Assessing the Fitness of Novel Scientific Evidence in the Post-*Daubert* Era: Pesticide Exposure Cases as a Paradigm for Determining Admissibility

by

Erin K.L. Mahaney

Originally published in ENVIRONMENTAL LAW
26 ENVTL. L. 1161 (1996)

ASSESSING THE FITNESS OF NOVEL SCIENTIFIC EVIDENCE IN THE POST-*DAUBERT* ERA: PESTICIDE EXPOSURE CASES AS A PARADIGM FOR DETERMINING ADMISSIBILITY

BY
Erin K.L. Mahaney*

The admissibility of novel scientific evidence proffered in toxic tort litigation presents considerable problems for courts today. In the wake of the U.S. Supreme Court's opinion in Daubert v. Merrell Dow Pharmaceuticals, Inc., *federal courts must conduct a two-step analysis under Federal Rule of Evidence 702 to determine the admissibility of scientific expert testimony. Whereas the first prong of the this test—scientific validity—has been oft-discussed, the second prong—a determination of "fit" that demands a highly specialized relevancy inquiry—has received far less scrutiny. The issue of fit warrants closer examination because it provides an important tool for the judge as gatekeeper. This Article first examines admissibility of expert testimony under Rule 702, focusing on how the* Daubert *Court characterized the fitness requirement. It next reviews the post-*Daubert *application of Rule 702's fitness test, discussing what circumstances might trigger application of the test. The Article concludes by theorizing on how a court would apply* Daubert's *principles in the context of pesticide exposure cases.*

I. INTRODUCTION

Problems inhere with the introduction of scientific evidence to prove general and specific causation. In particular, novel scientific evidence proffered in toxic tort litigation presents considerable problems for courts today. Novel scientific evidence refers to evidence or theories that have not received approbation from the judicial or scientific communities.[1] Un-

* M.S.L., Environmental Law, 1995, Vermont Law School; J.D. 1995, Vermont Law School; B.A., Environmental Science, 1987, University of California at Berkeley. I would like to thank Professor Kenneth Kreiling of Vermont Law School for his encouragement and support in the preparation of this Article.

[1] 3 J. WEINSTEIN & M. BERGER, WEINSTEIN'S EVIDENCE ¶ 702[03], at 702-43 (1995); *see* United States v. Downing, 753 F.2d 1224, 1231-39 (3d Cir. 1985) (discussing novel scientific evidence in the context of impeaching the reliability of eyewitness identifications). In some toxic tort cases, "genuine doubt exists within the scientific community whether a substance is capable of causing a particular harm or whether a substance at the doses delivered to the plaintiffs" was likely to cause the alleged injuries. G. Marc Whitehead & Larry D. Espel, *Admissibility of Expert Testimony: Past, Present and Future*, *in* TOXIC TORT CASE ESSENTIALS: STRATEGIES, EXPERTS, MOTIONS, AND ADR 513, 516 (PLI Litig. & Admin. Practice Course Handbook Series Order No. H-446, 1992).

proven scientific theories raise countervailing concerns that a liberal admission standard will impede the judicial process or that a restrictive standard will prevent courts from becoming fully informed about the latest scientific developments.[2] The U.S. Supreme Court addressed the admissibility of novel scientific evidence under Federal Rule of Evidence 702 in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*[3] It elucidated a two-part test that requires a preliminary assessment of 1) the validity of the scientific knowledge in question, and 2) the "fit" between the proffered scientific evidence and the circumstances of the plaintiff's case.[4] The second prong of this test—the fitness requirement—demands a more specialized inquiry into the relevancy of proffered scientific evidence.

While Rule 702's first requirement of scientific validity has been oft-discussed in case law and literature,[5] its fitness requirement has received far less attention. Nonetheless, the issue of fit warrants closer examination because it provides an important tool for the judge as gatekeeper. Not only must a theory be grounded upon reliable scientific knowledge, it also must be relevant to the facts of the case. Accordingly, when used in conjunction with Rule 702's first prong of scientific validity, the fitness requirement affords a valuable means of excluding "pseudoscientific assertions" without sanctioning a "stifling and repressive scientific orthodoxy [that] will be inimical to the search for truth."[6]

Pesticide exposure cases offer a paradigm for exploring the issues raised by the application of Federal Rule of Evidence 702's fitness requirement to novel scientific theories in the toxic tort context. These exposure cases typify many of the problems associated with evaluating the admissibility of novel scientific theories and are representative of the difficulty of proving causation in toxic tort cases generally.[7] Primarily, exposure cases

---

[2] Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 596-97 (1993). *See also* Bert Black et al., *Science and the Law in the Wake of* Daubert: *A New Search for Scientific Knowledge*, 72 TEX. L. REV. 715, 749-50 (1994) (discussing competing policy concerns regarding scientific evidence).

[3] 509 U.S. at 588-92.

[4] *Id.* at 592-93.

[5] *See, e.g., In re* Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741-45 (3d Cir. 1994), *cert. denied*, 115 S. Ct. 1253 (1995); Dunbar *ex rel.* Sorensen v. Shaklee Corp., 31 F.3d 638, 648 (8th Cir. 1994); United States v. Bonds, 12 F.3d 540, 558-65 (6th Cir. 1993); [1992 Interim Edition] MICHAEL H. GRAHAM, FEDERAL PRACTICE AND PROCEDURE: EVIDENCE § 6645 (Supp. 1996); Margaret A. Berger, *Procedural Paradigms for Applying the* Daubert *Test*, 78 MINN. L. REV. 1345, 1350 (1994); Bert Black et al., *Science and the Law in the Wake of* Daubert: *A New Search for Scientific Knowledge*, 72 TEX. L. REV. 715, 746-51 (1994); Joseph Sanders, *Scientific Validity, Admissibility, and Mass Torts After* Daubert, 78 MINN. L. REV. 1387, 1399-1406 (1994).

[6] *Id.* at 595-96.

[7] *See, e.g., Dunbar*, 31 F.3d at 648-49 (finding no reliable or relevant evidence that parents' consumption of chemically treated alfalfa tablets caused children's mental retardation); Joiner v. General Elec. Co., 78 F.3d 524, 534 (11th Cir. 1996) (allowing testimony that plaintiff's exposure to PCBs and their derivatives promoted lung cancer despite history of cigarette smoking); Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 318 (7th Cir. 1996) (finding testimony inadmissible regarding association between heart attack and three days' use of nicotine patch); *Paoli*, 35 F.3d at 717 (examining admissibility of testimony that plaintiffs' alleged injuries resulted from PCB and other chemical exposure).

present the intrinsic difficulty of proving a link between pesticide exposure and disease where biological and physiological mechanisms are poorly understood and epidemiological evidence is scarce.[8] Accordingly, they afford a useful tool for examining the *Daubert* Court's interpretation of Rule 702 as it applies to novel scientific evidence. Further, it is important to consider these cases because pesticide exposure cases may represent "first cases"[9] that become more common as the Environmental Protection Agency (EPA) reregisters pesticides, as scientific knowledge develops, or as "hot topics" arise, such as the controversial link between estrogenic chemicals and breast cancer.[10] Because pesticide exposure cases illustrate the difficulties in determining what is relevant evidence in cases involving novel scientific theories, they are a particularly apt vehicle for examining application of Rule 702's fitness test.

This Article first examines the admissibility of expert testimony under Rule 702 and how the *Daubert* Court elucidated the fitness requirement. Next the Article reviews the post-*Daubert* application of Rule 702's fitness test and discusses what circumstances might trigger application of the test. Judicial interpretation and application of this test are then used to examine the potential admissibility of scientific evidence in pesticide exposure cases, assuming that the requirements of the first prong—valid scientific knowledge—have been met. Finally, results of this examination are extrapolated to cases involving novel scientific evidence, and suggestions are provided for analyzing this evidence under Rule 702's fitness test.

II. FEDERAL RULE OF EVIDENCE 702

The complexity of scientific theories and evidence in toxic tort litigation often necessitates expert testimony that will assist the trier in making an intelligent evaluation of facts. Federal Rule of Evidence 702 provides for the admissibility of such testimony:

---

[8] Michael D. Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of* Agent Orange *and Bendectin Litigation*, 86 NW. U. L. REV. 643, 643 (1992).

[9] The first case scenario arises when early toxic tort claims are unsupported by scientific studies. Jean Macchiaroli Eggen, *Toxic Torts, Causation, and Scientific Evidence After* Daubert, 55 U. PITT. L. REV. 889, 947 (1994). The early silicone breast implant cases provide a recent example of a first case, and many other mass torts began as first case problems. *Id.* at 947-48. Exclusion of novel scientific theories would effectively bar the first case plaintiff from recovery. *Id.* at 947.

[10] A hot topic bias leads "investigators and publishers to prefer studies that address topics engendering great public interest." Green, *supra* note 8, at 678. For example, numerous articles have been published debating the possibility that estrogenic pesticides, such as DDT and DDE, contribute to increased risks of breast cancer in women and to other risks to men. *See* Frank Falck, Jr., et al., *Pesticides and Polychlorinated Biphenyl Residues in Human Breast Lipids and Their Relation to Breast Cancer*, 47 ARCHIVES ENVTL. HEALTH 143 (1992) (presenting a pilot study finding levels of PCB, DDE, and DDT elevated among malignant cancer cases); Paul Cotton, *Environmental Estrogenic Agents Area of Concern*, 271 JAMA 414 (1994) (implicating estrogen as a potential cause of breast cancer); Richard Stone, *Environmental Estrogens Stir Debate*, 265 SCIENCE 308 (1994) (discussing controversy over link between estrogenic chemicals and breast cancer).

