?

A. Yes.

Q. And, if we look at the questions that are asked and that are on 103 and 104, is -- I just have a quick question about it -- none of those 19 questions asked the smokers how many cigarettes they smoked per day, do they?

A. Um, no, they don't.

Q. Thank you.

Well, let's talk about number of cigarettes per day as a proxy for addiction. Isn't it true, Doctor, that not every smoker who smokes more than ten cigarettes per day is nicotine dependent as you define it.

A. Most are, but not all.

Q. And when we look at -- well, let's look at the bottom end of the range, let's look at people who smoke five or fewer cigarettes a day. You don't really think that adults who smoke fewer than five cigarettes per day are nicotine dependent, do

you?
A. Most are not, unless they are in an escalation phase of their smoking. So a young adult could be, but if you are stable, five cigarette per day or less smoker, then most are not dependent.
Q. And, in fact, a particular area of interest to you in your academic work has been examining a population that are sometimes referred to as "chippers", right?
A. Yes.
Q. And chippers are adults who smoke five or fewer cigarettes per day, correct?
A. In a stable pattern.
Q. Right. And they can smoke those five or fewer cigarettes a day for decades without becoming nicotine dependent, correct?
A. Yes.
Q. And chippers who smoke five or fewer cigarettes per day don't suffer withdrawal symptoms when they try to stop, do they?
A. Correct.
Q. For whatever reason, what you call negative reinforcement, smoking in order to avoid withdrawal doesn't occur in these people, right?
A. That's correct.
Q. And you've taken a look to try to figure out whether these people, somehow, are biologically different from other smokers, and basically you have not identified any differences,

have you?
A. Well, certainly not in terms of how they smoke their cigarettes. We've been looking at genetic differences and things like that, but it's not determined, exactly, why they're different.
Q. Now, let's talk about people who smoke in the gray area, 6 to 10 cigarettes per day, all right? And will you agree with me that that is a gray area in terms of whether or not those people are nicotine dependent?
A. Yes.
Q. You have not seen any published estimates, have you, of the percentage of people who smoke 6 to 10 cigarettes per day who are nicotine dependent?
A. Broken down in that area, no.
Q. In fact -- I'm sorry?
A. Our data will look at like 1 to 9, or something like that, but I have not seen something specifically 6 to 10.
Q. And, in fact, you have written, have you not, that smokers of up to 10 cigarettes per day do not have withdrawal symptoms and are not nicotine dependent, correct?
A. I may have written that. I don't believe that's quite true. I think some do and some don't.
Q. Well, you don't disagree with that's what you wrote in 1992, do you?
A. No, but that's not what I believe now. I think that

there are some people who even five cigarettes a day are dependent, and some people who are 10 who are not, so I think there is an overlap.

Q. The article that you wrote in 1992 was peer reviewed?

A. Most likely, yes.

Q. And it appeared in the New England Journal of Medicine, wasn't it?

A. It was peer reviewed.

Q. When did you decide -- when did you change your mind?

A. Well, there's been a lot of work looking at what -- why people smoke cigarettes and difficulty quitting, and it's been shown that there are a fair number of people who smoke fewer than 10 cigarettes per day who have great difficult quitting. And the bottom line, as I've said in my direct testimony about addiction, is when there's a loss of control over drug use, and so it does appear that there are some people who even with fewer than 10 cigarettes a day, now whether it's because of a very strong need for the effects of nicotine to deal with stress or mood, the sort of things that we talked about, it's not clear why. Most likely that's what's going on.

THE COURT: And are those people who are not in the phase of escalating their cigarette smoking?

THE WITNESS: Yes, right now I'm talking about sustained. Escalation is different. We can't talk about these numbers in the escalation phase because they're on their way up. In terms

of stable adults, I think there are some people who are addicted at less than 10 cigarettes per day. I can't give you a percentage.

BY MR. BIERSTEKER:

Q. Right, but that's fair. Thank you. You have also, I think, written in your expert report in this case that when people are asked to quit smoking, a lot of times what they'll do is they'll come in and say I cut back my smoking and I'm smoking 10 cigarettes per day, right?

A. Yes.

Q. And you say well, that's not surprising, because people who smoke 10 cigarettes per day can get enough nicotine from their cigarettes, if they smoke them pretty intensively, to maintain their addiction, right?

A. Well, with what I'm saying, specifically, is you can smoke 10 cigarettes per day and get as much as you are used to from smoking 20 a day.

Q. Well, --

A. That's what our research has shown.

Q. Well, isn't the implication that if you are smoking fewer than 10 cigarettes per day, you can't get as much as you were when you were smoking 20 cigarettes per day?

A. Right, but that doesn't mean that if someone is not decreasing that they couldn't still be dependent at a level of less than 10 a day.

Q. No, it's not impossible, I think we're talking about probabilities.
A. Well, I'm saying we're -- I think in recent years we're appreciating the fact that there are a fair number of people who are smoking 10 cigarettes a day who have difficulty not smoking.
Q. And there are some people who smoke more than 10 cigarettes per day who don't have difficulty not smoking, correct?
A. There are, but I think we're getting more of an appreciation that there are people in the 10 area -- we've always known there are some people who smoke a pack a day who are really lucky who can quit easily and just stop, but there are a lot of recent research suggesting that there are people in the 6 to 10 range who have difficulty quitting.
MR. BIERSTEKER: Your Honor, I pretty much concluded the examination that I wanted to do with respect to adults. I'm about to move on to the youth, the adolescents. It's a logical place to stop, but whatever you desire.
THE COURT: All right. How long, again, do you think the conclusion of yours will take?
MR. BIERSTEKER: Well, I chewed up, I guess, about a half an hour haven't I? I think if my estimate is correct, I'm looking at an hour, hour and a half.
THE COURT: An hour and a half.
MR. BIERSTEKER: An hour to an hour and a half.

THE COURT: All right. And does the government have a rough estimate for redirect?

MR. BIERSTEKER: I should further add, Your Honor, that Mr. Bernick was going to address a fairly narrow question with the witness. In the direct examination there was discussion about the rapidity with which nicotine is taken up in the brain and it's importance to assessing addictive potential, which relates to the idea of free nicotine and pH and he was going to briefly address that issue.

MR. BERNICK: I think I could tell the Court 45 minutes to an hour. It's a very technical area and it's very hard to compress it. I think it's going to take an hour.

THE COURT: And does the government have any estimates on its redirect?

MR. McCABE: Right now about less than an hour, Your Honor.

THE COURT: Okay. Not with that microphone, we'll put it that way. Less than an hour.

Well, we're cutting it close, everybody. I guess we'll just take an hour for lunch, even though it looked beautiful out, but 1:30, please, everyone.

(Thereupon, a luncheon recess was had beginning at 12:30 p.m.)

C E R T I F I C A T E

I, Scott L. Wallace, RDR-CRR, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

Scott L. Wallace, RDR, CRR
Official Court Reporter

Scott L. Wallace, RDR, CRR
Official Court Reporter

I N D E X

E X H I B I T S

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA,	:	CA No. 99-2496(GK)
	:	November 2, 2004
Plaintiff,	:	
	:	1:31 p.m.
	:	
v.	:	Washington, D.C.
	:	
PHILIP MORRIS USA, et al.,	:	
	:	
Defendants.	:	

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VOLUME 23
AFTERNOON SESSION
TRANSCRIPT OF TRIAL RECORD
BEFORE THE HONORABLE GLADYS KESSLER
UNITED STATES DISTRICT JUDGE

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P R O C E E D I N G S

THE COURT: Sorry we are late, everybody. Outside was just too much of a lure today.

All right, Mr. Biersteker, let's go.

MR. BIERSTEKER: Thank you, Your Honor.

NEAL BENOWITZ, M.D., Government's witness, RESUMES

CROSS-EXAMINATION (Cont'd.)

BY MR. BIERSTEKER:

Q. Good afternoon, Dr. Benowitz. Let's turn to youth as opposed to adults. And in your direct testimony you expressed the opinion that for youth smoking one cigarette per day or more is a reasonable proxy for addiction; right?

A. Yes.

Q. Okay. Now, the American Psychiatric Association does not have a separate standard for diagnosing nicotine dependence among adults versus youth; correct?

A. Correct.

Q. The criteria don't distinguish, they're the same; right?

A. Well, yeah, I don't think it really addresses the youth question.

Q. In fact, if you applied the DMS-4 criteria to youth, most youth are not nicotine dependent; correct?

A. The majority are not.

Q. We also discussed the Fagerstrom test. Isn't it true that most adolescents do not meet the criteria for nicotine

dependence under the Fagerstrom test?
A. Well, let me make it clear that there are not the criteria for dependence, there are higher levels of dependence and lower levels. The Fagerstrom is meant to assess severity, not make a diagnosis of dependence.
Q. Well, have you testified in the past that most youth do not meet the Fagerstrom test for nicotine dependence?
There's a Fagerstrom test specifically designed for nicotine dependence; yes?
THE COURT: Mr. Biersteker, you're dropping your voice a little bit.
A. There is a cutoff in points that's been used to say if someone has a moderate-to-high level of dependence versus a low level, and that's been sometimes used as a surrogate for dependence, but the test is not really developed for that purpose.
Q. But in point of fact, youth, when you use that cut-off point, most of them are not nicotine dependent; correct?
A. They are not highly dependent. There's no negative dependent or not dependent. It's either a high level or a low level. So most would not meet the high level of dependence, that's true.
Q. Isn't it true that in your opinion there simply aren't any good standards or tools for diagnosing nicotine dependence among adolescents?

A. Right, and what I said is that the best thing is to look at how it correlates to future behavior.
Q. To your knowledge, the criteria you talk about in this case in your direct testimony daily smoking, irrespective of the amount, as a measure of assessing nicotine dependence in underage smokers has not been scientifically validated; is that correct?
A. What has been validated is the predictive value for later smoking. It's not been -- it hasn't been validated against a dependence questionnaire, although there are data with DSM-4 that we talked about before from other studies, and there are relationships between cigarettes per day and symptoms of withdrawal and also autonomy.

So there have been some attempts to do it, but I don't think the final answer is in yet.
Q. So it has not been scientifically validated. That's the answer to my question; correct?
A. It's validated as a predictor, but it's not validated against a dependence instrument because that's still being worked out.
Q. When you say it's validated against a predictor, you're looking at whether or not youth who smoke now are going to be smoking sometime in the future; right?
A. Yes.
Q. Okay. And that could happen for a number of reasons that

really don't have anything to do with physical dependence on nicotine; correct?

A. I suppose that's possible. But what happens is when youth start smoking, they do become dependent and then they gradually escalate to cigarette consumption and that's part of the dependence process.

Now I guess it's possible someone could start and stop again and start again later on. That's unusual.

Q. Let's talk about that process of escalating consumption.

We discussed earlier that it takes about seven years for that process to complete itself; correct?

A. Yes.

Q. And the truth of the matter is you cannot pinpoint for me specifically where on the trajectory of increasing consumption somebody becomes nicotine dependent; correct?

A. Well, there's a lot of reasons to think that once a person starts smoking for pharmacologic reasons, starts smoking when they are alone, has difficulty quitting, that they're dependent, and that's what's been used operationally and when I've talked about it.

Q. Isn't it true that you cannot tell me where on the trajectory of increasing cigarette consumption somebody becomes nicotine dependent?

A. I think they become dependent when they are smoking daily.

Q. Let's take a look. You gave a deposition in a case called

Harvey in May of 2002. If I could have that, please.

And, Doctor, in that deposition --

MR. McCABE: I'm sorry. Did the witness receive a copy of that?

MR. BIERSTEKER: Do you want him to have a copy? Thank you.

BY MR. BIERSTEKER:

Q. And the examiner --

A. What page is this on?

Q. I'm sorry. It's on page 185.

A. Thank you.

Q. Are you with me? Line 6?

A. Yes.

Q. The examiner asked the question, "Well, that's my question to you. You used the word 'or will be addicted.' There are oftentimes in a period after which somebody starts smoking daily in which, while they may be on the road to addiction, they are not addicted yet. Would you agree with that?"

And you answered, "It is hard to know exactly when that point is because once you start smoking daily, there is an escalation that occurs typically over six or seven years from the first cigarette to when you plateau, and smoking rates will increase over that period of time. And it's hard to say at what point in time one becomes addicted."

And then you go on to say -- to observe, rather,

because most people when they become daily smokers continue. Right?

A. Yes.

Q. So let me take this in pieces.

The first piece is you don't know when on the road of escalating smoking somebody becomes addicted or not addicted; correct?

A. Well, you may not know exactly, but you can certainly say that a person is likely to become predicted -- to become addicted.

I guess the question would have to be broken down into exactly what operational definition for addiction is used. If it's smoking for pharmacologic reasons, I think that one cigarette a day would meet that.

Q. Well, wait a minute. If I may just stop you there.

I'm trying to distinguish between smoking for positive reinforcing effects. In other words, if somebody smokes a cigarette because they like the way they feel after they smoke, it makes them calmer or whatever, that's positive reinforcement; correct?

A. Yes.

Q. Okay. But if somebody smokes a cigarette because they feel a compulsion to do it to avoid withdrawal effects, they are starting to lose their ability to concentrate, they are starting to feel irritable, whatever, that's for negative reinforcement;

right?
A. Yes, sir.
Q. Okay. And what I'm trying to focus on when I say physically dependent are the people who smoke, not because they like the way it makes them feel, but because they are trying to avoid the withdrawal effects.
Are you with me?
A. Okay. I am, but I just need to say that the first is not insignificant. That is a component of addiction.
But I agree with you, if you're talking about physical dependence, then may require more than one cigarette a day before you see that.
Q. Are you saying that everybody who smokes a cigarette because they like the positive reinforcing of nicotine effects is dependent?
A. No. I'm saying that that is a substantial component of dependence.
Q. And then you go on to observe that, "Well, most people when they become daily smokers continue."
Well, that doesn't mean that when they are daily smokers they are nicotine dependent; correct?
A. That's why I said here they are or will become dependent.
Q. You didn't say that in your direct, that they are or will become dependent, did you?
A. No, but that's what I said in this testimony.

Q. Okay. Fine. So they are or will become dependent in your view.

And, in fact, when you compare, as you did during your direct examination -- when people are asked, for example, do you think you will be smoking down the road? And people say, well, I won't be, or I probably won't be, definitely won't be. Do you remember that?

A. Yes.

Q. Okay. What you did is you compared people's predictions about their future behavior with what they actually did over time; correct?

A. Yes.

Q. Now, it could be that there are differences in those percentages that are unrelated to negative reinforcement or smoking to avoid the withdrawal effects from nicotine; correct?

A. Yes.

Q. Okay. For example -- and I believe I made a note of this when Mr. Wells was examining you this morning -- you said that people will say that they want to quit without really meaning it, or people will say that I intend to try to quit without having any intention of doing it. Correct?

