UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA,	:	CA No. 99-2496(GK)
	:	March 15, 2005
Plaintiff,	:	
	:	9:33 a.m.
	:	
v.	:	Washington, D.C.
	:	
PHILIP MORRIS USA, et al.,	:	
	:	
Defendants.	:	

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VOLUME 76
MORNING 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: Good morning everybody.

This is United States of America versus Philip Morris. CA 99-2496.

Mr. Brody, you roughly anticipate about an hour; is that right?

MR. BRODY: Roughly an hour, Your Honor. Somewhere within 10 minutes either way.

THE COURT: Okay. Go ahead.

EDWIN LUTHER BRADLEY, Ph.D., Defendant's witness, RESUMES

CROSS-EXAMINATION (Cont'd.)

BY MR. BRODY:

Q. Dr. Bradley, I want to talk a little bit more this morning about the use of causal criteria and the evaluation of that.

Now, we saw yesterday that the Surgeon General has observed that those applying criteria weigh the totality of the evidence in a decision making process that synthesizes and, of necessity, involves a multidisciplinary judgment; correct.

A. That's what it said, yes.

Q. And it is important to look at all the evidence in evaluating whether a particular agent causes a particular disease; correct?

A. I would agree with that, yes.

Q. All right. We're going to hand you a copy of U.S. Exhibit 86746, which is a copy of IARC Monograph 83, Tobacco

Smoke and Involuntary Smoking. I apologize for the size of it but I think it runs about 1,452 pages.

THE COURT: One minute, everybody. You didn't give me that to read.

Go ahead, Mr. Brody.

BY MR. BRODY:

Q. Dr. Bradley, have you seen this before?

A. Yes. Not in the Xerox form, but I have seen it, yes.

Q. You've seen the orange book?

A. Yes, sir.

Q. I assume you haven't read the whole thing.

A. I've sort been through it, but I have not concentrated on the whole thing, you're correct.

Q. Now, in your written direct testimony at page 135 you identify the conclusion of the International Agency for Research on Cancer that there is sufficient evidence that involuntary smoking, exposure to second-hand or environmental tobacco smoke causes lung cancer in humans; right?

A. I don't have my report open, but that sounds correct.

Q. And you indicate that you, Edwin Bradley, disagree with that conclusion; right?

A. That's correct.

Q. Let's turn to page 3 of U.S. Exhibit 86746, and take a look at the IARC working group participants who came to the causal conclusion that you disagree with.

A. Yes. Yes, I'm on that page.
Q. Now, we see -- we will just talk about a few of them. Dr. Michael Alavanja from the Division of Cancer Epidemiology and Genetics at the National Cancer Institute; right?
A. That's correct.
Q. Dr. Patricia Buffler from the School of Public Health at Berkeley; correct?
A. Correct.
Q. We have Sir Richard Doll, who we talked about yesterday, the world famous epidemiologist and ground-breaking researcher in smoking and health from Oxford University; correct?
A. That's correct.
Q. Let's turn to page 4. Among others here, we have Dr. Allan Hackshaw who works in epidemiology and medical statistics from Barts & The Royal London School of Medicine; correct?
A. That's correct.
Q. Sir Richard Peto. And surely you know who Richard Peto is; correct?
A. Yes.
Q. Can you tell the court about Peto's work in the area of smoking and health?
A. Well, he has a lot of work in smoking and health and I think epidemiology, in general.
Q. Can you tell the court about any of that work in smoking and health that Sir Richard Peto has done?

A. Well, he's been at it a while.

I don't -- if you have specific article in mind. I mean, he's done a lot of work in that area. I know on active smoking, in particular.

Q. Can you tell us anything specific about any of that work that Sir Richard Peto has done?

A. I can't recall at this time.

Q. He's a world famous epidemiologist from Oxford; correct?

A. Oh, yes, that's correct.

Q. Now, Dr. Samet we talked about yesterday. He is the Chairman of the Department of Epidemiology at the Bloomberg School of Public Health at Johns Hopkins University; correct?

A. That's correct.

Q. And you were not, as we saw yesterday, you were not familiar with Dr. Samet's professional reputation as of at least 2002. Is that right?

A. That's correct.

Q. Have you since become at all familiar with his professional reputation?

A. Well, I mean, I've been familiar with some of his works. Now, in terms of his reputation, I know of things he's done and written. I think I said that.

Q. He is a medical doctor and epidemiologist; correct?

A. That's correct.

Q. He was an author or editor of the Surgeon General's Reports

on the Health Consequences of Smoking in 1984, 1985, 1986, 1989, 1990, 1994, 1998, and 2004 when he served as senior scientific editor and was a co-author on a number of chapters, correction?

A. That's correct.

Q. He has been -- he's been awarded the Surgeon General's Medallion; correct?

A. I would not know one way or the other.

Q. He served on the board of scientific counselors of the National Cancer Institute, hasn't he?

A. That, I can't verify yes or no.

Q. He has published voluminously in the area of cigarette smoking and disease; right?

A. Well, he has published articles in that area, that's correct.

Q. He is the recipient of the Joseph W. Cullen Award from the American Society of Clinical Oncology; correct?

A. Once again, I can't verify that.

Q. He's a member of the Institute of Medicine at the National Academy of Sciences. Did you know that?

A. Like I say, I can't verify yes or no.

Q. Continuing down the list. Michael Thun. He's the Vice President for Epidemiology and Surveillance Research at the American Cancer Society in Atlanta, Georgia; right?

A. Right. That's correct.

Q. Are you familiar with any of Dr. Thun's work?

A. Yes. He has several articles in the area of smoking and health.
Q. Dr. Jean Tredaniel works in the Unit of Thoracic Carcinogenesis at Saint-Louis Hospital in Paris; right?
A. Correct.
Q. And surely you've heard of Dr. Tredaniel before and are familiar with his work?
A. That's correct.
Q. Let's take a look at some of the information the IARC panel considered in reaching the conclusion that passive exposure causes lung cancer.

We can start at page 1200, which is within the section on smoke composition. That's going to be down a little bit there.
A. What page?
Q. 1,200.
A. Okay, I'm there.
Q. We can put those, the first part of it aside for now.

And I want you to take a look at Table 1.3 on the top page titled: Average values of 44 smoke constituents in the sidestream smoke of 12 commercial cigarette brands assayed in the 1999 Massachusetts Benchmark Study using Massachusetts smoking parameters.

Do you have that?
A. Yes, I do.

Q. And there we see data for constituents like benzo[a]pyrene, acetaldehyde, hydrogen cyanide, arsenic, and formaldehyde; correct?
A. That's correct.
Q. Now, you're not an expert in chemistry, are you?
A. No, sir.
Q. You have no expertise in the area of smoke composition, do you?
A. That's correct.
Q. In fact, you're not aware of what makes up tobacco smoke or what is or is not a carcinogen; correct?
A. That would be correct.
Q. The next table is Table 1.4 on page 1,201.
A. Yes.
Q. And there we see concentrations of selected gas-phase compounds in sidestream smoke of commercial cigarettes; correct?
A. Correct.
Q. And that includes things such as acrolein, isoprene and benzene; right?
A. That's correct.
Q. Again, that's outside your area of expertise, right?
A. Yes, sir.
Q. Next page, 1202. We see Table 1.5. Yields of IARC carcinogens in regular-sized Canadian cigarettes; correct?
A. Correct.

Q. And as you just testified, you don't know what is or is not a carcinogen; correct?
A. That is correct.
Q. Now, if you turn to page 1,207.
A. I'm there.
Q. You see the heading at the bottom of the page.
Charles, you're ahead. 1,207.
You see the heading at the bottom of the page: Measurements of nicotine and particulate in indoor air. Correct?
A. Correct.
Q. You have no expertise in respirable suspended particle measurement; correct?
A. That's correct.
Q. You have no expertise in fluorescent particulate matter; correct?
A. That's correct.
Q. Same answer for solanesol-particulate matter?
A. That's correct.
Q. Let's go to page 1,231 of Exhibit 86746. And you see the indication there: Studies of Cancer in Humans. Right?
A. Yes, sir, I see that.
Q. The first subsection is lung cancer, and we see a reference to cohort studies; correct?
A. Yes.

Q. And unlike case control studies that begin with individuals who are already sick, cohort studies, also known as prospective studies, begin with two groups selected for their similarities except for a single variable, in this case cigarette smoking, and these two groups are then followed to see who develops any particular disease; correct?

A. Well, they are not selected. They are naturally occurring. You observe them for a length of time and then the hope is that the two groups are similar in characteristics other than their exposure.

Q. And when you're doing that, you can -- well, when you do that, that's a cohort study; correct?

A. Right, that's a cohort study.

Q. And the authors of the IARC study, the panel, including the members that we specifically talked about, noted that there have been eight cohort studies of nonsmokers who were followed for several years to determine the risk for lung cancer. Six of these studies reported the risk of lung cancer associated with -- let me read this correctly.

Six of these studies reported the risk of lung cancer associated with exposure to secondhand smoke from the spouse. All six studies found that the risk for nonsmoking women with partners who smoked was higher than that for those whose partner did not" -- and you have to skip ahead. There's a table, but skip ahead to page 1234 -- "whose partner did not smoke. In

both cohort studies that reported on the effect in nonsmoking men whose wives smoked, the relative risk was increased. The two other cohort studies, which were based on general exposure to secondhand smoke, obtained similar results."

Correct?

A. That's the way it reads, yes.

Q. Every single one of them; right?

A. Well, they all showed an increase, but it doesn't say whether they showed a statistically significant increase.

Q. Let's turn to Table 2.1, pages 1,232 and 33.

Charles, maybe we could bring up both of them and take a look at the whole table we can fit it.

A. Pardon me. What page was that again?

Q. 1,232 and 1,233.

I'll tell you what, Charles. Why don't we do them one at a time?

The Garfinkel study had 176,739 participants; right?

A. Right. That's the ACS CPS-I study.

Q. And we talked yesterday about Hirayama, 91,540 participants; correct?

A. That's correct.

Q. And if we go down to the half of the table that's on the following page, 1,233 of the IARC report, we see that Cardenas looked at a cohort sample of 288,776; right?

A. That's right, that's the CPS-II study.

Q. Jee looked at 147,436; right?
A. Correct.
Q. Speizer looked at 121,700?
A. Correct.
Q. All right. Let's move ahead to page 1265. And Table 2.7 contains summary results of selected published meta-analyses of the risk for lung cancer in never-smokers exposed to secondhand smoke from the spouse. Correct?
A. I've got to find the table first.
Q. 1,265.
A. I have 66, I believe.
Q. I think it starts 1,265.
A. Well, the table is on 1,266. Which do you want?
No, you're correct. There's two different numbers on here.
Q. I thought so. Every single meta-analysis found an elevated risk for lung cancer; correct?
A. That's correct.
Q. And if we take Hackshaw as an example, we see an adjusted pooled relative risk of 1.26 with an adjustment for misclassification bias, exposure to secondhand smoke other than from a spouse --
THE COURT: Wait. Wait. Mr. Brody, you're way ahead of me.
MR. BRODY: We're looking at Hackshaw 1998, Your Honor.

THE COURT: Where are you?
MR. BRODY: Charles, can you light that?
THE COURT: All right. Now start your question again, please.
BY MR. BRODY:
Q. We see an adjusted pooled relative risk of 1.26 with adjustment for misclassification bias, exposure to secondhand smoke other than from a spouse, and dietary confounding. Correct?
A. Well, he adjusted actually for only one dietary confounder, and he made an assumption in his adjustment for background, but that's the three things he did adjust for.
Q. So the answer to my question is correct?
A. Well, it's correct that he adjusted for three things. I want to be clear that he's not adjusted for all dietary confounders.
Q. And a relative risk of 1.26 indicates a 26 percent greater likelihood of getting lung cancer; correct?
A. Not necessarily. That depends on how valid that estimate is.
Q. If the estimate is valid, a relative risk of 1.26 indicates a 26 percent greater likelihood of getting lung cancer; correct?
A. If it's a valid estimate, yes.
Q. Dr. Bradley, are you aware of what the 5-year survival rates are from a diagnosis of lung cancer?

A. I couldn't tell you off the hand, but I know it's -- I wouldn't -- it's fairly low.
Q. Does 15 percent refresh your recollection?
A. That sounds about right.
THE COURT: Now, I want to follow up on something. Your answer to one of Mr. Brody's questions was, "If it's a valid estimate."
Are you giving an opinion on the Hackshaw study as to whether it is or isn't a valid estimate, meaning the 1.26 adjusted point relative risk?
THE WITNESS: I claim it's not valid. He hadn't made all the adjustments.
In other words, he's adjusted for three things he wanted to adjust for, and it made a slight difference in his risk where it was not adjusted.
But, first of all, we don't know that -- first of all, in these types of studies, you never know if you have all the confounders. In other words, you only adjust for things that -- try to adjust things that are known confounders.
THE COURT: But that's always true.
THE WITNESS: That's always true, but that's one of the problems with the studies. That's why -- that's the problem with the study. You can't name all the confounders.
Secondly, you can only adjust for those where you have some measurement you can adjust for them.

In fact, in the Hackshaw study, his adjustments, he only had dietary adjustments on 4 of his 37 studies. In other words, that's what he based his -- I mean, his criteria on. So he did not make a full adjustment for all confounders.

We don't know -- in other words, the question is we don't if it's valid or not.

BY MR. BRODY:

Q. And Dr. Bradley, you disagree with all of these; right?

A. I didn't disagree under the assumptions they made and the computations they did, that they didn't come up with these particular values, but you have to understand these are all very small increases in relative risk, and they are all subject to the bias and confounders that I discuss.

Q. And a 26 percent greater chance of getting lung cancer does not pass the Bradley test that requires a relative risk of 2.0; correct?

A. That would not pass that test, that's correct.

Q. All right. Of the 15 pooled relative risks in the center column, 12 out of the 15 reported statistically significant pooled relative risk at the 95 percent confidence interval; correct?

A. Eleven, correct. Let's see.

Q. I'm sorry, 11 out of 15, you're correct.

A. Yes, 11 out of 15.

Q. And as to the 4 that did not report statistically

significant pooled relative risks at the 95 percent confidence interval, what that tell us is that we could not -- in fact, all that really tell us is that we could not completely rule out the null hypothesis with 95 percent certainty; correct?

A. Right. In other words, we cannot minimize the fact that risk could have caused those elevations.

Q. With 95 percent certainty; correct?

A. That's correct.

Q. As to those that did not report statistical significance at the 95 percent confidence interval; according to what we saw from Rothman yesterday, the confidence limits, while indicating that the data is statistically compatible with no association, also indicates that the data is more compatible with the positive association, according to Rothman; correct?

A. According to what Rothman said, that's correct.

Q. And, in fact -- if you still have Rothman up there -- he has another example on the subject of statistical significance in his chapter on statistical analysis in modern epidemiology, and that's JD 003150. I want to go to page 193.

A. 193, was it?

Q. Yes.

A. Yes, sir, I have it.

Q. And if you look at his example, he is comparing two studies. And the long and the short of it in his view is that there are dangers of using statistical significance as the primary basis

for inference; correct?
A. Let me read what he says here. Are you talking about the one that starts with 4?
Q. He has two hypothetical situations.
He notes that the two results differ in that one result indicates there may be a large effect. While the other offers evidence against a large effect, the irony is that the statistically-significant finding that offers evidence against a large effect while it is the finding that is not statistically significant that raises concern about a possibly large effect.
In these examples, statistical significance gives a message that is opposite of the appropriate interpretation. Correct?
A. Well, see, I disagree with that. In other words --
Q. Right. The Bradley test for statistical significance is inconsistent with Rothman's example; correct?
A. No. Rothman -- Rothman is pointing out that you can have a highly statistically significant result -- in other words, a small effect due to the fact you have a very large study. That's when you then, if you had that particular case, you would want to look at the actual magnitude of the risk to see if it's large enough to consider its valid.
But just because you have a very small -- in other words, if you run a small study and get a large risk, that doesn't mean anything. I think from the graph that I looked at

yesterday that Samet had, it's fairly obviously when you had a lot of imprecision, those are the ones that led to these very large risk. When you had a lot of precision, that they were small risk.

Q. And the passage that we just looked at from Rothman is inconsistent with the Bradley test that was presented in your written testimony and in the examination by Mr. Minton yesterday; correct?

A. I don't -- you know, to say it's totally inconsistent. I'm saying that if you can eliminate chance and just because you -- you know, just because you happen to run a small study and get a wide confidence interval doesn't give me much confidence that you have a very reliable value.

And I think he's implying here that you could have a small study with a large confidence interval, you happen to just, by chance, to get a large relative risk and therefore he's all excited.

And I'm saying there's more information in the one where he's got a small relative risk, but it's statistically significant. You know it's a very precise estimate and then you can concentrate on whether it's a valid estimate or not.

THE COURT: Isn't it fair to say, though, that there's a fundamental disagreement between you and Rothman on how much weight, if you will, should be given to the factor of statistical significance?

THE WITNESS: I would agree with that, yes.
THE COURT: And so it's a fundamental difference between two experts on that point?
THE WITNESS: He -- right. He de-emphasizes statistical significance.
THE COURT: Emphasizes it or he de-emphasizes?
THE WITNESS: De-emphasizes it. He de-emphasizes statistical significance which I strongly disagree with.
BY MR. BRODY:
Q. Let's move back to U.S. Exhibit 86746, the IARC report, and I want to move ahead to -- we're going to move ahead to page 1,328. And we will --
A. We're going ahead, though?
Q. Take as much time as you need to get there.
A. 1,328.
I'm there.
Q. And take a look at Table 3.2 captioned: Lung tumour yield in female Swiss albino mice, either gestating or non-gestating, exposed to simulated environmental tobacco smoke for varying time periods.
Do you see that?
A. Yes.
Q. And you see that the incidents of lung tumors went up with increased exposure time; correct?
A. That appears to be correct, yes.

Q. You've never conducted an inhalation exposure study; correct?
A. No, sir, I have not.
Q. Similarly referring you to the heading at page 1329, it's the next page.
A. Yes, sir, I'm there.
Q. Administration of condensates of sidestream smoke. You have no expertise in the comparative carcinogenicity of cigarette sidestream and mainstream smoke condensates; correct?
A. That's correct.
Q. Let's go to page 1,336. And this is part of a section of the report on absorption, distribution, metabolism and excretion that begins on page 1335; correct?
A. Yes, sir. You're correct.
Q. And at the top of that page we see the indication that "4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol (NNAL)" -- and I will sit down with our court reporter later so that we can make sure we get all the spellings correct -- "and it's glucuronides (NNAL-Gluc) are metabolites of the tobacco-specific lung carcinogen 4-(methylnitrosamino)-1-(2-pyridyl)-1-butanone (NMK)." Correct?
A. That's what it says, yes.
Q. And not only are carcinogens as we discussed outside your area of expertise, but so is the subject of metabolism and metabolites as biomarkers; correct?

A. Correct.
Q. If we go ahead to page 1,338 we see a discussion of protein adducts, and that is also outside your area of expertise; correct?
A. Yes, sir.
Q. In fact, the entire subject of biomarkers, whether they are chemical metabolites, protein adducts, breath compounds, blood compounds or particles is outside your area of expertise; correct?
A. That's correct.
Q. Go to page 1,377, please. And there we see the heading: Genetic and related effects. Correct?
A. Correct.
Q. You have no expertise in genetics, either; right?
A. That's correct.
Q. Take a look at page 52 to 53 of your written direct testimony. I want to start at the bottom of page 52 with where the following question appears.
"What types of heterogeneity problems are created if foreign studies are included in your meta-analysis?"
Do you see that?
A. Yes.
Q. And at the top of 53 your answer includes the assertion at lines 4 through 7, that compared with foreign populations, especially Asian populations, however, U.S. diets and lifestyles

are significantly different. There are also significant differences in housing construction and genetics." Do you see that?

A. Yes.

Q. What are the differences in housing construction in Asia that contribute to differences in comparative cardiovascular and lung cancer disease rates?

A. Well, there can be all sorts of environmental constructs that enter into that.

Q. The question is, what are the differences in housing construction in Asia that contribute to differences in comparative cardiovascular and lung cancer disease rates?

A. I don't know.

Q. What genes are different in Asian populations so as to contribute to differences in comparative cardiovascular and lung cancer disease rates?

A. I can't answer that.

Q. Going back to the IARC report. You understand, don't you, sir, that the panel of experts who prepared the report looked at all of the evidence we've talked about and everything else in this 1,452-page volume in arriving at their conclusions; correct?

A. That's correct.

Q. I want to shift gears a little bit and talk about your own background in this area, Dr. Bradley.

A. Okay.
Q. You're not an epidemiologist, correct, nor do you hold yourself out to be one?
A. That's correct.
Q. You're not a medical doctor?
A. That's correct.
Q. You're not qualified to treat patients, are you?
A. No, sir.
Q. You have no medical training at all?
A. That's correct.
Q. Now, I think we already established you're not a chemist, nor do you have degrees in chemistry?
A. That's correct.
Q. You're not an expert in physiology; correct?
A. That's correct.
Q. You're not a biologist?
A. That's correct.
Q. You're not an expert in pharmacology; correct?
A. That's correct.
Q. You're not an expert in oncology?
A. Correct.
Q. And you're not an expert in toxicology, either, are you?
A. No.
Q. Now, you were first approached by the tobacco industry regarding the health effects of exposure to secondhand smoke in

connection with two cases in the mid-1990s, the Broin case and the Butler case; correct?

A. That is correct.

Q. And at the time Don Kemna, K-e-m-n-a, a lawyer with Shook, Hardy & Bacon, came down to your offices in Vestavia Hills, Alabama, to meet with you at your litigation consulting company; correct?

A. That's correct.

Q. And at the time he told you he was representing both Philip Morris and Lorillard on that visit; correct?

A. I believe he did, yes. He did say that.

Q. You were still teaching at the University of Alabama, Birmingham, at the time, but even while you were teaching, the litigation consulting business quantitative research was taking 50 to 60 percent of your time; correct?

A. It was taking a lot of time, yes.

Q. 50 to 60 percent; correct?

A. I would say that's correct, yes.

Q. And just two years later, after the time of Mr. Kemna's visit, October 1, 1997, you retired from your position at UAB; correct?

