IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
-vs-	)	No. 99-CV-02496(GK)
	)	
PHILIP MORRIS, INC., et al.,	)	
	)	
Defendants.	)	

THE VIDEOTAPE DEPOSITION OF KENNETH LUDMERER, produced, sworn and examined on behalf of the Plaintiff, pursuant to Notice, on Wednesday, August 7, and Thursday, August 8, 2002, at the Office of the United States Attorney, 400 in the City of Kansas City, in the County of Jackson and State of Missouri, before me,

ALISON A. TRACY, RPR, CCR #554
of
JOHN M. BOWEN & ASSOCIATES
Court Reporters,

a Notary Public, Registered Professional Reporter and Certified Court Reporter, in a certain cause now pending in the United States District Court for the District of Columbia, wherein UNITED STATES OF AMERICA is Plaintiff and PHILIP MORRIS, INC., et al., are Defendant.

A p p e a r a n c e s

For the Plaintiff:
U.S. Department of Justice
Civil Division
1331 Pennsylvania Ave. N.W.
Suite 1150-20
Washington, D.C. 20004
By: Ms. Mary Jo Moltzen
Ms. Noelle M. Kurtin

For the Defendant Lorillard:
Shook, Hardy & Bacon
One Kansas City Place
1200 Main Street
Kansas City, Missouri 64105
By: Mr. David M. Woods

For the Defendant
Philip Morris: Hunton & Williams
1751 Pinnacle Drive
Suite 1700
McLean, Virginia 22102
By: Mr. Daniel C. Jordan

Also Present: Ms. Chris Walker-Byerley
Shook, Hardy & Bacon

Video Operator: Mr. Brent Christopher
Christopher Video
4024 State Line Road
Kansas City, Kansas 66130

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WITNESS: Kenneth Ludmerer

EXHIBITS

THE VIDEOGRAPHER: Today's date is August 7, 2002. The time is 9:18 AM. This is the deposition of Kenneth Ludmerer. My name is Brent Christopher from Christopher Video. The court reporter is Alison Tracy from John Bowen & Associates. The case caption is United States of America versus Philip Morris, Inc., et al. Civil Action No. 99-CV-02496. Counsel please state their appearances for the record.

MS. MOLTZEN: Mary Jo Moltzen representing the United States.

MS. KURTIN: Noelle Kurtin for the United States.

MR. WOODS: This is David Woods with Shook, Hardy & Bacon in Kansas City for Lorillard Tobacco Company.

THE VIDEOGRAPHER: Please swear the witness.

KENNETH LUDMERER,

the Witness of lawful age, being produced, sworn and examined on behalf of the Plaintiff, deposeth and saith:

DIRECT EXAMINATION

BY MS. MOLTZEN:

Q Dr. Ludmerer, would you please state your business address for the record.

A Washington University, Department of Medicine, 660 South Euclid Avenue, Campus Box 8066, St. Louis, Missouri 63110.

Q Have you ever been deposed before?

A Yes, I have.

Q This deposition is being conducted pursuant to the Federal Rules of Civil Procedure and the case management orders issued in this case. But it is important for the record that I give you some basic instructions which you have probably heard before and ask you some basic questions. You were given an oath at the beginning of the deposition. Do you understand that the answers you provide today are the same as if these answers were given to a judge in a courtroom?

A Yes, I do.

Q I'm going to ask you a series of questions. It is important that you understand my question before you begin to answer. So if you do not understand a question, you will ask for clarification, is that agreed to?

A Yes.

Q The court reporter will be taking down your answers to my questions. For that reason you must

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provide clear, verbal answers, no nods, shrugs, uh-huhs or huh-uhs. Is that agreed to?
A Yes, it is.
Q I will try to ask clear, concise questions today. But if you are confused in any way, please let me know. Is that understood?
A Yes, it is.
Q If you don't hear any part of a question, please ask that it be repeated. Is that agreed to?
A Yes.
Q If you do not ask a question -- to have a question clarified or repeated, I will assume that you heard and understood the question. Is that understood?
A Yes, it is.
Q It is important that you allow me to finish my question before you start to answer, and that I allow you to complete your answer before I begin my next question. Do you understand?
A Yes.
Q And the court reporter will let us know if we need to slow down or if for any reason she is having difficulty with hearing us. According to order number 150 in this case, I am to give you the following instruction at the beginning of this

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deposition. You must ask me rather than your own counsel for clarifications, definitions or explanations of any words, questions or documents presented during the course of this deposition. You are to address your inquiries regarding clarifications to me. If you need to take a break for any reason or if you just get tired, will you tell me?
A Yes.
Q There is one exception to that, there can be no break or recess between a question and a pending answer.
A Understood.
Q Have you taken any drugs or medication which might affect your ability to answer questions today?
A No, I have not.
Q Do you have any medical conditions or problems which might affect your ability to answer questions today?
A None that I'm aware of.
THE VIDEOGRAPHER: Going off the record. The time is 9:22 AM.
(Short recess was taken.)
THE VIDEOGRAPHER: We are back on the record. The time is 9:24 AM.

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MS. MOLTZEN: Could you introduce yourself, please.
MR. JORDAN: Dan Jordan with Hunton & Williams here on behalf of Philip Morris.
MS. MOLTZEN: Mr. Jordan just entered the room so he missed the preliminaries. Would you introduce yourself please?
MS. WALKER-BYERLEY: Chris Walker-Byerley with Shook, Hardy & Bacon.
Q One more question in those preliminaries. Is there anything else that might impair your ability to recall or tell the truth?
A None that I'm aware of. May I ask you a procedural question?
Q Absolutely?
A Actually two. I appreciate your going through the guidelines as you have. Having given seven or eight depositions in the course of my involvement over 15 years, the instructions that you have given in general are familiar and what I expected. Two specific questions. Are there any rules, procedures, ways of doing things that are different because this is a deposition in federal court with the U.S. Government as opposed to a civil court? As I recall previous depositions --

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I believe this is the first federal deposition, U.S. deposition that I have been involved with. Is there anything different that I should be aware of?
Q I have never taken a deposition in state court so I can't answer that. I'm sure there are some small technical differences but I can't think of any?
A Essentially the rules are the same. What you recounted now is what I was anticipating the guidelines would be. And my second question, I do not recall a previous video deposition. Are there any rules or procedures for you as well as for me that are different because this is being videotaped?
Q No, there are not.
A Thank you for that clarification.
Q You're welcome. Dr. Ludmerer, in what field of expertise are you offering your opinions as an expert in this case?
A As a historian in medicine dealing with the historical issue of how we came to our current understanding that cigarette smoking causes lung cancer.
Q Is the association between cigarette smoking and

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lung cancer the only disease that you will be offering opinions about?
A I'm not entirely certain what opinions, if any, I will be offering. I don't know if I will be asked to testify and, if so, what the nature of that will be. The focus of my research and opinions does deal with the issue of lung cancer specifically and cigarette smoking. On the other hand, the studies, particularly the magnificent prospective trials of the fifties and sixties which really became the basis of our current understanding that cigarette smoking causes lung cancer did demonstrate that cigarette smoking either caused or was associated with many other diseases as well. And the Surgeon General's report which what I reviewed as part of my study discusses other diseases as well.
So I think it would be fair to say that cigarette smoking and health from the scientific standpoint would be the focus of my testimony with a great emphasis on lung cancer, but it wouldn't surprise me if I were asked to make some comments on other illnesses as well. The focus is on cancer. I do want to make that point.
Q Will you be offering opinions about cigarette

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smoking and emphysema?
A Again I don't know what I will be asked to discuss or not.
Q Let me ask that in a different way then. Do you consider yourself an expert in the field of medical history and smoking as it relates to emphysema?
A I would say that I would consider my expertise smoking as it relates to lung cancer, that has always been the focus, not other diseases.
Q That is all true then for cardiovascular disease?
A That's correct.
Q That is also true for COPD, chronic obstructive pulmonary disease?
A That's correct. The focus of my study all along, my testimony if asked to testify is on cigarette smoking and lung cancer, and not these other conditions that you are mentioning.
Q I'm going to ask one more. Nicotine addiction?
A I'm not addressing that issue at all.
Q What is the value of the history of medicine as a science or discipline?
MR. WOODS: objection.
A Could you clarify that? The value? That's a broad -- I'm not trying to knit pick your

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question. Perhaps you could help me a bit with that.
Q This is a general, this is not specific to this case, but in a general overview how does the historian of medicine help us reach scholarly goals?
MR. WOODS: objection.
A Are you asking how the historian of medicine goes about the task of doing history, what can be learned from history of medicine?
Q That's my next question. I just wanted to -- we will move on to that then if this is unanswerable. In this particular area, the history of medicine, is it important that the historian also be a medical doctor?
A In this particular area? In my opinion no. I think a good historian of medicine is a good historian of medicine. Some historians of medicine do have medical as well as historical training as I do. There are certain topics in the history of medicine or the history of science in general that definitely do benefit, in my judgment, by a person who is intimately familiar with the science and the internal concepts of that field. But insofar as we are talking about this

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particular case and the historical evolution of our understanding that cigarette smoking causes lung cancer, it is not like reading this week's New England Journal of Medicine, Journal of Biochemistry. I think that a well-trained historian without medical qualifications certainly is qualified to do study in this area to speak on that. It would not require a medical background in my opinion.
Q Who do you consider to be some other authorities in this field of expertise that you are going to be testifying on today?
A In the history of medicine in general?
Q Let's start there, a couple of names from the history of medicine in general.
A The history of medicine is a large field so there are many fine historians of medicine, most of whom do not have MD degrees, appropos to your earlier question. Some of the leading historians of medicine today in my judgment, and this list is suggestive, not totally inclusive, but Charles Rosenberg, Barbara Rosenkrantz, Daniel Fox, Rose Mary Stephens, Judy Levitt, Juan Numbers, Gert Breeger. These would be examples of individuals who are very eminent figures in the history of

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medicine. Gert Breeger has an MD degree in addition to a Ph.D degree. The other individuals that I mentioned are peer Ph.D historians and in my judgment they are all outstanding scholars.

Q That was my general question. Now a more specific question. Who else do you generally considered authoritative in the field of the history of medicine as it pertains to smoke smoking and lung cancer?

A Well, a number of people have written on this and I have not reviewed for this deposition all of the secondary sources that I read back in the late eighties or early nineties when I did my research. There have been a number of important books and articles that I remember was in them, not necessarily who wrote them.

But from my perspective some of the best historical work by contemporary workers has included work by John Burnham, Alan Brandt whom I know is a witness for the plaintiff, I believe Sir Richard Doll who I don't know if he would call himself a historian, Ernest Wynder, both of them have written very helpful historical recollections of their experience and I have found those to be authoritative and reliable and helpful. Others

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who have written about this from an historical perspective, particularly as the field of chronic -- epidemiology of chronic diseases grew out of this controversy, Susser, I forget the first name, and Terrace. Vanderbrook would be another name. These would be examples of individuals that I think have written authoritatively. Of that group, Professors Burnham and Brandt are pure historians and they are both very fine historians in my opinion with deservedly high reputations.

The other individuals that I mentioned are not pure historians in that sense. They are more very thoughtful individuals, epidemiologists who lived through the events and wrote what I considered to be very helpful accounts of the events but they don't go to the history of medicine meetings and that type of thing.

Q Within your field, the history of medicine, describe the scientific method in a general sense, not for this case, but describe the scientific methodology employed to solve a problem or answer a question or tackle an issue.

A Gladly. I will speak in general because there will be specifics that are determined by the problem you study. But, as a generalization, the

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historian of medicine will want to do a lot of reading in secondary sources to help put the events under consideration in a proper context.

If you are writing about the history of the evolution of our understanding that cigarette smoking causes lung cancer, history of or the scientific understanding that cigarette smoking and disease more broadly; examples of important secondary reading, history of public health, history of cancer, history of NIH, scientific fundings, history of public health, preventive medicine. But there are a number of topics that around any specific issue you are examining and historians recognize that understanding the context is important to interpreting the events and bringing out their meaning and richness.

To summarize, Ms. Moltzen, I think I said context would be one important, learning everything you can about the general area and the subject to interpret events. One needs to be accurate in assessing primary sources. Secondary sources as well. But honesty and accuracy is important in all scholarly research. It is just as important in history as it is in any other field. You don't want to make up data. You don't

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want to falsify data. You don't want to pick and choose selectively. You have to be as fair and objective as possible and represent things as fairly as possible. So we could call it accuracy and fairness a second quality.

It is extremely important to be comprehensive, to look at everything. One of the most common errors in my judgment by non-historians who try to do historical work is that they are not comprehensive in their research. They will trace one idea but they won't look for alternative views or they won't look to see how that idea was received. What you really have to do as a historian is look at things from the perspective of the time, very comprehensive, get a total picture. Historians are aware of this but one of the easiest error for non-historians to make in trying to do history from my own personal experience teaching has been failure to be comprehensive.

Another qualification of doing history is or quality of doing good history of medicine is avoidance of hindsight. I think, and getting back to your first question, what does history have to offer. I wasn't trying to avoid the general

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question, but this is one way in my judgment that history does have something to offer. You can only make decisions and do things based on what you know at the time. No one knows the future. And one of the tasks of the historian is to bring to life and explain reality of what things were like at that particular time, not to apply current standards that may not yet have existed or been created to a previous time. It is unfair to be a Monday morning quarterback. We all know who won the Super Bowl last year but a lot of us particularly in St. Louis thought it was going to be the Rams, that they wouldn't be beaten.

I think what's going on today economically is another example. It is not at all clear whether this is fabulous time to invest long term in the stock market or if the market calamities that we have experienced the last few months are a prelude to even more calamities. Five or 10 or 15 years from now people will know. It would be easy for a non-historian to say gee, Mr. Woods, you should have put all of your money in this stock or gee, Mr. Woods, you should have sold everything. It is not so clear at the time. I think avoiding hindsight. Evaluating events in terms of what was

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known at the time, not what came to be known later. I think that's another important quality of good history.

And then if you are talking about the history of medicine or history of science specifically in distinction to other branches of history, history of medicine is one branch of history, there is an intellectual component to the history of medicine and history of science. And what historians of science and medicine learn is that history is messy. It is messy and it is untidy, and that the evolution of scientific knowledge is not a straight line of progress. This would be another distinction in my opinion in view of the trained historian of medicine versus someone who is not trained in the field, a scientist or physician who is looking back at the time.

It is easy to take what we know today and get a sense that it is just a straight line of progress. What you find in fact is that it didn't happen that way, that for every two steps forward, there were steps backward, steps sideways and that there was -- there have been many ideas that subsequently came to be accepted but then encountered hostility and resistance at that time,

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as surprising as that may seem to us today because we have accepted it. We find many instances where the common judgment advocated ideas that have subsequently been disbanded so the consensus is not always right. There is a lot of noise. For every step forward, a step backwards and sideways and false paths. There is an untidiness and messiness in the evolution of knowledge. It is not a straight line of progress from the ignorance of the past to the great certainty of the present. This type of view is something that historians of medicine and science acquire in their training and can bring to the public discussion or teaching discussion of issues in the field.

Q So those are the most important qualities of a good medical historian?

A As we sit here today I would say. I don't mean those to be exclusive, but I would certainly --

Q They are important?

A -- underscore their importance, yes.

Q What about the specific methodology that is used by a historian, steps one through 10? What are they?

MR. WOODS: **objection.**

A I'm not certain it is possible to answer that

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because there is a certain art and craft to doing history. There are as many ways to publish a good book as good books get published and different people go about the process in different ways and some people jump into the primary literature first and others do a lot of reading in secondary literature. Some people begin writing very early on, other people begin writing very late. I think that the general principles that I described before would apply to everyone. But I don't know of a protocol step 1 you do this, step 2 you do this, step 3. Part of it is problem-determined because different problems and questions in history will suggest different types of approaches. But there is a lot of individuality and variation as well. I think if you were to get 10 great historians they all have their own idiosyncracies and personal ways of doing things that were different from one to another.

Q Am I correct to say then that there is no one and one only methodology that is commonly accepted across the field of medical history?

A I'm not certain I would phrase it exactly like that. I think that there are certain principles of the history of medicine that are widely taught

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09:50 and implemented in the history of medicine
09:50 training programs, a certain educational and
09:50 factual background; so none of the things that a
09:50 person does in becoming a historian or a scholar
09:50 in any field is you learn what is there and you
09:50 get a sense of what is known, the current state of
09:50 knowledge is in your own particular research area
09:50 as well as more generally.
09:50 There is lots of discussion, much of which
09:50 comes at the seminar level. It is not that you
09:50 teach a course in methods but you will have a
09:50 seminar on methods, you will critique a paper or
09:51 you will do a draft of a chapter for a
09:51 dissertation, your mentor will go over it. So a
09:51 lot of the type of teaching and discussion is
09:51 informal as well as strictly formal.
09:51 But these issues of what type of evidence is
09:51 needed for the question at hand. How do you get
09:51 the evidence. How do you use the evidence fairly.
09:51 Have you been representative, have you been
09:51 comprehensive, have you brought about the proper
09:51 interpretations. Have you put it in a wider
09:51 context. These sorts of principles I think are
09:51 general. But in terms of a specific way to doing
09:51 something, a historian to wants to write a new

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09:51 biography of Abraham Lincoln, one could take a lot
09:51 of different comparable paths to the same goal and
09:52 that's the distinction I would like to make.
09:52 Q Has any court of law ever refused to qualify you
09:52 as an expert witness?
09:52 A No.
09:52 Q Has any party ever challenged your expert witness
09:52 status?
09:52 A Not that I'm aware of.
09:52 Q Have you ever smoked?
09:52 A No, I have not.
09:52 Q Do you believe that smoking causes disease?
09:52 A Yes, I do.
09:52 Q Why do you testify for the tobacco companies?
09:52 MR. WOODS: objection.
09:52 A Number 1, I'm testifying strictly historically,
09:52 not present day. But I'm an advocate of accuracy
09:52 in history. I'm not changing the historical
09:52 record to justify any cause, no matter how
09:52 politically correct it may seem to us today, and
09:53 my involvement with these cases as you perhaps
09:53 know began in 1988 and at that time plaintiffs in
09:53 other cases had witnesses who were completely
09:53 changing the historical record about this subject
09:53 and that testimony was brought to my attention. I

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09:53 will be very candid, Ms. Moltzen, it really
09:53 created a dilemma to me because I believe that
09:53 smoking causes cancer, I always have, still do,
09:53 and I believe that cigarette smoking is a very
09:53 serious health effect. But I was also terribly
09:53 upset to see the historical record being changed
09:53 in these cases to support a prefabricated concept
09:53 of public history. In my judgment I have an
09:54 advocacy to accuracy in history and to portray the
09:54 events as objectively as one possibly can and not
09:54 changing the facts. Not suing a doctor for not
09:54 using Penicillin before Penicillin was discovered,
09:54 this sort of thing.
09:54 So I sought counsel. I discussed the subject
09:54 with my department chairman, with the Dean of the
09:54 medical school, with I believe the Chancellor of
09:54 the university, certainly with two or three very
09:54 eminent, very senior, very wise members of the
09:54 faculty. They were all of the view it was
09:54 appropriate for me to be a witness, A, as long as
09:54 I was speaking strictly historically; B, as long
09:54 as I made clear that I don't believe that
09:55 cigarette smoking causes lung cancer, that it is a
09:55 major public health hazard, and so forth. Their
09:55 counsel was that an equally important principle

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09:55 was not changing the facts of history and it would
09:55 be appropriate for me to give a historical account
09:55 how we came to know what we did in the events that
09:55 culminated with the Surgeon General's report of
09:55 1964. So that's how I got to where I am. Would I
09:55 rather be testifying for the US government? Of
09:55 course I would. On the other hand, these were the
09:55 circumstances I sought counsel from leaders at my
09:55 university and that's how it came to be.
09:55 MS. MOLTZEN: Let's go off the record.
09:55 THE VIDEOGRAPHER: Going off the record.
The time is 9:51 a.m.
09:57 (Short recess was taken.)
(Deposition Exhibit Nos. 1 through 5
09:57 were marked for identification.)
09:57 THE VIDEOGRAPHER: Back on the record.
09:57 The time is 9:53 AM.
09:57 Q Dr. Ludmerer, I'm going to hand you what has been
09:57 marked as Deposition Exhibit Ludmerer number 1.
09:57 Have you seen that document before?
09:58 A These documents get confusing to me. I believe
09:58 this is the document that says I'm to be deposed
09:58 today?
09:58 Q It is.
09:58 A Yes, I have seen it before.

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09:58 Q It a Notice of Deposition of Joint Defendants' Expert Kenneth Ludmerer.
09:58 A Yes, I have seen that before.
09:58 Q Thank you. I'm going to hand you what has been marked as Deposition Exhibit Ludmerer 2. It is entitled Expert Report of Dr. Kenneth M Ludmerer, MD. Can you identify that document for the record?
09:58 A Yes, I have seen that before.
09:58 Q Did you write this report? Let's try this. On Page 7 there is a signature. Is that your signature?
09:59 A That is my signature.
09:59 Q Did you prepare this report?
09:59 A I participated in its preparation. I did not actually draft the report. It was drafted by individuals at one of the firms based on previous testimony, previous conversations, previous depositions. It was sent to me for editing so I read it, approved it, it represents my views. I did not physically compose it.
09:59 Q When you say one of the firms, who do you mean?
09:59 A Well, I presume it was the Shook, Hardy, Bacon firm.
09:59 Q Law firm?

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09:59 A Law firm. I would presume that, but I have been involved with a handful of cases as you know and quite frankly I don't know who initially prepared it and how it has been edited over time. The expert statements for the handful of cases I have been involved with have been very similar and they go back a long way. So I would be guessing to say that it was done at the Shook, Hardy, Bacon firm. It could have been another firm that represents the defense.
10:00 Q Do you know who you worked with in editing the drafts of the report?
10:00 A From that point it would be David Woods and Chris Walker who are here today.
10:00 Q I'm going to hand you what has been marked as Deposition Exhibit Ludmerer 3. Can you identify that for the record?
10:00 A Deposition 3 is a copy of my curriculum vitae.
10:00 Q Is this, is Exhibit 3 an accurate and current version of your CV?
10:01 A It is accurate but it is not current. I recently updated it, I think Mr. Woods provided you a new version of it. If it would help, I could mention to you the main changes.
10:01 Q That would be helpful. I think we will first mark this as the next exhibit.

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(Deposition Exhibit No. 6 was marked for identification.)
10:01 Q The updated CV has been marked as Deposition Exhibit Ludmerer 6. Can you tell us the main changes between that and number 3?
10:01 A Correct. Number 3, Ms. Moltzen, is June, 2001. Item number 6 is May, 2002. Basically they are the same but if you are looking at what the significant changes, I won't go through the small things, there are a few more published articles, that type of thing. If you look at the invited lectures and visiting professorships which is item --
10:02 Q Roman Numeral XI?
10:02 A Roman Numeral XI, it is clear from the earlier CV of June, 2001, that I received a lot of invitations to be a visiting lecturer, named professorship. I can't accept them all. There are 102 such named lectureships listed on the June, 2001 version. On the May, 2002 version we are up to 122. So in the 11 intervening months I delivered an additional 20 named lectureships or named visiting professorship in an educational institution 20 times.

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10:02 A second change is that, it is minor but it is something I'm proud of, on the June, 2001 version I list seven professional journals, either historical journals or medical journals in which I served on the editorial board. In January of this year I was invited to serve on the editorial board of Isis. It is a small change. It is eight journals rather than seven. On the other hand, Isis is a very important scholarly journal in the field of the history of science. It is the official journal of the History of Science Society so I'm proud to be on that board. So a small but it is present on the new version, it was not present on the old version.
10:04 And then lastly I would bring to your attention that in the spring of this year, 2002, I was elected to the American Academy of Arts and Sciences and that is indicated on the May, 2002 version by definition. It is not in the earlier version because I wasn't a member of the academy at that time.
10:04 Q Which Roman Numeral is it under?
10:04 A I listed it in two places, it is listed professional society because it is a professional society. But as you are aware, it is an extremely

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organization, one that I feel very honored to be
part of. I also listed it under awards and honors
where you frequently see it listed in professional
so I put it under the awards and honors category.
Those are the main changes. I'm sure I could take
out a microscope and additional paper and
additional community service board and so forth
but those are the chief changes from the earlier
version to the present version.

Q I'm going to hand you what has been marked as Deposition Exhibit Ludmerer 4 and it is entitled Joint Defendants' Expert Disclosure for Kenneth M. Ludmerer. This was the cover document that was sent to the United States along with your disclosure.

The reason I'm doing this is because in the second paragraph it says, "Accompanying this expert disclosure and report are the data, exhibits, and/or information that Dr. Ludmerer considered in forming the opinions expressed in his report; a curriculum vitae; publications authored by Dr. Ludmerer within the last 10 years; and transcripts of trial and deposition testimony within the last four years." And we are going to be take talking about some of those so I wanted

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that on the record. Instead of bringing all of the trial and deposition transcripts over the last four years with me, I made up a list, it has been marked as Deposition Exhibit 5. I am doing this because I don't want -- this is not a memory game. We don't have to sit here and you try to remember when and where.

A I appreciate that, thank you.

Q If this is incorrect, that's fine. It is just as a tool we can use. From the documents that your attorneys sent me, these were the cases over the last four years that you had either been deposed in or had testified at trial. As you look over that list, are there any errors there or are there any additions?

A We have a camera going, a videotape going so I will try not to be too silent. We have one, two, three, four, five, six, seven, eight, nine, 10, 10 events, four trials, six depositions. That looks about right. It is pretty close.

Q As we sit here you can't think of any additional cases that you were deposed in over the last four years that come to mind right now?

A Not that immediately come to mind. This looks right.

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Q Going back to your CV which was Exhibit -- it was 3 and 6, wasn't it? Is the education on that current and accurate?

A Yes, it is. There is nothing that is inaccurate in the earlier CV. It is just --

Q Incomplete?

A Or incomplete or inaccurate, it is just in the intervening year of some notable things happened. Without taking your time to go into every new article and every new committee and every new that I just highlighted what I considered to be the most important events of the last 11 months. Everything in the earlier CV is accurate.

Q As far as during your years of education, did you do any research projects yourself?

A Yes, I did.

Q Can you describe them?

A Are you talking college education, medical education?

Q Let's start with medical education.

A I interrupted formal medical school to do a project in the history of medicine.

Q Where was that?

A This was at John Hopkins, Baltimore, Maryland.

Q What did the project consist of?

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A I wrote my first book at that time, Genetics in American Society. And actually I think it might be more accurate to say that my research involvement goes back to my college days, my college undergraduate days which were at Harvard University, and I concentrated in the program called history and science, and the name is and science, not of science. And that was a very popular field of concentration for pre-medical students. You got as much science as if you had majored in conventional science so you didn't feel like you were depriving yourself. You could take as much science as if you had chosen to major in biology or chemistry, but there was much more emphasis on the liberal arts and history in general on the history of science in particular; and the department was administered by the history of science faculty at Harvard and our senior thesis were in the history of science.

So as a college undergraduate I essentially had a double major, history being one of them. I wrote my senior thesis on the history of the American eugenics movement and really made that a major project. That was a big activity for me at that time. I received the departmental prize for

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best thesis. It was really closer to a master's thesis than to a college undergraduate thesis.

I went to medical school at John Hopkins because that's where I had dreamed to go to medical school. I was lucky enough to get in, and really thought that would be the end of my work in the history. But by sheer coincidence Hopkins is one of the minority medical schools that has a history of medicine program in the school. There is a department the history of medicine, and we had required courses in the history of medicine in both the first and second years of medical school. I went to all of the lectures, my two traditional courses. I got to know the faculty well. And how many medical students have a genuine interest in medical history? Not that many, so it wasn't hard to get the know the faculty well. But that contact, that exposure gave me the idea of turning my college thesis into a book. So the presence of the department of the history of medicine facilitated that.

I took a leave of absence from medical school per se, I was a graduate student in the history of medicine at John Hopkins. I attended the seminars they asked me to do and did the other things that

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graduate students do but essentially I turned my college thesis into a book. That's the first book listed in my CV. It is entitled Genetics in American Society. It was an outgrowth of my college undergraduate thesis that I have the opportunity to pursue as a graduate student in the medical history at John Hopkins and that became my first book.

Q Did any of that research work and the eventual book that came out of it, is there anything in it is that is related to smoking and health?

A Not directly.

Q This covers a couple of sections of your CV. I want to talk about employment and experience and flesh out the CV a little bit. Research Associate, Department of the History of Science at Harvard University. What were your duties, what did you do at that point in time?

A I did work in the history of medicine full-time. This CV probably reads a bit differently from a conventional CV from a full-time Ph.D historian because I have combined the history of medicine with work in clinical medicine. I had done a residency, a medical residency in medicine we have post-doctoral fellowships and training vehicles

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that are much more common in medicine than they are in the arts and sciences. But essentially what happened was that I did my first book, I did my work in the history of medicine at John Hopkins that I described to you. I returned to medical school proper and received my MD degree from Hopkins. I went to Barnes Hospital, which is the teaching hospital of the Washington University School of Medicine in St. Louis, and did three years of an internal medicine residency, qualified for the boards in internal medicine, took the boards, passed them my first attempt, and then funded by the Department of Medicine went back to Harvard for two years as a post-doctoral student in the history of medicine. We are kind of making up terms because it was uniquely created by my department chairman to help promote my own academic endeavors. I remained very close to people at Harvard.

My first book had grown from my experiences as a Harvard undergraduate. I thought to myself you know if I can be at Harvard and get an idea for one book, maybe if I went back for a couple of years I can get an idea for a second book. So I was a full-time student in the history of science.

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I wasn't taking things for credit. I already had my degrees. But I was auditing courses, talking with people, which was is a large part of the experience, thinking, reading, reflecting, and that is when I became interested in the history of medical education as a subject and that began my -- my second book began during that two years as a post doctoral fellow at Harvard in the history of science.

Q It also says that, I take it during that time you were an instructor of medicine at Washington University. What kind of courses did you teach?

A Well, we were -- let me backtrack. My department chairman at Washington University, Dr. David Kipnis, gave me the opportunity to pursue a unique career, to be an academic internist with a significant academic participation at a first tier level in the history of medicine. No one had done that before, combining the two in that fashion. And he used conventional medical instruments, educational instruments to help me achieve those goals.

What we have in internal medicine are what are commonly -- all of medicine what are commonly called post-doctoral fellowships so say you finish

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a residency in internal medicine and you want to become an academic cardiologist. So you do a cardiology fellowship for a few years and that means you spend a portion of your time in clinical cardiology. But if you have academic goals, most of your time is in research. So we created a self-designed fellowship in general internal medicine in which I combined work in general internal medicine with what I did for most of the time which was research and study in the history of medicine. It gets complicated, and I apologize.

Q That's all right.

A I went back to Harvard for two academic years and did work full-time in the history of medicine and history of science and discovered medical education. The summers I came back to St. Louis to meet my clinical obligations for the fellowship and I attended on the medical service of the Veteran's Hospital.

Q What did that entail?

A That entails being responsible for a resident, an intern and a team of students, supervising them in their care of patients and teaching them as you go.

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Q So here when it says instructor of medicine, you did not actually teach students in a classroom?

A That is not entirely correct. Most teaching in all clinical departments is bedside and small group teaching. That is the type of teaching that I engaged in and that is the type of teaching that everyone engages in and most of the teaching that I did then and that I do now is of that sort. In addition to that, I'm talking clinical, I'm talking internal medicine, and clinical departments, the same would be true of pediatrics or surgery. There are conferences, there are rounds, and occasionally faculty members will give a talk on this subject or that subject or present a grand rounds and I have done some of that also.

But unlike the arts and science campus where a professor of history including myself will have a course on the history of medicine, as an instructor in internal medicine I don't offer course in internal medicine, I assume responsibility for the care of a group of patients and the students and house staff who are involved with their care and it is a small group, informal, teach as you go, this morning's discussion is going to be determined by who was admitted last night and what those issues involved and that type of thing.

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Q From '79 to '86, according to your CV, are you both and assistant professor of medicine at the School of Medicine at Washington University, and an assistant professor of history, Faculty of Arts and Sciences at Washington University. How did your duties change in those years from the prior years?

A There was an intervening year that we might mention. It is a year that I'm proud of so I mention it. But I was chief resident in internal medicine for the Washington University system. That was an entirely clinical year. It was not an historical year. We had two chief residents who essentially ran the clinical service and the teaching service in internal medicine. And if you will permit to say so, it is a great distinction to be chosen to be the chief resident and had always been a dream of mine. I was very product of that. That was '78, '79.

Q Does that include more administrative work than being the instructor of medicine?

