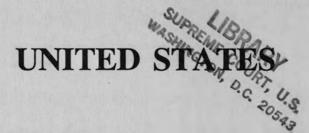
OFFICIAL TRANSCRIPT

PROCEEDINGS BEFORE

## THE SUPREME COURT

## **OF THE**



CAPTION: WILLIAM DAUBERT, ET UX., ETC., ET AL., v.

MERRELL DOW PHARMACEUTICALS

CASE NO: 92-102

PLACE: Washington, D.C.

DATE: Tuesday, March 30, 1993

PAGES: 1 - 45

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1 IN THE SUPREME COURT OF THE UNITED STATES 2 . . . . . . . . . . X WILLIAM DAUBERT, ET UX., ETC., : 3 4 ET AL., : 5 Petitioners : 6 v. : No. 92-102 7 MERRELL DOW PHARMACEUTICALS, : 8 INC. : 9 - - - - X 10 Washington, D.C. Tuesday, March 30, 1993 11 12 The above-entitled matter came on for oral 13 argument before the Supreme Court of the United States at 10:06 a.m. 14 **APPEARANCES:** 15 16 MICHAEL H. GOTTESMAN, ESQ., Washington, D.C.; on behalf of 17 the Petitioners. 18 CHARLES FRIED, ESQ., Cambridge, Massachusetts; on behalf 19 of the Respondent. 20 21 22 23 24 25 1

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1	PROCEEDINGS	
2	(10:06 a.m.)	
3	CHIEF JUSTICE REHNQUIST: We'll hear argument	
4	now in Number 92-102, William Daubert v. Merrell Dow	
5	Pharmaceuticals, Inc.	
6	Mr. Gottesman.	
7	ORAL ARGUMENT OF MICHAEL H. GOTTESMAN	
8	ON BEHALF OF THE PETITIONERS	
9	MR. GOTTESMAN: Mr. Chief Justice and may it	
10	please the Court:	
11	Jason Daubert was born missing a part of his	
12	right arm and lacking three fingers on one of his hands.	
13	Eric Schuller was born missing one of his hands and with	
14	one leg shorter than the other. In both instances their	
15	parents had taken Bendectin during the first 2 months of	
16	their pregnancy, the period in which the limbs are forming	
17	in the fetus.	
18	There were no other indications of what might	
19	have accounted for these birth defects. There were no	
20	genetic histories, or anything else of the like.	
21	Each of these petitioners, with their parents,	
22	sued in the State courts of California alleging that the	
23	birth defects had been caused by Bendectin and alleging	
24	further that Merrell Dow, the sole manufacturer of	
25	Bendectin, had been culpable as a matter of State tort law	
	3	
	ALDERGON REDORTING COMPANY INC	

in the manufacture and the distribution of the drug.

Among other things, the allegations are that Merrell had concealed the discoveries in its own laboratories of the effects that this drug had on animals that were tested and that it did not provide a warning consistent with what its own internal knowledge was of the propensities of the drug.

If the cases had remained in State court, it is 8 9 clear that the expert testimony about causation that is the subject before you today, that that expert testimony 10 would have been admissible as a matter of California law, 11 and we have asserted -- and the assertion is not 12 challenged -- that that evidence would also have been 13 sufficient as a matter of California law to prove 14 causation in this case. 15

But Merrell Dow removed both cases to Federal 16 court on diversity grounds, where they were consolidated, 17 and ultimately Merrell moved for summary judgment. Its 18 motion did not go to the question of culpability but 19 solely to the question of causation, and its contention 20 21 about causation was that Bendectin does not, in fact, 22 cause birth defects in humans and that the petitioners 23 would be unable to come forward with any admissible evidence that it does. 24

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And they anticipated in the motion that the

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petitioners indeed would have experts who say that there is causation, but their contention was that testimony would not be admissible under the Federal Rules of Evidence, and in consequence the petitioners would have no admissible evidence to prove causation.

Now, the petitioners countered with affidavits 6 7 and testimonies of eight experts, and I think it's important to note that these are experts several of whom 8 are very highly credentialed and important scientists in 9 their field. One, Adrian Gross, has been the chief of 10 toxicology for the Environmental Protection Agency and the 11 chief of pathology at the Food and Drug Administration, in 12 both roles responsible for making these very kinds of 13 determinations about causation. 14

15 Another, Shanna Swan, is the chief 16 epidemiologist for the State of California, responsible 17 for determining the causes of birth defects, and on -- we 18 have described others in our brief.

Each of these eight experts in their affidavits and testimony expressed their opinion that it is likelier than not that Bendectin is a teratogen in humans at the normal therapeutic dose, that is, that it causes birth defects in humans, and each has recited that the methodology by which they arrived at that conclusion is the methodology which is regularly and commonly employed

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by scientists in their fields for making these kinds of
 determinations.

Indeed, as is shown, and as the two governmental experts testified, the methodology they used here is precisely that which they use every day in the performance of their governmental functions, and governmental regulations which we have cited in our briefs say the same thing.

9 Now, what is striking, and I think needs to be 10 noticed, is that in this record there is nothing that 11 challenges that the methodology that these eight experts 12 employ is not the common and regular methodology for 13 making these determinations.

Merrell did not, in response to these 14 15 affidavits, make any record demonstration, did not cite a single person who claimed that this methodology was not 16 appropriately employed, but both courts below, responding 17 to and accepting the contention made by Merrell Dow, 18 19 concluded that the proper measure for determining admissibility of expert testimony under the Federal Rules 20 of Evidence is that which was prescribed in the Frye test, 21 22 namely that the methods and the principles on which the experts' opinions are based must be those that are 23 24 generally accepted in the scientific community, and 25 applying that standard, both courts said that that had not

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1 been demonstrated in this case by the petitioner.

Now, that poses the question of statutory
construction that this case presents.

4 QUESTION: Do you say that even under the Frye 5 test this evidence would be admissible, or as we take the 6 case it's either Frye applies or it doesn't?

