UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

JAN 29 1993

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MEMORANDUM FOR: B.J. Youngblood, Director
Division of High-Level Waste Management

FROM: Stuart A. Treby
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Rulemaking and Fuel Cycle

SUBJECT: U.S. DISTRICT COURT RULING ON EXPERT JUDGMENT

This memorandum responds to your request for our views on the recent United States District Court opinion captioned O'Conner v. Commonwealth Edison Co., Case No. 88-1272 (C.D. Ill., July 23, 1992). Your memorandum notes the Federal Rules of Evidence, which the O'Conner decision mainly addresses, are not legally binding in NRC licensing proceedings. You request, however, that we consider "the underlying logic" of the decision even though a licensing board would not be legally required to apply the decision.

In particular, you ask whether the Court's decision offers any lessons for the NRC staff in preparing to review the use of expert judgment in DOE's license application for a high-level waste (HLW) repository. You reference the Court's discussion of Rule 703 of the Federal Rules of Evidence, particularly its statement that an expert's opinion must have "a sufficient verifiable scientific basis," and you note some of the judgments needed to project HLW repository performance over 10,000 years may not be scientifically verifiable -- especially projections of future human activities.

Part I of this response describes the O'Conner opinion with specific reference to the "verifiable scientific basis" issue you identify. In brief, the Court rejected a medical expert's opinion that O'Conner's cataracts could have been caused only by radiation because that opinion had no support or acceptance within the field of experts in radiation induced cataracts. In Part I, we take time to detail underlying factual circumstances and pertinent aspects of the Court's rationale, to help you better understand our reasoning in Part II of this memorandum.

Part II, in particular, analyzes the significance of the O'Conner decision for DOE's use of expert judgment in the HLW repository license application. In sum, we see nothing in the O'Conner opinion to cause us to advise the NRC staff to change its approach to preparing for the DOE license application, and we would not expect the O'Conner decision, even if followed by an NRC licensing board, to pose any particular problems for DOE.

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I. Summary of O'Conner decision

In brief, a former nuclear power plant employee brought suit against the plant owner and others, claiming occupational radiation exposures caused him subsequently to develop bilateral cataracts. In support of his claim, he offered the expert opinion of one Dr. Scheribel, an ophthalmologist, that only radiation could have caused his cataracts. At issue for the Court was whether to admit Dr. Scheribel's opinion as testimony. Before further summarizing the decision, we briefly describe the Federal Rules of Evidence, particularly Rules 702 and 703, as well as the Frye v. United States doctrine[1] which governed the Court's admissibility determination.

The Federal Rules of Evidence regulate the admission of proof at the trial of a lawsuit "in the courts of the United States."[2] Rule 702[3], in particular, governs admission of the testimony of experts, and generally permits such testimony if the trier of fact (i.e., either the judge, or jury, as the case may be) will be aided by the testimony. The test can be articulated as, "[o]n this subject, can the jury receive from this person appreciable help?"[4] The Court will determine whether the state of the art in a particular discipline permits a rational and reliable opinion to be asserted by an expert that will aid the jury in reaching accurate results.[5]

Rule 703[6] addresses the bases of opinion testimony by experts; it

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[1] Frye v. United States, 293 F. 1013 (D.C. Cir. 1923).

[2] Federal Rule of Evidence 101.

[3] Rule 703 reads as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or other wise.

[4] See G. Weissenberger, Federal Evidence § 702.3 at 298-99 (1987).

[5] Unresolved is the extent to which Rule 702 differs from the standard set in Frye v. Unites States which held that novel scientific evidence should not be admitted until it "gained general acceptance in the particular field in which it belongs." 293 F. 1013, 1014.

[6] Rules 703 reads as follows:

generally permits the expert to predicate testimony on firsthand perceptions, on facts or information admitted in the hearing at which the expert is called to testify, or on information made known to the expert before the hearing. Rule 703 is said to bring judicial procedure in line with the custom and practice of most experts. The underlying rationale is that the usual, critical nature of the expert's determinations guarantees the trustworthiness of the information upon which he relies. The expert in a science is thought to be competent to judge the reliability of statements made to him by other investigators or technicians.[7]

Frye v. United States, 293 F. 1013 (1923) involved a court ruling that evidence of a "lie-detector" examination was inadmissible. However, the case is cited for a broader, generally applicable legal principle, that is, a special rule of admissibility for "scientific evidence."[8] Specifically, numerous subsequent court decisions refer to the following language from Frye:

> [W]hile courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field to which it belongs.

The Frye decision predates the Federal Rules of Evidence, and its present-day validity is therefore an open legal question on which courts rulings vary.[9] With this brief background, we return to the O'Conner decision addressed in your memorandum.

At issue in O'Conner was the admissibility of the opinion of Dr. Scheribel who was prepared to testify as follows:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to him at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinion or inferences upon the subject, the facts or data need not be admissible in evidence.

[7] G. Weissenberger, Federal Evidence § 703.2.

[8] McCormick on Evidence § 203 (2d ed. 1972).

[9] The United States Supreme Court granted review in a case (Daubert v. Merrell Dow Pharmaceuticals, Inc., 951 F.2d 1128 (9th Cir. 1991)) presenting the question whether the uniform Federal Rules of Evidence eliminate the "general acceptance" test of Frye. 61 U.S.L.W. 1128 (October 28, 1992). A ruling by the Court is possible by July 1993.

> I know what cataracts look like when they have been induced by radiation, by what ever dosage or time of exposure there was. Radiation cataracts are [a] clinically describable and definable condition which, when present, cannot be mistaken for anything else.

The Court made several, somewhat critical observations about this opinion. It stated "Dr Scheribel appear[ed] to be the only doctor or scientist who will make such a statement" and his opinion "directly contradict[ed] the consensus science that radiation induced cataracts are not pathognomonic."[10] It also said the sum total of Dr. Scheribel's experience with radiation induced cataracts was "observing only five patients who Dr. Scheribel believes had cataracts induced by radiation therapy for cancer."[11]

In addressing admissibility generally under the Federal Rules of Evidence, the Court described its role as follows:

> [The rules] allow a court to intercede and to limit expert testimony where a witness attempts to give an opinion on a subject for which he is not qualified, when there is no factual basis for that proffered opinion, when that opinion is based upon an error of logic and when the expert cannot supply the court with any verifiable scientific support for the opinion.[12]

Turning specifically to admissibility under Rule 702, the Court said Dr. Scheribel was an expert in general ophthalmology, but was not a qualified expert by experience, education or study, in the highly specialized field of radiation induced cataracts. Accordingly, it held Dr. Scheribel was not qualified to render the expert opinion quoted above, and that his testimony was therefore inadmissible on that basis alone under Rule 702.

Addressing next the issue of admissibility under Rule 703, the Court said:

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[10] Slip Opinion at 23. The Court defined "pathognomonic" as a medical term for a specifically distinctive characteristic of a disease or pathologic condition on which a diagnosis can be made

[11] Id. at 26. The five patients represented less than .12 percent of the total number of patients (i.e., approximately 4200 patients) Dr. Scheribel had treated for cataracts.

[12] Slip Opinion at 31 (emphasis added). The Court went on to say "Rules of both science and evidence require a scientist or an expert to have a verifiable scientific basis for his opinion." Id. at 32.

> An expert's opinion must have a sufficient verifiable scientific basis; the scientific data underlying his opinion must be of the type that is reasonably relied upon by experts in the field."[13]

The Court thereafter said it was accordingly required to examine the reliability of the expert's sources to determine whether they satisfied the threshold established by Rule 703. It then found none of the articles and references cited by Dr. Scheribel supported his opinion that a radiation induced cataract could not be mistaken for anything else. In addition, the Court cited testimony from other experts that Dr. Scheribel's opinion was not supported by the medical and scientific experts in the field of radiation induced cataracts. On these bases, the Court found Dr. Scheribel's opinion to be without verifiable scientific support.

As an independent ground for excluding the opinion under Rule 703, the Court said a reasonable expert in the field would not rely on the data and reasoning used by Dr. Scheribel. In particular, it thought Dr. Scheribel's limited experience with only five patients was an insufficient scientific basis from which to derive his "binding universal rule" that only radiation could have induced O'Conner's cataracts. It also faulted Dr. Scheribel for failing to assess properly O'Conner's radiation dose, and stated any expert in radiation induced cataracts would require knowledge of a patient's dose before finding causation. It also said an expert would not reasonably rely on the mere presence of cataracts alone which could have numerous causes, but would make further inquiries to rule out other possible causes. Dr. Scheribel's opinion, in the Court's view, therefore had "no verifiable scientific basis and no verifiable scientific reasoning process."[14]

Turning to the Frye doctrine, which the Court said it was required to apply under its particular governing judicial decisions, as a test of "the reliability of scientific evidence," it said "the methodology and reasoning used by an expert to reach his conclusion must be generally accepted within the relevant scientific community." It then ruled Dr. Scheribel's opinion was inadmissible under Frye because the opinion was based on a "binding universal rule" (i.e., radiation induced cataracts are pathognomonic) not

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[13] Id. at 36. The Court said it was particularly wary of "unfounded expert opinion" when causation is the issue, especially a claim of injury due to exposure to a toxic substance where such an opinion might "conform" with jurors' underlying fears of toxic substances.

[14] Slip Opinion at 53-54. Further, since Dr. Scheribel's opinion actually contradicted consensus science, the Court said it was "more dangerous than an opinion lacking a verifiable scientific foundation."

accepted by scientists who specialize in the field and never proved by Dr. Scheribel, because Dr. Scheribel did not consider numerous other variables he should have considered in determining cause, and because the experts on which Dr. Scheribel claimed to have relied all testified his reasoning and methodology were not accepted in the scientific community.

II. Discussion of Significance of O'Conner Opinion

For the reasons that follow, we do not believe the O'Conner decision, including the Court's statement expert opinion must have verifiable scientific support, provides any reason for the NRC staff to change its approach to addressing the use of expert judgment in DOE's repository license application. As Part I above shows, the O'Conner decision did not have to confront the problem of dealing with uncertainty, and therefore does not even address this central issue for expert opinion in the HLW repository case.[15] Rather, O'Conner is about the potential difficulties facing lay juries today in toxic tort litigation because of "junk science," that is, the reality that there is not much difficulty in finding a medical expert witness to testify to virtually any theory of medical causation short of the fantastic.[16] If anything, then, the O'Conner decision would seem to reaffirm the correctness of the staff's present course to insist on good science in DOE's use of expert judgment for the repository license application. In other

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[15] The O'Conner decision itself says the "real question" is: Should plaintiff's expert's "lone voice"(i.e., plaintiff's expert appears to be the only doctor or scientist who will make the statement that he made in a trial deposition) be allowed to testify against the vast scientific consensus?

[16] The defendants in O'Conner argued Dr. Scheribel opinion was junk science, failing to assist jury under Rule 702, that should not be admitted; they said cross-examination was insufficient because it relies on lay person to arbitrate complex scientific issues. Further, the junk science issue is evident in the following discussion of scientific validity by the O'Conner court:

> Rules of both science and evidence require a scientist or an expert to have a verifiable basis for his opinion. Such controls are important in both fields to minimize error due to "junk" science.

Slip Opinion at 32. The Court's concern for junk science is also evident in its discussion of Rule 703 where the Court expressed its concern the jury may blindly accept an expert's opinion that conforms to their underlying fears of toxic substances without carefully understanding or examining the basis for that opinion. Id. at 36.

words, for NRC's purposes, the likely significance of O'Conner is the Court's statement the rules of both science and evidence require a scientist or an expert to have a verifiable scientific basis for his opinion.[17] Therefore, in insisting on good science, staff is also laying the groundwork for the legal argument that the expert opinion on which it bases its review has "a sufficient verifiable scientific basis," to use the Court's terminology quoted in your memorandum. .

Further, the Court's use of the "verifiable scientific support" requirement in O'Conner does not appear to pose any new or unforeseen hurdles for expert opinion in the NRC repository licensing proceeding. For example, the Court found each of Dr. Scheribel's cited references failed to support his blanket assertion that a radiation induced cataract cannot be mistaken for anything else, and this finding was the Court's basis for its further finding Dr. Scheribel's opinion was without verifiable scientific support. In our view, a requirement that an expert's sources support his or her opinion should not present undue hardship for DOE.

Similarly, the O'Conner Court said an expert's opinion must have a valid and verifiable scientific reasoning process, and it found that Rule 703 of the Federal Rules of Evidence provided a yardstick: Would a reasonable expert in the field rely on the data and reasoning used? Again, we are inclined to speculate that DOE would not find such a yardstick to be a problem.

Further, in discussing the Frye doctrine (i.e., the methodology and reasoning used by an expert to reach his conclusion must be generally accepted within the relevant scientific community), the Court in O'Conner noted, generally, an expert's conclusion may be admissible even when it is controversial or unique; however, it is not admissible when scientific truth has so completely hardened as to prevent legitimate difference of true expert opinion in a particular concrete field. The Court then said a court should not rely on an expert opinion an expert would not tolerate in his or her professional life. We think the same can be said for DOE and NRC. Therefore, we doubt DOE would find the Court's application of the Frye doctrine to be troublesome for its use of expert judgment in the HLW repository license application.[18]

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[17] Slip Opinion at 32.

[18] The Frye doctrine has been criticized as stating general scientific acceptance as a proper condition for taking judicial notice of scientific facts, but not a criterion for the admissibility of scientific evidence. These critics argue any relevant conclusions supported by a qualified expert witness should be received unless there other reasons for exclusion. E.g., McCormick's Handbook of the Law of Evidence § 203, at 489 (2d ed.

We appreciate the opportunity to provide you our views on this matter. Should you have any additional questions or comments, please let us know.

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1972). Given the technical qualifications of the board members, and the consequent absence of need to protect a lay jury from expert opinions that lack scientific acceptance, the Frye doctrine might not be useful to a licensing board in the repository licensing proceeding.

The Use of Expert Judgment in Decision Making: A Summary Report of the U.S. Department of Energy's Workshop on the Use of Expert Judgment held in Albuquerque, New Mexico November 18-20, 1992

Abstract

Introduction

The U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) sponsored a workshop in Albuquerque, New Mexico, November 18-20, 1992, on the use of expert judgment on the Yucca Mountain Project. It was attended by over 120 participants, including senior OCRWM management; managers and technical staff representing Yucca Mountain Project participant organizations; and, university faculty members and consultants with experience assessing and applying expert judgments in decision making. The workshop objective was to enhance the quality of DOE/OCRWM decisions through the appropriate use of expert judgment.

This paper summarizes for senior OCRWM management the results of the workshop. In particular, it presents the principles of and experience in applying the judgment of qualified experts to technical and programmatic decisions for the high-level waste program. The paper begins by defining expert judgment and its role in making high-quality decisions. It then presents key issues for management's consideration with respect to the application of expert judgment, including successes and failures, strengths and weaknesses, and some important lessons learned from past experience, especially in the regulatory arena. It concludes by recommending actions for OCRWM's use of expert judgment in the future.

Definition of Expert Judgment

Expert judgment is applied when a decision maker chooses to consult one or more individuals with expertise in a relevant area before making a decision. Those with such expertise are referred to as experts. In cases where the decision maker does not consult other individuals before taking action, the decision maker is choosing to become the expert, and most of the potential biases that affect assessments of expert judgment are still present.

Expert judgment is always used in one form or another. In fact, as suggested by the workshop's keynote speaker, Professor Ronald A. Howard, if the topic of the workshop were changed from "the use of expert judgment" to "the use of human knowledge," then it would be clear that the question is not whether to use expert judgment, but how.

Data may be used along with expert judgment, but data alone can never substitute for using expert judgment in decision making. As was also suggested by Professor Howard, "data are meaningful only when interpreted according to models created from the knowledge of experts." In contrast, "human judgment is always used in decision making. For example, in law (whether to litigate or settle), in medicine (whether to operate), or in

politics (when to launch Operation Desert Storm). Action determined by data [rather than by expert judgment] is the exception, not the norm."

Workshop panelist, Professor Ralph L. Keeney, made the following distinctions on how expert judgments may be used:

- implicit versus explicit,
- qualitative versus quantitative, and
- formal or informal assessment.

To illustrate these distinctions, a decision maker choosing whether or not to initiate a series of surface-based tests at Yucca Mountain might explicitly consider the possible results of the experiments before beginning drilling; or, the consideration of possible results might be implicit in a decision whether or not to start drilling. If the decision maker consults a hydrologist for information on the possible results, the expert might give qualitative information (e.g., the experiment will provide valuable information on matrix flux in the unsaturated zone) or quantitative information (e.g., data from this experiment will narrow the current uncertainty about UZ flux in the matrix by a factor of 3 to 5). Finally, the method used to obtain the wisdom of the hydrologist might either be informal (e.g., a direct question by the decision maker) or might involve a formal elicitation of the hydrologist's information by a third party who specializes in assessing such judgments. The formal elicitation would include an assessment of the hydrologist's level of uncertainty about the possible results.

The Role of Expert Judgment in Making Quality Decisions

Professor Howard set forth the following set of necessary characteristics of high-quality decisions:

- The right organization--the appropriate number and timing of interactions among decision makers, experts, and analysts
- The right framing of the decision--the scope and focus of the decision, appropriate for the situation
- The right alternatives to be evaluated--creative, significantly different alternatives that can be acted upon
- The right information--accurate, reliable information that includes what is known and what is not yet known about each important variable affecting the decision
- The right preferences--clear statements of all the criteria to be used in the evaluation of alternatives
- The right logic and analysis--correct reasoning, including a level of modeling appropriate to the decision
- The right communication--clear, understandable communication to all affected constituencies
- The right commitment to action by the decision makers after information has been gathered and the analysis is complete.

Decision makers can spend from minutes to months ensuring that these characteristics are present; the right amount of time depends on the decision to be made. Procedures have been developed to measure the degree to which

these characteristics are present in any decision, and these techniques are commonly taught to executives in training programs on decision quality. Such programs also include training in the appropriate amount of effort to be expended on each of the characteristics for any particular decision.

The characteristic of high-quality decisions that was discussed at length in the workshop was that of having the right information. However, there was a significant amount of discussion of three other characteristics: the right frame, the right communication, and the right commitment to action. Failure in any of these areas can render useless even the best information-gathering activities.

Professor Howard described how quality decision making requires balanced, accurate incorporation of expert judgment/human knowledge, including properly interpreted available data. He identified levels of formal modeling and analysis that might be used to support a major decision:

- "Pilot-level" analysis, used to identify important factors about which expert judgment and quantitative models should be pursued
- "Full-scale, integrated" analysis, as might be appropriate in a business decision with a clearly identified decision maker
- "Defensible" analysis, such as might be required to back up recommendations regarding the suitability of the Yucca Mountain Site for repository development.

A major conclusion of his presentation was, "in a decision situation requiring defensible analysis, the incorporation of expert judgment requires a high level of professional competence, careful planning, and skillful execution. A good decision analysis is much more difficult and much more powerful than it looks."

Uncertainty associated with expert judgments was a major topic of discussion. Again, Professor Howard framed the discussion as follows: "a true expert is aware of the limits of his or her knowledge." An essential consideration in incorporating expert judgment is the degree of certainty associated with the judgment. In fact, the degree of uncertainty may be a very important factor in the decision, if, for example, the decision maker can find alternatives that are flexible and can be adjusted in the future as uncertainties are resolved.

A series of formal methods was described for eliciting expert judgments (including their uncertainties), for recognizing and correcting biases that may be present in such judgments, and for incorporating the judgments of multiple experts. These methods are well documented and can be trained, but they do require time if they are to be performed in an environment where defensibility is paramount.

A series of challenges was described for decision makers within OCRWM. These include the need to establish for each major policy decision the appropriate extent and formality of incorporating expert judgment. In particular, whether such judgments should be implicit or explicit, qualitative or quantitative, or informal or formal. Such determinations can be made using the principles of decision quality, which have been successfully taught and applied in several energy-related industries. Time and effort spent in formal elicitation of

expert judgment and in formal analysis of policy decisions is appropriately viewed as an investment, and decisions can be made whether the investments of various different magnitudes are worth their time and effort. Experience from corporate decision-making, using decision analysis and the formal elicitation of expert judgments indicated that it typically pays off 100 to 1000 times the cost in terms of improved decisions. Another challenge for policy makers is establishing the appropriate role for peer review as a part of a defensible decision-making process. If structured properly, peer reviews are straightforward extensions of the process of assessing expert judgment; therefore, they help to enhance the quality, defensibility, and scientific acceptability of DOE decisions.

Record of Successful Applications of Expert Judgment

OCRWM Experience

The underlying theme for workshop participants was that expert judgment, whether implicit or explicit, is a part of any technical or regulatory decision. This was portrayed as a spectrum from less formal uses--such as in developing the Site Characterization Plan for the Yucca Mountain site, in peer reviews, and in design reviews--to more formal uses in the site selection process and in prioritizing data needs.

The DOE panel members reviewed the role of decision analysis and expert judgment in the studies summarized in Table 1. The multiattribute utility analysis (MUA) that was used to rank candidate sites for site characterization was discussed in some detail. It was reported that the MUA was widely reviewed, both by the National Academy of Sciences and the broader scientific community, and reviews have been generally favorable. Issues were raised during discussions about whether DOE managers acted appropriately when they applied additional factors to adjust the order of preference derived from the MUA in order to arrive at the final three sites that were nominated for site characterization. The general position of those who voiced their views at the workshop was that managers should always have the prerogative to consider additional factors when utilizing the results from decision-aiding methods such as MUAs. However, the decision is most defensible when important factors are suggested at the beginning and are then included explicitly in the analysis.

Another instance in which the structured use of expert judgment played a key role in OCRWM decision making is the analysis of alternative design options for the Exploratory Studies Facility (ESF). Dominant factors influencing the results of this study included: 1) The impact of each option on the overall ESF schedule of completion, and 2) The responsiveness of each option to concerns raised by the Nuclear Regulatory Commission and the Nuclear Waste Technical Review Board. Consequently, the choice of an option depended heavily on the relative weight given to these two factors. Management assigned those weights and then based the selection of the current ESF design on the results of the analysis.

Workshop participants also discussed the analysis of the benefits and risks of exploration and testing in the Calico Hills unit, which underlies the potential repository. The possibility of adverse impacts on future site performance was weighed against the benefit of the information that would be

gained by the exploration. Initially, the study measured the benefits of exploring the Calico Hills unit only in terms of information gained about site suitability. At the conclusion of the cost-benefit analysis, managers felt that the value-of-information approach did not reflect all of the benefits of exploring the Calico Hills; in particular, the increase in scientific confidence that might accompany extensive exploration of that unit. Therefore, the criteria for evaluating benefits and risks were expanded to include scientific confidence, and the alternatives were re-evaluated.

Several studies have been conducted to identify site-testing activities that would be most valuable in detecting unsuitable site conditions and increasing regulatory and scientific confidence. These studies indicate that, due to the low probability of detecting unsuitable site conditions, the most likely benefit of conducting extensive site characterization of Yucca Mountain will be that of building scientific confidence about site conditions and processes, rather than detecting unsuitability conditions or demonstrating compliance with regulations.

Experience Outside OCRWM

Individuals with experience in the licensing arena raised questions about how licensing boards have reacted to information formally elicited from experts, particularly when a board was unable to scrutinize the individual experts. Experience with the board involved in licensing the LaCrosse Boiling Water Reactor (LBP-81-7) shows that elicited expert judgment was not only recognized by the board but, in fact, the board more severely questioned input that was not elicited using a formal method. A second example from the Big Rock Point (LBP-84-32) facility also suggested that the board recognized polled expert judgment after careful review of the credentials of the experts, and the Board raised concerns regarding the uncertainties in non-polled input. The overall conclusion was that elicited multiple-expert judgment has been successfully used and defended in the licensing arena.

Expert judgment has been broadly used in the Waste Isolation Pilot Plant (WIPP) project for obtaining probability distributions for performance assessment, for developing design characteristics for site markers, and for identifying uncertainties in hydrologic conditions. Formal procedures have been developed for selecting expert panel members, including scientists from outside the WIPP program. Using these formal methods provides extensive documentation of the rationale and assumptions behind assessed expert judgments, which can be subjected to peer review and can be reviewed by outside groups.

An assessment of the acute and chronic risks of ozone exposure, sponsored by the Environmental Protection Agency, began with a first round of probability assessments obtained by interviews with experts. The judgments obtained were then reviewed by the experts prior to a workshop in which the judgments were discussed among the panel members. Then, a second round of probability assessments was conducted, followed by a second review by the experts. The process was concluded with thorough documentation of the process and its results.

Several workshop participants provided insight into the use of expert judgment in the international scientific and regulatory communities. Compared to the

U.S. approaches, the European approach tends to use many experts in isolation, to provide less training, and to differentially weight the judgments of individual experts.

Key Concepts from the Workshop

Strengths and Limitations in Use of Expert Judgment

The strengths of using structured expert judgment were highlighted in a number of discussions at the workshop. From the viewpoint of the decision-maker, explicit methods provide information about the factors influencing a decision and about the differences among alternative decisions. The effects of uncertainties become measurable and risks associated with alternative decisions can be understood. In addition, the costs to reduce uncertainties can be quantified to provide a sound basis for informed decisions about whether either further data acquisition or other actions are warranted.

Using expert judgment to develop technical input to support decisions has other benefits as well. It forces specialists and generalists to work together to define and interpret technical information. Discussions during formal elicitations expose how alternative conceptual models influence the way an expert interprets empirical data. Explicit approaches provide a basis for thorough documentation, which has high value in programs of long duration in which many of the experts may not be available to defend their interpretations in the future.

Some limitations of using expert judgment were voiced by a number of workshop participants. One recurring theme was the amount of time it takes to structure properly and to conduct a thorough expert elicitation process. Training the experts, ensuring problem definition meets the expectations of responsible managers, and conducting the elicitations can be very time-consuming and costly. In some cases, complexity may be introduced during elicitation that is later shown to be unimportant and may result in confusion and increased costs. Another limitation that was noted was the need to be cautious so that decision-makers are not unduly constrained by input from expert elicitations. Workshop participants believed that managers must have room to consider other factors not include in the elicitation process without being accused of having poor management practices.

