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Vern R. Walker

Maurice A. Deane School of Law at Hofstra University

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Recommended Citation

Vern R. Walker, *Risk Characterization and The Weight of Evidence: Adapting Gatekeeping Concepts From The Courts*, 16 *Risk Analysis* 793 (1996)

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Risk Characterization and the Weight of Evidence: Adapting Gatekeeping Concepts from the Courts

Vern R. Walker^{1,2}

Received January 18, 1996; revised August 14, 1996

Risk characterization objectives include evaluating the weight of evidence underlying risk determinations, communicating that evaluation to nonexperts, guiding risk assessors to achieve consistency, and preserving deference for those reasonable expert judgments inherent in any risk determination. Similar objectives are shared by American courts that face the gatekeeping task of screening scientific evidence before it is presented to nonexpert factfinders, such as juries. This article surveys the judicial gatekeeping concepts of relevance, evidentiary reliability, legal sufficiency, presumptions, and standards of proof (particularly, preponderance of the evidence). It examines recent court decisions that have applied these concepts to the kinds of scientific information common in risk assessments, and suggests how to adapt these gatekeeping concepts for use in weight-of-evidence characterization. If we can develop and adopt a neutral framework for characterizing the weight of evidence underlying risk assessments, it might help clarify not only the current debate over risk characterization and risk management, but also the drafting of treaty provisions, such as those invoking the Precautionary Principle of international environmental law.

KEY WORDS: Risk characterization; weight of evidence; risk communication; law; evidence.

1. WEIGHT OF EVIDENCE IN REGULATORY AND JUDICIAL CONTEXTS

Risk characterization is being carefully re-examined today.⁽¹⁻⁶⁾ This article examines several concepts developed by American courts to supervise factfinding in civil litigation, and proposes that those concepts may be useful to regulators in evaluating the "weight of evidence," which is a critical component in risk characterization.

1.1. Regulatory Objectives Behind Weight-of-Evidence Frameworks

There are several regulatory objectives in adopting weight-of-evidence frameworks. One of those objectives is to develop a clear and transparent framework for evaluating the evidentiary support for risk determina-

tions.^(3,4,7) This allows scrutiny by others of the reasonableness of those evaluations.

A second objective is to summarize that evaluation in terms that nonexperts can understand.⁽³⁻⁶⁾ Weight-of-evidence determinations are intended to inform not only expert risk assessors, but also regulatory decisionmakers within the agency, courts reviewing administrative decisions, the legislative branch of government, the various stakeholders within the general public, and interested other nations (especially those who are signatories to environmental treaties).

A third objective is to provide guidance to agency experts in making weight-of-evidence determinations.^(3,4) A single system of evaluation would help produce uniformity, or at least consistency, in risk determinations throughout the various programs of an agency, and perhaps between agencies.

Finally, an adequate weight-of-evidence framework would help identify the nature and extent of the deference that is due to the expert discretionary judgment behind the risk determination. Deference is due when

¹ Hofstra University School of Law, 121 Hofstra University, Hempstead, New York 11550-1090.

² To whom all correspondence should be addressed.

residual uncertainties necessitate that judgment be exercised in framing problems within context, adopting assumptions to fill data gaps, and arriving at reasonable inferences and policies in the face of competing alternatives.⁽³⁻⁶⁾

There are persistent difficulties in achieving each of these regulatory objectives. For example, effective communication of information between expert and nonexpert, and sometimes between experts in different fields, requires a language accessible to all participants, yet adapted to the tasks at hand. Also, it is extremely difficult to summarize technical information without information censorship or loss, and without undue complexity and confusion.⁽⁶⁾ Evidence of the ongoing problems is the controversy about whether to structure risk characterization more toward conveying the kinds of analytic risk information that experts are now able to deliver,^(3,4) or more toward the diverse uses of risk managers and potentially affected parties.^(5,6)

