

United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 07-3350

Howard J. Polski; Sheryl L. Polski,	*
	*
Appellants,	*
	*
v.	* Appeal from the United States
	* District Court for the
	* District of Minnesota.
The Quigley Corporation,	*
	*
Appellees.	*

Submitted: May 14, 2008
Filed: August 13, 2008

Before WOLLMAN, MURPHY, and SMITH, Circuit Judges.

SMITH, Circuit Judge.

Howard and Sheryl Polski (collectively "the Polskis") brought suit against the Quigley Corporation ("Quigley"), alleging that they suffered severe and permanent impairment of their senses of taste and smell due to their use of Cold-Eeze, a nasal spray made and distributed by Quigley for the treatment of cold symptoms. The district court¹ granted Quigley's motion to exclude the opinion and testimony of the Polskis' sole causation expert. The court then granted Quigley's motion for summary

¹The Honorable Patrick J. Schiltz, United States District Judge for the District of Minnesota.

judgment. The Polskis appeal the court's decision excluding the expert testimony and the resulting summary judgment. We affirm.

I. *Background*

Because we are reviewing a grant of summary judgment, we describe the facts in the light most favorable to the Polskis, the nonmoving party. *Hervey v. County of Koochiching*, 527 F.3d 711, 715 (8th Cir. 2008). The Polskis, brother and sister, each used Cold-Eeze, as directed,² for several days in December 2003, to treat symptoms associated with the common cold. The Polskis each experienced a burning sensation in their nostrils and sneezing with each application of the spray. In mid-January 2004 they both realized that they had lost their sense of taste, after confiding to one another over a meal that they could not taste the food. In April 2004, the Polskis visited an otolaryngologist,³ who found no physical causes for their sensory loss.

The Polskis filed suit against Quigley, asserting claims for fraud, negligence, strict products liability, breach of express and implied warranties, and violations of Minn. Stat. Ann. § 325F.69, alleging that the use of Cold-Eeze caused their sensory loss. To prove that Cold-Eeze caused their impairments, which was essential for each

²The directions on the Cold-Eeze packaging, in relevant part, stated:

- Prime the pump by pumping several times into a clean tissue until COLD-EEZE® Nasal Spray dispenses
- Before use, blow your nose to clean your nostrils
- Insert the tip of the pump approximately 1/8" into one nostril and hold the other nostril closed
- Spray once into each nostril and inhale through the nose slowly and deeply
- Repeat every 2–4 hours at least six (6) times per day
- Continue use for an additional 48 hours after symptoms subside.

³An otolaryngologist is a doctor specializing in the diagnosis and treatment of disorders of the ear, nose, and throat.

of their claims, the Polskis offered the expert opinion of Dr. Bruce Jafek, M.D., a professor of otolaryngology at the University of Colorado School of Medicine. Dr. Jafek authored two reports in this case, one for each of the Polskis. In each report, Dr. Jafek opined that: (1) Cold-Eeze, when used as directed, comes into contact with the olfactory epithelium—the "smell tissue" located high inside the human nose; (2) the active ingredient in Cold-Eeze, zinc gluconate, is toxic to the olfactory epithelium; (3) Cold-Eeze, when used as directed, delivers a sufficient amount of zinc gluconate to the olfactory epithelium to damage the sense of smell; (4) the damage that the zinc gluconate in Cold-Eeze caused to the olfactory epithelium is permanent in some cases; and (5) the zinc gluconate in Cold-Eeze, and not something else, such as a virus, caused the Polskis to lose their sense of smell.

Quigley conceded that Dr. Jafek was qualified as a nasal health expert, but moved to exclude Dr. Jafek's testimony under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). In its motion, Quigley argued that Dr. Jafek's opinion was not based upon scientifically reliable evidence or testing but was merely an untested speculative theory. The district court agreed and struck Dr. Jafek's expert testimony. The court concluded that Dr. Jafek's causation opinion rested on the unproven premise that Cold-Eeze, when used as directed, comes into contact with the olfactory epithelium in humans. Consequently, his opinions were not sufficiently reliable to be admitted under Rule 702.

Because all of the Polski's claims required proof of causation and their causation evidence was based solely on Dr. Jafek's expert opinion, having concluded that Dr. Jafek's opinion was inadmissible, the court granted Quigley's motion for summary judgment. The Polskis now appeal, arguing that the district court erred in precluding Dr. Jafek's expert opinion.

II. Discussion

We review the district court's exclusion of expert testimony for an abuse of discretion. *Sappington v. Skyjack, Inc.*, 512 F.3d 440, 448 (8th Cir. 2008). Federal Rule of Evidence 702 provides:

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, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

When faced with a proffer of expert scientific testimony, the trial court must make "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93.