A. I said that can happen, yes.

Q. And, indeed, that's a significant problem. It's called the social acceptability of the response; correct?

A. It depends on the context in which someone is asked.

Q. Well, in fact, there are -- there is literature about this particular phenomenon, is there not?
A. Right, but what I was trying to say is that if there is a reason why a person should quit -- like if a doctor asks you, most people are more likely to say, "I'm going to quit," it's your personal doctor -- than if someone just gives you a random survey when there's no relationship to the person and doesn't matter, the person doesn't know you anyway, so you are much more likely to be truthful in the second situation than in the first situation.
Q. Well, with respect to the second situation, isn't it true that Dr. Giovino -- you know who he is; right?
A. Gio --
Q. G-i-o-v-i-n-o.
A. Gio-VAEN-no
Q. Sorry. I mispronounced it.
A. Yes.
Q. He's formerly from the Centers for Disease Control?
A. Yes.
Q. And he wrote an article in Tobacco Control in 1993 in which he observed that a high percentage of smokers indicated that they wanted to quit, but he said answering no to that question is probably socially unacceptable and he cautioned that researchers will need to take that into account in their deliberations or considerations of these data.

Do you remember that?
A. I don't specifically remember that article.
Q. Do you remember Dr. Kozlowski's article back in, I think 1980, which is entitled: What Researchers Make of What Cigarette Smokers Say: Filtering Smokers Hot Air.
A. I have a vague recollection of that paper.
Q. And he addressed the same phenomenon of people saying that they want to quit or that they intend to quit in the future when they really don't want to and they just want people to get off their back or they are trying to give a socially-acceptable answer?
A. Yes, I do remember that.
Q. And, again, the people who are smoking daily who continue, might continue to smoke because of positive reinforcement effects of nicotine, not negative ones; right?
A. Right. But again, as I say, that is an important component of addiction. That cannot be ignored and say that's not addiction.
Q. But you're also not saying that people who smoke for positive reinforcement from nicotine are addicted, are you, physically?
A. There are some --
THE COURT: Mr. Biersteker, you have to slow down, please.
MR. BIERSTEKER: I'm sorry.

A. I think you need to -- we need to get back to separate physical dependence from being addictive.

Physical dependence just means withdrawal symptoms.

Addiction or dependence broadly depends on positive reinforcement, negative reinforcement, environmental factors, a bunch of things play a role.

Physical dependence is a very technical term the way I'm using it. That just means withdrawal symptoms. You do not have to have withdrawal symptoms to be dependent.

Q. Okay. When you use your smoking as little as one cigarette a day as a proxy for addiction in youth, are you referring to physical dependence or dependence in the sense of they like it?

A. No. Dependence on the sense that they are smoking for pharmacologic reasons. They are smoking alone and they have difficulty not smoking. Those are the -- and that it has to do with effects of nicotine. So it's really that the behavior is being controlled by effects of nicotine, even though there's not necessarily physical dependence.

THE COURT: Would that be true if a person, a young person, is smoking only one cigarette a day?

THE WITNESS: Well, it doesn't -- not many people smoke just one cigarette a day. In theory, that's the case, but the average youth smoker probably smokes more like five to nine cigarettes who is a daily smoker.

So, not many people smoke just one cigarette a day. I

mean, it's hard when you get to one level, but that's not what most people do smoke.

THE COURT: But your test is -- or your definition is that if -- for a youth smoker. Now if you regularly smoke one a day, you're addicted.

THE WITNESS: Well, the problem is that the data don't really refine one, two, three or four. They talk about one to five in the range.

So I've used one, but in fact it's really the range of one to five because on average people will be smoking more like four when they become daily smokers.

BY MR. BIERSTEKER:

Q. Are you confident of that, Doctor? Have you looked at the national household survey data?

A. Pardon?

Q. Have you looked at the national household survey data?

A. With respect to what?

Q. With respect to smoking.

A. At various times in my career I have. I don't know what in particular you're referring to now.

Q. We talked earlier today about the government's efforts to assess nicotine dependence in the population using survey data; correct?

A. Yes.

Q. And I'm asking you, do you know whether or not the

government has looked at the national household survey data on 12 to 17-year-olds and specifically looked at those who smoked one cigarette per day, and only one cigarette per day, to assess the extent of nicotine dependence based upon the government's measure?

A. I don't know.

Q. And so you don't know whether or not the government's data showed that only 3 percent of youth who smoke one cigarette per day are nicotine dependent using the definition that the government employs in that work?

A. I have not looked at those data.

Q. So you haven't -- in coming up with your cigarette per day standards that you're presenting in your testimony to this court, you haven't attempted to validate that at least against that particular set of data; is that correct?

A. That's correct.

Q. And, indeed, you and Dr. Henningfield published an article some years ago entitled: Establishing a Nicotine Threshold For Addiction, the Implications of Tobacco Regulation. Correct?

A. Yes.

Q. And in that article you proposed setting a maximum amount of nicotine that could be in cigarettes; correct?

A. Correct.

Q. And the purpose in trying to set a maximum amount of nicotine that was in cigarettes was to avoid youth becoming

nicotine dependent; right?
A. Yes.
Q. And the measure that you advocated in that was, I believe, a daily nicotine intake of 5 milligrams per day, assuming you smoked 30 cigarettes; right?
A. Yes.
Q. All right. And just to translate that into cigarettes per day in the market as currently exists, isn't it true that on average cigarettes yield about 1 milligram of nicotine?
A. Yes.
Q. Okay. So your standard, then, is the equivalent of 5 cigarettes per day; correct? The standard you proposed.
A. Yes, although you have to take that much nicotine from smoking 30 cigarettes which would not be likely for a youth.
Q. I understand, but let's just focus on the quantitative amount which is you would not have proposed, would you, Doctor, a maximum nicotine amount of 5 milligrams per day which is equivalent to 5 cigarettes per day, 5 of today's cigarettes per today, that is five times higher than the standard you're telling this court to employ, would you?
A. I don't -- could you restate the question?
Q. Sure. Let me try it again. It was kind of confused.
In this court you're saying if somebody is getting 1 milligram of nicotine a day, i.e., somebody who smokes -- a youth who smokes one cigarette per day, it is highly likely that

they are nicotine dependent, I believe is your testimony; correct?
A. Yes.
Q. And that level is one-fifth of the level of nicotine intake that you advocated for regulatory purposes in order to prevent youth from becoming nicotine dependent; correct?
A. Yes, but it -- the issue of smoking 30 cigarettes versus one cigarette is important because there's also another aspect of what you get per cigarette that's reinforcing. There's a certain amount you have to get per cigarette before you get effects.

And the other issue is that if you're taking your 5 milligrams in 30 cigarettes, the amount you get per cigarette is also less reinforcing.

So it's not just the total amount per day, but it's himself the fact that the amount per cigarette is much less.
Q. Well, you can just smoke them more quickly one after another; right?
A. Right, but very few kids can smoke 30 cigarettes or have the money to or the time to, so it would be tough.
Q. In your direct you talk about the five stages of the development of nicotine addiction; right?
A. Yes.
Q. And the fifth stage you say is regular smoking, usually every day, and then you added a phrase. The phrase was "with an

internally regulated need for nicotine." Do you remember that?
A. Yes.
Q. By an internally regulated need for nicotine, do you mean that individuals are smoking to avoid negative reinforcement or withdrawal effects?
A. It may, but not necessarily. A person may get the situation where they need to have nicotine to deal with stress or anxiety or depression, so they may be using it for positive reinforcement, although usually people have some combination of both.
Q. In any event, the addictive minors are those who have reached the fifth stage of the dependence process that you identify; right?
A. The important part of that is that they are smoking for the effects of nicotine. They are not just smoking because their friends or smoking or they are at a party, they are really smoking for the effects of nicotine separate from just the process of smoking.
Q. Okay. I understand. And, Doctor, I understand the impulse to add qualifications, but I'm trying to move it along by asking, I think pretty precise questions, and if you could keep your answers shorter, it will facilitate the process.
You were not the first person to articulate these five stages of addiction among youth; right?
A. No. It was not from -- that was taken from other published

work.
Q. And, indeed, the published work to which you refer was something done by Dr. Flay and colleagues; correct?
A. Yes.
Q. And isn't it true that Dr. Flay and colleagues used 10 or more cigarettes per day as a proxy for addiction among high school seniors in the very article from which you took the five stages of nicotine dependence?
A. It could be. I don't remember that.
Q. Do you want to look?
A. Sure.
Q. Okay. Let's look at JD 067888.

First of all, do you recognize this as the article by Flay and colleagues entitled: Smoking Epidemiology, Cessation and Prevention, from which you took the concept of the five stages of nicotine dependence or addiction?
A. Yes.
Q. Okay. And if you will turn, please, Doctor, to page 292S, because it's in a supplement. At the top of the page. Let's see if I can zoom in.

And Flay and colleagues are writing there, and they say, "Nicotine dependence or addiction, fifth stage, occurs with the development of an internally regulated need for nicotine. About one-third of adult smokers probably become addicted before the end of high school, parens, the approximately 10 percent of

students who smoke 10 or more cigarettes per day, while two-thirds do not become addicted until after the transition to college or work."

Does this refresh your recollection about whether or not Dr. Flay and colleagues defined addiction at the end of high school as smoking 10 or more cigarettes per day?

A. That's what he states, but I have to say this is 1992 and there is a lot of research since then.

Q. You told the court that over 70 percent -- in your direct, written direct -- that over 70 percent of adult daily smokers began smoking daily by age 18. Do you remember that?

A. Yes.

Q. Okay. And you refer just at that point in your testimony to the 1994 Surgeon General's report. It's on page 39 of your direct if you want to look. But that's your reference; right?

A. Yes.

Q. Okay. Isn't it true that only 35 percent of adult smokers aged 30 to 39 were daily smokers by age 18?

THE COURT: What page did you refer to, please?

MR. BIERSTEKER: It's direct examination, Your Honor, page 30, lines 3 through 10.

A. I don't know where those data come from.

Q. Well, let's take a look at the Surgeon General's report. I assume that is the page to which you refer.

MR. BIERSTEKER: It's the 1994 Surgeon General's

report, U.S. Exhibit 64693 already admitted in evidence, Your Honor.

A. And what page was that again, please?

Q. 67. And I think if you look at that, Dr. Benowitz, we can see at the bottom line of the paragraph I've highlighted. Are you with me?

A. Yes.

Q. Let's set a little context first.

The Surgeon General is reporting in this paragraph that 71 percent of adults who ever smoked on a daily basis smoked daily when they were age 18; right?

A. Yes.

Q. Okay. But that's different than saying, the percentage of current smokers who are adults who smoked daily when they are at age 18; correct?

A. Yes.

Q. All right. And he addresses that issue in this very same paragraph. And, indeed, he says that -- he's talking about respondents who are age 30 to 39; correct?

A. Yes.

Q. And in the sentence right before the one that we just talked about, he says, "35 percent of the respondents had become daily smokers by the age of 18." Correct?

A. Yes, but I'm not sure that these respondents were all daily smokers.

What it says -- the next sentence is what I said before; that of those who had ever smoked daily, 71 percent had smoked daily by the age of 18.

Q. Right. But we've already talked about that. We've already agreed that those who are currently smoking -- that that is different than the percentage of current daily adult smokers who smoke daily by the age of 18; correct?

A. Yeah. Without seeing further data, to me, this looks like they are talking about 35 percent of people who had ever been a smoker, not had ever been a daily smoker.

Q. Let me ask the question this way.

You don't -- we don't know that the percentage that you gave to the court in your direct testimony is correct; is that right?

A. We don't know?

Q. No. We don't know that the percentage of current adult smokers who had been smoking daily is 71 percent; correct?

A. You mean if you take any particular age, we don't know that -- because some people may have quit? Is that your idea?

Q. People quit. Sure, that's one reason.

I'm just asking you. The number that you quote from the Surgeon General's report deals with ever daily smoking, it does not deal with people who are currently daily as adults.

And I think we've already established this; is that correct?

A. That's correct.
Q. And so in your testimony, I believe what you say is that adult -- over 70 percent of adult daily smokers smoked daily at age 18. Do you remember that?
A. Yes.
Q. Okay. And the truth of the matter is that that may not be the correct number. It's probably lower because this deals with those who had ever smoked daily; right?
A. Yeah. I'm not sure why it would be lower, though. I'm trying to think of mathematically how that could occur.
Q. Well, you just gave an example yourself, Doctor. People quit.
A. Well, but what you have to say is that there's a selective quitting, so that only the people who started smoking by age 18 quit, for some reason much more than the other ones.

And that doesn't make any sense because what we know is quite the opposite; that the earlier you start smoking the harder it is to quit.

So that -- I have to say these numbers just don't make any sense mathematically. I don't think it can be the case that this 35 percent represents current smokers age 35.
Q. The numbers upon which you based your testimony don't make sense to you; is that right?
A. No. This number that you gave me doesn't make sense.
Q. Do any of these numbers make since to you?

A. Yeah. The one that says of those ever smoked daily, 71 percent had smoked came by the age of 18. Those are the same data we talked about before. Those -- and those data have been cited widely.

What doesn't make sense is how you could take a snapshot of daily smokers and say only 35 percent smoked by age 18. There's no way mathematically that that can occur that I can figure out.

Q. Let me just ask you. Do you know the percentage of current adult smokers who smoked daily at age 18? Yes or no.

A. I have not seen data on that.

Q. Thank you. Let's turn to my final topic.

THE COURT: One other thing, Mr. Biersteker. I cannot find, although I know it's in here, the reference. It is not on page 31, which is what I think you told me.

MR. BIERSTEKER: That's what I understood, Your Honor. Let me look. Hang on.

39, Your Honor. I meant 39. If I said 31, I misspoke. Lines 3 through 10.

THE COURT: All right.

BY MR. BIERSTEKER:

Q. Let's talk about the completeness of compensation. Are you ready, Doctor?

A. Yes.

Q. Last topic. As I understood your testimony in your direct

examination you believe that smokers of the lowest tar cigarettes, the 0.2 milligrams FTC nicotine or below get 30 percent less nicotine. Is that right?
A. Yes.
Q. On average?
A. Yes.
Q. And you have calculated the percent compensation for that group and it's about 74 percent; is that correct?
A. That sounds right.
Q. And on that basis you believe that those very lowest ultralow-tar cigarettes, which are smoked by not many smokers, nonetheless pose a lesser risk of disease; correct?
A. I think it's likely. It's got to be validated, but I think it's likely.
Q. Now, even for higher FTC yields, the 0.3 to 1.5 milligrams of FTC nicotine, compensation is not 100 percent complete, is it?
A. No.
Q. In fact, you displayed a graph to the court during your oral direct examination yesterday that had data from Gori and Lynch in 1985; correct?
A. Yes.
Q. And I believe your testimony was that there was a 15 percent reduction in exposure to cigarette smoke, as measured by biomarkers for nicotine, over the point 3 milligrams to 1.5

milligram FTC nicotine range; is that correct?
A. Yes.
Q. Is that something you eyeballed or something you calculated?
A. I just did a rough calculation.
Q. How did you do that rough calculation?
You just pulled numbers off the way it looked to you when you read it off the graph?
A. Yeah. I tried to look at the numbers on the graph and then figure out what the change was over that span.
Q. You were looking at the plasma cotinine numbers when you did that?
A. Yes.
Q. Now, that daily intake -- that's a daily intake measure; right?
A. Yes.
Q. And so that measure would be net -- or would take into account might be a better way to put it -- that measure would take into account any tendency of the smokers of the cigarettes at the lower end of that range to smoke those cigarettes more intensively; correct?
A. Yes.
Q. And because it's a daily measure of nicotine intake, it also takes into account any tendency of the smokers of cigarettes at the lower end of that range to smoke more cigarettes; right?
A. Yes.