Approaches used to combine experts' opinions are controversial and could threaten the credibility of the output from a structured elicitation process. Some workshop participants noted that attempting to build a consensus alone may be problematic because it may preclude the inclusion of extreme opinions that may reflect highly creative, novel interpretations that should be carefully considered. It was also noted, however, that providing a broad range of alternate opinions to a decision maker may not be useful in some cases. An additional limitation in use of expert panels is the potential for a single highly opinionated expert to unduly influence other panel member's opinions.

Lessons Learned

Experience suggests that the distinction between decision-aiding and decision-making is important in defining the manner in which structured expert

judgment is used in supporting decisions. The key point was that a decision maker must have the latitude to consider factors other than those included in the analysis without being accused of inappropriate action. A parallel lesson was that early management involvement in defining the problem that should be addressed, as well as maintaining continuous attention to the focus and scope of the activity, are essential to ensuring that the outcome will be most useful to the decision maker. Workshop participants agreed that the degree of formalism used should depend on the context and complexity of the problem that is being analyzed. When the issues are complex with many interfaces, reliance on structured assessment techniques is preferred.

Discussions about whether expert judgment should ever substitute for hard data led to agreement among some workshop participants that expert judgment should be viewed as the mechanism for codifying, quantifying, and documenting scientific knowledge and bringing relevant scientific knowledge into the decision-making process. Data and expert judgment should not be viewed as interchangeable because data must always be interpreted in the context of models based on human judgment. In fact, it is the interpretation of data in a consistent framework that creates the body of scientific knowledge. Decision makers never rely on data alone; therefore, data are never a substitute for expert judgment and vice versa. On a related topic, reliance on expert judgment to build confidence about the validity of computer models and codes is viewed as particularly important. The lesson related to validation is that models can only be validated for a given set of conditions, rather than validated in some broader context.

A number of lessons were presented related to the make-up of expert panels. For example, the credentials of the experts are often controversial, and multiple experts for each discipline area enhance credibility for controversial decisions. Including individuals on a panel who are known to have strongly differing opinions is important so that uncertainties reflected in these opinions can be represented. It is important to train the panel members to understand the assessment methodology and about how experts should respond to elicitations. Workshop participants reported that experts are willing to work together and that interactions between specialists and generalists are valuable.

Recommendations

The workshop steering committee recommends the following actions:

1. Present a summary of the workshop's findings at the Director's Forum.

2. On a case-by-case, OCRWM should consider identifying the appropriate role for expert judgment in major program decisions (on a case-by case basis). This would include the appropriate degree of formalism in analysis and elicitation of expert judgment, the appropriate level of analysis and modeling, and whether or not to solicit outside expertise and public input. In decision-making situations involving formalized elicitation and analysis, managers need to help choose an appropriate organization frame for the decision and to be willing to interact frequently with analysis and elicitation teams. OCRWM managers should also be informed as to the best way to interpret the results of the formal use of expert judgment, especially when it includes quantitative statements of the experts'

knowledge and their degree of uncertainty. The plan developed for use of expert judgment by the WIPP Project can be a useful document in developing a plan for OCRWM.

3. OCRWM should consider initiating a training program in the elements of quality decision making and the formal use of expert judgment. Training programs could include the following:

   - An executive seminar in decision quality for YMP upper and middle managers
   - A seminar in decision analysis and the formal elicitation of judgment for those who provide expert judgment
   - Formal training in decision analysis for YMP analysts and those who elicit expert judgment.

4. OCRWM should consider conducting a test case involving the use of expert judgment in the regulatory context. Example topics might include climate, volcanism, socioeconomic impacts, or engineering examples.

5. OCRWM should consider conducting a series of meetings involving all stakeholders, such as DOE, the Nuclear Regulatory Commission, the Environmental Protection Agency (EPA), and the State of Nevada. In these meetings the stakeholders could:

   - explore methods to use to incorporate expert judgment
   - become familiar with each stakeholder's analytic methods and performance-assessment models, and
   - becoming familiar with and respectful of alternative approaches to the use of expert judgment.

6. OCRWM should consider further exploration of the use of expert judgment by other government bodies in regulatory environments (e.g., EPA).

Conclusions

March 18, 1993

NOTE TO: Joe Gray

FROM: Bill Reamer

SUBJECT: Expert Elicitation Testimony

Attached for your information are the papers I mentioned that address expert opinion and expert elicitation which are topics of interest to the ACNW, as reflected in its recent briefing of and letter to the Commission on the NRC repository licensing program.

In particular, you will find attached a paper on "The Use of Expert Judgment in the NRC's Licensing Process," prepared by Dan Fehringer with our assistance. That paper was used as the basis for presentation slides which are also attached; the paper was not finalized. Also attached is a reprint of our memorandum addressing a recent federal district court opinion on the admissibility of expert opinion that is "junk science;" you will see we draw conclusions regarding the significance of the court's opinion for repository design and licensing.

If we can be of further assistance, please let me know.

cc's: Commissioner Assistants

3/26

Bill Reamer
504-1640

Paul Pomeroy 3/26 mtg w/ JC on use of expert judgment in repository licensing

Pomeroy's concern is that there is no judicial dec'n that allows use of "expert judgment" in adjudicatory licensing proceedings

Pomeroy would like to see an NRC rule that would permit this sort of thing & rule that it is not "junk science." OGC doesn't think that it is necessary for NRC which has expert adjudicatory boards

Reamer will provide to OGC papers on this

No problem with using expert judgment in NRC licensing proceedings

Provide to Janet K for 3/26 briefing by Pomeroy

Stemglass slam dunk NUREG-1150 (1)

Paul Pomeroy / Rich Major / Bill Reamer / Marty Malsch

1) Federal Rules of Evidence.
- Fry doctrine -

Admissibility of experts
Fed Rules of Evidence
702 & 703
Narrow interpretation of 702 - Q - would it lead to throwing out expert judgment witnesses?
O'Connor Case -
Actuarial experts judgment - not allowed.

Prediction of what will happen in the future?
What is your track record

Iterative Ref. Assessment Phase 2.5 - staff will be using an expert judgment elicitation process

Legal & Ref. Assessment Workshop

Technical Review Board - will suggest this.

Elicitation process - has not been adjudicated

"Some substantial evidence" — basis for relying on one expert view & dispensing w/ another

Reamer

Issue is not an admissibility issue -
Q - Does "expert judgment" (educated guesses) qualify as "substantial evidence"?
How do you choose between equally (or equally illogical) views?

DRAFT -- 11/9/92

Use of Expert Judgment in the NRC's Licensing Process

INTRODUCTION

The NRC's decision to grant or deny a license for a repository will be based on a combination of fact and opinion. For example, measurements of site characteristics will be presented as facts, and those facts will be accompanied by opinions of technical experts regarding the appropriateness of the measurement locations and methods, the interpretation of the test results, and the use of the test results for projecting repository performance. The NRC's licensing process provides a forum (in the form of a public hearing) for evaluating the facts and opinions presented by the applicant and any contrasting views that might be offered by other parties. This paper begins with a brief description of the NRC's licensing process, with particular emphasis on the ways in which the opinions of technical experts are presented and evaluated at a hearing before a licensing board. (The appendix to the paper provides a more detailed description of the hearing process.) The paper then discusses some of the newer, formalized methods that have been suggested for obtaining and using expert judgments. Finally, the paper evaluates the compatibility of these formalized methods with the NRC's established licensing process.

DESCRIPTION OF NRC'S LICENSING PROCESS

Phases of the Licensing Process

The NRC's licensing process for a HLW repository consists of several phases. The first phase, prelicensing consultation between the NRC staff, the future applicant, and other interested parties, has been underway for several years. During this preapplication phase, plans for site characterization are developed, field investigations and tests are conducted, the results are evaluated in performance assessments for the proposed repository, and plans for further site characterization are developed or modified as appropriate.

After site characterization has been completed, a license application will be prepared and submitted to the NRC. The NRC staff will then initiate its review of the application, including the use of expert opinion in the applicant's demonstration of repository safety. The staff will prepare a safety evaluation report documenting the bases for the staff's findings. The license application and the staff's safety evaluation report are both submitted to an NRC licensing board and become part of the record for decision.

A hearing is required before a licensing board may authorize construction of a repository. The Commission will appoint a licensing board to preside at the hearing and make decisions on the license application. The applicant and the NRC staff will participate in the hearing. In addition, any person whose interest may be affected by the hearing may file a written petition for leave to intervene and must satisfy certain other legal prerequisites. The licensing board will determine the persons permitted to intervene as parties and the legal contentions

at issue in the hearing. Intervention will also be permitted for affected units of local government, as defined by the Nuclear Waste Policy Act. The applicant has the burden of proof in the hearing, and intervening parties and interested governmental participants have the right to present evidence and cross-examine witnesses of opposing parties. Generally speaking, the licensing board will make a decision based on the evidence in the record of the proceeding, and will determine the matters in controversy and whether the required legal findings should be made supporting issuance of the construction authorization as proposed.

After a licensing board has reached a decision to approve or to reject an application, any of the parties to the hearing can appeal that decision to the Commission. In addition, the Commission may review the decision on its own motion. The written decision of the licensing board, together with the entire record of the hearing, will therefore be transmitted to the Commission. The Commission may allow the licensing board's decision to become the final decision of the Commission, may modify the decision, or may send the case back to the licensing board for additional testimony on particular points or for further consideration of particular issues.

Role of Expert Judgment in Licensing

During the site characterization phase of repository development, the ways in which expert opinions are solicited and used are generally not of concern to the NRC staff. The exception is any case where use of expert opinion might prevent development of information considered by the NRC staff to be necessary to evaluate the safety of a repository. For example, if a proposed field test is thought to be unnecessary because of an expert opinion that the information to be acquired by the test is not important, the NRC staff would want to review and comment on the basis for that opinion. The NRC staff's mechanism for reviewing an opinion would consist of questions directed to the future applicant, to be followed by written comments expressing the NRC staff's views. NRC staff comments would be advisory in nature, and any recommendations contained in those comments would not be binding on the future applicant, the NRC staff, or the Commission.

During the license application review phase, the NRC staff's review of expert opinion focuses on the license application and any referenced supporting materials. As necessary, the NRC staff can direct requests for additional information to the applicant. The questions and the applicant's responses are docketed and become part of the record of the staff's license application review.

In contrast to the NRC staff's reviews of expert opinion described above, a licensing board's review of expert opinion during a hearing involves significant differences in the way in which expert opinion is presented and evaluated. The role of the expert in the NRC licensing process is to provide testimony that will assist the licensing board in making the necessary determinations in the proceeding. The expert may therefore testify as to any relevant matter within his or her specialized field and provide facts as well as inferences reasonably drawn from those facts. Typically, the parties to the hearing will submit the direct testimony of their supporting witnesses, including expert witnesses, in writing. The written testimony is not normally submitted under oath. The witness later swears to the truthfulness and correctness at the time of the

hearing as part of the offer of the testimony into evidence. The expert testimony of multiple witnesses may be received at the hearing on a panel or roundtable basis after submission of written testimony. Other parties will have the opportunity to cross-examine witnesses, including expert witnesses. The well-planned cross examination will explore the underlying factual basis of the expert witness's opinion, and will attempt to expose any deficiencies in the opinion. The licensing board may ask questions of the expert witness to assist its understanding and assessment of the expert testimony, and the board may invite its own experts to testify. The licensing board is also expected to use its expert knowledge and experience in evaluating and drawing conclusions from the evidence in making its decision.

If a licensing board's decision is appealed, the review of expert opinion during the appeal would be as follows. Ordinarily, the party raising an issue on appeal will need to show that the issue was raised in some manner to the licensing board or that the board improperly excluded the issue. Therefore, a party's appeal of the licensing board's decision might, for example, seek reversal of a licensing board ruling on the admissibility of certain expert testimony or it might appeal the weight given to such testimony by the licensing board in its decision. After reviewing all the parties' submissions and the record of the proceeding, the Commission could grant or deny such an appeal. The Commission could adopt, modify or set aside the licensing board's rulings, findings or conclusions on the issue appealed, or could remand the case to the board for further consideration. In so doing, the Commission would state the basis for its action. Generally, the decision to grant or deny an appeal would be made on the basis of the record established during the original licensing board review. Therefore, no new presentations of expert opinions would ordinarily occur during the appeal process. However, the Commission could reevaluate the significance of, or conclusions drawn from, opinions present in the record.

FORMALIZED METHODS FOR USE OF EXPERT JUDGMENT

A formalized process for obtaining and documenting expert judgments might include the following tasks[1,2].

Identification of Issues

The specific issue(s) to be addressed through expert judgment should be defined as clearly as possible. Poor definition of the issue(s) may make it difficult for experts to develop meaningful and defensible judgments.

Selection of Experts

The expert(s) selected to provide judgments should possess the necessary expertise and should be free of actual or perceived bias or conflict of interest. If a panel of experts is to be used, diversity of opinion and approaches for addressing the issue(s) may be desirable.

Training the Experts

Numerous studies have found that experts tend to be overly confident, and

sometimes biased, in their judgments. Techniques are available to help experts identify and eliminate potential biases, and to more realistically estimate the uncertainties in their judgments.

Developing the Judgments

"Decomposition" of an issue (i.e., breaking a big problem down into a number of smaller problems) can help an expert develop the requested judgments and can be particularly useful for documenting the basis for the final judgments. Elicitation techniques can also help prevent biases or inconsistencies in the final judgments.

Documenting the Results

The reasoning that underlies a judgment largely determines the weight that judgment will carry in an NRC licensing review. Elicitation techniques help an expert identify and articulate the basis for a judgment. Thorough documentation of that basis will expedite the NRC staff's review of a license application, and will assist in preparing testimony for submittal to a licensing hearing.

COMPATIBILITY WITH NRC LICENSING PROCESS

Admissibility of Expert Judgments

Opinions about the factual basis of a license application are relevant to a licensing decision and are admissible in a hearing. The legal system has long recognized the power of the expert to go beyond facts and to draw inferences in the form of opinions. (This assumes, of course, that the subject matter of the opinion relates to some recognized, specialized field and that the expert is sufficiently skilled in the field such that the opinion would probably aid in the search for truth.) By reason of his expertise in the specialized field, the expert is qualified to draw inferences from facts that the lay person would be unable to draw. The expert is not required to have firsthand knowledge of the underlying facts. By this reasoning, a wide range of expert judgments would be admissible in an NRC hearing, provided relevance to the decision at hand could be demonstrated. (A prerequisite, of course, for admissibility of expert judgment is establishment of the expertise of the person offering the judgment.)

Technical Experts versus Decision-Makers

At all phases of the NRC's licensing process, but especially during a hearing, it is necessary to distinguish between the judgments that can properly be provided by technical experts and those that are reserved for a "decision-maker" such as the licensing board. Technical experts can provide expert judgments only within their areas of technical expertise. For example, a volcanologist can serve as an expert only regarding the likelihood and effects of potential volcanic activity. A decision regarding the acceptability of a repository potentially threatened by volcanic activity would involve additional concerns outside the volcanologist's area of expertise. Generally, another person with a broader perspective of the overall repository system would make such a

decision.

Moreover, as evidenced by the foregoing description of the NRC hearing process, neither the licensing board nor the Commission is bound by the judgments of an expert witness in the hearing. It is possible that a board or the Commission will find that a particular expert judgment does not provide an adequate basis for a decision. For example, even if a volcanologist has presented a judgment that volcanism will not threaten a proposed repository, a board or the Commission might find that the technical basis underlying the expert's judgment is inadequate to support a decision to issue a license. Rather than being bound by the judgments of expert witnesses, the licensing board and the Commission will, in addition, use their own expert knowledge and experience in making their respective determinations in light of all the evidence in the record as a whole.

Combining Multiple Judgments

Expert judgments are sometimes produced by obtaining the individual judgments of several experts and then combining the individual opinions to produce a composite judgment. Use of multiple experts may be particularly valuable for estimating the full range of uncertainty involved in a judgment. However, two difficulties may be encountered. First, in some cases the weights applied to the individual judgments can significantly influence the result. If the weights are assigned by a non-expert (e.g., a performance assessment generalist), the credibility of the combined estimate could suffer. An ideal solution would be for the group of experts to determine its own weights (i.e., to form a sort of consensus estimate), but this might not always be possible. If other combination methods are used, the applicant must be capable of demonstrating their validity.

A second potential problem involves introduction of combined judgments into evidence during a hearing. As noted previously, written testimony is normally offered into evidence by a witness who later swears to its truthfulness during a hearing. Other parties to the hearing then have an opportunity to cross-examine the witness. A combined judgment involves several experts; if one or more of the experts were unable to appear as witnesses, the lack of opportunity for cross-examination might reduce the probative value of evidence introduced by such means.

Combining Multiple Models

If multiple models of a process (e.g., groundwater flow) exist, weights can be assigned to each model representing the estimated likelihood that each model is correct. Such weighting seems harmless enough, and may even be useful for clearly conveying the applicant's confidence in each model. However, the additional step of projecting repository performance using each model, assigning weights to each projection, and combining the weighted projections to produce a weighted average estimate of performance would be more problematical. Combining the projections of multiple models can obscure information relevant to a licensing decision (especially the range of possible performance) and can produce results that are difficult to interpret (e.g., if the weighted projection does not correspond to a physically possible outcome).

One goal of an NRC hearing is to determine, by a preponderance of the evidence,

that the performance predicted by the "correct" model will be acceptable, recognizing that there is uncertainty about which model is correct. Combining the projections of multiple models into a weighted average can help to evaluate uncertainties in projected performance, but should not be viewed as an acceptable substitute for determining the "correct" model. Thus, if the projections of multiple models are to be weighted and combined, the applicant must demonstrate that doing so will materially assist a licensing board in evaluating the acceptability of the proposed facility (e.g., by providing improved estimates of the uncertainties in projected performance).

SUMMARY AND CONCLUSIONS

Expert judgment has always played a major role in NRC licensing actions, and will continue to do so for a repository. Prior to a hearing, the potential applicant has wide latitude to use expert judgment without oversight by the NRC. The NRC staff will review only those uses that might prevent development of information considered necessary to evaluate the safety of a repository.

During a licensing hearing, any of the parties may present expert judgments if two criteria are met: (1) the person(s) offering the judgments are shown to possess appropriate expertise, and (2) the judgment(s) are shown to be relevant to the decision at hand. Formalized methods for obtaining and documenting expert judgments need not be used, but may be helpful for improving the quality of judgments and for clearly articulating the technical bases underlying the judgments. Combined judgments of multiple experts are admissible, but two difficulties could arise: (1) if the experts are unable to reach a consensus judgment, the method used to combine multiple judgments could become controversial, and (2) if one or more of the experts is unable to appear at the hearing as a witness, the lack of opportunity for cross-examination might reduce the value of the combined judgment.

One goal of an NRC hearing is to determine that the performance of a repository, as projected by the "correct" model of the facility, will be acceptable. If projections of multiple models are to be weighted and combined, the applicant must demonstrate that doing so will materially assist a licensing board in reaching its decision.

Use of Expert Judgment in NRC's Licensing Process

November 18, 1992

Daniel J. Fehringer

Contact: Daniel J. Fehringer
Phone: (301) 504-1426

INTRODUCTION

A licensing decision will be based on a combination of fact and opinion.

NRC's licensing process provides a forum (the hearing) for evaluating facts and opinions.

This talk discusses:

- NRC's licensing process.
- The role of exp. judgment in the process.
- Compatibility between formal methods for obtaining expert judgment and NRC hearings.

PHASES IN LICENSING PROCESS

Prelicensing consultation.

NRC staff review of license application.

Hearing.

Appeal/Commission review.

ROLES OF EXPERT JUDGMENT

Prelicensing consultation.

-Ensure adequacy of data collection.

NRC staff review of license application.

Hearing.

-Written evidence followed by sworn testimony.
-Cross-examination of witnesses.

Appeal/Commission review.

-Previously established record.

COMPATIBILITY WITH LICENSING PROCESS

Two criteria for admitting evidence:

-Establish expertise of expert(s).
-Show relevance of judgment(s).

Federal Rules of Evidence do not apply.

Expert(s) need not have first-hand knowledge of facts.

COMPATIBILITY (CONTINUED)

Expert judgments limited to area of expertise.

-Decision-makers, rather than technical experts, decide admissibility and relevance of evidence and overall acceptability of a facility.

Licensing board and Commission not bound by judgments of technical experts.

COMPATIBILITY (CONTINUED)

Combining multiple judgments.

-Judgments of panels are admissible.

-Potential problem if weighting method becomes controversial.

-Potential problem if members of panel are unavailable to provide sworn testimony.

COMPATIBILITY (CONTINUED)

Combining multiple models.

- -Assigning weights seems OK as expression of confidence.
- -Weighting and combining projections of models will be more controversial.
- -Hearing process tries to identify "correct" model for evaluating safety.
- -If projections are combined, result should be physically meaningful.

-Should not discard or down-play relevant information.

BOTTOM LINE

How can DOE be assured that its judgments will prevail during licensing?

There can be no such assurance:

- Judgments must meet a threshhold of "goodness."
- No protection against new information.
- No protection against new interpretations.
- Alternative judgments of other parties cannot be excluded from the hearing.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

MEMORANDUM FOR: B.J. Youngblood, Director
Division of High-Level Waste Management

FROM: Stuart A. Treby
Assistant General Counsel for
Rulemaking and Fuel Cycle

SUBJECT: U.S. DISTRICT COURT RULING ON EXPERT JUDGMENT

This memorandum responds to your request for our views on the recent United States District Court opinion captioned O'Conner v. Commonwealth Edison Co., Case No. 88-1272 (C.D. Ill., July 23, 1992). Your memorandum notes the Federal Rules of Evidence, which the O'Conner decision mainly addresses, are not legally binding in NRC licensing proceedings. You request, however, that we consider "the underlying logic" of the decision even though a licensing board would not be legally required to apply the decision.

In particular, you ask whether the Court's decision offers any lessons for the NRC staff in preparing to review the use of expert judgment in DOE's license application for a high-level waste (HLW) repository. You reference the Court's discussion of Rule 703 of the Federal Rules of Evidence, particularly its statement that an expert's opinion must have "a sufficient verifiable scientific basis," and you note some of the judgments needed to project HLW repository performance over 10,000 years may not be scientifically verifiable -- especially projections of future human activities.

Part I of this response describes the O'Conner opinion with specific reference to the "verifiable scientific basis" issue you identify. In brief, the Court rejected a medical expert's opinion that O'Conner's cataracts could have been caused only by radiation because that opinion had no support or acceptance within the field of experts in radiation induced cataracts. In Part I, we take time to detail underlying factual circumstances and pertinent aspects of the Court's rationale, to help you better understand our reasoning in Part II of this memorandum.

Part II, in particular, analyzes the significance of the O'Conner decision for DOE's use of expert judgment in the HLW repository license application. In sum, we see nothing in the O'Conner opinion to cause us to advise the NRC staff to change its approach to preparing for the DOE license application, and we would not expect the O'Conner decision, even if followed by an NRC licensing board, to pose any particular problems for DOE.

I. Summary of O'Conner decision

In brief, a former nuclear power plant employee brought suit against the plant owner and others, claiming occupational radiation exposures caused him subsequently to develop bilateral cataracts. In support of his claim, he offered the expert opinion of one Dr. Scheribel, an ophthalmologist, that only radiation could have caused his cataracts. At issue for the Court was whether to admit Dr. Scheribel's opinion as testimony. Before further summarizing the decision, we briefly describe the Federal Rules of Evidence, particularly Rules 702 and 703, as well as the Frye v. United States doctrine[1] which governed the Court's admissibility determination.

The Federal Rules of Evidence regulate the admission of proof at the trial of a lawsuit "in the courts of the United States."[2] Rule 702[3], in particular, governs admission of the testimony of experts, and generally permits such testimony if the trier of fact (i.e., either the judge, or jury, as the case may be) will be aided by the testimony. The test can be articulated as, "[o]n this subject, can the jury receive from this person appreciable help?"[4] The Court will determine whether the state of the art in a particular discipline permits a rational and reliable opinion to be asserted by an expert that will aid the jury in reaching accurate results.[5]

Rule 703[6] addresses the bases of opinion testimony by experts; it

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[1] Frye v. United States, 293 F. 1013 (D.C. Cir. 1923).

[2] Federal Rule of Evidence 101.

[3] Rule 703 reads as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or other wise.

[4] See G. Weissenberger, Federal Evidence § 702.3 at 298-99 (1987).

[5] Unresolved is the extent to which Rule 702 differs from the standard set in Frye v. Unites States which held that novel scientific evidence should not be admitted until it "gained general acceptance in the particular field in which it belongs." 293 F. 1013, 1014.

[6] Rules 703 reads as follows:

generally permits the expert to predicate testimony on firsthand perceptions, on facts or information admitted in the hearing at which the expert is called to testify, or on information made known to the expert before the hearing. Rule 703 is said to bring judicial procedure in line with the custom and practice of most experts. The underlying rationale is that the usual, critical nature of the expert's determinations guarantees the trustworthiness of the information upon which he relies. The expert in a science is thought to be competent to judge the reliability of statements made to him by other investigators or technicians.[7]

Frye v. United States, 293 F. 1013 (1923) involved a court ruling that evidence of a "lie-detector" examination was inadmissible. However, the case is cited for a broader, generally applicable legal principle, that is, a special rule of admissibility for "scientific evidence."[8] Specifically, numerous subsequent court decisions refer to the following language from Frye:

> [W]hile courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field to which it belongs.

The Frye decision predates the Federal Rules of Evidence, and its present-day validity is therefore an open legal question on which court rulings vary.[9] With this brief background, we return to the O'Conner decision addressed in your memorandum.

At issue in O'Conner was the admissibility of the opinion of Dr. Scheribel who was prepared to testify as follows:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to him at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinion or inferences upon the subject, the facts or data need not be admissible in evidence.

[7] G. Weissenberger, Federal Evidence § 703.2.

[8] McCormick on Evidence § 203 (2d ed. 1972).