> 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.[11]

The expert witness may explain the "scientific . . . principles relevant to the case, leaving the trier of fact to apply them to the facts," or the expert may "take the further step of suggesting the inference which should be drawn from applying the specialized knowledge to the facts."[12] The trier of fact's implicit unfamiliarity with the relevant scientific principles raises concerns regarding potential abuse of this Rule.[13] For example, scientific expert testimony could be used to mislead the trier, or it could be used as a trial technique to wear down adversaries.[14] Further, admission of meritless scientific testimony wastes judicial resources that could be better spent resolving other issues.[15] The U.S. Supreme Court addressed these concerns, in part, in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*[16]

In *Daubert*, the plaintiffs sued a pharmaceutical company to recover for birth defects allegedly caused by the mother's ingestion of Bendectin, a prescription anti-nausea drug.[17] The defendant moved for summary judgment, contending that the vast amount of epidemiological data available failed to show that Bendectin created a risk factor for birth defects.[18] Consequently, the defendant argued, the plaintiffs would be unable to provide admissible evidence to the contrary.[19] The plaintiffs responded with the testimony of eight experts who concluded that Bendectin could cause birth defects. The experts based their conclusions upon *in vitro* (whole, live animal) and *in vivo* (animal cell) studies, pharmacological studies of the drug's chemical structure, and reanalysis of previously published epidemiological studies.[20] The district and appellate courts, relying upon the "general acceptance" test established in *Frye v. United States*,[21] both determined that the plaintiffs' evidence was inadmissible because the studies

---

11 FED. R. EVID. 702.

12 FED. R. EVID. 702 advisory committee's note.

13 Kenneth R. Kreiling, *Scientific Evidence: Toward Providing the Lay Trier with the Comprehensible and Reliable Evidence Necessary to Meet the Goals of the Rules of Evidence*, 32 ARIZ. L. REV. 915, 941 (1990). *See also* Troyen A. Brennan, *Helping Courts with Toxic Torts: Some Proposals Regarding Alternative Methods for Presenting and Assessing Scientific Evidence in Common Law Courts*, 51 U. PITT. L. REV. 1, 20 (1989) (stating that toxic torts are a "fertile ground for manipulative testimony").

14 *See, e.g.*, United States v. Downing, 753 F.2d 1224, 1226 (3d Cir. 1985) (stating that to be admissible expert testimony must survive a balancing test in which the likelihood that the testimony will "overwhelm or mislead the jury" weighs against admissibility).

15 Joseph Sanders, *Scientific Validity, Admissibility, and Mass Torts after* Daubert, 78 MINN. L. REV. 1387, 1429 (1994).

16 509 U.S. 579 (1993).

17 *Id.* at 582.

18 *Id.*

19 *Id.*

20 *Id.* at 583.

21 293 F. 1013, 1014 (D.C. Cir. 1923). The *Frye* test required that expert testimony be "deduced from a well-recognized scientific principle or discovery . . . sufficiently established to have gained general acceptance in the field in which it belongs." *Id.*

relied upon by the plaintiffs' experts were not generally accepted in the field.[22] The Supreme Court granted certiorari "in light of sharp divisions among the courts regarding the proper standard for the admission of expert testimony."[23]

In *Daubert*, the Court held that the Federal Rules of Evidence furnish the standard for determining the admissibility of novel scientific evidence, thus superseding *Frye*.[24] The Court established Rule 702 as the "primary locus" of the federal judiciary's gatekeeping role in determining the admissibility of proffered expert testimony.[25] The Court located within Rule 702 a two-part test for determining the admissibility of expert testimony.[26] The first prong of the test requires the trier of fact to ascertain whether the expert's testimony pertains to validated scientific knowledge, thus establishing "a standard of evidentiary reliability."[27] The second prong of the test requires an assessment of whether the "reasoning or methodology properly can be applied to the facts in issue," thus establishing the relevancy of the testimony.[28] Evidence that is not relevant will not "assist the trier of fact to understand the evidence or to determine a fact in issue" and is inadmissible.[29] The Court characterized this facet of Rule 702 as one of fit—the expert testimony proffered in the case must be sufficiently tied to the facts of the case so that "'it will aid the jury in resolving a factual dispute.'"[30] Hence, this fitness requirement "requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility."[31]

The Court offered little guidance for determining fit in cases involving novel scientific theories. Although the Court noted that Rule 702 does not "apply specially or exclusively to unconventional evidence," it conceded that well-established propositions are less likely to be challenged, and are thus more easily defended under Rule 702.[32] It recognized that "'fit' is not always obvious, and scientific validity for one purpose is not necessarily

---

[22] *Daubert*, 509 U.S. at 583-84.

[23] *Id.* at 585.

[24] *Id.* at 587.

[25] *Id.* at 589.

[26] *Id.* at 592.

[27] *Id.* at 590. The Court declined to require absolute certainty about a subject of scientific testimony, recognizing that the scientific process is dynamic and that "arguably, there are no certainties in science." *Id.*

[28] *Id.* at 592.

[29] *Id.* at 591 (quoting FED. R. EVID. 702).

[30] *Id.* at 591 (quoting United States v. Downing, 753 F.2d 1224, 1242 (3d Cir. 1985)).

[31] *Id.* at 592. Hence, in making a preliminary determination of admissibility pursuant to Federal Rule of Evidence 104(a), a court must assess whether the expert will "testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue." *Id.*

For a criticism of the *Daubert* Court's requirement of pre-admission scrutiny under Rule 702 as contravening Congressional intent, see Leslie A. Lunney, *Protecting Juries from Themselves: Restricting the Admission of Expert Testimony in Toxic Tort Cases*, 48 SMU L. REV. 103 (1994).

[32] *Daubert*, 509 U.S. at 592 n.11.

scientific validity for other, unrelated purposes."[33] Justice Blackmun, writing for the majority opinion, noted:

> The study of the phases of the moon, for example, may provide valid scientific "knowledge" about whether a certain night was dark, and if darkness is a fact in issue, the knowledge will assist the trier of fact. However (absent creditable grounds supporting such a link), evidence that the moon was full on a certain night will not assist the trier of fact in determining whether an individual was unusually likely to have behaved irrationally on that night.[34]

The Court's "phases of the moon" example posits an obvious instance in which there is no scientific connection to the fact in issue. However, as the Ninth Circuit noted upon remand, "[t]he task before us is more daunting still when the dispute concerns matters at the very cutting edge of scientific research, where fact meets theory and certainty dissolves into probability."[35]

III. POST-*DAUBERT* APPLICATION OF RULE 702

Before determining the admissibility of scientific evidence in pesticide exposure cases, it is helpful to explore the analysis required under the second prong of Rule 702. In general, post-*Daubert* case law provides little guidance. A review of federal cases reveals that few courts have reached the second prong of the Rule 702 admissibility test. Many courts that have conducted a Rule 702 analysis ended their inquiry with a determination that the first prong, valid scientific knowledge, had not been met.[36] This makes sense, because testimony inadmissible under the first prong is implicitly unreliable,[37] and unreliable testimony will not assist the trier of fact. Other courts that admitted expert testimony mentioned, but rarely applied, the second-prong analysis.[38] It appears that Rule 702's fitness requirement is considerably less important in judicial analysis than

---

[33] *Id.* at 591.

[34] *Id.*

[35] Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311, 1316 (9th Cir.) (referring to *Daubert*'s two-part test), *cert. denied*, 116 S. Ct. 189 (1995).

[36] *See, e.g.*, O'Connor v. Commonwealth Edison Co., 13 F.3d 1090, 1107 n.20 (7th Cir.) (foregoing a consideration of proper fit because physician's expert testimony not grounded in scientific method), *cert. denied*, 114 S. Ct. 2711 (1994); Schmaltz v. Norfolk & W. Ry. Co., 878 F. Supp. 1119, 1124 n.2 (N.D. Ill. 1995) (rejecting expert opinions for lack of scientific method and not proceeding to proper fit test); Chikovsky v. Ortho Pharm. Corp., 832 F. Supp. 341, 346 n.7 (S.D. Fla. 1993) (excluding expert opinion under the first prong of the *Daubert* test and not deciding whether testimony would be helpful to the trier of fact). *But see* Grimes v. Hoffmann-LaRoche, Inc., 907 F. Supp. 33, 37 (D.N.H. 1995) (excluding expert's general causation testimony on reliability and fit grounds without actually determining methodological soundness of experiment).

[37] "[T]he requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Daubert*, 509 U.S. at 590.

[38] *See, e.g.*, Hopkins v. Dow Corning Corp., 33 F.3d 1116, 1125 (9th Cir. 1994) (finding expert testimony to be admissible without explicitly applying the second prong of the Rule 702 test); Cantrell v. GAF Corp., 999 F.2d 1007, 1014 (6th Cir. 1993) (finding expert testimony on association between asbestos exposure and laryngeal cancer admissible without addressing Rule 702's second prong).

the determination of scientific validity under the first prong.[39] There are exceptions, however, to the generally cursory application of the fitness test.[40]

A pre-*Daubert* case provides initial insight into Rule 702's fitness requirement. In *United States v. Downing*,[41] the court explored the admissibility of expert testimony under Rule 702 and advocated a fairly liberal approach towards admissibility.[42] It determined that expert testimony may be admissible under Rule 702 if it helps the trier of fact to understand difficult evidence, even if the evidence is within ordinary understanding.[43] Tempering this liberal approach, however, was the court's recognition of Rule 702's interplay with other rules, such as Rule 403, which courts use to exclude helpful evidence that is redundant or a waste of time.[44]

When the *Daubert* Court elucidated the second prong of Rule 702, it adopted Judge Becker's characterization of fit in *Downing*.[45] The *Downing* court had recognized that Rule 702 requires consideration of the relevancy, or fit, of the expert testimony.[46] Evidence or testimony that is not sufficiently tied to the facts of the case is not relevant, and therefore will not aid the trier of fact in making an informed decision.[47] Without expressly addressing concerns of judicial efficiency, the *Downing* court provided a means of facilitating its required fitness determinations. The court required future defendants seeking admission of expert testimony to make

---

[39] Indeed, the Third Circuit noted that an argument could be made that *Daubert*'s determination that reliability stems from valid scientific knowledge, rather than stemming from helpfulness to the trier of fact, diminishes the importance of the helpfulness inquiry. The court, however, stressed the conceptual importance of fit. *In re* Paoli R.R. Yard PCB Litig., 35 F.3d 717, 744-45 n.12 (3d Cir. 1994), *cert. denied*, 115 S. Ct. 1253 (1995).

