IN THE COURT OF APPEALS OF THE STATE OF WASHINGTON

SHERI L. EAKINS, a single woman,	)	**No. 27357-1-III**
Appellant,	)	
v.	)	**Division Three**
DR. PHIL HUBER AND JANE DOE HUBER, a married couple, AND SPOKANE CARDIOLOGY, P.S., a Washington State Corporation,	)	
Respondents.	)	**PUBLISHED OPINION**

Kulik, C.J. — Sheri Eakins appeals the trial court's summary judgment dismissal of her medical malpractice claim against Dr. Philip Huber and Spokane Cardiology, P.S. She contends the trial court erred by concluding that her proffered medical causation evidence failed to meet the standard set forth in *Frye v. United States*, 54 App. D.C. 46, 293 F. 1013 (1923). Ms. Eakins alleges that the stents containing nickel placed in her coronary artery caused a systemic allergic reaction. We conclude that Ms. Eakins's causation theory has not achieved general acceptance in the relevant scientific community

as required under *Frye*. Thus, we agree with the trial court's decision and affirm.

FACTS

In September 2004, Dr. Huber, a cardiologist at Spokane Cardiology, implanted three stainless steel stents in Ms. Eakins's right coronary artery to alleviate blockage. The stents were Boston Scientific TAXUS Express2 Paclitaxel-Eluting Coronary Stents, which contain 10 to 14 percent nickel. Ms. Eakins is allergic to nickel.

About two weeks after the surgery, Ms. Eakins developed a rash near the operation site. She also began to have episodes of joint pain and swelling, fevers, chills, sweating, elevated blood pressure, itching, and general aching. These symptoms continued to occur several times per month and lasted two to four days. Ms. Eakins attributed these symptoms to an allergic reaction to the stents.

Ms. Eakins moved to Arizona in February 2006. She continued to suffer from episodic allergic reactions. She was evaluated at the Mayo Clinic by several doctors; however, none was able to diagnose her condition or attribute her symptoms to the stents.

In August 2007, Ms. Eakins filed a medical malpractice lawsuit against Dr. Huber and Spokane Cardiology. She claimed that she informed Dr. Huber of her nickel allergy and, therefore, Dr. Huber's implantation of the nickel-containing stents fell below the standard of care. She claimed the stents caused her episodic systemic allergic reactions.

Ms. Eakins filed a declaration from Dr. Carl Adams, a cardiothoracic surgeon from Colorado, which stated that "on a more probable than not basis to a reasonable degree of medical certainty the care rendered to Sheri Eakins fell below the standard of care for a physician practicing in Washington State, and said failure resulted in injury to Ms. Eakins." Clerk's Papers (CP) at 10.

Dr. Huber moved for summary judgment, contending Ms. Eakins failed to establish a prima facie case of negligence because she lacked competent medical evidence establishing a causal relationship between her symptoms and the stents. He contended that Ms. Eakins's theory of causation was not supported by sufficient scientific data or peer-reviewed literature indicating general acceptance of the theory in the pertinent medical community under *Frye*.

In response, Ms. Eakins provided a supplemental declaration by Dr. Adams, who stated that the connection between implantation of stainless steel stents in patients with metal allergies to systemic allergic reactions is generally accepted in the medical community.

To support his opinion, Dr. Adams pointed out that the United States Food and Drug Administration (FDA) and the manufacturers of the TAXUS stent warn that patients with hypersensitivity to stainless steel may suffer an allergic reaction to stents. Dr.

Adams also cited several medical articles linking the TAXUS stents to allergic reactions, which will be discussed in detail below.

Dr. Adams explained what he believed to be the underlying mechanism of Ms. Eakins's allergic reactions:

> It is well established as a matter of basic chemistry that small amounts of nickel may leach from stainless steel when it is in contact with human tissue. Stents are placed inside a blood vessel where they are exposed to significant blood flow. Therefore during the time between implantation and the development of the epithelial cell coating there is a "window" when a small amount of nickel could enter the bloodstream. If a patient is sufficiently sensitive, that nickel would be expected to provoke some degree of allergic reaction. The reaction would be expected to be diffuse, due to the nickel spreading through the bloodstream. . . .
>
> The symptoms that Sheri Eakins attributes to metal allergy are in the nature of a systemic inflammatory response to the introduction of such an allergen, including rash, swollen joints, fever, sweats and elevated blood pressure. She reports a dramatic worsening of these conditions since the stent implantation. These are the same sort of symptoms found in the various studies referenced above.
>
> . . . .
>
> . . . From a clinical standpoint I believe any practitioner would conclude that the stent implantation was a significant causative factor in Ms. Eakins' current condition.

