

1 IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

2 IN AND FOR NEW CASTLE COUNTY

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4
5
6 IN RE: ASBESTOS LITIGATION

7 Civil Action
8 No. 77C-ASB-2
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11 BEFORE: HON. JOSEPH R. SLIGHTS, III., J.
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16 TRANSCRIPT OF DAUBERT HEARING
17 PM SESSION
18 - - - - -

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21 JOHN P. DONNELLY, RPR
22 MICHELE R. HONAKER
23 SUPERIOR COURT REPORTERS
500 N. KING STREET WILMINGTON, DELAWARE 19801
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October 18, 2005
Courtroom No. 8B
2:00 p.m.

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JOHN J. SPILLANE, ESQ.
BARON & BUDD, P.C.

CAMERON R. WADDELL, ESQ.
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JACOBS & CRUMPLAR
for Plaintiffs

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for Defendant Daimler-Chrysler

JAMES M. KRON, ESQ.
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for Defendant Daimler-Chrysler

STEVEN T. JOHNSON, ESQ.
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for Defendant OI, Inc.

1 ALSO PRESENT

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

1 (The trial resumed after the luncheon recess.)

2 THE COURT: Good afternoon.

3 MR. CRUMPLAR: Your Honor, one bit of good
4 news in terms of scheduling. I know Your Honor was
5 concerned we might have been losing a little time. I
6 understand from Mr. Terry I believe that Dr. Heintz
7 will not be called so that I think along with Dr. Lemen
8 he may not finish totally today, we hope so. We have
9 another witness I think that we probably will be
10 finished Wednesday at the latest Thursday morning.

11 MR. TARRY: We will try hard to be finished
12 tomorrow.

13 THE COURT: That means we should not be
14 waiting for a call on the deposition, is there some
15 plan to go forward?

16 MR. CRUMPLAR: No deposition either. I
17 want -- I know your office I think was making
18 arrangements.

19 THE COURT: I appreciate that. If we don't
20 complete Dr. Lemen today, he is available tomorrow to
21 continue.

22 MR. CRUMPLAR: After we went and bought him a
23 new shirt. In case that happens, I may have given him

1 a shirt if we finish up today.

2 THE COURT: He got that out of the deal.

3 Okay. I am ready to proceed, if you are.

4 MR. SPILLANE: Your Honor the plaintiffs call
5 Richard Lemen.

6 RICHARD A. LEMEN, PhD,
7 having been first called by the Plaintiff was
8 sworn on oath, was examined and testified as follows:

9 DIRECT EXAMINATION

10 BY MR. SPILLANE:

11 Q. Good afternoon, Dr. Lemen.

12 A. Good afternoon.

13 Q. We are here to talk about brakes or friction
14 products, chrysotile and disease. I want to go very
15 briefly through your background some of your
16 qualifications. Judge Slights has indicated he is
17 somewhat familiar with you. Touch on them briefly.
18 Can you give as brief overview of your -- very brief
19 overview of your working history what you do today?

20 A. I started out in public health in 1966, when I
21 started with the Missouri Division of Health as a
22 District sanitarian. Then I was drafted into the
23 United States Army, served another two years as a

1 preventative medicine specialist. After the Army I
2 went back to graduate school, and I applied for a
3 commission in the United States Public Health Service
4 Commission Corp. After I received my Masters Degree in
5 epidemiology. I went into the US Public Health Service
6 in 1970. I started out as a epidemiologist, industrial
7 hygienist. I worked -- started working in the area of
8 asbestos beryllium exposures during that time. For the
9 next two or three years, I spent most of my time going
10 into plants throughout the United States taking
11 measurements, conducting medical studies and conducting
12 epidemiological studies of workers in both beryllium
13 and asbestos plants.

14 I continued with public health services
15 studies but in other occupational groups throughout my
16 career, and foundries in smelters, and chemical plants
17 just to name a few. I then went more into
18 administration, kept practicing epidemiology, but went
19 more into administration and headed the Division of
20 Standard Development Technology Transfer, which was the
21 area within our institute that makes recommendations
22 for standards to protect workers in the workplace.

23 1988, I was named Assistant Director of NIOSH, National

1 Institute for Occupational Safety and Health, and moved
2 to Washington, DC where I represented our institute in
3 Washington, DC for the next four years.

4 In 1992, I was selected as Deputy Director or
5 the number two person in the institute, moved to
6 Atlanta, Georgia where the institute's headquarters
7 were there and the Centers for Disease Control and
8 Prevention, and in 1993, '94 Acting Director of the
9 Institute until a new director had been selected by the
10 Administration, and at that time I reverted back to my
11 permanent position as Deputy Director.

12 I retired from government service in 1996. I
13 started teaching at Emory University from 1996 to 2002
14 and I taught a course on international aspects of
15 occupational environmental medicine, and I also started
16 consulting at that time, and I started testifying
17 legislative -- litigation such as I am here today
18 testifying, and I retired again when I moved further
19 north of Atlanta from Emory because it was too far to
20 drive, and I have been pretty much just doing private
21 consultation in litigation testimony at the present
22 time. I did not mention I have a PhD in Epidemiology,
23 also.

1 Q. That is very briefly, Doctor, with regards to
2 your educational background you mentioned you have an
3 PhD in Epidemiology. Is it also true you have an MSPH
4 from the University of Missouri in Epidemiology and a
5 BS from Central Methodist College in Zoology and
6 Chemistry?

7 A. Yes.

8 Q. You and I have worked together many times
9 before, correct?

10 A. Yes, we have.

11 Q. You and I have been in rooms with Mr. Tarry on
12 several occasions before talking about the very issues
13 we are going to discuss today?

14 A. Yes, we have.

15 Q. Have you been asked to -- back up a little
16 bit, I think you may have touched on this. You are, in
17 fact, a former Assistant Surgeon General of the United
18 States, correct?

19 A. Yes, I am.

20 Q. Is that a picture I have of you there holding
21 your certificate or diploma indicating that you are in
22 fact an Assistant Surgeon General?

23 A. That was taken the day I was promoted to

1 Assistant Surgeon General.

2 Q. Does your uniform still fit?

3 A. As a matter of fact, it does.

4 Q. Have you been asked to lecture and give
5 testimony regarding asbestos dangers in various parts
6 of the world?

7 A. I have.

8 Q. I have a picture on the screen. Can you tell
9 us a little bit about what this is, please?

10 A. This was several years ago I think 19 -- I
11 think 2002, or 2003, not quite sure. I testified
12 before a Senate committee on a bill that Senator Patty
13 Murray had put forth to ban the use of asbestos in the
14 United States. She had asked me to come testify in
15 support of her bill, and I did that at her request.

16 Q. Is much of the testimony that you are going to
17 give today, essentially, the same or similar to the
18 testimony that you give in the United States Senate on
19 that occasion?

20 A. Yes, it would be.

21 Q. Have you published articles in the peer review
22 literature with regard to asbestos and asbestos
23 hazards?

1 A. I have.

2 Q. In fact, you have published an article on
3 friction products and asbestos disease in the peer
4 reviewed literature?

5 A. Yes, I have.

6 Q. Doctor, the first thing I want to do is
7 briefly -- it is working. Talk about general concepts
8 of epidemiology. I don't intend for this to be an
9 exhaustive review of epidemiology. Touch on some
10 basics. On the slides I have general causation and
11 specific causation. Is it fair to say when we are
12 discussing general causation, that we are really
13 discussing association, or risk and maybe the term
14 cause is inaccurate?

15 A. I would say that's true.

16 Q. Is this concept of general association, does
17 it involve a determination of whether a particular
18 substance that's under consideration causes the effect
19 it's been studied?

20 A. That is one part. Yes, sir.

21 Q. And specific causation, however, is more of an
22 area, say, what Dr. Hammar was talking about when you
23 are discussing a particular individual's disease and

1 whether or not that exposure is attributable -- that
2 disease is attributable to a specific substance to
3 which an individuals is exposed?

4 A. Correct.

5 Q. You don't come into court and make specific
6 causation statements ever, do you?

7 A. No, I don't.

8 Q. You are not here today to discuss with Judge
9 Slight's specific causation issues?

10 A. No, I am not.

11 Q. You are here today to discuss association and
12 risk; is that fair?

13 A. Correct.

14 Q. When discussing general association or risk,
15 what types of data do you evaluate?

16 A. Well, in addition to the actual
17 epidemiological data from epidemiological studies,
18 before you go into the epidemiological studies, you
19 need to know what is known about a particular substance
20 that you are looking at, or risk factor that you might
21 be looking at. You are going to want to look at that
22 substance from several perspectives, such as
23 mechanistic processes, is it feasible that there are

1 mechanisms that can introduce the substance into the
2 body, where it can actually cause disease.

3 You want to look at things such biological
4 principles. Is the body going to react to a substance
5 that may be introduced into it.

6 You are going to look at molecular studies
7 talked about by Dr. Dodson and Dr. Hammar. You are
8 going to talk about toxicological studies. What do we
9 know about the toxicity of material that you might be
10 looking at? And you are also going to be very
11 interested in what animal experimentation has taught
12 us. We do animal experimentation because that is a way
13 to learn something quicker than waiting for
14 observations in humans. We can actually dose the
15 animals at very high doses, and get reactions that are
16 much quicker time. That is something you can't do with
17 humans ethically or otherwise.

18 So an epidemiologist needs to have training in
19 all these other fields, at least to understand the
20 fields, not necessarily to be an expert in each of
21 these fields, but the epidemiologist must take into
22 consideration all of the these other aspects in
23 determining whether there is an association that can be

1 later brought in to specifics to look at causation.

2 Q. You mentioned earlier to the Court that when
3 you were employed previously in your career you did
4 field work when you were with NIOSH on asbestos
5 exposure and asbestos disease. When you were doing
6 that field epidemiology work, are these the types of
7 data and factors that you took into your evaluation
8 process?

9 A. Absolutely.

10 Q. When you come before this court today to give
11 opinions about friction products, association and
12 risks; is that the type of data that you include in
13 your evaluation process?

14 A. Yes, it is.

15 Q. Is your evaluation process any different than
16 the reasonable scientific methodologies that are used
17 throughout the world by other scientists?

18 A. I should think not.

19 Q. Doctor, before I go any further, I forget this
20 question, someone has to tell me to do it at the end.
21 When giving your opinions to the Court today, will you
22 agree to do so in terms of reasonable scientific
23 probability?

1 A. Yes, I will.

2 Q. I want to go on. Let's talk a little about
3 bit about what a few types of epidemiology studies are.
4 I want to focus on three things. First, let's talk
5 about case reports. Define for the Court what a case
6 report is?

7 A. Case report is really a report of an
8 individual case, a series of individual cases that a
9 clinician may find of interest. It may present new
10 data, new findings, and they feel that it's of
11 significance enough they want to publish it, put it
12 into the peer review literature so that other
13 clinicians can look at that data and it may bring them
14 to the point of saying well, I had a case like that not
15 too long ago, and serves the basis of really helping us
16 to determine whether or not there is enough information
17 to go forward with looking for further association.

18 So the case report is kind of the basic
19 building zone upon which an epidemiologist starts in
20 looking at cause relationships. Now, there are some
21 cases I think in my presentation I put together for
22 this today we will talk about in rare situations where
23 case reports can have much greater meaning than in just

1 a case report of, say, a lung cancer, which is not a
2 very rare condition, but a more rare condition such as
3 mesothelioma, or angiosarcoma of the liver may elicit a
4 little more response.

5 Q. We will get to those slides in a moment. As a
6 trained epidemiologist who has practiced epidemiology
7 in the field, are case reports part of the world of
8 data that you must incorporate when trying to determine
9 if this is an association?

10 A. Absolutely.

11 Q. Talk next about case control studies. What is
12 a case control study?

13 A. Case control study is generally there is
14 several times, but generally a case control study is,
15 for example, if you have a group of disease -- you have
16 a disease. It is occurring in a group of people. You
17 may want you would pull all of these people together,
18 those would constitute your cases. Then you would try
19 and compare those cases with age, sex, race, and other
20 factors that would best describe comparison between the
21 cases, and the non-cases. Look for what the
22 differences are between the cases, and the non-cases.
23 This often times gives you the ability to sort out what

1 action may be the causation, or causing the case
2 because you are able to control out for the confounding
3 factors by matching these much as we do with the case.

4 So the case control studies are matching to
5 refine our causation and look more closely at what may
6 be the cause for control for external factors that can
7 sometimes contribute, but by matching we can do that
8 control much easier.

9 Q. You mentioned a term that I think is going to
10 be discussed quite a bit by both yourself and
11 Dr. Goodman. I want to define that you mentioned
12 confounding factors. What is a confounder; what did
13 that mean?

14 A. Confounder to me means anything that can alter
15 the results of your study, such as if you are looking
16 at a group of lung cancer cases. We know one of the
17 risk factors for that is cigarettes smoking. You would
18 want to try to control, if you were not looking for
19 cigarettes smoking, looking at other factors that might
20 cause lung cancer, can only control for the cigarette
21 smoking to eliminate that from being a contributing
22 factor. Anything that contributes to the cause of the
23 disease, and if you can eliminate those confounding

1 factors then you can have a much better idea of if
2 there is a true association, that true association
3 exists.

4 Q. Is it fair to say if the confounding factors
5 are properly addressed or eliminated in an
6 epidemiological study, that a result of that study
7 whether it is positive, negative, or null can be
8 affected?

9 A. Oh, yes. Very much so.

10 Q. Now, we have discussed case control studies.
11 Contrast, what a cohort study is?

12 A. Basically what a cohort, this is what I
13 started out on when I came into Public Health Service,
14 large cohort studies identify a group of -- just use in
15 my case we identified a group of asbestos workers that
16 worked in a plant in Pennsylvania, over three thousand
17 of these workers. And we looked at those that had one
18 year of exposure between 1940 and 1968, and then we
19 trace all those people to see what their vital status
20 is; are they alive or dead, up to a certain point in
21 time. Such as say if you follow them through '68, what
22 was their vital status in 1968.

23 Once you have done that, then you pull their

1 death certificates and you try then to compare and in
2 this case it is mortality study. There can be
3 morbidity studies looking at the incidence of disease;
4 in this case talking about a mortality study. Then you
5 would compare the cohort, or the group of asbestos
6 workers mortality with a group of non-asbestos workers;
7 and they would be matched on age, sex, race and many
8 confounding factors as you could, and then you would
9 see if there is an elevation, or a decrease in their
10 mortality, compared to that of the comparison
11 population. We call that in epidemiology, at least for
12 the mortality study, a life table analysis.