A There is a bit more administrative work. Now the job has changed, by the way, because I was chief resident in '78, '79. But a chief resident has different duties today and has more administrative duties today than at that relatively simple time not that long ago. Yes, there are more administrative duties because you are making up the schedule and that sort of thing. The single hardest administrative duty was actually that because we had about 85 to 90 house officers. I'm defining the house officers as the interns, the first year residents and the second year residents. So we had to make up their schedule for the year. We also note that we had certain services to cover. We had four floors in private service, we had three floors in what we then called ward medicine, we had a Veteran's Hospital we had to staff, we had the city hospital, now closed, but we had a municipal hospital, we had to staff that, we had emergency room, we that coronary care room, we that electives. We had to keep them all staffed.

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It was our job to arrange each house officer's schedule on this month you are on ward medicine, the next month you are in emergency room, two months of private medicine. We had to make up the call schedule. Not only are you on

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ward medicine, but you are admitting every third night or every fourth night, this is when you are on, this is when you are off, this is who you are working with. So there was a significant amount of administrative work to create such a schedule.

It sounds simple but when you have close to 90 people and before computers and all the services, you try to take into account people's wishes and preferences. My best friend is being married in February, can my vacation come in February, this sort of thing so I can attend. To tell you the truth, it was a ton of work to do then. Fortunately it was done before the year began. The year was like July 1 to June 30 and my co-chief resident and I worked on the schedule like April and May. So by the time the year began it was pretty smooth going. The hard administrative job had been done. Putting together that schedule was a bear.

Then there are minor administrative things that come up all along. If there is a problem in the clinical service. One of the honors of being chief resident is that you are the one who is called and you resolve this issue, you put out that fire. So there is more administrative work

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than I had subsequently when I was actually a full faculty member. I didn't have to worry about some of the things they year when I was chief resident.

MS. MOLTZEN: Off the record.

THE VIDEOGRAPHER: Going off the record for a tape change. The time is 10:19 AM.

(Short recess was taken.)

(Deposition Exhibit Nos. 7 through 12 were marked for identification.)

THE VIDEOGRAPHER: We are back on the record. The time is 10:30 AM.

Q Dr. Ludmerer, from 1979 to 1986, you were assistant professor of medicine at the School of Medicine and assistant professor of history at the Faculty of Arts and Sciences both at Washington University. How did your duties change with those two new positions?

A I don't understand the question. How did I do the change?

Q How were those jobs different than what you had been doing previously which was it looks to me like chief resident and instructor of medicine?

A As chief resident, one is given the faculty title instructor. Essentially what happened in 1979 was I finished my training and joined the faculty.

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Because I was fully trained both in internal medicine and in the history of medicine, I qualified for an academic appointment in both departments. I was actually the first person that I'm aware of in the university who received a full academic appointment in two departments, in two different parts of the university. So I became an assistant professor of history in the Faculty of Arts and Sciences and assistant professor of medicine in the School of Medicine. I was on the tenure track. But essentially the earlier part of the CV deals with education and training, earlier research experience and so forth. Now I'm a faculty member, assistant professor.

Q What did that entail?

A It entailed clinical work, teaching and research. And the history of medicine side it together because the great gift that the department of medicine gave to me was in allowing the work that I did in the history of medicine to count as my scholarship in the department of medicine. I did not have to moonlight as a historian and do laboratory work during the day or clinical studies during the day or drug trials during the day. I had to be productive in a scholarly fashion as all

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members of the academic track were expected to be. As a publisher perish, if you don't get tenure, you are booted out type of thing.

But their gift to me was allowing my scholarship in the history of medicine to count. So I met my clinical obligations as an attending physician, attending on the internal medicine service, at that time I would estimate five months a year. That was similar to the attending I had done as a fellow. I had a resident and intern and couple of students and be responsible for that group of patients. The teaching would be small group tutorial individualized based on the cases. Every once in awhile you get asked to give a lecture or to take rounds or to do teaching with a larger group of people.

So from the department of medicine side I lumped the clinical and the teaching together because they go hand in hand. In the history side I began offering a similar course in the history of the American medical profession which I continue to do today. I would have occasional students, usually undergraduates, sometimes graduates, who would do research electives with me, tutorials, theses, dissertations, that type of

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thing, and the majority of my time was in research and the research was the history of medicine. And it was during that time that I wrote my second book, Learning to Heal, on the creation of how the system of medical education in the United States, where medical schools came from, where the teaching hospitals came from, how our system of educating physicians grew.

Q Then in 1986 you become associate professor both at the School of Medicine and on the Faculty of Arts and Sciences. Did your work change at all with that promotion?

A Not in any substantive way. I was promoted, I received tenure, so you are higher up in the academic ladder. But essentially my duties were the same. As one becomes more senior on the faculty, at least at my school sometimes it is more committee work, often on an ad hoc basis. I have always had a very close relationship and continue to do so with the chairs of both history and internal medicine as well as with the Dean of arts and science and the medical school as well as with the Chancellor of the university. Frequently each of those individuals would call me with special projects or I could appreciate your advice

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or input on this or that. As I was tenured in associate professor there was a bit more of that than there had been.

But the main change is that on the basis of the book that I mentioned, Learning to Heal, I was promoted, I got tenure, I knew I wouldn't have to leave St. Louis, and could relax in that sense. There was really no substantive change in my duties. The teaching clinical work and research and scholarship and history of medicine continued onward as it had before.

Q Were you still doing the same amount of clinical work? You had testified approximately five months a year.

A At that time we were doing -- at that time I was on one service or the other approximately five months a year. That didn't mean that it took all day every day to be on the service. It usually took the morning. Attending regulations at that time were not as stringent as they are now in terms of recordkeeping and documentation. So it didn't mean that I was all day long occupied. But I was responsible for a service approximately, in most -- it would vary from year to year. But on the average about five months a year. That was

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divided between Barnes Hospital, our main university teaching hospital, and the John Cochran Veteran's Hospital which is two or three miles from the university, it is an acute care Veteran's Hospital. We have a service there, all of our medical students and all of our Washington University internal medicine house staff rotate through the Veteran's Hospital, and accordingly we need some of our faculty to do attending rotations there. I did some of my attending rotations at the Veteran's Hospital and some back at Barnes, the mother hospital.

Q Then in 1992 you became a full professor of medicine at the School of Medicine and a professor of history on the faculty of arts and sciences?

A That's correct.

Q Does that continue up to the present?

A That is correct. I was promoted to full professor both in internal medicine and in history on the basis of my scholarship in the history of medicine. As I mentioned to you before, the gift that the department of medicine gave me was allowing scholarship in the history of medicine to count for the department, as long as it pertained to medicine, and they accepted that. That was

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novel. Other people are doing that today with positions based on mine. To my knowledge my appointment was the first that allowed me to do that clinical department to be a doctor and have an historical scholarship count as my scholarship instead of having to go through genetics and be a doctor. So I was promoted to full professor in both departments on the basis of progress accomplished to that point on what became my third book and my most recent book called Time to Heal. That was published about two and a half years ago. It hadn't come out yet but I was getting grant support for the book. I could demonstrate progress was occurring, people were excited about it, and I was promoted to full professor in both departments, and as with my promotion from assistant to associate professor, it was largely a change of stature. It is a greater honor to be a full professor than an associate professor. It was even easier to have the ear of the Dean or the Chancellor or the department chair in the history of medicine or that sort of thing. There were not any substantive changes in my work.

Q That was going to be my next question. Were you still doing about five months per year of clinical

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10:44 **work? Are you still doing?**
10:44 A Actually now it is about four. Somewhere in the
10:44 early or mid nineties when all of the hospital
10:44 mergers are occurring and all of the consolidation
10:44 of the health care system was occurring in
10:44 response to the possibility that the Clinton
10:45 administration might pass legislation, somewhere
10:45 around that time Barnes Hospital merged with
10:45 Jewish Hospital, which is an ancillary Washington
10:45 University teaching hospital, they are across the
10:45 street from each other, and then the house staff
10:45 merged, the Jewish Hospital used to have its own
10:45 house staff and we would have our house staff.
10:45 Now we have one house staff. The service became
10:45 larger, more complex, more to cover, and we
10:45 switched from -- and also with that we wanted to
10:45 give our students more ambulatory instruction
10:45 rather than pure inpatient instruction. To do all
10:45 of the, with the merger and the desire to increase
10:45 ambulatory instruction, from the time I had
10:46 arrived at Washington University in the mid
10:46 seventies as an intern through the mid nineties,
10:46 the clinical rotations were six weeks in duration
10:46 and I would have typically four rotations. With
10:46 these mergers that I have been describing, the

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10:46 clinical rotations were shortened to four weeks.
10:46 So and then I had four rotations as before but now
10:46 we are talking four week rotations rather than six
10:46 rotations. So on average my time in the clinical
10:46 service changed from about five months to four
10:46 months.
10:46 **Q Since 1979 have you maintained an office for the**
10:46 **private practice of medicine?**
10:46 A I do not have an outpatient practice. I'm part of
10:46 the Washington University faculty practice plan
10:47 which means that when I see patients they are
10:47 considered my private patients, and billing is
10:47 done by the Washington University business
10:47 department and I'm the physician of record and
10:47 responsible physician.
10:47 For various reasons my clinical work from the
10:47 beginning through the present has entirely been on
10:47 the inpatient service. I have not had an
10:47 outpatient practice following individuals as
10:47 ambulatory patients. If I were coming along today
10:47 it is very possible that I might have. But at the
10:47 time we did not have the division of general
10:47 internal medicine. I was only a general internist
10:47 on the full-time faculty of an intensely
10:47 research-oriented medical school which I think is

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10:47 second this year in NIH grants. It was an unusual
10:47 appointment.
10:47 My chair and I felt that if I had an
10:48 outpatient practice, what if I needed to go to
10:48 Washington to do research, how could I be
10:48 responsible for Mrs. Smith if she had a headache
10:48 or needed to call. There were just logistical
10:48 problems that suggested that it would be wiser
10:48 that I do all of my clinical work on the inpatient
10:48 service. I think that for me at the time was the
10:48 right decision and that's what we did and that's
10:48 what we have continued to do through the present.
10:48 Now today we have the division of general internal
10:48 medicine which we didn't have at that time. I was
10:48 appointed to the office of the chairman. I still
10:48 am in the office of the chairman. If I were
10:48 joining the faculty today I would probably be in
10:48 the division of general internal medicine. It is
10:48 likely today I would have an outpatient practice
10:48 in addition to inpatient attending, but this is
10:48 today, that was then, and that's how things came
10:48 about.
10:48 **Q Have you ever had a professional license denied?**
10:48 A No, I have not.
10:48 **Q Have you ever had a professional license**

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10:49 **suspended, revoked or limited?**
10:49 A No.
10:49 **Q Have you ever had any disciplinary action taken**
10:49 **against you?**
10:49 A No.
10:49 **Q I believe your CV says that you published three**
10:49 **books, not your CV, your expert report, Exhibit 2**
10:49 **at Page 1 says you published three books, more**
10:49 **than 30 original articles concerning the history**
10:49 **of medicine, and numerous book reviews. Were the**
10:49 **articles and book reviews peer reviewed?**
10:49 A The articles were peer reviewed. To my knowledge
10:49 the book reviews were not, would not be common for
10:49 a book review to be peer reviewed. It is common
10:49 practice in the history of medicine for articles
10:49 to be peer reviewed and most, if not all, of those
10:50 articles were peer reviewed. For book review
10:50 generally either depending on the journal, if it
10:50 is a small journal, the editor will contact you.
10:50 If it is a large journal they will have a book
10:50 reviewer specializing in book reviews. But in
10:50 general a scholar is contacted by the journal. We
10:50 have this book, would you be interested, we would
10:50 appreciate a review from you, are you interested
10:50 and able, that type of thing.. And if I'm able to,

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I try to accommodate. But those are not peer reviewed in the same sense that books or articles are peer reviewed, sent out to referees. It would just take too much time and effort.

Q Did you ever submit an article or a book review for publication that was not accepted by a journal?

A I have never submitted a book review that was not accepted. I recall one or two articles early in my career during my graduate student and history days that was submitted and not accepted.

Q Do you remember the topics?

A Yes, I do.

Q What were they?

A One topic dealt with a man named John Shaw Billings who is an eminent figure in 19th and early 20th century history of medicine, extraordinarily broad individual in each of his contributions. He was a statistician, a public health officer, he was a demographer, he was involved with the US Census of 1880 and 1890. He was the creator of Index Medicus. He founded the National Library of Medicine. Later he became the first director of the New York Public Library, was a quote unquote scientific influential whose views

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were widely sought and consulted, to leading public and private individuals of the time.

He was also a pioneer in the new medical education, learning by doing and the importance of having full-time faculty and converting students from passive observers who would listen to lectures to active learners who had clinical clerkships and learn by doing and become active in the process. So the first paper I ever wrote or one of the first papers I ever wrote was on John Shaw Billings. I submitted it to a journal and it was too unwieldy and they rejected it.

Q Do any of your publications, the articles or the books, deal directly with tobacco and health?

A Can I tell you about my other article that was rejected?

Q Of course you can.

A I say this because someone stole and plagiarized it.

Q Go ahead.

A The first article I ever wrote was the summer between my sophomore and junior year in the history of science program at Harvard that I mentioned to you before. I discovered that the history of eugenics as a subject I was interested

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in and indeed that became my first book.

Getting back to your earlier question how do people write books. There are lots of ways to do books. In the three books that I have done, they have grown out of articles. I didn't just one day decide I'm going to write a book on the history of eugenics. I got interested in the subject, I started writing articles on this aspect of it, that aspect of it, term papers, this and that, the knowledge of the field and the interest in the subject grew, and ultimately I could see a book, and the book grew in that fashion. But the first article I wrote was entitled Madison Grant, Portrait of a Racist. And it was a study of one of the racists in the early American eugenics movement. It was a darn good college undergraduate paper.

I was spending the summer living with some graduate students in the history of science at Harvard. They were excited about the paper, thought I should submit it for publication. My advisor in the history and science program thought it was a very good paper, submit it for publication. I said okay. And I may be 19 years old at this time, I never published a paper

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before, there is that excitement of seeing your name in print. I didn't need a lot of encouragement to send this paper off.

So I said where should I send it? They said send it to the Proceedings of the American Philosophical Society. In retrospect that was kind of an odd place to send it because they usually don't accept papers that are submitted in that fashion, but I didn't know anything better. And fortunately they rejected it. And I remember my advisor at Harvard asking me did you see any referee notes? I said no, there weren't any. And he said that's really odd, usually whether they accept an article or not, particularly if they don't accept an article, there are referee comments and explanations and so forth. That's unusual. I didn't know any better. I had never submitted an article before. I didn't think anything of it. But it was that paper that led me to my college thesis. As I indicated before as my college thesis that led me to the book in medical school.

Flash forward four years. I'm now in the middle of my career at John Hopkins, I've completed the first two years of medical school,

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now I'm a graduate student in the history of medicine program and I'm working full-time on my book. I see the book, that's what I'm working on. I came across somewhere a reference to this newly published article called Madison Grant, Portrait of a Racist in some obscure journal published from the southeast part of the country. It was my paper word for word, over 30 manuscript pages, literally word for word.

And what clearly happened is someone who refereed it from the American Philosophical Society said that doesn't warrant in our paper, in our publication, it is not a bad paper, this guy is probably some pre-med who is never going to do history of medicine again, I'm going to take it for myself, I'm going to publish it someplace obscure where it is hard to track down and I've got a free publication. That's what happened.

And I remember thinking to myself at that time I'm glad that it is his name on the paper and not mine because my understanding of the subject had grown and matured, I could see a book now that I didn't four years ago. I could see it was not a bad paper but I was much more mature and sophisticated in my understanding on the subject,

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and I remember thinking I'm glad that it is his name and not my name associated with it. I felt good about myself. I had internalized some of the proper values of publication, it is important the quality of the work that you do, not just publication for the sake of publication of getting your name out, that sort of thing.

So I mentioned it to my advisor who thought we should pursue things. I said no, let me just finish my book and I never did anything. Years later when I'm a little older and more mature, I thought back and I got to tell you I was annoyed, that that was not a nice thing that that person did to take my paper and published it under his name. And I tried to find it and I could not find it. So I have never been able to take action in that sense. So he did do a good job of burying it. That was the other paper that was not accepted for publication. It is out there under someone else's name somewhere.

Q I will ask the question that I didn't let you -- that I asked before you had finished your answer. Do any of your publications, the three books or the more than 30 articles, or even the book reviews, deal directly with tobacco and health or

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smoking and health?

MR. WOODS: Objection.

A Not directly. Indirectly in the sense that they deal with scientific knowledge and its evolution, and both the concepts and techniques are pertinent to understanding the subject of tobacco and cigarette smoking and health but they were not specific studies of cigarette smoking or health related issues.

Q Your CV also lists eight research grants. Were any of those grants for research into any aspect of cigarette smoking and human disease?

A No, they were not. They all in some fashion supported the work that I have done on medical education, US teaching hospitals, US medical schools and American health care delivery system.

Q Do any of the publications, again the three books or the 30 original articles or the numerous book reviews, do you indicate any of those publications that you have testified for the cigarette industry?

A I don't indicate mainly because it never occurred to me it would be significant; different topics, no conflict of interest. Historians consult on different types of topics regularly, more

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regularly today than in the past. I don't comment and it did not seem to me it was necessary to do so.

Q Who is it that you understand yourself to be working for in this case?

A In terms of plaintiff or witness experts? I'm not sure I understand the question. If you can rephrase the question.

Q Do you consider yourself to be working for all of the defendants in this case, or one particular defendant in this case, or for a law firm that has hired you?

A My understanding is that if I am asked to give expert testimony in this particular subject matter, that it applies to all of the companies that have been listed in the defense, that is my understanding, as opposed to Philip Morris alone or Lorillard alone, or something of that sort. That's my understanding.

Q This list that I had gen you before which was Exhibit 5, that only lists the deposition testimony and the trial testimony for the past four years. Do you know how many other times you have been deposed besides these six listed here?

A To the best that I can recall there was one

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11:01 deposition and one trial in what I call the early
11:01 phase of my involvement. We are talking late
11:02 eighties, early nineties. Because there was a six
11:02 or seven year period that I had no contact at all
11:02 with any of these issues. But back in late
11:02 eighties, early nineties, there was one deposition
11:02 and there was one trial.
11:02 Q What was the name of the case that the deposition
11:02 was in?
11:02 A The deposition was for the retrial of the
11:02 Cipollone case. I was not a participant in the
11:02 original Cipollone case. As you know that
11:02 apparently is the first individual smoker case
11:02 that was lost by the defense. Apparently the
11:02 judge issued an order for a retrial, and I was
11:02 originally contacted to be a witness for the
11:02 second Cipollone trial or the retrial, whatever
11:03 the correct terminology would be, and I did give a
11:03 two day deposition for that. Every other
11:03 deposition in here has been one day or even a few
11:03 hours. That was the longest deposition that I
11:03 have given. I don't know what that would be
11:03 called, retrial of Cipollone, Cipollone 2, but
11:03 that was the case.
11:03 Q And you said you had testified at another trial

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11:03 that is not on Exhibit number 5. Do you remember
11:03 the name of that trial?
11:03 A Yes, I do. That would have been the Kotler case.
11:03 That is Kotler with a K, if my memory is correct,
11:03 K-o-t-l-e-r. It was an individual smoker case.
11:03 The trial was held in Boston. That would have
11:03 been, if my memory is correct, 1991, early 1991, I
11:03 think like February of '91. And I appeared in
11:03 that case.
11:04 Q Do you remember the results of that case?
11:04 A There was a verdict in favor of the defense.
11:04 Q Just talking about depositions now. Have you ever
11:04 testified against the tobacco industry in your
11:04 depositions?
11:04 A No, I have not. By testified against, you mean by
11:04 a plaintiff?
11:04 Q Yes. Have you ever testified for a plaintiff in
11:04 any case, in any depositions?
11:04 A For a plaintiff. The experience I have had to
11:04 date has been at, the requests I have received
11:04 come from the defense. So the involvement to this
11:04 moment through this moment has been on the defense
11:04 side. The answer to your question would be no, I
11:04 have not been asked to give my testimony by a
11:04 plaintiff.

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11:04 Q Have you always been retained by Shook Hardy?
11:05 A No.
11:05 Q What other firms have you been retained by?
11:05 A I couldn't tell you precisely which firm for which
11:05 case. If my memory gets --
11:05 Q That's fine.
11:05 A To me there are a string of names. But the firms
11:05 that -- the firm other than Shook Hardy that I
11:05 have had the most contact with is the Arnold &
11:05 Porter law firm of Washington D.C. It was
11:05 actually members of the Arnold & Porter law firm
11:05 who initially contacted me back in the late
11:05 eighties. So the work that I did at that time
11:05 when I did my original work, the retrial of
11:05 Cipollone, that was Arnold & Porter. There have
11:05 been other firms as well. Arnold & Porter. If I
11:06 were -- the third firm where I have had no recent
11:06 contact but I had contact in the past was the
11:06 Decker Price firm which is East Coast. There are
11:06 individuals in their New York and Philadelphia
11:06 office that I had contact with. So I would say
11:06 those three firms are the ones that I have had
11:06 most of my contact with. In the last couple of
11:06 years it has been mainly the Shook Hardy Bacon law
11:06 firm. At the beginning it was mainly the Arnold &

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11:06 Porter law firm.
11:06 Q Do you remember who contacted you from the Arnold
11:06 & Porter law firm?
11:06 A Yes, I do.
11:06 Q What was his or her name?
11:06 A His name was and is Murray Garnick.
11:07 Q Did he initiate the first contact with you or did
11:07 you initiate the first contact?
11:07 A He initiated contact with me.
11:07 Q What was the -- did he ask you to do some kind of
11:07 job for him?
11:07 A Ultimately it led to that. It wasn't quite that
11:07 simple. But he explained to me that he was with
11:07 the Arnold & Porter law firm, that he was involved
11:07 with the defense at least at that time of Philip
11:07 Morris, that they had lost the Cipollone case, and
11:07 from what he told me an important issue in the
11:07 Cipollone case was the state of the art of our
11:07 understanding of how we came to know that lung
11:08 cancer was caused by cigarette smoking, and that
11:08 they were desirous of having a witness both with
11:08 the historical and medical qualifications to
11:08 address this issue and speak to it credibly and in
11:08 an objective and unbiased and fair fashion.
11:08 It was his claim to me that in the original

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trial the plaintiffs had a witness who was not an historian but speaking to history who was distorting the facts of history and that was one of the issues that needed to be addressed in the retrial. They wanted their own state of the art expert.

So I discussed it further with him and there were a number of important qualifications that we had. Number 1, would I have the freedom to pursue this completely, independently and thoroughly in ways that I thought were historically responsible and necessary, and his feeling was of course we wouldn't have it any other way. I said that I'm going to call it as it is, I don't know what I'm going to find. He said we have no problem with that. I said I want complete control over this. We wouldn't want it any other way. I was still a bit uncomfortable basically for the reasons that you asked before, because I do think cancer causes smoking -- that cigarette smoking causes cancer and we have known that since the Surgeon General's report and there was evidence building up to it before that. That's the common wisdom. I do consider cigarette smoking to be one of the great public health menaces in our country today. With

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my own patients if they smoke I tell them to stop. If they don't smoke, I tell them not to start.

So I said well let me see the testimony of this fellow. And I found that he was fraudulent. He was literally changing the facts of history to build an evidence case, literally changing the facts of history, and it was disturbing and troubling to me. The history in my view needs to be represented fairly. I felt an advocate of history, not an advocate of cigarette smoking, but to change history to support any cause, you start sending documents, getting x-rays before one can discover x-ray just occurred to me there is no limit to the mischief that can be done if you start changing the facts to support your view of the day. That's when I had the conversations that I mentioned to you before with all these people at the university, including my department chair and medical school Dean and people of that sort, and that's when I agreed to take the project.

The conditions with Murray Garnick were that it is my project, not yours. I will certainly alert you to what I find. I'm not going to sugarcoat things for you. I'm going to tell you what I find. This would be my project, not yours,

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I'm going to do it in a thorough, responsible fashion as I would anything I do in history, anything I have ever done. And let's make it clear that I'm speaking strictly historically. I'm not commenting on cigarettes as a health hazard. I am on record, cigarette smoking causes lung cancer. I'm not speaking to issues of subsequent 30, 40 years or company behavior, that sort of thing. I'm looking strictly historically.

My counselors at the university thought that was appropriate, if I did it responsibly, if I spoke strictly historically. Murray Garnick gave me the freedom to pursue this in a thorough, responsible fashion and I agreed. That's how I got started.

Q Who was the witness that testified at Cipollone?

A Jeffrey Harris.

Q And when you were reading his testimony, how did you know that he was distorting the history?

A He violated each of the general principles of history that I had mentioned to you before. I saw his report and I actually had original sources. He went so far as to commit fraud.

Q Did you know that, at the time you were reading the report did you know that, or did you have to

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do some research yourself before you knew that or believed that what he had testified to was fraudulent?

A Largely the latter. He was contending in that case that it was a scientific consensus known by everyone that cigarette smoking causes lung cancer in the 1930's. As a historian, even if you don't specialize in an area, you still keep up with the literature and there is a body of knowledge. And I had read work about cigarettes and the history of smoking. I had been a medical student and a physician myself. That was different from anything I had ever heard from anyone. So many of the claims of the report itself violated anything that I had ever seen written. It violated the common teaching about the subject both from the historical side and from the medical side that usually points to the first Surgeon General's point is the termination point when the consensus, when our present consensus emerged.

In addition, Murray Garnick included references that Dr. Harris used. Dr. Harris submitted an expert report and it looked very scholarly. He would literally -- he perpetrated fraud. He would do things like this, Ms. Moltzen.

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11:15 Say, for example, Mary Jo Moltzen would write an
11:15 article in the Journal of the American Medical
11:15 Association in 1936 and say the following. The
11:15 lung cancer appears to be increasing in frequency.
11:15 We are not certain if this is real or perceived
11:15 increase but certainly we think it is increasing
11:15 in frequency. The cause of lung cancer is
11:15 presently unknown. A number of factors have been
11:16 suggested as possible causes. Then he would list
11:16 15 or 20 causes, influence of pandemic of 1936,
11:16 air pollution, tarring of the roads, tomato juice
11:16 which was invoked for a brief while. Then he
11:16 would say a few people have suggested that
11:16 cigarette smoking causes lung cancer; however,
11:16 there is no data at the present time to support
11:16 any of these hypotheses, there is no data to
11:16 support the idea that cigarette smoking causes
11:16 lung cancer. At present we must consider the
11:16 cause of lung cancer unknown. That's what the
11:16 article would say.
11:16 In his expert report he would say Dr. Mary Jo
11:16 Moltzen writing in the prestigious Journal of the
11:16 American Medical Association in 1936 wrote, quote,
11:16 cigarette smoking causes lung cancer. He would
11:17 take those five words totally out of context. He

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11:17 would have a footnote of the citation so it would
11:17 look scholarly and authoritative but it was
11:17 fraudulent. As a historian I was troubled by
11:17 that. Just as a laboratory scientist would be
11:17 troubled by the discovery of fraud or creating
11:17 data or changing data. It was extremely troubling
11:17 to me to see the historical record literally
11:17 distorted in that type of a fashion. And that was
11:17 my conflict back in the eighties. Boy, cigarette
11:17 smoking is terrible.
11:17 Then I saw history being misrepresented in
11:17 this case, being changed, and I also very strongly
11:17 felt the advocate of history and not changing the
11:17 facts because of the case at hand and that's how I
11:17 got started. That led to the conversations that I
11:17 have related to you and that's how I agreed to
11:17 take on the case.
11:18 Q Garnick along with Jeffrey Harris's testimony you
11:18 said sent you reference materials. Throughout
11:18 that initial time when you were working for him
11:18 did he continue to send you documents?
11:18 A No, he did not. The only things that he sent me,
11:18 and I don't remember the exact sequence of events
11:18 because we are talking 14 years ago, but this was
11:18 early. The only thing he sent me on his own was

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11:18 the report and the documentation of the report.
11:18 And, if I recall, I asked to see that. He didn't
11:18 just send it to me. It came up in the
11:18 conversation, and I thought that before I made any
11:18 decision about my participation I should see that
11:18 report and quite frankly I don't remember if I
11:18 asked to see it or if he suggested it might be
11:18 useful to me in making a decision. We had a
11:18 conversation of that sort. He did send me the
11:19 material.
11:19 From that point on everything that I looked
11:19 at, everything in all of my bibliographies both
11:19 primary and secondary sources were things that I
11:19 did on my own initiative and found on my own.
11:19 That was the only thing he sent me. The sole
11:19 qualification would be that they had access to a
11:19 translation service and I surveyed the world's
11:19 published literature and fortunately the
11:19 overwhelming majority of it was in the English
11:19 language and even the Scandinavian countries like
11:19 that they tended to publish in English. But there
11:19 were occasional papers from South America or
11:19 Germany or France where I didn't speak the
11:19 language and thought it was important to review it
11:19 and I asked him if he could have them translated

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11:20 for me, so that was my request. They had some
11:20 sort of translation service, so at some future
11:20 time I would get the translated version of
11:20 articles that I asked myself to see.
11:20 Q That was going to be one of my later questions.
11:20 Do you speak any foreign languages?
11:20 A I used to be okay at Spanish but I'm not now.
11:20 Q Do you read any foreign languages?
11:20 A I used to be pretty good at Spanish but I'm not
11:20 now. There were some Spanish articles that I
11:20 wanted to see, and rather than trust my Spanish, I
11:20 asked for the translation service.
11:20 Q During that initial project from Mr. Garnick did
11:20 you have other meetings than the initial
11:20 conversation with him?
11:20 A Well, the initial conversation or two, I don't
11:20 remember if they were one or two or three, early
11:20 conversations, which led to my examination of the
11:21 Harris report, the claims he made, as I said what
11:21 was troubling to me was the way he went about
11:21 making the claims, that led to my undertaking the
11:21 project that I did to study the history of our
11:21 understanding of the causes of lung cancer and
11:21 particularly in relation to cigarette smoking.
11:21 That was 1988, 1989 that I did that project. And,

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11:21 as I said before, this once I got going was
11:21 totally my own initiative and direction and there
11:21 was no outside interference. There wasn't even a
11:21 glimpse of it. I did it as I would any historical
11:21 project of my own for publication. I don't recall
11:21 exactly, but over that time every few months we
11:21 have a meeting and I would present my findings and
11:22 we would discuss things.
11:22 Q Only to him or were there other attorneys also at
11:22 these meetings?
11:22 A At that time there were generally other attorneys.
11:22 Q What were the most number of attorneys that were
11:22 in any of these meetings?
11:22 A The most? Not all meetings were that large, but
11:22 there were meetings where there might have been
11:22 eight or 10. Most would be smaller with Murray
11:22 and one or two other people. I would say
11:22 typically there might be two or three attorneys.
11:22 But to answer your question what was the most?
11:22 I'm guessing eight or 10.
11:22 Q Let's get back from our shortcut to Mr. Garnick
11:22 and go back to, we were talking about the times
11:22 you have been deposed and my next question is have
11:23 you always testified as an expert witness as
11:23 opposed to a fact witness? If you don't know the

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11:23 differences, I will be glad to tell you.
11:23 A Please explain it to me. I don't understand.
11:23 Q A fact witness would be someone who would not be
11:23 paid for and they would, let's say in a car
11:23 accident, they would be on the side of the road
11:23 watching the accident and coming to court and
11:23 explaining what happened. Whereas the tire expert
11:23 or the brake expert might come in and say in most
11:23 cases by looking at these tread marks my expertise
11:23 says that he didn't put on the brakes. Have you
11:23 always testified as an expert as opposed to a
11:23 fact?
11:23 A It is my understanding the answer would be yes,
11:23 that I have always been an expert witness, as you
11:23 have defined it.
11:23 Q Have you ever been retained and prepared an expert
11:23 report like this but then you did not have to
11:23 testify at either deposition or trial?
11:23 MR. WOODS: Objection.
11:24 Q Not counting -- no.
11:24 A There are a couple of dimensions to that reply.
11:24 One I find very humorous. I have never at least
11:24 to date testified in a trial for which I have been
11:24 deposed. The depositions that I have given for
11:24 whatever reason either the cases were settled or

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11:24 they decided not to use me, or the cases went
11:24 away, I don't know. You understand this aspect.
11:24 I don't. I have not testified in any of the cases
11:24 for which I was deposed. Conversely, in each of
11:24 the cases for which, and there have been counting
11:25 Kotler in 1991 a total I believe of five, in none
11:25 of those cases was I deposed. Somehow calls came,
11:25 can you testify. So there were no depositions.
11:25 And there have been cases that I have declined to
11:25 testify for on tobacco related issues and other
11:25 issues largely because of other obligations and
11:25 lack of time.
11:25 Q Have you prepared expert reports for all of the
11:25 cases that I have on Exhibit number 5?
11:25 A I don't think so. And the reason for that is this
11:26 disconnect between depositions and trials.
11:26 Because for the Williams trial, Anderson trial,
11:26 there are four trials listed here, and I do not
11:26 recall having a statement such as the one that we
11:26 have for here. There was a call, a trial is
11:26 coming up, are you available, are you willing to
11:26 do so. I could be mistaken, and maybe there was
11:26 an expert statement from one of those, but in
11:26 general I do not remember expert statements for
11:26 the trials. There were expert statements that I

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11:26 remember for most of the depositions, but not for
11:26 the trials.
11:26 Q That's not unusual. But my question, now let's
11:26 twist this around. Have you ever written,
11:26 however, an expert report, and then you were never
11:27 called for the deposition and you were never
11:27 called to testify at trial? Can you remember an
11:27 expert report like that?
11:27 A That has happened. I couldn't give you the names
11:27 of the cases. But largely it has to do with
11:27 individual smoker cases and I might receive a call
11:27 in an earlier period from Arnold & Porter or more
11:27 recently from Dave Woods at Shook, Hardy & Bacon
11:27 and say there is a case in Vermont that has been
11:27 put up, in two years it might go to trial, can we
11:27 list you as a witness, and sometimes I will say
11:27 okay, fine, often there is an expert statement
11:27 that I sign associated with that and then nothing
11:27 ever happens, the case is dropped. The expert
11:27 statements would be very similar to the one that
11:28 you have seen for this case, but that has
11:28 happened. That for whatever reason the case is
11:28 dropped, dismissed, goes away, I don't know. But
11:28 I never hear anything further. As I have also
11:28 mentioned, sometimes I'm not able to testify if

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I'm too busy.
Q Do you have any idea, an estimate of the number of times that you have written a report and it has never gone any further?
MR. WOODS: **Objection.**
A I'm not sure --
Q If not, that's fine.
A -- what you mean by going further. Do you mean the case being dropped?
Q Deposition or trial. You have written an expert report but you have not been sworn, given sworn deposition testimony or sworn trial testimony. Do you have an estimate of the number of times?
A My guesstimate, I will put guesstimate rather than estimate, we are not talking a huge number of cases. We are talking a handful.
Q Five?
A Three, four, five. That is a guesstimate. It could be as low as one or two, maybe even seven or eight. I don't know. I'm just working away as a doctor and trying to do my book and I get a call from Dave, from Mr. Woods, we got a case in a couple of years in Austin, Texas, can we list you, and I said well, as far as I know my schedule is open in a couple of years, go ahead and list me.