[40] These exceptions, of course, will become the norm as courts become more comfortable with *Daubert*'s Rule 702 analysis. Indeed, it appears that 1995 may mark a turning point for courts addressing the fitness issue. *See, e.g.*, Homelite Div. of Textron Inc. v. Barber-Colman Co., 903 F. Supp. 1558, 1568-69 (W.D.N.C. 1995) (finding that households used in hazardous waste studies relied upon were not sufficiently similar to households at issue); *Grimes*, 907 F. Supp. at 35-38 (finding no evidence of similar chemical structure or concentrations that would allow expert to extrapolate to prescription drug at issue from behavior of other photosensitive chemicals); Benedi v. McNeil-P.P.C., Inc., 66 F.3d 1378, 1385 (4th Cir. 1995) (finding that expert testimony satisfied *Daubert*'s test of relevance and reliability); Cavallo v. Star Enter., 892 F. Supp. 756, 761-70 (E.D. Va. 1995) (finding no valid basis for expert to support leap from studies to the opinion in the case).

[41] 753 F.2d 1224 (3d Cir. 1985) (ruling on testimony regarding reliability of eyewitness identification).

[42] *Id.* at 1237.

[43] *Id.* at 1229.

[44] *Id.* at 1243. Federal Rule of Evidence 403 provides for the exclusion of relevant evidence on grounds of prejudice, confusion, waste of time, or needless presentation of cumulative evidence. FED. R. EVID. 403.

[45] Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 591 (1993).

[46] *Downing*, 753 F.2d at 1242.

[47] *Id.*

"an on-the-record detailed proffer to the court, including an explanation of precisely how the expert's testimony is relevant" to the facts in issue.[48]

Under Judge Becker's approach, failure to make a detailed proffer is sufficient grounds to exclude an expert's testimony.[49] For example, the *Downing* defendant, who wanted to introduce testimony concerning the reliability of eyewitness identification, should have made a detailed proffer establishing factors that may impair eyewitness identifications.[50] Absent the presence of such factors, the expert's testimony would not be helpful in attacking the reliability of eyewitness identifications. This practical requirement ensures that both the parties and the trier of fact have considered the fit of the testimony to the facts; the requirement also reduces the opportunity for manipulation of the proceedings and ensures an adequate record on appeal.

One would expect the Ninth Circuit's analysis upon remand to clarify Rule 702's fitness requirement; surprisingly, this is not the case. Although Judge Kozinski referred directly to the second prong of Rule 702 and noted factors in the experts' testimony bearing upon the issue of fit,[51] his subsequent analysis did not employ this specialized relevancy test. Rather, he assessed whether the experts' testimony could prove specific causation under California tort law.[52] He found that proof of specific causation required epidemiological studies to show that Bendectin more than doubled the likelihood of limb reduction birth defects.[53] Only one expert, Dr. Palmer, was willing to testify that Bendectin caused the plaintiffs' limb defects, but the court held his evidence inadmissible under Rule 702's validity requirement.[54] The other experts were not willing to testify regarding specific causation, and consequently their testimony was not helpful to the jury and was inadmissible under the second prong of Rule 702.[55] Be-

---

[48] *Id.* Requiring a detailed proffer is analogous to requiring disclosure of expert testimony under the subsequently enacted Federal Rule of Civil Procedure 26. *See* discussion *infra* Part IV.

[49] *Downing*, 753 F.2d at 1242.

[50] *Id.*

[51] Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311, 1320 (9th Cir.), *cert. denied*, 116 S. Ct. 189 (1995). The plaintiffs' experts testified regarding the teratogenic properties of Bendectin, its chemical structure, and statistical studies showing increased risk of birth defects. *Id.*

[52] *Id.* Because the pertinent inquiry in the case involved causation, Judge Kozinski determined that "[i]n assessing whether the proffered expert testimony 'will assist the trier of fact' in resolving this issue [of causation], we must look to the governing substantive standard." *Id.* (quoting FED. R. EVID. 702). *See also* Casey v. Ohio Med. Prods., 877 F. Supp. 1380, 1386 (N.D. Cal. 1995) (quoting *Daubert*, 43 F.3d at 1320) (interpreting the Ninth Circuit's definition of the required showing "as the need to demonstrate that, in this case halothane, 'more likely than not' caused the injury.")

[53] *Daubert*, 43 F.3d at 1321.

[54] *Id.* at 1319. Specifically, the court felt that Dr. Palmer's testimony was not predicated on an "understandable scientific basis," but rather on "[p]ersonal opinion." *Id.* (quoting Turpin v. Merrell Dow Pharm., Inc., 959 F.2d 1349, 1360 (6th Cir. 1992)). The court noted, however, that had Dr. Palmer's testimony survived the first prong, it would have easily met the fitness requirement because he was willing to testify that Bendectin caused the plaintiff's injuries. *Id.* at 1321 n.18.

[55] *Id.* at 1321.

cause the plaintiffs' experts could not augment their testimony regarding causation without altering their conclusions altogether, Judge Kozinski determined that remand would not cure the shortcomings in the plaintiffs' case.

Although Judge Kozinski purported to frame his inquiry under Rule 702's second prong, it appears that he may have misapplied *Daubert*'s requirement of "a valid scientific connection to the pertinent inquiry"[56] and used a sufficiency test in making his decision whether to remand or affirm the district court's grant of summary judgment.[57] Rather than examining the relevancy of the experts' testimony, Judge Kozinski weighed the experts' conclusions as to whether Bendectin caused the plaintiffs' injuries and thus examined the effect of their testimony.[58] Further, his analysis illustrates the potential confusion that courts may experience when determining whether plaintiffs have met their burden of proof in an admissibility hearing. It is true that making a preadmissibility determination under Rule 104(a) does require a preponderance of the evidence standard.[59] This standard, however, appears more applicable to the factual issues under Rule 702's first prong, or to the admissibility inquiry in its totality,[60] than to determinations of fit. Indeed, *Daubert*'s discussion of fit does not lend itself to application of the preponderance standard.[61] Even if *Daubert* is interpreted as requiring a heightened relevancy standard for expert testimony, this remains a lower threshold than the "merits standard of correctness" or preponderance of the evidence standard that Judge Kozinski used upon remand.[62]

---

[56] *Id.* at 1320 (quoting Daubert v. Merrell Dow Pharm., 509 U.S. 579, 592 (1993)). "With the exception of Dr. Palmer . . . the remaining experts proffered by plaintiffs were equally unprepared to testify that Bendectin caused plaintiffs' injuries . . . ." *Id.* at 1321.

[57] Even if expert testimony is admissible under Rule 702, it may be insufficient to withstand a motion for summary judgment because it fails to raise a triable issue of fact. Margaret A. Berger, *Evidentiary Framework*, *in* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 37, 52 (Federal Judicial Center 1995) [hereinafter REFERENCE MANUAL].

Other courts have acknowledged the fine line between performing *Daubert*'s admissibility calculus and weighing the expert's evidence. Cavallo v. Star Enter., 892 F. Supp. 756, 774-75 (E.D. Va. 1995). As one court noted, "[i]n conducting a *Daubert* inquiry at the summary judgment stage, the trial court must recognize the distinction between determining the sufficiency of the evidence and determining the admissibility of the evidence." Bowers v. N. Telecom, Inc., 905 F. Supp. 1004, 1007 (N.D. Fla. 1995). A sufficiency determination requires the plaintiffs to produce enough evidence to convince a juror that "their expert's opinion is correct, *i.e.*, that it is more likely than not true that the defendant's conduct caused the plaintiffs' injuries." *Id.* In contrast, a *Daubert* inquiry focuses on the reliability of the expert's opinion, and not on whether the opinion is correct. *Id.*

[58] *Daubert*, 43 F.3d at 1319-22.

[59] *Daubert*, 509 U.S. at 592 n.10 (citing Bourjaily v. United States, 483 U.S. 171, 175-76 (1987)).

[60] *But see, e.g.*, Grimes v. Hoffman-LaRoche, Inc., 907 F. Supp. 33, 35 (D.N.H. 1995) (holding that the burden lies with the proponent to demonstrate by a preponderance of the evidence that Rule 702's requirements have been met).

[61] *See* Sanders, *supra* note 15, at 1434 (discussing admissibility and sufficiency).

[62] *See* Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311, 1320-21 (9th Cir.), *cert. denied*, 116 S. Ct. 189 (1995); *In re* Paoli R.R. Yard PCB Litig., 35 F.3d 717, 744 (3d Cir. 1994), *cert. denied*, 115 S. Ct. 1253 (1995). *See also infra* note 67.