We recently explained Rule 702 and the *Daubert* standard, as follows:

The admissibility of expert testimony is governed by Federal Rule of Evidence 702; under Rule 702 the trial judge acts as a "gatekeeper" screening evidence for relevance and reliability. *Daubert*, 509 U.S. at 589, 113 S. Ct. 2786. "Rule 702 reflects an attempt to liberalize the rules governing the admission of expert testimony. The rule clearly is one of admissibility rather than exclusion." *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir. 2001) (internal quotations and citations omitted). "The exclusion of an expert's opinion is proper only if it is so fundamentally unsupported that it can offer no assistance to the jury." *Wood v. Minn. Mining & Mfg. Co.*, 112 F.3d 306, 309 (8th Cir. 1997) (internal quotations and citation omitted).

A district court should apply a three-part test when screening testimony under Rule 702.

First, evidence based on scientific, technical, or other specialized knowledge must be useful to the finder of fact in deciding the ultimate issue of fact. This is the basic rule of relevancy. Second, the proposed witness must be qualified to assist the finder of fact. Third, the proposed evidence must be reliable or trustworthy in an evidentiary sense, so that, if the finder of fact accepts it as true, it provides the assistance the finder of fact requires.

Lauzon, 270 F.3d at 686 (internal citations and quotations omitted).

In *Daubert*, the Supreme Court provided a non-exhaustive list of factors a district court should consider when performing its gatekeeper function, including,

1) whether the theory or technique can be (and has been) tested; 2) whether the theory or technique has been subjected to peer review and publication; 3) the known or potential rate of error; and 4) whether the theory has been generally accepted.

Lauzon, 270 F.3d at 686.

Subsequent cases have proposed additional factors, including, whether the expertise was developed for litigation or naturally flowed from the expert's research; whether the proposed expert ruled out other alternative explanations; and whether the proposed expert sufficiently connected the proposed testimony with the facts of the case. *Id.* at 686–87.

Sappington, 512 F.3d at 448–49.

In this case, the Polskis contend that the district court abused its discretion in excluding Dr. Jafek's expert testimony. They assert that the district court went beyond its "gatekeeping" duty and invaded the province of the jury by weighing the parties' disputed arguments of causation.

Quigley did not contest Dr. Jafek's qualifications to be an expert of otolaryngology, the anatomy of the nose, and the senses of taste and smell. Instead they challenged Dr. Jafek's opinion that Quigley's product, when used as directed, puts zinc gluconate on a person's olfactory epithelium. Based on his own knowledge and expertise, his research, the research of others, and his observation that Cold-Eeze delivers a straight line spray capable of traveling several feet, Dr. Jafek concluded that the Polski's use of Cold-Eeze caused their sensory loss. Dr. Jafek opined that the spray emitted from the Cold-Eeze bottle traveled into the nasal cavity and through the straight passageway to the olfactory epithelium, resulting in the zinc ions in the spray coming into direct contact with the olfactory epithelium of the user; Dr. Jafek's other conclusions all rely on the validity of this premise. Albeit conceivable that Quigley's spray bottle could expel some quantity of the medication the full distance in the nasal passage to the olfactory epithelium, Dr. Jafek never tested this theory—nor did anyone else.

The district court concluded that this untested theory was "not sufficiently reliable to be admitted under Rule 702." *Polski v. Quigley Corp.*, No. 04-4199, 2007 WL 2580550, at *5 (D. Minn. Sept. 5, 2007). After a thorough review, we find no abuse of discretion in the district court's decision to exclude Dr. Jafek's testimony.

Dr. Jafek's causation theory is based on his untested belief that Cold-Eeze, when used as directed, travels in a straight-line liquid movement capable of reaching the olfactory epithelium through the nasal passage, allowing the zinc ions in the drug to

come into contact with the difficult to access olfactory epithelium.⁴ The Polskis admit

⁴The same scientific research that Dr. Jafek primarily relies upon for the proposition that anosmia (the loss of smell) can result from zinc ions coming into direct contact with the olfactory epithelium, reached its conclusion after conducting an experiment in which a zinc-sulfate solution (not zinc-gluconate) was applied directly to the olfactory epithelium by inserting a long, needle-like sprayer "upward along the septum until definitely past the middle turbinate." Max M. Peet, Dean H. Echols, Harry J. Richter, *The Chemical Prophylaxis for Poliomyelitis: The Technic of Applying Zinc Sulfate Intranasally*, 108 JAMA 2184, 2186 (1937). An illustration within this journal article depicts such a sprayer carefully inserted high into the nose. *Id.* The researchers explained:

[I]n practically all instances the solution did not go above the middle turbinate if an ordinary atomizer was used with the tip of the spray introduced only slightly within the nostril. . . . It is evident that to be effective the spray must be directly applied to the olfactory area. We wish to especially emphasize this point. Ordinary spraying with the atomizer tip introduced below the middle turbinate will not suffice except in isolated instances.

Id.

Moreover, Dr. Jafek's own earlier writings discuss the difficulty in accessing the olfactory mucosa (epithelium) of the human nose:

[O]lfactory mucosa is almost anatomically inaccessible in living humans. It is sheltered, for good reason, as it contains naked nerve endings in direct contact with the outside world, which proximally communicate with the brain. To reach it, the biopsy instrument must pass approximately 7 cm deep into the nostril, the terminal portion blindly, into a 1.0 mm crevasse between the adjacent nasal bones (septum/perpendicular plate and superior turbinate of ethmoid). Direct visualization with even the smallest telescope (Machida, 1.5 mm) with coordinated biopsy is impossible.

