Case No. 111954

IN THE COURT OF APPEALS OF THE STATE OF KANSAS

EDWARD M. BEREAL,

Plaintiff / Appellant,

vs.

RAVI K. BAJAJ, M.D.,

and

WESLEY MEDICAL CENTER, L.L.C.,

Defendants / Appellees.

Appeal from the District Court of Sedgwick County
Honorable William Wooley, District Judge
District Court Case No. 11 CV 4356

BRIEF OF THE APPELLANT

JONATHAN STERNBERG, Kan. #25902
Jonathan Sternberg, Attorney, P.C.
2323 Grand Boulevard, Suite 1100
Kansas City, Missouri 64108
Telephone: (816) 292-7000
Facsimile: (816) 292-7050
jonathan@sternberg-law.com

COUNSEL FOR APPELLANT
EDWARD M. BEREAL

ORAL ARGUMENT REQUESTED

Table of Contents

Authorities:

Second Issue: The trial court erred in allowing the defendants' products liability expert, Yadin David, to testify to conclusions outside the scope of his disclosed pretrial report, which conclusions formed the whole of two of the defendants' affirmative defenses. As the plaintiff was disallowed from having his own products liability expert, the plaintiff had no possibility of countering

Nature of the Case

This is an injured plaintiff's appeal in a medical malpractice suit in which he sought recovery of damages against the defendants: (1) his treating physician and (2) the hospital who employed both the physician and other staff who treated the plaintiff.

The plaintiff suffered the injection of air into his aorta during a heart catheterization procedure the physician performed at the hospital, which caused a stroke and permanent paralysis. The defense did not dispute that air was injected into the plaintiff, injuring him, but instead lodged products liability affirmative defenses, claiming a defect in a machine involved in the procedure was responsible for the injury. After a 21-day trial, the jury found in favor of the defendants.

The plaintiff now appeals the trial court's judgment and seeks a new trial.

Statement of the Issues

I. The trial court erred in striking and then excluding the plaintiff's rebuttal expert witness, Dr. Suzanne Parisian, M.D. Disclosure of Dr. Parisian was timely, she was qualified to testify as an expert on the subjects in her report rebutting the defense's products liability expert, and her testimony would not have duplicated that of either of the plaintiff's other two expert witnesses, neither of whom gave or were qualified to give products liability opinions. As a result of Dr. Parisian's exclusion, the plaintiff had no ability to counter the defense's products liability expert and was left with only two experts, whereas the defense was allowed three.

II. The trial court erred in allowing the defendants' products liability expert, Yadin David, to testify to conclusions outside the scope of his disclosed pretrial report, which conclusions formed the whole of two of the defendants' affirmative defenses. As the plaintiff was disallowed from having his own products liability expert, the plaintiff had no possibility of countering Mr. David's surprise, undisclosed evidence, prejudicing the plaintiff and denying him a fair trial.

III. The trial court erred in denying the plaintiff judgment as a matter of law on the defendants' six affirmative defenses of products liability against Medrad under the KPLA. The only evidence introduced in support of those defenses, the testimony of expert Yadin David, was purely surmise and conjecture, and was insufficient to meet the defendants' burden under the KPLA. Mr. David never tested the Avanta or any of its components and was unable to identify any specific defect, none of the reports on which he relied identified any defect, and he admitted no power injector contains a remote air sensor.

Statement of Facts

A. Background

In 2009, Plaintiff/Appellant Edward Bereal complained of chest pain and showed a "slightly abnormal" EKG (R. 14 at 98; R. 20 at 119-20). His family had a history of heart disease, and, as his symptoms were "consistent with angina," he was referred to Defendant/Appellee Dr. Ravi Bajaj, M.D., a cardiologist at Defendant/Appellee Wesley Medical Center (R. 20 at 54-55, 119-20). Dr. Bajaj scheduled Mr. Bereal for a cardiac catheterization –a "heart cath" – on December 11, 2009, to "get definitive information about [Mr. Bereal's] coronary arteries" (R. 10 at 149-50; R. 14 at 96, 98; R. 20 at 47).

This was to be a simple, routine outpatient procedure of which thousands are performed at Wesley each year, and which Dr. Bajaj had performed 15,000 times (R. 13 at 116, 145; R. 20 at 85-86). It is undisputed, however, that, during Mr. Bereal's procedure, air was injected into his heart, causing an embolism and stroke, and resulting in lengthy inpatient care and permanent paralysis (R. 12 at 64, 129; R. 13 at 158; R. 15 at 55, 163, 168; R. 17 at 97; R. 20 at 42, 50-51, 53-55; R. 22 at 28).

This is Mr. Bereal's medical negligence action against Dr. Bajaj and Wesley for damages from that injury.

B. Mechanics of a Cardiac Catheterization Using the Medrad Avanta System

In a cardiac catheterization, long, thin tubes called "catheters" are placed in the patient's heart, and radiopaque contrast dye is injected into the patient's heart, the flow of which can be seen on an x-ray fluoroscope (R. 10 at 146-47, 156, 170; R. 12 at 18; R. 14 at 96-97). The procedure takes measurements of circulation pressures, blood flow, and oxygenation, and provides visualizations called "angiograms" so as to recommend how to

treat heart problems (R. 14 at 96-97). As with Mr. Bereal, the "most common reason" a heart cath is performed is to look for blockages in coronary arteries (R. 14 at 97).

