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Aimee Freeman, appellant, v. Hoffman-La Roche, Inc., and Roche Laboratories, Inc., appellees.

911 N.W.2d 591

Filed May 18, 2018. No. S-17-800.

1. **Trial: Expert Witnesses: Appeal and Error.** An appellate court reviews de novo whether the trial court applied the correct legal standards for admitting an expert's testimony.
2. ____: ____: ____. When the trial court has not abdicated its gatekeeping function under *Schafersman v. Agland Coop*, 262 Neb. 215, 631 N.W.2d 862 (2001), an appellate court reviews the trial court's decision to admit or exclude the evidence for an abuse of discretion.
3. **Judgments: Words and Phrases.** An abuse of discretion occurs when a trial court's decision is based upon reasons that are untenable or unreasonable or if its action is clearly against justice or conscience, reason, and evidence.
4. **Summary Judgment: Appeal and Error.** An appellate court will affirm a lower court's grant of summary judgment if the pleadings and admitted evidence show that there is no genuine issue as to any material facts or as to the ultimate inferences that may be drawn from those facts and that the moving party is entitled to judgment as a matter of law.
5. **Trial: Expert Witnesses.** Under the framework established by *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993), and *Schafersman v. Agland Coop*, 262 Neb. 215, 631 N.W.2d 862 (2001), if an expert's opinion involves scientific or specialized knowledge, a trial court must determine whether the reasoning or methodology underlying the testimony is valid (reliable). It must also determine whether that reasoning or methodology can be properly applied to the facts in issue.
6. ____: ____. A trial court can consider several nonexclusive factors in determining the reliability of an expert's opinion: (1) whether a theory

or technique can be (and has been) tested; (2) whether it has been subjected to peer review and publication; (3) whether, in respect to a particular technique, there is a high known or potential rate of error; (4) whether there are standards controlling the technique's operation; and (5) whether the theory or technique enjoys general acceptance within a relevant scientific community.

7. **Expert Witnesses.** Absent evidence that an expert's testimony grows out of the expert's own prelitigation research or that an expert's research has been subjected to peer review, experts must show that they reached their opinions by following an accepted method or procedure as it is practiced by others in their field.
8. **Courts: Expert Witnesses.** The objective of the trial court's gatekeeping responsibility is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.
9. **Evidence: Proof.** Failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial.

Appeal from the District Court for Douglas County: Leigh Ann Retelsdorf, Judge. Affirmed.

Jeffrey A. Silver, and Walter G. Campbell, Jr., and Noreek Davitian, of Krupnick, Campbell, Malone, Buser, Slama, Hancock & Liberman, P.A., and Michael D. Hook, of Hook, Bolton, Mitchell, Kirkland & McGhee, P.A., for appellant.

Jill Vinjamuri Gettman, of Gettman & Mills, L.L.P., Michael X. Imbroscio and Paul W. Schmidt, of Covington & Burling, L.L.P., and Colleen M. Hennessey, of Peabody & Arnold, L.L.P., for appellees.

Heavican, C.J., Miller-Lerman, Cassel, Stacy, and Funke, JJ., and Riedmann, Judge, and Martinez, District Judge.

Cassel, J.

I. INTRODUCTION

In this product liability action, the district court excluded the claimant's expert's testimony regarding causation. Summary judgment for the manufacturer and distributor followed. On

appeal, the claimant asserts that the exclusion exceeded the court's "gatekeeping" function. Because the record supports the court's conclusion that the expert's methodology was unreliable and conclusion-driven, we find no abuse of discretion in the exclusion and affirm the judgment.

II. BACKGROUND

Aimee Freeman brought a product liability action against Hoffman-La Roche, Inc., and Roche Laboratories, Inc. (collectively Roche), alleging that she developed a chronic medical condition and other side effects as a result of ingesting Accutane. Accutane, also known as isotretinoin, is a pharmaceutical drug manufactured and distributed by Roche for the treatment of chronic acne.

Freeman initially alleged that she suffered from ulcerative colitis—a type of inflammatory bowel disease (IBD)—which is a chronic condition characterized by ulceration of the colon and rectum. However, the expert witnesses generally agreed that Freeman had actually developed Crohn's disease—another type of IBD—which causes chronic inflammation and ulcers in any part of the gastrointestinal tract and tends to extend beyond and penetrate all layers of the gastrointestinal tract wall. Both ulcerative colitis and Crohn's disease share many of the same symptoms. But, as Freeman acknowledges, "there are differences in the clinical presentation of the disease[s] and the triggers statistically associated for developing [them]."[1]

As a material element for her product liability claims, Freeman was required to prove her injury was proximately caused by Roche's actions or inactions in manufacturing and distributing isotretinoin.[2] In other words, she had to show that ingesting isotretinoin could cause the development of Crohn's

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[1] Brief for appellant at 6.