Bruce W. Jafek, *Ultrastructure of Human Nasal Mucosa*, 98 Laryngoscope 1576,

that Dr. Jafek had not scientifically tested this theory. However, the Polskis assert that such testing could not ethically be conducted on live humans because research has shown that zinc may cause loss of smell and taste if it comes into contact with the olfactory epithelium. As the district court observed, however, Dr. Jafek's theory could have easily and ethically been tested by placing a substance with similar dispersal qualities to Cold-Eeze but lacking zinc or any other potential toxin into a Cold-Eeze bottle and administering the substance to participants as directed by Cold-Eeze's instructions. Following such an experiment, participants could be examined to determine whether the administered substance actually came into contact with the olfactory epithelium.

In short, we find no abuse of discretion in the district court's exclusion of Dr. Jafek's testimony. Dr. Jafek's causation theory relied on an unproven and indeed untested premise. The district court applied Rule 702 following *Daubert's* guidance, noting that "because Dr. Jafek's theory has not been tested *at all*, it has never been subjected to peer review and publication, nor has it been generally accepted in the scientific community, nor does it have a known or potential rate of error." *Polski*, 2007 WL 2580550, at *5. These are all valid considerations under *Daubert*.⁵

1576 (1983).

⁵In *Daubert*, the Supreme Court stated:

Ordinarily, a key question to be answered in determining whether a theory or technique is scientific knowledge that will assist the trier of fact will be whether it can be (and has been) tested. . . . Another pertinent consideration is whether the theory or technique has been subjected to peer review and publication. . . . Additionally, in the case of a particular scientific technique, the court ordinarily should consider the known or potential rate of error Finally, "general acceptance" can yet have a bearing on the inquiry.

Daubert, 509 U.S. at 593–94.

The Polskis had the burden of establishing, by a preponderance of the evidence, that Dr. Jafek's testimony was admissible under Rule 702. *Marmo v. Tyson Fresh Meats, Inc.* 457 F.3d 748, 757–58 (8th Cir. 2006) (citing *Daubert*, 509 U.S. at 589–90). This required sufficient proof that Dr. Jafek's testimony was "the product of reliable principles and methods," and that he "applied the principles and methods reliably to the facts of the case." Fed. R. Evid. 702. The district court explained that its decision "does not mean that Dr. Jafek's theory is necessarily *wrong*; it simply means that the theory meets none of the indicia of reliability identified in *Daubert* and therefore must be excluded." *Polski*, 2007 WL 2580550, at *5. The district court concluded that Dr. Jafek's testimony was not sufficiently reliable and too speculative to be presented to the jury. We do not consider this conclusion an abuse of discretion.⁶

As all of Dr. Jafek's other opinions relating to causation relied on his untested opinion that Cold-Eeze, when used as directed, comes into direct contact with the

⁶We note that Dr. Jafek's theory of causation offered in this case has been offered by plaintiffs in several other cases involving anosmia allegedly caused by the use of Zicam, another nasally-inhaled cold remedy containing zinc gluconate; in each of those cases, Dr. Jafek's testimony was excluded. *See Lusch v. Matrixx Initiatives, Inc.*, No. 05-292, 2007 WL 2816203 (D. Or. Sept. 25, 2007) (granting defendant's motions to exclude expert testimony and for summary judgment, ruling there was no reasonable scientific evidence supporting Dr. Jafek's theory); *O'Hanlon v. Matrixx Initiatives, Inc.*, No. 04-10391, 2007 WL 2446496 (C.D. Cal. Jan. 3, 2007); *Benkwith v. Matrixx Initiatives, Inc.*, 467 F. Supp. 2d 1316 (M.D. Ala. 2006) (same); *Hans v. Matrixx Initiatives, Inc.*, No. 04-540, 2006 WL 5229820 at *8 (W.D. Ky. Sept. 29, 2006) (excluding Dr. Jafek's expert testimony regarding Zicam's causation of anosmia because he "failed to show any of the steps which he says are necessary in order to cause permanent anosmia in a human" and therefore his testimony regarding the cause of plaintiff's anosmia "is unreliable and therefore inadmissible under Fed. R. Evid. 702"); *Sutherland v. Matrixx Initiatives, Inc.*, No. 04-0129, slip op. at *4–5 (N.D. Ala. Nov. 7, 2006) ("Despite this court's admiration for Dr. Jafek's professional accomplishments, it concludes that the methods and procedures he employed are not sufficiently reliable under *Daubert* and Rule 702 to allow him to share his opinions with a jury").

olfactory epithelium, the court excluded the remainder of Dr. Jafek's causation testimony. *Id.* at *6. Because the Polskis' claims required proof of causation and they relied solely on Dr. Jafek's testimony to establish such causation, once that evidence was excluded, the Polskis could not make a prima facie case. Thus, the district court's grant of summary judgment in favor of Quigley was proper.

III. *Conclusion*

Accordingly, we affirm the judgment of the district court.