7 MR. GOTTESMAN: Well, it was the contention 8 below, the Ninth Circuit having already adopted the Frye 9 case before this case, the petitioners were obliged to 10 argue to the Ninth Circuit that this evidence is 11 admissible even under the general acceptance test of 12 Frye's --

QUESTION: What base -- is that issue here? 13 MR. GOTTESMAN: It is here only in the sense 14 that the sole reason the Ninth Circuit gave for saying 15 that this was not generally accepted was its conclusion, 16 again not drawn from the record, that scientists will not 17 accept the opinions of experts and their methodologies 18 unless those experts have published and had peer review of 19 20 the opinions that they proffer.

Now, we do contend that as an assertion of what constitutes general acceptance, even were that the test, that that is an incorrect and a -- not only incorrect as a matter of fact, because the record shows that indeed scientists do, and a number of scientific organizations

have cited that -- that it is both incorrect as a statement of science and incorrect as a construction of the Federal rules. That is, that Publication and peer review is not a prerequisite for the admission of scientific expert testimony under the Federal rules.

6 But Your Honor has shaped, I think, the way in 7 which the statutory construction issue has to be addressed 8 here. The first question is whether the test that the 9 Ninth Circuit applied is indeed the correct construction 10 of this Federal statute. That is, does it require general 11 acceptance?

12 If the answer to that is no, and there seems to 13 be a rather wide consensus among the various groups in 14 this case that it should be no, the Court then does have 15 to address, I think, well, what is the correct 16 construction of the Federal rules so that, whether it's 17 going to decide this itself or remand for reconsideration, 18 there will be a determination of what the standard is.

And what I'd like to do is go through the statutory construction analysis in that two-step way, first demonstrating that general acceptance is not the test, which I think is rather the easier point, and then addressing what is the correct instruction, as to which --QUESTION: In making that argument, Mr. Gottesman, I hope you will address whether under

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Rule 702 the words, "scientific knowledge," tell us
 anything about what's required.

Webster's Dictionary defines "knowledge" as applying to a body of known facts or ideas or accepted as truths on good grounds, and I think the word "science" is defined as accumulated and accepted knowledge, so I am curious whether the language employed in 702 doesn't suggest some notion of accepted knowledge.

9 MR. GOTTESMAN: Well, let me jump ahead to that, 10 Your Honor, although I do want to ultimately get back to 11 laying a firmer foundation.

12 702 says that if scientific knowledge will 13 assist the court a qualified expert may testify thereto. 14 We agree that the word "thereto" qualifies the words, 15 "scientific knowledge," so really the question is what is 16 the importance of the word "thereto" as it relates to 17 scientific knowledge?

What the advisory committee note says -- and we suggest that this is very informative. I'd like to read it and then relate it to this case: "The rule recognizes that an expert on the stand may give a dissertation or exposition of scientific or other principles relevant to the case, leaving the trier of fact to apply them to the facts."

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Now, it then goes on and says, "The use of

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opinions is not abolished by the rule, however. It will 1 2 continue to be permissible for the expert to take the further step of suggesting the inference which should be 3 drawn from applying the specialized knowledge to the 4 fact," so that what the drafters contemplated in 702 is 5 that the expert would set forth what is known 6 7 scientifically, and from that would be permitted to infer what should be concluded from that. 8

9 Now, in this case, if you read the testimony of 10 these experts, they are putting forth scientific knowledge 11 on every page. They go through an explanation of what all 12 of the animal studies have shown, how to interpret them, 13 what their significance is --

14 QUESTION: Yes, but you --

QUESTION: Mr. Gottesman, does Rule 702 and 703 together give the trial court some discretion in allowing someone who is called to the stand and is qualified as an expert by showing background and so forth?

MR. GOTTESMAN: Yes. Rule 703 provides in terms that if the expert is drawing on facts and data which have been generated by others, as, indeed, our experts were, that those facts and data must be such as are reasonably relied upon by experts in that field for making determinations such as are before the Court.

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QUESTION: And that's a preliminary decision to

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1 be made by the trial judge.

2 MR. GOTTESMAN: Absolutely, and in this case the 3 record shows without contradiction that the facts and data 4 upon which these experts relied are indeed precisely the 5 facts and data upon which all experts rely in making 6 determinations of whether it is likelier than not that a 7 particular toxin is causing --

8 QUESTION: So it's your position that once a 9 witness is qualified as an expert, he can testify to 10 anything within the area of his expertise.

11 MR. GOTTESMAN: He -- assuming that what he's 12 testifying to is what the court needs help on. There are 13 two links to -- there's a need in this case to --

14 QUESTION: Well, I, you know, assume we weren't 15 interested in weather conditions in this case.

MR. GOTTESMAN: Right. That's right. I mean --QUESTION: So it's a matter of relevance, but within the area of causation with respect to birth defects, once any of these experts were qualified as a witness, they could testify as to matters of causation without reference to the methodology of the studies they relied upon.

23 MR. GOTTESMAN: I think the answer is yes and 24 no, Your Honor. They do have to satisfy the requirement 25 of 703 that the facts and data that they're relying on are

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those that scientists reasonably relied upon. That said,
 the office of sections 702 and 703 are completed.

There are still two gateways that may lead a 3 court to determine that that evidence is not admissible. 4 One is section 403, which says that even as to otherwise 5 6 admissible testimony, the court can make on a case-bycase basis -- and this Court has said that it is to be 7 determined on a case-by-case basis by the district 8 9 court -- the court can make a calculation of whether the probative value of that testimony is substantially 10 11 outweighed by the danger of misleading, confusing, or prejudicing the jury. 12

But it does not follow -- even if it is in the court's mind that the probative value is low, it does not automatically follow that it is outweighed by a danger of -- and incidentally, I want to be clear we don't think that in this case one could say that the probative value is low, but even if a court thought that, it doesn't follow that the jury is going to be confused or misled.