1.2. Judicial Gatekeeping Concepts

American courts, in their role as gatekeepers for the flow of evidence from litigating parties to factfinders, have developed several evaluative concepts that meet all four of these regulatory objectives and that might provide a set of concepts useful in the weight-of-evidence portion of risk characterizations. It is easiest to imagine the factfinding task in civil litigation as the function that is performed by a jury of nonexperts, although in many cases the nonexpert judge performs the factfinding function. The factfinder's task is to weigh all the evidence presented and to make "findings" about what will be deemed to be true for purposes of the lawsuit. The role of the judge-as-gatekeeper is to evaluate the evidence that the parties would like the factfinder to consider in making those findings. This gatekeeping function is shared by the appellate court in reviewing procedural and evidentiary objections, regardless of whether the factfinder is a jury or a trial court judge.

There is an informative parallel between, on the one hand, the role of court-as-gatekeeper vis-à-vis the nonexpert factfinder and, on the other hand, the role of expert agency vis-à-vis the nonexpert consumer of risk information. First, judges have developed these gatekeeping concepts to protect the integrity of the judicial factfinding process from manipulation by interested parties and by biased factfinders. This effort at rational neutrality includes evaluating the minimal reasonableness of proffered scientific testimony (for example, an expert opinion by a scientific witness), in order to decide

whether a reasonable factfinder would take the evidence into account or (in some cases) how it would be taken into account.

Second, judges have developed these gatekeeping concepts with an eye to explaining their gatekeeping decisions to interested parties, to other courts (especially appellate courts), and to the general public, all of whom have a vital interest in assuring that the judiciary is respecting the parties' right to jury trial.

Third, courts have developed these concepts as guidance for attorneys and judges, and in order that appellate courts can use them to oversee the decisions of trial courts. The concepts thus promote consistency between cases and equal treatment of evidence under the law.

Finally, judges want to defer to the expertise of scientists, as well as give deference to the jury as factfinder. Therefore, the gatekeeping concepts are designed to leave room for judgment within appropriate spheres: to allow wide latitude for expert witnesses to present their opinions and to permit the jury to make findings based on that evidence that the jury considers the most credible, while simultaneously retaining judicial control to ensure that witnesses and juries use their discretion within reasonable bounds. In parallel fashion, complex spheres of judgment coexist within risk assessment and risk management: the technical judgments of experts intertwine with the broader judgments of regulators and stakeholders. Consumers of risk information usually understand that they need to defer to the expertise of the agency in the technical aspects of risk determination, but they insist upon assuring themselves that the agency is acting reasonably in making those determinations.

Thus, there are significant parallels between the objectives behind risk characterization and the objectives of gatekeeping determinations in the courts. This article surveys several gatekeeping concepts developed by American courts over the course of this century, in order to suggest how similar concepts might be used by agencies to characterize the weight of evidence for nonexpert consumers of the risk information.

2. THE GATEKEEPING CONCEPTS OF AMERICAN COURTS

This section analyzes the principal gatekeeping concepts developed by the courts, with examples of how those concepts have been applied to scientific evidence.⁽⁸⁾

2.1. Relevance and Probative Value

The courts first divide the world of information qualitatively, by deciding whether or not information is “relevant” to the proposed finding. The Federal Rules of Evidence define “relevant evidence” as “evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.”⁽⁹⁾ Only relevant information should be admitted into evidence,⁽¹⁰⁾ and evidence that is relevant is considered to have some degree of “probative value.”

There is considerable debate, however, about what is meant by “probability” in this definition, and on how to measure degrees of “probative value.” Some theorists argue for an “objectivist” meaning of probability that expresses relative frequency of occurrence of some observable event, while others insist on a “subjectivist” degree-of-confidence interpretation, and still others argue for an “epistemic” interpretation that measures degree of evidentiary support. There are also two schools of thought on how to measure “probative value.” Some theorists contend that probative value can be measured on a fully quantitative scale between 0 and 1 (the classical Pascalian probability scale), while others prefer an ordinal scale (such as “low/moderate/high” probability). The use of a cardinal scale has the advantage of forging a conceptual tie with the standard probability calculus, and produces the following formulation: an item of evidence E_k is relevant to proving factual proposition F if but only if probability $(F|E_1, \dots, E_j, E_k) \neq$ probability $(F|E_1, \dots, E_j)$, where E_1, \dots, E_j are the remaining items of relevant information introduced into evidence.