[2] See, *Freeman v. Hoffman-La Roche, Inc.*, 260 Neb. 552, 618 N.W.2d 827 (2000); *King v. Burlington Northern Santa Fe Ry. Co.*, 277 Neb. 203, 762 N.W.2d 24 (2009).

disease and that her ingestion of isotretinoin did in fact cause her to develop the disease.[3] In order to meet this burden of proof, Freeman intended to call Dr. David B. Sachar as an expert witness to render opinions on the general and specific causation of her Crohn's disease.

Before trial, Roche filed a motion in limine seeking to preclude Sachar's testimony and challenged his opinions under the *Daubert*/*Schafersman* framework.[4] They did not suggest that Sachar was unqualified to testify as an expert; rather, they alleged that his opinions on causation were not based upon a properly applied and reliable methodology.

After conducting a *Daubert*/*Schafersman* hearing, the district court entered a 42-page order precluding Sachar from testifying. In its order, the court summarized the admitted evidence as well as the conclusions derived from the evidence. It also highlighted the key testimony of each of the experts concerning the evidence presented. In reviewing Sachar's analysis of and reliance on the different types of evidence, the court found Sachar's methodology was unreliable due to his inconsistent approach criticizing studies adverse to his theory. It further found that his "unabashedly cherry-pick[ing] supporting studies from an overwhelming contrary body of literature indicated, in no uncertain terms, his methodology was conclusion-driven." Additional facts and findings from the hearing and order are set forth in our analysis below.

After the court sustained the motion in limine, Roche filed a motion for summary judgment. The district court found that with the exclusion of Sachar's testimony, Freeman had no admissible expert evidence to establish a causal association between Accutane and IBD. Because Freeman could not

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[3] See *King v. Burlington Northern Santa Fe Ry. Co., supra* note 2.

[4] See, *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993); *Schafersman v. Agland Coop*, 262 Neb. 215, 631 N.W.2d 862 (2001).

raise a genuine dispute of material fact on causation without expert testimony, the court granted the motion for summary judgment.

Freeman timely appealed.

III. ASSIGNMENTS OF ERROR

Freeman assigns, restated and combined, that the district court erred in (1) concluding that her expert witness' opinions were not based upon valid reasoning or methodology; (2) precluding the testimony of her expert witness; and (3) granting summary judgment in favor of Roche on the issue of general causation when her expert witness' testimony, if allowed into evidence, would create an issue of fact on that issue.

IV. STANDARD OF REVIEW

[1-3] An appellate court reviews de novo whether the trial court applied the correct legal standards for admitting an expert's testimony.[5] When the trial court has not abdicated its *Schafersman*[6] gatekeeping function, an appellate court reviews the trial court's decision to limit or exclude the evidence for an abuse of discretion.[7] An abuse of discretion occurs when a trial court's decision is based upon reasons that are untenable or unreasonable or if its action is clearly against justice or conscience, reason, and evidence.[8]

[4] An appellate court will affirm a lower court's grant of summary judgment if the pleadings and admitted evidence show that there is no genuine issue as to any material facts or as to the ultimate inferences that may be drawn from those facts and that the moving party is entitled to judgment as a matter of law.[9]

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[5] *King v. Burlington Northern Santa Fe Ry. Co., supra* note 2.

[6] *Schafersman v. Agland Coop, supra* note 4.

[7] *Hemsley v. Langdon*, 299 Neb. 464, 909 N.W.2d 59 (2018).

[8] *Putnam v. Scherbring*, 297 Neb. 868, 902 N.W.2d 140 (2017).

[9] *Edwards v. Hy-Vee*, 294 Neb. 237, 883 N.W.2d 40 (2016).

V. ANALYSIS

1. Exclusion of Expert Testimony

Freeman argues that the district court deviated from its proper gatekeeping function and improperly determined the weight and credibility of Sachar's testimony. She does not contend that the court abdicated its role,[10] but, rather, that it required too much.[11] She suggests that Sachar's opinions were based on good grounds and should have been admitted to be evaluated by a jury. We disagree.

[5] Under our *Daubert*/*Schafersman* framework, if an expert's opinion involves scientific or specialized knowledge, a trial court must determine whether the reasoning or methodology underlying the testimony is valid (reliable).[12] It must also determine whether that reasoning or methodology can be properly applied to the facts in issue.[13]

[6] A trial court can consider several nonexclusive factors in determining the reliability of an expert's opinion: (1) whether a theory or technique can be (and has been) tested; (2) whether it has been subjected to peer review and publication; (3) whether, in respect to a particular technique, there is a high known or potential rate of error; (4) whether there are standards controlling the technique's operation; and (5) whether the theory or technique enjoys general acceptance within a relevant scientific community.[14] But, as we have previously stated, different factors may prove more significant in different cases, and additional factors may prove relevant under particular circumstances.[15]

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[10] See *Hemsley v. Langdon, supra* note 7.

[11] See *King v. Burlington Northern Santa Fe Ry. Co., supra* note 2.