20 QUESTION: Are there any other rules of evidence 21 that qualify? You said that was the first --

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MR. GOTTESMAN: Right.

23 QUESTION: That you'd have to look at, and the 24 second is?

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MR. GOTTESMAN: The other, and I think the more

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important safeguard, is not in the rules of evidence. The 1 more important safequard is that a court is entitled to 2 direct a verdict, or in the words of the new Federal rules 3 4 to direct a judgment, and likewise to grant summary judgment, if it concludes that even though there may be a 5 scintilla of evidence supporting the petitioners' 6 7 position, it is overwhelmingly refuted by the contrary evidence such that no reasonable juror could conclude on 8 9 this body of evidence that the point for which the expert 10 is contesting is true.

11 QUESTION: Well, but before we get to that 12 point, I notice that section 702 that Justice O'Connor 13 inquired about is not part of your calculus, so that once 14 the expert is qualified, subject to the other two sections 15 you mention, he can testify to any area within his 16 expertise whether or not it is based on studies.

MR. GOTTESMAN: Well, Your Honor, no -- 703, we suggest, is -- 703 is the provision in the Federal rules --

20 QUESTION: But you give no effect to 702 in this 21 calculus.

MR. GOTTESMAN: We do, Your Honor. 702 and 703 each have their proper office. 703 is the provision that addresses the same thing that the Frye rule did. That is, it says -- its title is "Bases for the Opinions of

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Experts: What is the Foundation that will be required for an expert's testimony to be admissible," and it spells out what those bases are, and it includes what one might say is a watered down version of the Frye rule, the requirement that the facts and data upon which the expert testifies be those that are reasonably relied upon by scientists.

8 The office of 702, we suggest, is quite 9 different. The two are not both talking about the same 10 thing, as respondent argues. This was a very carefully 11 drafted statute. Years were spent by draftsmen putting it 12 together.

QUESTION: Yes, but both refer to scientific 13 knowledge, in effect. I mean, that's the basis, and I 14 15 notice there are a number of briefs filed here, amicus briefs by people from the scientific community, and they 16 all tell us that scientific knowledge is more than just 17 18 one person's opinion, that the essence is that it has to be capable of being tested, and something that isn't 19 tested can't be said to be reliable, and if it isn't 20 reliable, it can't assist the trier of fact. 21

Now, doesn't that suggest that there's a role for the trial judge in determining at the outset what comes in?

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MR. GOTTESMAN: Your Honor, there is, I think, a

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confusion of two interfaces that I would like to suggest
 will explain the role of the arguments that Your Honor has
 just referred to about things have to be tested and
 validated and the like.

There are, if you will, two different scientific 5 modalities. One is when we are trying to decide that 6 something has been conclusively established so that we can 7 declare it to be a law of science, and there it is 8 undoubtedly true, scientists do not say, we have now 9 satisfied ourselves that there is an established truth, 10 another law of gravity, if you will, until we arrive at a 11 point of certainty that is replicable, conclusive, et 12 13 cetera, et cetera, but we live in a world of uncertainty, and for many purposes we can't wait until science arrives 14 at the conclusive answer. 15

Professor Nesson in his extremely cogent article makes this point and makes it, I think, as effectively as it appears anywhere in the literature: "There are several contexts in which we are called upon to decide things even though science doesn't have a conclusive answer, and we have to do the best we can."

He cites as an example the physician who has to decide how to treat a patient. If the physician needs to know, in order to do that, what is the cause, the physician doesn't say well, I give up, science hasn't got

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a conclusive answer yet. The physician says, I will have to make a judgment of what is likelier than not the cause based upon the materials at hand, and Professor Nesson argues, and, we submit, persuasively, that that is the same thing that a court is called upon to do when in a state of scientific uncertainty it has to decide whether causation occurred.

8 The issue here is not whether the plaintiffs can 9 prove this scientific proposition to the degree of 10 certainly that would make it like the law of gravity. The 11 issue is whether the plaintiffs can demonstrate that it is 12 likelier or not that this is causing that, and the 13 methodology --

QUESTION: And maybe the issue is whether the judge can review the expert's determination about the probabilities in this area of uncertainty.

I don't -- you say that the expert has to be an
expert. He has to be qualified as an expert in the field.
MR. GOTTESMAN: Indeed.

QUESTION: The data, you acknowledge, by reason of 703 has to be of a sort that the community would normally rely upon, but there remains the last step, and that is the expert's applying these data to the scientific problem that is relevant to the case and coming up with his conclusion.

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1 Is it your position that so long as an individual is an expert, whatever conclusion he arrives at 2 on the basis of this data that other experts consider 3 relevant data must be accepted by the court? 4 MR. GOTTESMAN: Your Honor, yes, subject to 5 6 Rule 403 and subject to the power that a judge always 7 exercises as a matter of substantive law to say that no reasonable juror could possibly be persuaded in light of 8 the imbalance of the others --9 QUESTION: Well but, no, that just goes to 10 11 whether his testimony is refuted by a lot of other 12 testimony. That's right. MR. GOTTESMAN: 13 QUESTION: I mean, if his is the only testimony, 14 presumably the jury could accept it. 15 What about section 401? 16 MR. GOTTESMAN: Section 401 defines relevance as 17 anything that makes -- that tends to show -- I don't -- I 18 forget the exact word. 19 20 OUESTION: It means evidence having any tendency --21 22 MR. GOTTESMAN: Any tendency, right. QUESTION: To make the existence of any fact 23 that is of consequence to the determination of the action 24 25 more probable or less probable than it --17 ALDERSON REPORTING COMPANY, INC.

MR. GOTTESMAN: That's right.

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2 QUESTION: Would be without the evidence. 3 MR. GOTTESMAN: Now, let me suggest what we 4 have --

5 QUESTION: Now, can't -- on the basis of that, 6 can't the court make a judgment that even though the data 7 is of the sort the scientific community would accept, and 8 even though this individual has wonderful credentials, it 9 really just doesn't parse?

