STATE OF MINNESOTA
IN COURT OF APPEALS
A08-1455

Patricia A. Zandi,
Appellant,

vs.

Wyeth a/k/a Wyeth, Inc. (f/k/a American Home Products Corporation), et al.,
Respondents,

Pfizer, Inc., et al.,
Respondents,

Barr Laboratories, Inc., et al.,
Respondents.

Filed July 21, 2009
Affirmed; motion denied
Larkin, Judge

Hennepin County District Court
File No. 27-CV-06-6744

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Considered and decided by Shumaker, Presiding Judge; Ross, Judge; and Larkin, Judge.

U N P U B L I S H E D O P I N I O N

LARKIN, Judge

Appellant sued several drug manufacturers after she was diagnosed with hormone-dependent breast cancer following years of hormone-replacement therapy. The district court awarded summary judgment to respondents Pfizer, Inc., Pharmacia & Upjohn Co., LLC, and Greenstone, Ltd. based on appellant's failure to raise a genuine issue of material fact regarding her claimed ingestion of drugs manufactured by these respondents. After holding that appellant's proffered specific-causation evidence does not satisfy the *Frye-Mack* standard and that appellant's experts are not qualified under Minn. R. Evid. 702, the district court awarded summary judgment to Wyeth, Inc. and Wyeth Pharmaceuticals, Inc. Because appellant failed to raise genuine issues of material fact related to elements of her claims, and because the district court properly applied the law and exercised its discretion, we affirm.

FACTS

Appellant Patricia A. Zandi commenced this action against respondent drug manufacturers Wyeth, Inc., Wyeth Pharmaceuticals, Inc., Pfizer, Inc., Pharmacia & Upjohn Company, LLC, Greenstone Ltd., Barr Laboratories, Inc., Barr Pharmaceuticals, Inc., and Duramed Pharmaceuticals, Inc. Zandi alleges that between approximately 1981

and 2001, she ingested hormone-replacement-therapy (HRT) drugs manufactured, designed, packaged, marketed, and distributed by respondents. In November 2001, Zandi was diagnosed with hormone-dependent breast cancer.[1] Zandi contends that respondents' HRT drugs caused her cancer. Zandi's claims included negligence, strict liability, breach of implied warranty, breach of express warranty, fraud, misrepresentation, and violation of the Minnesota fraudulent advertising act, the Minnesota Prevention of Consumer Fraud Act, and the Minnesota Uniform Deceptive Trade Practices Act.[2]

Zandi is a lifelong resident of New York. Her claims have no connection to Minnesota other than the lawsuit itself. She had never been to Minnesota prior to commencing this suit. All of her HRT and medical care occurred in New York. The parties agree that Zandi's claims are time-barred under New York's statute of limitations.

In September 2006, the district court granted a joint motion to dismiss Barr and Duramed from the action. Thereafter, all remaining respondents moved for summary judgment on the ground that Zandi's claims were time barred under New York's statute of limitations. The district court denied this motion based on its conclusion that Minnesota's statute of limitations governs Zandi's claims. In April 2007, Pfizer, Upjohn, and Greenstone moved for summary judgment, alleging that Zandi had produced no evidence that she had ingested drugs manufactured by them. The district court granted the motion, leaving only Wyeth and Wyeth Pharmaceuticals (Wyeth) as defendants.

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[1] Zandi assigns error to the district court's failure to distinguish between "breast cancer" in general and "hormone-dependent breast cancer." We recognize that Zandi's arguments concern hormone-dependent breast cancer.

[2] Zandi eventually withdrew her consumer protection claims.

In July 2007, Wyeth moved to exclude the testimony of Zandi's specific causation experts, Drs. Lester Layfield and Gail Bender, who opined that HRT is the most-likely cause of Zandi's breast cancer. The district court granted Wyeth's motion under the *Frye-Mack* standard and Minn. R. Evid. 702, concluding that:

> (i) neither Dr. Layfield nor Dr. Bender is 'qualified as an expert by knowledge, skill, experience, training, or education' to opine that [HRT] caused [Zandi's] breast cancer; (ii) the Doctors' opinions involve novel scientific theory, and [Zandi] has not established that the underlying scientific evidence is generally accepted in the relevant scientific community; and (iii) the opinions lack foundational reliability.

Wyeth then moved for summary judgment on the basis that Zandi had offered no evidence of specific causation. The district court granted Wyeth's motion, explaining that "[b]ecause [Zandi] has failed to present evidence that her breast cancer was causally connected to her [HRT drug] use, she has failed to provide evidence that [HRT] drugs were not safe, effective, fit and proper for their intended use."