[12] *State v. Braesch*, 292 Neb. 930, 874 N.W.2d 874 (2016).

[13] *Id.*

[14] *Id.*

[15] See *Epp v. Lauby*, 271 Neb. 640, 715 N.W.2d 501 (2006).

(a) Accepted Methodology

[7] Absent evidence that an expert's testimony grows out of the expert's own prelitigation research or that an expert's research has been subjected to peer review, experts must show that they reached their opinions by following an accepted method or procedure as it is practiced by others in their field.[16]

In this case, Sachar acknowledged that he had not written or published his opinions concerning isotretinoin use and Crohn's disease—limited to the colon or as a whole—despite writing over 220 published papers on IBD and approximately 60 books or book chapters on gastroenterology. He reached his opinion by employing what we have characterized as a "weight-of-the-evidence methodology,"[17] by reviewing data from different scientific fields, including animal tests, case reports, and epidemiological studies.

We have already determined that the weight-of-the-evidence methodology is a generally accepted method of determining causation.[18] Therefore, the focus shifted to whether the method was reliably applied. We limit our discussion to the factors that help to inform this analysis.

(b) Consistent Standards

Sachar opined that isotretinoin use was "a risk factor for the onset, development, triggering, [and] exacerbation of ulcerative colitis." And although he recognized that no study specifically determined that the same could be said for Crohn's disease, he theorized that isotretinoin would also be a risk factor for Crohn's disease of the colon, which he suggested was the appropriate diagnosis for Freeman's condition.

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[16] *State v. Braesch, supra* note 12.

[17] See *King v. Burlington Northern Santa Fe Ry. Co., supra* note 2, 277 Neb. at 221, 762 N.W.2d at 39.

[18] See *id.*

In reaching this conclusion, Sachar discredited all but one of the epidemiological studies finding no significant relation between isotretinoin use and IBD, because they did not distinguish between IBD as a whole and ulcerative colitis and Crohn's disease. Similarly, he found those studies that reported no association between isotretinoin use and Crohn's disease "wastes everybody's time," because they did not separately consider the different manifestations of Crohn's disease. However, Sachar acknowledged that the scientific community has yet to agree that a distinction between the different manifestations of Crohn's disease is necessary when studying Crohn's disease as a whole. And although he admitted that Crohn's disease has a different clinical presentation and different causes than ulcerative colitis, Sachar relied on the one epidemiological study concerning ulcerative colitis as "the closest surrogate we have to Crohn's disease of the colon."

Based upon this reasoning, Sachar disregarded what the other two expert witnesses found to be the most probative evidence. And one of those experts testified that Sachar's reasons were not supported by the scientific community. Significantly, Sachar did not require the same narrow focus on Crohn's disease of the colon in data from other scientific sources. In fact, in reviewing case reports, Sachar relied upon case reports of Crohn's disease and did not limit his examination to only those cases where disease of the colon was specifically reported. This suggests that Sachar was unduly critical of the majority of the studies which were adverse to his theory. And as the district court noted, it indicates that his methodology was conclusion-driven.

[8] While other factors may also suggest that Sachar's methodology was unreliably applied, we need not address them. The objective of the trial court's gatekeeping responsibility is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the

courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.[19] Clearly, cherrypicking studies from an overwhelmingly contrary body of literature without valid, supporting reasons for why the other studies were disregarded does not meet the standard of intellectual rigor required of expert witnesses. Accordingly, we cannot find that the district court abused its discretion in excluding Sachar's testimony.

2. Summary Judgment

[9] Two principles of law control our review of the summary judgment that followed. For one of them, we recall the well-known standard applicable to summary judgments, which we already have stated above. The other is a corollary of the first: Failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial.[20]

Freeman was required to establish causation to prevail at trial. Without Sachar's expert testimony, she could not meet this burden of proof. At oral argument, Freeman's counsel seemed to suggest otherwise. Specifically, counsel stated, "Roche, in their internal documents, admits there's an association—a causal association. The document I'm referring to is signed off by their Global Head of Safety. . . . Their very label on this drug says Accutane is associated with inflammatory bowel disease." To the extent that these documents are included in our record, we find no admission of a causal association. In fact, the cited document mentioned only an association, not a causal association. Similarly, the label states merely that "Accutane has been temporally associated with inflammatory bowel disease." And an association does not necessarily equate to causation.

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[19] See *Schafersman v. Agland Coop, supra* note 4.

[20] *Roskop Dairy v. GEA Farm Tech.*, 292 Neb. 148, 871 N.W.2d 776 (2015).

Because there was no genuine issue of fact as to the element of causation, Roche was entitled to judgment as a matter of law.

VI. CONCLUSION

The district court did not abuse its discretion in excluding the expert testimony after finding that the expert's methodology was unreliable and conclusion-driven. With the exclusion of this expert testimony, there remained no issue of material fact. Consequently, the district court did not err in granting summary judgment in favor of Roche. We affirm.

Affirmed.