These same foundational debates are important in risk characterization, although this article cannot explore those issues and the framework proposed here does not resolve them. The objective here is simply to introduce the concepts of relevance and probative value and to indicate their place in the arsenal of judicial gatekeeping concepts. The distinction between determining relevance and assessing degrees of probative value helps to separate the role of the judge from that of the factfinder. Ideally, the judge determines only whether proffered evidence is relevant at all, and the jury decides what degree of probative value (if any) to assign to the relevant evidence. In theory, the judge is kept from intruding unduly into the factfinding role of the jury, although the judge restricts the evidence that the factfinder can consider by ruling some information to be irrelevant and excluding it from the admitted evidence.

2.2. Evidentiary Reliability

There emerges from the numerous rules of evidence a further concept of “evidentiary reliability.” For example, a fact witness is not permitted to testify about an occurrence unless she has “personal knowledge” of the event—for example, unless she actually observed it.^(11,12) Another familiar example is the general rule against the admissibility of “hearsay”—a statement made outside the trial or hearing, but offered as evidence to prove the truth of the matter asserted.⁽¹³⁾ Although admissibility decisions may be guided by additional policies other than reliability,⁽¹⁴⁾ an important and central objective is to screen evidence for evidentiary reliability.

The United States Supreme Court has recently directed the federal courts to develop the concept of evidentiary reliability in the context of scientific opinions.⁽¹⁵⁾ The Federal Rules of Evidence direct the federal courts to do so in two steps. First, if the factual basis underlying the proffered opinion is not itself admissible into evidence, the courts must determine whether the facts or data involved are “of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject.”⁽¹⁶⁾ There is some dispute about whether a court should independently assess whether such reliance is “reasonable.”⁽¹⁷⁾ As a sample of issues of direct interest to risk assessment, some courts have ruled to be unreasonable the reliance on high-dose animal studies alone to decide that a chemical has caused cancer to particular people at low doses,⁽¹⁸⁾ the reliance on a plaintiff’s self-report of symptoms given in the context of litigation as the sole basis for a medical diagnosis,⁽¹⁸⁾ the ignoring of relevant and probative evidence cutting against the expert’s opinion,⁽¹⁸⁾ and the reliance on data that cannot be replicated or even explained.⁽¹⁹⁾

As the second step, courts scrutinize the theoretical basis for the proffered opinion.⁽²⁰⁾ In some situations, they are charged with determining whether the inferences and ultimate conclusions were derived by the “scientific method,” with the result that they have sufficient “scientific validity” to be trustworthy.⁽¹⁵⁾

Some courts apply this scrutiny of facts and methodology only generically, leaving to the trier of fact to determine the evidentiary reliability of the specific evidence in the case. For example, in ruling on the admissibility of DNA identification evidence, some courts evaluate only the broad principles underlying the techniques, and leave it to juries to evaluate whether a particular forensic lab sufficiently followed accepted procedures and produced reliable conclusions in the particular case.⁽²¹⁾

Other controversies within the courts might be highly instructive for risk characterization—such as the debate whether it is necessary or permissible to present quantitative statistics to juries to help them determine the weight to give DNA identification evidence, or whether qualitative characterizations of the likelihood of a random match are permissible or sufficient.^(22–24) The courts have devoted considerable attention to the issue of how to characterize probabilistic information for a nonexpert factfinder, even if that discussion occurs within additional policy considerations in criminal or civil proceedings.