Besides the physician, the procedure also involves a circulating nurse, a monitoring nurse, and a scrub tech (R. 10 at 150; R. 22 at 63). The monitoring nurse monitors the patient's vital signs and angiograms from an adjoining room, obtains information from the other team members, and also documents and keeps track of the procedure for records (R. 10 at 150-53, 155, 160-62; R. 22 at 63). The circulating nurse ensures the patient is comfortable and gives and documents any medication the physician orders, including the type, weight, and amount of contrast (R. 10 at 154-55, 157-58; R. 14 at 208; R. 22 at 64). The scrub tech prepares the patient, stays sterile, and assists the physician; only the physician and scrub tech are sterile (R. 10 at 165-66; R. 22 at 64).

The physician begins by inserting a tiny "femoral catheter" in the patient's groin, through the femoral artery, and into the aorta in the heart, where it is under pressure (R. 10 at 172; R. 14 at 101). To inject the dye, the physician uses either a hand-injection procedure or a power injector such as the Avanta Fluid Injection System manufactured by Medrad, which was used in Mr. Bereal's procedure (R. 10 at 146-47, 156; R. 12 at 18). The Avanta or another power injector "is a required piece of equipment in all cath labs" (R. 12 at 17). The angiograms are x-ray images of the procedure showing the dye going into the patient's heart and out into the vessels (R. 10 at 167). Using the Avanta, the physician hits a foot pedal, contrast goes in, and an image is taken, with each process taking only four seconds (R. 10 at 148-49, 168; R. 14 at 102-03, 116).

Besides contrast, saline also can be injected to flush the machine and ensure the catheters are clean (R. 10 at 171). A pressure transducer is connected, measuring blood

pressure in real time by translating fluid pressure into blood pressure as a "wave form," a "sine wave" visible on the monitoring screen (R. 10 at 156; R. 12 at 18-19, 46-47, 68).

Contrast and saline are separately stored in the Avanta's injector head, with a line primed from each storage and strung through the machine (R. 12 at 34). Essentially, the Avanta has plastic catheter tubing attached to it, which in turn is attached to the femoral catheter already inserted inside the patient (R. 10 at 147). Fluid under 400 PSI to 700 PSI of pressure in the Avanta then is injected into the patient's heart through catheters that are themselves at 1200 PSI (R. 10 at 148; R. 18 at 42).

It is crucial that all the tubing – both the Avanta's catheters and transducer and the catheter in the patient – must be purged of air; there is "no margin of error" for this (R. 13 at 76; R. 15 at 194; R. 18 at 64; R. 20 at 6). Otherwise, it is "extremely" "dangerous to the health and safety of a patient:" due to "block[ing] the blood flow to the heart and to the brain," air injection can cause serious injury, including stroke, and even death (R. 12 at 42, 46; R. 13 at 77; R. 14 at 105, 123, 126; R. 15 at 194; R. 18 at 128; R. 20 at 11-12). The Avanta's manual warns of this "multiple times" (R. 12 at 64-66).

As Dr. Bajaj's expert put it, failing to purge 100% of the air would violate the standard of care (R. 22 at 15). Both the physician and the scrub tech are charged with ensuring air is completely purged, and the physician has the primary "role to double check and ensure that there's no air present" (R. 13 at 77; R. 20 at 5). The Avanta does not have a remote air sensor alarm – as all parties' experts testified, no power injector system does (R. 10 at 147-48; R. 16 at 44-45; R. 18 at 234).

Per the Avanta's instructions, its pressure transducer must be purged of air by hand using a syringe and then filled with saline before use (R. 11 at 37-38, 43-44, 81-82;

R. 12 at 46-47, 50-51, 60, 66-67). It has a stopcock to allow excess fluid out of the catheter leading from it, which, after purging, must be turned so air cannot come in (R. 11 at 83-84; R. 12 at 61-62). Medrad does not manufacture transducers; compatible ones are purchased from another maker (R. 12 at 47; R. 14 at 229).

The femoral catheter, already in the patient, also is drawn back with a syringe by the physician to ensure it is air-free (R. 11 at 94, 96). A syringe is attached and blood is pulled out, and another syringe is attached to fill it with contrast (R. 14 at 109, 197-98).

Witnesses differed on the importance of filling the femoral catheter with contrast. The plaintiff's expert, Dr. Michael Fifer, director of catheterization at the Massachusetts General Hospital and professor at the Harvard Medical School, testified this is very important because it is the only way to ensure "there's no air in the catheter" (R. 14 at 80, 82, 84, 109, 150-51). Dr. Bajaj said this is not true, claiming "the body does it for you" (R. 20 at 91, 94-95). His expert, a cardiologist in Wichita, said filling the femoral catheter with dye is "a matter of preference but not a standard of care issue" (R. 22 at 21).