MR. GOTTESMAN: Well, Your Honor, I could imagine that there would be a case such as that. This certainly is not it. It certainly -- there is a tendency to -- proving the point, to know, as these experts have testified and cited published reports for, and that the Government has confirmed, that Bendectin causes limb defects in animals.

17 It certainly tends to prove the causation point 18 that in vitro studies have identified exactly what it is 19 that Bendectin does that causes the limb reductions, and 20 that is that it impairs a particular substance whose 21 function is to bind the cartilage cells and thus to create 22 the limbs. This is Dr. Newman's testimony from the in 23 vitro studies of this.

And it is probative to know that that substance, which is impaired by Bendectin in animals, is the same

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substance that performs the same mission in binding the 1 2 cartilage cells and forming the predicate for the limbs in human beings, and it is probative to know that the 3 chemical composition in Bendectin is extremely close in 4 composition to the chemical composition of other chemicals 5 6 which are widely believed to be teratogens in humans, and 7 it is probative to know that when studies were done on 8 human populations, a larger proportion of the women who took Bendectin gave birth to children with limb defects 9 than the proportion who did not. All of this is 10 probative. 11

12 What the lower courts have said was yes, but prove to us to a degree of statistical certainty which 13 would give us 95 percent confidence that the human 14 epidemiological data is reflective, that these higher 15 16 numbers for the mothers who used Bendectin were not the 17 product of random chance but in fact are demonstrating the linkage between this drug and the symptoms observed. It 18 is --19

20 QUESTION: Did the court of appeals, 21 Mr. Gottesman, actually say that you had to prove to a 22 95-per-cent certainty?

MR. GOTTESMAN: It's not quite clear, Your
Honor. The district court clearly did.

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QUESTION: I thought you said a minute ago that

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1 it did. You said, the courts.

2 MR. GOTTESMAN: Well, I'm sorry. The district 3 court clearly did. The court of appeals said that Shanna 4 Swan and Jay Glasser, the two epidemiologists -- well, let 5 me back up a minute.

The court of appeals definitely said explicitly 6 7 you can't prove your case just on the basis of animal and chemical data, and they said that although there are four 8 experts' affidavits saying that in appropriate cases you 9 can make a determination that it is likelier than not just 10 from animal and chemical data, and saying that that is the 11 12 view of the Government agencies for which they work, and in the absence of any contradictory evidence from the 13 other side. Both lower courts said you can't do it from 14 15 that.

16 The court of appeals didn't say exactly what the epidemiological evidence would have to prove, except that 17 18 it plainly rejected what was demonstrated, and what was demonstrated by Shanna Swan was that if you used a degree 19 of confidence lower than 95 percent but still sufficient 20 to prove the point as likelier than not, the 21 epidemiological evidence is positive, so that implicitly 22 the Ninth Circuit was saying we will not accept that 23 24 showing at least if you have not published your results. 25 Now --

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QUESTION: Mr. Gottesman, is it fair to say that 1 2 what you are telling us is that once an expert has been qualified as an expert in the field, and once the expert 3 has at least made a showing or a showing is at least 4 possible that the expert has based some opinion on the 5 kind of facts and data that 703 refer to, that the 6 testimony of the expert himself, that he is competent to 7 express an opinion on probability -- i.e., the 51 percent 8 or better chance -- is sufficient to satisfy the 9 10 foundation or knowledge requirement of 702?

11 MR. GOTTESMAN: Yes, Your Honor. That is --12 QUESTION: So that any expert who says, I can 13 testify to a probability, necessarily qualifies as 14 competent to -- or as having satisfied the foundational 15 requirement of 702. It's as simple as that.

MR. GOTTESMAN: Yes, subject to the back -again, assuming that he has satisfied 703 and subject to the back-ups of 403 and the power of the court to direct a verdict in appropriate cases.

20 QUESTION: So, Mr. Gottesman, you in essence 21 reject the view of, let's say, the Third Circuit in the 22 Downing case and the view expressed here by the Solicitor 23 General that there are certain foundation requirements the 24 court would look at?

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MR. GOTTESMAN: I would say that we believe that

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1 Congress rejected it, Your Honor. Congress relied, as 2 this Court has repeatedly said, on the adversarial process 3 to demonstrate that a marginal expert's testimony is, in 4 fact, marginal. There are some who disagree with that. 5 There are arguments that the rules should be changed, but 6 we think that's the proper reading of the rules as they 7 presently exist.

8 QUESTION: It seems to me, counsel, that 703 9 simply says that underlying background facts and data are 10 admissible if the expert reasonably relied upon them, but 11 that does not go to the question of the qualification of 12 the expert to speak to the subject under 702.

MR. GOTTESMAN: Well, the qualifications in this case have not been challenged, Your Honor. These experts are -- at least, it is not disputed that they are qualified to testify. We agree that of course the expert's qualifications to testify on the subject that he's being asked to testify about are within the power of the court to determine. Section 702 expressly says that.

20 QUESTION: But -- maybe I'll just modify Justice 21 Kennedy's question slightly. You are saying that 702 in 22 effect substitutes for the foundational requirement.

23 We'll assume the expert is qualified. The 24 question is whether there is a foundation for the opinion, 25 and you are simply saying that provided the expert can be

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said to have relied upon facts and data and provided that 1 2 the expert is indeed qualified as an expert in the field, that the readiness of the expert to couch his testimony in 3 terms of a probability judgment is a sufficient 4 satisfaction of the foundational requirement of 702. 5 MR. GOTTESMAN: That's correct, Your Honor, and 6 7 we think the --QUESTION: Every expert basically is guaranteed 8 qualification at least, or is guaranteed success on 9 foundation, so long as it is his own opinion that he does 10 have a foundation. 11 12 MR. GOTTESMAN: And it is within the area of his expertise, that's correct, subject again to 403. 13 I would like to reserve the remainder of my 14 time, if I might. 15 16 QUESTION: Very well, Mr. Gottesman. Mr. Fried, we'll hear from you. 17 ORAL ARGUMENT OF CHARLES FRIED 18 MR. FRIED: Thank you, Mr. Chief Justice, and 19 20 may it please the Court: 21 In our view, scientific knowledge, which is what 22 Rule 702 allows an expert to testify to, is that body of propositions which have been produced by the methods and 23 procedures of science, and it is the heart of our claim 24 that the propositions offered by petitioner's witnesses 25 23

have not been produced by the methods and procedures of
 science.