A. That's correct.

Q. And part of the reason that you retired from your teaching position was because testifying and reviewing legal cases had become so time-consuming; correct?

A. That was part of it.
Q. And so retiring and going to emeritus status freed up your time for litigation because you have no required duties at the university; correct?
A. That's correct.
Q. You've been testifying in litigation since 1981; right?
A. I think I first testified about mid-1980s.
Q. You've been involved in litigation consulting since 1981; correct?
A. I've been involved in -- actually around the same time, mid-1980. 1981 I was doing some other types of consulting.
Q. You've been retained as a legal consultant well over 50 times; correct?
A. Oh, I would say yes.
Q. And being a litigation witness and consultant has been your only job for the past 8 years; right?
A. Well, it's not my only job, but it's the bulk of the business that I do, yes.
Q. And that business, you know, professional witness, litigation consultant is a full-time job; right?
A. Well, it would be as full time as I would want it to be.
Q. Okay. And over the past 8 years there have been times when it's been full time; right?
A. There have been times, yes.
Q. And let's talk briefly about how lucrative it is.

Your written direct examination says that your consulting firm has already received $200,000 for your work in this case; correct?

A. That's correct.

Q. And how much unbilled time do you have right now?

A. I really don't know. That should be -- when this report was written, that should have been probably through the end of February. So I can't tell you offhand.

Q. So you have the additional time that you took to, you know, finalize the written direct before it was filed, to prepare to testify, to come in and testify today, those types of things?

A. Yes, sir.

Q. Do you expect to bill for that time?

A. Yes, sir, I do.

Q. Do you bill for your travel time?

A. Yes, sir, I do.

Q. You've been a witness in a number of cases for the tobacco industry in addition to this one; correct?

A. Yes, that's correct.

Q. There was the Cantley case in Alabama; correct?

A. Well, actually, that was the first case I was asked about. That case never went to trial. That case eventually was either dismissed or dropped. I don't know which.

Q. You were approached and retained in that case; correct?

A. That's correct.

Q. You testified in the Broin litigation in Florida?
A. Yes, sir, I did.
Q. The Butler case in Mississippi?
A. Yes, sir.
Q. You were retained in the Fahey case in Massachusetts; correct?
A. That's correct.
Q. And you testified in the Tompkin case in Ohio?
A. Correct.
Q. The Atkin case in Alabama?
A. In a deposition, that's correct.
Q. You testified in the Seborn case, I believe?
A. Also by deposition, yes.
Q. You were retained in the Brown case in New Jersey?
A. Correct.
Q. The Roach case in Missouri?
A. Correct.
Q. And the Carter case in Pennsylvania; correct?
A. Correct.
Q. Did we miss any of the tobacco cases?
A. There has been some other cases other than those.
Q. How many?
A. I don't know. Approximately, I guess, 25 to 30 cases.
Q. You've appeared on behalf of Altria Group, formerly known as Philip Morris Companies, Inc.; Philip Morris USA, R.J. Reynolds,

Lorillard, Brown & Williamson, British American Tobacco Investments Limited, and Liggett Group; correct?
A. That's correct.
Q. And that is over roughly the past 10, 11 years; right?
A. That's correct, yes.
Q. Can you give me a total amount of money that you've been paid for work on those cases?
A. I don't -- I don't know the total amount.
Q. More than $2 million?
A. No. This case here, the one that we're in now, the Department of Justice case, is the one that I've actually spent the most of any time on. All the other cases combined would be maybe two or three times what I've done in this case.
Q. Okay. So another four to 600,000 on top of the 200,000 here. So we're looking at 600, $800,000; correct?
A. Yeah. I can't tell you exactly, but that would seem about right, yes.
Q. A good number of those cases were cases involving claims by cigarette smokers against tobacco manufacturers as opposed to claims involving passive exposure and disease; right?
A. Some of those were, yes.
Q. And at every one of those cases you offered the opinion that cigarette smoking was not associated with the disease suffered by the particular plaintiff or plaintiffs; correct?
A. That is incorrect.

Q. We can look at some of them. In that way the position that you have taken -- let me ask you this.

In 1997, in fact, you testified that the Surgeon General's warning stating: Smoking causes lung cancer, heart disease, and emphysema was false; correct?

A. I never said that.

Q. Let's look at your testimony in the Broin deposition from May 7th of 1997, and I want to go to page 22 look at lines 14 to 19.

The question was, "Well, the statement is, smoking causes lung cancer, heart disease and emphysema. My understanding of what you're telling me is, that statement is false because it does not have the word may in it, correct?"

Your answer was, "That could be my -- that would be correct."

That was your testimony; correct?

A. Well, I didn't say the statement was false. I said it may cause. I mean, we were talking --

Q. Dr. Bradley, you were asked, "My understanding of what you're telling me is, that statement is false, because it does not have the word may in it."

And your answer was, "That would be correct."

That was your testimony; correct?

A. That's what I said, yes.

Q. And that testimony was under oath; correct?

A. That's correct.
Q. Now, let's go back to the chronology we started on your involvement with ETS for litigation.
Broin involved claims by flight attendants based on exposure to secondhand smoke; correct?
A. Pardon? I missed the question.
Q. Broin involved claims by flight attendants based on exposure to secondhand smoke; correct?
A. That's correct.
Q. After the initial meeting with Mr. Kemna from Shook Hardy in 1995 you began to deal more with Bernard O'Neill from Shook, Hardy & Bacon; correct?
A. That's correct.
Q. That's the Bernard O'Neill that we saw in the letter from Dr. Tweedie yesterday; correct?
A. That would be correct, yes.
Q. Now, you recall, you spent about -- I think about 75 hours before your deposition in the Broin case looking at various studies and reports related to secondhand smoking disease?
A. That may be correct. It's been so long, I just don't recall.
Q. And by trial, I believe in that case you had spent approximately 175 hours, or if we use the 40-hour workweek, slightly under 4 and a half weeks' time on the issues in that case; correct?

A. Like I said, I just don't recall.
Q. All right. Well, let's look at the Broin trial, and this is volume 128 from October 6, 1997, and I want to go to page 15959. Let me know when you're there.
A. 15959. Right?
Q. Yes.
A. Yes.
Q. Let's look at lines 21 to 23. You were asked, "I understood you to say you had 175 hours in the Broin case."

And your answer was, "That's approximately right." Correct?
A. Yes.
Q. Now, you did your work in that case, your 175 hours, and you came to trial and expressed a conclusion that every single study that had ever reached the conclusion that exposure to secondhand smoke is a cause of disease, and the United States Surgeon General were wrong. Is that right?
A. Well, I said I came to the conclusion that you couldn't establish association between exposure to ETS and lung cancer.
Q. Let's look at page 15962 of that same transcript, line 21 to -- Charles, we can bring up both of them -- 15963, line 9.

And you were asked, "Well, what I'm asking you, because my understanding is with respect -- that with respect to any epidemiology study you looked at and you read, you do not agree with one single conclusion of any study from anywhere which said

there was an association between secondhand smoke and lung cancer or any other disease, is that correct?"

And you said, "I would agree with that, yes. I believe the confounding that they haven't accounted for can easily explain the results on all the studies, yes."

That was your testimony; correct?

A. Yes, sir.

Q. That was the testimony you gave after you did 175 hours of work on the case; right?

A. That's correct.

Q. All right. Of course, in the Broin trial, you also said that for you, as a statistician, cause is by definition unprovable; correct?

A. Well, what I said, association alone cannot prove causation, that's correct.

Q. Let's look at your testimony at page 15987, same transcript, and this is at lines 20 to 22.

You were asked, "Well, as a statistician cause is by definition unprovable." Your answer was, "That is correct."

A. Where is?

Q. Lines 20 to 22?

A. One moment.

Well, that's correct because statistics alone you cannot prove causation.

Q. That was your testimony and that testimony was under oath;

correct?
A. That's correct.
Q. And you're here today to tell the court that every single study ETS exposure is cause of lung cancer or heart disease is wrong, that Sir Richard Peto is wrong, that Sir Richard Doll is wrong, that the United States Surgeon General is wrong, that the U.S. Environmental Protection Agency is wrong, that the World Health Organization is wrong, that the International Agency for Research on Cancer is wrong, that the National Research Council will is wrong, and the American Heart Association is wrong.
That's your testimony; correct?
A. Well, my testimony is that you cannot -- that the epidemiological evidence is not establishing association between ETS and an increased risk of lung cancer or disease.
Q. And your testimony is that every single one of those studies and every single one of those organizations that I just named is wrong; correct?
A. No. What I said --
MR. MINTON: Objection, Your Honor, asked and answered.
THE COURT: The objection is overruled.
BY MR. BRODY:
Q. Dr. Bradley, your testimony is that every single study and every single one of those organizations and persons that I named are wrong; correct?
A. My -- I said -- I didn't say they were wrong. I said that

my opinion is that it's not been established.

Now, they have other judgments and methodologies they used to come to the conclusion. Using my methodology, I cannot establish an association.

Q. And you are here to tell the court that every single one of those persons' studies and organizations is wrong, correct, in their conclusions?

A. If they are concluding that it's established that there is an association between exposure to ETS and an increased incidence of heart disease and lung cancer.

Q. And that would be under your methodology, the Bradley test that we've talked about over the last couple of days; correct?

A. That's correct.

Q. At the time you were hired by the tobacco companies in Broin and spent your 75 hours --

THE COURT: No. Excuse me. 175.

MR. BRODY: I'm sorry. 175 hours.

BY MR. BRODY:

Q. Reviewing papers, you had never published a single thing on passive exposure and disease; correct?

A. That's correct.

Q. And to this day you have not published anything on passive exposure or ETS and disease; correct?

A. That's correct.

Q. You've never conducted a population-based case control study

to determine or evaluate the relationship between ETS and lung cancer; correct?

A. That's correct.

Q. None of the meta-analyses that we see in your written direct testimony have ever been published; correct?

A. That's correct.

Q. Now, approximately 35 to 40 percent of the publications on which you have been listed as an author have involved dentistry; right?

A. That may be correct.

Q. Let's look at the Broin trial, page 15964, lines 4 through 15. You have it?

A. What page was that?

Q. 15964. You were asked, "Now, you know, I looked at the various articles you have done. You have done a large number of articles on dental subjects; correct?"

And your answer was, "Probably about 35 to 40 percent of the effort I have done has involved dentistry, but you have to be careful that dentistry doesn't just include caries, or cavities, and orthodontics. The department over at the school there included an oral biology department. There's a lot of relationships among those schools with other departments in the university. But I'd say 35 to 40 percent would be dentally related."

That was your testimony; correct?

A. That's right.
Q. And that testimony was under oath?
A. Yes.
Q. According to your CV, Dr. Bradley, you have been the lead author on exactly two publications since 1973; correct?
A. That may be correct.
Q. And you have been the lead author on exactly one abstract in your entire career, and that was in 1970; correct?
A. That may be correct, yes.
Q. You have never served on the editorial board of a scientific journal, have you?
A. No.
Q. Your CV does not show that you've ever held a research grant; correct?
A. Not as a principal investigator, that's correct.
Q. And your CV does not reflect any service on a governmental review panel; is that correct?
A. That's correct.
Q. Of the publications listed on your CV, in addition to the 35 to 40 percent related to dentistry, I think you're listed as a co-author on about 56 articles dealing with anesthesia, a dozen related to fertility and sterility, and 14 on things related to surgery, like suture techniques. Does that sound right?
A. Well, I'd have to go through and count them, but I have papers in cardiology, cardiac surgery and things like that,

also.
Q. Does my count sound about right, sir?
A. I'd have to go back and check, but you know, I'll take your representation.
Q. Well, we can look at it. It's Joint Defense Exhibit 25137.
And the only question I have is of the publications listed on your CV, in addition to the 35 to 40 percent related to dentistry, you're listed as an author on about 56 articles dealing with anesthesia, a dozen related to fertility and sterility, and 14 on things related to surgery, like suture techniques. Does that sound about right?
A. I said that sounds about right.
THE COURT: Of those publications, what percentage, if any, were related to consulting work that you were doing for which you were being paid?
THE WITNESS: None of them.
THE COURT: None?
THE WITNESS: Right. You know, now obviously, there were research grants at the university, but those are not consulting. For example, you have federal research grants and that's where a lot of this work comes from. None of it was related to any consulting I was doing.
THE COURT: All right.
BY MR. BRODY:
Q. And as you said, you've never held a research grant as

principal investigator; correct?
A. That's correct.
Q. Now, not only have you never published anything on environmental tobacco smoke, but you've not written or published a single article on smoking and health; correct?
A. That's correct.
Q. And, in fact, not only have you never written or published any articles about smoking and health, you've never even written a letter to the editor of a journal about the subject of smoking and health; correct?
A. That's correct.
Q. And the number of publications you have been involved with on smoking and health, zero, is one less than the number of publications on your CV dealing with bird repellency; right? Is that correct?
A. Yes. That's correct.
MR. BRODY: Your Honor, we have no further questions.
At this time I would like to ask if Dr. Bradley could be excused so we can make a short motion.
THE COURT: All right. Would you step down, please, for a few minutes?
(Dr. Bradley left the courtroom.)
MR. BRODY: Your Honor, Dr. Bradley's testimony presents several challenges to Rule 702.
He has admitted that the rule he applies is not

recognized in a field of biostatistics. He admitted that yesterday.

He offers an opinion on whether passive exposure is a cause of disease, specifically using the word "cause" in his testimony, and yet for him cause is unprovable.

He has no regular work outside paid litigation consulting and has never published in the field smoking and health, for which he is offering testimony for this court.

Now, the advisory committee notes to Rule 702 outline factors for a court to consider in evaluating whether testimony from an expert should be admitted.

The advisory committee noted that a nonexhaustive checklist includes things like whether a technique or theory has been subject to peer review and publication, the existence and maintenance of standards and controls, whether the technique or theory has been generally accepted in the scientific community.

The advisory committee notes to Rule 702 also recognize, when considering whether a witness's testimony is reliable the court is permitted to examine whether the expert is being careful as he would in his regular professional work outside his paid litigation and consulting, noting that a trial court is required to assure itself that the expert employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.

There can't be such a standard applied here where the

witness has not published in the field, has done nothing in this area outside of litigation, has no other position at this time, and, according to his own admission, applies a standard that is not recognized in his field.

Quite frankly, the fact that he offers an opinion as to whether ETS exposure is causal disease and yet for him by definition cause is unprovable is quite remarkable in and of itself.

All of these factors as well as the other things that we have heard from Dr. Bradley during his testimony counsel strongly against the admission of his testimony in this case, and Rule 702 is a rule that is a threshold for admissibility.

We would ask that the court not receive Dr. Bradley's testimony based on the important considerations in Rule 702 and the standards and factors contained in both the rule and the advisory committee notes and the case law that has interpreted Rule 702 and applied Rule 702 fairly consistently throughout federal courts.

THE COURT: Mr. Minton.

MR. MINTON: With respect to the particular biostatistical criterion that Mr. Brody just mentioned, strength, Mr. Brody obviously took a very narrow and I think unfair view of what Dr. Bradley, in fact, said both in his written direct examination and on cross-examination.

He did suggest that the relative risk of 2 was an

appropriate benchmark for him to use in the context of the ETS studies. He tried to tell Mr. Brody that he had also applied 1.5.

What Mr. Brody interestingly didn't even ask him about was the section of his written direct where he pointed to any variety of other scientists who pointed to levels of strength which were appropriate in evaluating the strength of an association and how one generates scientific confidence with respect to the strength of the association.

He did not say that an evaluation of strength was not recognized in the biostatistical field. As a matter of fact, the Surgeon General's Report itself says that strength is related to the confidence that one can have about a particular estimate being problematic because of bias.

With respect to the area of biostatistics and whether or not in order to qualify as an expert in biostatistics, I'm not aware that there's a subcategory of smoking and health biostatistician that needs to be qualified in order for Dr. Bradley to testify.

Obviously, he needs to be familiar with the epidemiologic literature, and I think that his testimony and his report, in fact, demonstrates that he is familiar with the relevant ETS epidemiology as he's testified about.

But there is no -- there is no minimum bar that says that an expert has to have published himself independently in

that area in order to qualify as an expert under Rule 702. In other words, there's no showing that there's a different branch of biostatistics that is uniquely relevant somehow to his ability to be recognized as an expert in this courtroom.

And with respect to the final factor, there's an odd juxtaposition going on here. The Surgeon General's Report from 1964 to 2004 say one thing very plainly, and that is association cannot prove causation.

So to the extent that the DOJ would seek to disqualify Dr. Bradley on the basis that he acknowledges the same fundamental doctrine that the Surgeon General does, that seems an odd way to try to disqualify Dr. Bradley as an expert.

THE COURT: I'm going to rule as follows.

As everyone knows from Rule 702, the advisory committee notes and, of course, the fairly substantial amount of Supreme Court case law on these issues, the court is supposed to be a gatekeeper under Rule 702. But the reason the court is supposed to be a gatekeeper primarily is so that the jury, i.e., the fact finder, has scientifically-reliable evidence on which to base its determinations.

In this case, obviously, the court is the fact finder, and therefore the primary concern -- I don't know if I want to use the word primary -- but a significant concern that is addressed in Rule 702 is not at issue at this point.

There is no question that Dr. Bradley is an expert in

the field of biostatistics. There's also no question that all of the issues which the government very effectively raised in its cross-examination will go to my determinations about the credibility of this witness, both personal credibility and substantive credibility in terms of the testimony he's offered, and will weigh very heavily with me in terms of ultimate findings of fact.

But because we don't have a jury present, I don't think it's necessary to strike his testimony in toto, especially given the fact that he is an expert in biostatistics. And, as I've indicated, all of the issues the government raised will be certainly factored into my judgment.

I think you have completed your cross, Mr. Brody.

MR. BRODY: Yes, Your Honor.

THE COURT: And your redirect, Mr. Minton, is going to be quite short?

MR. MINTON: I think less than a half an hour, Your Honor.

THE COURT: All right. Let's call the witness back in and conclude that.

(Dr. Bradley returned to the courtroom.)

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

MR. MINTON: Thank you, Your Honor.

REDIRECT EXAMINATION

BY MR. MINTON:

Q. Dr. Bradley, with respect to the work that biostatisticians do and whether they are typically the lead author or not, the way that biostatisticians interact in epidemiologic studies, is it typical or atypical for the biostatistician to be the lead author?
A. That would be atypical.
Q. And how about the receipt of funding. Who normally gets the grant when there is a grant involved in a research proposal? Is it the biostatistician or the principal investigator?
A. It's the principal investigator usually, yes.
Q. And the biostatistical criteria the biostatisticians apply, do they defer from one area of health inquiry or another or are they the same?
A. They are all the same.
Q. Now, with respect to mainstream smoking, let's get one thing straight.

Is it your opinion that, from a biostatistical standpoint, that the epidemiologic evidence with respect to mainstream smoking is sufficient to conclude that mainstream smoking is a cause of lung cancer?
A. Well, as I've said before, I believe that mainstream smoking in a sufficient amount and duration can -- does cause lung cancer.

That does require one area which I'm not an expert. That's the biological plausibility. So if I'm willing to accept

that for mainstream smoking, yes, then active smoking does cause lung cancer.

Q. So the only qualification you were intending to make when Mr. Brody was asking you and he showed you that deposition transcript is that a person has to smoke enough?

MR. BRODY: Objection, leading.

THE COURT: Sustained.

BY MR. MINTON:

Q. Was the amount of exposure a qualification that you intended to refer to in your answer?

A. Yes, the amount of exposure.

Q. Mr. Brody asked you some questions about genetics and housing differences and asked you if you were an expert specifically in that area when it came to heterogeneity and your review of the foreign studies, and you said you weren't an expert in Asian housing structures or in genetics.

Have those issues, however, been raised in the ETS epidemiologic literature when it comes to the propriety or impropriety of combining those foreign studies into a meta-analysis?

A. Yes, sir, they have.

Q. And, for instance, what did EPA conclude in 1992 when it came to the conclusion of whether the foreign studies were to, heterogeneous, to include in a meta-analysis of the U.S. population in an estimate of lung cancer risk?

A. Well, they never combined all studies into one summary risk, they only did it by a country. So they did not include foreign studies in their estimate of risk, lung cancer risks.
Q. Mr. Brody asked you a series of questions that had to do with various animal research and laboratory research on the measurement of ETS exposure.
Do you recall those questions generally? And he was pointing you to the IARC report, sections of the IARC report.
A. Yes, sir, I remember those.
Q. What did Dr. Samet say about the reliability of exposure measurements in terms of quantifying human exposure in the ETS studies?
A. Well, he says they were -- I don't remember his exact wording -- but he said they were unreliable. That -- he put emphasis on the simple, where you're exposed or not, but the actual magnitude of exposure, the amount of exposure were not reliable.
Q. Now, you were asked a question about the relationship between statistical significance and magnitude of the effect when Mr. Brody put a passage up there from Rothman's second edition of modern epidemiology, and I think that there was a response that you wanted to amplify with respect to that and the use of statistical significance in terms of a comparison to strength. Do you recall that, generally?
A. Yes, I recall that.

Q. Do you recall what it was that you wanted to add?
A. Yes. That when you run a statistical test, the test -- or the magnitude of the test that you get, it measures statistical significance, is based on three basic factors.

One is the actual difference between the two groups you're measuring. A second would be the size of the study that you're conducting. A third would be the inherent variability that exists in some underlying structure of the study.

Now, it's a well known principle that if you have even a very small difference but a large enough study, you can get a statistically-significant result.

That is, statistical significance may cause a rejection of the null hypothesis, you have some slightly elevated risk if we're talking about relative risk.

(Repeating) That if you take a small difference, but you have a large enough sample size, you can always detect a statistically-significant difference, but that doesn't mean that difference be is meaningful.

For example, as we pointed out before, we have to determine whether the estimate is valid, or even in another context, we would have some clinical meaning. Is it large enough to be meaningful?

On the other hand -- and this occurs quite frequently in the ETS literature -- you can have small studies. And very small studies can lead to very large risks which are not

statistically significant, but then they appear as if, Oh, well, if I had more people, I'd have a -- you know, I'd have a statistically-significant result.

But, as we well know from looking at Dr. Samet's charts, those studies that have the actual largest number of subjects, that is the best precision were the ones that were closest to unity.