Q. So that reduction is net of both of the possible forms of compensation; correct?
A. Correct.
Q. I eyeballed it, too, and I think your number is a little low, 15 percent, I think it's more like 23 percent. So let's just take a look and I've got a series of demonstratives that come straight out of the article. I'll give you the article and then we will put up the three demonstratives.
The article is JD 040325. Do you have it, Doctor?
A. Yes.
Q. And if you will turn to page 319, you will see the graph that was reproduced on your demonstrative yesterday. It's the one in the middle, the plasma cotinine.
Let me see if I can get the scale in, too.
And here's what I'll do. Let's take these in order. First, I just had some technical people blow it up to make it bigger.
Okay?
A. Yes.
Q. And then I had them draw lines, what I'm told are absolutely parallel. Does that look about right to you?
A. Yes.
Q. And if you calculate the percent, you just divide 249 by 321, you end up with something about 77 percent, which means a 23 percent reduction in exposure; correct?

A. Yes.
Q. Okay. And a 23 percent reduction in exposure is not that much less than the 30 percent reduction in exposure that you find significant for the lowest ultralow-tar cigarettes; correct?
A. Well, the 30 percent reduction is really a clear deviation in the slope. I mean, a lot of studies have shown that the very bottom ones are just a much different population than the span across other cigarettes. So I think that the ultralows really are a different breed.

Certainly, within this, if -- there may be 23 percent across the whole span, but if you look at the popular cigarettes, which are the ones in the point 5 to 1 milligram yield, then the difference in cotinine levels is actually quite small.
Q. Gee, these data look pretty linear to me.

In fact, the authors drew an estimated regression line that went all the way through it that was straight, didn't they?
A. Yes.
Q. And, in fact, they found a highly-statistically significant relationship between FTC nicotine yield and plasma cotinine; correct?
A. Right. It was correlated, but the slope was shallow.
Q. Well, so what that means, though, is that smokers of the lower-tar cigarettes, after taking into account any tendency to

smoke more cigarettes or any tendency to smoke those cigarettes more intensively, were getting less nicotine; right?

A. That's what this shows, yes.

Q. And doesn't that suggest that those smokers are also getting less tar?

A. It's hard to know for sure because there is an interaction between smoking behavior and tar-to-nicotine ratios.

If you assume that tar-to-nicotine ratio was the same, then your statement is correct. But when someone -- or someone or a machine smokes a cigarette more intensively, the tar yield relative to nicotine goes up.

So, for example, a study we did showed that if you looked at a biomarker for tar, even though the machine determined tar-nicotine ratio is much lower for low-yield cigarettes when they are smoked more intensively by a person they are the same as higher yield cigarettes.

Q. The ratio is?

A. Ratio is.

Q. Well, if the ratio is the same if they are getting exposed to less nicotine they must, therefore, be getting exposed to less tar; correct?

A. Well, they -- they may be. My point is that you can't necessarily predict that; you really would have to measure it. In fact, we can measure it now.

Q. In your direct examination you talked about three different

kinds of studies with respect to compensation, and the first kind of study I want to look at -- we will talk about all three -- is the cross-sectional study.

And just to make sure we are all on the same page, the cross-sectional studies looked at smokers at a given point in time in the real world smoking their usual brand, and they measure how much nicotine they have been exposed to by using some biomarker, and they also obtained information from them on the yield, the machine yield, of their cigarettes.

A. Yes, it could be nicotine or some other biomarker, but that's correct.

Q. And as with the study from Gori and Lynch that we just had up on the screen, those studies -- the relationship in those studies between FTC nicotine yield and the different biomarkers is one that takes into account both forms of compensation; that is, smoking more cigarettes to the extent that it occurs or smoking cigarettes more intensively; takes into account both; right?

A. Yes.

Q. And you think that the cross-sectional studies provide the best estimate of chemical exposure to smokers smoking different brands of cigarettes; correct?

A. I do.

Q. And it's your opinion that the cross-sectional studies showed that the relationship between FTC nicotine yields and

biomarkers is a weak one; right?
A. Yes.
Q. And by a weak relationship, you mean that the correlation between FTC nicotine and these different biomarkers is low?
A. No. I mean the slope is shallow.
Q. You mean the slope is shallow?
A. The correlation is just a matter of how many samples you collect. You can see a high correlation with a very shallow slope, but the real issue is when you reduce the brand, how much of a reduction is there in exposure. If the slope is really shallow, then there's not much. The correlation talks about how much noise there is in that relationship.
Q. I understand. Let me first establish what you presented in chapter 3 of Monograph 13.
A. Yes.
MR. BIERSTEKER: And so that's U.S. Exhibit 58700, which I believe is already in evidence, Your Honor.
Q. And if you could turn to page 50, Doctor. That's going to be trouble.
When you're talking about the cross-sectional studies in Monograph 13, when you're talking about it, you say there's a weak or no significant correlation; right?
A. Yes.
Q. And, in fact, if you turn to page -- the next page, 51 to 52, you there -- hang on -- lay out in a table a number of

studies that are cross-sectional studies; correct?
A. Yes.
Q. And in the Result section -- I realize it's hard to see, but I don't think I can fit it in any other way -- you report the correlation for each and every study down the line; correct?
A. Yes.
Q. And in fact, isn't it true, Doctor -- and I think you just said this -- but you can have a really high correlation and you can still have significant amounts of compensation; correct?
A. I think I said the correlation was independent of the slope.
Q. That's the point, isn't it? Let me try it this way.
Correlation coefficient of the kind presented in this table are not the same thing as the slope which is a measure of the percent compensation; correct?
A. Right.
Q. Fine. And if I told you what the correlation coefficient was as you set forth in all of these different studies, you could not tell me what the slope or the percent compensation was in any of them; correct?
A. Right.
Q. All right. And in order to do that -- and the other point is also true. Not only are they not the same thing, but you can have high correlations with high compensation and you can have low correlations with low compensation because there's a bunch of noise, as you put it; correct?

A. Yeah. There's a problem with when the correlation is low so it's not significant, then it's hard to know how much of it is just statistical in fluke. So correlation is important for determining a significance of a relationship, but not the slope.
Q. And, in fact, I think over half of these -- well, I think over half of these were statistically significant correlations; correct?
A. Yes.
Q. Now, nowhere in Monograph 13 do you present the slopes or the percent compensation for all of those studies. The only thing you really present are the correlations. Correct?
A. I present several figures that show different studies, but you're correct, I don't calculate the slopes for each of these.
Q. And, in fact, I don't think you ever calculated the percent calculation for any of these cross-sectional studies until I deposed you in a case called Turner in Illinois last year and handed you a calculator so you could do it. Is that correct?
A. That sounds correct.
Q. And it's true that you didn't calculate the percent compensation for any of those cross-sectional studies in Monograph 13 despite the fact that in the monograph you say that that's what you're going to do; right?
A. Well, what was basically looked at were the curves. But you're right, I did not calculate the slopes.
Q. And, indeed, on page 44 of the monograph you tell readers

that you're going to do that where the data are available; correct?
A. Yes. Now, it does require having the raw data and it was done -- but, you're right, it was not done because the data were not available.
Q. Actually, if you go to the underlying articles that you cite in that table, Doctor, for a large number of them, you can't compute the percent compensation; correct?
A. If you have the data for each of the time points you can do that, yes.
Q. What do you mean "each of the time points"? These are cross-sectional studies, Doctor.
A. I don't mean time points. I mean each of the cigarette brand cuts. If you have the data you can do that.
Q. In fact, do you know whether or not after I took your deposition in that putative Illinois lights class action case, a report was filed by one of the defense experts in that case where he computed the percent compensation in all of those cross-sectional studies?
MR. BIERSTEKER: A report, Your Honor, that has also been submitted in this case.
THE COURT: In the defense case?
MR. BIERSTEKER: In this case, the United States vs Philip Morris.
THE COURT: No, but I said in the defense case.

MR. BIERSTEKER: Oh, yes, Your Honor.
A. Yes, I do think -- and I think I reviewed that, but I don't recall -- I had some concerns about the methodology, but I don't recall what those concerns were.
Q. All right. Well, isn't it true -- and we can pull it out if you want to see it -- but that Dr. Wecker looked at the percent compensation -- and, first of all, he looked at a very specific brand -- a very specific range of smokers. He looked at those who were smoking light cigarettes versus those who were smoking full flavored or regular cigarettes. Do you remember that?
A. Yes.
Q. I think you will find it on page 1.
MR. McCABE: Excuse me, Your Honor. Could the United States have a copy?
MR. BIERSTEKER: Sure.
BY MR. BIERSTEKER:
Q. Page 2, I guess it is.
And in his report on page 2, which is JD 065989, Dr. Wecker reports -- let's just take this in steps -- that he was able to look at nicotine intake for smokers of regular cigarettes and smokers of light cigarettes, those cross-sectional studies from your table in Monograph 13.
First of all, do you see that?
A. Yes.
MR. BIERSTEKER: Zoom in? Sorry. Better?

THE COURT: Yes.
BY MR. BIERSTEKER:
Q. And, in your view, the degree of compensation is likely to be highest when you compare the smokers of regular cigarettes to the smokers of light cigarettes than if you looked outside of that range; correct?
A. Yes.
Q. All right. And Dr. Wecker went in and did that where he could for the different studies in Table 3-1 of your chapter of Monograph 13 --
MR. McCABE: Objection, Your Honor, lack of foundation.
Q. -- and he reports that the median compensation amount was 47 percent; correct?
THE COURT: Let me deal with the objection.
What do you mean lack of foundation? The question was being formulated.
MR. BIERSTEKER: Let me just rephrase the question. If there's still an objection it can be interposed.
THE COURT: All right.
BY MR. BIERSTEKER:
Q. Isn't it true that Dr. Wecker, in his report, says that when he computed the percent compensation as between regular and light smokers for the studies in your table of Monograph 13, the median compensation amount that he found was 47 percent?
A. That is what he writes.

Q. And did you go back and check his calculations?
A. I have not.
Q. So you cannot dispute that finding; is that correct?
A. It doesn't make any sense to me, but I've not checked it.
If you just visually look at the curves, they do not look like 47 percent.
Q. If we visually look at the curves for a couple of studies for which you chose to present them; correct?
A. There are many studies, not just the two that I showed you.
Q. I understand. If compensation, as Dr. Wecker reports, is about 50 percent as between regular cigarette smokers and smokers of light cigarettes, that means there's less compensation there than there is for the ultralow-tar cigarettes where you said it was 74 percent and that you found was significant; correct?
A. If that's correct, then you're right, but again I'm skeptical.
Q. Why didn't you check?
A. Pardon?
Q. Why didn't you check his calculations?
A. I really don't remember the context in which I've seen this document. I don't know.
Q. Let's talk --
A. I don't think I have a copy of this. I think I saw it at some point in time in the Turner case.

Q. Let's move on to the experimental studies.

And I think you said this in your direct, but the percent compensation in the larger long-term experimental studies is about 75 or 80 percent; correct?

A. Yes.

Q. And that's not complete compensation, either, is it?

A. Correct.

Q. Now, in your direct examination you discuss some of the advantages and disadvantages of the experimental studies; correct?

A. Yes.

Q. And I think you might have left out something that is an advantage and I want to ask you about it.

In science, randomized experiments provide the best evidence of cause and effect; right?

A. Yes.

Q. And let me just explore for a moment with you why that's so, so that we all understand.

If you take a group of a thousand people and you put 500 of them on one-half of a room and 500 on the other half and you do it randomly, flipping a coin or however you're going to do it. Right? Are you with me?

A. Yes.

Q. On average, the two groups should be the same; right?

A. Yes.

Q. You should have the same number of men on both sides of the room?
A. Right.
Q. Same number of red heads?
A. Right.
Q. Same number of introverts?
A. Right.
Q. And it doesn't matter whether you can measure the characteristics, whether they are obvious to you or not, on average the two groups should be the same; right?
A. Right.
Q. And so if in an experiment you then take one group that is on average exactly the same as another and you give it some sort of intervention, you say, "I'm going to give you the drug and I'm going to give you the placebo," that enables you to isolate the cause and effect of the drug; correct?
A. Assuming that the study groups are large enough so they are really comparable. Both groups are comparable, yes.
Q. You've got to have a big enough group of people. You can't do it with 10 people, can you?
A. It depends on what characteristics you're talking about and how important they are, but the bigger the better.
Q. So would it be fair to say that the experimental switching stems where people are split into two groups; right?
A. Yes.

Q. And one group is randomly assigned to smoke a lower-tar cigarette and another group is assigned to smoke a higher-tar cigarette; right?
A. Yes.
Q. That those studies should enable you to isolate the causal effect of the differences in the design of the cigarettes without any confounding or clouding of the data by differences in the characteristics of the two group of people?
A. Well, that is one attribute of a randomized study, that's correct.
Q. Let's talk about the last category, the spontaneous brand switching studies.

You talk in your direct examination about your 1987 study with Lynch; is that correct?
A. Yes.
Q. And isn't it true that that is the only peer-reviewed pure spontaneous brand switching study?
A. Well, there's also the Peach study, but I don't remember -- I don't know if that fits in the category that you're suggesting.
Q. I don't think it does. And let me ask you a couple of questions to see whether you agree.

In your study you got baseline data on what cigarettes people smoked and a biomarker for nicotine; right?
A. Yes.

Q. And you also looked at other characteristics like gender, but those are the two key variables; right?
A. Yes.
Q. And then you waited and you followed them for 5 years; right?
A. Yes.
Q. And you had -- you weren't able to following up with all of them, but you got about half of them or so to come back into the lab again; right?
A. Yes.
Q. And when they came back in, you again measured the biomarker for nicotine; right?
A. Yes.
Q. And you again asked them what cigarette you're smoking to see if they had changed the FTC nicotine yield of their cigarettes in the intervening 5 years; correct?
A. Correct.
Q. Okay. In contrast, while Peach followed people over time, too, Peach didn't get any baseline data on biomarker for nicotine; correct?
A. That's correct.
Q. Okay. So in that sense, that's what I mean -- a pure spontaneous brand switching study in my mind is a study where you have baseline and follow-up data on a nicotine biomarker. Would you agree with that?