3 As the Court in the Turpin case said regarding petitioner's crucial witness here -- and I say crucial, 4 5 because it is the only witness. Dr. Palmer, he's the only 6 witness to testify that it is his opinion that Bendectin caused the limb defects of these petitioners -- said of 7 Dr. Palmer, "Personal opinion, not science, is testifying 8 here. No known basis is offered." So we do not speak 9 10 about propositions that have attained the level of 11 certainty of the laws of gravity.

I think that this contention shows the whole procedure of the petitioners and their amici attack on what not only this Court -- not only on the courts below but a number of courts have done. They caricature what it is that the courts below have said about the requirement of publication and peer review.

None of those courts have said, and it would have been an absurd thing to say, that scientific opinions or propositions may not be testified to if they have not been published. There are many scientific opinions which are either too particular, too fresh, or of too limited interest to be able to attain publication.

What these courts have said is that publication and dissemination to the scientific community is a factor.

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The Downing-DeLuca court, say the Third Circuit, 1 specifically said that it is a factor in determining the 2 reliability of scientific evidence whether it has been 3 exposed -- and I believe I used the Third Circuit's own 4 words -- exposed to scientific scrutiny. 5 6 Now, publication and peer review --7 QUESTION: Is that formulation that you've just given us a modification of the Frye rule? 8 MR. FRIED: Your Honor, it is a specification, 9 an explication of the approach which the Frye rule 10 exemplifies. We think --11 OUESTION: That sounds to me like a 12 modification. 13 (Laughter.) 14 MR. FRIED: Well, if you will, it's a 15 modification. 16 QUESTION: And I think it's important because 17 one reading of the Ninth Circuit is that it -- opinion, 18 not the only reading, but I think one reading of the Ninth 19 20 Circuit is that it relied on the Frye rule per se, without 21 this modification or explication that we're discussing. MR. FRIED: Well, as to the opinion of the Ninth 22 Circuit, I think that is virtually -- that opinion is 23 virtually a summary affirmance. There are some judges who 24 25 take about 5 pages for a summary affirmance. 25

In fact, the Ninth Circuit specifically stated that it was incorporating the judgments on the same packet of opinions in the First, the D.C., and the Fifth Circuits, as they said, "for the reasons stated by our sister circuits," and those opinions are very detailed, go into the witnesses' testimony in great detail, and that is incorporated by reference.

8 The Ninth Circuit, having seen that the Federal 9 courts have passed on this a number of times, simply 10 incorporated that by reference.

Now, it's quite clear that the Ninth Circuit was relying on Rule 702. It cited the Solomon case, and the Solomon case is a 702 case. The district court relied on Rule 703. The Lynch court, the First Circuit, whose opinion was adopted by reference by the Ninth Circuit, relied on 703 and 403.

Now, Frye, I think, is simply a shorthand way of designating an approach, and this is another one of the caricatures which the petitioners are required to emit in order to take a very general approach and make it seem extreme.

The Frye rule is a very brief sentence in a very brief opinion in 1923. It represents an approach. It is an approach which says, and it was familiar in the Federal courts, it was stated very well by Judge Hand in 1901,

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that the courts must look to scientific standards to
 validate scientific claims.

Now, that approach, which I submit is very general, is an approach which reappears in the Federal rules, and why should it not? The very words which Justice O'Connor was emphasizing -- scientific knowledge -- bring that approach into the Federal rules. Why should that approach have been abandoned without a word?

Now, if there had been something like a discriminate rule -- the Frye rule -- then there would be an argument, and I would think we would be in equipoise at best, but the Frye rule itself is a rather ambiguous -very ambiguous statement.

15 If you look at what the Frye rule itself is --16 let me read it to you from that decision: "The thing from 17 which the deduction is made must be sufficiently 18 established to have gained general acceptance in the 19 particular field in which it belongs."

That leaves many questions unanswered, and what I suggest is, it is representative of an approach that there must be a foundation, the foundation must be a foundation in scientific knowledge, and that the courts look to the community of science and to scientific standards to validate scientific claims.

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QUESTION: Who was the author of the Frye 1 2 opinion? 3 MR. FRIED: You had me there, Mr. Justice -- Justice Blackmun. I'm afraid I can't tell 4 5 you. I should know -- I beg your pardon? 6 QUESTION: So should I. 7 (Laughter.) MR. FRIED: May I return to the publication and 8 peer review factor, because a factor is all that it is. 9 10 There are many circumstances, as the Solicitor General 11 points out, where publication and peer review would be impossible and inappropriate. This is not such a 12 circumstance. 13 What the petitioners' witnesses were seeking to 14 do was to propose a general proposition about the chemical 15 properties of a much-studied subject. The substance under 16 consideration, Bendectin, had been studied for over a 17 generation and had generated a vast body of published 18 19 research. What the Ninth Circuit and the other circuits 20 have been saying, and here the Fifth Circuit is 21 22 particularly explicit, in that circumstance where witnesses are seeking to build upon in order to contradict 23 24 a vast body of unanimous published research, then they 25 must operate in pari materia. They, too, must submit

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their research with a clear statement of their premises,
 their methodologies, their conclusions.

3 QUESTION: Well, that -- Mr. Fried, that's fine 4 if you're trying to get a Ph.D., but how do the rules of 5 evidence justify that requirement?