13 In other words, we take them through the same
14 as we would the comparison group, and try and determine
15 what their expected numbers of death would be at
16 certain points in time, and then we are able to
17 determine whether or not they have an excess or an
18 decrease and then we measure that statistically to
19 determine whether or not that excess is an statistical
20 excess, or a statistical deficit. We go both ways. We
21 call that a two-tail-type analysis. So that is
22 basically what a cohort study is. You can do this
23 thing, as I said, for morbidity, as well as mortality

1 in a cohort study.

2 Q. I went to law school because I don't like
3 science. Forgive me if I oversimplify this. Is it
4 fair to say association in epidemiological terms is
5 essentially measured through risk, a mathematical
6 formulas?

7 A. Measured through an -- I wouldn't call it
8 risk. I would say its association is major through
9 mathematical formulas. We usually use a certain type
10 of formula which is pretty much standard technology and
11 looking at cohort studies we generally consider that
12 they reflect a puissant distribution. That comparison
13 group usually that comparison group will be the United
14 States population or a State population, have the same
15 type of characteristic. So that's what we do is try to
16 measure associations statistically.

17 Q. Go through, briefly, what some of those
18 measures of association are that may be discussed in
19 some of the reports that His Honor has read and have
20 been submitted. Tell us what an odds ration is; how it
21 is used, how it is calculated?

22 A. Odds ratio is the comparison of odds being
23 exposed if you have the disease as to the odds of being

1 exposed if you don't have the disease. Probably one of
2 the oldest of our measurements, and we use this
3 generally to express the association or lack of
4 association in case control studies. It is oftentimes
5 used, it is an approximation of the relative risk, and
6 we will go to what relative risk is in a minute.

7 Relative risk is the incidence rate ratio, and
8 it talks about what the incidence of disease is in the
9 exposed group compared to the incidence of disease in
10 the unexposed group. We generally speak relative risk
11 when we look at cohort studies. It may be expressed as
12 a standard mortality ratio, if it is a mortality study,
13 or a standard incidence ratio if it is a morbidity
14 study. We generally use the relative risk in that
15 format when we are looking at the cohort studies.

16 Q. When we come up with numbers in our
17 calculations for relative risk, can you tell the Court
18 what those numbers mean?

19 A. Generally, this is a very simplistic analysis,
20 or a simplistic definition, but if the relative risk is
21 greater -- or equals one, generally we consider there
22 is no association. If it is greater than one, then
23 there is an association in a positive direction. If it

1 is less than one, there is association, but it is in
2 the negative direction. So that's a very simplistic
3 way to explain relatives risk.

4 Q. Now, we discussed previously with other
5 witnesses the disease mesothelioma, and the idea that
6 the expected rate of the disease for mesothelioma,
7 absent asbestos exposure, as Dr Hammar I believe said
8 is either zero or undefined?

9 A. Generally that's true. There are some
10 estimates that would bring it up to, I think Dr. Hammar
11 mentioned Huncharke Analysis that says it may be in the
12 neighborhood of less than one in a million. Others say
13 it could be high as one or two per million but in
14 general, until asbestos and the disease was identified
15 as being associated with asbestos, generally there was
16 no background, and I think a good example of this is in
17 Japan, the only place I know they have been looking at
18 comparing the relative risk or background of
19 mesothelioma by decades from as asbestos was
20 introduced. And as asbestos consumption went up in
21 Japan, so did the background level.

22 Q. When you have a rare disease such as
23 mesothelioma, is it unusual to find epidemiological

1 studies where a relative risk or some measure of
2 association was not calculated?

3 A. No.

4 Q. When you have a rare disease such as
5 mesothelioma, when the expected rate, absent exposure,
6 is zero, is it always a meaningful calculation or to
7 break it down in simple mathematical terms; do you have
8 a numerator divided by a denominator, which is zero?

9 A. You actually get, as I think Dr Hammar said
10 this morning, you are looking at Infinity. You really
11 can't make a measurement or come up with an accurate
12 relative risk. That is why the studies that
13 Dr. Selikoff and others have done do not express a
14 relative risk for mesothelioma.

15 Q. In fact, has it not been published in
16 literature by Dr. Selikoff and others in the studies
17 that the expected rate is, in fact, zero?

18 A. Dr. Selikoff has said that. Yes.

19 Q. Define for us, if you could, what a
20 Standardized Mortality Ratio is, or SMR is?

21 A. I think I did that already for you. It is
22 basically relative risk when we are looking at
23 mortality studies, comparison of the observed number of

1 deaths to the expected number of deaths.

2 Q. And what is attributable risk?

3 A. That is the amount of disease among exposed
4 workers that can be attributed to that exposure. In
5 other words, above what might be background, if there
6 is such a thing as background.

7 Q. Has it been published in the scientific
8 literature other witnesses in this area have testified
9 that attributable risk is also a key, or the key
10 measure of association for the relation between, say,
11 mesothelioma and asbestos?

12 A. I think that's true. Yes.

13 Q. Real quickly so I have built a complete
14 record. Define for us real quick what the statistical
15 significance, confidence interval, and P Value are?

16 A. Statistical significance is measured through
17 statistical tests to determine if, say the odds ratio
18 or the relative risk actually is happening by chance,
19 or it is very unlikely that it is happening by chance.
20 Usually we measure this at 95 percent confidence
21 interval. So if we Do that it is usually less than
22 five percent that it is going to occur by chance. That
23 is why we put a confidence interval in. We look at

1 what the confidence interval is surrounding the
2 relative risk and, generally, if the confidence
3 interval does not include one, it's either above or
4 below, does not include one, it can be considered as
5 statistically significant in what direction it's going;
6 either above. If you have a very wide confidence
7 interval, you generally have less confidence that it's
8 not occurring by chance. If you have a narrow
9 confidence interval, you can be more assured that it is
10 very unlikely it's happening by chance. But you have
11 to look, I believe in reality, at the confidence
12 intervals at both the bottom and the top in making an
13 association judgement, and you must say that a lot of
14 this is judgement. So the P Value then just measures
15 that confidence interval.

16 Q. I want to touch on something that was
17 discussed with Dr. Hammar before I go too far into your
18 testimony.

19 Mr. Tarry spend a lot of time asking
20 Dr. Hammar questions about accuracy, and he used a
21 reference from the textbook that Dr. Dodson and
22 Dr. Hammar have authored that recently came out,
23 specifically referenced page 241, which happens to be

1 part of Chapter 6, I believe which was authored by
2 yourself; is that correct?

3 A. Correct.

4 Q. Specifically, we were discussing the
5 references on page 241 to the Australia experience in
6 the 58 cases, et cetera, et cetera. You were present
7 in the courtroom. You remember all that?

8 A. Yes, I do.

9 Q. Were you present when Mr. Tarry was asking
10 Dr. Hammar questions about the inaccuracies of the data
11 presented in this textbook?

12 A. Yes, I was.

13 Q. I want to discuss that just briefly because if
14 we are going to discuss accuracies, let's make sure an
15 accurate record is presented to the Court. This book
16 just came out a little while ago. I just got my copy
17 less than ten days ago. Did you just write this ten
18 days ago?

19 A. No, this was a chapter written over a year ago
20 and it usually takes some time for a chapter to be
21 printed after you have written it. So the data in the
22 chapter is usually dated by the time book comes out.
23 There is need for revision when a book comes out. It

1 is true in most scientific publications, unfortunately.

2 Q. We mentioned briefly you published in peer
3 review literature an article entitled Asbestos in
4 Brakes; Exposures and Risk of Disease. It came out in
5 2004, correct?

6 A. I did.

7 Q. Was this chapter written before you wrote your
8 paper?

9 A. This chapter was written before I wrote the
10 paper.

11 Q. When you wrote -- as you wrote the chapter,
12 you got more information, and you wrote your paper?

13 A. Right.

14 Q. The discussion between the 58 cases, 43 cases;
15 was that information included in your paper when you
16 published it?

17 A. Yes, it was.

18 Q. When you got the galley proofs back from the
19 publisher, when did that occur, approximately?

20 A. That was several months before publication, I
21 would say, maybe five months or so, and I then added a
22 reference to the publication, 433, you can see in the
23 next paragraph. If you go to the reference in the

1 back, that refers to my new paper. So if the reader
2 were reading this, they would go to the new paper to
3 get additional information. They would see the new
4 numbers.

5 Q. In fact, when the language preceding reference
6 433 states that for a more detailed analysis, see
7 McDonald, et al and references your paper. Correct?

8 A. Yes.

9 Q. What was your purpose of including that
10 paragraph when you got the galley proofs back that you
11 had written some before?

12 A. You can't really change the galley proofs
13 substantially. What did I was added that sentence to
14 refer them to the new paper that I wrote that had more
15 updated information than was in the textbook. So the
16 reader could go, and as a matter of fact, I had over
17 700 references in this chapter, which is a lot of
18 references for a paper. It was to enable the reader of
19 this textbook where to go to get further information,
20 if they really wanted to study this in detail. That is
21 why the references are in there. That is why that new
22 reference was put in after I got the galley proofs
23 back.

1 Q. Since you published your paper in 2004, have
2 you gotten even more information about the data
3 included in the Henderson and Leigh study?

4 A. Yes, I have. I have been able to read the
5 deposition that was referred to this morning, and in a
6 recent affidavit that I did, a few weeks ago, I updated
7 that information and have put the new information in
8 that and if there is an update in this chapter, or if I
9 redo my paper, I will do that, but as I said,
10 scientific information is changing almost daily.

11 Q. We will get to your specific opinions, then I
12 believe Mr. Tarry was the one that was kind enough to
13 forward you Mr. Leigh's deposition?

14 A. Actually he was. It was from Mr. Tarry that I
15 was able to have the new information because normally,
16 the deposition would not be something that I would
17 normally read in the scientific literature.

18 Q. On your behalf when you wrote Chapter 6, there
19 wasn't any intent to mislead or leave out information,
20 was there?

21 A. No, sir.

22 Q. Your opinions with regard to the Australian
23 information have continued to evolve as you have gotten

1 more information?

2 A. Yes, they have.

3 Q. Let's go back, I want to get into the some of
4 the types of epidemiological evidence that you evaluate
5 when reaching your opinions and conclusions. We talked
6 about Dr. Checkoway's text earlier today. I want to
7 get back on the subject of case reports.

8 You say that case reports are information that
9 an epidemiologist should include in the evaluation
10 process. Tell us why, please?

11 A. I think case reports are important to include
12 because they give you a general idea of what's actually
13 being seen by the clinicians. And this information is
14 important for several reasons. One reason is that it
15 gives you a window in which to look at what the
16 clinicians are seeing that might be new and adds to the
17 information that you have already gotten from your
18 review of the past history of a particular disease, or
19 a particular substance.

20 Secondly, as Checkoway and his colleagues
21 point out in this textbook on research methods and
22 occupational epidemiology, that case reports when you
23 are looking at very rare diseases what we call Sentinel

1 diseases. That is a disease is caused -- generally has
2 one principal cause, maybe a few other causes,
3 generally recognized as one principal cause. The
4 institute I work for, NIOSH, actually I think kind of
5 invented that word sentinel disease. We put out a list
6 of occupational diseases that is were sentinel; for
7 example berylliosis is a sentinel disease for exposure
8 to beryllium. Asbestosis is a sentinel disease for
9 exposure to asbestos. Mesothelioma, because in men
10 about 80 percent of mesotheliomas have been traced to
11 an association with asbestos, is a sentinel disease for
12 looking at exposure to asbestos.

13 When you have very rare tumors like this, I
14 mentioned earlier angiosarcoma of the liver, that is a
15 very rare tumor that only a few cases have been
16 reported, all been reported and associated with vinyl
17 chloride exposures. When you get a case report of a
18 sentinel disease, they carry a lot more weight in the
19 epidemiologist's mind than do case reports of, say, a
20 very common disease.

21 Q. So is it fair to say then it is important to
22 make a distinction between the relative importance of a
23 case report in a rare disease, than the importance of a

1 case report when, say, a white Ford Taurus struck
2 someone and broke their leg?

3 A. In my opinion, yes. I think that's what
4 Dr. Checkoway and his colleagues were saying in their
5 textbook.

6 Q. We talked quite a bit today about Dr. Wagner
7 study in 1960 it was based on 33 case reports. I don't
8 want to revisit all that. I want to ask you about
9 something else Dr. Hammar talked about; therapeutic
10 radiation, that therapeutic radiation been accepted in
11 the scientific medical communities as a cause of
12 mesothelioma?

13 A. I think most of us that have been studying
14 mesothelioma for a good number of years would think and
15 accept that therapeutic radiation as a cause. When
16 they -- we don't have epidemiological studies, we have
17 enough significant case reports to allow us to make
18 that causation. If you look at textbooks in this area,
19 talking about therapeutic radiation as being associated
20 at least with the development of mesothelioma.

21 Q. So there is no epidemiological studies of
22 therapeutic radiation, only a series of 12 case
23 reports. Yet it is accepted within the scientific

1 community it is a cause of mesothelioma?

2 A. I think most would accept that. Yes.

3 Q. Let's touch briefly on the issue of specific
4 causation, which is not your area, but for a clinician
5 like Dr. Hammar. What is your understanding of the
6 type of information that a clinician has to look at in
7 order to make that causative statement?

8 A. Biggest information that a clinician needs to
9 look at is the epidemiological literature to start
10 with, what is known in the epidemiological literature
11 which are known in review publications, what do the
12 toxicological literature say. What does the
13 pathological literature say. What do the cellular
14 biologists say, then put that all in the context with
15 the epidemiology in putting together a determination of
16 specific cause. So epidemiology and these other
17 factors we talked about at the beginning of my
18 testimony today, are all important for the clinician to
19 look at.

20 Then the clinician needs to go into a history
21 of exposure. When a physician in the 1700s by the name
22 of Ramazini came about, he was what we call the father
23 of occupational medicine today. He added to the

1 Hypocrites had said about taking patient histories. He
2 said that you should add to take patient histories.
3 What occupation did you have, or what job did you do,
4 or what were you exposed to. It is important for the
5 clinician to look at history of exposure, and then to
6 look at latency of disease. I think Dr. Hammar talked
7 about that all of these things should be taken into
8 consideration by the clinician in making a specific
9 causation determination.

10 Q. You mentioned occupational history. Are you
11 familiar with the document called the Helsinki
12 Criteria?

13 A. Yes, I am.

14 Q. Can you tell us a little bit about that,
15 please?

16 A. Yes. The Helsinki Criteria was put together
17 by a group of scientists in Finland I think in 1998 or
18 somewhere in that neighborhood. I had previously been
19 asked by Finnish Government to chair a committee to
20 evaluate their asbestos program from 1990 to 1995 which
21 I did. One of our recommendations was to bring a group
22 of scientists together to look at what attribution
23 criteria should be put together for asbestos. Helsinki

1 Criteria did bring that a group together. I wasn't on
2 the group, it brought a group together out of our
3 recommendation to look at attribution criteria. The
4 scientists that were brought together had 100s if not
5 1000s of publications on asbestos. What they did was
6 sit down for a few days and looked at what should we
7 put together for a clinician to use in making
8 attribution for specific causation what is what the
9 Helsinki Criteria was.