The Third and the Seventh Circuits both have provided guidance regarding the fitness aspect of Rule 702 in their early post-*Daubert* decisions. The Third Circuit, in *In re Paoli Railroad Yard PCB Litigation*,[63] acknowledged the difficulties in determining fit under Rule 702 when it stated that "a challenge to 'fit' is very close to a challenge to the expert's ultimate conclusion about the particular case, and yet it is part of the judge's admissibility calculus under *Daubert*." The fitness aspect of this admissibility calculus depends on "'the proffered connection between the scientific research or test result to be presented and particular disputed factual issues in the case.'"[64] "For example," the court noted,

> animal studies may be methodologically acceptable to show that chemical X increases the risk of cancer in animals, but they may not be methodologically acceptable to show that chemical X increases the risk of cancer in humans .... [I]n order for animal studies to be admissible to prove causation in humans, there must be good grounds to extrapolate from animals to humans, just as the methodology of the studies must constitute good grounds to reach conclusions about the animals themselves.[65]

The court required each step of the expert's analysis to be reliable "all the way through the step that connects the work of the expert to the particular case."[66] Although this step-by-step reliability determination falls within Rule 702's first prong, it could be used to facilitate a determination of fit because it clarifies how the expert took the final external validity step, or extrapolated to the facts of the case.[67]

The Third Circuit's approach is in keeping with the liberal spirit of admissibility enunciated in *Daubert*, yet it also upholds the judge's gatekeeping role. Even if an expert's testimony is deemed scientifically valid under Rule 702's first prong, the "testimony will be excluded if it is not scientific knowledge *for purposes of the case*."[68] Accordingly, the *Downing* prerequisite of a "detailed proffer" demonstrating the relevance of the testimony is implicitly required under the Third Circuit's analysis.[69] A detailed proffer illuminates the relevancy of the testimony and diminishes the potential for adversarial manipulation. The expert's delineation of the external validity step, which more clearly demonstrates how the expert's testimony fits the facts in issue, would assist the judge's gatekeeping decisions. The focus here is upon the logical, analytical progression

---

63 35 F.3d at 746.

64 *Id.* at 743 (quoting United States v. Downing, 753 F.2d 1224, 1237 (3d Cir. 1985)).

65 *Id.* The court relied upon a "good grounds" standard in evaluating both reliability and fit. *Id.* at 743-45. This standard is "lower than the merits standard of correctness," *id.* at 743, yet it is "more than bare . . . relevance," *id.* at 745.

66 *Id.* at 743.

67 External validity "refers to the extent to which a research finding can be generalized to different situations, settings, persons, or times." Kreiling, *supra* note 13, at 969. *See* Sanders, *supra* note 15, at 1404 (discussing threats to external validity).

68 *Paoli*, 35 F.3d at 743.

69 *Id.*

establishing how the underlying methodology applies to the facts in issue.[70]

Further, the Third Circuit reaffirmed its statement in *Downing* that Rule 403 may operate independently to exclude evidence deemed admissible under Rule 702.[71] The *Daubert* Court acknowledged that the inherent difficulty in evaluating expert evidence creates the potential for misleading the jury.[72] This risk allows a judge exercising Rule 403 to have more authority over expert witnesses than lay witnesses.[73] The *Paoli* Court, however, noting that *Daubert* installed Rule 702 as "the primary locus of a court's gatekeeping role," determined that "exclusion under Rule 403 should be rare."[74] Hence, in order for testimony to warrant exclusion under Rule 403, "there must be something *particularly* confusing about the scientific evidence at issue," rather than scientific complexity in general.[75] The court's stringent interpretation of Rule 403's function perhaps promotes an even more liberal admissibility standard than that envisioned by the *Daubert* Court.

The Seventh Circuit also has offered some guidance in interpreting Rule 702's fitness requirement. In *Porter v. Whitehall Laboratories*,[76] a products liability action in which a consumer died of renal failure after consuming a drug containing ibuprofen, the Seventh Circuit approved the lower court's exclusion of the plaintiff's expert's testimony. The district court had considered the critical question in determining admissibility to be "whether the expert can shed light on a controverted fact to assist the jury in its evaluation."[77] "The expert performs this function . . . by comparing data from the case before the court with known scientific relationships

---

[70] This requirement of a detailed proffer may place a significant burden on the proponent of evidence and the judge who evaluates the proffer. This issue and Professor Margaret Berger's proposal for alleviating this burden are discussed *infra* Part IV.

[71] *Paoli*, 35 F.3d at 746. Somewhat surprisingly, testimony may be helpful even if the expert's conclusions are inaccurate, so long as the expert's "'technique or principle [is] sufficiently reliable so that it will aid the jury in reaching accurate results.'" *Id.* at 744 (citing DeLuca v. Merrell Dow Pharm., Inc., 911 F.2d 941, 956 (3d Cir. 1990) (quoting WEINSTEIN & BERGER, *supra* note 1, ¶ 702[03], at 702-35 (1988)), *cert. denied*, 510 U.S. 1044 (1994)). *But see id.* at 799 (Roth, J., concurring) (arguing that inaccurate information is not helpful).

[72] Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 595 (1993) (citing FED. R. EVID. 403).

[73] *Id.* (citing Jack B. Weinstein, *Rule 702 of the Federal Rules of Evidence is Sound; It Should Not Be Amended*, 138 F.R.D. 631, 632 (1991)).

[74] *Paoli*, 35 F.3d at 747 n.16.

[75] *Id.* at 747. The court also addressed procedural concerns regarding the Rule 403/702 balancing test. It reaffirmed its earlier decision that "Rule 403 is rarely appropriate as a basis of *pre-trial* exclusion, because a judge cannot ascertain potential relevance until that judge has a virtual surrogate for a trial record." *Id.* An in limine hearing may create such a record. *Id.*

[76] 9 F.3d 607, 614 (7th Cir. 1993). Although the district court heard the *Porter* case prior to the *Daubert* decision, it "anticipated well the Court's analysis" in *Daubert*. *Id.* at 616. The circuit court stated that the district court's decision to exclude the testimony was the "proper application of the [*Daubert*] Court's directive that the method 'fit' the factual situation." *Id.*

[77] *Id.* at 610-11.

and then stating a conclusion about that data based on the comparison."[78] Because the role of the expert is that of "'a conduit of facts,'"[79] an expert's "mere guess or conjecture"[80] that the facts of a case "'fit an expert's own unsupported, unproven hypothesis does not help determine a fact in issue and is therefore inadmissible.'"[81] Hence, "suggested scientific testimony must 'fit' the issue to which the expert is testifying."[82]

The district court found that the experts could not compare data establishing a causal connection to the instant facts of the case.[83] Facts that the experts relied upon in formulating their causal hypotheses were inapplicable to the case.[84] For example, one expert relied upon animal experiments to formulate his theory of causation.[85] The timing of the chain of events leading to the injury was critical to his theory.[86] However, because the expert could only speculate as to the chronology of the plaintiff's injury, he could not apply the theory to the factual situation at hand.[87] Another expert, a pharmacologist, testified that a determination of causation would require an investigation into several factors: other medications taken concomitantly that could be causally related to the effect, any abnormal body processes that could have contributed to the effect, any environmental factors, and any intercurrent illnesses.[88] To undertake this analysis, the expert stated that it would be necessary to rule out other causes of kidney failure.[89] Because the expert did know what those other causes might be, he could not rule them out.[90] Consequently, he could not apply his methodology to the patient, and the district court excluded his testimony.[91] Accordingly, the appellate court held that there was no fit.[92]

---

78 *Id.* at 611.

79 *Id.* (quoting Porter v. Whitehall Lab., Inc., 791 F. Supp. 1335, 1343 (S.D. Ind. 1992)).

80 *Id.*

81 *Id.* at 612 (quoting *Porter*, 791 F. Supp. at 1344). This sentiment was repeated in Bradley v. Brown, 852 F. Supp. 690 (N.D. Ind.), *aff'd*, 42 F.3d 434 (7th Cir. 1994), when the expert witnesses could not provide testimony explaining why a particular individual contracts multiple chemical sensitivity (MCS) disorder. *Id.* at 700. The district court found that the testimony provided was anecdotal, hypothetical, and not helpful: "plaintiffs' own evidence clearly establishes that the 'science' of MCS's etiology has not progressed from the plausible, that is, the hypothetical, to knowledge capable of assisting a fact-finder, jury or judge." *Id.*

82 *Porter*, 9 F.3d at 616.

83 *Porter*, 791 F. Supp. at 1344.

84 *Id.*

85 *Porter*, 9 F.3d at 616.

86 *Id.*

87 *Id.*

88 *Id.*

89 *Id.*

90 *Id.*

91 *Porter*, 791 F. Supp. at 1344. Similarly, in Bradley v. Brown, 852 F. Supp. 690, 700 (N.D. Ind.), *aff'd*, 42 F.3d 434 (7th Cir. 1994), the district court excluded doctors' testimony concerning the development of plaintiffs' MCS following an acute pesticide poisoning incident in an office building. *Id.* The court noted that the symptoms reported were "'not consistent with the accepted toxicological properties of the chemicals.'" *Id.* at 700 (quoting Nancy Fiedler et al., *Evaluation of Chemically Sensitive Patients*, 34 J. OCCUPATIONAL MED. 529, 529 (1992)).

92 *Porter*, 9 F.3d at 616.

These cases demonstrate that Rule 702's validity inquiry should not subsume the Rule's fitness requirement. *Daubert*'s fitness test is slightly more focused and requires more analysis than previous helpfulness, relevance-based analyses under Rule 702. Nonetheless, it should not be very difficult for courts, who are already used to the notions of "helpfulness" and "relevance," to administer the test.[93] The Third Circuit's requirement of a detailed proffer demonstrating the fit of expert testimony would serve to clarify the issues, alleviate adversarial exploitation of the rules governing admissibility, and foster judicial efficiency. Further, an examination of the expert's final validity step will demonstrate the fit of the expert's testimony with the facts in issue. Such an analysis would not be unduly burdensome because a court must examine scientific methodology under Rule 702's first prong. This first inquiry would probably reveal the logical progression leading to the expert's final external validity step. The Seventh Circuit's opinion demonstrates the importance of fitting the facts and the methodology so that factors evaluated in the underlying methodology correspond sufficiently to the facts of the case. The guidance provided by these courts is helpful in assessing the future admissibility of novel scientific evidence. The Third and Seventh Circuits demonstrate how courts can balance countervailing concerns of liberally admitting expert testimony and excluding meritless testimony without getting bogged down in an unwieldy system of evidentiary review.