6 MR. FRIED: The rules of evidence, Mr. Chief 7 Justice, require that the testimony be to scientific 8 knowledge. Scientific knowledge is knowledge produced by 9 the methods and procedures of science, and under certain 10 circumstances there is no more elementary method of 11 science than the method of dissemination for criticism, 12 replication, and review by the scientific community.

QUESTION: How can we know that on this record? MR. FRIED: I think that is a matter of which judicial notice may be taken, that replication, that the community of science is the test of what is science is one of the most elementary facts of which educated men and women are aware, that science is not personal opinion. It has been stated many times by many courts.

20 QUESTION: Mr. Fried, could I ask you a question 21 about the studies in this case, the animal studies as an 22 example? Now, let's assume that maybe they don't really 23 tell us anything about human beings, and therefore an 24 opinion based on them might not be relevant or helpful, 25 but are the animal studies themselves, insofar as they

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prove anything about animals, scientific knowledge within
 the meaning of the rule in your view?

3 MR. FRIED: These animal studies, if properly 4 conducted, and some of them were, are scientific 5 knowledge, without doubt.

6 The opinion based upon them is an opinion which does not comport with Rule 703, because Rule 703 -- and 7 here the advisory committee notes are particularly 8 important -- does not speak only of the type of 9 information, but also the selection of information, and 10 the reference there to public opinion research in the 11 advisory committee note, Your Honor, makes that quite 12 explicit, that certainly to prove -- in the Zippo case 13 which they cite, to prove that there's confusion one would 14 use survey data, but one would have to use survey data in 15 16 a way that survey data specialists use survey data, and that's --17

QUESTION: Just a little more -- just stick with the animal studies for a moment. If we assume they are scientific knowledge, what is it in 703 -- what language in 703 makes it impermissible for an expert to express an opinion based on that scientific knowledge?

23 MR. FRIED: Animal data are not reasonably 24 relied on by experts in the field to reach a conclusion 25 about human teratogenicity at least in the face of an

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overwhelming burden of human data which points in the
 opposite direction.

Animal studies are, indeed, used. They are used by the FDA, they are used quite generally to raise a suspicion. They are like a scaffolding, but when the building is up, the animal studies drop away. The animal studies cannot support a building which will not stand --

8 QUESTION: Mr. Fried, again, how are we supposed to know this? I mean, if someone on behalf of the 9 defendants had testified to this effect, that would be 10 something in the record that we could take notice of and 11 12 perhaps the trial court could have taken note, but you know, you're a lawyer, you're not a doctor, and here you 13 are telling me that certain things are so in the 14 scientific field. You may know, but I don't. 15

MR. FRIED: Well, there were introduced among other things a number of learned treatises on exactly this point about he importance of human studies in this -- in the birth defects area, and how human studies trump animal studies, so there were -- learned treatises were introduced.

QUESTION: This was introduced in this case?
MR. FRIED: Yes, Your Honor.
QUESTION: In the trial court.
MR. FRIED: And they were also introduced in a

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number of the other case whose records were submitted in
 this case.

Furthermore, the Canadian study which was introduced by defendants, which was a meta-analysis of all the human studies, made this statement, and finally the petitioners' own witnesses, some of them -- not all of them, but their own witnesses stated that it is inappropriate to reach conclusions about human teratogenicity on the basis of animal studies.

10 There is one well-known textbook which points 11 out that there are 1,200 known animal teratogens and only 12 30 known human teratogens, so the court quite properly, 13 under Rule 104(a), reached this conclusion, and I would 14 take it that that is a determination by the two courts 15 below, and not only the two courts below, a number of 16 other courts.

QUESTION: Well, what does Rule 104(a) say? 17 MR. FRIED: Rule 104(a) allows the trial court, 18 indeed, requires the trial court to make a preliminary 19 20 foundational inquiry whether a proper foundation has been laid for any testimony, whether it's opinion testimony 21 based on personal observation, or scientific testimony. 22 That authorizes the court to make a foundational inquiry, 23 which is, indeed, what happened here. 24

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QUESTION: Did the court of appeals rely on

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1 104(a)?

2 MR. FRIED: I believe it cited 104(a), but I 3 can't say that with certainty. That was in any case 4 the -- that is in any case the authorization to the courts 5 to engage in this inquiry. I believe that this Court in 6 the Bourjaily case --

QUESTION: Mr. Fried, I take it that your answer to the questions of the Chief Justice and Justice Stevens are that you place principally reliance on Rule 703, and you say that this was not evidence on which an expert could reasonably rely. I had thought the purpose of 703 was just to allow the admission in evidence of facts that are essentially hearsay facts.

MR. FRIED: It allows -- Rule 703 - QUESTION: And that gives no really necessary
 play to Rule 702 at all.

MR. FRIED: Well, it is our position, elaborated
in the brief, that 703 confirms and works along with 702.

19 703 allows an expert to base his opinion on 20 hearsay evidence on the premise that the hearsay evidence 21 is being used in a way, in accordance with the principle 22 of 702 -- that is, to allow the expert to testify to 23 scientific knowledge -- otherwise one would have the 24 anomalous result that an expert may not rely on hearsay 25 evidence in a way that's aberrant, but may rely on

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personal observation in a way that is aberrant, and we --QUESTION: Mr. Fried, may I inquire what the standard of appellate review is of decisions to exclude scientific evidence testimony? Is it de novo, or do we have an abuse of discretion standard?

6 MR. FRIED: The general criteria which were 7 stated in the courts here are criteria of law. The 8 application of those criteria to a particular fact 9 situation is a discretionary judgment.

10 However, where you have recurring fact 11 situations -- indeed, an identical fact situation, which is in fact what you have here, then the correct 12 application of a general standard should yield a uniform 13 result, and it becomes an abuse of discretion to apply 14 that general standard incorrectly to a recurring fact 15 situation, and courts of appeals, as the Fifth Circuit 16 did --17

18 QUESTION: I'm a little lost. Is it an abuse of 19 discretion standard?

20 (Laughter.)