CP at 92-93.

Dr. Huber, in turn, filed the declaration of Dr. Garrison Ayars, a board-certified internist, allergist, and immunologist. Dr. Ayars stated that "on a more probable than not basis, that the field of medicine and in particular, the fields of allergy and immunology,

have not generally accepted any causal relationship between the placement of a Taxus stent in a coronary artery and the development of a systemic reaction like that claimed by Ms. Eakins." CP at 155. He asserted, "There is no body of peer reviewed, competent, medical literature supporting the causal relationship between the placement of a coronary artery stent and the development of the broad systemic reaction claimed by Ms. Eakins." CP at 157.

The trial court granted Dr. Huber's motion for summary judgment, finding: (1) Dr. Adams's proffered testimony did not satisfy the *Frye* requirement of showing general acceptance in the medical community; (2) Dr. Adams's causation theory lacked a foundation in scientific theory, learned treatises, or testing and validation in the scientific community; and (3) Ms. Eakins failed to establish a genuine issue of material fact on the causation element of her standard of care with admissible expert testimony.

Ms. Eakins moved for reconsideration and submitted additional articles from medical literature to support her position. The trial court denied the motion for reconsideration. Ms. Eakins appeals.

ANALYSIS

The issue before us is whether the trial court erred by granting summary judgment based on its conclusion that Dr. Adams's causation theory did not satisfy *Frye*.

Summary judgment is proper only when the pleadings, depositions, and admissions in the record, together with any affidavits, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. CR 56(c); *Young v. Key Pharms.*, *Inc*., 112 Wn.2d 216, 225, 770 P.2d 182 (1989). The purpose of a summary judgment motion is to avoid an unnecessary trial where no genuine issue as to a material fact exists. *Young*, 112 Wn.2d at 226. Summary judgment is proper in a medical malpractice case if the plaintiff lacks competent medical evidence to establish a prima facie case. *Id.* We review a grant of summary judgment de novo, viewing the facts and reasonable inferences in the light most favorable to the nonmoving party. *Lybbert v. Grant County*, 141 Wn.2d 29, 34, 1 P.3d 1124 (2000).

Generally, expert medical testimony on the issue of proximate cause is required in medical malpractice cases. *McLaughlin v. Cooke*, 112 Wn.2d 829, 837, 774 P.2d 1171 (1989). When novel scientific or medical evidence is at issue, Washington courts apply the *Frye* test. *State v. Copeland*, 130 Wn.2d 244, 922 P.2d 1304 (1996). Under *Frye*, evidence derived from a scientific theory or principle is admissible only if the theory or principle has achieved general acceptance in the relevant scientific community. *State v. Riker*, 123 Wn.2d 351, 359, 869 P.2d 43 (1994).

Frye held:

[W]hile courts will go a long way in admitting expert testimony deduced

> from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.

Frye, 293 F. at 1014.

In examining evidence under this standard, courts look at whether the underlying theory is generally accepted in the appropriate scientific community and whether there are experiments or studies using that theory that are capable of producing reliable results and are generally accepted in the scientific community. *Riker*, 123 Wn.2d at 359; *Copeland*, 130 Wn.2d at 255.

We do not evaluate whether the scientific theory is correct, but whether it has achieved general acceptance in the relevant scientific community. *Riker*, 123 Wn.2d at 359-60. The *Frye* test recognizes that judges do not have the expertise to assess the validity of a challenged scientific theory and, therefore, they must defer this judgment to the qualified scientists. *State v. Cauthron*, 120 Wn.2d 879, 887, 846 P.2d 502 (1993), *overruled in part on other grounds by State v. Buckner*, 133 Wn.2d 63, 941 P.2d 667 (1997). Thus, "'scientists in the field must make the initial determination whether an experimental principle is reliable and accurate.'" *Copeland*, 130 Wn.2d at 255 (quoting *State v. Canaday*, 90 Wn.2d 808, 813, 585 P.2d 1185 (1978)). The main rationale for the test is that it ensures the reliability of scientific evidence. *Id.* "If there is a significant

dispute between qualified experts as to the validity of scientific evidence, it may not be admitted." *Cauthron*, 120 Wn.2d at 887.