2.3. Legal Sufficiency

Evidence might be relevant (have probative value) and have evidentiary reliability, but “no reasonable person” would draw the needed finding from it. This notion is captured in the concept of “legal sufficiency,” which refers to a *threshold* weight of *total* evidence needed before a factfinder could rationally infer the proposed conclusion.⁽²⁵⁾ This concept is used by judges to scrutinize the admissible evidence considered as a whole, and to hold juries to minimal standards of rationality in drawing inferences from that evidence.⁽²⁵⁾ Juries are not allowed to guess or “speculate” about the facts when the evidence is ruled to be legally insufficient to warrant the conclusion.

A paradigm example of legally sufficient evidence is conflicting testimony from two fact witnesses about what each actually observed at the same event.⁽²⁵⁾ The factfinder must determine what is most likely to have really happened, after assessing the credibility of each witness—taking into account different potentials for error in observation, memory, and communication, as well as degrees of good faith in providing the testimony. Such conflicting testimony is legally sufficient to warrant a finding on the most likely course of events. On the other hand, testimony at variance with the physical laws of nature (not merely with other eyewitness testimony) might be ruled by the courts as legally insufficient to warrant a finding.

The courts have begun to develop sufficiency-of-evidence rules tailored specifically to scientific evidence concerning risk. In the product liability cases involving Bendectin, at least one court has held that epidemiologic evidence failing to show statistically significant results is insufficient to sustain a finding of “generic causation.”⁽²⁶⁾ “Generic causation” is the question of whether ingestion of Bendectin can cause any developmental in-

jury in humans at all—the issue that risk assessors call “hazard identification.”

In cases involving “specific causation,” in which what must be proved is that a *particular* exposure probably caused a *specific* person’s injury, courts have held that if the sole evidence of causation is epidemiologic, then the evidence is legally insufficient unless it shows a relative risk of at least 2.0.^(27–29) In such a case, the proof must be by a “preponderance of the evidence”: the plaintiff must prove that the injury was caused “more likely than not” by the exposure rather than by background causes alone. Thus, the judicial reasoning goes, a rational person would not conclude this unless the expected baseline incidence is less than the expected incremental incidence due to the exposure, which would be true only if the relative risk of those exposed is at least 2.0.

2.4. Presumptions

Beyond the minimal requirements of relevance, evidentiary reliability, and legal sufficiency, courts and legislatures also create “presumptions,” which are rules of inference that either permit or direct the trier of fact to draw certain conclusions under certain conditions. A presumption sets up a rule of inference requiring that *if* specified antecedent findings are made, *then* a further finding *must* be made in the absence of counterevidence. For example, from the mailing of a properly addressed letter containing proper postage, there often arises in law a presumption that the letter was received, provided there is no evidence of nonreceipt.⁽³⁰⁾ In the face of such a presumption, only under specified conditions is the factfinder justified in failing to make the inference. Presumptions therefore determine degrees of probative value beyond the minimum of legal sufficiency.

Courts recognize two types of legal presumption. The first type merely institutionalizes an inference rule based on logic, probability, and common experience. For example, the presumption about receipt of a properly mailed letter is based on the probability of delivery. The presumption forces a party who claims *not* to have received the letter to come forward with affirmative evidence of *nonreceipt*. If, however, such counterevidence is in fact produced, the presumption “vanishes” and the factfinder is free to weigh all the evidence and find whether the letter was in fact received. This first kind of presumption directs a finding in the absence of any *legally sufficient* counterevidence.^(31,17) If propositions A and B are found to be true, then proposition C must also

be found to be true in the absence of legally sufficient evidence of not-C.⁽²⁵⁾

The second type of presumption implements substantive policy, and goes beyond merely codifying probabilities.⁽³²⁾ Examples are the presumption that a person is dead if not heard from for a certain number of years,⁽³³⁾ or that a person intends the ordinary consequences of her voluntary acts.⁽³⁴⁾ In the United States Supreme Court's 1980 review of OSHA's final benzene rule,⁽³⁵⁾ the Court interpreted OSHA's policy assumption that a human carcinogen has no safe exposure level as a substantive presumption that impermissibly placed on industry the burden of proving the existence of a safe threshold level. The Court held that Congress intended, on the contrary, to place on OSHA the burden of proving that exposure at pre-regulation levels "presents a significant risk of material health impairment" in order to justify regulation. Another court has held that in the federal pesticide statute Congress intended that the burden of proving product safety should always rest on the registrant of the pesticide.⁽³⁶⁾ This second kind of presumption directs that if proposition A is found to be true, then there must be a finding of B unless the opponent *proves* not-B to be *true*. Such presumptions place a burden of *proving* the negation of proposition B on the opponent.

