

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

IN AND FOR NEW CASTLE COUNTY

IN RE: ASBESTOS LITIGATION) C.A. No. 77C-ASB-2

BEFORE: HONORABLE JOSEPH R. SLIGHTS, III, J.

APPEARANCES:

JOHN J. SPILLANE, ESQ.
BARON & BUDD, P.C.
for the Plaintiff

CAMERON R. WADDELL, ESQ.
LeBLANC & WADDELL, LLP
for the Plaintiff

JOSEPH BIDEN, III, ESQ.
BIFFERATO, GENTILOTTI, BIDEN & BALICK
for the Plaintiff

THOMAS C. CRUMPLAR, ESQ.
JACOBS & CRUMPLAR
for the Plaintiff

DAUBERT HEARING TRANSCRIPT
THURSDAY, OCTOBER 20, 2005 - A.M. SESSION

SUPERIOR COURT OFFICIAL REPORTERS
500 N. King Street, Suite 2609, 2nd Floor
Wilmington, Delaware 19801-3725

APPEARANCES CONTINUED:

SAMUEL L. TARRY, JR., ESQ.
 McGUIREWOODS LLP
 for the Defendant DaimlerChrysler

JAMES M. KRON, ESQ.
 SOMERS S. PRICE, JR., ESQ.
 POTTER, ANDERSON & CORROON LLP
 for the Defendant DaimlerChrysler

STEVEN T. JOHNSON, ESQ.
 PEPPLER, JOHNSON, CANTU & SCHMIDT, PLLC
 for the Defendant OI, Inc.

TED GIANARIS, ESQ.
 SIMMONS COOPER LLC
 for Defendant

ALSO PRESENT:

David deBruim	Joseph A. Gabay
Erin Farris	Christian J. Singewald
William A. Kohlburg	C. Scott Reese
Kathleen D. Hadley	Miranda D. Clifton
Michael Angelides	Gary Kaplan
Melissa Crowe	Mark Reardon
Perry J. Browder	Kai Seelaus
Amy Garrett	J. Michael Johnson
Christopher Lyon	Neal Glenn
Bernard Kuery	Christine Boyd
Francis J. Gribbin	Eric Henry
Margaret England	

- - - - -
 OCTOBER 20, 2005
 Courtroom No. 8B
 9:45 a.m.

PRESENT:

As noted.

- - - - -

1 THE COURT: Good morning.

2 MR. TARRY: May it please the Court.

3 THE COURT: Yes.

4 MR. TARRY: Your Honor, Daimler-Chrysler would
5 call Dr. Michael Goodman.

6 MICHAEL GOODMAN, M.D.
7 having first been duly sworn, was examined and testified
8 as follows:

9 DIRECT EXAMINATION

10 BY MR. TARRY:

11 Q. Good morning, Dr. Goodman.

12 A. Good morning.

13 Q. You're an epidemiologist, sir?

14 A. Yes.

15 Q. And where are you currently employed?

16 A. I am on faculty of the Department of
17 Epidemiology, Emory University School of Public Health.

18 Q. And have you reached some conclusions on the
19 risk of asbestos-related disease in auto mechanics?

20 A. Yes, I have.

21 Q. And are you prepared to share those conclusions
22 with the Court today?

23 A. Yes.

1 Q. Can I get you to agree in advance that any
2 conclusions you express will be done so to a reasonable
3 degree of medical and scientific probability?

4 A. Yes.

5 Q. Do you have an opinion about whether or not
6 auto mechanics, people who work on cars, are at an
7 increased risk for the disease of mesothelioma?

8 A. Yes, I do have an opinion.

9 Q. Was that your opinion on that, your conclusion?

10 A. My conclusion is that persons involved in
11 automobile repair are not at increased risk of
12 mesothelioma.

13 Q. And have you reached a conclusion as to whether
14 those same individuals are at an increased risk for lung
15 cancer?

16 A. Yes, I have reached a conclusion.

17 Q. What's your conclusion on that question?

18 A. My conclusion is that persons involved in
19 automobile repair are not at increased risk of lung
20 cancer --

21 Q. Finally --

22 A. -- due to their occupation.

23 Q. And have you reached conclusion as to whether

1 those individuals are at an increased risk for the
2 disease asbestosis?

3 A. Yes.

4 Q. And what is your conclusion on that question?

5 A. And my conclusion is that persons involved in
6 motor-vehicle repair are not at increased risk of
7 asbestosis.

8 Q. I'd like to talk very briefly about your
9 background and training for the Court.

10 A. Sure.

11 Q. You have a little bit of an accent. Where are
12 you from originally?

13 A. I was born in Lithuania.

14 Q. And did you do your medical training there?

15 A. Yes. I went to medical school there.

16 Q. Tell us about your medical training.

17 A. I went to medical school between '79 and '84.
18 And it's a six-year program in many countries. And then
19 I did internship in pediatrics and, then, I practiced
20 for three years in a small rural hospital in Lithuania.
21 And, then, I moved to the capital city, where I did the
22 fellowship in what's called academic pediatrics. And
23 then I left the country.

1 Q. You were a pediatrician over there?

2 A. Correct.

3 Q. When did you come to the United States?

4 A. 1990.

5 Q. You applied for an exit visa?

6 A. No, I was -- I was awarded a political refugee
7 status.

8 Q. All right. And tell us about your medical
9 training, scientific training since you've been in the
10 United States.

11 A. When I entered the country, first thing, if you
12 want to be a physician in the United States, you have to
13 pass a number of exams, which I did. And, then, you
14 have to reach -- get another training -- if you pass the
15 exams and you qualify, then you can undergo additional
16 training in a medical discipline of your choice. In my
17 case, I was already pediatrician back in Lithuania, so I
18 did another residency, three years of residency, in
19 pediatrics and became board eligible in pediatrics.
20 And, then, I decided to move on and --

21 Q. Let me stop you.

22 You're board certified in pediatrics?

23 A. Yes, I am board certified in pediatrics.

1 And then I decided to move on and doing the
2 program in preventive medicine. It was a second
3 residency, basically back to back, in Baltimore at Johns
4 Hopkins, and I did two years.

5 Q. Is that the School of Public Health at Johns
6 Hopkins University?

7 A. John Hopkins University. Now it's called
8 Bloomberg School of Public Health. And I spent two
9 years there as a resident in preventive medicine.

10 Q. All right. You're what is called a medical
11 epidemiologist now, or --

12 A. Well --

13 Q. Physician epidemiologist?

14 A. Yes, you can call me that. That's probably the
15 most accurate way to characterize what I do.

16 Q. Can you tell us about your training at Johns
17 Hopkins.

18 A. The program in preventive medicine includes two
19 stages: You first get a degree in Public Health,
20 Masters in Public Health. You basically go back to
21 school. And after that, the second stage, second year
22 of it, once you have your degree, is some hands-on
23 training in various areas of practice of preventive

1 medicine. And after that, you became board eligible --
2 not right away. You have to work for a year, become
3 board eligible in preventive medicine.

4 Q. And what did you do upon your completion of the
5 program at Johns Hopkins?

6 A. At the end of my training, I had a six-month
7 appointment with the World Health Organization in
8 Jamaica, which did work on measles and polio
9 vaccination.

10 Q. And did you participate in a study of the --
11 for the United States government?

12 A. Yes. That was part of my training. I also was
13 another -- in another rotation that I had, I did a study
14 for the Department of Health and Human Services. It
15 actually was three -- a series of three studies on
16 vaccines and vaccine-related injuries.

17 Q. All right. And did you, in fact, obtain board
18 certification in the field of preventive medicine?

19 A. A year after graduation, you can sit for the
20 boards in preventive medicine, and that's what I did.

21 Q. I want to ask a quick question about your
22 training in pediatrics because, in the brief that was
23 submitted to the Court, there was a little bit of fun we

1 had, I think, I think we had you have a background in
2 pediatrics.

3 A. Right.

4 Q. Is it abnormal for people in the
5 epidemiological field to have had their medical training
6 in a wide variety of fields?

7 A. Those of us who go to -- entry epidemiologist
8 through clinical disciplines usually have a degree or
9 training or board certification in areas that are not
10 necessarily related to epidemiology. So, no, it's not
11 unusual.

12 Q. You've heard some of the testimony, you've
13 heard references to Dr. Rothman.

14 A. Yes, that's one of the most commonly cited
15 books in epidemiology, and Rothman is the editor.

16 Q. And Dr. Rothman is one of the leading
17 epidemiologists in the country; correct?

18 A. Perhaps, yes.

19 Q. Do you happen to know what his background is?

20 A. He's a dentist.

21 Q. He was a dentist before expanding into
22 epidemiology?

23 A. And if I may add, you know, the other book that

1 I like a lot personally is -- the one I was trained at
2 Hopkins, is introductory, more introductory course in
3 epidemiology, authored by Dr. Leon Gordis, who is a
4 pediatrician.

5 Q. Dr. Gordis is also a pediatrician?

6 A. He's a pediatrician.

7 Q. Dr. Gordis teaches epidemiology where?

8 A. At Hopkins.

9 Q. What was the first job you took after
10 completing all this training?

11 A. After my training was complete, my first job
12 was with company called Exponent.

13 Q. Tell us briefly about Exponent and what that
14 is.

15 A. Exponent is a large consulting and research
16 company.

17 Q. Publicly traded company?

18 A. I think so, yes.

19 Q. And what does Exponent do?

20 A. Exponent is really multidisciplinary group of
21 people. It includes several hundred experts in various
22 fields of knowledge, from engineering, to medicine, to
23 epidemiology, to behavioral sciences, and so forth.

1 Most of them Ph.D. or Masters-level training.

2 And the structure -- the way Exponent is
3 structured has three major groups. It has the -- what
4 is called the engineering group. They do various things
5 that are related to structures and a lot of physics, a
6 lot of engineer science. Then, there's a health group.
7 That includes physicians, biostatisticians,
8 epidemiologists, with a doctoral degree in Epidemiology,
9 Ph.D.s. And, then, there is an environmental group, and
10 that group includes toxicologists, people that are
11 well-versed in risk assessment and exposure assessments
12 and things of that nature.

13 Q. All right. You were in the health group?

14 A. I was in the health group.

15 Q. Can you tell the Court very briefly, just in
16 succinct terms, how you practiced epidemiology when you
17 were at Exponent.

18 A. It's really not that different than what I do
19 now at Emory. You conduct studies, you write reports,
20 you obtain funding for studies. I did quite a bit of
21 teaching while at Exponent, although not classroom
22 teaching, but residents. Preventive Medicine residents
23 from Hopkins would come to my office and just do

1 rotation, just like I did when I was a resident, while I
2 was still there.

3 And the only difference is that, at the
4 university, the bulk of your funding comes from the
5 government; whereas, at Exponent, the bulk of your
6 funding comes from industry.

7 Q. All right. Privately funded research?

8 A. Correct.

9 Q. Okay. But does Exponent also do work for the
10 government, for the federal government, for the state
11 government?

12 A. Yes, that's true, yes.

13 Q. Now, finally, would you tell us about your
14 current responsibilities at Emory University.

15 A. I'm assistant professor. I started two years
16 ago. My charge is to develop a research program in
17 cancer epidemiology. So, first two years were very
18 busy, primarily writing grants to obtain funding for
19 research projects.

20 I also slowly increased my teaching load. I --
21 right now, I co-teach several courses but, you know, I
22 have a luxury of not being responsible for one single
23 course. So, I co-teach a course on Introductory

1 Epidemiology. I co-teach a course on Cancer
2 Epidemiology. I also teach the major part of the course
3 on Medical Research and Evidence Based Medicine for
4 people who are receiving their training in Pediatrics.

5 Q. There are specialties within the big field of
6 epidemiology; correct?

7 A. Correct.

8 Q. And within the field of epidemiology, are you
9 considered a specialist in what's called cancer
10 epidemiology?

11 A. This is what I do virtually hundred percent.
12 Well --

13 Q. Virtually a hundred percent?

14 A. Eighty-five percent, 85 percent, virtually a
15 hundred.

16 Q. And just for the record, what sorts of cancer
17 studies are you now currently engaged in?

18 A. We have now seven research projects that
19 started between the time I -- I joined faculty at Emory
20 and today. I think it was seven at the last count.

21 Q. What types of cancer?

22 A. Breast cancer, lung cancer, prostate cancer,
23 colon cancer, tongue cancer. And there are also some

1 studies that deal with all cancers, more of looking at
2 accuracy of information about cancers that is collected
3 by registries.

4 Q. And I think you're teaching Introductory
5 Epidemiology, and you've also taught a class there on
6 prostate cancer; correct?

7 A. Prostate cancer, pediatric cancers are the
8 classes that I typically teach in the Cancer
9 Epidemiology course.

10 Q. And your current research or ongoing research
11 is funded by the American Cancer Society, CDC, the
12 National Cancer Institute, and the Department of
13 Defense, among others?

14 A. Correct.

15 Q. Have you also done research on particular types
16 of carcinogens like asbestos?

17 A. Yes, I have.

18 Q. All right. Tell us about that.

19 A. Well, I've done work that's related to
20 carcinogenicity of asbestos, of course. I've done some
21 methodological work that relates to carcinogenic
22 exposures for breast cancer.

23 Right now, most of work that I do, most of the

1 work that I'm hoping to do in the future as well, is
2 interaction, look at interaction between dietary
3 components, particularly the -- the modern diets and
4 genetic -- genetic factors. So, exposures in that case
5 would be components of what people eat.

6 Q. Now, on the screen, we have a paper I believe
7 you're lead author on. What is that paper?

8 A. That paper, I think it was my first publication
9 -- well, maybe not first, but one of the earlier
10 publications with -- when I joined Exponent. And it's
11 metaanalysis of cancer in asbestos-exposed occupational
12 cohorts.

13 Q. And when did you complete that?

14 A. The paper came out in '99.

15 Q. Has that document or that study been cited by
16 the U.S. Government?

17 A. Yes.

18 Q. Have you done other epidemiological research
19 into asbestos?

20 A. Yes. Last year, I coauthored two papers that
21 relate specifically to risk of mesothelioma and lung
22 cancer in motor-vehicle mechanics, people engaged in
23 motor-vehicle repair.

1 Q. All right. And did you present the results of
2 that research to any expert scientific group?

3 A. There was a meeting in December of 2003, if I'm
4 -- if I remember correctly, in Baltimore, where we first
5 presented those results. This is slide of poster. It
6 was a wall poster.

7 Q. Yeah. And what is the Society For Risk
8 Analysis?

9 A. Society For Risk Analysis is -- is a group of
10 people engaged in risk assessment. And it is a
11 multidisciplinary group. It includes epidemiologists
12 and toxicologists and regulators and so forth.

13 Q. And did you -- that's another slide, I guess,
14 from the presentation you gave.

15 A. Just second half of it, yes.

16 Q. Did the research actually get published?

17 A. Yes, it did.

18 Q. All right. And where was that published?

19 A. That came out in journal, in *Annals of*
20 *Occupational Hygiene* in June of 2004.

21 Q. June of 2004?

22 A. June, I think, yes.

23 Q. Any other asbestos-related research you've

1 published on this topic?

2 A. Well, then, as I said, I wasn't the first
3 author, but I was co-author of another paper by Dr.
4 Patrick Hessel.

5 Q. And is that the study that's depicted on the
6 screen now?

7 A. Yes, that's the one.

8 Q. I want to discuss asbestos in general. And
9 you've been here for some of -- or a lot of testimony
10 and you've heard a lot of it, so I'd like go through it
11 as briefly as possible when there are points we agree
12 on.

13 You agree that there are different types of
14 asbestos and that word is sort of a generic term for a
15 wide variety of heterogeneous fibers; correct?

16 A. Yes, I agree with that.

17 Q. And do you agree that the circumstances of
18 exposure vary?

19 A. Yes, that's true.

20 Q. Have epidemiologists studied the relationship
21 between various exposure circumstances and the diseases
22 at issue?

23 A. Research started several decades ago, and it's

1 still ongoing.

2 Q. And just in summary, what have they found?
3 What have the researchers found?

4 A. Generally, they found that asbestos is
5 irrefutably, in many circumstances, causally related to
6 mesothelioma, lung cancer, and, of course, asbestosis.

7 Q. And how did they establish that?

8 A. Well, the reason why we know that asbestos is
9 related to, say, lung cancer is because there are
10 systematic epidemiological analytic studies.

11 Q. In other words, just to clear it up, was the
12 connection between asbestos fibers and disease
13 discovered in a laboratory?

14 A. The -- the connection was established in human
15 epidemiological studies.

16 Q. All right. Now, once you have epidemiology
17 establishing an increased risk, does that mean you know
18 everything you need to know?

19 A. No.

20 Q. All right. Why?

21 A. Well, because, as we touched upon just a minute
22 ago, the circumstances of exposure and the types of
23 materials that are called by term asbestos are extremely

1 heterogeneous and, therefore, the risks are --
2 heterogeneous, meaning discrepant, very different; and,
3 therefore, the risks also vary widely.

4 Q. Now, the Court has seen this quote from
5 Dr. Selikoff, who's one of the early pioneers in the
6 research, and I think you agree with what Dr. Selikoff
7 says here, don't you?

8 A. Yes.

9 Q. All right. And, specifically, when
10 Dr. Selikoff is talking about the differences not only
11 in the circumstances of exposure but, also, in the
12 fibers, he says, that -- about the middle there,
13 "Duration of exposure, variety, and a grade of asbestos
14 used." Do you know what he means when he says "variety
15 of grade"?

16 A. Grade is not my field. But as -- as I
17 understand it, grade is another term for fiber length.

18 Q. All right. And in the course of reviewing
19 documents in the asbestos litigation, are you aware of
20 some explanation of what grade means --

21 A. Yes.

22 Q. -- even though you never worked in the asbestos
23 industry?

1 A. Yes. There is a paper that's not necessarily
2 in my field but provides an explanation of what grades
3 mean and what -- how the various grades were used.

4 Q. All right. And what about that information is
5 important to you as an epidemiologist?

6 A. Well, if I look at applications of various
7 grades, and, particularly, if we are interested in
8 friction fibers, it appears that brakes and clutches
9 that would be sources of friction fiber exposures are,
10 at least in this publication, related to Grade 7, which
11 is the highest grade, the shortest fibers.

12 Q. Shortest fibers?

13 A. Yes.

14 Q. All right now, why is the difference in fibers
15 specially important when you're trying to figure out
16 whether there's an association between an exposure and a
17 disease?

18 A. As we discussed a minute ago, it is -- it is a
19 very heterogeneous group of potential exposures. So,
20 fiber length is only one component. But, clearly, there
21 is evidence that that may be an important component.

22 Chemical composition, of course, is another
23 important component. Various morphologic, meaning

1 structural, characteristics, as well as physical and
2 chemical characteristics of fibers themselves may -- I
3 don't know what they are, but they may affect the
4 biological effects.

5 Q. And as I think the other experts previously
6 testified to, there are various scientists who are
7 researching those differences to this present day;
8 correct?

9 A. As far as I know, it's an active area of
10 research.

11 Q. Right. And what we have up on the screen, I
12 believe, is taken from the EPA's peer review panel that
13 was put together by the contractor we've heard a lot
14 about. Is that a part of the report?

15 A. Yes, that's one of the statements in the
16 executive summary.

17 Q. All right. And do you agree with that? Let me
18 just -- "Factors that influence toxicity: Health
19 effects from asbestos and SVFs ultimately are functions
20 of fiber dose, fiber dimension, the length and diameter,
21 and fiber durability, or persistence in the lung, as
22 determined by the mineral type, the amorphous or
23 crystalline structure, and the surface chemistry." Do

1 you agree with that?