[9] The United States Supreme Court granted review in a case (Daubert v. Merrell Dow Pharmaceuticals, Inc., 951 F.2d 1128 (9th Cir. 1991)) presenting the question whether the uniform Federal Rules of Evidence eliminate the "general acceptance" test of Frye. 61 U.S.L.W. 1128 (October 28, 1992). A ruling by the Court is possible by July 1993.

> I know what cataracts look like when they have been induced by radiation, by what ever dosage or time of exposure there was. Radiation cataracts are [a] clinically describable and definable condition which, when present, cannot be mistaken for anything else.

The Court made several, somewhat critical observations about this opinion. It stated "Dr Scheribel appear[ed] to be the only doctor or scientist who will make such a statement" and his opinion "directly contradict[ed] the consensus science that radiation induced cataracts are not pathognomonic."[10] It also said the sum total of Dr. Scheribel's experience with radiation induced cataracts was "observing only five patients who Dr. Scheribel believes had cataracts induced by radiation therapy for cancer."[11]

In addressing admissibility generally under the Federal Rules of Evidence, the Court described its role as follows:

> [The rules] allow a court to intercede and to limit expert testimony where a witness attempts to give an opinion on a subject for which he is not qualified, when there is no factual basis for that proffered opinion, when that opinion is based upon an error of logic and when the expert cannot supply the court with any verifiable scientific support for the opinion.[12]

Turning specifically to admissibility under Rule 702, the Court said Dr. Scheribel was an expert in general ophthalmology, but was not a qualified expert by experience, education or study, in the highly specialized field of radiation induced cataracts. Accordingly, it held Dr. Scheribel was not qualified to render the expert opinion quoted above, and that his testimony was therefore inadmissible on that basis alone under Rule 702.

Addressing next the issue of admissibility under Rule 703, the Court said:

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[10] Slip Opinion at 23. The Court defined "pathognomonic" as a medical term for a specifically distinctive characteristic of a disease or pathologic condition on which a diagnosis can be made

[11] Id. at 26. The five patients represented less than .12 percent of the total number of patients (i.e., approximately 4200 patients) Dr. Scheribel had treated for cataracts.

[12] Slip Opinion at 31 (emphasis added). The Court went on to say "Rules of both science and evidence require a scientist or an expert to have a verifiable scientific basis for his opinion." Id. at 32.

> An expert's opinion must have a sufficient verifiable scientific basis; the scientific data underlying his opinion must be of the type that is reasonably relied upon by experts in the field."[13]

The Court thereafter said it was accordingly required to examine the reliability of the expert's sources to determine whether they satisfied the threshold established by Rule 703. It then found none of the articles and references cited by Dr. Scheribel supported his opinion that a radiation induced cataract could not be mistaken for anything else. In addition, the Court cited testimony from other experts that Dr. Scheribel's opinion was not supported by the medical and scientific experts in the field of radiation induced cataracts. On these bases, the Court found Dr. Scheribel's opinion to be without verifiable scientific support.

As an independent ground for excluding the opinion under Rule 703, the Court said a reasonable expert in the field would not rely on the data and reasoning used by Dr. Scheribel. In particular, it thought Dr. Scheribel's limited experience with only five patients was an insufficient scientific basis from which to derive his "binding universal rule" that only radiation could have induced O'Conner's cataracts. It also faulted Dr. Scheribel for failing to assess properly O'Conner's radiation dose, and stated any expert in radiation induced cataracts would require knowledge of a patient's dose before finding causation. It also said an expert would not reasonably rely on the mere presence of cataracts alone which could have numerous causes, but would make further inquiries to rule out other possible causes. Dr. Scheribel's opinion, in the Court's view, therefore had "no verifiable scientific basis and no verifiable scientific reasoning process."[14]

Turning to the Frye doctrine, which the Court said it was required to apply under its particular governing judicial decisions, as a test of "the reliability of scientific evidence," it said "the methodology and reasoning used by an expert to reach his conclusion must be generally accepted within the relevant scientific community." It then ruled Dr. Scheribel's opinion was inadmissible under Frye because the opinion was based on a "binding universal rule" (i.e., radiation induced cataracts are pathognomonic) not

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[13] Id. at 36. The Court said it was particularly wary of "unfounded expert opinion" when causation is the issue, especially a claim of injury due to exposure to a toxic substance where such an opinion might "conform" with jurors' underlying fears of toxic substances.

[14] Slip Opinion at 53-54. Further, since Dr. Scheribel's opinion actually contradicted consensus science, the Court said it was "more dangerous than an opinion lacking a verifiable scientific foundation."

accepted by scientists who specialize in the field and never proved by Dr. Scheribel, because Dr. Scheribel did not consider numerous other variables he should have considered in determining cause, and because the experts on which Dr. Scheribel claimed to have relied all testified his reasoning and methodology were not accepted in the scientific community.

II. Discussion of Significance of O'Conner Opinion

For the reasons that follow, we do not believe the O'Conner decision, including the Court's statement expert opinion must have verifiable scientific support, provides any reason for the NRC staff to change its approach to addressing the use of expert judgment in DOE's repository license application. As Part I above shows, the O'Conner decision did not have to confront the problem of dealing with uncertainty, and therefore does not even address this central issue for expert opinion in the HLW repository case.[15] Rather, O'Conner is about the potential difficulties facing lay juries today in toxic tort litigation because of "junk science," that is, the reality that there is not much difficulty in finding a medical expert witness to testify to virtually any theory of medical causation short of the fantastic.[16] If anything, then, the O'Conner decision would seem to reaffirm the correctness of the staff's present course to insist on good science in DOE's use of expert judgment for the repository license application. In other

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[15] The O'Conner decision itself says the "real question" is: Should plaintiff's expert's "lone voice"(i.e., plaintiff's expert appears to be the only doctor or scientist who will make the statement that he made in a trial deposition) be allowed to testify against the vast scientific consensus?

[16] The defendants in O'Conner argued Dr. Scheribel opinion was junk science, failing to assist jury under Rule 702, that should not be admitted; they said cross-examination was insufficient because it relies on lay person to arbitrate complex scientific issues. Further, the junk science issue is evident in the following discussion of scientific validity by the O'Conner court:

> Rules of both science and evidence require a scientist or an expert to have a verifiable basis for his opinion. Such controls are important in both fields to minimize error due to "junk" science.

Slip Opinion at 32. The Court's concern for junk science is also evident in its discussion of Rule 703 where the Court expressed its concern the jury may blindly accept an expert's opinion that conforms to their underlying fears of toxic substances without carefully understanding or examining the basis for that opinion. Id. at 36.

words, for NRC's purposes, the likely significance of O'Conner is the Court's statement the rules of both science and evidence require a scientist or an expert to have a verifiable scientific basis for his opinion.[17] Therefore, in insisting on good science, staff is also laying the groundwork for the legal argument that the expert opinion on which it bases its review has "a sufficient verifiable scientific basis," to use the Court's terminology quoted in your memorandum.

Further, the Court's use of the "verifiable scientific support" requirement in O'Conner does not appear to pose any new or unforeseen hurdles for expert opinion in the NRC repository licensing proceeding. For example, the Court found each of Dr. Scheribel's cited references failed to support his blanket assertion that a radiation induced cataract cannot be mistaken for anything else, and this finding was the Court's basis for its further finding Dr. Scheribel's opinion was without verifiable scientific support. In our view, a requirement that an expert's sources support his or her opinion should not present undue hardship for DOE.

Similarly, the O'Conner Court said an expert's opinion must have a valid and verifiable scientific reasoning process, and it found that Rule 703 of the Federal Rules of Evidence provided a yardstick: Would a reasonable expert in the field rely on the data and reasoning used? Again, we are inclined to speculate that DOE would not find such a yardstick to be a problem.

Further, in discussing the Frye doctrine (i.e., the methodology and reasoning used by an expert to reach his conclusion must be generally accepted within the relevant scientific community), the Court in O'Conner noted, generally, an expert's conclusion may be admissible even when it is controversial or unique; however, it is not admissible when scientific truth has so completely hardened as to prevent legitimate difference of true expert opinion in a particular concrete field. The Court then said a court should not rely on an expert opinion an expert would not tolerate in his or her professional life. We think the same can be said for DOE and NRC. Therefore, we doubt DOE would find the Court's application of the Frye doctrine to be troublesome for its use of expert judgment in the HLW repository license application.[18]

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[17] Slip Opinion at 32.

[18] The Frye doctrine has been criticized as stating general scientific acceptance as a proper condition for taking judicial notice of scientific facts, but not a criterion for the admissibility of scientific evidence. These critics argue any relevant conclusions supported by a qualified expert witness should be received unless there other reasons for exclusion. E.g., McCormick's Handbook of the Law of Evidence § 203, at 489 (2d ed.

We appreciate the opportunity to provide you our views on this matter. Should you have any additional questions or comments, please let us know.

Stuart A. Treby
Assistant General Counsel
for Rulemaking and Fuel Cycle

1972). Given the technical qualifications of the board members, and the consequent absence of need to protect a lay jury from expert opinions that lack scientific acceptance, the Frye doctrine might not be useful to a licensing board in the repository licensing proceeding.

1 to the side, which is against all procedures. But, again,
2 you made some very good points also.
3 MR. MOELLER: Any other questions or comments?
4 [No response.]
5 MR. MOELLER: I hear none. Well, we thank you,
6 Mr. Silva, for your presentation, and sharing our work with
7 us.
8 MR. SILVA: Thank you.
9 MR. MOELLER: We will take a break now and resume
10 at about 10 after 10:00.
11 [Recess.]
12 MR. MOELLER: The meeting will resume. We will
13 move ahead now with the next item on our agenda, which is a
14 discussion of the acceptance of scientific evidence, based
15 primarily on expert judgment. We have with us Donald Jose,
16 who is a lawyer, who has extensive experience in this area,
17 and, indeed, you have been provided with a number of
18 articles written by Mr. Jose, as well as the key court
19 decisions that he has participated in.
20 In the way of background, I wanted to point out
21 that Donald Jose graduated from Westmar College in Iowa,
22 with a degree in Political Science, and then he received his
23 Law Degree from the University of Iowa College of Law, and
24 he was subsequently admitted to the Iowa State Bar. He then
25 worked for the Department of Justice. And, Don, I guess you

1 were here in Washington when you worked with them, and was
2 involved in a multitude of landmark decisions related to rad
3 protection. But, the thing I admire most about Don, and I
4 must share it with you, is that he is a licensed auto
5 mechanic. And he and I were talking about dwell meters, and
6 setting the points, which you people who don't remember, you
7 know, prior to the electronic ignition systems, you wouldn't
8 appreciate it. But, it was an art, and it is one way to
9 through law school.
10 MR. HINZE: Does that mean he can do something
11 while having a cigarette hanging out of the side of his
12 mouth?
13 MR. MOELLER: No. He has no cigarettes hanging
14 out.
15 Don, it is a pleasure to welcome you, and we look
16 forward to an illuminating discussion. We have been
17 awaiting this for a long time.
18 MR. JOSE: Many years ago -- let me turn my mike
19 on. There. I hope that that is working.
20 MR. MOELLER: Yes.
21 MR. JOSE: Many years ago, when I was a young
22 lawyer in the Department of Justice, I was assigned tasks
23 like defending psychiatric malpractice cases, and defending
24 medical malpractice cases. And then I was assigned to
25 specialize in the catastrophically injured plaintiff, like

1 brain damaged infants. And they kind of gave me cases that
2 were considered impossible cases. So, when radiation came
3 along, I was a likely candidate to get involved in those
4 kind of cases, and I did. I found it to be fascinating.
5 The first thing I had to do was learn something about the
6 science, because what I had been doing for maybe the last
7 10, 15 years, at least the last 10 years is trying to
8 understand enough about the science so that, as this new
9 field of law works it way through the courts and rules our
10 set up in the legal system to process these kinds of claims,
11 that those rules will be scientifically accurate, so that
12 the claims that are process through the legal system will
13 yield the result that scientists would yield, had they
14 decided those claims. In other words, injured people should
15 recover, and people who weren't injured should not recover.
16 And, maybe some kinds of claims shouldn't even be in the
17 traditional legal system.
18 What I thought I would do first is give you a
19 little bit of an overview of some of the cases, some of the
20 ideas that I have been thinking about. Some of it will be
21 things that have been argued in litigated in cases. About
22 half of it will be stuff that hasn't been yet argued and
23 litigated, that I am still thinking about, as to whether or
24 not these are good rules and procedures. And, over the next
25 decade, these kind of things, in he latter half of my first

1 talk, will be the kinds of things that might appear in
2 litigation.
3 The second thing I will do, I will move after that
4 to a second outline. In the second outline I will focus
5 primarily on the question of science in the courtroom. I
6 like to call it junk science, because it has a nice ring to
7 it I think. But, the court deals with the problem not so
8 much of respectable science, the courts deal with the
9 problem of not respectable science affecting the litigation
10 process, and how that ought to be controlled. And we will
11 talk a little bit about one of the cases where I faced that
12 problem. I faced it in large numbers of cases actually.
13 And I will mention this case before the Supreme Court right
14 now, which is looking at that problem.
15 I have a couple of things for you. I have
16 outlines that -- everything I show is on a viewgraph here.
17 There are outlines available for you. And I also have a
18 court opinion. Actually this is not a court opinion, this
19 is a brief. One of the cases that you might have seen some
20 things about is called O'Conner. O'Conner had three issues,
21 what is the duty owed; is the Price Anderson Act
22 constitutional, and number three, junk science. All three
23 issues were taken on appeal to the United States Court of
24 Appeals for the Seventh Circuit. You might have read the
25 District Court opinion in that case. This is my brief in

1 the Court of Appeals. I argued this before the Seventh
2 Circuit just about a week and a half ago in Chicago. The
3 Seventh Circuit said that, on the junk science issue, they
4 are probably going to wait until the Supreme Court rules in
5 Daubert, and then issue their ruling. So, we will probably
6 have something back from the Seventh Circuit at the end of
7 this year.
8 [Slide.]
9 MR. JOSE: Now, a couple of introductory things.
10 What are some of the emerging issues in litigation? You can
11 leave the lights on I think, if people can see.
12 What are some of the emerging issues in
13 litigation? A couple of them that I deal with are can you
14 argue, or should you be able to argue that compliance with
15 regulatory standards is a defense? Every one of you who
16 drives your car down the highway, and you look up and you
17 see a sign that says 55 miles per hour, you would like to be
18 able when the police officer pulls you over and wants to
19 give you a speeding ticket, you would like to be able to
20 say, now, wait a minute, the limit was 55, and I was only
21 driving 50, so you can't fine me for speeding. Is there any
22 similar type of defense?
23 Imagine yourself driving down the highway, and you
24 look up there, and there is the sign that says 55 miles an
25 hour, so you drive at 55 or 50. Then you turn off onto

1 another road, and you look now for the new speed limit on
2 this other road, and there you see a nice big sign that says
3 as slow as reasonably achievable.
4 [Laughter.]
5 MR. JOSE: How do you drive? You can't do
6 anything but pull over and stop, because any police officer
7 can ticket you for anything he thinks is appropriate on that
8 particular roadway, and any jury, six months after you got
9 your ticket, can say, well, we think that the standard ought
10 to be 20. So, it becomes I think unworkable in the courts
11 to use ALARA as a standard of care for juries to judge
12 defendants in tort suits. And I think the proper one is
13 regulatory controls. Now, we are going to look at that in
14 detail.
15 The second poi I am going to discuss is
16 screening of scientific opinion testimony. And I will
17 discuss that very briefly now, and then I will go to a whole
18 second lecture, and a whole second outline on that.
19 The third one will be the proper use of
20 epidemiology. This is something that I have been struggling
21 with for some time. You are probably familiar with a device
22 known as probability of causation. I am sort of trying to
23 invent a new device that I call attributable group odds. I
24 kind of like invent my own language for stuff too, because I
25 am trying to do it in a way that common ordinary people

1 would understand. And they'll understand odds, but they are
2 not going to understand probability or causation too well.
3 See, the jurors are never at your level of sophistication.
4 The jurors are always at the level of a blue collar worker
5 out there. If you got asked to send somebody to trial for a
6 three-month trial to serve on a jury from your office, who
7 would you send? The most dispensable person, right? The
8 stupidest person you have got -- the person who doesn't do
9 anything of value in your office. That is the one you would
10 be willing to go have sit on my jury. And so I have to deal
11 with things on a different level than you deal with them.
12 What should proper use of dose in causation
13 decisions, when you are thinking about -- when the courts
14 are thinking about causation, how should they use dose? And
15 here I am thinking of an idea called the cancer doubling
16 dose concept. I got this from genetics, radiation genetics
17 talks about a genetics doubling dose. And, I think if we
18 were to think about what amount of radiation would double
19 the cancer in a particular group of people, then that I
20 would call the cancer doubling dose. We will look at that
21 in more detail.
22 And the final thing is something called statutory
23 employer. And that is really, if there is an accident on
24 the job, the employer is not responsible for that accident,
25 but the employee files for worker's compensation benefit.

1 The employee does not have to show that the employer was at
2 fault. All he has to show is that an accident happened on
3 the job, and he gets his worker's compensation benefits.
4 The same thing is true with many occupational diseases. The
5 worker does not have to show that the employer was at fault
6 in giving him an occupational disease, just that he got the
7 disease on the job. And, if that happens, then he is
8 entitled to some benefits.
9 Well, it seems to me, when we are dealing with
10 radiation causing a cancer, what we are really dealing with
11 is an occupational disease. If it happens to a nuclear
12 worker, it is an occupational disease. Now, cancer we don't
13 think of normally as occupational diseases. But, if the
14 amount of radiation a person received on the job, which is a
15 toxin to which he was exposed, happened to cause him to
16 develop, not a broken leg, but a disease, a cancer, than is
17 that not an occupational disease? And it might occur once
18 out of a thousand, once out of 10,000. But, maybe many of
19 these cases ought to be thought of that way, and they ought
20 to be resolved under the workers compensation analysis in
21 the state.
22 Now, let me jump ahead quickly, and tell you that
23 there are two problems with that. One problem is that in
24 many states cancer is not included as a listed occupational
25 disease. And I encourage utilities all over the country to

1 go back and look at that particular state law for their
2 workers compensation, particularly the section on
3 occupational diseases.
4 Usually there is a workers compensation act, and
5 an occupational diseases act under state law. And I
6 encourage them to look at that occupational diseases act,
7 and to consider, if they knew for sure that one of their
8 employees got cancer on the job, could he qualify under
9 state workers compensation occupational disease for benefit?
10 And, if not, then maybe they ought to try to lobby to change
11 those rules. And the occupational diseases act, in most
12 states, would need some amending in order to list cancer as
13 an occupational disease, and the circumstances under which
14 it should be so considered.
15 Now, in many cases where I am dealing with, you
16 have a large utility, but the power plant itself runs on a
17 relatively small number of people, except when there is an
18 outage, then large numbers come in during a three-month
19 outage. And all of those numbers of people are where many
20 of the cases come from, because they are not routine
21 employees, you know, they are a plumber, a pipe fitter, and
22 they come in for a month or two, and then they get sick, and
23 then they think that there is a connection. They are not
24 quite that sophisticated radiologically as many of the
25 people who are regular employees of the plant.

1 There is a doctrine called statutory employer,
2 which says that you can have workers compensation benefits
3 cover not only your employees, but employees of contractors
4 who work for you can be covered under your workers
5 compensation, if you have a sufficient amount of control
6 over them and every radiation worker will be controlled by
7 the utility. So, we will look at that in a little more
8 detail.
9 MR. MOELLER: Don?
10 MR. JOSE: Yes?
11 MR. MOELLER: We have a couple of questions.
12 Marty?
13 MR. JOSE: Yes?
14 MR. STEINDLER: Yes. On that last one -- what
15 other things are excluded from being filed under workmen's
16 comp provision, other than cancer?
17 MR. JOSE: Any accident on the job is included.
18 So, falling off a ladder, being cut, you know, crushed, any
19 traumatic-type of event is included as a work-related
20 accident. Then when you look into the occupational
21 diseases, each state has a list, and the list that each
22 state has kind of depends on that state's experience. For
23 example, in Kentucky, you will find black lung. In
24 Connecticut, where there are some textile mills, you will
25 find brown lung, asbestos, you will find. So, you have to

1 look at the law, and see the listing of diseases that they
2 have included. There are usually about 10 or 15 diseases
3 that are included.
4 MR. STEINDLER: And most of those are
5 characterizable by having a fairly clear experiential
6 relationship with some occupation?
7 MR. JOSE: Yes, that is right. That is usually
8 how they got there.
9 MR. STEINDLER: In that sense, cancer might well
10 be startling different?
11 MR. JOSE: That's right. Usually the last one on
12 the list is -- and anything else that seems to fit certain
13 criteria of being related that we haven't thought of. So,
14 usually, there is a little open-ended section on the back.
15 There has been fighting over the years in that
16 particular area as to whether or not heart attacks should be
17 considered occupational diseases. Cancer, of course, I
18 think there would be a great dispute as to whether that
19 ought to be an occupational disease, because 30 percent of
20 all employees in all factories, in all industries will have
21 cancer sometime in their lifetime. So, employers would be
22 unhappy to see cancer -- just the mere fact that you have
23 cancer considered an occupational disease, unless there is
24 some specific link to that industry.
25 MR. MOELLER: I guess that was going to be my

1 comment. I gather it wouldn't just be cancer, in general,
2 but it might be a certain kind of leukemia, and so forth?
3 MR. JOSE: Right.
4 MR. MOELLER: Okay.
5 MR. JOSE: And it might be linked to a certain
6 industry.
7 MR. MOELLER: Right.
8 MR. JOSE: The listing might say certain kinds of
9 disease in a certain industry. If you were to deal with
10 radiation, I think what you would want to say is only those
11 cancers -- you would say that cancer will be considered a
12 radiation-induced -- or cancer will be considered an
13 occupational disease in -- among occupations which expose
14 people to radiation, which would include all of the x-ray
15 technicians in hospitals, medical radionuclide workers,
16 which would include all of the radiologists. It would
17 include nuclear workers at various facilities. And then you
18 would want to limit it, and you would say, but, for it to be
19 considered such, it must be one of the kinds of cancer that
20 has been identified as being radiologic, and it must have at
21 least a three-year latency period from the date of exposure
22 to expression of the cancer, if it is a leukemia, and it
23 must have at least a 10-year latency period, if it is a
24 solid tumor. I am not trying to write that legislation, but
25 I am just saying that, if it were to be categorized, one

1 would want to try to describe the types of cancer you are
2 dealing with as those which are more likely to be
3 radiogenic.
4 MR. STEINDLER: One other point. You started out
5 by asking is compliance with the standard a defense.
6 MR. JOSE: Right.
7 MR. STEINDLER: And then you cite ALARA. I
8 assume, on the basis of at least what we have, and
9 reasonably good sense, ALARA is not a standard?
10 MR. JOSE: That has always been my position. But,
11 not all courts agree. And there is a comment in Silkwood v.
12 United States, by the Supreme Court, about ALARA being a
13 standard. And when I trace that down, that is a side
14 comment. And the reason that comment is in there, because
15 that issue was never really litigated in that case, is
16 because somebody from the NRC testified at the trial in the
17 District Court of Silkwood that ALARA was the standards.
18 MR. STEINDLER: I mean, even the Department of
19 Energy agrees that it is not a standard.
20 MR. JOSE: That is right. It is not a standard.
21 MR. STEINDLER: Yes. Okay.
22 MR. JOSE: I have always represented it as being a
23 philosophy of perfection. I always try, when I try a case,
24 to try it with excellence. That is my philosophy of
25 perfection. Every doctor I go to for surgery, I hope he

1 tries to operate with perfection. But, if he does a grade B
2 job on my surgery, instead of a grade A, he is not guilty of
3 malpractice. And ALARA is that professional philosophy to
4 keep pushing the industry, and pushing the profession
5 towards excellence.
6 What particular things could be -- regulations, or
7 regulatory controls which could be considered to be
8 defenses? Well, we know the NRC regulations. DOE has
9 regulations. We could even jump down to NCRP and ICRP
10 recommendations, although they are not regulations, I will
11 show you in a minute. If you don't have a regulation on
12 point, you can look to that source. States have
13 regulations. ALARA is so attractive to lawyers, because it
14 has this little word "reasonable." And lawyers are all
15 trained in tort law that duty of care is to act as a
16 reasonable man, unless you were trained in law school in the
17 last 15 years, then it is no longer the reasonable man's
18 standard, it is the reasonable person standard. But, that
19 reasonableness is like a magnet to lawyers, and they just
20 jump right into that.
21 You might have a specific situation where you have
22 a pregnant worker, so you are dealing with the fetal dose
23 limits, in her case.
24 [Slide.]
25 MR. JOSE: Now, in Johnston v. United States, many

1 people got excited about that case some time ago, because of
2 comments it made about certain expert witnesses. I tried
3 that case. I cross examined those expert witnesses. But,
4 really, what it said about those people is not of
5 importance. It was of interest, but not of importance.
6 What is really of importance in the Johnston Case, from a
7 legal point of view, is this. You are dealing with radium,
8 and you are dealing with a plant that is changing, or
9 refurbishing aircraft instrument dials, so it has some
10 radium, and it has some contamination. Kansas was an
11 agreement state with the NRC. The NRC itself, as we know,
12 does not really regulate radium.
13 And so, where are were going to find a standard to
14 apply? Where are we going to be able to say this is the
15 regulation? There is no regulation, in a sense, on radium
16 that we can point to. So, what Judge Kelly did -- and this
17 is what is so important about that whole point, that whole
18 case -- is he began thinking through this, and he said now,
19 why should I or any jury decide what is reasonable in the
20 amount of radium, and the amount of exposures allowed to
21 people? He said I am going to turn to the NCRP and the
22 ICRP, made up of the most knowledgeable, and most eminent
23 scientists, who spent all of this time on it, and I am going
24 to accept what -- I am going to defer to what it is that
25 they consider to be safe, as their recommendations. This

1 Court is certainly ill-equipped to second-guess those
2 scientists by setting different standards of safety in these
3 tort suits. This Court readily adopts these exposure
4 standards. So, that was the start of what I call in law
5 consensus science -- identifying consensus science in this
6 field, and then the legal system deferring to that consensus
7 science, and adopting that consensus science as the
8 standards that they use to analyze the cases.
9 Now, let's go quickly to one of the latest ones,
10 and that is the O'Conner Case. And I am going to talk now
11 about what I call O'Conner I. There are three decisions in
12 O'Conner, I am on O'Conner I, and that has to do with the
13 duty owed. In O'Conner I, as you are looking at the duty
14 owed, one of the things you have to notice is that, in the
15 Price Anderson Act, and I argued this just recently, and
16 caught a lot of flack on it in the Seventh Circuit Court of
17 Appeals. I said that the Price Anderson Act, as part of the
18 Atomic Energy Act, is saying that it allows the application
19 of state law, so long as that state law is not contrary to
20 the Atomic Energy Act. And the regulations of the NRC would
21 be sub-parts of the Atomic Energy Act.
22 [Slide.]
23 MR. JOSE: Now, actually the language -- you see
24 those brackets, Atomic Energy Act -- actually, the language
25 in the Price Anderson Act says that the Price Anderson Act

1 allows application for state law, so long as it is not
2 inconsistent to Section 2011, which is really the beginning
3 section of the Price Anderson Act, itself. So, the Judge in
4 the Seventh Circuit said no, you are reading it too broadly.
5 And I said, but there are a whole line of cases that say the
6 Federal Government has exclusive control over Federal
7 safety, and Congress intended that this conflict not exist,
8 and that language should be read broadly. But, you see,
9 unless -- "inconsistent with" is the important part of the
10 language there.
11 Now, let's look at some more comments from Judge
12 Mimh in this case, O'Conner I. "In determining the
13 likelihood of the injury from radiation, the Court believes
14 that it should give deference to the administration
15 regulations which are the result of an agency's applied
16 expertise." No judge or jury is ever going to have enough
17 knowledge in a field to have the expertise behind its
18 judgment that the regulations have had behind them. And
19 this judge is recognizing that.
20 "In order to determine whether or not the Federal
21 regulation in this case can be established to the standard
22 of care, this Court must look to the policy reasons for
23 imposing a duty under Illinois law." Now, he is doing an
24 analysis of state law in Illinois. The first part was an
25 analysis of Federal preemption and judicial deference. Now,

1 he is looking at Illinois state law.