We review the admissibility of evidence under *Frye* de novo. *Copeland*, 130 Wn.2d at 255. Such review involves a mixed question of law and fact. *Id.* To determine whether a consensus of scientific opinion has been achieved, the reviewing court examines expert testimony, scientific writings that have been subject to peer review and publication, secondary legal sources, and legal authority from other jurisdictions. *Id.* at 256-57; *Cauthron*, 120 Wn.2d at 888; *Grant v. Boccia*, 133 Wn. App. 176, 179, 137 P.3d 20 (2006). However, "the relevant inquiry is general acceptance by the scientists, not the courts." *Cauthron*, 120 Wn.2d at 888.

Novel Scientific Evidence

Ms. Eakins first contends that *Frye* is inapplicable here because Dr. Adams's causation theory is not novel. She claims that Dr. Adams's opinion is based on a well-settled scientific principle that is supported by FDA and manufacturers' warnings and scientific studies. Ms. Eakins also points out that Dr. Adams's opinion was based upon his experience and acquired knowledge as a practicing cardiologist, not novel scientific principles, and, therefore, is not subject to *Frye*.

Ms. Eakins is correct that evidence that does not involve new methods of proof or

new scientific principles does not implicate *Frye*. *See, e.g.*, *State v. Ortiz*, 119 Wn.2d 294, 311, 831 P.2d 1060 (1992) (expert testimony on tracking human beings not subject to *Frye*); *State v. Noltie*, 57 Wn. App. 21, 786 P.2d 332 (1990) (colposcopy not a novel scientific theory or technique even though its use in child abuse cases was relatively recent), *aff'd*, 116 Wn.2d 831, 809 P.2d 190 (1991).

In support of her argument, Ms. Eakins relies in part on *State v. Young*, 62 Wn. App. 895, 802 P.2d 829, 817 P.2d 412 (1991). At issue in *Young* was the admissibility under *Frye* of a doctor's opinion that certain colposcopic observations were consistent with sexual penetration. *Id.* at 906. Noting the doctor's testimony did not involve any new methods of proof or scientific principles, the court concluded *Frye* did not apply, stating, "[the doctor] merely testified that certain clinical findings existed, and that in her own professional experience those clinical findings were consistent with penetration and abuse." *Id.*

This case is distinguishable from *Young*. In *Young*, the doctor's opinion was not based on a new medical theory but on her extensive experience performing thousands of colposcopic examinations. *Id.* at 899. In contrast here, as will be discussed in greater detail below, Dr. Adams's opinion was not based on practical experience or a well-settled medical theory but on a hypothetical link between stainless steel stent placements and

allergic reactions in patients with metal sensitivities. Further, Dr. Adams's opinion required specialized background knowledge regarding the underlying mechanism of allergic responses and an analysis of complex medical studies. *See Ortiz*, 119 Wn.2d at 311 (finding *Frye* inapplicable because "no particularized background knowledge would be necessary to an understanding of the evidence").

Ms. Eakins's argument is undermined by the significant expert dispute regarding Dr. Adams's causation opinion. Dr. Ayars opined that the alleged link between stainless steel stents and diffuse allergic reactions in patients with metal sensitivities is speculative and unsupported by epidemiologic studies. And none of the numerous physicians who evaluated Ms. Eakins endorsed Dr. Adams's theory.

Further, we could find no legal authority from Washington or other jurisdictions addressing the medical causation theory at issue here. *See State v. Hayden*, 90 Wn. App. 100, 107, 950 P.2d 1024 (1998) (finding that enhanced digital imaging was not a novel process but nevertheless addressing the *Frye* issue because whether the process was well accepted was a question of first impression). For all of these reasons, Ms. Eakins's causation theory is a novel theory subject to *Frye*.