10 Q. What does that say is the most reliable method
11 of attributing mesothelioma to asbestos exposure?

12 A. Occupational history, history of exposure and
13 occupational history.

14 Q. I want to get into now just talk about
15 chrysotile asbestos, in general, in the Bradford Hill
16 criteria as that pertained to chrysotile asbestos.
17 What is the Bradford Hill criteria or I am using a bad
18 words, what are the Bradford Hill considerations, I
19 think Dr. Hill said we shouldn't call them criteria?

20 A. Correct.

21 Q. Tell us what are the Bradford Hill
22 considerations?

23 A. This was something put together in 1965 when

1 Bradford Hill, a bio-statistician gave a lecture and in
2 that lecture, he was asked to put together what an
3 epidemiologist should consider when looking at
4 associations. He listed nine different criteria and
5 the criteria listed in this slide plausibility,
6 coherent, strength of association, et cetera, are the
7 nine that he put together. What he said that is very
8 important is that none of these nine should stand alone
9 by themselves, but that they are important
10 considerations to look at.

11 In today's world, they are some that are more
12 important than others. But in 1965, this was what he
13 thought epidemiologists should look at. There are
14 other considerations that have been put out, the
15 Surgeon General of United States has a similar set of
16 criteria they establish for when they put out the
17 smoking report in 1965, and others have put out
18 considerations, but I find this one to be rather an
19 exclusive one, and not the only one, by any means, but
20 one that you can use if you want to look at these nine
21 different areas.

22 Q. Are you the only epidemiologist in the
23 scientific community that's every used the Bradford

1 Hill considerations to determine association?

2 A. No, not at all.

3 Q. Is this a generally accepted reliable
4 scientific methodology within the scientific community?

5 A. I would say it is. I would say if Bradford
6 Hill were alive today, re-writing it he may make it a
7 little different with some of the associations, but in
8 general I think they would all hold up quite well, with
9 some modification.

10 Q. Have you published in the peer reviewed
11 literature your opinions applying the Bradford Hill
12 considerations to chrysotile asbestos?

13 A. I have.

14 Q. Just briefly tell us what is your conclusion
15 regarding chrysotile asbestos; does chrysotile asbestos
16 cause all asbestos diseases?

17 A. Yes.

18 Q. Let's run through them real quick. I do think
19 it needs to be in the record. Talk about plausibility.
20 I want to go through, let's define them then go through
21 and find out how they apply to chrysotile asbestos.
22 What is biological plausibility?

23 A. It's the assessment of whether or not the

1 theory that explains how an exposure causes a disease
2 is consistent with other known mechanisms of the
3 disease. I think as we look at asbestos and chrysotile
4 in particular, we will see how this fits.

5 Q. Tell us about coherence. What is coherence?

6 A. It addresses the issue of consistency and --

7 Q. Sorry --

8 A. Then we have strength of association.

9 Q. What does that mean?

10 A. It looks at the power of the study. Is the
11 power sensitive enough to really show a difference if
12 there is a difference one way or the other.

13 Q. Now you used consistency in your definition of
14 coherence. Consistency of the observed association is
15 its own separate consideration. Tell us what the
16 difference between the two is?

17 A. In the consistency of the observed observation
18 or association, it inquires as to whether or not the
19 proposed effect has been or can be observed repeatedly
20 after different circumstances, and I think that's the
21 main difference.

22 Q. Tell us about what is biologic gradient?

23 A. This is looking at issues such as dose effect,

1 did the increase in dose cause more disease, decrease
2 in dose cause less disease.

3 Q. How about experiment or experimental evidence,
4 tell us what that is, please?

5 A. This is basically relating to animal studies
6 and the studies in the laboratory, that would look at
7 associations between the substance you are looking at
8 and reactions to cellular or animal mechanism.

9 Q. Same type of information you referenced
10 earlier when discussing the world of data that
11 epidemiologists should consider?

12 A. Yes.

13 Q. Analogy. What is that?

14 A. Take also into consideration the
15 epidemiological and other studies as they are
16 determined whether or not if an analogous substance
17 such as in the case of asbestos caused adverse health
18 affects, might be looking at other fibers, other types
19 of substances similar to asbestos; and do they cause
20 health affects.

21 Q. How about specificity of the association.
22 Tell us a little bit about that, please?

23 A. Specificity is one that Bradford Hill may have

1 want to change if he came back because here it says in
2 his criteria that each cause has a single or logically
3 related similar effects. We know that chemical
4 exposures and cigarette smoking is a good example, can
5 have multiple effects. We know cigarette smoking not
6 only cause lung cancer, but kidney damage, it can
7 cause neurologic problems. I think the later Surgeon
8 General's report lists about 15 different conditions
9 that cigarette smoking can cause. It is not like
10 bacteria, generally cause one disease, and only one
11 disease. But with the new chemical nature that we are
12 living in, we often get multiple diseases.

13 Asbestos is a good example because it causes
14 asbestosis, it causes lung cancer, causes mesothelioma
15 and there is associations of other diseases along with
16 asbestos exposure. So this is one when I was talking
17 earlier that I think would be one that Bradford Hill
18 would probably change in his criteria, were he alive
19 today.

20 Q. Lastly, define temporality for us?

21 A. That is easy. It just means does the effect
22 occur after the exposure. And in the case that we are
23 talking about today, it meets that very easily.

1 Q. What I want to do now let's go through and
2 apply Bradford Hill's considerations for determining
3 association to the questions of whether chrysotile
4 causes mesothelioma and other asbestos diseases.

5 We are going to focus on mesothelioma. What
6 essentially is the application of these factors be the
7 same for asbestosis and lung cancer?

8 A. Yes.

9 Q. Talk about plausibility, does the Bradford
10 Hill considerations -- does plausibility, is it
11 satisfied under the analysis of chrysotile?

12 A. Based upon the analysis I did, yes, it is. I
13 can read these or I don't know how you, sir, would like
14 me to do that, or --

15 THE COURT: I can see them here if you want to
16 highlight them.

17 BY MR. SPILLANE:

18 Q. What can I do, absent objection, we can submit
19 a copy of the Power Point presentation of these into
20 the record?

21 MR. TARRY: No objection.

22 THE WITNESS: I could sit here and read them.

23 THE COURT: No need for you to do that, sir.

1 BY MR. SPILLANE:

2 Q. Let's talk about coherence. Is coherence
3 satisfied under the application for chrysotile?

4 A. In my opinion, yes, and the bottom one that
5 there is no biological argument why chrysotile is
6 incapable of causing mesothelioma is one I would
7 highlight in this one.

8 Q. This slide, is there any question anywhere in
9 the medical or scientific literature that chrysotile
10 asbestos causes asbestosis?

11 A. No.

12 Q. Is there any question in the medical and
13 scientific literature that chrysotile asbestos causes
14 human cancer?

15 A. No.

16 Q. How about cellular damage, genetic damage,
17 animal fibrosis or animal cancer?

18 A. No. These have all been shown in the
19 scientific literature to occur with exposure to
20 chrysotile, as well as amosite and crocidolite.

21 Q. Does the literature say it causes animal
22 mesothelioma?

23 A. It does.

1 Q. And is it your opinion that the
2 medical/scientific literature shows that chrysotile
3 asbestos causes human mesothelioma?

4 A. Yes, it does.

5 Q. Come back on that in a little while. How
6 about strength of association, is the Bradford Hill
7 strength of association element satisfied?

8 A. For chrysotile, yes, it is.

9 Q. I left that out of my question. That was an
10 important part of the question.

11 I want to stop here and talk about this a
12 little bit. We have it in here on mixed exposures to
13 chrysotile and amphiboles. What is important about
14 that, Doctor?

15 A. I think this is important because I -- this
16 morning you heard Dr. Hammar talking about cigarette
17 smoking in its relationship to asbestos exposure, and
18 how when you smoke, cigarettes and exposed to asbestos
19 it increases one's risk of developing lung cancer.
20 What we found when we looked at exposures to different
21 types of asbestos, that there is probably no doubt for
22 mesothelioma that on a dose by dose basis amphiboles
23 are most potent than chrysotile.

1 But in looking at what happens when you have
2 amphiboles together with chrysotile or the serpentines,
3 it appears from the epidemiological literature this is
4 more than just an additive effect, it is synergistic.
5 In other words, that you get more disease when you have
6 mixed exposure then you do from the individual
7 exposures to each of the fiber types alone.

8 This is one example. There is another example
9 in my presentation, a study by Acheson that shows the
10 same thing. This is a paper that Dr. Stayner and I
11 wrote. I guess this -- this is one that Dr. Stayner
12 and I wrote in 1996 that talks about that issue.

13 Q. We will discuss the Acheson article in a few
14 minutes. Yesterday, Dr. Dodson was questioned about
15 the Hodson and Darden article that states the relative
16 potency between chrysotile, amosite to crocidolite is
17 one 100 to 500. Is that universally accepted relative
18 potency in the literature?

19 A. I don't think it is at all. I think this is
20 one that is out there. There are several out there.
21 They tend to be one of the higher ones. There are
22 others that are lower. And I think we heard yesterday
23 EPA had one that was higher -- not EPA, but the

1 contractor.

2 Q. Aren't there animal studies, injection studies
3 that show that in animals chrysotile asbestos is
4 actually more potent or carcinogenic than crocidolite?

5 A. Absolutely.

6 Q. Is it fair to say -- it is pretty universally
7 accepted that amphibole asbestos is more potent than
8 chrysotile, but what that relative potency is in
9 somewhat in dispute?

10 A. I think when you say that you have to keep in
11 mind that is only for mesothelioma. The evidence is
12 not for asbestosis, it is not for lung cancer, but it
13 is only in the area of mesothelioma that that potency
14 difference seems to occur. When we look add it we did
15 not find a difference in lung cancer, we didn't find a
16 difference in asbestosis.

17 Q. Thank you, Doctor.

18 Even without mixed exposures, are there
19 epidemiological studies of chrysotile with no
20 contamination, or no proven contamination that showed
21 elevated risks of mesothelioma?

22 A. There are very few. What few do exist would
23 indicate that even chrysotile alone, in the human

1 epidemiological studies, can cause mesothelioma.
2 Unfortunately or fortunately, I don't know just
3 neutrally, most commercial forms of chrysotile are
4 contaminated with amphibole, either tremolite
5 or anthophyllite type of asbestos. There are some
6 populations that shown on this slide here that have
7 looked at populations that are considered to be
8 amphibole contaminated free, very limited to their
9 contamination, if any.

10 Q. Are there studies of individuals who have had
11 mixed exposures but predominantly chrysotile exposure
12 that show an increased risk for development of
13 mesothelioma?

14 A. Yes, on this next slide lays out three of
15 those.

16 Q. How about biological gradient, is that
17 consideration satisfied for chrysotile asbestos?

18 A. Yes, it is. We do know that all of
19 mesothelioma tends to be a dose dependant disease. I
20 think as Dr. Hammar said this morning, it is recognized
21 that lower doses are capable of causing mesothelioma
22 then they are for causing asbestosis and lung cancer,
23 but even that, we know that it is dose dependent, I

1 think Dr. Rogers sums that up in this when he says
2 "like other forms of asbestos, there is an increased
3 risk of mesothelioma with increased exposure to
4 chrysotile."

5 Q. Next category is experimental. We talked
6 about experimental evidence. Is that consideration
7 satisfied for chrysotile asbestos?

8 A. Yes.

9 Q. How about analogy. Is analogy satisfied?

10 A. Yes.

11 Q. Specificity?

12 A. Yes.

13 Q. How about temporality?

14 A. Yes.

15 Q. You have to have exposure before you can have
16 the disease?

17 A. Correct.

18 Q. Is the United States the only country that
19 recognizes chrysotile asbestos is hazardous?

20 A. No, not at all.

21 Q. This is not a unique position taken by
22 scientists in the United States?

23 A. No, we have now seen some 30, I think the

1 latest is about 30 countries that have banned the use
2 of all forms of asbestos. The United States has not
3 done that yet. That is what Senator Murray's bill
4 would do, but this country is still allowing some
5 amount of asbestos to be used. I think that will stop,
6 but almost all of the western countries and Europe, as
7 you can see on this global map, and others, have
8 stopped the use of all forms of asbestos, including
9 chrysotile.

10 Q. Now, obviously you were with the United States
11 Public Health Service. You were at NIOSH. The types
12 of information you were discussing, we briefly went
13 through the chrysotile asbestos. Did it include
14 toxicological studies?

15 A. Yes.

16 Q. Did it include experimental animal studies?

17 A. Yes.

18 Q. Did it include human data?

19 A. Yes, it does.

20 Q. Did it, in fact, include case reports?

21 A. Yes, it does.

22 Q. All of the information that you discussed
23 earlier, that you included in your analysis, is that

1 the same type of information and analysis that was
2 employed by scientist in regulatory agencies throughout
3 the world?

4 A. Yes, it is.

5 Q. In fact, Doctor, are there not all of these
6 governmental agencies that I listed on the screen, have
7 all of them issued statements that chrysotile causes
8 mesothelioma?

9 A. They have.

10 Q. Does that include OSHA?

11 A. It does.

12 Q. NIOSH?

13 A. Yes.

14 Q. International Agency for Research on Cancer?

15 A. Yes.

16 Q. United States Consumer Products Safety
17 Commission?

18 A. Yes.

19 Q. National Toxicology Program?

20 A. Yes.

21 Q. United States Department of Health and Human
22 Services?

23 A. Yes.

1 Q. American Cancer Society?

2 A. Yes.

3 Q. World Trade Organization?

4 A. Yes.

5 Q. Agency for Toxic Substances and Disease
6 Registry?

7 A. Yes.

8 Q. National Academy of Sciences?

9 A. Yes.

10 Q. Surgeon General of the United States?

11 A. Yes.

12 Q. World Health Organization?

13 A. Yes.

14 Q. How about the Environmental Protection Agency?

15 A. Yes.

16 Q. Now were you present in the courtroom
17 yesterday when this Eastern Research Group report came
18 up?

19 A. I was.

20 Q. There was discussion about that being prepared
21 for the EPA. It was acknowledged that is not the EPA's
22 position on chrysotile; is that true?

23 A. That is true.

1 Q. What is the EPA's current position on
2 chrysotile asbestos?

3 A. Well, the last I knew, is that they consider
4 all forms of asbestos, including chrysotile, capable of
5 causing asbestosis, lung cancer, and mesothelioma.

6 Q. Now, it is your opinion that chrysotile
7 asbestos causes all forms of asbestos disease,
8 including mesothelioma. Correct?