A. Yes. Those are two different designs, that's correct.
Q. Okay. And in that sense, I mean that yours really is the only peer-reviewed pure spontaneous brand switching study; correct?
A. Well, the only complete study I would say, yes.
Q. Now, your sample in your study was not one that's representative of the United States; correct?
A. I think these were people who were sampled in shopping malls, but I don't -- I don't remember the distribution.

This was a study that -- Dr. Lynch was involved with the sampling and my laboratory was involved with the analysis of the samples and the data analysis part of it.

Q. Let's take a look at the article. It's JD 063010.

And, Doctor, just, if you could, look at the second sentence in the discussion section beginning on the second page and let me just read it. "Our sample is not representative of the population of smokers in the United States."

Do you see that?

A. Yes.
Q. Does that refresh your memory as to whether or not the sample that you used in this study was representative of smokers in the United States?
A. Yeah. What I said first was true. They are from shopping malls, but probably because of that we had a high percent of women who spent more time in shopping malls, and if they are in

shopping malls they are less likely to be fully employed, so those were differences.

Q. Your study as not been replicated, has it?

A. No.

Q. And you think it should be; right?

A. Yes.

Q. And the reason you think it should be is that replication in science is a test of the reliability of the results from the study?

A. Yes.

Q. Let's talk about the results -- I do this with some trepidation -- as presented in figure 1 on page 1192. And let's start with the left-hand box. Okay? Are you with me?

A. Yes.

Q. The left-hand box is daily exposure to nicotine as measured by plasma cotinine; correct?

A. Right.

Q. And if we look at that figure in the left-hand box there are three different groups of people; right?

A. Yes.

Q. Okay. We are going to talk about all three of those, but the individuals who increased their nicotine yields from baseline to follow up, B and S, is the line I highlighted; right?

A. Right.

Q. And they were the people who, at the beginning of the study, were smoking the lowest tar and nicotine cigarettes; correct?
A. Yes.
Q. And at the beginning of the study, the people smoking the lowest tar and nicotine cigarettes were taking in the smallest amount of nicotine each day as measured by plasma cotinine; correct?
A. Yes.
Q. And, in fact, if you look up on the table, it's a little higher up on the page, but you present some data, and at baseline these folks were all smoking about the same number of cigarettes per day, weren't they?
A. Yes.
Q. Okay. And at follow up, the line that comes down, that's the one with the squares, those are the folks who during the course of the study switched to a lower tar and nicotine cigarette; correct?
A. Yes.
Q. So the people who switched to a lower tar and nicotine cigarette during the course of this study, they are the ones who at follow up, now they have the lowest nicotine intake per day based on plasma cotinine; correct?
A. Yes.
Q. So the people who switched to a higher tar and nicotine cigarette increased their daily intake of nicotine as measured

in this study, and the people who switched to a lower tar and nicotine cigarette decreased their intake of nicotine as measured by plasma cotinine; correct?

A. Yes.

Q. And, in fact, all three groups sort of moved in the direction you would have anticipated. I mean the trends are right, on the left-hand one.

Again the people who increased the yields, increased; the people who decreased, decreased; and the people who stayed the same, stayed about the same; right?

A. Yes.

Q. Now, let's talk about the right-hand column which is the per cigarette data. And in order to get that, you don't have separate measurements per cigarette; you just divide the daily plasma cotinine by the self-reported number of cigarettes somebody smokes; right?

A. Yes, and that gives you a measure of how much they are taking in per cigarette.

Q. And self-reported number of cigarettes smoked is not -- people tend to round, don't they?

A. They do.

Q. So that's probably a less precise measure than the measure of plasma cotinine per day; correct?

A. Yes.

Q. Let's see if we can do this.

At baseline, on average, the smokers who smoked the cigarettes with the lowest FTC nicotine yield, those are the circle guys again, the line that goes up sharply?
A. Yes.
Q. So that baseline, the folks smoking the lowest tar and nicotine cigarettes had the lowest estimated nicotine intake per cigarette; correct?
A. Yes.
Q. And at follow up five years later, the square box -- the line that goes across -- those are the people who are smoking the lowest tar and nicotine cigarettes. They are the ones who reduced the tar and nicotine yields of their brands; correct?
A. Yes.
Q. And in comparison to the other two groups, they now have the lowest calculated plasma cotinine intake per cigarette; correct?
A. Yes. I'm not sure if it's statistically significant, but certainly the averages are less.
Q. You don't present that calculation, I don't think.
A. No.
Q. All right. Now, let's talk about the trends.
The people who increased went up per cigarette; correct?
A. Yes.
Q. The people who didn't change their cigarette, the control group, the triangles, they increased the amount of nicotine they

were taking from each individual cigarette, too, didn't they?
A. Yes.
Q. And you don't know why that happened, do you?
A. No.
Q. It's not a case of escalating consumption because that baseline, all these people were in their 40s; right?
A. Yes. I'm not sure why there was an increase. It might have been a statistical chance thing. I don't know.
Q. Well, you refer to that group who didn't change their cigarette brands, the ones with the boxes, the triangles there as the control group; right?
A. Yes.
Q. And the thing about this is that the people who decreased the FTC nicotine yields of their brands basically stayed about the same on a per cigarette basis as calculated in this chart; right?
A. Yes.
Q. And so that kind of raises the question about what comparison you should make. And so let me ask you the question.
Isn't it true that in assessing these data one should compare the people who changed their cigarettes, the groups who changed their cigarettes, to what happened to the group that did not?
A. That certainly is a valid statistical approach.
Q. And the results from the control group suggests that if

people who switched to lower-yield cigarettes hadn't done so, they would have increased the amount that they were getting from each cigarette. They would have followed the triangle line; right?

A. That could be, yes.

Q. But the individuals who switched to a lower tar and nicotine cigarette didn't have that increase even on a per cigarette basis; correct?

A. Correct.

Q. And if we wanted to, we could calculate the percent compensation for the people who switched to a lower tar and nicotine cigarette compared to the controls, which we did in your Turner deposition. Do you remember that?

A. Vaguely.

Q. Do you remember that the percent compensation was only about 28 percent?

A. I don't remember the details of that.

Q. Let me just see if I can refresh your recollection on that.

MR. BIERSTEKER: If I could have Dr. Benowitz deposition in Turner dated May 9, 2003, and we're going to look at page 79 to 80.

Q. This isn't going to be terribly obvious, I'm afraid. But if you look at it in context, Doctor -- and you're free to look at pages surrounding it -- oops, going the wrong way -- I say, I came out with 24 percent, and then you say you came out with

28 percent.

First of all, did you just see the numbers?

A. Yes.

Q. Okay. And if you look back a couple of pages, it's clear that what we were talking about was the article that we've got up on the screen here, isn't it?

A. Yes. I don't remember which exact data points we were analyzing, but it was this article.

Q. In a way, isn't it true that the left-hand panel of this study, because it takes into account both forms of potential compensation, changes in cigarettes per day as well as changes in intake due to changes in the way they are smoked, is more important to understanding the phenomenon of compensation overall than the right-hand panel is?

A. Well, that would be the case, except that we found something which was not expected, which was that we found people who cut their yields down, smoked many fewer cigarettes per day, which is not true for the general population.

So, we speculated -- we don't know for sure -- that these were people who in fact were trying to quit smoking or reduce their exposure because they did something which is quite different than the whole population.

In general, people who are smoking low-yield cigarettes smoke as many or more slightly than higher-yield cigarettes, but we found a substantial reduction.

So, for whatever reason, these are not characteristic of low yield smokers in the population, which is why we could not explain -- why I don't think this is representative of the whole population.

Q. Well, in fact, all three of these groups, at least the point estimate, the cigarettes they smoked per day went down.

A. But in the low yield they went down a lot more.

Q. They went down a lot more. 6.6 cigarettes on average; right?

A. That's a pretty substantial change. And so we -- again, I said we speculated. These were people who are either trying to quit or cut back.

Q. But that is speculation; correct?

A. Yeah. But we do know that on average people who are smoking lower-yield cigarettes smoke the same or even slightly more than higher-yield cigarettes, and that was not the case after the switch. It was the case before the switch, but not after the switch.

Q. Now, in your testimony in this case as well as in Monograph 13, you compare this and this (indicating), and you say compensation per cigarette is complete; right?

A. Well, I basically said that there was no difference in intake per cigarette.

Q. On that basis you assumed -- you say compensation is a hundred percent complete; right?

A. Yes.
Q. Now, you say in your study on the first page that one of the goals you had was to recruit approximately 100 controls; right?
A. Yes.
Q. You shouldn't ignore the controls when you analyze the data, should you?
A. No.
Q. And by making the comparison that you chose to make in Monograph 13 and in your testimony in this case, that's what you do; you ignore the controls, don't you?
A. Well, we didn't make that comparison to the controls in the statistical analysis. We did comment on the behavior of the controls.

We just made the observation that per cigarette the intake of nicotine stayed the same. That's on the face of it valid.

The question is what happened to the controls? Why did the controls increase?

So, the question you're asking is a little bit different thing. It's if you intervene with two interventions, what happens?

What we did in our analysis is say, well, if we look at people who are smoking low-yield cigarettes at two different -- at one time when they switched down, what's that intake per cigarette? That's a different question than what you're asking.

Q. You know, I guess what I'm asking, though, is what's the proper comparison to make in order to interpret the study. Let me try to go back to the FDA paradigm.

You said earlier in your testimony that you participate in clinical trials with the FDA; right?

A. Yes.

Q. And isn't it true that the FDA requires that those clinical trials be what they call -- I guess the term of art is adequate and well controlled; right?

A. Yes.

Q. And the FDA requires that conclusions about the safety and efficacy of a drug getting tested in a clinical trial get compared to the control group, usually the group that takes the placebo; right?

A. Right, but there you're comparing the effects of an intervention.

Q. Well, here we're comparing the effects of switching. So let me try to just follow up on this hypothetical a little bit more and then turn back to your study.

If you did a randomized trial with a drug that was supposed to lower or affect cholesterol levels and you got your treatment group and you got your control group, the control group that's a placebo.

Now, what you find is that in the treatment group cholesterol levels go down, but you also find that in the

control group that got the placebo, they went down even more. Are you with me?

A. Yes.

Q. That drug is not effective, is it?

A. No, but what you are comparing is the effect of the intervention versus the effect of the experiment per se, and what you're saying is what's -- what's the change that's due to the intervention.

Q. Right. And what the question I would propose to you one should have ask in analyzing your study is what is the effect of changing on a per cigarette basis -- again, we already know overall they go down -- but what is the effect of changing on a per cigarette basis compared to what it would have been if you hadn't changed?

A. Well, if this was a controlled clinical trial -- and that was the question you asked, is what was the effect of changing versus not changing -- then your analysis is exactly correct.

These were not randomized. These were people who self-selected. And if we asked the question what happens when you switched to a low-yield cigarette, that was what we analyzed.

Now, if you said what happens in comparison to those people who didn't switch, then your analysis is correct.

Q. In fact, we know that what happens when you switch to a low-yield cigarette is that your overall nicotine intake goes

down.
A. That's what this trial showed, yes. But it was all due to smoking fewer cigarettes.
Q. Somebody could have gotten to the same position by smoking the same number of cigarettes and dropping their per cigarette intake; right?
A. But your question is what does the product deliver, not putting aside the compensation mechanism in general. What are the characteristics of the product?
Does a lower yield product deliver the same as higher yield product? This study says yes, it can deliver the exactly the same amount.
Q. But when you look at the population overall and you say what happened to them, you find that they decreased their yield; right? Their intake, rather.
A. What do you mean the population as a whole?
Q. The group that switched had the lowest at the end, and in the beginning they are about the same as the controls; right?
A. Because they smoked fewer cigarettes, and that was puzzle, we don't know why.
Q. Exactly. But that's why you have a control group; right?
A. But this is not a randomized control group, it's a convenience control group.
Q. I'm sorry. Let me follow that up.
You don't know why the control group increased the

amount of nicotine they were taking out of each cigarette; right?

A. Correct.

Q. By the same token, you don't know why the group that switched to lower tar and nicotine cigarettes maintained about the same intake per cigarette as calculated from self-reported number of cigarettes smoked; right?

A. Right.

Q. And the reason I proposed to you that you want to compare the group that switched from the lower-tar cigarette to the group that did not is because something might have happened.

For example, there were smoking restrictions that were imposed in the 1980s when you were doing this study; right?

A. Yes.

Q. Okay. And smoking restrictions might have prevented the people in this study from smoking as many cigarettes per day as they were at the beginning of the study; right?

A. Yes.

Q. Okay. We can sit here and we can hypothesize different reasons for why people changed the number of cigarettes they smoked per day the way they did and why they might have maintained or increased the amount of nicotine they took from each cigarette, but the point of the matter is we don't know and that's why the safest and the best way to interpret this study is to compare the folks who switched to the people who did not;

correct?

A. Well, that's addressing a different question.

That's saying if you switch, do you look different from people who stay the same based -- in this population? And what you say is fair.

If the question is people who switch products, does their exposure per cigarette change? Then you don't need a control group. You can say that it doesn't change. It depends on what question you're asking, and we were asking the latter question.

Q. You certainly would not generalize from this study -- I don't know how many people you have. What is it? Actually, I can tell you.

You have 62 people who switched to a lower tar and nicotine cigarette; right?

A. Right.

Q. And as we've discussed, your sample isn't representative of the population of smokers in the United States; correct?

A. Correct.

Q. And you would not infer from what happened to these 62 people on a per cigarette basis, which is based upon a rounded sort of estimates, the number of cigarettes smoked per day anyway, what happens to people's per cigarette intake when they switch across the whole country, would you?

A. No. And I have to say when we did the analysis in Monograph

13 we didn't rely just on this study or this type of study, we tried to look at multiple studies and see, Well, does it look like there's a lot of compensation? And the bottom line was, yes. It's not a hundred percent, but it's substantial.

So this is just one of many bodies of evidence. But I agree with you that you wouldn't take this one study and say this is what all switchers do.

Q. And, in fact -- let me just try to wrap it up. The main point that I think it's been made -- let me just make sure -- is that on a per day basis the smokers who switched to a higher tar and nicotine cigarette, even though they decreased the number of cigarettes they smoked per day, took in more nicotine; right?

A. They did.

Q. And isn't it reasonable to infer they took in more nicotine because they were smoking higher-yield cigarettes?

A. It could be. We speculated that these were for people who were still in sort of an acquisition phase of dependence --

Q. I know.

A. -- but it's just speculation.

Q. And it's kind of unlikely given that they were all, on average, age 42 in the beginning -- excuse me -- 40 years old in the beginning; right?

A. Well, for whatever reason they increased, which is not a common behavior to increase from low-yield cigarettes to high-yield cigarettes. Usually people go the other way around.