2 A. It is a very general statement, but I think
3 there's no reason to disagree with that.

4 Q. All right. Let's talk about epidemiology and
5 its application here.

6 What is -- in a broad sense, what is
7 epidemiology?

8 A. The textbook definition is that epidemiology is
9 a science, field of science, that concerns itself with
10 distribution and determinants of disease and other
11 health-related states in human populations.

12 Q. And how do you identify those associations?

13 A. Well, there are two parts to epidemiology. And
14 as the definition -- you know, the definition gives you
15 a clue: The distribution of how much, where, in what
16 circumstances of, say, disease.

17 Determinants is, what are other factors that
18 are associated and ultimately, what are the factors that
19 are causative of those diseases or health-related
20 states.

21 Q. Let me narrow it down to your field because
22 mesothelioma is a type of cancer, as is lung cancer,
23 obviously; right?

1 A. Correct.

2 Q. All right. Where does epidemiology fit
3 specifically my the matrix of research on cancer
4 investigation?

5 A. Well, cancer investigation, of course, is a
6 very broad -- broad term. One can look at cancer
7 survival, the treatment, or -- or access to care. But
8 one can also look at potential causes of cancer --

9 Q. All right.

10 A. -- and what we call etiological research,
11 cancer research. And in etiological cancer research,
12 human epidemiological studies are the most important
13 tool in identifying potential risk factors and/or
14 causes.

15 Q. All right. Is that because we don't know all
16 of the causes? We can't --

17 A. Certainly. Most of the time, we don't know the
18 causes. It's an exception rather than the rule when we
19 do.

20 Q. And others, we don't have a full appreciation
21 and understanding of the complete biological mechanism
22 from which to predict outcomes; correct?

23 A. For the majority of cancers, we are just

1 scratching the surface now.

2 Q. All right. Now, the next slide -- go back.
3 The next slide is taken from something called the IARC
4 Monographs. What is IARC?

5 A. IARC stands for International Agency For
6 Research on Cancer.

7 Q. What is that?

8 A. IARC is a part of WHO, World Health
9 Organization. It's located in Lyon, France. And IARC
10 is -- one of the functions -- there's multiple
11 functions. But one of the functions of IARC is to
12 develop guidance documents for various potential
13 carcinogenic substances.

14 IARC does, but not much, regional research.
15 But most of what they do is convening panels of experts
16 and evaluating the evidence, weighting it, and, then,
17 determining whether or not a particular substance
18 provides exposure circumstances which entail increased
19 risk of cancer --

20 Q. All right.

21 A. -- in humans.

22 Q. All right. Now, just let's explain this in a
23 little bit of detail.

1 IARC has a monograph on the methods in which
2 something can be classified as a carcinogen.

3 A. Correct.

4 Q. All right.

5 A. And --

6 Q. Go ahead.

7 A. I should say, the preamble for IARC monographs,
8 it doesn't matter, it will be the same for all -- all
9 issues.

10 Q. Okay. All right. Thank you.

11 Group one, "The agent or mixture is
12 carcinogenic to humans," or "is considered carcinogenic
13 to humans."

14 A. Yes.

15 Q. That's what their group one would constitute:
16 "The exposure circumstance entails exposures that are
17 carcinogenic to humans."

18 A. Correct.

19 Q. You understand what they mean, then?

20 A. Yes.

21 Q. And the categories used, "When there is
22 sufficient evidence of carcinogenicity in humans,
23 exceptionally, an agent or mixture may be placed in this

1 category when evidence in humans is less than
2 sufficient, but there is sufficient evidence for
3 carcinogenicity in experimental animals and strong
4 evidence in exposed humans that the agent or mixture
5 acts through a relevant mechanism of carcinogenicity."
6 You agree with that?

7 A. That's the most recent definition. Until about
8 a couple of years ago, the second part did not exist
9 there. But, yes, that's the way they evaluate
10 carcinogens.

11 Q. All right. Two very important questions for
12 this proceeding that I want to ask you in a very
13 straight manner and get a succinct answer from you on.

14 If I ask the question, is asbestos -- I'm
15 asking for your conclusions on this, all right -- is
16 asbestos carcinogenic in humans, using this rubric, what
17 is your conclusion?

18 A. Yes.

19 Q. If I ask you the same question about
20 chrysotile, meaning all of the heterogeneous fibers that
21 we call chrysotile, what is your answer?

22 A. Yes.

23 Q. Yes, it is carcinogenic?

1 A. Yes.

2 Q. Now, how do epidemiologists investigate
3 associations?

4 A. The cornerstone of epidemiological research is
5 really the same as cornerstone of any analytical
6 research. And what -- what -- what's important is the
7 ability and the need to follow what's called a
8 scientific method.

9 Q. All right. Very briefly, because I think
10 Court's heard this, what is important about the
11 scientific method in epidemiology?

12 A. Scientific method is, of course, a concept that
13 caught in probably elementary school.

14 You begin with an observation that allows you
15 to generate a hypothesis. And, then -- then, the
16 research begins. Then, you set out to test that
17 hypothesis in a structured manner.

18 The most important thing about scientific
19 method that takes you from an observational -- from an
20 observation to a tested hypothesis is the ability to
21 utilize controls, or a comparison group.

22 You know, a very quick example from elementary
23 school would be, if I observe that plants thrive in the

1 presence of daylight, my hypothesis would be that plants
2 need light to grow. How I test that hypothesis is a
3 different matter. For instance, the way we did it when
4 I was in third grade, you take a jar, a glass jar, fill
5 it with cotton, add some water, put a bean on top, and
6 take an identical jar, an identical amount of water and
7 cotton and an identical bean; put one in the closet and
8 the other one on the windowsill. You come back ten days
9 later and, in that case, sure enough, one bean actually
10 develops sprouts and the other one was still dry.

11 Now, it was 30 of us in the class, and we
12 reproduced this experiment multiple times. That
13 scientific method is a very low elementary school level.

14 Interestingly, that conceptually, sort of from
15 cognitive point of view, research follows the same
16 approach.

17 Q. All right. And I appreciate that. But let's
18 move from it elementary school up to modern cancer
19 research.

20 What type of literature generates the
21 hypothesis that then gets tested?

22 A. Well, there is a variety of sources for
23 hypothesis. It can be mechanistic studies, for example,

1 using cell cultures or an animal experiment. Or, very
2 often, it is case reports.

3 Q. And we have heard that term run around. Just
4 define quickly what a case report is. And we've got a
5 slide on the screen to help you do that.

6 A. Case reports is observation, documented, a
7 series of observations documented by a, say, physician
8 or a researcher. Usually, it's the clinician, the
9 physician who treats patients, who documents and reports
10 those cases.

11 Let's say -- this slide shows a hypothetical
12 example which actually led to a -- there was a
13 hypothesis that was entertained in the literature for
14 quite a while, is that, let's say physician observes
15 one, two, maybe three cases of pancreatic cancer in his
16 or her practice, and he observes, also, that pancreatic
17 cancer, people who come to him, patients, are heavy
18 coffee drinkers. You know, the idea that legitimately
19 may occur, and it may become a hypothesis, is that
20 coffee drinking somehow increases the risk of pancreatic
21 cancer.

22 Q. Let me stop you right there.

23 It's not your opinion that that's illegitimate,

1 to have a concern raised if you see some cases come in?

2 A. No, no, that's how research begins, by
3 formulating the hypothesis.

4 Q. All right and is it, though, accurate science
5 to then reach the conclusion that some number must be
6 significant without a control group?

7 A. No. Well --

8 Q. We're going to come to that.

9 A. Almost never, let's put it that way. Almost
10 never. There are exceptions.

11 Q. How do the epidemiologists then test the
12 hypothesis?

13 A. Well, so, we have a case report and, now, we
14 have a hypothesis.

15 The next question is, frequency. You know,
16 that's the first building block of an epidemiological
17 study. How common is pancreatic cancer among coffee
18 drinkers? We go out, recruit 1,000 volunteers at
19 Starbucks, say, in 1990 -- I don't know if Starbucks
20 existed back there.

21 Q. West Coast.

22 A. Yeah, in Seattle.

23 And follow them for ten years until the year

1 2000. And ten years later, we identified ten cases of
2 pancreatic cancer. So, of course, the numbers are
3 hypothetical. They're all rounded for simplicity. But
4 the point is that we took a group of people, we follow
5 them over time and, at the end of followup, we counted
6 cases. And now we know there are ten cases among 1,000
7 coffee, heavy coffee drinkers.

8 And the question that immediately arises after
9 that is, so what? Because we don't know whether, in
10 fact, that is a lot, or a few, or just what one would
11 expect.

12 Q. Because some people might have gotten the
13 disease without any coffee at all?

14 A. Because people get disease, no matter what.
15 Some people get disease, no matter what. But we don't
16 know.

17 So, the next step is to identify a similar
18 cohort. And I must say that this particular flow of
19 logic, flow of steps is a -- would be a cohort study.

20 Q. And let me just footnote this. We've talked
21 about two different kinds of studies: Predominantly,
22 cohort studies and case control studies, this is the
23 first, cohort study?

1 A. Cohort study, we begin identifying people with
2 and without exposure of interest -- in this case, coffee
3 consumption. So, what's missing is, we don't know what
4 happens in the absence of coffee consumption. And what
5 one can do is identify, say, a similar group of 1,000
6 people who don't drink coffee ever, follow them for ten
7 years, and count cases at the end of that followup.

8 Let's say we found ten cases. Now is the time
9 to put these two groups side by side and conduct the
10 analysis of what -- what does it all mean?

11 In this particular example, we have ten cases
12 that were observed where one can say it's ten cases per
13 thousand per -- per ten years, which is the same as one
14 case per thousand per year --

15 Q. Okay.

16 A. -- per -- per thousand person years, in the
17 exposed group, exposed meaning coffee drinkers, and
18 exactly the same number in the nonexposed group.

19 Q. But we've oversimplified the math. It's
20 extremely rare that there's the same number of people in
21 the control group as in the study group; correct?

22 A. Almost never happens.

23 Q. None of the studies have equal numbers. It's

1 actually a ratio that you're looking at or a fraction;
2 correct?

3 A. It depends on the study design. It depends on
4 the study design. It can be a fraction in a cohort
5 study that calculates SMR.

6 Q. Okay.

7 A. But the concept is this: We divide the
8 observed -- cases among the exposed by the expected
9 number that would have occurred anyway and, then, if
10 that ratio is one, you conclude there is no difference,
11 or close to one.

12 Q. Now, very quickly, show us the same -- how the
13 math works, the same type of study when you might have a
14 positive finding, because what you just illustrated was
15 a negative finding, no increased risk.

16 A. Right. We conclude that coffee consumption is
17 not associated with pancreatic cancer.

18 A very similar conceptual example using
19 different disease and different exposure is lung cancer
20 among smokers. You begin by observing a lot of lung
21 cancer among people who tend to smoke. Hypothesis is,
22 is lung cancer caused by smoking or associated with it?
23 You begin -- always begin with an association before you

1 move on.

2 One thousand regular cigarette smokers, we
3 found 100 cases. Among non-smokers, you found only ten
4 cases at the end of cohort. You have put the two
5 results side by side, the difference is ten-fold, which
6 is actually not a hypothetical number. It's the number
7 one would expect in the regular smoker, or round
8 about -- can be much higher and that can be a little bit
9 lower, depending on how much. But the conclusion is,
10 smokers are ten times more likely to develop lung cancer
11 than do non-smokers.

12 Q. That's cohort. Briefly show us in reverse how
13 the case-control design works.

14 A. The case-control design is less intuitive. The
15 case-control design begins with disease in question.

16 Q. And we just need to make sure that this is
17 understood. Most of the studies we're going to talk
18 about on this topic are case-control studies; correct?

19 A. That is correct.

20 Q. All right.

21 A. The case-control studies begin with an illness
22 of interest. Let's take the same example of pancreatic
23 cancer and coffee and just play it backwards.

1 Let's say, in a hospital or a cancer -- or a
2 cancer registry, assuming we have a good cancer
3 registry, we identify 1000 cases of pancreatic cancer.
4 We interview these people and find out how many of these
5 are coffee drinkers. And let's say, in our example, 250
6 of those drink coffee regularly, which is 25 percent.

7 Then, the next step is, is it -- is this
8 percent similar or different in people without
9 pancreatic cancer, in healthy individuals, which one
10 would call controls. Let's say we identified 1,000
11 controls, we asked them about their coffee consumption,
12 or documented it any other way, and it turns out that
13 250 of those 1,000 healthy controls do not drink coffee,
14 do not -- do drink coffee and 75 don't.

15 You put these two results side by side. The
16 proportions of people who consume coffee -- in this
17 case, our hypothetical carcinogen -- are equal.

18 Q. All right.

19 A. And that allows you to conclude that there is
20 no increased risk.

21 Q. Now, that mathematically came out to 1.0;
22 correct?

23 A. Both instances, they -- mathematically, they

1 would be 1.0.

2 Q. That's a negative study?

3 A. Right.

4 Q. Statistically speaking, when epidemiologists
5 finish this research and analyze it, do they need it to
6 be 1.0? What conclusion do you draw if it comes out to
7 be .9 or .8 or 1.1, something statistically around that
8 1.0 bulls eye?

9 A. Each and every result, individual result, has
10 some uncertainty arising with what's called random
11 error. Random errors very simply means that there is a
12 chance that plays a role in what exact result you're
13 going to observe. So, that random error is quantified.
14 People usually use 95 percent confidence intervals,
15 around their best estimate.

16 Let's say your best estimate is one, but your
17 confidence interval goes from 0.7 to 1.3. That's fine.
18 What if your result is not 1, but, say, 1.5 and your
19 confidence interval comes from 0.4 to 2 or 2.2. The
20 confidence -- can I show it on the flip chart.

21 MR. TARRY: May he get down.

22 THE COURT: Yes, he may.

23 MR. TARRY: And, your Honor, if this is too

1 pedantic, we can move.

2 THE COURT: No, it's very helpful, thank you.

3 BY MR. TARRY:

4 A. We've already discussed that 1 means equal
5 risk in people who are exposed and unexposed. But the
6 real life study, the actual result is, say, 1.5. The
7 confidence interval.

8 Q. Confidence?

9 A. Confidence interval, what we called 95 percent,
10 by convention, confidence, CI, confidence interval, may
11 go from 0.4 to 2.2. The 1 is included in that interval.
12 Therefore, researcher cannot conclude that his or her
13 results is different from what's called known, or 1.

14 Q. From that one study?

15 A. That one particular study.

16 Now, if the confidence interval, for instance,
17 goes from 1.2 to 1.7, the interval no longer includes 1
18 and, then, the conclusion would be that this result is
19 unlikely to be explained by chance alone. There may be
20 other explanations and other limitations but, by chance
21 alone, it's unlikely -- we have only 2.5 percent in each
22 way that your result is different than this interval.

23 Q. All right. Before you take the stand again

1 while you're up, let me ask you to do a couple of other
2 things.

3 We were talking about case-control studies.
4 And maybe using smoking and lung cancer again, can you
5 show the math, how the math works in a basic fashion, in
6 a case-controlled study where there's a positive
7 finding.

8 A. Yeah.

9 Q. And we'll agree, hypothetical --

10 A. The math is important because that's how --
11 they think, they think in two-by-two tables all the
12 time.

13 The premise is a two-by-two table, four cells.
14 You have disease and you have exposure. People can have
15 disease or they may be disease-free. They may have
16 exposure or they may get -- they may be exposed or they
17 may be nonexposed. This way, our study group is divided
18 into four categories. People that are sick and have
19 exposure or had exposure in the past; people who are
20 healthy, no disease, but have exposure; people who are
21 sick and have no exposure; and people who are healthy,
22 or don't have the disease of interest.

23 Q. They don't have the particular disease?

1 A. Control.

2 Q. Right.

3 A. And neither have the disease of interest, nor
4 the exposure of concern. They are labeled A, B, C, D.

5 Let's -- an example, we go to a -- to a
6 hospital and we identify a hundred cases of lung cancer.
7 And we take a hundred cases of trauma patients rolling
8 into the emergency room consecutively. We hope they're
9 representative of the general population.

10 Q. People from the trauma unit are going to be our
11 control group?

12 A. Our cases of lung cancers. Our controls,
13 maybe. That's one of the ways to do it, is, say, random
14 visits to the emergency room for trauma, for reasons
15 that are not cancer.

16 Q. I don't want to get you too sidetracked. But
17 is it important to actually try to get control groups
18 from the same area --

19 A. Yes, it is.

20 Q. -- if it's possible?

21 A. There's a variety of -- control selection is a
22 very important part of it.

23 Q. Okay.

1 A. So, we have a hundred cases. And we have 100
2 control.

3 We ask them, "Do you smoke?" or, "Did you smoke
4 in the past?" The most important thing is what happened
5 in the past. And -- which is not surprising. You might
6 find 80 people out of a hundred that are smokers with
7 the lung cancer, and maybe 20 that have lung cancer but
8 are nonsmokers.

9 Among your just people who roll in the
10 ambulance, for instance, you may have what's
11 representative of the general population. 25/75 is not
12 -- is not unreasonable. That's probably what -- number
13 of people who smoke among controls.

14 Q. Twenty-five people in the trauma unit smoke?

15 A. And 75 who don't.

16 Q. Right.

17 A. Now is the time to calculate the odds ratio.
18 But before do you the odds ratio, you do the odds. The
19 odds of smoking, if you have lung cancer, are 80 by 20
20 equal four to one. The odds of smoking, if you don't
21 have lung cancer, 25 by 75 equals one third. The ratio
22 of the two, that's the odds ratio.

23 Q. We need to verbalize this for the court

1 reporter.

2 A. I'm sorry. The ratio of the two, four divided
3 by one third equals 12. The conclusion is, exactly as
4 it is with the -- with the cohort study, although we did
5 it differently, is that people who smoke are 12 times
6 more likely to have lung cancer than people who don't.

7 Q. One last thing before you take the stand.

8 Another type of study we're going to discuss on
9 the friction product exposures is called a PMR,
10 proportionate mortality study.

11 A. Yes, it is a common design.

12 Q. Can you give a brief explanation of that study
13 design.

14 A. Yeah. PMR is proportion mortality, or
15 proportionate incidence study.

16 Q. Which would P-I --

17 A. P-I-R instead of P-M-R.

18 It deals with proportions. Typically, it's
19 mortality -- proportions of people who die from a
20 particular cause out of total number of deaths in a
21 given area and given period of time.

22 Let's say we're doing a study of -- our
23 hypothesis of interest is, do teachers develop stroke or

1 die from stroke more commonly than general population?
2 We take a certain -- you know, a well-defined area that
3 has death certificates. Death certificates, of course,
4 document two things: They document occupation and they
5 document cause of death. It's not the best way to
6 collect information, but it's available so people do
7 that.

8 Let's say we had a 100,000 deaths total in a
9 population of -- in --

10 Q. Wilmington?

11 A. I don't know, Delaware, in five years. We have
12 that database, we have all these death certificates,
13 total 100,000 deaths. Of those, 2,000 were due to
14 stroke -- two percent. And we say, "Okay, among those,
15 let me just pull out all the teachers." Let's say 1,000
16 deaths out of our hundred thousand.

17 Q. One thousand stroke-related deaths?

18 A. No, total deaths.

19 Q. Total deaths, sorry.

20 A. Occurred among teachers. And these are
21 teachers. The other ones are everybody. And we counted
22 and we found that there were, let's say, 40 deaths due
23 to stroke.