Zandi requested leave to submit a motion for reconsideration of the district court's orders excluding the testimony of her specific causation experts and granting summary judgment for Wyeth. The district court authorized Zandi to file her motion and a ten-page brief. Zandi filed her motion, a brief, and an affidavit containing 15 new exhibits. The district court refused to consider the new exhibits and ultimately denied Zandi's motion for reconsideration. This appeal follows.

D E C I S I O N

I. Summary Judgment for Pfizer, Upjohn, and Greenstone

A motion for summary judgment shall be granted when the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that either party is entitled to a judgment as a matter of law." Minn. R. Civ. P. 56.03. "On an appeal from summary judgment, we ask two questions: (1) whether there are any genuine issues of material fact and (2) whether the [district] court[] erred in [its] application of the law." *State by Cooper v. French*, 460 N.W.2d 2, 4 (Minn. 1990). "[T]he reviewing court must view the evidence in the light most favorable to the party against whom judgment was granted." *Fabio v. Bellomo*, 504 N.W.2d 758, 761 (Minn. 1993).

> [T]here is no genuine issue of material fact for trial when the nonmoving party presents evidence which merely creates a metaphysical doubt as to a factual issue and which is not sufficiently probative with respect to an essential element of the nonmoving party's case to permit reasonable persons to draw different conclusions.

DLH, Inc. v. Russ, 566 N.W.2d 60, 71 (Minn. 1997). "[W]hen the nonmoving party bears the burden of proof on an element essential to the nonmoving party's case, the nonmoving party must make a showing sufficient to establish that essential element." *Id.*; *see also Schroeder v. St. Louis County*, 708 N.W.2d 497, 507 (Minn. 2006) (describing *substantial evidence* as "incorrect legal standard" and clarifying that "summary judgment is inappropriate if the nonmoving party has the burden of proof on

an issue and presents *sufficient evidence* to permit reasonable persons to draw different conclusions").

The district court determined, and the parties do not dispute, that New York substantive law applies to Zandi's claims. To succeed on her products-liability claim, Zandi must prove that she ingested HRT drugs manufactured or sold by respondents. *See, e.g., Healey v. Firestone Tire & Rubber Co.*, 663 N.E.2d 901, 902-03 (N.Y. 1996) (reversing the trial court and appellate division's determination that "the plaintiff had submitted sufficient circumstantial evidence to permit the inference that Firestone made the accident rim"). "[O]ne of the necessary elements plaintiff in a strict products liability cause of action must establish by competent proof is that it was the defendant who manufactured and placed in the stream of commerce the injury-causing defective product." *Id.* at 903 (citations omitted). A plaintiff may establish the identity of the manufacturer of a defective product by circumstantial evidence. *Id.* But "[t]he circumstantial evidence of identity of the manufacturer of a defective product causing personal injury must establish that it is reasonably probable, not merely possible or evenly balanced, that the defendant was the source of the offending product." *Id.* It is insufficient to show speculative or conjectural evidence of the manufacturer's identity. *Id.*

Pfizer manufactured and directly or indirectly sold HRT drugs, including Provera. Upjohn, a subsidiary of Pfizer, also manufactured and sold Provera. Greenstone manufactured and sold HRT drugs including a generic version of medroxyprogesterone acetate (MPA), the chemical name for Provera. Zandi asserts that she was prescribed and

then ingested HRT drugs manufactured by respondents Pfizer, Upjohn, and Greenstone, including Provera and the Greenstone-manufactured generic version of MPA. Respondents moved for summary judgment, arguing that Zandi failed to produce any evidence that she ingested Provera or a Greenstone-manufactured generic version of MPA.

The district court held that Zandi failed to establish a genuine issue of material fact regarding her alleged ingestion of HRT drugs manufactured by Pfizer, Upjohn, and Greenstone and granted summary judgment for these respondents. The district court concluded that it is undisputed that (1) "generic versions of the medication [MPA] were on the market at the time [Zandi] began taking medication"; (2) "the physicians who made the 'Provera' notations in the medical records testified that this word was meant to indicate the generic drug [MPA]"; and (3) "New York state law required pharmacies to fill prescriptions with the generic drug unless the prescribing physician had marked 'd.a.w.' on the prescription slip, which was not the case with any of the prescription slips offered into evidence by [Zandi]."[3]

