IN THE CIRCUIT COURT OF OHIO COUNTY
WHEELING, WEST VIRGINIA

IN RE:
TOBACCO LITIGATION CASE NO. 00-C-6000
MEDICAL MONITORING CASES

* * *

JURY TRIAL

Whereupon the above-entitled matter came on for hearing before the Honorable Arthur M. Recht at the Ohio County Courthouse, Wheeling, West Virginia, and the proceedings are as follows.

* * *

VOLUME 7-A

September 24, 2001

8:30 a.m.

* * *

I N D E X

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(There are other counsel representing interested parties also present in the courtroom gallery.)

Monday Morning Session
September 24, 2001
8:30 a.m.
-- -- --
P R O C E E D I N G S
-- -- --

(In open court with a jury present.)
THE COURT: Be seated, please.
Good morning, everybody. You lost one of your number. There is nothing wrong, nothing -- just that he had a personal problem or personal situation that he had to be excused.
All right. We are in the middle of Dr. Gaziano's cross-examination?
MR. NEWBOLD: Yes, sir.
THE COURT: Is he here?
MR. SEGAL: Yes, he is, Your Honor.
THE COURT: Doctor, step forward, please.
Is there a desire to readminister the oath to Dr. Gaziano?
MR. NEWBOLD: No, Your Honor.
THE COURT: Doctor, step forward, please, sir. Please consider yourself under the oath that was administered to you on Wednesday, I believe it was.

THE WITNESS: All right, sir.
THE COURT: All right. Mr. Newbold.
MR. NEWBOLD: May it please the Court. Good morning, ladies and gentlemen of the jury

-- -- --

DOMINIC GAZIANO, M.D.,
being first duly sworn by the Clerk, testifies and says as follows:

-- -- --

CROSS-EXAMINATION (Cont'd)

BY MR. NEWBOLD:

Q. Good morning, Dr. Gaziano.
A. Good morning, Mr. Newbold.
Q. Dr. Gaziano, since we have been away from each other and from the jury for several days, the Court has allowed me to simply ask you a few questions to refresh the jury on your testimony of last week, which is what I'm going to do now. Is that okay, sir?
A. Yes, sir.
Q. Okay. The substance of your opinion in this case is that the detection of lung cancer and COPD through medical monitoring -- that's what you testified about?

A. Yes, sir.
Q. Okay. And we have agreed, Doctor, that you have not written anything on the subject of medical monitoring?
A. Yes, sir.
Q. Okay. And we have agreed that you have nothing that's been peer reviewed or published in a peer-reviewed journal on the subject of medical monitoring?
A. Yes, sir.
Q. In fact, you have written nothing whatsoever on the subject of medical monitoring; is that correct, sir?
A. That's correct.
Q. And you have taught no class on medical monitoring?
A. No, sir.
Q. And you have never lectured on medical monitoring?
A. No, sir.
Q. All right. You have never been in charge of the design of a medical screening program or a medical monitoring program?
A. No, sir.

Q. All right. And you have never conducted a screening program of smokers to determine whether or not they have lung cancer?
A. No.
Q. All right. And when you first formulated your opinions in this case, when your deposition was taken, you had no scientific opinion on the feasibility of the medical monitoring program recommended by the plaintiffs?
A. Yes, sir.
Q. Okay. And when you first formulated your opinions in this case, you had not evaluated the methodology set forth in the Guide to Clinical Preventive Services, which was this blue book, on how to assess whether a medical monitoring program or screening program is safe and effective?
A. At that time, yes, sir, that's correct.
Q. Okay. And you now know, however, that contained within this book is the criteria that the United States Preventive Task Services uses to assess whether or not screening is reasonably necessary?
A. Yes, sir. But I just want to add that some screening tests fall outside that particular

particular recommendation. But other than that, I have no personal experience with it.

Q. Okay. And Doctor, we had talked about the difference between diagnosing and medical monitoring, and you do not hold yourself out to be an expert on medical monitoring?

A. That's correct.

Q. Okay.

Now, Doctor, the plaintiffs in this case during opening argument -- opening statement, I'm sorry -- used a board wherein they described the monitoring recommendations that they are proposing for this class of plaintiffs, which is, age 40, spirometry for COPD.

And then age 45, spirometry for COPD, and then a spirometry test every two years thereafter. Is that correct, sir?

A. Yes, sir.

Q. And insofar as long lung cancer is concerned, what the plaintiffs are proposing is a CT scan, or sometimes called a CAT scan, starting at age 50 and then once every year, and that's for the early detection of lung cancer; is that correct, sir?

A. Yes, sir.

Q. And you understand of course, that this particular program was designed by a particular doctor whose name was Dr. Burns?
A. Yes, sir.
Q. Okay. Now, you have never spoken with Dr. Burns specifically about this program, have you?
A. No, sir. I have never spoken specifically. I did recall a teleconference that was a year and a half ago with the law firm calling the conference in which I was a participant, and I believe Dr. Burns was in the teleconference as well.
Q. But you had no input into the program before it came into existence, did you, sir?
A. I had no input, no, sir.
Q. All right. So you have never met Dr. Burns?
A. No, sir.
Q. And to your knowledge, Dr. Burns' program, as proposed by the plaintiffs, has not been published anywhere?
A. Not specifically that way, because it's a unique program.
Q. Well, that's my question, sir. This unique program of giving spirometries to people with a five pack year history of smoking at age 40 and then

every two years thereafter, and then, age 50, for a CAT scan and every year thereafter, specifically has that program been published anywhere?

A. Not that very specific program, no, sir.

Q. Okay. Now -- and when I talk about this program, I mean this program.

A. I see.

Q. Okay. Now, Doctor, this program, the program that the plaintiffs are recommending for all the West Virginia people who have a five-year pack -- five pack year history of smoking, has not been peer reviewed either, has it?

A. I don't think so.

Q. Okay. And to your knowledge, this particular program, the program that they want for West Virginia smokers, has not been published in any peer-reviewed journal, has it?

A. No, sir.

Q. To your knowledge, Dr. Burns' program, which is the program they recommend for these plaintiffs, has not been tested through any randomized trial or cohort study, has it, this particular program?

A. Well, it's a very strict definition of a

program. But similar ones have been tested.
Q. I'm not asking you about similar.
A. But this one has not been tested, no, sir, not this specific program.
Q. Okay. And this specific program, the one that they want to have for the residents of West Virginia, has not been subject of any case control study, has it?
A. Not that I'm aware of, no, sir.
Q. In fact, this program has not been the subject of uncontrolled experiments, has it, sir? This particular program --
A. No, sir, it hasn't.
Q. In fact, for this specific program, there are no data that support or even reflect upon the safety and efficacy of Dr. Burns' proposed program, this program, five pack year history, spirometry at 40 --
A. Would you repeat that question, please?
Q. Yes, sir. In fact, there are no data supporting or that even reflect upon the safety and efficacy of Dr. Burns' proposed program as a program; that's true?
A. I am going to say that that's not true,

that there is in evidence a body of literature that does speak to the safety of -- and effectiveness of these programs.

Q. You know, Doctor, you recall when your deposition was taken on August the 22nd. Do you recall that, sir?

A. Yes, sir.

MR. NEWBOLD: Do you have a copy for the other side, please, and a copy for the Court.

May I approach the bench, Your Honor?

THE COURT: All right.

MR. NEWBOLD: And I have a copy for the witness, Your Honor. Shall I hand it to him or --

THE COURT: Well, here, it will be a little easier.

THE WITNESS: Okay.

BY MR. NEWBOLD:

Q. Sir, I would like to direct your attention to your deposition of August the 22nd.

A. All right.

Q. Do you have that, sir?

A. Well, I'm not sure what you are referring to.

Q. Page 364, Lines 15 through 19. Would you

put that on the screen please, Jason. Could you blow that up, please.

Doctor, I have this up on the board so that the jury can see it as well. And, when I took your deposition on August the 22nd, I asked you the exact question that I asked you:

Question: In fact, there are no data supporting or that even reflect upon the safety and efficacy of Dr. Burns' proposed program as a program; that's true?

And on August the 22nd of last year, you answered: I believe that's true.

Is that correct, sir?

A. That's what it says here, and I believe that's correct as far as that data is concerned. But --

Q. Thank you, sir. That's the question I asked you, whether or not you gave me that answer to my deposition question on that day?

A. I modified my answer a little bit this morning, which I think is appropriate, an appropriate response. But did I say that.

Q. You did say that on August 22nd when I asked you that under oath; is that correct, sir?

A. Well, I'm still under oath, and, in fact, my response is truthful today that this specific test is not been subject -- the specific age and the specific individual and the specific group of individuals has not been tested.

It would be unusual for it to be because this is unique, this is the first time. But that doesn't mean that studies haven't been done that are similar and which you can transfer at least some experience with to get an idea of safety. And that's the way I answered it today.

Now, you know, however that comes out, that's my answer today based upon my knowledge today.

Q. Thank you, sir.

But this is a unique program. This is a program that has never been tested before as it sits here right now. Is that correct?

A. Yes, sir.

Q. Okay. Now, Doctor, insofar as this particular test is concerned, which is a CAT scan at age 50 to detect lung cancer, you testified on Wednesday that nobody says that a single CT, that nobody says that a single CT will separate malignant cancers from benign nodules in the first sweep; is

that correct, sir?
A. Yes, sir.
Q. All right. So that, after you do the first sweep, the first cut, this one CT scan that the plaintiffs want to give to these 270,000 West Virginians will not tell you which of the nodules that are seen are benign and which of the nodules are malignant; is that correct?
A. Yes, sir. I think I testified to that earlier.
Q. Okay. The thing that the CAT scan looks for, it simply looks for a noncalcified nodules of a certain size; is that correct?
A. Yes, sir.
Q. So with this first CAT scan, the only thing that the plaintiffs are proposing once a year with that CAT scan, all you know is whether or not they have nodules. At this point, you can't say that they are cancer, can you, sir, at this -- is that right?
A. No. Well, for the most part, yes, sir.
Q. Okay. So at this point with a single CAT scan, you could not tell everyone in this class who tested positive that they had cancer based on this

CAT scan alone; is that correct, sir?
A. That's correct.
Q. What you can say is that the CAT scan picks up nodules, about 10 percent of which may be actual cancers; is that correct, sir?
A. That means that it is a low sensitivity test -- yes.
Q. That's correct, okay.
A. And a high specific test, at that stage -- at that phase, at that phase.
Q. At that phase, at that stage. So what you would have to do then in order to either diagnose or detect which of those nodules are cancer, you would have to have a follow-up procedure to determine what is cancer and what is not; is that correct?
A. Absolutely, yes, sir.
Q. Absolutely.
Doctor, neither you or any qualified doctor in the State of West Virginia would tell any of their patients, based upon this single CT and this CT scan only, that they have lung cancer?
A. No, sir, I would not.
Q. You would not?
A. No.

Q. Okay. And the reason that you would not is that because you would have to take further steps to say, okay, what I see now may be and may not be, but now I'm going to have to take some further steps to determine which of these nodules is cancer and which is not; is that correct?

A. Yes, sir.

Q. All right. And that's just a part of the standard care of practice in the State of West Virginia when you see a suspicious lung nodule; is that correct?

A. I think that's probably a world standard, certainly a national standard, yes, sir.

Q. Now, the CAT scan procedure that -- let me strike that.

Now, these follow-up procedures that you would have to do in order to say that you detected lung cancer or that you have diagnosed lung cancer, those follow-up procedures would vary from individual to individual, would they not?

A. Yes, sir.

Q. Now, the plaintiffs' medical monitoring program, you understand that all they are recommending is one CAT scan at age 50 and then one

CAT scan every year thereafter, no follow-ups? You understand that, sir?

A. I take your word for what it is. I haven't specifically gone into the specifics, but that's my impression. But I haven't seen or read the particular --

Q. That's your impression?

A. Yes, sir. I take your word for it.

Q. So then with no follow-up studies, in this particular plan, it would be impossible to say to any of these class members who went through the first CAT scan, You have cancer; is that correct?

A. There is one -- if I may answer with a modification.

Q. Okay. Your answer is yes; is that correct?

A. Yes. With a modification. That this test -- I'm not sure if it is to be organized in a way that there is follow-up. But, if you say that's all that is possible, a yearly CT, there is some benefit, but it's not as recommended -- as one would recommend, as I understand the literature because, if you get a CT scan in a year, that becomes a follow-up on the nodules you found the first year. And that will give the clinician some idea of the

nature of the lesion, particularly if it's growing.
So it has some value. It is not -- it is not what has been proposed by people who do this as screening operations, particularly Mayo Clinic and Columbia.
Q. But Dr. Gaziano, surely, if you saw somebody who had a suspicious nodule on this first CAT scan, you wouldn't wait for one year to test them again, would you?
A. No, no. No, I would not.
Q. Thank you.
Now, this study is... One moment, please.
MR. NEWBOLD: May we have one second, Your Honor?
THE COURT: Sure.
BY MR. NEWBOLD:
Q. Dr. Gaziano, I would now like to turn to some other topics.
When you testified on Wednesday, you talked about some various articles. You talked about a JAMA article, I believe, Journal of the American Medical Association, and you talked about an article from the New England Journal of Medicine; is that correct, sir?

A. I may have, yes, sir.
Q. All right. And the essence of both of those articles was the fact that some doctors had written in to these journals, these medical journals, and basically said that they disagree with the National Cancer Institute and some of the other major health organizations, they disagree, and they think that lung screening for cancer should go in right now; whereas, national public health organizations like the NCI feel that it's too early to tell; is that correct, sir?
A. Yes, sir.
Q. All right. And you testified to us that, in order to form your opinions in this case, that you have spent hundreds of hours reviewing various peer reviewed medical journals within your specialty and within the topics that we are talking about today; is that correct?
A. Yes, sir.
Q. All right. And you told the jury that there are these various peer-reviewed articles, like in JAMA or the New England Journal of Medicine that doctors rely upon in forming their opinions; is that correct, sir?

Yes, sir.
Q. And of course you know that the reason we are here today is -- and and tomorrow and tomorrow and tomorrow, is that we are going to hear a lot of opinions from experts like yourself, and the jury will make the decision on what they think. You know that, don't you, sir?
A. Yes, sir.
Q. And you also then would agree with me that it's important that the jury hear both sides of these issues; is that correct?
A. Yes, sir.
Q. Now, there is a debate right now in the country. There are some doctors who believe that there should be helical CAT scans right now to detect early lung cancer; is that correct, sir?
A. Yes.
Q. But on the other hand, there is no major health organization, at least according to Dr. Petty, who would recommend -- well, let me strike that question. Let me do it this way.
The first article that you talked to us about is the JAMA article which is called Screening Stages For Early Detection of Lung Cancer. And although we

didn't have the entire article with us at the time, I actually have the book.