Q. Jamie, could you bring up 17168? U.S. Exhibit.

And we brought up 17168. Was that the chart of Dr. Samet that you were referring to, Dr. Bradley?

A. Right.

Q. Is that the specific point that you're discussing?

A. Right. For example, if you look at the largest -- the tallest bar that's on the graph, vertical bar, that's the least imprecise estimate, but it also gave the largest relative risk.

THE COURT: The least precise?

THE WITNESS: Least precise. I'm sorry. I made a double negative. I meant to say least precise or most imprecise, but it also gave the largest relative risk. And that's not surprising because results can vary widely with a small study.

THE COURT: But, of course, many of the studies that were considered in the IARC report covered very substantial numbers of people, did they not?

THE WITNESS: Well, those would be the cohort studies.

Now, that's true. However, you've got to understand with a cohort study you're still going to have very few observed lung cancers.

For example, as I tried to point out among never smokers, that rate is only 14 of a hundred thousand anyway. So if you had a study, let's say with a hundred thousand individuals, you may not observe more than 20 lung cancer deaths in a short period of time.

BY MR. MINTON:

Q. Let's go right to the issue the court just asked about, using the example that Mr. Brody used from the 6 cohort studies in IARC.

Do I need to focus that manually?

We have up Table 2.2 from the 2004 IARC document that Mr. Brody pointed you to. He didn't point you to this table, however, which has the adjusted relative risk or the summary risk from the cohort studies that he pointed out to you.

Do those have -- both in response to the question that the Judge just asked you -- do those have both the number of cases of lung cancer and the odds ratios that are computed for those six cohort studies?

A. Yes, they do.

Q. All right. Is there one in those cohort studies that met statistical significance?

A. No.

Q. In terms of the numbers, the Ns on those -- of those studies, are those the numbers that you're referring to in terms of small numbers?
A. Right. And, of course, the two largest that are relative to my calculations are the Garfinkel and the Cardenas, which are the CPS-I and II studies. Those are the largest ones and yet they give the smallest relative risk.
Q. Did you do your own meta-analysis or chronology of meta-analysis in this case to look at what the trend has been in the results computed in meta-analysis?
A. Yes, sir, I did.
Q. Could you bring up 0220116, Jamie, please?
And is 020116 your summary of those meta-analyses?
A. Yes, sir, it is.
Q. And what is the trend that's indicated there?
A. Well, the trend shows that as we've gotten more and more studies, they've gotten closer and closer to unity,
MR. MINTON: That's at page 139, by the way, of Dr. Bradley's direct, Your Honor.
Q. And is that trend consistent again with your observation in Dr. Samet's chart that as the sample sizes got larger and the estimates got more precise, the more they tended to congregate near 1?
A. Correct. As we are collecting more and more information, then the results seems to be tending to 1.

Q. Dr. Bradley, Mr. Brody asked you a series of questions that dealt with a concept, and I'll probably get the phrase wrong, so I want to look at -- you can take that off the screen, Jamie.

Well, I can remember it well enough, it was page 24 of the 2004 Surgeon General's Report and it talked about looking at multiple lines of evidence in assessing causality.

Do you remember that?

A. Yes, sir, I do.

Q. But he also showed you a series of documents, and you said you wanted to go to page 21 and he said, "Well, we will get to that," but we never did and we will get to that now.

But he also showed you an article that had been written by Sir Austin Bradford Hill in 1965. Do you remember that?

A. I remember that, yes.

Q. And let me ask if he happened to show you this excerpt -- first of all, is it your testimony that in order to assess causality, that you first have to establish an association?

A. That is my testimony, yes.

Q. And is it your testimony that absent a demonstration of association from a biostatistical perspective, that there cannot be proof of causality?

A. That's correct.

THE COURT: Is there anything in the Surgeon General's Reports that disagrees with that basic principle?

THE WITNESS: No, I don't believe there is.

BY MR. MINTON:
Q. Dr. Bradley, what I've put up on the screen is an excerpt that Mr. Brody didn't show you from page 295 of the Hill article. Could you read the highlighted portion, please?
A. Yes. "Disregarding, then, any such problem in semantics, we have this situation. Our observations reveal an association between two variables, perfectly clear-cut and beyond what we would care to attribute to the play of chance. What aspects of that association should we especially consider before deciding that the most likely interpretation of it is causation?"
Q. Is Hill saying there that one must first establish association before one can establish causation?
A. Yes, sir, and that's what I've tried to point out yesterday.
Q. And during the entire two hours of your cross-examination did Mr. Brody put up one piece of data or one element of your method to try to show that association had not been demonstrated? In other words, the data that you relied on, did he point to any of that?
A. No.
Q. Let's go to the Surgeon General's Report on page 21 that you mentioned while Mr. Brody was asking you about this.
Does the Surgeon General on page 21 of the 2004 report say anything about the necessity of first showing association before analyzing causality?
A. Yes, sir, he does.

Q. What's the statement?
A. The statement -- well, we have to put it in perspective.
He talks about the Hill -- in general, about Hill criteria, and then he says, "All these criteria were meant to be applied to an already-established statistical association."
Q. Okay. Let's look at how long that has been the Surgeon General's doctrine. I'm going to put up page 20 of the 1964 Surgeon General's Report. Would you read the highlighted portion?
A. Yes. This is from the 1964 Surgeon General's Report.
"Judgment on this point is based upon indirect and direct measures of the suggested association. If it be shown that an association exists, then the question is asked: Does the association have a causal significance?"
Q. And again is that a clear statement that you first have to show association before you go on to conclude causality?
A. Yes, sir, it is.
THE COURT: And then, of course, in the very next paragraph in the second sentence the Surgeon General says, "The causal significance of an association is a matter of judgment which goes beyond any statements of statistical probability."
Is that correct?
THE WITNESS: That's correct. But if I may clarify.
THE COURT: Go ahead.
THE WITNESS: What they are referring to there is the

situation where you get a statistically-significant result, and the point is you can't, just because it's statistically significant, say that means causation. There are things you have to do beyond that -- if you follow what I'm saying -- as opposed to if it's not statistical significant, you don't need to go any further, but if it is, you need to go further.

BY MR. MINTON:

Q. Let's clear that up, too. Did you ever in your analysis stop at just the level of statistical significance and say, No, I don't have to go any further in my biostatistical analysis?

A. No, sir, I went beyond that.

Q. Mr. Brody asked you a number of questions and focused on your use of the relative risk of 2 in your expert report and the reference to that in your written direct.

Do you remember generally that line of questions?

A. Yes, sir, I do.

Q. First of all, let's look at the core principle here that we are analyzing. Let me put up again page 21 of the 2004 Surgeon General's Report.

The highlighted portion says, "The larger the measured effect, the less likely that an unmeasured or poorly controlled confounder could account for it completely. Associations that have a small magnitude or a weak statistical strength are more likely to reflect chance, modest, bias, or unmeasured weak confounding."

Do you agree with that?
A. Yes, sir, I do.
Q. And at page 15473 yesterday, you testified that what you were trying to point out, in response to one of Mr. Brody's questions, was that in the context of the studies for ETS with the problems of bias and confounding that exists in those studies, why you believed that 2 was an appropriate benchmark.
Do you recall generally that line of questioning?
A. Yes, sir, I do.
Q. All right. Let me ask you about the relationship between biostatistical strength and scientific confidence about validity.
Is the level of biostatistical strength that is sufficient for scientific confidence about the validity of an association, is that a function of the particular types of studies that are being evaluated?
A. Yes, sir, it is.
Q. Okay. Might it be appropriate to apply a level of less than 2, and maybe even substantially less than 2, if different types of studies with different types of study architectures were producing the data?
A. Yes, sir, that's correct.
Q. And you've mentioned randomized controlled clinical trials in your testimony.
A. That's correct.

Q. Might it be appropriate to use a lesser magnitude of association in assessing whether you could have scientific confidence about the validity of the result if randomized controlled clinical trials were the studies providing the data?
A. Yes, and also along with that, you would have to have an accurate measure of exposure, whatever that may be.
Q. You also told Mr. Brody that you could have different benchmarks for the strength of the association depending on the types of studies, but let me ask you just a preliminary question.

Did you review the ETS studies at the strength level of 1.5 in your written testimony and report the results of that analysis in your written testimony?
A. Yes, sir, I did.
Q. And did your overall conclusion about the ETS literature and there being no valid association between ETS exposure and lung cancer or heart disease having been demonstrated, did review at 1.5 change that basic overall conclusion?
A. No, it won't change my opinion.
Q. Now, Mr. Brody asked you a number of questions about the specific use of 2 as a benchmark, and you told him at page 15 -- well, it was page 54 of the daily I got, and I don't have the exact transcript page -- but there's no set rule about what level to use in the literature, but that there is literature that suggested the use of 2.

Do you remember Mr. Brody mentioning Dr. Doll and Dr. Peto and, as a matter of fact, their credentials and their standing as epidemiologists who had worked in the tobacco and health area?

A. Yes, sir, I do.

Q. Okay. Let's see if they've ever suggested that the relative risk of 2 is a relevant benchmark for biostatistical confidence about an estimate of relative risk.

Jamie, could you please bring up pages 1218 and 1219 of JD 061256?

First of all, is that exhibit a document entitled: The causes of cancer quantitative estimates of avoidable risks of cancer in the United States today?

A. Yes.

Q. And was it written by Sir Richard Doll and Sir Richard Peto?

A. Yes, sir, it was.

Q. And if you could turn to page 1218 in the right column.

At the bottom there's a section that is entitled: Limitations of epidemiology. Do you see that?

A. Yes, sir, I do.

Q. Okay. And could you please read that first paragraph?

A. (Reading) The situation is, however, very different when the induced disease is as common as cancer of the lung or cancer of the breast is now.

In these circumstances, human studies will be able to

detect a specific risk only if the absolute risk of death is quite large. Even risks that will ultimately kill, for instance, 1 percent or more of the exposed population may be overlooked or attributed to chance unless a very large scale investigation is undertaken.

In these circumstances, too, when the cancer rates among exposed people are only a moderate multiple of those of the unexposed, i.e., from the relative risk lies between 1 and 2, as for kidney cancer among smokers or breast cancer among women who have been treated with reserpine. For an excellent discussion of latter examples, see Labarth 1979. Problems of interpretation may become acute. It may be extremely difficult to disentangle the various contributions of biased information confounding of two or more factors in the cause and the effect.

Q. Do you agree with the passage you just read?

A. Yes, sir, I do.

Q. Is it consistent with your analysis in this case?

A. Yes, sir, it is.

Q. Are Doll and Peto suggesting 2 as an appropriate benchmark for evaluating the strength of association in terms of the scientific confidence of eliminating bias and confounding?

A. I believe they are, yes, sir.

Q. Is Norman Brezlow a well known biostatistician at the Fred Hutchinson Cancer Research Center in Seattle, Washington?

A. Yes.

Q. Did Dr. Brezlow write a scientific treatise for IARC entitled: Statistical Methods in Cancer Research?
A. He did.
MR. MINTON: Rich, could you please hand Dr. Bradley that? Do we have an extra copy for the Department of Justice? It's JD 025151.
Jamie, while we are waiting, could you please bring up page 36?
Q. Is there a discussion -- first of all, is JD 025151 an IARC publication entitled: Statistical Methods in Cancer Research?
A. Yes, sir, it is.
Q. And one of the authors is Dr. Norman Brezlow?
A. Right. The other is Day and then there are various contributors to this particular monograph.
Q. And that's an IARC -- an official IARC publication?
A. Right. It's commissioned by IARC to describe statistical methods appropriate in the investigation of cancer research.
Q. And over on page 36, is Dr. Brezlow generally discussing concepts of bias and confounding?
A. Actually, it's Dr. Phillip Cole who actually authored that chapter, but they are adopting his chapter, but he does address the concept of relative risk.
Q. All right. Let me show you an excerpt on page 36. And does that excerpt say, "The strength of the association relates to causality. Relative risks of less than 2.0 may readily reflect

some unperceived bias or confounding factors. Those over 5.0 are unlikely to do so." Do you see that?

A. Yes, sir.

Q. And is Dr. Cole in this IARC publication specifically referring to a benchmark of 2.0 in assessing the strength of association?

A. Yes, sir, he is.

Q. Let's look at JD 025150. We are just going to look at the first page. Is that a publication from the National Cancer Institute, Office of Cancer Communications?

A. That's correct.

Q. And directing your attention to the third paragraph, Dr. Bradley, do you see the statement, "In epidemiologic research, relative risks of less than 2 are considered small and are usually difficult to interpret. Such increases may be due to chance, statistical bias, or effects of confounding factors that are sometimes evident."

A. Not evident.

Q. Excuse me. Not evident.

A. Yes, sir, I see that.

Q. And do you agree with that statement?

A. Yes, sir, I do.

Q. And is NCI in this document suggesting 2.0 as a possible benchmark for the evaluation of the strength of association in assessing scientific confidence about bias and confounding being

adequately excluded?

MR. BRODY: Two objections, Your Honor. Leading and a scientific foundation for what, you know, NCI considers.

I also think it's a mischaracterization. It's a leading question based on a mischaracterization of the document. I've let these go, but --

THE COURT: I don't think it's a mischaracterization. Yes, it was leading, but it's not a mischaracterization.

Next question, please.

BY MR. MINTON:

Q. Well, the question was: Is NCI in this document appearing to acknowledge 2.0 as a benchmark for achieving scientific confidence that bias and confounding have been minimized in terms of assessing the validity of association?

A. I believe they are, yes.

Q. Mr. Brody asked you yesterday about an article in the New England Journal of Medicine. I think it was the only odds or hazards ratio that he pointed to, perhaps, in the context of that discussion.

Do you recall that?

A. I recall it, yes.

MR. BRODY: Just for clarification. Which of the two New England Journal articles are we referring to?

MR. MINTON: I'm talking about U.S. Exhibit 93173, and it had to do with the -- the title of the article was: Impact

of high normal blood pressure on the risk of cardiovascular disease.

Q. Do you remember that article?

A. Yes.

Q. Had you ever seen that article before?

A. No, sir, I've not.

Q. It refers to something called a hazard ratio.

What's a hazard ratio?

A. Well, a hazard ratio can be the same thing as an odds ratio that we've been talking about, seeming that the variables are appropriately defined.

Q. All right. And Mr. Brody pointed to hazard ratios in that article. First of all -- well, Mr. Brody pointed you to hazard ratios in that article of 2.5 for women and 1.6 for men, and I'm going to hand you the study, Dr. Bradley.

And my first question is: What is the relationship that was being investigated in that study?

MR. MINTON: May I approach, Your Honor?

THE COURT: Yes, you may.

THE WITNESS: I need to review this just a second, if I may.

THE COURT: Well, I think this is probably as good a time as any to take our morning break because we are pretty far beyond where we usually do.

So I will allow the Doctor to look at this article. Of

course, he may not discuss it with anybody, but he can review the article, which he testified he hasn't seen, and then we will take 15 minutes. And you should be almost done, Mr. Minton.

MR. MINTON: I am, Your Honor.

(Recess began at 11:10 a.m.)

(Recess ended at 11:29 a.m.)

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

BY MR. MINTON:

Q. Dr. Bradley, when we broke we were about to address the -- what were the variables that the authors in the New England Journal of Medicine article, that's U.S. Exhibit 93175, had studied. Have you had a chance to look at that article?

A. Yes, sir, I have.

Q. And what were the variables that were being studied?

A. Well, the outcome was whether one developed some type of cardiovascular disease and the exposure in this case, the variable of interest was whether they had what's called a high normal blood pressure reading.

Q. Okay. Were the investigators actually measuring blood pressure?

A. Right. There was no proxy here. They, in fact, actually measured blood pressure.

Q. And how does that differ from the ETS studies?

A. Well, there in the ETS studies, as I tried to point out, the ETS was not directing measure. It was measured through proxies,

and in some cases the answer was provided by a proxy.
Q. If you could look over on pages 1294 to 1296, did the authors make any statement in that article whether or not they were claiming that the hazard ratio that they were reporting was somehow free of bias or confounding?
A. They did investigate that.
Q. What did they say?
A. They said that even though they showed elevated odds -- I mean, odds hazard ratios, which we can think of as odds ratios in this particular situation, that they are uncertain as to whether it's solely due to the blood pressure levels.
Q. So did they make any statement in that article that the odds ratio that they had calculated offered scientific confidence that they had not eliminated bias or confounding?
A. They said they had not eliminated biases and confounders.
Q. You recall Mr. Brody asked you a series of questions about the Enstrom and Cabot article?
A. Yes.
MR. MINTON: Jamie, could you bring up 024496, please, at page 1060?
Q. It's kind of hard to see, Dr. Bradley, but at the bottom of that page there's a notation about funding. And my question is simply --
A. Which page are we on?
Q. 1060. Maybe I gave you the wrong page.

A. No, it just has multiple. They are not in numerical order.
Q. I apologize.
A. I'm on the page now.
Q. I just have one question. Was the -- was funding acknowledged in that article itself and did that funding refer to -- Jamie I think you need to move the image down just a bit.

Well, I don't know if we can get it both up there at the same time.

Does the article itself acknowledge specifically funding from CIAR?
A. Yes, it does.
Q. To the extent that you used epidemiologic studies in your biostatistical analysis, they are identified in the various charts and demonstratives in your testimony; correct?
A. That's correct.
Q. While he was cross-examining you, did Mr. Brody point to a single one of those studies and suggest to you that either the data that were used or reported out, that study or the method that were used were flawed?
A. No, sir.
Q. Did Dr. Smith, in the 2003 article that you referred to in your live direct, did he address whether, despite criticisms that had been made of the Enstrom and Cabot article, for instance, whether anyone had pointed out any actual flaws in that paper?

A. He said nobody had pointed out any actual flaws.
Q. Now, Dr. Bradley, a final topic. Is it correct to say that the 2004 Surgeon General's Report endorses a methodologic analysis of causal criteria in terms of making a judgment about causation?
A. Yes, sir.
Q. And certain of those criteria subsume or include the biostatistical factors that you've used; right?
A. That's correct.
Q. And let's take the 1964 Surgeon General's Report as an example and, in particular, the Surgeon General's inquiry with respect to cigarette smoking, active smoking in lung cancer.

In that report did the Surgeon General go through criterion by criterion and weigh the evidence, including the biostatistical evidence of an association?
A. Yes, sir, he did.
Q. And that was the method that the Surgeon General still endorses in the year 2004; correct?
A. Yes, sir, it is.
Q. Now, turning your attention to the 1986 Surgeon General's Report. If we look in that report, will we find anywhere that kind of systematic point-by-point evaluation of those causal and biostatistical criteria as we see in the '64 report and as we see in the 2004 report?
A. No, sir.

Q. All right. And with respect to, for instance, the statistical significance criterion. Of the five U.S. studies that the 1986 Surgeon General's Report cited or pointed to in that report, how many met the criterion of statistical significance?

MR. BRODY: Objection, beyond the scope of cross, Your Honor.

THE COURT: No. Objection is overruled.

You may answer the question.

A. None.

Q. And let me move to your next biostatistical factor and point you to some language from the 1986 Surgeon General's Report on that.

This is from page 13 of the 1986 Surgeon General's Report. Would you read the highlighted language, Dr. Bradley?

A. It says, (Reading) More data on the dose and distribution of ETS exposure in the population are needed in order to accurately estimate the magnitude of risk in the U.S. population.

Q. So they didn't estimate the magnitude of risk in the U.S. population in terms of their analysis in the 1986 Surgeon General's Report, they said more data were needed; correct?

A. That's correct.

Q. And with respect to Dr. Samet's written testimony in this case, did Dr. Samet go through a point-by-point evaluation of the biostatistical evidence for the three criteria that you have

used in your report?
A. No, sir.
Q. As of today, 2005, has there been any public health organization that has come forward and could point to anything as far as you know that you got wrong in terms of your analysis of those biostatistical criteria or have suggested that those biostatistical criteria are met?
MR. BRODY: Objection, Your Honor. The witness testified that none of his work has ever been published, and I think the question is has anyone pointed to his analysis and -- well, anything that he got wrong?
The question was: Has any public health organization come forward and could point to anything as far as you know that you got wrong in terms of your analysis? That was the question.
THE COURT: And they may have gotten it some other way other than publication. The government might have given it to them. And besides which, now that I think of it, this would be on the Web with -- well, perhaps not on the Web, but it was filed publicly. It's a public document. So the real point is a slightly separate question.
Objection is overruled.
A. The answer is no.
Q. Dr. Bradley, in terms of the actual analysis that you did and reported out and the conclusions based on that data, which are all reported out in charts in your report that are similar

to 020161, is there any publication by any public health organization that you're aware of that is in substantive conflict with your analysis of those biostatistical criteria?

A. I don't believe so.

Q. Thank you.

MR. MINTON: That concludes my examination of Dr. Bradley.

THE COURT: Dr. Bradley, thank you. You may step down at this time.

Mr. Biersteker, are you ready with your next witness?

MR. BIERSTEKER: I am indeed, Your Honor. Defendants call as their next witness Dr. William E. Wecker.

MR. GETTE: I'm sorry, Your Honor, I was trying to get situated. We do have some pending objections with respect to this witness that we filed last week.

THE COURT: I've looked at them. We can do the one-hour demonstrative and then I will rule in terms of what's in and what's out.

MR. GETTE: Thank you, Your Honor.

THE DEPUTY CLERK: Please raise your right hand.

WILLIAM E. WECKER, Ph.D., Defendant's witness, SWORN

THE DEPUTY CLERK: You may be seated.

MR. BIERSTEKER: May I proceed, Your Honor?

THE COURT: Yes, please.

DIRECT EXAMINATION

BY MR. BIERSTEKER:
Q. Dr. Wecker, you have with you on the witness stand your written direct examination prepared pursuant to Order 471 in this case. Are there any changes that you wish to make to that written direct?
A. Yes.
Q. Please tell the court what they are.
A. On page 17, line 1, the number 2.5 should be 2.3.
Q. Okay.
A. That change has its effect further down the page. So that in line 3 as a result of the change the 7.5 needs to be changed to 6.9.
Q. All right.
A. Then in line 5, 2.5 again changes to 2.3. 7.5.
THE COURT: Is it 2.2 or 2.3?
THE WITNESS: 2.3, Your Honor.
A. So in line 5, you see the erroneous 2.5 should be 2.3.
The 7.5 should again be 6.9.
And finally on line 9, there's a 7.5 that should be 6.9.
There is a change on page 20.
Q. All right.
A. Line 10. Where you read the words "computer program", delete "computer program", replace with the word "regression."
And the last change on page 34, line 6, it reads "less

than 0.6," it should be "less than or equal to 0.6." Those are the only changes.

