United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued December 3, 1996 Decided January 21, 1997

No. 95-7241

DONALD RAYNOR, SR., ET AL., APPELLANT

v.

MERRELL PHARMACEUTICALS INC., APPELLEE

Appeal from the United States District Court
for the District of Columbia
(No. 83-cv03506)

Kenneth J. Chesebro argued the cause for appellant. With him on the brief was *Barry J. Nace*.

Walter A. Smith, Jr. argued the cause for appellee. With him on the brief was *Stephen G. Vaskovz*.

Before: SILBERMAN, WILLIAMS and GINSBURG, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* WILLIAMS.

WILLIAMS, *Circuit Judge*: This appeal arises out of a personal injury claim filed by Donald Raynor, Jr. and his parents against Merrell Pharmaceuticals, Inc., alleging that Merrell's anti-nausea drug, Bendectin, caused Raynor's birth defects. After a jury awarded $300,000 in compensatory damages, Merrell filed motions for judgment notwithstanding the verdict ("JNOV") and for a new trial. The district judge granted the former based upon our decision in *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988). On the first appeal of the judge's ruling, this court remanded to the district court for further consideration in light of the Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). *Griffin v. Richardson-Merrell, Inc.*, No. 93-7109, 1993 WL 483935 (D.C. Cir. Nov. 12, 1993) (per curiam). After analyzing the admissibility of plaintiffs' evidence using the *Daubert* factors, the district court confirmed its original judgment.

Rule 50

Plaintiffs argue that JNOV under Federal Rule of Civil Procedure 50 (currently titled a

"Judgment as a Matter of Law") is an improper remedy for evidentiary errors at trial. Rather, according to plaintiffs, the only appropriate remedy for errors in the admission of evidence is a motion for a new trial under Rule 59(a). On plaintiffs' view JNOV is reserved for cases where the evidence presented was of insufficient weight to raise an issue for the jury.

Although plaintiffs concede that they failed to raise this issue before the district court, they argue that our decision in *Richardson*, 857 F.2d at 823, made raising it futile. If this were the case, plaintiffs might conceivably benefit from the "supervening-decision doctrine," which allows us to consider issues not raised at trial where "the law was so well-settled at the time of trial that any attempt to challenge it would have appeared pointless," but where the law had changed in the appellant's favor between trial court's decision and appeal. *United States v. Washington*, 12 F.3d 1128, 1138-39 (D.C. Cir. 1994).

We assume arguendo that two post-*Richardson* circuit court decisions adopting the view that evidence may not be excluded on a JNOV motion, *Douglass v. Eaton Corp.*, 956 F.2d 1339, 1343-44 (6th Cir. 1992); *Jackson v. Pleasant Grove Health Care Center*, 980 F.2d 692, 695-96 (11th Cir. 1993), could be "supervening decisions" of sufficient magnitude to trigger the doctrine of that name.[1] But even with that assumption, *Richardson* fails to establish the sort of circuit rule required by *Washington*, i.e., one that would render "pointless" an objection to resting JNOV on an exclusion of evidence previously admitted. In fact, the *Richardson* court simply did not address the issue.

To be sure, the *Richardson* court upheld the grant of a JNOV motion in a case factually similar to this one, and the opinion, although it discusses the evidence's sufficiency, clearly rests on its inadmissibility. *Richardson*, 857 F.2d at 825 n.9. As plaintiffs acknowledge, however, the issue

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[1]Plaintiffs attempt to have their cake and eat it too. On the one hand, they claim that the novelty of decisions limiting the district court's use of the JNOV justifies their failure to object. On the other, in their attempt to convince us to adopt the rule barring the use of JNOV for admissibility errors, they claim that the restrictive rule belongs to "[a] virtually unbroken string of federal appellate court decisions" since 1940.