Application of Frye Standard/General Acceptance in Scientific Community

We now address the issue of whether Dr. Adams's causation theory is generally

accepted in the relevant scientific community. As detailed above, Dr. Adams, a highly qualified expert in the pertinent field of interventional cardiology, opined that the nickel in stainless steel stents had been shown to cause diffuse allergic reactions in patients with metal allergies. He explained that small amounts of nickel might leach from the stent when it is first implanted and the allergen would then enter the bloodstream, potentially causing allergic reactions similar to those suffered by Ms. Eakins. Ms. Eakins argues that numerous medical journals and manufacturer and FDA warnings support Dr. Adams's causation theory. However, we conclude the medical literature provided by Ms. Eakins does not establish expert consensus regarding the causation theory.

For example, in support of his opinion, Dr. Adams cites a 2006 journal publication by Dr. Jonathan R. Nebeker, and a news story from *ScienceDaily* about the article. The Nebeker article concluded, "The FDA reports and autopsy findings suggest that DES[1] may be a cause of systemic and intrastent hypersensitivity reactions." CP at 113, 213 (Jonathan R. Nebeker et al., *Hypersensitivity Cases Associated with Drug-Eluting Coronary Stents*, 47 J. of Am. C. of Cardiology Found. 175, 182 (2006)).

However, the Nebeker article simply identifies reports of potential hypersensitivity reactions to DES gathered from the Research on Adverse Drug/Device Events and Reports (RADAR) project. This project noted 17 cases of hypersensitivity to DES out of

5,781 reports. The purpose of the RADAR project was to identify potential causes of these hypersensitivity reactions, which included rashes, hives, itching, and joint pain or swelling.

Significantly, the article cautioned, "it is not appropriate to draw inferences that hypersensitivity reactions are more frequently caused by the stent than concomitant drugs." CP at 116, 218 (Nebeker, *supra*, at 180). In fact, the Nebeker article suggests that the polymer coatings on DES are a more likely cause of allergic responses than nickel:

> Non-drug components of the DES are potential causes of hypersensitivity. The polymer coating can fragment and expose metal struts, raising concern that nickel and molybdenum in the stainless steel may cause hypersensitivity. However, bare-metal stents have not been demonstrated to cause hypereosinophilic, IgE-mediated reactions . . . *The polymers coating the DES are a more likely cause of late, persistent hypersensitivity.*

CP at 116, 218 (emphasis added) (references omitted) (Nebeker, *supra*, at 180).

Further, Dr. Ayars concluded the Nebeker article failed to support a probable causal relationship between stent placement, nickel sensitivity, and Ms. Eakins's symptoms. He explained:

> The article also highlights the difficulty in drawing the causal relationship asserted by Ms. Eakins. The stainless steel stents are coated with polymers which hold the drugs that inhibit an inflammatory reaction

[1] Drug-eluting stents.

> that would cause re-stenosis. Additionally, coronary artery stents are frequently placed in conjunction with other prescribed medications. This article speculates that a wide array of post-placement medications and even the drugs which are impregnated on the metal stents may be the cause of hypersensitivity reactions.

CP at 160.

Thus, the Nebeker article does not support general acceptance of Dr. Adams's causation theory. The authors themselves note the limitations of the study, stating, "Further study is warranted to characterize the incidence and course of these events, to develop tests that predict or confirm the development of stent-associated hypersensitivity." CP at 117, 219 (Nebeker, *supra*, at 181).

Further, Ms. Eakins submits that an article by Dr. Nicholas Kounis, which discusses the Nebeker article, supports Dr. Adams's causation theory. However, the Kounis article does not establish scientific consensus pertaining to Dr. Adams's theory. It simply states, "All three components of DES could be responsible for inducing allergic reactions and Kounis syndrome.[2] . . . Patients positive for allergic patch-test reactions to stent metal components nickel and molybdenum appear to have increased rates of in-stent thrombosis." CP at 125 (Nicholas G. Kounis et al, *Allergic Reactions Following Implantation of Drug-Eluting Stents: A Manifestation of Kounis Syndrome?*, 48 J. of Am. C. of Cardiology Found. 592 (2006)).