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That has happened a few times, three, four, five, I'm guessing at that number.
Q I have asked you this question as far as depositions went and I have given you my definition of a fact witness versus an expert witness but that was with depositions. So the question again now for trial testimony. Have you ever testified -- have you always testified as an expert witness at trial?
MR. WOODS: **Objection.**
Q Rather than a fact witness?
MR. WOODS: **Same objection.**
A As far as I understand from the definitions that you have given me, I have been an expert witness at trial.
Q Is Deposition Exhibit 5 which lists the trials and depositions over the last four years, in each of those four trials and those six depositions that you have testified at, did your opinions -- did your testimony always deal with medical knowledge and the relationship to smoking and health or smoking and disease?
MR. WOODS: **Objection.**
A The testimony that I have given in each of these cases has been very similar. It has always been

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historical. It has always been on the evolution of our understanding of the causes of lung cancer and particularly in relation to cigarette smoking so it has been similar historical testimony, early 20th century culminating with the Surgeon General's report in '64. There is the same -- nothing has changed about that from one deposition or trial to another.
THE VIDEOGRAPHER: Going off the record for a tape change. The time is 11:27 AM.
(Short recess was taken.)
THE VIDEOGRAPHER: We are back on the record. The time is 11:35 AM.
Q Dr. Ludmerer, when you are working on one of the tobacco cases, what percentage of your total, I will let you use the time period, your total workday, your work week, your work month is devoted to working on the tobacco litigation?
A I would estimate that for the duration of this period that you have here on Exhibit 5, that the last four years which is around the time that my participation resumed, I think I mentioned to you that I had that early activity the late eighties, early nineties, then literally no contact at all for roughly a six year period and then things

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resumed somewhere around here. I would estimate that since the resumption of my involvement with the depositions and trials that you have listed here, through the present, that my work as an expert witness accounts for five percent or less of my professional time. I would estimate probably closer to three or four percent. I am talking in terms of a year. Obviously today all day long is the deposition. But I'm not going to be deposed -- whenever the deposition is over I'm going to be back doing my regular thing. Cumulatively over the course of a year I would say somewhere between three and five percent of my time is involved with these types of -- these types of cases.
Q Has your medical or business conduct ever been subject of investigation by a professional review organization?
A No.
Q Has it ever been the subject of review or investigation by a law enforcement authority?
A Are you talking about my work as a doctor?
Q Your work as a doctor.
A No, I have never had any questions or investigations of that sort.

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Q Have you ever brought a lawsuit?
A No.
Q Have you ever been sued?
A No.
Q The judge in this particular case is Judge Gladys Kessler. Have you ever appeared before Judge Kessler before?
A To my knowledge I haven't. I do not recognize that name.
Q If you look at your expert report that is Exhibit 2, on Page 1, the third paragraph and it says, "I understand that defendants may call me to testify in this matter on the issue of the evolution of medical knowledge of smoking and disease." I want to qualify that statement a little bit. When you talk about the medical knowledge of smoking and disease, are you limiting it to the scientific and medical community?
A That is correct. In this report the term medical and scientific are often used interchangeably. I'm referring to our scientific understanding, or medical understanding to use a synonym, in distinction to popular perceptions, common knowledge. Those are issues that I do not address. If I may make one other qualification

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that I just happened to notice. I'm really talking cigarette smoking, not all smoking. I'm not talking about pipes and cigars and other forms and earlier forms of smoking. If I were writing this today I think I would insert the adjective cigarette before the word smoking.
Q What about that last word, disease, would you keep that as all disease or would you change that to lung cancer?
A I think I would essentially respond as I did before, the focus is lung cancer. But you cannot investigate this literature without discovering that cigarette smoking became associated in some cases in the causal fashion with other diseases as well. So the focus is lung cancer on the other hand, particularly in the pre 1964 period. I certainly did learn of other associations.
Q And again when we are talking about medical knowledge, are you limiting this to knowledge of those in the United States, the scientific and medical community in the United States, or do your opinions deal with world wide?
A The latter, world wide. The scientific community as you know is an international community. Workers in United States read publications in the

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Netherlands or France or England and vice versa. And the literature that I consulted was international literature. So two important qualifications to reiterate are scientific community in distinction to popular perceptions and that indeed the international views, not necessarily US views alone.
Q When you talk about the medical and scientific community, does that include the scientists who worked for the tobacco industry?
A It does if they published in the subject. Scientists from any industry are part of the bonafide members of the scientific community. I studied the published scientific literature and insofar as they have -- as they may publish articles on the subject, then I encountered those in my research and encountered those in my view. I did not take it upon myself to examine laboratory notebooks, unpublished work of anyone whether they be at the NIH or medical school or cancer institute or at a company.
Q And because the research studies that you included in your expert report only are published works, does that put the context, as you described earlier, out of balance?

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MR. WOODS: objection.
A In my judgment absolutely not. It is an excellent question and one that is always enjoyable talking about with students and so forth. The scientific literature is the currency of science. It is the accepted way to understand the state of knowledge of the original papers, the review articles, the textbooks or whatever they may be. So now I should say, and I'm speaking as an historian now, that interesting questions can be asked and interesting information can be learned in select cases looking at how a certain scientist may have come to the published view that they did. How did Banting and Best discover insulin. There was an outstanding book on that subject by a fine scholar, Michael Bliss, who looks at the unpublished work and the notebooks and how did the ideas develop, it allows you to ask questions such as how hypotheses formed, how are they tested, what is the reality of life like in the laboratory.
Another great scholar in my opinion in the history of medicine, in the history of science, is Larry Holmes from Yale who has published a number of important books, very esoteric and take a lot

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of scientific understanding to read, but he has looked at Pasteur and Claude Bernard, I could give you some of the names, he has looked at Krebbs, the notebooks, and how did ideas develop. This is a sub theme in the history of medicine, not many people have done this type of research. There is a certain esoteric quality to it going through laboratory notebooks and that type of thing. I do wish to mention for completion. In general every published paper in any science is a pre-history, goes through drafts, you are always hammering it out in seminars and conferences and there is a pre-history to anything that is published. To look at the published literature what finally gets to the New England Journal of Medicine or Nature or Science or Cell or whatever the journal may happen to be, to review that literature is considered very acceptable in terms of understanding the current thinking of the time and also review articles are very helpful too.

Sometimes authors will --

Q I'm sorry, what is a review article?

A Review articles. By that I mean when you will take an expert in the subject who will review the state of knowledge 2002 on a certain subject or

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1948 on a certain subject. Not reporting a new finding, but what do we know about this subject, covering it from different aspects, from the published literature. A synthesis and interpretation of current understanding. You could almost call it a textbook chapter that appears in a journal as opposed to a book. Those are helpful too. But using the published scientific medical literature is a very acceptable technique.

Q I think it is on Page 2 of your report you say, throw away sentence, very top, "A summary of the opinions that I am expected to offer at trial is set forth below." Are the opinions that are set forth below in this report accurate and complete as of today?

A In my judgment, yes.

THE VIDEOGRAPHER: Going off the record. The time is 11:46 AM.

(Lunch recess was taken.)

THE VIDEOGRAPHER: Back on the record. The time is 12:23 PM.

Q Dr. Ludmerer, Page 1 of your expert report, the fourth paragraph, the first sentence says, "In conducting my study, I followed standard

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historical methods." Now I'm not asking for the specific methods here because we will go into your primary and secondary sources in detail. But when you say standard historical methods, what do you mean by that term?

A I'm referring to the discussion of techniques that we had before, the importance of understanding the context of the events that you are studying. Looking at secondary literature, both to get a sense of what other people have said about the subject as well as to give you a context to help interpret the events that you, yourself, are studying. Then appropriate use of primary sources. As we discussed before, the specific primary sources will depend on the topic. But making certain that the primary sources are identified, that they are looked at in a comprehensive fashion, not in a selective fashion. Either you look at everything or if you are not able to look at everything, you have a system to make sure that what you do see is representative and not biased, that you report accurately. Theoretical framework about the history of medicine, a seasoned historian will bring into the project to begin with what you already know in the

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general framework. The text of things we talked about before. But specifically understanding the context through secondary sources, and then identifying the appropriate primary sources and using them in an appropriate fashion.

Q That paragraph goes on to say, "My research had two parts; first I reviewed the secondary literature, that is the literature that people wrote after the fact." What do you mean by after the fact?

A Essentially someone looking back at a later point of time reflecting on things. Historical research -- excuse me, historical publications by definition are secondary publications. A biography of Abraham Lincoln would be a secondary source in contrast to letters that he may have written himself, diaries he may have kept, speeches or articles he may have written which would be considered primary sources.

Q What about a biography written, let's just say that Lincoln had written a biography in 1862 or an autobiography. Is that a primary or secondary source?

A Well it depends on the subject. And one can get philosophical and debate some of the esoteric

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aspects of these things. If a scholar today were writing a biography of Lincoln and Lincoln had written an autobiography in 1882, which or course he couldn't have, he was already dead, but say he had done so in 1862 when he was still alive, I would probably tend to define that as primary source. Because even though he is giving his interpretations and assessments and still at the time, I would suspect it would have a greater value as a primary source to today's historians than as a secondary source. These things can get esoteric.

For example, what if you have primary sources in a certain field, important articles in the history of the evolution of our understanding of lung cancer and cigarette smoking, maybe the most important clinical and pathological studies. Well essentially they are primary sources, they were published at the time. But what if you collect these into a published book that you can use in a classroom so you are reading it. Historians have debated whether that becomes a secondary source or primary source. It is possible to at the edge of to engage in debate about what constitutes a primary source and a secondary source. In general

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it is pretty straight forward. I think that today Lincoln's autobiography from 1962 that would probably be a primary source.

Q What processes did you use to -- you said that you shouldn't try to be selective, but at some point in time you had to select your secondary resources?

A That's correct.

Q What kind of process did you use to choose which secondary resources?

A Secondary? Well from my general background as an historian in medicine, I identified topics that I thought would be useful in providing a context, understanding this debate and this intellectual evolution. These sources were listed in the bibliography, secondary bibliography. Examples, what have others -- I'm talking 1988 and '89 when I did this project. What accounts of the tobacco controversy have been written, so I read pretty much all of the published accounts that have been written to that point in time to get a sense of the feel and what others were saying. I read work in the history of public and the history of preventive medicine, the history of cancer. It was interesting to learn how barren a field of

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research cancer was if you are looking the mid 19th century when it was an area that you went in only if you wanted to have a dead end career in science because the intellectual challenges was so great at that time. I read about the NIH and the development of research support for biomedical research. These are examples of the types of subjects that I read about when I did my quote unquote secondary research.

Q How did you select those particular topics?

MR. WOODS: objection.

A Experience as a scholar and teacher in the history of medicine made it clear that these were areas that were very pertinent to understanding the evolution of our understanding of the causes of lung cancer. Public health, the history of cancer, the history of cigarette smoking, the history of research support, they were from experience and previous research and previous teaching I had done and I knew these were relevant considerations to understanding that subject.

Q Were your selections, do you believe your selections were comprehensive?

A I believe that they were thorough and that they were representative. I have a list that is pretty

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extensive. I looked at everything I could find on the subjects that I've related to you so I believe that -- in fact, the second -- the study of secondary literature was one chapter of the research project, an entire chapter that I undertook at the time. We are talking 1988, 1989, it was in and of itself, if I recall correctly, the subject of one of the handful of meetings that took place between myself and attorneys representing some of the defense firms. So I did do it I think in a very fair and comprehensive and thorough fashion.

You have to set boundaries. I did not seek out to be exhaustive. I think it was pretty thorough and pretty comprehensive. Even more so, and I suspect you will get into this, when I got to the primary literature, there I made every possible effort to be completely comprehensive, an exhaustive effort not to miss anything, to make sure I saw everything. The secondary literature I think was done thoroughly and comprehensively. But I can't say that I missed an article in a book that might have helped.

Q You just said that it was the first chapter of your research project. But you are using that

What had been writte by 1989? After 1989?
Klugen + all other histories written Since Then...
Cippolone Case was what made Then histories possible? Yes?

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word chapter figuratively, correct?
A Correct.
Q You didn't really write a Chapter 1?
A The first thing I did.
Q Then my next question is, as part of that initial project for Arnold & Porter, did you produce some kind of written document?
A No, I did not.
Q Did you review literature only in English? I'm sorry, we are still on the secondary literature.
A That's correct. Everything that I reviewed in the secondary literature was written in English, that is correct.
Q And did you review any letters or correspondence or memos that weren't in the -- that weren't found in some publication or another?
MR. WOODS: Objection.
A I'm not certain I understand that question. Could you rephrase that please?
Q There might be some, let's just say internal correspondence in a company that never was meant to be published but for one reason or another might now have found its way into a book about the tobacco industry, let's say. So then I couldn't say to you did you only review literature that was

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published because that would include those kind of internal memorandums and letters.
MR. WOODS: Objection.
Q Did you review any published letters and memorandums?
MR. WOODS: Objection.
A Are you referring from tobacco companies or in general?
Q In general.
A I think it would be fair to say that in the review of the secondary literature, everything was secondary, it was published. I don't think anyone looking at that list today would have any doubt that that's secondary literature. Now, any time a historian is doing a book they are going to be primarily quoting documents. So you can read, using our example of President Lincoln, you can read a biography of Lincoln and letters will be quoted in that. So I really don't remember the specifics of everything I read. But I would be surprised if there were not primary documents quoted in some, if not most of the secondary sources. The nature of the documents would depend on the nature of the book. A book on cancer research or our history of understanding of that

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might cite primary papers, reading someone's letter. History of the public health movement might have a different type of primary document, or the public health association went on record and such and such or president so and so wrote a letter. I'm sure there are primary sources in the book. I can't really speak very well at this point to the various letters and so forth that were cited in those books. But I would be startled if they didn't cite themselves primary sources. To me or to anyone reading them today you are reading a secondary source. An historian is writing from primary sources as well as secondary sources. So I'm close to certain that there are primary sources in those books.
Q Now I'm not sure where to put this next category, whether it is primary or secondary. It probably doesn't even matter. Let me know if it does or not. Often in the scientific journals there will be an article that you read and that you used as one of your reference materials; and then either maybe in that issue or a following issue there will be an editorial and then maybe later there will be back and forth letters to the editor. Did you consider those as part of your reference

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materials?
MR. WOODS: Objection.
A Yes, I did. Certainly there frequently is give and take in the medical and scientific literature such as you describe. An article will frequently be accompanied by an editorial. Sometimes that will prompt someone else to write a response that appears in a later issue. I read all of those to the best I could identify them in the period 1930 to 1964 and they would be considered, from my perspective, primary sources in terms of this project. So if someone wrote an article and then there was an editorial in the same issue on that, I would read the editorial as well as the article. I would define both as primary sources.
Q Will the letters to the editor and editorials, are they also included in your list of reference materials?
A Insofar as I cited letters to the editor, they would be listed and I would consider them to be primary materials. They are part of the debate going on in the thirties or the forties or the fifties or the sixties or whatever it is. I did not systematically search out letters to the editor in the way that I systematically sought out

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12:43 the original articles, review articles and
12:43 editorials.
12:43 **Q Have you ever done any similar kind of review or a**
12:44 **massy of articles with the respect to any other**
12:44 **medical or scientific topic?**
12:44 A Well the techniques that I followed for this
12:44 project were similar to the techniques that I
12:44 followed for my three books. The specifics, of
12:44 course, vary, but in terms of techniques and
12:44 methods, I would say that the approaches were
12:44 similar.
12:44 **Q At the bottom of Page 1 and the top of Page 2 you**
12:44 **say, "Second, I reviewed the primary literature,**
12:44 **articles published in the scientific literature**
12:44 **between 1930 and 1964." What was your purpose in**
12:44 **reviewing the primary literature?**
12:45 A Well the primary literature is really the language
12:45 of communication in science, getting back to some
12:45 of the conversation that we were having before
12:45 lunch. The published article or the official
12:45 response to it as an editorial might be or a
12:45 sounding board position might be. This is the
12:45 currency of science, the published scientific
12:45 literature, and those are considered primary
12:45 sources and ultimately I felt the responsibility

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12:45 as a responsible historian not to draw conclusions
12:45 about this issue from what others have written
12:45 about it but to go back and see the primary data
12:45 myself. That's what really makes it original
12:45 research, when you start examining the primary
12:45 data.
12:45 You can learn a lot from secondary
12:45 literature, it certainly can help in terms of
12:45 developing a general context, certainly can help
12:46 in terms of teaching. If you are teaching a
12:46 survey course in the history of medicine, you use
12:46 the secondary literature to put together a
12:46 lecture. But it doesn't give you that same sense
12:46 of knowledge and authority of really doing the
12:46 original research yourself. In any historical
12:46 subject you need to deal with primary sources, to
12:46 get into the meat of it yourself, and this
12:46 particular case not what those in 1988 d0990
12:46 were saying about lung cancer but what were people
12:46 at the time saying about it. Well, there is
12:46 scientific literature. So I did a systematic,
12:46 comprehensive, indeed exhaustive review of the
12:46 workds published scientific literature in1930
12:46 through January, 1964.
12:46 **Q Did you first review the secondary materials and**

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12:47 **then start going into the primary materials?**
12:47 A My recollection is that there was overlap. But,
12:47 as a generalization, I focused on the secondary
12:47 sources first. I could read a book at home. I
12:47 couldn't check out a journal from the library from
12:47 1938 but I could check out a book. So as a
12:47 generalization I did the secondary literature
12:47 first and the primary literature afterwards. But
12:47 I'm sure there was overlap. I would be finishing
12:47 the secondary literature, have a few extra hours
12:47 so I could go to the library and start the primary
12:47 literature. But as a generalization, the primary
12:47 sources after doing the secondary sources.
12:47 **Q What process did you use to select the primary**
12:47 **literature?**
12:47 A That was an easy one because of the availability
12:48 of the Index Medicus which is a bibliography to
12:48 the biomedical -- the published biomedical
12:48 literature and the same way that the reader's
12:48 guide is a published bibliography to popular
12:48 magazines and periodicals. I had to do it
12:48 manually because the computerized literature
12:48 searches weren't being done at that time.
12:48 Actually they were being done at that time but the
12:48 earlier years were not on it. But each year there

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12:48 is a publication -- there is a publication called
12:48 Index Medicus. And I think issues come up
12:48 monthly, but they are bound together and each year
12:48 there is a volume. It is by year, 1930, 1931,
12:48 1932, so forth. This is an exhaustive
12:49 bibliography to the world's biomedical literature.
12:49 I'm purporting your earlier question was this US
12:49 or international. The world's scientific
12:49 literature is listed there.
12:49 And what I did was go through the categories
12:49 because the index was listed by subjects. There
12:49 may have been author index too but I did it by
12:49 subject. And I looked under four topics; lung
12:49 cancer, bronchogenic cancer -- curiously I would
12:49 have thought there would have been one entry, but
12:49 in fact there were two entries during this time,
12:49 lung cancer and bronchogenic cancer, and many
12:49 articles would actually be listed in both. But,
12:49 in fact, there were articles that for whatever
12:50 reason would be listed in lung cancer but not
12:50 under bronchogenic cancer or vice versa. So to be
12:50 complete, I looked at both. In addition, I looked
12:50 under tobacco and under cigarettes. I forget if
12:50 it was tobacco smoking and cigarettes. There were
12:50 two tobacco-related entries that were present. So

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there were a total of four entries. I literally wrote every one of them down. I tend to write on these notebooks too except I use the smaller version of this. So I would go to the Index Medicus, 1930, I wrote down every article from each of the four categories that I mentioned. And in my judgment, as far as humanly possible, I had in front of me the world's scientific literature on that subject. Included original articles, clinical reports, case descriptions, editorials. It did not index letters to the editor. I did that from 1930 to January, 1964. I wrote down the complete list, every article I could find under those topics so I had as close to humanly possible I believe the world's scientific literature on that subject. Then I went and read every one of them.

Q Do you remember how many articles that was?

A Yes, and they presumably have been made available to you as part of the materials. But I would say all together in the range of 1100, 1200 articles with the number of articles increasing significantly after 1950 reflecting the watershed year of 1950 and how intensely this became a subject of scientific inquiry at that time. But

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if you were to take the three -- I have three bibliographies. One is 1930 to 1950. That made sense because 1950 was such a watershed year in view of everyone who had studied the subject. I agree with that interpretation.

Then there is a second bibliography 1950 to 1959. The only reason it stops in 1959 is that the number of articles each year is increasing and, as I mentioned before, periodically there were meetings with the Arnold & Porter group and others who may have chosen to attend in which I would discuss the findings and what I found and here is what we have. There was so much material after 1950 that we decided to have a conversation in 1950 to 1959 and then I completed this on 1960 to January, 1964.

Q I'm going to hand you what has been marked as Ludmerer Deposition Exhibit 7. Can you identify this one?

A Yes, I can. This is Exhibit 7. This is a copy of the bibliography and my comments having read the articles from the 1930 to 1950 period. Between that period there were 276, in the range of 280 articles, plus or minus one or two, I identified from the Index Medicus in the fashion that I

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described to you. I would have my notebook, I would have the Index Medicus, I would be in the library to do this. I would look under lung cancer, bronchogenic cancer, under cigarettes, under tobacco, and I literally wrote down every article that appeared in Index Medicus. I did not duplicate. So if there was an article that was listed under lung cancer and under bronchogenic cancer, as much as possible I only entered it once. I'm sure I slipped a few times but essentially I entered it one time.

Then after generating the bibliography, I went and read the articles and evaluated what the author had to say. This is comprehensive. Everything is there. It is representative. All views are there. It meets sound historical methodological approaches because you find out not only what people are saying but what people had to say about that view, did they accept it or not, did they reject it or not, did it create a stir. Everything is there. Then these comments over here I would read the article and sort of summarize what it was about, what the point was, etc., etc.

Q Dr. Ludmerer, would you agree that this document

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is very difficult to read?

A Yes, I would.

Q Do you have your original notes?

A No.

Q Do you know where they are?

A Plaintiff attorney Mark Edell took them from us in 1990, promised to return them, never has done so.

Q I just want to put on the record the United States reserves its right to depose Dr. Ludmerer on these reference materials should the United States ever obtain a copy that it can read.

A May I put on the record that as far as these things go, I would love to have my originals returned to me. I cannot read these any better than you can. But a plaintiff attorney from another case, not related to the US government, took them and never returned them.

Q Do you remember the name of the law firm?

A I remember the name of the lawyer but not the law firm. The lawyer was Mark Edell.

Q Was it in the Cipollone case?

A This had to do with the retrial of Cipollone. Mark Edell was the attorney who won the original verdict. He was the attorney who was leading things for the retrial of the case and he was the

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12:57 1 attorney somewhere in New Jersey, who deposed me
12:57 2 on my first deposition, the one I mentioned
12:57 3 before, for the retrial of the Cipollone case, in
12:57 4 1990. And I had my originals there at his
12:57 5 request. And instead of going through copies, we
12:57 6 went through originals. He said you know,
12:57 7 wouldn't it be great if these were typed up and
12:57 8 transcribed. I said fine. Then he said you know,
12:57 9 I would like my staff to transcribe these so we
12:57 10 will all have a written copy of it. Your
12:57 11 handwriting is not very good. Even on the
12:57 12 original my handwriting is not always very good.
12:57 13 To tell you the truth, I was a little
12:58 14 apprehensive. I felt that -- I was concerned
12:58 15 about getting them back. But it wasn't my call
12:58 16 and the attorneys from Arnold & Porter said that's
12:58 17 satisfactory with us, please return them in a
12:58 18 prompt fashion. He said I promise I will do so.
12:58 19 He has never returned them. For awhile I know
12:58 20 attorneys from Arnold & Porter were periodically
12:58 21 calling him but they have just given up. He has
12:58 22 never returned them. I don't even know if they
12:58 23 exist. I don't know if they are in an office
12:58 24 drawer somewhere or if he destroyed them. I have
12:58 25 never seen them back.

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12:58 1 Q When did you put together this original document?
12:58 2 A All of this work was done in 1988 and 1989. I
12:58 3 might add, just for completeness, that serendipity
12:58 4 influences things. Why a person does what they
12:58 5 do, how they get involved. As I told you before,
12:58 6 I did not contact Arnold & Porter; they contacted
12:59 7 me. Part of the serendipity of my involvement is
12:59 8 that I was between projects. I just completed my
12:59 9 second book, Learning to Heal, the one that I had
12:59 10 received tenure and promotion to associate
12:59 11 professor for. I hadn't quite gotten into the new
12:59 12 book that became, the new project that became the
12:59 13 Time to Heal. So I had a window of opportunity to
12:59 14 do this study that I would not have had had Murray
12:59 15 Garnick called me a year earlier or a year later.
12:59 16 That's the serendipity. This entire study from
12:59 17 which my opinions today are based was done in
12:59 18 1988, 1989.
12:59 19 Q There are some notations that I can read because
12:59 20 I'm going to ask you about and if you can't read
12:59 21 them, please let me know. On that, for the
13:00 22 record, this set that I gave Dr. Ludmerer is Bates
13:00 23 numbered A as in apple, P as in Peter, 5 024 0566
13:00 24 to 0638. On that first page, 0566, I seems to me
13:00 25 that out in the left-hand margin near the top is

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13:00 1 the date 2/16/91.
13:00 2 A That's correct.
13:00 3 Q So my question is, if you were doing this in '88
13:00 4 and '89, why do I keep running across that date?
13:00 5 A The reason that you run across different dates is
13:00 6 that I consulted this at different times.
13:00 7 Q So that's a notation of a day of consultation?
13:01 8 A Right, because I did the project in 1988 and 1999
13:01 9 (sic) but then as you know there was a deposition
13:01 10 in 1990, trial testimony in 1991, and at that time
13:01 11 I would go back and review the notes and sometimes
13:01 12 on a second reading or third reading in
13:01 13 preparation for a deposition or for trial
13:01 14 testimony something would catch my eye for some
13:01 15 reason. The fact you find February, '91 I suspect
13:01 16 it has to do with the Kotler trial, I was
13:01 17 reviewing my copy, one of these things for the
13:01 18 Kotler trial and something caught my eye and I
13:01 19 just made a point that this caught my eye now as
13:02 20 opposed to when I did it before.
13:02 21 Q So the date is more of what caught my eye as
13:02 22 opposed to an additional section of notes written
13:02 23 on that date?
13:02 24 A That is correct. The basic notes that you see
13:02 25 were done in 1988 and 1989. But as I thumb

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13:02 1 through this myself I see a number of February,
13:02 2 1991 and that had to do with my review of the
13:02 3 notes in preparation for the Kotler trial.
13:02 4 Q Would you tell me again what the notes generally
13:02 5 had to do with?
13:02 6 A Are you talking about the notes underneath the
13:02 7 article?
13:02 8 Q First of all there will always be an author's
13:02 9 name, I take it?
13:02 10 A That's correct.
13:02 11 Q And the name of an article?
13:02 12 A Correct. You will see, to the degree these poor
13:02 13 qualities let us see, there is a complete
13:02 14 citation, you have authors, you have titles of
13:03 15 article, primary lung cancer, 18 autopsy cases,
13:03 16 I'm reading from number 2, NEJM, that's New
13:03 17 England Journal of Medicine, volume 203, pages 473
13:03 18 to 477, September 4, 1930.
13:03 19 Q 30 maybe?
13:03 20 A 30. Again I have something under it that is a
13:03 21 clinical review, it discusses some of the clinical
13:03 22 behavior. You will see the next point under it
13:03 23 etiology not discussed, which was an important
13:03 24 observation. And I did that at the time of
13:03 25 original reading for each of those. Two years

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later, three years later with the Kotler trial I went back and looked at some of this to refresh myself then for whatever reason something caught my mind in February of '91 and those are the February, '91 marks that you see in the left.

Q To the best of your memory do most of the notes have to do with a summary of the article or what you thought were the important points in the article?

A That is correct. That I can go even stronger and say that they entirely have to do with the summation of what was in the article and what was it about, that type of thing, yes. Was it a clinical study, was it a review, was it controlled, was it not controlled, what did they find, what did they conclude. But I would say exclusively there is a summation of what the article was about. If I can just add a general historical point as you are thumbing through. I looked at in each of these cases the entire article as an entirety because accuracy, fairness and comprehensiveness and not taking things out of context are important. A person can be ambivalent in an article on anything. You can take one quotation, but if it is not put in context that

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would suggest that the person has a certain view; but you can take another quotation from the same article and it would give a different interpretation. I read the entire article and had summations about the overall thrust as opposed to what the non-trained individual, the individual not trained in history would do. It is easy if you are biased or if you are not trained in history, you have to pick and choose selectively. These comments referred to the entire article and the entire articles were read.

Q On the last page which is Bates numbered 0638, at the bottom half of that page there is the date again, 2/16/91, then it looks to me like a table. Can you explain what that bottom half of that page is, if you remember?

A I'm going to try. I can't guarantee. A, this was 11 years ago, and B the copy is poor. I can only speculate what I was doing there. I would rather not. I'm sorry, I just don't remember that.

Q That's fine.

A Clearly I was putting something together in the context of refreshing myself on the subject and organizing my thoughts for the preparation for the testimony I was going to give in the Kotler case.

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But beyond that, I'm really not able to say what I was trying to do.

Q But that table was written in February of '91 rather than as part of your original survey?

A That is correct, because you see a date 2/16/01. I was reviewing these meager copies that we had and doing some type of thinking about the subject in preparation for Kotler and that table had something to do with that but I can't tell you anything more at this time. That's about as far as I can go.

Q That's fine. I'm going to hand you what has been marked as Deposition Exhibit Ludmerer 8. This is another document that your attorneys sent us as reference materials.

A Correct.

Q For the record, the Bates number is AP5 024 0639 to 0669. Can you identify what this document is?

A Yes, I can.

Q Would you please?

A Yes. This was the bibliography to the original report prepared and written and filed by Dr. Jeffrey Harris in the original Cipollone case. He wrote an expert report, this is a bibliography to that report.