IV. Federal Rule of Civil Procedure 26

Concerns still exist, however, regarding the procedural aspects of a Rule 702 inquiry. How will the parties and the judge obtain the information necessary to make an informed decision about novel scientific evidence, and what will trigger the Rule 702 inquiry? Pursuant to Federal Rule of Evidence 104(a), which governs preliminary questions of admissibility, the burden is on the proponent of the evidence to demonstrate admissibility. Theoretically, the opponent of novel scientific evidence need only raise a question of admissibility. It would tremendously burden the proponent of expert testimony to have to make a detailed proffer, as the Third Circuit requires, for every bit of novel scientific evidence. Review of such proffers accordingly would strain judicial resources and hamper attempts to streamline the judicial system. How, then, can courts ensure that novel scientific evidence fits the instant case, without unduly bogging down the judicial system or allowing the inquiry to become yet another strategic ploy among parties? The recently amended Federal Rule of Civil Procedure 26 (Rule 26) provides some guidance. Further, as discussed below,

[93] Indeed, one court proudly asserted that it did not require any scientific training or use anything more than "the customary legal tools of logical reasoning to carry out its gatekeeping function." Cavallo v. Star Enter., 892 F. Supp. 756, 775 (E.D. Va. 1995) (citation omitted). Further, "[p]roper application of *Daubert* simply does not require that district judges be trained scientists." *Id.* at 775 n.47 (noting that 35 years had passed since the court had had any scientific involvement and that the court's clerks were "blissfully innocent" of any scientific training).

Professor Margaret Berger has offered some suggestions concerning the burden of proof in a preadmissibility inquiry.[94]

Amendments to Rule 26, which became effective after the *Daubert* decision, provide for disclosure of expert testimony. Specifically, Rule 26 requires a party to disclose "the identity of any person who may be used at trial to present evidence under Rules 702, 703, or 705 of the Federal Rules of Evidence."[95] This disclosure is to be accompanied by a written report containing "a complete statement of all opinions to be expressed and the basis and reasons therefor; the data or other information considered by the witness in forming the opinions"; and a listing of other cases in which the witness has testified in the preceding four years.[96] Absent direction from the court or stipulation by the parties, the disclosures are to be made at least ninety days before the trial date or the date the case is to be ready for trial.[97] Hence, this provision requires experts to provide written reports containing their opinions and bases for their opinions, but does not require them to divulge their methodology.[98]

When used in conjunction with the *Downing* court's requirement of a detailed proffer, Rule 26 provides a means of facilitating the judge's role as gatekeeper and the parties' own trial strategies. Although the written reports probably will not include information relevant to Rule 702's two-pronged inquiry, they do offer a starting point for exploring these issues.[99] When combined, however, with a detailed proffer demonstrating the relevancy of the expert's opinion to the controverted issue, an inquiry under Rule 702's second prong becomes a much simpler task. Both the parties and the judge have before them readily available information concerning the general bases for the expert's opinion and how these bases fit the facts of the instant case.

Nonetheless, there remains the question of how Rule 702 review is triggered. Requiring a detailed proffer and delineation of how the expert extrapolated from scientific studies to the facts at issue places a significant burden on the proponent of the testimony in terms of cost, efficiency, and fairness. Further, it would strain judicial resources to require the judge to review a proffer for each and every bit of proposed testimony. Hence, when should the proponent of the proffered testimony be required to make this showing?

In civil cases, Professor Margaret Berger suggests that courts place the initial burden upon the opponent of expert testimony to demonstrate deficiencies in the proffered testimony.[100] Under her approach, mere

---

[94] *See infra* notes 99-110 and accompanying text. Professor Berger is Professor of Law at Brooklyn Law School.

[95] FED. R. CIV. P. 26(a)(2)(A).

[96] FED. R. CIV. P. 26(a)(2)(B).

[97] FED. R. CIV. P. 26(a)(2)(C).

[98] Berger, *supra* note 57, at 50.

[99] Margaret A. Berger, *Procedural Paradigms for Applying the* Daubert *Test*, 78 MINN. L. REV. 1345, 1370 (1994) (noting that *Daubert* informs the parties of issues warranting further exploration).

[100] *Id.* at 1365.

claims that the other side's evidence is inadmissible would be insufficient to warrant a judicial inquiry.[101] Absent self-evident flaws, the opponent of the evidence would have to demonstrate a distinct problem with the evidence before the court would initiate judicial screening.[102] The reports required under Rule 26 should provide litigants with enough information so that subsequent depositions can "focus economically and efficiently on points that need elaboration."[103] Only then would the proponent bear the burden of showing that the challenged evidence is admissible.[104] Ultimately, "[t]he parties should specify the specific methodological details about which their experts disagree before the court is required to expend time on the [in limine] motion."[105]

Professor Berger argues that placing the burden of production on the civil defendant "furthers the prime evidentiary objective of accurate fact-finding."[106] First, she contends that *Daubert* indicates the Supreme Court's preference for the liberal admissibility of evidence.[107] Hence, scientific evidence should be deemed admissible until the opposing party provides specific evidence to the contrary.[108] Second, in keeping with the disclosure policies evinced by Rule 26, this requirement would increase the amount of information available to the court and the parties. Judicial access to information better allows the court to consider numerous complex factors inherent in the Rule 702 analysis.[109] Third, this requirement would reduce manipulative trial tactics and serve judicial economy by requiring the defendant to point out definite flaws in the proponent's methodology rather than merely claiming that the "other side's expert is relying on invalid science" or that the evidence does not fit the case.[110]

Professor Berger's proposal is probably an anathema to most defense counsel. Nonetheless, rigorous application of Rule 702's two-pronged test does require consideration of the circumstances necessary to trigger the test. Opponents of novel scientific evidence certainly, and understandably, will attempt to render such evidence inadmissible and thus increase their chances of a favorable summary judgment.[111] Consequently, this question is likely to arise frequently, and requiring opponents to raise explicit and adequate grounds for their objections would provide a means of streamlining the inevitable evidentiary disputes. This requirement may appear to add yet another layer of paperwork and delay to a decidedly imperfect system, but when used in conjunction with the Rules of Civil Procedure, it

---

101 *Id.* at 1367.
102 *Id.* at 1367, 1371.
103 *Id.* at 1371.
104 *Id.* at 1365.
105 *Id.* at 1371.
106 *Id.* at 1366.
107 *Id.* at 1349-50, 1365.
108 *Id.* at 1365.
109 *Id.* at 1366.
110 *Id.* at 1367.
111 Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 595-96 (1993) (noting that courts are free to direct summary judgment); *see also* Berger, *supra* note 57, at 51-52 (discussing admissibility versus sufficiency of evidence).

may ultimately conserve resources by culling meritless challenges to expert testimony. Further, it is important to consider one of the larger goals that a preliminary inquiry strives to achieve: the disclosure of information, which thereby facilitates more efficient and informed judicial decisionmaking.

V. Admissibility of Evidence in Pesticide Exposure Cases

A. Toxic Tort Cases Generally

Introduction of scientific evidence in toxic tort litigation to prove causal relationships is inherently problematic.[112] Establishment of a causal connection is complicated by uncertainty regarding the length or amount of exposure, the latency period between the exposure and onset of the injury, lack of understanding of the causation mechanism, possible intervening causes, and a lack of scientific knowledge generally.[113] The myriad uncertainties concerning causal relationships typically necessitate the development of novel scientific theories regarding such relationships. Consequently, proof of causation, particularly specific causation, is often the most difficult and disputed aspect of the toxic tort plaintiff's case.[114]

B. Pesticide Exposure Cases

Pesticide exposure cases typify many of the problems associated with evaluating the admissibility of novel scientific evidence theories in the toxic tort context. Theories linking pesticide exposure to latent disease are not so well established as to warrant judicial notice or scientific unanimity.[115] This is largely due to the paucity of scientific data regarding biochemical mechanisms inducing disease, possible synergistic effects, and pesticide toxicity.[116] Further, available data address pesticides' effects on animals, but data addressing effects on humans are scarce.[117] This scarcity is a product of the innate difficulties in studying human populations, including the long period between exposure and initial symptoms of

---

112 Rachel Carson characterized this problem:

> When one is concerned with the mysterious and wonderful functioning of the human body, cause and effect are seldom simple and easily demonstrated relationships. They may be widely separated both in space and time. To discover the agent of disease and death depends on a patient piecing together of many seemingly distinct and unrelated facts developed through a vast amount of research in widely separated fields.

Rachel Carson, Silent Spring 189 (25th anniv. ed. 1987).

113 Eggen, *supra* note 9, at 895-96.

114 *Id.*

115 *See* United States v. Downing, 753 F.2d 1224, 1234 (3d Cir. 1985) (defining novel scientific evidence).

116 Most testing occurred in the 1950's and 1960's, when researchers did not test for possible latent teratogenic, reproductive, or carcinogenic effects of pesticides. *See* Dorothy Blair, *Uncertainties in Pesticide Risk Estimation and Consumer Concern*, 24 Nutrition Today 13, 14 (Nov./Dec. 1989).