21 MR. FRIED: It's an abuse of discretion standard 22 in a particular case. The criteria are legal standards, 23 and therefore are reviewable de novo, and where the facts 24 do not vary from case to case, then the application of 25 standard to facts must indeed be uniform.

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1 QUESTION: Can you also tell me whether the socalled Frye principle was followed in civil cases 2 generally, or was it just in the criminal field? 3 MR. FRIED: I am informed -- actually, I'm 4 5 informed by petitioners' counsel -- that there are no 6 instances of Frye being cited in civil cases prior to the Federal rules, but it is also the case that expert 7 testimony had not become an important problem at that 8 9 point.

10 There is nothing in the statement of the Frye 11 rules to suggest, or the approach to suggest that this is 12 a matter only of interest in a criminal context where, by 13 the way, it binds prosecution as well as defense.

14 QUESTION: Mr. --

QUESTION: Would you mind commenting before you're through on the proposed standard of the Solicitor General, your former office, and that of Judge Becker in the Downing case?

MR. FRIED: In our view, the standard offered by the Solicitor General does not differ from the standard we offer. Rather, it is a matter of emphasis.

We do not say that dissemination, clear statement, an offer for peer review after dissemination -this is not some bureaucratic requirement -- is a necessary or sufficient condition for admissibility. The

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1 Solicitor General does not say so.

We both say that in the circumstances of this case, where petitioners' testimony seeks to comment on, build on and refute a vast body of published statement, and there is no exigency, there are no pressing needs, that that factor is determinate.

7 The Third Circuit also recognized that exposure 8 to scientific scrutiny is a factor, and if something is a 9 factor there must be cases in which the factor is 10 determinate, and we say this is that case. So we do not 11 think there is a great difference between us, except of 12 emphasis.

QUESTION: Mr. Fried, there is, I take it, a difference between the SG's and Judge Becker's view on the Frye test on the admissibility of an opinion based upon what the Solicitor General called a significant minority view. I take it Frye would not let that in. Is that true?

MR. FRIED: Yes, and I think that the Solicitor General is correct there. This is very nicely illustrated by the controversy petitioners raise particularly in connection with the testimony of Dr. Swan about the socalled Rothman mode of analysis.

Now, the tests which petitioners seek to refute have all been done by a particular statistical technique

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requiring a 95-percent confidence level. Dr. Rothman, who
 is petitioners' amicus, offers a different statistical
 technique involving nested confidence intervals,
 displaying a vast amount of data. That is a minority
 view.

We do not claim, the Solicitor General does not claim, I don't think it would be reasonable to claim that the Dr. Rothman procedure is ipso facto inadmissible. That would not be proper.

What is the case is that Dr. Swan, so far as we 10 know, never used the Dr. Rothman principle. She simply 11 pointed at it and said that I have something here which 12 contradicts everything else using these other techniques, 13 and that shows why clear statement, dissemination to the 14 scientific community, an invitation for replication and 15 16 comment, where all that is possible, is absolutely 17 crucial.

18 If Dr. Swan had such a Rothman -- such a Rothman 19 analysis, she should have published it. She never has. 20 In 18 -- sorry, in 1987 she testified, no, I haven't 21 published it yet -- not yet. This testimony was offered 22 in 1989. In 1993, so far as we know, she still has not 23 clearly stated her premises, set them out, and allowed the 24 scientific community to comment upon them.

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QUESTION: So the significance of the minority

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view is in part a function of circumstantial evidence, in
 a way. It is to be assessed in part by a court based on
 the way the person claiming to offer it has behaved in the
 past.

5 MR. FRIED: Well, I don't believe Your Honor --6 QUESTION: I.e., has the person stepped up to 7 the plate and subjected this to scrutiny or has the person 8 not?

9 MR. FRIED: Well, it's not a comment on the behavior of the witness. It's a comment on the behavior, 10 if you wish, of the proposition -- Has the proposition 11 stepped up to the plate? -- and it's quite interesting 12 that in the First Circuit case, the Lynch case, Dr. Swan 13 had been forced to say something about her premises and 14 methods, and the First Circuit went into it in some detail 15 and totally devastated it as arbitrary and unexplained and 16 quite unreliable. 17

18 That illustrates the importance of the 19 publication peer review factor, and it is only a factor, 20 in appropriate cases.

QUESTION: Let me ask you a nuts-and-bolts question. Let's assume that we agree that Frye is too starchy a standard and we, like you, would find a place for the Solicitor General's view in construing 702. What should we do in this case?

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1 MR. FRIED: Oh, I think quite clearly that in 2 this case there was a judgment, and that judgment was 3 well-based, and the decision should be affirmed.

QUESTION: Should we adopt the Solicitor General's -- let's -- and I'm not suggesting that I'm about to do it, but if I were, should I take this opportunity to urge adoption of the Solicitor General's standards, or should I send this case -- affirm this case with a view that the Solicitor General's standard is open for development in the lower Federal courts?

MR. FRIED: Well, the most striking thing is the Solicitor General in applying his standard concludes that he decision should be affirmed and that the Solicitor General's standards clearly lead to the denial of admissibility in this case.

16 It's been so often said that the Court sits to review judgments and not to revise opinions. The opinion 17 in the Ninth Circuit may be viewed as a little breezy and 18 19 a little summary, but I think the reason for that is the Ninth Circuit said the Federal courts had seen these same 20 witnesses, this same testimony over and over again. 21 It has parsed these witnesses and this testimony over and 22 23 over again.