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Q And were there articles in this bibliography that you had not read for your original study?

A I actually reviewed this prior to undertaking my own original study, in terms of the sequence of events. This is the first thing that I did.

Q My fault for labeling them backwards.

A That's hard to know, even for me it is hard to know. The copies are so poor. This gets back to the conversation we had before lunch. You asked what I think is a very important question. I'm a doctor, I believe that lung cancer -- I believe that lung cancer is caused by cigarette smoking. We have known it for close to four decades. Cigarette smoking is a great public health menace. I tell my patients not to smoke if they don't smoke, I tell them to stop if they do, etc., etc., etc.. You asked how does that viewpoint lend yourself to being a witness for the defense.

And it was really this document that led me to realize that I'm an advocate for public health, I'm also an advocate for the integrity of history and not changing the facts of history to support your political or social view of the present. So I read the Harris report which looks like a very proper, academic report, it is lengthy, it is well

Possible to get the Jeffry Harris affidavit from Cipollone?

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typed, highly footnoted. But reading the text itself from my general knowledge both as a historian of medicine and as a physician, there were many statements in there that were frankly wrong, and many of them had footnotes. So I compared his statements with the original sources, and to my surprise and disappointment I found that he had in many cases actually misrepresented the articles here. He would claim in his report that the article -- that the author had made a certain statement. You read the article, that statement had not been made. He fabricated it. He committed fraud. It was distressing to me as I described before.

And I was ready not to accept this assignment until I read that report and wrestled with the issue that I described to you before of boy, I wish everyone in the world would stop smoking tomorrow. On the other hand, I'm an advocate for the integrity of history, not changing it. That's when I consulted the Dean and my department chairman, a few people like that and how I got into the case. But historically it preceded my own research. This was my careful, obviously careful study of the Harris report because I not

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only looked at his quotations but compared his quotations with the sources.

When I found he was misrepresenting them, that was disturbing to me and that led to my willingness to speak as an advocate of history in these issues after consulting some of the university leadership. This came first and then, Deposition Exhibit 8 came first, that was part of the history, the Harris report, that's when I said to Murray Garnick, I will undertake the study. First I did the secondary reading as we described, then I entered my own primary reading which I did in the systematic way that I described to you. This was actually the first thing that I did.

Q Deposition Exhibit 8 in chronology comes before Deposition Exhibit 7?

A That's correct.

Q There are lots of notes in the margins on Deposition Exhibit number 8. Are those your notes or are those someone else's notes?

A Those are mine.

Q And generally what were you commenting on in those notes? Because again I cannot read most of this.

A I can't do much better than you can with many of these. Again for the same reason, but in

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principal I can -- they there are two important points. Number 1, I did the same thing in general that I did subsequently where I would read an article and I would have some sort of summation, whether it was about what they did, how they came down. In addition to that there were a number of important examples where as I mentioned before I found that Dr. Harris misrepresented what was in these articles and there were comments to that effect that he says that Dr. Smith said this when in fact if you look at the article he took it out of context where he says something else.

Q You made a comment to that effect?

A I made a comment to those effects on this bibliography where that occurred. He has a lot of sources here. It is not that every article is misrepresented, it is that maybe six or eight or 10 key articles from that from the period are misrepresented, and I made comments. But the copy is so poor I can't – I'm having the same difficulty everyone else has, reading it. Maybe Mark Edell will be kind enough to return the originals so I will be able to read this better.

Q The next exhibit I'm going to pass you is Exhibit number 9, Ludmerer 9, and again this --

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THE VIDEOGRAPHER: Off the record for a tape change. The time is 1:11 PM.

(Short recess was taken.)

THE VIDEOGRAPHER: Back on the record. The time is 1:18 PM.

MR. WOODS: This is David Woods. Because the Court has what I understand is a pretty strict rule on what objections I can make versus not make, I didn't want to say anything earlier, but when Ms. Moltzen reserves her rights to potentially reopen the deposition in the event she is successful in extracting these long lost notes from Mr. Edell, I didn't want my silence to indicate acquiescence to her having any such rights. In the event she actually is able to get those original notes out of Mr. Edell, we can take it from there. That's all I want to say.

Q I think we left off as I handed you Ludmerer Deposition Exhibit 9, and again this was something that I received from your attorneys as reference materials. The Bates number is AP5 024 0997 to 1056. Again, they are very difficult to read but I do believe that the title on them is Paradigm. Could you tell me what this document is?

A You are correct, the title is Paradigm. This is a

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figurative chapter of the original project done toward the end of the project. Quite frankly, Ms. Moltzen, I don't remember if it was the last thing I did or one of the last things I did, but it does very much have to do with the issue of methods of history that we talked about before, doing it properly, bringing a context to what you are doing, the historical framework and understanding of how medicine and science evolved that a trained historian of medicine develops in the process of acquiring that training.

Particularly when I got to the literature of the fifties and sixties, it occurred to me that much of the debate at that time had a Kuhnian explanation. By Kuhnian I'm referring to the greatest historian, philosopher of science, Thomas Kuhn, K-u-h-n, who wrote seminal works on paradigm shifts, scientific revolution, this sort of thing. When one world view replaces another. And it struck me that we were experiencing such a paradigm shift in the investigations of lung cancer in the fifties and sixties. The epidemiology, the old epidemiology was that of infectious diseases. We have a new discipline being created, epidemiology of chronic diseases

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with new canons of truth, new ways to show causality; instead of having to show specific causes, you are talking risk factors. Instead of having to have laboratory or experimental confirmation that something is a toxin, you can arrive at such conclusions indirectly through epidemiological studies if certain criteria are met. It was one world review emerging and challenging the traditional view that you have to demonstrate it in the laboratory, that there are specific causes of disease, etc.

So to understand that point better, I did some work in the area of scientific revolutions, paradigm shifts, and that is the theme of Exhibit 9, and indeed that's what I maintain today. The debate at that time had much to do with the creation of a new field, new canons of proof, no definitions of causality, new definitions of risk, a newer view had to replace a traditional world view. This literally helped me understand that phenomena.

Q Was this set up along the same lines as Exhibits Number 7 and 8 where you read the literature, and then for each one that you list here you will have the name of the article or the book and the author

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and then you will have some comments summarizing what it says. Or is this done in a different method?

A I would say this is actually an amalgam. I generated a bibliography called Paradigm, or something to that effect, which is a bibliography of secondary sources, and its analogies with the earlier bibliography --

Q I don't mean to interrupt. This may help. I'm going to hand you what has been labeled as Ludmerer Deposition Exhibit 10 and it is called Paradigm. It looks like a bibliography. I apologize if that was not a helpful interruption.

A Actually it was a helpful interruption. I appreciate you doing that. This is a study of secondary literature. I would make the same comments about it that I did about the earlier secondary bibliography. I think this is very thorough, I think it is very comprehensive and representative on literature dealing with this issue of paradigm as it existed in April of 1989 when I did this. I do not claim this to be exhaustive and completely inclusive as I would claim for my primary search when I went to the Index Medicus. This is pretty good. And as a

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historian of medicine who keeps up with the field, you know what some of the important sources are to begin with, you pick up sources, you see what their bibliographies are, literature searches, you talk with friends, and you put together a representative bibliography. And that is Exhibit 10. In Exhibit 9 I did not approach it in the same fashion that I did the original sources.

Q Exhibit 7?

A Exhibit 7, to use that as an example. Exhibit 7 I look at every article and commented on them. On Exhibit 10 I looked at everything here. On the other hand, not surprisingly, some of the books or articles proved to be more useful than others. Some of them stimulated ideas and syntheses and interpretations in my mind, and that's really what this is. When I would read something from Lilianfeld or from whoever it may be, that would stimulate an idea or teach me something or help me understand something, I kept these notes of it. But it is not a systematic or comprehensive discussion of what Reference Number 1 said, what Reference Number 2 said. This was a -- more accurately can be described as a working document that helped me understand the subject.

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13:30 **Q As a document, though, you did consider this and**
13:30 **use this in coming up with your initial**
13:30 **conclusions?**
13:31 A That is correct. But, as I say, in distinction to
13:31 the primary sources with Exhibit 7 being an
13:31 example where after looking at each article and
13:31 making comments on each article, I did not
13:31 necessarily write down comments of everything on
13:31 this bibliography. If something was helpful or
13:31 taught me something or helped pull something
13:31 together, I would. But there were other things
13:31 that I didn't learn anything that I didn't already
13:31 know or weren't as helpful as I hoped it might be,
13:31 and I didn't feel the need to write this specific
13:31 comment on here. By "here" I mean Exhibit 9.
13:31 **Q How did you go about selecting these 56 items?**
13:31 A Well, as I mentioned before, there is an art as
13:31 well as a science, but by staying up with the
13:31 literature, by having been a professionally
13:32 trained historian of medicine, I knew Thomas Kuhn
13:32 and some of the articles or books on this theme of
13:32 scientific revolution, paradigm shift, that sort
13:32 of thing. I did a bibliography search and I
13:32 learned of other articles, more recent articles
13:32 that were interpreting those decades in exactly

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13:32 the same fashion. Susser, for example, Number 52,
13:32 Epidemiology in the United States after World War
13:32 II. The evolution of technique. Terrorists.
13:32 Number 53 what he is calling the second
13:32 epidemiological revolution. So I did a literature
13:32 search, there was already an emerging literature
13:32 developing at this point that a scientific
13:32 revolution or paradigm shift was in fact
13:32 occurring.
13:33 Other literature searches helped, sometimes
13:33 references for -- you would read something and
13:33 there would be references to something in a
13:33 bibliography or citations and you would pick that
13:33 up. Consult historical colleagues, "Anything on
13:33 the paradigm issue or scientific revolution that I
13:33 should know of that I haven't?" It is an art.
13:33 **Q I can see where most of these fit into the**
13:33 **definition of secondary sources that you were**
13:33 **talking about. I do have -- would you look at**
13:33 **Number 9, please, Jerome Cornfield. He is writing**
13:33 **in 1951 and he is applying it to cancer of the**
13:33 **lung, breast and cervix.**
13:33 MR. WOODS: **Objection.**
13:33 **Q Isn't that a primary source?**
13:34 A I would say that is a correct characterization.

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13:34 Actually, as I look at this, there are -- this
13:34 list includes primary and secondary sources,
13:34 because what I would find is that some of the
13:34 articles that I would be finding on my own
13:34 themselves would talk about this conflict in world
13:34 view. Traditionally medical science demanded
13:34 experimental view, but we knew epidemiologists
13:34 feel there are other ways to do this. Some of the
13:34 sources from the fifties and sixties contributed
13:34 to this view of a paradigm shift. That's what got
13:35 me thinking of it in the first place when I read
13:35 some of the articles form the fifties and sixties
13:35 and they would use words such as paradigm shift,
13:35 new ways of proof. Some of the challenges and
13:35 discussions that were going on at the time about
13:35 how does one really demonstrate a cause, what type
13:35 of criteria do you need? So I appreciate your
13:35 making that point. I think that it would be more
13:35 accurate to characterize this bibliography as
13:35 consisting of both primary and secondary sources.
13:35 **Q And also to characterize this bibliography as not**
13:35 **being exhaustive?**
13:35 A I would not claim that it is exhaustive. I would
13:35 claim that it is sufficient, but I would not claim
13:35 it is exhaustive, that every article or book on

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13:35 the subject of paradigm or scientific revolution
13:35 is there. I would claim that it is sufficient and
13:35 thorough and comprehensive.
13:35 **Q Sufficient for what purpose?**
13:35 A Sufficient for the purpose of developing and being
13:35 able to defend the viewpoint that a revolution was
13:35 going on within epidemiology itself, what Susser
13:35 called the epidemiological revolution, new
13:35 standards of causation, new ways of demonstrating
13:36 proof. Basically to understand the evolution of
13:36 the epidemiology of chronic diseases as a new
13:36 discipline, how that grew, how that became
13:36 institutionalized, sufficient to tell a
13:36 responsible story.
13:36 **Q What is the time period of that second**
13:36 **epidemiological revolution?**
13:36 A Basically at the threat of the tobacco
13:36 controversy. Largely out of the tobacco
13:36 controversy, to a secondary degree out of the
13:36 Framingham study. It was largely embedded in the
13:36 tobacco controversy. So the time period would be
13:36 roughly 1950 to the mid sixties.
13:36 **Q I'm going to hand you what has been labeled as**
13:36 **Ludmerer Deposition Exhibit Number 11. Can you**
13:36 **identify that document for me?**

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13:37 A Yes.
13:37 **Q What is it?**
13:37 A Item 11 is entitled Supplemental Bibliography.
13:37 **Q While you are looking that over, for the record I will say that the Bates number on this is AP5 024 1062. The second page is 1063. The third and last page cannot be read. I'm sorry, go ahead.**
13:37 A I do not remember precisely at what point this was put together. If I were to hazard a guess --
13:37 **Q Did you put it together?**
13:37 A Yes, I did. It would have been at one of two points. I think it is most likely that this was put together in late 1990 or early 1991, in preparation for my first trial appearance at the Kotler case. I did my work, as I mentioned to you before, in '88 and '89, but now a couple of years later there is a trial, you find a few new things, you find you forgot to put a few things in. A supplementary bibliography was put together for the sake of thoroughness and complete revelation to the opposing side of everything that I had consulted. I believe it was done at that time.
13:39 **Q To put these in a chronological order then, Deposition Exhibit 8 comes first, that's the Harris bibliography?**

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13:39 A That's correct.
13:39 **Q Then Deposition Exhibit Number 7, which is the 1930 to 1950 portion of your materials, in time comes next, is that correct?**
13:39 A Actually, that is not correct. There would be the original bibliography of secondary sources that would come next. This is a generalization that I did, most of my work on what historians call context first, then I jumped into the primary sources. That would have been second, then this would have been afterwards.
13:39 **Q Does the Paradigm then, Exhibit 9, come before the exhibit we are working on now, Exhibit 11, the supplementary bibliography that you think might have been written in '91?**
13:40 A I'm sorry, I didn't hear that question. Could you repeat it please?
13:40 **Q The paradigm work, does that come before the supplemental?**
13:40 A Yes. Paradigm was part of what I call the original crutch, I think in '88, 1989. That, the supplemental bibliography, was the additional sources put together I believe before the Kotler trial that either I discovered in preparation for that or that just for some reason didn't get

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13:40 included in one of the earlier bibliographies. By the way, between here and there, there is a similar bibliography, 1950 to '59, 1960 to '64 which is 1988, '89.
13:41 **Q And this Exhibit Number 11, I take it that again it is a mixture of primary and secondary, is that correct?**
13:41 A I can't see it. May I see it, please? That is correct.
13:41 **Q I'm handing you what has been marked as Ludmerer Deposition Exhibit 12. Can you identify that?**
13:41 A Exhibit 12 is entitled Additional Bibliography, and there are 24 items on it. Most of the sources as I look through quickly are secondary sources, but actually it is a mixture of primary and secondary sources. Actually, as I look through it probably it is a mixture, a combination of secondary and primary sources. This was put together for completeness sake in this more recent year of my involvement. My opinions basically come from the '98, '99 study.
13:43 **Q You mean '88, '89?**
13:43 A Yes, '88. What did I say?
13:43 **Q I think you said '98, '99.**
13:43 A '88, '89. As I think I mentioned, six years went

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13:43 by with no contact at all, then the last four or five years there has been a flurry of cases and occasional deposition or trial that I have been involved with. This is just a supplemental bibliography of things that I encountered in that more recent preparation for completeness or may have forgotten to put on one of the earlier bibliographies. The objective was complete disclosure to the plaintiff of everything that I have seen. I haven't gone through and checked. I would suspect that some of the things here are in those earlier bibliographies. But just to be sure everything was listed we put together a supplemental bibliography, we called it Additional Bibliography, November 2001, so you would have a record of everything that I have consulted.
(Deposition Exhibit No. 13 was marked for identification.)
13:44 **Q I'm going to hand you what has been marked as Ludmerer Deposition Exhibit 13 and it is part one of the 1964 report of the advisory committee to the Surgeon General of the Public Health Service entitled Smoking and Health. On Page 19, heading Chapter 3, this particular chapter is called Criteria for Judgment. "In making**

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13:45 **critical appraisals of data and interpretations**
13:45 **and in formulating" --**
13:45 A What line are you on?
13:45 **Q The very top. "In making critical appraisals of**
13:45 **data and interpretations and in formulating its**
13:45 **own conclusions, the Surgeon General's advisory**
13:45 **committee on smoking and health, ..., made**
13:45 **decisions or judgments at three levels." And it**
13:45 **looks like they look at the validity of a**
13:45 **publication or report and the elements they used**
13:45 **for the competence of the training of the**
13:45 **investigator, degree of freedom from bias, design**
13:45 **and scope of the investigation, adequacy of**
13:45 **facilities and resources, and adequacy of**
13:45 **controls. Did you make any value judgments when**
13:45 **you were reading and reviewing the various**
13:46 **studies?**
13:46 MR. WOODS: **Objection.**
13:46 A I don't know that I formally went through in a
13:46 systematic way and gave each paper a numerical
13:46 score or that sort of thing. On the other hand, I
13:46 do think it is important to point out that part of
13:46 reading the literature is to read it critically.
13:46 In that sense I did. I did take into account not
13:46 only who wrote things, the Nobel laureate said

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13:46 something, the leader in the field, you take that,
13:46 one tends to take that more seriously than if a
13:47 post-doc in an unimportant lab said something.
13:47 The emphasis is part of critical review of
13:47 everything. But I did notice the type of study
13:47 that it was. Was there data or was it
13:47 speculation? Was it a controlled study or an
13:47 uncontrolled study? Is this a formal
13:47 epidemiological, well-controlled, retrospective
13:47 study with good controls, such as we saw after
13:47 1950, or is this an uncontrolled study. I got 100
13:47 patients, 80 of them, 80 percent smoke, maybe
13:47 smoking is the cause.
13:47 I would distinguish between that and a letter
13:47 to the editor where someone would say I have no
13:47 data, but maybe this is going on or maybe that is
13:47 going on. So I do think it would be fair to say
13:48 that in the formation of my opinions I looked not
13:48 only at what was said but who said it, how it said
13:48 it, what was the evidence to substantiate that,
13:48 how did other people react to it and so forth,
13:48 yes.
13:48 **Q Did source of funding go into your judgment?**
13:48 A Not at all.
13:48 **Q Why not?**

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13:48 A In science what matters is ideas and proof and
13:48 argument, and not who happened to fund it, not
13:48 whether it is National Institute of Health or
13:48 whether it is Memorial Sloan-Kettering or a
13:48 private foundation or whatever. It is the ideas
13:48 that count. Many projects also -- again, I'm glad
13:48 you asked that question because it illustrates
13:48 some of the complexities of the history and the
13:48 untidiness of history. This whole issue of
13:48 funding also depends on chronology. If you are
13:49 looking before World War II, there was very little
13:49 funding of any sort, and people often did studies
13:49 on their own, they did work at night and they
13:49 would go back to the hospital and do retrospective
13:49 reviews, they would have small grants. This era
13:49 of larger funding is really post World War II
13:49 phenomena.
13:49 The issue of funding becomes additionally
13:49 complex in that you find many studies that have
13:49 multiple sources of funding, private and public.
13:49 But basically ideas count and I did not do -- not
13:49 sources of money. Science is a marketplace of
13:49 ideas, you have to be able to demonstrate and
13:49 prove and persuade others and ultimately over the
13:49 long run that is what is important, not who your

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13:49 funder happened to be.
13:49 **Q Do you believe the source of funding can ever**
13:49 **influence scientific independence?**
13:50 A You know, I don't know. It wouldn't surprise me
13:50 if you can find an occasional instance when that
13:50 happened. I would submit that that would be an
13:50 aberration. Because one of the last things
13:50 scientists wants to do is to be exposed as a
13:50 fraud. It would destroy a scientist's reputation
13:50 if it could be shown that funding sources
13:50 influenced one's viewpoint. Now we are all
13:50 biased, all of us have our biases and prejudices.
13:50 But I'm talking about fabrication, changing data,
13:50 changing meaning, this sort of thing that goes
13:50 beyond the bias that each one of us carries in our
13:50 day-to-day world. The scientist who can be shown
13:50 to be unfair, dishonest, is a person who has lost
13:51 a career. We have aberrations in the history of
13:51 science where that has happened, but those are
13:51 considered aberrations.
13:51 **Q Do you remember if any of the primary literature**
13:51 **that you reviewed was published as a result of**
13:51 **tobacco industry funded projects?**
13:51 A Yes, I do. Now I do want to underscore, as I did
13:51 before, that I did not do a systematic review of

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funding sources in my study of the papers. I looked carefully at the papers and what they said and what the type of paper was, is this a clinical study, a pathological study, epidemiological study, experimental study of some sort, was it controlled, does the data seem to be or are the conclusions validated. All of those sorts of things I looked at. It is very common, as I said before, for investigators, particularly after 1950, to have multiple sources of funding because that's when the private foundations like American Cancer, American Heart are as starting to grow, that's when the National Institutes of Health is also taking off.

And I also noticed that some of the papers were funded by the tobacco industry, either I think it is the TIRC or individual companies, and I can recall – I didn't systematically study it, but there were papers that had conclusions that were critical of the tobacco industry that were supported by either TIRC money or supported by one of the companies.

For example, one of the confirmations that the carcinogenic agent, benzoapyrene, exists in cigarette smoke, which was published was done by a

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scientist working at, I believe the American Tobacco Company. One of the published confirmations of the skin painting experiments was published I remember by Dr. Bock who was employed by one of the tobacco companies. I observed this anecdotally. I didn't systematically see it. I don't have a graph that I can give you. I did see studies that had observations or conclusions that helped build the case against cigarette smoking that in some way were funded by either a tobacco company or the TIRC. Most of the papers, of course, had other sources of funding. American Heart, American Lung, National Institutes of Health, so forth, that's where the majority of it came from.

Q You said you remember some TIRC and industry funded projects that where the result was against smoking or that came out saying that smoking did cause cancer. Do you remember if there were any studies that came out promoting the idea that it was still an open question?

MR. WOODS: objection.

A Well there were a number of studies and a number of papers and essays and articles in the fifties and sixties that did express their skepticism of

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the evidence. Less the observations themselves, more the interpretations and what conclusions can be drawn from epidemiological data in the absence of the traditional experimental laboratory type of confirmation that medical science at that time was accustomed to. So there were plenty of those in the fifties and sixties. They decreased with time because you have a building consensus, a growing consensus. In the 1950's a heck of a lot of skepticism about the idea that lung cancer might be caused by cigarette smoking, then you start seeing the building of the consensus in the early pronouncements by public health agencies and you start to witness a turn in sentiment within the scientific community and it grows year by year.

I like to use the term a growing consensus, an emerging consensus. On the other hand you continued to see skepticism toward that view by responsible scientists through the early sixties, through the Surgeon General's report. To my knowledge in the great majority of these cases, these were independent scientists. These were not tobacco company scientists. They tended to be laboratory workers, Memorial Sloan-Kettering, Yale, National Institutes of Health, many of them

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were statisticians. These were the types of individuals who in the fifties and sixties were still expressing their reservations about the hypothesis; not about the data, but about the meaning or interpretations that could be concluded from it.

Q I want to clarify my question and your answer. My question was, did you see articles funded by the tobacco industry that discussed -- that supported the open controversy? And you said there were plenty of articles like that. But I had limited it to tobacco industry articles. Were you limiting it to it in your answer also?

A No. Again I have not at any point studied ideas in relation to funding sources. And as I said before, in science what matters is idea and proof and evidence and persuasion ultimately and not who the funder happens to be.

If one is looking at those who expressed their doubts about being able to draw causal conclusions from existing evidence in the fifties and sixties, the great majority of those people to my knowledge had no relationship to the tobacco industry. I'm making that point. These are people, as I said they tended to be people of the

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traditional paradigm that you needed to have laboratory confirmation or experimental conversation. They were laboratory workers, not epidemiologists. They were suspicious, intellectually what does this mean. It doesn't meet the traditional standards. And the ones who immediately come to mind were funded by major private cancer institutions such as Memorial Sloan-Kettering, they were medical schools such as Yale, many of them with the National Cancer Institute. They were the laboratory workers and they were government funded.

Q Was all of the primary literature that you reviewed published in peer reviewed journals?

A I believe that is a requirement to be listed in Index Medicus so I believe the answer to that is yes. There is something in medicine that we call throw-aways, things are published in them, you get it because you are a doctor, and there is stuff in it. Everything I reviewed is from the Index Medicus; and if not 100 percent peer reviewed, it was 99.9 percent peer reviewed.

Q I was originally going to ask you if all of the primary literature you reviewed was on the subject of smoking and health but now that you have

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explained the paradigm to me I already know the answer to that. Is it not true that all of the primary literature that you reviewed for your study was not on the subject of smoking and health?

A It really relates to smoking and disease because these are original studies that were helped building a new field, the field of epidemiology of chronic diseases. That was central to solving the lung cancer questions. So I would say it does relate to the issue of smoking and health.

Q But all of those articles do not discuss smoking and health, is that correct?

A Which articles are you referring to?

Q In the work you did entitled Paradigm?

A Do have you that Paradigm bibliography? That would help me more. I believe it is correct to say that some of the literature that I consulted in this issue of understanding the second epidemiological revolution is a more general secondary literature to help me understand scientific revolutions and paradigm that help me understand the events of smoking and health but don't necessarily discuss smoking and health per se. For example, I list Thomas Kuhn in his

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classic book, the Structure of Scientific Revolutions. If a person is going to talk about scientific revolutions, if a person is going to talk about paradigm changes, if a person is going to talk about the establishment of a new field or new ways of demonstrating causation, you got to understand Thomas Kuhn and his work in scientific revolutions. But the issue of cigarette smoking and public health is not something that Kuhn discusses in the book. So both types of items are on this bibliography. Some items specifically come out of the smoking health controversy. When you see participants in the study talking of these terms, we got a new paradigm, we got to persuade others about it. That comes from the primary literature. But if you were reading Thomas Kuhn, if you are reading the literature on scientific revolutions itself, that is necessary in my opinion to understanding the paradigm shift that was occurring. But you are correct it doesn't necessarily talk about tobacco or lung cancer per se. It gets back to principles of history, putting things in context, understanding the context of the events more fully that you are studying. So both types of things are here.

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Q I asked you this for the secondary literature, now I'm going to ask it for the primary literature. Did you review any internal tobacco industry documents in your review of the primary literature?

A No, I didn't. And this has to do with issues of setting boundaries. Now that you mention this, this is something that I would also like to be an addendum to my response to your earlier question of how historians do work. One of the things you have to do is be able to put boundaries around a project, where you begin at a point, where you end at a point, why something is included, why something might not be included, otherwise you are doing research for life and not writing anything.

The study I did is, one chapter of it obviously is a very complex case and complex series of events. I studied things as a historian of medicine, the evolution or scientific understanding of the causes of lung cancer that culminated with the consensus that grew in '64 with the Surgeon General's report, the last step of the process.

I did not go into other areas, company behavior, company signs, what companies knew, what

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14:03 they didn't know, how they acted. It was not
14:03 necessary for what I did. I have not reviewed
14:03 company documents. In the same way I haven't
14:03 studied public opinion or public perceptions.
14:03 That was not part of the project that I did.
14:04 **Q Did you believe that the internal documents of the**
14:04 **industry were not important to the context?**
14:04 A I think that for the project that I did, the state
14:04 of scientific knowledge of the causes of lung
14:04 cancer and how we investigated that and how we
14:04 came to conclusions that we did, I maintain that
14:04 the acceptable currency is the published
14:04 scientific literature. This is pretty standard in
14:04 the history of medicine. Insofar as company
14:04 scientists may have published, and that was part
14:04 of what I looked at as I indicated to you before,
14:04 on the other hand reviewing company attitudes,
14:04 company responses, company behaviors, I understand
14:05 the relevance of those issues to these cases but I
14:05 do not feel that they were pertinent to the role
14:05 that I played in this. I have not done that.
14:05 **Q Did you review the articles in a publication put**
14:05 **out quarterly by the Tobacco Institute called**
14:05 **Tobacco and Health?**
14:05 A No, I did not.

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14:05 **Q Are you familiar with the term TIRC?**
14:05 A I have heard the term. I don't know much about
14:05 it.
14:05 **Q What do you know about it?**
14:05 A I know that the mounting scientific information,
14:05 building a case that cigarette smoking might be
14:06 the cause of lung cancer, I say "might be" because
14:06 we are talking '53, but the tobacco industry
14:06 concerned about this issue, it is my understanding
14:06 that in response they formed an organization
14:06 called the TIRC. I always forget what those
14:06 initials stand for, Tobacco Institute Research
14:06 Council or something. I don't know to what degree
14:06 they were involved with supporting research. I
14:06 know that there was an industry organization that
14:06 funded certain research. I don't remember to what
14:06 -- I don't know to what degree TIRC was a
14:06 supportive research, to what degree it was part of
14:06 the public relations campaign that you were
14:06 alluding to before with some of the documents, or
14:06 it did both. I really don't know much about it.
14:06 I have not studied it, I have no intention to
14:06 study it. It is again out of my area.
14:06 **Q Then you cannot tell me how many of the articles**
14:06 **that you reviewed were published as a result of**

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14:07 **funding by TIRC?**
14:07 A That is correct. I cannot tell you exactly. But
14:07 I can't say that about any funding source. I mean
14:07 as we sit here today ideas, as I said before, what
14:07 matters in science ultimately is the quality of
14:07 ideas and evidence and not the funding sources. I
14:07 cannot tell you how many of the articles were
14:07 supported by the National Cancer Institute, how
14:07 many by the National Institutes of Health, how
14:07 many by the Public Health Service, how many by the
14:07 American Cancer Society, how many by the American
14:07 Heart Association, how many by local foundations,
14:07 how many by an individual tobacco company, how
14:07 many by the TIRC. I am unable to speak to that.
14:07 I can say just impressionistically that the
14:08 majority of published sources were published from
14:08 funds that did not involve TIRC or tobacco money
14:08 or tobacco interest. I can also tell you
14:08 anecdotally that I would occasionally encounter a
14:08 published study that had been funded by the TIRC.
14:08 I can't tell you how many that that would happen.
14:08 Some of them had conclusions that were actually on
14:08 the side that cigarette smoking is dangerous.
14:08 There were those.
14:08 In my opinion the two most important that I

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14:08 remember as we sit here today were the Bock
14:08 article which was a confirmation of skin painting
14:08 and one of the confirmations that benzoapyrene
14:08 exists in cigarette smoke.
14:08 **Q As I understand the manner in which you reached**
14:08 **your conclusions, you selected primary and**
14:09 **secondary sources, and then read those sources and**
14:09 **made notes about those sources. What else, what**
14:09 **other techniques did you use in your analysis when**
14:09 **you got to that point, the notes?**
14:09 A Well historians are limited by available evidence.
14:09 When you get beyond primary sources and get beyond
14:09 secondary sources there really isn't much else for
14:09 a historian to look at. I think I was complete
14:09 and comprehensive in looking at pertinent sources
14:09 that addressed this. I think what is especially
14:09 important was my review of primary sources,
14:09 because I was exhaustive and the published peer
14:09 review scientific literature which shows on the
14:09 one hand an evolving consensus but also shows the
14:09 debates that were occurring at the time, debates
14:10 that we had forgotten about because that was 40,
14:10 50 years today. We all know today that
14:10 epidemiology works, this is the role of history.
14:10 I think the exhaustive 100 percent examination of

why no interviews

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14:10 primary sources was indispensable to the opinions
14:10 that I formed. What does a historian do? Make a
14:10 good conscious effort to look at everything you
14:10 can realistically look at. You try to be
14:10 comprehensive. You try to be representative and
14:10 look at all sides of the story, look at opposing
14:10 views, not only what ideas were put out there but
14:10 how people responded to them. You look at
14:10 secondary sources to put things in context and
14:10 help explain these events that you are learning
14:10 from the primary sources; and in a good conscious,
14:10 good faith way you try to put it together. That's
14:10 exactly what I did in my work.
14:10 Q Did you discuss your findings and conclusions with
14:11 any other historians?
14:11 A I remember having occasional conversations at the
14:11 time, we are going back close to 15 years ago.
14:11 But I had conversation -- one of the fun things
14:11 about scholarship is the opportunity is to talk
14:11 and discuss your ideas. I had conversations both
14:11 with historians as well as with physicians who
14:11 lived through the period. Does this make sense to
14:11 you. So I had conversations with a variety of
14:11 people.
14:11 Q Other than the notes that you made on your various

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14:11 primary and secondary source listings, did you
14:11 make any other kinds of notes or outlines or
14:11 reports or comments?
14:11 A No, I did not.
14:12 Q Looking back at it from hindsight, what else could
14:12 you have done in reaching your conclusions?
14:12 A In hindsight I don't think there is anything else
14:12 that I could have done reaching my conclusions for
14:12 the project that I was studying. I believe that I
14:12 studied this more thoroughly, more
14:12 comprehensively, more representatively, more
14:12 systematically than anyone in the world had done.
14:12 I don't think that there is anything else I could
14:12 have done. Now I could have changed careers. I
14:12 could have said instead of focusing on my
14:12 interested medical education I'm going to change
14:12 subjects and start exploring other aspects of
14:12 this. You mentioned a number of them in your
14:12 earlier questions, but I wasn't really interested
14:12 in this. This was a project that came at that
14:13 interval between finishing one book in medical
14:13 education, getting started in another book in
14:13 medical education. That's where my heart and
14:13 passion is. That's where I would estimate 95 to
14:13 97 percent of my time today is and I went back to

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14:13 it.
14:13 Q Have you ever written any article with respect to
14:13 your study?
14:13 A I have not done so.
14:13 Q Why not?
14:13 A Two reasons. Number 1, from the very beginning
14:13 one of the conditions that I insisted on with
14:13 Arnold & Porter in terms of whether I would
14:13 undertake this was the complete freedom, including
14:13 the freedom to publish. So there were never any
14:13 restrictions. On the other hand, I don't know how
14:14 it is for you, but for me writing is hard work,
14:14 and the additional amount of time that would have
14:14 been involved just to sit down and write a paper
14:14 would have been substantial. And though I did
14:14 this research in a very responsible and exhaustive
14:14 fashion, I didn't learn anything new. The common
14:14 wisdom that I had always heard even before
14:14 beginning this is you got some early studies in
14:14 the twenties and thirties and forties suggesting
14:14 smoking might cause lung cancer, you got a
14:14 watershed year of 1950, then you got this becoming
14:14 perhaps the most intensely investigated scientific
14:14 issue in the world, various controversies going on
14:14 at the root of which is the creation of a new

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14:14 field of the epidemiology of chronic diseases, it
14:15 culminates with the last step of the Surgeon
14:15 General's report which helped bring clinical
14:15 epidemiology to maturity, which helped erase any
14:15 residual doubt that there might have been in the
14:15 scientific community that could be used as a
14:15 convenient data or understanding that cigarette
14:15 smoking causes lung cancer, the '64 Surgeon
14:15 General's report. That all was common knowledge
14:15 in the history of medicine. All the secondary
14:15 sources that I read had essentially similar
14:15 explanations. Had I found something different,
14:15 that would have been worth writing about. But the
14:15 fact is I didn't want to be the 21st person to
14:15 confirm the skin painting experiment. I didn't
14:15 think it was a valuable use of my time so I wasn't
14:15 really inclined to do that.
14:15 In addition, as I was finishing what I call
14:15 the first stage, the late eighties, early
14:15 nineties, those continued to appear important
14:16 papers by respected historians, most notably John
14:16 Burnham and Allan Brandt who I know is an expert
14:16 for you, that made essentially the same points, I
14:16 thought they were excellent papers. I saw little
14:16 to be gained from me doing all the work to write

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down John Burnham and Allan Brandt and many others have said it very well. I wasn't adding anything to it. Now I had found a new book to work on, I wanted to get back to work on that.