2 "Under Illinois law, the duty to impose is a

3 question of law to be decided by the Court. The imposition

4 of a duty is an act of judicial policy-making." So, if it

5 is the determination of what duty you owe to another person,

6 is a question of judicial policy-making, then the judge has

7 the authority to begin thinking about the kind of things I

8 urge them to think about.

9 And there is a restatement of torts that is

10 adopted in most of the states. The restatement of torts are

11 like some general principles of tort law that are kind of

12 set out there as general statements of truth. One of them

13 is that the court may adopt, as a standard of conduct of a

14 reasonable man, the requirements of a legislative enactment

15 or an administrative regulation whose purpose is found to be

16 exclusively, or, in part A, to protect a class of persons

17 which includes the one whose interest is invaded. Think of

18 a nuclear worker. The regulations were designed to protect

19 him -- to protect a particular interest which was invaded.

20 They are trying to protect him from too much radiation

21 exposure. That is the interest he claims was invaded in the

22 lawsuit -- to protect that interest against the kind of harm

23 that has resulted. They are developed to protect him from

24 getting cancer, and he alleges he gets cancer, in this case,

25 it was cataracts -- and to protect that interest against the

1 particular hazard from which the harm results. And they are
2 designed to protect that interest against the hazard of
3 radiation causing these diseases.
4 So, as a matter of Illinois policy, as a matter of
5 restatement of torts, general principles, as a matter of
6 Federal preemption, what I argued with Judge Mimh was right
7 -- that permissible dose limits, by God, if the Federal
8 Government tells you it is permissible, then it is
9 permissible, isn't it? The permissible dose limits ought to
10 be the standard of care.
11 Now, I think though that this last analysis of his
12 was the most important. Because, you know, law can be
13 tricky. Law can be just kind of looking at precedents, you
14 know, and kind of finding arguments. But, let's cut through
15 all of that, and let's just ask ourselves what makes sense?
16 What is fair? Shouldn't law be fair, as a general rule?
17 And I think this last one was probably the best of his
18 reasonings.
19 "In a highly-technical field such as this,
20 although a plaintiff should be provided with a very high
21 level of protection from excessive exposure to radiation, a
22 defendant public utility should also be provided with some
23 clear statement regarding how it may limit a worker's dose,
24 without exposing the worker to injury, or itself to
25 liability."

1 Now, isn't it only fair that when you are driving
2 down that highway you get to look up and see a sign, and the
3 sign says 55 miles an hour, instead of as slow as reasonable
4 achievable? Isn't that only fair to you, to give you some
5 numerical warning, so that you can conduct your behavior
6 within the bounds of those numerical numbers, and,
7 therefore, be protected against being fined by some judge or
8 jury, or given a speeding ticket? Well, it is the same
9 thing for a utility.
10 MR. HINZE: But, you have the word "how" -- I
11 mean, the word "how" is there, rather than "what" -- how it
12 may limit, rather than what the limit is. In other words,
13 how far does that go? The statement regarding how it may
14 limit?
15 MR. JOSE: Yes.
16 MR. HINZE: And that goes beyond the --
17 MR. JOSE: What it may limit? How it may limit?
18 I think that was a distinction that was not important to the
19 judge. He wasn't reading that any differently. I think all
20 he was reading is that how it may limit, or what it may --
21 how it may limit is the same as what numbers it might allow.
22 MR. HINZE: I see.
23 MR. JOSE: He is reading that -- just how it
24 connects.
25 MR. HINZE: My reading of it was quite different

1 than that.

2 MR. JOSE: Okay.

3 MR. STEINDLER: If the Judge equated those two,

4 then I think there is a lesson in English somewhere. The

5 how is a methodology statement, rather than a standard

6 statement, which is I think what you are getting at.

7 MR. HINZE: Exactly. It is quite different.

8 MR. JOSE: Okay. Good point. That is a good

9 point. You're right. It would be better of the Judge had

10 said what dose it may allow.

11 MR. HINZE: Yes.

12 MR. JOSE: Right. That's right. Good point.

13 That's right. The Judge is -- the next time I see that

14 Judge I will correct him for you. That is very wise. Okay.

15 Thank you.

16 MR. STEINDLER: It is a good thing you are a

17 licensed mechanic.

18 MR. JOSE: Yes. A couple of questions here on

19 scientific testimony. I am going to move through this real

20 fast, because I am going to deal with it in more detail

21 later. The only thing I am going to point out here to you

22 is not all of this stuff that I am showing in the outline.

23 I am going to skip a couple of pages and come down to the

24 Daubert Case.

25 MR. HINZE: Incidently, are we going to get copies

1 of this?

2 MR. JOSE: Yes.

3 MR. HINZE: Good show.

4 MR. JOSE: And the stuff I am just skipping now,

5 you will get in more detail in a minute.

6 [Slide.]

7 MR. JOSE: On Daubert. Daubert is Bendectin.

8 Now, Bendectin is an interesting drug, because my wife has

9 been pregnant twice, and the first time she was pregnant she

10 took Bendectin all the time. The second time she was

11 pregnant, every time I went in to get more Bendectin, it was

12 like double in price, and triple in price, and quadruple in

13 price. And now it is no longer available, so we can have no

14 more children, because she does not want to be sick like a

15 dog. So, it has always been something that interested me.

16 Nevertheless, there are these cases around the

17 country, pharmaceutical cases now. These are considered

18 pharmaceutical law. And I am using it because legal

19 principles relate through all of these fields I believe.

20 Now, here is a situation where there are about 30

21 epidemiological studies that have been conducted, and they

22 all show negative excess limb reduction birth defects among

23 mothers who have taken Bendectin. And each of the 30

24 epidemiologists conducting each of the studies have come to

25 that conclusion. However, there are still a number of

1 lawsuits involving this, and plaintiff has an expert in
2 Daubert who says yes, but I have re-analyzed all of these
3 studies, they like to call it meta-analysis. And there is
4 such a thing as meta-analysis. I have taken 30 negative
5 studies, I pooled all of the information, and I see positive
6 trends. You see, now there are some times where that could
7 be valid. But, nevertheless, it is also a very dangerous
8 thing.
9 And then the expert says I have reanalyzed all of
10 this. I think there is causation here, plus I look at
11 animal experiments. Usually those are where the doses might
12 be, you know, a hundred or a thousand times greater. And I
13 look at chemical analysis, and I say certain components of
14 Bendectin are kind of like certain components of other
15 things. And because they are kind of chemically the same, I
16 would kind of expect them to chemically act the same,
17 therefore, I might suspect that Bendectin, under some
18 circumstances, would cause limb reductions.
19 Well, the District Court -- all over the country,
20 the courts are facing this problem, and some courts let
21 these people testify and some don't. Sometimes they let the
22 people testify, and there is a million or $2 million
23 verdict, because the jury sits there, and they hear this
24 conflicting testimony, and they look at a limb reduction
25 three year-old, a little kid with penguin arms, or

1 something, you know, and they look on the other side over
2 there is this large pharmaceutical company, and they say,
3 oh, hell, I mean, who cares, this pharmaceutical company has
4 got all of this money, and look at this poor kid, give him a
5 couple of million, they will never miss it, and it is so
6 important to him. And so that is the emotional decision-
7 making process that can often occur.
8 So the Courts are trying to make these decisions
9 scientifically correct, and not just emotional and sympathy.
10 And some judges have said, even after a trial awarding
11 millions of dollars, we will overturn that verdict, because
12 it was only based on emotion.
13 Now, the District Court in Daubert said that this
14 person could not testify. In fact, there were about four
15 experts like this, and they could not testify. And they
16 weren't necessarily bad people. Then it went to the Court
17 of Appeals, and the Court of Appeals said that those people
18 could not testify. And then it has been appealed to the
19 United States Supreme Court.
20 The briefs have been filed in it, and there are a
21 number of Amicus Briefs field. One of the Amicus Briefs is
22 filed by the United States Department of Justice. And I
23 tell you all this -- it should be argued maybe in six
24 months, and it may be decided in a year or so. I will tell
25 you, legally, the whole thing is going to turn around on the

1 rules of evidence, 702 and 703. And, in my next set of
2 slides, I am going to show you 702 and 703, and we will talk
3 in detail. Yes?
4 MR. STEINDLER: What was the basis for the Lower
5 Court's throwing them out?
6 MR. JOSE: The Lower Court threw them out because,
7 under Rule 702 and 703, the Lower Court felt that the
8 testimony didn't have a sufficient scientific basis to be
9 allowed into evidence. There wasn't a sufficient scientific
10 support or foundation for the opinion that the expert wanted
11 to express.
12 MR. STEINDLER: Was that opinion generated by a
13 judge looking at the qualifications of the expert, or how
14 did the judge come to that conclusion?
15 MR. JOSE: Not on the qualifications of the
16 expert, but looking more under what is called Rule 703, the
17 methodology, the scientific basis upon which that expert
18 wants to express their opinion. Do you have an opinion?
19 That's nice. What is the basis of your opinion? I don't
20 care about your degrees. What is the basis of your opinion.
21 MR. STEINDLER: Okay. And the Judge made the
22 decision on the basis of that statement of where my opinion
23 comes from?
24 MR. JOSE: Right. And the Judge is basically
25 saying in these cases -- all the Judges that rejected them

1 are basically saying now, wait a minute here. People are
2 not like cells in petri dishes. People are not like
3 animals. People are like people. And, if you don't have
4 any knowledge of people, then maybe you can extrapolate from
5 cells in petri dishes, and maybe you can extrapolate from
6 fruit flies or something; but, if you do have people,
7 studies of people, and the studies of people, you have 30 of
8 them, and they are all negative, then I think we are going
9 to say, you know, to hell with the flies. I mean, if flies
10 react a certain way, but you have studied 30 groups of
11 people, and they react differently, then we are going to
12 kind of say you are bound by the way the people really
13 react. And that is what the Courts are saying -- that
14 they are looking at those 30 epidemiological studies. If
15 those didn't exist, then the courts would come down
16 differently.
17 MR. POMEROY: Don, excuse me? Can I interrupt you
18 too?
19 MR. JOSE: Yes, sure.
20 MR. POMEROY: I just wanted to ask you, in a
21 science article that discussed the Bendectin cases, it talks
22 also about the question of the Fry Doctrine --
23 MR. JOSE: Yes.
24 MR. POMEROY: -- which does certainly get involved
25 in that.

1 MR. JOSE: Yes.

2 MR. POMEROY: And, reading that article, I have
3 the feeling that part of the rejection process was that,
4 indeed, this expert testimony had not been published in a
5 peer review journal, which was a key part of its
6 acceptability, is that --

7 MR. JOSE: Yes. And Fry will be on the next
8 lecture.

9 MR. POMEROY: Okay.

10 MR. JOSE: And peer-reviewed is one of the
11 screening tests.

12 MR. POMEROY: Right. If you would get back to it.

13 MR. JOSE: Let me just hold that, if I could, for
14 a second.

15 What I wanted to just show you here was what the
16 Department of Justice is suggesting the Supreme Court should
17 use as the test for screening of expert testimony. Now,
18 this is only in an Amicus Brief, by the Department of
19 Justice, recently filed with the U.S. Supreme Court. This
20 isn't the law, but the Department is suggesting that a
21 judge, in deciding whether or not expert testimony is
22 allowed into evidence in a case, go through this four-part
23 analysis. And it is a weighing and balancing test to ask
24 whether the technique has achieved substantial acceptance by
25 at least a significant minority within the field.

1 Now, the Fry test would say, you know, it is a
2 respected doctrine? This is lower than the Fry. This
3 standard is lower than Fry. We will see that in a minute.
4 Only a reasonable, significant minority has to believe in
5 it. Then, the Department of Justice says well, when you
6 look at it, ask yourself whether the potential rate or
7 possibility of error can be estimated, and, if so, what it
8 might be? And, if the error rate can be estimated, and the
9 error rate is very high, then the person who objects to the
10 admission of that evidence has a better basis for objecting.
11 If this technique will be right 10 percent of the time,
12 maybe it should not be allowed in. If it is going to be
13 right 80 percent of the time, maybe it should be allowed in.
14 The degree to which subjectivity in the analysis
15 renders intelligent evaluation of the expert's conclusions
16 impractical, requiring the trier to take their conclusions
17 on faith. If the guy says look, I have got a degree, you
18 have got to believe me on faith, because I cannot explain it
19 to you, it is too complex, well, maybe that is the kind of
20 thing you ought to be questioned, or real suspect about.
21 And, in fact, that was basically one dosimetry experts great
22 error. His particular technique, through many cases, has
23 been I am this wonderful person. I know all about
24 dosimetry. It is much too complex for you to ever
25 understand. You just have to believe me and except it on

1 faith. And, of course, when that person was cross-examined
2 in-depth, there was nothing to accept on faith anymore.
3 But, this is a technique which is a charlatan technique.
4 Just believe me on faith. I have got the degree.
5 The extent to which the expert has exposed his
6 methodology and conclusions to his peers through
7 publications and peer review. Now, have you who are the
8 expert who wants to give this opinion, based upon this
9 analysis or thinking process, or methodology, have you
10 published anywhere? Have you allowed your peers in the
11 scientific community, through the peer review publication
12 process, had a chance to comment and debate on it? Maybe
13 you haven't published, because you know you can't get it in
14 the literature anywhere, because it is such a wacky idea, I
15 don't know. But, that is something to look at. And you
16 become more suspicious of something that has never been
17 published.
18 MR. STEINDLER: That last one, it seems to me, is
19 awfully fragile --
20 MR. JOSE: Yes.
21 MR. STEINDLER: -- because of the wide variation
22 in the quality of journals or publication areas. On the
23 face of it, it seems to me, that particular one could be
24 strengthened significantly by making some reference to a
25 generally-acceptable journal or making some commentary about

1 the potential quality where you publish it. Why didn't they
2 do that?
3 MR. JOSE: There was a big fight within the
4 department -- well, I don't know how much I should answer
5 that for you. There were competing interests in setting
6 forth these kinds of tests. One interest was that the tests
7 should be narrow. Another interest was that the test should
8 be wide. It depends upon which part of the Federal
9 Government you represent or defend. The Department of
10 Justice represents all parts of the Federal Government. It
11 represents the EPA, when the EPA is wanting to argue
12 something on the forefront of scientific discoveries, and
13 get everybody excited about a lot of radon gas, in a lot of
14 people's houses, causing 50,000 lung cancers per year in the
15 United States. And so the Department of Justice had to sort
16 of balance what it was saying.
17 I would argue that that last test, for example,
18 should, at the very least, say that the publication process
19 should be within the academic journals of that particular
20 expertise. I am not impressed by Dr. Carl Johnson's
21 publication of his Mormon telephone survey in JAMA, the
22 Journal of the American Medical Association. I would be
23 more impressed if he had been able to publish that in the
24 Journal of Epidemiology. If you are doing an
25 epidemiological study, then it should be tested by peer

1 review in the epidemiological professional publications, not
2 so much in some other field.
3 MR. HINZE: I am more interested in that number
4 four.
5 MR. JOSE: Yes.
6 MR. HINZE: And I wonder, and I am concerned about
7 this -- what does the "or otherwise" -- what does that refer
8 to? Peer publications? "Or otherwise."
9 MR. JOSE: Yes.
10 MR. HINZE: That is a huge --
11 MR. JOSE: Right. Maybe publishing a book. Maybe
12 -- I don't know. I that is not defined. I think that would
13 be -- I think the argument on that would be is there any
14 other scientific discussion of this particular theory?
15 Maybe at seminars -- maybe the person was invited at a
16 national meeting of this scientific body to present a paper
17 on this subject, and to discuss it and debate it. So, there
18 could be ways that scientists deal with things beyond the
19 peer review literature.
20 MR. HINZE: But, there is a very limited record of
21 the discussion of the interaction, which may lead to the
22 exposure of the fallacy of the methodology of the science
23 here.
24 MR. JOSE: Right.
25 MR. HINZE: And just because it is presented, it

1 should not make it proper, even if it is presented before a
2 peer review panel.
3 MR. JOSE: That is right.
4 MR. HINZE: But, if there is no solid
5 documentation -- and I can cite chapter and verse on a
6 number of cases where this is the situation.
7 MR. JOSE: Yes. I fully agree. I am, by the way,
8 not a proponent of the Department of Justice four-part test.
9 I think they are wrong. That is not what I would do, but, I
10 wanted you to see it. I thought it was important, because
11 the Supreme Court, in Daubert, may adopt a test like that of
12 weighing and balancing this kind of expert testimony, and
13 they may do it in that kind of general language, so that you
14 just go through a four-part analysis. And then it is like
15 your problem is here, here is the expert testimony. It goes
16 through this black box of this four-part general analysis,
17 and what cranks out on the other end is yes, it can be
18 admitted, or no it can't, and you really can't understand
19 why, because it is all of this general discussion. But,
20 that maybe where they come down.
21 MR. POMEROY: Don, are we going to come back to
22 that some more at some point? Because there certainly were
23 other important briefs filed as well, particularly the
24 Academy of Sciences, the AAAS, and also by Steven Gould, and
25 other people, who had very differing views on that question

1 of what constitutes good science, basically, in the
2 bottomline.
3 MR. JOSE: Right.
4 MR. POMEROY: Will we get back to that?
5 MR. JOSE: No. I am going to get back to the
6 issue of science and Rule 702 and 703, but I am not going to
7 go back to Daubert. But, if you want to -- and I don't know
8 what all of those other briefs were. So, if you have some
9 comments.
10 MR. POMEROY: Well, I don't want to spend a lot of
11 time on it.
12 MR. JOSE: Sure.
13 MR. POMEROY: But, one group, led by the American
14 Society of Law, Medicine and Ethics, and other people,
15 including an editor of epidemiology had many statements,
16 including statements like the peer -- this is all calculated
17 to infuriate Bill -- but the peer review industry, as a
18 wholly unregulated collection of completely independent and
19 unsupervised periodicals. And they urged that judges and
20 juries, in each case, weight all of the relevant scientific
21 evidence themselves. Whereas, I believe the Academy's
22 brief, and the AAAS brief, which were both filed, due to
23 timing, with the defendant, in that case, indicated that the
24 trial judge should have complete control over making that
25 judgment as to what was good science himself.

1 MR. JOSE: I would sort of follow that line.

2 MR. POMEROY: Well, I think I would too.

3 MR. JOSE: Yes.

4 MR. POMEROY: But, I think there is a substantial

5 body of people that might not.

6 MR. JOSE: Yes.

7 MR. POMEROY: I just wondered -- I had a feeling,

8 in reading O'Conner III anyway, that -- between 702 and 703,

9 and the Fry Doctrine, there was a fairly -- the Courts had a

10 fairly good way of determining what constituted good expert

11 opinion.

12 MR. JOSE: Right. My feeling on that particular

13 subject is that we don't need any new tests -- that we have

14 the rules of evidence. All we need is to kick judges in the

15 butt and get them to go to work. They need to read the

16 scientific literature, and they need to exercise the

17 authority that they have got under the existing rules to

18 screen that testimony. And, if you can get a judge to do

19 that, then you can accomplish, without any changes at all in

20 the law, something like O'Conner III. But, it is an awful

21 lot of work for a judge to learn enough about the science to

22 make those decisions. But, I think that is his job. That

23 is his responsibility.

24 MR. STEINDLER: I think it is unrealistic to

25 expect the judge to become sufficiently versed in the

1 particular science to be able to not only read the
2 literature, and read the words, and look them up in the
3 dictionary, but also to understand both the words
4 themselves, as well as the implication.
5 MR. JOSE: There is another provision in the rules
6 of evidence, which is very rarely used, that allows the
7 judge to appoint a court-appointed expert witness. And
8 usually, when it is used, the court-appointed expert witness
9 then looks at the evidence and testifies at trial. I think
10 that that rule is broad enough to allow the judge to go hire
11 for himself, for example, an epidemiologist from a respected
12 institution to be like his tutor, an to help him through
13 this field. So, I would like to see judges use that
14 technique to gain assistance in the technical aspects from
15 respected bodies, or from particular people in the field.
16 Okay. Yes?
17 MR. POMEROY: I had a question with regard to just
18 the applicability of the Fry Doctrine, from your
19 perspective.
20 MR. JOSE: Yes.
21 MR. POMEROY: Normally, in a hearing, in an
22 administrative hearing structure, and finally, in the Court
23 structure, which I assume the repository will go through, is
24 the Fry Doctrine normally applied in the administrative
25 hearing structure?

1 MR. JOSE: No. What I am talking about are the
2 Federal Rules of Evidence, 702 and 703, and the Fry Doctrine
3 are applied in the Federal Courts. And some Federal Courts
4 around the country don't even use the Fry Doctrine. But,
5 administrative hearings are not required to use the Federal
6 Rules of Evidence.
7 Usually what happens is administrative hearings -
8 - they sort of like get this idea that lawyers are bad, and
9 that the rules of law are bad. And they sort of get this
10 idea that let everything in, let everybody have their say.
11 And so, in the administrative arena, usually almost anybody
12 can say almost anything, and then somebody has to sort of
13 sort through it.
14 I think that the rules of evidence in an
15 administrative hearing may be ought to be applied. I mean,
16 I would urge a little more scrutiny on the types of evidence
17 that are allowed, unless what it is is you are just holding
18 a public hearing. If you are just holding public hearings
19 for people to express their feelings, then you let everybody
20 express their feelings; but, if you are sort of litigating
21 an issue, then I think in fact law has some validity. But,
22 there are some kinds of evidence that are more valid than
23 other kinds of evidence, and just to let everything in isn't
24 a good idea.
25 MR. POMEROY: Then could you see the situation

1 where somebody -- and presumably there is somebody out there
2 that will do this -- that would challenge the testimony of
3 experts within the administrative hearing structure when it
4 gets to a court situation, based on the lack of strict
5 applicability of the Federal Rules of Evidence?
6 MR. JOSE: Yes.
7 MR. POMEROY: And the Fry Doctrine?
8 MR. JOSE: Yes. What I would say -- I would do
9 two things about it. One thing I would do, in the
10 administrative hearing process, I would say that you would
11 have to rely on rigid cross examination. You should allow
12 cross examination, and you have to rely on rigid cross
13 examination.
14 The other thing I would do in an administrative
15 hearing is I wouldn't -- if I had a panel before whom this
16 process was to be heard, I would make sure that that panel
17 includes scientific expertise. I do not care if we have got
18 a lawyer on that panel or not. I care a lot more if I have
19 got scientists on that panel. The decision-making process
20 should be scientific, not legal. So, if you had three
21 people on it, I would make sure one at least was a
22 scientist, for example.
23 MR. STEINDLER: The model that I would recommend
24 to you is the Atomic Safety and Licensing Board --
25 MR. JOSE: Yes. I like that.