Zandi does not dispute that generic versions of MPA were available on the market during the time she took HRT drugs. She does not dispute the fact that none of her proffered prescription slips contain the term "d.a.w." And Zandi acknowledges that New York law requires that a prescription be filled with a generic version of a prescribed medication when a generic version is available. But Zandi argues that an exception to

[3] The term "d.a.w." means "dispense as written," disallowing generic substitutions for brand-name prescription drugs. N.Y. Educ. Law § 6810(6)(a) (McKinney 2001).

this requirement creates uncertainty regarding whether she was always provided a generic substitute for Provera. The language Zandi relies upon for this proposition states:

> Notwithstanding any other provision of this section or any other law, when a generic drug is not available and the brand name drug originally prescribed is available and the pharmacist agrees to dispense the brand name product for a price that will not exceed the price that would have been charged for the generic substitute had it been available, substitution of a generic drug product will not be required.

N.Y. Educ. Law § 6810(6)(a).

This language provides an exception to the general requirement that pharmacists dispense a generic substitute for a prescribed medication. But Zandi carries the burden to prove she ingested Provera, and she offered no evidence that she received Provera manufactured by Pfizer or Upjohn instead of a generic substitute under this exception. At best, this statutory exception allows speculation that Zandi might have sometimes received Provera. Speculation is insufficient to create a genuine issue of material fact for trial. *Nicollet Restoration, Inc. v. City of St. Paul*, 533 N.W.2d 845, 848 (Minn. 1995).

Moreover, Zandi inappropriately attempts to shift the burden of proof to respondents, requiring Pfizer and Upjohn to demonstrate that Zandi did *not* ingest Provera, and requiring Greenstone to demonstrate that she did *not* ingest a Greenstone-manufactured generic substitute for MPA. "[W]hen the nonmoving party bears the burden of proof on an element essential to the nonmoving party's case, the nonmoving party must make a showing sufficient to establish that essential element." *DLH*, 566 N.W.2d at 71. Although Zandi presented evidence that she was prescribed Provera, she did not present admissible evidence indicating that she received and ingested Provera, or

a generic version of MPA manufactured by Greenstone. Zandi must establish that it is reasonably probable, not merely possible, that Pfizer, Upjohn, and Greenstone were the source of the HRT drugs that she ingested. *See, e.g.*, *Healey*, 663 N.E.2d at 903. Because Zandi failed to raise a genuine issue of material fact regarding whether she ingested HRT drugs manufactured and sold by Pfizer, Upjohn, and Greenstone, the district court did not err by granting summary judgment in favor of these respondents. Accordingly, we affirm summary judgment for Pfizer, Upjohn, and Greenstone. Because we affirm on this ground, we do not address respondents' alternative choice-of-law and statute-of-limitations argument.

II. Summary Judgment for Wyeth

Zandi offered the expert testimony of Drs. Layfield and Bender to prove that HRT drugs caused her breast cancer. The district court evaluated the proffered testimony under the *Frye-Mack* standard and the requirements of Minn. R. Evid. 702 and ruled that it was inadmissible. The district court then granted Wyeth's motion for summary judgment. Zandi challenges the district court's award of summary judgment based on the underlying evidentiary ruling.

The Frye-Mack Standard

Minnesota courts use the *Frye-Mack* standard to determine the admissibility of novel scientific evidence. *Goeb v. Tharaldson*, 615 N.W.2d 800, 814 (Minn. 2000). Under this two-pronged standard, the proponent of scientific evidence must establish that the scientific theory is generally accepted in the relevant medical or scientific community "and that the principles and methodology used are reliable." *McDonough v. Allina*

Health Sys., 685 N.W.2d 688, 694 (Minn. App. 2004). When novel scientific evidence is offered, (1) "the district court must determine whether it is generally accepted in the relevant scientific community"; (2) "the particular scientific evidence in each case must be shown to have foundational reliability"; and (3) "as with all testimony by experts, the evidence must satisfy the requirements of Minn. R. Evid. 402 and 702—be relevant, be given by a witness qualified as an expert, and be helpful to the trier of fact." *Goeb*, 615 N.W.2d at 814.

Whether a particular principle or technique is generally accepted in the relevant scientific community is a question of law that we review de novo. *Id.* at 815. But district court determinations regarding foundational reliability are reviewed under an abuse of discretion standard. *Id.*

Zandi's claims are based on the following two propositions: (1) it is generally accepted that HRT causes hormone-dependent breast cancer, and (2) there is a generally accepted method of diagnosing the cause of hormone-dependent breast cancer in an individual. The district court concluded that neither proposition meets the *Frye-Mack* standard. We do not review the district court's determination regarding Zandi's first proposition because even if the relevant scientific community generally accepts that HRT causes hormone-dependent breast cancer, Zandi fails to establish that the relevant scientific community generally agrees that there is a method of diagnosing the cause of breast cancer in a particular person.