MR. NEWBOLD: Do we have another copy of this?

THE WITNESS: I have the article myself, somewhere.

MR. NEWBOLD: I have the whole book.

Judge, may I approach the bench so I can give you a copy of this?

THE COURT: Sure.

MR. NEWBOLD: I assume you have this. I have got copies, Scott.

BY MR. NEWBOLD:

Q. Okay. This is, for the ladies and gentlemen of the jury, this is a JAMA magazine; is that correct, sir?

A. Yes, sir.

Q. And this is a magazine -- do you subscribe to this?

A. Yes, I do.

Q. It comes out how often?

A. Weekly.

Q. It's a weekly, all right. And you were quoting from the, Screening Strategies For Early Detection of Lung Cancer, right, sir?

A. Yes, sir.
Q. Which is on Page 1977?
A. Yes, sir.
MR. NEWBOLD: Could you put that put that up for me, Jason. Could you dim the lights, please. That's tab 31.
BY MR. NEWBOLD:
Q. This is the article you talked about to the jury; is that correct, sir?
A. Yes, sir, it is.
Q. And in this article, this is written by a man whose name is Richard Petty?
A. Thomas Petty.
Q. Thomas Petty, I'm sorry.
THE COURT: Richard is the race car driver.
MR. NEWBOLD: Well, now you know where my real expertise lies, Your Honor; it's not this.
BY MR. NEWBOLD:
Q. Okay. Now, Dr. Petty, he acknowledges in the very first paragraph of this --
MR. NEWBOLD: Could you blow up the third sentence, which says "no major medical organization." Can you do that on the small one or not?

We will do it on the next one.
BY MR. NEWBOLD:
Q. Take a look at your article. Dr. Petty states in this article that no major medical organization in the United States recommends any form of screening for lung cancer.
Did I read that correctly, sir?
A. Where is that? You have to point it out. It's a three- or four-page article. You have to direct me to it.
Q. Go to Tab 32.
A. I'm sure he said that.
Q. Well, if you go down to the third sentence?
A. Which page and which sentence?
Q. Can you blow up that highlighted portion?
A. Okay. That's at the beginning.
Q. I'm on Page 1977; okay?
A. All right.
Q. And it says -- and I have blown it up for the jury -- it says:
Current knowledge and available technology could change the outcome of lung cancer. But screening and even case finding in patients at high risk is still not recommended. No major medical

organization in the United States recommends any form of screening for lung cancer.

Is that what Dr. Petty says?

A. May I just continue reading from that sentence?

Q. You may.

A. Yes, all right. For this reason --

Q. Take it up, will you?

A. For this reason, lung cancer is not diagnosed until it is symptomatic and usually when it is in advanced and incurable stages.

That's the basis for his rethinking this screening business.

There is one slight modification in terms of major organizations. The American Cancer Society has changed from no screening to we are going to think about screening. They haven't decided one way or the other, but they have modified their position

And so there is one organization who is beginning to move in the direction -- or at least rethinking it. Let's just put it that way.

Q. Okay. I understand that, sir.

As a matter of fact, if you will take a look at the very top of the article, what it says is

"controversies." There is a debate going on in the medical community; is that correct, sir?

A. Yes.

Q. See, it says "controversies."

And Dr. Petty is a doctor who thinks that, let's do it now, let's not wait; whereas, he admits that no major public health organization is recommending it at this time. Is that correct?

A. Yes, sir.

Q. Now, and what you have told me is that the American Cancer Society is thinking about it, but not quite yet; is that right, sir?

A. They are thinking about the idea of no cancer screening for lung cancer with the idea that maybe it's time to change. But they haven't changed.

Q. Okay. Now, public health organizations like the National Institute of Health and the American Cancer Society, et cetera and so forth, they are the guardians of the public health; they are the ones who look at tests and make a determination whether or not they are safe, accurate and effective. Is that correct, sir?

A. I think that's their purpose, yes, sir. There are individual doctors who are in the capacity

to make those decisions.
Q. And one of the things the public health organizations want to make sure of before they recommend a test is they want to make sure it does more good than harm. You would agree with that, wouldn't you, sir?
A. Yes, sir.
Q. Let's go back to this article on the controversy. There was actually another article that was right behind that one, wasn't there, sir?
A. Yes, sir, there was.
Q. And that was on Page 1980.
MR. NEWBOLD: Could you put that up for me, please? And turn to page 1980, please. Right there, okay, thank you.
BY MR. NEWBOLD:
Q. Now, that's an article that was written in the exact same publication, JAMA, that you told the jury about?
A. Yes, sir.
Q. Right. But you didn't tell the jury about what Dr. Frame had to say, did you?
A. You didn't let me tell the jury about a lot of what I had to say in this particular regard,

Mr. Newbold. So, to be fair to me, don't hold me responsible for not getting out the word. There is a body of literature, but I was limited in what I could express.

So having said that, I was aware of that, and I knew of that, and I have no problem with giving the pros and cons of this particular issue.

Q. Okay.

MR. NEWBOLD: Could you blow that up for me, please, the routine screening for lung cancer. Maybe some day but not yet, right here.

BY MR. NEWBOLD:

Q. So what Dr. Frame is doing, he's taking the other side of the argument. He's saying maybe it will work, but the evidence is not quite in yet. Is that correct, sir?

A. Yes, sir. That's what he is saying.

Q. All right. Let's see -- now, do you know who Dr. Frame is?

A. I read that article, and his position is at the end of it, and I can't recall.

Q. You know that he's a member of the United States Preventive Services Task Force who wrote this book?

A. I didn't know that, sir.
Q. Let's see what Dr. Frame has to say about this particular controversy.
MR. NEWBOLD: Let's blow up the first paragraph.
BY MR. NEWBOLD:
Q. Dr. Frame is an honest doctor, so he starts off with what you said: Lung cancer is the leading cause of cancer death worldwide and accounts for 28 percent of all cancer deaths in the United States. It is largely a preventable disease. In the United States, more than 90 percent of lung cancer cases are related to cigarette smoking.
Next paragraph, please, that's highlighted.
He says then: It is not surprising that screening for the early detection of lung cancer at a curable stage has been a research priority for many years.
Indeed, 8 prospective studies of screening for early lung cancer either by periodic chest radiographs or by sputum cytologic tests have been reported in the past 40 years.
Unfortunately these studies have all reached a common conclusion: Early screening does not lead to

reduced mortality from lung cancer.
Is that what he says, sir?
A. He should have added one other word to that. Early screening by chest x-rays does not lead to reduced mortality from lung cancer, because that's what they were looking at.
Q. Let's go to the next paragraph, please.
A. So that's what he was saying, actually.
Q. Okay. At present no major organizations recommend any form of routine lung cancer screening for either the general population or smokers.
Next subject, please.
Lead-time bias, length bias, and overdiagnosis are three explanations for why screening can superficially appear to be beneficial and yet not improve mortality.
Screening for lung cancer is the classic example of a situation in which screening detects early cancers, and patients whose cancers are detected by screening have longer survival, yet screening does not improve mortality.
Is that what he says, sir?
A. He said that in referring to the chest x-ray screening, which is not the CT screening, yes,

sir.
Q. Next paragraph, please.
Now we are going to get to what you are talking about, sir.
A. I see.
Q. You see, you have to read the whole article, not just part of it.
A. I read the whole article. I just want to make sure you are quoting the whole article.
Q. I will, sir, you know that.
The most important new technology with potential to screen for lung cancer is low-dose helical computed tomography, CT.
That's what we are talking about in this case, right, sir?
A. Yes, sir.
Q. Recent studies from the United States, Canada and Japan have shown low-dose helical CT to be much more sensitive than traditional radiography for the detection of small noncalcified nodules and early lung cancers. However, it is not very specific. The positive predictive value for low-dose helical CT scan in the early lung cancer axons project, ELCAP, study was 12 percent. That's

Claudia Henschke; right?
A. Yes.
Q. 20 percent of the cohort underwent further evaluation, including at least serial traditional CT scans, because of a false positive low-dose helical CT scan result.
Next slide.
No controlled studies have been reported using low-dose helical CT or improved cytologic screening demonstrating reduced mortality related to screening for lung cancer.
Next slide, please.
There are several potential harms from lung cancer screening. First, there are direct adverse effects of screening and follow-up, such as radiation exposure, surgical morbidity and mortality, and complications occurring from biopsy.
Now, those harms they are talking about is what may happen to you in the follow-up procedures; is that correct, sir?
A. It may happen, and those issues have been taken up by those who advocate this type of screening and pointing out the very limited nature of it.

Given the low positive predictive value of the screening test, the direct adverse effects from screening and follow-up will most often affect persons who do not have cancer.

That means people who have a false positive and now they are trying to figure out if they really have cancer; is that right, sir?

A. Yes, sir. I'm not sure I would call it false positive, though. I just say the test is not -- the first test is not to find cancer, but to find nodules, and it does find nodules. So if we are to say the test is to find nodules, it finds nodules imminently.

Q. Then the people who have the follow-up procedures, those are the ones who this author thinks is the most likely to suffer harm; is that correct?

A. Well, certainly that's true, but --

Q. Go on to the next one.

A. All right.

Q. A significant potential harm of screening is that -- no, the one before that.

Given the low positive predictive value of the screening test, the direct adverse effects of

screening and follow-up will most often affect persons who do not have cancer.

Is that what he says, sir?

A. Yes, sir.

Q. Next, please?

Here is another problem that he sees about screening:

A significant potential harm of screening is that smokers will interpret negative results of screening tests as assurance that they are disease-free and will be less motivated to quit smoking. Smokers may also interpret widespread screening as an indication that lung cancer is a curable disease.

Is that what he says, sir?

A. Yes, sir.

Q. Next, please. He concludes by saying:

Screening for lung cancer should not be part of a rational evidence-based screening program.

Next, please? Is that the last on this one?

And then this is the end of it:

These recommendations call for research, primary prevention, and honest dialogue between physicians and patients, but they do not call for

routine screening of high-risk persons. A recommendation for routine screening at this time would impede efforts to understand the best strategies for the early detection and treatment of lung cancer.

So that's another side of this story, right, sir?

A. Yes, sir.

MR. NEWBOLD: Take it off, please.

BY MR. NEWBOLD:

Q. Now, you showed the jury another article, and that's Tab 50. This is from Chest magazine.

MR. NEWBOLD: Could I see Tab 50, please.

MR. FURR: Bill, take it off, please.

MR. NEWBOLD: Your Honor, we have a technical problem here.

THE COURT: All right. What do you want to do?

MR. NEWBOLD: I'm going to try to figure it out.

THE COURT: Do you want time to fix it?

MR. NEWBOLD: Well, I'm not too sure I can fix it on the run here. In fact, I know I can't.

BY MR. NEWBOLD:

Q. Doctor, do you recall testifying about an article from the New England Journal of Medicine, and it was called The Lung Cancer Overdiagnosis Bias?
A. That was in Chest, I believe.
Q. In Chest, I'm sorry.
A. Yes, sir.
Q. You recall that?
A. I believe it was. Can you hold it up and let me look at it to see what you are talking about.
Q. Well, that's the issue.
MR. NEWBOLD: May I approach the bench, Your Honor?
THE COURT: Sure.
(At sidebar:)
MR. NEWBOLD: The problem is it hasn't been shown up. I don't want to show this, but nonetheless I have to refresh his memory.
THE COURT: Do you want him to --
MR. NEWBOLD: Yeah, he can see that.
(In open court:)
BY MR. NEWBOLD:
Q. You recall testifying about that in Chest magazine?

A. Yes, sir.
Q. And that was an article written by -- what was the doctor's name, please?
A. Grannis, Frederick Grannis.
Q. Okay. And Dr. Grannis at that time was another individual doctor who was disagreeing with the National Cancer Institute and the fact that the National Cancer Institute does not recommend these types of helical CAT scans for the early detection of lung cancer; is that correct?
A. Yes, sir.
Q. Okay. Can you speak into the microphone a little more, please, sir, or pull it towards you.
A. Yes, sir.
Q. Now, I want to make sure that everybody in this room understands who the National Cancer Institute is. So I want to ask you a few questions about the National Cancer Institute because, now, we have had two individual doctors who are disagreeing with the National Cancer Institute.
So the National Cancer Institute is an institution of the National Institutes of Health, or the NIH; is that correct?
A. Yes, sir.

Q. And the NIH is part of the Department of Health and Human Services; is that correct?
A. Yes, sir.
Q. So that means that the NCI, the National Cancer Institute, is part of the same agency of the federal government as the office of the Surgeon General of the United States?
A. Yes, sir.
Q. All right. And you would agree with me that the NCI is reputable --
A. Yes, sir.
Q -- highly regarded organization in its efforts on tobacco use and lung cancer?
A. Yes, sir.
Q. And is one of the foremost authoritative institutions working on the causes of cancer, the prevention of cancer, and the treatment of cancer?
A. Yes, sir.
Q. All right. Now, did you know that the National Cancer Institute has a budget that exceeds 3.3 million -- billion, billion, $3.3 billion a year?
A. I'm not familiar with their budget, sir.
MR. NEWBOLD: Put up Tab 47, please. Dim the

lights, please. Can you zoom that in a little bit.
BY MR. NEWBOLD:
Q. Okay. This is the National Cancer Institute, the NCI, it's the 2002 NCI budget. Our total fiscal year 2002 budget request is five billion thirty million dollars. This represents an increase of $1,524,928,000 from the previous year. Are you familiar with that?
A. I don't keep track of the expenditures of the agencies. No, I wasn't familiar with it.
Q. Do you know that the National Cancer Institute intends to spend $67 million next year on cancer tobacco research alone?
A. I know it's significant, yes, sir.
Q. Okay. And you know that the NCI supports literally thousands of cancer researchers across the country?
A. Yes, sir.
Q. And you also know that it publishes one of the leading authoritative journals on cancer research, which is called the Journal of the National Cancer Institute?
A. Yes, sir.
Q. And you are familiar with that, aren't you?