Q. With those changes, Dr. Wecker, do you adopt your written direct examination as your testimony in this case?

A. Yes.

MR. BIERSTEKER: Your Honor, I would ask that the court accept the written direct examination pursuant to Order 471.

THE COURT: Yes, it may be admitted.

MR. BIERSTEKER: Thank you.

And at this time I would also ask that the court accept Dr. Wecker as an expert in statistics, although I understand that there are some pending objections, and if you wanted to defer a ruling on that, that would be fine.

MR. GETTE: The government would like to reserve on that and include some potential voir dire, Your Honor, examination of the witness.

THE COURT: All right. I will reserve on it.

BY MR. BIERSTEKER:

Q. In your written direct examination, Dr. Wecker, you discuss whether smokers who switch to lower tar and nicotine brands increase the number of cigarettes they smoke each day, and one of the analyses you discuss is the analysis which appears in Monograph 13 as figure 4-7. That's U.S. Exhibit 58700 already in evidence.

If we could display that, Jamie.

All right. That is the reproduction of that figure from the monograph. And one of the errors you discuss in your written direct examination was the inclusion of two highly correlated predictor variables, change in tar and change in nicotine while only looking at the change in nicotine to interpret the results in this figure.

And as you further noted in your written direct, there appears to be a basic factual dispute. Dr. Burns said, Oh, no, change in tar -- in fact, they list the covariates in the figure itself, and change in tar is not among them, along with the slope of minus 2.31. But Dr. Burns said, No. Change in tar is not one of the variables included in this regression, and you took issue with that in your written direct.

So I guess for the sake of the court, I wanted to ask one threshold question before we go down and pursue and run to ground this factual issue, and that is: Why should we care?

Is that important whether or not the change in tar variable is included in this regression that yields this figure or not?

A. Yes, it's very important because if -- and I believe I'm correct -- but let's just say that if I'm correct that the change in tar variable is included in the regression that underlies the figure 4-7, then the depiction on 4-7 does not accurately portray what would occur to change in cigarettes per day if you changed to lower brand.

Because when changing to a lower brand, both tar and nicotine change, both would have to be taken into account, and this display only looks at one, holds the other constant, which is not a correct procedure.

Q. All right. And with that indication of why it's important to look at this, have you prepared some demonstratives that you believe show why you think change in tar is included in the regression that generates this figure?

A. Yes.

Q. All right. If we could please display J-DEM 06056, Jamie.

All right. What are you showing in this demonstrative, Dr. Wecker?

A. This is the regression that I ran to replicate the results in figure 4-7. You can see under -- where I've underscored in the chart with the yellow line the negative 2.31 figure, with a lot of other decimal places that are not material here, but the 2.31 figure, that is a part of figure 4-7, and it's associated with this cryptic NDF variable, which stands for -- DF, difference in nicotine, meaning difference in nicotine, change in nicotine.

So there's your change in nicotine variable, which is displayed in figure 4-7, along with this slope of minus 2.31. And right below it is the change in tar variable that is not taken into account when -- or at least not properly taken into account when constructing 4-7.

Q. If you take out the TDF, or change in tar variable, do you still get a slope of minus 2.31, the same slope that was in figure 4-7?
A. No. If you were to run a slightly different regression as I have, which is simply to take away the DTF, or change in tar variable, all these submits change, and minus 2.31 becomes a completely different number.
Q. All right. Why don't we display J-DEM 060520? And what is displayed, Doctor, in this demonstrative?
A. This is, in a chart I made in the style of figure 4-7, looking at the change in nicotine yield as associated with change of brand and how it would be associated with change in cigarettes per day, but without the problem present in figure 4-7 because I've taken out the change in tar variable.

And so this is the quite different result of a number much closer to zero, minus 0.65 cigarettes per day per milligram change in nicotine.
Q. I see there's a note on the bottom. So am I correct in reading that, that the only change you made from the regression that replicated figure 4-7 was to remove the change in tar variable?
A. Yes.
Q. And when you did that, as you, I think, pointed out, you got a very different slope for the change in nicotine?
A. Well, all of the coefficients changed, including the age and

the other ones listed at the top of the page, but the one that is of interest is the one I changed on nicotine, and it changed dramatically to minus 0.65.

Q. Why don't we display then the next demonstrative, which would be 060566, and if we could put that up, Jamie, side by side with 567.

All right. It's a little hard to read when we do it that way, but maybe we could enlarge the top part that way?

Doctor, what are you showing in this demonstrative 060566?

A. Yes. The enlarged equation at the top portion of the display is the equation that was used to actually make the figure 4-7. It makes the dots. The line is easy to make. A high school student could make the line if he knows the slope. But making all those dots that you recall is a computer chore and this one does that work.

And this is the point -- and you can read it in the acronym ADJCDF -- where adjusting of the change in cigarettes per day is going on.

What's happening here is that 4-7 intends to look at the effect of change in nicotine yield holding everything else constant, or you could say subtracting out all the other effects, and this is where that happens.

There's a minus sign, and the CDF is subtracting out all the other effects like effect of age or baseline tar and so

on. And one of the things it's subtracting out is that number .12 and so on times the change in tar variable. And you can see that that very same number is, in fact, all -- well, let's just focus on that one. That very same number is coming from the regression in the display below where it's been highlighted.

Q. Let me just ask you a question.

The document on the top, which is the J-DEM 060566, is that something that you generated or is that something that Dr. Burns through the University of California produced to us?

A. That was produced by Dr. Burns.

Q. Now, I notice, Dr. Wecker, that the numbers in your replication on the bottom half of what's on the screen and the numbers on the top half are very close together, but once you get out to the fourth or fifth decimal place there are some differences. Why is that?

A. That's just rounding differences.

Different computers handle internally numbers in different ways and that leads to slightly different -- slight differences in the fourth or fifth or sixth decimal place.

Q. Before we leave this particular area, the change in cigarettes per day, I want to display, if I could, Jamie, J-DEM 060519. 519.

And this is basically, to close it out, when you looked at changes in cigarettes per day in that data set that was used

in figure 4-7, you displayed your result in this demonstrative. Why don't you explain it to the court?

A. Yes. This result shows that there is practically no change at all in cigarettes per day that is associated with changes in nicotine yield.

It's based on the very same regression that is used to construct figure 4-7, but the reason it gets such a different result is that it's not trying to hold the change in tar constant while changing the nicotine. It's a basic impossibility as I understand the choice of commercial cigarettes. And so that any appreciable change in tar when you change brand is accompanied by a necessary change in nicotine, so you wouldn't want to try to hold that variable constant.

When I allow that variation to take place I see there's essentially no change in cigarettes per day.

Q. All right. Why don't we turn to our next topic, which would be figure 4-5 in Monograph 13, and Jamie, why don't we just pull that figure up. J-DEM 060531.

This is a straight replication of what's in the monograph. And in your written direct you explain that the third set of bars, the one on the far right, was not limited to people -- was not limited to the data that appears in the first two bars with the difference that they have flat cigarettes per day and flat tar. And I wanted you to elaborate on that testimony as to the error you identified in this particular

figure. And to do that, have you prepared a series of demonstratives?

A. Yes.

Q. Why don't I have J-DEM 060560, please?

And, Dr. Wecker, why don't you explain what we are showing to the court in this particular demonstrative?

A. Yes. This is the first of a handful of computer level errors. This is truly a typo -- typographical error, but it's a typographical error in a computer program and it has major consequences. And I'll try to explain it.

I've listed only 10 individuals here. There's actually thousands of cases like this.

The first ID number there is a male with a certain age.

And the next variable with the name "Alike," which has a value of zero, is a determination that was made by the computer calculation of Dr. Burns and his statistical associates.

That the cigarettes per day value for this particular individual didn't change as it was reported in the survey, in the various follow-ups in the survey. And that would be a correct determination if you looked to the right based on the data here, which shows that this individual reported a level of 30 in 1959, and then there's a missing value, and then a 30 and a 30 again.

And so it's -- that is a sensible conclusion to reach

based on this data. There was no apparent change in CPD, with one lingering question about this missing data in 1961.

Now, therein lies the error. It turns out that this little typo in the computer program had the effect of completely dropping all 1961 data.

THE COURT: What's the typo? That they left out all of the '61 data?

THE WITNESS: That, Your Honor, is the effect of the typo. The typo, which I can show in a -- I have their computer program if it's within the procedure to allow to show it.

THE COURT: Just tell me what's the typo.

THE WITNESS: They typed C2, they meant to type CQ.

THE COURT: Say that again.

THE WITNESS: They typed C2. They left out the Q.

So they put the information from the 1961 data in the place in the computer that is labeled C2. Then they went looking in a different place, CQ2, and there was nothing there.

It's very easy to see if we could show the computer program. It's as if it's a misfiled file where you say, "File this under Jones" and they accidentally file it under Smith. They go back and look at Jones, there's nothing there.

THE COURT: And did you ever discuss this with Dr. Burns?

THE WITNESS: I've never actually met Dr. Burns, but I've -- I wrote a report in which I described in great detail

the attachment exactly where the typo was, how to fix it, what's its consequences were. And I believe it's in the record a memo from his -- Doctor -- or Mr. Shanks, his statistical helper, that acknowledges that that is indeed a typo. And that's my interpretation, but I can only give you what I read.

MR. BIERSTEKER: I think we can actually do -- if Your Honor -- I hadn't planned on doing this and this might make us take a little longer, but if you look at JD -- we will need to get a copy.

THE COURT: Mr. Biersteker, I'll make it a little shorter. If you can show me what Mr. Shanks wrote back and if he did, in fact, acknowledge that it was an error, I don't have to see the details of this computer mistake.

MR. BIERSTEKER: We will get that on a break, Your Honor. I'm not sure we have that immediately available to us here, but we will get it.

BY MR. BIERSTEKER:

Q. In any event, if we could go back to J-DEM 060560 and display the last column.

A. Yes. Appearing on the right -- and I asked Jamie to hold that portion of the chart for a moment -- is the actual data that was misfiled, misplaced.

So if that data hadn't been accidentally dropped, then this person, this first person, would have not been what the computer was looking for, a flat CPD person because there's a

change there. You can see it in the last person easily. Twenty in 1959 and then 40 in 1961, and then back to 20.

Since the computer program was seeking people, it did not change cigarettes per day, they would have rejected these individuals for not having a flat cigarettes per day.

THE COURT: Would they have rejected the people on lines 1, 2, 3, 4 -- on all of those lines?

THE WITNESS: Everyone, Your Honor, because their requirement is that they don't change their cigarettes per day, a severe restriction, and a lot of individuals are not going to be included in the third bar.

THE COURT: I understand.

THE WITNESS: But there's a reason for it, a stated reason for it, and that's Dr. Burns' reason and we can come to his reasoning. I'm just going through the nitty-gritty here.

BY MR. BIERSTEKER:

Q. You mentioned that this demonstrative was illustrative.

How many people, because of this typographical error, were -- approximately -- were dropped from the analysis -- excuse me -- were included in the analysis when they should have been dropped?

A. 8,723.

Q. May I please have the next demonstrative, J-DEM 060559?

And Dr. Wecker, were there other problems with the constant cigarettes per day or flat CPD that are illustrated by

this figure?
A. Yes.
Q. All right. Why don't you explain it, please?
A. This study, first the top portion of the chart and you see a list of individuals, and the alike variable has been set equal to zero by the computer calculation, and zero means for this particular calculation that these are people to be included. They are alike in terms of cigarettes per day.

But you can see that, by eye, none of the individuals in the top portion are alike. They all differ. So by the intent, as I understand it, they would not have been included, but the computer -- there was a flaw in the logic and it included them.

The flaw, again I don't know if it is best to characterize it as a typo or just a moment of inattention, but I know exactly where the spot is in the code, and the code simply says: If the 1959 value is missing, stop looking, this person has all -- is a flat CPD person.

That's obviously faulty logic and it results in including a lot of individuals that I think were not intended to be included.
Q. And I think there's an illustration of this on the bottom half. But am I correct that this same flaw, if 1959 is missing, include them, assume that they didn't change their cigarettes per day, does that result in the inclusion of people about whom

we know nothing about their cigarettes smoked per day?
A. Yes, because the logic says to first look at 1959. If it's missing, stop, include the person. So, this -- here are 10 people about whom we have no information on their cigarettes per day in an analysis where the intent is, and the important aspect is, to have a constant or unchanging cigarettes per day, and we are including a bunch of people about whom we have no knowledge.
Q. And are these, are the individuals included in this demonstrative the universe of everybody who was affected by the: If it's missing in 1959, include them, assume that their cigarettes per day were alike or is it illustrative?
A. There's more than this.
Q. When you corrected the flat cigarettes per day errors that you have discussed, how did you, Dr. Wecker, in your analyses define flat cigarettes per day?
A. My -- I changed their logic, which was flawed, to simply look at every one of the cigarette per day values, including the ones that were dropped. I reinstated them, the 1961 values. And if they were all the same, then that person was deemed a flat CPD person and included.

If there was no information on cigarettes per day, like the case at the bottom, or if there was only one value in which -- which gives no information on whether there's changing going on, those were not included. Just the ones where I could affirmatively find at least two values that were no different.

Q. And may I please have J-DEM 060558, Jamie?

This one looks pretty complicated, and in fact, it is. Why don't you explain this one to the court?

A. Yes. The best approach to this chart is to take it in little pieces. If we could highlight just the portion toward the middle where it says "original values." Thank you.

Those are the data as -- at the beginning of the computer analysis. These are ACS-1, American Cancer Society data, as coded by Dr. Burns to record the amount of tar in the brands that the respondents indicated they smoked. That's the starting point.

Now, the issue in the error here is different. This is not an issue of flat cigarettes per day any more. I'm on to a different point.

Q. Okay.

A. One of the variables that is required here in this analysis for it to go forward is to know the 1959 or baseline tar value. And you can see that that should not be a problem because every person on this list of 25 has a recorded value for their 1959 baseline tar.

Well, in the next set of values -- if we could highlight that maybe with a different color. Yes, that's good. The green area.

What the programmers did that worked with Dr. Burns was a perfectly sensible thing. They simply copied the 1959 values

into every follow-up study, so that the same value appears over and over and over again.

Although that might ordinarily seem not like a good procedure for their computer implementation, I have no quarrel with it, because then when they are doing the analysis of the 1961 data, they have handy right there in a file named 61 the baseline tar they need, and they know that it originally came from '59.

So in making the first two sets of bars they used the green information and made no mistake when they went to find the amount of baseline tar.

I don't have an explanation for how the mistake occurred, but I can see that when they went to the third set of bars they did not follow through and copy all of the values the way they did with the green section.

Q. And the third set of bars, that's the one that's labeled Set 3 values up there?

A. Right. The one that's now in red.

THE COURT: Are you saying that the first mistake was that the programmers copied the green bars inaccurately?

THE WITNESS: Your Honor, that's perfectly fine, that part. The intent and --

THE COURT: And what was the mistake? I'm sorry, I missed it.

THE WITNESS: The mistake is that the red data doesn't

look like the green data. There's a bunch of dots in there.

The green data are fine because they record in all the places you need to look in the analysis the baseline tar value, which is one of the variables required. But some of the green data got dropped when moving to the third set of bars.

THE COURT: I see.

THE WITNESS: I don't have full insight into how that happened, but I know it happened because I can look at the data and see it.

And, consequently, when they come to the analysis for that first individual in the first row they are going to have to -- the computer forces them to drop some of the follow-up data, and so we end up with portions of data for some people being retained, and portions that should be retained being dropped, and therefore, there is a loss of underlying data that shouldn't have been lost.

BY MR. BIERSTEKER:

Q. And how widespread? How many people or observations were -- how many people were part of the data for that person lost as a result of the error that you show up there?

A. The number of people affected by this error is very large. 15,820 different men.

THE COURT: How do you know that they dropped the data as opposed to not having data to include in the red bars?

THE WITNESS: I know that, Your Honor, because the data

that should be included is exactly the 1959 data, and I can see it's there. There's no missing 1959 data. This is another issue of misfiling. The data is there. It's known to them. But they intended to file it in a storage location as in the green bars in a number of different copies.

They went to the copying machine and they copied that file over and over again. They filed it four different times so they could always find it easily when they did the computation.

But they -- when they did the red portion, they didn't file it every time and, therefore, when they went looking for it, it wasn't there.

BY MR. BIERSTEKER:

Q. And just -- maybe this is clear, but maybe it's not. I know this is sometimes difficult stuff.

But basically in the red bar over there, Doctor, given the way their computer program worked, we should see the 1959 values replicated everywhere. Is that what you're saying? Just as we see it in the green set.

A. Yes. If they had used the green information for the third set of bars, there would have been no problem.

Q. Before we move on to the next error in this particular program, why don't -- I have marked as JD 053679.

MR. BIERSTEKER: If I may approach, Your Honor?

THE COURT: Yes.

MR. BIERSTEKER: Thank you.

Q. Doctor, do you recognize this particular exhibit?
A. Yes.
Q. And what is it?
A. This is a memo written by Thomas G. Shanks in January of 2003 on the subject of my report in a case known as Miles and, in particular, he discusses these computer errors.
Q. And Mr. Shanks, who is Mr. Shanks?
A. He's a statistical expert who worked together with Dr. Burns in, especially the statistical side of the work that was done in this case -- or not only in this case, in Monograph 13.
Q. And here he refers to the typographical error that was the subject of the court's inquiry, the omission of that letter C from the CP2, and he says it was most likely caused and he's got a couple of causes.

But, basically, is Mr. Shanks acknowledging the error that you point out in that paragraph?
A. Yes. It makes me think I misspoke. I said a moment ago that he dropped the Q. Maybe he dropped the C. But, anyway, he dropped one of them. And I think another spot in this paragraph that's helpful is that he refers to it as a bug.
Q. Right. I don't see that particular reference. Do you?
A. Well, maybe that's somewhere else.
Q. All right. Fine. Why don't we move on to the second error in figure 4-5 -- which is those sets of bars, Your Honor -- and you identified in your written direct the second error was that

the analysis was not limited to people who had constant or flat tar for all the different periods when they were observed.

And if I could have J-DEM 060561.

And, Dr. Wecker, if you could explain this demonstrative to the court?

A. Yes. This is on the subject of tar and whether or not it's flat or whether it's changing.

As I understood the construction of the third set of bars and the intent of them, both flat cigarettes per day unchanging and flat tar, basically brand or very close to the same brand were to be flat, but here we have individuals that are clearly changing tar and they are being included because the alike variable is determined to include them in the third set of bars.

Q. And again, this is an issue that you note for, I don't know, maybe 10 people here, but was it a problem that was more widespread?

A. Oh, yes. There were at least 9,000 or more individuals affected by this problem.

Q. Let's just quickly wrap this up. Talk for a minute about the effect of the different errors with respect to figure 4-5 and we will move on after that to 4-18, our last topic.

If I could have J-DEM 060554? And what is this demonstrative, Dr. Wecker?

A. This is I guess two things at once.

On the left-hand side, it shows figure 4-5, and then on the right-hand side it shows what the difference is when I fix all of the bugs and missing data and correct logic that I've described here today.

Q. Did you do this analysis for men and women combined?

A. Yes.

Q. Why did you do that?

A. Well, there's both men and women in the ACS-1 data set. And I know that others who have looked at these kind of questions, have looked at both men and women, and it just seemed sensible to look at the women in the data set, and so I did.

THE COURT: What does the final corrected figure 4-5 actually tell us? What's the bottom line on that graph?

THE WITNESS: Your Honor, I think it says this. That if one used figure 4-5 as the basis for an argument that there's some kind of bias in the first two sets of bars in figure 4-5 and that bias is now investigated and perhaps cured by the third set of bars, and when that cure takes place we see an important difference between prior literature and the work on the left side of the chart, because prior literature and the left side of the chart suggests increasing risk with increasing tar. Whereas, the third set suggests all levels of tar have about the same risk.

But there were errors in 4-5, in my view, if anyone were to credit my view in this. These errors are important and

they are -- they go throughout the analysis and deal with thousands and thousands of individuals. And so one would want to fix those. And when I fix, I see higher tar is associated with higher risk in the fixed set on the right.

Now, I think maybe I should stop or I'll soon be unresponsive. You may choose to ask me about those whiskers.

BY MR. BIERSTEKER:

Q. What about the whiskers, Dr. Wecker?

A. Thank you. I hope not to be an unruly witness here.

There is another observation about the bars on the right-hand side, and that is by the time I implement all of the flat rules and all of the fixes, there is not a great deal of data left.

And that's just a matter of applying the medicine, the third set of bars is -- that has been prescribed by Dr. Burns, to cure a problem in the first two, but the medicine has this side effect, that in trying to find all these people with flat CPD in tar, a lot of people have to be set aside, and you're left with a lot fewer, and the result is the accuracy with which you can make estimates goes down, and that is the plus or minus factors that we've all heard about in reporting statistical results.

That's why those black vertical lines have gotten so much wider here, but even though they are wider, the results are -- should still show a statistically significant increase.

Q. And if you combine and you look at men and women together, does that at least partially address this problem of having dropped so many people?

A. Yes. That's one good reason to look at the women, because now you can add a lot more data and have a better appreciation of this effect.

Q. All right. So why don't we look at the analysis for women, which was J-DEM 060535. And just briefly explain this, please, Doctor.

A. Yes, the title explains it. This is men and women in the analysis, so now more data is available.

Basically, the first two sets of bars have the same feature that, with the men alone, and the third two set of bars again with a little more data now because the women have been added. Still with all the corrections and requirements for flat CPD in tar, so I'm trying to implement as I understand the intent of figure 4-5. We show elevated risk for elevated levels of tar.

Q. And as you point out in your written direct, Dr. Burns has changed his testimony and now says No, it's only supposed to be flat cigarettes, but tar should be allowed to vary. It doesn't have to be constant tar through all periods of observations.

Have you made these same corrections, but allowing tar to change in an analysis of figure 4-5?