The district court concluded that "[d]etermining the cause of cancer in an individual . . . is not a generally accepted practice in the scientific or medical

communities." Based on our review of the evidentiary record, we agree. Zandi's treating physician, Dr. Janet Sung, agreed that communicating to Zandi that HRT caused her breast cancer would be outside her area of expertise, and, even though Dr. Sung diagnoses breast cancer in many patients, to her knowledge, there is no known way for a physician to determine the cause of breast cancer in a specific patient. Dr. Sung's testimony is consistent with the testimony of Wyeth's expert, Dr. Todd Tuttle, Director of the Breast Cancer Center at the University of Minnesota. Dr. Tuttle stated that "[t]here is simply not enough information to know or determine what causes breast cancer."

Zandi's own expert, Dr. Layfield, admitted that he has never determined the cause of breast cancer in a particular individual and he knows of no medical professional in a clinical setting who determines the cause of breast cancer in a particular individual. Dr. Layfield's deposition indicates as much:

> Q: [T]here is no published protocol or methodology setting forth an accepted way of analyzing the cause of breast cancer in a particular[,] specific patient . . . .
> DR. LAYFIELD: Not that I'm aware of.

Dr. Bender likewise conceded that there is no known, accepted method of determining the cause of a particular individual's breast cancer. When asked whether there is any tested protocol or guideline that supports the reliability of the method that she has used to determine breast cancer causation, Dr. Bender responded, "I am not aware of anything."

Despite their concessions that there is not a generally accepted method to determine the cause of an individual's breast cancer, Drs. Layfield and Bender opined

that HRT was the likely cause of Zandi's breast cancer. They base their specific-causation opinions on epidemiological studies and differential diagnosis. Zandi stresses that it was appropriate for her specific-causation experts to rely on epidemiological studies. But epidemiological studies cannot establish the specific cause of an individual's cancer. Zandi acknowledges this in her brief, quoting the *Reference Guide on Epidemiology* as follows:

> Epidemiology is concerned with the incidence of disease in populations and does not address the question of cause of an individual's disease. This question, sometimes referred to as specific causation, is beyond the domain of the science of epidemiology. Epidemiology has its limits at the point where an inference is made that the relationship between an agent and a disease is causal (general causation) and where magnitude of excess risk attributed to the agent has been determined; that is, *epidemiology addresses whether an agent can cause disease, not whether an agent did cause a specific plaintiff's disease*.

Michael D. Green et al., *Reference Guide on Epidemiology*, *in Reference Manual on Scientific Evidence* 333, 381-82 (Fed. Jud. Ctr. 2d ed. 2000) (emphasis added).

Although it may be appropriate to rely on epidemiology studies to demonstrate a correlation between HRT and hormone-dependent breast cancer, the epidemiological studies cannot be the sole basis for the experts' opinions that HRT caused Zandi's breast cancer. Given that epidemiology does not address the cause of an individual's disease, Zandi's experts must rely on something other than epidemiology to conclude that HRT caused Zandi's cancer. Zandi's experts rely on differential diagnosis.

A differential diagnosis adopts a process of elimination to identify cause; it "eliminates the possibility of competing causes or confounding factors." *Goeb*, 615

N.W.2d at 815. "In performing a differential diagnosis, a physician begins by ruling in all scientifically plausible causes of the patient's injury. The physician then rules out the least plausible causes of injury until the most likely cause remains." *McDonough*, 685 N.W.2d at 695 n.3 (quotation omitted); *see Bland v. Verizon Wireless, (VAW) L.L.C.*, 538 F.3d 893, 897 (8th Cir. 2008) (explaining that a "differential diagnosis is a technique that identifies the cause of a medical condition by eliminating the likely causes until the most probable cause is isolated" (quotation omitted)).

The district court concluded that "breast cancer does not lend itself to differential diagnosis because the scientific community has not accepted that breast cancer has a limited number of discrete and recognized possible causes such that ruling out one cause would implicate another." The district court further determined that the differential diagnosis of Drs. Layfield and Bender lacked foundational reliability.