I can guarantee you though, had I found something different that had in some way contradicted the common wisdom, then I would have taken the effort to have written. But since everything I found was confirmatory -- I like doing new things. I don't get much joy being the 19th person to confirm something that is already known and already been written about. So I went back to my own work. That's where my efforts have been since then.

Q On Page 2 of your report, the section is headed Overview of Opinions. And the first paragraph is, "I expect to explain the principles of historical analysis. Specifically I expect to testify about the historical analysis of developments in scientific and medical knowledge." Is there anything you want to add about the principles of historical analysis that you haven't testified to this morning and this afternoon?

A Let me just reflect on that out loud to make sure I haven't omitted anything. We have done a pretty

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thorough job as we have gone. We've talked about the importance of having a context, we have talked about the importance of being accurate and fair in how you represent material, that was my criticism you recall of Dr. Harris's report. You have importance of being comprehensive, looking at all sides of the issue, not just one point of view, but the responses to it and what other issues there were, what sort of rehashing was evoked, that type of thing. You have the importance of not using hindsight. People at the time made judgments based on what is known then, not on what is subsequently known and that thing, we have discussed that. We have discussed the importance of understanding how science and medicine do not evolve in straight lines from ignorance to truth and all the messiness of that, how the consensus can be wrong, how seemingly have a rational idea and can ultimately turn out to be correct. How good work can be overlooked for honest reasons but ignored and then rediscovered, things of that sort. We talked about the importance of putting borders on project, otherwise you never get anything done. For me the border was the scientific understanding of the causes of lung

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cancer, not issues of company behavior, public opinion, so forth. So I'm saying this out loud just as an aid to myself but I think we've covered it.

THE VIDEOGRAPHER: Going off the record for a tape change. The time is 2:16 PM.

(Short recess was taken.)

THE VIDEOGRAPHER: We are back on the record. The time is 2:31 PM.

Q Dr. Ludmerer, on Page 2 of your report, the second paragraph, under "Overview opinions" states, "I also expect to testify about the state of medical knowledge of smoking cigarettes, disease, and a possible relationship between cigarette smoking and disease in the United States from the early 1900 to January, 1964."

A couple of questions. Here you have limited this opinion strictly to the United States, correct?

A Correct.

Q Smoking and disease in the United States. Again when you say state of medical knowledge, that's not popular knowledge, that's the medical and scientific community, is that correct?

A That is correct. I'm using medical and scientific

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interchangeably, both of which are completely different from community or popular so that is a correct statement.

Q Or media knowledge?

A Correct.

Q And again, you use the word disease so we are not just speaking of lung cancer, we are talking about many, many diseases that might be associated with smoking, is that correct?

A That's correct. As you can see from my bibliography, the focus of my research, the focus of my opinions is on lung cancer. On the other hand one get a sense of other associations and other diseases. So I think it fair to use the term "disease."

Q This statement also starts, in the early 1900's, it goes to January, 1964.

A Correct.

Q Do you consider yourself qualified to give an expert opinion with respect to the state of the medical knowledge of smoking cigarettes, disease, and a possible relationship between cigarette smoking and disease in the United States after January, 1964?

A Not as an expert. I have not studied that and I

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am not prepared to speak about events and the scientific study after January, '64.

Q This relates to the term "state of medical knowledge." Wasn't the state of medical knowledge--

A Excuse me, where are you?

Q That same sentence, the second paragraph. "The state of medical knowledge." Wasn't the state of medical knowledge in this country the same in December, 1963, as it was in January, 1964 after the Surgeon General's report was released?

A I would not agree with that statement, because of the extraordinary power and impact of the Surgeon General's report itself which in my estimation made a major intellectual contribution to our understanding of this issue, particularly its annunciation of the five criteria. I believe the Surgeon General's report, although it was based on existing work, that is true, I believe it made a new intellectual contribution of its own. It was more than just a summation. I consider it one of the great scientific documents of the 20th century.

Q But as far as the state of medical knowledge, it was based on existing medical knowledge, is that

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correct?

A It was based on existing data and studies. But the issue always in science is not just data but how you interpret the data and what conclusions you can draw from it. So it is correct that the Surgeon General's report evaluated existing studies, including unpublished studies, so from that perspective the Surgeon General's committee had access to information that the general scientific community might have, but the question is what sense do you make of this. And it was brilliant in terms of how it interpreted the data, the definition of the five criteria of causality, how one can use epidemiological tools particularly with coherency to draw conclusions about causality and the absence of direct laboratory evidence that the scientific community for centuries traditionally been accustomed to. In my mind that is a pretty important conceptual revolution. It is not new data. It's a conceptual revolution and I think in my opinion is the final step in the evolution of our current recognition that cigarette smoking causes lung cancer. It helped create a new field, the field of chronic epidemiology, epidemiology of chronic diseases.

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All of that ties in with each other. In my estimate it is an original contribution, an incredibly important contribution, and to make the statement that things in December of '63 were the same as in January of '64, I do not believe that is a correct statement because of the importance of the Surgeon General's first report.

Q Let me reword it then. What I meant to say was to take the term you use here, that you just testified that there was no new data. The state of medical knowledge, the data that was available in December, 1963, the medical data that was available, was no different than the medical data that was available the day after the Surgeon General's report was released, is that true?

A If you are looking at the basic data itself, I think that is correct. If you are looking at ways of thinking and interpreting data, ways of making sense of the world, that did change.

Q You said some of the Surgeon General's, some of the articles that they used, some of the studies they reviewed were unpublished. Do you know what percentage of the studies that the Surgeon General considers in the 1964 report were unpublished?

A The Surgeon General, as I recall, doesn't say

All of one count.

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specifically so I don't know what percentage that would be. But it does make a point of two things that I think are pertinent to that. Number 1, it points out how much new published information appeared in the intervening four or five years. How much new material there was for it to evaluate and to consider, how the case had grown stronger even from Surgeon General Burney's 1959 statement. So the amount of published information is larger and more impressive in '64 even than it had been a few years before then. In addition to that, the Surgeon General points out the inspiring cooperation it received from all sorts of scientists and workers who shared unpublished information or we have this article going to press or this sort of thing with them. It doesn't give an amount of that but it does make a point of praising the scientific community in general for sharing with them the latest that may not have yet made press.

Q When you say intervening four or five years, you are talking about the years between the January, '64 Surgeon General's report and Surgeon General Burney's 1959 statement on smoking and lung cancer?

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14:43 A That is correct. I am saying that the scientific case that cigarette smoking causes lung cancer grew stronger from 1959 through January, 1964 and that medical sentiment -- and the Surgeon General comments on this too, that one reason they did the report was that as much sentiment as there may have been in 1959, that there has been a decided shift in the intervening four or five years as new information has come in and new data has come in and that medical sentiment has shifted yet even further from 1959 to 1964. That is correct.

Q The next sentence in that section starts, "Beginning in 1950," it says, "Beginning in 1950, medical and scientific articles began appearing in the leading scientific and medical journals, suggesting a possible link between cigarette smoking and lung cancer." And then I want you to skip to the next page now, Page 3. The heading is "Statements of opinions and basis." Your first sentence there is, "I have concluded based upon my review of the literature that there was no credible evidence linking cigarette smoking to lung cancer or any life-threatening disease before 1950." Is that still your opinion as we sit here today?

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A Yes, it is. I think I would elaborate in a way that will shorten the summation. It is hard to do. But the two specific points are number 1, there were concerns of the health hazards of cigarette smoking expressed before 1950. I do not want to give the impression that I am unaware of those. That is very much part of this story. On the other hand, the amount and quality of data in the 1930's and forties was really pretty minimal. It was speculative, uncontrolled studies, letters to the editors, experimental studies that couldn't be replicated by other individuals.

Participants in this, in these events look at 1950 as a watershed year. That's not my term, that's Sir Richard Doll's term, how the evidence that began appearing in 1950 was so much more impressive and disturbing than the types of evidence that had been there before, if you are looking at cigarette smoking and lung cancer. I'm paraphrasing Sir Richard Doll, but he says reports about cigarette smoking and lung cancer go back for awhile but it wasn't until 1950 with the publication of the various reports that for the first time a sufficient amount of high quality information obtained in a sufficiently responsible way was assembled to persuade more than a handful of people that cigarette smoking was a real possibility as the cause of lung cancer, something of that sort. I would agree with that phraseology.

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If you examine the Surgeon General's report, the Surgeon General essentially says the same thing in 1964 report, that earlier suggestions and studies go back, but 1950 is a watershed year. So I do maintain the importance of 1950. And then the types of hazards that were associated with cigarette smoking, the other part of your question, before 1950, Buerger's Disease, tobacco amblyopia, the suggestion had been made that cigarette smoking might cause lung cancer but you have to put things in context. It was not an idea that evoked much of a response if you were looking at the thirties and the forties. Textbooks didn't mention it, review articles didn't mention it. If people mentioned it at all, often they said we have heard this idea but there is no data, it is speculative. One of the pioneers, one of the leaders the prospectus study says as late as 1947 he considered it to be nonsense. So those would be the two changes or the two events; the linkage of cigarette smoking with other illnesses before 1950 but the focus of lung cancer really emerging with 1950 and those studies as well with other serious diseases, then the importance of 1950 as a watershed year.

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Not the first time anyone made the suggestion or made the claim, but when using Dr. Doll's words, when you have a sufficient amount of responsibly obtained and credible evidence being brought forth to persuade the entire scientific community, not just a handful of those at the margin that cigarette smoking might be responsible for a material amount of significant disease. Something like that. I'm paraphrasing Dr. Doll. But I would agree with that new prediction.

Q Well what Dr. Doll then is saying is that more impressive, more disturbing and more persuasive medical and scientific articles began appearing in 1950 but that's not what you say here. You say beginning in 1950 medical and scientific articles began appearing. Would you agree that before 1950, medical and scientific articles began appearing in leading scientific and medical journals suggesting a possible link between cigarette smoking and lung cancer?

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14:50 A I'm saying that to be accurate one has to be comprehensive, and you have to look at the quality of the article and the response to them. I would adhere to this view and it is very consistent with Dr. Doll. The suggestion that smoking causes lung cancer is not a new suggestion. But the quality of evidence was very poor and if you look at the scientific community, there are not many people who are persuaded by that. If you look at the reviews of the subject of lung cancer as late as 1947, 1948, '49, you see the cause of lung cancer being listed as unknown, you don't see in the textbooks relations with cigarette smoking being drawn. That's what changes after 1950. Not the idea, but the fact that now we are getting some well done studies, the evidence it is not just someone writing a letter to the editor or doing an uncontrolled study but that the first of the better done epidemiology studies that led to the second revolution in epidemiology, the quality of the data, the amount of the data, and that's why so many people, including Dr. Doll, and several of the surgeon generals look at 1950 and use the term watershed year. I agree with that.

But of course it is correct to point out and

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important to point out that the idea is not a new one. It is not that no one had ever made that suggestion before, the suggestion that lung cancer is caused by cigarette smoking does go back for a few decades. No one had data. It was speculative for the most part, and that was the problem. It also violated common sense based on existing paradigms. Those are the things that changed in 1950, why in 1950 you have a whole new ear and understanding of these relationships.

Q Did you read an article by Alton Ochsner, O-C-H-S-N-E-R, and Michael DeBakey, D-E, capital B-A-K-E-Y, called "The symposium on cancer analysis of 79 collected cases and presentation of seven personal cases in surgery, gynecology and obstetrics, written in 1939?

A Yes, I did.

Q Is it still your opinion that that particular article did not suggest a possible link between cigarette smoking and lung cancer?

A That article suggested a link between cigarette smoking and lung cancer and in fact it attracted a lot of attention. The problem is that it had no data. There were no controls. Scientists -- and again this is why one has to be comprehensive if

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you are to be a responsible historian. If you look at Menne and Anderson writing in JAMA, for example, in 1941, they talk about that essentially what we have is speculation but not data.

The Ochsner and DeBakey articles of 1939 and 1941 were uncontrolled. They actually studied the subject and retracted that view. They did a controlled study, which they did not do in 1939 and 1941. They were unable to demonstrate a relationship between cigarette smoking and lung cancer, and between 1947 and 1948 wrote seven or eight public retractions of that concept. So my personal view that their inability to demonstrate the relationship that they hypothesized in 1939 was one of the major reasons why there was still in the western world skepticism toward that concept in the late forties. They advanced the idea, they studied it, they had negative results, they concluded they were wrong, they retracted their conclusion. Now, of course, later on they came on board. But I think the '48 study needs retraction has to be added to the '39. So there is a lot of staccato. This --

Q Would you agree that the article was published before 1950?

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A Yes, of course.

Q Would you agree that it appeared in a leading scientific and medical journal?

A Of course.

Q Would you agree that it suggested a possible link between cigarette smoking and lung cancer?

A Yes, I would.

Q Have you -- are you familiar with the article by A. Arkin, A-R-K-I-N, and D.H. Wagner, W-A-G-N-E-R, entitled "Primary Carcinoma of the Lung," published in the Journal of the American Medical Association in 1936?

A Yes, I am.

Q Was this article published before 1936?

A It was published --

Q Before 1950?

A Yes, it was.

Q Is the Journal of the American Medical Association a leading scientific and medical journal?

A I consider it to be so.

Q And did the article suggest a possible link between cancer smoking and lung cancer?

A It offered that as a speculation, but again getting back to principles of doing history, it is important to assess the quality, the validity. It

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was important. It was an important suggestion. Subsequently proved to be correct. But that paper was not a controlled study. It was not an epidemiological study. It was another of the handful of studies that appeared in the thirties and forties where you had some well-intentioned physicians, use often chest surgeons who had their own series of patients but did not have controls. And they would say 80 percent of our patients with lung cancer smoke but they didn't have any controls. Smoking had already become a very widespread habit in the United States. Maybe 70, 80 percent of the general population smoked. It was not considered -- without the controls it was not considered persuasive by people at the time. I think that context has to be added and that explains the opinion of the Surgeon General and Dr. Doll and others. The suggestion has been made, there are clinical studies, but it wasn't until 1950 that you have a sufficient body of quality data and representative data obtained in a responsible way.

An uncontrolled study is not a responsible epidemiology study. That's why they call 1950 the watershed year. They are calling it a watershed

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because of the quality of work that came out and the degree of concern that this working both in the scientific community. No one, them or I, is saying that no one made the suggestion before. You are providing some excellent examples of people who in earlier years threw in that suggestion.

I would cite again Dr. Menne Anderson in 1941 also writing in the American Journal of Medical Association who used the words, "This is pure speculative nonsense. We need data. And without controls and epidemiological studies, no conclusions could be considered verifiable."

Q But your opinion as it stands now is incorrect without all of those qualifications, correct?

A Which opinion are you referring to?

Q Beginning in 1950 medical and scientific articles began appearing --

A What page are you on?

Q I'm on Page 2, the head of the section is called "Overview of opinions." It's the third paragraph. It starts, "Beginning in 1950."

A Well, I think that's a correct statement, beginning in 1950 you got an outpouring of important, well-done, well-conducted studies that

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shocked the scientific community and brought even more attention to the issue.

Q Outpouring is not the word you use. You used the word "begin." "Medical articles begin appearing." Not an outpouring begins appearing. Just medical and scientific articles.

A Well, I think that as nice of a person as you obviously are that I think you are doing a little bit of quibbling over years. They began appearing then. I'm adding for elaboration of a short document that the number of articles begin to soar. But I think it is correct, 1950, the amount and the nature of the evidence changes, and that's the point that I make here and that's the point that I will continue to make.

Q But you would agree that before 1950 the medical and scientific articles had begun appearing in leading scientific and medical journals, suggesting the possible link between cigarette smoking and lung cancer without any qualifications?

A I would very much agree with the statement that the suggestion that cigarette smoking causes lung cancer had been made before 1950. I'm pointing out that the evidence to document that statement

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was pretty scantly. I'm pointing out that an historian has to look at things in context how people respond to the ideas. Not many people bought into that view. But yes, you can find that statement there.

But what I'm doing is at the one hand acknowledging the accuracy of that statement but at the same time trying to be representative and point out that you have to be comprehensive and look at all of the data and see how people responded to it, and the degree of concern that was evoked by the early suggestions was minimal compared with the degree of concern that came in the watershed year of 1950. As I said before, Ochsner and DeBakey's failure to demonstrate the relationship that they postulated in 1939 and 1941 in my opinion contributed to the relative lack of concern before 1950.

Q Are you aware of an article by Raymond Pearl, P-E-A-R-L, entitled "Tobacco Smoking and Longevity" in the publication Science in 1938?

A Correct. That's another notable part of the pre-1950 literature. He was --

Q Does that article suggest a possible link between cigarette smoking and lung cancer?

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A My recollection is that it talks about cigarette smoking and decreased longevity. Without seeing the article I don't know if it says anything -- I don't remember if it says anything specifically about longevity. Pearl is actually one of my people that I admire. He was an eminent biologist. He played a role in my first book on the eugenics movement in American society. I admire Raymond Pearl. He was a biometrician.

But again, from the standpoint of responsible history, one needs to be comprehensive and look at the entirety of the data to get a sense of what was going on rather than to pick and choose selectively. This can easily be done by picking the examples that you are. Pearl was criticized for very statistical reasons at the time. Dr. Doll himself in his recollections of the smoking controversy discusses how Pearl was considered a marginal figure, that there were flaws with his argument, people tended to discount it. In retrospect we know that he was right. But at the time it did not evoke a considerable amount of concern. But it was there. It is notable and it should be commented on. It was very much a part of the printed pre-1950 literature.

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Q What about the article by Frederick Hoffman, H-O-F-F-M-A-N entitled "Cancer and Smoking Habits," in the Annals of Surgery in 1931, was that article published before 1950?

A Yes, it was.

Q Was it in a leading scientific and medical journal?

A Yes, it was.

Q And did it suggest a possible link between cigarette smoking and lung cancer?

A I remember that Hoffman had an article. Do you happen to have a copy of the article to show me? Because I do not remember that article as well as I do the others to see the exact wording. Were there controls? I really don't think so. Was he talking about lung cancer, was he talking about cancer of the mouth and pipe smoking. I just don't remember. Sometimes these things are confused because the literature relating pipe smoking and oral cancer is struggling and cigarette smoking and lung cancer. I'm looking at cigarette smoking and lung cancer and those are the sorts of articles you need to look at. I would have to see the Hoffman.

Q No, I don't have it with me. How about F.E. Tylecote, T-Y-L-E-C-O-T-E, his article is "Cancer of the lung," published in Lancet in 1927. Was that article published before 1950?

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A Yes, it was, and as I said, there were a number of articles in the twenties and thirties and forties that made the suggestion. I would have to see that particular article. I recall Dr. Doll's description of it being correct, the article is that it lacks data, is not done in a responsible way. I would have to again see what he had in the way of controls. The allegation and assertion is being made during this period. What is lacking is much in the way of evidence or controls or experimental studies to back up that assertion at a time that lots of people smoke are smoking and not getting sick. So again the response that that article evoked was small relative to the response that occurred to the 1950 articles. But yes, it was there, of course it was.

Q In the next sentence, we are still on Page 2 of that fourth paragraph, "There were varying views within the scientific community regarding these studies." I'm just curious, besides published medical and scientific articles, what else do members of the medical and scientific community refer to or consider or rely on when they are forming their views and beliefs about an issue?

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MR. WOODS: Objection.

A You are referring to -- can you show me where you are referring?

Q We are on Page 2, on the fourth paragraph.

A Beginning in 1950?

Q I'm sorry, third paragraph. We discussed that first sentence. Now we are on the second sentence of that paragraph when you talk about varying views within the scientific community regarding the studies. Besides the studies, I'm just asking you a general question, besides scientific studies, published articles, what do members of the scientific and medical community rely on, consider, what are some other tools they use when they are coming up with their views or beliefs on a medical or scientific issue?

MR. WOODS: Objection.

A Well, the major source of information as you suggest is the literature itself, as we have been talking about all day long. The scientific literature is the currency. I think, wearing my medical hat now, not just the historical hat, people talk about articles. It is not just that

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something comes out. Again, you have to put yourself in the reality of the real world at the time things happen and not some abstract idealized notion.

The fact that an article is written even in a prestigious journal doesn't necessarily mean that it is correct, doesn't necessarily mean that it is read. If it is read, someone may read it six months later and not immediately because it gets stuck in the pile. All sorts of practical things that make sense in a common sense happen in a way that scientists operate.

In addition, science is a social phenomena. Scientists are not individual actors working by themselves. Part of the fun of it is that you are talking with others, you are conversing, you are interchanging, you are exchanging views; so if you do have a notable article come out, you discuss it, you have a journal club, you have seminars, someone presents it or maybe you are having lunch, did you see Dr. Smith's article in last week's New England Journal of Medicine. You did? What do you think about it. There is a lot of this that goes on.

Sociologists have talked about opinion

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setters in science. It is not if you got 500,000 physicians, it is not that every physician reads the article immediately but the view of certain opinion setters, the leading people in the field, the chairs and that sort of thing influences others. There is a permutation process. I could go on. But these are examples of part of the informal process of scientific dialog.

Q I believe it is the next paragraph, it starts, "I expect to testify how the findings of these studies were addressed by public health officials. One response considered by the public health community was the reduction in tar and nicotine yields as a possible means of reducing the risks associated with cigarettes."

When did the public health community consider reducing tar and nicotine yields? What years?

A I will acknowledge to you that of all the sentences in this summary review, this is the one that, this particular sentence is the one that I have been least involved with or thought the least about. Given that qualification, I know that Dr. Wynder himself published in the mid fifties on the issue of developing filters and hoping that that might obviate the cancer problem. In addition,

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this is discussed not at great length, but it is discussed in the first Surgeon General's report where they talk about the possibility of adding additives to cigarettes that in some way might counteract the apparent carcinogen. In the fifties I would say with Dr. Wynder, I don't remember if it was the mid fifties or late fifties, I would tend to say the mid fifties he wrote about this in some of his published statements, and this concept was pursued in the Surgeon General's report of '64.

Q How about the public health -- public health community's response to the reduction of nicotine yields, what years are we talking about the public health community acting?

A I'm glad you asked that because nicotine is not something that I have really looked into. My knowledge of nicotine is that little was known about it. The Surgeon General report in 1964 considers cigarette smoking to be a habit not to be addictive. The Surgeon General's report was less concerned about the biological consequences of nicotine than today we are. Quite frankly if this had been sent to me for my editing and review today I would scratch that out. I appreciate you

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bringing that up. I'm talking about reduction in tar. I'm only addressing lung cancer, not issues of addiction and physiological stuff like that. Let's delete those two words. We will make a note that should I ever be asked to have an expert statement like that in the future, those two will not be there.

Q The two words being "tar" and "nicotine"?

A The two words being "and nicotine".

Q Were there any other responses by the public health community other than the creation of the first Surgeon General's advisory committee and the public health community's reduction in tar yields as a possible means of reducing risks?

A Yes, there were.

Q What were some of those?

A The chief response was the growing view, beginning in 1954, that it is better not to smoke at all. And you see various health organizations start taking positions in the mid to late fifties on this issue. Each of them set in their own way, some said it more strongly, some said it less strongly. You see the growing consensus that we have inherited today that cigarette smoking is the cause of lung cancer, better off not to smoke.

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The first use of the term primary prevention that I'm aware of from the American Public Health Association was 1954. Somewhere around '56 or '57, and you probably know these organizations better than I, but various medical organizations in the United States and in other countries began taking positions to the effect that cigarette smoking is a health danger. Often they would revise an earlier opinion and come out with a later opinion stronger than the earlier opinion, which to my perspective is evidence of this growing consensus, new information coming and the rising tide.

The best example is probably the public health surgeon -- the Public Health Service. Surgeon General Burney in 1957 signed that excessive cigarette smoking is -- or he may have even said may be one of the causes in lung cancer toward a stronger statement in 1959 when he says that cigarette smoking is the principal cause of lung cancer. You see these types of statements from the Public Health Service, from other public health organizations beginning in the fifties and this recognition that and growing acceptance by the cigarette smoking causes lung cancer and a

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material amount of other disease, it's catching on, it is growing, year by year it grows stronger. I would say that was an even louder response than the idea of looking for a safer smoke.

Q The last paragraph on Page 2 starts, "I understand," "I understand that I may be asked to offer opinions regarding the opinions and testimony expressed by other witnesses in the case. I receive the right to supplement this report based on my continuing review of academic literature and on the opinions expressed by other experts in this case." We are speaking as of today. Have you reviewed the opinions and testimony expressed by any other witnesses in this case?

MR. WOODS: Objection.

A I haven't -- if by testimony you mean depositions and that type to thing?

Q I think that would be the main example that I would cite.

A To my recollection I have not reviewed depositions of witnesses for either defense or plaintiff in this case.

Q Have you reviewed any academic literature since January 30, 2002, that's when you signed the

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report, not listed on the reference material supplied to the United States?

A No, I haven't.

Q Have you reviewed the opinions expressed by other experts in this case? And my example to you would be by reading their expert reports?

A I have read the expert reports of Allan Brandt and Robert Proctor.

Q Have you read the report of Peter English?

A No.

Q Has the review of these deposition -- of these expert reports changed any of the opinions in your original report?

A No, they have not.

Q Based on any work that you have done since January 30, 2002, have you supplemented this report at all?

A No, I have not.

Q Turning to Page 3 of your report, that first sentence, "I have concluded, based upon my review of literature, that there was no credible scientific evidence linking cigarette smoke to lung cancer or any life-threatening disease before 1950." What is your definition of credible scientific evidence?

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A Evidence means just the evidence, as opposed to speculation and hypothesis. If you are looking at clinical studies, you need controls. To have a series of studies without controls is not really a bonafide epidemiological study even by the old fashioned standards, retrospective standards and standards that existed at that time. This was common very frequently in the thirties and forties.

One of my favorite examples is the one I mentioned to you before, Menne and Anderson, in which they acknowledged that the suggestion had been made many times and you listed yourself before a number of people who had suggested that cigarette smoking caused lung cancer, but just on the basis of speculation, hey, I have got 80 patients that I have operated on, most of them smoke, there is more smoking in the world today than there was, maybe it is cigarette smoking. But without controls, without proper study, such conclusions, you don't really have evidence, you have speculation. So I'm distinguishing between hypothesizing and speculation and that type of thing versus real evidence that you get from a well-controlled, well done study. And credible,

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I'm also using that as a shorthand for reproducibility.

One of the important aspects in all of scientific work is not in merely making an observation, but in doing it in such a way that other people can follow your techniques and do the same thing and reproduce it. So there were also some laboratory studies, primitive laboratory studies in the twenties and thirties. And the person whose name is most frequently associated with that is Roffo from South America but no one could confirm what he did. And that led his work to be discounted at the time. People tried to confirm his homographic studies and skin painting studies. They were all unsuccessful. And he was also, as Dr. Doll points out, very vague in experimental details that he provided. So people thought that he had not done what he asserted that he had done.

So these, so reproducibility in evidence as opposed to speculation are really the things that I'm referring to here. As I said before in my own view, Dr. Ochsner's inability to demonstrate a relationship in the 1940's I personally believe was instrumental in the skepticism toward the idea

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that cigarette smoking causes lung cancer that persisted through 1950 and he retracted that idea that has to be added to the discussion. And all of this changes of course with using Dr. Doll's term, the watershed years of 1950.

Q Exhibit 7 which is your – the articles, the studies that you read and they were written or published between 1930 and 1950, contained 279 items.

A Right.

Q Is it your testimony that none of those 279 pieces of primary literature have any credible scientific evidence linking cigarette smoking to lung cancer?

A I'm saying that it is my testimony that, using 1950 as an arbitrary turning date, it would be more accurate to say that the cause of lung cancer is unknown. I think that would be a more accurate way of saying that. I think this statement that the cause of lung cancer is at present unknown is in every review of the subject, published review of the subject of lung cancer between 1930 and 1945.

Q I'm sorry, you are in the wrong place. The sentence that I just said doesn't say anything about lung cancer and unknown. It says no

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credible scientific evidence linking cigarette smoking to lung cancer.

A Well there is another question. Maybe it should be read back because I want to make sure we are on the same wave length.

(The following question was read back:

Q Is it your testimony that none of those 279 pieces of primary literature have any credible scientific evidence linking cigarette smoking to lung cancer?)

A What I'm saying is that the evidence was weak and not taken very seriously. And historians have to look at the response to studies, not just the studies themselves. Someone makes a claim, how did the rest of the scientific community react to the claim. What I'm saying is that despite the suggestions that were made by the several people that you mentioned, those suggestions evoked relatively little concern prior to 1950. The common teaching prior to 1950 was that the cause among cancer is unknown. Someone will go on to say that a number of factors have been suggested as possible causes, they would often list 15 factors, including cigarette smoking, but they would go on to say that we really have no evidence

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to substantiate any of these at the moment. The cause of lung cancer is unknown. This would be the tone of the literature and of the textbooks through the late forties. It is the watershed year of 1950 in which that claim evokes much greater attention and much greater concern.

Q On your Exhibit 7 you have listed 279 pieces of primary literature you read. My question is, is it your testimony, your opinion, that in none of these 2– we will forget about the 12 articles that I had earlier. Now we have 279 that you have written down; that in none of those is there any credible scientific evidence linking cigarette smoking to lung cancer?