2.5. Standards of Proof

Standards of proof define the degree of probative value needed to warrant a finding. Standards of proof provide decision rules for finding facts in the face of uncertainty.⁽²⁵⁾ The three common standards in American courts are: proof by a preponderance of the evidence, proof by clear and convincing evidence, and proof beyond a reasonable doubt. Each standard tells the factfinder what level of residual uncertainty is tolerable in the factfinding process.

The default standard of proof in civil litigation is the "preponderance of the evidence" standard.⁽²⁵⁾ This is also the legal standard under which administrative agencies normally operate.⁽³⁵⁾ Under this standard, the trier of fact should find a proposition to be true if, but only if, it is supported by the "greater weight" or "greater convincing force" of the evidence.⁽²⁵⁾ That is, the factfinder should find a proposition to be true for legal purposes whenever the evidence makes that proposition even slightly more probable than its negation. For the jury to find proposition A to be true, the jury need not be certain that A is true, or even confident that A is true. Rather, A need only be more probable than not-A.

When a higher level of confidence is needed before a legal finding should be made, the courts often instruct the factfinder to use a higher standard of proof. For example, in proceedings involving deprivations of individual rights, such as commitment to a mental institution, courts may require clear and convincing evidence.⁽¹²⁾ "Clear and convincing proof" has been described as proof "sufficiently strong to command the unhesitating assent of every reasonable mind."⁽³⁷⁾

In criminal cases, of course, the jury is told to acquit the defendant if the jury has a reasonable doubt about any fact necessary to establish guilt.⁽¹²⁾ In such cases, the results of finding an innocent defendant to be guilty are so unacceptable that the higher standard of proof is used to lower the expected error rate for positive findings.

3. ADAPTING PARALLEL CONCEPTS FOR RISK CHARACTERIZATION

Five judicial gatekeeping concepts have been discussed: relevance and probative value, evidentiary reliability, legal sufficiency, presumptions, and standards of proof. Each concept has a considerable body of theory and case-application behind it. These concepts have been developed to identify levels at which judges can reasonably scrutinize the value of technical information. Similar concepts might prove useful in risk characterization. They can be used to evaluate the weight of the underlying evidence, in terms the nonexpert would understand, without encroaching upon the expertise and judgment of the risk assessment expert. They also offer focal points at which the risk manager, the courts, and the public should be able to agree that it is reasonable to expect adequate explanation. The conceptual framework I suggest is depicted in Fig. 1.

First, some information should not be taken into account at all because it is not relevant. That is, the truth or falsehood of irrelevant information would not affect the probability of the risk determination, and a risk characterization should help the information consumer not to be misled by irrelevant evidence. In addition, a risk characterization should identify the kinds of information that are relevant. Some information is highly relevant (such as likelihood or level of exposure), but its influence on the final determination might be overlooked or unduly discounted by a nonexpert.