117 Fina P. Kaloyanova & Mostafa A. El Batawi, Human Toxicology of Pesticides 168 (1991). Further, limited study-group sizes may impair the unequivocal determination of whether pesticides have affected a study's parameters. *Id.*

disease, the need for large numbers of study groups, and in particular, the difficulty in documenting exposure to specific pesticides.[118] Existing studies are often subject to various interpretations.[119] Nonetheless, "[p]esticides are a major source of public concern because of their known toxicity, their widespread use, their persistence in the environment, and their possible association with delayed health effects."[120]

Although agricultural workers and chemical plant workers face the greatest exposure to pesticides, "[l]ittle is known about the extent or magnitude of chronic health problems related to occupational exposure to pesticides" in the United States.[121] Even the number of affected workers is unknown;[122] estimates range from 20,000 to 300,000 farmworkers each year.[123] Few states require mandatory reporting of pesticide-related illnesses, and underreporting is likely.[124] Some studies have addressed the

---

[118] Aaron Blair et al., *Estimating Exposure to Pesticides in Epidemiological Studies of Cancer*, *in* BIOLOGICAL MONITORING FOR PESTICIDE EXPOSURE: MEASUREMENT, ESTIMATION & RISK REDUCTION 38, 38 (Rhoda G.M. Wang et al. eds., 1989).

[119] *See* Robert Levine, *Recognized and Possible Effects of Pesticides in Humans*, *in* 1 HANDBOOK OF PESTICIDE TOXICOLOGY 275 (Wayland J. Hayes, Jr. & Edward R. Laws, Jr. eds., 1991) (presenting a comprehensive review of pesticide exposure studies and controversies).

[120] Ketty Mobed et al., *Occupational Health Problems Among Migrant and Seasonal Farm Workers*, 157 W.J. MED. 367, 369 (1992). Epidemiological and animal studies indicate a link between exposure and reproductive disorders, birth defects, cancer, liver and kidney tumors, neurological disorders, and leukemia. 2 MARGIE T. SEARCY, A GUIDE TO TOXIC TORTS § 23.03[6], at 23-37 to 23-40 (1995).

Conventional pesticide use in the United States has grown tremendously over the past few decades, from approximately 540 million pounds in 1964 to over one billion pounds in 1991. JENNIFER CURTIS ET AL., AFTER SILENT SPRING: THE UNSOLVED PROBLEMS OF PESTICIDE USE IN THE UNITED STATES 6 (1993). More than 75% of these pesticides are used in agriculture. *Id.* at 7.

[121] Mobed et al., *supra* note 120, at 369. U.S. Bureau of Labor Statistics reports that "farmworkers endure[d] the highest rate of chemical-related illness of any occupational group: 5.5 per 1000 workers" during 1977. CURTIS ET AL., *supra* note 120, at 17 (citing Field Sanitation, 52 Fed. Reg. 16,050, 16,059 (May 1, 1987) (codified at 29 C.F.R. § 1928.110 (1995))). In 1975 in California, the second most frequent source of systemic poisoning stemmed from the agricultural sector. OCCUPATIONAL HEALTH BRANCH, STATE OF CAL. DEP'T OF HEALTH, OCCUPATIONAL DISEASE IN CALIFORNIA 7 (1975). Most of these poisonings resulted from pesticide exposure. *Id.*

[122] Mobed et al., *supra* note 120, at 369.

[123] *See State Reporting Systems Provide Few Details on Pesticide Illness Cases, GAO Report States*, 23 O.S.H. Rep. (BNA) 1013, 1014 (1994) [hereinafter *GAO Report*] (reporting estimates of 20,000 to 300,000); CURTIS ET AL., *supra* note 120, at 16 (reporting an estimate of 300,000).

[124] California's pesticide reporting program is the only one in the nation that is well-developed. There is a need for more solid data ranging from the number of illnesses to the number of annual exposures. *GAO Report*, *supra* note 123, at 1013. *See also* William S. Pease et al., Preventing Pesticide-related Illness in California Agriculture: Strategies & Priorities 55-56 (1993) (discussing the limitations of California's Pesticide Illness Surveillance Program).

Many of these illnesses may go unreported because migrant farmworkers lack access to health care, do not understand their symptoms, or fear jeopardizing their jobs. Paula M. Lantz et al., *Peer Discussions of Cancer among Hispanic Farm Workers*, 109 PUB. HEALTH REP. 512 (1994). Of course, illegal farmworkers would be even more reluctant to report any exposure. Nonetheless, they remain an important source of information; virtually all epi-

association of cancer and pesticide exposure among farmers and permanent farm help, but few population-based studies have been published about the effects upon migrant and seasonal farmworkers.[125]

Scientific uncertainty is further compounded by lack of information regarding toxic effects of pesticides.[126] More than four hundred pesticides currently on the market were registered before the enactment of the current requirements for health and environmental effects testing.[127] Amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)[128] require the Environmental Protection Agency (EPA) to reregister pesticides, but this effort has been hampered by lack of money, data, and will.[129] Consequently, EPA had reregistered only twenty-seven pesticides by 1993.[130]

Public concern is exacerbated by misunderstanding regarding both the certainty necessary to implement regulatory policy and the certainty necessary to resolve legal disputes.[131] In the regulatory arena, public agencies rely upon risk-assessment data to make public health policy. For example, EPA uses high-dose animal studies and extrapolates these data to humans when assessing the hazardous, toxic, or carcinogenic characteristics of chemicals.[132] For public policy reasons, EPA chooses to rely upon conservative risk levels, which are unlikely to be exceeded. Therefore, it uses an individual with maximum exposures for seventy years as its model for assessment.[133] Hence, these risk assessments are not necessarily based upon realistic exposure models and do not necessarily establish probable risks, but rather indicate EPA's decision to make conservative

---

sodes of pesticide residue poisoning investigated in California between 1973-75 involved illegal workers. OCCUPATIONAL HEALTH SECTION & CTR. FOR HEALTH STATISTICS, STATE OF CAL. DEP'T OF HEALTH, OCCUPATIONAL DISEASE IN CALIFORNIA ATTRIBUTED TO PESTICIDES AND OTHER AGRICULTURAL CHEMICALS 1971-1973, at 9 (1976).

Further, medical personnel often have limited understanding of pesticide toxicity and its effects. Molly Joel Coye, *What Physicians Don't Know About Occupational Exposure to Pesticides*, *in* PESTICIDE EXPOSURE AND THE ROLE OF THE PHYSICIAN 3, 3 (Jennifer Curtis ed., 1986) [hereinafter PESTICIDE EXPOSURE]. Physicians have little training in recognizing nonacute pesticide poisonings. *Id.* Consequently, diagnosis of pesticide-induced illness is difficult, and even acute exposure poisonings may be misdiagnosed if the link to pesticide exposure is not made. *Id.*

125 Mobed et al., *supra* note 120, at 369. Difficulties in surveying occupational injury in migrant and seasonal farmworkers are numerous, including locating and identifying workers, gaining their cooperation after a long work day, and underreporting of symptoms. *Id.*

126 Blair, *supra* note 116, at 14.

127 *Id.* "Testing for reproductive, teratogenic and mutagenic effects [of pesticides] was not required until 1970." *Id.* (citing LAWRIE MOTT & M. BROAD, PESTICIDES IN FOOD: WHAT THE PUBLIC NEEDS TO KNOW (1984)).

128 7 U.S.C. §§ 136-136y (1994).

129 Blair, *supra* note 116, at 14.

130 CURTIS ET AL., *supra* note 120, at 38 (citing U.S. ENVTL. PROTECTION AGENCY, PESTICIDE REREGISTRATION PROGRESS REPORT 1, EPA 738-R-93-001 (1993)).

131 The *Daubert* Court recognized a similar issue when it alluded to the "important difference between the quest for truth in the courtroom and the quest for truth in the laboratory." Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 596-97 (1993).

132 Whitehead & Espel, *supra* note 1, at 532-34.

133 *Id.* at 533.

public policy choices.[134] The public seems to misinterpret these regulatory policy choices as scientifically valid evidence of a chemical's potent effects.[135]

In the pesticide exposure context, expert opinion regarding causal relationships will depend a great deal upon individual facts. Some generalizations, however, may be made about the admissibility of the various types of studies. Assuming valid methodology under the first prong of Rule 702, this paper will examine the admissibility and fit of studies that typically would be offered to prove individual causation in a pesticide exposure case involving a farmworker.

C. Epidemiological Studies

Case studies that reveal clusters of disease, where the incidence of disease is substantially higher than anticipated, readily capture the public's attention. These "cluster cases" raise suspicion and fear.[136] Notwithstanding any evidence supporting or negating a causal relationship, it seems to be human nature to believe that there is a cause and effect where there are clusters of illness.[137] Hence, epidemiological studies[138] and toxic tort cases[139] are often precipitated by these clusters. These clusters, however, rarely demonstrate evidence of health risks and rarely lead to any

---

[134] *Id.* at 534.

[135] The public seems to misinterpret these regulatory policy choices as scientifically valid evidence of a chemical's potent effects while, at the same time, distrusting agencies for making arbitrary decisions. *See, e.g.*, STEPHEN BREYER, BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION 49-51 (1993) (commenting that the public is unlikely to consider agency risk conclusions as a "combination of science, fact, value, and administration," and instead may "overemphasize a risk analysis's oversimplified 'bottom line' while nonetheless suspecting that something about it is arbitrary"); Adam M. Finkel, *A Second Opinion on an Environmental Misdiagnosis: The Risky Prescriptions of Breaking the Vicious Circle*, 3 N.Y.U. ENVTL. L.J. 295, 298 (1995) (noting that a certain portion of academia, industry, and print and electronic media argue that "risk assessment systematically overestimates the magnitude of environmental problems by using conservative measures of risk leading directly to over-regulation and fueling public paranoia").