1 Now, we know that the number in the general
2 population is two percent. Therefore, here, we would
3 have expected 20 deaths, 20 expected deaths, based on
4 two percent out of the 1,000. But observed number of
5 deaths is 40. Hence, the PMR, proportionate mortality
6 ratio, for teachers and stroke is 40 observed divided by
7 20 expected.

8 This is not necessarily a measure of relative
9 risk because we don't have people in the population.
10 This is a measure of proportionate mortality.

11 Q. Yeah. Are there other limitations of the study
12 design that make it, in your opinion, less reliable for
13 calculating the relative risk, or risk of an
14 occupational exposure?

15 A. Yes. The first, as I mentioned, is that you
16 don't have the underlying population of healthy people
17 from which to draw. Your underlying population are all
18 deaths as opposed to all people.

19 The second one is, usually, those types of
20 studies are limited by information. They just don't
21 have enough information. As I said, if it is a death
22 certificate study, you have the cause of death and you
23 have the occupation. You don't have a whole lot of what

1 happened before that. So, it certainly needs to be
2 considered as a major limitation.

3 Q. Those are some of the limitations that you
4 identified in the studies we're going to discuss later
5 when you performed the systematic review and
6 metaanalysis?

7 A. It's not that I identify. It's sort of well
8 known.

9 Q. That you identified in your paper that we're
10 going to talk about.

11 A. Right.

12 Q. You can take the stand.

13 Dr. Goodman, that's, by no means, all the
14 different study designs, is it?

15 A. No, there's a number of other studies that are
16 available.

17 Q. The last witness who testified yesterday,
18 Dr. Frank, mentioned in some detail a study by Nicholson
19 and others at Mount Sinai, up in New York City in the
20 early 1980s, pursuant to a NIOSH contract. Do you
21 remember that discussion?

22 A. Yes, I do.

23 Q. What kind of -- and there was -- I'm not sure

1 it was made clear on the record what kind of study that
2 was. What kind of study was the --

3 A. Yeah. That particular study, looked -- as
4 opposed to events -- you know, there are two things that
5 can happen to people. There are events, death, and
6 newly diagnosed diseases and death. We can have states,
7 where the onset is not known -- for instance, x-ray
8 abnormalities or blood pressure. Nobody knows, really,
9 when, at what point in time, somebody develops high
10 blood pressure. You know when person might be diagnosed
11 with blood pressure, but that's not necessarily -- I
12 mean, it's an event, but typically, blood pressure is a
13 long-lasting state that a person lives in. And because
14 you don't have the onset time, and because it's a
15 long-lasting event, those studies -- typically, there's
16 no other choice but to study them through what's called
17 cross-sectional designs.

18 Q. Cross-sectional?

19 A. Cross-sectional design.

20 Q. Right. Is that the design that was talked
21 about yesterday?

22 A. Yes. The difference between --

23 Q. Do you need some water?

1 A. I'm fine. I have it.

2 The difference between a cohort study and a
3 case-control study is that, in a cross-sectional study
4 -- well, here's how I would explain it to students.

5 Let's say you're watching a who-done-it movie,
6 you know, the detective story. You -- a cohort study,
7 you start from the beginning and you watch all the way
8 to the end and you -- the event being the murder. A
9 cross -- a case-control study, the same movie is watched
10 backwards. You can still understand what's happening,
11 it's just backwards.

12 Q. You start with the murder and look to see who
13 had the gun?

14 A. Right. There is a school of thought, maybe
15 that's more logical to do it because nobody ever
16 investigates prospectively. This is a different issue.

17 A cross-sectional study, unlike the cohort and
18 a case control, is a snapshot. All we have is one frame
19 from a movie. You know at a given point in time, in a
20 two-by-two table, there was exposure and/or disease, or
21 none, but you don't know what preceded what. That's the
22 most important issue about cross-sectional studies, that
23 the issue of temporality, chicken-and-egg issue, is

1 unresolved in cross-sectional study.

2 Q. What are they used for? What are
3 cross-sectional studies? What's the usefulness of a
4 cross-sectional study?

5 A. The states -- as I said, the states of
6 conditions are -- are probably the only way to study.
7 You know, with cross sectional -- I mean, they're very
8 important and useful. The problem is because of absence
9 of temporality, you may have some trouble interpreting.

10 The only exception that textbooks usually say
11 is that, if you look at things that are present at
12 birth -- color of your eyes, that certainly doesn't
13 change, so you know that preceded whatever outcome
14 you're looking at. In other -- in other situations,
15 it's a snapshot.

16 Q. In your field -- and, in fact, what this Court
17 ultimately is going to have to do -- weight of the
18 evidence is important; correct?

19 A. Correct.

20 Q. And you've touched upon something called
21 consistency. I'd like you to explain. What does
22 consistency mean to an epidemiologist?

23 A. Well, even the scientific method in -- back in

1 elementary school requires that experiment should be
2 repeated.

3 Q. The experiment should be repeated?

4 A. Should be repeated. Same applies for
5 nonexperimental studies, observational studies, the ones
6 that are typically conducted in cancer research.

7 Q. And just let me footnote for the record again,
8 when we say observational studies and epidemiology,
9 they're sort of synonyms for each other; correct?

10 A. Well, you can have an epidemiological study
11 that are clinical trials, of course, too, which will be
12 an experiment.

13 Q. Right.

14 A. But in most circumstances, when you're looking
15 at potential harmful exposures, you're testing
16 hypothesis for disease causation, clinical trials are
17 not ethical and/or feasible. But --

18 Q. What does -- yeah, I'm sorry for interrupting
19 you.

20 What would you define consistency to mean in
21 epidemiology?

22 A. What it means is, you have to collect all the
23 relevant information and evaluate it in its totality

1 and -- to see whether or not studies tends to agree or
2 disagree with each other. Studies that test the same
3 hypothesis, they may use different methods, can be done
4 at different places, can be done by different
5 researchers, but they have to test the same hypothesis.
6 That's important.

7 And that's where consistency -- I mean, that's
8 what people use before they draw conclusions, presence
9 or absence of an association.

10 Q. Can you explain it briefly to the Court, using
11 this slide that is a compilation of some different
12 studies and their results?

13 A. Yeah. Let me just take a minute and orient us
14 with respect to this -- the slide itself.

15 There's no cursor, is there? There's no
16 pointer or anything? It's all right.

17 MR. TARRY: Does the touch screen work?

18 THE COURT: It might work.

19 THE WITNESS: Oh, yeah.

20 BY MR. TARRY:

21 Q. There you go.

22 A. This is a graph showing real studies from --
23 conducted in real life. And they look at lung cancer,

1 relative risk of lung cancer associated with smoking
2 approximately one pack of cigarettes per day. The Y
3 axis -- the X axis, the horizontal axis, is a relative
4 risk estimate from those studies. Again, one is
5 important to find the one always because that's your
6 known elevation, meaning that risk is not elevated.
7 And, then, the Y axis, the vertical axis, is the one
8 that lists actual studies. It's the first author and,
9 typical fashion, how you show publication -- say
10 McLaughlin, Siemiatycki, and so forth.

11 And, then, what we do -- and that's one way to
12 do it. You can tabulate numbers. But it's -- visually,
13 it's frequently much easier to do it. You show the best
14 estimate. That's -- in this case, for McLaughlin, it's
15 roughly ten, and a confidence interval, because the
16 graph -- here, you see mostly the lower -- the lower
17 bound of the interval because we ran out of space on the
18 axis.

19 Q. Okay. But it's in the middle?

20 A. Yes, it's written, actually. It says ten and
21 the confidence interval, CI, between 8.8 and 11.2. So,
22 you know, that with a 95 confidence, you know that's
23 exactly 10. But with 95 percent confidence, you know

1 the result is somewhere between roughly 9 and 11.

2 Q. And then, statistically speaking, using the
3 methods employed by those researchers in those studies,
4 you would note that the statistical probability of there
5 being no association between smoking and lung cancer is
6 what?

7 A. It's very, very low, extremely low. But the
8 point is that, of course, there is a consistency of
9 findings.

10 Some of the studies don't have a confidence
11 interval because these are earlier studies done in the
12 seventies, that one done in the eighties, and they just
13 didn't calculate it, the confidence interval.

14 Q. We talked about -- just to juxtapose the
15 situation, we talked about the coffee, real-world coffee
16 example, bladder cancer.

17 A. Right.

18 Q. Can you explain what they found when they
19 studied that hypothesis, that there might be an
20 association.

21 A. Yeah. These are actually real-life studies of
22 coffee drinkers, and these are cohort studies. There
23 have been number of those over the years. These are

1 studies of relative risk of pancreatic cancer in coffee
2 drinkers compared to the general population or maybe, in
3 some cases, compared to nondrinkers. And, as you can
4 see, there is a -- there is a study, for instance by
5 Mills, M-I-L-L-S, 1988, that shows that almost more than
6 twofold increase in risk.

7 Q. Twice as many people he observed?

8 A. Correct. The number of observed compared to
9 the number of expected was more than twofold higher.
10 But, yeah, because the numbers were small, the
11 confidence interval is extremely wide, goes from -- all
12 the way from 8 to roughly 0.7, and includes 1. So,
13 that's -- we say, if this was the only study, you would
14 have to sit and wait for other evidence to come in. You
15 know, if other studies found the relative risk right
16 around 2, even though they may be nonsignificant, in
17 aggregate, you would have to say that, as the number of
18 studies increases, your overall precision increases.

19 In this case, of course, and when other studies
20 were put on the same graph, you know, that's just --
21 they just randomly scattered around 1 -- some above,
22 some below.

23 Q. Bottom line, does this present a picture of

1 consistency among the research or inconsistency?

2 A. Well, that would say consistent lack of
3 association.

4 Q. Even though there are a couple that
5 statistically identified what appeared to be to them
6 maybe a little bit of an increased risk?

7 A. It is typical to have one or two outliers.

8 Q. Okay. Thank you, Dr. Goodman.

9 Now, with respect to the testimony you've heard
10 in this courtroom about cancer and the biological
11 mechanisms of cancer, you agree that it's a broad term,
12 cancer?

13 A. Yes. It's a very broad term.

14 Q. Cancer occurs in different sites in the body?

15 A. Yes.

16 Q. And there are different histologies, which
17 means different cell types in cancer?

18 A. Right, different tissue characteristics.

19 Q. Why is that important to an epidemiologist?

20 A. Well, because cancer is certainly not one
21 disease. And even within a known category of cancer,
22 that's -- an example, good example, would be leukemia.
23 Not only leukemia can come from different cells in the

1 bone marrow, but even within the same cell category,
2 depending on the age, they behave as completely
3 different diseases. For example, acute lymphoblastic
4 leukemia is a different disease if it's contracted at
5 the age of one versus the age of four or the age of 12,
6 and completely different disease, or large different
7 disease, if it's contracted by a adult in the 40s or
8 50s.

9 Now, if say, lymphoblastic leukemia in a
10 four-year-old, it seems like a pretty narrow category.
11 But it isn't, because once people look at the actual
12 molecular features of those cancer cells, we know quite
13 a bit about it, they all have this fingerprint, a
14 chromosomal abnormality, fingerprint, that would
15 distinguish them even with that narrowly defined group
16 with extreme amount of variability with respect to
17 prognosis, treatment that's required -- some would
18 respond to certain chemotherapy and some will require
19 different chemotherapy -- and survival.

20 So, just to show how, you know -- cancer, of
21 course, is a -- is a category of diseases. But even if
22 you keep zooming in on them more and more specific
23 categories -- there's probably o end to it, there's no

1 end to our understanding of how different types of
2 cancer vary.

3 Q. Now, unlike Dr. Hammar, you don't diagnose
4 mesothelioma?

5 A. No, I don't.

6 Q. But mesothelioma being one of the cancers, does
7 that same analysis apply for mesothelioma in terms of
8 variety?

9 A. I'm not a pathologist, but I do know enough to
10 say that it's a very heterogeneous group of tumors.

11 MR. TARRY: Your Honor, at this time, we're
12 about to move in the nuts-and-bolts substances. If
13 there are questions about the fundamentals.

14 THE COURT: No.

15 MR. TARRY: We're ready to go.

16 THE COURT: Ready to go.

17 BY MR. TARRY:

18 Q. Dr. Goodman, have epidemiologists studied the
19 associations between circumstances of exposure to
20 asbestos and disease, in particular mesothelioma?

21 A. Yes, they have, extensively.

22 Q. All right. And can you just give us a quick
23 overview of some of the sorts of things they found?

1 A. Well, there are a number of circumstances where
2 people exposed to asbestos have increased risk of
3 developing mesothelioma, and very large increase in
4 risk.

5 Q. Now, in the field of occupational epidemiology,
6 is the occupation often used as, what Checkoway terms, a
7 surrogate for exposure cat -- exposure circumstances?

8 A. Yes, that's one way to characterize exposure.

9 Q. But why do you do it that way?

10 A. Well, because, if you characterize occupation,
11 you may evaluate people who are unified by certain types
12 of exposures.

13 Q. Does that mean they all have exactly the same
14 exposure?

15 A. No, of course not.

16 Q. Okay. There is a variety of exposure even with
17 that cohort; correct?

18 A. Certainly.

19 Q. All right. Now, what are some of the cohorts
20 or some of the -- well, then, let's just clarify one
21 thing.

22 Is it your contention, or anybody else's, that
23 something about the job title inoculates anybody or

1 makes them more prone to disease?

2 A. Not that I know.

3 Q. It's a method of measure; correct?

4 A. Correct.

5 Q. All right. What are some of the occupations
6 where associations have been strongly demonstrated?

7 A. Well, certainly, insulators is the first group
8 that comes to mind. They have been studied, of course,
9 since the 1960s. And I think we just jumped --

10 Q. We just jumped ahead. That's all right.

11 A. And there is consistent evidence that the risk
12 is not only increased, but it increased very
13 dramatically for people who are characterized as
14 insulators.

15 Well, for instance, as I said, this is -- this
16 is the scale that goes from up until 10. But some of
17 the estimates are -- relative risk intervals are off the
18 charts. For instance, the study by McDonald gives you a
19 relative risk of 46. The study of Spirites gives you a
20 relative risk of three. The study by Ossiander -- it's
21 a Finnish study -- gives you a relative risk of 263.

22 Q. Now, Doctor, that sounds to me to be
23 inconsistent. That does sound like pretty widely

1 varying numbers.

2 A. Sure. They are variant, although, you know,
3 one thing that is consistent, the relative risk are all
4 elevated. So, one cannot say that the risk is not
5 increased --

6 Q. And, in fact --

7 A. -- if a person in an insulator.

8 Q. Are those studies done by different people at
9 different times in different parts of the world, looking
10 at just different areas of exposure?

11 A. Yes. McDonald is Canadian. Spirites is United
12 States, Ossiander is Finland, Teschke is British
13 Columbia, and Milham ad Ossiander are from Washington
14 State.

15 Q. And back to this issue of consistency, is it a
16 good thing or bad thing that you have a diversity
17 amongst studies, when you accumulate that body of
18 evidence? Let me define what I'm talking about.

19 When I say diversity of studies, different
20 researchers, different studies looking at different
21 people?

22 A. Well, good or bad thing, I really don't know.

23 Q. Okay, that's a bad question.

1 When you have different studies by different
2 people, using potentially different designs at different
3 times, what does that do to aid you in determining
4 whether there's consistency or not?

5 A. Right. The conclusions are much easier when
6 you have consistency amongst studies. It depends what
7 conclusions we are ready to draw.

8 In this case, I'm certain that -- that
9 elevation of risk of mesothelioma among insulators is
10 present, and it's high -- you know, whatever you define
11 as high.

12 THE COURT: Can I ask one question --

13 MR. TARRY: Please do, at anytime.

14 THE COURT: -- so I'm clear.

15 So, the notion of consistency in
16 epidemiological studies, is it driven by the hypothesis
17 that you're testing? In other words, if the hypothesis
18 is, insulators are at a higher relative risk of
19 developing disease, if all of the studies show that, in
20 fact, that is an accurate hypothesis, are those studies
21 then consistent, even though they may differ in regards
22 to the extent of the relative risk?

23 THE WITNESS: Yes.

1 THE COURT: I mean, I guess what I'm asking is,
2 when you're looking at consistency, is that what you're
3 looking at, meaning are all of them showing a consistent
4 increase?

5 THE WITNESS: I understand the question.

6 The question can be posed differently. You can
7 say either evidence of increased risk. And the answer
8 is unequivocally yes. Now, the next questions could be,
9 is it 10? Then, I'm not sure. It could be three, it
10 could be 46. But I know it's not one, that's for sure.

11 I mean, it depends how you phrase it. But if
12 -- from a perspective of causality, it's just important
13 to know that the risk is elevated in those
14 circumstances. And that elevation is not trivial. It's
15 large. We can conclude that from these data.

16 BY MR. TARRY:

17 Q. Let's look at another cohort, shipyard workers.
18 Both with respect to insulators and shipyard workers, to
19 your understanding, is there any debate about the
20 association between exposure and disease in these
21 cohorts?

22 A. Yeah. As a group, as a group, shipyard
23 workers, by all means, are at increased risk of

1 developing mesothelioma.

2 Q. Are you aware of any debate about that in the
3 scientific community?

4 A. I don't think so.

5 Q. Let's look at the next one. These are some
6 examples. But what about boiler installation and
7 repair?

8 A. Well, it's the same story, more or less. If
9 you look at the totality of evidence, the studies are
10 decisively on the right from the -- you do have an
11 outlier. I mean, Milham and Osslander, 2001, shows no
12 increase in risk. I mean, if you're confronted with
13 that, if you're interested to find out what happened,
14 you might want to go into the actual study and dig
15 through it and find out what the reason is. Maybe
16 they're right and everybody else is wrong. That's
17 rarely the case. Typically, it's the other way around.

18 Q. How about plumbers and pipefitters?

19 A. Same -- really, the eyeball test is pretty
20 clear and unequivocal, that it's to the right from the
21 1.

22 Q. Now, let's talk about auto mechanics or car
23 repair.

1 Have epidemiologists studied auto mechanics and
2 mesothelioma?

3 A. Yes.

4 Q. And what have they found?

5 A. No study found an increase in -- a significant
6 increase in risk of mesothelioma among people engaged in
7 motor-vehicle repair.

8 Q. All right. And just to clarify, does that
9 finding mean that car mechanics aren't expected to come
10 down with mesothelioma from time to time?

11 A. No, it does not mean that.

12 Q. Does that mean that physicians and clinics are
13 not going to observe cases of mesothelioma in people who
14 work on cars?

15 A. No, it does not mean that.

16 Q. All right. Why is that?

17 A. Because we have epidemiology to show that the
18 risk is not elevated.

19 Q. But to reconcile these two things, you're
20 saying there's no association between the two -- why is
21 it that auto mechanics may still show up with
22 mesothelioma?

23 A. Because no occupations group, particularly

1 occupational group that is large, as large as people
2 engaged in motor-vehicle repair, will have zero cases.
3 You will have cases -- motor vehicle mechanics account
4 for several million people. Many of them are
5 blue-collar workers.

6 Q. How do you know that? You just stated -- how
7 do you know that there are that many people?

8 A. Well, there are estimates from the United
9 States, that number of people engaged professionally i
10 motor-vehicle repair is about five million.