---

[2] Kounis syndrome is described as "the concurrence of acute coronary events with

Dr. Ayars states that this letter "suggests, but does not establish, a possible connection between the placement of metal stents and thrombosis or restenosis in the stent. The letter does not support the proposition claimed by Ms. Eakins and her expert as she did not have coronary artery stenosis." CP at 162.

Next, the *ScienceDaily* article discussing the Nebeker article does not support Dr. Adams's theory. First, Dr. Ayars points out that the article is not peer reviewed. Further, it simply restates the Nebeker conclusion that "the polymer coating on the stent itself is the most probable cause of hypersensitivity in the majority of cases." CP at 131 (*Drug-eluting Stents May Cause Allergic Reactions*, ScienceDaily, Dec. 30, 2005). Finally, we note that the article quotes a physician who directs a cardiac catheterization lab, who cautions, "'It is important to keep the findings in perspective . . . Drug-eluting stents are a life-saving advance used by hundreds of thousands of people that have greatly reduced the risk of restenosis. We are in no way recommending they be used less.'" CP at 131 (ScienceDaily, *supra*).

Dr. Adams also referenced a 2000 article in *The Lancet* to support his theory. It notes that allergic reactions to metal, particularly nickel, have occurred in patients with orthopedic, dental, and other stainless steel implants. It then states, "Whether similar

---

allergic or hypersensitivity reactions." CP at 125.

reactions occur around stents and trigger restenosis in patients with allergy to metal is not known." Ralf Köster et al., *Nickel and molybdenum contact allergies in patients with coronary in-stent restenosis*, 356 The Lancet 1895 (Dec. 2, 2000).

We fail to see how this article establishes scientific consensus of Dr. Adams's theory. First, the article is limited to a study of the hypothetical relationship between placement of a stainless steel coronary stent and restenosis. However, Ms. Eakins does not have restenosis. Furthermore, the article states that its findings are preliminary and any such relationship or association between stents and restenosis is hypothetical, and notes the limitations of the study, including the small and selected population. Köster, *supra*, at 1897.

Next, Ms. Eakins relies on a 2008 article in *Contact Dermatitis*, which concludes, "there is little doubt that these medical devices [DES], in rare instances, can induce allergic reactions." CP at 199 (Golara Honari et al., *Hypersensitivity reactions associated with endovascular devices*, 59 Contact Dermatitis 7, 18 (July 2008)). However, this article states that "allergic reactions to endoprotheses are still unpredictable processes that are not fully understood." CP at 205 (Honari, *supra*, at 7). The article also cites the RADAR study discussed in the Nebeker article and notes, "Although rare, these data suggest spectrums of hypersensitivity responses to DESs, *while no specific allergen has*

been identified." CP at 210 (emphasis added) (Honari, *supra*, at 12).

The authors also point out the limitations of the available data, stating, "The majority of current data regarding putative sensitivity reactions to endovascular and other cardiovascular biomaterials is based either on anecdotal case reports or data gathered from small cohorts." CP at 198 (Honari, *supra*, at 17). The authors state that additional "prospective, longitudinal studies" are needed to understand fully the role of hypersensitivity reactions in patients receiving endovascular devices and concludes, "Further studies with larger cohorts of patients are needed before drawing more definite conclusions." CP at 200, 210 (Honari, *supra*, at 19, 12).

The authors also emphasize that a mere association between stainless steel implants and allergic reactions in patients with metal allergies does not necessarily prove causation. In the context of stainless steel orthopedic implants, they write:

> Review of a number of published reports on metal sensitivity in patients with joint implants shows that the prevalence of metal sensitivity in patients with a failed or failing prosthetic joint is approximately 6 times that of the general population and approximately 2 to 3 times that of all patients with a metal implant. *However, this association does not prove a causal effect.* It is still not known whether these patients are metal sensitive as a result of device failure, or whether the device failure occurred because of a pre-existing metal sensitivity, or because of alternate mechanisms. *The same concept may apply to other implants including endovascular devices.*

CP at 199 (emphasis added) (references omitted) (Honari, *supra*, at 18).