[136] For example, between 1981-1984, children of farmworkers in a farmworker community in Fowler, California were diagnosed with leukemia at a rate 35 times higher than normal. Mary Cabrera, *Legal Remedies for Victims of Pesticide Exposure*, 1 KAN. J.L. & PUB. POL'Y 113, 114 (1991). It is understandable that such an extraordinarily high incidence of illness is cause for concern and would raise questions regarding potential causes.

[137] For example, an expert testified regarding the association between asbestos exposure and laryngeal cancer. Cantrell v. GAF Corp., 999 F.2d 1007, 1012 (6th Cir. 1993). He based his opinion on epidemiologic evidence and his observation that 3 workers out of 150 suffered laryngeal cancer, whereas the incidence of laryngeal cancer in the general population is 4 per 100,000 individuals per year. *Id.* at 1012-13. He stated: "'That by itself doesn't prove that something there is causing . . . the problem, but that kind of prevalence or incidence is very high . . . . One would want to look at more prevalent [sic] studies but, still . . . those are stark, striking contradictions.'" *Id.* at 1013.

[138] Mobed et al., *supra* note 120, at 372 (describing results of a general health screening project carried out on 1,717 children following observation of a cancer cluster in the farmworker community of McFarland, California). During the decade between 1975 and 1985, children in McFarland developed cancer at four times the expected rate. Cabrera, *supra* note 136, at 114.

[139] Whitehead & Espel, *supra* note 1, at 520.

ascertainable cause.[140] Experts may attempt to point to cancer clusters in agricultural or industrial communities to demonstrate suspected causal relationships between pesticide exposure and disease, but even drawing general causation inferences is difficult or impossible. Consequently, it is unlikely that courts will admit these studies under Rule 702 because it is difficult for an expert to draw inferences from studies that do not offer information on exposure or other possible causes for the individual facts of the plaintiff's case.

Epidemiological studies that consider occupational exposure among agricultural workers suggest a tentative correlation between pesticide exposure and cancer.[141] There are two primary types of epidemiological studies: cohort studies and case-control studies.[142] Both of these studies attempt to determine if there is an association between exposure to an agent and a disease.[143] Cohort studies use exposure to an agent as the independent variable.[144] In the pesticide exposure context, employment records provide a major source of information regarding exposure in a cohort.[145] The researcher identifies two groups: one that is exposed to the agent and one that is not exposed. Both groups are followed over time, and the proportion of those who develop the disease in each group is compared. Under this approach, statisticians would try to disprove the null hypothesis that there is no difference between the two groups.[146] Disproof of the null hypothesis involves a rejection of the assertion that the observed difference was attributable to random error and, subsequently, *may* support the theory that a greater proportion of those who have been exposed to the agent will develop the disease.[147] A strength of this study design is that the researcher can establish a temporal relationship between exposure and the onset of disease.[148] Weaknesses of this study design are that other factors may be responsible for the disease,[149] and that it is very difficult to conduct a long-term study on a migratory population.[150]

For example, cohort studies exist that demonstrate an association between pesticide exposures and cholinesterase depression among

---

[140] *Id.* at 521. Specifically, the evidence of causation is rarely strong enough to rule out the possibility that the cluster is simply a statistical fluctuation. *See also* Cabrera, *supra* note 136, at 114 (presenting a situation wherein cancer clusters admitted no conclusive proof of causation).

[141] CURTIS ET AL., *supra* note 120, at 9.

[142] Blair et al., *supra* note 118, at 39.

[143] Linda A. Bailey et al., *Reference Guide on Epidemiology*, *in* REFERENCE MANUAL, supra note 57, at 121, 134.

[144] *Id.*

[145] Blair et al., *supra* note 118, at 39.

[146] Bailey et al., *supra* note 143, at 152.

[147] *Id.*

[148] *Id.* at 135.

[149] *Id.*

[150] Mobed et al., *supra* note 120, at 369.

farmworkers.[151] Cholinesterase, a nervous system enzyme, is essential for proper nervous system function. Organophosphate pesticides inhibit cholinesterase, which allows the uninhibited accumulation of acetylcholine and subsequent interference with the neuromuscular junction.[152] This results in rapid twitching of certain muscles and can culminate in paralysis and death due to respiratory failure.[153] Cholinesterase depression is generally accepted as an indication of pesticide exposure.[154]

In general, testimony regarding these studies may be admissible under the second prong of Rule 702 if it is offered to prove pesticide exposure. It may even be admissible in demonstrating a connection between exposure and ensuing neurotoxic effects. Specifically, fit questions may arise regarding the expert's extrapolation from these studies to the plaintiff's case. In particular, the factors evaluated in the study, such as the level and duration of exposure, should be sufficiently similar to the plaintiff's case to enable an expert to draw a reasonable analogy that will survive the fitness test.

Case-control studies use disease as the independent variable.[155] The researcher begins with a case group that has the disease being studied and a control group that does not have the disease.[156] The researcher then compares past exposures and may find a higher proportion of past exposures among the case group.[157] Case-control studies can be accomplished more quickly and less expensively than cohort studies and may reveal weaker associations.[158] However, researchers are dependent upon past exposures, and faulty memories among the groups create a potential for biased data.[159]

Some completed case-control studies suggest a link between pesticides and herbicides and various cancers.[160] Testimony regarding these

---

[151] Stephen Ciesielski, Abstract, *Pesticide Exposures, Cholinesterase Depression, and Symptoms Among North Carolina Migrant Farmworkers*, 271 JAMA 1300F, 1300F (1994) (noting that farmworkers exhibit significantly lower cholinesterase levels than nonfarmworkers); C. Sagerser et al., *Occupational Pesticide Poisoning in Apple Orchards—Washington, 1993*, 42 MORBIDITY MORTALITY WKLY. REP. 993, 993 (1994) (noting that after an acute exposure episode, farmworkers demonstrated cholinesterase levels depressed by 25% to 97% below the lower limit of normal in 88% of cases).

[152] JOHN M. JOHNSON & GEORGE M. WARE, PESTICIDE LITIGATION MANUAL § 10.03[3][c], at 10-6 (1996).

[153] *Id.*

[154] Lisa Peck Lindelef, *California Farmworkers: Legal Remedies for Pesticide Exposure*, 7 STAN. ENVTL. L.J. 72, 78 (1987-88); Ciesielski, *supra* note 151 (farmworkers exhibiting significantly lower cholinesterase levels than nonfarmworkers); James B. Knaak & Barry W. Wilson, *Dermal Dose-Cholinesterase Response and Percutaneous Absorption Studies with Several Cholinesterase Inhibitors*, *in* DERMAL EXPOSURE RELATED TO PESTICIDE USE 63 (Richard C. Honeycutt et al. eds., 1985) [hereinafter DERMAL EXPOSURE].

[155] Bailey et al., *supra* note 143, at 134.

[156] *Id.*

[157] *Id.* at 136.

[158] *Id.*

[159] *Id. See also* Blair et al., *supra* note 118, at 41 (presenting differential recall as a serious problem).

[160] *See* Mary H. O'Brien, *Those "Swedish Studies" by Hardell: Phenoxy Herbicides, Chorophenols, and Cancer*, *in* PESTICIDE EXPOSURE, *supra* note 124, at 83, 83 (discussing

studies may warrant admissibility under the second prong of Rule 702 if there is a fit between the diagnostic criteria of these studies and data from the instant case. For example, the proffered studies should be based on groups of people who experienced occupational exposure to pesticides, rather than members of the general public with average pesticide exposure.[161] At the very least, the studies should involve the same types of pesticides involved in the exposure at issue. In general, the greater the number of correlative factors between the studies and the exposure, the easier it would be to demonstrate fit. Making a determination of fitness under Rule 702 requires a careful examination of the study's underlying factors, the facts at issue, and the expert's extrapolative step from the study to the plaintiff's case.[162]

D. Animal Studies

Because there are few epidemiological studies available, animal studies constitute the primary source of information regarding the carcinogenic, teratogenic, or other disease-inducing properties of pesticides.[163] In general, scientists expose animals to a toxic substance and extrapolate the observed results to human beings through a series of assumptions and mathematical models.[164] Debate over the utility of these studies in litiga-

---

soft-tissue sarcoma and malignant lymphoma among farmers and forestry workers); *see also* Levine, *supra* note 119, at 319 (discussing Swedish and similar studies at length); J. GORDON MILLICHAP, ENVIRONMENTAL POISONS IN OUR FOOD 189 (1983) (discussing the potential link between environmental poisons and Parkinson's disease); 1 COMMITTEE ON ENVTL. EPIDEMIOLOGY, NAT'L RESEARCH COUNCIL, ENVIRONMENTAL EPIDEMIOLOGY 207 (1991) (discussing the potential link between pesticides and non-Hodgkin's lymphoma and other cancers).

161 *In re* Paoli R.R. Yard PCB Litig., 35 F.3d 717, 778 (3d Cir. 1994) (admitting testimony regarding epidemiological studies), *cert. denied*, 115 S. Ct. 1253 (1995).

162 Realistically, however, finding such an ideal study is unlikely because of the general scarcity and narrow spectrum of epidemiological studies. This raises concerns regarding plaintiffs' abilities to bring "first case" suits where there is a paucity of evidence demonstrating fit. To remedy this situation, Michael Green advocates allowing plaintiffs to bring suit on the basis of *available evidence* where stronger evidence is lacking. Green, *supra* note 8, at 680. One court did just this when it allowed the plaintiff to rely upon a variety of literature and personal medical data to support his assertion that a combination of alcohol and acetaminophen damaged his liver. Benedi v. McNeil-P.P.C., Inc., 66 F.3d 1378, 1384 (4th Cir. 1995). The court noted an earlier case where it refused to let the defendant escape liability merely because the plaintiff lacked epidemiological evidence. *Id.* (citing City of Greenville v. W.R. Grace & Co., 827 F.2d 975, 980 n.2 (4th Cir. 1987)).