A. Yes, sir.
MR. NEWBOLD: Could you give me Tab 48, please?
BY MR. NEWBOLD:
Q. This is the cancer net. Now, you testified to me on direct examination or -- on direct examination by Mr. Segal that you also go on to the internet from time to time to do your research or look up things?
A. Yes, sir.
Q. And you understand of course that the National Cancer Institute -- can you blow this up, please -- the National Cancer Institute has something called CancerNet, where they put out their various announcements and their pronouncements and their findings from time to time.
Are you aware of that, sir?
A. Yes, sir.
Q. And I'm sure you have seen that, have you not?
A. I don't think I have looked that up.
Q. You have never used that?
A. Not this particular source, no.
Q. Can we go to the next highlighted area,

please?
    The editorial board for the -- can you make that bigger? I can't read it.
    The editorial boards are responsible for the maintenance and accuracy of the PDQ cancer information summaries. There is a separate editorial board to cover each type of PDQ summary. Treatment summaries for adult cancers, treatment summaries for childhood cancers, cancer screening and prevention summaries -- that's what we are talking about now, cancer screening?
    A. Yes.
    Q. Supportive care summaries, cancer genetics summaries, and cancer complementary and alternative medicine summaries.
    Go down, please.
    Each editorial board is multitiered and has members representing various cancer and other related specialties for each area. There is a core editorial board that meets to discuss and modify cancer information summaries based on review of recently published data.
    Next, please.
    Go down to the next one.

Go down to the last one, please.
The members of the screening board that comes up with these recommendations are in the fields of oncology, cancer prevention, statistics, epidemiology and economics. The screening and prevention board currently meets six times a year to write and update information on cancer screening, early detection -- that's what we are talking about, isn't it, sir?
A. Yes, sir.
Q. -- and prevention of cancer.
So that's what the NCI does, is that right, sir; they are very interested in cancer screening, would you agree with me?
A. That's one thing that they do; that board specifically looks at that area, yes, sir.
Q. Are you familiar, do you know the fact that they even have a special group within the NCI that's called the "early detection research group," which is a part of the NCI's Division of Cancer Prevention? Did you know that?
A. No.
MR. NEWBOLD: Tab 49, please. Can you blow up early detection research group.

Okay, now, go down to their mission statement or what they do.

BY MR. NEWBOLD:

Q. Sir, were you aware that, within the NCI, that they are specifically focused on the topic that is before this jury, and it's called the Early Detection Research Group. It develops scientific information and concepts for dissemination of knowledge regarding early detection techniques, practices and strategies to reduce mortality and morbidity from cancer?

Manages and supports clinical trials of early detection, clinical trials of early detection and biorepository related to prostate, lung, colon and ovarian cancer and annualizes research results for screening for breast and other cancers.

Supports clinical trials for other appropriate research, fosters technological development and statistical modeling of new technologies and encourages the publication of specific findings and adoption of early detection practices. Were you aware of that?

A. I was aware they were active in that.

Q. So you would agree with me then that the

NCI, with its billions of dollars, is an authoritative and -- an authoritative group when it comes to whether or not CTs should be used for the early detection of cancer?

A. I believe they are authoritative, yes, sir.

Q. Thank you.

Were you aware of the fact that the national institute -- the National Cancer Institute is currently in the process of trying to decide whether or not helical CT screening does more good than harm?

A. Yes, sir, I'm aware of a study to that effect.

Q. All right. Well, let's see what the national institute has to say in a press release of April the 11th of 2000 about spiral CT scans for lung cancer.

MR. NEWBOLD: Tab 52, please. Would you blow that up.

First of all, go to the top, at the very top.

BY MR. NEWBOLD:

Q. Right here, the National Cancer Institute, press release.

Press releases is one of the ways that the National Cancer Institute let's its feelings ands

opinions be known to doctors; is that correct, doctor?

A. Yes, sir.

Q. So here, they are talking about exactly what we are talking about, spiral CT scans for lung cancer.

It starts off again, Lung cancer, which is most frequently caused by cigarette smoking, is the leading cause of cancer-related death in the United States, claiming almost 157,000 lives in 2000.

Spiral computed tomography, CT or CAT scans are being advertised as a new way to find early lung cancer in smokers and former smokers. However, questions about the technology's risks and benefits remain unanswered.

Is that what that says, sir?

A. Yes, sir.

Q. Next paragraph, please.

Promising evidence from several studies shows that the scans can detect small lung cancers. But detecting these early tumors has not been proven to reduce the likelihood of dying from lung cancer, the gold standard for any cancer screening test.

The National Cancer Institute is designinv a large study that should conclusively answer whether spiral CT does in fact reduce mortality.

So the NCI is now looking into this issue, and it's going to issue its opinion as to whether or not this is a good idea; is that correct, sir?

A. Yes.

Q. All right. Next.

While spiral CT scans may eventually prove to be an effective lung cancer screening tool, they can trigger unnecessary invasive testing or even chest surgery.

Scarring from smoking and other noncancerous changes in the lungs can mimic tumors on CT scans, challenging the radiologists who read them. Interpretations of the scans can vary, leading to confusion about recommendations for follow-up care.

Next, please.

Christine D. Berg, M.D, chief of the Lung and Upper Aerodigestive Cancer Research Group at the National Cancer Institue, estimates that 20 percent to 40 percent of CAT scans of

smokers will show abnormalities that are not cancer.
Is that correct, sir?
A. Yes, sir.
Q. Next, please.
The physician may also advise an immediate lung biopsy, a potentially risky procedure that involves the removal of a small amount of tissue, either through a scope fed down the windpipe, bronchoscopy -- that's one of the follow-up procedures we talked about, sir?
A. Yes.
Q. Something somebody might have to do to find out whether they actually have cancer; is that right?
A. That's what all screening tests have to go through. All those who are screened have to go through that, whatever it is, yes, sir.
Q. Or with a needle through the rib cage -- they stick a needle through your rib cage? Why do they do that?
A. Because they see a spot on CT that may or may not be cancer, and you can localize that by CT and stick a very fine needle, after numbing the skin, and get into that and get a few cells and

smear it on a slide and send it to the pathologist to determine if he sees cancer cells on that slide. And that's one of the intermediate steps to evaluate a CT that may show a lesion that could be cancer.

Q. Possible complications from biopsies include partial collapse of the lung, bleeding, infection and pain and discomfort.

Is that correct, sir?

A. Yes. I think we discussed some -- most of those before.

Q. Depending on the size and location of the nodule, chest surgery, thoracotomy, to obtain a larger biopsy may be recommended. Thoracotomy is a major surgery that removes substantial amounts of lung tissue; the procedure can damage nerves in the chest and may lead to chronic pain.

Is that correct, sir?

A. Yes, sir.

Q. Next, please.

But recently some hospitals have begun promoting spiral CT scans to smokers for early detection of lung cancer, despite the lack of solid evidence.

Next, please.

Some experts worry that this marketing may lull smokers into falsely believing that they can continue smoking without increasing their risk of dying from lung cancer. But the only proven way to reduce the risk of lung cancer is not to smoke. 85 percent of all lung cancers are caused by smoking. For people who do smoke, quitting reduces the risk of lung cancer considerably over the course of several years.

Is that what the NCI says, sir?

A. Yes, sir.

Q. Next, please.

The NCI study will track several thousand smokers and former smokers to see if those who are screened with spiral CT scans have a lower mortality rate than those who do not undergo the scans.

Next, please. That's it.

Now, Doctor, in addition to the National Cancer Institute, there are other national public health organizations that are looking into whether or not CT screens for the early detection of cancer is a good thing to do; isn't that correct, sir?

A. Yes.

Q. And one of those organizations is the

American Lung Association; is that correct?
A. Yes, sir.
Q. And are you familiar with the American Lung Association?
A. Yes, sir.
Q. Is that a reputable organization?
A. Yes, sir.
Q. Is that an authoritative organization?
A. Yes, it is.
Q. Is the American Lung Association committed to the prevention and cure of various lung diseases, such as lung cancer, COPD and emphysema?
A. Yes, sir.
Q. And the lung -- and the American Lung Cancer also publishes articles about their opinions as to whether or not helical CT scans are a good thing; is that correct, sir?
A. Yes, sir.
MR. NEWBOLD: Tab 51, please.
BY MR. NEWBOLD:
Q. Let's take a look at what the American Lung Association says about screening.
American Lung Association statement on new CT screening technique for lung cancer, July 13, 2000.

Next, please.

A study recently published in The Lancet predicted that death rates from lung cancer could be greatly reduced if smokers and former smokers were routinely given CT scans of their lungs.

The researchers used a new technique called a helical low dose CT scan, which is much more sensitive than conventional chest x-rays and can detect tumors when they are small.

It is generally believed that small tumors are more likely than large ones to be cured.

Next, please.

The American Lung Association believes this is an important study which may represent a significant advance, and that finding lung cancer early should increase cure rates.

However, it is prepremature for the lung association to endorse screening of all at-risk patients with this method.

So in other words, the American Lung Association says it's too early, all the evidence is

not in. Is that correct, sir?
A. That's their position, yes, sir.
Q. The technique is not widely available yet, and its use requires specialized knowledge -- doctors using the CT technique must be able to distinguish cancerous nodules in the lung from noncancerous nodules. Further, patients and control groups have not yet been followed up to determine whether, in fact, the CT technique will lead to higher cure rates.
That's what the American lung cancer (sic) says, right, sir?
A. American Lung Association.
Q. I mean the American Lung Association?
A. Yes, sir.
Q. Now, a fellow who wrote this is normal H. Edelman, M.D, scientific consultant for the American Lung Association; is that correct, sir?
A. Yes, sir.
Q. And the reason these articles are put out as one of two official journals published by the American Lung Association through its medical section, the American Thoracic Society, its purpose is to provide pulmonary physicians and researchers

with state of the art information on the causes and treatment of lung diseases.

That's why they are sending these things out; is that right?

A. Yes, sir.

Q. Another public health organization is the American Cancer Society; is that correct, sir?

A. Yes, sir.

Q. And you have heard of the American Cancer Society?

A. Yes, I have.

Q. That's a public health organization?

A. Yes, sir.

Q. They are concerned with cancer?

A. Yes, sir.

Q. They are concerned with the link between cigarette smoking and cancer?

A. Yes, sir.

Q. They are concerned with finding early detection techniques for cancer?

A. Yes, sir.

Q. They have the best interest of the American public at heart?

A. Yes, sir.

Q. They want to do everything that they can to detect cancer as early as possible if they think that it's the thing to do and that it's worthwhile?

A. Yes, sir.

Q. Let's see Tab 55, please.

Let's take a look and see what the American Cancer Society says about the early detection of cancer.

Would you blow this up, please.

American Cancer Society guidelines for the early detection of cancer.

Next.

This is by Robert A. Smith, Ph.D., Curtis J. Mettlin, Ph.D., Dr. Davis, and I can't read the rest.

Next, please.

Dr. Smith is a director of cancer screening for the American Cancer Society in Atlanta. Dr. Mettlin is a professor of epidemiology at Rosswell Park Cancer Institute in Buffalo. Dr. Davis is currently the senior scientist researcher at Triangle Park, North Carolina, and Dr. Eyre is the executive vice president for research and medical affairs for the American Cancer Society in Atlanta.

Next. Just go to the next highlighted portion, please.
Go to the next one.
MR. NEWBOLD: Your Honor, we obviously have a technical glitch. May we have a minute to look at the hard copy?
THE COURT: Well, you have something on there now. That's not what you wanted?
MR. NEWBOLD: Okay.
BY MR. NEWBOLD:
Q. Now, Doctor, the American Cancer Society looks not only at lung cancer; it looks at all types of cancers to determine whether or not screening tests are worthwhile; is that correct?
A. Yes, sir.
Q. For example, they look at the early detection of breast cancer. Is that correct?
A. Yes, sir.
Q. Next slide, please.
And the ACS recommends that women should begin annual screening at the age -- next, please -- of 18, or after the onset of sexual activity, whichever comes first. After three consecutively negative Pap tests, screening may be performed less frequently at

the discretion of the physician.
    Then they talk about -- so in other words, they are recommending a screening test for breast cancer; is that correct, sir?
    A. Yes, sir.
    Q. All right. Now we go to the early detection of prostate cancer. Next slide, please.
    And the American Cancer Society -- I won't read this whole thing, but they are recommending that the PSA blood test and DREs be offered annually beginning for men at age 50 who have at least a ten-year life expectancy, as well as to younger men who are at high risk. So they are recommending cancer screening?
    A. I would like to make a comment about the prostate cancer screening. This was one of those screens that was not recommended by the cancer society, and the public and the physicians went ahead with it. Now they recommend it because they found that it saves lives.
    And the same thing can be said for the Pap smear in the female genital system; that it was not studied in a randomized controlled trial, but it was -- but it is now probably one of the best tests

for saving lives.
    So the American Cancer Society recommends two tests, the Pap smear and the PSA for prostate, for cancer screening, and neither one of these tests underwent the fire and brimstone that the early, early national groups are considering. So I just want to make sure that we speak -- we get these recommendations in perspective.
    Q. Next, please.
    This is the recommendation for colorectal surveillance or screening that the American Cancer Society recommends; is that true, sir?
    A. Yes, sir.
    Q. Next, please.
    Now we get to lung cancer. And the American Cancer Society says: At this time, no organization recommends routine screening for lung cancer either among the general adult population or in individuals who are at higher risk due to tobacco or occupational exposures.
    That's the American Cancer Society's position on screening, sir, for lung cancer?
    A. Yes, sir. But I believe, somewhere in that article -- and I'm not sure if it's there or more

subsequent, recommendation is that we cannot -- they retreated from that somewhat to state that they have an open mind in this particular issue, and I think it's in that article, but I'm not sure. There may be another one.

Q. Next, please.

A. Okay. They brought it out.

Q. Recommend --

A. Did you a good job. I appreciate you --

Q. I want to make sure that everything you want is in these articles I'm going to show you and the jury; okay?

A. Well, okay.

Q. In spite of the limitations of existing data, it is generally accepted that a lung cancer screening is not effective. Whereas it would be more appropriate to regard the current evidence-based situation as one in which there are insufficient data to recommend for or against lung cancer screening.

That's the American Cancer Society's position at this time, insufficient evidence for or against; yes, sir?

A. Well, may we go back to that just one

moment, please?
Q. Sure, absolutely.
A. I think it's very important. I think it's generally accepted lung cancer screening was not effective using chest x-rays, and that is really what they are saying.
But the current issue of CT is after they went to the Varese conference in Italy, they could see the potential of it and had to rethink that issue, yes, sir.
Q. Now, they are saying there is insufficient data to recommend for or against lung cancer screening. That's their position?
A. That's what it says, yes, sir.
Q. Next, please.
At this time, the American Cancer Society does not recommend routine screening for lung cancer among the general adult population or in individuals who are at higher risk due to tobacco or occupational exposures.
That's the American Cancer Society's position?
A. Yes, sir.
MR. NEWBOLD, Your Honor, may I fill my water glass. I'm just about dry.