9 A. That is my opinion.

10 Q. In reaching your opinion, did you use the --
11 evaluate much of the same data, use the same
12 scientifically reliable methodologies that scientists
13 throughout the world have used in reaching their
14 conclusions?

15 A. I did.

16 Q. Is there anything unique about the information
17 you looked at, or your methodologies in reaching your
18 conclusions?

19 A. No.

20 Q. Is it the same type of information and
21 methodologies used outside of a legal context?

22 A. Absolutely.

23 Q. Real quickly, consistency; is that

1 consideration satisfied?

2 A. In my opinion, yes.

3 Q. And, again, consistency means has the proposed
4 affect observed repeatedly under different
5 circumstances?

6 A. Yes, that is why I have listed here, various
7 studies that have shown chrysotile causing disease in
8 various situations, such as among miners, textile
9 workers, friction products manufacturers and users and
10 cement manufacturers.

11 Q. You mentioned friction products manufacturers,
12 but also have there been reports in the literature
13 about friction products users, i.e., mechanics
14 developing mesothelioma?

15 A. Yes, there have, in my paper I listed some
16 over 165 I think at the time, different reports of that
17 occurring.

18 Q. In fact, was there not a letter that you
19 submitted to Dr. Tata, not, in fact, submit a letter to
20 the editor where she pointed in her letter there might
21 be an additional 40 reports that were not included in
22 your paper?

23 A. Correct.

1 Q. Briefly, we will wrap up on chrysotile in
2 general, using and epidemiological analysis of
3 chrysotile, it is your opinion that chrysotile is, in
4 fact, a cause of all asbestos diseases, including
5 mesothelioma?

6 A. That is my opinion. Yes.

7 Q. Chrysler has come into court and argued that
8 absence occupation specific epidemiology standards that
9 meet a standard they have set forth, you can't say that
10 chrysotile from friction products causes disease. Do
11 you agree with their position?

12 A. No, I don't. I don't think that the job
13 category is the only factor to look at. I think that
14 what we are looking at, if there is exposure, and if
15 that exposure is to asbestos and that exposure is
16 respirable asbestos, it can added to the risk of your
17 body's burden of asbestos putting a person, or groups
18 of persons, in an increased risk. It is not the job
19 title, it is the exposure.

20 Q. In fact, that is a phrase that is repeated
21 throughout the medical literature; you did not make
22 that, up did you?

23 A. No I think the first time I heard that was

1 probably from Dr. Selikoff when I was working on -- I
2 was -- when I was with NIOSH I was in charge of some of
3 the grants that he had. I think he was always talking
4 about not the job, it's the exposure. And I think
5 Dr. Selikoff is probably the first person that really
6 pounded that into my head, don't look just at jobs,
7 look at the exposure.

8 Q. You agree with that statement?

9 A. I do very much so.

10 Q. And would you agree with that statement that
11 is as it applies to users of asbestos-containing
12 friction products that it is not their job title that
13 will determines whether or not they have disease, it is
14 the exposure that they get from the use of those
15 products?

16 A. Yes, I think you can have, such as you have
17 with friction products where you have, in general,
18 exposures are fairly low compared to insulation workers
19 or other workers with asbestos. There are those few
20 friction workers that have high exposures. The
21 literature documents that these high exposures exist.
22 There are epidemiological studies that show people with
23 those exposure concentrations develop disease.

1 Q. Is the fact that maybe someone who uses
2 calcium silicate pipecovering on a daily basis may have
3 a higher rate of disease than someone that uses
4 asbestos-containing friction products, does that mean
5 that a brake mechanic is not at an increased risk for
6 disease?

7 A. No.

8 Q. Simply because his number is not as high as a
9 pipe insulator?

10 A. No. What it really means is that the pipe
11 insulators generally have been exposed to higher
12 concentrations, but so have some of the brake workers,
13 because in some cases where they have blown the
14 material with high pressure hoses, and their exposures
15 are quite high, but on average they happen to be lower.

16 Q. Now, have you talked about part of your
17 analysis includes looking at epidemiological studies.
18 Are all epidemiological studies the same?

19 A. No.

20 Q. Are there limitations on some epidemiological
21 studies?

22 A. Yes, most epidemiological studies do have
23 limitations. It is the exceptional epidemiological

1 study that does not have a limitation.

2 Q. Can some of these limitations also be
3 considered confounders?

4 A. Very definitely.

5 Q. Tell us some of -- describe or walk us through
6 some of the study limitations that you have put on this
7 screen slides you prepared for us?

8 A. Some of the most common ones you find in
9 occupational studies are inclusion criteria. I have
10 seen and where when you look at a job title, you may
11 include people that have that job title, but don't
12 actually carry that out of the plant. You might
13 include people that are in that occupational group that
14 are actually secretaries, or people that work on the
15 periphery. So unless you really observe what the job
16 title or the occupational category means, you may be
17 including people in your study that really are not at
18 the risk of developing disease.

19 In other words, they are not exposed. That is
20 why when we are doing these types of studies at NIOSH
21 we went into the field. We observed what the person
22 did during their work day. We knew whether or not they
23 were exposed or not exposed. So many epidemiological

1 studies don't take that into consideration. They
2 include everybody that has the title of mechanic, for
3 example, or auto workers, and there are many sub-jobs
4 that fit into these categories of people that don't
5 actually have exposure to, in this case, brakes. They
6 might be an auto mechanic, they never have exposure to
7 brakes.

8 So inclusion criteria can often cause a large
9 confounders by including people that are not at risk,
10 because they are not exposed. Latency, another one,
11 looking at populations that have a latency of, say,
12 less than ten years. You wouldn't expect them to be at
13 risk of developing a disease like mesothelioma because
14 we know from previous epidemiology that it is a disease
15 that usually takes 20, 30, 40 years to develop. So why
16 would you look at a population that had 70 percent of
17 the workers with less than ten years latency. What
18 that would do would be to dilute the overall effect
19 making your risk of disease very low, and would
20 obliterate really the small persons that had the longer
21 latencies by including shorter latencies with them. I
22 hope I am being clear on that.

23 Exposure is another group. It kind of fits

1 into the inclusion criteria, that is you don't want to
2 include people --

3 THE COURT: Let me just -- are you saying that
4 the selection of the subjects for the study can be
5 skewed or can skew the results depending on the latency
6 period, meaning you include people who have a more
7 recent temporal exposure?

8 A. Correct.

9 Q. That will skew the results?

10 A. Yes, generally bringing results down lower.

11 BY MR. SPILLANE:

12 Q. Dr. Lemen on that subject, can you also skew
13 the results with regard to latency by not following
14 your study group long enough and allowing disease a
15 chance to develop?

16 A. Absolutely. I think a perfect example of that
17 is a study that I was an author on in 1971, that we
18 published of the friction textile plant in
19 Pennsylvania. We had when we published in '71, we had
20 zero mesothelioma. We updated that study and included
21 another ten years latency, and after that we had 17
22 mesotheliomas. So I think you have to make sure you
23 have enough latency to observe the effects. And so you

1 can do that by cutting off your observation period
2 before you have had enough latency to observe an
3 effect.

4 Q. I apologize, I interrupted as you were about
5 to move on and continue.

6 A. Next one power. Depending on the rarity of
7 the disease. I think power is very important in brake
8 studies. Here is a population in general have low
9 exposures to asbestos. You are going to need a much
10 larger population of people actually exposed to bring
11 the power up enough to actually show there is an affect
12 if there is an affect. In other words, if the
13 exposures are low, you have generally got to have more
14 people in your population that have actual exposure to
15 be able to determine if there is an affect, or not an
16 affect. Do you understand?

17 THE COURT: I am following.

18 THE WITNESS: Please stop me if I am not doing
19 it the right way.

20 THE COURT: Thank you.

21 THE WITNESS: I think those are the things
22 that are really -- those are some of the things that
23 really come out as strong confounders that one must

1 look at in evaluating epidemiological studies.

2 BY MR. SPILLANE:

3 Q. You have evaluated the epidemiological studies
4 that have been purported to study exposures and
5 association of users of asbestos-containing friction
6 products; is that correct?

7 A. Yes, I have.

8 Q. Do many, if, in fact, not all of the studies
9 in that area suffer from some, or multiple of these
10 study limitations or confounders?

11 A. Yes, they do.

12 Q. We will go through those and discuss those. I
13 want to talk now next about the idea of lack of
14 epidemiological studies. Can you discuss with us why
15 there may not be as many or epidemiological studies as
16 one would like to see?

17 A. I think I have to go back in time and go back
18 into the history of work that I did at NIOSH. In 1975,
19 or thereabouts, Dr. Selikoff contacted our institute
20 about brake workers and brake exposures. At the time
21 he brought the brake manufacturers -- NIOSH brought the
22 brake manufacturers and people from Dr. Selikoff's
23 laboratory together for a meeting in Rockville,

1 Maryland. And at that meeting we asked them to present
2 the data that they had. Dr. Selikoff presented data
3 from his laboratory, I think we will discuss in a few
4 minutes. That showed there were exposures in the brake
5 mechanic area that should raise our concern about the
6 possibility of disease occurring in that population.

7 The brake companies did the same, and as a
8 result, NIOSH put out what we call a current
9 intelligence bulletin. We put out a warning to all the
10 brake mechanics in the United States, here is this
11 information. It looks like exposures can be quite high
12 in some areas of brake work areas and here is what we
13 think you ought to do to reduce exposures, because the
14 main thing in reducing asbestos disease is to reduce
15 the dust.

16 The lower you can get the dust that contains
17 the asbestos down, the lower the risk of developing
18 disease. We put out a brochure and sent that to as
19 many of the brake mechanics as we could. What we
20 didn't do is we looked at the feasibility of doing a
21 study because of, in general, lower exposures and the
22 fact that most brake workers were in small shops would
23 be -- they would suffer from so much difference in

1 homogeneity, each shop was different, each workplace is
2 different.

3 And we decided that we wouldn't do a study
4 because; one, the cost of the study would be
5 prohibitive; and secondly, if we put out what we knew
6 about asbestos already; that is reduce exposures, don't
7 use air hoses to blow out the dust, use vacuums to
8 vacuum it out with filters on it that would keep the
9 dust out, we could reduce the risk without having to
10 spend large amounts of money to do the epidemiological
11 studies to come up with evidence. In other words, we
12 did not want to wait and count the bodies or count the
13 people that had disease before we acted.

14 So what we did is put this out. I feel that
15 in 1975 by doing that we reduced exposures even more.
16 We reduced ability then to really find suitable cohorts
17 to really study this problem. I think we are suffering
18 today because if you look at the brake worker cohort
19 studies, the ones that started -- did not start until
20 after really, the majority that we talked about today,
21 in litigation, or once it started in the '90s or after,
22 most of those, I believe, were started due to
23 litigation activity, just because everybody said you

1 had to have epidemiology. I don't think you have to
2 have the epidemiology if you already have the proof
3 that asbestos causes disease at certain exposures.
4 That is what our institute took.

5 We don't do exposures because several reasons;
6 cost, inadequate personnel do the studies, lack of
7 suitable cohorts, because of the inability to control
8 for the confounders. These are all factors that are
9 resulted in very few studies of brake workers being
10 done.

11 Q. I want to make sure I am clear when you were
12 working with the agency, a decision was made not to do
13 an epidemiological study of brake mechanics, it wasn't
14 made because you did not expect to see disease in brake
15 mechanics?

16 A. No, we put out a bulletin showing that we did
17 expect to see disease, as long as these preventative
18 measures were not put in place.

19 Q. The fact that medical literature and peer
20 review literature binders at local medical schools are
21 not busting with epidemiological studies of occupation
22 specific brake workers; in your opinion does that mean
23 that they don't get disease or they are not at an

1 increased risk for disease?

2 A. No, not at all.

3 Q. Take a step back. We have been talking a lot
4 about mesothelioma and cancers. Let's talk about
5 non-malignant lung disease. Is it your opinion that
6 brake workers or users of asbestos-containing friction
7 products are n at an increased risk of developing
8 non-malignant disease?

9 A. Yes.

10 Q. Tell us why?

11 A. Several studies listed here, this is one from
12 Dr. Selikoff's group that first brought our attention
13 to this. This is a study about where they examined 104
14 vehicle maintenance workers, they found 29 percent or
15 little over a 4th with decreased vital capacity,
16 another 4th had chest x-ray abnormalities that were
17 consistent with asbestos-related disease, and both
18 chest x-ray, restrictive lung function tests showed
19 greater abnormalities after 20 years showing more
20 exposure they had in this work area, the greater the
21 disease symptoms and signs were increasing.

22 So this is one study that shows a nonmalignant
23 disease response in workers consistent with what we

1 know about asbestos-related diseases.

2 Q. It the Nicholson study also an additional
3 study that you rely on?

4 A. Yes, this is another one of the Selikoff group
5 of studies, showed greater prevalence and x-ray
6 abnormalities in garage mechanics who repaired brakes I
7 think that is important who repaired brakes because
8 many of the epidemiological studies that have been done
9 to date that have looked at so-called brake repair
10 workers looked at the rubric garage mechanic and they
11 never defined they do brake work or don't do brake
12 work. Selikoff's group actually looked at garage
13 mechanics who repaired brakes, and compared them to
14 blue collar controls, or to other garage workers that
15 did not repair brakes.

16 They found that this was greater prevalence of
17 x-ray abnormalities in that group that did the break
18 work. And we will talk about this, I think, a little
19 bit later, but the epidemiological studies that have
20 been done, as I said, generally don't define them down
21 that fine. They generally define them as garage
22 mechanics, or vehicle mechanics. They don't ever say
23 they did brake work. They just put them in that

1 category.

2 Secondly, Selikoff's group then found
3 significant excessive seen in workers who ground, and
4 machined the brake linings prior to their installation
5 on larger vehicles. We often hear that that does not
6 occur, but we found and Dr. Selikoff find, both of our
7 groups found, in going into the garages where brake
8 work was done, often times they did have to grind the
9 brakes to make them fit properly. They did not all
10 come ready made, even though supposedly they are
11 supposed to.

12 And then, lastly, the x-ray abnormalities
13 tended to occur in those that did have the asbestos
14 exposure.

15 Q. Not all of the studies that you rely on were
16 done by Selikoff in the time frame?

17 A. No, those are 2 that are done by the group.

18 Q. You have a slide prepared on a study that was
19 done in 2003?

20 A. Yes, this is a study that came out recently,
21 that showed evidence of asbestos exposure, and lung
22 function changes occurring in people that were exposed
23 to asbestos in brake linings. And, again, looking at

1 people actually working with the brakes, not putting
2 them in a category of vehicle mechanics, or motor
3 mechanics, but people that actually had hands-on work
4 with the brakes.

5 Q. Let's shift gears here a little bit. Talk
6 about the different types of epidemiological studies,
7 on the uses of asbestos. Can you tell us about the
8 different types of studies that do exist.