But this is what we found.
Q. The folks who did not change the tar and nicotine yield to their cigarettes kept their intake of nicotine roughly constant or might have gone up a little bit; right?
A. Yes.
Q. And the folks who switched to the lower-tar cigarettes decreased their daily intake of nicotine; correct?
A. But it was due to smoking fewer cigarettes.
Q. In this particular study?
A. Yes.
Q. Fair enough.
MR. BIERSTEKER: I think I may be done, Your Honor.
If you want to take maybe the afternoon break to give me an opportunity to look, I'll be happy to do that.
THE COURT: Okay. Let's take 15 minutes, everybody.
(Recess began at 2:53 p.m.)
(Recess ended at 3:13 p.m.)
THE COURT: Mr. Bernick.
MR. BERNICK: Yes, Your Honor. Mr. Biersteker informs me that his examination is concluded, so I'm going to pick up --
THE COURT: Oh, I know it had concluded. Anyway, go ahead.
MR. BERNICK: And I'm going to do my best to cover this and get the doctor out of here this afternoon.
CROSS-EXAMINATION

BY MR. BERNICK:

Q. So, Dr. Benowitz, you and I met just a few moments ago and we never met before, had we?

A. No.

Q. I want to try to cover the subject of ammonia and to do so in one hour, so we're going to have to make some progress here, but obviously if it's important for you to explain things during course of it that are responsive to my question, this is not intended to curtail either my examination or your testimony, but let's try to move through things here.

I want to ask you in particular about the impact of pH on nicotine absorption which as you will recall was part of your testimony on direct examination; correct?

A. Yes.

Q. And, in fact, it was your testimony that the nicotine from cigarettes is absorb rapidly into the human body; is that correct?

A. Yes.

Q. And, in fact, I believe your testimony is that the speed with which nicotine is absorbed is an important feature of the addictive qualities of smoking; correct?

A. Yes.

Q. Is it also true that absorption of nicotine in certain parts of the body -- certain parts of the respiratory system can be affected by pH?

A. Yes.
Q. Let's go through a little bit on pH and then become a little bit more specific.
Before we began here this afternoon I did a little chart here, which I'm sure you would have anticipated, is going to go from zero to 14. This is the pH scale.
PH scale goes from 0 to 14; correct?
A. Yes.
Q. And neutral is 7, which is in the middle; correct?
A. Yes.
Q. From 0 to 7 is acidic and from 7 to 14 is basic; correct?
A. Yes.
Q. Okay. Now, nicotine, I think you've made clear -- that has been the subject of testimony in this case, the form, the chemical form that nicotine takes --
THE COURT: Now, let me just interrupt for a minute. Two reasons, Mr. Bernick, that, despite our time constraints, you can't go too fast. One is the court reporter, the second is me. I have to be able to follow everything. So, I'd just keep that in mind.
MR. BERNICK: Okay.
BY MR. BERNICK:
Q. The chemical form that nicotine takes is dependent in part upon the pH environment in which the nicotine is located; correct?

MR. McCABE: Objection, Your Honor. The expert witness provided no testimony regarding pH or ammonia in his direct testimony filed with the court.

MR. BERNICK: It's a fairly simple response, Your Honor.

Number one, is that he was qualified and presented as an expert in nicotine pharmacology. We would show, according to his own articles, that this is a central feature of nicotine pharmacology is looking at pH.

The pH does affect absorption. The question is where does it affect absorption. He specifically raised the issue of absorption in his direct examination. He specifically tied that to addictiveness.

The issue of pH and addictiveness in how cigarettes use or don't use ammonia and how it relates to pH is a central aspect of our defense that, in fact, cigarettes are not more addictive by virtue of ammonia or pH.

So he's clearly opened the door in a variety of areas.

Moreover, his expert report in the case specifically discusses this. There's been testimony in the case from Dr. Farone; that Dr. Farone discussed his opinions both with Dr. Pankow and with Dr. Benowitz. Dr. Benowitz is here.

So, I don't think that this is a situation where Ockham's razor can be used to somehow draw a line very carefully to exclude this area of important testimony. Dr. Benowitz is

finally here. Let's find out what he has to say.

THE COURT: Government have anything further?

I'm going to allow the questioning. It is true it was not discussed in his direct, but certainly the issue of absorption and how that affects addiction was very important to the direct.

And, of course, at any point when Dr. Benowitz doesn't know an answer, he will tell us he doesn't know it. That's all.

BY MR. BERNICK:

Q. I think the question with which we left off was: Is it a fact that the chemical form of nicotine can be affected -- is affected, all other things being equal -- by whether the environment in which the nicotine is located is either acidic or basic?

A. Yes.

Q. And, in fact, if we're talking about an acidic environment, the nicotine is to varying degrees, depending upon acidity, going to be in bound form, and if it's in a basic environment the nicotine is going to be free, in free form or protonated; correct?

A. Yes.

Q. I'm sorry. Unprotonated.

A. Yes. It's not all bound and all free, but the proportion of the two changes with pH.

Q. And if we go to the Surgeon General's reports -- I'm showing

you U.S. Exhibit 60598, which is the 1982 Surgeon General report that's in evidence -- the Surgeon General's report creates a chart that's kind of like this chart. It has the pH scale on the bottom and then a percentage of nicotine along the side. I'll just put a hundred percent here. And it describes the relationship of bound and free nicotine depending upon pH; correct?

A. More or less. This talks about protonated nicotine. You're talking about bound nicotine. You're talking about what's in the smoke. But -- and, in general --

Q. Tell me what to put over here. What goes below 7? Protonated or unprotonated?

A. It depends, if you're talking about nicotine in a solution, that's what this figure from the Surgeon General's report talks about.

If you're talking about nicotine in smoke, then this relates to the bound versus free.

Q. Let's just talk about what's here.

The Surgeon General obviously thought that this graph was important because it elucidated the kinds of nicotine that could be found in smoke and in the human body; correct?

A. Right. This just talks about whether it's protonated or not protonated.

Q. So below 7, is it protonated or nonprotonated? Below 7.

A. It is protonated.

Q. Above 7, is it protonated or unprotonated?
A. Unprotonated.
THE COURT: And the definition of that term again, Dr. Benowitz? I know we've had it defined.
THE WITNESS: Protonated, it has to do with whether there is a hydrogen attached to it that gives it a charge, so if it's protonated, it means it's also charged. And unprotonated is like free base.
BY MR. BERNICK:
Q. Would it be better if we said free base, your words just now?
A. That's fine.
Q. If we look at the Surgeon General's curve, what we see is that if we simplify so that we don't make this distinction between mono and diprotonated, which are the first two curves, and simply draw the curve for the unprotonated nicotine, would that be the free base nicotine?
A. Yes.
Q. Essentially the way the curve looks, if I'm not mistaken, is it comes along and it starts to sweep up and eventually it looks something like that; right?
A. Yes.
Q. And that describes, essentially, as you increase in pH and the solution becomes more alkaline or more basic, nicotine in that solution is going to be increasingly -- in fact,

dramatically increasingly in a free base or unprotonated form; correct?

A. Yes.

Q. Okay. I would then like to take a look at the question of measurements that have been made of smoke pH over time. Has it been true that various people have sought to measure the pH of smoke over time?

A. Yes.

Q. And if we begin with JD 040395. Do you recall that a Dr. Morie from Eastman -- Tennessee, Eastman, published a paper in 1972 relating to the pH of smoke from U.S. commercial cigarettes?

A. Okay.

Q. Now, I'm going to do a little scale over here. We're going to come out to Morie in 1972. And what Morie reports in 1972 is that the pH of smoke is between -- from domestic blend cigarettes is from 5.2 to 6.2; correct?

A. Yes.

Q. So that would be something, just roughing it out on this chart, it would be kind of something in this area.

Is that Morie says it's 5.2 to 6.2. Dr. Brutaman and Hoffman published another paper in 1974 where they also recorded various measurements, correct?

A. Yes. I have to say I don't know where Dr. Morie got these numbers. I don't think he measured them himself, but he found

numbers somewhere.
Q. Well, you're familiar with Dr. Morie's paper. You've testified about it before; correct?
A. Right. But I'm saying that it doesn't say how he measured. He just gives a number.
Q. He gives a number. And again you are familiar with this paper, are you not?
A. Yes, I've seen it before.
Q. And you're also familiar with the Brutaman and Hoffman paper in 1974; correct?
A. I think so. I haven't seen the paper yet.
Q. Well, Brutaman and Hoffman published a paper that was actually cited by the Surgeon General in the 1982 report; correct?
A. I don't know.
Q. Brutaman and Hoffman, do you recall he had these curves -- this is JD 000735 -- where he showed the pH of various mainstream smoke of various tobacco products. And we see that under his data -- if we take 4, 5 and 6 -- 4 is the Kentucky reference cigarette, 5 is a blended filter tip cigarette, and 6 is the blended cigarettes without filters. Do you see that?
A. Yes.
MR. McCABE: Objection, Your Honor. The witness just received the paper and he said he didn't recall. At least he should have the opportunity to review the paper before the

questions are asked.

THE COURT: He can certainly take a look at it.

Have you ever seen it before?

THE WITNESS: I have seen it before, not recently, but I'm looking at the figure now, so....

BY MR. BERNICK:

Q. Isn't it true that what he shows, that what Dr. Brutaman and Hoffman show is that the pH deliveries of total mainstream smoke for these different cigarette products is somewhere between 5.5 and 6.2?

A. Yes.

Q. This is 5.5 and 6.2, and this is in 1974; correct?

A. Yes.

Q. And if we take a look, the Surgeon General over time in the various reports also has talked about the pH of mainstream smoke from U.S. cigarettes; correct?

A. Yes.

Q. And in the 1982 report, as an example, and this is Exhibit 60598, is it true that the Surgeon General at this point says that for U.S. blended cigarettes, the pH of the mainstream smoke varies between 5.5 and 6.2?

A. Yes.

Q. Is it basically the same interval reported by Brutaman. This is Surgeon General 1982, 5.5 to 6.2; correct?

A. Yes.

Q. And then you, yourself, have published a paper in much more recent times where the lead author was Mia Sohn; correct?
A. Yes.
Q. And, I'm sorry, I don't have -- what's the exhibit number of this? Do you have that? It's the one in Nursing Oncology. 2003, November 2003.
This is JD 013052. You yourself published an article together with Dr. Sohn in November of 2003; correct?
A. Yes.
Q. And in your article you give a review of tobacco use and dependence, do you not?
A. Yes.
Q. This is now -- we are all the way over here in '03, and it's Sohn, and you're one of the other authors; correct?
A. Yes.
Q. Isn't it true that what you report is that in U.S. cigarettes the pH range is between 5.5 and about 6; correct?
A. Yes.
Q. Now, if we take a look at all these different reports over time, would it be reasonable -- reasonable -- Dr. Benowitz, to say that by and large the pH of smoke by the techniques being used to measure it has been consistently reported for U.S. cigarettes as between basically 5.2 and 6.5?
A. Yes.
Q. Now, it is true that there are now people have explored

different techniques for either measuring or calculating pH; correct?

A. Yes.

THE COURT: 5.2 to 6.5?

MR. BERNICK: 5.2 to 6.5. Some of the figures, Your Honor, go up to about 6.5, and I don't want to quibble around that with the witness. It does not make that much difference to my examination.

BY MR. BERNICK:

Q. At the time that you wrote in November of 2003 and you used the figures 5.5 to 6.0, you were already cognizant of the fact that people like Dr. Pankow were using different techniques in an effort to pursue other theories; correct?

A. Yes.

Q. And it is also true that any of these techniques and all of these techniques have limitations, do they not?

A. Yes.

Q. And it is also true that over approximately 30 years of time techniques that have been used most frequently are the techniques that are reflected in the various numbers that I've put up on the chart. That is, these are the techniques that generally have been used to measure pH of smoke; correct?

A. Right. But I do have to say that Dr. Pankow's technique has been thought to be a significant advance in the field because it's been tough to measure pH in the past.

Q. Well, Pankow's technique has actually varied over time, has it not?
A. Well, the main part of it is just looking at the partitions of nicotine and then backcalculating pH.
Q. But using -- he's done partitioning of different kinds of particles and different contexts; correct?
A. Yes.
Q. Prepared differently?
A. Yes.
Q. And the paper that he did, he actually submitted in 2003 even before your own paper was published; correct? His most recent paper.
A. Yes, I think so.
Q. And, in fact, isn't it also true you say that this is the method that's now been preferred? You don't even mention the method in your own paper, do you?
A. Well, this was a global review of --
Q. Do you mention the paper?
A. No, I don't.
Q. Okay. And, in fact, in papers that Dr. Henningfeld, who will testify here shortly, has written on this entire subject, he doesn't say that Dr. Pankow's method is the preferred method, he says that there's now a debate, a debate about how to do this measurement; correct?
A. I don't know what he said.

Q. Are you not familiar with Dr. Henningfield's paper that was published in April of this year?
A. I don't know which paper you're talking about. He's published lots of papers.
Q. A paper that he co-authored with Dr. Pankow himself?
A. I have read a paper.
Q. In that paper don't Dr. Pankow and Henningfield themselves say that his technique is part of a debate?
A. It could be. I don't remember the words. I don't remember every word of every article I read.
Q. In any event, you would agree with me, as you've testified previously, that the 5.2 to 6.5 range is a reasonable range for the pH of smoke?
A. Well --
Q. Hasn't that been your testimony?
A. That certainly is the range that has been determined by techniques up to the present time.
Q. Well, but your testimony more specifically in the Schwartz case was that it was a reasonable range; correct?
A. Yeah. Well, I stand by what I said. This was the best that could be done.
Q. Is there something that -- I don't want to quarrel with you. Is there some reason why you wouldn't say, as you said when you testified at trial in Schwartz, that it was reasonable?
A. Well, the only question would be, as we just talked about,

is whether the Pankow technique will turn out to be better.
Q. Turn out to be. But at this point in time, and as you have testified, the technique that had been used historically was a reasonable technique?
A. Yes.
Q. Okay. Now, if we assume that that technique is reasonable, and we assume that the range is somewhere between 5.2 to 6.5, whatever, isn't it a fact that at this range virtually all of the nicotine is protonated; that is, it's bound nicotine?
A. Yes.
Q. And that's exactly what it is that Surgeon General said, actually repeatedly, but beginning in the 1979 Surgeon General's report; correct?
A. Yes.
Q. Let's take the next step. Let's talk about factors affecting pH. I'm going to go from this board to another one.
It's true that there are a variety of factors -- excuse me, Dr. Benowitz -- that can affect pH?
A. Yes.
Q. In fact, if we just go to basic agronomics -- that is, how tobacco is grown and how it's harvested -- isn't it true that one of the factors that can affect pH is stalk position?
A. Yes.
Q. Tobacco taken from up on top of the plant has more nicotine than tobacco taken from the bottom of the plant; correct?

MR. McCABE: Objection, Your Honor. The witness is not an --

THE COURT: No, but he's clearly familiar, and this is so basic, that even I know it at this point, so I'll allow him to testify.

MR. BERNICK: We will move through it very quickly then.

BY MR. BERNICK:

Q. We are agreeable, are we not, that stalk position can affect pH?

A. Yes.

Q. And stalk position can affect pH even to the point of -- this is again from JD 000735 cited in the '92 Surgeon General's report.