A. Yes.

Q. If we could have J-DEM 06537, please. And again briefly explain it for the court.
A. This is the chart you asked about where now the third set of bars has all the computer typos fixed, and it implements flat cigarettes per day with a more appropriate logic, but I do not impose a requirement that the tar has to be flat based on the more recent testimony of Dr. Burns, that that was the variation that he had in mind all along.
Q. And does it continue to show an effect of tar on lung cancer risk?
A. Yes. I think a fair reading here is there is increased risk with increased tar.
Q. In your written direct you -- at page 38, there's a pretty long quote you got from Monograph 13. And the quote, if I could paraphrase it, is basically to the effect that while the smokers who switched to lower-yield cigarettes increase the number of cigarettes they smoked per day, then the results in the first two sets of bars in figure 4-5 may be biased and may not actually reflect the reduction in risk, if any, for lower-tar cigarettes.
And if I could display, please, Jamie, J-DEM 060519 again.
You investigated that and you wrote in your written direct that the smokers who switched did not increase the cigarettes they smoked per day, and you also discussed some

published literature about that.

But for now I want to know what is the implication of the result that, in fact, you found that smokers who switched to lower-tar cigarettes did not increase the cigarettes they smoked per day for that right most set of bars in figure 4-5?

A. Could we go back to that --

Q. Sure.

A. -- the 4-5 chart so I can make reference?

Q. Sure.

A. This is a very important point. The whole motivation --

Q. Maybe we should pull it up. I think it's J-DEM 060538. If I've got to wrong one, let me know.

A. Anyone will do.

Q. This is a different one, actually. Well, maybe 32. 532 0605. Does this do it?

A. Anyone will do, because my point isn't particular to any one of these variations.

Q. Let's use this.

A. From a more fundamental point about the motivation for making the third set of bars in the first place. I think it's an unavoidable, easy interpretation, that the reason that Dr. Burns was motivated to create this third set of bars is that he thought the first two could contain a bias and he even understood how that bias could possibly come about.

But it's a bias that comes about from an increase in

cigarettes per day when individuals switch to lower levels of tar, and there's a reason why that could result in a bias.

But if they aren't switched -- if they aren't changing cigarettes per day, and that's what I found, then there's no bias to cure, there's no need to do the third set of bars in the first place and all that work is a waste of time.

MR. GETTE: Objection, Your Honor. I move to strike that. The whole answer was premised on what the witness said with Dr. Burns was motivated to do. As this witness has testified, he's never even talked to Dr. Burns regarding the results that he found in his investigations.

THE COURT: Well, he certainly testified to that extent.

Mr. Biersteker, did you want to phrase the question differently?

MR. BIERSTEKER: Yes, sure.

BY MR. BIERSTEKER:

Q. You have an understanding, do you not, Dr. Wecker, about what the purpose of the third set of bars is; correct?

A. Yes.

Q. And does that -- where does your understanding of that purpose come from?

A. Monograph 13 lays it out in black and white.

Q. Have you also reviewed the testimony of Dr. Burns when he was asked questions about what the motivation was for doing the

third set of bars?
A. I read some of the testimony, not a lot of it.
Q. Before we leave this, then, is there another way to check whether or not controlling for cigarettes smoked per day, as was done in these first two sets of bars, introduces a bias?
A. Yes, there's a much easier way.
Q. Okay. Why don't we display that? That's J-DEM 060538. Excuse me. 32. I misspoke. Although I suppose either one would do. 32. There we go.

No, I was wrong. I apologize. 38. I had it right the first time. What did you do to check?
A. If one has the concern that the first two sets of bars might be misleading because of a bias, and that that bias occurs when a cigarette per day variable is included in the analysis, as was the case in the first two sets of bars, an easy way to check if there is such a problem is to simply take the cigarettes per day variable out.

If the cigarettes per day variable is causing a problem, simply remove it, and if the results don't change, then you know that it was not causing any problem in the first place. That's the fast and easy way to check if there's a problem.

Now, what this chart that you've put here, this number 538, shows is that when I removed the cigarette per day variable and look at the left-hand side of the chart -- that's the place to look now, the first two sets of bars -- they continue to tell

the same basic story of increasing risk with increasing tar. So that would I think tell anyone, it certainly tells me, that if you're concerned about a problem when you include the CPD variable, take it out and see if it makes any difference. If it doesn't make any difference, then one could have saved all of that work on the third set of bars.

Q. All right. Let's move to the last thing, which if we could start with displaying J-DEM 060548. The court has seen this demonstrative before, and it's also what Dr. Burns, when I asked him about it. It's also included in your written direct. And it's accompanied with a long quote from Monograph 13 on page 50 to 51 of your written direct, which suggests that if lung cancer rates at a given age are declining more rapidly than one would expect from changes in the percentage of people who smoke, then that would suggest a benefit from lower-tar cigarettes.

And the court, when we read that particular excerpt to Dr. Burns, commented that it may not have been the most felicitously phrased.

And I guess what I would like to do is have you explain, Dr. Wecker, what you did here and whether or not you think that what you've done comports with what Monograph 13 suggests ought to be done.

A. Yes. Let me explain a bit of the reason for the chart, if that's not wandering too far from the question in details which are harder.

The point that I think, as far as I know originates with Dr. Peto in England, is that -- and others have observed this -- that sure enough, the lung cancer rates are declining in the United States and in the United Kingdom. But a reasonable question arises, because smoking prevalences, the proportion of people who smoke is also declining, maybe that the amount of the decline in the lung cancer rates could be explained as nothing more than the decline in the percentage of people who smoke, or it could be that the decline in the lung cancer rates is too steep to be traced exclusively to the reduction in the percentage of people who smoke.

And it is exactly this idea of Dr. Peto that gets at that question, because the Peto idea is, Well, let's use the lung cancer rates from CPS-I, 1960s data, on risk and then make projections forward for lung cancer rates reducing those projections for the reducing prevalence or percentage of people who smoke. So the projections -- if there's nothing going on with prevalence, the projections ought to not have any systematic bias to them. They may not be perfect, but they won't have it slope one way or another.

But if, as in a chart as I have, this number 548, you compare the difference between lung cancer rates predicted from historical values and then adjusted for decreasing prevalence and you find that the drop that's left over is still noticeable, then that argues that something else is going on, and that

something else may well be a drop in tar.

So, Dr. Peto also points out that it's important to do this for younger people, and he's got some details, but I followed his prescription as it's prescribed also on page 140 of the Monograph 13 and this is the chart I see. There is, indeed, a drop in lung cancer rates that's greater than one could explain by the drop in prevalences.

Q. Is there any other reason, other than the suggestion made by Monograph 13, that this might be a good thing to look at why you did this particular analysis?

A. Yes. There's several reasons I thought to do this.

First, I was aware that Dr. Peto had done a calculation like this on data from the United Kingdom, and he had seen in the United Kingdom this kind of a drop in lung cancer rates greater than could be explained by reference to a drop in smoking prevalence.

Not only that, Dr. Peto had looked at United States' data and seen the same thing, and I believe reported that in perhaps more than one place, but one place it's comes to mind is a letter he wrote to Dr. Burns.

When I add to that, that Monograph 13, although it discussed this procedure on page 140, didn't actually show the result, I thought maybe I should follow up on that. And so when I follow up on that, I see the same thing that Dr. Peto sees, a drop in lung cancer risk greater than could be explained by the

drop in prevalence alone.

Q. All right.

MR. BIERSTEKER: Thank you very much. I think that concludes the oral direct. He's available for cross.

THE COURT: All right. Doctor, you may step down at this time. And let me take a few minutes on other matters.

In terms of the witnesses for next week, let me check who they are and the order in which they are going to be called. Based upon the defendants' second submission of witnesses, I believe the order will be -- somebody should correct me if I am wrong -- Read, Appleton, Dietz, Albino, and Powell. Is that correct?

MR. REDGRAVE: Yes, Your Honor. Rowell.

THE COURT: Oh. My own handwriting is so bad. Rowell. And that would be the fifth person. You all have reason to believe you can get all those people done next week?

MR. BERNICK: I think an awful lot depends on where we are with Mr. McAllister, Dr. McAllister by the end of this week. If he spills over to next week, then I think it's going to be pretty tight. If he does not, or doesn't significantly spill over -- Dr. Read is a relatively short witness. Dr. Appleton is a relatively short witness.

THE COURT: None of them are experts, right?

MR. BERNICK: They are all fact witnesses, with the exception of Dr. Rowell. They are all, as Your Honor will see,

scientific witnesses, so it's still technical material, but Rowell is the only expert in the group. So we are still hopeful, but it really does depend upon Dr. McAllister.

THE COURT: All right. A couple of other things that we left unresolved from yesterday's very unproductive discussion at the end of the day, and we are not going to have one of those discussions today. I want to make that clear to everybody.

Let me clarify one issue that the defendants raised. And I don't think -- well, I know it doesn't take any briefing. If this is one of the issues that is unclear from Orders 886 and 894. Neither of those orders ever intended -- and I don't believe by that language did -- limit the government substantively to those nondisgorgement remedies which it presented in its initial expert witness reports.

I would have thought that it was crystal clear, particularly from Order 886 -- 896 simply dealt with schedules -- but from Order 886, that because of the enormous impact of the Court of Appeals' decision, that the government, in reevaluating its position and the impact of that decision on the evidence it had planned to introduce on nondisgorgement remedies, that the government might well be presenting new evidence on nondisgorgement remedies. And because of that, a schedule was then drawn up, after consultation with the parties, for the filing of expert witness reports and the taking of new depositions. That's why we are going to all of this trouble.

Now, I hope that's an answer to the issue raised by the defendants yesterday.

MR. BERNICK: Well, is Your Honor referring to the issue concerning Dr. Bazerman specifically or the issue raised with regard to the description of what the witnesses will testify in the remedies phase?

THE COURT: It may cover both issues. I just want to clarify that particular point. I want to avoid, for the sake of all counsel who have plenty to do, and for the sake of me who has plenty to read, any undue briefing on this issue.

MR. BERNICK: The concerns that I raised about the description are really animated by what I'll say is almost precisely the same understanding on our part as what Your Honor just recited. That is, to be more specific.

THE COURT: I understand there are additional problems in your view, and I must say in mine as well, with the government's descriptions. Let me pull those all out for a moment.

MS. EUBANKS: Your Honor, before we turn to the description, just so that we are clear. Defendants filed their motion last nights, and I was wondering if your comments were addressing the motion that they filed last night.

THE COURT: What was that motion? I don't think so.

MS. EUBANKS: One to expedite and one dealing with the remedies issue.

THE COURT: Oh, a motion for expedited briefing; is that right?

MS. EUBANKS: That was one.

THE COURT: On their motion to strike Dr. Bazerman's testimony; is that right?

MS. EUBANKS: Correct.

THE COURT: I certainly didn't read the substance of the motion to strike. I did indeed read the motion for expedited briefing. Having read it, I wanted to make clear what the basis of Orders 886 and 894, what the basis was. So in that sense I had hoped to at least speed things up.

In terms of the substance of Dr. Bazerman's testimony, I didn't know if that was the basis of your motion, and that's why I wanted to bring this to your attention this morning.

MR. BERNICK: I appreciate that, Your Honor. I think Mr. Webb will talk about Dr. Bazerman, in particular, but there are a couple of different layers here. One layer is with respect to remedies that they articulated before can, as the court already ordered that they can develop new expert opinions and new evidence, we understand Your Honor's order to provide precisely that.

THE COURT: You suggested something different yesterday. I couldn't believe --

MR. BERNICK: Then I apologize for not being clear. It's precisely because of that latitude that it becomes then

very critical for us to know exactly what they are doing, even with respect to witnesses where the opinions haven't changed, because if they've got new evidence, then we have to know how that evidence now relates to the old remedies.

Likewise, if they got factual testimony, the factual testimony for a given fact witness may now have a very different cast to it to the extent that now it is used to support a new remedy -- I'm sorry -- a new theory of remedies.

But there's always another line here that I want to be clear on generally, and I think Mr. Webb will then address that in connection with Dr. Bazerman, which is that we did not understand your prior orders to say that the government can actually seek totally new nondisgorgement remedies against the backdrop where repeatedly the defense put to the government interrogatories that asked them to articulate what all of the different nonmonetary remedies might be, and they answered those interrogatories and they committed to a list of nonmonetary remedies.

Now, we understand that if the remedies were listed before and they didn't include them in an expert report -- if they listed the remedies before, but they weren't covered by an expert report, Your Honor has given the government latitude to now do that. But we did not understand your prior orders to allow the government now to articulate wholly new remedies that have never been identified before in the case, and I think that

that is really what Mr. Webb would talk about in connection with that.

THE COURT: Let me clear about one thing.

Is it correct that the government is indeed articulating brand-new remedies?

MS. EUBANKS: I don't agree with that assessment based on the 46 pages in response to the fourth set of interrogatories that the United States served in this case. And I would really oppose discussing this. This is the substance of the motion that was put before the court last night if we are to talk about with specifics with respect to Dr. Bazerman's testimony and what's being proffered. This is substantively the motion.

THE COURT: Is Dr. Bazerman's testimony in the defendants' view the only testimony that purports to present totally new remedies?

MR. BERNICK: Well, based upon the way that we read these description presently, we don't see anybody else who falls into that category. I believe that's correct. Is there one more?

Okay, yes. Mr. Biersteker points out that there's the -- right -- that's really a fair point. Obviously, these things are unclear. That's part of the problem.

If you take a look at Dr. Gruber's description, there's kind of, we will call it the youth look back remedy, which basically says on the going forward basis, if it turns out that

our ads result, or that we engage in activities that result in youth smoking, that is going forward, our activities are monitored. If they result in youth smoking by people who are under the age of 21, then there will be appropriate sanctions.

THE COURT: There are two issues here, everybody.

Number one is the issue of whether the government's written description, short written description submitted, I believe, March 11th is sufficient.

MR. BERNICK: Yes.

THE COURT: That's one issue.

MR. BERNICK: Right.

THE COURT: The second issue is one of new remedies. Let me deal with the first issue first, which is kind of logical. The government has to submit its expert witness reports next Monday where there's very little time between now and next Monday.

As a practical matter, it seems to me to make a lot more sense and to avoid duplication of work on the part of government counsel to not require any amendment of this list of remedies. And when I say list, I mean the amendment of the description of the remedies these witnesses would talk about, between today, March 15th, and next Monday, March 21st. That just doesn't make any sense. We should move forward from the date of March 21st when they have to provide the expert witness reports.

Now, I do recognize that the descriptions provided are very summary and certainly very summary in terms of the defendants, in reliance upon them, having to go out and find appropriate experts to respond.

And so, therefore, even though I'm not anxious to do this, as you can certainly tell, I would consider moving a deadline -- I know nobody wants to move deadlines forward, but everybody also complains they don't have enough time to do everything -- but I would consider giving the defendants another week, I think only a week, to make up for this loss in time, and I think that would square things away.

MR. BERNICK: That sounds --

THE COURT: Wait just a minute, please. Let me call on everybody. And I don't want people going on and on.

Mr. Webb.

MR. WEBB: I was going to say that's acceptable.

MS. EUBANKS: I was going to say, Your Honor, that I would like to look at the scheduling.

THE COURT: I know you're having trouble with your voice.

MS. EUBANKS: I was going to say, Your Honor, if we could look at the schedule over the lunch break. I have some concerns if they are pushed back a week where that's going to put us in the discovery when they submit their reports.

THE COURT: Well, there may have to be several dates

pushed back a week. There may be. And as I say, I'm reluctantly willing to do that because I do think that it's very difficult to work with these very summary statements. You can look at things over lunch. We will address the issue immediately after lunch and for a brief period of time.

Now let me turn to issue number 2, which is the motion that is pending before me, which I have not read. I told you all that. I read the motion for expedited briefing.

MR. WEBB: Maybe we could simply this. I know your time is valuable. Rather than argue about Dr. Bazerman today, we believe it's a brand-new extraordinary remedy, and I'm not here to argue it.

The only issue that I would respectfully urge you to address is to expedite it so that we can get it resolved, okay, because it's a big deal in this case, and we filed a motion to expedite.

THE COURT: It's certainly a big deal if I adopt it.

MR. WEBB: It is.

THE COURT: I don't mean that lightly, everybody.

MR. WEBB: I didn't take it that way, and it's a huge issue, and we do believe it's an extraordinary new remedy, but rather than argue it --

THE COURT: No, I don't want to hear argument.

MR. WEBB: All I was going to say is we believe it's a new remedy. I heard Ms. Eubanks just say she doesn't

necessarily believe it is, but she has not had a chance to file a response. I'm willing just to wait until we hear the response and address it with the court. And I would simply respectfully ask to grant our motion to expedite, only so we can get it resolved quickly. So if we don't have to start searching for this brand-new mystical witness we won't -- we won't do so.

THE COURT: Now, yesterday you addressed the issue. I think at that point, in all candor, everybody, I might have reached the point of not listening as carefully as I usually try to, because at some point -- what's the word the statisticians all use? Background noise takes over. So let me hear from the government briefly on this point.

The defendants are asking that you file your opposition by Thursday. I'll give you until Monday if you need it for your opposition.

MS. EUBANKS: Your Honor, we would like to file it. We are filing the expert reports on Monday. That's an enormous amount of work. Alongside of the expert reports your order requires the materials, the 26(a)(2)(b) materials.

THE COURT: What are you requesting in terms of filing your opposition?

MS. EUBANKS: We could file it next Wednesday, Your Honor.

THE COURT: All right, I'll do that. I do recognize -- first of all, that's still less than the 11 days, yes.

MS. EUBANKS: Yes, it is.

THE COURT: That the rules require. And this is a very busy time for everybody. And I will rule expeditiously on this as opposed to some other motions which have raised a lot of other problems.

Then if the government's opposition is due on next Wednesday, which would be March 23rd, I believe -- let me check everybody -- yes, the 23rd, then I assume the defendants could get their reply in on the 25th?

MR. WEBB: Yes.

THE COURT: All right. Close of business, please. That will be Friday, the 25th.

And yes, I know that's a little bit longer than the defendants would like, but we are sort going day by day. There have been a lot of last minute changes, and I'm trying to accommodate everybody's reasonable needs as best I can. We may have some postponement.

Also I'm going to raise one other issue. So far, I think you all have been incredibly lucky, if you want to put it that way, to get my undivided attention four days a week without any interruptions.

I will tell you now that I'm not quite sure how I've managed to do that, except I've got some very good law clerks and I've worked all sorts of hours. Right now, I have some TRO's pending in Guantanamo Bay cases that have just come in. I

haven't had a chance to read them or anything else. But bottom line is if they need to be litigated, they are going to take precedents.

Now, as you know, TRO hearings are not extensive -- well, they are not evidentiary hearings and they are not -- not usually extensive. These are issues of profound significance to everybody concerned, and I may need to take some time for oral argument on those. I can't tell you yet how that's all going to play out since I just got the papers on ECF this morning.

MS. EUBANKS: Your Honor, we are certainly aware of that. I did want to mention with respect to Order 886 that was entered last night --

THE COURT: 886 last night?

MS. EUBANKS: Maybe today this came in. The Gulson objections, the memorandum opinion came --

THE COURT: But it's not 886.

MS. EUBANKS: 896. I'm sorry. I misspoke.

THE COURT: There was a problem, I gather, from my second with the actual order. Is that what you're referring to?

MS. EUBANKS: I'm referring to Order 896, but not to a problem. There is the question of the unsealing of the written direct and the unsealing of the transcript of the live testimony and all of the filings that are under seal pursuant to Orders 878 and 8679, and I note that the order did not address that. If that's intentional, then we will have to file a separate

motion.

But as I recall the events, it was placed under seal pending a resolution of the Gulson issue, and now that the Gulson issue has been resolved by 896, it would seem appropriate to unseal the written direct, the live testimony and the filings that were under seal pursuant to Orders 878 and 879. Rather than create additional paperwork for the court putting that in the form of a particular motion, we can submit a proposed order that accomplishes that if that's the court's intent.

THE COURT: Of course, everybody is looking at Mr. Sheffler.

MR. SHEFFLER: Your Honor, if I may, I think that makes sense. I think we should get together with Justice and make sure that we have the transcript conform to what your rulings were, and then we will submit an order that addresses the Gulson outstanding issues.

THE COURT: That's fine. That's good. I think we covered three issues in what, 10 minutes, which is a little more efficient than yesterday.

All right. Let's take until 2:00 o'clock, please, everybody.

(Lunch recess began at 12:55 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

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA,	.	
	.	
Plaintiff,	.	Docket No. CA99-02496
	.	
v.	.	
	.	
PHILIP MORRIS USA, et al.,	.	Washington, D.C.
	.	March 15, 2005
	.	
Defendants.	.	
. . . . .	.	

VOLUME 76
AFTERNOON SESSION
TRANSCRIPT OF BENCH TRIAL PROCEEDINGS
BEFORE THE HONORABLE GLADYS KESSLER,
UNITED STATES DISTRICT JUDGE

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AFTERNOON SESSION, MARCH 15, 2005

THE COURT: We are ready for cross-examination of the witness.

MR. GETTE: Thank you, Your Honor.

CROSS-EXAMINATION OF WILLIAM E. WECKER, Ph.D.

BY MR. GETTE:

Q. James Gette on behalf of the United States. Dr. Wecker, good afternoon.

A. Good afternoon.

Q. This morning you spent a fair amount of time talking about issues related to Monograph 13, and we're going to come back to those specific things a little later on, but initially I'd like to talk about some of your qualifications that are relevant to Monograph 13 and just run through a couple of items. First, you're not a medical doctor, are you?

A. That's correct, I'm not.

Q. Okay. I've had Charles put up U.S. 18208, a demonstrative we'll use just to capture the information as we go through this. Charles, can you pop a "no" in there? Great.

And as such, you've never treated people with smoking-related diseases or nicotine addictions, have you?