163 Examples of these studies include: Knaak & Wilson, *supra* note 154, at 63 (examining dermal toxicity of pesticides and behavior of pesticides in rats); G.J. Marco et al., *Radiotracer Approaches to Rodent Dermal Studies*, *in* DERMAL EXPOSURE, supra note 154, at 43 (giving approaches for determining potential dermal penetration and rate of excretion of pesticides in rodents); Robert B.L. Van Lier, *The Use of Monkey Percutaneous Absorption Studies*, *in* DERMAL EXPOSURE, supra note 154, at 81 (using absorption rate studies in rhesus monkeys to predict risk to humans). In addition, there are studies that link lawncare use of 2,4-D to increased cancer incidence in dogs. CURTIS ET AL., *supra* note 120, at 14.

164 Jack L. Landau & W. Hugh O'Riordan, *Of Mice and Men: The Admissibility of Animal Studies to Prove Causation in Toxic Tort Litigation*, 25 IDAHO L. REV. 521, 534 (1989). Three types of animal studies are commonly used to study the effects of toxic agents: the LD50 study (discussed *infra* note 170), the short-term toxicity study, and the chronic or long-term toxicity study. *Id.*

tion relates to the primary use of these studies to fulfill regulatory objectives of protecting the public from unknown risks, as opposed to demonstrating specific causation in toxic tort litigation.[165] Animal studies are often criticized for providing little reliable insight into human responses to toxic agents.[166] This criticism stems from variability in laboratory conditions,[167] the variety of responses observed within the same[168] and different[169] species of animals, the administration of extremely high doses,[170] the inherently arbitrary selection of low-dose extrapolation models,[171] and the unreliability of interspecies extrapolation.[172]

This approach, however, which extrapolates from high-dose levels in animal studies to more acceptable levels for humans, is being reconsidered. For example, EPA and the National Toxicology Program (NTP) have considered using low-dose chemical tests that will more accurately reflect levels found in humans.[173] EPA has drafted guidelines for toxic chemical regulation that will require assessment of how a chemical's structure affects its toxicity and how toxic chemicals are absorbed, metabolized, and distributed in the body.[174] This data will be used to judge whether high-dose extrapolations provide a realistic indication of a chemical's low-dose risks.[175] Ultimately, this more detailed analysis may provide information concerning causal relationships. However, EPA's more detailed assessments may also further delay regulatory action.[176]

Until such data are available, however, Rule 702's fitness requirement may preclude admissibility of these studies as proof of a connection between pesticide exposure and disease. This determination, however, will depend upon the purpose in proffering such evidence. If animal studies are offered to prove actual causation in humans, it would be difficult to determine the fit of such a connection.[177] For example, it would be diffi-

---

165 JOHNSON & WARE, *supra* note 152, § 6.04, at 6-11 to 6-12.

166 *Id.* at 6-11.

167 Landau & O'Riordan, *supra* note 164, at 540. For example, the room temperature, noise, and overcrowding in different laboratories may influence testing conditions. *Id.*

168 For example, the Sherman strain of rats is particularly resistant to carcinogens and shows no carcinogenic effects at high doses. EARON S. DAVIS & VALERIE A. WILK, TOXIC CHEMICALS: THE INTERFACE BETWEEN LAW AND SCIENCE 38 (1982). In contrast, other strains of rats are less resistant and demonstrate a higher incidence of cancer. *Id.*

169 Landau & O'Riordan, *supra* note 164, at 543.

170 JOHNSON & WARE, *supra* note 152, § 6.04, at 6-11. For example, the lethal dose 50 (LD50) is used to determine the dose-response relationship for a compound and is defined as "the dose at which a compound kills 50% of laboratory animals within a period of a few days." Bernard D. Goldstein & Mary Sue Henifin, *Reference Guide on Toxicology*, *in* REFERENCE MANUAL, *supra* note 57, at 181, 188. This necessarily requires extremely high doses, higher than those to which humans are typically exposed. Landau & O'Riordan, *supra* note 164, at 535.

171 Landau & O'Riordan, *supra* note 164, at 546.

172 *Id.* at 543.

173 Richard Stone, *A Molecular Approach to Cancer Risk*, 268 SCIENCE 356 (1995).

174 *Id.*

175 *Id.*

176 *Id.*

177 *See, e.g.*, Joiner v. General Elec. Co., 78 F.3d 524, 538-39 (11th Cir. 1996) (Smith, J., dissenting) (citing fitness and reliability studies in admitting animal studies).

cult to demonstrate sufficient fit between a rat developing cancer after a lifetime of high doses and a human developing cancer at much lower doses. This indicates a lack of fit between both the species involved and the doses experienced.[178] Hence, animal studies should be excluded under Rule 702 when they are offered for purposes for which they were not designed.

Nonetheless, animal studies may be admissible if they are offered to support "sound and generally accepted propositions," such as acute poisoning episodes, general carcinogenicity of pesticides, or disease mechanisms.[179] For example, the high doses given to laboratory animals may be analogous to a dose experienced in an acute pesticide poisoning event. Further, a study may be offered to demonstrate the general carcinogenicity of certain pesticides, rather than demonstrating specific causation. Finally, animal studies may demonstrate the mechanism of disease—where a disease attacks or the mode of action[180] a pesticide uses—if human and animal physiology are sufficiently analogous. Knowledge of the mode of action is useful in determining whether alleged effects of a pesticide can logically be attributed to a pesticide, thus indicating the feasibility of occurrence.[181] Despite the acknowledged controversy over the fit of animal studies to proof of causation in humans, at the very least, animal studies may provide assistance in eliminating from consideration chemicals that do not cause disease in humans.[182]

---

[178] Similarly, in the *Agent Orange* case, Judge Weinstein found that animal studies were not helpful because the studies involved different biological species and there was no evidence that the plaintiffs were exposed to the high doses used in laboratory experiments. *In re* Agent Orange Prod. Liab. Litig., 611 F. Supp. 1223, 1241 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987). *See* Christopher L. Callahan, *Establishment of Causation in Toxic Tort Litigation*, 23 ARIZ. ST. L.J. 605, 640 (1991) (stating that "[a]nimal studies have not been well received by the judiciary"). However, some courts have admitted animal studies. *See, e.g.*, Shirkey v. Eli Lilly & Co., 852 F.2d 227, 237 (7th Cir. 1988); Wells by Maihafer v. Ortho Pharm. Corp., 615 F. Supp. 262, 266, 282 (N.D. Ga. 1985); *In re* Richardson-Merrell, Inc. Bendectin Prods. Liab. Litig., 624 F. Supp. 1212, 1237 (S.D. Ohio 1985); United States v. Vertac Chemical Corp., 489 F. Supp. 870, 881 (E.D. Ark. 1980); McEwen v. Ortho Pharm. Corp., 528 P.2d 522, 531 (Or. 1974).

[179] JOHNSON & WARE, *supra* note 152, § 6.04, at 6-13. *See also* Villari v. Terminix Int'l, Inc., 692 F. Supp. 568, 570, 572 (E.D. Pa. 1988) (holding that the probative value of the results of animal studies to predict the carcinogenicity of termiticides in humans was not substantially outweighed by their potential prejudice).

[180] "[M]ode of action comprises the sum of anatomical, physiological, and biochemical responses that make up the total toxic action of a chemical, as well as the physical (location) and molecular (degradation) fate of the chemical in the organism." JOHNSON & WARE, *supra* note 152, § 10.02, at 10-2. EPA requires detailed mode of action studies, which establish how a specific chemical affects the target organism, for the registration of pesticides. *Id.* Modes of action are largely unknown because many pesticides have not been reregistered. *Id.*

[181] *Id.* § 10.01, at 10-1.

[182] *In re* Paoli R.R. Yard PCB Litig., 35 F.3d 717, 781 (3d Cir. 1994) (allowing animal studies as proof of harmful effects of PCBs), *cert. denied*, 115 S. Ct. 1253 (1995).

VI. CONCLUSION

An evaluation of the admissibility of novel scientific theories that lack general support in the scientific community requires common sense, attention to detail, and a commitment to the judge's gatekeeping role under Rule 702. Rule 702's fitness requirement is vulnerable to extremes of both cursory and overly stringent review. For example, review of the available case law reveals that some jurisdictions may subsume Rule 702's fitness requirement within the validity inquiry required under the first prong of Rule 702. In contrast, an overly rigorous application of the fitness test may result in a challenge to the expert's conclusions regarding external validity, contrary to *Daubert's* admonition that Rule 702's focus "must be solely on principles and methodology, not on the conclusions that they generate."[183] Further, there is the question of what will trigger judicial review under Rule 702.

Nonetheless, application of the fitness requirement is an important aspect of the balance between liberal admission of expert testimony and exclusion of contextually marginal scientific evidence. In addition to the implementation of Federal Rule of Civil Procedure 26, the judge's role as gatekeeper may be simplified by requiring a detailed proffer of the testimony. This proffer should demonstrate a logical progression in the expert's analysis that leads to the final step of extrapolating from studies to the facts in issue. Further, the factors relied upon in the expert's hypothesis should parallel the facts in the case, unless the differences can be explained using sound scientific practice. Finally, the judge should consider the interplay of Rule 702 with the other Rules of Evidence, such as Rule 403, which proscribes the use of evidence that may mislead the jury.

[183] Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 595 (1993).