11 Q. That's occupational?

12 A. That's an estimate.

13 Q. Wait a minute. Is that occupational, or is
14 that people who might go out in their yard?

15 A. Occupation.

16 Q. That just the occupational?

17 A. Yes.

18 Q. And o you have any estimate at all as to how
19 many people might be hobby mechanics?

20 A. No, no.

21 Q. It's a larger number than that; correct?

22 A. I would expect that's a large number. I don't
23 know what that number is.

1 Q. All right. So, in other words, you're not
2 talking about a small amount of people?

3 A. No. It's a -- it's a large occupational group.

4 Q. And even with a very rare disease, just
5 statistically, you're going to see cases; correct?

6 A. Correct.

7 Q. How many studies did you consider before
8 reaching your conclusion that you expressed to the
9 Court?

10 A. On mesothelioma, there are 18 studies that I've
11 counted to date.

12 Q. Let's talk about the first one.

13 THE COURT: Before we get into the individual
14 studies, maybe this might be a good tie to take our
15 morning break.

16 MR. TARRY: All right.

17 THE COURT: It seems like a logical break
18 point. Why don't we say we'll recess for ten minutes,
19 come back at ten past.

20 MR. CRUMPLAR: Your Honor, before you leave,
21 not related to this, but another asbestos matter, the
22 upcoming trial, I know that, originally, we were having
23 jury selection next Wednesday. I mean the

1 qualifications and then final selection on the 30th.
2 We've got a message that it moved to the 2nd. Mr.
3 Jacobs is going to try that, as me.

4 On the 2nd, which is Wednesday, will that be
5 final jury selection and opening statement, or is
6 everything moved back a week?

7 THE COURT: I honestly have no idea.

8 MR. CRUMPLAR: Okay.

9 THE COURT: I'm not driving the scheduling
10 train there. Commissioner White --

11 MR. CRUMPLAR: We'll check. We've called, and
12 we're trying to move our experts.

13 THE COURT: What I do gather, tough, is that --
14 because I understood that there was some concern about
15 the notice of the change, and Commissioner White says
16 that he gave notice of this change several weeks ago.
17 So, I'm not clear why that is a concern. In any event,
18 check with Commissioner White.

19 MR. CRUMPLAR: I will do that. Thank you.

20 (Short recess.)

21 MR. TARRY: May it please the Court.

22 THE COURT: Yes.

23 BY MR. TARRY:

1 Q. Dr. Goodman, all of the studies we're about to
2 discuss, almost all, are going to have cases of
3 mesothelioma where there was some history of work with
4 friction products or in an environment where that may
5 have occurred, correct?

6 A. Correct.

7 Q. All right. The Court will indulge me for maybe
8 beating a dead horse, but why is that not surprising
9 that there will be cases like that?

10 A. Yeah, any -- any occupational group that is
11 large will have cases. Cases will occur among teachers
12 and accountants. The question is whether or not
13 occupation puts a person at increased risk. You know,
14 everybody who's born on the day 1 of life is at risk for
15 disease, in this case mesothelioma. At some risk.
16 Mesotheliomas have been described in newborns. So the
17 risk starts immediately. And then over a period of life
18 you can do things or expose yourself to things that will
19 increase that risk, or you may be engaged in activities
20 that do not increase that risk and your risk can stay at
21 not increased level.

22 So in a group like garage mechanics, the risk
23 is exist. It's never zero. It's just wrong. I mean, a

1 newborn has a non-zero risk of mesothelioma, the moment
2 that person -- that newborn is breathing air and has
3 lungs.

4 And that's why, you know, it's not surprising
5 at all that groups like car mechanics or teachers or
6 accountants develop mesothelioma.

7 Q. And do you understand whether there's any
8 debate in the community about what percentage, albeit
9 hypothetically, of the mesotheliomas that occur may be
10 what we call spontaneous or may be caused by
11 mesothelioma?

12 A. There is a range of estimates, but there's no
13 way to measure it directly.

14 Q. All right.

15 A. But the range of estimates is somewhere between
16 10 percent and, you know, maybe 25 percent of -- well,
17 let me back up or a second.

18 There are several definitions of what one would
19 call spontaneous mesothelioma. There is a mesothelioma
20 that can occur in the absence of known occupational
21 exposure history. There is mesothelioma that can occur
22 without any exposure history, occupational or
23 non-occupational, and then finally is there a proportion

1 of mesotheliomas that can occur without asbestos. And,
2 you know, depending how you define it, you may have
3 different proportions in the total. But, you know, for
4 people without occupational asbestos history, it's about
5 20 percent.

6 Q. Well, and whether it's your opinion about it or
7 somebody else's opinion about it, is that a fact? Is
8 that something that we know and can observe or is that
9 an estimate or hypothesis?

10 A. Yes, that's been observed over and over again.

11 Q. It's been observed?

12 A. Right.

13 Q. The percentage has?

14 A. The fact that some people have unexplained,
15 unexplained cases of mesothelioma.

16 Q. Yes. Let me clarify because you might not have
17 understood the question.

18 A. Sorry.

19 Q. Any specific number that a researcher puts on
20 that, the percentage, is that a fact, is that a known
21 thing or is that more of an estimate or hypothesis?

22 A. Two things. One, it is an observed thing, if
23 you calculate a percentage of total cases. If your

1 denominator's the cases, then you can inquire about the
2 exposures and find out what proportion of people you
3 were unable to identify any exposures.

4 The other question is, what is the rate or the
5 incidence of mesothelioma among the unexposed? It's a
6 very different question. There are a measure now of
7 people without any exposure, and that's the trickiest
8 part of all. That's where you are in the estimate land.
9 You don't have measures directly.

10 Q. And that was one of the distinctions we drew
11 with Dr. Lemen, the difference between an incidence,
12 right, and a supposed background rate, right?

13 A. There is incidence and there is various
14 definitions of background rate.

15 Q. Last definitional thing before we go into the
16 studies themselves. The term "confounder" was used
17 yesterday by Dr. Lemen. What is a confounder?

18 A. A confounder is a factor. In a -- in a
19 epidemiological study evaluating association between the
20 exposure X and disease Y, a confounder is a third factor
21 Z that is associated with both X and Y. And the point
22 is that the best way to demonstrate a concept of
23 confounder is to show an example.

1 Q. Would you like to show it? Is that all right?

2 A. Yeah. Not even necessary. It's fine. Some of
3 the studies that found a positive association, early
4 studies, between coffee drinking and pancreatic cancer,
5 they found an increased in risk in coffee drinkers, were
6 done -- were performed in a very crude way. They just
7 basically did a schematic thing that we showed on the
8 board. Do you drink coffee? Yes, no. Pancreatic
9 cancer; yes, no.

10 The point is that pancreatic cancer is known to
11 be associated with smoking. Relative risk is not as
12 high for lung cancer, but it is an established risk
13 factor for smoking. Now, smoking in this case also,
14 particularly in the older years, used to be associated
15 with cigarette -- with coffee consumption. So what you
16 have is a triangle. You have --

17 Q. What do you --

18 A. I'll show you.

19 Q. When people who liked their coffee also used to
20 like their cigarettes?

21 A. Correct. This is pancreatic cancer. That's
22 your effect. This is coffee. That's hypothesized
23 carcinogen. If you don't take into account smoking, you

1 will observe an association between coffee and
2 pancreatic cancer because you fail to look at people who
3 smoke. More of coffee drinkers will be smoking than
4 non-coffee drinkers. And, of course, more pancreatic
5 cancer patients will be smoking than with people without
6 the disease.

7 And that's a confounder. That's what a
8 textbook of confounder definition is.

9 Q. Let me take -- go ahead. Take the stand.

10 But with regard to the studies we're about to
11 discuss, we showed slides where certain circumstances of
12 exposure to given products and a given environment
13 showed a strong association with the disease, correct?

14 A. Yes.

15 Q. Shipyard?

16 A. Yes.

17 Q. All right. Can those exposures, because
18 they've been demonstrated in the absence of anything
19 else to have an association consistently with the
20 disease?

21 A. With the disease.

22 Q. Can those exposures become confounders in other
23 studies?

1 A. Well, same triangle. Same concept. You have
2 exposures that are clearly associated with disease,
3 insulation, shipyard work. You also know that car
4 mechanics are blue-collar workers. They're manual
5 workers. These manual workers will be more likely to
6 have exposures elsewhere than people, say, of
7 white-collar occupations. And that's the issue of
8 confounding. In this particular case, the most powerful
9 confounder of all is that third factor, is other
10 asbestos exposures that need to be considered, if
11 possible.

12 Q. And, in fact, are some of these studies going
13 to attempt to control for those confounders?

14 A. Yes.

15 Q. All right. And the reason you control for
16 those confounders gets back to the question about why
17 you see cases to begin with, correct?

18 A. Yeah. Can I explain a confounder? Just one
19 more thing.

20 Q. Yes.

21 A. Because I think it is important. There are
22 two -- two ways you can deal with it, with a confounder.
23 You can match. If I'm doing a study of coffee and

1 pancreatic cancer, I can make sure that my cases in my
2 controls are matched by smoking. For each smoking case
3 I have a smoking control, and for each nonsmoking case I
4 have nonsmoking control. Then the only difference
5 between the two would be coffee, but not cigarettes
6 anymore because cigarettes are controlled. They are --
7 they're fixed. The frequency of smoking will be the
8 same.

9 So you can match. The other thing you can do
10 is if the data set is unmatched, you have a mishmash of
11 smokers and nonsmokers in both groups and they're not
12 the same, then you can do what's called adjust. And
13 that's an analytical technique that allows you to
14 calculate the relative risk after taking into
15 consideration smoking, in other words, the more pure
16 result.

17 Q. And very briefly, how do you adjust for that?

18 A. Well, there's a number of ways to do it. There
19 is so called stratified analysis.

20 Q. Stratified?

21 A. Stratified analysis. When you -- I have a
22 slide of that, but it's printed. I can probably...

23 Q. Put it on the overhead. Can you -- Doctor, you

1 can get down.

2 A. We have our cases and we have our controls. We
3 have people who drink coffee and those who don't. If
4 one were to take this two-by-two table at face value,
5 they would find the odds ratio is 2.15. That's the
6 bottom bullet. In other words, if the numbers were just
7 taken as is, you would find a two-fold increase in risk
8 among people who drink coffee compared to those who
9 don't.

10 Now, the next step is what you do is stratify.
11 The same two-by-two table, now it's split into two
12 tables, smokers and nonsmokers. The numbers all add up.
13 It's the same numbers from -- but the distributions of
14 them within cells are different now depending on their
15 smoking status.

16 Now, if one were to -- so the left side is
17 smokers. The right side is nonsmokers. Smokers alone
18 gives you a relative risk of 1. The association went
19 away. Nonsmokers alone give you a relative risk of 1.
20 The association is no longer observed. And that's, you
21 know, the definition of confounding, and that's how you
22 deal with it in a stratified analysis.

23 Q. Dr. Goodman, just to wrap that up then. Given

1 the presence of confounders and given the fact that this
2 is a disease that, albeit rare, does appear to occur
3 naturally in the population even in the absence of
4 asbestos exposure, is it surprising for researchers to
5 find cases of mesothelioma among car mechanics or shade
6 tree mechanics or spouses of them?

7 A. No.

8 Q. McDonald and McDonald, is it an epidemiological
9 study?

10 A. Yes, it is.

11 Q. Which study design is the McDonald study?

12 A. That's a case control study.

13 Q. All right. And how did they do it? Where did
14 they do it?

15 A. The study was conducted in -- throughout the
16 United States and Canada. I think the Canadian data
17 were collected over a period of 13 years or so. And the
18 U.S. data were collected just for one year, 1973.

19 Q. Is it just a study of garage mechanics?

20 A. No. Well, yeah. An important feature of case
21 control studies, they allow you to test several
22 hypotheses at the same time because if you have
23 occupational information, for example, or exposure

1 information, you don't have to limit yourself to just
2 one exposure. One can say in a study of pancreatic
3 cancer, one can look at coffee, ice cream, and
4 cigarettes at the same time as long as you adjust for
5 them for each other.

6 So, therefore, rarely do you have case control
7 studies limited to a single exposure or single
8 occupational group. Usually, they look at several.

9 Q. So are they testing a hypothesis about one
10 circumstance of exposure or about a whole bunch of them?

11 A. A whole bunch.

12 Q. Tell us what they did.

13 A. What they did, they contacted members of the
14 pathology societies in the U.S. and Canada and asked
15 them to report each and every case of mesothelioma that
16 was diagnosed. As I said, in Canada about 12 years. In
17 U.S. just one year, bigger country.

18 And then -- this is a case control study, but
19 so-called hospital-based case control study. Then they
20 said, We'll compare them to people who have cancer in
21 the lungs, but metastasizing from other sites. And this
22 has advantages and disadvantages, of course.

23 Q. What is the disadvantage?

1 A. Well, the disadvantage is you don't have -- the
2 ideal case control study takes populations that's
3 representative of the general population. Your control
4 are representative of the general population. There has
5 to be a sample of people at large. People with
6 metastases into the lungs certainly are not
7 representative of the population at large. That's --
8 you know, that's an important issue. It's not a
9 confounder. It's a limitation.

10 Q. Right. That's a limitation that the authors
11 noted in their section called limitations?

12 A. I'm pretty sure they did, and if they didn't,
13 we probably did.

14 Q. That's a limitation of the study that you
15 observed in your meta-analysis paper?

16 A. Yeah, we noted that.

17 Q. You noted that. And just in case this wasn't
18 clear yesterday, all studies that go through the
19 peer-review publication process have limitations,
20 correct?

21 A. Correct.

22 Q. And, in fact, part of the paper is a section
23 entitled limitations, right?

1 A. Usually people say a thing or two about their
2 reservations or cautions.

3 Q. So if we wanted to throw some criticism at a
4 paper, it would be pretty easy because the authors
5 always tell us the limitations based on the hypothesis
6 and the way they went about trying to test the
7 hypothesis, correct?

8 A. Most of the time, you know, it's sort of part
9 of the discussion section. That has to be -- well, not
10 doesn't have to be, but typically it is.

11 Q. All right. What did the McDonalds find?

12 A. Well, they had an interesting analysis. They
13 took the occupational history in what they called
14 hierarchical or maybe what one would call an
15 hierarchical manner. If the person is known to have
16 occupation that's very high risk, say an insulator, they
17 would rank them very high. So if somebody was an
18 insulator and then a shipyard worker and then a piano
19 tuner, these people would be counted as insulators.
20 That's sort of -- it's a clever way of taking care of
21 these powerful confounders because it's much more
22 important to know that he was an insulator than that he
23 was a piano tuner.

1 If, for example, the person was a shipyard, but
2 never an insulator, he would be called a shipyard worker
3 and so forth until they got down to the category for
4 which they -- you know, the bottom of the hierarchy.

5 And there they have a total of 156 cases and
6 156 controls were matched by age to take care of
7 confounding by age, the matched analysis. And among
8 those 156, that's after removing the --

9 MR. TARRY: May he leave the stand?

10 THE COURT: Yes.

11 THE WITNESS: After removing the heavy exposed.
12 If you recall, the relative risk for insulators was 46
13 there. So after removing those people, they ended up
14 with 11 what they called garage workers, among cases,
15 and 12 among controls. The total number is 156 for
16 each. And that will leave us with 145 and 144 here.
17 This two-by-two table gives you an odd ratio of 0.9 with
18 a confidence interval from .35 to 2.3.

19 BY MR. TARRY:

20 Q. So -- but did they conclude that a .9 was a
21 protective finding?

22 A. No, not at all.

23 Q. All right.

1 A. Not at all. I mean, nobody would conclude
2 that.

3 Q. We've got the quote on the call-out on the
4 screen. What did they conclude?

5 A. They stated no increased in risk was found in
6 garage workers, certainly exposed to chrysotile from
7 brake linings.

8 Q. They considered that an exposed group that
9 potentially might have a risk?

10 A. Yes. They felt that was important enough to
11 mention that in the -- in the discussion of the results.

12 Q. Anything else particularly important he needs
13 to understand about the McDonald study?

14 A. Well, there's a lot of things that they've
15 really done. You know, there's some strengths of the
16 study as well.

17 Q. What is some of the strengths of the study?

18 A. Well, this hierarchical category situation,
19 it's a very clever way to do it. I mean, I think that's
20 the only -- the only study that did it that way, that
21 particular way, because what you're doing is you're
22 removing really powerful -- you're removing all of the
23 heavy artillery before you analyze other occupations.

1 There are other ways to do it, but that's one way to do
2 it and I think it's a very interesting way to do it.

3 The other thing is, because it's an interview
4 study, the problem -- and it's a next-of-kin interview,
5 of course. So the problem of doing healthy controls, on
6 the one hand, it's good because they are representative
7 of the general population. On the other hand, their
8 recall would be very different, if you have people that
9 are alive and healthy and say families of people who are
10 deceased from mesothelioma. So that may be another
11 consideration. One, they said, We'll take another fatal
12 disease that manifests itself in the lungs, but not a
13 lung cancer. And that way the recall from next of kin
14 may be not perfect, but it's comparable. It's not
15 skewed. I mean, that's the thinking behind it.

16 So it has -- you know, like anything, it has
17 its strengths and weaknesses.

18 Q. What's the next study you considered?

19 A. I think in --

20 THE COURT: Can I stop you on the McDonald
21 study? I just want to -- absorbing what you just said.
22 Next-of-kin interviews were done both for --

23 THE WITNESS: Yes.

1 THE COURT: -- the control set and --

2 THE WITNESS: And for the cases.

3 THE COURT: So is that a matching sort of?

4 THE WITNESS: Yes, I mean -- right. That --
5 why do I say that? That's one way to make sure
6 that even if information is incomplete, it's equally
7 incomplete. You -- there is a tip of the iceberg,
8 almost always, but at least you're comparing the
9 equal -- the two icebergs have equal chance of showing
10 the tip.

11 BY MR. TARRY:

12 Q. It might be appropriate to talk about
13 differential or non-differential at this point. Do you
14 want to do that? We can wait. Okay.

15 THE COURT: My question was answered.

16 MR. TARRY: Okay.

17 THE COURT: Thank you.

18 BY MR. TARRY:

19 Q. What's the next study you considered?

20 A. The next study in chronological order was
21 published in 1980. And it's actually not on the screen.

22 Q. It's '83, correct?

23 A. No, 1980. That's a study by Peterson and

1 Milham. It's not on the screen, and the reason it's not
2 on the screen is it was a PMR study, large PMR study, of
3 deaths at -- the proportionate mortality ratio site of
4 all deaths in California that happened between 1959 and
5 1961. That's only two years, of course, but it's a
6 large state so it's quite a few deaths.

7 And they looked at various occupational groups
8 and evaluated proportionate mortality ratios for various
9 groups. For the category defined as mechanics and
10 repairman, automobile there was zero cases of pleural
11 mesothelioma and zero cases of peritoneal mesothelioma.
12 And there's nothing to show on the screen because they
13 just found nothing, but it is still a study that
14 addressed that issue.

15 Q. Just clarify that. They didn't find any cases
16 so there's no way to do a meaningful two-by-two
17 calculation, if it had been that design, and there's no
18 way to calculate PMR if you don't have --

19 A. No, you can't. You just have no cases.

20 Q. What was the next study?

21 A. The next study is Teta. That's 1983.

22 Q. We've heard some about that. That's the
23 mesothelioma Connecticut study?

1 A. Yes.

2 Q. And what study design did they employ?

3 A. Teta is a case -- population-based case control
4 study. The mesotheliomas were taken from the
5 Connecticut Tumor Registry.

6 Q. We've heard about another registry. There's a
7 registry also the State of Connecticut keeps?

8 A. Well, yes, that actually goes back to the
9 1950s, 1955. SEERR which was mentioned here early,
10 SEERR, Surveillance and Epidemiology End Results
11 Registry, was established in 1973. So Connecticut was
12 basically an earlier study proceeding by 20 years.