Zandi did not provide evidence that the applicable medical or scientific community generally accepts differential diagnosis as a method of diagnosing the cause of a person's hormone-dependent breast cancer. Even if Zandi had offered such evidence, the proffered differential diagnosis must have foundational reliability. The proponent of the evidence must establish that the methodology used to obtain the evidence is reliable and conforms to procedures necessary to ensure reliability. *Goeb*, 615 N.W.2d at 814. For differential diagnosis to be sufficiently reliable to prove causation, the diagnostician should "rule out all other hypotheses, or at least explain why the other conceivable causes are excludable." *McDonough*, 685 N.W.2d at 695.

The district court concluded that the differential diagnoses of Drs. Layfield and Bender were unreliable because the doctors "did no more than give conclusory statements, with no reasoning or foundational basis, to rule out [Zandi's] other risk factors." Dr. Layfield admitted that Zandi's family history was a risk factor, but dismissed that factor on the basis that Zandi's sister also developed breast cancer and received HRT. Dr. Layfield testified that because Zandi's sister had HRT, he "believe[d] that hormone therapy substantially increase[d] her risk of developing breast cancer" and that in his mind, it "equaled out." But Dr. Layfield did not conduct a differential diagnosis on Zandi's sister to determine whether HRT caused her breast cancer. If Dr. Layfield did not evaluate Zandi's sister to determine the cause of her breast cancer, then he failed to rule out family history as a plausible cause of both women's breast cancer. The district court concluded that Dr. Layfield's opinion is conclusory and lacks foundation. The district court's determination is sound and not an abuse of discretion.

Dr. Layfield also relied on the results of a Ki-67 proliferation test to support his specific-causation opinion.[4] Dr. Layfield concluded that HRT was a substantial factor in causing Zandi's breast cancer because Zandi's test showed a lower proliferation rate in her tumor after Zandi stopped taking HRT drugs.

Dr. Layfield's testimony establishes that the Ki-67 test is generally used to determine a patient's prognosis. He conceded that the Ki-67 test was not developed to determine the cause of a patient's breast cancer. The district court noted that Zandi

[4] The Ki-67 test is an immunochemical assay that purports to measure the percentage of dividing cells by comparing the area stained positively for an antibody to the total area of the section of tissue tested.

acknowledged that the Ki-67 test is not generally used to determine the cause of a patient's breast cancer and that one proliferation test could not, on its own, support a case-specific causation opinion.

Because it is undisputed that the Ki-67 test was not designed and is not generally used for the purpose of determining the cause of a patient's cancer, its use to determine causation is novel and therefore subject to the *Frye-Mack* standard. Zandi argues that use of the Ki-67 test in this case satisfies the first prong of *Frye-Mack* because there is a peer-review, published study on the test. *See* Ramachandran Prasad et al., *Short-Term Biologic Response to Withdrawal of Hormone Replacement Therapy in Patients with Invasive Breast Carcinoma*, 98 Cancer 2539 (Dec. 15, 2003) (Prasad study). But the Prasad study does not assert that the Ki-67 test can determine, or even assist to determine, the cause of breast cancer in a particular individual. Dr. Layfield acknowledged in his testimony:

> Q: [T]he purpose of the Prasad paper was not to determine a causal relationship between hormone therapy and breast cancer, was it?
> DR. LAYFIELD: No, it was not.
> Q: In fact, there's nothing in the Prasad paper that says, "This information is adequate to support a conclusion that hormone therapy causes breast cancer." That conclusion is not here?
> DR. LAYFIELD: I didn't say it was.

Zandi argues that the Ki-67 test is reliable proof of causation when used in conjunction with a differential diagnosis. We are not persuaded. Zandi fails to show that the Ki-67 test is a generally accepted means of determining causation. And, as discussed above, Dr. Layfield's differential diagnosis lacks foundational reliability. Thus,

Dr. Layfield's Ki-67 test and differential diagnosis combined do not satisfy the *Frye-Mack* standard.

The district court also concluded that Dr. Bender failed to conduct a proper differential diagnosis because, "Bender admitted that in reaching her conclusion that [Zandi's] ingestion of [HRT] caused her breast cancer, she did so without eliminating these other risk factors as potential causes." When asked whether it is necessary to rule out other causes to determine the cause of a particular patient's breast cancer, Dr. Bender testified that she does not "think that it's a matter of ruling in or ruling out. . . . [She thinks that] different causes can work independently or they can work synergistically in the development of breast cancer." Dr. Bender's suggestion that it is possible to conduct a reliable differential diagnosis without ruling out other hypotheses, or at least explaining why the other conceivable causes are excludable, indicates that her differential diagnosis is not sufficiently reliable to prove causation. *McDonough*, 685 N.W.2d at 695. We therefore conclude that the district court did not abuse its discretion by determining that Dr. Bender's differential diagnosis lacks foundational reliability.