9 A. One of the things that I have done in my
10 career is looked at a history of asbestos usage, and by
11 all estimates there are at least three thousand
12 different applications. When we, at NIOSH, did our
13 occupational exposure surveys, we found 377 different
14 occupational groups that existed, and that of those 200
15 had exposures to asbestos in some form or another.

16 And each group had multiple specific job
17 titles. So there wasn't one job title for each of the
18 asbestos exposures but there were multiple job titles.
19 And we also found in looking at that that only a small
20 number of these have been studied epidemiologically.
21 When you look at asbestos you can probably break it
22 down and say that less than a dozen of the job
23 categories have adequately been studied; out of the 200

1 categories that we were looking at of job titles.
2 Raise that to 377 occupational groups, but probably a
3 dozen or a little bit more than a dozen have ever been
4 studied in the history of asbestos. That means there
5 are some, you know, 190 or 180 still out there that
6 have never been studied.

7 Q. As a trained epidemiologist who has practiced
8 field epidemiology, is it your opinion if an
9 occupational title has not been studied yet, those
10 individuals are exposed to asbestos in the workplace
11 above environmental levels, they are not at an
12 increased risk?

13 A. Not at all. That is why what I think what
14 Dr. Selikoff said earlier, what I have learned in my
15 career that it is not the job title, it is the exposure
16 within the job title.

17 Q. Talk briefly about the specific occupations
18 that you prepared slides on that have shown increased
19 risks. Now, I don't see friction workers or garage
20 mechanics on there. In your opinion, does that mean
21 that garage mechanics, or users of asbestos-containing
22 friction products that are exposed at levels above
23 environmental exposures where disease has occurred, has

1 been reported in the literature, they are not at an
2 increased risk of developing disease?

3 A. Not at all. They are not at the same
4 increased risk as say insulation workers, or
5 boilermakers, people that have traditionally the whole
6 work force exposed to extremely high levels of
7 asbestos. They just don't come up on the radar screen
8 that way. There are exposures in the brake area that
9 have high enough and get into the same levels of those
10 other exposures that develop disease. It does not mean
11 they are not going have disease because they don't fall
12 into this listing that we put together in our surveys.

13 Q. Last thing before we move on. Are there
14 epidemiological studies of specific industries that
15 show increased PMRs?

16 A. Same is true as with jobs, and these are from
17 that same survey where we looked at the 200 different
18 job titles, I think it was 377 different occupational
19 groups. And these are just the ones that came up with
20 the highest risks, but they had the highest exposures,
21 also, in general. And most people in those job
22 categories were exposed, compared to vehicle mechanics
23 where you have a lot that are not exposed.

1 Q. I want to touch briefly on something you have
2 on your slide ship and boat building and repair. That
3 is not talking about the guy that repairs the canoe on
4 the corner shop?

5 A. No, we are talking about major shipyards.

6 Q. Did the fact you don't have on your slides the
7 automotive industry mean, in your opinion, that users
8 of asbestos-containing friction products who are
9 exposed to chrysotile asbestos are not at an increased
10 risk of developing asbestos disease?

11 A. No, not at all.

12 MR. SPILLANE: This might be a good time to
13 break.

14 THE COURT: Take our afternoon recess. We
15 will break for ten minutes, return at 20 'til.

16 (A short recess was taken.)
17
18
19
20
21
22
23

1 MR. SPILLANE: Thank you, Your Honor

2 BY MR. SPILLANE:

3 Q. All right, Dr. Lemen, we have been spending a
4 lot of time mentioning exposures and doses, that's the
5 area I want to go to next is mesothelioma asbestos
6 disease and dose response.

7 Are asbestos diseases does response diseases?

8 A. Yes.

9 Q. What does that mean?

10 A. That means that the more exposure you have the
11 higher the risk of developing disease.

12 Q. And there's a paper that you and I have
13 discussed before the Watsonville papers published in
14 1998, can you tell us a little about what that paper
15 said and why that's significant for you?

16 A. This is one of the few papers that has looked
17 at low dose exposures for mesothelioma. This paper is
18 mixed exposures to asbestos. That is, it is not just
19 chrysotile but it is to amphibole also.

20 And what it has done is actually to break down
21 the exposure categories into relatively low dose
22 exposures. For example, the ranges are on the slide
23 are .001 to .495 f/cc, next .5 to .599 f/cc, etc., and

1 on up.

2 Very few papers have been able to do this and
3 the graph of the writing actually illustrates the
4 findings that they found as the exposure number of
5 fiber exposures per year went up, the odds ratios went
6 up. For example, in the 0.01 to .495 f/cc years, the
7 odds ratio was 1.2. It didn't show significance
8 because the confidence interval was .8 to 1.8. But as
9 the exposure then went up into the area of .5 to 9.99
10 f/cc years, the odds ratio increased to 4.2 with a 95
11 degree confidence interval being 2.0 to 8.8.

12 And the next exposure level 1 to 9.9 fibers,
13 the odds ratio went up to 5.2. When it got greater
14 than ten fiber per cc years it went up to 8.7. So this
15 is a very good graphic illustration, I think, of how
16 dose response works; and for mesothelioma how it works
17 at the lower concentrations.

18 Q. And this idea of dose and dose response, are
19 we talking just an individual dose or are we talking
20 about cumulative doses?

21 A. We're talking about cumulative dose. And
22 that's why it's measured in fiber per cc years as
23 opposed to fibers per cc.

1 Q. Now you mentioned that this was a mixed
2 exposure study, both amphiboles and chrysotile. What I
3 want to touch on is that concept, right now, of mixed
4 exposures.

5 Are you familiar with the paper that
6 Dr. Nicholson exposed in 1982 on occupational exposures
7 to asbestos?

8 A. Yes.

9 Q. In that paper, did Dr. Nicholson discuss the
10 average years of employment for somebody who works as
11 an automobile mechanic and is thus being exposed to
12 asbestos from those products?

13 A. Yes, he did.

14 Q. And I believe in the paper he says that in the
15 1940s the average years of employment in that industry
16 was about two and a half, 2.7 years before they moved
17 on to other trades?

18 A. Somewhere in that neighborhood, and he was
19 looking at garage mechanics in small job operations,
20 generally.

21 Q. Now I think he then went in the 50s it was 6
22 years, the 60s 7.7 and the 70s seven years?

23 A. Right.

1 Q. But is that important when we're discussing
2 exposures to users of asbestos products the fact that
3 they may only be in that industry on average a
4 relatively small amount of years, but then move onto
5 other trades where they add to their cumulative
6 exposure in other trades?

7 A. It's very important for that reason, because
8 not only do they have the brake exposure they could go
9 into other industries where other asbestos exposures
10 occur causing them to have exposures to other types of
11 asbestos or other types of materials. But it gives
12 them a greater opportunity of having mixed exposures as
13 compared to say an insulation worker that generally
14 stays in that career the majority of their working
15 life.

16 Q. Isn't it appropriate as a scientist using
17 scientifically reliable methodologies to ignore those
18 exposures that they got from asbestos containing
19 friction products if they develop a disease when
20 determining the association or causing that disease?

21 A. In my opinion not at all. And that's why I
22 think I wanted to put in my presentation, which we're
23 looking at today. The idea that studies have shown

1 that mixed exposures are very significant.

2 So a brake worker, if you take all the other
3 exposures out that's one exposure, but if you look at
4 the mixed exposures and add the other exposures, that
5 brake exposure is one area after exposure that adds to
6 the total body burden.

7 It may not be the only exposure, but it adds
8 to that. And without that exposure the body burden
9 would be less and therefore the risk would be less.

10 Q. And when we talked earlier, real briefly, you
11 mentioned the Acheson study is the Acheson study
12 another study that shows the idea of this mixed
13 exposure of increased risk?

14 A. I actually think the Acheson study probably
15 shows it graphically better than our own study that I
16 talked about in 1996. His study was in '79 where he
17 showed the relative risk was one for no asbestos in the
18 lung tissue; and the relative risk was six for
19 chrysotile in the lung tissue.

20 For amphiboles it jumped up to 12, but then
21 when you looked and found both chrysotile and
22 amphiboles that risk jumped up to 61, which, as I said
23 earlier, is much more than additive, it is actually a

1 synergistic effect. In other words, the two together
2 equal more than the sum of the two together.

3 So it is important that mixtures act in
4 increasingly exposure response.

5 Q. Now, we talked about the idea of whether it is
6 appropriate or not to ignore exposures say from
7 asbestos-containing friction products compared to other
8 exposures. Are you the only scientist that has that
9 opinion?

10 A. No.

11 Q. Now, we talked a lot about Dr. Henderson
12 earlier with Dr. Hammar. What does Dr. Henderson say
13 about whether or not it is valid to exclude one
14 exposure or the other?

15 A. Well, as it is quotes right here and I'll read
16 it: When one is faced with multiple exposures to that
17 asbestos the following points emerge: Specifically
18 from mesothelioma induction provided that the
19 characteristics and time for each exposure are
20 appropriate for a biological effect, one, it is not
21 valid to point to one exposure among the others and
22 incriminate it as the sole cause of mesothelioma with
23 exoneration of the other exposures. Two, it is not

1 valid to point to one exposure and exonerate it from a
2 causative role in the development of mesothelioma and
3 to incriminate all the others.

4 In such circumstances, it is not the presence
5 or absence of an effect that is in question, but the
6 magnitude of each effect and proportion to the others.

7 Q. Now, you were present in the courtroom when
8 Dr. Hammar testified is this kind of getting into the
9 area that he discussed that nobody can really say which
10 specific exposure or fiber actually started the
11 carcinogenic process but that they all in a cumulative
12 nature contributed to the disease?

13 A. Yes.

14 Q. On a very simplistic level, me as a lawyer,
15 have you heard it referred to as each and every
16 exposure contributes to the disease?

17 A. Yes.

18 Q. And is that -- not necessarily that phrase,
19 but that concept -- something that you agree with?

20 A. It is.

21 Q. All right. Now, let's get into the types of
22 exposures that the medical and scientific literature
23 says that automobile mechanics actually receive when

1 using these products.

2 But before we want to get there, I want to
3 talk about how they are exposed. And I want to talk
4 about, as I understand it, there's two ways that they
5 are exposed. Can they be exposed both in installing
6 new linings as well as removing old?

7 A. Correct.

8 Q. Can you tell us a little about that and how
9 they are exposed?

10 A. Well, in the new linings they are exposed by
11 manipulating the new brake pads. That is, they may
12 have to cut them, they may have to grind them, they may
13 have to Hammar them or shape them in ways to fit.
14 Sometimes they don't have to do anything to them, other
15 times they do. So there can be exposure from those
16 particular activities.

17 And the second area where they are removing
18 the breaks, often times they get stuck and they have to
19 pry them out, they have to Hammar them out, sometimes
20 chisel them out to get all of the used brake pad away.

21 And they also have to clean out the brake drum
22 itself, and through those two processes they can get
23 exposure to asbestos. Even though some have talked

1 about the changing nature of the fiber and to a
2 nonasbestos form fibers -- nonfibrous material called
3 fosterite. All of the studies have indicated that
4 there still is some of the asbestos left in tact in the
5 brake drum.

6 Q. And I want to touch briefly on this idea of
7 fosterite. During the exposure that occurs during the
8 grinding or beveling before the brakes are installed
9 has there been any conversion of any of the chrysotile
10 to fosterite?

11 A. No, you're talking about an asbestos that has
12 not been altered by heat and the only way fosterite
13 occurs in the first place is to be altered by the
14 heat.

15 In other words, when the chrysotile is heated
16 up to a point that it dehydrates, loses its water from
17 the fiber itself, that's when it converts into the
18 fosterite. That usually occurs at about 600 degrees
19 and some have said lower, but generally that's the
20 range that it occurs at.

21 Q. Now, were you present in the courtroom when
22 Dr. Dodson was showing the slides of the asbestos that
23 he viewed under his transmission electron microscope

1 after the test, where he poured water on some brake
2 shoes?

3 A. I am. I was, sorry.

4 Q. Have you also seen other slides or images of
5 chrysotile asbestos fibers that have been omitted from
6 other products that weren't asbestos-containing
7 friction products?

8 A. Yes, I have.

9 Q. Was there anything unusual about the fibers
10 that Dr. Dodson showed in his slides from the slides
11 from other products that you have seen?

12 A. Not that I could tell.

13 Q. Now you're not a microscopist, though?

14 A. That's correct.

15 Q. But based on your scientific training it
16 looked pretty much the same?

17 A. Yes, sir.

18 Q. Now, and I want to make sure that I understood
19 you correctly, this whole idea of converting to
20 fosterite, even when old brakes are removed and
21 exposure from blow outs or brushing the brake dust left
22 behind, that's not all fosterite?

23 A. No, no it's not. It varies from study to

1 study, but our studies, when I was with NIOSH, would
2 show that we could have quite a bit of chrysotile left,
3 some did convert to fosterite.

4 And my paper that I wrote in 2004 I went into
5 this in great detail about what we found and there's no
6 doubt that some of it changes to fosterite, but not all
7 of it.

8 Q. Now, let's talk about some of the studies, I
9 think this may be one that you touched on earlier that
10 lead to the OSHA or NIOSH warning. In the LLOYD study
11 from 1975 tell us a little about the types of asbestos
12 exposures that he measured from doing brake and
13 friction product work.

14 A. First of all let me correct you, Lloyd is not
15 a study.

16 Q. Thank you, Doctor.

17 A. This is a report from NIOSH based upon what I
18 talked about earlier, when NIOSH brought together the
19 people from Selikoff's group and the brake manufactures
20 and put out an alert, the Current Intelligence
21 Bulletin. Dr. Lloyd signed the letter and the report
22 that went out, and what he reported were the
23 concentrations that were reported to NIOSH during that

1 meeting.

2 And in that we found -- we were reported to
3 that average peak asbestos air concentrations could
4 range as high as 10.5, 3.75, 37.3 fibers. These are
5 all greater than five micron in length or per
6 millimeter or per cc, which is the same as per
7 millimeter. And that the present findings indicate
8 that enough asbestos is present and preserved in the
9 brake to produce significant exposure during certain
10 brake servicing procedures.

11 It was these type of exposures that lead NIOSH
12 to put out its Current Intelligence Bulletin. And in
13 that bulletin, NIOSH recommended that labels be put
14 onto the material and labels be posted in the working
15 area. And this is what the label said.

16 Q. You said "current," is that still in effect?

17 A. Yes. Well, it is called Current when it went
18 out in '75 but it is still current, but it was also
19 current in '75.

20 Q. Now, there is a couple of words in here that
21 are in the call outs that I want to touch on and
22 examine. We're talking about peak asbestos
23 concentrations, are you familiar with the term

1 threshold limit value or TLV?