13 Q. Let me just stop you. Who conducted this
14 study? Dr. Teta, obviously?

15 A. Dr. Teta.

16 Q. And her colleagues, where were they?

17 A. I think they were at Yale.

18 Q. Yale University?

19 A. Uh-hmm.

20 Q. And do you recall who funded that study?

21 A. No, I don't.

22 Q. Okay. We might get to that later. What did
23 they do and what did they conclude?

1 A. The controls were death from all causes,
2 regardless of diagnosis. And they again looked at a
3 variety of occupational categories. In this particular
4 group they used the category called automobile repair
5 and related services. The results do not show the
6 entire breakdown of cases and controls, but --

7 Q. This is one chart from the study?

8 A. That's right. But the chart highlights the
9 result that's most pertinent to -- to the hypothesis at
10 question here.

11 And automobile repair and related service has
12 an odds ratio of .65. Actually, they call it relative
13 risk in the table, but it's odds ratio. And that's
14 based in one case and five controls in the total group
15 of six exposed individuals.

16 Q. Now --

17 A. And that's, of course, it's a tiny number,
18 really small.

19 Q. Now, how did they determine what somebody's job
20 was?

21 A. Yeah. I mean, the feature of Teta studies that
22 unlike, say, McDonald, they did not interview people.

23 Q. Okay. So there was no interview done?

1 A. There was no interview done. Connecticut has,
2 you know, an interesting feature. They have what's
3 called town directories. So people just keep logs of
4 their residence and what they do for a living.

5 Q. Is that like a phone book with occupation?

6 A. Yeah, I've never seen it, but Dr. Teta
7 described it to me. And you can -- you know, you find a
8 person. You go to find a town book that precedes the
9 death, of course. And you try and reconstruct the
10 occupational history.

11 Q. Will those towns put them out every year or
12 over a certain period?

13 A. I don't know the details, but I know those were
14 available and I'm pretty sure she describes it. The
15 thing here is, on the one hand, of course, if the record
16 is incomplete in the book, then you have incomplete
17 information and you may have to go to the death
18 certificate. On the other hand, there's no recall here
19 involved. This was information collected before. In
20 other words, it wasn't -- before anything happened to
21 these people. And, therefore, you don't expect it to be
22 skewed one way or the other by -- by just relying on
23 recall.

1 Q. Let me just give you an example. If you wanted
2 to know what that particular subject was doing
3 occupationally in 1964, did they ask them to recall what
4 they were doing in 1964 or did they go to a document
5 that showed what they were doing in 1964?

6 A. No, there were no interviews. They went to
7 these town registries.

8 Q. Is there anything else about the Teta study
9 that the Court should know about in your opinion?

10 A. Well, the main limitation, of course, is small
11 sample size. That's really the -- with a confident --
12 if this were the only study on earth, you know, and I
13 had -- one had to draw conclusions. You look at the
14 result of .65 confidence interval from .08, which is
15 tenfold decrease in risk to a 12-fold decrease in risk
16 to 5.53, which is almost six-fold increase in risk. You
17 don't know. The only way this study may be of -- needs
18 to be evaluated is as part of the totality of the
19 evidence.

20 Q. What's the next study you considered?

21 A. Spirtas.

22 Q. And who is Dr. Spirtas?

23 A. Spirta still works for National Cancer

1 Institute. And he's the one who started the study back
2 in the '70s. He's an industrial hygienist and
3 epidemiologist, works for the NCI.

4 This is the first publication of their study
5 that now had I think three different papers published
6 based on those data. It's an abstract that was
7 presented at the Society For Epidemiological Research
8 back in 1985. And as an abstract, you don't really have
9 much information. They just don't have enough space
10 there. But the point is that -- two things that are
11 important. One, it's -- it's a registry-based study
12 where they find cases in the population-based tumor
13 registry, Los Angeles and New York.

14 The other thing is that controls were selected
15 from V.A. Hospitals, Veteran Administration Hospitals.
16 The reason why you may want to get controls from V.A.
17 Hospital, it's much easier to contact patients and their
18 families if you have to conduct the next-of-kin
19 interviews. People don't leave the system. V.A., from
20 that point of view, it's a very good study population
21 because they're stable. They don't move a whole lot,
22 and they stay within the V.A. system even if they move.

23 So the controls were people from the V.A.

1 Hospitals as well as -- but the only thing they did they
2 removed cancers and other respiratory disease.

3 Q. How many subjects did they have in the study,
4 approximately?

5 A. In this particular study, they had 259 cases
6 and 259 age-matched controls. They made sure that the
7 control is the same age as the case.

8 Q. Just so we're clear. 259 cases of what?

9 A. Malignant mesothelioma.

10 Q. Rare disease, is that a big number or a small
11 number?

12 A. For a case control study it's a nice number.
13 You know, it's a good, big number.

14 And it actually shows in the confidence
15 interval that the larger your sample size -- in the
16 two-by-two tables the bigger the number, the tighter
17 your confidence interval is. And here it's 1 and
18 it's .6 to 1.6. If you compare it to Teta, for example,
19 it's a much larger sample.

20 Q. Now, you mentioned that there were two subject
21 papers based on the same National Cancer Institute data
22 set. Tell me about the next one.

23 A. The next study was published in '94 by Spirtas.

1 It did not address the hypothesis of individual
2 occupations.

3 Q. What did it do?

4 A. They set out to test a hypothesis for, or
5 answer the question as to what is the contribution of
6 asbestos exposure from all sources to mesothelioma in
7 terms of relative risk, exposed versus non-exposed, and
8 in terms of what's called attributable risk. That is,
9 the proportion of people whose disease can be attributed
10 to asbestos exposures.

11 Q. This is sort of back to that question about
12 what percentage of mesotheliomas might be related to
13 asbestos?

14 A. Correct. I mean, people -- a lot of people
15 besides 20 percent -- in men. It's in men. Does not
16 apply to women. Without occupational exposures use the
17 Spirtas estimate. This actually comes from the Spirtas
18 '94 study. But the study did not -- did not calculate
19 odds ratio, relative risk estimates, specifically for --
20 the category's important, brake lining installation and
21 repair. It's not garage mechanics or motor mechanics.
22 They're much more specific in their questioning.

23 Now, another useful thing about Spirtas is that

1 they actually described the difficulty of exposures --
2 multiple exposures during a person's lifetime. If I
3 recall correctly, they said that 33 percent of -- they
4 use brake mechanics or brake installation repair people
5 as an example. 33 percent of those work in shipyards
6 and 55 percent of those had previous history of
7 working -- working as insulators.

8 Q. Let me ask you to repeat that again so we're
9 clear. Of the cases they were looking at where there
10 was a history of automotive work, right?

11 A. Well, I don't think it was cases. Everybody
12 who was involved in brake installation and repair.

13 Q. Right. Case end controls?

14 A. Case end controls.

15 Q. Okay. What percentage of them had high risk
16 occupations elsewhere?

17 A. If I recall correctly, 33 had ship building and
18 shipyard experience, and 55 percent had performed
19 insulation work.

20 Q. What was the next study you considered?

21 A. Woitowitz and Rodelsperger, '94.

22 Q. Now, we've heard about them. Who are Woitowitz
23 and Rodelsperger? Do you know those researchers?

1 A. Yeah, I know both of them. Woitowitz and
2 Rodelsperger run an occupational health clinic in a town
3 called Gechingen in Germany, not far from Frankfurt.

4 Q. Now, we've got a call-out on the screen, and
5 this is from the 1994 study. But so that we set the
6 historical record straight, before they published this
7 study, did they also publish sort of a case series
8 study?

9 A. Yes, they did.

10 Q. And what -- where they raised a hypothesis,
11 right?

12 A. Well, actually, in their mind they thought they
13 answered the hypothesis when they wrote the paper. They
14 say, We observed four mechanics in -- four cases of
15 mesothelioma in our clinic among car mechanics. And,
16 therefore, we think being a car mechanic puts one at
17 risk -- at increased risk of developing mesothelioma.
18 And that was a case report.

19 Q. Why did they think that?

20 A. I think it was published in '91, three years
21 before this paper.

22 Q. Why did they think that, just because they had
23 four cases?

1 A. Well, yeah. They shouldn't have said that.

2 Q. All right.

3 A. The point is they shouldn't have said that.

4 Q. All right. And did they later then go and get
5 a control group to test that hypothesis to see whether
6 there was an association?

7 A. Yes. Then they got two groups of controls.
8 One in the population, from the population. I don't
9 know how they selected them. It's not very well
10 described in the paper. And one in the hospitals when
11 they would pick patients who underwent lung resection,
12 in other words, people who had a piece of their lung
13 removed for whatever reason, maybe lung cancer.

14 Q. Right. Let me stop you. When they were
15 constructing their actual analytical study this time
16 around, did they do something interesting with respect
17 to this question that was raised yesterday about maybe
18 differences in the risk of people who did brake repair
19 versus people who were just employed as mechanics?

20 A. Yes, they had several categories. One category
21 was called motor mechanic or automotive mechanics, and
22 the other category was called definitely engaged in
23 brake installation and repair. Doesn't mean that others

1 were not, but those that they know for sure were engaged
2 in brake installation and repair.

3 Q. Why is that important? What does that allow
4 them to do, as I think you're going to show us?

5 A. What one can do this way is define your
6 exposure in two different ways. One is the sort of a
7 more vague category of motor mechanics, and the other
8 was much more specific of people who we know were
9 exposed to friction fibers. And the results were not
10 all that different. They were very comparable. If one
11 were to combine both sets of controls, you have odds
12 ratio for all mechanics, 0.87, and it's non-significant,
13 the confidence interval between the 0.4 and 1.7 -- 0.43
14 and 1.7. And if you take a subset with definitely
15 engaged in brake installation and repair, then your odds
16 ratios are 0.89.

17 MR. TARRY: Your Honor.

18 THE WITNESS: Virtually the same.

19 MR. TARRY: Have we defined statistical
20 significance?

21 THE COURT: Yes.

22 MR. TARRY: We did.

23 THE WITNESS: Virtually the same. Both result

1 in non-significant. And, of course, the number of
2 people definitely engaged in brake installation and
3 repair is smaller because it's a subset. So your
4 confidence interval is a little bit wider. It goes
5 from .31 to 2.47.

6 BY MR. TARRY:

7 Q. What's important about the Woitowitz and
8 Rodelsperger analytical study?

9 A. Yeah, it's not the greatest study, but what
10 they did is they asked this question twice in different
11 ways. They asked car mechanics and they asked brake
12 mechanics. And the answer is really indistinguishable.
13 They couldn't tell the difference between one and the
14 other.

15 Q. What's the next study?

16 A. Well, it's important to know their conclusion,
17 though.

18 Q. Go back, because --

19 A. They're very cautious. They say, From these
20 results, there is no evidence that car mechanics are
21 exposed to an increased risk of mesothelioma even if
22 they do brake repairs. And then they can say, But
23 asbestos exposure in other employment is an important

1 confounding factor. So that if there is a mesothelioma
2 risk for car mechanics, but if it were small, it would
3 not be detectable.

4 Q. Do you agree with that conclusion?

5 A. It's very fair, yes.

6 Q. What was the next study you considered?

7 A. Coggon.

8 Q. Who is Coggon and what kind of study is that?

9 A. Coggon is -- I think he's from the University
10 of South Hampton in England. It's a PMR study,
11 proportionate mortality ratio study, that took place in
12 all of England and Wales between '79 and '80 and then
13 between 1982 and 1990.

14 Q. Does that mean they're looking at all of the
15 deaths and causes of deaths between 1979, and what was
16 the other -- what was the last one?

17 A. And '90.

18 Q. And '90?

19 A. With a two-year interval in between. I don't
20 know why. Maybe they didn't have the data.

21 Q. Does that mean they're looking at all of the
22 causes of death within that time period within that
23 region?

1 A. Correct.

2 Q. And what did they conclude?

3 A. Well, first they found that they observed a
4 number of cases for category as they define it -- well,
5 the cases are defined not as mesothelioma. It's a
6 different definition, pleural cancer. It's important to
7 know that although the majority of pleural cancers are
8 mesotheliomas, there is -- there are some
9 non-mesothelioma pleural cancers.

10 Q. Would it be fair to say that this study defined
11 it by the site of the cancer; not by the histology?

12 A. That's true. And it's a death certificate
13 study. So, of course, that -- it's certainly -- it
14 certainly have limitation of a death certificate study.
15 So observed number of cases is 12, expected 26, based on
16 the general population. That would give the PMR of
17 0.46, and actually that one is significant. It's
18 significantly less than 1. Why? Because it's probably
19 confounded by other exposures. They were unable to take
20 it into consideration.

21 Q. All right. And from that calculation, what did
22 they conclude?

23 A. Well, they -- they state that notable for an

1 absence of significant risk are motor mechanics by whom
2 concerns have been raised because of the presence of
3 asbestos in brake linings. It seems that this exposure
4 has no important effect on mortality from mesothelioma
5 or asbestosis.

6 I have to mention that they did calculate PMR
7 for asbestosis.

8 Q. What was the PMR for asbestosis among this
9 cohort of motor mechanics?

10 A. I'll tell you in a minute.

11 0.8.

12 Q. Is that higher or lower than expected?

13 A. That's less than 1.

14 Q. And, again, that's the occupation at the time
15 of death. It doesn't tell you what the person did when
16 they were 20 years old in this study?

17 A. That's right. It's problematic. Those kind of
18 studies are problematic.

19 Q. This was a study design that you told the Judge
20 earlier you consider less informative than the case
21 control cohort design?

22 A. Not that I consider. I mean, most people would
23 agree with that.

1 Q. What's the next study you considered?

2 A. Hodgson.

3 Q. What kind of study was Hodgson?

4 A. PMR. A follow-up of Coggon. It just came out
5 later and included larger geographical region as well as
6 more years of data.

7 Q. Did they find more or less than expected deaths
8 for the mechanics?

9 A. The thing with Hodgson, of course, is that they
10 don't give numbers. They provide you with a graph, but
11 you can still figure out what the results were. They --
12 to make it easier on -- for the reader, they grouped
13 people into three categories. The category -- and
14 ranked them with respect to PMR because they understand
15 very well, just like we just discussed, that the actual
16 estimate for PMR, it's not necessarily a very meaningful
17 measure. What is more meaningful is where various
18 occupations rank in -- in the scheme of things.

19 So you start with -- they started with plumbers
20 and gas fitters and carpenters. They have a little bit
21 different definitions. And electricians, construction
22 workers, and production figures and so forth. Then they
23 move into what's call group A: security workers,

1 protections maintenance, other service occupation, post
2 men, stove keepers. Then they move into group B: sales
3 reps, teachers and lecturers, managers of transport
4 facilities, bar men, and office managers. And then
5 group C with the lowest level of PMR are motor
6 mechanics, coal miners, and farmers.

7 Q. Right. There's a statistical anomaly we may
8 need to clarify. How can it be possible that with 1
9 being the line of delineation between positive and
10 negative that there are only a handful, my word, of
11 occupations that are positive and everything else is
12 negative? Is that because -- does this chart represent
13 an equal distribution of deaths or is that because there
14 are overwhelmingly -- an overwhelmingly disproportionate
15 of deaths among those handful of occupations?

16 A. Yes. Certainly, certainly. A big chunk of
17 mesothelioma conditions, diseases and death from
18 mesothelioma, are attributable to a relative finite
19 number of occupations. I would say so. Doesn't mean
20 that other people are not going to develop it.

21 Q. Right.

22 A. But the bulk will be contributed by these heavy
23 hitters.

1 Q. What we saw -- what this also tells us,
2 correct, is that there are deaths among sales reps and
3 managers and teachers and bar men and office managers
4 from this disease?

5 A. Certainly. And then, again, it's a PMR study,
6 so that one needs to take that into consideration.

7 Q. It has its limitations?

8 A. Right.

9 Q. Is the Teschke study the next one you
10 considered or is there one in between that?

11 A. Yes, Teschke is the next study.

12 Q. And Dr. Teschke and Dr. Checkoway, who we
13 discussed a little bit, are where?

14 A. Dr. Teschke is -- I think she's at University
15 of British Columbia now. Maybe she's at University of
16 Washington.

17 Q. How about Dr. Checkoway? Where is he?

18 A. He's definitely at University of Washington.

19 And --

20 Q. What sort of study design did they set up and
21 what were they looking to test?

22 A. Well, this is a population-based control study
23 of mesothelioma that took place in British Columbia.

1 And that's the study that's probably worth spending just
2 a couple more minutes because it's more informative.

3 Q. Why is it more informative? What's especially
4 informative about the Teschke study?

5 A. Well, there's certain things about how they
6 went about doing the study that makes it more informed.

7 Q. All right. What were they setting out to test?

8 A. Again, it's a case -- population case control
9 study so they evaluated relative risks or odds ratios in
10 a variety of occupations.

11 Q. How did they do that?

12 A. The cases came from histologically-confirmed
13 pleural mesothelioma in -- diagnosed in British Columbia
14 for two years, 1990 through '92. Actually, that makes
15 it -- yeah, September through August will be two years.

16 Controls were very different in this study, and
17 that's, you know --

18 Q. Who were the controls?

19 A. The controls were voters, people selected from
20 voter registries, living in British Columbia. Of
21 course, it's also not perfect because not everybody
22 votes. So it's only if you're a voter, you have a
23 chance of getting a control. But it's certainly a

1 different way to look at things compared to, say,
2 McDonald who used cancers from other sites or Woitowitz
3 who used resection and some undefined population control
4 group or death from other causes. So, you know, that's
5 one thing about them that's important.

6 The other thing about them that's important,
7 they actually were able to conduct interviews in person,
8 at least for some people. They were able to conduct
9 interviews with cases and not next of kin, but not for
10 everybody.

11 So now, of course, the problem now arises, what
12 do you do with controls because controls are healthy
13 voters? If you have next-of-kin interviews with cases,
14 or at least some of them -- they are probably a very
15 large proportion -- you can't interview each and every
16 control directly. You will be introducing bias,
17 information bias it's called.

18 So what they did, they matched next-of-kin
19 interviews with cases. Even though control is alive,
20 they will interview his wife.

21 Q. Slow down. Let's explain that. How did they
22 match?

23 A. Yeah. Well, if the cases -- it's frequency

1 match. If they saw that they ended up with 20 percent
2 of interviews, let's say, directly and 80 percent next
3 of kin, they will say it's a problem. So what are we
4 going to do? We'll interview 20 percent of alive
5 controls, next of kin nevertheless.

6 Q. Right.

7 A. And whatever, just to match it up. So that the
8 proportions of people that were interviewed directly
9 among cases and the proportion of people who were
10 interviewed directly among controls was the same.

11 Q. What information did they have pertaining to
12 motor vehicle mechanics?

13 A. They did three types of analysis.

14 Q. Would it be appropriate for you to show maybe
15 two-by-two tables of --

16 A. Sure.

17 Q. Of the numbers that they had?

18 A. Sure.

19 Q. Is this one study where they looked at more
20 than one thing?

21 A. Yes.

22 Q. Within the category?

23 A. Yes.

1 So the first cut is the definition of
2 exposures, vehicle mechanics. So the --

3 Q. The occupation?

4 A. The occupation's vehicle mechanics. This is
5 disease. This is control. This is motor vehicle
6 mechanics. This is not. Ever never. Very simple --
7 very simple crude analysis.

8 Q. "Ever never" meaning they're taking --

9 A. Mechanics.

10 Q. They're not mechanics ever?

11 A. Ever.

12 Q. Right.

13 A. This particular analysis, this is vehicle
14 mechanics, gives you an odds ratio, 0.8. It's
15 non-significant. Confidence interval between 0.2 and
16 2.3.