THE COURT: Sure can.
MR. NEWBOLD: Let's go to Tab 57, please.
BY MR. NEWBOLD:
Q. The article which I am going to put on the board now is from the New England Journal of Medicine. I believe -- can you show me that, please. And I believe you have already testified that the New England Journal of Medicine is the number one medical journal in the United States; is that correct, sir?
A. Yes, sir.
Q. And you consider it to be authoritative?
A. Yes, sir.
Q. And you rely upon it in forming your opinions; is that correct, sir?
A. Yes, sir.
Q. All right. Let's see what the New England Journal of Medicine -- as a matter of fact, one of the articles that you used in direct examination was from the New England Journal of Medicine; is that so?
A. It may have been. I don't remember.
Q. Okay. I think you still have it in front of you, but I believe that it is.

Well, let's let's see what the New England Journal of Medicine has to say about this topic, screening for lung cancer.

First of all, this is a review article; right?

A. Yes, sir.

Q. And a review article is where doctors don't have all the time in the world to review everything so that very prestigious journals like the New England Journal of Medicine will sort of put everything and put it together and have a review; is that right?

A. By an author.

Q. By an author?

A. Yes, sir.

Q. Okay. So let's see who the authors are. Let's take a look at the authors. This is Edward F. Patz, Jr., M.D.; philip C. Goodman, M.D., and Gerald Parker M.D., Ph.D. Let's go at the bottom and see who they are. They are from the Department of Radiology, Duke University Medical Center, and the Departments of Medicine and Cancer Genetic, Rosswell Park Cancer Institute, Buffalo, New York.

Let's go to the first paragraph.

Lung cancer is the leading cause of death

from cancer among men and women in the United States.

Next.

What is the date on this? Let's go back to the date on this, please. Right here at the bottom. Okay this is from last year, right, the date?

Okay. Let's go to the first item. In fact, it's November 22nd of last year.

There has long been interest in screening to detect lung cancers when they are smaller and presumably at earlier and more curable stages, as witnessed by the support for previous screening trials using chest radiography and cytologic examination of sputum.

Unfortunately, these studies failed to reach the ultimate goal of a diagnostic screening test, a decrease in disease-specific mortality.

The screened groups had the same number of deaths from lung cancer as the control groups, and screening was effectively abandoned.

Next, please.

With the development of newer forms of technology, there has been a resurgent interest in screening for lung cancer, and patients have requested the examination after learning of the new possibilities through the media.

Data obstained from subjects at the time of study entry, prevalence screening data, from recent trials using low dose computed tomography, CT --

That's what we are talking about today; right?

A. Yes.

Q. -- suggest that this technique could save lives in persons at high risk. These data, however, are often confusing. Before any new screening recommendations are made, detailed analysis of the CT trials are needed, including analyses of morbidity and mortality data, as well as a cost-benefit study.

We review screening for lung cancer, including prior trials, ongoing early-detection studies, potential limitations, and recommendations based on published data.

Next, please.

So they start off as kind of like a primer on screening.

Some fundamentals about screening: Screening is performed to detect disease at a stage when cure or control is possible.

Persons with a positive result on screening can be further evaluated to determine whether they actually have the disease. Ideally, once the diagnosis is established, early intervention should change the course of the disease, resulting in decreased mortality, the number of disease-specific deaths relative to the total number of persons evaluated.

Although survival from the time of diagnosis of the disease is commonly reported in screening trials, it is not an appropriate measure of a diagnostic screening test and can be misleading because it is subject to lead-time bias, length-time bias, and overdiagnosis bias. An effect on mortality rather than survival is necessary to validate potential screening methods.

Next, please.

The principles of screening can be

applied to lung cancer, but success depends on several basic assumptions. There must be effective treatment at the preclinical, asymptomatic stage that can reduce mortality in the screened group as compared with the unscreened group.

In addition, the sensitivity, specificity, accessibility, cost, and associated morbidity of the screening tests must be reasonable.

Next, please.

The true clinical significance of the small tumors found by screening is unknown, and their effect on mortality awaits future investigation.

Next, please.

The ability of CT to identify smaller nodules than those routinely seen on chest radiographs has generated interest in this technique as a potential screening tool.

However, the size of the nodule at diagnosis does not necessarily correlate with the clinical outcome. It cannot be assumed that the biologic behavoir of lung cancer, the

the result of a variety of genetic changes, parallels anatomical size.

This is hard to say. It says it cannot be assumed that the behavior of lung cancer, the result of a variety of genetic changes, parallels anatomical size.

Next, please.

The assumptions that size correlates with biologic behavior and that small lesions are equivalent to early-stage disease have not been confirmed for lung cancer. Tumors may already have demonstrated their potential to remain localized or to metastasize by the time they are visible on CT imaging.

Next, please.

Now we get to the current recommendations. So these are these doctors writing in the New England Journal of Medicine as to what they think.

Although there is public and political pressure, based only on low-dose CT prevalence-screening data, to change clinical practice rapidly and to offer mass lung cancer screening, there should be no compromise or shortcuts in the rigorous scientific process

required to determine whether this practice is justified.

Too often, presumed solutions have prematurely become standard medical care before the appropriate studies have been completed. We strongly recommend that well-designed studies be conducted, completed, analyzed, and validated before a mass screening program is implemented.

Until these trials clearly confirm a reduction in mortality from lung cancer, only carefully monitored studies should enroll patients for lung cancer screening.

So once again, what these doctors are saying, it may be good, it may not be good; what's necessary is to do the necessary tests to make sure that it does more good than harm. Isn't that correct, sir?

A. May I answer, because I think this requires a little bit of an analytical review of this particular Dr. Patz and what he is saying. May I answer to critique this particular reference, because there are better minds than I have who have taken these points and says he is incorrect?

But if I'm able to hit upon what some of the

other opinions related to this, I think it would be appropriate based upon this study --

Q. Sir, let me do it this way --

A -- this article, I mean.

Q -- because in order to, so we can move along and get this thing done a little earlier. Mr. Segal will have an opportunity to ask you questions on redirect examination.

But at this time all I would simply like to ask you is to confirm that this is the opinion of these doctors that are contained in the New England Journal of Medicine; is that correct, sir?

A. Yes, sir.

Q. Okay. I want to go now to Tab No. 59. I'm going to show you now what I think might be the latest update from the National Cancer Institute, and this is an update from July of 2001.

This is, I think, the latest word from the National Cancer Institute about whether or not we should do CT scans. So it's from the CancerNet, which is the NCI, Screening for Lung Cancer, Screening Detection.

Next, please.

There are intensive efforts to improve

lung cancer screening with newer technologists, for example, low radiation dose computed tomography, and molecular techniques which, although promising, have not been validated in large controlled studies.

Helical computed tomography, spiral CT, is a new modality of potential use in screening. Lack of appropriate mortality data and the high probability of overdiagnosis, identification through screening of tumors with little to no clinical significance, argue strongly against immediate acceptance of this new test into clinical practice.

That's the latest word from the National Cancer Institute; is that correct, sir?

A. Yes, sir.

Q. Now, finally, Doctor, in our search through the literature, I want to show you -- and I'm not going to put it on the board quite yet, but I'm going to show you the consensus statement of the Society of Thoracic Radiology.

And it's about whether or not there should be screening for lung cancer with helical CTs. And the reason I think this is so important -- strike that.

You testified on direct about Claudia Henschke's studies; is that correct?

A. Yes, sir.

Q. And Claudia Henschke is the woman who did the ELCAP studies, and she was the one who first came up with this idea about using helical CTs to see whether or not they should be used generally to detect lung cancer; is that correct, sir?

A. Yes.

Q. All right. Let's see what Claudia Henschke has to say about that.

Next slide, please. Can you blow this up, please.

This is a consensus statement of the Society of Thoracic Radiology, Screening for Lung Cancer with Helical Computed Tomography, and it's written by Denise Aberle, Dr. Gordon Gamsu, Dr. Claudia Henschke, who we just talked about, David P. Naidich, Doctor, and Stephen J. Swensen, M.D.

Next slide, please.

And this is current. This is what Claudia Henschke, who invented this, has to say about whether it should be used generally.

This consensus statement by the Society of

Thoracic Radiology is a summary of the current understanding of low dose computed tomography, CT, for screening for lung cancer.

Lung cancer is the most common fatal malignancy in the industrialized world. Unlike the the next three most common cancers, screening for lung cancer is not currently recommended by cancer organizations.

Improvements in CT technology make lung screening feasible. Early prevalence data indicate that about two-thirds of lung cancers that are detected by CT screening are at an early stage.

Other data support the postulate that patients with lung cancers detected at this early stage have better rates of survival. Whether this will translate into an improved disease specific mortality is yet to be demonstrated.

Next slide, please.

It is the consensus of this committee -- and that includes Claudia Henschke -- that mass screening for lung cancer with CT is not currently advocated.

Suitable subjects who wish to participate should be encouraged to do so in controlled trials, so that the value of CT screening can be ascertained as soon as possible.

But right now, Dr. Gaziano, you would agree with me that Dr. Henschke says that mass screening for lung cancer with CT is not currently advocated; is that correct, sir?

A. Yes, sir.

MR. NEWBOLD: May we approach, Your Honor.

THE COURT: All right.

(At sidebar:)

MR. NEWBOLD: I don't know what your pleasure is. I'm about to switch topics. Should I keep going?

THE COURT: We need to go till 20 after so the one juror can take her shot.

MR. NEWBOLD: Okay, thank you.

(In open court:)

BY MR. NEWBOLD:

Q. Doctor, I would like to go to another topic now, if I may.

A. All right.

Q. You testified on direct that you believe

that there was an increased risk of lung cancer and COPD for people who have a five pack year history of smoking; is that correct?

A. Yes, sir.

Q. Okay. Now, Doctor, there never has been a study that has demonstrated an association between smoking and COPD and lung cancer using as study subjects persons who have a five-year pack history?

A. I believe that's correct, yes, sir.

Q. No study?

A. I think there are some inferential studies, but I'm not aware of any looking at those specific two diseases as it relates to that. There are some inferential studies that indicate that smoking a few cigarettes a day, there is a significant health hazard.

There are studies that indicate that household contacts of smokers have an increased risk of cancer and respiratory symptoms. Those are published in the Surgeon General's reports. But looking at it in that particular way, five pack years, I'm not aware of any particular study.

Q. There is no study that looked at people who only have a five pack year history, and there is no

study that determined that, because of that five pack year history, that it had any link to cancer, lung cancer or COPD; is that correct, sir?

A. As I said -- that's correct. But as I said previously, there are studies that indicate increased mortality figures for people who smoke at that level, and that there are associated mortality with people who are exposed to relatively limited amount of smoking -- smoke.

Q. Doctor, if you quit smoking, if a person quits smoking for ten to fifteen years, the Surgeon General of the United States says that that person's risk for lung cancer is about the same as a nonsmoker. Would you agree with that, sir?

A. Yes. The Surgeon General says it's almost that, but it doesn't quite reach that of nonsmokers.

Q. And that's not what I said. I said is about the same as nonsmokers; is that correct, sir?

A. Well, I wanted to clarify that a little bit.

Q. Well, as a matter of fact, when your deposition was taken, your clarification was, when someone has quit smoking for ten to fifteen years, that their risk of lung cancer is slight?

A. To be specific, the Surgeon General's report is that it's twice that of -- it goes from ten times that of a never-smoker to twice that of a never smoker.

MR. NEWBOLD: Could you give me Tab No. 20, please, Jason.

Next, please. Next, page, please.

Blow that up, please.

BY MR. NEWBOLD:

Q. The Surgeon General said in his 1979 report that ex-smokers experience decreasing lung cancer mortality rates which approach the rates of nonsmokers after ten to fifteen years of cessation.

The residual risk of developing lung cancer in ex-smokers is proportional to the overall dosage of lifetime cigarette smoking exposure and inversely related to the interval since cessation.

Is that what the 1979 Surgeon General's report said, sir?

A. That's correct, yes, sir.

Q. And what you told me -- take that off, please -- when your deposition was taken, that you believe that, if a person has quit smoking for ten to fifteen years, that his or her chance of getting

lung cancer was slight. Do you recall that, sir?
A. I said "slight," and today I said that slight transfers into two times background risk.
Q. Now, Doctor, if you quit smoking before you get COPD or emphysema, you won't get it; right?
A. That's correct.
Q. Okay. And if you quit smoking and then have a spirometry test done, and that spirometry test is normal, there is no point in retesting the person; is that correct?
A. I have said that probably in public forums several times, yes, sir.
Q. All right. So, if you have a 25-year-old person who is in this class, and he or she has a five-year pack history, okay, and now she quits for fifteen years, and now she is 40, okay, if she didn't have COPD before she quit -- strike that.
If she quit smoking in this fifteen years between being 25 and 40, and she tests normal on her first spirometry test, then there is no reason for her to ever be tested again; is that correct?
A. That's my opinion.
Q. Now, she still doesn't smoke, and she still doesn't smoke, and she still doesn't smoke, and she

hasn't smoked for 25 years. And now she is 50 and she gets her first CT scan, her risk of lung cancer is very, very, very slight, isn't it, sir, if she's quit smoking for 25 years?

A. Yes.

Q. And yet you think she should be tested every year for the rest of her life?

A. You know, this five pack year level, if you are going to draw me into it -- you don't let me be involved in certain aspects, and then you want my opinion for certain aspects.

But what I would like to say, the five pack year, as as I understand it, and I wasn't involved in the evolution, is to pick up every potential person at risk.

That doesn't mean the group for five pack years. That's where it begins. The group includes people who smoked significantly longer. So if you want to talk about the five-year as being some issue, you may, and you can take that up with Dr. Burns.

But as far as -- it's a starting point and some people may start at a different place, and some people start at that point. And I'm not going to

get into what is a proper place to start.
Q. But you understand, don't you, sir, that someone can be in this class with as little as a five pack year history, just that?
A. Yes, sir, and there is good -- and if it's a person as you described, it would be very low, yes, sir.
Q. Okay. Doctor, a smoker comes into your office when you were still practicing in 1997, no spirometry, you tell him to quit smoking?
A. Yes, sir.
Q. Okay. A smoker comes into your office, you give him a spirometry, and it's normal. You tell him to quit smoking?
A. Yes, sir.
Q. A smoker comes into your office, and you give him a test, and he has COPD. Do you tell him to quit smoking?
A. Yes, sir.
Q. A smoker comes into your office, and you give them a spirometry test, and he has emphysema. Do you tell him to quit?
A. Yes, sir.
Q. So regardless of if he comes in and gets

the test or he comes in and comes in and gets a test or doesn't get a test, your advice to a smoker is always the same, and that is to quit; isn't that right?