We can see here that stalk position can make a difference -- and can make a difference in pH in the order of 1 unit; correct?

A. Yes.

Q. There are seasonal variations in tobacco and pH; correct?

A. Yes.

Q. If we deal with different kinds of leaf -- that is, types of tobacco -- those can also affect pH; correct?

A. Yes.

Q. And, for example, the difference between barley and flue-cured can produce a difference of, again as much as a unit

of pH; correct?
A. I think so.
Q. If we talk about types of cigarettes which used these different types of tobacco, we can get French cigarettes versus U.S. cigarettes -- I'm not going to make any political comparisons here -- French cigarettes versus U.S. cigarettes can be a difference of up to 1 pH unit; correct?
A. Yes.
Q. And, finally, when we talk about sugars, it's often the case, it's been true for a very long time, that different sugars are added to the tobacco leaf during the cigarette fabrication process; correct?
A. Yes.
Q. And sugars, if you add sugars in, adding sugars decreases pH, less sugar will mean that the pH is higher; correct?
A. I believe that's correct.
Q. If you have more sugar, you're going to have a more acidic slope; correct?
A. I think so.
Q. Now, isn't it a fact that no study -- even with these potential differences -- no study tells us, for example, that French cigarettes are more or less addictive than U.S. cigarettes; correct?
A. That's correct.
Q. Let's push on and talk about ammonia. Let's put this on the

board here and talk about ammonia.

Ammonia generally has been added in connection with the process of making reconstituted sheet; correct.

A. Yes.

Q. I've got a little demonstrative here. I don't want to spend a lot of time on this, and if you don't know about it, tell me right away and we will spend even less time because we don't have much.

But basically when tobacco paper sheet is made out here at the bottom, there are several steps where you pulverize the tobacco, you then treat it, you then age the slurry, and then you put it between the two rollers and you dry it out and then it goes for a cutting and processing; correct?

A. Yes.

Q. In that process, isn't it true that historically ammonia has been added during the treatment stage, and when it's added in the slurry, it releases pectin, and pectin serves as a binding agent to keep that sheet together; correct?

A. Yes.

Q. So ammonia as added has served a manufacturing process purpose; correct?

A. That's my understanding, yes.

Q. And if we talk, therefore, about recon -- reconstituted tobacco -- isn't it true that if you have reconstituted tobacco this has the effect -- reconstitution has the effect of lowering

the amount of nicotine in the mix; correct? That is, recon has lower nicotine than you find in the traditional blend; correct?
A. In general, that's true.
Q. Okay. Now, I want to get to what I think counts here, which is that ammonia, when it's used as part of recon, as indicated in this chart, recon involves a combination or a recipe where you're doing a lot of things at once. You're using reconstituted tobacco, which is more oriented towards the stem rather than the leaf; correct?
A. Yes.
Q. You're using ammonia for the binding purpose that's been described and you're also adding sugars into the process; correct?
A. Yes.
Q. So now the question becomes if you take this combo, what does the combo do to pH? And people have looked at that question; correct?
A. This is really getting beyond my area of expertise in terms of this manufacturing issue.
Q. I don't mean to ask you as a manufacturing issue. I'm asking on the pH side.
Are you familiar with the fact that different people have studied the effect of adding ammonia as part of recon on pH? For example, Dr. Pankow.
MR. McCABE: Objection. The witness just testified

that he wasn't familiar with this area of testimony.

MR. BERNICK: Well, I think --

THE COURT: The question --

MR. BERNICK: Let me rephrase the question. I'll withdraw it and rephrase it.

THE COURT: All right.

BY MR. BERNICK:

Q. Dr. Benowitz, isn't it true that ever since at least the ironworkers' trial in 1998, you specifically have commented in your testimony on whether, in fact, the addition of ammonia changes pH and, therefore, changes the absorption qualities of smoke in the human body?

A. Well, what I have said --

MR. McCABE: Objection. What he's testified to before has no relevance in this action.

THE COURT: No. Objection is overruled.

A. What I've said is that I've seen tobacco company documents that indicate that adding ammonia has the potential for increasing pH.

But I have no personal experience with this. I don't know how much ammonia is added. I don't know how much pH is affected. I really do not know any details of ammonia and the tobacco manufacturing process and the impact on pH.

Q. You're really sure you want to stand by that, Dr. Benowitz? I mean, in fairness.

A. Yeah. Anything I know is what I just read in tobacco company documents.
Q. Well, first of all, isn't it true that what you testified -- what you submitted as part of your expert report in this case actually says, "One engineering approach is to add ammonium salts to tobacco. Adding ammonia increases the amount of free, paren, unprotonated, close paren, nicotine in the smoke, which results in a greater perceived nicotine impact by smoker."
Wasn't that your own expert report in this case?
A. Yes, but in terms of the details of what ammonia does in the manufacturing process, this is what I have read in tobacco company documents. I've never been involved in manufacturing cigarettes and adding ammonia.
Q. You submitted this as your expert opinion in this case, did you not, Dr. Benowitz?
A. Yes, but then that's based on tobacco company documents.
Q. So you don't know whether this is true or false?
A. Well, that's what the document -- that's what industry says in the documents.
Q. With due respect, I know that the industry documents comment on this, and I'm not asking you about the industry documents. I'm asking you about whether as an expert the opinion that you offered here was a true opinion or not.
A. If the documents are true, then this is true.
Q. You don't say that in the expert report, do you?

A. Well, I don't know -- this is not cited. But, you know, I've never manufactured a cigarette, and everything I know about ammonia is what I've read in industry documents.
Q. You've never read Dr. Pankow's study of ammonia?
A. Well, yes, I know what his study shows, but I don't know that -- that -- how that relates to the manufacturing thing you were talking about.
Q. Set aside all the manufacturing. Just forget it. I only want to ask you about pH measurements.
A. Well, if you add ammonia to tobacco smoke in certain levels you can affect pH, and that's been the argument about whether it affects the amount of free base and the absorption and impact.
Q. I'm happy to and I'm prepared -- are you familiar with the study that was done by Dr. Reichert at Lab Stat on the pH of different cigarettes for the state of Massachusetts?
A. Yes, I think so.
Q. And are you conversant? Are you prepared to talk as an expert about that data?
A. I've just looked at that data casually. I'm not prepared to talk about that as an expert.
Q. Maybe we can short-circuit this because I do not want to ask you something that you're not capable of offering expert testimony in.

Can you state as an expert that the ammonia that's been added to U.S. cigarettes made by these defendants has had any

impact whatsoever on the pH of smoke that they deliver?
A. No, I do not have any information about that.
Q. That will make my examination faster.
Let me talk about absorption. Incidentally, you're very familiar with Dr. Henningfield, are you not?
A. Yes.
Q. And you and he have worked together and published papers together; correct?
A. Yes.
Q. And you're familiar with his area of expertise and what he's qualified in?
A. To some extent, yes.
Q. Well, how long have you guys worked together?
A. Well, I don't know every single thing he does, but I know much of his work.
Q. Is he any more qualified than you are to talk about whether the addition of ammonia as it done in U.S. cigarettes actually has had the effect of changing pH in mainstream smoke?
Are you -- is he any more qualified than you to testify to that matter as an expert based on your knowledge?
A. I have no idea what research he's done in that area, so I can't comment on that.
Q. Have you and he ever talked about that?
A. Talked about?
Q. Whether the addition of ammonia to U.S. cigarettes as it

takes place affects pH.
A. We've never had the conversation about whether he knows any data about that.
Q. Have you ever seen any paper that he's ever published that analyzes that question scientifically?
A. I think he's stated that that's what he believes. I don't recall data supporting that fact.
Q. Has he ever told you that, in fact, that it's true scientifically that the addition of ammonia to U.S. cigarettes has had the effect of raising the pH of delivered smoke?
A. I think that's what he believes, but I don't know that I've ever -- we ever talked about what the data are supporting that.
Q. Have you ever talked with Dr. Farone about that issue?
A. We have had conversations. I don't know if we talked about the magnitude of effect. What he's told me is that he has data that indicates that ammonia allows the easier dissociation of nicotine from tobacco fiber.
Q. Have you ever looked at that data?
A. No.
Q. Have you ever expressed any agreement with Dr. Farone on any subject at all relating to the effect of adding ammonia on pH?
A. Expressed? Well, he has data that I don't have access to. It's not my area of expertise, so I've not either accepted or challenged it. I have no comment about it.
Q. Do you know what that -- have you ever seen the data?

A. No.
Q. Has Dr. Farone ever published the data?
A. I have no idea.
Q. Are you aware of whether Dr. Farone has ever produced that data in litigation at all?
A. I have no idea.
Q. Now, Dr. Farone is not qualified as an expert in your view, is he, to express views as an expert on whether the addition of ammonia to U.S. cigarettes affects the absorption of nicotine in the human body? He doesn't have those qualifications, does he?
MR. McCABE: Objection, Your Honor, calls for a legal conclusion.
THE COURT: Sustained.
BY MR. BERNICK:
Q. Let me ask it a differently. I won't ask for the ultimate legal question. I'll ask within your interactions with Dr. Farone in your field, is he in your field somebody who is recognized as an authority on the question of whether adding ammonia to cigarettes affects the absorption of nicotine by the smoker?
MR. McCABE: Objection, Your Honor, calls for the same effect in the answer.
MR. BERNICK: I'm --
THE COURT: Sustained. I don't think he should be commenting on Dr. Farone's degree of expertise. Dr. Farone

testified.

MR. BERNICK: Fair enough. I'll drop it. I just want then a fact.

BY MR. BERNICK:

Q. Have you ever seen Dr. Farone present a paper at any scholarly conference that you're aware of addressing the issue of whether ammonia in U.S. cigarettes affects absorption?

Have you ever seen him or heard of him delivering such a paper?

MR. McCABE: Objection, Your Honor, relevance.

THE COURT: He can answer yes or no.

A. Not at a meeting that I've been at. I don't recall.

Q. Have you ever seen an article published in the peer review journal by Dr. Farone on that subject?

A. I don't think so.

Q. Have you ever come into contact with Dr. Farone in any context other than litigation?

A. I might have met him at a meeting. I don't have the specific recollection.

Q. How many times have you seen him -- or how many times has he been in the same cases as you ever been in litigation?

THE COURT: Sustained on the basis of irrelevance.

Q. Dr. Benowitz, I want to pursue then the question -- set aside cigarettes and manufacturer and talk about absorption. Okay?

All I've done here is to put on a board -- this is J-DEM 010082, which is a profile of certain parts of the human anatomy and I've drawn some categories over here to fill in. And I'm going to try to fill it in as promptly as we can.

First, let's talk about cigars. Is it true that cigars, cigar smoke has a higher pH than what we talked about in connection with cigarettes?

MR. McCABE: Objection, Your Honor. He doesn't talk about cigars in his testimony.

THE COURT: That's true.

MR. BERNICK: I can establish a foundation I think quite easily.

BY MR. BERNICK:

Q. Is it true that our knowledge about how nicotine is absorbed in the human body is based not only on information relating to cigarettes but information relating to cigars?

MR. McCABE: Objection, Your Honor. Beyond the scope of the direct.

MR. BERNICK: It is directly relevant as I think Your Honor will see in a few questions.

THE COURT: I'll allow a couple of questions. Go ahead.

BY MR. BERNICK:

Q. Well, let me just ask you this so maybe we can prompt a little bit of focus here.

It's true, is it not, that the pH of cigar smoke does affect its absorption in the human body?

A. Yes, it affects the site of absorption.

Q. Site of absorption.

In order to get to that point, can we understand that cigars, as reported in the Surgeon General's own reports and as reported in your own articles, Dr. Benowitz, cigar smoke probably has a pH between 6.5 and 8.5?

MR. McCABE: Objection, Your Honor, beyond the scope.

MR. BERNICK: It is centrally relevant. It's in his own articles, and we're going to see how pH has an impact on site of absorption, including the contrast between cigars and cigarettes, which is extremely instructive. It's in the Surgeon General reports. It's in his own articles.

MR. McCABE: Your Honor, the objection wasn't relevancy, it was the scope of the direct.

MR. BERNICK: This is directly relevant to the same subject.

THE COURT: I'm going to allow it. It certainly appears to me to be related to direct.

It may be on redirect, that it comes out that there is no reason to compare cigars and cigarettes or discuss them in the same breath, but for now, it certainly appears to me that they are related. So you may go ahead.

BY MR. BERNICK:

Q. Did I get that range about right?
A. Yes.
Q. Is it true that in the mouth and throat area cigar smoke, from a taste and sensation point of view, is harsh?
A. Yes.
Q. And can be irritating?
A. Yes.
Q. Is it true that in terms of absorption, due to its high pH, it being alkaline, that cigar smoke is readily absorbed in what's call the buccal or buccal mucosa which is the membranes around the mouth and the throat?
A. Yes.
Q. So here we have high absorption; correct?
A. Yes.
Q. Is it true that when we come down to the lung, that cigar smoke is rarely inhaled, precisely because of its harshness and irritation?
A. It depends if you're a primary or secondary cigar smoker.
Q. I'm sorry. I don't understand. I don't understand what you're referring to.

What are you referring to?

A. A secondary cigar smoker is a person who smoked cigarettes before and switches to cigars and some of those do inhale. If you're a person who just smokes cigar, most cigar smokers don't inhale.

Q. One reason they don't inhale is it's pretty irritating to do that?
A. Yes.
Q. There's been testimony in this case that by increasing pH it makes the smoke less irritating. Does that make any sense to you?
A. No.
Q. Let's now talk about cigarettes.
Cigarettes we've seen have been at least rated as having a pH between 5.5 and 6.5; correct?
A. Yes.
Q. And based upon the little chart that we drew, there's a pretty significant decline in free base or unprotonated nicotine when you come down from 8.5 to 6.5 to 5.5, isn't there?
A. Yes.
Q. Okay? At this pH is it true that there still can be an effect of nicotine, including specifically the free nicotine in the mouth and throat area with cigarettes?
A. Yes.
Q. And what is that effect called?
A. It's been called impact, it's been called bite, different terms.
Q. And impact refers to a sensory experience; correct?
A. Yes.
Q. That is, in the afferent nerves or the sensation around the

back of the throat; correct?
A. Yes.
Q. Just so we are clear, we are talking -- impact, we are always talking about anatomically over here; correct?
A. Yes.
Q. It's true, is it not, that the impact -- there can be a greater impact if there's free nicotine because it is absorbed more readily at that location?
A. Not because it's absorbed more, it's because it is free to interact with the afferent nerves.
Q. Fair enough.
Is it also true that to have impact, you are not talking about the nicotine going up into the brain. You're simply talking about its interaction with sensory nerves in the area?
A. Yes.
Q. Now, the brain ultimately can become aware of the fact that there are those sensory experiences taking place; correct?
A. Yes.
Q. Okay. And people have asked you, have they not, whether the fact of there being impact from cigarettes itself is part of the addictiveness of cigarettes?
You've been asked that question, have you not?
A. Yes.
Q. Hasn't your testimony consistently been that you can't say

as a scientist that impact actually either addicts or enhances addiction? You just can't make that statement as an expert today; correct?