1 MR. STEINDLER: -- which is functional in that
2 sense.
3 MR. JOSE: Right. I agree.
4 MR. STEINDLER: Two technical, one legal.
5 MR. JOSE: Yes.
6 MR. STEINDLER: And the legal does have
7 significant technical background.
8 MR. JOSE: Right. I think that that's wonderful.
9 I like that very much.
10 MR. POMEROY: Let me ask you two other questions.
11 MR. JOSE: Yes.
12 MR. POMEROY: The first one relates again to the
13 Bendectin Case, and mainly, is it reasonable to assign to
14 the Supreme Court the general question which is my
15 interpretation of what they are being asked, namely, what is
16 good science? Is it reasonable for the Supreme Court to
17 make that kind of judgment, given that I think both
18 administrative hearing judges, the judges in the courts, and
19 certainly the scientific community, and all good trial
20 lawyers I think can recognize what good science is? But,
21 the legal definition of good science may diverge from that.
22 MR. JOSE: Yes. I think it is reasonable to ask
23 the Supreme Court to do that, and necessary. Because, you
24 see, from my point of view on it, it is not a question of
25 them passing judgment on somebody's science, it is a

1 question of the Supreme Court passing judgment on the
2 admissibility of evidence. What kind of evidence should be
3 admissible? You say well, I saw Mr. Smith kill Mr. Jones.
4 You can testify. You want to say well, I didn't see
5 anything, I didn't hear anything, I mean, I wasn't even in
6 that city that night that that murder happened, however, I
7 was riding in a subway and I overheard somebody say that
8 they saw Mr. Jones kill Mr. Smith, and I don't know who that
9 person was, can you testify? No. Because the probative
10 nature of that overheard conversation is so low that the
11 courts aren't going to allow that to come in. So, that is
12 an evidentiary issue, they call it the hearsay rule. That
13 testimony will not be allowed in.
14 Science is like that. What the courts ought to do
15 with science is say there are some kinds of science that
16 will assist the jury, and ought to be allowed in. There are
17 other kinds of science that are so unlikely to assist the
18 jury that it will not be allowed in. We close at 12:00?
19 In the next lecture we are going to get into some
20 of these kind of things in a little more detailed
21 discussion.
22 [Slide.]
23 MR. JOSE: All I am going to mention are two
24 things about Attributable Group Odds, and that is
25 epidemiology has something to say; but epidemiology also has

1 its limits. For example, you can go down here and say that
2 epidemiology can expect a hundred normal cancers in a group,
3 and see 150, so it can contribute the extra 50 to radiation
4 causation, or whatever factors, smoking, or whatever factor
5 it happens to be looking at. But, what its limit is is it
6 can't tell you which of the 150 cancers it now sees, or the
7 100 naturally occurring, which are the 50 extra. See, that
8 is precisely the question that the courts always must face.
9 It's not whether there are excess cancers, it is not what
10 the risk is. That's not what he regulators are concerned
11 with. It is always whether or not this particular person is
12 one of the hundred or one of the 50.
13 MR. HINZE: Doesn't it also have to consider the
14 variability, from group to group, area to area.
15 MR. JOSE: That's right.
16 MR. HINZE: And so, this 100 really had to be
17 followed by a plus or minus --
18 MR. JOSE: Exactly.
19 MR. HINZE: -- some kind of measure of deviation?
20 MR. JOSE: Right. That's right. Maybe plus or
21 minus 10 percent of something, right. I didn't put that in,
22 because I just wanted to be very simplistic and show the
23 point that epidemiology isn't even asking the same question
24 that the courts are asking. And the regulators aren't
25 asking the same question. The epidemiologist is saying is

1 there an excess of this disease in this group? Regulators
2 are saying what is the risk, so we can set safety limits?
3 What might that risk be? But, the courts are always asking
4 a different question. They are asking it person-specific.
5 Both the regulators and the epidemiologists can deal with
6 group truth. That is all they need to know, group truth --
7 what is true about the group.
8 The courts always have to deal with person-
9 specific truth. What is true about this person? Is he one
10 of the 100, or one of the 50? And the question then becomes
11 how does epidemiology come up with an answer?
12 I am going to skip the idea of attributable group
13 odds.
14 MR. HINZE: Excuse me.
15 MR. JOSE: Yes.
16 MR. HINZE: This is not a trivial matter, moving
17 to the repository arena, because we have the problem of
18 representativeness.
19 MR. JOSE: Yes.
20 MR. HINZE: And I think that is really what you
21 were talking about. And it is of great concern to many of
22 us -- this term representative, which we here ad nauseam.
23 How does that fit into -- you know, it is easy to put a
24 hundred normal cancers here.
25 MR. JOSE: Right.

1 MR. HINZE: But, how do you decide -- how does the
2 Court decide that that is a representative number?
3 MR. JOSE: Yes. Well, let me go to attributable
4 group odds, which I was going to skip.
5 MR. HINZE: Is that out of context here?
6 MR. JOSE: No. But, here is the thing I am trying
7 to deal with. What I am trying to think about is when you
8 do probability of causation analysis for an individual, you
9 are always coming up with some number. And you may have a
10 PC of .01, and that maybe the same as odds of one out of a
11 hundred, one time in a hundred times will this particular
12 exposure cause this particular cancer in this particular
13 person, assuming that you are dealing with representative
14 groups. But, whenever you have a device which yields those
15 numbers, then it is not easy for the Court to short-circuit
16 that case without it going through the full judicial
17 process. Because, you see, the plaintiff can always make a
18 very valid point. Yes, only once in a hundred times -- only
19 once in a hundred cases, will this thing happen, but my
20 client is that one and he deserves his day in court.
21 So, as long as you calculate any number, a risk of
22 one in a thousand, a risk of one in 10,000, the particular
23 plaintiff who is dealing, not with group numbers, but
24 dealing with person-specific truth, can always say I am that
25 one. Well, everybody is that one. Everybody can say they

1 are that one. So, this process then becomes bogged down, in
2 a sense, in tremendous resources, looking at every
3 particular individual.
4 I am suggesting maybe that, instead of using PC
5 that way, there ought to be a device used, I just called it
6 trial group odds, where all you are dealing with are the
7 observed excess cancers. You can look at this later -- it
8 is not part of the file through -- observed numbers of cases
9 over the expected number of cases. And you are dealing only
10 with observed, you are not dealing with any risk below what
11 is observed. So, what happens is, in a case where you have
12 an observed number of cases for a particular group, or
13 particular dose -- let's say, people living around the
14 repository, let's say that they get five millirem exposure
15 from living there, and you observe in this time period a
16 hundred cancers there, you expect a hundred cancers there,
17 and somebody has got a cancer there. Under PC, you
18 calculate a one percent chance. Well, then he gets to
19 litigate his case because he is that one rare case.
20 Under a device like this, what you do is you
21 calculate a zero, because you are only dealing with the
22 observed numbers. So, what happens is, when you get down to
23 the level at which nothing is observed, your methodology
24 starts calculating zeros. And then the courts can say, now
25 wait a minute, if the method we are using for analysis

1 calculates a zero, then why should this person have their
2 day in court?
3 On the other hand, if you do that, and if you use
4 that rigidly, once you begin to double the cancers in a
5 group -- let's say that you expect a hundred, and you
6 observe 200, you are going to end up with a calculation of
7 50 percent, or a probability or causation of .50. If you
8 are using this method to determine causation, as soon as you
9 double the rate of cancers in that population, then the
10 person who caused the doubling most pay for every cancer
11 they caused, and for every naturally occurring cancer,
12 because the attributable group odds will be the same for
13 every person in that group.
14 If this is the device that is used, then at some
15 level that particular employer pays for a lot of cancers
16 that they never caused at all. They are just naturally
17 occurring. That's part of the problem.
18 MR. STEINDLER: Where would you cut that number
19 off?
20 MR. JOSE: Well, what I would do is I would say at
21 50 percent. Below 50 percent, plaintiff cannot prove he has
22 a case.
23 MR. STEINDLER: Is that an arbitrary number?
24 MR. JOSE: No, it's because the rules of evidence
25 are that you must -- the plaintiff has the burden to prove

1 more likely than not that this disease was caused by that
2 particular exposure, and if you use a numerical analysis and
3 I say you want to testify that you think that disease was
4 caused by that exposure, what's your analysis, here's your
5 analysis, the number is less than 50-50, you can't testify
6 because your analysis is insufficient to meet that burden of
7 proof.
8 On the other hand, if I use that technique, then I
9 know that as soon as the numbers are greater than 50-50,
10 everybody wins. We know that employer has to pay for
11 naturally occurring cancers.
12 Now I guess I don't know whether that's good
13 social policy or not. I sort of think I'm willing to accept
14 it because of an employer doubles the rate of cancer in his
15 worker population, let him pay for all the naturally
16 occurring ones, too, but I'm not sure that that's the proper
17 social policy judgment.
18 Mainly I'm looking here for a device that can
19 yield zeros for those very low dose numbers so you avoid
20 this problem of somebody saying I'm the one in a thousand
21 because if he is the one in a thousand then doesn't he
22 deserve to have his case tried?
23 MR. STEINDLER: But your answer to that question
24 is no.
25 MR. JOSE: Let's go to junk -- well, I'll just

1 basically make this comment on cancer doubling doses and
2 then we'll hit junk science.
3 Cancer doubling doses is simply that amount -- if
4 this concept were to be used would be that amount of
5 radiation given to a group of people which would double the
6 number of naturally occurring cancers in that group or, if
7 you wanted to look at it not as groups of people but you
8 wanted to look at it as to individuals, somebody who has
9 breast cancer, you would say what amount of radiation given
10 to that individual would double the incidence of breast
11 cancer in that population and if she got more than that, she
12 automatically wins; if she got less than that, she
13 automatically loses.
14 That would be the way to use or to think about
15 cancer doubling doses.
16 Now let's go to junk science because that's where
17 I think you folks want to spend more time. Here's how I
18 define junk science.
19 Junk science I say is a scientific opinion which
20 would not be able to withstand normal peer review scientific
21 publication but is offered in court to assist laymen in the
22 resolution of a difficult legal problem.
23 Well, I question if it couldn't withstand normal
24 scientific peer review, how is it going to really assist
25 laymen in finding the truth. What's wrong with it?

1 Well, any lay jury usually consists of blue collar
2 type people with high school education. They generally
3 can't comprehend expert testimony and they can't accurately
4 decide a scientific conflict. Thus, they just see two
5 competing experts and they think each represents an equally
6 valid point of view.
7 They think that the fringe nut represents 50
8 percent of the scientific community and the mainline expert
9 represents the other 50 percent and that's kind of just the
10 impression they get.
11 If the court doesn't screen it, then the jury is
12 just sort of picking between what they think is a 50-50
13 split in the scientific point of view.
14 MR. POMEROY: That would state, however, that you
15 think that the court or the judge in this case could -- can
16 in fact determine what would be acceptable in a peer review
17 process.
18 MR. JOSE: Yes, that's right, and I think that's
19 what a court has to do. They have to do that screening and
20 they can't do it unless they learn something about the
21 science and they don't want to do that because, after all,
22 that's why they became judges.
23 They were kind of dumb in science. If they were
24 smart in science --
25 (Laughter)

1 That's true. If you look at every judge around
2 the country, if he had been smart in science he would have
3 been a doctor. He gets more respect and earns more money.
4 He became a judge because he didn't know enough -- couldn't
5 handle science and now we make them do these things and
6 that's why these judges all hate me at first because I ask
7 them to do a lot of hard work.
8 Let's look at the rules of evidence now because
9 I'm suggesting that these rules of evidence in fact can
10 already be used.
11 MR. STEINDLER: Excuse me. The key to your
12 definition or what's wrong with junk science is that there
13 is no intermediary process between the statement by the junk
14 scientist, the statement by what you would call perhaps the
15 legitimate scientist, and the decision-making process that
16 the jurors have to go through.
17 You're assuming that the space in between is a
18 vacuum. That's hardly ever the case.
19 Have you discounted the explanatory opportunities
20 of both sides, both counsels, as being either illegitimate
21 or not functional?
22 MR. JOSE: There's a couple of things. First of
23 all, the American Trial Lawyers Association, which is a
24 group of plaintiffs' attorneys, have filed a brief in
25 Daubert.

1 I haven't read it but what I have heard and read
2 about the brief is that their position is that as long as a
3 person has a degree she's allowed to testify.
4 So I get on the stand and I say, hey, Judge, I've
5 got an MD degree, I want to give my opinion to the jury, you
6 now, Judge, become totally irrelevant; because I've got the
7 degree, I can get to talk directly to those jurors and you
8 are no longer part of the process.
9 That is one of the positions argued by some people
10 apparently in the Daubert case.
11 Now I think that in reality what judges like to do
12 is they like to say, hey, this is difficult stuff, I don't
13 want to deal with it, we'll leave it for cross-examination,
14 you know, you let the guy testify, you cross-examine, you
15 fight all this stuff out.
16 I say that's not good enough, although I have done
17 that. I mean if that didn't exist, how could I earn a
18 living? I spend my life cross-examining experts and I know
19 it can be done, but it's extremely difficult and takes a lot
20 of time.
21 I've had many experts on the witness stand three
22 days under cross-examination and I've been successful but I
23 don't have enough faith in the system to think that that's
24 the best way to do it.
25 I would like to see something other than relying

1 on the opposing counsel to show the errors. I think that's
2 very risky.
3 Now Rule 702, we're going to look at the rules of
4 evidence, decisions judges are supposed to make before --
5 Here's something happening in a courtroom and they
6 offer something and I say objection, Your Honor. The judge
7 has got to say what's the basis of your objection. Violates
8 Rule 702 and 703. Sustained or overruled, he's got to rule.
9 I'm saying this is the test now existing that he's
10 got to think himself through.
11 Rule 702 says in the Federal Rules of Evidence if
12 scientific, technical or other specialized knowledge will
13 assist a trier of fact to understand the evidence, or to
14 determine a fact in issue, a witness qualified as an expert
15 by knowledge, skill, experience, training or education may
16 testify thereto in the form of an opinion or otherwise.
17 This we basically say is the qualifications of the
18 person who is being offered as an expert but it's more than
19 that. It also -- I highlight the language "assist." It
20 should be something that will assist and I say junk science
21 can that really assist a witness?
22 If you can identify something as junk science, how
23 can that assist? I mean I don't care what kind of degrees
24 this guy has got. If what he's saying is junk science, it's
25 not going to assist anybody in finding the truth.

1 Examples would be the lie detector machine. This
2 is the Fry case. Early on, the earliest forms of the lie
3 detector machine were being offered into evidence in
4 criminal cases and they were being excluded in Fry v. United
5 States. It was a criminal case.
6 The doctrine was they were just not accepted yet
7 as being accurate within the scientific community and so
8 they were not allowed in. That ruling tends to remain true
9 today.
10 Blood alcohol tests for driving while intoxicated
11 is different because it's felt to be accurate enough. What
12 about an arresting officer's skill in knowing beer or --
13 A recent case in Pennsylvania a year ago saying
14 that an arresting officer's conviction for drinking underage
15 cannot be sustained merely on the arresting officer saying
16 what the kid had in his hand in the can looked and smelled
17 and tasted like beer to me and instead he as the arresting
18 officer has got to have medical analysis or some sort of
19 scientific analysis that indeed it was alcohol, just his
20 opinion isn't good enough.
21 In Bendectin litigation, we talked about that
22 briefly so I won't mention it again, about the problems with
23 analysis or reanalysis of data.
24 MR. POMEROY: Before we leave 702, though, let's
25 talk about it for just a minute. I agree with much of what

1 you said about the junk science but let's look at it from
2 another aspect.
3 We expect in this particular instance that we'll
4 have large numbers of people who are extremely well trained
5 one way or another testifying on specific aspects of the
6 repository suitability.
7 The one set I don't think we have much trouble
8 with and that is a group of experts testifying basically on
9 a set of data that may or may not exist in the scientific
10 literature. I think that's a straightforward kind of
11 situation.
12 What I'm concerned about is the question that
13 arose when I read in O'Connor III, citation in case law,
14 where somebody who is trained as an actuary wanted to
15 testify on future economic trends, I believe.
16 MR. JOSE: Yes.
17 MR. POMEROY: And that testimony was excluded
18 because nobody questioned the expertise in actuarial matters
19 but questioned the expertise in future economic trends.
20 To go quickly to one end of the spectrum here,
21 given our current regulations we might have a group of
22 people testifying on, for example, the state of society
23 10,000 years from now.
24 Now in my opinion, either everybody is an expert
25 in that field or nobody is an expert in that field, yet you

1 can have groups of people who you could select for their
2 knowledgability or their capability of thinking about the
3 future and come forward with some probability perhaps to
4 three significant figures with regard to the future state of
5 society.
6 Where I think we'll run into it is somewhere in
7 the middle between that, people who understand perfectly
8 what they're testifying about and people at that other end
9 of the spectrum.
10 I'm concerned that somebody that from a legal
11 standpoint could challenge every expert some place in the
12 middle and say we don't challenge your expertise as a
13 seismologist, for example, but how much expertise do you
14 have in predicting earthquakes that occur 10,000 years in
15 the future, how many have you successfully predicted.
16 I wonder whether somebody could challenge the
17 whole expert testimony, every expert's testimony, based on
18 that distinction between what you have been trained and know
19 something about versus the particular subject you're
20 testifying to.
21 I wondered if you could discourse on that for a
22 minute or two.
23 MR. JOSE: There's a lot of answers because
24 there's a lot of parts to that.
25 First, as to the case with the actuary, I don't

1 strongly defend that. I thought that that was a little bit
2 too narrow of a ruling by the judge but I cited it in my
3 brief for psychological reasons and that's because, you see,
4 Judge Nims -- who I was before -- had decided that case and
5 was kind of proud of it, so I cited it to him and it came
6 back in the opinion because it was something he had done
7 once before. I don't necessarily defend -- I think I was a
8 little narrow.
9 In terms of when you are dealing with something
10 that in fact is not a well defined body of science -- what
11 might society be like in 10,000 years, what might the state
12 of technology be like in 10,000 years -- in some ways that's
13 not like saying what do we know about epidemiology.
14 I think what you have to first do is define the
15 field within which the issues lies and then when you define
16 that field, if you define that field narrowly or broadly it
17 depends upon whom I qualify.
18 The example that you used almost any thinking
19 person might qualify and, in fact, somebody who maybe is an
20 author -- Melvin Tofler, didn't he write Future Shock?
21 Maybe he's as good on that as you are, or me, probably a lot
22 better than me.
23 Yes, sometimes the field you're looking at is so
24 broad and so unknown that there is not an academic
25 discipline for it. Then I think 702 and 703 would say,

1 well, that person is allowed to testify.

2 Now the easy answer, there is an easy answer to

3 your dilemma. The easy answer to your dilemma is it doesn't

4 matter because probably in the first instance where those

5 questions come up you will be in administrative bodies of

6 law or administrative hearings, the Federal Rules of

7 Evidence will not apply, and they'll just let anybody

8 testify anyway. Administrative bodies tend to be very lax

9 in who they allow.

10 MR. POMEROY: Just to clarify, what I'm

11 envisioning there is that that would happen and then in the

12 later court sessions somebody could challenge every expert

13 and by that mode actually weaken the case for acceptability

14 to such an extent that it might not be possible to go

15 forward.

16 MR. JOSE: Yes, and I think that that might be

17 something that you might see. I think you might see anybody

18 who disagrees with somebody's conclusion look for a way to

19 attack the admissibility of that testimony. I think that's

20 a risk.

21 MR. STEINDLER: Let me pursue that just a little.

22 If in fact it turns out that there are portions of the

23 regulations put together by the NRC for which it is not

24 obviously possible to qualify experts, except in the generic

25 sense we've just talked about where everybody can apply,

1 then we in principle have no way to resolve the issue and a
2 license, for example, can't be granted, you can't move
3 forward.
4 Which in turn drives me to the question should it
5 be a requirement in all regulatory agencies that all
6 regulations be so arranged that experts to talk on the
7 subject should be qualifiable?
8 MR. JOSE: Yes, I think it should.
9 MR. STEINDLER: What do you do when --
10 MR. JOSE: There should be some screening of
11 experts before they are allowed to testify.
12 MR. STEINDLER: No, no. I'm sorry. That's not
13 what I meant.
14 What I meant was that the regulations need to be
15 so formulated that it is obvious that should this issue come
16 before a court where 703, for example, applies that there is
17 a way to qualify an expert on that topic.
18 MR. JOSE: Yes.
19 MR. STEINDLER: And that should be considered
20 before the regulation is finally put in place.
21 MR. JOSE: Yes, although that's a little putting
22 the cart before the horse because that's pretty hard to do.
23 I think it's good to think about that but there might be
24 areas within which it's hard to do that because of the
25 scientific --

1 MR. STEINDLER: What I want to drive you to is
2 that the current societal outlook has changed drastically in
3 the last 50 years and it's going to get worse in that regard
4 because we now make regulations that almost by definition
5 look into the future.
6 MR. JOSE: Yes.
7 MR. STEINDLER: Ours is a more extreme case
8 perhaps than some, although the EPA has got the same set of
9 general problems, albeit to a shorter time scale.
10 I don't see that there is much help being gained
11 by the Federal Rules of Evidence or anything else I've seen
12 so far that allows us to unravel this in a fairly clear
13 fashion.
14 MR. JOSE: Well, let's put some things together.
15 I know you're interested in expert testimony and
16 admissibility of expert testimony and I started out with the
17 federal permissible dose limits as the standard of care and
18 that seemed to be offbeat, not on point.
19 Notice how when the courts were looking for what
20 to trust on the standard of care they began looking for
21 consensus of science.
22 What I suggest is perhaps part of the answer to
23 your dilemma lies in the doctrine of judicial deference to
24 agency expertise, which is part of the thinking process that
25 led to O'Connor I, that when the agency amasses expertise to

1 address a problem and to set forth regulations relating to
2 it, then the court ought to give some deference to that
3 agency judgment.
4 MR. STEINDLER: That's not the position that the
5 potential applicant is in. The potential applicant is asked
6 to come in and demonstrate that he or she has met the
7 regulations.
8 It isn't that the applicant can go back and say,
9 yeah, it looks like we can manage what the NCRP or somebody
10 else has said is the numerical number.
11 The applicant has got to come rolling in and say
12 we think that the future state of society -- to use Paul's
13 analysis -- is such-and-such.
14 I have been asked, in response to a question, I
15 have been asked by the NRC to do this exercise. I can't
16 fall back on some consensus agency or even the regulators to
17 defend me having come up with a particular number. The
18 sense is that I'm left hanging out there to dry, which is
19 the problem that we're trying to address.
20 MR. JOSE: I'm not sure I fully understand. Let
21 me respond this way.
22 If what you're saying is a repository ought to be
23 constructed so as to meet these criteria for releases and
24 those criteria for releases ought to be deferred to by the
25 court, and if the person then comes forward and says I can

1 meet those criteria for release with this technique or this
2 device in construction, first as to local residents who say,
3 well, the criteria for release are just not conservative
4 enough I would say those people should not be listened to,
5 other than maybe politely, because the court ought to defer
6 to the expert judgment of the agency and the standards for
7 releases ought to be accepted as the duty of care, like the
8 O'Connor doctrine.
9 As to the person who comes in, the contractor or
10 whatever, who comes in and says I can build it to those
11 levels, thinking how long the geological formation is going
12 to remain secure.
13 MR. POMEROY: You see, that's the crux of the
14 matter because you can say what the standards are but that's
15 straightforward.
16 When you then say that in order to meet those
17 standards my experts in seismology, for example, testify
18 that the probability of a magnitude seven earthquake is less
19 than ten to the minus four so therefore I don't have to
20 consider that as a possible disruptive influence.
21 Now all of those experts that make that testimony
22 have to have some basis for testifying that it's less than
23 ten to the minus four, but how many of them are qualified in
24 a legal sense to make that determination is a key question
25 and that brings --

1 MR. JOSE: I see there's a problem. Let me work
2 through a little bit further and I think we'll see some
3 answers.
4 MR. HINZE: Let me raise -- I'm having some
5 trouble and let me --
6 MR. JOSE: I am, too.
7 (Laughter.)
8 MR. HINZE: Let me make an analysis with this
9 committee's activities.
10 We select people to appear before the committee on
11 problems that we advise the commission on and we go through
12 a rather rigorous procedure to establish the authenticity of
13 their credentials of the people that appear before us.
14 We do not ask the people to get up in front of us
15 and to give us their opinion and sit down. We go through,
16 as you are amply aware, a rather rigorous procedure of
17 questioning and understanding the body of science which has
18 led the person to the conclusion which they express and then
19 we as a body evaluate that whole procedure, the methodology
20 and the data that are involved in that and we reach a
21 conclusion and decide whether we should pass that on to the
22 commission or not.
23 What's the difference between that and what a good
24 administrative hearing should go through? We are --
25 MR. JOSE: There's no difference between either

1 that or what a good administrative hearing should go through
2 or what a court, a judge, should go through in analyzing
3 these things, other than a judge has these rules, 702 and
4 703. He has things he has to follow in his analysis, or
5 should follow, and administrative bodies don't. It's a
6 little more open and you are a little more open in terms of
7 there is no federal rule of evidence that limits who you
8 have speak or how you think of analyze so it's just a little
9 more formal.
10 MR. HINZE: That's not entirely true because at
11 the beginning of each meeting, Dr. Moeller makes the point
12 to the public that if anyone wishes to address this
13 committee, and that's in the Federal Register announcement,
14 if anyone wishes to address this committee that they will be
15 heard as long as they have any legitimate basis, if they
16 have a degree type of thing, we'll listen.
17 That doesn't mean that their rationale and their
18 methodology leads to a sound conclusion and part of our job
19 is to make that evaluation so it seems to me that there's
20 not much difference.
21 MR. JOSE: I think that's right and in reality
22 what you're saying is that the way a thinking person thinks
23 through a problem ought to be the same, whether that
24 thinking person sits on this advisory committee or sits on
25 an administrative board or is a federal judge or is a juror.

1 Part of the problem that I always have is, of
2 course, is that I never have jurors as smart as you guys and
3 so I always have to develop techniques that are a little
4 more simplistic.
5 MR. POMEROY: I can see why you're such a good
6 trial lawyer.
7 MR. JOSE: And the courts need to screen.
8 MR. POMEROY: Let me pose one more question and
9 then perhaps you can answer it sometime as we're going
10 through.
11 One scenario that we envision in this repository
12 situation is that at some point, and perhaps at all points
13 throughout this, we'll have groups of experts in different
14 fields testifying from different perspectives.
15 The Department of Energy will have sets of
16 experts. The NRC staff presumably will have sets of experts
17 and one or more outside. The intervenors may have excellent
18 sets of investigators.
19 All of those might qualify -- all those groups of
20 experts might qualify under 702, for example, in a general
21 way. All of them will be testifying presumably on the total
22 database that's been developed for the particular situation.
23 I suspect they will come to quite different
24 conclusions based on that data and their expertise through
25 some sort of a reasoning process.