A. Not necessarily. The urgency --

Q. There are some people you say, Keep smoking?

A. No.

Q. You tell them to quit?

A. You tell them to quit in different manners and different -- the purpose of a spirometry is to give someone the informed consent to let them know they have a disease. And how they react to that knowledge is a combination of what the doctor does for the patient and what he perceives that he should do.

And so to find the disease is important for a doctor, and I think it's important for the patient. And what one does with that information is -- by the doctor and the patient, is a variable thing.

Q. Is there any circumstance that you can ever think of that a patient of yours has come in and has tested either negative or positive on a spirometry where you would tell them go on and keep smoking?

A. Well, heck, no.
Q. Thank you, sir.
MR. NEWBOLD: I have no further questions of this witness.
MR. SEGAL: Your Honor, can we approach for a moment, please.
THE COURT: All right.
(At sidebar:)
MR. SEGAL: I realize the 48-hour rule doesn't apply to articles which will be used in cross, but I was wondering if I might be favored with them because it's a little difficult to track the ones that, if you don't know -- sometimes you can't see the dates and all that. And I kind of need that to be sure that the years of the articles and what I need to redirect him on.
I have them on my desk, I think, but I don't want to take a quote out of something and say he didn't read this, let's read this now and not know what I'm dealing with.
THE COURT: What are you asking for?
MR. SEGAL: I'm asking for copies of that --
MR. NEWBOLD: I will be more than happy. The reason I didn't do it that way, Your Honor, it is so

cumbersome to come back and forth. I have copies of the articles.

THE COURT: From now on, that's what you are asking for. What are you asking for right now?

MR. SEGAL: I didn't want to interrupt him. I would like copies of the articles.

MR. NEWBOLD: He may have them.

THE COURT: And then what do you want?

MR. SEGAL: I want to take a break.

THE COURT: That's what I thought. Get right to the chase. I can take it. I'm a big boy. You can give it to me straight.

MR. SEGAL: I can get started for ten or fifteen minutes.

THE COURT: Do you have about that, and then you want to take a break?

MR. SEGAL: Because you want to go as close to 10:30 as you can.

THE COURT: And you let me know when you are ready.

MR. SEGAL: Okay.

(In open court:)

THE COURT: Do you want to leave the lights on?

MR. SEGAL: You can leave them on. If I'm

missing some, I may need them to bring it up.
THE COURT: All right.
MR. SEGAL: Can you leave the book?
MR. NEWBOLD: All right.

-- -- --

REDIRECT EXAMINATION

BY MR. SEGAL:

Q. Good morning. We have gone over several articles this morning, and I think we need to talk about some of the statements that were quoted to you and what's in them. But before we do that, I want to know something. You have been screening people for black lung disease in the State of West Virginia for how long?

A. Thirty years.

Q. And for whom have you been screening those people for over thirty years?

A. Mostly the federal government, the Department of Labor.

Q. Have you also --

A. I have done other screens for groups and individuals, patients.

Q. Did you need this book to tell you how to screen them?

A. No.
Q. Did you ever see this book in your thirty years of practice before they handed it to you at your deposition?
A. No. But I went through it over the weekend and found it interesting. Actually I had reviewed it before, but not since the previous deposition.
Q. With regards to asbestos, people who have worked around asbestos, would you give these folks some idea of the different tradespeople you have seen over the years both in your practice --
MR. NEWBOLD: Objection, Your Honor. Objection, Your Honor. This is -- may we approach, or shall I make my objection standing here?
THE COURT: What's the objection?
MR. NEWBOLD: The objection is, it's clearly outside the scope of direct; it's outside the scope of cross.
THE COURT: The objection will be overruled.
BY MR. SEGAL:
Q. Would you tell these folks the types of tradespeople you have screened over the years for the presence or absence of asbestos-related diseases?

A. Well, I have screened steel millworkers in this particular part of the country, in the upper Ohio Valley. Boilermakers, steamfitters, pipefitters, janitors, electricians, just about most construction trades who have worked in the construction industry in the United States, particularly West Virginia.

Q. Did you need this book to tell you how to do those screening tests?

A. No.

Q. Tuberculosis, are you particularly involved in the early detection or diagnosis of tuberculosis?

A. Yes, sir.

Q. Could you explain to the jury how it is you are involved in the screening for people who are suspected of suffering from tuberculosis?

A. Well, I have been for 28 years the Kanawha County clinician for TB, which means that most TB in Kanawha County is referred to my clinic in the public health area. So I see people who have established disease.

I also screen people for disease who have been exposed to a bus driver in Kanawha County. Five thousand -- I mean, not five thousand, five hundred

children were exposed, and we screened all those children. So that's how I get involved with it.

Q. Do you need this book to tell you how to do those screenings?

A. No, sir.

Q. Mr. Newbold showed you an article, and I want to show the jury something about these articles. Can we go to ELMO, please.

Now, if you recall -- or let me ask you, do you recall that Mr. Newbold read you a quote this morning from the article he said was written by Dr. Frame, Routine Screening for Lung Cancer, Maybe Some Day But Not Yet. Do you remember he showed you that article?

A. Yes, sir.

Q. And did you read you the quote that said:

> Indeed, 8 prospective studies for screening for early lung cancer either by periodic chest radiographs or by sputum cytologic tests have been reported in the past forty years?

Is that a quote you were read today and asked about?

A. Yes, sir.

Q. Now, what I want the jury to understand about these articles --

MR. SEGAL: Do we have that here?

BY MR. SEGAL:

Q. -- when a scientist or a physician makes a statement, if they want to back it up, they can put a little footnote right there which in this case says three to ten.

Tell the ladies and gentlemen of the jury when you see those footnote numbers three to ten, what the doctor is saying about the previous statement he made?

A. Well, basically it means that that statement is based upon articles in the literature and you could look in the back where they are listed, and article number three or ten were articles he used.

Q. And those articles are articles that are listed right on the back page of this very paper, three through ten, to support that statement about retrospective studies that was quoted to you today; is that right?

A. Yes, sir.

Q. Well, why don't we look at, Doctor, the

date of the articles, the date of the articles three through ten, let's take a peak at that, to support that statement.

Three through ten -- what did I do with that -- those articles were written in 1966.

By the way, you would agree that the Cancer of Respiratory Diseases --

A. Cancer Research.

Q. Cancer Research is an authoritative journal?

A. Yes.

Q. What's this one?

A. British Medical Journal.

Q. The British Medical Journal, that's an authoritative journal?

A. Yes, sir.

Q. Chest, certainly very authoritative in your view?

A. Yes, sir.

Q. These are all journals you would rely upon; right?

A. Yes, sir.

Q. But the articles that he was citing were published in 1966, 1968, 1969, 1984, 1986, 1986, and

1986.
So the most recent was 1986 and the oldest was 1966.
A. Yes, sir. That's what I was trying to get across when we are talking about studies fail to support. They are old studies and they don't take into account the modern technology.
Q. Well, we will go to Dr. Henschke, but just give them an idea, when was Dr. Henschke's work and the other doctors who they have seen their names, when was that work done?
A. It was in 1999.
Q. '99?
A. It was done a little earlier, but it was published in '99.
Q. So almost a decade and a half after the most recent of these?
A. Yes.
Q. And there was an interesting quote he showed you and it doesn't have a footnote. Look at this quote he showed you.
MR. SEGAL: It's like working with a mirror, Judge, I'm sorry.
BY MR. SEGAL:

Q. Now, you were read this sentence:
A significant potential harm of screening is that smokers will interpret negative results of screening tests as assurance that they are disease free and will be less motivated to quit smoking.
There is no footnote there, is there, Doctor?
A. No.
Q. In your review of the literature, are there articles to support that statement by this Dr. Frame?
A. That's an opinion, no, sir.
Q. There are no published articles to support that kind of statement, are there, Doctor?
A. No.
Q. And you were shown -- I need the Henschke article, please, and then -- may I just see the Henschke article you showed the composite statement?
MR. NEWBOLD: Yes. The thoracic society --
MR. SEGAL: It was their statement.
MR. NEWBOLD: The last one I showed?
MR. SEGAL: Yeah.
MR. NEWBOLD: May I have Tab No. 60?

Is that it, Scott?
MR. SEGAL: Yes, thank you.
BY MR. SEGAL:
Q. You were shown, Doctor, this article, a consensus statement and there is Dr. Aberle, Gordon Gamsu, Dr. Henschke is on there, Dr. Swensen, Dr. Naidich; okay? Do you recall seeing that?
A. Yes, sir.
Q. And you wanted to respond to that, but before you do, Dr. Henschke's published in this article quite a bit in the past two years, hasn't she?
A. She has.
Q. I want to show you now an article --
THE COURT: Do you need time to get that ready?
MR. SEGAL: Give me two -- I just want to point out this one conclusion and I will sit down, Judge, I promise.
THE COURT: Okay.
MR. SEGAL: Just give me two seconds. This will be the last one.
THE COURT: All right.
BY MR. SEGAL:

Q. She's also written an article recently on the Early Lung Cancer Action Project: A Summary of the Findings on Baseline Screening. And she wrote that with McCauley, Yankelevitz, Naidich, McGuinness, Miettinen, Libby, Pasmantier, Koizumi, Altorki and Smith; is that correct? That's a 2001 article, isn't it?

A. Yes, sir.

Q. And Dr. Gaziano, am I correct that the conclusion in that 2001 article that they reached, all those doctors, in that 2001 article:

> Conclusion: Baseline CT screening for lung cancer provides for detecting the disease at earlier and presumably more commonly curable stages in a cost-effective manner.

That was their conclusion, was it?

A. Yes.

Q. That was published in The Oncologist in the year 2001?

A. Yes, sir.

Q. And The Oncologist is certainly a reputable scientific journal which you and other physicians rely upon in formulating your opinions?

A. Yes, sir.

MR. SEGAL: Thank you, Dr. Gaziano.
I have a bit more, Judge --
THE COURT: I know you do. Let's take the morning break now. All right.
(A recess is taken.)
(In open court with a jury present.)
THE COURT: Be seated, please.
All right.
MR. SEGAL: Thank you, Your Honor.
BY MR. SEGAL:
Q. Dr. Gaziano, I want to talk for a moment about the article that you were shown, screening strategies, this is the Petty article. That's the one that you were talking about both on direct and cross. And one of the statements you were shown today which I want to talk to you about was that it said that no major medical organization in the United States recommends any form of screening for lung cancer.
For this reason, lung cancer -- that being the lack of screening -- lung cancer is not diagnosed until it is symptomatic and usually when it is in advanced and incurable stages.
That's what you were saying on direct --

A. Yes, sir.
Q -- when you were here with the jury last week?
A. Yes, sir.
Q. Now, let me ask you this: Based upon Dr. Henschke's work and all those articles that you were shown this morning, is the early detection, if that's the question, is early detection of lung cancer possible with this new modality? Does everybody agree it is?
A. Absolutely, yes.
Q. The question that they are debating is not whether early detection is possible, it's whether that will reduce mortality?
A. That's what some people questioned, although some people think that -- because the overwhelming sensitivity of this test -- and I did look up sensitivity and specificity and positive predictive value -- the early sensitivity of this test has gotten everybody's attention.
And the fact that these problems that we have seen, about several people who are talking about the problems with patients knowing about it, has been shown that both in Mayo Clinic and Columbia, it is

small and manageable.
So there is a body, a strong authoritative body, out there saying there is enough evidence now, let's go ahead with it.
Q. All right. But even those who are saying they want more evidence, they don't want more evidence that it can early detect. What they want more evidence about is will it reduce mortality?
A. Yes, sir.
Q. All right.
Because nobody is suggesting that the machines won't early detect the condition?
A. No, sir.
Q. Now, the other thing is that Mr. Newbold asked you about, all these -- having a needle stuck through your ribs and having your chest cut open for biopsy and all that.
Here is my question: Although he showed you quotes of people who said that may happen, based upon the ongoing studies, are there any reports that it is happening?
A. Well, the thing that he alluded to, certainly needle biopsies are happening, and certainly needle biopsies can produce what's called

discomfort and morbidity.

The fact that it -- if it produces death, it's exceedingly rare, well within the acceptable follow-up of cancer. When you are weighing the death of one out of five hundred people that you have screened versus saving a hundred individuals with incurable lung cancer, you have to weigh these things.

And the evidence, according to the studies, if done according to a certain manner -- and we hope it's done according to a certain manner -- that ultimately it is safe. It puts the patient through some discomfort, but it's essentially a safe procedure. And I feel that the literature is very strong in that regard.

Q. How about also with regards to the -- that that accounts for a very small segment of those who are going to benefit from the early detection?

A. Well, you know, it depends on cost and what the patients have to go through. Clearly, you have to evaluate those.

If I can speak on spirometry. Spirometry is safe, it's cheap, it has a -- because it is -- the gold standard defines it. It is very specific and

very sensitive and has a positive predictive value of over 90 percent.

So basically I hope -- and we have an enormous amount of authoritative sources supporting that. As far as the lung, CT scanning, we have -- what was the question, I'm sorry? I'm sorry.

Q. Is it safe and that the group that ultimately has to go to these --

A. Okay. Basically the studies have shown that the Mayo Clinic can handle this. Columbia can handle this. They are not worried about all these bogey men that is being up upon the screen; they could handle it.

And they are saying, we go through a systematic way, and no more than any other test that you might go through. If you go to the Mayo Clinic and you get screened for something else, they can handle it.

And the most important thing is that Mayo Clinic doesn't kill people, and Claudia Henschke hasn't killed any one. The worst thing that happened -- and it's a miracle. The worst thing that happened is that they have had 28 people that they operated on -- and that's where the morbidity

and mortality might come from.
    Even thoracotomy in current modern medicine is exceedingly safe. They had one death -- I mean, one false positive, one person who didn't have cancer; 27 had cancer, and none of them died. Nobody died in that study.
    So -- and so, when you are talking about sensitivity and specificity, if you are looking at the end point of opening the chest, it's 90 percent sensitive and 90 percent plus specific.
    Q. With regards to the Petty study, I want to show you two other things about that.
    You were shown that study, but here is one more of those -- one of those quotes. It says:
    The NLHEP -- would you tell the ladies and gentlemen of the jury what that is.
    A. Well, that's the National Lung Health Experimental Project.
        Encourages all primary care practitioners to perform spirometric testing in smokers older than 45 years and in anyone with cough, shortness of breath, wheezing, or mucus hypersecretion.
    Q. And the citation for that, so people will

know who is saying that, that is 34 that was published in Chest in the year 2000.