A. Right. I said that I think it's likely, but I can't prove it.

Q. Okay. And, therefore, if we are here as an expert talking about what might be so, you'll say it might be so, I think it might be likely, but you can't present us the data or the proof today; correct?

A. Correct.

Q. Okay. Let's talk about absorption. That is beyond the sensory effects, how much actually gets absorbed at this point; that is, in the mouth and throat.

Isn't it a fact that there is little absorption of cigarette smoke in the mouth and throat?

A. Well, little absorption of nicotine.

Q. Little absorption of nicotine?

A. Yes.

Q. Now, let's talk about the lung.

The situation in the lung with cigarette smoke is that 90 percent of the nicotine is absorbed rapidly. Isn't that a fact?

A. Yes.

Q. And when we get down into the lungs in contrast to the oral and upper throat, the lungs are an incredibly -- I want to say

crinkled, curvy, very compacted set of lots and lots of cavities; correct?
A. Yes.
Q. If you actually -- I think it's been said that if you were to take the lung sacs and spread them all out, that they actually are so -- there's so much surface area, it would be almost like the area of a football field; correct?
A. That or a couple of tennis courts. People use different analogies.
Q. A lot of area?
A. Yes.
Q. Isn't it true that in that area, that is in the lung area, the bodily fluids in that area are basically in the 7 pH area, actually a little bit over 7?
A. About 7.4.
Q. 7.4. And because of the -- of that higher pH and the overwhelming amount of fluid and surface area, that by the time the smoke gets down into the lung, it is -- the nicotine is absorbed rapidly regardless of pH?
A. Well, I like to just qualify the answer to that if I can.
Q. First of all, can we establish that not only have you published that statement, but you published it repeatedly and you've testified to that repeatedly?
A. No, I'm not going to say that that's incorrect. That is correct. But I know the question that's come up is whether pH

can make it be absorbed even faster than rapid.
Q. Okay.
A. So that's the qualification. This is absolutely true.
Q. This is absolutely true.
And what you're saying is that there is a question that's been raised about whether pH might have an effect of speeding it up.
A. Right.
Q. And that's what it is at this point, it's a question; correct?
A. I've not seen empirical data to support it.
Q. Let's talk a little bit about that and then I think we can close out my examination.
I want to show you J-DEM 010086, and I think you will see that it's exactly the same graphic, but I've put the word "theory" up at the right-hand, which is the theory that you've just talked about. I think you said it was a question. Right?
A. Yes.
Q. I want to talk a little bit about that as it relates to the same kind of diagram.
The first thing I want to do is to explore all the different steps of the theory, and I want to do it very, very quickly because I think we can do it quickly and then I want to talk a little bit about what kind of inquiries have been done.
First, I've got a little circle here that I'll tell you

is supposed to represent a part of the lung, an area of the alveoli. Okay? And then I've blown this up. Alveoli. I've blown it up big so we can look in like we're looking in with kind of a magnifying glass. It's actually probably a microscope and the scales won't make any sense, but you tell me if I'm going astray.

If we were to take that little microscope in there, we could do a cross-section or look cross-sectionally at the membrane between the space outside -- or within the lung, the cavity of the lung on the one hand, and the membrane that then is the surface, the inner surface of the lung. And that's what I mean to represent here is the membrane.

Is there a name for that membrane? Is it the alveolar sac.

A. Well, the whole thing is called the alveoli. The membrane is sometimes called the alveolar capillary membrane. It's just the liner through which things get absorbed.

Q. And inside of this line -- inside of these linings there will be blood. This will be a capillary, for example.

A. Blood vessels, yes.

Q. Now, as I understand the theory, step one is to take a particle of smoke and determine whether changes in -- what the effect might be if there are changes in pH.

So step one is the pH -- determining the pH of the particles; correct?

A. Yes.
Q. We will put a little 1 here.
Then the second step of the theory is that if the pH is high enough, it will, in going into vapor, it will go into vapor in less time; right?
A. Right, so there's more nicotine in the vapor phase.
Q. The nicotine goes out of the particle and into vapor more quickly or in greater proportions; correct?
A. Yes.
Q. If that's so -- this is step 2.
Step 3 would be that if there is a higher level of vapor, that nicotine will be absorbed into the bloodstream more quickly?
A. Yes.
Q. And if it's absorbed into the bloodstream, that's number -- that's absorption -- let's see, 1, 2. That's step 3.
If it's absorbed more quickly, it will then make its way out of the lung -- which is the carotid artery? Which artery, is it -- which artery takes it to the brain?
A. Well, it goes in the lung and out to the carotid artery.
Q. This one here?
A. Yes.
Q. I'm glad I didn't show you my chart.
It goes out over here into the brain. That's step 4. And the idea is that if it's faster here -- that is, if there's

higher pH, it vaporizes more quickly and it makes its way into the bloodstream more quickly -- maybe it makes it's way to the brain. There's a saving in time to the brain more quickly; correct?

A. Yes.

Q. And if it makes its way to the brain more quickly, in order for it to be significant, it has to be perceived, it has to be perceptible to the smoker; right?

A. Yes.

Q. So the difference here has got to make a difference all along. And ultimately step 5 is that it's perceptible to the smoker, and if perceptible to the smoker leads them to step 6, which is it effects smoking behavior.

And if it affects smoking behavior in a certain way, step 7 is that maybe it increases the level of addictiveness. Correct?

A. Yes.

Q. Is this basically the theory that we're talking about?

A. Yes.

Q. Okay. Let me get a couple of points in place here.

As we sit here today, isn't it true that we don't really know what the pH of smoke particles in the alveolar space is. No one has actually done that measurement; correct?

A. Correct. I think one -- people have assumed that it's the same as the smoke going in, but it may change on the way down.

Q. We just don't know.

No one has taken the step of demonstrating that any changes in pH lead to a higher level or a higher concentration of vapor; correct?

A. Well, that's really basic physical chemistry. That will happen just by laws of physical chemistry.

Q. We say physical chemistry. This is something kind of -- the law of nature.

A. Right.

Q. So I'll say law of nature.

But because we don't know that there's a difference what the pH is, we don't know that, in fact, particle pH actually does -- has changed the level of vapor in the lung; correct?

A. Correct.

Q. Likewise, we don't know today that changes in pH involving any kind of cigarette actually does change the rate of absorption; correct?

A. Well, we know if there is more nicotine in the vapor phase, that nicotine will be absorbed faster, but we don't know how much more there is in that phase.

Q. We don't know whether this is significantly faster; correct?

A. Right. We don't -- well, at least I don't know the time parameters.

Q. Don't know the time parameters.

In fact, in your testimony you've referred to Dr. Chaning Robertson, have you not?
A. Right. He's the person who really I think is the best person to try to get if time frame of this.
Q. And Dr. Chaning Robertson actually has only set out his theories on this when he testified in the Minnesota trial; correct?
A. I guess so.
Q. Well, I cross-examined him at that trial, and I will represent to you that he said that the absorption phase in any event is milliseconds.
Do you have any reason to disagree that the absorption phase is a matter of milliseconds?
A. No.
Q. If it's a matter of milliseconds, we know that the time that it takes for blood in the capillary here to get up to the brain is between 15 and 20 seconds; correct?
A. Correct.
Q. And, as a result, would you agree with me that if the potential effect on absorption is a difference of milliseconds, that that's unlikely to make a real difference in the time that it takes to get to the brain?
A. If that's the only time parameter, then I would say yes.
Q. And you would certainly agree with me -- I think you've testified in connection with the Rose article -- that even a

difference of going from 20 to 30 seconds really wouldn't make a difference to the smoker, would it?
A. Well, I think I speculated about that. I don't know that anyone has looked at that experimentally.
Q. Well, your testimony under oath in the Blue Cross & Blue Shield case was that if Rose was right in his article and it took 30 seconds to get to your peak concentrations rather than 15 or 20, that was unlikely to make a difference; correct?
MR. McCABE: Objection, Your Honor, argumentative. If he wants to show him the testimony from the Blue Cross & Blue Shield to see if he agrees with it.
THE COURT: I think he's trying to deal with prior testimony as quickly as possible.
Do you need to see that testimony?
THE WITNESS: No. I think the issue is not whether -- the issue is really whether -- none of it is reinforcing, because I think it would be reinforcing at 30 second or 14 seconds. Whether it could be more reinforcing, that's the question, and I don't have information about that.
BY MR. BERNICK:
Q. You just don't know.
So when it comes to the question of whether this difference in milliseconds would make a difference in terms of perception of the smoker, that's again something that you don't know?

A. Right. The studies have just not been done.
Q. The same thing is true of behavior; whether any potential speed in milliseconds would affect behavior, that's another unknown?
A. Correct.
Q. And whether any fluctuations -- for example, at the present time as an expert you really can't say one way or another whether any changes to the pH of smoke that results from any aspect of commercial cigarettes, you can't say as an expert that any of that has an actual effect on the addictiveness of smoking, can you?
A. I know of no such data, that's correct.
Q. What?
A. I know of no such data, you are correct.
Q. In fact, isn't it true that -- going back to the first point that I asked you. There's actually an article that's been published by Doctors Henningfield and Pankow that reviewed this situation, say that there's a debate, it then poses all kinds of areas of research into all these different features, proposes research because right now what actually happens in the lung as concerns pH is unclear; correct?
A. To my knowledge, it is unclear.
Q. Dr. Benowitz, isn't it true that when you've been asked flat out whether the addition of ammonia is likely to have any systemic effect on nicotine, whenever you've been asked that

question, your testimony has been that that is unlikely, that the only likely effect of changing pH is sensory effect; correct?

A. Well the latter I certainly have said.

Whether pH -- if you really changed pH by adding ammonia, whether that affected the rate of absorption, I have said just needs to be experimentally tested because it's not been tested.

Q. But isn't it true that what you have said, and what you've been confronted really in litigation with this very question, is that you've said the degree of likelihood that any change in pH would affect the sensory properties that we talked about but would not affect the systemic absorption? Hasn't that been your testimony?

MR. McCABE: Objection, Your Honor, asked and answered.

THE COURT: Overruled.

A. Well, again, I certainly have said the major impact that I think is likely would be on sensory impact, but I've also said that whether ammonia and pH affects absorption just needs to be studied. It's not been studied.

Q. Isn't it true that, based on science today -- there's been some discussion about what was the key to the success of Marlboro historically -- isn't it true today that to say that the success of Marlboro is driven by ammonia is speculation?

MR. McCABE: Objection, Your Honor. He doesn't offer

any testimony regarding any specific brand of cigarette.

THE COURT: Sustained.

MR. BERNICK: I have no further questions. I have some documents to offer. I would like to offer --

THE COURT: Let's deal with the documents later.

MR. BERNICK: Sure. I'm sorry, Your Honor.

THE COURT: What's the government going to do about redirect? How long do you think your redirect will be?

MR. McCABE: About an hour, Your Honor.

THE COURT: Okay.

MR. BERNICK: I did my best, Your Honor.

THE COURT: All right. Let's go.

I'm just going to stand up, everybody, for a minute. I don't know if everybody else wants to take a stretch. You're welcome to.

Whenever you're ready.

MR. McCABE: Thank you, Your Honor.

REDIRECT EXAMINATION

BY MR. McCABE:

Q. Good afternoon, Dr. Benowitz.

Dr. Benowitz, do you recall counsel asking you about the timing of when the criteria for addiction were articulated for the 1988 Surgeon General's report?

A. Yes.

Q. And do you recall testifying that the criteria are

articulated towards the end of that report's development?
A. Yes.
Q. Dr. Benowitz, were the conclusions in the 1988 Surgeon General's report based upon science?
A. Absolutely.
Q. What science were they based upon?
A. We extensively reviewed the literature on the effects of nicotine on the brain, the absorption of nicotine, the data on smoking behavior, smoking patterns on quitting smoking, treating smoking. It was an extensive review of all the behavioral aspects of smoking and -- and addiction.
Q. Thank you, Dr. Benowitz.

Dr. Benowitz, were the criteria a combination of criteria that had been previously identified by other scientific and medical bodies or were they brand-new criteria?
A. The criteria put out in the Surgeon General's reports were really directly taken from the World Health Organization definitions of dependence. It was not any invention. It was really sort of restating the World Health Organization definition in an operational sense.
Q. Dr. Benowitz, did you rely on any statement from the defendant tobacco companies in your direct testimony -- I'm sorry -- in your direct written testimony?
A. Any statements?
Q. Any statements made by the tobacco companies.

A. I don't recall.
Q. Dr. Benowitz, I want to move you on a little bit to a discussion you had earlier, the testimony regarding the Kandel and Breslau studies?
A. Yes.
Q. In your cross-examination, Dr. Benowitz, you were asked about the Kandel and Breslau studies. What portion of the age of the smoking population did these studies address?
A. I would have to go back and take a look at that to give you an exact answer. I must have it here somewhere.
MR. McCABE: Your Honor, may I approach? I have a copy of one of the studies right here.
THE COURT: You may.
BY MR. McCABE:
Q. Dr. Benowitz, I'm handing you the Breslau study for your review.
A. Thank you.
Well, this was part of the national survey on co-modity (ph) which is really looking at smoking and psychiatric disease, and it was a large set of 4,000 people, age 15 to 54 years.
Q. Thank you, Dr. Benowitz.
Have you been able to review the Kandel study?
MR. McCABE: Your Honor, if I may approach.
THE COURT: Yes.
BY MR. McCABE:

Q. Dr. Kessler, I'm handing you the Kandel study.
A. Thank you.
Well this was taken from another national survey in individuals of 12 years and older.
Q. Dr. Benowitz, with respect to your estimation of addiction based upon smoking more than five cigarettes a day, what portion by age of the smoking population were you addressing?
A. The data that I was looking at primarily were data from high school seniors where we have the best data relating cigarette consumption to later smoking behaviors.
Q. And is this distinction significant with respect to the applicability of the Kandel and Breslau studies?
A. Well, it is. They were looking at different age groups. As I said before, they were also looking at proxy indicators of addiction, which I think are problematic.
Q. Dr. Benowitz, can you explain for the court what a proxy measure is, please?
A. Well, the DSM-4 has got a set of questions that can be asked to get answers to address the seven criteria, and to make the diagnosis of addiction you need to be positive on three of those seven criteria.
The Breslau and Kandel studies did not ask questions to individuals. They took data that had been collected for another reason but which had information that would have been relevant to some of the DSM criteria. So they tried to then translate

the questions that were asked into questions that might relate to the DSM criteria. So it's not the same as giving the full DSM.

Q. Dr. Benowitz, can you explain for the court the significance of using proxy measures with respect to the applicability of these studies to your conclusions regarding the addiction for 21-year-olds smoking more than 5 cigarettes per today?

A. Well, other studies have looked at the regular DSM, which -- first, I do have a problem with the DSM in general. I think it underestimates addiction.