17 Q. What other type of hypothesis did they test
18 with respect to this type of work?

19 A. Then they said instead of doing all vehicle
20 mechanics, let's evaluate a subset of people who are
21 specifically engaged because they asked two types of
22 questions. They asked what did you do for a living and
23 also they asked what kind of activities you were engaged

1 in.

2 So they did brake installation and repair, a
3 category -- same as Spirtas. The numbers, of course,
4 are smaller because not all vehicle mechanics report
5 being engaged in brake installation and repair.

6 And, perhaps, they didn't have job descriptions
7 for everybody. So at these two-by-two tables, the
8 numbers, of course, get smaller, gives you an odds ratio
9 of .3 with very wide confidence intervals, from 0
10 virtually to 1.4.

11 Then they said, Well, the problem with this
12 analysis is that we cannot consider other asbestos
13 exposures.

14 Q. Is that another way of saying we haven't
15 considered confounders yet?

16 A. Correct.

17 Q. All right.

18 A. I mean, the confounders really -- I mean,
19 they've considered other confounders. They've
20 considered age, for example. That's controlled for age
21 and other things. But they did not consider other
22 asbestos exposures.

23 So what they said, Let us only take a look at

1 where vehicle mechanics and as far as we can tell,
2 vehicle mechanics only, no other exposures, and compare
3 them with people who had no exposures. Basically that's
4 where you compare vehicle mechanics that never worked as
5 insulators or shipyard workers to librarians and
6 lawyers. People -- that would be basically end up with
7 a majority of white-collar occupations.

8 Q. What did they conclude from that?

9 A. Well, first of all, there was only one case, of
10 course. That's -- you know, the funnel gets tighter and
11 tighter once you get to the bottom.

12 Q. Just explain. There was only one case of what?

13 A. A person who was a motor vehicle mechanic
14 without any other --

15 Q. Only one case of mesothelioma?

16 A. Correct.

17 Q. In a vehicle mechanic without what?

18 A. Without any other identifiable occupational
19 asbestos exposure.

20 Q. Okay.

21 A. And there were 15 controls.

22 Q. So there were 15 people who -- healthy or
23 non-diseased vehicle mechanics who had no other

1 occupational exposure?

2 A. Correct.

3 Of course, with one case, you know, that gets
4 you .4, 0.3, from 0 to 3. It's a very wide confidence
5 interval, but the best estimate -- it's important to
6 remember that it's not the probability of any results
7 and between is more or less equal. It's not. The best
8 estimate is still this one. As you move away from the
9 best estimate, the probability of more and more extreme
10 results dropping.

11 So this is vehicle mechanic without any other
12 asbestos exposure as far as the authors can tell, of
13 course.

14 Q. All right. And what conclusion from this data
15 did the researchers draw?

16 A. Well, actually, this relates to something else.
17 Although they don't show the data, they also did the
18 same thing for brake installation and repair without any
19 exposures. And that's one -- and that's when they
20 say --

21 Q. I switched on you. There are two conclusions.
22 You want this one or you want the first one?

23 A. They don't show the results, but they just

1 simply say at the very end of the paper that the results
2 were the same as for vehicle mechanics altogether, after
3 removal of other exposures.

4 Q. How many different hypotheses did they test?

5 A. Oh, I forgot to mention. They also did the
6 same thing twice for each analysis was done without
7 consideration of latency and with at least 20 years of
8 waiting, meaning if somebody was exposed, say, within 20
9 years, they would not count that person. They will only
10 count people, and appropriately one can do that, who
11 were exposed 20 years or earlier before they were
12 diagnosed with the disease.

13 Q. When they controlled that way, did the numbers
14 change significantly?

15 A. No, not at all. I mean, the result basically
16 stayed the same.

17 Q. It was negative either way?

18 A. Yes. And numbers were very small. Once you
19 cut, it's really -- you know, the cells become very
20 small.

21 Q. Now, relative to those relatively small
22 numbers, Dr. Lemen I think had a slide yesterday and, in
23 fact, in his chapter in the book references a statement

1 that the authors made that was presented as a cautionary
2 statement. Do you recall that?

3 A. Yes, I do.

4 Q. What he says -- what he said -- what he says in
5 the book was that Teschke, et al did not find an excess
6 of mesothelioma among vehicle mechanics, but because
7 their findings were based on small numbers, judgments
8 about any causal associations would be speculative
9 according to the authors.

10 Now, first of all, is that precisely what they
11 said? I don't want to nitpick, but causal associations,
12 is that the word -- is that the term they used in the
13 paper?

14 A. You know, it's easier. You want to just put it
15 up, what they said?

16 Q. Let's show what they actually said. Let me
17 have that. The last thing they said about the paper.

18 A. Several occupations and exposure scenarios were
19 identified that had not previously been linked to
20 mesothelioma.

21 And, indeed --

22 Q. Yeah, stop there. What are they talking about
23 there?

1 A. They're talking about findings that surprised
2 them because they were positive. For example, they had
3 gardeners that had increased risk.

4 Q. But they reported -- although they didn't
5 conclude anything, they reported an increased risk about
6 gardeners. Is that right?

7 A. Yeah. There were some other --

8 Q. That's all right. That's one example.

9 A. But gardeners is a good example because they
10 found an increased risk among gardeners.

11 Q. And when they said they found an increased
12 risk, that's finding an association. If there's no
13 increased risk, is that an association or a
14 non-association?

15 A. Yeah. An association means that you had a
16 departure from normal. You had a departure from 1.
17 That is significant, of course. I mean, all of them
18 would have some departure, but the point is if there is
19 a large departure that seems to be significant, you
20 start thinking.

21 So they said: Several occupation exposure
22 scenarios were identified that had not previously been
23 linked to mesothelioma. All except nonasbestos mining

1 involved small numbers.

2 So it seems like they also found an association
3 for nonasbestos mining and that association was
4 significant.

5 Therefore, judgments about whether these
6 associations were causal would be speculative.

7 Q. All right. But let me ask you a very simple
8 question. Was this cautionary statement made about all
9 of the findings or was it a specific statement about
10 taking caution not to leap to conclusions about some of
11 these new, quote, unquote, associations they technically
12 reported?

13 A. Yes. It's clearly -- they clearly talk about
14 associations that they didn't expect to see, and
15 sometimes you get those when you have multiple --
16 multiple analysis in one study.

17 MR. TARRY: Your Honor, we've got probably five
18 or six more of these. Do you want to break now or keep
19 pushing?

20 THE COURT: My conference this afternoon is at
21 2.

22 MR. TARRY: Would it make sense for us to take
23 a lunch break at 2 if people can survive? Is that

1 amenable?

2 THE COURT: Let me just double-check with staff
3 and see if we can get some folks rotating through. But
4 for now, why don't we take a recess for 10 minutes, and
5 we'll see where we're going for the balance of the day.

6 (Recess taken.)

7 BY MR. TARRY:

8 Q. Dr. Goodman, what was the next study you
9 considered after Teschke?

10 A. Next one was Agudo.

11 Q. Tell us very quickly, if you could, who
12 Dr. Agudo is and what sort of studies he did.

13 A. This was a study done in two areas of Spain,
14 one in up north in Barcelona, and the other one south in
15 Cadiz. And they identified mesotheliomas from
16 hospitals. It wasn't a population-based, a
17 registry-based study. And they studied hospital
18 controls but in a sort of innovative way.

19 Q. How's that?

20 A. The way they did it is they selected a sample
21 of general population first as control, randomly. And
22 they said for each control selected in the hospital, in
23 the general population, they will match a control in the

1 hospital. It sort of halfway between true population
2 control and a true hospital control.

3 In other words, they say, okay, I've
4 identified, let's say, 50 people in the general
5 population, and they have certain characteristics; age,
6 sex, whatever. But I'm not going to interview them.
7 I'm going to interview exactly the same person at the
8 hospital. I've never seen control selection done quite
9 that way. They actually published a paper just on that
10 particular issue. Seems to be working for me. It's an
11 interesting way. Basically, they're bridging between
12 the hospital control and population control.

13 Q. What did they find with respect to the
14 hypothesis?

15 A. You have to really dig through the paper before
16 you found the results pertinent to this question. But
17 they do have results for mechanics, motor vehicles, as
18 they defined that category in Spain. There were three
19 cases and 14 controls. And the reference category was
20 formed -- by reference category here they say unexposed
21 people -- were the same 51 cases and 148 controls who
22 never worked in any of what they called listed
23 occupations. Listed occupations are the ones they

1 thought a priori. Would be occupations that may pose a
2 risk. And that a priori including mechanics.

3 Q. Are those numbers presented there on the
4 screen?

5 A. Yes. If you put in the numbers in a table,
6 again, 314, 51, and 148, you would get a relative risk,
7 an observation of 0.62. And again, confidence
8 intervals, .1 and 2.3.

9 Q. A handful of other studies. Is there a study
10 called Milham and Osslander from 2001?

11 A. Yes.

12 Q. Did you consider that study?

13 A. Yes.

14 Q. What about it did you consider?

15 A. It's a PMR study done in the state of
16 Washington. One interesting thing about it, the study
17 collected cases in 1950. So now they have 50 years
18 worth of deaths, I mean, thousands and thousands of
19 deaths. And they do PMR analysis. Again, it's
20 imperfect. But an interesting thing is that it expands
21 such a huge interval of time.

22 Q. What information, if any, pertained to auto
23 mechanics or car repair?

1 A. They have a category called automobile
2 mechanics and repair workers. And they had seven
3 observed and nine expected cases, nine expected based on
4 general population, seven observed in that particular
5 category. And that's a PMR of .75.

6 Q. Now, the Court has heard about NIOSH. Does
7 NIOSH also collect mortality data? Did they?

8 A. Yes. What NIOSH has is what they called
9 occupational mortality surveillance database. And it's
10 unlike Milham and Ossiander -- or previously we
11 discussed Petersen and Milham -- these are state-wide
12 registries; NIOSH selects 28 states.

13 Q. 28 states?

14 A. 28 states throughout the country. And
15 basically the same analysis. Few years, of course.
16 They only have -- let's see -- 14 years worth of data
17 1984 through 1998.

18 Q. The NIOSH data, the U. S. federal government
19 looked at how many states for how many years?

20 A. 28 states, 14 years.

21 Q. And what data do they present?

22 A. Same thing. They have -- the total number of
23 observed mesotheliomas is 15, expected 19. And, you

1 know, this is a nonsignificant PMR of .8.

2 Q. Continuing along with other studies on
3 mesothelioma, did you consider a study done by Hansen
4 and Miersen in 2003?

5 A. Yes.

6 Q. What is the Hansen and Miersen study of 2003?

7 A. Hansen and Miersen study is a case controlled
8 study which is a follow-up of another Danish study
9 called Olsen and Jensen, not to confuse with a Hansen
10 study that's a different study.

11 Q. All right. Yesterday Dr. Lemen and I had a
12 discussion that might have been muddled on the record
13 about Hansen 1989. That's a different study than this;
14 is that correct?

15 A. A different study, different Hansen.

16 Q. Right. Now, Olsen and Jensen, I think you
17 testified used some next of kin interviews that Hansen
18 '89 relied on; is that correct or not?

19 A. No.

20 Q. All right. Tell us about the Hansen and
21 Miersen study of 2003.

22 A. Well, let's begin with Olsen and Hansen. It's
23 easier to do that. Olsen and Jensen is a PIR, instead

1 of PMR, PIR study. That was published in '87. And what
2 they have is this: They have a cancer registry data and
3 -- so it's not a death certificate any more. It's
4 actually a newly diagnosed case that's reported to the
5 registry. Person can be alive.

6 So -- and then what they do, they match it, the
7 link. You see, in Denmark, unlike in the United States,
8 everybody is accounted for. People don't really move.
9 It's about six million population country. And
10 everybody has records. So what they do they would link
11 incidence data, say a case was diagnosed with a certain
12 cancer, and they link those data with what's called
13 Denmark supplemental pension fund and the central
14 population registry.

15 So, you know, if I'm diagnosed with lung cancer
16 tomorrow, they will be able to tell what kind of --
17 because I pay taxes, so forth -- they can tell me what
18 occupations I've held.

19 Q. Just in it interest of time, we'll submit these
20 studies for the Court's consideration. But what was the
21 conclusion?

22 A. The point is Olsen and Jensen found no cases in
23 '87. They kept collecting the data. And just two years

1 ago, 2003, they published in Danish this Hansen and
2 Miersen paper. They had ten cases by then. So that it
3 now went for 27 years, from 1978 to 1997, the data set.
4 So unlike '87, ten years later they had ten cases.

5 And they observed number was ten, expected was
6 12. And that's a PIR, relative risk of point A.

7 Q. Just to wrap this up on mesothelioma, was there
8 two more studies published in this year, 2005, that you
9 considered?

10 A. Yes. Actually, there was one more study
11 published in 2004. That would be Hessel. And two more
12 in 2005.

13 Q. Let's come back to Hessel, because there's
14 another issue I want to discuss in a little bit more
15 detail.

16 A. Okay.

17 Q. Tell us about the McElvenny study that was
18 published earlier --

19 A. Yeah. The two most recent studies, a
20 McElvenny, out of England -- Great Britain, rather --
21 that -- we discussed Coggin followed up by Hodgson.
22 This is a third follow-up.

23 Q. The same data set --

1 A. PMR, British. Results are identical .48. A
2 lot more cases. 60 cases now.

3 Q. Now, what about Welch? What is Welch?

4 A. Welch is a study of peritoneal mesothelioma,
5 specifically. It's a hospital-based study.

6 Q. Let's make that distinction. Peritoneal
7 mesothelioma was discussed earlier before the Court.
8 But that's a different site in the pleura?

9 A. Yes.

10 Q. Is peritoneal more rare or more common
11 mesothelioma?

12 A. It's more rare, in general.

13 Q. Yeah. Very quickly, what did Dr. Welch attempt
14 to do?

15 A. Dr. Welch basically borrowed the Spirtas
16 questionnaire.

17 Q. I am not sure she's a doctor.

18 A. Neither am I.

19 Q. What did Welch do?

20 A. Took the Spirtas questionnaire, the one that
21 was used by the NCI study and applied to a
22 hospital-based case controlled study of mesothelioma --
23 and as controls they use another rare tumor, the cancer

1 of the appendix -- and applied the same questionnaire.

2 The problem is, just like Spirtas '94, there
3 are no numbers specifically, you know, for each
4 category. They do have -- they do report numbers of
5 people, but they don't tell us who was doing what in
6 terms of occupational histories.

7 But if you plug those numbers, the number of
8 exposed mesothelioma cases would be eight. The
9 number -- I'm sorry. The category is exactly the same,
10 brake installation and repair; eight exposed cases, six
11 exposed controls, 16 nonexposed cases, 18 controls.
12 It's a total of 24 cases, 24 controls.

13 They give you an odds ratio of 1.5.

14 Q. Did the authors calculate that or did you
15 calculate it from the data presented?

16 A. Yeah. They did not report that number.

17 Q. Even though they didn't report it, you went
18 ahead and calculated it. Am I correct that you have
19 included it on the compendium slide that is now up on
20 the screen?

21 A. Right.

22 Q. Let's summarize the results of the studies you
23 considered mesothelioma in auto mechanics. Does this

1 slide present all of those studies plotted on the graph
2 you explained earlier?

3 A. Yes. These are -- I think that's 15 out of 18
4 studies.

5 Q. I'm going to ask you about Hessel in just a
6 moment when we talk about lung cancer and on one other
7 issue. But what is your conclusion based on this
8 depiction of the body of evidence from epidemiology?

9 A. Well, if one looks at this set of results,
10 there is no evidence whatsoever to conclude that risk of
11 mesothelioma in people engaged in -- this is a broadest
12 category -- in people defined as garage mechanics, motor
13 vehicle mechanics, or brake installation repair workers
14 is elevated. It's indistinguishable from one.

15 Q. Now, Dr. Frank said yesterday in response to a
16 question about cohort study design -- let me back up.
17 The purple are case control studies, and the green are
18 PMR studies on this chart?

19 A. And there are two studies that didn't have an
20 estimate because they have no cases.

21 Q. You have not identified any cohort studies. In
22 fact, Dr. Frank yesterday, in response to a question,
23 said there were no cohort studies of garage mechanics or

1 brake mechanics. Is that true?

2 A. No, that's not true.

3 Q. But yet you don't have any cohort studies up
4 here. Why is that?

5 A. Because none of them were able to calculate
6 relative risk or SMR. However, they provide data that
7 are very much in keeping with this model.

8 Q. In particular, let me ask you about a study
9 called Gustavsson.

10 A. Right.

11 Q. Is Gustavsson a cohort study?

12 A. Yes, it is.

13 Q. And what did Gustavsson do in their study and
14 what findings did --

15 A. Gustavsson is a Swedish done in Stockholm
16 garages. They primarily focussed on lung cancer. And,
17 you know, lung cancer is -- there is really a lot of
18 information that can be discussed on lung cancer. They
19 did say they had two mesotheliomas in their workforce.
20 Although, it's just in the discussion phase. But that's
21 an interesting thing.

22 One mesothelioma case was a garage worker, but
23 he was an electrician. And electricians clearly have an

1 elevated risk of -- he was never a -- fixing vehicles.
2 He was an electrician. About the second one, they don't
3 say what he was doing, so we don't know. We also know
4 that both of them had exposures or may have had
5 exposures, to precisely to quote Gustavsson, elsewhere
6 besides the garage, so --

7 Q. A simple question: Are the cohort studies that
8 have been done, the moving going forward studies on car
9 repair, garage mechanics, however defined, are those
10 studies consistent with an association between exposure
11 to friction fibers and mesothelioma?

12 A. They're consisted with no association.

13 You know, one more thing. And another thing
14 that is really important, I think, is Jarvholm.
15 Literally it's important because --

16 Q. Jarvhom, J-A --

17 A. J-A-R-V-H-O-L-M. 1988. And that study, the
18 reason why it's so important because it includes almost
19 20,000 motor mechanics as recorded in the Swedish
20 census.

21 Q. How many years did they follow?

22 A. 20 years of follow-up.

23 Q. 20,000 mechanics followed for 20 years. And

1 what did they find?

2 A. That gives you roughly 400,000 person years of
3 follow-up. They found one case of mesothelioma about
4 which they say that this case was a construction worker.

5 Q. Who also worked in a garage?

6 A. Who also was at some point during a census a
7 car mechanic.

8 Q. Just for the sake of comparison so the Court
9 can understand, 20,000 persons followed for 20 years
10 resulted in one case?

11 A. Didn't result in one. It was one case.

12 Q. It was the result of an observation of one
13 case. How does that compare to similar work, similar
14 size cohorts like what Dr. Selikoff did in the 1960s?

15 A. Yes. They Selikoff cohort is very similar
16 size. I think it's just under 18,000.

17 Q. Insulators?

18 A. Insulators. And followed for around 20 years.
19 And there was 180 cases.

20 Q. Dr. Selikoff in a similar cohort found how many
21 cases of mesothelioma?

22 A. 180.

23 Q. You are a coauthor of the study listed in the

1 middle of the upper part of the chart, Hessel, 2004.

2 You've also told the Court about that?

3 A. Yes.

4 Q. What did that add to the literature?

5 A. Well, the Hessel is additional analysis of the
6 NCI data set.

7 Q. Why did you do additional analyses?

8 A. When we were reviewing the literature, a couple
9 of questions remained unanswered. And we were hoping to
10 answer those by analyzing the National Council Institute
11 data set. That's why we contacted Spirtas. And he just
12 sent it to us.