Zandi argues that the district court erred by failing to recognize the distinction between "causation" and "promotion" of hormone-dependent breast cancer. Zandi defines "causation" as the "initiation of the first abnormal breast cancer cells." Zandi defines "promotion" as the process by which existing hormone-dependent abnormal cells are transformed into cancerous cells. Zandi's attempt to distinguish between causation and promotion is confusing and contradictory. In one instance, Zandi states that "hormones are necessary to promote a nonmalignant abnormality into a malignant one"

but then states that her "experts do not contend that [HRT] creates or initiates cancer cells, but rather promotes cancer in hormone-dependent abnormal cells." In another example, Zandi states, "Zandi's experts do not purport to establish causation for initiation of the first abnormal breast cancer cells. Zandi's experts seek only to establish the use of [HRT] by Zandi was a substantial cause in promotion or growth in her [hormone] sensitive tumor or benign lesion into cancer."

We strain to understand Zandi's argument that she does not claim that HRT caused her "first abnormal breast cancer cells" given her contention that HRT transforms "nonmalignant abnormalit[ies]" and "benign lesion[s]" into cancer. But even if we accept Zandi's distinction between causation and promotion, and only consider whether HRT promoted the growth of Zandi's preexisting breast cancer cells, Zandi presents no evidence that the relevant scientific community generally accepts that there is a method of diagnosing the specific cause of the proliferation of breast cancer cells in an individual.

Zandi also argues that if this record does not satisfy the *Frye-Mack* standard, then none will. Zandi's predicament reflects the nature of the *Frye-Mack* standard. The *Frye-Mack* standard represents a more conservative approach to the admissibility of scientific evidence. *Goeb*, 615 N.W.2d at 812. "[C]ritics of the *Frye* general acceptance standard claim that it may at times exclude cutting-edge but otherwise demonstrably reliable, probative evidence, and thus represents a more conservative approach to the admissibility of scientific evidence." *Id.* Despite this criticism, the supreme court continues to adhere to the *Frye-Mack* standard. *Id.* at 814 (reaffirming the supreme court's adherence to the

Frye-Mack standard and rejecting the contention that it should adopt the federal *Daubert* standard in its place). On this record, we conclude that there is not a method of diagnosing the specific cause of a particular woman's breast cancer that is generally accepted in the relevant scientific community. This reality leaves Zandi without a legally sufficient ability to prove specific causation.

Because Zandi fails to demonstrate that there is a method for diagnosing the cause of an individual's breast cancer that is generally accepted in the relevant scientific community, Zandi's evidence does not satisfy the *Frye-Mack* standard. This conclusion necessarily refutes Zandi's claim that her proffered evidence is not novel and that *Frye-Mack* is inapplicable. *See Goeb*, 615 N.W.2d at 814 (explaining that the *Frye-Mack* standard of admissibility applies when novel scientific evidence is offered). The district court did not err by excluding Zandi's proffered expert testimony regarding specific causation under the *Frye-Mack* standard.

Minn. R. Evid. 702

In addition to satisfying the *Frye-Mack* standard for admissibility, Zandi must demonstrate that her experts are qualified to testify under Minn. R. Evid. 702. *Goeb*, 615 N.W.2d at 814. Minn. R. Evid. 702 establishes that an expert opinion is admissible "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue." Minn. R. Evid. 702 requires that a witness have "knowledge, skill, experience, training, or education" to qualify as an expert on the subject of the offered opinion. This is referred to as the "knowledge requirement" and it "may be satisfied by either formal education or sufficient

occupational experience." *Gross v. Victoria Station Farms, Inc.*, 578 N.W.2d 757, 761 (Minn. 1998). But a witness's competence depends upon both scientific knowledge and practical experience. *Id.* A witness who is not competent or qualified cannot give expert testimony. *Teffeteller v. Univ. of Minn.*, 645 N.W.2d 420, 427 (Minn. 2002).