1 It seems to me that that's where the Fry doctrine
2 comes to the fore and is that correct and is that how the
3 structure is going to judge those conflicting sets of
4 scientific opinion?
5 MR. JOSE: Yes and yes.
6 MR. POMEROY: Fine. Go on.
7 MR. JOSE: 702 is only the beginning. It's the
8 first cut. It's just do you have a degree, are you even in
9 this field.
10 The next cut on whether or not you ought to be
11 allowed to testify as an expert is 703 and it says now the
12 facts or data in the particular case upon which an expert
13 bases an opinion or inference may be those perceived by or
14 made known to him at or before the hearing.
15 If of a type reasonably relied upon by experts in
16 the particular field -- sounds like Fry -- in forming
17 opinions or inferences upon the subject, the facts or data
18 need not be admissible into evidence.
19 So now we're dealing with not just looking at the
20 man's degrees and the field within which he says he has
21 expertise and is that the field that we're looking at -- is
22 it geology and is he a geologist -- but we're also --
23 It may be we're dealing with geology and he's a
24 novelist. He may be a great novelist but he loses under
25 702.

1 What if he is a geologist? Then the next step is
2 to look at the methodology that he's using.
3 It's important to look at Rule 702 and notice that
4 it really says when you ask that phrase if of the type
5 reasonably relied upon by experts in the field it only
6 modifies or data.
7 It's really saying in a very technical narrow way
8 that the expert has to be in that field and he must use the
9 kind of data that other people in the field use.
10 Many courts have gone a step further beyond that
11 and what they say is not only does the data have to be of
12 the type, but his methodology must be of a type reasonably
13 relied upon by others in the field.
14 This is coming a step further and this is saying
15 you've got the degree, you're in the right field, the data
16 you're looking at to come to your conclusion is the right
17 data, and the method of analysis is scientifically valid,
18 therefore now we're going to let you express your opinion.
19 We're increasingly refining and taking different
20 cuts of this.
21 MR. MOELLER: The first paragraph on the previous
22 one, the first paragraph under 703, I find I'm missing the
23 point.
24 The second sentence says "if of a type" dah-de-
25 dah "in forming opinions, the facts or data need not be

1 admissible."

2 In other words, his or her conclusions can be

3 presented without the supporting data?

4 MR. JOSE: That's right. A medical doctor can,

5 for example -- remember we had hearsay?

6 MR. MOELLER: Yes.

7 MR. JOSE: Hearsay is not admissible but every

8 medical doctor in dealing with a patient first takes a

9 history of what happened to you and the doctor on the basis

10 of that history makes a determination, so suddenly you've

11 got all those medical workers and the doctor is coming to

12 conclusions based upon really hearsay, what somebody else

13 says they saw or heard or felt or whatever.

14 Elements of that may not be admissible into

15 evidence, but the doctor's opinion can still be admitted

16 into evidence if he's relying on the kinds of stuff that

17 other doctors rely upon in treating people.

18 It is kind of turkey in the sense that you can

19 actually have data that for some other rule of evidence

20 isn't admissible or you can actually have a large body of

21 data that you don't introduce into evidence and the expert

22 can still get on the witness stand and testify to give an

23 opinion without that data going in.

24 MR. STEINDLER: It does sound a little bit like

25 the data are wrong but the conclusion is right.

1 MR. JOSE: That's right but it's that the data are
2 inadmissible, maybe, and the conclusions are admissible
3 because that's what we're talking about.
4 The last thing I want to show you involves the
5 O'Conner III opinion. Let me talk about this last part of
6 the O'Conner opinion.
7 In the 703 analysis, O'Conner III uses a different
8 word that I think is important. The judge used the word
9 "verifiable" and the judge is saying there that not only do
10 we want an expert in the field, not only do we want facts or
11 data underlying that expert's analysis which are the kinds
12 of facts or data those kinds of geologists or whatever
13 normally look at, not only do we want a methodology that is
14 normally used by those kind of people in the field, but we
15 want some verifiability.
16 We want the expert to be able to say that my
17 analysis or the principles I'm using here are verifiable in
18 the scientific literature.
19 The judge says why do you believe what you
20 believe. What's the source of your thinking and these
21 principles, and he says, well, I cite these articles and
22 these textbooks.
23 Is there some verifiability, and this is in a
24 sense like the peer review process.
25 See, if there is no verifiability to what that

1 expert is wanting to say, then is it really science at all?
2 Now it might be the brand new discovery, but I
3 would argue that science ought to -- the courts ought to let
4 science be science and science ought to make its new
5 discoveries and publish them and the courts ought not to be
6 the place for litigating the very newest scientific
7 discoveries.
8 If that's really true, they can publish it and
9 other scientists will believe it, it will be verifiable and
10 two years from now it can be used in litigation.
11 If you let the judges and jurors decide what's
12 really new and now, you are really in a risky area.
13 MR. STEINDLER: In the case of predictive science,
14 which is where our problems are, that requirement would rule
15 out the ability to settle issues.
16 MR. JOSE: Well, what is verifiable is not the
17 bottom line. I'm not saying your opinion, the bottom line
18 is verifiable. I'm saying what's verifiable is your
19 methodology, your reasoning process, the data.
20 If you say that part of my analysis is that
21 gravity pulls down and not up, is that scientific principle
22 upon which your analysis is based verifiable in the field of
23 science?
24 MR. STEINDLER: Do you mean verify or validate?
25 MR. JOSE: I mean -- Well, the judge uses

1 verifiable.

2 MR. STEINDLER: What does the judge mean by that?

3 MR. JOSE: I think what he meant is simply this,

4 look, you've got an opinion and you say that this is your

5 method of analysis, tell me where else I can read about

6 that, can I go out and verify, myself, through published

7 scientific literature in that field that the method, the

8 formula you want to use, the thinking process is accepted as

9 right?

10 MR. STEINDLER: I was right in my first statement

11 and especially since, as Paul just pointed out, it is not

12 unlikely that we're going to have three different groups of

13 so-called experts using fundamentally the same basic

14 information come to three different opinions.

15 Any judge looks at that and says I obviously can't

16 verify any one of those because I can go to the same data

17 and come up with any one of three different answers and I

18 don't know which is likely to be correct.

19 MR. JOSE: Well, what the judge is only doing is

20 screening the admissibility. He's not -- This is not to

21 give him the answers to who is right or wrong. It's just

22 who gets to speak, who gets to be considered, so all those

23 three people come in using the same field, all being

24 geologists, let's say, all using standard data that

25 geologists use, all using verifiable methods coming to

1 different conclusions.

2 The answer is that they all get to testify and now

3 the judge had got three different opinions that he's going

4 to have to weigh and balance to determine which is right.

5 I guess I would then begin to come back to say is

6 there not a place at that point in time for judicial

7 deference to agency expertise, is there some way that when

8 the judge is beginning to look at those things, not only

9 will the judge say I will accept the agency standards, but

10 if the agency itself is issuing a license to somebody on the

11 basis of that particular person saying that it can build to

12 these limits and the agency analyzing that person's claims

13 and feeling that that person in fact can do that and giving

14 that person a license, isn't that entitled to some judicial

15 deference.

16 MR. STEINDLER: I think my original question about

17 what do you mean by "verifiable" remains the uncertainty.

18 I think what you're saying to us is that the

19 protocol for arriving at a decision, taking data and doing

20 something with it, is identifiable even though there may be

21 three different conclusions you finally reached depending on

22 who is doing this data manipulation or thinking about it.

23 If the issue is then that this protocol is

24 identifiable, if that's what you mean by verifiable, then my

25 comment doesn't hold.

1 If on the other hand a judge looking at the same
2 data and fairly knowledgeable uses the protocol and comes up
3 with one set of answers, the other two presumably would not
4 be then allowed to be brought into court because that
5 methodology clearly is faulty and hence not verifiable.
6 MR. JOSE: Correct. You're thinking of internal
7 verifiability and in fact that should be part of it, yes,
8 but there should be internal consistency. You do the math
9 and you don't get three different answers. You get one
10 answer.
11 The use of this term "verifiable" would include
12 both of your comments of thinking.
13 MR. STEINDLER: If I may just make just one other
14 comment and that is the answer to the question should the
15 agency expertise not be relied on, I think the answer is
16 clearly no.
17 We can go back to radiation safety and radiation
18 protection with the agency. If it had been relied on, in
19 terms of modern knowledge it would have made, I don't know
20 if grievous errors but significant errors as the radiation
21 protection limits keep being depressed as new information is
22 brought in.
23 There may be something sacrosanct about the
24 quality of the agency science but some of us may really
25 challenge that fairly successfully.

1 MR. JOSE: I would only say that that challenging
2 then ought to be done within the agency's process and if the
3 agency is wrong on the standards it sets, the agency ought
4 to change those standards.
5 It ought not to be the courts saying that the
6 agencies are wrong.
7 If the speed limit is wrong, I think you still get
8 judged by the speed limit whether you like it or not. If
9 you think the speed limit is wrong and you can convince the
10 government to change the speed limit, then that's where
11 your argument should be made, with the government, that in
12 fact they should change the speed limit, but until it's
13 changed you get judged by that limit and, once it's changed,
14 you're judged by the new limit.
15 So when the agencies are wrong, and they have been
16 wrong in the past, then they should change but the people
17 who lived under those old rules should be judged under those
18 old rules.
19 MR. POMEROY: I think back on number three of your
20 previous slide, I think it said that the methodology did not
21 necessarily have to meet a high standard of acceptance in
22 the scientific community. Is that what that number three
23 said, roughly?
24 MR. JOSE: Yes, that's correct.
25 I'm going to just show you Fry, since that has

1 come up. I think maybe it's about time to stop here but I'm
2 happy to keep going.
3 Under Fry, there's just a little gloss put on
4 these things where the courts said the methodology and the
5 reasoning used by an expert to reach his conclusion must be
6 generally accepted within the relevant scientific community.
7 It's saying is that lie detector test generally
8 accepted within the scientific community as validly telling
9 whether people are lying or not and if the person who is a
10 proponent, who is offering the evidence, some scientific
11 device or analysis, cannot show that that particular device
12 or methodology or reasoning is generally accepted within the
13 relevant scientific community, then that should not be
14 allowed into evidence.
15 Now remember the Department of Justice's first
16 criteria. The first criteria of the four that the
17 Department of Justice had was not general acceptance.
18 Department of Justice's first criteria was just -
19 - let me see if I can find it quickly for us -- it was a
20 lower level.
21 Here is the Department of Justice's first proposed
22 criteria -- whether the technique at issue has achieved
23 substantial acceptance by at least a significant minority
24 within the field.
25 That's a little different, a lesser test than Fry

1 which says the methodology and reasoning used by an expert
2 to reach his conclusion must be generally accepted. Under
3 Fry, it's the majority rule but under Department of
4 Justice's proposal a minority, some substantial acceptance
5 by a significant minority is sufficient to allow it into
6 evidence.
7 MR. POMEROY: Then that number three that you had
8 on a couple of slides back referred to what -- obviously not
9 the last slide you showed but within the Federal Rules of
10 Evidence. Is that what it was?
11 MR. JOSE: 702 and 703? I just don't recall what
12 number three you're referring to.
13 MR. POMEROY: It had to do with the methodology
14 not being required --
15 MR. JOSE: Let me find that if I can.
16 703 Can be read narrowly or broadly. If it's read
17 narrowly, that's the plain language, and the plain language
18 doesn't require that the methodology at all be reasonably
19 accepted. It only requires that the facts or data be of the
20 kind reasonably accepted. Now, most federal courts do not
21 read it that narrowly. They read it more broadly, and they
22 apply that phrase, modifying phrase to the methodology
23 itself.
24 However, one of the issues before the Supreme
25 Court in Daubert is that this should be read narrowly.

1 Basically all the guy's got to say is look, I'm a medical
2 doctor. Medical doctors rely upon physical examinations. I
3 gave the plaintiff a physical examination, and I can say
4 whatever I want.
5 MR. POMEROY: All of those lower court cases in
6 the victim situation have said it isn't published and
7 therefore, as I understand it, that it's not published and
8 therefore, it's not admissible.
9 MR. JOSE: The lower court cases really, I think,
10 have come to this conclusion in Bendectin, and that's why it
11 might be a unique field. I think what they're saying there
12 is not quite simply is not that it's not published and
13 therefore it's not admissible. I think what they're saying
14 is here's an issue. Is Bendectin positive of limb reduction
15 birth defects? The plaintiff says, that's what happened to
16 me. Does that medication cause that? Is that a field that
17 we know nothing about? No. In fact, there are 30 studies,
18 and they're all negative.
19 So, in the context of a field where you have a
20 large body of epidemiological evidence, and it is all
21 negative, we will not allow an expert to come in and testify
22 to the contrary. I think that's the basic understanding.
23 Now, if you had the same issue and there were no
24 epidemiological studies at all, is Bendectin causative of
25 birth defects, limb reduction birth defects? We don't know.

1 There's no studies at all. Then you might have the court
2 say well, we'll look at animal data and scientific chemical
3 analysis. But when you do have those 30 epidemiological
4 studies, the courts feel like there's some truth out there
5 that ought to circumscribe what's allowable.
6 So, it's not just a question of is it published or
7 not in literature, it's there is a consistent publication
8 all going the other way. So, why should we let this expert
9 testify to the opposite?
10 MR. POMEROY: I guess that comes back to your
11 suggested methodology because, as I understood it, the
12 question of whether or not the one in 30 parts of the case,
13 there is perhaps one possible birth defect in 30 cases or
14 something like that.
15 MR. JOSE: That's right.
16 MR. POMEROY: It may not be separable from the
17 general population and so therefore some tests, as you're
18 suggesting, might be useful.
19 MR. JOSE: So now to come back for the plaintiff's
20 lawyer on this whole line, and that is to say well, of
21 course you wouldn't expect to see it. It doesn't mean it's
22 not there. This only happened once out of 100 times, but it
23 happened to my client. It's a tragedy. If it only happens
24 once out of 100 times, and since it's so rare that it
25 happens, it just doesn't appear in the epidemiological

1 literature. It is what epidemiologists call an effect which
2 is so infrequent that it is in the noise level of the
3 diagnostic technique of epidemiology. It's within that
4 natural fluctuation, but it's still there, and I ought to be
5 allowed by day in court to argue it.
6 That would be their point, and that's why, you
7 see, I have problems with devices, when you're doing
8 numerical analysis which yield risk of one in 1,000, one in
9 10,000. I have trouble with that being used as a screening
10 mechanism for the admissibility of testimony because that
11 plaintiff can always say he's that one in 1,000. I think a
12 device to be used for screening should yield zeros when
13 you're dealing with dose levels. I think I'm over time
14 here, but I'm happy to keep talking. I enjoy this.
15 MR. MOELLER: Let's go ahead. As long as you're
16 happy or you're comfortable, let's go ahead.
17 MR. STEINDLER: The write-up that I'm looking at
18 is the one in Science on the Bendectin case. It certainly
19 sounds to me as though if this woman, Shanu Helen Swan, the
20 University of California, Berkley expert, had in fact
21 published her data on the connection between birth defects
22 and the drug, then it could have been admitted as evidence,
23 even though it contradicted the 30 cases that had been
24 apparently published. So, the lack of publication
25 apparently was the disqualifying factor.

1 MR. JOSE: One of the factors that was important
2 and if she had published, then it would be better for her
3 because then, you see, you could argue wait a minute, this
4 isn't 30 and zero. This is 30 and one.
5 MR. STEINDLER: Well, but the point is it is still
6 30 and one. One happens to be, you know, in manuscript form
7 that has never seen the peer review.
8 MR. JOSE: Why not?
9 MR. STEINDLER: I don't know.
10 MR. JOSE: Maybe it's not a good epidemiological
11 study.
12 MR. STEINDLER: Well, that's certainly a
13 possibility. Can you say something about the quality of the
14 30, just because it's been in some journal? That's my case.
15 MR. JOSE: Yes, I understand that.
16 MR. STEINDLER: That was my original case.
17 MR. JOSE: And peer review is an imperfect thing.
18 I don't claim that everything that gets published is valid
19 and everything that's rejected is invalid. Peer review is a
20 very imperfect screening process, but at least it's the
21 scientists' own screening process in their own field of
22 expertise. That ought to be respected by the judicial legal
23 decision makers.
24 MR. STEINDLER: Unless it's published in the New
25 England Journal of Medicine.

1 MR. JOSE: Well, it's better --

2 MR. STEINDLER: I'm sorry. This is not a trivial

3 issue. We have talked about this among ourselves. This is

4 a potentially serious problem as it relates to how this

5 waste management issues.

6 MR. JOSE: Yes.

7 MR. STEINDLER: Of the issues, particularly

8 prediction of the future, are going to get resolved, if and

9 when they get resolved.

10 MR. JOSE: I think when you talk about predictions

11 for the future, you are in an inherently speculative area.

12 MR. STEINDLER: Absolutely.

13 MR. JOSE: And once you are in that area, you

14 can't quite analyze it all these different ways, because

15 these different ways are sort of saying, we have knowledge.

16 We have truth, and we know it's out there somewhere, and

17 we're just trying to apply it to the particular facts of

18 this case in some fair. way. What you're struggling with is

19 not the same. You're struggling with where maybe we don't

20 have a lot of knowledge or truth for 10,000 years into the

21 future. So, you can't say there's a well established body

22 of science or field of science from which you decide what

23 gets in or what gets out. You're pretty much left in a

24 field where a lot of different people get to speculate.

25 MR. HINZE: I would like to take some exception to

1 that.

2 MR. JOSE: Yes. Well, good, I hope I'm wrong.

3 MR. HINZE: This whole business of verifiability

4 in the predictive realm, and just to prove your point that

5 you can have people with reasonable backgrounds that come up

6 with different opinions, let me give an example.

7 MR. JOSE: And there's nothing wrong with that.

8 MR. HINZE: No, but there is a good case which has

9 just gone through the National Academy of Science, and that

10 is that there was a scientist and his collaborators came up

11 with a viewpoint about a coupling of geological processes

12 which might lead to rather destructive effects upon a

13 repository that's located in a particular locality. There

14 was sufficient concern about this, that the National Academy

15 of Science convened a group to look into this. A very

16 reputable scientist who looked at the entire process said

17 basically that the conclusions about the coupling of the

18 processes leading to the hazards were not acceptable, that

19 the -- and they predicted into the future, that the coupling

20 of these processes would not lead to this.

21 I think that there has been attempts at refuting

22 this and counter arguments, and I think the vast majority of

23 people that would look at the body of evidence there would

24 say that though all of those things brought together allowed

25 one to reliably predict within certain uncertainty ranges

1 what the future is going to be. So, I am much less negative
2 than some of my colleagues about our ability to predict into
3 the future if we have good science and good data upon which
4 to operate.
5 MR. JOSE: Let's go back quick, if I could, just
6 to one of the places where we started this morning, and that
7 was with the Johnston opinion, where a court is using
8 something that I don't know if I talked much about, but
9 years ago I thought about this concept of consensus science,
10 and some scientists say that's a false statement because
11 there is not much consensus in science. It seems to me that
12 one of the things you ought to think about -- I don't mean
13 you guys, I just mean anybody dealing in this field, ought
14 to think about, and that is are scientists basically evil
15 people, or are scientists basically seeking the truth? And
16 is science a process that is generally designed to weed out
17 false ideas and to affirm correct ideas? And are the
18 leading scientists in the country basically respectable
19 people?
20 Now, if we say that science itself, by its very
21 processes, tries to honestly identify air and find truth and
22 verify that truth -- you know you have a hypothesis and you
23 test it and you verify it. Somebody says, I discovered cold
24 fusion. Everybody else tries it, and they can't do it, so
25 they verify that that's not right. Science basically works

1 that way, and if scientists basically have integrity because
2 they have to to survive under that system, and if then the
3 leading scientists in any field are to be respected, then
4 should not the judicial process defer or make an effort to
5 defer to consensus science?
6 Is maybe part of the answer to a problem like
7 yours an Academy of Sciences panel that comes to a
8 conclusion about a certain repository issue or a certain
9 technique for building which would meet criteria that the
10 agency sets up, and then if there is some sort of Academy of
11 Science panel that answers the difficult question that
12 projects for 10,000 years into the future, then could a
13 court someday say, this group, the such and such committee
14 of the National Academy of Sciences, has reviewed all of
15 this. They're the most knowledgeable and eminent
16 scientists. They spent many hours studying all of this and
17 all of the underlying papers, and they've come to the
18 conclusion that this repository can be built this way and
19 considered safe enough for the public living nearby or the
20 nation as a whole. This court is certainly ill-equipped to
21 second guess those scientists by setting different -- coming
22 to a different conclusion about the safety in this
23 administrative hearing or lawsuit or wherever we are. This
24 court adopts or defers to that expertise. Maybe that's kind
25 of a way to let science be science and control the process.

1 MR. STEINDLER: I think your argument would seem
2 reasonable if it hadn't been for the spate of ethics issues
3 that have arisen in the last two years among scientists and
4 their mode of operation. I think the science community at
5 large has become somewhat blackened by the exercise and
6 publicity of a few, and I don't know what kind of opinion
7 you would get from your blue collar Jerry, the guy on the
8 street or whoever have you. If you posed a sufficiently
9 neutral but pointed question at them saying, you know, do
10 you trust the scientists, are they honest people, et cetera,
11 et cetera --
12 MR. JOSE: Yes. We're asking that of a judge, and
13 remember that the federal judge or the judge who's looking
14 at this, at least I'm suggesting, that although scientists
15 may be a little less than totally pure and stained, as long
16 as the judge is comparing them to the lawyers he sees in his
17 courtroom every day, you guys come out really good.
18 MR. STEINDLER: I have no other comment.
19 MR. MOELLER: Any other questions?
20 MR. POMEROY: For one more minute, let's try going
21 back to the question of what constitutes verifiability, in
22 the sense of, for example, in another field that I happen to
23 be in, there's a large amount of what we call gray
24 literature. That is, literature which may or may not have
25 been peer reviewed internally in some agency, and it's been

1 published in the form of an agency publication or something
2 like an agency publication. One could imagine, if we looked
3 at that kind of evidence, one could imagine that you could
4 look at the basis and so forth of that evidence, but would
5 that constitute the kind of publication that you are looking
6 for in verifiability, for example?
7 MR. JOSE: I always thought gray literature meant
8 something published by anybody over 55. I would say --
9 MR. HINZE: How do you spell your name?
10 MR. JOSE: I would say that no, that that gray
11 literature would not constitute verifiability in the way
12 Judge Mimh was using that word because what Judge Mimh was
13 trying to say is where can I go in a medical school library
14 to find some statement that, in fact, a person could look in
15 another person's eyes and see cataracts, which are so
16 clinically unique that they must have been caused by
17 radiation and nothing else? That's the essence of what this
18 man wanted to say, and Judge Mimh says, look, where can I
19 verify that that is true? Where can I go?
20 So, some gray literature which is not published
21 hasn't made it through the peer review process wouldn't help
22 the judge. He couldn't go to that library and look it up.
23 Now, those kinds of things perhaps could be briefed and
24 attached as exhibits and provided to the court, so in that
25 way it could be used. But just the way Judge Mimh was

1 thinking about it was not to include anything like that,
2 just to say look, you're a medical doctor. This is a
3 medical, scientific truth. Show me where I can read it in a
4 book someplace, and if you can't do that, then how are you
5 going to assist the jury? Why should I let you testify?
6 MR. POMEROY: I thought that was such an easy case
7 in some ways because it was so obvious.
8 MR. JOSE: Yes, right.
9 MR. POMEROY: It would have helped to have a
10 harder case, perhaps, to work with.
11 MR. JOSE: It was a lot harder case before I
12 started working on it.
13 MR. POMEROY: That's all the questions I have.
14 MR. JOSE: It was in litigation for about eight
15 years now, and it was in litigation three or four years
16 before I got involved. At the time I got involved, nobody
17 knew or had discovered that although this man had bilateral
18 posterior cataracts at age 44, his father had bilateral
19 posterior subcapsular cataracts at age 39. That was not
20 known.
21 MR. HINZE: I would like to support your statement
22 about the imperfection of the peer review process. There
23 are colleagues in my department who, perhaps facetiously,
24 suggest that we should make more room in our library by
25 removing all journals that are more than 10 years old, that

1 the body of knowledge that exists before 10 years is
2 irrelevant. That's said rather facetiously, but the point
3 is made that just because we're talking about publication,
4 what we're really talking about is a series of publications
5 and making certain that we don't take something out of
6 context.
7 MR. JOSE: Right.
8 MR. HINZE: It has always been my belief that
9 every scientist has the right to go around the country and
10 remove one publication or his or hers from all of the
11 libraries. We all have written a publication that we want
12 to see eliminated from the process.
13 MR. JOSE: I fully understand that. What I'm
14 really saying is that I believe law should follow science,
15 not attempt to lead it, you see. Science should be science,
16 and law should then follow what the current scientific
17 thinking is and not attempt to be out in the forefront with
18 new discoveries, because the legal system is not the place
19 to test well the validities of claims of new discoveries.
20 So, to that extent, law will always be a few years behind
21 the latest scientific thinking perhaps, but much safer, and
22 that's were I depart from my friends at the EPA, for
23 example, who want to litigate all of their cases on the
24 forefront, I suppose, as science. The balance the
25 Department of Justice has to do in the test you saw them

1 present.

2 I think it's much safer for the courts to stay a

3 number of years behind the leading edge science instead of

4 trying to be right on that cutting edge because, you know,

5 we're not talking with academic interest. I mean, we're

6 saying, this guy's got cancer over here and he wants $2

7 million from you, and we want to give you the social stigma

8 and blame of having caused cancer in that man. Now, I think

9 maybe that's an important judgement to be making, and maybe

10 we'd better be a few years behind scientific knowledge

11 instead of a few years ahead and wrong when we make those

12 decisions.

13 MR. MOELLER: Well, Don, thank you so much. I

14 know I speak on behalf of the entire Committee and all of

15 our members of the public who are here to express our

16 appreciate for this stimulating session this morning.

17 MR. JOSE: Don't they ever get to ask questions?

18 MR. MOELLER: You not only covered the field, but

19 it was an outstanding tutorial for all of us, and we do

20 thank you so much. We appreciate it.

21 MR. STEINDLER: Do we really want to go to lunch

22 with this -- we don't have a chance like this too often.