A Well I would say there was very little, little credible scientific evidence. Certainly the suggestion had been made, but what is lacking is on the clinical side, controls. What is lacking on the experimental side is reproducibility because the investigator who claimed that he had been able to induce skin cancer with cigarette fragments and identify benzoapyrene no one could confirm that work and he was discounted. That is what I am saying. Also, putting things in context, very few of these articles before 1950

Did he not have those on his list?

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really deal with the issue of causation. And again this gets back to the historian's responsibility of looking at things in the context of the time, not with our present understanding. That's an no-no in history. Scientists in all fields address questions that they consider answerable with the techniques at the time.

The great majority of studies before 1950 are not studies of the causes of lung cancer. Those are clinical studies of various aspects of the presentation and management of the disease; is the increase in lung cancer that we are seeing perceived or real, how does lung cancer behave, what are the cell types, where does it go, what organs does it metastasize to, how does it metastasize, how does one make the diagnosis, how does one treat it, etc., etc. That really is the flavor of this information.

It would be an error on my part in this discussion not to bring that point to your attention if you are looking at the pre-1950 literature. It is easy to look at the handful of papers that do go into the issue of cause. That is a very tiny amount of the literature on lung cancer before 1950 because the tools were

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primitive. As the marr change compared with the post 1950 period where the issue of causation, not clinical behavior and treatment of lung cancer becomes the focus of concern.

Q What percent of these 279 articles talk about not causation, but links between cigarette smoking and lung cancer?

A It depends on how you talk about links. I would say the typical review, the typical article might be our experience with lung cancer. Here is our patient -- here is our population of patients and we have seen maybe three patients with lung cancer and here is how it compares with the general experience, here is how we believe the diagnosis should be made, how is how it should be treated, here is how it spreads.

In those reviews many papers would have a discussion of etiology. If you consider the one paragraph discussion of etiology to be a discussion of cause, then the number gets higher. If, on the other hand, you read that paragraph and say the cause of lung cancer is currently unknown, here is a few things that have been suggested as possibilities but we don't have any data, if you consider that a discussion of lung cancer and

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cigarette smoking, then the percentage would be higher. If you would discount that type of paragraph in a larger article, then very few of the papers really dealt with the issue of cause in the way the papers that you cited today do.

Q We are not talking about cause. We are talking about linking, linking cigarette smoking to lung cancer. Haven't hit the discussion about causation yet. Would you say at least 10 percent, at least 28 of these articles?

MR. WOODS: objection.

A I haven't counted them or read them since 1988. But as a guesstimate, I would say less than ten percent. You are cherry picking. You are picking the very best articles over a several decade period. The typical article in here would say, as I said before, the cause of lung cancer is unknown, a number of factors have been suggested as possible causes but we don't have evidence to support any of these at the moment. The cause of lung cancer is unknown. If you really wish to understand the tenor of the period, what people at the time are saying, that's a pretty accurate reflection.

Q I'm trying to understand the tenor of your word

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here which is no. If I'm cherry-picking, I'm sorry, but it is in your opinion. You are saying there is no credible scientific evidence linking cigarette smoking to lung cancer before 1950 and this is your 1930 to 1950, and all I'm asking you is, therefore you are saying that in these 279 articles you are telling us there is no credible evidence linking, linking cigarette smoking and lung cancer.

MR. WOODS: objection.

A Well, I would say that qualitatively the essence of what I have been saying is correct.

Q How about quantitatively?

A And close to quantitatively. If I were writing this today I'm sure I would -- I had this discussion with Mr. Woods last night, I would put little credible scientific evidence rather than no credible scientific evidence. And actually as part of my testimony as I said before, that concern about this issue goes back awhile. But data is needed and that is what was lacking, plus ability is needed, that is what was lacking. It is not just a question of Dr. Tylecote thinking that writing a letter to Lancet do people believe this. I agree with the phraseology of Dr. Doll.

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15:31 As I said before he says that the suggestion that
15:31 cigarette smoking causes lung cancer goes back to
15:32 the twenties and thirties and forties. But it is
15:32 not until 1950 that a sufficient amount of good
15:32 scientific information is collected in a
15:32 responsible way that persuades more than a mere
15:32 handful of people to think that cigarette smoking
15:32 is the cause of lung cancer and other material
15:32 disease. I agree with Dr. Doll and that is my
15:32 testimony. I personally do not like the word no
15:32 in here because it leads to a sense of absolutism
15:32 which I'm really not trying to suggest. And I
15:32 would change it to little rather than no.
15:32 Q Page 3, the second sentence in that paragraph,
15:32 beginning --
15:32 THE VIDEOGRAPHER: Going off the record
15:32 for a tape change. The time is 3:29 PM.
15:40 (Short recess was taken.)
15:40 THE VIDEOGRAPHER: We are back on the
15:40 record. The time is 3:36 PM.
15:40 A May I make a brief statement qualification? I
15:40 believe this was contained in the conversation we
15:40 had prior to the break, but just to make sure, I
15:40 would like to say on that paragraph, again
15:40 documents get sent to you, you read them quickly,

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15:40 you sign them. If I were writing this today I
15:40 would not use the word no, I would use the word
15:41 little. And my main point is not to argue over no
15:41 versus little. My main point is remains the same,
15:41 to contrast the quantity and quality of scientific
15:41 evidence and the degree of concern evoked in the
15:41 rest of the scientific community before 1950 and
15:41 after 1950. 1950 is a watershed. That's really
15:41 the point that I'm making. Not to deny that there
15:41 were serious individuals who had genuine concerns
15:41 that smoking might cause lung cancer before 1950.
15:41 I don't want that wording to cause my main point
15:41 to be lost. I don't think it was, but I wanted to
15:41 make that clarification.
15:41 Q At the bottom of that same paragraph, the last
15:41 sentence says, "Rather the issue of whether
15:41 smoking caused disease was the subject of debate,
15:41 with reputable scientists on both sides." What
15:41 were the two sides?
15:42 A The issue was not the data that was being
15:42 accumulated from the epidemiological studies. The
15:42 issue was the interpretation of the data, whether
15:42 these new types of studies and the inferences that
15:42 could be drawn from them were sufficient to allow
15:42 conclusions about cause and effect to be made.

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15:42 Everyone that I'm aware of was worried about the
15:42 data. I don't know of anyone who was cavalier
15:42 toward it in the scientific community. The
15:42 question was are these statistical associations or
15:42 is there a true cause and effect relationship
15:42 between cigarette smoking and lung cancer. It was
15:42 the interpretation of the data that generated most
15:42 of the discussion. Other studies of course were
15:42 being conducted, pathological studies and studies
15:42 of skin painting studies and constituents of smoke
15:42 and other things. But the lack of an animal
15:43 model, the lack of an experimental model, the
15:43 lack of the ability to show in the traditional
15:43 fashion that cigarette smoking causes lung cancer
15:43 the same way that if you give someone measles who
15:43 hasn't had it they are going to contract measles,
17 and you are contracting them by coax postulates,
15:43 those traditional standards hadn't been met. That
15:43 was really the nature of the debate. Given what
15:43 conclusions we can draw from these new
15:43 epidemiological studies, by "new" I mean chronic
15:43 diseases. Epidemiology is do we have a
15:43 statistical association or do we have true cause
15:43 and effect.
15:43 Q Were there just two sides to that debate then or

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15:43 were there three, that with one group saying
15:43 smoking causes disease, the other group you call
15:44 them here both sides, saying smoking does not
15:44 cause disease, and a third group saying we don't
15:44 know yet whether smoking causes disease or not?
15:44 A Actually it depends on kind of how deep into the
15:44 story you want to go. But if one wants to get
15:44 subtle, there were groups, there were various sub
15:44 groups. There were some people and some people
15:44 became convinced early on, by early on, early mid
15:44 fifties, that cigarette smoking caused lung
15:44 cancer. There are others who said we are worried
15:44 but we really don't know. There were others who
15:44 said that, as you are saying now, that we can draw
15:44 -- we are worried but in the absence of an animal
15:44 model or traditional postulates of causation being
15:44 shown we are unable to draw that conclusion.
15:45 It actually gets more complex still because
15:45 even particularly -- now again let me make an
15:45 aside. We are talking about a rapid dynamic here
15:45 from skepticism in 1950 to a new consensus by
15:45 1964, the creation of the new field, the
15:45 epidemiology of chronic diseases. From a
15:45 historical perspective a lot happened quickly.
15:45 And year by year the tone changes and new studies

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come out. So what you say about 1952 is not the same as '55 or '58 or '61. So all of these qualifications have to be put into it. But particularly in the fifties, less so in the sixties, but particularly in the fifties you have other levels of debate, much of which had to do with debates among the epidemiologists themselves, not over just over the issue of whether cigarette smoking caused lung cancer, but how strong a cause it was. Was it a major problem or a minor problem relative to pollution or environmental exposure or something of this sort.

There was some epidemiologists, the majority of epidemiologists were saying that cigarette smoking causes lung cancer and it is a major cause and they of course were at the front of the bandwagon. But there were epidemiologists who were saying, "I think cigarette smoking contributes to lung cancer but it is a minor cause relative to occupational exposure or pollution or that sort of thing. From the early and mid fifties you have additional levels of debates that are going on. So it is more complex if you pursue it.

Q Do we have a group, maybe we don't, that says

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smoking does not cause cancer, lung cancer?

MR. WOODS: **objection.**

A Who are you talking about?

Q Well here I think in your statement here I think you are talking about between 1950 and 1964, and you talk about a consensus within the medical and scientific community, and then you say that there is reputable scientists on both sides. So we have talked about those reputable scientists on the side that say cigarette smoking does cause lung cancer, then you talked about the reputable scientists who say it may, but you don't have the proof so we are not going to say one way or the other. I'm asking, is there another group of reputable scientists between '50 and '64 who are saying doesn't cause it?

A If there are, Ms. Moltzen, I don't know of any. The debate had to do with what conclusions could be drawn from the epidemiological studies, what inferences were justifiable. I don't know of any responsible scientists who were saying that cigarette smoking is safe. I don't know of any responsible scientists of this period who were saying that I'm not worried. Everyone I know of is saying, "Hey, we have got something to worry

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about." The question was do these new standards prove it or in fact is this a false correlation and smoking is not guilty of the charges that have been put to it. I think they would phrase it like that. I don't know of individuals who are saying the whole subject is baloney, cigarette smoking is safe. I'm sure you can find people on the fringes, but I'm unaware of that view that responsible scientific community. It was more over is the statistical association merely that or are we able to conclude cause and effect. That is a more accurate representation.

Q The Surgeon General made a statement in here that I was going to ask you about. It is on Page 32 of his report.

A I think that's right here.

Q It is. It is under cardiovascular disease, the very top section. We are not talking about lung cancer here but it is more a statement of -- what he says here is the committee -- goes down to about the fourth line, "The committee considers it more prudent from the public health viewpoint to assume that the established association has causative meaning than to suspend judgment until no uncertainty remains." Do you believe that

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that, from a public health viewpoint, that that is a prudent way to look at the evidence that was out there between '50 and '64?

A If you are talking about cardiovascular disease as indeed they are talking about, I agree with that statement, believe it is a responsible statement. Medicine differs from science because as a physician or as a public health advocate you don't not have the luxury of waiting for all of that information. You have someone who is sick who is in front of you now and you have to make a decision. You may not know if this drug or that drug is the best or if you need any drug at all, but the patient is ill, is suffering, you don't have time to wait. So there are differences in the practice of medicine from science where you go off and you do an experiment, you wait for the data to come in.

And similarly, in public health, there may be sufficient worry where it may be prudent to make a recommendation rather than wade through all of the data. That's precisely the situation that occurred with coronary artery disease. It was ironic because the prospective studies as you know showed that cigarette smoking was related to or in

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some cases causally with a range of disease, not just lung cancer. The whole thing began with lung cancer. One of the surprises that occurred and people were surprised is the range of illnesses that are being associated with it. Now, some of the associations were very loose statistically and had other biological explanations. An excellent one in the Surgeon General's report is liver disease because so many people drink and smoke. So statistical association, the small statistical association they saw had other explanations. Coronary artery disease posed a real problem because the toll on the nation's health that appeared to be the result from coronary artery disease was much more than for lung cancer.

They began to study lung cancer, they are finding all this morbidity and mortality from coronary artery disease. The problem was the specificity was not as great. The chances of developing coronary artery disease, if I recall correctly, were about, it was 1.7 to 1, the nonsmoker versus the smoker for coronary artery disease versus 10 to 20 to 1 for lung cancer. The specificity was not as high. There are other factors that we were linking played a role in

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coronary artery disease, lipid levels, things of that sort.

On the other hand, if you just calculate the number of smokers who had coronary artery disease, it was several fold the number who developed lung cancer and that was a very disturbing finding and that led to the wording that you were pointing out over here and in my opinion that was very responsible.

Q Is that a responsible attitude, if we get away from coronary heart disease, let's talk about another chronic disease where there are some established associations, maybe lung cancer in the fifties. Is it still responsible to say that it is more prudent from the public health viewpoint to assume that the established association has causative meaning than to suspend judgment until no uncertainty remains?

A I'm not an expert in public health and in recommendations and degree of certainty that is needed so I'm really not the proper person to give an expert response, but I'm not trying to avoid it either. And I would say a couple of things. One, is that the degree to which you decide to act prudently is going to reflect the amount and power

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of the evidence, and the amount and power of the evidence was growing year by year. There was much more evidence in 1957 than in '53 or '54. There was more evidence in '62 than in '57. One has to be, in my judgment, very specific. At some point public health officials or physicians will make recommendations in a state of uncertainty. But you have to have enough evidence to justify that.

Then the second point to bring out is just how fragile this whole area of public health recommendations is because should you have a mammogram or not, should you have hormonal supplement. All of these things are coming out. You have epidemiological data suggesting one form of behavior, then they are contradicted by another. Just extraordinary confusion among the public and among the medical profession, the public health officials what to do. Add on to the fact that you are not -- you are talking about people's lives and life styles. There are economic implications with certain things. To change recommendations frequently you can do ill by having a recommendation or changing it as well as do good. It is a very difficult issue in my judgment in that the whole public health field and

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recommendations that we give the public. But again, I'm speaking as a reasonably well-informed citizen, not as an expert in public health and what recommendations to give.

Q In that same paragraph you use the word "debate." Rather the issue of whether smoking caused disease --

A Which paragraph are you in?

Q We are --

A Are we still on cardiovascular diseases?

Q Let's go back to your expert report.

A My expert report.

Q Page 3, paragraph starting -- the first paragraph. You talk in there about, the last sentence, "Rather the issue of whether smoking caused disease was the subject of debate with reputable scientists on both sides." Do you have any opinion on whether the tobacco industry shaped that debate by using its financial and public relations resources?

A I have no information to that effect. Candidly I would be surprised, just knowing how independent scientists are, knowing how many of the people of smokers who themselves at the start of the study then stopped smoking when they analyzed their own

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15:57 data, knowing that the worse thing that can happen
15:57 to a scientist is to be shown to be acting in some
15:58 sort of fraudulent or biased way. We all have our
15:58 biases, but it is one thing to have a point of
15:58 view, it is another thing to fabricate data, to
15:58 invent data, to suppress data. Scientists are
15:58 awfully independent people. We know that people
15:58 like Dr. Wynder and Dr. Graham and Dr. Doll and
15:58 Hill and Hammond are a very independent group. So
15:58 I have no direct information on that, but I would
15:58 be surprised. I'm always open to learn new
15:58 things, but I would be surprised.
15:58 Q At Page 3, the first paragraph, and it starts with
15:58 the fourth line down, "At no time between 1950 and
15:58 January, 1964 -- when the Surgeon General's
15:59 advisory committee report was released -- was
15:59 there a consensus within the medical and
15:59 scientific community that cigarette smoking caused
15:59 lung cancer, heart disease, or other
15:59 life-threatening diseases."
15:59 Who makes up the medical and scientific
15:59 community in the United States?
15:59 A Well, in general all those who are qualified
15:59 investigators you are talking about. Medical
15:59 school faculty, people at teaching hospitals, you

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15:59 are talking about in some cases people who might
15:59 be private companies, pharmaceutical companies,
15:59 for example, you are talking about private as well
15:59 as public research organizations, major private
15:59 cancer research organizations, for example being
15:59 Memorial Sloan-Kettering, publicly the National
15:59 Cancer Institute. You take the whole thing
16:00 together. The faculty and the people who are
16:00 doing research and the post-doctoral fellows and
16:00 so forth. It is a loose definition. So I would
16:00 be inclusive, not exclusive.
16:00 Q What do you mean by the term "consensus"?
16:00 A I'm glad you ask that. Because basically I mean
16:00 textbook teaching where you have individuals of
16:00 divergent backgrounds and perspectives and
16:00 temperaments and intellectual perspectives all of
16:00 who agree; textbook teaching, where you have --
16:00 where there is no debate, no serious debate on the
16:00 particular issue, where it becomes textbook
16:00 teaching, conventional. And again, I want to
16:00 stress among individuals from all perspectives and
16:00 traditions, not just a consensus within that,
16:00 epidemiologists, for example, but being able to
16:01 persuade the laboratory workers that their science
16:01 is a valid one, that type of thing.

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16:01 Q In December, 1963, was it textbook teaching that
16:01 cigarette smoking caused lung cancer, heart
16:01 disease and other life-threatening diseases?
16:01 A As I said before, this is certainly one of the
16:01 most intensely investigated issues in all of
16:01 bio-medicine. An enormous amount of information
16:01 is coming out, new analytical techniques are
16:01 coming out, new ways to analyze the data are
16:01 coming out. Epidemiology of chronic disease is
16:01 growing as a field and it could do statistical
16:02 calculations, for example, in 1959 that it could
16:02 not in '56 or '52. Year by year things are
16:02 changing.
16:02 What I would say if you are talking December,
16:02 1963, is that you got a near consensus. If you
16:02 compare the overall sentiment in 1963 within the
16:02 medical community that cigarette smoking causes
16:02 lung cancer, it is stronger than it was even a few
16:02 years ago, even a few years before that. The
16:02 Surgeon General, by the way, points out how even
16:02 from 1959 to the appearance of the report there
16:02 was a decided change in sentiment within the
16:02 scientific community. So it is not people lined
16:02 up evenly in one side. You have a growing
16:02 consensus that starts with 1950 and each year

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16:02 becomes stronger. If you are looking at December,
16:03 1963, most people are on board.
16:03 What I have discovered in my research acting
16:03 as a responsible historian, looking at all of the
16:03 information, is that you have pockets of
16:03 responsible disagreement even through 1963,
16:03 disagreement that later went away, and that's why
16:03 I would not say you had a consensus in 1963. I
16:03 think the most important disagreement came from
16:03 laboratory scientists who were troubled by the
16:03 ambiguity of the experimental evidence and
16:03 inability to have an animal model. The most vocal
16:03 such groups came from the most -- some of the most
16:03 important places in American and world wide
16:03 medicine. In particular the National Cancer
16:03 Institute and Memorial Sloan-Kettering. Those
16:03 were not people on tobacco company's payroll.
16:03 Those were people who had a different world view.
16:04 Even in '61, '62, is '63, laboratory workers from
16:04 those institutions were publishing paper were
16:04 worried, but in the absence of biological data we
16:04 are unwilling to conclude that there is a causal
16:04 relationship. Then some of the statistical
16:04 criticisms of Dr. Fisher and Berkson were still
16:04 unanswered. So those were the main pockets of

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doubt.

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sense, the only thing wrong with these criticisms is that scientific fact ultimately showed that they were on the wrong side, but the logic and the power is very powerful even today. The author says in this paper, "If I had been there in the late fifties and early sixties and read Dr. Berkson's papers I'm not sure what side of the debate I would have come down on." And finally I think it is important regarding Dr. Berkson that the Surgeon General's report itself addressed his objections. I believe that is extraordinarily important both to the legitimacy of Dr. Berkson as an individual as well as in answering residual doubts, creating a consensus and so forth. But the Surgeon General addressed his criticisms. Essentially the report said Dr. Berkson is right in his criticisms. There are certain biases in these studies and analyses that are there, but the magnitude is much less than he claims. So even with these biases, the conclusion that cigarette smoking causes lung cancer we believe is a valid conclusion. The fact that the Surgeon General report addresses Dr. Berkson on those criticism in my opinion is evidence that he was a serious man taken seriously by his contemporaries.

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Now this is much different from 1962, '61, '60. Each year you have the growing consensus. But in my judgment it took the Surgeon General's report to really clench things, to persuade the remaining residue of laboratory workers that this method of analysis was valid and so forth. That's why I considered it such an important document.

Q Wasn't Berkson's opinion pretty marginal?

A I would disagree with that. That's an incorrect statement. Number 1, Berkson was considered to be the most important biostatistician in the United States, so he was very highly regarded at the time. Number 2, if you read his objections you find that there is a great, in my opinion, a great deal of credibility to them, if you actually read them.

One of the most important articles for me in formulating my views was an article entitled "Those Who Were Wrong." And I forget the author of the article, but it would be in the bibliography. It this an eminent epidemiologist who actually went back and read the statistical criticisms of Dr. Berkson and said, "You know, they really" -- and Dr. Fisher, they really make

Q Do you know if Dr. Berkson, if any of his research was funded by the tobacco industry?

A I have no information on that one way or the other. But I don't think it would make any difference to me if it were.

(Deposition Exhibit No. 14 was marked for identification.)

Q I'm going to hand you what has been marked as Ludmerer Deposition Exhibit 14. It is a report by BAT Co Scientists, visit to United States and Canada, in April and May of 1958. And the Bates number is 105408490 to 8499. And the second page lists many of the places that they visited including medical schools, also tobacco companies. On the third page, which is headed up Page 2, there is an introduction, and then the second section is called "Causation of lung cancer." These BAT Co scientists say, "With one exception, (H.S.N. Greene,) G-R-E-E-N-E, the individuals whom we met believed that smoking causes lung cancer. If by "causation" we mean any chain of events which leads finally to lung cancer and which involves smoking as an indispensable link. In the United States only Berkson, apparently, is now prepared to doubt the statistical evidence and his

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16:09 reasoning is nowhere thought to be sound."
16:09 Do you disagree with their opinion of Dr.
16:09 Berkson?
16:09 A Yes, I do, very much. I have actually seen this
16:09 document before because in a previous deposition
16:10 it has been presented to me. And aside from the
16:10 usual qualifications that a responsible historian
16:10 would have about any document, who wrote it and
16:10 what were the circumstances and who was it for and
16:10 how was it received and what were the reactions to
16:10 it and that whole litany of things that you see
16:10 about documents. The fact is that though that
16:10 statement is there, it is an incorrect statement.
16:10 It is wrong. Dr. Berkson was the leading medical
16:10 statistician in this country. He was widely
16:10 recognized around the world for his contributions.
16:10 As I indicated before, he was so notable that
16:10 there is a section in the Surgeon General's report
16:10 that specifically addresses objections that he
16:10 raised and they said, "You are right, it is just
16:10 that the magnitude doesn't change the results." I
16:11 have seen no one refer to Dr. Berkson
16:11 disparagingly other than in this document and I
16:11 would disagree with their characterization of him.
16:11 Q Is it possible to take the word "consensus" and

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16:11 turn it into numbers so that you could say after
16:11 January, 1964 a majority of the scientific and
16:11 medical community – medical community agreed that
16:11 cigarette smoking causes cancer, heart disease or
16:12 other life-threatening diseases?
16:12 A Could you please repeat that? Probably the day
16:12 but there is something --
16:12 Q I'm trying to understand if I can put the word
16:12 "consensus," which you have described in very
16:12 conceptual terms, into numbers so that if we lined
16:12 up the scientific and medical community and we
16:12 said only 49 percent of them believed there was
16:12 a – believed that there was a connection, that is
16:12 not a consensus. How big quantitatively do you
16:12 have to get before you get a consensus?
16:12 A I'm speaking personally on that because
16:12 philosophers and historians can debate these
16:12 issues and they get theoretical. But I think from
16:12 a pragmatic standpoint, it is a judgment call.
16:12 Like anything in history, like anything in
16:12 science, just as the Surgeon General acknowledges
16:12 that conclusions about causation ultimately are
16:13 judgment calls and science and scholarships and
16:13 history are making judgment calls, and I think it
16:13 would be an error to try to equate it with a

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16:13 certain percentage of the popular vote.
16:13 Now I would say two additional things. You
16:13 got to have an awfully high percentage. You are
16:13 not talking 70/30, 80/20. You are talking
16:13 virtually everyone. But there are qualitative
16:13 aspects that help one recognize a consensus. Do
16:13 you have ongoing debate or does the debate end.
16:13 Are people who continue to advocate a certain
16:13 view, is that a mainstream view or have they
16:13 become marginalized. There are qualitative
16:14 aspects to that. And also it is very important to
16:14 keep in mind, particularly when you are in the
16:14 70/30, 80/20, 90/10, this is how we are going from
16:14 the early fifties to mid fifties to late fifties
16:14 to early sixties, each year the number grows. You
16:14 also have to look at who is on your team. It is
16:14 not numbers alone but it is the intellectual
16:14 stature of the person, of the people who are
16:14 speaking. If any one of us were to have Michael
16:14 Jordan as a partner I will bet that team of two
16:14 would beat the rest of us combined in basketball.
16:14 And I think that is one reason that these,
16:14 what I'm calling residual doubt amidst a growing
16:14 majority and emerging consensus was a real one in
16:15 the early sixties. Who did it come from? No one

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16:15 was intellectually more important in these debates
16:15 than Ronald Fisher, who is the greatest scientific
16:15 mind of all and whose work was the basis of
16:15 epidemiology of chronic diseases. The fact that
16:15 Fisher and other biostatisticians continued to
16:15 express their reservations was important beyond
16:15 numbers. It is like giving me Michael Jordan on
16:15 my team. Fisher was one of the dominant
16:15 biologists of the 20th century. The fact that the
16:15 leading laboratory workers at the National Cancer
16:15 Institute and NIH did not yet accept the new
16:15 paradigm that you can accept – that you can make
16:15 causal inferences from epidemiological studies.
16:15 The quality of some of this group of residual
16:15 doubters counted as well. So it is not numbers
16:15 alone. And you find -- if you pick and choose
16:16 selectively and just tell the story of one
16:16 discovery leading to another and the growing
16:16 consensus, you get one view. If you look at the
16:16 literature exhaustively and comprehensively as I
16:16 do, you essentially get the same picture, but you
16:16 also realize that not everyone went along yet with
16:16 the growing consensus, and these were leading
16:16 responsible people that was legitimate and it took
16:16 the Surgeon General's report to get everyone on

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board.
Q Has the debate ended today?
MR. WOODS: Objection.
A Which debate?
Q You said one of the things you have to look at when you are deciding about consensus is the quality of the people; and did the debate end?
A I think the evidence clearly points to the appearance of the 1964 Surgeon General's report and an extraordinary intellectual contribution that it made as we talked about before, the five criteria and how one uses this information. Not the information per se, but how you use it and draw inferences and conclusions from it. I think, Number 1, it is accurate to say that our current consensus, that cigarette smoking causes lung cancer, emerges from that. Number 2, I haven't studied things since 1964, but I do know that the epidemiology of chronic disease emerges a new discipline from this debate and has become an important part of biomedicine. Even if you are a laboratory worker today, you recognize that there is an alternative mode of showing causation besides demonstrating it in an experimental way which laboratory workers of the fifties and

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sixties had to learn to accept. So I don't know of anyone today, if you are talking 2002, who would say that this is not an alternative paradigm.

Now, you can find responsible scientists, we got them in my own university, who will tell their patients not to smoke, who will talk about the hazards of cigarette smoking and both the personal and public health menace it is. When they get with their laboratory groups in seminars and say and we still have holes in the biological evidence, we need more work. But that's a different sort of thing. They accept the epidemiological data. I certainly accept it.

Q I believe the statement you use eventually in here is in the aftermath. I apologize if I'm quoting that wrong, but --
A You are probably quoting it correctly.
Q I want to know but -- I got it now, Page 6 of your report. The sentence, it is the second paragraph, "In 1964 the advisory committee." If we go down to the seventh line there is a sentence in there that starts, "Even though a consensus about causation developed in the aftermath of the 1964 report." I don't mean to be nitpicky, I really

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want to know what you mean about that term. Give me -- what is aftermath? What are we talking about?
A I appreciate your asking it. I appreciate the tenor of the conversation we have been having all day long where we can discuss things. It is very possible if I were writing this today I might use slightly different words. Let me just explain my views to you which is really what you need. Number 1, I maintain that our current consensus that cigarette smoking causes lung disease and other diseases as well, that the final step in the process that gave that consensus was the 1964 Surgeon General's report. It didn't come out of the blue. There is a growing consensus year by year.

But this consensus, this lack of debate, this acceptance even by laboratory scientists, you know that is, Surgeon General is right, there are other ways to prove causation, that dates the '64 Surgeon General's report we have inherited since then. That is the first and most important point that I'm making.

The second point that I wish to make in this, and this is where things get tricky because

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history is messy and untidy and also it is hard to say things in a seven page report. This has very much to do with the issue of scientific revolutions and paradigms.

In my opinion the most important contribution of the Surgeon General's report, '64, great document that that is, is not merely in demonstrating that cigarette smoking causes lung disease and other diseases as well, but in bringing about the maturation of a new field and acceptance of this new field by the rest of the biomedical community, epidemiology of chronic diseases, because these same techniques have now been used to study many other problems as well and have become an important part of medical research. In my opinion that general contribution is even greater than the specific observation that cigarette smoking causes lung cancer, as important as that is. This gets us back to context, this gets us back to how historians think about problems, this gets us back to scientific revolutions. Is everyone going to change their mind immediately? And the answer is probably not. People who have studied scientific revolutions, again we go back to my paradigm bibliography, have

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16:22 pointed out that when you have one world view
16:23 arising to challenge or replace another,
16:23 ultimately it is less that residual doubters are
16:23 persuaded, it is that they die off or retire.
16:23 There is that element to it.
16:23 Consider someone who is 50 years old in 1950,
16:23 an eminent laboratory worker at the top of his
16:23 field, internationally renown, who has been
16:23 brought up with the old paradigm that you need
16:23 laboratory confirmation, who has heard all of the
16:23 arguments. Such an individual who in December,
16:23 '63, may not have bought into clinical
16:23 epidemiology, might not in '64, he is set in his
16:23 ways. Is such a person irresponsible?
16:23 What I'm really trying to say there, and
16:24 can't do it very well in the short number of
16:24 pages, is that if you were looking at doubters,
16:24 you have to look at who they were, when they spoke
16:24 and how they framed it. For example, the best
16:24 example that I know of is Dr. Brownlee from the
16:24 University of Chicago. By coincidence I
16:24 discovered his review of the Surgeon General's
16:24 report that was published in 1965 in the Journal
16:24 of American Statistical Association. This is a
16:24 statistician speaking, not a laboratory person.