A witness's competence to testify on a particular subject matter "is a question of fact peculiarly within the province of the trial judge." *Cornfeldt v. Tongen*, 262 N.W.2d 684, 692 (Minn. 1977). Courts require "both sufficient scientific knowledge of and some practical experience with the subject matter" of medical experts' offered testimony. *Id.* "The definitive criteria in guidance of the trial court's determination of the qualifications of an expert witness . . . rest primarily on occupational experience." *Id.* (quotation omitted). Occupational experience is classified as the kind of experience "which is obtained casually and incidentally, yet steadily and adequately, in the course of some occupation or livelihood." *Id.* (quotation omitted).

> A district court's evidentiary ruling on the admissibility of an expert opinion rests within the sound discretion of the trial court and will not be reversed unless it is based on an erroneous view of the law or it is an abuse of discretion. The district court has considerable discretion in determining the sufficiency of foundation laid for expert opinion. Even if evidence has probative value, it is still within the district court's discretion to exclude the testimony.

Gross, 578 N.W.2d at 760-61 (quotation and citations omitted). The standard is "very deferential." *Id.* The standard is so deferential, in fact, that "even if [the reviewing court] would have reached a different conclusion as to the sufficiency of the foundation, the

decision of the district court judge will not be reversed absent clear abuse of discretion." *Id.* (quotation omitted).

Zandi's first expert, Dr. Lester Layfield, earned his medical degree from the University of California, Los Angeles (UCLA) in 1989. Dr. Layfield served as a resident in pathology at the University of Washington and at UCLA before beginning a career in academia. Dr. Layfield has taught at UCLA, the University of Iowa Hospitals and Clinics, Duke University Medical Center, and the University of Utah School of Medicine. He has published over 230 manuscripts in the medical literature and has conducted research in the areas of fine-needle aspiration cytology of the breast and immunohistochemical and molecular markers associated with carcinomas in the breast. Dr. Layfield served as Head of Surgical Pathology at Duke University and the University of Utah. Dr. Layfield uses pathological methods to diagnose approximately 3,500 surgical samples annually, and 250 of those are from the breast. Dr. Layfield has opined that to a reasonable degree of medical certainty, HRT was the most-likely cause of Zandi's breast cancer.

The district court made a number of findings regarding Dr. Layfield's knowledge, experience, and qualifications to render an opinion regarding the cause of Zandi's breast cancer. The district court concluded that (1) "[Dr.] Layfield has never determined the cause of breast cancer in a particular individual and he knows of no medical professional in a clinical setting who determines the cause of breast cancer in a particular individual"; (2) "he admits that there is no published protocol for determining the cause of breast cancer in a particular patient"; (3) "the methodology that [Dr.] Layfield used to determine

the cause of [Zandi's] breast cancer was a methodology that he put together himself for use in the current case and two other cases." The district court concluded that the evidence does not demonstrate that "[Dr.] Layfield has knowledge, skill, experience, training, or education in the area of determining the cause of breast cancer in a particular individual," despite Dr. Layfield's otherwise impressive credentials.

Dr. Gail Bender earned her medical degree from the University of Minnesota in 1975. Dr. Bender is board certified in Oncology, a diplomat of the National Board of Medical Examiners and the American Board of Internal Medicine, and a fellow of the American College of Physicians. She has been involved in breast cancer research with the National Cancer Institute as well as other, local, regional, and national research organizations since 1981. For the past 30 years, about half of her practice has focused on the treatment of metastatic breast cancer. Dr. Bender opined that it was "within a reasonable degree of medical certainty, that [Zandi's] [i]ngestion of [HRT] was a substantial contributing factor in her development of ER/PR positive breast cancer."

The district court made the following conclusions as to Dr. Bender's knowledge and experience: (1) "[Dr.] Bender has told patients the cause of their breast cancer approximately 12 times in the last 5 years"; (2) in determining the cause of breast cancer, "[Dr.] Bender considers whether a woman was on [HRT] for several years and whether she was diagnosed with hormone-dependent breast cancer during that time"; and (3) "[Dr.] Bender admitted that there is no protocol or guideline that has been tested to evaluate whether there is a reliable or generally accepted method to determine the cause of breast cancer." The district court further concluded that "[t]here was no evidence

before the [c]ourt that [Dr.] Bender has any knowledge, skill, experience, training or education in the area of determining the cause of breast cancer in a particular patient." The district court commented on the fact that Dr. Bender has identified the cause of cancer in 12 patients over 5 years and explained that "[t]o the extent that [Dr. Bender] claims to have experience in making such a determination, there is no foundational reliability for her statements about what caused breast cancer in a particular woman."