2 A. I am.

3 Q. Explain to us what that is, Doctor.

4 A. Well, a TLV is something that the American
5 Conference of Industrial Hygienists put out. It is the
6 same basic theory as the OSHA, PEL, which is
7 permissible exposure limit. And it measures what the
8 average exposures are over an eight-hour working shift
9 as compared to peak exposures, which are usually
10 measured over 15-minute or 30-minute periods of time
11 occurring during the work shift.

12 Q. Is the idea that an average exposure is
13 dangerous and a peak exposure is not or vis versa?

14 A. Neither. Neither, actually. The idea is that
15 if you contain your average exposure during a workday
16 to the PEL or the TLV that the risk of disease is going
17 to be low. But they also have peak levels that mean
18 that you cannot exceed these peak levels because even
19 if they average out to below the TLV or the PEL, they
20 are still dangerous.

21 So the peak levels do have a lot of
22 significance, in that they do add greater
23 concentrations of asbestos. And, two, the work

1 environment for short periods of time, which can
2 increase the exposure to the worker.

3 Q. And thus increase the risk?

4 A. Yes.

5 Q. Now, have these threshold limit values
6 continued to be adjusted over time as we learn more and
7 more about asbestos and disease?

8 A. Absolutely.

9 Q. And has the threshold limit value continued to
10 be lowered as time has gone on?

11 A. Yes, it has.

12 Q. What did it start out at and what is it
13 currently at today?

14 A. When first OSHA came into existence in 1972 or
15 '71 the first standard that went out was in '72 and it
16 was at 5 f/cc as an average. It has now gone down to
17 .1 f/cc.

18 Q. And have the peak exposure limits also been
19 adjusted over time?

20 A. They have.

21 Q. What did those start out at and what are they
22 at now?

23 A. They were much higher. The first standard

1 actually didn't have a peak exposure standard, it was
2 in the second, I think, that they put the peak in.

3 We do not have the peak exposures now, but --
4 or we didn't then, but the peak exposures are very low
5 now, like double the .1 to .2.

6 Q. Now when NIOSH came out with the threshold
7 limit values, what was their intent? Were they
8 protecting against asbestoses, cancer, what was their
9 intent to protect against?

10 A. Well, first of all I need to correct you again
11 NIOSH never put out a TLV.

12 Q. That's why I need you here, Doctor.

13 A. NIOSH put out a recommended exposure level, an
14 REL. And this gets confusing. The recommended
15 exposure limit that NIOSH put out was to protect
16 against noncarcinogenic effects of asbestos.

17 In our criteria documents we always said that
18 we thought that this would eliminate the disease,
19 asbestoses, and reduce the amount of cancer. But in
20 1976 we said that the only way to eliminate cancer from
21 exposure to asbestos was to a ban the use of asbestos
22 in the workplace.

23 So NIOSH never put a standard recommendation

1 out that they felt was considered inclusive for the
2 protection against cancer. OSHA never put out a PEL
3 that they thought was all-inclusive for protection
4 against cancer. They felt the same way, it would have
5 lowered the risk but it would not have eliminated
6 entirely.

7 As a matter of fact, the current OSHA standard
8 of .15 f/cc OSHA still projects that the risk of
9 developing an asbestos-related cancer is about three,
10 three and a half per thousand workers. So it's not a
11 zero risk standard by any means.

12 Q. Let's move onto another study, Roll study are
13 you familiar with the Roll paper from 1976?

14 A. Yes; this is actually one of the papers that
15 NIOSH reported on and Roll continued looking at this
16 and these are the numbers that he found.

17 Q. And are these levels of exposure at which we
18 have seen disease occur?

19 A. Yes.

20 Q. How about the Capanin paper from 1987, are you
21 familiar with that?

22 A. I am.

23 Q. What type of exposures do they report, say on

1 the grinding of brake linings as it relates to trucks
2 and buses?

3 A. Well, their exposure range was .3 to 125 f/cc.
4 And then they go through the median being samples, etc.
5 But here again is just another example that during
6 certain parts of the operation you can get peak
7 exposures that are quite high and can add to the
8 overall body burden a significant amount of an
9 asbestos.

10 Q. And because they add to the overall body
11 burden, is that significant since asbestos diseases are
12 dose response diseases?

13 A. Absolutely. And I think that's the difference
14 between the average concentrations and the peak
15 concentrations. You have to look at what is going into
16 the body. These peak concentrations mean that for a
17 certain period of time you're capable of breathing in
18 this amount of fiber, which is much higher than the
19 average amount of fiber, and the PEL or the TLV or
20 whatever you want to call it.

21 Q. And Capanin also found levels that ranged from
22 less than .1 to 8.2 on the cleaning of brake drums --
23 or drum breaks in passenger cars?

1 A. Yes.

2 Q. Back to the EPA. Are you familiar with the
3 EPA guidance for preventing asbestos disease among auto
4 mechanics or the Gold book?

5 A. Yes, I am.

6 Q. What type of information is reported in that
7 document from the EPA?

8 A. Similar type of information updated from what
9 NIOSH put out in 1975. EPA put out another document in
10 1986 with additional information, and in theirs they
11 were measuring numbers of 72 f/cc. They expressed it
12 was 72 million fibers, but that's what they are talking
13 about as compared to the 39 that NIOSH found, 4.8
14 million f/cc.

15 And they claim in their document that was sent
16 out to garage mechanics and other places where brake
17 work was done that all of these brake cleaning methods
18 can release enough asbestos into the garage so that an
19 average of over one million of the larger fibers can be
20 breathed each day by workers in the garage.

21 These brake cleaning methods can also cause
22 customers to be exposed since asbestos from brake work
23 can be spread 75 feet away from the mechanics. So here

1 we have got people that may not work directly with it
2 that could also be at risk of the disease in some
3 cases.

4 Q. And I believe that in your paper from 2004, if
5 my memory serves me correctly, you referenced some
6 documents from the Friction Material Standards
7 Institute that actually indicate just the handling of
8 brake shoes in the garage can in fact release asbestos
9 fibers?

10 A. Yes, I did.

11 Q. Would that in fact be consistent with the
12 study that Dr. Dodson conducted and discussed with His
13 Honor yesterday?

14 A. It would be, yes.

15 Q. Are you also familiar with the Faigout paper,
16 F-A-I-G-O-U-T, from 1985?

17 A. Faigout, yes.

18 Q. Faigout.

19 A. Yes, the studies shows that fibers are indeed
20 released when asbestos-containing brakes are ground.
21 That many of the released asbestos structures are
22 indeed fibers and not just bound into bundles, clusters
23 or matrixes. And that sufficient amounts exceed the

1 then 1985 OSHA 15-minute sealing of 10 f/cc. And the
2 current excursion limit -- they changed the name from
3 sealing to excursion limit -- had one fiber cc over a
4 30-minute period. And that was 1986, I guess, '84 OSHA
5 standard.

6 Q. And all of these papers that we have shown are
7 showing that measurements taken out in the industry are
8 revealing exposures at levels where disease can and has
9 occurred?

10 A. Yes, it has. -- I mean, yes, they do.

11 Q. Now, are there other papers that are in the
12 literature -- and let me back up a little bit. This is
13 not an exhaustive review of all the literature on
14 exposures?

15 A. No, not at all.

16 Q. Are there other papers in the literature that
17 in fact show smaller exposures?

18 A. There are. There are studies, and I have
19 reported in my book a study by Mr. Blake that showed
20 extremely low exposures that was done in the automobile
21 industry. So there are ranges going from virtually no
22 exposure up to ranges as high as what we're reporting
23 here.

1 I think the high ranges are important because
2 it shows there is that capability, while maybe small,
3 of having exposures that are clearly capable of causing
4 disease.

5 Q. And are you familiar with Dr. Paustenbach's
6 paper about exposures?

7 A. Yes, very much so.

8 Q. Now I want to take you through an exercise and
9 see if you can do this for me. I want to apply with
10 the idea of dose response, cumulative exposure -- let's
11 make some assumptions and apply the numbers that Dr.
12 Paustenbach reports to the Iwatsubo study.

13 But before we do that, let me ask you:
14 Dr. Paustenbach, his measurements in his paper, was he
15 saying that he was measuring every fiber that was in
16 the air?

17 A. No, actually Dr. Paustenbach didn't measure
18 any fiber. He took measurements about 200 samples that
19 had taken by NIOSH and other agencies and other
20 researchers and combined them all together in a review
21 paper. I don't think Dr. Paustenbach or his staff made
22 any of the measurements themselves, but they were
23 general measurements that represented about 200

1 samples.

2 Q. Were those measurements that they put together
3 made by polarized light microscopy?

4 A. They were. So they would have accounted for
5 not just asbestos but other fibers in the air as well.

6 Q. And because of the limits of light microscopy
7 that we discussed with Dr. Dodson, is it your opinion
8 that those measurements were counting every asbestos
9 fiber?

10 A. Well, they probably counted only the fibers
11 that were of regulatory nature, because they didn't
12 count those less than five micron, they didn't count
13 the real thin fibers that Dr. Dodson talked about
14 wouldn't be seen by the polarized light microscope. So
15 -- and I think you'll see later on in the presentation,
16 Your Honor, that about -- and I'll say that now about
17 90 percent of the fibers that we counted or that NIOSH
18 counted in the workplace, about 90 percent were all
19 less than five microns, only about ten percent were
20 above five microns when we went ahead and took the PCM
21 method and compared it by using the electron
22 microscope.

23 Q. And in fact were some of the number that

1 Dr. Paustenbach reviewed and put together were some of
2 those measures taken when dust control measures were
3 actually in place?

4 A. Yes.

5 Q. Would that have reduced the exposures?

6 A. Yes.

7 Q. And were those controls in place because of
8 the warning that we were discussing earlier to the best
9 of your knowledge?

10 A. I would hope that they were in place because
11 of the NIOSH warning in '75 as well as the EPA warning
12 in '86, and many of these samples were taken after that
13 period of time.

14 Q. Let's go through this exercise and see what
15 kinds of results we get in terms of cumulative exposure
16 in dose response if we assume some of Dr. Paustenbach's
17 numbers. Can you walk us through that exercise?

18 A. Yes. What I have done is I have taken the
19 Iwatsubo study and applied it to numbers that were
20 recorded in the Paustenbach study, the high range
21 numbers actually. If you look at the automobile
22 mechanics, I think he had a .04 f/cc, which would give
23 your odds ratio of 1.2, which was not significant, as

1 we remembered in looking at the '95 confidence
2 interval. But if you look -- and I think -- if you
3 look at the higher level, though, dropped down to the
4 third one of the auto mechanic, the .68 fibers, that
5 puts it in that second category that it Iwatsubo --
6 I'll get it right in a minute -- stated, and that was
7 the odds ratio was 4.2, which was significant.

8 So at high range there was significant
9 exposure that certainly raised the odds ratio more than
10 you would expect in the general population. And
11 looking at the truck mechanics, looking at the bigger
12 brakes, at the higher level that went up to 5.2 and
13 again significant.

14 So the average exposures, they weren't
15 significant. But when you got up to the higher range
16 as Dr. Hammar was talking about, you have to look at
17 the range of the confidence intervals, you do see that
18 there are some that get up into the high enough range,
19 above the average, that can cause a significant amount
20 of disease.

21 Q. And it's your opinion, as a trained and
22 practicing epidemiologist, that exposure analysis
23 should look not just at the average exposure but

1 consider the entire range of exposure including these
2 peak exposures?

3 A. I do.

4 Q. Now, you have had an opportunity -- I'm sorry,
5 did I cut you off?

6 A. No. I was just going to say the average
7 exposures give you some comfort, and I think that
8 comfort is that in general you can say the risk is
9 probable fairly low overall for brake mechanics. But
10 what it does when you look at the peak exposures tell
11 you there's still some brake mechanics that are going
12 to fall in that higher risk category, and it is those
13 few that you need to be worried about.

14 Q. Now you have had an opportunity to review the
15 epidemiological literature that at least has been
16 purported to report on associations or the risk of
17 brake mechanics?

18 A. I have.

19 Q. All right. I'm going to go through those and
20 let's talk about those. Let's talk about some of them
21 by themselves and then we'll get into talking about
22 them and others, particularly in the context of
23 Dr. Goodman's meta-analysis that he has published

1 recently. Okay?

2 A. Yes, sir.

3 Q. First, let's talk about the Rushton study.

4 Have you had an opportunity to review the Rushton
5 study?

6 A. I have.

7 Q. And what does that study tell us?

8 A. Well, this was a study done in 1983 of London
9 Transit Executive Bus Garages, so this is a large group
10 of people, unlike we normally see in garage mechanics,
11 this was a fairly large group.

12 What it founds was that they had traced these
13 people through 1975, but 89 percent, almost 90 percent,
14 was still alive at the end of the study. So they only
15 had 8 percent of the study population deceased. And
16 they didn't talk about what the brake exposures were,
17 they didn't discuss that. But their duration of follow
18 up, they said, was only six years.

19 So it's very hard from this study to make any
20 strong conclusions because of the fact that the
21 majority of the population was still alive and hadn't
22 died, so the risk could not really be measured in that
23 8 percent that had died. And that the duration of

1 follow up being so short made it very hard to really
2 exclude chance from any of the findings that they
3 reported.

4 And they did no analysis of brake mechanics as
5 they reported in their study, that I could find.

6 Q. Now I want to touch on one thing that you have
7 got on your slide. The duration of follow up is short,
8 an average of six years. Is this the idea of the
9 latency confounder that we were talking about earlier
10 when Your Honor asked you a question that if you don't
11 follow the cohort long enough you don't allow the
12 latent disease to develop, that is a confounder?

13 A. Yes.

14 Q. Now, I want to take one step back before I go
15 further, in your published paper on asbestos and
16 brakes, exposure and risk of disease, you state that
17 the results of -- that the epidemiological studies are
18 equivocal?

19 A. Yes, I did.

20 Q. And is that still your opinion?

21 A. That is still my opinion. By equivocal I mean
22 that they can be interpreted one way or the other,
23 basically. They don't tell you enough information to

1 let you make a decision one way or the other.

2 Q. And is that -- I may be over simplifying this,
3 but is that's essentially because of the confounders
4 from which these studies suffer?

5 A. Yes, it is.

6 Q. Now, I want to keep that in mind as we're
7 going through these studies, if you would for me,
8 Doctor.

9 Let's talk next about the Teta study from
10 1983. Are you familiar with that?

11 A. Yes, I am.

12 Q. Can you tell us about that, please.

13 A. The Teta study was from the Connecticut Tumor
14 Registry. She and her coauthors looked at the category
15 for automobile repair and what they found was a
16 relative risk of .66, nonsignificant because you can
17 see from the 95 percent confidence interval. But the
18 authors themselves concluded that they had difficulties
19 in ascertaining the occupational histories, and that
20 the true number of occupational cases may be obscured.
21 In other words, they may not have been able to identify
22 all the occupational cases because they were having
23 difficult in ascertaining what the occupational

1 histories were.