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16:24 And he was critical of the report basically
16:24 because he felt that for all of the information
16:24 that has been assembled without direct biological
16:24 confirmation you cannot draw conclusions about
16:24 causality. Now this is 1965. It is not 2002.
16:24 He was very cautious in his wording. He was
16:24 acknowledging that he was worried about the
16:25 evidence, he was not saying that cigarette smoking
16:25 is safe, but he is saying by traditional canons
16:25 the case has not been proved. Scientists are
16:25 independent.
16:25 I know the Surgeon General came up with these
16:25 new criteria and people are trying to say there
16:25 are ways to prove things without direct biological
16:25 experimental confirmation. I just don't go along
16:25 with that. And I'm unwilling to say that a person
16:25 like that is acting irresponsibly. That is really
16:25 what I'm saying. Even though I would also say you
16:25 got the consensus. Most people jumped on board.
16:25 The laboratory workers who in the sixties were
16:25 saying you can't do it epidemiologically, they
16:25 quieted down, it enters the textbooks. I'm making
16:25 that qualification that for the Brownlee type of
16:25 person.
16:25 **Q For the people who do decide to jump aboard**

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16:25 **though, I'm Midwestern through and through, very**
16:26 **practical, born and bred in Minnesota, so it just**
16:26 **seems to me that just because I get the Surgeon**
16:26 **General's report in the mail, when you use**
16:26 **aftermath, you do not necessarily mean within the**
16:26 **next couple of days I go eureka and suddenly the**
16:26 **consensus has -- there is a total consensus?**
16:26 A That's correct. Aftermath is hard to quantify in
16:26 a precise way and here I'm relying on secondary
16:26 reading that I have done rather than primary
16:26 reading. But we are talking weeks, months,
16:26 someone may be on vacation when the Surgeon
16:26 General's report comes out. As I discussed before
16:26 in response to one of your questions, a lot of
16:26 consensus building or consensus deconstruction
16:26 occurs not from the paper itself but the informal
16:26 conversations, opinions of -- opinion makers, Dr.
16:26 Smith the Surgeon General's report came out, do
16:27 you really believe it, do you buy into it. I do.
16:27 Then the students or the other people say I might
16:27 as well. We are talking about a process that on
16:27 the one hand did not occur the next day
16:27 immediately but nonetheless move relatively
16:27 quickly.
16:27 You find epidemiology being accepted as a

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16:27 discipline in medical schools, and departments
16:27 being created and textbooks being written and new
16:27 organizations being formed and a lot of evidence
16:27 of this sort of the acceptance of a field. You
16:27 find that the published articles that would
16:27 dispute the causation hypothesis that you find
16:27 from reputable people even in the '61, '62, '63,
16:27 they stop appearing, I think that's notable. So
16:27 it is hard --
16:27 I think you are exactly right that it is hard
16:27 to give a precise time frame to it. We are
16:27 talking something pretty quickly. Of course as
16:27 you know better than I, the report led to the
16:27 legislation requiring warning labels. A lot of
16:28 things happening suggesting that things had
16:28 changed. Epidemiologists who lived through the
16:28 period talk about how even by the mid sixties the
16:28 field of epidemiology was much more secure than it
16:28 had been even a few years before. One can go on
16:28 and on with these sorts of examples. But it was
16:28 pretty quick.
16:28 **Q Do you have an opinion on when there was a**
16:28 **consensus within the medical and scientific**
16:28 **community that cigarette smoking was linked to**
16:28 **coronary heart disease?**

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16:28 A I believe from secondary sources that the Surgeon
16:28 General's report was accepted as a whole so that
16:29 it drew causal conclusions about cigarette smoking
16:29 and bronchitis, as far as I'm aware from secondary
16:29 sources, as well as personal experience in medical
16:29 school, I'm just recalling anecdotally that was
16:29 accepted that the concerns of coronary artery
16:29 disease were real, so forth. I'm unaware of
16:29 anyone -- I'm not saying it didn't happen, I'm
16:29 just saying I'm unaware of someone saying I accept
16:29 this conclusion of the Surgeon General's report
16:29 but not that conclusion. If it happened, I'm not
16:29 aware of it.
16:29 Q Are you familiar with the Frank Statement?
16:29 A Yes, I am.
16:29 Q If I use that term.
(Deposition Exhibit No. 15 was marked
for identification.)
16:30 Q I'm handing you what has been marked as Ludmerer
16:30 Exhibit 15. The Bates number on that one is CTR
16:30 PUBLIC STMT 000010. The Frank Statement was
16:30 published in what year, do you remember?
16:30 A Yes, I do. That would be sometime in January of
16:30 1954.
16:30 Q The first paragraph says, "Recent reports on

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16:30 experiments with mice have given wide publicity to
16:30 a theory that cigarette smoking is in some way
16:30 linked with lung cancer in human beings." Do you
16:31 know what experiments TIRC is talking about here?
16:31 A Yes, I do. They are referring to the Wynder
16:31 Graham skin painting experiments which were
16:31 published late 1953, November, December, '53,
16:31 somewhere in that ball park.
16:31 Q And then the third paragraph is, "At the same
16:31 time, we feel it is in the public interest to call
16:31 attention to the fact that eminent doctors and
16:31 research scientists have publicly questioned the
16:31 claimed significance of these experiments." Who
16:31 were a couple of those eminent doctors and
16:31 research scientists, if you know?
16:31 A I think the best place to start would be Dr.
16:31 Wynder and Graham themselves who made a point in
16:31 the paper that their positive experiments in mice
16:31 was not proof that cigarette smoking in the way
16:31 human beings smoke cigarettes caused lung cancer
16:31 in humans. It was obviously consistent with that
16:32 claim but they themselves explicitly in the papers
16:32 say their major reason for doing it was to see if
16:32 they could identify something in cigarette smoking
16:32 that might be carcinogenic and then you would have

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16:32 a tool for other studies. They also themselves
16:32 made the claim that though consistent with the
16:32 hypothesis, this is not a proof of that. So the
16:32 authors of the studies themselves are a very good
16:32 place to begin.
16:32 Q Then in the next paragraph there are some points
16:32 that are numbered 1, 2, 3 and 4. And number 4
16:32 says, "Statistics purporting to link cigarette
16:32 smoking with the disease could apply with equal
16:32 force to any one of many other aspects of modern
16:32 life." Do you know what other aspects of modern
16:32 life are being alluded to here?
16:32 A Yes. Now, again we are looking January, 1954 so
16:33 we have to put it in the context of the time. A
16:33 lot of the possibilities that would come up in the
16:33 thirties and forties had already been excluded.
16:33 You will remember from some of my earlier comments
16:33 that I pointed out how a typical review article of
16:33 the thirties or forties might have 15 or 20
16:33 possibilities, now we are down to a handful. The
16:33 major ones were if we are talking January, '54 --
16:33 Q I believe you are right.
16:33 A Because of the appearance of this, that included
16:33 occupational exposure, environmental pollution,
16:33 tarring of the roads, exhaust fumes, radiation,

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16:33 the whole fall-out issue. But the same type of
16:34 statistical correlation between the tarring of the
16:34 roads, between the pollution of the atmosphere,
16:34 between exhaust fumes occurred as it did with
16:34 cigarette smoking. So it is my understanding that
16:34 those handful of associations are what were meant
16:34 by that statement. By the way, that's a smaller
16:34 list than of the thirties and forties. But in the
16:34 context of January, 1954, in my judgment it is a
16:34 reasonable list.
16:34 Q Why is the list smaller than in the thirties and
16:34 forties?
16:34 A Because there was -- because in science, evidence
16:34 counts. And people are now really investigating
16:34 the issue more intensely and with more refined
16:34 techniques and methodologies. The influence of
16:35 pandemic of 1819 that some people thought was a
16:35 cause of lung cancer, there was no evidence to
16:35 document that. Could lung cancer arise from
16:35 previous infection of the lung, you have an
16:35 abscess, Tuberculosis, there was no evidence of
16:35 that. When I was a medical student in the 1970's,
16:35 even then I recall hearing house officers and
16:35 attending physicians speak of this phenomena that
16:35 they called scar carcinoma, the idea of the lung

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cancer coming out of the scar. Trauma had been ruled out. There are things that from our perspective looked silly, but again the historian analyzes things at the time. In the thirties, it is in my bibliography, it really astounded me, there were seven, eight, 10 papers suggesting tomato juice was the cause of lung cancer. No one had any evidence to document that. So in this period you have 15, 20, maybe even 25 possibilities bandied about. But now people -- not only are more people investigating the cause of lung cancer --

Q When you use the word now, you mean January, 1954?

A January '54, and since 1950 it really became a hot issue. Epidemiological techniques are being refined, developed and refined, some of these earlier ideas are not finding evidence to verify them. So the 15 to 20, 25 possible causes that you hear about in the thirties are now narrowed down to half a dozen or so by January, 1954. We should add genetics. Genetics is not a statistical association but 1954 the gene is identified, genetics is developing as a science. In 1954 stomach cancer was shown to have a genetic cause. Some people thought that ultimate answer

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for lung cancer might be a genetic one. Of course we also should put other. There was no guarantee at the time that any of these possibilities would ultimately be shown to be the factor. We were down to maybe half a dozen or so if you are talking January of '54. Most of which have this type of statistical association.

THE VIDEOGRAPHER: Going off the record for a tape change. The time is 4:33 PM.

(Short recess was taken.)

THE VIDEOGRAPHER: We are back on the record. The time is 4:44 PM.

Q Dr. Ludmerer, on Page 4 of your report --

A Of my report?

Q Your report, this is the last sentence, it is going to go on to Page 5. It says, "Between the mid 1950's and early 1960's researchers were unable to identify any agent or combination of agents in tobacco smoke that could account for its alleged cancer-causing activity."

Did researchers identify any kind of hazardous -- at that point many time, I'm sorry, any kind of hazardous chemicals in tobacco smoke?

A Yes, they did.

Q What kind of chemicals?

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A The most important single observation was the detection of benzoapyrene, an organic polycyclical chemical. The first conclusive demonstration of that was 1954 that subsequently was confirmed many times. As I indicated confirmation and replication were of part of the scientific process. Other polycyclics were subsequently identified and then ultimately lots of other different types of chemicals as well. The single most important discovery I believe was the discovery of benzoapyrene in 1954. It was confirmed according to the Surgeon General 19 times in the intervening decade by 1964.

Q And what date was it widely concluded that the amount of benzoapyrene in tobacco smoke was simply too small to have a cancer causing effect?

A Almost from the beginning.

Q That was again I'm sorry, did you say a --

A The first discovery was 1964 of the presence of benzoapyrene.

Q '64?

A Excuse me, '54 was the first discovery. Now when did people start noticing that you got a problem with dosage? I'm not entirely sure when the first one was but I know as early as '56 or '57 Dr.

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Wynder himself discussed this problem of dosage and this became a recurrent theme in the literature. As we sit here today I recall an article from Lancet in 1962 that discussed the same problem. Benzoapyrene is there and by now other known carcinogens as well. But the dose is too low to account for the observed carcinogenic properties of cigarette smoke. This is also a thing I'm sure you are aware in Surgeon General's report itself, in the report it calls this, a quote, puzzling anomaly. That's the Surgeon General's term, not Ludmerer's term.

They would have expected theoretically 40 times the amount of benzoapyrene than investigators were able to demonstrate if benzoapyrene were the cause of the carcinogenic potential they were seeing in cigarette smoke. That's what the discussion was about.

Q Up to the Surgeon General's report then in 1964, had any agent or combination of agents and in tobacco smoke that could account for its cancer causing activity, was any agent identified?

MR. WOODS: Objection.

A The problem as I understand it through the Surgeon General's report was that no single agent or

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combination of what by then was a large number of known agents, was sufficient to account for the carcinogenic potential. And this was troubling -- a troubling piece of evidence. They thought it would be easy, benzoapyrene, here you have the high dosages, and that's the cause. It led to a discussion of promoters and co-carcinogens and things of that sort. But it was largely the theoretical level. If you look at the 1964 Surgeon General's report is dominant observation is what the Surgeon General calls a puzzling anomaly. Lots of carcinogens demonstrated be present in cigarette smoke but such low dosages that we are unable to relate the carcinogenic properties to those chemicals. So either there is something else that we are not -- it didn't keep them from accepting -- you don't have to know the mechanism to know that something causes a problem. You don't have to know about vitamins to know that citrus fruit will prevent scurvy and if you develop scurvy you can give citrus fruit. In terms of the biological reaction. It was troubling. They thought they had identified the carcinogen but it turned out with further inquiry they really hadn't at 1964.

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And I would like to volunteer this. I know in depositions witnesses should say less rather than little, but just in terms of the theme we have been taking of words I would say differently and so forth if I proofread it a little more carefully of that sort.

Q What page should I turn to?

A Turn to Page 5. First sentence of that page, "The inability to identify this unknown agent was also considered strong evidence against the causation hypothesis in the 1950's and the early 1960's." Literally that's true. And I defend that but quite frankly I would phrase it differently and talk about, say something to the effect that the inability to identify this unknown agent was disturbing in terms of proving the causation, the hypothesis, something of that sort.

There are a few places in this report as we talked about already where words are a little more dogmatic or axiomatic than I really intend them to be, and I would like to correct the wording of that now.

Q This is on Page 6 --

A Of my report?

Q Of your report. It is that first paragraph where

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you are discussing the disagreement in the statistical community. You talk about Fisher in England and Berkson at the Mayo Clinic, and then the second to the last sentence, "These are only a few of the many scientists at the time who questioned whether the scientific evidence of that time established that smoking caused lung cancer." Can you give me the names of two other scientists in addition to Berkson and Fisher who questioned that?

A Who questioned whether cigarette smoking caused lung cancer?

Q I think it is who questioned whether the scientific evidence at that time established that smoking caused lung cancer.

A Well, there are lots of such individuals. Though, as I said before, we've got a very rapid dynamic so people who may have expressed skepticism in 1956 may have jumped on board by 1960. So there is a dynamic. By the way, American Lung Association, one of the major public health associations, I think it was the Lung Association, refused to accept causality in 1956. But in 1960 it did. So again you have this evolving dynamic. But in terms of the scientists themselves, in

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addition to Drs. Fisher and Berkson, you got several different types of people. In my opinion the most important were the eminent laboratory workers who just were of the world view they need laboratory confirmation. Examples would include Dr. Frank Corsfeld who was in charge of things at Memorial Sloan-Kettering. Dr. Stanley Greenam who was charge of the private cancer institute in Philadelphia, who would include Dr. Rod Heller who is director of the National Cancer Institute, it would include Stewart and Shear who respectively were the most important pathologists and the most important experimental cancer researcher at the National Cancer Institute. But laboratory types of people.

In addition to that, there were lots of people on the front lines who had yet to be persuaded. By that I'm talking pulmonary physicians, lung surgeons and so forth who are part of a general community who ultimately came on board in terms of the final consensus but through the sixties are continuing to write articles expressing their disbelief at the causal hypothesis. These were all groups of people in addition to the statisticians like Berkson and

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16:59 Fisher.
16:59 **Q Now, in that last sentence on Page 6, first paragraph, --**
16:59 A I also would like to make an important qualification in my answer to the last question in that sentence. I said it before but I think it is so important that I would like to say it again. From 1950 with the initial retrospective studies through the Surgeon General's report, you got one of the most dynamic rapidly changing and developing areas in all of medicine and you have what I like to call a growing consensus or evolving consensus or emerging consensus. I am not saying that people were suspending judgment during this period or that you have people equally lined up on both sides waiting the final dictate from the Surgeon Generals. It wasn't like that at all. Each year more evidence is accumulated, new statistical techniques are devised, new studies are published, there is an ongoing dialog among all investigators that was invigorating and stimulated further research.
17:00 You find year by year more and more physicians and scientists being converted to the view that cigarette smoking causes lung cancer,

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17:01 and I agree with the Surgeon General's characterization in his report that even from the '59 public health statement through '64 there was an additional turn of sentiment and more people from the scientific community who came on board. What I'm saying is that you didn't yet have that full consensus and that you had responsible people even in the sixties who had not yet come on board. I'm not trying to suggest the suspension of belief or people lining up on both sides or anything of that sort. I don't wish my views to be misinterpreted.
Q Page 6, second paragraph, "These areas of disagreement continued in scientific circles up through and even beyond the Surgeon General's advisory committee report of 1964." Now, am I right to assume that you did not read primary literature after January of 1964?
A That is correct.
Q So this opinion is based more on secondary literature?
A Well, it is based on -- actually that opinion comes from primary sources that I found. I didn't systematically review, but you read something, you look at the bibliography and the references and

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17:02 that leads you to other things. And what I found were things such as Professor Brownlee's negative review of the Surgeon General's report that appeared in the Journal of the American Statistical Association in 1965. I would call that a primary source. And I use that in the context we said before. I'm not saying there wasn't a consensus. I'm not saying that the public debate didn't quiet down. But am I willing to say that someone who may not have gone along with the Surgeon General's report, particularly someone later in their career, particularly someone who had a different paradigm, am I willing to speak in a derogatory fashion about that person? I'm not. That's what I'm really trying to say here.
Q All I'm trying to figure out is how far your actual literature review went. For instance, that article you mentioned just now --
A That was 1965.
Q That was probably the last piece of primary literature that you read?
A That's correct.
Q Will I find that in one of the bibliographies?
A Yes. And I found that by accident. By accident I

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17:03 mean you read an article, including secondary sources, I look at the sources, so I found that and I couldn't tell you where offhand, but this worked out 13, 14, 15 years ago, but I found it in a bibliography of a secondary source and I went and looked at the original.
Q Are there many other articles between January of 1964 and January, 1965, that you have reviewed included in your references and are part of your opinions?
A Not many. That may even be the only one. It is notable because it illustrates so many important points. But I did stop my primary study of the literature with January, 1964. It was serendipity that I learned of the Brownlee. It taught me a lot but I did not systematically go beyond 1964, I'm not testifying beyond 1964.
Q This is on Page 6 and it is that second paragraph. Several questions about terminology so I will just jump in. It is that paragraph that starts, "In 1964 the advisory committee made the judgment," then ends with, "embraced the report." That's about three sentences. Again you are talking about the consensus. Again I just want to make sure we are still talking about the consensus

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among the scientific and medical community, correct?

A That's correct. And again, on this question of wording and tone, the real point that I am making has to do with this issue of legitimate disagreement, paradigm shift, scientific revolution, to get the 100 percent of people on board rather than the 98 or 99 percent. The last one or two percent usually has to die off or retire as opposed to being persuaded. It doesn't mean they are being dishonest or acting in an unethical fashion or some sort. There are people like Dr. Brownlee who had a different paradigm could not accept the new paradigm. That's really a point that I'm making. I am maintaining that our consensus came with the Surgeon General's report. I'm not moving that back.

Q Is it true, though, that the consensus was growing ever since, during the fifties and the early sixties?

A Well, as I have been attempting to say all day, we got a watershed, that's Dr. Doll's term, in 1950, and from that point forward the scientific community was very worried that cigarette smoking caused lung cancer. Now, there is a lot of

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disbelief initially and even the authors of the retrospective studies were very careful and would not conclude cause and effect relationship. That really changes in the mid fifties as you know with prospective studies. As I have been saying all day, this is a dynamic.

There was a substantial body of information available to the Surgeon General in 1964 that his predecessor, Dr. Burney, didn't have in 1959. New work is continuing to be done. New methods are continuing to be developed and applied. New proofs are continuing to be demonstrated. So every year you find the scientific community more concerned. And I have been using the term growing consensus, evolving consensus, to describe the phenomena that the Surgeon General describes it. Even from '59 to '64 there was a decided term sentiment in the scientific community with even more people accepting the causation hypothesis. So it is a very rapid dynamic. Each year in response to evidence and argument more and more people are jumping on board, and that continues through the Surgeon General's report which is the terminal event in this chain that goes back for a considerable period of time.

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Q A couple other terms you have used throughout the day are retroactive and prospective.

A Retrospective.

Q Retrospective and prospective studies. Can you for a layman just define what those are?

A Yes. Retrospective means looking backwards. Prospective means looking forward. The retrospective clinical studies, typically you would get some patients with lung cancer and then do chart reviews and try to get a control group that is as close to the patient, group of patients as you have and control for as many variables that you think of to see what factors might be different between those who develop lung cancer and healthy population that did not. Initial epidemiological studies that were published, they continue to be published, but beginning in 1950, were retrospective studies.

Prospective studies means going forward. The prospective studies began being published in the 1950's. They were continued beyond that time. They didn't stop then. They began in the fifties and continued. There you have a large population of patients, you divided them between those who smoked and those who didn't smoke, and you

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followed forward over time with what happened to them. For various technical and mathematical reasons the intellectual power of the prospective studies is much greater than those of retrospective studies, so they were very instrumental in changing opinion on this issue.

Q Do you know what the public position of the tobacco industry about causation was when the Surgeon General's report was released?

A No, I don't. I have not studied the tobacco industries position on these issues at all. It is out of my area and I haven't studied it and have no intention to do so. That's a different expert, you can ask him about that.

Q We are near the end of Page 6, that second paragraph, and I'm going to read whole section because if I just read the sentence I have a question about it is out of context. "Merely because a consensus had developed does not mean that people cannot legitimately disagree. Many of the dissenting scientists disagreed with the judgment of the 1964 report because they did not accept that epidemiology could prove causality. They held out for a higher standard of proof, one requiring experimental proof of causation." It is

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17:12 a general question about the term higher standard
17:12 of proof. What are the various levels of
17:12 scientific proof?
17:12 A Well, that depends on what your world view is.
17:12 Again, you are dealing with basic theoretical and
17:12 philosophical issues. The traditional standard of
17:12 proof has been the experimental model. So if I
17:12 want to demonstrate that lack of insulin causes
17:12 diabetes, I have to get people or dogs and take
17:12 out the pancreas and show that it produces
17:12 diabetes. Then even better if I give them
17:12 insulin, they do well. An experimental
17:12 demonstration.
17:12 In the area of toxicology, and pharmacology
17:13 which is fairly closely related to cancer, if you
17:13 are talking about an agent that causes disease,
17:13 this was a traditional standard, if you got a
17:13 poison you have to be able to show with animals
17:13 that it is a poison. Humans, you can do it with
17:13 humans too, although that is not ethical in most
17:13 cases. This laboratory demonstration and an
17:13 experiment that arsenic makes you sick or that an
17:13 overdose of a certain medication makes you sick,
17:13 this was the traditional method of showing
17:13 causation that dominated medicines from the dawn

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17:13 of the modern era with anatomy, vesalius (ph) and
17:13 so forth. It was also the dominant paradigm in
17:13 old infectious disease, epidemiology and public
17:13 health, where you -- the so-called true separate
17:13 form of epidemiology because you would use coax
17:14 postulates. If you got -- if someone were ill
17:14 with an infection you can culture the organism and
17:14 show that it is there. So this laboratory model
17:14 applied to infection in the epidemiology of
17:14 infectious diseases as opposed to -- as well.
17:14 Now chronic disease has come along in the
17:14 middle of the century and started receiving the
17:14 focus after World War II. And the problem that
17:14 medical science faced was that the tools of the
17:14 infections disease epidemiology or the old
17:14 epidemiology as a generalization were not
17:14 suitable, were not powerful enough to show cause
17:14 and effect for cancer and other chronic diseases,
17:14 and the laboratory people were having a hard time
17:15 too because cancer was a tough nut to crack. Keep
17:15 in mind the context of the time. We are talking
17:15 forties and fifties. We are not talking electron
17:15 microscopes and inframerics and geno projects. We
17:15 are talking test tubes and beakers. And in fact
17:15 DNA wasn't even identified structurally until '53

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17:15 or '54. So the experimentalists were not having
17:15 the same -- any more luck with chronic diseases
17:15 either. But the traditional standard of proof
17:15 that applied both for causation did involve this
17:15 ability to show in an experimental fashion that
17:15 this agent causes disease. You could do it with
17:15 infections, coax postulates. You could do it in a
17:15 laboratory by giving an animal a toxin. And that
17:15 was unsuccessful with lung cancer and other
17:16 chronic diseases as well.
17:16 So as a result, we have the creation of a new
17:16 discipline, the epidemiology of chronic diseases.
17:16 One of the authors that I cite in my bibliography
17:16 calls this the second epidemiological revolution.
17:16 Infectious disease epidemiology being the first.
17:16 You start doing not only retrospective studies but
17:16 very well designed retrospective studies in terms
17:16 of patient selection and randomization and
17:16 controls and variables that you look at. And even
17:16 more important development is the development of
17:16 the prospective studies and not only their conduct
17:16 but the statistical analysis that is done and what
17:16 use of the data that you make, and then how one
17:16 can make inferences about causality in the absence
17:16 of direct experimental proof. This was the great

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17:17 contribution of the Surgeon General's report in my
17:17 opinion with this five criteria for causality,
17:17 some of which was statistical. Coherence was
17:17 important. The fact that the biological evidence
17:17 was consistent with the hypothesis strengthened
17:17 the epidemiological evidence; and many people,
17:17 including Dr. Wynder, considered coherence to most
17:17 important of the five criteria.
17:17 A new discipline is created which allows
17:17 medical science to draw conclusions about
17:17 causality even in the absence of direct
17:17 experimental proof. It is inferential. There is
17:17 more uncertainty. We will still draw conclusions.
17:17 And that's what happened. You have a new world
17:17 view arising to co-exist with the whole view. You
17:17 have the development of the epidemiology of
17:17 chronic diseases as a new field in biomedicine.
17:18 It is spread in medical schools and teaching and
17:18 training programs and so forth. It is a respected
17:18 discipline today. This is the period that it is
17:18 being created.
17:18 These are the concepts that I'm referring to
17:18 here, how people, particularly the older
17:18 generation who have grown up with traditional
17:18 paradigm, that you need experimental evidence.

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17:18 Some of them were reluctant to accept the new paradigm that even without direct experimental data you could draw conclusions about causality. What happens over the 1950 to 1964 period is that even most of the laboratory workers were converted to the new view. Even most of the statisticians were converted to the new view. And the remaining few might have been 60, 65, 70 years old in 1964 who still may have been responsibly skeptical, retired and died. And the use of words depends on the context. If you were talking the views of traditional laboratory workers in the 1950's and 1960's, they would say you need a higher standard of proof, you need an experimental documentation and verification.

If I were writing this today very candidly I would attempt not to be provocative. I would say they held out for the traditional standard of proof. As I sit here today I prefer that word to a higher standard of proof. The fact that it is different doesn't mean it is higher. But you have a new standard and I would change that word if we were -- if I were editing it today.

Q You mentioned a couple of times the second epidemiological revolution. What was the time

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period of the first epidemiological revolution?

A Well in general people they are talking about epidemiology for infectious diseases so you are going back to the 18th, 19th century, particularly late 19th century after development of bacteriology and germ theory of disease because now epidemiologists can really track infections diseases with contacts and culture and so forth. Probably late 19th century would be a good time to look at that aspect of it.

Then you got the mid 20th century and infectious diseases certainly don't go away but they are less important in terms of the toll they are taking on Western society. You got these chronic diseases. The intellectual tools of infectious disease epidemiology were unsatisfactory and incapable of solving the problems of chronic diseases, so a new field was created. As I said before, in my judgment that's the most important and most exciting consequence of this investigation into lung cancer. To show that cigarette smoking causes lung cancer and other diseases is a heck of an important contribution. I'm even equally if not more impressed by a new field that can be applied to

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other problems, high blood pressure, cholesterol, etc.

Q I'm going to give you an example of a study that -- and I don't have a medical background so I apologize if I'm using the wrong terminology -- but it is one I have seen a lot and I find real interesting. I believe it is a map of London, I believe we are in the 18th or 19th century, I believe it is map of all of the wells in a certain area of London that had a high cholera epidemic, and it shows -- let's say there is eight wells, a series of dots where people have gotten cholera. Whoever did this study realized they were centered around one particular well; closed down the well, the cholera epidemic went down drastically.

A That was Dr. Snow.

Q Is that an epidemiological study or an experimental, or are there some other divisions that we haven't been talking about today?

A You know, I believe in simplicity, especially late in the day. I call that an outstanding and extraordinarily important epidemiological study. The infectious disease epidemiology wasn't fully matured yet because this is before the germ theory of disease so he wasn't able to culture the

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organism as later epidemiologists might have been able to do.

The concept that I think is relevant here is that chronic diseases behave differently from acute diseases, and particularly infectious diseases, that's why the type of diagram that Dr. Snow successfully did for cholera didn't work in lung cancer. In the world view of all scientists, including epidemiologists in the mid century, you are custom of thinking of a single cause. Now we think of relative risk. That's one of the contributions of the new epidemiology. And the concept of disease causation that was traditionally accepted, if something causes a disease it happens right away or within a reasonably measurable period of time.

These are among the reasons why initially there was so much skepticism towards cigarette smoking as a cause of lung cancer. It didn't fit the paradigm of the day. If it really is cigarette smoking, why is it that people who start smoking don't get lung cancer. The concept of a latency, of latency, the concept of a lag period had yet to be developed. It was developed, but it had yet to be developed, at least as skepticism.

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Another way that the chronic -- that the tools of the earlier year were not satisfactory for the problems of chronic disease is the fact that -- with acute illnesses in general everyone gets sick. If you have never had measles and you are exposed to someone with measles, you get it. If you are exposed to someone with venereal disease you will probably get it. You contract it. If you fall off the fourth floor of a building you are probably going to hurt yourself. If you take this toxin or that poison, you are going to get sick. The only question is what the dosage is. Everything happens immediately.

The latency period, the lag period were puzzling and mysterious to the people of the mid century who had grown up on the traditional acute disease model. In addition, the fact that with acute diseases you were at great risk. With lung cancer you were at little risk. This was disturbing to people at the time in terms of initial acceptance.

There were 18,000 -- in 1930 there were approximately 3,000 deaths from lung cancer. In 1950 there were approximately 18,000 deaths from lung cancer. Even with the 1950 figures, I don't

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know if there are 50 million smokers in the U.S., but roughly three or four smokers out of 10,000 developed lung cancer and died from it. That did not make sense with the traditional view where if you are exposed to a toxin it is going to cause it. So all of these things had to be worked out and were worked out.

And the second revolution in epidemiology was central to developing these concepts. But those concepts didn't exist at the time. We know them now, it makes sense to us now, but they all had to be figured out and demonstrated and proved and argued and this sort of thing and that was the fifties and sixties.

THE VIDEOGRAPHER: Going off the record. The time is 5:22 PM.

(The deposition stood in recess at 5:22 p.m. to reconvene on August 8, 2002, at 8:30 a.m.)

AUGUST 8, 2002 - VOLUME II OF KENNETH LUDMERER

THE VIDEOGRAPHER: Today's date is August 8, 2002. The time is 8:42 AM. This is the continuation of the deposition of Kenneth Ludmerer. Please proceed.

MS. MOLTZEN: I would like all of us to introduce ourselves for this tape this morning too

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in case these two depositions get mixed up. So I'm Mary Jo Moltzen representing the United States.

MS. KURTIN: Noelle Kurtin representing the United States.

MR. WOODS: David Woods with Shook, Hardy & Bacon representing Lorillard Tobacco Company.

MS. WALKER-BYERLEY: Chris Walker-Byerley with Shook, Hardy & Bacon.

MR. JORDAN: Dan Jordan of Hunton & Williams representing Philip Morris.

THE WITNESS: I'm Ken Ludmerer, the person doing deposed.

DIRECT EXAMINATION (Continued)

BY MS. MOLTZEN:

Q Dr. Ludmerer, you understand that what brings us here today is a lawsuit in which the United States has sued some of the tobacco companies and other entities, correct?

A Correct.

Q What do you understand the allegations in this particular case to be?

A Candidly I don't understand the case very well so I probably will learn something now. But it is my understanding that there are two aspects of the

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case; one is the effort of the United States Government to recover money for payments that it has made over some previous period of time in the Medicare and Medicaid programs for tobacco-related illness, and then secondly I have heard that there is something involving RICO with this case but I can't even tell you what RICO is and I don't understand it and I don't know what those issues are. But that's my understanding of the case.

Q When did you first hear about this particular case?

A I don't remember exactly, frankly. As I mentioned yesterday, maybe three percent of my time the last few years has been on these sorts of issues. If Mr. Woods should call me there is a deposition or a trial and in a day or two for that. It is not something that I carefully follow. But I don't know. The papers, the last couple of years I remember hearing, reading references to the Department of Justice case and didn't pay much attention to it. It is my recollection that Mr. Woods contacted me about being a witness in this case early of this year, 2002. But that's about it.