We note that in order for a decision to qualify as supervening it must be decided after plaintiff's chance to raise the issue in the district court. In fact the district court granted the motion for a JNOV on April 13, 1993, well after both *Douglas* and *Jackson*, the later of which was decided January 4, 1993.

of whether JNOV can be granted to redress errors of admissibility "was neither briefed ... nor discussed, in *Richardson*." Rep. Br. at 3, quoting Appellants' Memorandum in Opposition to Motion for Summary Affirmance. Although the *Richardson* court upheld the JNOV motion, it neither considered, nor had implicitly to resolve, the question of whether such a motion was appropriate for admissibility errors. It therefore provides no holding on this question, and cannot justify plaintiffs' failure to object at trial. Thus they have waived their Rule 50 argument.

Of course, if *Richardson* did create binding law establishing the propriety of JNOV for admissibility errors, this panel would be bound by that precedent, despite the two intervening circuit court decisions that back plaintiffs' position. Moreover, the rule rejecting resolution of an evidentiary issue on a motion for JNOV rests on imputed reliance; if the evidence had been excluded in the course of trial, the offering party might have offered a substitute. See *Jackson*, 980 F.2d at 696. Plaintiffs' failure to object strongly suggests the absence of any such reliance.

Daubert

Plaintiffs argue that the district court inappropriately deemed their expert testimony inadmissible. We review the district court's judgment for abuse of discretion. *Joy v. Bell Helicopter Textron, Inc.*, 999 F.2d 549, 567 (D.C. Cir. 1993) (district court has broad discretion regarding the admission or exclusion of expert testimony under Rule 702); see also *Lust v. Merrell Dow Pharmaceuticals, Inc.*, 89 F.3d 594, 596-97 (9th Cir. 1996) (abuse of discretion review applies to F.R.E. 702 ruling); *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 318 (7th Cir. 1996) (same).

In *Richardson* this court held that similar evidence was inadmissible:

> These three types of studies then—chemical, *in vitro*, and *in vivo*—cannot furnish a sufficient foundation for a conclusion that Bendectin caused the birth defects at issue in this case. Studies of this kind, singly or in combination, are not capable of proving causation in human beings in the face of the overwhelming body of contradictory epidemiological evidence.

857 F.2d at 830. *Richardson* was decided under Federal Rule of Evidence 703, which provides an exception to the hearsay rule for the facts and data underlying expert testimony:

> If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

In reliance on *Richardson*, the district court initially found plaintiffs' evidence inadmissible under Rule 703. If we were to consider this case under Rule 703, nothing would compel us to deviate from our holding in *Richardson*. Plaintiffs make much of *Ambrosini v. Labarraque*, 966 F.2d 1464, 1468 (D.C. Cir. 1992) ("*Ambrosini I*"), in which we distinguished *Richardson* in part on the ground that the expert in that case had conceded that the data was not the type upon which an expert would reasonably rely. See also *Ambrosini v. Labarraque*, 101 F.3d 129, 138 (D.C. Cir. 1996) (citing expert's concession as one distinguishing factor) ("*Ambrosini II*"). But the more critical distinction in *Ambrosini* was that whereas Bendectin had "been extensively studied and a wealth of published epidemiological data ha[d] been amassed, none of which has concluded that the drug is teratogenic," *id*. at 138 (quoting *Richardson*), the drug in question in *Ambrosini*, Depo- Provera, had not been the subject of such a wealth of studies. Plaintiffs ask us to distinguish *Richardson* and apply the two *Ambrosini* cases, pointing to the assertions of their expert (Dr. Thoman) that, contrary to the scientists whose work this court found dispositive in *Richardson*, see 857 F.2d at 831 (noting that no published work found statistically significant association between Bendectin and birth defects), it was reasonable to form an opinion as to causation without data statistically significant at the 95% confidence level. But nothing in the *Ambrosini* cases suggests that one expert's conclusory assertion of some lower threshold of statistical significance could undercut the force of the Bendectin studies found controlling in *Richardson*. See *In re Paoli Railroad Yd. PCB Litigation*, 35 F.3d 717, 748 (3d Cir. 1994) (judge must make independent inquiry regarding reasonableness of reliance).