Contrary to Ms. Eakins's assertion, the Honari article does not establish scientific consensus regarding Dr. Adams's causation theory. At most, it hypothesizes that nickel is a potential allergen in coronary stents. It emphasizes that research on the issue is preliminary, that more studies are needed before the underlying mechanism of biomaterial incompatibility is understood, and that most reported cases of sensitivity reactions are anecdotal.

Moreover, the record reveals significant dispute about Dr. Adams's causation theory. Dr. Ayars reviewed Ms. Eakins's medical records and strongly disagreed with Dr. Adams's opinion, stating that the fields of medicine and allergy had not generally accepted any causal relationship between the placement of a TAXUS stent and Ms. Eakins's symptoms.

Dr. Ayars explained that anecdotal reports of allergic reactions to stents in patients with metal sensitivities were insufficient to establish general acceptance of a scientific theory, which requires subjection of a hypothesis to controlled scientific or epidemiologic trials, both of which are lacking in this case. He pointed out that none of the articles submitted by Dr. Adams supports the theory that the stainless steel stents caused, on a more probable than not basis, Ms. Eakins's systemic reactions. He also noted that the FDA retracted its initial caution that stents may cause hypersensitivity reactions based on

the lack of compelling evidence of a significant relationship.

Further, Dr. Ayars stated that "it is highly plausible that any of Ms. Eakins' symptoms could be a reaction to the multitude of medications prescribed to and consumed by Ms. Eakins." CP at 163. He also criticized Dr. Adams's hypothesis that allergens are released from the TAXUS stent, pointing out that no peer reviewed literature indicated that such stents leach their metallic components. Additionally, he stated that Dr. Adams's theory made no physiological sense because "the one focal point where there would exist the largest amount of nickel, the coronary artery itself, appears to be unaffected in the case of Ms. Eakins." CP at 165.

Finally, none of Ms. Eakins's treating physicians concluded that the stents were the probable cause of her symptoms. For example, Dr. John Lynch, a cardiologist, who evaluated Ms. Eakins at the Mayo Clinic in Arizona in 2006, stated, "[T]here is no significant data, though there are anecdotal cases of stent allergy. I have never encountered a case with such systemic manifestations of symptoms [as] Ms. Eakins." CP at 37. Dr. Harry Teaford, who evaluated Ms. Eakins in 2006, found it "problematic whether or not [her] symptoms are in fact related to metal allergy." CP at 31. He noted:

> Problems with stents have been attributed not only to metal allergy but also to polymers and elutants used in the stents. . . . I would note that the literature indicates that the relation between metal allergy and in-stent restenosis has been inconclusive. . . . The absence of stent stenosis or vascular abnormality or other localized abnormality around the stent would

> argue against a hypersensitivity reaction to the stent . . . I discussed with her that sometimes patients may have symptoms associated with the use of medications.

CP at 31-32.

Dr. Bernard Villegas, another of Ms. Eakins's physicians, concluded, "I have no way [of] truly determining which of her symptoms are caused by her allergy." CP at 152. Finally, Dr. Alison Adams, a rheumatologist who evaluated Ms. Eakins in 2006, stated, "At this time, we have no evidence in the medical literature to support that [Ms. Eakins's symptoms are] due to a nickel allergy." CP at 35.

Given that medical studies do not establish a causal relationship between stainless steel stents and the types of reactions suffered by Ms. Eakins and the disagreement among medical experts in the pertinent fields of allergy and cardiology about the cause of Ms. Eakins's symptoms, we conclude no scientific consensus exists as to Dr. Adams's causation theory. At most, the medical studies indicate that it is a possibility, not a probability, that the nickel in stainless steel stents cause allergic reactions in patients with nickel allergies. However, the record indicates that this theory needs further empirical testing and that the few anecdotal reports of hypersensitivity reactions to DES do not establish a causal relationship between placement of such stents and these reactions. More specifically, for our purposes, they do not establish that nickel, as opposed to other

allergens, cause such responses. Therefore, Ms. Eakins fails to establish a genuine issue of material fact as to the causation component of her claim.

Accordingly, we affirm the trial court's summary judgment dismissal of Ms. Eakins's medical malpractice claim.

_____
Kulik, C.J.

WE CONCUR:

_____
Brown, J.

_____
Korsmo, J.