2 So those were confounders that could not be
3 ignored when you're making a study. This may mean they
4 have either underreported or overreported, but you
5 can't find an answer because of these confounders that
6 they, themselves, pointed out.

7 Q. And as I understand you, these are -- are you
8 okay?

9 A. I'm just got something in my throat. I have
10 been drinking water, but it has not been helping much.

11 THE COURT: Do you want to take a break?

12 THE WITNESS: I'll keep going until I lose my
13 voice.

14 BY MR. SPILLANE:

15 Q. Doctor, if it would help, I have been handed a
16 small cough drop.

17 A. That might help, thank you. Okay.

18 Q. Let's next talk about Dr. Rodelsperger, are
19 you familiar with this paper from 1986?

20 A. Yes, I am.

21 Q. Can you tell us about that paper and what it
22 reports?

23 A. Dr. Rodelsperger and his colleagues reported

1 four cases of mesothelioma from their clinic in
2 Germany. In their paper they said that there were
3 about 300,000 automobile mechanics in Germany.

4 And this really could be considered more or
5 less a case report. These four cases that they found
6 in their clinic, because it certainly wasn't
7 representative of all of the other cases that may have
8 have occurred in other clinics throughout Germany, but
9 it is one report that they brought out of these four
10 cases.

11 Q. And that is something I wanted to touch on.
12 This is just a report of four cases from their clinic,
13 not from the entire country?

14 A. Right. That's correct.

15 Q. Do you think that they have four to eight
16 million patients in their clinic, Doctor?

17 A. No. No, not at all.

18 Q. Considering the background levels of asbestos
19 or of mesothelioma that we have discussed with
20 Dr. Hillerdahl and others, do you think that in your
21 opinion four mesotheliomas from just their clinic is a
22 significant number?

23 A. I think it is a significant number. Now,

1 another observer of this paper, Dr. Wong, actually said
2 this is not about background. I don't know how he came
3 to that conclusion. But four cases, as we listened to
4 Dr. Hammar this morning and knowing what the background
5 is, I think, is a very significant finding.

6 Q. Next, let's talk about Neuman from 2001. Are
7 you familiar with that paper?

8 A. Yes. He looked at the German mesothelioma
9 registry and he reported 48 cases in the automobile
10 sector. Again, we don't know if those 48 did brake
11 work or whether they were automobile salesman or what
12 they were. They were just in the automobile sector, so
13 it really doesn't tell us a lot about the brake
14 workers.

15 Q. Would that be a limitation or confounder of
16 this study?

17 A. Absolutely.

18 Q. How about Woitowitz and Rodessperger from
19 1994, are you familiar with that?

20 A. Yes.

21 Q. Can you tell us a bit about that, please.

22 A. They did a case control study and found six
23 cases of mesothelioma among 324, who they says that

1 definitely had been engaged in brake work. And four of
2 those six had no other exposures but their exposure to
3 asbestos and brake work.

4 Q. In your opinion, Doctor, is that a significant
5 finding?

6 A. I think it's significant. Again, giving the
7 background of mesothelioma being -- if you want to take
8 the high figure one to two per million cases per year,
9 that's a fairly significant amount.

10 Q. How about Jarvholm and Brisman from 1998, are
11 you familiar with that paper?

12 A. Yes; they had one case of mesothelioma among
13 mechanics in a Swedish death registry.

14 Q. Were there any confounding factors in your
15 opinion in this study?

16 A. Well, I think the bottom line, you know, the
17 lung cancer cases indicated that there was exposures
18 probably to chemicals and smoking in that population,
19 so those are things that probably were unable to be
20 controlled for, so, again those are confounders that
21 obscured those results.

22 Q. How about Hansen from 1989, are you familiar
23 with the Hansen paper?

1 A. Yes.

2 Q. Can you tell us a little about that, please,
3 Doctor.

4 A. Well, this showed one mesothelioma and no
5 increase in lung cancer, but the authors reported
6 several confounders in this study being a short follow
7 up, just ten years; and that the next of kin interviews
8 they were done may have biased their responses; and
9 that the lack of adequate occupational histories was
10 another confounder; and that smoking could have been a
11 confounder, particularly to the lung cancer cases.

12 Q. Several things you touched on there I want to
13 talk about. First, this idea of next of kin
14 interviews, explain to us as an epidemiologist why
15 would an epidemiologist interview someone's next of kin
16 about their exposure instead of going to the person
17 that has the disease?

18 A. Well, in most cases in mesothelioma the
19 persons are deceased so they don't have the opportunity
20 to go to the patient themselves. So they resort to
21 going to the next of kin and this is particularly
22 interesting because when you go to next of kin you
23 usually say, What was their normal occupation? The

1 next of kin can particularly underreport those people
2 that may have been brake workers early in their career
3 and just forgot about that.

4 In other words, the historical data you get
5 from next of kin interviews is often skewed to the most
6 recent occupations or the most general occupations, and
7 often neglects what you would have got from interview
8 from the actual person about what their work history
9 would have been earlier in their lives. So next of kin
10 interviews, while they are better than no interview at
11 all, do suffer some problems with their recall bias,
12 and that recall bias tends to the later occupations
13 being more prevalent in their mind than their earlier
14 occupations.

15 Q. Doctor, have you heard the term "shade tree"
16 mechanic?

17 A. I have, and that's -- again, I should have
18 said that, you know, from what we have heard and what
19 Nicholson said, a lot of mechanics have very short
20 periods of time that they do mechanic work or brake
21 work. And a lot of them may have reported they did it
22 only like a shade tree mechanic. That is, their home
23 changed their own brake shoes or something like that,

1 and that exposure was forgotten.

2 Q. Have you ever been asked to consult on cases
3 where a "shade tree" mechanic even may have had a
4 grinding machine in his garage?

5 A. I have, yes.

6 Q. Would there be anything different about the
7 asbestos being omitted from those brake shoes that he
8 ground at his house than from the ones that maybe he
9 would have done if he had worked for a GM, Ford or
10 Chrysler dealership?

11 A. No, there wouldn't, except I think he would
12 more than likely have controls on his exposure in
13 dealerships than he would in his home.

14 Q. If someone is conducting a study and they are
15 interviewing a next of kin about "occupational
16 exposures" would it seem reasonable that say these
17 shade tree exposures would be completely ignored?

18 A. Well, that's what I'm saying that if they were
19 asking about occupational exposures the next of kin may
20 not have even considered the fact that doing their own
21 brake work was something that might be useful for the
22 total review of the exposure that the person might have
23 had.

1 Q. Now, we also talked earlier about the idea of
2 cohort studies. When examining the disease population,
3 say in this case many of them who are deceased, to the
4 controlled population, often times is the control
5 population living?

6 A. Yes.

7 Q. Would you have --

8 A. In this case, I think that was true and so
9 they were able to interview more of the control
10 population firsthand than they were the mesothelioma
11 population.

12 Q. And, Doctor, as an epidemiologist, if you're
13 able to interview the person himself or herself that's
14 included in the control population, yet you have to
15 interview next of kin and may not be getting accurate
16 information for the diseased population, would that
17 have a tendency to skew the results towards a negative
18 or null finding?

19 A. Absolutely.

20 Q. And why is that?

21 A. Because the person themselves tend to have a
22 better memory of what they did then say their next of
23 kin. As I talked about, the next of kin might forget

1 those older exposures whereas the actual person may not
2 forget those.

3 Q. Okay. And also in the Hansen study they talk
4 about -- you indicate that one of the confounders is a
5 lack of an adequate occupational history. And I want
6 to go back to something that we talked about briefly
7 earlier, and that is the Helsinki criteria, and revisit
8 -- and first of all let me say this document is this
9 entitled Minority Opinion?

10 A. No, Consensus Opinion.

11 Q. What does that mean it's a consensus report?

12 A. It means the majority or the consensus of the
13 people at that conference had agreed upon the findings
14 of fact that are placed in this document.

15 Q. And what are they saying here, right in the
16 introductory paragraph, about -- let me read it to you
17 and you tell me if I read it right. It says, "In
18 general reliable work histories provide the most
19 practical and useful measure of occupational asbestos
20 exposure." Did I read that correctly?

21 A. Yes.

22 Q. So at least according to the Helsinki criteria
23 is the lack of adequate exposure or occupational

1 histories a confounding factor for the Hansen study?

2 A. Yes.

3 Q. And I want to direct you to one other comment
4 that the authors in the Hansen study make. Despite the
5 findings that they report, do they not in fact state in
6 their paper: "That asbestos exposure is known to occur
7 during the replacement of brake linings and the single
8 case of pleural mesothelioma is an indication that this
9 exposure has not been negligible."

10 A. I would agree with that.

11 Q. Now, let's move on next to a study that's just
12 part of the literature and it was discussed earlier
13 today with Dr. Hammar, and that's the Henderson study.
14 And you and I touched on it briefly today about how
15 some of your opinions have changed as you have gotten
16 more information.

17 A. Right.

18 Q. Walk us through, Doctor, what the numbers as
19 you think they should be and what the significance, if
20 any, this report has for you or this information has
21 for you.

22 A. Well, I think when we first saw the report in
23 2001, they reported the 58 cases, came up with a

1 tenfold excess over background. And the Lee and
2 Driscoll paper in 2003, that number had come down that
3 28 mesotheliomas and compared to the 58, which cuts the
4 risk estimate by half.

5 In other words, they are now at about a
6 fivefold excess. And as reported this morning, the
7 number for the lifetime risk that Lee and Driscoll
8 reported was about .7, or in other words about twice
9 that, for the Australian population.

10 I think there's a table in there that compares
11 it to the Australian population for men, which was
12 about .7 and about 14 times greater for Australian
13 woman. So the numbers are changing. The latest
14 numbers would indicate that we're down to this
15 neighborhood of about 28 of mesotheliomas or about a
16 fivefold access risk, according to the latest numbers I
17 have. And I believe that's from the deposition that
18 was given by Dr. Lee that was shown on the screen this
19 morning.

20 Q. And I'm showing a -- the front page of an
21 affidavit that you recently signed, just about a month
22 ago in another case, September 12th of 1995?

23 A. Right.

1 Q. And, in fact, I believe you state that after
2 having an opportunity to review Dr. Lee's deposition
3 and some of the issues, inaccuracies, mistakes,
4 whatever we want to call them, that you feel that upon
5 reexamination perhaps only 28 cases may have been
6 solely exposed to asbestos from brakes. Is that
7 accurate?

8 A. Right.

9 Q. Now, if your opinion does this -- would it
10 change the risk as originally reported by Henderson and
11 lee?

12 A. Well it changes the original risk, but it
13 still has an exceptionally high risk by being a
14 fivefold excess. I mean, this is not a trivial risk.

15 Q. And is this just one of the studies that you
16 think is part of the overall epidemiological picture
17 with regard to friction products?

18 A. Yes, I never did not put all of my reasoning
19 on the epidemiology behind the Australian Tumor
20 Registry. I tried to take it as one part of many other
21 factors that I looked at in putting my summary paper
22 together and coming to my conclusions about the
23 potential for disease among brake repair workers.

1 Q. And I want to make sure I don't misrepresent
2 anything, even including this information included in
3 this recent affidavit, is it still your opinion that
4 the epidemiological studies purported to measure risk
5 or association with friction products is equivocal?

6 A. Yes, I still believe that to be true.

7 Q. Now, I want to touch on one issue we touched
8 on a little bit earlier with regard to one of the other
9 studies, perhaps the Hansen study. I want to touch on
10 something that Your Honor -- His Honor asked you a
11 question about earlier, and that was this latency
12 issue. As it relates to the Australian data, when we
13 were discussing this earlier, this idea of latency or
14 confounder, does it relate to the idea that if you
15 don't follow the subjects long enough you may not allow
16 time for disease to occur?

17 A. Yes; and that's what I was trying to
18 illustrate, I think, when I was talking earlier about
19 the study that we did published the first time in '71
20 and then again in the late '70 where he added about ten
21 years of latency. We saw no mesotheliomas in the
22 first, and then after we observed in for another ten
23 years we found 17 mesotheliomas.

1 So it is crucial to look at the cohort long
2 enough to have enough latency, particularly for these
3 long latency diseases, like mesothelioma.

4 Q. Now I want to turn to -- let's talk about --
5 Dr. Goodman is going to testify in this proceeding and
6 I want to talk about the meta-analysis that he and
7 others published in 2004, have you had an opportunity
8 to review that paper?

9 A. Yes, I have.

10 Q. Can you kind of overall summarize for us what
11 that paper reports?

12 A. Well, as I read his paper, and he's here, so
13 I'm sure if I make a mistake he's going to correct it
14 so I'll leave that up to him to correct, but I believe
15 that he used 17 studies to show that there was no
16 excess risk of mesothelioma. He broke that down to 17
17 of the 17 studies for mesothelioma at least, because he
18 was looking at lung cancer and mesothelioma.

19 And the mesothelioma area 7 of the 17 studies
20 had what he called positive scores in their scoring
21 system that they had set up to qualify the studies for
22 their meta-analysis. The score, as I read it, the
23 highest was a score of nine, and the tier one group,

1 which was his highest group for the meta-analysis, four
2 of the seven studies had scores between three and five
3 with nine being the highest and three of those -- three
4 then of the seven had scores that ranged between zero
5 and two.

6 So overall, he didn't find that the
7 meta-analysis supported a risk of developing
8 mesothelioma from exposure during brake work. And I
9 think the rest of these slides go into it in more
10 detail about each of the studies. But overall his
11 meta-analysis did not show an excess.

12 Now, I have some problems with meta-analysis
13 that I don't know if I should go into right now, but I
14 can go into those.

15 Q. Let's talk about that. So Dr. Goodman's paper
16 was not an original case controlled study or a cohort
17 study?

18 A. Not from my understanding, it was a
19 meta-analysis using other studies that had been done to
20 pull the data into one set of numbers.

21 Q. What is a meta-analysis?

22 A. Meta-analysis was first started some years ago
23 as analyses to be used in controlled pharmaceutical

1 trials.

2 In other words, when one group of patients
3 were given a drug and another group of patients were
4 maybe given a placebo to compare the efficacy. In
5 other words the ability of the drug to take effect to
6 do what it was supposed to do whether it was to prevent
7 disease or cure disease, whatever it was supposed to
8 do. And the reason meta-analysis is used was because
9 we're looking at using individual patients that may
10 have a lot of different characteristics, but what the
11 meta-analysis could do would be control for the amount
12 of dose and other factors so that they would cut down
13 tremendously on the confounders.