Second, some information might be *prima facie* relevant, but the uncertainty about its accuracy is so great that it lacks *evidentiary reliability*. A study might lack evidentiary reliability because its data lack sufficient

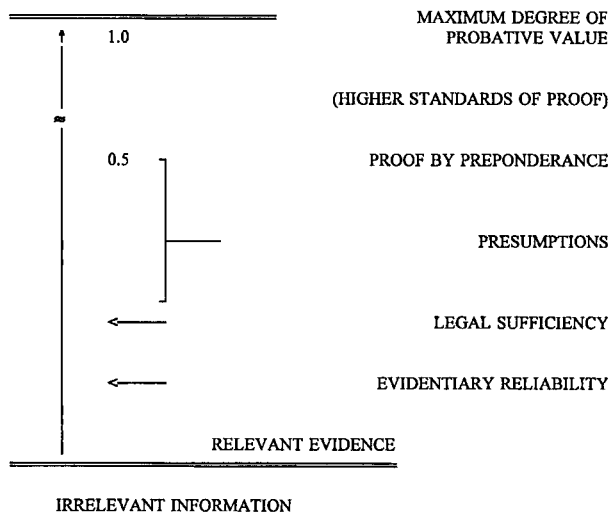


Fig. 1. Adapting evaluative concepts for weight-of-evidence characterization.

guarantees of validity or measurement reliability. For example, the study's sampling uncertainty might be too great or its statistical power too low, or there may be other serious methodological deficiencies. Studies should be evaluated individually to determine whether they meet minimal methodological criteria for evidentiary reliability.

Third, although individual items of information might be relevant and reasonably reliable, the body of evidence, considered as a whole and relative to a given conclusion, might have such low probative value that *no reasonable person* would consider it *sufficient support* for drawing the needed conclusion. This might be the situation with case reports or with epidemiologic studies that show an association that is not quite statistically significant: they might suggest causal hypotheses for further study, but not warrant a causal inference. A broader debate today is about going beyond merely getting the "science right" within the risk assessment, to getting the "right science" within that assessment—not only the natural sciences, but also the behavioral, social, and economic sciences.⁽³⁻⁶⁾ In part, the debate is about what scientific information a reasonable nonexpert would require as the basis for risk characterization.

Fourth, the use of presumptions as default rules of inference is perfectly acceptable, but individual presumptions need to be justified on understandable grounds. Some presumptions might be justified entirely by probability of joint occurrence, based on experience. Such presumptions create an incentive for private parties who have access to important information to produce it before the agency. Other presumptions are based on sub-

stantive policies, such as a policy of fairness concerning which interest should bear the burden of residual uncertainty. There might well be a question whether this second kind of presumption can be legally created by an administrative agency, if the presumption has not been built into the substantive law by the legislature. The risk characterization should identify the major presumptions on which the risk estimate is based, as well as the rationales for those presumptions.

Fifth, the concept of a standard of proof addresses the question of how probative or conclusive the evidence must be in order to warrant a risk determination. A (mere) preponderance of the evidence is probably the appropriate standard for risk assessment generally, although occasions might arise when a less stringent or a more stringent standard might be appropriate. Part of fully understanding a risk estimate is knowing under what standard of proof the major findings were reached.

4. CONCLUSIONS

This array of concepts, or one similar to it, might provide a useful conceptual framework for evaluating the weight of evidence for a risk estimate, and for characterizing that risk for the nonexpert decisionmaker. These concepts offer the possibility of summarizing the weight of the underlying evidence in terms that the nonexpert can understand, of simplifying increasingly technical risk characterizations, and of identifying the levels on which it is reasonable to expect adequate explanation. These concepts also enable the consumers of risk information (both regulators and the general public) to insist upon such reasonable explanation without encroaching upon the expertise and judgment of the risk assessment scientist.

If such a conceptual framework for weight-of-evidence characterization were to be adopted by risk assessors, it might be useful in several contexts in addition to the context of reporting to regulatory decisionmakers and the general public. First, such a framework might help clarify the complex interactive relationship between risk assessment and risk management, and help create a linguistic channel for conveying information between the two activities. Second, the framework might help regulatory agencies to explain their actions to courts and legislatures, because the framework derives from gatekeeping concepts that judges and lawyers are accustomed to using. Finally, such a neutral framework might help in treaty drafting and implementation—for example, in stating the conditions of scientific uncertainty under which the Precautionary Principle of international

law requires action that is protective of the environment.⁽³⁸⁾

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