23 Let me ask you another question.

24 MR. JOSE: Yes.

25 MR. STEINDLER: That has only indirectly a

1 relationship to science, and it deals with the issue of
2 models.
3 MR. JOSE: Okay. I have only an indirect
4 relationship to science and law myself.
5 MR. STEINDLER: I'm not so sure. It deals with
6 the question of models, and we have before us a whole bunch
7 of documents that relate to models and how you construct
8 them and how you defend your ability to meet whatever the
9 criteria you happen to be, be they federal rules or whatever
10 have you. Have you had any experience in examining the
11 applicability and validity, admissibility of models, and
12 what sort of issues do you see that either have arisen or
13 could arise? Preferably focus on models -- again, look out
14 into the future.
15 MR. JOSE: I don't like models, because I like to
16 deal, insofar as possible, in what we know exists rather
17 than what we model or think or expect. But we do have to
18 deal with models. We have to deal with dose reconstruction,
19 for example, and whenever you deal with dose reconstruction,
20 for example, we are always dealing with referenced man, and
21 that's a model for how radionucleides would go through the
22 body.
23 I remember some scientists early on when I was
24 dealing with these issues, one of the things they said to me
25 was -- one of the fellows was sort of the influential, said

1 to me, if you have data on the one hand and if you have a
2 model on the other hand, always trust the data instead of
3 the model. Always, you know, give reliance on the data.
4 That particular person was faced at one point in his career
5 with data on neutron enhancement of sulphur on telephone
6 poles at Hiroshima, and on modeling that said the neutrons
7 weren't there. He chose the data, and many years later,
8 people said T65D was wrong and DS86 was right. Nowadays, it
9 seems like other people are finding data.
10 So, I've sort of clung to that and try to stick
11 with data, but when you do have to do modeling, then I think
12 I always do modeling on the basis of consensus science. I
13 dealt with an expert once who was having a little bit of
14 difficulties in his career, an eminent man, and I said, I'd
15 like you to do some dose reconstruction, but you must use
16 all of the ICRP and the NCRP models. We simply won't do it
17 any other way. He said, well, I'll think about it, and
18 wrote me back a little bit later, several weeks later,
19 saying, I'm afraid I can't help you. Well, I never used
20 that guy as an expert. In fact, I ended up cross examining
21 him.
22 I think if modeling is to be used, then it must,
23 inasmuch as possible, be consensus science upon which the
24 model is built. I would say models built on non-consensus
25 science, whatever extreme, ought to be disregarded by the

1 courts. You, I suppose, are in an area where modeling is
2 inevitable, and your question is --
3 MR. STEINDLER: We don't have a choice.
4 MR. JOSE: The question is is the modeling built
5 on consensus science verifiable scientific principles.
6 Insofar as it is, then I would say that that's a valid
7 model.
8 MR. STEINDLER: It's not usually the question.
9 MR. JOSE: Okay.
10 MR. STEINDLER: Usually the question is are the
11 assumptions on which the model is based valid for the
12 extrapolation or the predictions that is going to be
13 eventually done with that model?
14 MR. JOSE: Well, I'd go one step further. I
15 wouldn't just say assumptions, however wild, valid to use
16 this way, but are the assumptions consensus science
17 assumptions? Are the underlying assumptions reasonably
18 accurate? I mean, you could have wild assumptions and yet
19 have a valid method that leads you down some --
20 MR. STEINDLER: Sure.
21 MR. JOSE: So, I would look, too, at the -- the
22 assumptions they chose -- I mean, here's a range of
23 possibilities. That was a problem I had with one expert.
24 Every time there was a range of options to choose, he chose
25 a wild extreme. Now, then he did the math. His math was

1 right. This guy didn't make mistakes in math. He just
2 always, always chose wild extreme assumptions and worked on
3 that basis.
4 MR. HINZE: That way he's always right. He's
5 always within the extremes.
6 MR. JOSE: He's always where he wants to go, is
7 what is was, yes.
8 MR. STEINDLER: So, your methodology, then, would
9 be to rely on consensus science as a defense against the
10 challenge about whether or not this constitutes expert
11 judgment that should be admissible?
12 MR. JOSE: Yes. I would say expert judgment has
13 to be made. The methodology has to be reasonable, and it
14 has to be the kind of thinking process, the math has to be
15 right, essentially, the logic has to be right. The
16 assumptions, the underlying assumptions that they're
17 starting from have to be, insofar as possible, consensus
18 assumptions, not wild extremes. Once you go through that
19 process, you have assumptions which are not extremes. There
20 would be a consensus in the scientific community in that
21 field that those assumptions are reasonable and the
22 methodology is a methodology which is within the scientific
23 community recognized as valid. There's nothing wrong with
24 the math.
25 There's nothing wrong with the logic, and you come

1 out with conclusions, then. Those conclusions ought to be
2 respected, not only admissible in evidence by the courts.
3 Part of what we're talking about is admissibility. I'd
4 argue further. I'd argue that if a group from the National
5 Academy of Sciences did that, then their conclusion not only
6 is admissible in evidence, it ought to be deferred to by the
7 decision maker.
8 MR. STEINDLER: The implication of that general
9 conclusion, I think is that there should be a push made by
10 DOE and NRC to essentially converge on the consensus model
11 for each of the exercises that they're going through, be it
12 scenario analysis or corrosion rate prediction or whatever
13 have you, rather than everybody using their own model and
14 hoping that they come to some similar conclusion.
15 MR. HINZE: I think at this stage, we need
16 multiple models, but we need to converge.
17 MR. STEINDLER: Convergence is what I'm looking
18 at, yes.
19 MR. JOSE: That would make great sense to me. You
20 realize, of course, I don't know anything about what you're
21 talking about.
22 MR. STEINDLER: That's all right. There are times
23 we wonder about ourselves.
24 MR. POMEROY: I still somehow see the scenario
25 where we're going to have groups of very competent and

1 respected experts going through this process and coming with
2 acceptable methodologies using the same database, coming to
3 different conclusions, and of course, that's the function
4 finally of the decision maker to evaluate what the best
5 science is. That's, of course, why it's interesting to
6 define in the Supreme Court what is good science in a legal
7 sense because we certainly need that definition before we
8 get to the best science.
9 MR. JOSE: Yes, but I guess I'd say that there is,
10 perhaps, the field you're looking at, unlike mathematics.
11 There is, perhaps, no one pure precise irrefutably accurate
12 answer. There is, probably, in the field you're looking at,
13 some range of acceptable belief. The scientific and legal
14 process ought to screen to cut off testimony on both ends,
15 to lop off the unacceptable low ranges and the unacceptable
16 high ranges, and you may be stuck with some variance, and I
17 don't know what, a factor of two or a factor of four or
18 something, as to what people kind of predict. I guess I
19 would say that what you might hope is that your criteria are
20 below that range, that your range falls beyond the criteria.
21 If you find yourself in that position, then does it really
22 matter too much what that range is? I don't know. I mean,
23 I don't know how all this stuff relates to you guys.
24 Also, remember all I'm saying here is what's
25 admissible and what's not admissible, kind of like threshold

1 screening. It's not necessarily the ultimate decision,
2 right?
3 MR. POMEROY: Right.
4 MR. JOSE: Thank you for your time.
5 MR. MOELLER: Thank you. Not to prolong this
6 still further, but I understand that William Reamer is here
7 and Dan Fehrenger. Do either of you have comments you want
8 to offer or anyone else who wants to comment?
9 [No response.]
10 MR. MOELLER: I see none. Okay, well let me thank
11 Don once again, and I'll try real fast now to take a lunch
12 break. Come back at 1:30.
13 [Whereupon, at 12:35 p.m., the hearing was
14 recessed, to reconvene this same day at 1:30 p.m.]
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1 AFTERNOON SESSION

2 [1:30 p.m.]

3 MR. MOELLER: The meeting will resume. The first
4 item for this afternoon is a review of the NRC staff views
5 on the possible impacts of the Energy Policy Act of 1992,
6 particularly as related obviously to the ongoing agency
7 initiatives in the high level waste arena.

8 We have with us Robert Kennedy and Dan Fehringer,
9 and John Linehan. John is probably more as a resource, I am
10 not sure. I gather that I will call on Robert to begin. We
11 do have the background information.

12 MR. JOHNSON: Obviously, you are aware that back
13 in November the Commission did request the staff to give its
14 views on the impacts of Section 801 of the MPA. On February
15 9, the memo that you are referring to, was our response to
16 them. That has been available to you. I imagine that you
17 have all had a chance to read it. In my presentation this
18 afternoon I am just going to highlight and summarize some of
19 the main points in that. Then, based on your questions,
20 either I or Dan Fehringer can discuss some of the questions
21 that you may have.

22 MR. MOELLER: Excuse me. I am corrected now. I
23 have been saying Robert Kennedy. I guess that's because I
24 am from Massachusetts. Our speaker is Robert Johnson.
25 Excuse me. There are people other than the Kennedy's.

(2)

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EMERGING ISSUES IN LITIGATION

1. Compliance with regulatory controls as a defense.

   The O'Conner Doctrine

2. Screening of scientific opinion testimony.

   Junk Science

3. Proper use of epidemiology.

   Attributable Group Odds (AGO)

4. Proper use of dose in causation decisions.

   Cancer Doubling Dose (CDD)

5. Proper tort immunity for worker's compensation coverage.

   Statutory Employer

COMPLIANCE WITH REGULATORY CONTROLS AS A DEFENSE

1. What numerical standards exist which must be complied with and therefore could serve as the standard of care?

   A. NRC Regulations (10 CFR § 20.101, 20.104, 20.105, 20.106)

   B. DOE Regulation (5480.11?)

   C. NCRP Recommendations ?

D. ICRP Recommendations ?

C. State Regulations

D. ALARA

E. Fetal Dose Limits (500 millirem in 9 months)

2. Johnston v. United States, 597 F. Supp. 374 (D. Kan. 1984).

A. Radium

B. Kansas was an agreement state with NRC

C. The Court:

> These two groups [NCRP and ICRP] are made up of the most knowledgeable and most eminent scientists [who] have spent many hours studying scientific papers that in turn reflect many hours of scientific work in order to determine what levels or amounts of radiation should be considered safe enough to use as safety standards. This Court is certainly ill-equipped to second guess those scientists by setting different standards of safety in these tort suits... This Court readily adopts these exposure standards.

Johnston, page 391.

3. The O'Conner Doctrine

A. Preemption by Congress

> "The Price-Anderson Act only allows the application of state law as long as it is not contrary to the [Atomic Energy] Act, (*see*, 42 U.S.C. § 2014(hh))." 748 F. Supp. at 678.

B. Judicial Deference to Agency Expertise

> "In determining the likelihood of the injury from radiation, this Court believes that it should give deference to the administrative

regulations which are the result of an agency's applied expertise." 748 F.Supp. at 677.

C. State Law policy for setting the standard of care.

"In order to determine whether or not the federal regulation in this case can be established as the standard of care, this Court must look to the policy reasons for imposing a duty under Illinois law. Under Illinois law, the duty to be imposed is a question of law to be decided by the Court. [cite omitted] The imposition of a duty is an act of judicial policy making." 748 F.Supp. at 677.

D. Restatement (2d) of Torts, § 286 (1965).

"The court may adopt as a standard of conduct of a reasonable man the requirements of a legislative enactment or administrative regulation whose purpose is found to be exclusively or in part (a) to protect a class of persons which includes the one whose interest is invaded, and (b) to protect a particular interest which is invaded, and (c) to protect that interest against the kind of harm that has resulted, and (d) to protect that interest against the particular hazard from which the harm results."

E. General Fairness and Good Public Policy

"In a highly technical field such as this, although a plaintiff should be provided a very high level [of] protection from excessive exposure from radiation, a defendant public utility should also be provided with some clear statement regarding how it may limit a worker's dose without exposing the worker to injury or itself to liability."

SCREENING OF SCIENTIFIC OPINION TESTIMONY

1. Junk science is a "scientific opinion" which would not be able to withstand the normal scientific publication peer review process but yet is offered in court to "assist" laymen in the resolution of a difficult legal problem.

2. <u>O'Conner III</u>

A. The issue was what caused cataracts in a nuclear worker.

B. The testimony of Plaintiff's expert was:

> "I know what cataracts look like when they have been induced by radiation, by what ever dosage or time of exposure there was. Radiation cataracts are [a] clinically describable and definable condition which, when present, cannot be mistaken for anything else."

C. The scientific truth is that radiation induced cataracts are always of the posterior subcapsular type but not all posterior subcapsular cataracts are radiation induced. Just because it is true that all men are human (except for those who are pigs or rats) does not make it true that all humans are men.

D. The Court:

"In science, a proposition is not true just because one claiming to be an 'expert' is willing to make such a statement. In law, a statement is not admissible just because a self-proclaimed 'expert' is willing to say it on the witness stand. Scientific truths must be verifiable or they are not <u>scientific</u> truths at all. Rules of both science and evidence require a scientist or an expert to have a verifiable scientific basis for his opinion. Such controls are important in both fields to minimize error due to 'junk' science." (page 32)

"An expert's opinion must have a sufficient verifiable scientific basis; the scientific data underlying his opinion must be of the type that is reasonably relied upon by experts in the field...(page 36)...Whether an expert's opinion has a sufficiently verifiable scientific basis is an issue of law for the court to decide.(page 36)...[the Court then examines each of Dr. Scheribel's cited references and consensus science literature on point]...The court finds that the 'opinion' Dr. Scheribel intends to give to the jury is not only without verifiable scientific support, it is actually directly contradicted by his own claimed sources and by consensus medical science. Such a scientifically erroneous 'opinion' cannot help the jury discover the truth here. It could only serve to mislead them. (pages 44-45)... Just as a medical opinion without a verifiable scientific basis is inadmissible, an expert opinion that <u>actually contradicts directly</u> the scientific consensus is inadmissible. (page 52)... Having exercised its duty mandated by Rule 703 to examine the basis of expert opinion testimony and the reasoning process used, the court finds that Dr. Scheribel's opinion had no verifiable scientific basis and no

verifiable scientific reasoning process. The court further finds that Dr. Scheribel's opinion directly contradicts consensus science. (page 53)... The court therefore finds that Dr. Scheribel's opinion must be excluded under Rules 703 and 403." (page 54)

"Relying upon cross-examination to expose the error is not sufficient ... because that mechanism relies upon an unsophisticated lay person to arbitrate complex scientific issues which they may not even comprehend." (page 24)

3. Daubert v. Merrel Dow

A. Bendectin Case where Plaintiff's expert wants to testify that Bendectin caused Plaintiff's limb reduction birth defect even though 30 epidemiological studies have been conducted and all have been negative. Plaintiff's expert bases his opinion on a "reanalysis" of those existing studies, on animal experiments, and on chemical analysis.

B. The Federal District Court said that Plaintiff's expert could not testify. The United States Court of Appeals for the Ninth Circuit said that Plaintiff's expert could not testify. Now the United States Supreme Court will decide the case.

C. The test for admissibility of expert testimony as urged by the United States Department of Justice in their Amicus Brief.

1. Whether the technique at issue has achieved substantial acceptance by at least a significant minority within the field.

2. Whether the potential rate or possibility of error can be estimated (and the extent to which any uncertainty on this score would tend to favor the opponent of the evidence).

3. The degree to which subjectivity in the analysis renders intelligent evaluation of the expert's conclusions impractical, requiring the trier to take the conclusions "on faith."

4. The extent to which the expert has exposed his methodology or conclusions to peers through publications or otherwise.

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THE USE OF EPIDEMIOLOGY

I. Attributable Group Odds (AGO) rather than PC

A. Radiation case problems

1. radiation causes cancers which are also naturally appearing

2. a radiation cancer appears no different biologically or clinically than a natural cancer

3. assume no dose threshold for cancer effect

4. assume any dose has a risk

5. epidemiology is only way to see radiation induced cancers

6. epidemiology can expect 100 normal cancers in a group and see 150 so it can attribute the extra 50 to radiation causation but it simply cannot tell you which person is one of the 100 normal cancers and which person is one of the 50 radiation caused cancers

B. Yet epidemiology has some scientific truth which should be used, but how?

C. Some say to use PC but I say AGO is better

II. Attributable Group Odds (AGO)

A. AGO = ORR - 1/ORR
Attributable Group Odds is Observed Relative Risk minus one divided by Observed Relative Risk

B. ORR = ONC/ENC
Observed Relative Risk is the Observed Number of Cases divided by the Expected Number of Cases

C. Assume that we have a study which has 100 observed number of case and 100 expected number of cases. We can calculate the AGO for a plaintiff as follows:

AGO = ORR - 1/ORR
ORR = ONC/ENC
ORR = 100/100
ORR = 1
AGO = 1 - 1/1
AGO = 0/1
AGO = 0 or 0%

D. Assume that we have a study which has 200 observed cases and 100 expected cases. We can calculate AGO as follows:

AGO = ORR - 1/ORR
ORR = ONC/ENC
ORR = 200/100
ORR = 2
AGO = 2 - 1/2
AGO = 1/2 or .50 or 50%

E. Some considerations

1. Will have to use a proxy group for the plaintiff since he is usually not a part of an epidemiological study. This can be done by simply placing him in a composite dose group from existing studies. Thus, if he got 10 rem he can be put into a group consisting to the 10 rem exposures from all existing studies.

2. This method does not recognize a risk for doses below which any excess cancers have been seen in existing epidemiological studies.

3. This method will tend to make the employer or defendant responsible for all naturally occurring cancers in a group of people once he more than doubles their rate of cancer since each person now will have an AGO of more than 50%.

CANCER DOUBLING DOSE

1. What amount of radiation given to a group of people will double the naturally occurring cancers in that group? If you were to conduct an epidemiological study of two groups of people with 1,000 persons in each group, what amount of radiation would you need to give the irradiated group in order to get a Relative Risk of 2.00 for all cancers combined? [lets just say 250 rem, for example]

2. What amount of radiation would it take to double the amount of leukemia in a group of people? [lets just say 100 rem, for example]

3. What amount of radiation would it take to double the amount of cataracts? [lets just say 1,000 rem, for example]

4. Now what is the Cancer Doubling Dose?

5. What is the cancer type the plaintiff has? What is the acute injury (such as cataracts) he wants to attribute to radiation exposure?

6. What amount of radiation given to a large group would create an Attributable Group Odd of more than 50% for the specific type of cancer (or other injury) which the plaintiff has? If he can prove that dose, and if he uses AGO, he will win.

7. With this approach an employer can almost double the amount of cancer in his workers and still get away "scott free." But if he more than doubles the amount of cancer in his workers he will have to pay damages for all of the cancers he caused and also for all of the cancers which would have occurred naturally in that work force anyway.

STATUTORY EMPLOYER

1. Many states have a legal doctrine which allows the employer who really exercised the detailed control over the worker to be held responsible for worker's compensation payments and to be entitled to tort immunity.

2. You just have to research the law of the state you are in.

3. Every nuclear worker should be able to qualify because the utility will exercise detailed control over him due to the nuclear hazard in the work place.

4. I have won this in California and in New Jersey even though in both states the local lawyers on the case told me that it would be impossible to win this issue. Don't give up. Just prove the control in a way which cannot be denied.

THE VALID USE OF EPIDEMIOLOGY TO DETERMINE CAUSATION IN A RADIATION CASE

Donald E. Jose[1]

The issue of causation in a radiation case has certain unique problems that do not exist in most normal tort cases. First, the cancers that radiation can cause are not biologically or clinically distinguishable from the many natural cases of the very same cancer. Radiation, at least at low doses, does not cause any unique diseases but rather just hypothetically elevates the number of natural cancers in the exposed group. Thus, no medical expert can look at a certain plaintiff's cancer and tell that radiation caused it rather than that it simply appeared naturally. Second, an assumption has always been made that any dose of radiation has some chance of causing a cancer. It has simply been assumed that even one gamma ray could happen to strike a normal cell in such a way as to cause a change which later makes that cell turn into the first cancer cell. Thus, any dose has associated with it some risk. Third, epidemiology is the only way that any radiation induced cancers can be shown to even exist. A very large number of epidemiological studies have been conducted which do show excess cancers at doses above about 30 to 50 rem. Thus, science is able to "prove" that some radiation induced cancers do exist. Fourth, epidemiology has important limits. It can look at a group of people and say that there are 100 natural cancers in that group and an additional 50 excess cancers caused by radiation. But of those 150 people with cancer, epidemiology is unable to tell which are the 100 with the natural cancers and which are the 50 with the radiation induced cancers. Epidemiology can identify group truths but it cannot identify person specific truths. Unfortunately, a lawsuit is interested in exactly what epidemiology <u>cannot</u> answer: what is the exact cause of this particular person's disease.

Yet, epidemiology does have some information which should be used, if possible, to help answer the very difficult causation question which exists in each of these radiation cases. One attempt to use that epidemiological data has been the device known as Probability of Causation or PC. Much has been written on this device and its limitations. The purpose of this paper is not to review those comments but rather to present an alternative way to use epidemiology "group truths" to answer the person specific question raised by a lawsuit. While radiation cases raise the problems discussed above, it is also true that other toxic tort agents will involve the same problems.

Increasingly courts around the country are asked to resolve causation questions which presently lie beyond the boundaries of normal diagnostic medicine. A doctor can reasonably opine that a car bumper hitting a pedestrian's leg caused the

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[1] Mr. Jose is a partner in the law firm of Jose & Wiedis which specializes in radiation litigation. He has been a partner in the law firm of Pepper, Hamilton & Scheetz and he has been a trial attorney, senior trial attorney and assistant director in the Torts Branch of the Civil Division of the U.S. Department of Justice

fracture which he treated in that leg.[2]

The problem arises when an agent is capable of increasing the incidence of a disease which naturally occurs in the population anyway and when the disease caused by that agent is medically indistinguishable from the naturally occurring disease. In such a situation, modern diagnostic medicine cannot look at a person with that disease and with some history of exposure to the agent and tell us whether that particular person's disease was caused by his or her exposure to the agent or whether it is just a naturally occurring example of the disease which that person would have developed even if he or she had never been exposed to the agent at all.

Modern medical science is able to find answers in some situations where traditional individual diagnostic medicine cannot. For example, if an agent doubles the rate of cancer in a population but traditional individual diagnostic medicine cannot look at a specific person's cancer and say whether it was caused by the agent or is a naturally occurring cancer, epidemiologists can still statistically "prove" that twice as many people in the population have cancer as ought to have cancer. Furthermore, they can offer some insight as to the probable cause of these excess cancers. If the group is exposed to a carcinogenic agent which is known to cause the very types of cancer which appear in the population and if the group is average in every other way, the epidemiologist can logically deduce that the exposure to the carcinogenic agent caused the excess cancers.

But here we reach the limit of what epidemiology can offer to us. It can only deal with the problem on the group level. It can offer insight and causation opinion on group issues but not on individual issues. The new epidemiologic techniques are not better at telling us the cause of a certain person's cancer than were the old diagnostic medical techniques. Yet, there is a way to make use of those group insights and group statistics by attributing them to a person within that group.

Lets look at what we can "know" about a group from the use of epidemiological techniques. We can know that a certain group of people have been

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[2] If he has all of the underlying facts correct! I once had a case in Ohio concerning a man with fractured bones in his back who blamed it on improper arrest by federal agents. He sued the United States as the employer of those persons because they allegedly "broke" his back. The arrest fight just didn't seem sufficient to cause the physical injury to me, even though the plaintiff had a score of medical doctors who claimed cause and effect. On a hunch, I checked all local area hospital emergency rooms for records on this guy and found one. Three days before the event over which he was suing he came to the emergency room in severe pain and told them that he had a fight with his brother and that his brother broke a chair across his back. X-rays showed fractures but he signed out against medical advice with only pain medication. Three days later he picked a fight with a federal agent trying to arrest him and sued the United States for his broken back. Many doctors, including the federally paid doctor who examined him in jail, concluded that the arrest fighting must have caused the fractured bones in his back because he obviously had the fractures and he told them that he was just fine before the arrest and his brother confirmed his story of being fine before the arrest! Sometimes criminals are smarter than medical doctors. When the true facts surfaced the suit was dropped.

normal[3] in all known regards except for their exposure to one carcinogenic agent. (An example would be the so called "Atomic Soldiers" who were a normal group of soldiers in every way except for their attendance at the atmospheric testing of nuclear weapons.) For such a group we would expect to see the same rate of cancer as in any other group like them which was not exposed to the carcinogenic agent. We might call this the "baseline" cancer rate or the "natural" cancer rate. If their doses of the carcinogenic substance were sufficiently high, we would expect to see additional cancer, above and beyond the baseline, which were caused by the exposure to the carcinogenic agent. If we observed twice as many cancers appear in this group as appear in an identical group of soldiers who did not attend atmospheric tests, we would be able to say that their radiation dose doubled their cancer rate. But we still cannot select an individual soldier with cancer and tell from these epidemiological data whether or not his particular cancer is one of the naturally occurring cancers or is one of the radiation induced cancers.

Epidemiology only allows us to say is that the group has a certain experience as a group. But can we somehow fairly attribute this group truth to an individual within that group in a way which tells us what the odds are that his cancer is one of the natural cancers or that it is one of the excess cancers? Attributable Group Odds (AGO) allows us to do this. We simply define AGO as being equal to the Observed Relative Risk (ORR) minus 1 divided by the Observed Relative Risk. The Observed Relative Risk is defined as the observed number of cases divided by the expected number of cases. Essentially, this formula is the same as the NIH Radioepidemiological Tables equation for PC. The difference is in how I have defined the terms and specifically in the fact that I only use data of observed excess cancers. No risk below the observed excess cancers is recognized. My selected phrases emphasize that we are calculating group odds and attributing them to an individual. We are not calculating a probability of causation. It is an assignment of "group truth" (and not any unobserved risk) to an individual within the group. We are calculating the odds that he falls into the excess cancer group as opposed to falling into the naturally occurring cancer group. And we only do this calculation when there is a group of excess cancers in the first place. We do not use any linear or linear-

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[3] The exact definition of what constitutes normalcy is sometime quite elusive. For the purposes used here the author, and most epidemiologists, would be interested in only those factors which would tend to make the group more likely to develop the disease or diseases being studied. For example, in a study of radon gas possibly causing lung cancer as long as the group has no traits which make them more or less likely to develop lung cancer than the "average" american population group, the epidemiologist would consider them a normal group. However, if lung cancer was being studied and the group contained no smokers, they would not be normal and natural incidence lung cancer data for "average" americans cannot be used because it would tend to hide any excess radon induced lung cancer cases appearing in the group under study. Also, if the study is about lung cancer and every member of the group is a very heavy smoker, once again "average" american population data cannot be used because it will tend to show an increase in lung cancers which will seem to be attributed to radon when, in fact, there were really no extra lung cancers when compared to a group the same size made up of all heavy smokers.

quadratic dose response curve to estimate any risk we do not actually see.