Q That was my next question, who first contacted you

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08:49 to ask you to work on this case. And it was Mr.
08:49 Woods?
08:49 A That's my recollection as we sit here today that
08:49 it was Mr. Woods. It is not something I would say
08:49 with absolute certainty, but it is highly likely.
08:49 Q And the approximate time period was early in 2002?
08:49 A It would have either have been late 2001 or early
08:49 2002. It would have been no later than early 2002
08:49 because I notice that my expert statement is dated
08:49 January 30 of 2002. It is possible that he made
08:49 his original contact with me sometime last fall of
08:49 last year. Frankly I don't remember precisely.
08:49 Q Do you remember what kind of information you were
08:49 given about this case at that first contact and
08:49 what was expected of you?
08:50 A Well essentially what I said before in terms of my
08:50 understanding of the case that it had to do with
08:50 an attempt to, I don't know what the word would
08:50 be, recoup or reclaim payments made in previous
08:50 years under the Medicare program, federal moneys
08:50 for cigarette-related illness; and then in
08:50 addition, the issue of RICO was in some way
08:50 involved with the case. I didn't understand it
08:50 then, I don't understand it now. And if this case
08:50 moved forward, would I be willing to give my

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08:50 conventional historical testimony that we have
08:50 been discussing on how we came to know that
08:50 cigarette smoking causes lung cancer. I said if
08:50 my time permits I would be glad to do it.
08:50 Q Other than asking you to give testimony, did he
08:50 ask you to do anything else?
08:50 A No.
08:51 Q Since that initial contact what work have you
08:51 performed?
08:51 A I performed no new work. And I would say, by the
08:51 way, that that is true of my involvement with each
08:51 of the approximately 10 depositions or trials over
08:51 the last four or five years that we went over
08:51 yesterday. There has been no new work. My
08:51 opinions are based on the work that I did in '88
08:51 and '89 and I have had no new work to do. I
08:51 report what I did back then. I have not been
08:51 doing new work.
08:51 Q How many hours, other than the six hours and 23
08:51 minutes of this deposition over the last two days,
08:51 have you put in on this case so far?
08:51 A I would have to add them up, which I haven't done,
08:52 but I would say maybe 15 or so. We had a meeting
08:52 here in Kansas City last week and discussed some
08:52 of the issues. I flew in late Monday -- excuse

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08:52 me, late Tuesday, we talked a little bit about it
08:52 then, reviewed a few of the key papers and so
08:52 forth over the weekend, so it adds up to maybe 15
08:52 hours, something of that sort.
08:52 Q When you say looked at some of the key papers,
08:52 what do you consider to be the key papers?
08:52 A I took a look at the Surgeon General's report,
08:52 some of the important primary or secondary sources
08:52 in the literature, just my bibliographies to
08:52 refresh myself with the names and to be as up to
08:52 date as I can for questions that you might have
08:52 about some of the specifics.
08:52 Q When you say Surgeon General's -- did you say
08:52 Surgeon General's reports?
08:52 A I said the Surgeon General's report singular
08:53 referring to the '64 report, not other reports.
08:53 Q How much do you charge per hour for your work?
08:53 A As stated in the disclosure itself, $350 per hour.
08:53 Q In addition to the $350 per hour, do you also have
08:53 any kind of daily charge when you are on travel or
08:53 do you still charge on an hourly basis?
08:53 A If I'm away overnight, as we were yesterday,
08:53 instead of 24 hours I have a $3500 rate if I'm
08:53 overnight.
08:53 Q I want to correct something that neither of us

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08:53 made an error yesterday but I want to make this as
08:53 complete as we can. I had given you Exhibit,
08:54 Deposition Exhibit 5 which I tried to compile a
08:54 list of the deposition and trial testimony that
08:54 your attorneys had sent me. I had 10 cases on
08:54 that. That was in the last four years. Then
08:54 during our discussion yesterday you added two
08:54 more, you added the Cipollone deposition and the
08:54 Kotler trial. They were before -- they were
08:54 longer than four years, you went back to the
08:54 beginning for those?
08:54 A That's correct.
08:54 Q I think -- there is one more case I want to
08:54 mention. Did you also possibly either testify by
08:54 deposition or at trial in a case Moore for the
08:54 State of Mississippi in 1997?
08:54 A Is that an Attorney General case, State Attorney
08:54 General case?
08:54 Q Could very well have been.
08:54 A The answer to that is yes.
08:54 Q I just wanted to make this complete for both you
08:55 and I. So we have not only 12 but we have 13.
08:55 A That's correct.
08:55 Q Was that a deposition or trial?
08:55 A That was a deposition.

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Q And you testified to this a couple times yesterday that you did the original work and then you testified both in Kotler and Cipollone, is that correct?
A Correction, I did not testify in the Cipollone case. I gave a deposition as part of the pretrial work for the re-trial of Cipollone. I did not appear at trial in Cipollone and I was not part of the first Cipollone case.
Q Thank you. Those were in the early nineties. Then there was a break?
A About six years.
Q About six years. And who initiated the contact after that six year break?
A That was Murray Garnick of Arnold & Porter who is the individual that we discussed yesterday who contacted me back in the late eighties. Now, as I said yesterday, I've got other things to do in my life. Total amount of my professional time that has gone into these activities I estimate maybe three percent.
So the first time Mr. Garnick contacted me in 1996 was to appear in an individual smoker case in the state of Florida, this was the first contact in five or six years, and I declined because I was

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too busy.
And then he contacted me roughly a year later, maybe it was six months later, but a period of time after that, in regard to the Attorneys General cases as a group that were being brought, and at that time I said if I'm able to make the time to testify, I will do so. And it was that conversation that led to the Mississippi-Moore deposition. And you are right, this is the last four years through '98. That deposition was 1997 and not on here. But that was the sequence of events. Then you have a complete record I think of everything going forward.
Q Thank you very much. In that initial work that you did in those two years, you had mentioned yesterday that periodically you would have meetings with one or more attorneys. At those meetings were there any other people present except you and attorneys?
A There was some paralegals.
Q Were there other experts?
A As we sit here today I do not remember any contact or discussions with other experts at any time.
Q Were there other historians at the meetings?
A No, there were not.

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Q What is the total amount you have earned from doing the tobacco litigation work to this date?
A I would say somewhere between 500 and $550,000.
You mean from the very beginning?
Q From the very beginning.
A Correct.
Q I believe you said you probably have spent about 15 hours on this case, correct?
A Something of that sort.
Q These questions should be pretty easy to answer then. Approximately how much time have you spent reviewing documents and materials in coming up with your opinions for this case?
A I'm not sure I understand the question. Are you talking about the specific review for this case or are you talking about the original work that led to my opinions back in --
Q I believe that your expert report says the initial work took about 1,000 hours, is that correct?
A That's correct. It was a big project. As I mentioned before, had Murray Garnick called me a year earlier or a year later I wouldn't have been able to undertake it because of other projects of my own. But the serendipity of the circumstances was that I was between books and was able to fill

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up the time while I was looking for a new book to work on.
So the original research that my opinions are based on goes back then. And then I have done for this case what I typically do, I'll spend a little bit of time reviewing notes that you have and records and that sort of thing, refresh myself on names and dates, take a quick look at the Surgeon General's report, things of that sort, as my specific preparation for the deposition.
Q So it would just be a couple of hours then? The question was how much time have you spent reviewing documents for this case.
A A few hours.
Q We are not counting the initial work. 1,000 and two all together?
A A few hours.
Q Did you read the -- do you know what a complaint in a case is?
A I can guess.
Q It is the initial pleading that the plaintiff files with the court. Did you read the United States's complaint in this case?
A I do not remember having read that. I won't say that I haven't, but I don't remember having read

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it.
Q Then the term of art for the response is called the Answer and so each of the defendants then answered the allegations in the complaint. Did you read any of the defendants' answers in this case?
A No, I did not.
Q Do you know what an interrogatory is?
A No.
Q Once the complaint and answers have been exchanged, the judge sets up a certain amount of time in which discovery can be done, including depositions. But you can also write written questions to each other, asking them to answer, and then the interrogatories come in and then you answer the interrogatories. Do you remember in this case reading any of the interrogatory answers?
A I can say definitely I have not seen any interrogatories.
Q Did you read other expert reports from this case?
A Yes, I did.
Q Which ones were they?
A I read the Brandt report and the Proctor report.
Q Did you read any depositions from this case?

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A Not that I recall.
Q The expert report is Exhibit 2?
A Correct. My expert report?
Q Your expert report.
A It is Exhibit 2. I have it in front of me.
Q Okay. Did you prepare the expert report by yourself?
MR. WOODS: objection.
A As we discussed yesterday, it was a team effort between myself and representatives of a legal defense team. I did not draft the original report. It was drafted for me to save me time. But it came out of conversations we have had, it has come out of depositions and trial testimony and it reflects my views. I proofread it and signed it. I did some editing. As we discussed yesterday, quite candidly, I did not look at it very carefully when it came, because if I were doing this today there are certain wordings that we would change, that I would change as we discussed yesterday. But I did approve it and it does represent my views. But I didn't sit down and do the original drafting.
Q When you received the draft from the attorneys and you said you proofed it and edited it, do you

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remember if you made any changes at that time?
A My recollection is I made a few changes in wording and tone and so forth. I really cannot tell you precisely what they are but I do remember making a few changes and suggestions. My only comment to that would be that if I were doing it today I would have made a few more, the ones that we indicated yesterday. But I'm pretty sure I made a few changes at that time.
Q Did you preserve a copy of that draft report with your changes on it?
A No. I think I made a few changes either by pencil or pen on it and sent it back to them and let them put it in their own word processor and incorporate the changes. They sent me back a copy for signing.
Q What proportion of this current report, Exhibit 2, is new or different from your original report?
A Could you please explain to me what you mean by my original report?
Q For the first case -- what was the first case that you had to write an expert report?
A Frankly I don't remember because each case is different. And I know there have been other expert reports but not invariably, and I just

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don't remember which of these required an expert report and which didn't.
Q Are there a lot of -- what proportion of this report is different from the most recent report that you have written?
MR. WOODS: objection.
A There is no substantive difference among any of the reports. All of the reports express the same general views. All of the reports relate to opinions that I formed back in 1988, 1989 when I did the original work. I do recall that the requirements of the cases are different so some of the expert reports are shorter, others are longer. But essentially in terms of the substance and opinions, they say the same thing. There have been no changes substantively from one to another. In form there may have been, some will be shorter and some will be longer, but no changes of opinion or meaning.
Q Have you ever met any of the other historians testifying for the tobacco defendants in this case?
A I don't know who the other defendants are so I would be pleased to respond to that if given the names but very frankly I don't know who the other

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09:06 1 experts are.
09:06 2 **Q Have you ever met with Peter English?**
09:06 3 A I do know Peter English.
09:06 4 **Q Who is Peter English?**
09:06 5 A Peter English is a highly regarded physician
09:07 6 historian. He is actually a pediatrician
09:07 7 historian at Duke. He has written a number of
09:07 8 books about rheumatic fever and early physiology.
09:07 9 He is also a well-regarded pediatrician. We have
09:07 10 never discussed legal issues together. In fact, I
09:07 11 didn't even know he was a witness in this
09:07 12 litigation until now. But I am acquainted with
09:07 13 him, think well of him.
09:07 14 **Q Are you familiar with Surgeon General Burney's, it**
09:07 15 **wasn't his report, but it was the report of the**
09:07 16 **study group on smoking and health organized the**
09:07 17 **urging of the Surgeon General Burney in about**
09:07 18 **1957? Are you familiar with the conclusions of**
09:08 19 **that report?**
09:08 20 MR. WOODS: **Objection.**
09:08 21 A Well certainly I recall that the first public
09:08 22 health statement was Surgeon General Burney's 1957
09:08 23 statement, I do remember that, yes.
09:08 24 **Q And are you aware that in 1957 public health**
09:08 25 **officials in Great Britain, I believe the group is**

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09:08 1 **called the Medical Research Council, issued a**
09:08 2 **statement discussing the causal relationship**
09:08 3 **between tobacco smoking and lung cancer?**
09:08 4 A Yes, I am. As we talked about yesterday, and also
09:08 5 as in my previous testimony, just as a
09:08 6 generalization, this is the period that you see a
09:08 7 number of important public health organizations,
09:08 8 private, public, United States and other countries
09:09 9 starting to take stands on that. There were quite
09:09 10 a few others as well.
09:09 11 **Q You mentioned this yesterday, I believe, that**
09:09 12 **again then in 1959 Surgeon General Burney issued a**
09:09 13 **statement on behalf of the Public Health Service.**
09:09 14 **Are you aware of that?**
09:09 15 A That's correct.
09:09 16 **Q And –**
09:09 17 A That was a stronger statement than this '57
09:09 18 statement which again indicates in my judgment the
09:09 19 growing consensus and greater degree of confidence
09:09 20 about drawing conclusions. '59 – as we talked
09:09 21 about yesterday this is a rapidly changing
09:09 22 dynamic. Each year new information coming in, new
09:09 23 tools to analyze information are being developed.
09:09 24 So his statement of 1959 is a stronger statement
09:09 25 than his 1957 statement.

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09:09 1 **Q And then are you aware that in 1960 the World**
09:09 2 **Health Organization study group also issued a**
09:09 3 **statement about the relationship between cancer,**
09:10 4 **lung cancer and smoking?**
09:10 5 A I am aware that the World Health Organization came
09:10 6 out with a statement, and I will take it as a
09:10 7 given that the years that you are citing are
09:10 8 correct because I could not recite specifically
09:10 9 which group, which year. But as a generalization
09:10 10 I'm aware that many important health organizations
09:10 11 are taking statements one year and then another,
09:10 12 then the next year someone else jumps on board,
09:10 13 the next year someone else jumps on board and so
09:10 14 forth. I just want to state for the record if I
09:10 15 were taking a test I couldn't say it was World
09:10 16 Health Organization of '59 or '60, or '60 or '61.
09:10 17 I don't have that type of recall as we sit here
09:10 18 today.
09:10 19 **Q Would you agree it was before the Surgeon**
09:10 20 **General's 1964 report?**
09:10 21 A Yes. As I have been saying consistently, it is
09:10 22 the late fifties that you are pointing out that
09:10 23 you see many such groups taking such positions,
09:11 24 and increasing into the sixties.
09:11 25 **Q Then I want you to turn to Page 6 of your report,**

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09:11 1 **and this is going to the sentence that is going to**
09:11 2 **go from the bottom of Page 6 over to Page 7. "In**
09:11 3 **conclusion, although the question of a**
09:11 4 **relationship between cigarette smoking and lung**
09:11 5 **cancer has certainly become a major concern**
09:11 6 **between 1950 and 1964, there was no consensus**
09:11 7 **during this time period among scientific and**
09:11 8 **medical authorities that cigarette smoking was**
09:11 9 **hazardous to health." Is that still your opinion**
09:11 10 **as we sit here today?**
09:12 11 A Yes, it is, and it is the opinion that I was
09:12 12 giving yesterday. If I were writing this today, I
09:12 13 think I would add a few adjectives and describe
09:12 14 things as we have been discussing for the past day
09:12 15 about evolving consensus, the growing consensus
09:12 16 because tide is definitely turning. As we
09:12 17 discussed yesterday, to say that there is not a
09:12 18 consensus does not mean that you have equal
09:12 19 numbers of people on both sides reserving
09:12 20 judgment. If you were talking the early sixties,
09:12 21 I would say -- I agree with the Surgeon General,
09:12 22 that the general opinion decidedly had moved to
09:12 23 accept the view that cigarette smoking caused lung
09:12 24 cancer. But for a consensus, not for a dominant
09:12 25 view, not for the overwhelming view, not for the

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near consensus, if you are talking a consensus, what scientists of divergent perspectives and traditions and views all except for the laboratory workers going along with it as well as epidemiologists, but practicing physicians and chest surgeons as well as the scientists who are studying it, for serious challenge of the argument to evaporate, that terminal step in my judgment required the first Surgeon General's report and that's when our current consensus -- we have a near consensus before then, a growing consensus, but my research being comprehensive in looking at everything that was said found that even in the early sixties there were responsible groups, responsible scientists who had not yet come on board. Fewer of them in the sixties compared to the fifties, but not every group had come on board. The American Medical Association, for example, is an example of a group that was -- that changed its view in response to the Surgeon General's report. That's another example of how the report in my opinion brought about the final consensus.

So I would say that a near consensus. But the terminal step in this event that goes back all

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the way to early observations and suggestions of the twenties and thirties and forties it terminates, is brought to conclusion with the Surgeon General's report. And my judgment, our current consensus that cigarette smoking causes lung cancer dates from there.

Q The reason I had asked you about some of those statements by medical and health authorities is because of the wording of this particular sentence. And I know we talked about words yesterday, but the precision of words is my currency, and I'm sure as a scientists it is your --

A Right.

Q All of a sudden here you had changed from scientific and medical community to scientific and medical authorities. So that's why I went back and I picked out scientific and medical authorities.

A Well now there I would say the same thing. Authority and communities. There were authoritative scientists in the early sixties who remained skeptical because of the lack of biological information. There were authoritative organizations, the most prominent being the

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American Medical Association. So you can look at it either way. I think either statement is correct. You can look at authorities who had yet to come on board or you can look at it at the community more largely. But I think there either word would be correct.

And this gets back, in my judgment, to the evolutionary nature of science. Particularly when you have creation of a new model or a new paradigm, something big that people wrestle with or really debate, you are always going to have people who are at the beginning and accepting a new idea or concept, most people will be somewhere in the broad middle, as we discussed yesterday, many people depend on the views of the opinion makers, then you all have some people who are more conservative for whatever reason who are among the last to come on board. That's really where things were in the early sixties. Most people, but not quite all, had come on board. Whether you use the term authorities such as the laboratory scientists at the National Cancer Institute, Memorial Sloan-Kettering, Philadelphia Cancer Institute, or whether you use organizations such as the AMA, or whether you use practicing physicians who see

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patients every day. Most people had come on board but you still had this tail end in the early 1960's. After the Surgeon General's report this tail end came on board and that's why I personally would date the consensus to the Surgeon General's report.

Q Am I correct to say then the change from previously using the word community and in this one using authorities, you really by changing that word weren't trying to reflect a difference or a distinction?

A No, I really wasn't. The important point is that the same observation is present if you are looking at a scientific authority who is doing research and writing papers, if you are looking at the organizations that are taking positions, and if you are looking at the general medical community that is practicing medicine. So the same phenomena is occurring with all of these. The general medical community includes all of these people. Obviously some individuals are leaders and opinion setters and most are not. But if you are looking at the early sixties, there is no question that the dominant opinion within the medical community had changed. Regardless of

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09:18 whether you are defining medical community the
09:18 practicing community or the research community,
09:18 there is no question that sentiment has changed.
09:18 I agree with the Surgeon General's
09:18 observation that there had been a decided opinion.
09:18 But if you are asking the question when did
09:18 everyone jump on board? When did disagreements
09:18 stop? I agree with Dr. Sir Richard Doll who says
09:18 the Surgeon General's report, that's when it
09:18 stopped. I agree with all of the secondary
09:18 literature that says the Surgeon General's report
09:18 brought everyone on board. We know the AMA came
09:18 on board as a result of that. We know that
09:18 laboratory workers who were persuaded that this
09:18 was a legitimate new discipline and epidemiology
09:18 of chronic disease established itself. The few
09:18 who were responsible exceptions as we discussed
09:18 yesterday people as such as Dr. Brownlee who wrote
09:19 the critical review. In the next few years he
09:19 retired and died. We know that Sir Richard Doll
09:19 himself says that with the '64 Surgeon General's
09:19 report that was the time that serious scientific
09:19 opposition ended; and that is consistent with what
09:19 I have found in my work.
09:19 Q Does consensus require unanimity?

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09:19 A As we discussed yesterday, no. It is a judgment
09:19 call. It is not a 100 percent view. Certainly
09:19 requires a near unanimity, but it is a
09:19 qualitative, not a quantitative assessment. It
09:19 depends on who the dissenters are. If a physics
09:19 graduate student doesn't go along with a certain
09:19 concept, people are likely not to pay much
09:19 attention. If Professor Einstein doesn't go along
09:19 what a certain concept, people are likely to put a
09:19 lot of credence to that.
09:19 That, by the way, is one of the reasons for
09:20 the lingering doubts in the early sixties because
09:20 the greatest scientific figure in my judgment by
09:20 far of these events was Sir Ron Fisher. He was
09:20 the Einstein of biology. And I don't mean this in
09:20 any way to be derogatory to the great scientists
09:20 who created the field of epidemiology of chronic
09:20 disease but they did it based upon the fundamental
09:20 work that Fisher did mathematically. Fisher is
09:20 one of the giants of 20th century biology. He was
09:20 part of the evolutionary genetic synthesis showing
09:20 that mathematically you can reconcile Darwinian
09:20 evolution with Medalian genetics. His repeat
09:20 created the field of biostatistics. The
09:20 mathematical tools that epidemiologists use to

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09:20 analyze data came from some of Fisher's basic
09:21 work. So for Fisher to have objections it is like
09:21 Michael Jordan being on my team. This is not just
09:21 an average person. So you have to look at who is
09:21 objecting, why people are objecting. But again by
09:21 definition you are not going to have the consensus
09:21 if you have -- a consensus means people have come
09:21 together, people of divergent views; in this case
09:21 the laboratory people have accepted epidemiology.
09:21 That happens with the Surgeon General's report.
09:21 People of divergent views and traditions and
09:21 sympathies and perspectives accepting an idea or
09:21 concept, which isn't to say that you can't find
09:21 somewhere someone somewhere who may object, but
09:21 that person has become marginal.
09:21 And all of these things happened with the
09:21 Surgeon General's report. In Dr. Doll's words,
09:21 I'm quoting from a paper he wrote that recounts
09:22 the history of this, he is not a professional
09:22 historian but lived through and he participated
09:22 and he remembers events and these are very
09:22 important issues to him. He is among the many who
09:22 says that with the first Surgeon General's report
09:22 serious scientific opposition to the idea is
09:22 subsided and we moved on to the next step. And I

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09:22 would agree with that interpretation.
09:22 Q When I asked the questions before, it was about
09:22 preparation, it was the preparation of the expert
09:22 report. Now I'm moving on to preparation for this
09:22 particular deposition. What did you do to prepare
09:22 for this deposition?
09:22 A Well I did what I mentioned in answer to your
09:22 question a few minutes ago. I had two meetings
09:22 with Mr. Woods, with Dave Woods and with Chris
09:23 Walker-Byerley to discuss some of the issues of
09:23 the case. Over the weekend I reviewed some of my
09:23 own notes, took a look at the Surgeon General's
09:23 report, things of that sort, some of the key
09:23 articles, refresh myself on some of the names and
09:23 dates and sequence and that type of thing.
09:23 Q How long was your first meeting with your
09:23 attorneys?
09:23 A Well this would have been I think Wednesday or
09:23 Thursday of last week. And I would say it went
09:23 approximately four hours.
09:23 Q Was anyone in attendance besides your attorneys
09:23 and you?
09:23 MR. WOODS: objection.
09:23 Q I'm sorry, your attorney and your attorney's
09:23 assistant?

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MR. WOODS: objection.
Q Between David Woods and Chris Walker-Byerley, was anyone in the room besides those two?
A For the approximately four hours of discussion we had -- there was three of us. There was an attorney whose name I do not remember who is involved with this case who walked in the room toward the end of the meeting, said hello, was there for two or three minutes. I don't really consider that person as being part of the meeting but I did see another individual while I was there. The substantive conversation for the four hours that we met was with Chris and Dave.
Q How long was the second meeting?
A That would have been -- what day is today?
Q Today is Thursday, the 9th -- 8th.
A So that would have been Tuesday, flew in late Tuesday and we met for, I don't know, two or three hours.
Q Who was at that meeting besides you, Chris Byerley and David Woods?
A The same two individuals.
Q Did you have any other meetings with anyone else about this case?
A No.

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Q Did you have any phone conversations with your attorneys about this case in preparation for your deposition?
A I had a number of telephone calls, by a number of I mean three, four or five with either Dave or Chris, but largely over the logistical details. We didn't discuss substantive things but there were questions of dates and times and flights and when do you need me, those sort of things. So there were a handful of telephone calls with one or the other of them on that type of detail. Substantive conversations we had the two meetings that I mentioned to you.
Q Was any correspondence, whether it be paper or fax or electronic E-mails, exchanged between you and your attorneys in preparation for this deposition?
MR. WOODS: objection.
A I do not recall any correspondence on any substantive issue. There were a couple of E-mails pertaining to flights and travel arrangements and things of that sort. I had an electronic ticket by definition that came by E-mail.
Q Earlier you said that you spent about 15 hours total preparing for this case?
A Maybe it was 10, maybe it was 16, you know.

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Q Of all that time part of it of course was preparing and working on the expert report. How much of that was spent on preparing for this deposition?
MR. WOODS: objection.
A Well, I would say essentially all of those 10 or 15 hours has been on the deposition. The expert report as you know came in January, I took a very quick look at it, edited a few things. Obviously today I wish I had taken an even closer look at it, but that was a matter of minutes.
Q Do you anticipate reviewing any additional materials in this case?
A I reserve the right to should something appear somewhere that I should know about, but I have no intention at this time of doing so. There is nothing I'm aware of that I would be doing.
Q At this point in time do you anticipate rendering any additional opinions in this case?
A No, I do not.
Q If you do any further work or form any further opinions concerning the subject matter of this litigation, please inform your attorneys so that he or she may direct you to amend your report.
MR. WOODS: objection.

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MS. MOLTZEN: I would like to take a break.
THE VIDEOGRAPHER: Going off the record. The time is 9:24 AM.
(Short recess was taken.)
THE VIDEOGRAPHER: Back on the record. The time is 9:34 AM.
Q Dr. Ludmerer, while we were on the break your attorney handed me a deposition that he hadn't provided to the United States before in the case of Harvey versus ABB Lummus, L-u-m-m-u-s, Global, Inc. It was deposition testimony that you gave on May 13 of this year. Do you remember this case?
A I did give a deposition in May of this year. If I did not recognize its absence from this list you showed me yesterday, then I apologize. But it is correct that I did give a deposition in May of this year for the Harvey case was an individual smoker case.
Q So now I believe we have all 14 cases to the best of our knowledge?
A To the best of our knowledge. That includes the two cases from the early, I call it the early period, and then 12 depositions or trials from 1997 through the present.

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09:39 Q **Why did you start testifying again after the early**
09:39 **period?**
09:39 A Well, there are two dimensions to that. Number 1
09:39 is I did not immediately start testifying because
09:40 the first time that I was contacted about a case
09:40 and maybe even the second time I declined because
09:40 I was too busy with other projects. But then the
09:40 chief reason is that things were very quiet at
09:40 that time in tobacco litigation. I hadn't heard
09:40 from them. I didn't have any contact with
09:40 representatives of the defense for roughly six
09:40 years.
09:40 So when they contacted me again, the issues
09:40 were very similar as they were before and I felt
09:40 that again the same tension we discussed
09:40 yesterday; on the one hand a very firm conviction
09:40 that smoking is hazardous and causes cancer and
09:40 other diseases, a desire that everyone in the
09:40 world would stop smoking tomorrow; but at the same
09:41 time the same advocacy of history as a field and
09:41 having the historical events correctly delineated.
09:41 There were witnesses -- there were claims, I
09:41 should say, in some of those other cases that were
09:41 quite false, fictitious in terms of the scientific
09:41 aspect of the story. So for the same reason --

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09:41 and I consulted leaders of Washington University
09:41 again and reviewed the issues with them. For the
09:41 same reasons that I agreed to participate in the
09:41 late eighties, I agreed to participate again when
09:41 I had the time, only when I had the time, in some
09:41 of these more recent cases.
09:42 But the chief reason that for six or seven
09:42 years there is no involvement, apparently nothing
09:42 was happening, at least nothing that they needed
09:42 me for. I was not contacted at all by any of the
09:42 legal firms representing the defense. I certainly
09:42 had no wish or inclination of my own to contact
09:42 them so we went our merry ways.
09:42 MS. MOLTZEN: I want to put on the
09:42 record the United States reserves its right to
09:42 depose Dr. Ludmerer if it finds anything in this
09:42 deposition in Harvey versus ABB Lummus.
09:42 MR. WOODS: I recognize your reservation
09:42 of rights. Whether you have the rights is another
09:42 thing.
09:42 Q **Have you prepared any charts or exhibits for this**
09:43 **case?**
09:43 A No, I have not.
09:43 Q **In the four trials that you have testified in,**
09:43 **five trials that you testified in, did you prepare**

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09:43 **any demonstrative exhibits for those trials?**
09:43 A In a couple of the cases there were
09:43 demonstratives. I don't have them but there were
09:43 demonstratives in a couple of cases.
09:43 Q **Do you remember what those demonstrative exhibits**
09:43 **were?**
09:43 A Not precisely. There was a demonstrative that I
09:43 recall that summed up the principles of how one
09:43 goes about doing the history of medicine. We
09:43 talked about those things yesterday,
09:44 comprehensiveness, fairness, looking at all of the
09:44 evidence, the evolutionary nature of medical
09:44 knowledge, things of that sort, avoiding
09:44 hindsight. So there was one demonstrative that
09:44 listed those things as bullet points. I recall a
09:44 demonstrative that showed competing explanations
09:44 for the cause of lung cancer circa '53 and '54.
09:44 Exactly the things that we discussed yesterday,
09:44 tobacco number 1, a genetic cause, radiation,
09:44 pollution, a few other possibilities, including
09:44 other, including the idea, including the
09:44 possibility that none of the things we were
09:44 presently looking at would be bear out to be the
09:44 cause and would have to keep doing work.
09:44 There was a demonstrative showing how new

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09:45 work continued to be done; that the growing
09:45 evolving consensus and the types of work that were
09:45 done in the mid fifties and late fifties and early
09:45 sixties to help lead to the consensus. I'm
09:45 speaking from memory. But these were the sorts of
09:45 things that were --
09:45 Q **In one of the trial transcripts that I read, and I**
09:45 **believe it was Boeken, am I saying that right**
09:45 **B-o-e-k-e-n?**
09:45 A I think so.
09:45 Q **There was a demonstrative evidence, exhibit, that**
09:45 **I believe was titled Controversies Regarding Lung**
09:45 **Cancer and Smoking, 1954 to '64. And from the**
09:45 **testimony it sounded to me like number 1 was**
09:45 **controversy among epidemiologists, number 2 was**
09:45 **controversy among statisticians, and number 3 was**
09:45 **epidemiologists versus experimentalists. Did that**
09:45 **demonstrative exhibit reflect your discussion**
09:46 **yesterday about the disputes between those groups?**
09:46 A Yes, it did. Substantively those topics were part
09:46 of our conversation yesterday, and we are talking
09:46 mid fifties, particularly, though it continues
09:46 through the Surgeon General's report. But there
09:46 were disagreements within the epidemiologists as
09:46 we discussed; less over the validity of

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epidemiology, less over the issue of does cigarette smoking cause lung cancer, more over the issue of proportion. With the majority of epidemiologists saying that lung cancer is the main cause; environment, pollution, things of that sort are the minor cause, but there were epidemiologists. The most notable was Hueper who was a chief epidemiologist at the National Cancer Institute so we are not talking about a minor figure, who was of the other view, cigarette smoking is a factor, but a minor factor. A major factor has to would with atmosphere, environment and pollution.

Actually that debate continues through the Surgeon General's report and the Surgeon General discusses this and draws the conclusion that the other epidemiologists were correct, Hueper was wrong, cigarette smoking was the major factor; environment, pollution as Hueper suggested were factors but minor. Then there was very, and I think ultimately more powerful criticisms that came from the statisticians themselves, Fisher and Berkson. Epidemiology is an applied science and is filled out of the work of basic statistics in terms of the mathematical tools. And the

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criticisms of leading statisticians about bias and the studies not being properly designed, the data not being properly analyzed, populations of patients not being representative, these types of criticisms as Berkson and Fisher made in the mid and late fifties and early sixties, those worry people and engendered responses. And that's also continued through the Surgeon General's report.

Then lastly, again we discussed this yesterday, an issue that I think was the most important issue of all, the most powerful issue of all is this whole issue of world view, how does one in medicine demonstrate something to be a cause, what do we mean by cause and what nature of proof do we have to have. Do we continue to insist on having experimental proof as we traditionally have done in medicine, or, in the absence of definitive experimental proof can we by inference draw conclusions about causality from other types of data. And that world view issue I think was really the heat of it. That's why in my opinion we are talking about a paradigm shift, a classic scientific revolution, one world view arising to stand with -- I won't say replace another, we still believe in experiments -- but to

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stand with it, the creation of a new science.

I believe that third was the most important issue at all at the time. And those things -- I will trust you when you say there was an exhibit, I don't remember exactly which trials had exhibits and which didn't and what they said. Certainly the exhibit that you describe incorporates those concepts that I have reviewed now and that we discussed yesterday.

MS. MOLTZEN: Thank you. The United States has no more questions for Dr. Ludmerer. Off the record.

THE VIDEOGRAPHER: Going off the record. The time is 9:45 AM.

THE VIDEOGRAPHER: We are back on the record. The time is 9:46 AM.

MR. WOODS: I have no questions.

MS. MOLTZEN: The United States does want to put on the record that the United States used 7 hours and 16 minutes for the deposition of Dr. Ludmerer.

MR. JORDAN: I have no questions.

THE VIDEOGRAPHER: This concludes the deposition. We are going off the record at 9:46 AM.

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(Witness excused.)

KENNETH LUDMERER

Subscribed and sworn to before me this

day of , .

NOTARY PUBLIC

My commission expires:

UNITED STATES OF AMERICA -vs- PHILIP MORRIS, INC., et al.

CERTIFICATE

STATE OF MISSOURI)
) ss.
COUNTY OF JACKSON)

I, ALISON A. TRACY, a Notary Public and Certified Shorthand Reporter, do certify that pursuant to Notice, at the offices of the United States Attorney, 400 East Ninth Street, Fifth Floor, in the City of Kansas City, in the County of Jackson and State of Missouri,

KENNETH LUDMERER

came before me, was duly sworn to testify the whole truth of his knowledge of the matters in controversy aforesaid, was examined and his examination then written in stenotype by me and afterward typed, and subscribed by the witness as hereinbefore set out, on the day in that behalf aforesaid; and said deposition is herewith returned.

I further certify that I am not counsel, attorney or relative of either party, or clerk or stenographer of either party or of the attorney of either party, or otherwise interested in the event of this suit.

IN WITNESS WHEREOF, I have hereunto set my seal at my office in said County and State, this day of , 2002.

My Commission expires April 26, 2006.

ALISON A. TRACY, CCR #554