A. Yes.

Q. From the National Health Lung Education Program; correct?

A. Correct.

Q. And in fact, as of the year 2000, for a current smoker, with regards to spirometry, okay, except for the one test when you are 40, for people over 45, that's exactly what they are suggesting, who are current smokers?

A. Well, that's what I meant. I said, the specific of this screening is not -- but there are other authorities who say that it is close, yes, sir.

Q. To sum up your opinion:

Computed tomography will provide a higher yield of detection than standard chest radiography.

And there is a footnote ten and without blinding everyong, that's Dr. Henschke's original 1999 study; correct?

A. Yes.

Q. Follow-up of patients with moderate to high

degrees of dysplasia will identify even more lesions. What does that mean?

A. That means studying the sputum cytology.

Q. Hopefully this new nationwide effort plus a change in attitude about screening will identify many more patients with lung cancer so a higher cure rate can be expected, compared with the dismal outcome when lung cancer is diagnosed as incidental finding or on the basis of symptoms, which usually represents advanced and often metastatic stages of disease.

That's your view, isn't it, Doctor?

A. Yes, sir.

Q. The same thing you said when you were here last week?

A. Yes, sir.

Q. Finally, you were shown this article that you told the jury about. Well, that's got to do, part of it, with a -- part of it has got to do with an Italian study. And I want to read a couple of things. Is this the article you were shown, the American Cancer Society guidelines for the early detection of cancer?

A. You have apparently a computer print out

but, yes, it's the same article.

Q. You talked about a little bit about breast screening. I just want to go through their findings in that very same article. And changes which occur over time as we learn more and more.

You were mentioning breast cancer. Let's look at what they say. The early detection. Since 1977, the American Cancer Society guidelines for the early detection of breast cancer have been updated five times, most recently in 1992 and 1997.

> The genesis of the 1997 update was increasing evidence in the literature that the detectable preclinical phase, the sojourn time, for breast cancer had a shorter duration in premenopausal women compared with postmenopausal women.
>
> Data from the two-county study estimated mean sojourn times for women between the ages of 40 and 49 at 1.7 years compared with more than 3.3 years for women older than age 50.
>
> These findings, coupled with accumulating data on the value of screening for premenopausal women indicated that the recommendation originally made in 1983 --

namely, that women ages 40 to 49 undergo mammography every one to two years -- should be reconsidered as it was not consistent with accumulating evidence.

And indeed, isn't it also true, Doctor, that a lot of that accumulating evidence in these recommendations were made before they ever had mortality studies; isn't that true?

A. Yes, sir.

Q. And with regards to mortality studies, I want to talk about the early detection of prostate cancer. I'm afraid I'm going to have to go read it because I can't get it any bigger.

It says here:

The impact -- first of all, it says the principal strenghts of the PSA test -- that's the one for prostate cancer; right?

A. The blood test, yes, sir.

Q. -- are its superior sensitivity, reasonable cost and high patient acceptance. The principle drawback of the test is its imperfect specificity owing to the fact that common conditions such as benign prostatic hyperplasia and prostatitis can cause borderline or even markedly abnormal test

results.
Doctor, does that mean that people who have this test may get told by their doctor, You may have prostate cancer, when really all they have got is prostatic hyperplasia or prostatitis?
A. Well, yes, sir.
Q. That's exactly what it is saying, isn't it?
A. Absolutely.
Q. And these two conditions are not fatal, are they?
A. No, sir.
Q. But your doctor might tell if you have this test, which most American males do after a certain year, I think you have got prostate cancer, but what do they have to do before they tell you they are sure?
A. They have to biopsy the prostate, stick a needle in it. It's uncomfortable, it's not pleasant, you are on your head, et cetera.
Q. The false positive results can lead to expensive diagnostic evaluations an unwarranted patient anxiety.
That means the patient is scared?
A. Yeah.

Q. At the other extreme, the high sensitivity of the test can result in overdiagnosis, the chance that small, indolent tumors which might require no treatment and which may never have surfaced clinically, would be gathered in the same net as an aggressive, potentially life-threatening cancer.

Now, how does this explanation equate to what you have been telling these folks about the early diagnosis of lung cancer?

A. Well, I think the thing that I wanted to stress is that there is no such thing as an indolent, quiescent lung cancer. One of the statements he made, which is very well contradicted in the literature is, people with lung cancer found in an early stage, two studies indicate that, within a few years, 95 percent are dead if they have not had surgical removal.

A study of the failed screening of -- that we have talked about in the United States, and the successful screening they have in Japan, people who don't want to have surgery with Stage 1, early lung cancer, die.

Okay. Now, we don't have that in prostate cancer. This is -- presents some sort of dilemma to

the urologist, who will get an elevated CBC and a positive diagnosis.

They have to go through the -- actually it's a wrenching decision as to whether to go aggressive treatment with someone with prostate cancer.

Q. But they go on to say:

> Despite all that, the impact of the PSA and related testing on mortality was not immediately apparent from the early studies.

So they were doing that without knowing whether it would reduce mortality early on, weren't they?

A. Well, it was a good screening test.

Q. No randomized controlled trials of PSA-based prostate cancer screening had been performed before it became a widespread practice.

Is that a true statement?

A. Yes, sir. And it's recommended by that organization.

Q. And are these randomized controlled trials the same thing Mr. Newbold was reading you quotes from people saying that's what we ought to do before we recommend this for folks?

A. Yes.

Q. The observed increase in detection and the

stage shift at diagnosis -- is that stage shift, is that what you have been telling us about all along?

A. That's the other thing Dr. Patz is real off the base in saying, if you find lung cancer early, maybe if you leave it alone, nothing will happen, and the patient will die 50 years later of a car accident.

Well, there is good evidence that, again, that just isn't so. People with lung cancer at any stage die within a few years --

Q. And let's look at --

A -- or a few months.

Q. What they reported in the very article Mr. Newbold showed you this morning.

> The observed increase in detection and the stage shift at diagnosis, without eventual impact on mortality, would be evidence that prostate cancer screening was actually ineffective.
>
> However, evidence is now accruing that mortality has, in fact, been reduced. Between 1990 and 1995, the prostate cancer death rate in the United States for white men younger than 75 years of age fell more than 14 percent.

This may be coincidental to the preceding increase in PSA use, but there are few other changes in treatment or diagnosis that would account for the decline in the death rates.

So what they are saying there, Doctor, is that, although you might have thought it was going to be ineffective, the preliminary data between '90 and '95 because they do the test would indicate that it may reduce mortality?

A. Yes, sir.

Q. Now, they also in here mentioned that these folks, based upon this Italian meeting --

A. I wish you would stop calling it an Italian meeting. World meeting, because Americans were there in full number.

Q. It was held in Italy. That's what I should say.

A. I know.

Q. This is the quote he read you this morning where they are talking about they are not going to, as they leave the conference in Verase, Italy, the international conference on the prevention and early diagnosis of lung cancer, they are not going to recommend one way or another whether or not to do

the screening.
Do you recall him showing you that quote?
A. Yes, sir.
Q. Okay. Well, I had Mr. Gruenloh pull the actual consensus statement from that meeting. That's the actual consensus statement from the International Conference on the Prevention and Early Diagnosis of Lung Cancer. Am I right about that?
A. Yes, sir.
Q. And let's look at, if we can --
MR. NEWBOLD: Could I have a copy of that, please, sir?
MR. SEGAL: This is the only one I have, I'm sorry. But I can show you what I'm going to read before I read it.
MR. NEWBOLD: Thank you.
BY MR. SEGAL:
Q. And you have read this paper before, Doctor, right? This is something you relied upon?
A. Yes, sir.
Q. For those who develop lung cancer, outcome is dramatically better when the disease is detected at an early stage and surgically treated.
You agree?

A. Yes.
Q. Unfortunately, at this time, the majority of lung cancers are diagnosed when the disease is overtly symptomatic, and in an advanced stage when prognosis is extremely poor.
That means you are probably going to die?
A. Yes.
Q. Available clinical data demonstrate that the vast majority of curable lung cancers are currently detected by chest x-rays and CT scan, although there is no proven strategy to assure early detection.
That's what they were saying when they left the international conference?
A. Yes, sir.
Q. The conference encourages national governments and public health organizations involved in cancer prevention and control to more aggressively address tobacco control and to urgently consider the issues surrounding the early detection of lung cancer. The conference recognizes that current and former smokers must be advised of their continuing risk of lung cancer.
That's people who smoke and people who used to

smoke have to be advised of their continuing risk of lung cancer; right?

A. Yes, sir.

Q. In order to address these issues, organizations must support research on new diagnostic techniques?

Let me ask you something. In your review of all this literature -- let me ask you something else.

Were you aware that the tobacco companies who are here in the courtroom took an ad out in the 50s that said they put the health of their consumers paramount to every other --

MR. NEWBOLD: Objection. This is totally outside the scope.

THE COURT: I'm sorry?

MR. NEWBOLD: Outside the scope.

THE COURT: All right.

MR. NEWBOLD: He's not been offered for this purpose either, Your Honor. He's beyond --

MR. SEGAL: Can I --

THE COURT: All right. The objection will be sustained.

BY MR. SEGAL:

Q. Doctor, let me ask you this, in all those articles that you have gone over with the jury that you read in preparation, they talk about who supports that research, don't they?
A. Sometimes.
Q. And in fact, I think one of the articles you were shown today was supported by the Eastman Kodak Company, wasn't it?
A. I don't remember.
Q. All right. Have you seen any of this research on the new diagnostic techniques being funded by Lorillard, RJR, Philip Morris, Brown & Williamson? Have you seen any research being funded by those people in these areas of the new techniques?
A. I'm just going to say I don't know because I don't look into who sponsored it with that much interest.
Q. Finally, one last thing about this, where they are talking about that we need -- they recognize that current and former smokers must be advised of their continuing risk of lung cancer; in that regard, let me ask this.
This paper and what they were recommending back then, that was before Henschke published her very

first article, much less her follow-up articles, wasn't it?

A. I don't -- if you show me the date, and I have forgotten whether it was --

Q. Sure. I believe it was December 9th, 1998, conference?

A. Oh, yes. That was before.

Q. I will show it to you.

A. She published in Lancet in -- I trust you.

Q. So they were making this recommendation well before?

A. Yes.

Q. Okay. Last area.

We have talked a lot about what it will early detect, what spirometry will early detect. You were finally asked some questions about quitting. Will quitting, if you quit right now, will it eliminate your risk of developing a lung cancer?

A. No.

Q. Will it stop COPD if you have already developed COPD or emphysema?

A. It won't stop it, no, sir. It will slow it down, but it won't stop it.

Q. It will slow it down.

Will quitting early detect the presence of a lung cancer?
A. No.
Q. Will quitting early detect the presence of COPD?
A. No.
Q. Will quitting early detect the presence of emphysema?
A. No.
Q. And in each of those three conditions, is one of the problems you face as a clinician that, by the time people get to your office with symptoms, it's normally too late?
A. Well, basically for COPD and lung cancer, that's very much the problem, yes, sir.
MR. SEGAL: If you will give me two seconds, Doctor.
Thank you, Dr. Gaziano. Thank you, Your Honor.
THE COURT: Recross-examination?
MR. NEWBOLD: Yes, Your Honor.

-- -- --

RECROSS EXAMINATION

BY MR. NEWBOLD:
Q. Quitting smoking, we are going to talk

about quitting smoking a little bit.
A. Okay.
Q. If you have emphysema, there is no cure for emphysema; right? There is no cure?
A. Yes, sir, that's correct.
Q. But if you -- and emphysema sort of progresses, it gets worse; the more you smoke, the more emphysema gets worse or your problems breathing get worse; is that right?
A. Yes, sir.
Q. But if you quit smoking, then it doesn't get worse any more, does it?
A. It gets worse only as a factor --
Q. Right.
A. It gets worse only as an aging factor of age, but not due to cigarettes.
Q. Everybody has problems with aging with their lung capacity, right, sir?
A. Yes, sir.
Q. We are all in that same downhill slope as far as our lung capacity and whether we smoke or not?
A. Yes, sir.
Q. So what you are saying is, if you smoke, the ski slope is steeper. If you quit smoking, it

will then level out and won't progress any further other than what it would have progressed simply by getting older?

A. That's correct, yes, sir.

Q. Okay. We covered this a lot, but I just want to make sure that we all understand it. When you say -- you know what I'm going to ask you.

A. I think I do.

Q. You do.

A. Uh-huh.

Q. When you tell Mr. Segal and this jury that a CAT -- a CT scan can detect lung cancer only, that's not what you mean, because a CT scan alone does not detect or diagnose lung cancer; correct?

A. That's correct.

Q. Okay. You have to do all these follow-up procedures that are not included in this plan; right?

A. Well, you know, as I have said before, I'm not sure of the absolute specifics of the plan, what it include and what it doesn't include, so I'm not going to get into it.

I'm note going to get into it. All I'm saying is, that test requires follow-up. And what plan is involved with it, I'm not here to say, and I don't

know.
Q. But this CAT scan alone at age 50 does not detect or diagnose lung cancer; correct?
A. Specifically, no.
Q. Okay. You talked about prostate screening methods?
A. Yes, sir.
Q. Which are now recommended by these various public health organizations; correct?
A. Yes, sir.
Q. But CT scans are not recommended by these organizations for the early detection of cancer, are they, sir?
A. No, sir. I think it's a bit early, but they are not.
Q. Thank you.
Now, sir, I want to talk about -- could I have Tab 32 up, please.
Now, in Tab No. 32, you talked about the fact that they had some footnotes that were fairly old in that article.
Go to the second -- yeah, on the second paragraph that's highlighted? Okay. Go to the next -- do you see those footnotes three to ten

which the plaintiffs talked about and was critical because they were old footnotes, because it talked about some old tests.

But that was really just a setup, was it not, Doctor, to talk about the new technology, which is on Page 1982?

MR. NEWBOLD: Jason, right here.

BY MR. NEWBOLD:

Q. Talking about the new developments. So the Frame article was not stuck in the past. He was talking about the new low dose helical CT scans and specifically about the Henschke study; correct?

A. Yes, sir.

Q. All right. And then -- I always hated footnotes when I was in college, but now we are back into footnotes. Let's go to the some of footnotes in the back of the article. Let's go down to like 19.

Okay. That's the footnote where he's actual footnoting, not ancient history, but he's actually footnoting the Henschke study, itself, 1999.

Go down to the next one, Jason.

Then we have got a footnote, 1998, which is the Japanese study.