Plaintiffs argue, however, that our Rule 703 holding has no force in light of the Supreme Court's decision in *Daubert*. While *Daubert* creates no obvious bar to applying Rule 703 as we have done in the past, it leaves obscure the relation between that rule and the rule at issue in *Daubert*, Rule 702, which states that an expert may testify if the "scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue." The *Daubert* Court found Rule 702 the "primary locus" of the district court's obligation to screen scientific evidence presented by expert testimony, 509 U.S. at 589, but also instructed the judge to "be mindful of other applicable rules" such as Rule 703, *id*. at 595. Courts have begun to explore the relationship

between Rules 702 and 703 following *Daubert*. See, e.g., *In re Paoli*, 35 F.3d at 748 (holding that Rule 703 is the equivalent to Rule 702's reliability requirement). We need not do so, however, because we find that plaintiffs' evidence is inadmissible under Rule 702.

The Court in *Daubert* directed federal courts first to determine whether the proffered expert's evidence is "scientific knowledge," which it said required consideration of the following: (1) whether the theory or technique can be (or has been) tested; (2) whether the theory or technique has been subject to peer review and publication; (3) the known or potential rate of error of the methodology; and (4) the general acceptance of the methodology. 509 U.S. at 593-95. In addition, the court must conclude that the expert testimony will "assist the trier of fact to understand or determine a fact in issue." *Id*. at 592.

Plaintiffs contend that the district court erroneously applied the principles of *Daubert* by focusing on the conclusions of their experts rather than on the methodology. They are correct that the Supreme Court stated that the inquiry should "focus ... solely on principles and methodology, not on the conclusions that they generate." *Id*. at 595. The line is not all that clear, as propositions may be formulated as conclusions or methodologies with comparatively minor linguistic adjustment. Here, however, the primary question can properly be formulated as whether it is methodologically sound to draw an inference that a drug causes human birth defects from chemical structure, *in vivo* animal studies, and *in vitro* studies, when epidemiological evidence is to the contrary. The secondary question is whether one expert's "differential diagnosis," which apparently seeks to determine cause by process of elimination, is methodologically sound in this context.

None of the plaintiffs' experts had published their conclusions regarding Bendectin, nor had their work been subject to peer review (factor # 2). See *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) (noting that this factor may be particularly important where conclusions have been drawn solely for purpose of litigation: "a scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office"); cf. *Ambrosini II*, 101 F.3d at 139 (noting concern about risk of "gun for hire" testimony).

The experts' methodology also suffers from "testing" problems (factor # 1). The only way

to test whether data from non-human studies can be extrapolated to humans would be to conduct human experiments or to use epidemiological data. In fact, the experts' conclusions have been tested by the latter method and have been found wanting. We do not believe that when the *Daubert* opinion directed courts to consider whether the "theory or technique ... can be (and has been) tested," 509 U.S. at 593, it meant that a "theory or technique" that has been *contradicted* is on that account *more* likely to qualify as "scientific knowledge." Rather the reverse.

Similarly, where sound epidemiological studies produce opposite results from nonepidemiological ones, the rate of error of the latter is likely to be quite high (factor # 3). Of course epidemiological evidence does not always trump the nonepidemiological. Here, however, plaintiffs make no serious argument that the epidemiological sample sizes have been too small to detect the relationship between Bendectin and birth defects, a relationship that has been studied for hundreds of thousands of subjects.

In addition to the *in vivo*, *in vitro*, and chemical data, plaintiffs put forth an expert, Dr. Thoman, who conducted a methodology called "differential diagnosis," an approach presumably designed to eliminate other possible causes of Raynor's birth defect. Based upon this analysis, Dr. Thoman points to Bendectin as the cause. He relied upon family history, parental background, genetic history, physical examination, pregnancy history, and toxicology. Nonetheless, Dr. Thoman provided "no tested or testable theory to explain how, from this limited information, he was able to eliminate all other potential causes of birth defects."[2] *Daubert*, 43 F.3d at 1319. Although we found testimony ruling out alternative causes admissible in *Ambrosini II*, 101 F.3d at 139-40, that testimony on specific causation had legitimacy only as follow-up to admissible evidence that the drug in question *could* in general cause birth defects. That first step, establishing a link between Bendectin and human birth defects (general causation), is missing here. In addition, while the *Ambrosini* expert evidently was able to show the implausibility of all but a few other possible causes, see *id*. at 140, Dr. Thoman,

[2]Of course, an expert testifying simply that Bendectin was more likely than not the cause of the birth defects would not have to completely "eliminate" every other possibility, no matter how small. Dr. Thoman's purported elimination of alternative explanations was, however, exceedingly vague, amounting to little more than a reference to "family history," examination of the child, "any laboratory tests," and "genetic studies." App. 47.

whose methodology remains obscure, failed to offer any comprehensive understanding of the etiology of birth defects.