A. That's correct.

Q. Okay. Let's pop a "no" in there.

Now, in the course of your work and your life, you've never published any peer-reviewed articles regarding health

consequences of smoking, have you?
A. That's correct.
Q. Okay. So, let's pop a "no" in there.
And you've never acted as a scientific editor for even a single Surgeon General's Report, correct?
A. Correct.
Q. And you've never acted as an author for any portion of a Surgeon General's Report, correct?
A. Correct.
Q. You've never acted as a peer reviewer for any Surgeon General's Report, correct?
A. I have not.
Q. Let's talk a little bit about awards that you've received in the area of smoking and health research. In fact, you've received no awards in that area; is that correct?
A. That's correct.
Q. So, let's put "none" in that category.
Now, it's also true that you never received a scientific grant to study smoking and health issues or addiction issues, correct?
A. Correct.
Q. And you've never been qualified by a Court as an expert on the issues of addiction or compensation, correct?
A. Correct.
Q. And similarly, you've never been qualified by a Court as

an expert on smoking and health, correct?
A. That's correct, unless as a qualification, I've been qualified as an expert in statistics and statistical methods and the subject of my testimony was in that area, but --
Q. But you've never been qualified as an expert in the subject of smoking and health?
A. You're right, I just wanted a qualification.
Q. So let's put a "no" there.
Now, let's talk a little bit about years spent researching smoking and health issues. First, before we even get to that, let me ask you a question. You're not relying upon, and you haven't cited to, any tobacco industry documents in developing the opinions that you've offered in this case, correct?
A. Correct.
Q. Okay. And you've not done a comprehensive review of industry documents to see how they might impact the opinions that you've offered in this case, correct?
A. Correct.
Q. Okay. So, in terms of conducting a review of tobacco industry documents, let's put "none" there.
And finally, I'd like to talk about the years that you've spent researching smoking and health issues, and we put on the demonstrative here some of the time spent by Dr. Burns and Dr. Benowitz researching smoking and health issues. Aside from the work that you've done, specifically in litigation, you've

spent no time researching the issues of smoking and health, correct?

A. That's not quite right, but close. If I can elaborate?

Q. Well, have you ever published a peer-reviewed article related to smoking and health?

A. No, I have not.

Q. Have you ever published a peer-reviewed article related to addiction?

A. I have not.

Q. Ever published with respect to compensation?

A. No, I have not.

Q. Okay. And you wouldn't consider yourself an expert, as we said, in the areas of compensation or addiction, correct?

A. I would not, except where an issue of statistical methods might be involved, then I would claim expertise.

THE COURT: Dr. Wecker, would you keep your voice up, please, when you are speaking and you may want to talk more directly into the microphone.

THE WITNESS: Thank you, Your Honor.

BY MR. GETTE:

Q. And when it comes to the analysis that you've offered in this case in particular, I'm correct, am I not, that none of that analysis has been published, correct?

A. It's made public, but it's not published in the sense of academic journals, you're correct.

Q. It's never been submitted to an academic journal?
A. Correct.
Q. Now, your education is in statistics and mathematics, correct?
A. Yes.
Q. And I'd like to talk about the qualifications with respect to a few of the other people who were involved in Monograph 13, not just Dr. Burns and Dr. Benowitz, and I'm thinking along the lines of Drs. Samet and Thun at this point. Your education having been in the areas of statistics and mathematics, you didn't receive a degree in epidemiology, did you?
A. Not separately, no.
Q. Okay. And in fact, when you were in the academic field in teaching, you taught in the area of statistics and mathematics, correct?
A. Yes.
Q. And that was in business school, I believe, correct?
A. I had an appointment in a business school, but I taught students from all over the university in different courses.
Q. And your appointment wasn't in the Department of Epidemiology, correct?
A. Correct.
Q. Now, you're also not an expert in cigarette design, correct?

A. Correct.
Q. And in fact, the issue of cigarette design wasn't even considered by you in terms of reaching the opinions that you offered in this case, correct?
A. Except as it has implications for the data I examined, you are correct.
Q. Without a level of -- any level of expertise in cigarette design, obviously it could not have been factored in as an element in the equations that you're doing or the analysis that you're presenting to the Court, correct?
A. Actually, I don't agree with that, but if I could explain. I'm so close to correct I could probably help you out there.
Q. Well, you're not suggesting, are you, that you did analysis of cigarette design as a component of either the preparation of your opinions in this case, are you?
A. One reasonable interpretation of what I did is yes, because I did analysis of lung cancer risks for different cigarette designs. I'm not a cigarette designer, but I am a statistical analyst of data and the data I analyzed were put in different categories by cigarette design.
Q. Well, the different cigarette design that we're talking about here is, if I understand you, is low tar versus a full flavored cigarette, correct?
A. In various categories in-between, but to simplify it,

yes.
Q. In that context, you didn't take into consideration the design elements of the cigarette that lead a given cigarette to be measured as light or low tar under the FTC method, did you?
A. Only the element as to the yield from the FTC test.
Q. The yield, not the design that caused the yield?
A. That's right.
Q. So you didn't look at perforations in filters, that sort of thing?
A. That's right, that's correct.
Q. And you didn't consider what impact the design features of a cigarette might have on health as it's smoked by a smoker, correct?
A. I disagree with that. That's exactly what I did do.
Q. Well --
A. Because I looked at the different categories of cigarette design and computed the lung cancer health risks.
Q. On various levels of tar cigarettes, correct?
A. Yes.
Q. Right. But you didn't look at those actual design components in that cigarette and parse out what impact the design features that lead to the difference in tar and nicotine would have on a smoker, did you?
A. You're correct, I did not do the parsing out you suggest in the question.

Q. And with respect to design features, do you know what impact ventilation, or vent holes, will have in terms of the health consequences for a smoker?
A. You mean other things equal?
Q. Exactly.
A. I do not.
Q. And the same is true for the burn rate of a cigarette, correct?
A. Correct, other things equal, I haven't parsed that out.
Q. And other things equal, you haven't parsed out what change in the tobacco constituents of a cigarette from today versus 50 years ago would be, correct?
A. Except to the extent that they would influence the tar yields, you're correct.
Q. Now, I'd like to talk about some of the analyses that were considered by the authors in Monograph 13, and if we could pull up U.S. 58700. Before we actually turn to the text of that document, let me ask you, this morning you talked about some analyses that you attributed to Dr. Burns, correct?
A. Yes.
Q. And in your written direct you talk about some things that you related that you attribute to Dr. Benowitz, correct?
A. Yes.
Q. Now, there were numerous other authors on Monograph 13, correct?

A. Yes.
Q. So -- and, in fact, on chapter 4, which you offer several opinions regarding that you attribute to Dr. Burns, there were additional authors on that chapter itself, correct?
A. Yes.
Q. And so, the analysis that you continued to attribute to Dr. Burns, was actually a collaborative effort of many other people as well, correct?
A. Yes.
Q. And they put their name on the product that came out of that collaborative effort, correct?
A. Different names on different chapters, yes.
Q. And they put the whole thing through a series of review steps, correct?
A. Yes.
Q. And those review steps included people who aren't even listed as authors on the Monograph chapters, correct?
A. Yes.
Q. And it ultimately went to the point of being approved by the National Cancer Institute for publication, correct?
A. Yes.
Q. Now, let's look at page 10 of the exhibit that I handed you, which is U.S. 58700, and let's look at conclusion number one. And this is in the introductory chapter of Monograph 13, which is the overall conclusions of the Monograph. And it says,

"epidemiological and other scientific evidence, including patterns of mortality from smoking-caused diseases, does not indicate a benefit to public health from changes in cigarette design and manufacturing over the last 50 years." I read that properly, yes?

A. Yes.

Q. Do you disagree with this conclusion, Dr. Wecker?

A. Yes.

Q. And have you weighed all of the epidemiological and other scientific evidence that plays into the conclusion that is laid out in this conclusion?

A. No, I don't reach my opinion by weighing all the evidence, but mainly on my own statistical work replicating and correcting figure 4-5.

Q. So, having not weighed all the evidence, as you just testified, you didn't look at issues as we've just discussed a moment ago, for example, cigarette design and what impact that may have on how smokers smoke cigarettes, for example, correct?

A. That's where I keep thinking I have done that because what's important is the differences in the lung cancer risks, and how they relate to the different levels of tar and nicotine in cigarettes. I've made that analysis.

Q. But you haven't looked at how cigarette design actually leads individuals to smoke a cigarette differently, correct?

A. No, I have not.

Q. And if we look at chapter 2 of Monograph 13, the individuals who all got together and put together this piece of work, that was ultimately approved by the National Cancer Institute, they did look at the issue of cigarette design?
A. Yes, that's the chapter on cigarette design.
Q. And that's authored by someone by the name of Lynn Kozlowski, correct?
A. Yes, and others.
Q. Now, with respect to chapter 3, that's the chapter authored by Dr. Benowitz?
A. Yes.
Q. And you've already testified to the Court that you're not an expert in compensation, right?
A. I'm not an expert in the behavioral details of how compensation comes about. I have some familiarity with the data and I've done some calculations.
Q. And in addition to compensation, you talk about behavioral details, that's what you called it. Aside from compensation, you have never studied the behavioral actions, aside from compensation, related to how individuals smoke cigarettes, correct?
A. You are correct.
Q. And if we continue through and we look at chapter 5 of Monograph 13, chapter 5 is about chemical studies and bioassays?
A. Yes.

Q. Now, you're not a biologist?
A. Correct.
Q. You're not a biochemist?
A. Correct.
Q. And so the analysis that was done in chapter 5 was not something within the area of your expertise as well, correct?
A. Yes, but what I'm more sure of is I did not study or comment on chapter 5.
Q. In fact, aside from chapters 3 and 4 of Monograph 13, you didn't comment on any other chapters, did you?
A. That's right.
Q. And in fact, in large part that's driven because you aren't an expert in the subjects discussed in those other chapters, correct?
A. Unless there is statistical methodology involved, I would not claim expertise.
Q. Not an expert in risk perception, for example?
A. I've studied that, but as a statistician, how to elicit risk perceptions.
Q. Not as a psychologist?
A. No, but psychologists go to the meetings on that subject and I've attended them. It's a statistical question, but it overlaps with psychology.
Q. So, you've attended some meetings with some psychologists, but you're not a psychologist?

A. I am not.
Q. And so, in fact, the entire opinion that you offer here is based solely on your analysis of chapters 3 and 4 of Monograph 13, correct?
A. Yes. You say -- you're correct, it's based on that analysis, but I didn't -- I did look at some other materials that were not in Monograph 13.
Q. You looked at some other materials that were in Monograph 13?
A. That are not contained within the covers of Monograph 13 that are related to my inquiry of Monograph 13, like the Peto letter and the Garfinkel article and some other things like that.
Q. So you looked at some other materials other than Monograph 13, but within Monograph 13 itself your analysis was limited to, and your opinions offered are limited to those two chapters in Monograph 13, chapters 3 and 4?
A. Yes.
Q. And if we could go back to page 10 -- actually, Charles, let's jump over to page 146, and if we look at conclusion number 6 -- and here we're at chapter 4, correct, Dr. Wecker? This is the chapter that you attributed to Dr. Burns but was, in fact, authored by himself and others, correct?
A. Yes, and I stand corrected, I'm used to thinking of Dr. Burns because that's where I've been getting the work, I

didn't mean to suggest that he was the only author of the chapter. I'm sorry if I did.

Q. Let's look at conclusion 6. There it says, "there is no convincing evidence that changes in cigarette design between 1950 and the mid 1980s have resulted in an important decrease in the disease burden caused by cigarette use either for smokers as a group or for the whole population." Correct?

A. Yes.

Q. And you disagree with that conclusion as well, correct?

A. Yes.

Q. Let me then ask you some questions about what you considered and didn't consider in terms of reaching your opinion that you disagree with this statement. And first I'd like to look at the 2004 Surgeon General's Report. You didn't consider that in reaching your opinion that disagreed with the conclusion that I just read to you, did you?

A. That's correct.

Q. Okay. And if we pull up page 25 of the 2004 Surgeon General's Report, -- I'm sorry, I need to give you an exhibit number, don't I, Charles? 88621. This one's rather large. I dropped the image on that one. Can I get a copy of it on hard? Thank you.

I'm going to put it up in hard copy on the screen.

Okay. I'd like to look at the major conclusions there, and if you look at major conclusion number 3 on page 25, you'll

see that the Surgeon General had concluded that "smoking cigarettes with lower machine-measured yields of tar and nicotine provides no clear benefit to health." Correct?

A. Yes.

Q. And that was something that you didn't consider in reaching your opinions in this case as you've testified, correct?

A. That's correct.

Q. And I'd like you to look also at page 61 of that report by the Surgeon General, and if you look at item number 3, it says "although characteristics of cigarettes have changed during the last 50 years and yields of tar and nicotine have declined substantially, as assessed by the Federal Trade Commission's test protocol, the risk of lung cancer in smokers has not declined."

And that was a piece that you did not consider in reaching the opinions that you've offered in this case, correct?

A. I didn't consider it and I disagree with it.

Q. Let's look at some other things that you didn't consider. I'd like to look at U.S. Exhibit 93139. We'll do some housekeeping in a second.

A. Can you take that?

Q. Sure. Would you grab the Surgeon General's Report from Dr. Wecker?

Now, this is a publication of the Scientific Advisory

Committee On Tobacco Product Regulation. Are you familiar with that organization?

A. I've read some things with those titles, but I have no great familiarity with it.

Q. Okay. They advise the World Health Organization on smoking issues, don't they?

A. That's my understanding.

Q. And if we look at the first page of what the scientific -- the last paragraph. And actually let's go over this. It's clearer here. What the Scientific Advisory Committee to the World Health Organization said was, "as a consequence of the conventional format for conveying tar and nicotine information, the consumer believes that the low-yield cigarettes provide an alternative to smoking cessation." First of all, with respect to that sentence alone, you have no opinion with respect to that sentence, do you?

A. You're correct.

Q. Okay. But then the Scientific Advisory Committee goes on to say, "this belief persists even though it is now accepted that low-yield cigarettes do not offer any proven health benefit in comparison to higher yield cigarettes." And you didn't consider that when reaching the opinions that you've offered in this case, did you?

A. That's correct.

Q. I'd like to look at one last thing you didn't consider in

offering your opinions in this case. It's at U.S. Exhibit 86657 and this is a report to the Canadian Minister of Health from the Ministerial Advisory Counsel On Tobacco Control in Canada. You did not consider this in reaching your opinions in this case, did you?

A. That's correct.

Q. And if we go to the first page of that document -- it's going to be about page 4 for you, Charles -- and we go down to the bottom left-hand column, you'll see there's a question 1. I'll let you catch up with me.

A. Okay.

Q. And the question posed was, "in what measures are cigarettes that are marketed as 'light' or 'mild', first, more hazardous than other cigarettes? Less hazardous than other cigarettes? About the same level of hazard as other cigarettes? Of unknown different hazard?" And the expert panel advising the Minister of Health in Canada came back and said the expert panel found that there is no convincing evidence of a meaningful health benefit to either individuals, nor to the whole population, resulting from cigarettes marked as 'light' or 'mild'." And you didn't consider that information when reaching your opinions in this case either, did you?

A. That's correct.

Q. Dr. Wecker, I'd like to move on to some other issues now. First, you've testified for defendants, the defendants in this

case, in other litigation as well, correct?
A. Yes.
Q. And in fact, you've been involved in consulting and testifying on behalf of the defendants for about a decade now, at least, correct?
A. Yes.
Q. And in fact, when did you first start testifying on behalf of defendants in this case?
A. I don't recall the first time. It was in the 1990s.
Q. Okay. And you've testified at least -- in at least a dozen different actions on behalf of these defendants, correct?
A. You mean to include deposition testimony, I take it?
Q. Let me ask that differently. You've been retained to consult with defendants in at least a dozen different pieces of litigation, correct?
A. Yes, that sounds about right.
Q. Okay. And in most of those cases, you've given depositions, correct?
A. Yes.
Q. And in some of those cases you've testified at trial?
A. Yes.
Q. Now, your testimony in this case relates to statistical associations between the -- between different tar level cigarettes and lung cancer, correct?
A. Part of it, yes.

Q. All of your testimony relates to some form of statistical association, correct?
A. You mean in this case?
Q. Correct.
A. No, not really. I'd say it's broader than that.
Q. Okay. Let me ask it this way: As a statistician, without a designed experiment you're not able to offer opinions as to causation, correct?
A. That's right. For a statistician it takes an experimental design to reach a causal conclusion.
Q. And in the opinions that you've offered in this case, you don't have available to you any design experiments, correct?
A. Well, there's some experimental switching studies.
Q. Let's put the compensation piece aside, you're correct in that. So let's put Dr. Benowitz aside and talk about the issues related to chapter 4, which you testified in large part about this morning?
A. Right, Monograph 13 is observational data.
Q. Observational data. There's no design experiment in there?
A. At least the parts I'm working on. I didn't read the whole thing.
Q. And the parts you're working on, not having a designed experiment, you're not able to offer a causal conclusion, correct?

A. Right, somebody might, but not a statistician. It would be outside of my expertise.
Q. And in fact, at deposition, I think, you told me to reach a causal conclusion at that point would require some sort of expertise beyond what you possess as a statistician, correct?
A. Either a design experiment or some expertise outside of statistics is required.
Q. I want to ask you a couple of follow-up questions with respect to causation and some of the prior testimony that you've given on behalf of defendants. In fact, in 1997, for example, in a case called -- I picked the one I definitely can't pronounce.
A. Karbiwynk is the pronunciation and you can do the spelling.
Q. Karbiwynk, I'll give the spelling later, even that's tough.
You testified in that case that the collective understanding of science cannot tell what caused the epidemic of lung cancer in the 20th century, correct?
A. I don't recall those words, but I -- if I said them, I'd love to qualify them.
Q. Well, let's pull up the Karbiwynk transcript at -- and Charles, it's going to be page 3643 and 3644.
And if you look at that, you were asked, "What caused this epidemic of lung cancer in the 20th century?"

And you answered, "I don't think we know -- or science -- I don't mean just me, but science knows what makes the lung cancer line go up, anymore than they know what makes the stomach cancer go down."

A. Right, I remember what I had in mind at that time and I still think that.

Q. And that is that you can't prove a statistical -- I'm sorry, you can't prove cause of lung cancer as a statistician?

A. No, that's a separate issue, and I'll be glad to explain briefly, if you would like.

Q. Well, you did -- you continued to testify in 1997, also in the Minnesota case, correct, that I don't believe that anybody has shown, that smoking causes lung cancer, correct?

A. It's very helpful for me to see the transcript, because when I see it then I know what I was talking about.

Q. That's the November 13th, 1997 deposition in the Minnesota case, and we're at page 214.

And you were asked, "Are you saying that that study shows that smoking does not cause lung cancer, can you answer that question for me?"

And you say, "Answer: I don't believe that anybody has shown that smoking causes lung cancer."

That was your testimony, correct?

A. And it continues.

Q. You continue to hold that belief, correct?

A. No, you left off in mid-sentence and I think that's important.
Q. You did say, "but I believe those judgments have been made by others. Judgments of that kind have been made."
A. Right, I think one can reach judgments and state, and I would agree that the evidence is very strong, even overwhelming on this point, but for clarity of thinking, we must say that it's a judgment, and not what I would call a proof. Because we don't understand all there is to know about cancer and we don't have all the facts, so that's -- I would call that a judgment, a reasonable judgment, and I wouldn't disagree with it, but I wouldn't call it a proof.
Q. And those sorts of judgments, because you're a statistician, you leave to others to make, correct?
A. Unless I'm doing a designed experiment, then I will stand and defend that I have proved a causal link.
Q. So, like with the issues from Monograph 13 where you have no design experiment, you would leave the issue of whether smoking causes lung cancer to individuals with other types of expertise, correct?
A. I will leave it to anyone who chooses to reach a judgment in that area, certainly.
Q. But as a statistician, you don't feel qualified to opine on smoking being a cause of lung cancer, correct?
A. I have nothing important to say other than what I've said

now, the evidence is strong, even overwhelming. I certainly don't dispute it, and I think all my testimony today, you should assume that smoking causes lung cancer. I'm not exactly on the other side of this issue, I'm just pointing out the limitations of statistical science.

Q. And that limitation, of not having design experiment, continues for most of the opinions that you offer in this case, correct?

A. Right. There's some experimental data we have, but none of it in Monograph 13.

Q. So you would leave the judgments about causation to individuals with other types of expertise, correct?

A. I leave it, but it makes it sound like I have a choice. Other people get to do whatever they choose in life, I don't get to tell them what to do.

Q. Others get to do what they do in life because they're qualified with certain sorts of qualifications, correct?

A. Perhaps. I just didn't mean that I was giving permission. It would sound preposterous.

Q. Sir, I want to make sure we're reaching the right end point here. As a statistician, you cannot confirm for this Court that higher tar yield cigarettes cause greater risk of disease, correct?

A. That's right, I can say they're associated and the association is clear and consistent and convincing, but I can't

go that last step.
Q. And conversely, as a statistician, you cannot confirm for this Court that lower tar yield cigarettes cause a reduced risk of disease, correct?
A. That's correct. I can say the association is strong and convincing and I can make a judgment, as anyone can, but I can't claim to have proved cause. That would be too strong a statement.
Q. Let's turn back to your analysis now. You've offered several opinions regarding the shortcomings of Monograph 13, correct?
A. Yes.
Q. And I'd like to explore for a moment what you've offered in place of Monograph 13. And I'd like to simply start by reiterating the point that the analysis that you've done in this case, the analysis that was initially written for the Turner case that was provided to us here, the analysis that was written in the Miles case several years ago, none of that has been subjected to an academic peer review process, correct?
A. That's right.
Q. And outside of litigation, have you offered any of that work that we just talked about from Turner, from Miles, from this case, for review by any experts in the field of disease causation, for example?
A. Yes, I have.