Okay. Thank you.
So you would agree Dr. Frame was also footnoting and quoting more recent sources?
A. Yes, sir.
Q. Okay. Now, you were shown -- and I don't have this on my tab. This is the early lung cancer axons project, summary of findings on baseline screening, which was a Claudia Henschke article.
And I think the indication was is that it contradicted her consensus statement that screening was not recommended. So I want to show you something about these two.
First, I want to show you Tab No. 60. Let's do it this way.
MR. NEWBOLD: Tab No. 60, Jason? Okay. Blow that up, please, in the middle.
BY MR. NEWBOLD:
Q. Okay. This is the article that I showed you where Claudia Henschke says that:
Unlike the next three most common cancers, screening for lung cancer is not currently recommended by cancer organizations.
And then she goes on to say they should continue to look at the value.

MR. NEWBOLD: Please go down, Jason, to the bottom of this so I can show the jury the date -- to the top, I'm sorry. Right at the top.

That's 2001. So she said it is not recommended in 2001. Is that correct, sir?

A. Yes, sir.

Q. All right. Now --

A. According to that statement, yes, sir.

Q. Now, take that off.

Let's go to the ELMO, please. I avoid the ELMO at all cost.

THE COURT: I see why.

MR. NEWBOLD: I could never figure these things out to save me. Which way do I go to make it go up? I want to put this on it right here, down here.

All right.

BY MR. NEWBOLD:

Q. This article -- thank you, Scott.

This article was actually received in 2000. So she actually wrote that which Mr. Segal showed you in 2000, and then it was published in 2001; is that correct, sir, received October 10, 2000?

A. I see it there. Oh, yes, it's 2001, yes.

The oncologist.
Q. But she wrote it and she submitted it in 2000; is that correct, sir?
A. Yes, sir.
Q. So therefore she wrote and submitted this Article one year before she published her consensus statement where she did not recommend helical CTs for mass screening; isn't that correct, sir?
A. I believe that's correct, although I don't have the specific dates of the other article.
Q. Now, I want to turn to -- look at that, I did it -- her conclusion, Claudia Henschke's conclusion in that article, was that:

> The accruing evidence from the ELCAP and others, while still insufficient, is continuing to heighten the prospects for cost-effective screening for the cancer that is now the main cause of cancer deaths in both genders.

So Claudia Henschke herself, once again, is saying that the evidence as to whether or not this should be recommended for everybody is still insufficient; isn't that correct, sir?
A. That's what she says, yes, sir.
Q. Thank you.

MR. NEWBOLD: I have no further questions of this witness, Your Honor.
THE COURT: All right. May this witness now be excused, not subject to recall?
MR. SEGAL: I would so move, Your Honor.
MR. NEWBOLD: Yes, Your Honor.
THE COURT: Thank you very much, Doctor.
THE WITNESS: I appreciate it.
THE COURT: You may be excused, sir.
(Witness excused)
THE COURT: All right. Call your next witness or whatever you are going to do next.
MR. SEGAL: Your Honor, at this time I would like to move the admission -- Your Honor, at this time, I would like to move the admission of what Mr. Baker assures me is the correct list, being Plaintiffs' NM 6746, Plaintiffs' Exhibit 16756, Plaintiffs' Exhibit 1518, Plaintiffs' Exhibit 12762, Plaintiffs' Exhibit 1521, Plaintiffs' Exhibit 11026, Plaintiffs' Exhibit 11015, Plaintiffs' Exhibit 22948, Plaintiffs' Exhibit 11389, and Plaintiffs' Exhibit 75204.009. I move those into evidence at this time, Your Honor, and be requested that I be allowed to publish them to the jury.

THE COURT: Any objection?
MR. NEWBOLD: No objection, Your Honor.
THE COURT: All right. Plaintiff's Exhibits -- are they all NM numbers.
MR. SEGAL: Yes, Your Honor.
THE COURT: NM 6746, 16756, 1518, 12762, 1521, 11026, 11015, 22948, 11389, and 75204.009 all will be admitted in evidence and made a part of the record in this proceeding, may be published to the jury at the convenience of counsel
(The exhibit is so admitted.)
MR. SEGAL: Your Honor, may I approach?
THE COURT: Yes.
MR. SEGAL: This is the November 26th, this is the November 26th, 1973, press release by the American Tobacco Company. And we can see this is a press release,
It is the American Tobacco Company in New York. It's dated November 26, 1953, and it says:
Paul M. Hahn, president of the American Tobacco Company, took issue today with what he called loose talk on the subject of smoking in relation to lung cancer.
The public is entitled to know the facts.

We are confident that long range, impartial investigation and other objective research will confirm the view that neither tobacco nor its products contribute to the incidence of lung cancer. We wish to the public to know these facts so that they themselves may be informed and also be in a position to deal intelligently with the subject when misinformation comes to their attention.

THE COURT: Is there a counterdesignation?

MR. WOODSIDE: There is, Your Honor.

THE COURT: All right.

MR. WOODSIDE: Thank you.

The American Tobacco Company is working at and supporting scientific research of a fundamental nature in this field, within its own laboratory and in independent institutions. That completes our counterdesignation.

THE COURT: All right.

MR. SEGAL: Would you publish to the jury, please, Ms. Gina, 16756.

This is an undated statement by the CTR and TI, and I would like you to go ahead and put this up first. You can see this is from the Tobacco

Industry Research Committee and the Tobacco Institute, Incorporated. It's a statement about tobacco and health.

We shall continue all possible efforts to bring the facts to light. In that spirit, we are cooperating with the Public Health Service in its plan to have a special study group review all presently available research.

MR. NEWBOLD: No counter, Your Honor.

MR. SEGAL: Would you show them 1518. Your Honor, may I approach?

THE COURT: All right.

MR. SEGAL: Judge, this is a 18962 press release by George Allen, who is the president of the Tobacco Institute. It was issued by Hill & Knowlton. You can see this is for the Tobacco Institute incorporated, it's from Hill & Knowlton, Incorporated. It's for immediate release on March 7th, 1962. And it says george Allen comments on British smoking report.

In this search, I am proud that the tobacco industry supports continued independent research, aimed at getting the full facts about cancer and other diseases. This will be done

in the laboratories and not by pronouncements by me or anyone else.

MR. THOMAS: No counter, Your Honor.

THE COURT: All right.

MR. SEGAL: I would like to approach on 12762.

THE COURT: All right.

MR. SEGAL: Your Honor, this is the November 18th, 1962, radio broadcast transcript by George Allen, president of the Tobacco Institute. You can see here, ladies and gentlemen, radio broadcast transcript, the program was the smoking question part (II). It was November 18, 1962, at 8:05 p.m, the station was the Mutual Broadcasting System in Washington, D.C, and it was regarding cigarette smoking and lung cancer.

The Smoking Question.

Mr. Allen: I'd be glad to, Mr. Trohan. The Tobacco Institute is an association of the tobacco manufacturers which regard the smoking and health question as a very serious one and one which deserves very earnest and energetic, scientific investigation and experimentation.

MR. SEGAL: I think that's it for us; right?

THE COURT: Is there some counterdesignations?

MR. WOODSIDE: Yes, Your Honor.
It follows Mr. Segal's designation by Mr. Allen:

We support that activity through a sister organization, the Tobacco Research Committee, which has done more investigation in the eight years since it was established than any other private scientific organization or medical organization in the specific subject of lung cancer.

Question: How much money has this committee spent?

Response by Mr. Allen: During its eight years, it has made well over one hundred individual grants to independent scientists, laboratories, technicians and various kinds of experimenters. And the total of these grants is well over five million dollars at the present moment.

Mr. Trohan: In other words, the tobacco industry supplies an awful lot of tax money to us. Should this be considered or should this be strictly a health survey?

Mr. Allen: I think it ought to be

strictly a health survey myself. Now, I'm speaking personally. However, I happen to come from a tobacco area. I'm a very small scale a tobacco farmer myself.

There are, all together, we estimate, about 17 million people in the United States who, in one way or another, obtain their livelihood either directly or indirectly from tobacco, either the growing, the handling of the leaf, the warehouses, the manufacturers, the wholesalers and retail distributors.

Incidentally, there are reckoned to be 1,500,000 individual retail outlets of one sort or another, so a lot of people are involved, not to speak of the fact that, so far as the revenue to the United States government is concerned, tobacco, I believe, is second in the amount of excise taxes.

MR. WOODSIDE: Your Honor, that would complete my designations.

THE COURT: All right.

MR. SEGAL: Your Honor, I would like to publish and approach to 1521.

THE COURT: All right.

MR. SEGAL: This is a short one, Your Honor. This is a 1962 press release by the Tobacco Institute. It's a statement by George Allen, the president.

Here we have it, for the Tobacco Institute from Washington, D.C., this is for p.m. release Thursday, December 27, 1962, CR in the year-end editions. It's the tobacco economy, 1962 review and outlook. It's by George V. Allen, president of the Tobacco Institute.

And there is just one sentence in here -- oh, yeah. It was issued by Hill & Knowlton, once again, that's hard to read, but what that banner says is, Hill & Knowlton, Inc., 150 east 42nd Street, New York, New York, and if you could go to the quote, please, from Mr. Allen.

> During 1963, the Surgeon General's Advisory Committee on Smoking and Health will review existing knowledge about smoking and health.
>
> Our industry is cooperating with this group in the hope that it will be a thorough study and, as the Surgeon General has said, will be concerned not only with tobacco but all

other factors which may be involved.

The American Medical Association has also announced plans to conduct a review and the industry will extend cooperation to this group as well.

Is that it on that one?

Your Honor, at this time -- is there a counter on that one?

MR. THOMAS: Yes, there is. Your Honor, I have not been introduced to the jury. May I introduce myself?

THE COURT: Yes.

MR. THOMAS: Good morning, I'm Dave Thomas, I'm from Allen Guthrie & McHugh in Charleston, West Virginia, and I represent one of the defendants in the case.

Counterdesignation for the same document you just heard from:

We can predict that tobacco will continue to provide a livelihood for millions; for growers, warehousemen, transporters, retailers, wholesalers, manufacturers and the thousands of suppliers who provide the goods and services that are necessary for any major industry.

Thank you.

MR. SEGAL: Your Honor, at this time I would like to approach on 11026 and publish that, please.

THE COURT: All right.

MR. SEGAL: Ladies and gentlemen, this is a 1963 speech, which is stapled to my finger -- this is a 1963 speech by George Allen, the president of the the Tobacco Institute.

There you can see the Tobacco Institute's border heading. And this is Tobacco and the Public Interest by George V. Allen, President of the Tobacco Institute, Incorporated.

And if we could go, please, to the top of that:

> George V. Allen, President, the Tobacco Institute, delivered the following address before the September, 1963 meeting of the National Association of State Departments of Agriculture.
>
> We are vitally interested in getting the scientific facts that will provide answers to questions about smoking and health. We also want full knowledge about the cause or causes of those diseases with which smoking has been

statistically associated.
MR. THOMAS: Counterdesignations, Your Honor?
THE COURT: All right.
MR. THOMAS: Those of us who work with tobacco share with the millions who use tobacco products a concern over questions raised about cigarettes and health.
First, as human beings, we are interested in the health of our fellow man.
Second, we have a natural interest in the future welfare of our industry, and of the industry's customers.
In view of this, it seems to me there ought to be a respite from theories, resolutions and emotional statements, for a time at least, so that scientists can objectively evaluate what is known and what is not known.
Perhaps then the scientists can determine the areas of research that must be undertaken and work together to solve these health problems.
We do know that, in laboratories around the world, scientists are investigating many possible factors in lung cancer and heart disease, in addition to smoking.

These include viruses, previous lung infections, diet, stress and strain, environmental and occupational pollutants and many others.

(4) inhalation of tobacco smoke by laboratory animals some many experiments over the years has consistently failed to produce lung cancer.

(6) extensive chemical tests have failed to specify any substance, as found in cigarette smoke, that accounts for lung cancer.

I believe that's all, Your Honor.

MR. SEGAL: Your Honor, I would like to approach on 11015 and publish that.

THE COURT: All right.

MR. SEGAL: Ladies and gentlemen, this is a speech by Joseph Cullman, who is the president of Philip Morris. These are the remarks of Joseph F. Cullman, 3rd, who was president of Philip Morris, Inc. These were remarks made to the South Carolina Tobacco Warehouse Association in Myrtle Beach, South Carolina, on June the 7th, 1966. Those remarks included:

> First of all, we feel a deep sense of responsibility to our cigarette smokers.
>
> All of us who work in this industry feel

a deep concern over questions raised about cigarettes and health. We will not rest until we learn the scientific facts that will provide solutions to the medical problems in question.

We intend to leave no research question unanswered in our quest for the truth.

What have we done to help find the truth? This industry has allocated nearly twenty million dollars for the support of research projects by independent scientists, through the Council for Tobacco Research U.S.A. and through the American Medical Association Education and Research Foundation. If more funds are needed for this research, I am sure the industry will provide them.

I believe it is in the best interests of the public, as well as the industry itself, to encourage the kind of research that will provide the facts, all the facts. And that is exactly what we will continue to do.

MR. KLEIN: No counters, Your Honor.

THE COURT: All right.

MR. SEGAL: Your Honor, I would like to approach on 22948.

THE COURT: All right.

MR. SEGAL: This is a press release by the Tobacco Institute. Here we have the Tobacco Institute, once again, Washington, D.C. Contact, William Kloepfer, Jr., and this is for use on and after Sunday, January 3, 1971.

Kornegay said Tobacco companies in 1971 will pool more than four million dollars for support of independent scientific research on smoking and health questions, adding, quote, so long as hundreds of thousands of nonsmokers are crippled or die prematurely from cancer and respiratory ailments, there is no excuse for continued failure of the voluntary health associations to apply every available dollar to the search for the keys to these scourges.

Kornegay declarified that every statistical path linking smoking to some form of ill health leads directly to a locked door. In 1971, we have a great opportunity for new efforts to find the keys.

Any organization in a position to apply resources in the search for those keys and which fails to do so will continue to be guilty

of cruel neglect of those whom it pretends to serve.

MR. THOMAS: One counter, Your Honor. A 1971 document.

The public has total awareness that smoking may be a health hazard, he says, but they demand facts, not surmise.

Thank you, Your Honor.

THE COURT: All right.

MR. SEGAL: Your Honor, I would like to approach on 11389.

THE COURT: All right.

MR. SEGAL: Ladies and gentlemen, this is the November 19, 1973 speech by James Bowling, who was the vice president of Philip Morris. This is James C. Bowling, and here it is.

The tobacco industry has long felt a deep moral commitment in helping to find the answers to the questions that have been raised about our products.