13 The first question was, if you recall, we have
14 brake installation and repair as an exposure definition,
15 which is a valuable definition of exposure. But all we
16 had was this very crude estimate from Spirtas '85, which
17 was 1.0 with a confidence interval between 0.6 and 1.6.

18 Then you had this '94 pretty long study, pretty
19 extensive study, but it did not look at mechanics. And
20 it also told us that 33 percent of motor vehicle
21 mechanics were engaged in ship building or ship repair,
22 shipyard work, and 55 percent were engaged in
23 installation work.

1 So we felt that that might be an opportunity to
2 do additional analysis. One is to look at whether or
3 not one can evaluate risk associated with brake lining
4 installation and repair and adjust for other exposures.
5 That's typically not done. People just split it up and
6 say you compare vehicle mechanics only to people who
7 were not engaged in any asbestos-related jobs.

8 So the other way is to do it in model in what's
9 called logistic regression model where you adjust
10 analytically for other exposures.

11 Then we also did the traditional way, where you
12 just eliminate people with mixed exposures and look at
13 people who were brake installation and repair workers
14 only, compare them who had no known history of
15 occupational exposure.

16 The third analysis that was never done before
17 is to look at duration of job. Because most studies --
18 the only exception is Gustavsson -- do not have direct
19 industrial hygiene measures. Duration of exposure is a
20 surrogate, I mean, albeit imperfect, but a surrogate for
21 exposures level for dose response. You would expect,
22 say, that people who work more than ten years have a
23 statistically significant difference in terms of risk

1 compared with people who work less than ten years. Or
2 you have more cases. You can do five, ten, or 25 years,
3 for instance.

4 Q. Dr. Goodman, we'll submit this study to the
5 Court, also. But quickly, did the data indicate that
6 the people who engaged in this work longer had a higher
7 risk of disease?

8 A. No.

9 Q. All right. Did the data indicate a dose
10 responsive relationship at all?

11 A. That's one way to look at dose responsive. And
12 there was no dose responsive. It stayed flat,
13 regardless of whether people were less than ten years or
14 more than ten years.

15 Q. On this hypothesis that was expressed regarding
16 possibly synergy between chrysotile and other types of
17 fibers, did the data indicate that there's a synergy
18 between working in a garage and having other
19 occupational exposures?

20 A. No. They did not indicate.

21 But the important thing that -- we actually
22 tested the hypothesis of synergy by using what's called
23 interaction term. An interaction term would look at

1 synergy or departure from a regular logistic regression
2 model in -- between other exposures and the brake
3 mechanic. And none of those interaction terms -- I
4 don't want to overload you with technical -- were
5 significant. Basically, they did not -- were not
6 present in the model.

7 Q. Now, you also performed a systematic review of
8 the occupational epidemiology; correct?

9 A. Yes, I have.

10 Q. That's the meta analysis paper that we've
11 discussed?

12 A. Yes.

13 Q. I'm going to ask you a couple questions about
14 that. But do we have a slide that's -- we'll go through
15 this very quickly. This is a slide that you compiled
16 that shows where the research was done and how it was
17 funded; correct?

18 A. Yes.

19 Q. It's actually a second page to it. We'll just
20 go through that. Go back. Up one to Teschke. I think
21 the Court has already seen both those slides. Go down
22 to -- right there.

23 We're talking about your meta analysis. Was it

1 just a calculation or were you doing two different
2 things?

3 A. Yes. The meta -- we set out to do the meta
4 analysis to do two things. One is just a qualitative
5 evaluation and, you know, critique of each study
6 individually in a systematic way.

7 Q. What is the process for doing that?

8 A. Yeah. For meta analysis or in general?

9 Q. For a systematic review. What's the process
10 for conducting a systematic review? Because that might
11 mean something different to me than to an
12 epidemiologist.

13 A. Yeah. It's very important. A systematic
14 review, you begin like any study. You begin with a
15 hypothesis. You state your hypothesis. In our case the
16 hypothesis was just like the hypothesis set out to
17 tested by any of the individual studies. What is the
18 evidence of the association between mesothelioma and
19 motor vehicle repair using various definitions using a
20 epidemiological data, data that's either reports,
21 relative risk estimates, or allow you to calculate
22 relative risk based on data included by authors?

23 So once you state the hypothesis, then the

1 first thing you do, you identify all relevant study.
2 The two key words, "all" and "relevant." You know, you
3 don't want to miss anything, but you also don't want to
4 include studies that are irrelevant to the hypothesis,
5 to the specific hypothesis you are testing.

6 After you've done that, you go through each
7 study one by one. And there is multiple ways to do it.
8 Laden, for example, just described them.

9 Q. Laden is at Harvard. That's a study that was
10 also submitted?

11 A. Right. Laden just described them. And it's a
12 perfectly reasonable way to do it just one by one in a
13 sort of systematic academic fashion. Many of you put
14 together tables and show what individual studies showed.

15 We decided, because studies are not created
16 equal -- many of them have strengths and many of them
17 have weakness and all of them have different strengths
18 and weaknesses -- we decided that if we set certain
19 number of criteria -- they have well-accepted criteria
20 for study quality -- and score the studies so that we
21 can understand the relative trustworthiness -- that's a
22 good word -- trustworthiness of the result, then you can
23 do -- take it to the next step and take the studies and

1 combine them in what's called a pooled analysis or meta
2 analysis. You take several risk estimates. And there's
3 a statistical significance that allows you to say,
4 what's the best average estimate for these studies --

5 Q. Even though there's a heterogeneity?

6 A. Well, if there was a heterogeneity, I wouldn't
7 have combined them. Because you can't combine
8 heterogenic studies. Your job is to go find out why the
9 heterogeneity occurs. But if you do that in tiers,
10 there was no heterogeneity. Studies that were, say,
11 tier one were very similar to each other. And studies
12 in tier two were somewhat similar although not exactly
13 the same as tier one. And tier three we did not even
14 analyze --

15 Q. In fact, is there a formula for heterogeneity?

16 A. Of course, yeah. There's a test for
17 heterogeneity.

18 Q. Did you present that in the paper?

19 A. Yes. One of the tables shows heterogeneity.
20 Heterogeneity is a lay term, but it's also a
21 mathematical term. You can test whether or not there is
22 a disagreement.

23 Q. Dr. Goodman, in the interest of time I want to

1 move into another topic. Before I do that, tell the
2 Court what's important about -- in your opinion, about
3 the result of the meta analysis.

4 A. There are three rows. It's not necessarily the
5 three tiers that we use, but the three informative rows.
6 The first row are what we called tier one studies. And
7 we do not insist that that's necessarily the best set of
8 studies. This is the set of the studies that happen to
9 be tier one compared to every other study. I mean,
10 there may be other ways to do it. But these are studies
11 that are, in our opinion, and based on our scoring, were
12 the most accurate.

13 Then the second row, the green color, are
14 studies that we're able to eliminate other exposures.
15 In other words, look at -- compare people who were
16 engaged in brake repair to those -- again, with a
17 caveat -- to the best of their knowledge that did not
18 have any exposure. So essentially comparing motor
19 vehicle mechanics to essentially white collar workers or
20 blue collar workers that are engaged in things that are
21 not related to asbestos.

22 And the third tier -- it's not a tier in terms
23 of quality, but it's a way to look at this, third

1 hypothesis, is studies that define exposures of brake
2 workers as opposed to a garage work or motor vehicle
3 repairs.

4 And the bottom of each of these colors gives a
5 meta relative risk, meta RR. That meta RR for tier one
6 is -- you see what happens with meta analysis; it takes
7 care of the frequency of sample size issue. We have
8 small studies with very wide confidence intervals. The
9 estimates are very imprecise. So a meta analysis allows
10 you to combine them as if it's one study. So the
11 confidence interval becomes much more precise.

12 So for tier one you get a one, basically, for
13 studies to look -- eliminated other exposures and
14 compared mechanics without other known asbestos
15 exposures to people without any asbestos exposure is
16 basically one. If you do it for brake work, if you
17 define your exposure as brake work as opposed to motor
18 vehicle work, you get basically one.

19 Q. Did you hear the testimony from some of the
20 previous experts that in their opinions on, again, all
21 of the things being equal, just on a volume dose basis,
22 it takes the most exposure to get asbestosis, less for
23 lung cancer, and even less for mesothelioma? Did you

1 hear that?

2 A. Yes, I heard that.

3 Q. Is that something you agree with or disagree
4 with?

5 A. Well, it's a very general statement. But
6 overall there is a hierarchy, I think, that mesothelioma
7 would be, as many of the experts pointed out, would be a
8 signal tumor if there is an increase incidence.

9 Q. If I understand right, of the three diseases
10 we're talking about, mesothelioma, in your opinion, like
11 you heard, is the one of the three that requires on a
12 volume of dose basis the least?

13 A. It's the most sensitive end point. That's the
14 one that you will see a red flag earlier than others.

15 Q. Stated another way, you would expect that lung
16 cancer, you require a larger dose of whichever kind of
17 fibers to result in lung cancer; is that correct?

18 A. Yes. I mean, the reason I'm saying is that is
19 just because there are studies that show just that.

20 Q. I hope I phrased that as a hypothesis and
21 opinion. I know you're not establishing that.

22 With respect to lung cancer, let me ask you,
23 how does the lung cancer epidemiology differ from the

1 epidemiology of mesothelioma?

2 A. Well, they're different -- it's very different
3 challenges. When you do studies of lung cancer, the
4 challenges that you're facing are very different. The
5 problem with mesothelioma is that it's rare and,
6 therefore, even large cohort studies, unless people are
7 insulators, will give you no cases, so you cannot really
8 evaluate the risk. All you can say whether it's rare or
9 common.

10 That's why the mesothelioma just like, you
11 know, other rare cancers suits most -- lends itself best
12 to case control design. Because you can collect cases
13 from multiple sources and take controls and analyze
14 that, particularly -- case control studies are
15 particularly useful if you have rare disease and common
16 exposure. And being a brake mechanic is a common
17 exposure. Mesothelioma is a rare disease.

18 The reverse is true for cohort studies. If you
19 have common disease but rare exposure, you must pare
20 off, rounding out that exposed people even though you
21 have maybe several hundred, follow them over time. But
22 with a common disease you can end up seeing quite a few.
23 Prostate cancer lends itself perfectly to a cohort study

1 or even lung cancer.

2 Q. How many causes potentially are there of lung
3 cancer that are under study?

4 A. Yeah. So challenges of lung cancer and
5 mesothelioma, as I said, are different.

6 Now, nonconfounders. For mesothelioma age is
7 important confounder, like any other cancers. The other
8 confounder is other exposure. That's more or less it.
9 You know, you don't have to worry a whole lot about
10 other things because it's so specific.

11 With lung cancer there are multiple causes and,
12 therefore, there are multiple confounders.

13 Q. Your meta analysis was not just for
14 mesothelioma, but you also did a systematic review of
15 the literature for lung cancer, also?

16 A. Yes.

17 Q. We'll discuss that in a moment.

18 Do you agree that the first and foremost risk
19 factor for lung cancer is smoking?

20 A. Yes.

21 Q. With respect to asbestos, do you believe that
22 asbestos is a risk factor for lung cancer?

23 A. Absolutely.

1 Q. Is the risk smaller or larger than for
2 mesothelioma?

3 A. Smaller. It's a general statement. But,
4 generally speaking, smaller.

5 Q. Should smoking be taken into account if you're
6 going to study the potential relationship or association
7 between auto work and lung cancer?

8 A. Yes.

9 Q. And, succinctly, why is that?

10 A. Because automobile mechanics in studies have
11 been shown to be an occupational group that ranks among
12 the highest with respect to smoking habits, both with
13 respect to intensity -- how many cigarettes per day --
14 as well as frequency of habit in terms of prevalence,
15 percent of people who smoke versus those who don't.

16 I think the previous slide ranked them. The Y
17 axis is the cigarettes per day. So mechanics on
18 average, averaging both smokers and nonsmokers, smoke
19 about eight cigarettes per day. The other people who
20 beat them to it are supervisors and production
21 occupations. And then -- next slide. And here it's
22 prevalent, basically, the percent of people that smoke.
23 And there they rank number four.

1 Q. Now, do you have a graph that shows studies of
2 lung cancer where smoking was controlled for --

3 A. Yes. You have to control for smoking. And you
4 have to control for smoking and control for smoking
5 adequately. If it's the ever never category, you just
6 use pack years; that won't do. So these are the studies
7 that adequately control for smoking.

8 Q. We won't go through each one of these studies
9 like we did for mesothelioma. We'll have those
10 submitted on the record, also. But what is your
11 conclusion from that presentation of the literature?

12 A. Well, the smoking adjusted relative risk for
13 lung cancer among motor vehicle mechanics are no
14 different than one as a group. And this is old studies.
15 I think there are about 30 of them.

16 Q. Let me ask you about one study. Those are all
17 the studies whether they controlled for smoking or not?

18 A. Only those on the first slide did a good job of
19 doing that.

20 Q. These are all the studies?

21 A. All, each and every.

22 Q. I'm going to ask you about one study in
23 particular. But just with respect to all of the studies

1 taken together, is that a consistent or an inconsistent
2 finding to you?

3 A. Yes. This is one.

4 Q. Okay. Now, Gustavsson we talked earlier. Is
5 Gustavsson also concerned with a hypothesis about lung
6 cancer?

7 A. Gustavsson, yeah, it is. It's a cohort study
8 that we discussed a little bit earlier.

9 Q. That followed all of those auto mechanics for
10 all these --

11 A. These are not auto mechanics. These are people
12 who worked in municipal garages in Stockholm.

13 Q. So all sorts of people?

14 A. Yes.

15 Q. What was particularly important about the
16 Gustavsson --

17 A. Well, they set up industrial hygiene
18 measurements. They actually set out pumps. And they
19 would calculate concentrations of fibers per CC and then
20 convert it into dose.

21 Q. So there was a question from the Court either
22 yesterday or the day before about how you account for
23 exposure. Am I correct that Gustavsson actually had

1 measurements of whatever kind of fibers it was they were
2 being exposed to during the study?

3 A. Yes, they had measurements. But of the most
4 important thing is not only did they measure, but they
5 actually analyzed by exposure level, just for lung
6 cancer. Because, of course, with mesothelioma they
7 couldn't do much.

8 Q. Is that important because you could test the
9 hypothesis whether more exposure in terms of volume
10 equals more risk of disease?

11 A. That's right. They tested the dose responsive.

12 Q. What did they conclude on that?

13 A. Well, they conducted the analysis...

14 (Pause.)

15 BY MR. TARRY:

16 Q. Did they find people with more exposure were at
17 increased risk of lung cancer than people with less
18 exposure?

19 A. Yes. Let me give you the actual numbers. It
20 will be easier. That way I just need a second because
21 it's... I need to find it.

22 (Pause.)

23 THE WITNESS: Here we go.

1 They conducted what's called a nested case
2 control analysis within a cohort. That's probably the
3 best of all if you can do it. You have a cohort. You
4 collect data prospectively. You follow people all of
5 the time. But then your analysis is a case control
6 study within a cohort. So everybody is counted for you.
7 You don't just run around sampling or recruiting people.
8 Nested case control study, if possible, is one of the
9 best designs. And you control people within the same
10 occupational group. So chances are that they're more
11 homogenous with respect to social economic status,
12 lifestyle habits, and whatnot.

13 Q. Okay.

14 A. So here we have -- they calculate what's called
15 an asbestos index, which is a measure based on both
16 duration of employment and levels that they had at the
17 garage, the actual fiber levels. That asbestos indices
18 basically provide them with four categories; zero to 20,
19 20 to 40, 40 to 60, and 60 plus, more than 60. That
20 would be the highest.

21 The lowest categories, zero to 20, would be
22 your unexposed in the case control study. That's
23 relative risk of one by definition. Because it's a

1 reference group. Then if you go up the level -- can I
2 just draw it?

3 THE COURT: Yes.

4 THE WITNESS: So zero to 20 is a comparison.
5 And that's -- always will be one. So everybody is
6 compared to them. Then the next category is 20 to 40,
7 then 40 to 60, and then 60 plus.

8 So 20 to 40 had a relative risk of 1.6, which
9 was not significant, 1.67 actually, which was not
10 significant, from 0.5 to five. Then as exposure
11 increased, the risk decreased to 1.26. And, again, it
12 was not significant. And then as exposure increased
13 further, the risk decreased further to 1.2.

14 BY MR. TARRY:

15 Q. Dr. Goodman, yesterday Dr. Frank was asked a
16 question at the very end I want to ask you about. He
17 drew a line like this (indicating), talking about dose
18 response. He was asked, do you mean assume, Dr. Frank,
19 a linear non-threshold dose responsive curve for these
20 diseases? And I believe with the exception of
21 asbestosis, he answered yes to the first two.

22 Is this consistent -- is this data consistent
23 with a hypothesis of a linear no threshold dose

1 responsive curve?

2 A. For this particular type of exposure, the data
3 are most consistent with an average of a flat line.
4 Because it's -- you would expect some fluctuations, but
5 overall you have no increase with increasing dose.

6 Q. So if there's a theory that friction fibers
7 ought to contribute to disease in linear no threshold
8 manner, would the Gustavsson report study support that
9 hypothesis?

10 A. No.

11 Q. All right. Your conclusion on lung cancer is
12 that auto mechanics are not at an increased risk?

13 A. Yes.

14 Q. All right. And is that just your conclusion or
15 have others who did systematic reviews of the literature
16 come to the same conclusion?

17 A. Yes.

18 Q. Dr. Laden we talked about earlier. We'll
19 submit that paper. Go ahead to the next one.

20 Is it surprising to you, given that the data
21 don't support an increased risk for mesothelioma, that
22 there would not be one for lung cancer?

23 A. No.

1 Q. Why?

2 A. Well, these are the studies selected using two
3 important a priori criteria. One, is that these are all
4 cohort studies. So these are the studies that reported
5 and calculated relative risk for both lung cancer and
6 mesothelioma.

7 And the studies for which reported unequivocal
8 increase in lung cancer, you know, the relative risk
9 of -- all of those are significant. All of them are
10 ones you can't miss, you know, 2.8, roughly three -- and
11 one even has a relative risk of 17. That's the asbestos
12 sprayers in Finland. And then side by side is the
13 analogous result for mesothelioma.

14 And even though lung cancer, of course, is
15 elevated in each those studies, this is a very different
16 circumstances of exposure. Lung cancer, of course, is
17 elevated in all of these studies. Mesothelioma is in
18 double digits -- actually, in triple digits in one
19 particular case. The relative risk for mesothelioma for
20 the Finnish studies is 263.

21 Q. The Court was told that smoking and asbestos
22 exposure, just mentioned generically, are either
23 additive or synergistic or multiplicative for lung

1 cancer. Do you agree with?

2 A. There are circumstances when smoking and
3 asbestos clearly act synergistically. And there are
4 circumstances where they don't. And there's a hole
5 bunch of in between.

6 Q. Let me ask you very briefly to come down, and
7 using the basic formula both for additive hypothesis and
8 assuming a multiplicative hypothesis, show what the
9 results of the epidemiology would be for mechanics, auto
10 mechanics.

11 Additive.

12 A. Yes.

13 Q. If it's additive, how do you add smoking and
14 whatever contribution from friction products?

15 A. There are two ways of looking at how the two
16 factors, both of which are risk factors, interact. And
17 with respect to asbestosis and smoking, probably the
18 very first paper that came out on this was conducted
19 within the group of insulators. And first off was
20 Hammond, the American Cancer Society head of research
21 back then.

22 And what he reported -- I think it's in '79 --
23 is that asbestos alone in the absence of smoking, people

1 who they thought were not smokers -- it's a bit
2 unclear -- gave a relative risk of five. Smoking alone
3 in people that, according to author's information had no
4 asbestos exposure, was about ten. But people who had
5 exposure to both -- no room here -- but it goes high.
6 It goes to 50.