Q. Have you offered it for review by experts outside of litigation for that review?
A. I'd have to say I don't understand the part of your question that says "outside litigation".
Q. Fair enough.
A. There is material in litigation, but the expert was kind of an outside reviewer.
Q. You've -- as we said, you've never submitted it for peer review in an academic journal?
A. Correct.
Q. And in fact, your analysis was prepared specifically for use in the litigation context, correct?
A. I think that's fair. I understood that to be the case.
Q. You did the analysis at the request of counsel, correct?
A. That's right.
Q. And in fact, you've never done any analysis in the smoking and health arena that wasn't at the request of counsel, correct?
A. That's correct.
Q. I'd like to look at some of the types of research that went into Monograph 13 and just find out whether it's the type of research you've ever done before, all right? And I'd like to start by talking about some of the types of research that Dr. Benowitz presents in chapter 3 of Monograph 13. And there he talks about experimental force switching studies is one

component -- one type of evidence that he looks at, correct?
A. Correct.
Q. You never conducted an experimental force switching study, have you?
A. I have not.
Q. Dr. Benowitz has, correct?
A. Yes.
Q. And then let's look -- he then moves on and looks at cross-sectional self selected brand studies, correct?
A. Yes.
Q. And you've never conducted a cross-sectional self selected brand study, correct?
A. Correct.
Q. Dr. Benowitz has, correct?
A. Correct.
Q. And then he turns and he looks at spontaneous brand switching studies, correct?
A. Yes.
Q. And in that third line of investigations, spontaneous brand switching studies, you've never conducted a spontaneous brand switching study, correct?
A. Correct.
Q. Dr. Benowitz has, hasn't he?
A. Yes, I think so.
Q. Now, I'd like to talk a little bit about what is done in

chapter 4 and your experience, or lack of experience, in those areas. And there, Dr. Burns and his colleagues also look at three different types of data, correct?

A. Help me with the three kinds.

Q. Sure. They look at epidemiological studies, they look at temporal trends in lung cancer death rates in major cohort studies?

A. Yes, they do that.

Q. And they look at age specific lung cancer in comparison to age specific smoking behavior, correct?

A. Yes, they do that.

Q. So I'd like to look at each of those three different areas and I'd like to start with the temporal trends in lung cancer death rates in major cohort studies. Have you been involved if any of those major cohort studies?

A. No.

Q. And those include the CPS Studies, correct?

A. Yes.

Q. And the British Physicians Studies?

A. Yes.

Q. And with respect to age specific lung cancer in comparison to age specific smoking behavior, have you ever published in that area?

A. No.

Q. Have you ever published in the area of epidemiological

studies related to tar content and disease burden?
A. No.
Q. Dr. Burns has published in those areas, hasn't he?
A. Yes.
Q. In fact, in all of those different areas, correct?
A. I think so, yes.
Q. Let's turn now to some of the things you talked about specifically this morning, and again, by looking at some of your analysis of what occurred in chapter 4 of Monograph 13. And first, I'd like to look at some of the things that you don't report on in your analysis in this case. And if we could bring up U.S. 17804.

This is a chart that's included in Monograph 13, correct?
A. I think so, but to check, do you have a page?
Q. It's page 122.
A. Yes, it's a -- not an exact copy, but it looks very similar.
Q. And this presents analysis of lung cancer rates from the CPS-I data as compared to the CPS-II data, correct?
A. Yes.
Q. And what this demonstrates is that, in fact, the rate of deaths per 100,000 people, for both male smokers and female smokers, increased from the time of CPS-I to the time of CPS-II, correct?
A. In the samples from CPS-I to CPS-II, that's correct,

they're not random samples of the United States.
Q. They're samples demonstrating an increase in deaths from smoking, correct?
A. From one sample compared to the other, yes.
Q. And the first sample was taken in the late 1950s, correct?
A. Basically 1960s. It started in '59.
Q. Fair enough. It began in '59 and continued for several years into the 1960s, correct?
A. Right.
Q. And the second one began in 1982 and continued after that, correct?
A. Correct.
Q. And both of them had six-year follow-up studies, correct?
A. Well, CPS-I had several two-year follow ups. If you leave a couple out you can get to a six-year follow-up, yes.
Q. Let me re ask that. They had follow ups over a six-year period, correct?
A. Right.
Q. And what the authors in Monograph 13 and the National Cancer Institute concluded from this information was that lung cancer death rates for males, even after being adjusted for differences in the number of cigarettes smoked per day and duration of smoking, increased from CPS-I to CPS-II, correct?
A. I agree with that. The rates are higher in CPS-II.

Q. And that was -- the same was true for women as well, correct?
A. Yes.
Q. And the percentage of smokers in the United States smoking "light" and "low-tar" cigarettes was much higher during the 1980s as compared to the 1960s, wasn't it?
A. Yes.
Q. You offer no criticism in the testimony that you provided to this Court of this analysis, correct?
A. Well, I think I do. It certainly stands in opposition to the analysis that I presented showing a decline in rates.
Q. It certainly does stand in opposition, doesn't it?
A. And in that sense it stands as a criticism.
Q. And there's nothing specific in your written direct, however, that discusses this data, does it?
A. That's true, I did not discuss this chart.
Q. And the same is true for the British Physician's Study, correct? You didn't offer any criticism or discussion, specifically, of the British Physician's Study in the written direct that you've provided to this Court, correct?
A. Correct.
Q. And in fact, the findings from the British Physician's Study stand in opposition to the conclusions that you've provided to the Court as well, correct?
A. I think what stands in opposition would be the

interpretation that a chart, like the one you have on display, as to what the proper interpretation of that could be. The chart by itself doesn't stand in opposition. I think you may have said that badly, but if you want to interpret that a certain way then it would be in opposition.

Q. Let me -- we're talking about the British Physician's Study now?

A. This chart, or the one from there that we haven't got up.

Q. Okay. And the authors in Monograph 13 present the findings of the British Physicians Studies, correct?

A. I think they do, yes.

Q. Let's look at page 120, and that's U.S. 58700. Charles, if you could pull that up, and actually, I want to go to the first full paragraph of text there. I'm sorry, paragraph of text, not the -- begins the British Physician's Study.

And there the authors, all of them in chapter 4 of Monograph 13, indicate that, "The British Physician's Study examined lung cancer mortality rates with a follow-up period of over 40 years." And they skip down and they say, "Lung cancer death rates in male smokers age standardized to the same age distribution in the two follow-up intervals, increased by 19 percent to 314 per 100,000 during the second half of the study, compared to 264 per 100,000 during the first 20 years of follow-up." So that, the British Physician Study, showed an increase in the lung cancer rate per 100,000 over the period, the

20-year period being studied, correct?
A. Yes.
Q. And the time periods in comparison there were '51 to '71 versus '71 to '91, correct?
A. I have forgotten the dates. It sounds right. It says in here, yes.
Q. And again, in the time period of '71 to '91 substantially more individuals in the United Kingdom were smoking "light" and "low-tar" cigarettes as compared to 1951 to 1971, correct?
A. Yes.
Q. And this study you don't mention at all in your written direct testimony, correct?
A. Correct.
MR. GETTE: Your Honor, I'm getting ready to shift into a new subject, if you think this is --
THE COURT: Mr. Biersteker looks unhappy at the thought of a break, but nobody else does. Why don't we take 10 minutes now everybody, and we'll be going until 4:30 and stop at 4:30 then. All rise.
(Thereupon, a break was had from 3:01 p.m. until 3:16 p.m.)
THE COURT: All right. Mr. Gette, please.
MR. GETTE: Thank you, Your Honor.
BY MR. GETTE:
Q. Dr. Wecker, I'd like to turn back just briefly to the two

conclusions that we looked at from Monograph 13 earlier. The first is at page 10. That's U.S. Exhibit 58700.

And if we look at Conclusion Number 1, notice it talks about "The epidemiological and other scientific evidence, including patterns of mortality from smoking-caused diseases," correct? Plural there, not "smoking-caused disease," correct?

A. Yes.

Q. Okay. And then I'd like to look at the Conclusion Number 6 from Chapter 4; that's at page 146. And there it says, "There is no convincing evidence that changes in cigarette design between 1950 and the mid 1980s have resulted in an important decrease in the disease burden caused by cigarette use either for smokers as a group or for the whole population."

And "disease burden" there isn't limited to lung cancer, is it?

A. It could mean the lung cancer. It's vague enough. It could mean other diseases as well.

Q. Well, it's "disease burden caused by cigarette use," correct?

A. Yes.

Q. And as you understand it, there's disease burden caused by cigarette use other than lung cancer, correct?

A. Yes.

Q. And in fact, heart disease is a disease burden caused by cigarette use, correct?

A. That's what it -- the judgment is, yes.
Q. And chronic obstructive pulmonary diseases?
A. Yes.
Q. And in fact, do you know whether -- well, it's true, isn't it, that in fact lung cancer is not the leading disease burden caused by cigarette use; heart attacks are -- or heart disease is, correct?
You may not know the answer to that. That's fine.
A. Well, I have studied it and I'm not sure. There's a lot more heart disease, but research does not attribute all of it to smoking, whereas most of the lung cancer is attributed to smoking. So I guess I don't have an answer at the moment, but I can't confirm -- I can't tell you one way or another.
Q. So you can't tell us one way or the other whether that's true, correct?
A. Not at the moment. I have worked on it, but I don't know offhand.
Q. Now, your analyses that you present in the written direct that you provided to the Court analyzes only data related to lung cancer, correct?
A. In terms of -- on the risk side of things, that's correct. There was other data.
Q. There was other data, but the only risk that was being reviewed by your analyses was lung cancer, correct?
A. When I was -- yes, when I was looking at risks, it was

lung cancer risks.
Q. You weren't looking at heart disease risks?
A. Right.
Q. You weren't looking at risk of COPD?
A. Right.
Q. Now, the opinions that were expressed by the authors of Monograph 13 and adopted by the National Cancer Institute -- neither of those two conclusions that we just looked at limited themselves to lung cancer, did they?
A. That's correct.
Q. Also, in your analysis that you presented to the Court, did you do any calculation or estimation of the number of people who defer quitting because they switched to light or low-tar cigarettes?
A. No.
Q. Do you know whether the authors of Monograph 13 considered that information?
A. As I recall, they discussed it, but I don't recall any calculation.
Q. You do recall them discussing it in the Monograph, however?
A. That's my -- I recall it. I couldn't find you the page, but I think it was in there.
Q. Okay. I'd like to turn now to the colorful chart that we had this morning, one of them, anyhow.

Charles, let me have you pull up --

I know you said that generally, these charts will portray the same type of information for different -- no matter which one we pick. I'd like to start with JDEM 060536.

Now, the analysis that was initially done by Dr. Burns related to this issue and you testified to in this morning. It was about determining whether or not controlling the analysis based on cigarettes per day would bias the results, correct?

A. That's the right issue.

Q. That's the issue --

A. You're stating the issue well, yes.

Q. Okay. And that's the issue that Dr. Burns said in Monograph 13 and his other coauthors said they were trying to address, correct?

A. Yes. I have to add one little thing so we're not confused. They said if there is a source of bias, they have a plan for addressing it.

Q. And their analysis was to get -- well, you said it this morning: They expressed some concern that there might be a biasing going on here, correct?

A. Correct.

Q. And they wanted to get to the bottom of that, correct?

A. Correct.

Q. And that's what led to this whole analysis. And --

A. To the third set of bars, not the whole thing.

Q. Correct. The first two set of bars were kind of preexisting information, correct -- or analyses?
A. They were done specifically for Monograph 13 and showed what prior research had also showed. And then the point that you're raising about dealing with the possible biases -- that's the purpose of the third set of bars.
Q. And so the first two set of bars, as you suggested, were consistent with other findings that had already been expressed in the scientific literature, correct?
A. Correct.
Q. And in Monograph 13, the authors acknowledged that the scientific literature existed and was available, correct?
A. Yes.
Q. And they acknowledged that some of that information in terms of epidemiological studies seemed to suggest some relationship between tar levels and disease burden, correct?
A. Yes.
Q. And they thought, well, perhaps the results of that prior information that's out there is being caused by a bias caused by cigarettes per day being included in the analysis, correct?
A. Correct.
Q. Now, having gone through that analysis and wanting to reach conclusion, I'd like to pull up page 96 of U.S. 58700.
Now, we spent a fair amount of time this morning on this issue. You spent a fair amount of time in your written direct

discussing this issue, correct?
A. Yes.
Q. You presented to the Court demonstrative exhibits and a whole range of different analyses that varied slightly one to the other presenting these three sets of bars, correct?
A. Yes.
Q. And that was because you supposedly disagreed with the conclusion of the authors in Monograph 13, correct?
A. That really wasn't the purpose. The purpose for putting up several of these charts was to fix typographical and other computer errors and then see what happened.
Q. Right. So you wanted to fix the errors you believed existed in their programming and see what happened?
A. Right. And perhaps more fundamentally, to address this issue that they raised and you've articulated well about the bias or potential bias.
Q. And ultimately regarding that bias, let's look at the paragraph that starts with the heading right there. And what the authors in Monograph 13 say is: "A reexamination of the CPS-I data set was inconclusive as to whether compensatory changes in the number of cigarettes smoked per day when smokers switched to a lower nicotine cigarette introduce a bias sufficient to explain the observed increased lung cancer risk among smokers of high yield cigarettes." Correct?
A. You've read it correctly.

Q. So in fact, right here in the first paragraph, the first sentence where the authors of Monograph 13 are talking about their new analysis of the American Cancer Society Cancer Prevention Study I data, they say we couldn't tell whether cigarettes per day caused a bias, correct?
A. That's what the sentence reads and I would disagree with it. I mean, I have a different opinion. That's clearly what they're saying. I think you can tell and that there isn't a bias.
Q. Well, they certainly didn't suggest, however, that they could now dismiss all of that other data and all those other epidemiological studies that were out there and available to them, did they?
A. That's the clear impression I got from reading the document, that this document was cast as a kind of revolution in the science and that the old way of thinking and the old studies were off and that, in fact, Monograph 13 was suggesting that differences in tar don't matter to health risk. That's the impression I got.
Q. Well, this revelation that you're talking about, one of the things that would have been a revelation clearly would have been if Dr. Burns and his colleagues could have emphatically said: "Yes, cigarettes per day bias this and, therefore, we can ignore all of that epidemiological data"? That would have been a revelation, wouldn't it?

A. It would have been a mistake.
Q. It would have been a mistake, but it would have been a revelation; it would have changed a lot of thinking, correct?
A. If they were right.
Q. Right. And what he says is we can't tell if it does, correct?
A. That's -- yes, that's what that particular sentence says. I think the course of the document is a little different.
Q. We're looking at the sentence here, Doctor, and we're talking about the analysis -- and this sentence refers to this analysis that we've been looking at with the three sets of bars, correct?
A. Yes, you're correct and I apologize for being argumentative. You're correct.
Q. Now, let's quickly -- since Dr. Burns has already said this was inconclusive, let's just quickly look at these bars.
And, Charles, if you will pull up again 060536.
Now, in the Turner Report that you produce to us in this case, you said that the first two sets of bars: "Show a dose-response relationship of increasing lung cancer risk associated with increasing levels of tar." Correct?
A. Yes.
Q. And when you say "dose-response relationship" there, you mean that each successive bar in the analysis as you move to the right increases in terms of the odds ratio that we see in the

vertical axis, right?
A. It does increase in that way, but I don't think I intended that strong a statement. I just mean that the higher tar is clearly associated with the higher risk.
Q. So higher tar associated with higher risk --
A. Right.
Q. -- correct?
Now, if you look at the third set of bars from your corrected calculation here -- and let's look at the blue set of bars. That's tar levels of 18 to 21.5 milligrams, correct?
A. Correct.
Q. And then if we look at the red one, that's greater than 25.9 milligrams, correct?
A. Correct.
Q. And so the red one has more tar, yes --
A. It does.
Q. -- than the blue and, therefore, a dose-response relationship would suggest that the red bar should be higher than the blue bar, correct?
A. It -- if the sample sizes were large enough, that's what I would expect, yes.
Q. So that's what you would expect, but that's not what you got here, is it?
A. That's not what we have here. And I explained that it has to do with the fact that we've thrown away almost all the

data by the time we've gotten to this point.

Q. Now --

THE COURT: Well, why doesn't that rationale apply to all three of the bars in your final set, if you will? Either the bars are valid or they're not valid because, according to you, so much of the data was not used.

THE WITNESS: Two answers -- two parts to the answer, Your Honor. First, I eventually have concluded that it's not necessary to look at the third set of bars at all because they're curing a problem that doesn't exist. And in the course of the curing, they are causing a great deal of trouble because they're throwing away most of the data.

The second reason is that, because they've reduced the amount of data so much, I found it helpful to look at the women to get more data to try to get a sample size adequate to produce a reliable estimate. And when I do that, the precision is greater and it shows unambiguously what is only borderline in this case: Higher tar, at greater risk.

THE COURT: Are you saying that final red bar that reflects more than a tar level in excess of 25.9 is borderline?

THE WITNESS: No, Your Honor. That's clearly a result that tells us practically nothing because there's so little data in there. That's what those great, tall vertical lines are telling us. There's not much information in that bar because not many people are in that category.

When you look at the middle set of bars, there's a lot more people and then the accuracy improves.

BY MR. GETTE:

Q. Let's follow-up on that a little bit because you said -- you added women to try and correct for the lack of data. So let's pull up JDEM 060537.

Do you have that in front you, Doctor?

A. Yes.

Q. Now you've added women, correct ?

A. Yes.

Q. And the red bar -- now it's higher than the blue bar, correct?

A. Yes.

Q. But it's lower than the yellow bar?

A. Yes.

Q. And I think what you called "whisker hairs" --

A. The vertical lines are -- statisticians call them "whiskers."

Q. Okay. The whiskers still are so great they go right off the page, don't they?

A. Yes. You can tell how big they are because they're symmetrical around the top of the bar.

Q. And in fact, if we talk about the this statistically a little bit more, if you look at the blue bar, for example, given the confidence interval that you have on that -- let me back up

one second.

The green bar is kind of your comparison bar, right? And that always sets the odds ratio at 1, correct?

A. Right.

Q. And then you're doing a comparison from that odds ratio of 1 either up or down, correct?

A. Right.

Q. And in fact, if we look at the blue bar and we look at the whisker on the blue bar, that blue bar isn't statistically different than 1, is it?

A. That's correct. It's borderline and should get your attention, but it's not significantly different than one.

Q. Okay. Let's go back to 060536 for a moment. And there if we look at the whiskers, we find that the blue line, the yellow line and the red line -- none of those are statistically different from 1, are they?

A. That's correct. Only the orange line is even borderline.

Q. And let me come back to the issue of women for a second. You said you added them to try and increase your sample size. We looked at whether or not that ended up giving you a dose-response relationship, but now I'd like to ask you if you know why the authors of Monograph 13 chose not to include women.

A. They said something about that, but I've forgotten it now.

Q. Did you take what they said into account when you offered

your opinions to the Court?
A. Yes, because I read it, but I decided it was a good idea to look at the women anyway. And other researchers have done so.
Q. So you did it because some other researchers had done it?
A. And it seemed like a good idea to me.
Q. Let's just see if I can -- let's go to 060533.
This is a chart that you created, based on basically running the information from Monograph 13 for women as opposed to men, correct?
A. Correct.
Q. So in Monograph 13, they display and provide the information in Figure 4-5 only with respect to men, correct?
A. Correct.
Q. So you came along and you took the data that they provided to you and you said, "Well, I'll do the same thing for women," correct?
A. Correct.
Q. And this is what you got?
A. Correct.
Q. Okay. And if you notice, even in the left-hand side, all right, there we already don't see a complete dose-response relationship across all four bars, do we?
A. You -- the way I would say it, you do see a dose-response relationship because there's strong evidence here that higher

tar goes hand in hand with higher risk, but you can't parse it out by the individual categories because those vertical bars are showing that you can't distinguish the blue and the orange bar from the green bar.

Q. Right. Because they're not statistically different from 1, correct?

A. They are -- right. That could be explained by sampling variation. That's the point of doing those whiskers.

Q. And in fact, sampling error on that one we're looking at right now could in fact create a situation where the green and the blue and the yellow lines are all straight across and only the red one's a little bit higher, correct?

A. That would be speculation, but it's possible.

Q. It's possible.

THE COURT: But even in that first set of bars, the particular bar from 21.5 to 25.9 is lower than the bar for 18.0 to 21.5. How do you explain that? Although it's not much lower, but it's a little lower.

THE WITNESS: Yes. The explanation, Your Honor, is that those fine differences are essentially meaningless in a statistical estimate of this kind because that tiny difference is so small compared to the size of those confidence intervals.

About -- the better interpretation is that the best estimate we can make is the height of the bars, but -- and we can rule out -- we can essentially rule out anything outside of the

vertical whiskers. Remaining as a possibility are the things inside the whiskers.

THE COURT: Seems to me you're saying the best estimation we can make is the height of the bars except when it doesn't comport with the theory that we're pushing.

THE WITNESS: No, it's always the height of the bar is the best estimate. It's a statistical term of art.

THE COURT: But you've just told me that the height of that orange bar and the fact that it's lower than the blue bar, even though it represents a higher level of tar -- that there's some kind of an explanation for that, right?

THE WITNESS: I don't believe I've said quite that, Your Honor. What I've said is that the proper interpretation of, say, that orange bar combined with the whisker is, if you had to pick a single number, the best estimate is the height of the bar, but it would be unwise to pick a single number without noticing that sampling error could have by chance caused that number to be high or low compared to the truth, but we can pretty much rule out anything outside the whisker.

THE COURT: Fine.

BY MR. GETTE:

Q. Now, you characterize the difference between the blue and the yellow there as "essentially meaningless." Those were the words that you just used in your last answer. Are you aware that Dr. Burns and his colleagues who wrote Monograph 13 in fact

have concluded that that's not essentially meaningless and that that is exactly why they didn't include women in their analysis, because there was no dose-response relationship even in the baseline case?

A. Well, I see a dose-response relationship because the significantly elevated red bar tells me higher tar, significantly elevated in risk over the low case.

Q. Dr. Wecker, my question was: Were you aware that the authors of Monograph 13 have concluded that that's exactly why they didn't include women in their analysis?

A. I've read it, but I don't recall that.

Q. I'd like to move on from this now and talk a little bit more about some of the analysis in Chapter 4 of Monograph 13. And here I'd just like to really talk about your analyses in a very general way.

First, Dr. Wecker, let me ask you: Did you have any data available to you that you analyzed regarding cigarettes per day that was not available to the authors of Monograph 13?

A. I don't think so.

Q. In fact, putting cigarettes per day aside, you didn't have any data available to you that wasn't also available to the authors of Monograph 13, correct?

A. Yes.

Q. I'd like to turn now to the other chart from Chapter 4 and the analysis related to that that you talked about this

morning. And this is your analysis regarding age-specific mortality. Do you recall that testimony this morning?

A. Yes.

Q. Okay. And you presented to the Court a chart that showed a single analysis of -- age 40 individuals, correct?

A. Correct.

Q. Okay. And in your written direct, you were asked the question: "Did you make the comparison between predicted and actual lung cancer mortality rates for other specific ages, not just age 40? "

And you replied: "I prepared a second chart, 060549, that clearly shows the same downward slope for age cohorts from 40 to 50."