14 And, therefore, they were comparing a
15 homogeneous population, that is with very few
16 confounders to their controls, which was always a
17 homogeneous population with very few confounders. And
18 that was the original purpose for the meta-analysis.

19 But meta-analysis then became used for
20 observational studies, and that's where we ran into
21 some problems of trying to control for the confounders.
22 And that's the big problem with meta-analysis is the
23 ability to control confounders.

1 Now, what Dr. Goodman did was try and control
2 for confounders by putting them in the categories and
3 ranking them by what he thought were the best studies
4 versus the worse studies trying to control for
5 homogeneity and eliminate the heterogeneity.

6 This paper by Dr. Bailar, who is the ex-editor
7 of the National Cancer Institute, and now a professor
8 at the University of Chicago wrote about the promise of
9 meta-analysis. I just wanted to share with you some of
10 his concerns, which I share also.

11 And that is major problems with implementation
12 of meta-analysis have been common. There have been a
13 wide variety of these, including failure of the
14 investigator performing the meta-analysis to understand
15 the basic issues: Carelessness and abstracting and
16 summarizing appropriate papers, failure to consider
17 important covariants, bias on the part of the
18 meta-analyst, and perhaps most often overstatements on
19 the strength and precision of the results.

20 It is not uncommon to find that two or more
21 meta-anlyses done at about the same time by
22 investigators with the same access to literature reach
23 income compare -- incompatible or even contradictory

1 conclusions.

2 Such disagreement argues powerfully against
3 any motion that meta-analysis offers an insured way to
4 distill the truth from a collection of research
5 reports.

6 I think that this is important because it does
7 point out, very concisely, Dr. Bailar has summarized
8 very precisely what some of the major problems with
9 meta-analysis are.

10 Q. And Dr. Bailar also discusses in his paper --
11 tell me if you agree with this: He says, Doing a
12 meta-analysis correctly demands expertise in both the
13 method and the substance and hence almost always
14 requires collaboration between clinicians and an
15 experienced statistician. Do you agree with that?

16 A. I agree with that.

17 Q. Now, let me make sure I understand. Does
18 method, does that mean experience in conducting
19 meta-analysis?

20 A. That and also an understanding of what the
21 methods were used in the studies that were being used
22 in the meta-analysis.

23 Q. And the substance that Dr. Bailar is talking

1 about in the area of chrysotile asbestos-containing
2 friction products, would the substance be chrysotile?

3 A. It would be chrysotile. It would be all of
4 those issues that we talked about earlier; that being
5 biological issues, the persistence, the coherence, all
6 of those issues that we listed earlier.

7 Q. And as a trained epidemiologist, would you
8 expect someone conducting a meta-analysis to have some
9 definitive opinions and conclusions about chrysotile if
10 they truly have expertise on the substance?

11 A. I would, yes.

12 Q. And would you think it would be in your
13 opinion, Doctor, is it scientifically sound and
14 scientifically reliable with someone conducting a
15 meta-analysis on chrysotile asbestos-containing
16 friction products actually have some definitive
17 opinions about the carcinogenicity of chrysotile
18 asbestos?

19 A. I think that would be useful, yes.

20 Q. Let's talk about Dr. Goodman's "tier one"
21 studies. The first one he discusses is the McDonald
22 and McDonald paper. Are you familiar with that paper?

23 A. I am.

1 Q. Can you tell me about that, please.

2 A. Well it is a case controlled study, as
3 Dr. Goodman points out, involving 11 cases of
4 mesothelioma. The Drs. McDonald -- Corbitt and
5 Allison, they are husband and wife team -- compared
6 mesothelioma cases with pulmonary metastasizes from
7 nonpulmonary malignancies.

8 They had 12 controls that all had garage
9 occupations, but they didn't explain in their study
10 what those garage occupations were, so we don't know if
11 they did brake work or not. They were garage
12 occupations. They came up with an overall odds ratio
13 of .91 that was not significant, confidence interval at
14 95 percent of .35 to 2.34.

15 As I see the confounders, they are: One,
16 hospital based cancer cases may not be representative
17 of the general population. First of all because they
18 are in the hospital and they are sick, so using
19 hospital controls may not be a good control population
20 to use. And that has been discussed in various
21 epidemiological texts that I have looked at. So
22 probably could have used that as one population
23 control, but getting another nonhospitalization control

1 would be useful.

2 Secondly, the occupational category -- and I
3 think I hit on this already -- defined as garage was
4 not very specific as to brake exposure.

5 Q. And if garage workers say theoretically
6 includes the secretary in the garage, the guy that
7 cleans the toilets at night, etc., etc.,
8 hypothetically, if that's included in this broad
9 insufficient definition, could that skew the results
10 toward a negative or null hypothesis?

11 A. It certainly could. They may have high
12 exposure, don't get me wrong, but their exposure is
13 going to be different than the brake mechanic himself
14 or herself.

15 Q. Hypothetically, a garage occupation could
16 include somebody that washes the car outside before
17 someone picks it up outside?

18 A. I believe so.

19 Q. So in your opinion there are some confounding
20 factors that make the McDonald paper equivocal, fair?

21 A. Yes, I do believe that.

22 Q. In your opinion do you believe that
23 Dr. Goodman's meta-analysis has properly controlled for

1 those confounders?

2 A. I didn't see how his meta-analysis did control
3 for those.

4 One of the problems, again in talking
5 generally about meta-analysis, is if you have problems
6 with the studies going into the meta-analysis you're
7 going to have problems with the data that are coming
8 out from the meta-analysis. Because the meta-analysis
9 is not going to be able to control for all the
10 confounders. They are still going to be some in there,
11 no matter what you do.

12 Q. So if you have problems going in, you're going
13 to have --

14 A. Have problems coming out, right.

15 Q. Next we touched a little bit on this study
16 earlier, the Teta study?

17 A. While I think, just briefly, we have already
18 talked about that, but nonspecific exposure, again, was
19 a problem with this analysis, and the inability to
20 eliminate other exposures due to small sample size.

21 And we also talked about the difficulty in
22 this study in giving occupational histories, so these
23 are three different things that are confounders here.

1 Q. And let me see if I can ask one question that
2 might cover each of these: In each of these studies
3 we're going to cover on the tier one and tier two
4 studies from Dr. Goodman's paper, do you have an
5 opinion about whether or not he appropriately
6 controlled for the confounders for any of these
7 studies?

8 A. Again, I didn't see how his analysis could
9 adequately control for these. I think he attempted to
10 control for these by ranking the studies, by putting
11 them in tier one and tier two, and that's appropriate
12 for what an a meta-analysis should try and do. But,
13 again, if you have got large problems with the studies
14 to begin with, those problems aren't going to wash out
15 in the meta-analysis itself.

16 Q. So with Teta we have problems going in and
17 problems coming out?

18 A. In my opinion, yes.

19 Q. Let's talk about the Hessel paper from 2004.
20 Can you tell us about the Hessel paper?

21 A. Hessel paper was another one that Dr. Goodman
22 included. Hessel was a follow up of a paper by Dr.
23 Robert Spiritus, who I used to work with, who was at

1 the National Cancer Institute, who looked at the SEER
2 data that Dr. Hammar mentioned, the surveillance data
3 that represented about 13 percent of the hospital cases
4 throughout the United States.

5 The SEER data originally reported, I think,
6 eight cases of mesothelioma. And, basically, what
7 Hessel did is go in and take out what Spiritus said
8 were the confounders before other exposures -- many of
9 them were shipyard workers and had other asbestos
10 exposures. And what they did is they eliminated all
11 these other exposures and came down to one case that
12 only had brake exposure. And as we have already talked
13 about, I don't think eliminating these other exposures
14 was the appropriate thing to do, because you eliminate
15 the fact that other exposures could contribute to the
16 overall burden of disease. So here we're left with one
17 case that actually had brake exposure. So one case is
18 really hard to work with.

19 And I think that from that you almost have to
20 say that this study really doesn't mean a lot because
21 they excluded every person with mixed exposures.

22 And, again, the data from the SEER database --
23 in my paper I go into this in detail, but since it

1 represents about 13 percent, a paper that came out of
2 NIOSH by Dr. Wong and others, saying that the SEER data
3 is this small sample that it -- misses about 80 percent
4 of the mesothelioma cases in the United States because
5 of the coding system.

6 There's a coding system called the
7 International Classification of Diseases. Up to the
8 Tenth Edition, the Tenth Edition is the current
9 edition. Prior to that there was no specific codes for
10 mesothelioma, you had to code them in with other types
11 of pleural cancers. Now the Tenth Edition does have
12 individual codes and that went into effect in 1999. So
13 you have an actual code for the different types of
14 mesothelioma, whether it be pleural or peritoneal.

15 We hope that will increase the coding, will
16 increase the ability to report mesothelioma and bring
17 it up to about 80 to 90 percent of what it was before.
18 But the ICD coding system was a problem for
19 mesothelioma and the SEER data. Now, it wasn't a
20 problem for other cancers in the SEER data, but it was
21 for mesothelioma.

22 So working with the SEER data is a big under
23 representation of the total number of mesotheliomas

1 that are occurring in this country.

2 Q. Okay. With regard to Hessel, confounders, we
3 have a low response rate; we have potentially under
4 reporting all the mesotheliomas from the SEER data
5 base; and not really a scientifically real world point
6 of view by exposing mixed exposures. Is that fair?

7 A. Yes.

8 Q. So once again problems in, problems out?

9 A. Yes.

10 Q. Let's talk next about the Teschke study. Are
11 you familiar with Teschke?

12 A. Yes, it was the fourth of the seventh.

13 Q. Excuse me?

14 A. It was the fourth of the four studies in tier
15 one of the seven studies. And it was a case control
16 study, and it matched data from British Columbia cancer
17 agency with the voters in that area. Here again they
18 used the category Vehicle Mechanics. They had six
19 cases and 20 controls with an odds ratio of .8 that was
20 not significant. And then when they broke it down to
21 brake installation and repair cases, they had two cases
22 with 17 controls, again, nonsignificant.

23 This study -- if you go the next thing,

1 yeah -- I think had several confounders that concerned
2 me: One was the small size of the study, meaning that
3 the risk estimates would be imprecise for some of the
4 occupational groups.

5 Secondly, that the grouping of the occupations
6 were likely to result in a biasing risk estimate
7 downward towards the null. And that the major
8 occupations at risk would have been easily detected,
9 but that was because they had the high exposures. And
10 I think that the Teschke study did find those risks to
11 be quite well. But they would find the high exposure
12 ones but when they got to the low exposures that's when
13 they were having trouble trying to do this because the
14 confounding factors of the groupings of the
15 occupations, that's the way they did it, and because of
16 the number of cases that they had.

17 And here again we get into this next of kin
18 interview. A third of the cases were next of kin
19 interviews, when only one seventh of the controls were
20 next to kin, which it meant that a third of those that
21 had mesothelioma they didn't interview -- two-thirds
22 they didn't interview. They only interviewed a third
23 of those, whereas the majority of those that were in

1 the controls were able to be interviewed.

2 So there was a big differential between next
3 of kin reporting and the cases as compared to the next
4 of kin reporting in the controls.

5 Q. So once again we have problems in, we're going
6 to have problems coming out?

7 A. As I see it, yes.

8 Q. Now Dr. Goodman uses this is paper to say that
9 there's no association or risk between the use of
10 asbestos-containing friction products in mesothelioma.
11 But doesn't Teschke say that maybe you shouldn't use
12 the paper to say that?

13 A. Well, yes, Teschke makes a very good statement
14 at the end of the paper that says: That all, meaning
15 jobs and occupations, except nonasbestos mining,
16 involve small numbers; therefore, judgments about
17 whether these associations were causal would be
18 speculative.

19 And I think that's a good point that when
20 you're doing a meta-analysis you should look at what
21 the authors say about how you use the paper. And here
22 again the authors say you shouldn't use it for that
23 purpose, but it was thrown into the meta-analysis as

1 one of the higher scoring papers to be used in the
2 meta-analysis.

3 Q. In fact, Teschke also makes a statement that
4 seems pretty consistent with that Dr. Checkoway has
5 said when it is written that mesothelioma is a rare
6 cancer with one major etiologic exposure; therefore,
7 surveillance using each case as a sentinel event might
8 seem more reasonable for this disease than for cancers
9 with multifactorial causation?

10 A. I think that sums it up. And I think it sums
11 it up what Checkoway would say and I think it would sum
12 up what I would say. You have got a situation here
13 where you have got very little evidence in the
14 epidemiological literature. It is equivocal in what I
15 say. You do have evidence that exposures exist that
16 are high enough to cause disease. You probably have a
17 lower amount of disease in auto mechanics than you do
18 in say insulation workers or boilermakers or others
19 that have eight hours a day, five days a week exposed
20 to asbestos.

21 But the point is the studies, as I see it,
22 don't mean there's no risk. There is some risk because
23 of the exposures and there's enough data to show that

1 what you need to do is take these on an individual
2 case-by-case basis and look at them.

3 I don't think you can throw out the whole
4 category and say there's no risk, but I think each case
5 has to be taken on an individual by individual basis
6 and evaluate the exposure, the findings and the tissue,
7 the occupational histories, and not to throw it out.

8 In other words, if you take the meta-analysis
9 and you take just the epidemiology, I think you're kind
10 of throwing the baby out of the bath water, so to
11 speak. You're throwing out some cases that might
12 really have existed because the exposures did occur in
13 those few cases.

14 Q. Doctor, in your opinion, should you also
15 consider chrysotile epidemiology in general in this
16 equation?

17 A. Well that's what I was saying when I was
18 talking because I think the chrysotile epidemiology is
19 critical. I don't think there's any doubt that
20 chrysotile is capable of causing mesothelioma. I don't
21 think there's any doubt that exposures that we have
22 shown in these slides are capable in causes asbestos
23 related diseases.

1 And that's why I made the statement I just
2 made.

3 Q. Let's move onto the tier two studies --

4 THE COURT: Mr. Spillane, is this a good
5 time to break, do you think?

6 MR. SPILLANE: This would be fine. I
7 probably have maybe another 20 to 30 minutes,
8 maybe this would be a good time to break.

9 THE COURT: All right. Why don't we do
10 that then for the day. We'll return back here
11 at nine o'clock. I still have us down going
12 till five tomorrow and still have Thursday
13 available if we need it. So it sounds like
14 we're back on schedule as of today.

15 If there are any issues that we need to
16 discuss before nine, I'll be upstairs before
17 that. If you want to come up and get me, I'd be
18 able to do that, just let me know. Okay.

19 (Whereupon, Court is in recess.)
20
21
22
23

CERTIFICATE OF COURT STENOGRAPHER

We, Official Court Stenographers 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 hand this 18th day of OCTOBER,
2005.

Cert. # 161-PS
156-PS

John P. Donnelly, RPR
Michele R. Honaker
Official Court Stenographer

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