The Brock case is meticulous in its parsing. The Lynch case is meticulous in its parsing, and the Ninth

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Circuit said, for the reasons in those circuits, as well 1 as for the reasons they give, we rule this inadmissible. 2 QUESTION: But those cases weren't parsing 3 the -- based on the Solicitor General's standards. 4 MR. FRIED: The Brock case is very revealing in 5 6 this. The Brock case speaks my language, I believe, and the Solicitor General's language. The Brock case says, we 7 don't say that this is the be-all and the end-all, the 8 9 failure to state and disseminate and open to scrutiny. What we do say is that it's very important here. It 10 certainly gets our attention. 11 12 QUESTION: Mr. Fried, is it not true that in Brock they didn't hold the testimony inadmissible, they 13 held it insufficient? 14 MR. FRIED: They held it insufficient because 15 16 they were acting on JNOV. They had already been -- it had 17 admitted and the court was --QUESTION: Under Brock, then, we would have to 18 assume this testimony was admissible. 19 MR. FRIED: I don't believe that that assumption 20 21 is --QUESTION: At last, that's what the Ninth 22 Circuit said about Brock. 23 24 MR. FRIED: Brock was a sufficiency rather than 25 an admissibility case. I would suggest, Justice Stevens, 40

that if a court says, this is evidence which is so unreliable, which is so marginal that no jury could rest an opinion on it, that that is the equivalent of saying, it is also not evidence which constitutes scientific knowledge, or which, if considered by the jury, would not mislead, prejudice --

QUESTION: Well, that may be, but I suppose one possible disposition in this very case, if we weren't sure about the admissibility but we thought they'd applied the wrong standard, would be to send it back and either say, review the admissibility issue again, or, the evidence is admissible but you may still grant your summary judgment for the defendants, as they did in Brock.

MR. FRIED: Well, it's striking that the Brock court as well as the Ninth Circuit treated those two standards as really interchangeable. You can either do it on summary judgment or you can do it as to admissibility.

In both cases, what we are talking about, Justice Stevens, is the duty and authority of a Federal judge to assure that a jury verdict either has been or will be rationally based.

QUESTION: But are you taking the position that if we held the testimony to be admissible we must necessarily say the motion for summary judgment should be denied?

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MR. FRIED: Well, I would certainly hesitate a 1 while before I said that. 2 3 QUESTION: I would think you would, yes. 4 (Laughter.) 5 QUESTION: But that seems to be your argument. 6 MR. FRIED: I would say that the Ninth Circuit 7 and the Fifth Circuit were treating those as 8 interchangeable issues, as was the Turpin decision in the Sixth Circuit on summary judgment. They were treating 9 those as equivalent issues. 10 QUESTION: Well, was it a submission on summary 11 12 judgment that summary judgment should be granted because 13 the plaintiff could not come up with admissible testimony? MR. FRIED: That was the decision in this case. 14 15 QUESTION: Yes. 16 MR. FRIED: That was the decision in the Lynch 17 case. QUESTION: Yes. 18 MR. FRIED: That was the decision in the 19 20 Richardson case, and those cases also were incorporated by 21 reference by the Ninth Circuit guite explicitly, and they 22 did not -- and they were not summary judgment, they were indeed admissibility cases. 23 QUESTION: Well, do you think those cases -- all 24 25 of those cases spoke your language? 42 ALDERSON REPORTING COMPANY, INC.

(Laughter.)

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2	MR. FRIED: Well, I don't know whether they
3	would speak my language in another case, but what they
4	said was to emphasize a factor which is dispositive here.
5	I cannot believe that the Lynch court or the Richardson
6	court would say of an opinion about what caused a
7	particular accident that that opinion had to be published
8	or peer-reviewed certainly not.
9	Those cases referred to publication and peer
10	review in the context of the circumstances, in the context
11	of that case.
12	QUESTION: Why do you think this factor is
13	determinative in this case?
14	MR. FRIED: It is determinative because the
15	petitioners seek to overcome and, indeed, use published
16	peer review material.
17	I thank the Court for its attention.
18	QUESTION: Professor Fried, there are Harvard
19	Law School professors on both sides of this case, aren't
20	there?
21	MR. FRIED: Yes. There are Harvard law
22	professors all over the Court this week, Your Honor.
23	(Laughter.)
24	QUESTION: I thought you could lead us out of
25	the wilderness and get together up there.
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MR. FRIED: I hoped I had, Your Honor. Thank

2 you.

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QUESTION: Thank you, Mr. Fried.

Mr. Gottesman, you have 1 minute remaining. REBUTTAL ARGUMENT OF MICHAEL H. GOTTESMAN

ON BEHALF OF THE PETITIONERS 6 7 MR. GOTTESMAN: Thank you, Your Honor. 8 The Brock court expressly said the testimony was 9 admissible. The question of whether it's sufficient to --10 on the merits is a question of State law, not Federal, and 11 it's our contention you would have to look to California 12 law to decide whether California would agree, for example, 13 with the District of Columbia that this evidence was

14 sufficient.

The human data does not in this case trump the animal data. The animal data here is that a larger percentage of women who took Bendectin gave birth to children with limb defects.

The question is, how confident can we be that that is in fact probative of causation, not at a 95 percent level, but what Drs. Swan and Glassman said was applying the Rothman technique, a published technique and doing the arithmetic, that you find that this does link causation likelier than not.

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Professor Fried said that in 1975 the problem of

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experts was not perceived as it was now. Look at the advisory committee note to Rule 706. That note says we are worried about shopping for experts, we were worried for venal experts --CHIEF JUSTICE REHNQUIST: Thank you, Mr. Gottesman. MR. GOTTESMAN: Thank you, Your Honor. CHIEF JUSTICE REHNQUIST: The case is submitted. (Whereupon, at 11:06 a.m. the case in the above-entitled matter was submitted.) 

## CERTIFICATION

Alderson Reporting Company, Inc., hereby certifies that the attached pages represents an accurate transcription of electronic sound recording of the oral argument before the Supreme Court of The United States in the Matter of: No. 92–102

William Daubert, et ux., etc., eta., Petitioners v. Merrell Dow Pharmaceuticals, Inc.

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and that these attached pages constitutes the original transcript of the proceedings for the records of the court.

BY Am Mani Federico

(REPORTER)