And I'd like to put that on the board. And that is 060549, JDEM.

Now, Dr. Wecker, you suggest in that testimony that this is basically the same analysis, just plotting everyone 40 to 50 instead of just 40-year-olds, correct?

A. With one other plotting difference -- is that they're all starting at the same origin in the upper left. You'll see that they are radiating from the same point.

Q. Sir, in fact, this is a slightly different mapping than what you provided in the chart that only showed 40-year-olds, correct?

A. It's slightly different only in that respect, that the

lines are starting from a common point, so you can see the slopes. But other than that, there's no difference.

Q. Dr. Wecker, I notice you've been using a binder for your testimony. Is that something that you brought with you today?

A. Yes. These are the exhibits that we used.

Q. And does that include notes that you prepared to assist yourself in testifying today?

A. There are notes that I made on them over time, yes, and maybe I'll look at them and maybe they'll be helpful.

Q. Okay. I just wanted to -- I notice that it looked differently from what I've seen because of the handwritten notes that you were flipping and I just wanted to clarify what it was you were using there.

Now, when you prepared this chart, you didn't simply use data that came directly from Monograph 13, did you?

A. No, it doesn't -- you can't find any data in Monograph 13. You have to go look at the underlying sources.

Q. And -- but the underlying sources here go beyond simply, for example, the programs that the authors in Monograph 13 used to generate data, correct?

A. I don't think of them as generating data. They're using data that has been collected by other people.

Q. Fair enough. Let me try and put it this way.

In some instances, when you looked at, for example, Table 4-5, which we just finished looking at, there you actually

received programs that were used by the authors of Monograph 13 to generate those tables, correct?

A. Right.

Q. And you simply used that with some corrections to generate your own analyses, correct?

A. Yes.

Q. And in this instance, you actually went back to source data to create the analysis rather than just taking programs that had been created by the authors of Monograph 13, correct?

A. I went back to source data in both cases, but I think I understand the difference that you're suggesting, that there was more programming effort on my part than the case we're looking at now.

Q. Right. And in fact, if we -- just to show an example that demonstrates that there's a difference here and you weren't just taking material from Monograph 13, if we look at U.S. 93177, this is actually, essentially the same chart, correct?

And this comes from the backup data that you provided with the Turner report in this case. This is just basically a replication of the same chart, correct?

A. Yes, they look similar.

Q. Okay. And if you flip to the second page -- actually, let me have you flip to the third page. These -- when you did the analysis that resulted in the chart we're talking about, you

were plotting the difference between actual death rates and predicted death rates, correct?

A. Correct.

Q. And here, if we look at page 3 of U.S. 93177, and we blow up, particularly, the last, like, five or six lines, this chart represents the estimations, right? The predicted death rates that you used in plotting the chart, correct?

A. I'd have to study that just a moment. It may, but judging from the title, it's related to my analysis of figure 18, where there was a certain scaling going on. That is not the case in 60549 and so -- in any event, this is not the underlying work paper for 60549. So I can't be sure. I'd have to just get out some numbers and check it.

Q. All right. Well, let me try and help short circuit this. Let's go up to the very top title, the thick line across the top. And it says "Burns figure 18 a-i.XLS," et cetera, et cetera. And it says "Extended to 2000 by WEW," correct?

A. Right.

Q. And so what you had done here is actually -- the authors of Monograph 13, they stopped at 1992 in their analysis, correct?

A. I think even '88 in some cases.

Q. Okay. But you extended it out to 2000, correct?

A. By getting the actual data where they made a projection.

Q. Right. So you got the data that they used to do their

projections and you did your own projections, correct?
A. No, I did no projections. I added -- well, the data we're talking about now, the additional data I got, was to replace their projections with actual data that was available, the more recent updated data.
Q. But these weren't their projections.
A. No. This would be three of those projections.
Q. Right. These were not the projections for Monograph 13.
A. Well, it's complicated.
Q. Well, you've extended this to 2000, we know that, correct?
A. Yes, we've added actual data to 2000.
Q. And we know that the Monograph 13 authors stopped at '92, correct?
A. Let me look at their chart for just a moment. No, it looks like it goes beyond that. That's what I thought.
Q. What are you referring to?
A. I'm looking at 418, which is a related piece of work, and I can see numbers there going out past '92.
Q. So it's your testimony that the authors of Monograph 13 went beyond 1992?
A. I can see them right here, yes. I can see a '94 figure in 418C, just as an example.
Q. Do you see anything beyond 1994?
A. No, not yet.

Q. Do you see anything in the year 2000?
A. No, I don't think they went that far.
Q. And in doing your analysis, did you consider whether you should have stopped in 1992?
A. I considered it and decided to employ the most recent available data to have more data available.
Q. Now, some of the data that's relied on here comes from the national health institute survey, correct?
A. Yes.
Q. NHIS, correct?
A. Yes.
Q. Was there a change in the definition of smoker in 1992 in the NHIS?
A. I don't remember that.
Q. Do you know whether the authors of Monograph 13 based their analysis, in part, and how to conduct that analysis on the fact that the definition of smoker changed in the NHIS in 1992?
A. I don't know that.
Q. Okay. Now, when you did your comparison between estimated death rates and actual death rates, did you scale any of the data?
A. Not in this analysis that we're talking about, no.
Q. Do you know if the authors of Monograph 13 scaled their data?
A. They did it -- they had both scaled and unscaled data and

for a chart that they presented, which is not the analysis of 548, they used what they called "scaled data."

For my analysis of 548 and 549, I used unscaled projections.

Q. And I'd like to go back and look at what the authors of Monograph 13 were saying about this. If we could turn to page 140 of Monograph 13. It's U.S. 58700. And if we blow up the text at the bottom there, it is from this text in Monograph 13 that you derive the idea to create the two charts that we've been talking about now, for the last several minutes, correct?

A. Yes.

Q. And, in fact, in your written testimony, you said you did that because the authors in Monograph 13 said they did it, but they never showed you the chart, correct?

A. Correct.

Q. You know, first thing I'd like to do is to look at what they say they were going to do, and they say -- beginning with the word "When sequential birth cohorts are examined."

Do you see that, Dr. Wecker?

A. Yes.

Q. "When sequential birth cohorts are examined in this manner for age-specific lung cancer death rate at ages under 50, there is no discernible slope for cohorts born after 1930. And the slope for older cohorts and for older ages is in the direction of increasing risk with the younger cohorts," correct?

A. Yes.
Q. And that's what you were trying to do, correct?
A. I was trying -- I was trying to make the chart, that they're evidently referring to when they write this sentence, but which, in fact, is not present in the monograph.
Q. So, the first thing I would like to talk about is, they say if you look at age-specific lung cancer death rates at ages under 50, now your chart shows ages 40 to 50, correct?
A. Correct.
Q. Doesn't show anybody under the age of 40, correct?
A. Right.
Q. You know what happens to the slope when you go to ages under 40?
A. No.
Q. Okay.
A. It may be that Peto's data shows that, but I don't recall it offhand.
Q. The data that you presented, the chart that you presented to the Court, doesn't show that, right?
A. Right, 40 to 50.
Q. And there's no mention in this paragraph here that suggests that the authors intended to use unscaled data, is there?
A. There's no mention, but I know that you wouldn't want to do that.

Q. My question is, did the authors indicate a desire to use unscaled data?
A. No, and correctly so. I'm sorry, they didn't indicate a desire because they didn't mention it one way or another.
Q. Correct. And here in this language that the authors in Monograph 13 presented, did they say that they wanted to compare or to present their information all based off the 1930 to 1934 cohort?
A. I don't think so.
Q. Okay. Now, if we pull up U.S. 93177 -- we could have done this on your demonstrative just as easily, but all of your lines start in 1930 to '34 at zero, correct?
A. Yes.
Q. Now, the actual minus predicted for all those different ages is not zero from 1930 to '34, is it?
A. It isn't. That's why it says on the vertical axis, relative to the 1930 to '34 cohort efforts.
Q. Right. And you indicate that?
A. Right.
Q. And so all of yours are built off a relative comparison of 1930 to '34, correct? Let me -- I can understand why you wouldn't like that question. Your charts are built all relative to 1930 to '34, correct?
A. They're displayed -- the slopes are displayed, beginning at the level of the 40-year-olds in the 30 to 34-year old

cohort.
Q. In the paragraph that we just looked at in Monograph 13, did the authors express any intent to draw the line that they want to see the slope of relative to the 1930 to '34 cohort?
A. No, they said nothing about it one way or another.
Q. Okay. Now, if we could look at U.S. Exhibit 18211. Now, Dr. Wecker, this is an analysis that takes into consideration the things we've just been talking about.
It's not all done relative to 1930 to '34. It uses scale data to U.S. mortality rates, and it includes everybody down to 28-year olds, not just 40 to 50. And if you look at that, you'll agree with me, will you not, that the cluster of information seems to cluster around the zero on the vertical axis and doesn't have a discernible slope, does it?
A. It's hard to tell the way the scale is, but I think you told me this was scale data and I would not recommend looking at --
Q. Dr. Wecker, my question was, do you see a discernible slope?
MR. BIERSTEKER: Objection, this witness has been very cooperative, he ought to be entitled to explain that answer.
THE COURT: The objection's overruled.
THE WITNESS: I'm sorry, the next question.
BY MR. GETTE:
Q. The question is: Does this show a discernible slope?

A. I can't tell, I would have to explode this bottom part, it's all crushed together, I can't see it.
Q. I'd like to move on, Dr. Wecker, to another area of your testimony that you didn't discuss this morning but was in your written testimony. It's related to the association of receptivity to smoking in youth.
Do you recall that testimony?
A. Yes.
Q. And let me ask you, aside from the analysis of the issue of tobacco marketing and adolescent smoking that you prepared for counsel, you have never conducted any other analyses of the issue of tobacco marketing in adolescent smoking, have you?
A. Aside from what?
Q. Preparing such analyses for counsel?
A. In this case?
Q. In this case or others.
A. Or others. You're correct. I've done it outside of this case, but always at requests of counsel.
Q. You don't consider yourself a marketing expert?
A. Correct.
Q. You've never published any peer-reviewed articles specifically on the topic of marketing?
A. I have published one on the use of statistics in marketing.
Q. Focused on the statistical aspects of studying marketing.

A. Right.
Q. You're not a psychologist or a psychiatrist?
A. Correct.
Q. And you didn't -- I asked you that earlier, so I won't put you through that again.
You're not an expert in youth smoking behavior.
A. Correct.
Q. And you've never published any peer-reviewed articles in that -- in the area of youth smoking behavior, correct?
A. Correct.
Q. Now, you talk about substantial in that testimony, the Pierce -- an article by an author by the name of Pierce, correct?
A. Yes.
Q. Okay. And if we pull up that testimony -- Charles, it's at page 54 of the written direct.
Do you have your direct testimony in front of you?
A. Yes, I do.
Q. And if you blow up the numbered items in the middle of the page, you say in your testimony that you've reviewed those four articles, the Pierce article, the Biener article, Sargent article, and the Choi article, correct?
A. Yes.
Q. Now, prior to your submission of testimony in this case, you never disclosed to the United States that you had reviewed

the Sargent or the Choi articles, correct?
A. That's true, because I hadn't.
Q. And in fact, throughout the testimony that you provide to the Court here, other than saying you reviewed them, you don't mention them, correct?
A. That's correct. I was told that was the procedure.
Q. And I'd like to go to page 56 of your testimony. And we'll come back to some of those other articles, but now we're staying with the Pierce one for now.
And at lines 18 through 21, you were asked what results about receptivity and smoking did the Pierce article report?
And you answered the Pierce article claims that, "In the group of nonsusceptible never-smokers, 34 percent of all experimentation in California between 1993 and 1996 can be attributed to tobacco promotional activities," correct?
A. Yes.
Q. And in your testimony then, you go on to point out that that result was not statistically significant, correct?
A. That's correct.
Q. Now, there is, however, a finding in the Pierce article that is statistically significant, isn't there?
A. I was looking for the copy of the article. I don't -- there may be, but I don't recall it.
Q. Okay. Let's pull up the article. That would be U.S. 64696. And if we go to the third page, in the bottom of

the right-hand column, the very bottom, the authors report, do they not, on some findings related to receptivity, and whether or not that is correlated to movement along the smoking continuum?

A. Yes.

Q. And, in fact, it says, starting about in the middle there, it says "Those who had a favorite advertisement."

Right above that, Charles. Right there. Right down to the end.

It says "Those who had a favorite advertisement but who were not willing to use a promotional item," that would be the moderate level of receptivity, correct? When they say "the moderate level," they're talking about the moderate level of receptivity, correct?

A. Just a moment, let me study it. Right.

Q. Okay. And they say "Those with moderate level of receptivity were 82 percent more likely to progress toward smoking, which is a statistically significant increase compared with those at the minimal level."

You don't quarrel with that finding, do you?

A. I think I agree, as they've defined these terms, that that's what they found.

Q. So, you agree that the finding of 82 percent was statistically significant?

A. I'm not going to dispute it, but I can't confirm it,

because I don't have those papers with me. But I'm not going to dispute it because I think I would remember if I was of that view.

Q. It's not in the testimony that you provided to the Court, that that's an inaccurate statement, is it?

A. I'm not claiming it's inaccurate and it's not in the testimony.

Q. Right.

A. What I wanted to alert you to is I've done a lot of other analysis on this that I didn't bring along, so I might have looked into it.

Q. But my question was: You didn't tell the Court any -- you didn't suggest to the Court that you disagreed with this?

A. Didn't then and I'm not now.

Q. Okay. Sir, let's put that statistically significant finding to the side for a moment and come back to the finding that you said was not statistically significant.

Even that finding demonstrated a dose-response relationship, correct?

A. I don't think so. It was like the ones we were looking at earlier. It was not dispositive of a dose-response relationship because it was not significantly different than zero.

Q. Well, it wasn't statistically different from zero --

A. Right.

Q. -- that led to the conclusion that you reported to the Court, that the finding wasn't statistically significant, correct?
A. Right.
Q. That doesn't mean that the best point estimates didn't show a dose-response relationship, does it?
A. It doesn't. It's -- a couple of "nots" in there, but I'm agreeing with you.
The thing I add is that one needs to interpret that along with the confidence intervals, just like the whiskers. And this is one of those cases where the confidence is such, you can't conclude it's any different than zero.
Q. Well, I thought when we were talking about that before, despite the whiskers, you were telling us there was a dose-response relationship?
A. That's because there was a bar that was statistically significant. It doesn't rise from the ones that were not.
Q. But in that instance it only takes one bar out of three to make it --
A. I think in any case.
Q. -- to make the grade?
A. I think in any instance, if I report a higher risk associated with higher tars, I would term that a dose response.
Q. But here, despite the fact that in each of the three levels, the best point estimate was increasing, you say, because

of the confidence intervals, you would not call that a dose-response relationship?

A. I don't understand that question. Here, I'm lost.

Q. Okay. In the Pierce article.

A. The 34 percent was not statistically significant.

Q. And my question was now: They were looking at three different levels of receptivity in Pierce, correct?

A. Yes.

Q. Low, moderate and high, correct?

A. Right.

Q. And if the best point estimate, a relating on -- comparing receptivity to transition to smoking, from the low to the medium to the high, each stepped up, you would still say that doesn't show a dose-response relationship because of the confidence intervals, correct?

A. If they're not.

MR. BIERSTEKER: Objection. Objection.

THE COURT: Excuse me. Excuse me, Doctor.

MR. BIERSTEKER: I object to the form of the question and I can expand on that objection if you would like.

There are two different analyses and I'm not sure that the witness or the examiner are necessarily talking about the same one. That's --

THE COURT: Well, if the witness is unsure of the question, he may say so. He was certainly about to promptly

respond, and so I'll let him do so.

THE WITNESS: Shall I respond?

BY MR. GETTE:

Q. Sure.

A. In the 34 percent analysis -- just so we're looking at the same thing -- that's a 2 by 2 table where they collapsed some of the categories you were talking about.

I'm saying that, as a general proposition, whether that particular 34 percent analysis or any other analysis, where the results are not statistically significant, then I would, as a general proposition, not conclude a dose-response relationship.

Q. Let's move on and look at some analyses of Pierce that you --

THE COURT: Let me just ask one final question. It would be your view that you're not prepared to find a dose-response relationship any time you are not satisfied that there is statistical significance?

THE WITNESS: Yes, Your Honor, that is my position.

BY MR. GETTE:

Q. I'd like to look now at your demonstrative JDEM 060552. And here you present in the first line the finding of the Pierce Study, correct, that showed a 34.3 percent --

A. Right, that is the very same 34 percent on the right-hand side, in red, that we were talking about.

Q. Okay. And that related to progression of youth to

smoking, actual smoking consumption, right?
A. Yes.
Q. And the standard that the author in Pierce used was that the individual be -- have smoked at least a hundred cigarettes in their life, correct?
A. No, I don't think so. For that one, I think it was even one puff would do it.
Q. Rather than slow us down, let me come back to that, then. Let me ask you about whether or not you've considered some other materials in reaching the opinions that you expressed relative to the Pierce article.

In reaching your opinion, did you review the Cochrane Systematic Review that related to the relationship between cigarette advertising and promotion and adolescent smoking behavior?
A. No.
Q. Were you aware that there was a systematic review of the literature on that issue available?
A. I was not; I'm not familiar with that document.
Q. So you didn't consider it, obviously, when you offered your opinions, then, correct?
A. That's correct.
Q. And not being aware of the document, you don't know whether or not it's consistent with the findings presented in the Pierce article, correct?

A. I don't know that. I know it wouldn't effect my arithmetic, but I don't know -- it has no affect on my calculation.
Q. Now, you talk about also -- the question was, though, whether or not you knew it was consistent with the findings in the Pierce study, not whether or not it would impact your calculations.
A. But the question is ambiguous. So the findings in the Pierce study -- I have findings in the Pierce study and I wasn't sure if you were talking about the 34 percent and the lack of statistical significance or the Pierce 34 percent itself, and so I tried to cover both categories.
Q. Either way we slice it, you don't know whether the Cochrane study --
A. I haven't read it.
Q. -- is consistent, correct?
A. Right. I have not read that document.
Q. Let's look at the Biener and Siegel study. And I'd like to pull up U.S. 72922. And let's go to page 409.
First, Dr. Wecker, this is the Biener and Siegel article that you were referring to in your testimony, correct?
A. Yes.
Q. And if we go to page 409 and we look at the first column there and the second sentence -- you can blow up the whole paragraph there, Charles -- the authors of the Biener and Siegel

study say that: "This analysis found that adolescents who were highly receptive to marketing in 1993 were more than twice as likely to become an established smoker by 1997, compared with those who had low receptivity," correct?

A. Yes.

Q. And that finding was statistically significant, correct?

A. Just a moment. Let me read it. Yes.

Q. And that looked at, instead of progression along the smoking continuum, that actually looked at smoking to establish smoking, correct?

A. Just a moment. Yes.

Q. And in this study, established smoking, for this study at least, was that the individual had smoked at least a hundred cigarettes in their lifetime, correct?

A. Correct.

Q. And nothing in your analysis indicates that the authors of this study did anything wrong in the statistical work that they did to reach this finding, correct?

A. Correct.

Q. And in fact, you haven't had an opportunity to review the underlying work that Biener and Siegel did, correct?

A. Yes and no. I can't review their underlying data, but I did review the underlying work by applying their methods to Pierce data.

Q. You applied it, not to the data that they used, though,

correct?
A. Right, that's not available to me, but you said "review their work." And so I think I reviewed their work as I've explained.
Q. Do you recall, by the way, what data was used by Biener and Siegel in preparing their study?
A. I think it was a Massachusetts-based study.
Q. And have you sought out that data from the state of Massachusetts?
A. I've asked counsel to try to get it for us, but they were not able to do that.
Q. My question was, did you contact the state of Massachusetts and ask for that data?
A. No, I didn't do that directly.
Q. Do you know if you had whether they would give it to you?
A. I assume I have less clout with the state of Massachusetts than some lawyer might, so --
Q. Well --
A. I don't know. I can only speculate what would happen if I call, but my speculation, I wouldn't have any better luck.
Q. And putting aside the speculation of who counsel talked to or not, you did not contact the state of Massachusetts, right?
A. That's correct.
Q. And you don't know what they would have told you if you

had?

A. I have no way to know that.

MR. GETTE: Your Honor, we're very close and I'm just about to move on to another area that I know would not be finished in the three or four minutes we have remaining.

THE COURT: I didn't think you were going to finish today, based on your estimates.

Based on your estimates, you should have an hour and a half or 2 hours at the most; is that right?

MR. GETTE: I certainly would say an hour and a half is the outside limit, Your Honor. I think we can probably even do it more quickly than that.

THE COURT: And Mr. Biersteker, any idea on redirect?

MR. BIERSTEKER: So far, Your Honor, so far I think it would be fairly limited. Maybe half an hour at this juncture.

THE COURT: Well, then, we should be able to finish this witness in the morning.

MR. BIERSTEKER: I would hope so.

THE COURT: All right, everybody, we would take a recess.

MR. GETTE: Your Honor, one last item. I am sorry. Since the witness did indicate that there were notes that he had prepared that he was relying upon, I certainly would like to mark those as an exhibit to his testimony, and obviously have that made available to us to review.

MR. BIERSTEKER: I have no problem with that.

THE COURT: And I thought his testimony was -- maybe I misunderstood, but I thought he had said he had written some notes on his direct testimony in order to help him with his oral testimony.

Is that correct, Doctor or had you made separate notes?

THE WITNESS: Well, they're not separate, they're of the character you just said. They're identifying sources of information and page numbers, that sort of thing.

THE COURT: All right. So copies should be made of that.

MR. GETTE: And then an instruction for the witness, Your Honor.

THE COURT: Yes. Our usual instructions. Our instructions always are, you may not talk with counsel about your testimony, you may not do any homework, like reviewing your testimony or any of the articles or materials you relied upon in preparing your testimony. You just come in fresh tomorrow morning.

THE WITNESS: Thank you, Your Honor.

THE COURT: All right. 9:30 tomorrow, please, everybody.

(Proceedings adjourned at 4:29 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

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