Since normally we will not actually be able to use the plaintiff's precise group (i.e., nuclear workers at TMI for example) since there may be no completed epidemiological study on his group, we must use a proxy group. If the plaintiff received a dose of 3.5 rem over four years, we can put him into the dose group of three to four rem from all existing epidemiologic studies which included the specific cancer which the plaintiff has. We can examine all existing studies to see if any excess cancers have been seen at under 5 rem. If the answer is no, then we can calculate an AGO which is equal to zero as follows (the terms are defined above):

$$ORR = ONC/ENC$$
$$ORR = 1$$
$$AGO = (ORR - 1)/ORR$$
$$AGO = 1 - 1/1$$
$$AGO = 0/1$$
$$AGO = 0$$

Consequently, no reasonable jury could conclude, more likely than not, that radiation caused his cancer. No expert could opine that radiation caused his cancer since such an opinion would be mere speculation. Summary judgment should be granted for the defendant. In great contrast, PC calculates numbers well below any observed excess cancer. AGO will calculate a zero for any dose at which no respected epidemiological study shows excess cancers. Although there is still some debate as to whether T65D or DS86 is a better estimate of the dose received by each of the Japanese survivors and whether the BEIR III or the BEIR V risk estimates are better, however these are resolved it seems safe to predict that there will be general agreement that no excess cancers are observed below doses of 30 rem to 50 rem, depending on specific cancer type. The point of citing these numbers is that when the very latest data is examined for use in a specific case, it is quite likely that the AGO calculated for a specific cancer will be 0 unless the plaintiff's dose exceeds 30 to 50 rem.

If we have a dose which is large enough to double the number of cancers seen in an exposed group, then the AGO would be calculated as follows:

$$ORR = ONC/ENC$$
$$ORR = 2$$
$$AGO=(ORR - 1)/ORR$$
$$AGO = 2 - 1/2$$
$$AGO = 1/2$$
$$AGO = .5 \text{ or } 50\%$$

Thus, once the number of cancers is more than doubled in a group of people, the odds are more likely than not that this particular plaintiff is one of the radiation induced cases rather than one of the naturally occurring cases. Certainly, such a statistic is a valid basis upon which a reasonable expert could opine that this particular plaintiff's cancer was caused by his radiation exposure. It is in fact mathematically true that "more likely than not" this particular plaintiff is one of those who have a radiation induced cancer.

For a particular fact situation which falls between these two examples the calculated AGO will fall somewhere between 0% and 50%. This is the ground over which reasonable people might disagree. Should an AGO of only 10% be sufficient to serve as the foundation of an expert opinion that this particular plaintiff's cancer was caused by radiation? Or should such an expert's opinion be excluded for having an insufficient scientific basis? This dispute is likely to be fought over doses from 50 to 200 rem.

For the vast majority of radiation cases AGO would calculate zero Attributable Group Odds because the dose of the plaintiff is going to be below 50 rem. In such a situation there should be no valid scientific foundation upon which a reasonable expert can base an opinion of causation and thus summary judgment should be granted to the defendant. That is a main strength of AGO over PC. While PC will continue to calculate some number for small doses, AGO will not. PC, even though a small number, allows the plaintiff to have the argument: "The odds may only be one in a thousand, but my client <u>is that one</u> and should get his day in court before a jury." And plaintiff's expert can also say: "The odds may be only one in a thousand but that one case has to appear somewhere and my opinion is that it appeared here." AGO does not allow the plaintiff's counsel or the plaintiff's expert to make these arguments.

It is true that there will still be a fight over what dose the plaintiff really received and over what epidemiologic studies ought to be included, but AGO is a significant advancement over PC because it is more epidemiologically honest and is a better way to incorporate current scientific knowledge without bringing scientific speculation into litigation decisions.

(3)

THE "JUNK SCIENCE" PROBLEM IN RADIATION LITIGATION

I. What is "Junk Science?"

Junk Science is a "scientific opinion" which would not be able to withstand the normal scientific publication peer review process but yet is offered in court to "assist" laymen in the resolution of a difficult legal problem.

II. What is wrong with "Junk Science?"

A lay jury usually consists of blue-collar type people with a high school education. They generally cannot comprehend expert testimony. Nor can they accurately decide a scientific conflict. Thus, they simply see two competing experts as each representing an equally valid scientific point of view. If the Court does not somehow "screen" expert testimony, the jury will believe that the "nut" expert represents about 50% of the scientific community and that the "mainline" expert represents the other 50%.

III. What do the Federal Rules of Evidence require?

A. Rule 702

"If scientific, technical, or other specialized knowledge will ASSIST the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise."

1. Can "Junk Science" really ASSIST a lay jury in finding truth?

2. The "lie detector" machine.

3. The blood alcohol level test.

4. The arresting officer's skill in "knowing" beer or drugs.

5. In Bendectin litigation one doctor went around the country testifying that when he combined all of the negative epidemiological studies on Bendectin and birth defects, he found a positive effect which then justified him in concluding that Bendectin caused this particular child's birth defect. Some courts let him testify and some didn't. Some juries

awarded millions of dollars and some cases were dismissed without trial. Would allowing him to testify ASSIST the jury in finding the truth? The answer to that depends in part upon how much the Judge knows about epidemiology, doesn't it?

B. Rule 703

"The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to him at or before the hearing. If OF A TYPE REASONABLY RELIED UPON BY EXPERTS IN THE PARTICULAR FIELD in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence."

1. What needs to be OF A TYPE REASONABLY RELIED UPON BY EXPERTS IN THE PARTICULAR FIELD?

2. The language of the rule only requires that the FACTS or DATA be OF A TYPE REASONABLY RELIED UPON BY EXPERTS IN THE PARTICULAR FIELD.

3. The plain meaning of the language of the rule DOES NOT require that the expert's METHODOLOGY be OF A TYPE REASONABLY RELIED UPON BY EXPERTS IN THE PARTICULAR FIELD, only his FACTS OR DATA need be so.

4. Some courts have stuck to the plain meaning of the language used in Rule 10 and will analyze an expert's right to testify in court no further than some surface evidence of expertise and some surface validity to the facts or data he uses. For example, a medical doctor will usually be allowed to express an opinion that a certain occupational radiation exposure caused a plaintiff's cancer based upon nothing other than his general education and general reading.

5. Other courts have attempted to screen expert testimony so as to exclude testimony which will not really ASSIST the jury. They have done so by being more stringent as to what qualifications they will accept under Rule 702 and by extending the Rule 703 limiting clause to the experts methodology as well as to the facts or data upon which he relies. One line of cases, known as the Fry line, also requires that the methodology or reasoning must be GENERALLY ACCEPTED WITHIN THE RELEVANT SCIENTIFIC COMMUNITY.

6. The very latest radiation litigation case to deal with these issues has added the concept VERIFIABILITY to all we have discussed so far. It is that an expert's opinion or methodology must be verifiable in the appropriate peer reviewed scientific literature. The logic behind this rule is that scientific opinion which is not verifiable in the scientific literature because it cannot get past scientific peer review is not trustworthy enough for a jury to base a ruling upon.

IV. <u>O'Conner v. Commonwealth Edison Co.</u>
O'Conner I - 748 F.Supp. 672 (1990) - The Duty Owed Issue
O'Conner II - 770 F.Supp. 448 (1991) - Price Anderson Act
O'Conner III - ___ F.Supp. ___ (1992) - Junk Science

V. Highlights of O'Conner III

A. The basic facts of the case.

In Sept/Oct of 1983 James Richard O'Conner worked as a pipe fitter at Commonwealth Edison's Quad Cities BWR. He was 43 years old at the time and had only worked in nuclear plants a few times before. He wore all the proper protective clothing. His dosimetry consisted of one film badge and two SRPDs, one regular and one digital.

He felt warm on the night of October 3 and therefore felt that something had happened to overexpose him. One SRPD from that night read .045 rem and the other read .038 rem. His film badges totaled 1.465 rem for all of September and October combined. Approximately seven months later James O'Conner, at age 44, was diagnosed as having bilateral cataracts of the posterior subcapsular type. Radiation induced cataracts are always of that type but have never been seen to occur below an acute dose of 200 rem or a chronic dose of 600 rem.

B. The plaintiff's expert's proposed testimony.

Dr. Karl Scheribel is a respected board certified ophthalmologist who examined Mr. O'Conner in 1985 and took a verbal history from him that he had cataracts caused by a radiation exposure in October of 1983. Dr. Scheribel observed posterior subcapsular cataracts and concluded that indeed Mr. O'Conner has two radiation induced cataracts. Therefore, O'Conner simply must have gotten what ever dose is necessary to cause such an effect. Consequently, Dr. Scheribel's opinion became crucial to the plaintiff on the dose issue as well as on the causation issue. The precise language of Dr. Scheribel was:

"I know what cataracts look like when they have been induced by radiation, by what ever dosage or time of exposure there was. Radiation cataracts are [a] clinically describable and definable condition which, when present, cannot be mistaken for anything else."

C. The evidentiary problem. Can Dr. Scheribel testify?

1. If so, Summary Judgment cannot be granted and the case must be tired before a jury.

2. Is he an Expert under Rule 702 of the Federal Rules of Evidence?

3. Is his testimony admissible under Rule 703 of the Federal Rules of Evidence?

4. Is his testimony admissible under Fry?

5. Only if Dr. Scheribel is not allowed to testify can summary judgment be granted to the defendant because then the plaintiff would have no evidence upon which a reasonable jury could conclude that his cataracts were caused by his occupational radiation exposure.

D. The Court's Analysis.

1. The power of the trial judge.

"The Federal Rules of Evidence allow a court to intercede and to limit expert testimony where a witness attempts to give an opinion on a subject for which he is not qualified, when there is no factual basis for that proffered opinion, when that opinion is based upon an error of logic, and when the expert cannot supply the court with any verifiable scientific support for the opinion." (page 31)

2. Basic philosophy.

"In science, a proposition is not true just because one claiming to be an 'expert' is willing to make such a statement. In law, a statement is not admissible just because a self-proclaimed 'expert' is willing to say it on the witness stand. Scientific truths must be verifiable or they are not <u>scientific</u> truths at all. Rules of both science and evidence require a scientist or an expert to have a verifiable scientific basis for his opinion. Such controls are important in both fields to minimize error due to 'junk' science." (page 32)

3. Rule 702.

"...the unique, sophisticated and highly specialized field of radiation induced cataracts..." (page 33)

"...this field is highly specialized and is not a part of the routine practice of ordinary ophthalmologists. It requires a demonstrated expertise, if not by experience, at least by a study of all the published literature." (page 35)

"Dr. Scheribel has no such experience and did not even take the time to examine the published literature before giving his bald opinion. Accordingly, Dr. Scheribel is not qualified to render an expert opinion that radiation cataracts are pathognomonic or that plaintiff's cataracts could only be caused by radiation exposure." (page 35)

4. Rule 703.

"An expert's opinion must have a sufficient verifiable scientific basis; the scientific data underlying his opinion must be of the type that is reasonably relied upon by experts in the field...(page 36)...Whether an expert's opinion has a sufficiently verifiable scientific basis is an issue of law for the court to decide.(page 36)...[the Court then examines each of Dr. Scheribel's cited

references and consensus science literature on point]...The court finds that the 'opinion' Dr. Scheribel intends to give to the jury is not only without verifiable scientific support, it is actually directly contradicted by his own claimed sources and by consensus medical science. Such a scientifically erroneous 'opinion' cannot help the jury discover the truth here. It could only serve to mislead them. (pages 44-45)... Just as a medical opinion without a verifiable scientific basis is inadmissible, an expert opinion that actually contradicts directly the scientific consensus is inadmissible. (page 52)... Having exercised its duty mandated by Rule 703 to examine the basis of expert opinion testimony and the reasoning process used, the court finds that Dr. Scheribel's opinion had no verifiable scientific basis and no verifiable scientific reasoning process. The court further finds that Dr. Scheribel's opinion directly contradicts consensus science. (page 53)... The court therefore finds that Dr. Scheribel's opinion must be excluded under Rules 703 and 403." (page 54)

5. Fry .

"Under Fry, the methodology and reasoning used by an expert to reach his conclusion must be generally accepted within the relevant scientific community." (page 57)

"Here, Dr. Scheribel's opinion is based on an underlying erroneous opinion that radiation induced cataracts are pathognomonic. This 'binding universal rule' is not accepted by scientists who specialize in the field of radiation induced cataracts." (page 58)

"His opinion is further flawed because he did not consider the numerous variables that should have been considered in determining cause... especially the fact that O'Conner's father also developed posterior subcapsular cataracts at the age of 39." (pages 58-59)

Each expert in the field of radiation induced cataracts, including Dr. Apple, on whose work Dr. Scheribel claims to rely, has testified that Dr. Scheribel's reasoning and methodology are not accepted in the scientific community." (page 60)

6. Conclusion

"After seven years of extensive litigation...entry of summary judgment is mandated for the defendants." (page 67)

VI. What does O'Conner III mean to radiation litigation and to any cases involving expert witnesses under rules 702 and 703?

A. Courts have an obligation to scrutinize expert opinion testimony and not just rely upon cross examination at trial to reveal the truth.

"Relying upon cross-examination to expose the error is not sufficient, defendant's claim, because that mechanism relies upon an unsophisticated lay person to arbitrate complex scientific issues which they may not even comprehend." (page 24)

B. In scrutinizing expert opinion testimony the Judge has to ask the expert what sources he relies upon and what his reasoning process is. Then the Judge has to read these sources and think through the reasoning process to test the expert's methodology for accuracy, logic and verifiability. This is a heavy burden on Judges who are not scientifically trained.

C. The testimony of "fringe scientists" should be excluded long before trial and the case dismissed if the plaintiff's attorney cannot find reliable scientists to testify for the plaintiff. A large number of presently pending cases (perhaps 70%) would not be sustainable if fringe scientists were identified and excluded.

D. The concept of VERIFIABLE scientific opinion testimony is an addition to the wording of Rule 703 which TECHNICALLY requires only that the expert's FACTS OR DATA be of the type REASONABLY RELIED UPON BY EXPERTS IN THE PARTICULAR FIELD IN FORMING OPINIONS.

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CAUSATION IN TOXIC TORTS: WHY RULINGS IN MANY CASES ARE AND WILL BE UNFAIR

By Donald E. Jose*

Causation fairness in tort law is a concept designed to allow injured parties to recover while preventing defendants from paying for injuries that they did not cause. However, the newly developing field of toxic torts currently leaves the legal system no option but to be unfair on the causation issue. This is so because cancers caused by a toxic chemical or agent (like ionizing radiation) cannot be scientifically distinguished from the many background cases of naturally occurring cancer. This article explores the dilemma posed by the fundamental unfairness of causation rulings in toxic tort cases and suggests some solutions.

The American Cancer Society tells us that "about 73 million Americans now living will eventually have cancer; about 30 percent, according to present rates. Over the years, cancer will strike in approximately three out of four families." [1] Consequently, there is a huge background of *naturally* occurring cancers in any population exposed to a toxic chemical or agent. Many of these agents will produce cancers that are scientifically indistinguishable from the naturally occurring cancers. For example, "cancers induced by radiation are indistinguishable from those occurring naturally; hence, their existence can be inferred only on the basis of a statistical excess above the natural incidence." [2]

The traditional evidentiary test required for a disease caused by exposure to some agent is to have a medical doctor, who is an expert on the disease, testify "to a reasonable degree of medical certainty" that the disease was caused by exposure to the agent.

In situations where the toxic agent causes diseases that are indistinguishable from naturally occurring cases of the same disease, this traditional test cannot be met. In fact, evidence of any harm at all will only be observable in group statistics. For example, if radiation does cause some cancers in a group of exposed people the existence of their radiation-induced cancers "can be inferred only on the basis of a statistical excess above the natural incidence." [3]

Three hypothetical examples can illustrate the difficulty of determining causation in toxic tort cases.

A Nine Percent Chance

In the first hypothetical let us assume a group 1,000 people, among which one can expect 300 naturally occurring cancers.

Let us then assume that the group was exposed to a toxic agent that produced 30 excess unidentifiable cancers. From the total of 330 cases of cancer no one can tell whether a particular individual is one of the 300 naturally occurring cancers or one of the 30 cases caused by exposure to a toxic agent. However, an "odds analysis" can be performed. For any person with cancer the "odds" are 30 out of 330, which is one in 11, or nine percent, that the individual's particular cancer was caused by the toxic agent.

If such evidence is accepted by the courts as sufficient to prove causation to "a reasonable degree of medical certainty," then every single person in the group of 330 with cancer can recover because they each share the same statistical "odds."

Such a result would be grossly unfair to the defendant because it forces him to pay full damages to 300 persons who have a naturally occurring cancer that the defendant did not cause.

A Fifty Percent Chance

In the second hypothetical let us also assume a group of 1,000 people that contains 300 naturally occurring cancers. The group is exposed to a toxic agent that causes 300 additional indistinguishable cancers for a total of 600 cancers out of 1,000 people. This would be viewed as an epidemic. For any single person with cancer, the "odds" are 300 out of 600, or 50 percent, that exposure to the toxic agent caused that person's

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[1] *1986 Cancer Facts and Figures*, American Cancer Society, p. 1 (1986).

[2] *The Effects on Populations of Exposures to Low Levels of Ionizing Radiation*, Committee on the Biological Effects of Ionizing Radiation National Academy Press, p. 137 (1980). (This book is commonly known as BEIR III).

[3] BEIR III, *supra* at 137.

particular cancer. The odds for each of the 600 people are the same.

If such statistical evidence is accepted by the courts as enough to prove causation to "a reasonable degree of medical certainty," the defendant will be treated unfairly. Just as in the first hypothetical, the defendant will have to pay full damages to 300 people who have a cancer that he did not cause.

On the other hand, if these "odds" are not sufficient to prove causation, then the defendant will have been allowed to cause 300 cancers without paying one penny in compensation. That is unfair to the plaintiffs.

A Seventy-One Percent Chance

In the third hypothetical let us assume a final group of 1,000 people who express 300 naturally occurring cancers. The group is exposed to an extremely strong toxic agent that causes 700 excess cancers. In other words, every single member of the group dies from cancer. For any single one of the 1,000 people who have cancer the "odds" are now 700 in 1,000 or one in 1.4 or 70 percent that the person's particular cancer was a case that was caused by the exposure rather than one that was a naturally occurring case of cancer.

If the courts accept such odds as 70 percent as being sufficient to prove causation to "a reasonable degree of medical certainty," this will be unfair to the defendant, who still has to pay fully for 300 cases of naturally occurring cancer.

On the other hand, if the courts do not accept the 70 percent "odds" as sufficient proof, then tort law is saying that a person can literally cause 100 percent of the cancer deaths in a group of people and yet escape paying any damages simply because among the 1,000 deaths there also were many cases of naturally occurring cancer that cannot be specifically identified. That is not fair and society would not accept it as being just.

Note that the "odds" cannot ever be 100 percent even though everyone dies from cancer since there are so many cases of naturally occurring cancer.

Science Cannot Produce Evidence Required By Law

The core problem is that science is unable to separate naturally occurring cancers from those caused by exposure to the toxic agent. Thus, science is unable to produce the evidence that law needs to resolve equitably such toxic tort cases. The approach that is currently available is a gross statistical analysis of group numbers.

Without more precise person-specific scientific information there is nothing the law can do that will not result in unfairness to either the plaintiff or the defendant. It must be recognized that until the ability to produce adequate scientific evidence improves, these particular types of toxic tort cases will result in unfairness to someone. But which party should bear this unfairness? That is a matter of social policy, not legal analysis.

A Rough Form of Group Justice

One possible social policy solution is to recognize that the tort system is incapable of doing individual justice under the present state of scientific knowledge. One goal of individual justice is abandoned, society can substitute the goal of group justice. This would do rough justice to the group as a whole.

In the first hypothetical the "odds" were only nine percent that anyone assumed to have had cancer developed that disease from exposure to the toxic agent. Since it is impossible to identify those few valid cases and fully compensate those individuals, perhaps the legal system should force the defendant to pay for nine percent of the damages of all the individuals in the group who developed a cancer.

In the second hypothetical the defendant would pay half of the damages suffered by all those who developed cancer. In the third example the defendant would pay 70 percent of the damages of all members of the group.

Traditional Analysis Cannot Identify Those Harmed

In other words, the law recognizes that the defendant is actually harming people but traditional tort law analysis of the proximate causation issue simply is not capable of identifying those "harmed" individuals. Consequently, when valid epidemiological evidence is offered proving that excess cancers do in fact exist, the law should assume proximate causation for social policy reasons, and use the "odds" analysis to limit the damages awarded so that the defendant does not have to pay for more harm than he really caused.

This is not individual justice but it is a rough form of group justice that may be better than the result obtained under strict adherence to traditional principles of tort law. However, there are many problems raised by this proposed solution.

How could such a drastic change in tort law be effected? Can courts adopt the analysis themselves or is legislation required? What undesirable side effects would be created?

While the group justice concept seems quite simple, its implementation would be very complex. For example, the exact "odds" necessary to fairly distribute damages will not be known until every member of the original group dies. At that point it is too late to personally compensate any of the persons who suffered from the excess cancers. In other words, precise group justice can only be accomplished after the injured persons are no longer alive to benefit from the award. So why go to all of this effort to change the law when the beneficiaries would not be around to enjoy the benefits anyway?

Reducing the Accuracy

Any attempt to set the percentage of damages to be awarded while the victims are still alive would reduce the accuracy of that number. The natural cancer rate actually would change from state to state and from group to group. The natural rate is not known with precision and anyway is subject to normal biological and statistical variation.

It is commonly assumed that the natural rate could easily vary by 10 percent just due to statistical factors alone. Thus, in every group of 1,000 persons there will not be exactly 300 cases of naturally occurring cancers.

With only a 10 percent variation on a 30 percent rate the effective rate would be anywhere from 27 percent to 33 percent.

Consequently, the 330 total cancers in the first hypothetical was 33 percent of the group assumed and therefore *all* assumed cancers could be attributed to natural rather than man-made causes.

If a defendant were forced to pay nine percent of the damages of each of the 330 persons, he might have to pay damages although he did not cause even one case of cancer.

A Statistical Change Without An Actual Change

Another problem with the group justice concept is that the calculated percentage may be a statistical illusion due to too small a group of plaintiffs. If a particular rare disease occurs at random in 10 out of every 1,000 individuals, the natural rate of that disease is one percent. Those 10 normal cases will not be distributed equally among the 1,000 individuals.

For example, if 20 of the 1,000 individuals lived in each of the 50 states, what is the chance that the 10 cases would each appear in a different state? What is the chance that two or more of the rare cancers would appear in the same state?

If two cases happened to appear in the same state, then the rate for that state would be two out of 20 or 10 percent. If only one case of the rare cancer appears in a particular state (and they must appear in some state), then the rate for that state is one out of 20 or five percent. Note that the rate changed from one percent to 10 percent to five percent *without any actual change in the number of actual cases of the cancer*. Only the size of the group we happened to select for examination was changed.

Obviously, the smaller the number of plaintiffs in a group the less valid any statistical analysis will be. Once again, the "odds ratio" device used to do rough group justice is actually yielding an inaccurate and unfair result. These are only six examples; further analysis will yield many more.

Tort Law Will Struggle With Fairness

Unfortunately, in the newly developing field of toxic torts the law is forced to consider questions that look far beyond the ability of science to provide answers. Until science can definitely identify which agent caused each cancer, the law will be unable to provide perfect fairness or perfect justice to all of the litigants before it.

True, the traditional analysis is unfair to some of the litigants. However, any attempt to change the legal system's causation standards for social policy reasons ultimately also will be unfair to some of the litigants.

While we all need to continue to explore how tort law can best contribute to solving the problem of toxic agents in the environment, we also need to be careful that any attempted improvements do not substitute one form of unfairness for another. The struggle to introduce fairness into the legal system's determination of causation in toxic tort cases can be expected to continue for decades.

BNA ANALYSIS

ENVIRONMENTAL EXPOSURE

Radiation

BILL TO INCREASE LIABILITY FOR ACCIDENTS REPORTED BY SENATE ENVIRONMENT SUBCOMMITEE

Liability of nuclear power plant operators and federal government contractors involved in disposal of high-level radioactive waste for claims arising from accidents would increase from $665 million to about $2.3 billion, under amendments to the Price-Anderson Act reported by a Senate environment subcommittee June 25.

The bill, S. 1225, reported by the Senate Environment and Public Works Nuclear Regulations Subcommittee, also would expand the government's indemnification of high-level radioactive waste disposal operations to cover the liability — up from the $500 million ceiling under current law.

The measure stipulates that all indemnified claims arising from disposal of non-defense related radioactive waste would be paid from the nuclear waste fund — a contingency fund supported by a per-kilowatt fee on nuclear power plants — but includes no provision for increased funding of the account.

Claims arising from defense-related, high-level radioactive waste would be paid for by general revenues, under the measure.

In addition, the bill would extend by 25 years the authority of the Department of Energy to enter into agreements of indemnification with contractors engaged in high-level radioactive waste disposal, taking the cutoff date from Aug. 1, 1987, under current law to Aug. 1, 2012.

Reactor Liability

Additional liability for nuclear power plant licensees would be paid for through an increase in the standard deferred premium that may be charged retroactively to all licensees following a nuclear incident, under the bill.

The increase, from the current level of $5 million to not less than $15 million and not more than $20 million, would raise up to an additional $75 million per nuclear plant into the pooled liability fund established under the Act. Based on an assumption of 115 reactors, the total amount available to the fund would be $2.3 billion.

Under the bill, the Nuclear Regulatory Commission would be required to promulgate formal rulemaking within one year of enactment that would establish a level in the $15 million to $20 million range at which to set the maximum standard deferred premium for each licensed reactor.

A separate provision of the bill would increase the aggregate liability for a single nuclear incident for