Twenty years ago, in 1953, the major American cigarette companies formally acknowledged a commitment to research by establishing the Council for Tobacco Research

U.S.A.

The council is financed as a joint effort by the major tobacco companies. Its responsibility is to act as the primary mechanism through which the companies pool their research grant funds.

MR. KLEIN: One brief counter, Your Honor.

THE COURT: All right.

MR. KLEIN: Since its founding, the council has provided more than fifty million dollars to a wide variety of distinguished scientific institutions for independent research.

The industry also provided funds to Washington University in St. Louis and the Harvard Medical School for extensive and basic research programs.

Thank you.

MR. SEGAL: Your Honor, finally I would like to approach and publish on 75204.09. This document relates -- it's the 1954 Lorillard's annual report. We can see there it says, the P. Lorrilard Company, annual report, 1954. And in that report is the following statement:

Cigarette Smoking and Lung Cancer.

The industry continued to be harassed in

1954 by repeated attempts of some researchers to associate cigarette smoking with lung cancer.

Corporate statesmanship dictates the course we must follow in this matter. While confident that Lorillard products are not injurious to human health, we are actively engaged in seeking scientifically to determine the truth in our own laboratories and with the industry through the Tobacco Industry Research Committee.

MR. NEWBOLD: One counter, Your Honor.

THE COURT: All right.

MR. NEWBOLD: However, many distinguished men of medicine and recognized authorities in the health field stepped forward in 1954 to challenge the evidence.

One eminent cancer authority is quoted in in an Associated Press dispatch as calling his medical colleagues who started this controversy fanatics on the subject of nonsmoking.

Leonard Engel, in an article entitled Do We Have To Give Up Smoking in the December Harper's Magazine, to cite only one of many

articles by leading medical writers in 1954 took a penetrating look at the evidence today and then went on to explain why he is not giving up cigarettes.

THE COURT: All right.

MR. SEGAL: Your Honor, at this time I would like to present to the ladies and gentlemen the prior testimony of Dr. James F. Glenn. It was given on May 26th, 1994. At the time of his testimony, Dr. Glenn was chairman of the Council for Tobacco Research.

THE COURT: All right. Do you have somebody --

MR. EVANS: Your Honor, may I approach?

THE COURT: You are going to be the reader, or the witness, I should say?

MR. EVANS: Thank you, Your Honor.

THE COURT: You are going to be using the overahead screen, Mr. Segal?

MR. SEGAL: No, Your Honor. I don't think so.

THE COURT: Let's turn the lights on.

MR. SEGAL: Okay.

-- -- --

JAMES F. GLENN,
being first duly sworn in deposition, testifies and says as follows:

-- -- --

Q. Out of the 296 studies in your index, were where you funded about?

MR. THOMAS: Your Honor, I'm sorry, I'm not working from the same script.

THE COURT: All right. Do you and Mr. Thomas want to get together?

MR. THOMAS: That's not the designation I have, Your Honor. I'm sorry.

THE COURT: Well, let's see where we are.

THE COURT: Are you all right now?

MR. SEGAL: All right. Are you ready, Mr. Glenn?

Q. Out of the 296 studies in your index where you funded about 19.5 million in grants, as I see from the index, only ten or about ten of the projects have anything to do with tobacco. Do you dispute that?

A. No, sir.

THE COURT: Is Mr. Evans going to remain as the --

MR. THOMAS: Yes, one question -- two questions and two answers.
THE COURT: All right.
MR. THOMAS: Dropping down, Dr. Glenn.
Q. Dr. Glenn, has the Council for Tobacco Research conducted or financed research that has found that smoking cigarettes or using oral tobacco increases the likelihood of a person developing lung cancer?
A. I didn't hear your question, sir.
Q. Has the CTR conducted or financed research that has found that smoking cigarettes or using oral tobacco increases the likelihood of a person getting lung cancer?
A. Yes, sir.
MR. THOMAS: Thank you.
MR. SEGAL: Your Honor, the next testimony we are going to read is the prior testimony of Dr. Harmon McAllister McAllister taken October 20th, 2000, in this case. And at the time of his deposition, Dr. McAllister was the vice president of the Council for Tobacco Research.
THE COURT: All right.
-- -- --

HARMON McALLISTER,
being first duly sworn in deposition, testifies and says as follows:

-- -- --

Q. Could you please state your full name and spell your last name for the record.
A. Harlan McAllister, M-c A-l-l-i-s-t-e-r.
Q. And what is your current employment?
A. I am an employee of the Council for Tobacco Research here in New York.
Q. How many employees are currently part of CTR?
A. There are three.
Q. Who are they and what are their titles?
A. Dr. James Glenn is president, the CEO; Lauren Police is the secretary and treasurer.
Q. And yourself?
A. And myself, I'm the vice president.
Q. How many publications resulted from CTR-sponsored research?
A. Somewhere between six and seven

thousand, on the high end of that, that we know about. There are probably lots of others. We just don't know about them.

Q. How many of those publications were cited by the various Surgeon General reports on smoking and health?

A. Citations were around six hundred, but some were cited multiply, so the range of articles is probably in the range of three hundred or so.

Q. Three hundred articles were cited?

A. At least three hundred, yes.

Q. And approximately seven thousand articles were published as a result of CTR research; correct?

A. Yes. High sixes, yes.

Q. Over the course of CTR's existence, you indicated that the CTR spent three hundred million in total for grants and contracts?

A. Yes.

THE COURT: Is there a --

MR. THOMAS: No counterdesignations.

THE COURT: No counters, all right, fine. Do you want the lights out now?

MR. SEGAL: No -- yeah -- well --
THE COURT: Okay.
MR. SEGAL: Your Honor, the next group of documents which I will read, we are going to have to break. I don't mind doing that. But I just want you to know I'm going to get started, but I'm not going to get finished.
THE COURT: We will go for fifteen minutes, and then we will pick it up again at 1:00. Is that all right?
MR. SEGAL: Okay. Your Honor, at this time I'm going to move the admission of -- and by the way, just for Nick and them, we have typed up the exact numbers so, when I'm done this morning...
Your Honor, we are going to move the admission of Plaintiff's Exhibits 6045, 76910.019, 10386, 21388, Exhibit 10813, Exhibit 33829, Exhibit 11360, Exhibit 22881, Exhibit 13784, Exhibit 1396, Exhibit 1195, Exhibit 435, Exhibit 9648, Exhibit 24978, Exhibit 1405, Exhibit 473, Exhibit 797, Exhibit 19671, Exhibit 36983, Exhibit 40176, and Exhibit 20759.
THE COURT: All right. Any objection?
MR. KLEIN: Nothing further, Your Honor.

THE COURT: All right.
MR. SEGAL: Your Honor, if --
THE COURT: I understand. Subject of course to the prior rulings, all those exhibits will be admitted into evidence and made a part of the record in this proceeding, and they may be published to the jury at the convenience of counsel
(The exhibits are so admitted.)
MR. SEGAL: May I approach? We can go with 6045, if you would please put that up.
Ladies and gentlemen, this is authored by Mr. Gross, who is an executive of Hill & Knowlton, the tobacco industry's -- there it is. Here we are, Hill & Knowlton, this is 1933. Wait, I need to read it -- I didn't get to read it. It's 1953. 1953. Background material on the cigarette industry client.

The following information was given us by the presidents of the leading tobacco companies at the Hotel Plaza this morning.

The group was called together by Mr. Paul Hahn, president of the American Tobacco Company. The chief executive officers of all the leading companies, R. J. Reynolds, Philip

Morris, Benson & Hedges, U.S. tobacco company, Brown & Williamson, have agreed to go along with a public relations program on the health issue.

They feel that they should sponsor a public relations campaign which is positive in nature and is entirely, quote, pro cigarettes, closed quote.

They are confident they can supply us with comprehensive and authoritative scientific material which completely refutes the health charges.

They are also emphatic in saying that the entire activity is a long-term, continuing program, since they feel that the problem is one of promoting cigarettes and protecting them from these and other attacks that may be expected in the future.

Each of the company presidents attending emphasized the fact that they consider the program to be a long-term one.

And finally, present at the meeting: Were Paul Hahn, president of the American Tobacco Company; Joseph Cullman, Jr., chairman and president, Benson

& Hedges; O. Parker McComas, president, Philip Morris and Company, Ltd, Inc.; J. Whitney Peterson, president, U.S. Tobacco Company.

And I believe that's all.

THE COURT: Mr. Thomas?

MR. THOMAS: Thank you, Your Honor. We do have some counters.

The industry's position.

The industry is strongly convinced that there is no sound scientific basis for the charges that have been made.

They point out that the National Cancer Institute of the U.S. Public Health Administration, which is a government agency and supported by congressional appropriations, has officially refuted the tie-up between cigarette smoking and cancer.

Heading: "Responses to Questions."

The companies' answers to questions put them by John Hill and the undersigned provide valuable background. They are as follows:

Will the cigarette companies organize themselves into an association publicly announced, which will openly sponsor their

public relations activities?

The companies replied that they have no desire to set up a smoke screen or front type of organization.

Do they accept the principle that public health is paramount to all else, and would they issue a public statement spelling this out?

Everyone present wholeheartedly agreed to this principle and readily consented to widespread dissemination of a sound statement of principle.

That's a all, thank you, Your Honor.

MR. SEGAL: Your Honor, at this time I would like to approach on 76910.19, the Frank Statement, and I would like to publish certain portions of the Frank Statement. Here it is, the Frank Statement to Cigarette Smokers.

Many people have asked us what we are doing to meet the public's concern aroused by the recent reports. Here is the answer:

(1) we are pledging aid and assistance to the research effort into all phases of tobacco use and health. This joint financial aid will of course be in addition to what is already

being contributed by individual companies.

(2) for this purpose, we are establishing a joint industry group consisting initially of the undersigned. This group will be known as Tobacco Industry Research Committee.

(3) in charge of the research activities of the committee will be a scientist of unimpeachable integrity and national repute. In addition, there will be an advisory board of scientists disinterested in the cigarette industry. A group of distinguished men from medicine, science and education will be invited to serve on this board. These scientists will advise the committee on its research activities.

Thank you.

MR. KLEIN: Nothing further, Your Honor.

THE COURT: All right.

MR. SEGAL: Next one I would like to approach is 10386.

THE COURT: All right.

MR. SEGAL: This is authored by H.R. Hammer, director of research and development at the American Tobacco Company. And it's a memo, and it says:

The search for a scientific director has been their responsibility from the beginning; whereas, I have participated in the activity for only a few weeks. However, I am in the unique position of being able to understand some of the difficulties which have confronted them.

It is difficult to describe the sense of great responsibility which one feels when approaching an interview of a prospective candidate.

We cannot help but wonder how the individual members of the technical committee would assess this man; what the fourteen members of the TIRC would think of him; what impression he would make upon the public; how he would meet the press; and above all, what effect, over a period of years, he will have upon the fortues of the tobacco industry for, once the dye is cast, there is no retreat from the decision. It is for better or for worse. I might cite three examples. Clayton Loosli, Lee Clark, Leon Jacobson.

We have, therefore, come to the

conclusion that we must be satisfied with someone with a reputation for integrity, of reasonable confidence, and, above all, one who is safe for the industry.

And you can see the initials HRH, which, as I indicated, Your Honor, it's agreed that's H.R. Hammer, who was the director of research and development, American Tobacco Company.

THE COURT: All right.

MS. MIDDELHOFF: No counters, Your Honor.

MR. SEGAL: Next I would like to approach on is 21388.

THE COURT: All right.

MR. SEGAL: All right, here what we have is the author is D.G.I. Felton. The secondary author was Bentley, who is Imperial Tobacco Company Director of research, and another secondary author was Reid, who was a research scientist at Wills Australian Tobacco Company, a sister company to B&W.

This is a report on a visit to the United States and Canada, the visit was from the 17th of April through the 12th day of May, 1958, and it's by H. R. Bentley, D. G. I. Felton and W. W. Reid, who I just explained which companies they were from.

And the itinerary shows, there is the itinerary, that they met on the 28th with the TIRC, the Tobacco Institute Research Committee, New York, with Messrs. Hoyt, Thompson from Hill & Knowlton, then they met with the Industrial Technical Committee of the TIRC in Richmond on the 5th with Messrs. Hammer, Chairman Hoyt and Heckett.

And the 8th, the TIRC in New York with Dr. Little and Dr. Hockett and on the 10th the TIRC in New York with the Scientific Advisory Board of the TIRC.

Attitude of the U.S. Industry to Biological Testing.

Liggett & Meyers stayed out of TIRC originally because they doubted the sincerity of TIRC motives and believed that the organization was too unwieldy to work efficiently. They remain convinced that their misgivings were justified.

In their opinion, TIRC has done little if anything constructive, the constantly reiterated, quote, not proven statements in the face of mounting contrary evidence has thoroughly discredited TIRC, and the SAB of

TIRC is supporting almost without exception projects which are not related directly to smoking and lung cancer.

Liggetts felt that the problem was sufficiently serious to justify large scale investment by the company directly in experimental research on smoke and cancer, accepting privately that a strong case against tobacco had been made out and avoiding any public comment until their own research had provided something concrete to offer.

That concludes that.

MS. MIDDELHOFF: No counters, Your Honor.

THE COURT: All right.

MR. SEGAL: Your Honor, I would like to approach on 10831.

THE COURT: Let me just take a look at it.

It looks like it's short.

MR. SEGAL: Very short.

MR. SEGAL: On 10831, this is the author of this document is Geoff Todd, he's a senior scientist at the Tobacco Research Council in England, the secondary author was P. J. Rogers, who was a senior scientist at the Tobacco Research Council in

England.
It's a report on policy aspects of the smoking and health situation in the United States.
And the date on that document is October 1964.
Council for Tobacco Research:

> As we know, CTR supports only fundamental research of little relevance to present day problems.
>
> The Council for Tobacco Research, U.S.A: CTR continues as before to confine its research to the diseases with which smoking is statistically associated but not to support research into the product.
>
> The Scientific Advisory Board of CTR continue to act and decide on applications for grants to carry out research on what appeared to us to be projects of no more than remote relevance to current problems.
>
> Although L&M have now joined CTR, this was solely in order to present a united front, and L&M's scientific staff are as highly critical of CTR's research policy as ever.

MR. KLEIN: No counters, Your Honor.
THE COURT: All right. This would be a

convenient time to take the noon break. Please don't discuss the case among yourselves nor permit anybody to discuss it with you. We will see you back here at 1:00.

Mr. Newbold, here are some materials you gave me.

(Thereupon, a luncheon recess is taken at 12:00 noon.)