To be admissible, Zandi's specific causation experts must have special learning and practical experience that informs the specific subject matter of their testimony—identifying the cause of hormone-dependent breast cancer in a particular patient. *See, e.g.*, *Teffeteller*, 645 N.W.2d at 426-27 (affirming the district court's determination that doctor was unqualified to testify on the medical issue before the court because although he had extensive experience in pediatrics, he had not treated patients with cancer, or patients who had undergone bone marrow transplants). Although Dr. Layfield has experience with immunohistochemical and molecular markers associated with carcinomas in the breast, only 250 of the 3,500 surgical samples he diagnoses annually are from the breast. It is not Dr. Layfield's practice to identify the cause of cancer in a particular individual. Dr. Layfield has neither the formal education nor the occupational experience necessary to testify as to the cause of Zandi's breast cancer. The district court did not abuse its discretion by concluding that Dr. Layfield is not qualified as an expert in this case.

Even though Dr. Bender has focused approximately half of her practice for the past 30 years on the treatment of metastatic breast cancer, she concedes that she does not

know that "in general [she] can determine the cause of an individual patient's [breast] cancer" and that she is not an "expert in assessing an individual patient's risk of breast cancer." Applying the deferential standard of review, we cannot say that the district court abused its discretion in determining that this experience is insufficient to qualify Dr. Bender to render an opinion regarding the cause of Zandi's breast cancer.

Given the very deferential standard of review that applies when reviewing a district court's ruling on the admissibility of expert testimony, we hold that the district court did not abuse its discretion by determining that Zandi's specific-causation experts lack the requisite knowledge, skill, experience, training, or education to testify regarding the cause of Zandi's breast cancer. The district court did not abuse its discretion by excluding Zandi's proffered expert testimony regarding specific causation under Minn. R. Evid. 702.

Summary Judgment

"[W]hen the nonmoving party bears the burden of proof on an element essential to the nonmoving party's case, the nonmoving party must make a showing sufficient to establish that essential element." *DLH*, 566 N.W.2d at 71. Causation is generally a question of fact for the jury, and it "becomes a question of law where different minds can reasonably arrive at only one result." *Paidar v. Hughes*, 615 N.W.2d 276, 281 (Minn. 2000) (quotation omitted). Whether the district court properly granted summary judgment on the issue of medical causation is determined by reviewing the evidence in the light most favorable to the party against whom summary judgment was granted. *Goeb*, 615 N.W.2d at 816-17. Without the testimony of Drs. Layfield and Bender, Zandi

fails to provide any evidence that Wyeth's HRT drugs caused her injury. Absent evidence of specific causation, Wyeth was entitled to summary judgment as a matter of law. *Id.* at 817. Because we affirm on this ground, we do not address Wyeth's alternative choice-of-law and statute-of-limitations argument.

III. Motion to Strike

Zandi's motion for reconsideration in the district court was accompanied by an affidavit that included 15 new exhibits. The district court concluded that, on a motion for reconsideration, it is inappropriate to consider evidence that was not before the district court at the time it granted summary judgment. It therefore declined to consider Zandi's affidavit and exhibits.[5] "The district court record cannot be supplemented by new evidence after the court grants summary judgment." *Sullivan v. Spot Weld, Inc.*, 560 N.W.2d 712, 716 (Minn. App. 1997), *review denied* (Minn. Apr. 24, 1997). The district court correctly refused to consider the materials. Zandi included some of the same documents in the appendix to her brief for this appeal. Wyeth requests that we strike these documents and any references to them in Zandi's brief.

"The papers filed in the [district] court, the exhibits, and the transcript of the proceedings, if any, shall constitute the record on appeal in all cases." Minn. R. Civ. App. P. 110.01. The general rule is that an appellate court may not base its decision on matters outside the record on appeal, and may not consider matters not produced and received in evidence below. *Thiele v. Stich*, 425 N.W.2d 580, 582 (Minn. 1988). Zandi

[5] On appeal, Zandi does not claim that the district court erred in this determination.

argues that a motion to strike is inappropriate because the documents were filed in district court, and therefore are part of the record on appeal under Minn. R. Civ. App. P. 110.01.

Typically, motions to strike are brought when a party attempts to introduce new matters on appeal. In this case, the challenged documents were filed in the district court with Zandi's motion for reconsideration but were not considered by the district court. Because the documents were filed in the district court and are a part of the record on appeal, we deny the motion to strike. However, we have limited our review to those documents that were considered by the district court when it made its summary judgment determination.

Affirmed; motion denied.

Dated: _____ _____
The Honorable Michelle A. Larkin