But given that you use that, other studies of daily smokers in high school have shown dependence rates of 60 percent. So, I think that's much more realistic.

The most important thing is that the reason for being concerned about dependence has to do with their behavior whether they can quit and whether they will quit.

And the most powerful data are the data that show that if you smoked 1 to 5 cigarettes per day as a high school senior, 70 percent of those individuals will be smokers later on, and if you smoke more than that, then a higher percentage will be.

So the most essential aspect of addiction is really loss of control of drug use which means that when you want to stop, you can't. And smoking on a daily basis by a high school senior predicts continued smoking.

Q. Dr. Benowitz, have you discussed the Kandel and Breslau

articles in your prior peer reviewed and published work?
A. I don't recall.
Q. Dr. Benowitz, I'd like to show you what has been marked previously as U.S. Exhibit Number 92011. I would like you to take a look the a page 628 for me, please.
A. Yes, I see it.
Q. I'm sorry. First of all, Dr. Benowitz, could you please just identify this document for the court?
A. This was an article on nicotine addiction that was published in a journal called Primary Care in September of 1999.
Q. And if I could refer you to page 628. Do you at any point on the page address the Kandel-Breslau studies?
A. Well, yes. What I do is mention the fact that the DSM has been used by others, including Kandel and Breslau, I think inaccurately characterizes dependence. And then I go through and I explain why the criteria in the DSM are not applicable for tobacco.

I think it's important for the court to understand that the DSM was not developed for tobacco but for other drugs of abuse, like heroin and alcohol, and has been adapted for tobacco, but some of the questions are really not relevant for tobacco use as written in the DSM.

THE COURT: Wasn't the DSM in all its various editions designed to help practitioners diagnose mental illness?

THE WITNESS: Yes, specifically psychiatrists to

diagnose mental illnesses. And, in fact, this is not -- the DSM is rarely ever used in clinical medicine. It's been used as a research tool. But you're absolutely right, the DSM is used extensively by psychiatrists to diagnose mental illnesses.

BY MR. McCABE:

Q. Dr. Benowitz, this U.S. Exhibit 92011, which you've identified for the court. Can you tell me who authored this paper?

A. This was my review on nicotine addiction.

Q. Thank you, Dr. Benowitz.

Dr. Benowitz, you testified earlier today that there are studies that show 60 to 70 percent of smokers meet the definition of addiction under the DSM-4 criteria.

Could you identify for the court what studies those figures come from?

A. There is a study by Stanton. There is another study -- I don't remember which one. There are studies looking at other addiction criteria.

I think I did mention that Lofland has found rates with an addiction scale that's been developed recently to look a loss of autonomy of 90 percent in daily smokers. So it depends which scale is you used. But the only paper I can think of offhand is the Stanton paper for the DSM.

Q. Thank you, Dr. Benowitz.

Dr. Benowitz, I would like to take back from you the

Kandel study for a moment, please.

Dr. Benowitz, you testified earlier today regarding this chart with Mr. Biersteker and its effects showing the number of cigarettes smoked per day with the percentage of dependence.

Is this figure from the Kandel article relevant to your conclusions regarding the 5 plus cigarettes standard you testified to?

A. No. As I said before -- and actually I've discussed this extensively with Dr. Kandel. I think that this proxy DSM measure that she has used substantially underestimates dependence at each level of cigarette smoking.

Q. Could you please bring up U.S. demonstrative Exhibit Number 17378?

Dr. Benowitz, you're looking at what we discussed yesterday, which was marked as U.S. demonstrative Exhibit Number 17378, which was two tables: 2-8 and 2-9. Do you remember discussing this table, Dr. Benowitz?

A. Yes.

Q. Dr. Benowitz, in terms of relevance to your conclusions regarding addiction for 21-year-olds smoking more than 5 cigarettes per day, is this exhibit more relevant for you than the Kandel article?

A. Yes, because the issue is really what happens to tobacco use in the future if you're talking about a predictor. And these

are the best data that I know that relate a given consumption rate to future smoking.

And this says if you smoke 1 to 5 cigarettes every day as a high school senior, then 70 percent of those people will be still smoking 5 years later, and most will be smoking as much or more. In fact, most will be smoking more.

Q. Thank you, Dr. Benowitz.

Dr. Benowitz, you testified earlier regarding the Pankow article; correct?

A. Yes.

Q. And you testified that Pankow's technique was a significant advance. Could you tell the court what you meant by that statement?

A. Well, it's been very difficult to measure pH for technical reasons.

If you put smoke in water, then the water can affect the pH. If you try to put cigarette smoke over a glass electrode, it's unclear what it's really measuring.

And what Dr. Pankow has done is really to say, okay, if we look at how much nicotine or some other substance is bound versus unbound in a given amount of smoke, we can then use that calculation to figure out what the pH must have been to explain that proportion of bound or unbound. Actually, it's free to bound.

And so this is really looking at a realistic way to

look at pH that doesn't depend on interaction of a smoke with some electrode. You're really measuring the pH of the smoke particle by looking at its effect on partition of constituents. So I think it's got great promise as giving us a better indicator of pH than we've had in the past.

Q. Doctor --

MR. McCABE: Your Honor, may I approach the witness?

THE COURT: Yes, you may.

BY MR. McCABE:

Q. Dr. Benowitz, I'm going to hand you what's been marked as U.S. Exhibit 88093, which is article by James Pankow, et al., titled: Percent free base nicotine in the tobacco smoke particulate matter of selected commercial and reference cigarettes.

MR. BERNICK: Is that the '01 article or '03 article?

THE WITNESS: 2003.

BY MR. McCABE:

Q. Dr. Benowitz, are you familiar with this article?

A. Yes.

MR. BERNICK: My only objection, Your Honor, is that this was the article that I specifically asked him about and I believe he testified that he had some familiarity with it but not the details of it. Otherwise, I would have gone into the details of the article.

I have no problem if he examines. I may want to have a

couple of questions to follow through on it.

THE COURT: Well, let me hear how detailed the questions are and whether they open the door to further questioning.

BY MR. McCABE:

Q. Dr. Benowitz, is this the article that was the subject of Mr. Bernick's questioning of you today?

A. Yes.

Q. And is it your understanding Dr. Pankow measured the pH of smoke of marketed cigarettes?

A. Yes, sir.

Q. Dr. Benowitz, I'd like to draw your attention to Table 1 of the article. Do you have that, Dr. Benowitz?

A. Yes.

Q. And if you could look at -- I'd like to draw your attention to the second column from the right for that chart, Dr. Benowitz.

For the column pH, does Dr. Pankow list the pH that he found for the initial puffs of a Marlboro cigarette?

A. Yes.

Q. What is that figure?

A. 7.08.

Q. And does Dr. Pankow list the pH for the initial puff of the Winston cigarette?

A. Of Winston?

Q. Yes.
A. 6.78.
Q. And how about for the Virginia Slim cigarette, Dr. Benowitz?
A. 6.91.
Q. Dr. Benowitz, how do these pHs compare to the measurements of pH shown to you by Mr. Bernick during his cross-examination?
A. Well, these pH ranges are up. They are shifted up about 1 pH unit or so from the ones described by Mr. Bernick.
Q. What is the effect of that?
A. This would mean that a greater proportion of nicotine would be in the unbound or vapor phase.
Q. Thank you, Dr. Benowitz.

Dr. Benowitz, I'd like to draw your attention to Joint Defendants' Exhibit Number 65989, which is the expert report of William Wecker in the litigation of Julie Turner, et al. vs R.J. Reynolds Tobacco Company, et al.

Are you familiar with this report, Dr. Benowitz?
A. Well, I certainly looked at it today. I may have seen it before in the Turner case. I don't remember for sure.
Q. Dr. Benowitz, you testified earlier today that if you visually look at the curves here they do not look like 47 percent. Could you explain to the court what you meant by that?
A. Well, if you say there's 47 percent compensation -- say you make it easy and you say it's 50 percent compensation. And if you went -- say you went from a cigarette of a .3 milligram

yield to a 1.2 milligram yield, if there was full compensation, then the cotinine levels would be the same at both levels.

If there was zero compensation, then there would be a five fold difference in levels.

So the person with a .3 would be taking in .3 per cigarette, and the person at the 12 would be taking in -- at 1.2 would be taking in 1.2. There would be a four fold difference.

If there's a 50 percent compensation, it would mean that the person at the low end would be taking more, but only half as much as if it was full compensation.

So what we would be seeing instead of a shallow slope that has 15 or maybe -- even if it was 23 percent, as we talked about as a slope, you would be seeing a slope that is quite substantial.

You would be seeing probably at least a 50 percent or greater difference between the lower yield and higher yield if you had compensation that was 50 percent, and that's just not been seen in any of the data. Not my data.

And I have to say that besides the Gori study, there have been six or eight or ten other studies that have looked at the same question and they all show very similar shallow slope or most of them do.

Q. Dr. Benowitz, you earlier testified that you were skeptical of the information in the Wecker report. Does your previous answer fully explain the skepticism?

A. Yes. Also Dr. Wecker, at least in this report, doesn't say anything other than he chose some studies and he did a calculation of light cigarette smokers versus regular smokers -- I don't know which points he chose -- and calculated a median compensation amount.

There just is not enough detail here to know what he did or how he did it or what he selected or what he didn't select.

I think one would need to really have a complete dataset and an explanation for which data were chosen and why before I could validate these calculations.

Q. Thank you, Dr. Benowitz.

Dr. Benowitz, I want to take you back to yesterday. There was testimony that you provided regarding your 1983 study that was -- the focus of -- which was discussed in Judge Gesell's opinion yesterday.

A. Yes.

Q. Do you remember that?

A. Yes.

Q. Dr. Benowitz, do you remember testifying yesterday that your study had been replicated enumerable times by other scientists?

A. Yes. If you look at the table in Monograph 13, I've listed quite a few studies that have used the same cross-sectional design in the U.S. and other countries, and those studies show basically the same picture, that there's a very shallow slope

between the machine yield and cotinine levels.
Q. So they show the same results?
A. Basically the same. Some show slopes slightly more, some show that's even flatter than I showed, but it's basically the same.
Q. Thank you, Dr. Benowitz.
MR. McCABE: Your Honor, may I have one moment?
THE COURT: Yes.
(Pause)
MR. McCABE: Your Honor, the United States has no further questions for Dr. Benowitz at this time.
The United States would like to note that you had reserved judgment on his qualifications as an expert for the areas proffered yesterday.
THE COURT: The doctor will certainly be accepted as an expert in the areas that the government proffered to me yesterday. No question.
MR. McCABE: One final note. The United States would also like to offer U.S. Exhibit Number 92011 which was just handed to him.
THE COURT: We are not going to do exhibits this afternoon.
Dr. Benowitz, you may step down. Thank you.
THE WITNESS: Thank you very much.
THE COURT: We were supposed to break at 4:30. What's

the problem?

MR. BERNICK: I just want to add a couple of follow-up questions if we're not going to have enough time, but I did have a couple of follow-up questions on the Pankow article. It will take me about four minutes.

THE COURT: I think either one or two questions were asked about that article. Only one or two questions. I'm not going to allow recross, no.

And just to be more specific. Not only were there only one or at the most two questions asked, but they were not the kind of detailed questions, and did not call for the kind of detailed answers, that Dr. Benowitz made clear in his response to Mr. Bernick that he was simply not prepared to provide.

Now, everybody, let me say a couple of things.

Dr. Benowitz, you can go. That's the whole reason we sat so late.

Everybody is misjudging witnesses, and what's happening is we are consistently sitting later and later. We are leaving things hanging and undecided, like exhibits. That is not the orderly way to proceed, everyone.

We've got out-of-town witnesses. I do everything I can to accommodate them. I know that they are extremely busy people. But at some point we need time to catch up on our witnesses and to catch up on exhibit lists.

The government has two people scheduled for the next

two days. Is that realistic? I'm not at all sure it is.

Mr. Brody?

MR. BRODY: Your Honor, it's three people.

THE COURT: Oh, three.

MR. BRODY: To fill out the week.

THE COURT: That makes it even better; right, Mr. Brody?

MR. BRODY: I think it is realistic that we will finish them all. The first witness tomorrow is Mr. Wulchin. He is not an adverse witness, so --

THE COURT: You've got Ms. Ward.

MR. BRODY: Ms. Ward.

THE COURT: And she's not an adverse witness?

MR. BRODY: She is an adverse witness.

THE COURT: Just a little.

MR. BRODY: But based on the corrections that we received from her, based on the estimates of what counsel for R.J. Reynolds is going to have for her, it's my expectation that we can finish certainly finish Mr. Wulchin tomorrow morning; that we can do most of Ms. Ward's examination tomorrow afternoon. There may be some carryover to Thursday morning. And based on the estimates that we got on Dr. Weitzman, that we can finish his testimony on Thursday. I think it's a fairly safe assessment.

THE COURT: He covered a lot of ground in his

testimony. What did the defendants expect? Who is going to be doing his cross?

MR. NEWBOLD: Bill Newbold for the record.

Michael Minton will be doing Dr. Weitzman's cross and he anticipates about three hours, Your Honor.

THE COURT: That doesn't surprise me.

And you're going to have an hour of direct of him.

MR. BRODY: I'm optimistic that we can finish him on Thursday because I -- given the estimates that we've received from defendants on Mr. Wulchin, it may even be that we would get to Ms. Ward before lunch tomorrow.

THE COURT: Everybody going to be awake tomorrow? I don't know about that.

MR. BRODY: That's another issue entirely.

THE COURT: That is. I think that will affect everybody.

I want to tell you, there are a couple of things, but I'll just deal with one or two right now in terms of planning.

Next Tuesday we definitely have to stop at, certainly no later than 4:25, no later than, since we have an executive session; I don't miss those.

And on Wednesday I'm sorry to say there is a plea in a criminal case that I -- it was impossible to get the lawyers on any Friday and, therefore, on Wednesday we're going to have to break at 3:00 o'clock, everybody.

And then, of course, Thursday and Friday we are off. I want everyone to build in time.

Is Dr. Weitzman -- yes, he's from out of the city.

MR. BRODY: He's from Rochester, New York.

THE COURT: So he's going to be in a hurry to get back to Rochester, isn't he?

MR. BRODY: I think he will be eager to get back to Rochester. But, as I said, I'm optimistic that we will be able to complete his testimony.

THE COURT: Well, I'm telling you if we don't get to it this week, I am going to put aside as much time as we need, and I don't think it will be all that extensive, but I'm going to put aside time Monday morning to pick up all the pieces on all of these witnesses who are hanging out there, and of course it's all in terms of exhibits, but we've simply got to get that done for the record.

Why did I think there was one other thing?

9:30 tomorrow morning, everybody, please.

(Proceedings concluded at 4:44 p.m.)

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CERTIFICATE

I, EDWARD N. HAWKINS, Official Court Reporter, certify that the foregoing pages are a correct transcript from the record of proceedings in the above-entitled matter.

Edward N. Hawkins, RMR