7 The point is -- and that's the model that this
8 data fits the best, meaning if I'm already five fold
9 increase in risk, my risk went up five fold, and on top
10 of it I start smoking, then it's ten times more.

11 An alternative model where data sometimes fit
12 and actually in cases of asbestos exposed workers fits
13 as well is so-called additive model. That would be
14 five, and ten, and 14. The reason how math works is,
15 for multiplicative, not 15, but 14.

16 Q. Ten plus five is 14 in the additive model?

17 A. Well, that's how it works. If the model is
18 multiplicative, then the two factors, say, factor A and
19 B together, relative risk -- this is relative risk for
20 factors A and B together -- compared to people who are
21 exposed to neither, is relative risk of A times relative
22 risk of B. That's easy.

23 Now, for additive molds, relative risk of A

1 plus B equals relative risk of A minus one. Because
2 relative risk minus one is excess risk, above and beyond
3 what should have happened anyway, plus relative risk of
4 B minus one, plus one. Because there is a background.
5 So that if it's five and 15, that's four -- five and
6 ten, it's four and nine and one, it's 14.

7 Q. Very quickly, though, for auto mechanics, based
8 on epidemiology, what is the contribution of smoking to
9 risk on the above --

10 A. It's ten. Smoking gives you a relative risk of
11 ten.

12 Q. Smoking gives you a relative risk of ten. And
13 you add what contribution for working in a garage?

14 A. You add a one.

15 Q. Or you subtract one --

16 A. Well, if it's additive, then you have a
17 relative risk ten minus one plus one minus one plus one
18 equals ten. If it's multiplicative, regardless of what
19 model you pick, ten times one equals ten. In other
20 words, if one of the components does not increase risk,
21 unless the data indicates otherwise -- you have to
22 always say that -- unless the data indicates otherwise,
23 one cannot conclude there is a synergy.

1 Q. Let me ask it in a simple non-mathematical way.
2 If a smoker goes to work in a garage, does the
3 epidemiology suggest that the garage work adds to that
4 person's risk of lung cancer?

5 A. No. We have studies that actually looked at
6 that issue by separating smokers and nonsmokers and
7 looking at that risk separately, the study by Blair; and
8 there is a study by, Hrubec, H-R-U-B-E-C. Both of them
9 found no increase in risk whether a person is smoker or
10 nonsmoker when you looked at them separately, otherwise
11 you would have expected difference.

12 Q. Before we wrap up on asbestosis, we promised
13 the Court we would show the chart from the Hessel study
14 where this synergistic effect was tested. Can you just
15 very briefly explain what that is?

16 A. Yes. That is additional analysis of one of
17 several that we did. They have hypotheses we test with
18 these analyses. If you add brake work to other known
19 risks, you would expect a sum total risks that's higher.

20 People with no -- the comparison is for people
21 with no history of brake work and insulators who were
22 both insulators and have history of brake work; and
23 similar for ship builders, comparison of people who are

1 ship builders but never worked on brakes and people who
2 are ship builders and worked on brakes. And at least
3 from these data -- this, of course, is a small data set
4 -- at least from this data there's no evidence that
5 you -- there is a contribution by brakes.

6 Q. If you don't see risk for mesothelioma and you
7 don't see risk for lung cancer, would you expect to see
8 risk for asbestosis?

9 A. No.

10 Q. Why not?

11 A. Because asbestosis -- and I think there was
12 agreement in this room -- that asbestosis would require
13 much higher doses.

14 Q. Have there been studies published to support
15 the conclusion that auto mechanics do not have increased
16 risk of asbestosis?

17 A. Well, there -- the trick with asbestosis is
18 it's hard to study with regular design other than
19 cross-sectional studies. Because it's a state as
20 opposed to an event. Although the Coggon analysis, the
21 PMR analysis from the U. K, they did analyze proportion
22 mortality from asbestosis and found no increase.

23 Q. How about the other PMRs?

1 A. I don't remember seeing episodes anywhere, but
2 that's the one that is just because it's there; they
3 discuss it in the same breath as mesothelioma.

4 Now, cross-sectional studies, there were
5 several of them. There's one in Switzerland,
6 Lobboilog --

7 Q. Spell that for the court reporter.

8 A. L-O-B-B-O-I-L-O-G. There's one in Germany,
9 Eilenhausen, E-I-L-E-N-H-A-U-S-E-N, et al. And then, of
10 course, there is one in Sweden, study by Marcus,
11 M-A-R-C-U-S.

12 And, of course, there's two Mount Sinai
13 studies. There is a Lorimer, 1976, a study that's a
14 descriptive study that did not use controls that
15 reported -- and actually that was one of the earlier
16 reasons why people got concerned about asbestos-related
17 disease, not just asbestosis, of course, primarily
18 mesothelioma. It was triggered by the Lorimer report in
19 the seventies. Because they evaluated a group of brake
20 mechanics and found, or reported rather, reported x-ray
21 changes that in their mind were consistent with
22 asbestosis and, therefore, concluded asbestosis may be
23 elevated in that group.

1 Then to follow up, 1984 -- '84 by Nicholson
2 that used a control group. And I've read this paper
3 multiple times. I haven't seen anywhere mentioning of
4 the word "asbestosis."

5 Q. That's the question I was going to go ask you
6 Dr. Frank testified, if I heard correctly, that
7 Dr. Nicholson reported cases of asbestosis; is that
8 correct?

9 A. The word "asbestosis" was not seen as a
10 diagnosis identified in any of these papers.

11 Q. Does the literature suggest, in your opinion,
12 an increased risk of asbestosis among car mechanics,
13 brake repair workers, or people who work in garages?

14 A. No. I have not seen studies that would be --
15 any of those cross-sectional studies that were found a
16 true diagnosis of asbestosis.

17 Q. Now, Dr. Frank said, I think also, that the
18 risk of asbestosis was shown to increase with exposure
19 in those garages. Do you believe that's the conclusion
20 of the Nicholson report?

21 A. No.

22 Q. All right. And I believe Dr. Frank also said
23 that --

1 A. I'm sorry. The conclusion may be there, but I
2 know the data well enough to --

3 Q. I'll ask you to explain that to the Court in a
4 second.

5 Dr. Frank also said that Nicholson had found
6 out it was latency. Is that accurate?

7 A. No.

8 Q. Based on the data?

9 A. No. I don't think there is even a conclusion
10 about latency.

11 MR. TARRY: Your Honor, about to wrap up.

12 If you could come down. And I'm going to put
13 these tables up and ask you to explain these conclusions
14 to the Court.

15 (Pause.)

16 THE WITNESS: This is Table 11. They looked at
17 the issue in several different ways. The Table 11 looks
18 at x-ray changes in people who did brake work and did no
19 brake work. And the critical numbers here, these two
20 lines (indicating), people who did no brake work, the
21 percent with 1./0 or greater parenchymal change, which
22 is not specific of asbestosis, is 20.7. A similar
23 percent for people who did brake work is a little bit

1 lower, 18.5. This actually continues for various
2 categories.

3 An important thing, of course, these -- they
4 don't report these levels of significance.

5 BY MR. TARRY:

6 Q. How is that usually reported?

7 A. You can easily report a p-value. P-value is
8 the probability your differences are observed due to
9 chance. P-value less than .05 is considered to be
10 significant. And this is not significant at all. From
11 statistical point of view these results are the same.
12 By no means I'm saying that brake work have lower
13 proportion of change. I'm just saying there is no
14 evidence of increase.

15 Now, the next table, that's very important,
16 because this is not adjusted for age. And one needs to
17 adjust for age. That's Table 13. Again, brake work, no
18 brake work. There are other categories that are
19 important, of course, and maybe they're informative.
20 But really, the gist of this analysis is brake work
21 versus no brake work.

22 And here, after adjustment for age, there is a
23 difference but in the opposite direction. There's

1 18.6 percent for people with no brake work, and
2 24.5 percent, people with brake work. But these
3 differences are not statistically significant.

4 There's a quick way to eyeball it. And that
5 is, if the intervals overlap, instead of looking at the
6 number, one needs to look at the intervals. And if
7 those intervals overlap, then statistically one cannot
8 conclude the difference is real, not due to chance
9 alone. So 24.5 minus 2.5 is 22. 18.65 plus 4.1 is
10 22.7. The intervals are overlapping.

11 Q. Table 16 also is an important table. Why is
12 that?

13 A. Table 16 is very important. There you see a
14 big difference among people who did brake work and
15 people who did not do brake work. That difference is,
16 in fact, statistically significant because here you get
17 as far as 23.4. And the intervals are not overlapping.
18 That's the real difference.

19 But the most important thing here is the lower
20 row, the percentage of participants with other asbestos
21 exposure. And the percentage of participants is higher
22 than any other category. So we don't know whether
23 that's an explanation -- an explanation that was offered

1 is that these particular categories involved in
2 grinding. But it couldn't just as well be that the
3 difference is explained by differences in other
4 exposures.

5 Most important thing, though, most important
6 thing, though, if there is no increase in risk in
7 mesothelioma and no increase in risk of lung cancer, it
8 appears inconceivable that asbestosis as disease, not as
9 x-ray changes -- because it's pretty nonspecific
10 finding -- would be elevated. But anyway, this is one
11 of the important conclusions that comes from that table.

12 Q. What about their analysis of the percentage of
13 individuals who had the x-ray abnormalities when they
14 grouped them by years of garage work? What can you make
15 of that, and are there some inconsistencies there?

16 A. There were two tables that both of which are --
17 could be potentially very useful. One is looking at
18 duration of work. In other words, people -- in this
19 case, they use more than 30 years and less than
20 30 years. Duration is not the same thing as latency. I
21 know this. This is just not right. Duration is the
22 measure of dose. It's not a latency.

23 The problem with this table is that all we know

1 is that, compared to within the group that did the brake
2 work, we don't know whether the same pattern -- and
3 there is a difference, of course -- 19.4 versus 28.7.
4 But we don't know whether or not the same pattern would
5 have occurred among people who did not do the brake
6 work. That's the right way to do the analysis, before
7 you conclude that that's an occupation that doesn't.
8 All you know is that people who work longer tend to have
9 worse lungs or more changes on the lungs.

10 One second. And then it's possible perhaps to
11 recalculate, do the same thing for known brake work.
12 Because the number is a given. It's a bit of a problem,
13 though. If one -- and it's just -- you just don't know
14 what numbers are showing. Because three out of 48 is
15 not 27 percent. And it's not a matter of opinion.

16 Similarly, if you add 94 plus 170 plus 18 plus
17 31, you'll never get 413. That's why it's very hard to
18 recalculate -- it's possible sometimes to just take the
19 data from a study and recalculate to answer a question
20 that you're interested in, but here I sort give up.

21 Now, the latencies is the next table, 17(b).
22 They don't call it latency. It's years since onset of
23 exposure; not the same thing, a completely different

1 thing than duration of exposure, and has nothing to do
2 with duration follow-up. There's a different thing. Be
3 happy to explain it. But the point is that, if one were
4 to look at latency, these differences are no longer
5 significant. The confidence intervals largely overlap.

6 MR. TARRY: Questions, Your Honor?

7 THE COURT: No.

8 BY MR. TARRY:

9 Q. Dr. Goodman, in summation, is the data
10 presented by Nicholson to NIOSH in 1984 consistent with
11 a hypothesis that garage work, whether brake work in
12 particular was involved or not, increases the risk of
13 asbestosis?

14 A. No.

15 Q. We talked about epidemiology of what I'm going
16 to call friction fiber exposure, whether brake work was
17 involved or not. Why don't you put greater weight than
18 you have on other asbestos exposures or chrysotile
19 exposure from other settings?

20 A. Well --

21 Q. Let me back up. Withdraw that question.

22 Have you disregarded other epidemiology and
23 other scientific literature?

1 A. No. I have reviewed other epidemiologic
2 studies as well as literature from other fields of
3 knowledge.

4 Q. Why then have you not put more weight on those
5 studies of other exposure settings than on the garage?

6 A. Yeah. I think it takes us back to the issue of
7 systematic literature review. And if you recall, the
8 first step was to formulate a hypothesis and then go
9 through the literature and pick studies that are
10 relevant studies that actually test the hypothesis that
11 you are interested in.

12 And, you know, if one can make assumptions in
13 the absence of the data, one can make assumption -- and
14 that's a reasonable thing to do, and, you know,
15 researchers do it all the time -- when they don't have
16 the data, they might assume that a similar set of
17 circumstances applicable to this particular set of
18 circumstances, no problem with that.

19 But if you have the data that are relevant, you
20 can't operate based on assumptions. And that's why, you
21 know, the relevance of studies of miners and millers in
22 China is questionable at best with respect to studies of
23 brake mechanics.

1 Q. And if you consider evidence outside of
2 epidemiology like the Langer paper that we've heard --
3 the most recent Langer paper we've talked about -- first
4 off, is that a paper that you are familiar with?

5 A. Yes. I cite it in my review.

6 Q. Even if you're not an expert in mineralogy, as
7 an epidemiologist who has to make determinations about
8 the degree of relevance in certain types of
9 epidemiologic studies, how do those studies form your
10 opinion on how to make a systematic review?

11 A. Well, if they're relevant, then, you know,
12 they're certainly important. The problem with studies
13 of other fields is that there's not much out there that
14 would be specifically relevant to the exposure to
15 friction fibers and risk of disease in either humans or
16 animals, or at least I'm not aware of any studies that
17 would test that hypothesis specifically.

18 Two studies that come to mind that came out
19 recently -- I both cite in my review when I discuss
20 epidemiology -- because it is puzzling, I must say.
21 Most people who set out to look at this occupation were
22 -- had an expectation that they will find an increased
23 risk. That's why, you know, you often see those

1 comments in the discussion sections as to the authors,
2 you know, they didn't expect it to happen.

3 So the next question is: Are all these studies
4 wrong or is there an explanation that we just don't
5 have? And, you know, the two studies that I mentioned
6 that are relevant is the study by Langer, *Reduction of*
7 *Biological Potential of Chrysotile Asbestos Arising From*
8 *Conditions of Servicing Brake Pads*, and the other study
9 that is relevant from sort of a biological is a study by
10 Roggli when he compared -- and I know the shortcomings
11 of comparing pleural tissue to -- expressed shortcomings
12 of comparing pleural tissue to lung tissue. But that's
13 the study that's relevant. Because it's associated with
14 motor vehicle mechanics and people who have no exposure.
15 I just don't have any other relevant studies from other
16 sister disciplines.

17 Q. Dealing with friction fibers?

18 A. Dealing with friction fibers.

19 MR. TARRY: Your Honor, I think, in the
20 interest of time, we cut out a lot where we were
21 originally going to discuss about the data and claims
22 made about data from Australia. I think, in the
23 interest of time, if there were many questions about

1 that data, I would proffer the witness, who is familiar
2 with it and has reviewed all of the raw data from
3 Australia, if there were any lingering questions about
4 it; otherwise, I turn the witness at this point for any
5 other questions.

6 THE COURT: I think that you posed a question
7 when you were discussing other studies about attempting
8 to explain whatever differences may exist there in
9 conclusions from the epidemiological studies we've been
10 discussing; are they wrong or is there perhaps some
11 other explanation for the differences that -- did you
12 call them in other system disciplines?

13 THE WITNESS: Sister disciplines.

14 THE COURT: Have you undertaken to do that as
15 it relates to Langer and is it Roggli?

16 THE WITNESS: No. Unfortunately, it's not my
17 field. But I must say I'm more than anybody else
18 curious to find out what actually happens when you take,
19 honest to God, brake fibers and use it even in animal
20 tissue or cell cultures. I just don't know what
21 happens. And if the results are contradicting
22 epidemiologists, I don't have to scratch our head and
23 think about it. But it's not my field, regrettably.

1 But you can't use just studies of short fibers
2 because not all short fibers are the same. You can't
3 just describe chrysotile because it's a heterogenous
4 group of minerals. I don't know what exactly happens to
5 these fibers before they get into the airway. Sure,
6 they get into the airway of all these people, but
7 something is happening.

8 THE COURT: And it's correct to say -- and I'm
9 sure that this is fundamental -- but what you are able
10 to draw from the epidemiology that exists, based on your
11 interpretation of it, there is no increased risk.

12 THE WITNESS: Correct.

13 THE COURT: The reason why that is is not
14 something that epidemiology tries to answer. The reason
15 why there is no increase in risk is not something that
16 epidemiology is going to answer; that would be left to
17 one of the sister disciplines --

18 THE WITNESS: Well --

19 THE COURT: -- if they want to test that
20 hypothesis?

21 THE WITNESS: The traditional epidemiology, the
22 one that we discussed today can only talk about presence
23 or absence of association. Of course, if you have an

1 association, then you can move onto Bradford Hill
2 criteria. If you don't have an association, then you
3 have to look for biological plausibility of those
4 findings.

5 And the future of epidemiology is something
6 that I more or less started practice now is molecular
7 epidemiology studies, which is sort of marriage of lab
8 science with population studies. These are sort of the
9 20th century epidemiology. But it is time to move into
10 21st century with occupational study.

11 THE COURT: Has there been an effort to take
12 the studies that you reported in your data study and
13 look for a biological plausibility?

14 THE WITNESS: Well, the only relevant studies
15 are Langer -- that I can find are Langer, and some with
16 Roggli, too. There are people who hypothesize. But the
17 point is explanations may be half a dozen. Is it short
18 fibers? Could be. Is it because it's the lowest grade
19 chrysotile? Could be. Is it because those fibers
20 undergo all those kinds of changes before they become a
21 brake? Could be. Is it because they undergo additional
22 changes after -- when the brake is replaced, after the
23 actual braking occurs? Could be.

1 What we do know, they cannot be the same as
2 fibers they got from the ground, the ones that you find
3 in insulation. We know they're different. But the only
4 way to explain why they're different biologically is
5 perhaps to marry lab science with epidemiology.

6 THE COURT: That hasn't been done yet?

7 THE WITNESS: No, not that I know.

8 THE COURT: Those are all the questions I have
9 for you.

10 Here's what I'm thinking, my two o'clock
11 conference is going to not take any more than a half
12 hour, which would put us to 2:30. If we took an hour
13 luncheon recess, that would bring us back here at 2:45.
14 Would that be adequate to complete cross-examination and
15 do the brief sort of wrap it up that we discussed
16 yesterday?

17 MR. WADDELL: Yes, sir, I believe.

18 THE COURT: Why don't we do that then. And if
19 it looks like we're running short on time, then we can
20 discuss what our options are at that point.

21 All right. We stand in recess then until 2:45.

22 (Whereupon a lunch recess was taken at 1:46
23 p.m.)

CERTIFICATE OF COURT REPORTER

We, Lynne B. Coale, Registered Diplomate Reporter and Certified Realtime Reporter, and Domenic Verechia, Registered Professional Reporter, and Patricia Ganci, Certified Realtime Reporter, Official Court Reporters of the Superior Court, State of Delaware, do hereby certify that the foregoing is an accurate transcript of the proceedings had, as reported by us, in the Superior Court of the State of Delaware, in and for New Castle County, in the case herein stated, as the same remains of record in the Office of the Prothonotary at Wilmington, Delaware.

WITNESS our hands this 18th day of October,
2005.

Lynne Bell Coale, RDR, CRR
Official Court Reporter, Cert. # 165-PS

Domenic Verechia, RPR
Official Court Reporter, Cert. # 162-PS

Patricia Ganci, CRR
Official Court Reporter, Cert. #163-PS

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