Nor can plaintiffs' methodology be said to enjoy "general acceptance" (factor # 4). Here, we reiterate our holding in *Richardson*: "Studies of this kind, singly or in combination, are not capable of proving causation in human beings in the face of the overwhelming body of contradictory epidemiological evidence." 857 F.2d at 830; see also *Ealy v. Richardson-Merrell, Inc.*, 897 F.2d 1159, 1161-63 (D.C. Cir. 1990); cf. *Ambrosini II*, 101 F.3d at 138 (distinguishing *Richardson* based on lack of overwhelming body of contradictory epidemiological evidence). Plaintiffs have provided no convincing argument that the medical profession disagrees. Thus we find that the district court correctly applied the *Daubert* test.

Finally, we note that even if the expert testimony were admissible under *Daubert*, it is unlikely that a jury could reasonably find it sufficient to show causation. The question of sufficiency would be a substantive rule under *Erie Railroad Co. v. Tompkins*, 304 U.S. 64 (1938), and therefore governed by District of Columbia law.[3] Our past Bendectin decisions have not classified plaintiffs' evidence similar to that presented here as insufficient as a matter of law, having noted the District of Columbia's decision in *Oxendine v. Merrell Dow Pharmaceuticals, Inc.*, 506 A.2d 1100 (D.C. 1986) ("*Oxendine I*"), which reinstated a jury verdict on the ground that the totality of evidence was enough for the jury to find a causal link between Bendectin and birth defects. See *Richardson*, 857 F.2d at 825 n.9; *Ealy*, 897 F.2d at 1163. In *Ealy*, however, we said that *Oxendine I* was not likely to be "directly exportable" to cases taking into account the additional epidemiological evidence available since that decision. *Id*. We believe this conclusion even more true today than in 1990 when we originally suggested it. On the most recent remand in the *Oxendine* litigation, *Oxendine v. Merrell Dow Pharmaceuticals Inc.*, No. 82-1245, 1996 WL 680992 (D.C. Super. Oct. 24, 1996), the trial court (although ultimately holding for defendants on admissibility rather than sufficiency grounds)

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[3]Plaintiffs argue that the appropriate substantive law is that of the District of Columbia, a premise that appears undisputed by defendants, at least so far as the record before us demonstrates. See *Raynor v. Richardson-Merrell, Inc.*, No. 83-3506, 1993 WL 484200, *3 n.3 (D.D.C. 1993). Thus, we proceed on this assumption.

provided an 82-page survey of Bendectin research, and concluded that Merrell had "established, by clear and convincing evidence, that post-1983 evidence makes it clear that Bendectin is not a human teratogen and that "all responsible scientific thought' agrees with this conclusion." *Id*. at *33. In addition, in Bendectin cases after *Oxendine I* several circuits have held that, as a matter of law, plaintiffs' expert testimony was insufficient to prove causation. See, e.g., *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, 311-15 (5th Cir. 1989) (lack of epidemiological proof fatal, particularly where only other evidence is animal studies); *Lynch v. Merrell-Nat'l Labs*, 830 F.2d 1190, 1195-97 (1st Cir. 1987) (analysis of chemical structure and effect on animals incapable of proving causation in human beings in the absence of any confirmatory epidemiological data); but see *DeLuca v. Merrell Dow Pharmaceutical, Inc.*, 911 F.2d 941 (3rd Cir. 1990) (reversing summary judgment in favor of pharmaceutical company and remanding for analysis of evidence by district court under Rule 702 without commenting on the sufficiency of that evidence).

Because the district court was within its discretion in finding the plaintiffs' expert evidence inadmissible under Rule 702, the judgment is

Affirmed.