Coming out from the injector are other catheter tubes (R. 11 at 38). A specialized one called an MPAT, manufactured by Medrad, is attached to those tubes (R. 11 at 44, 104-05; R. 18 at 101). Finally, another specialized one called a SPAT, also manufactured by Medrad, is attached to the MPAT (R. 11 at 43, 45, 104-05; R. 16 at 179-80). The transducer's tubing plugs into the SPAT (R. 15 at 107).

Upon the respective connection of each of the initial tubing, the MPAT, and the SPAT, a "purge button" on the Avanta's interface is pressed to purge them of air and ensure only fluid is in them (R. 11 at 38-41; R. 12 at 43-44). The user is prompted

through this process, which "pushes all the air out" and then pushes saline and contrast in so "it drips out" (R. 12 at 36-37, 39, 41-42). Each cycle lasts eight seconds (R. 12 at 39).

The object is to "ensure a fluid-to-fluid connection" between the femoral catheter and the SPAT to "make sure that there's no air present" anywhere in the system (R. 11 at 96; R. 12 at 51-52; R. 14 at 198). This connection means that, while fluid is coming out of the terminal end of the SPAT and blood is coming out of the femoral catheter, they are hooked together (R. 14 at 198). Then, a stopcock on the SPAT is turned to ensure there is no air in the catheter (R. 14 at 198). Dr. Fifer said this is "absolutely mandatory" (R. 14 at 199). Dr. Bajaj claimed this was not true, and his expert said it is "possible" that a small amount of air might remain absent this, but this still was not true (R. 20 at 97; R. 22 at 18, 20-21). Dr. Bajaj's expert said air only needs to be purged before the connection is made, not afterward, but it is "not inappropriate" to do so afterward, too (R. 22 at 21, 40).

The physician and scrub tech also visually inspect all tubing to determine that all air is out (R. 11 at 90-92; R. 12 at 41, 45-46). If any remains, the purging process must be "repeat[ed]" (R. 12 at 41, 45-46). This also was Wesley's written policy (R. 13 at 79-83; R. 15 at 139). Moreover, the Avanta contains air sensors (though not in the SPAT) that, if air is noticed going through, will pause the machine and the user must designate that any air has been cleared before he or she can continue (R. 12 at 37-38, 128).

Once the fluid-to-fluid connection is made between the SPAT and the femoral catheter and the physician and the scrub tech have ensured that all air is out, contrast and saline are injected from the machine as necessary, through the tubing, the MPAT, and the SPAT, and into the patient (R. 11 at 100-08). As the contrast is under pressure, it comes out quickly (R. 11 at 109-13; R. 14 at 102).

C. Mr. Bereal's Catheterization Procedure, Stroke, and Paralysis

On December 11, 2009, Mr. Bereal came to Wesley for his heart cath (R. 10 at 149-50; R. 14 at 96; R. 20 at 44, 47). Dr. Bajaj was the physician, Travis January was the monitoring nurse, Stacy Cody was the scrub tech, and Michael Stilwell was the circulating nurse (R. 10 at 187; R. 14 at 208; R. 18 at 107; R. 20 at 5).

On November 17, 2009, three weeks prior, Wesley's Avantas received a software upgrade allowing the user to hit one button to purge both the saline and contrast lines simultaneously (R. 12 at 52-53). This upgrade also required manual air purging of part of the transducer (R. 12 at 67-68; R. 13 at 167-68; R. 18 at 77, 145-46). The upgrade was not unusual, and happened all the time (R. 15 at 19-20, 137; R. 17 at 228-29; R. 18 at 58).

There was no record that any member of Mr. Bereal's cath team received training on the upgrade until after his procedure (R. 12 at 54-56; R. 13 at 167; R. 16 at 38-41). Wesley had no record that Ms. Cody ever had received any training on the Avanta at all until after Mr. Bereal's procedure (R. 16 at 38-41). Wesley's manager of cardiovascular services, Dick Lewis, claimed these records existed but were missing (R. 16 at 41). The cath lab charge nurse, Lisa Willhite, said they were kept in her desk, but, after Mr. Bereal's procedure, she returned from a vacation to find them gone (R. 18 at 224, 228).

Both Mr. Lewis and Ms. Cody claimed she was trained on the Avanta anyway (R. 16 at 139; R. 18 at 102). But Ms. Cody admitted she never read the Avanta's manual until preparing for her deposition below (R. 18 at 104, 152-53). Nonetheless, she said she had prepped the system many times before Mr. Bereal's procedure (R. 18 at 64-65).

Wesley hired Ms. Cody in 2008, and by the time of Mr. Bereal's procedure had given her only one evaluation, on which she was found to "almost never" demonstrate

"respect, compassion, and professionalism towards" patients, and received a "failing" grade overall (R. 16 at 44; R. 18 at 54-55). Nonetheless, Dr. Bajaj said she was "a competent and qualified scrub tech" (R. 20 at 92).

It was Ms. Cody and Dr. Bajaj who were responsible for purging all the air from the catheters and the Avanta system for Mr. Bereal's procedure (R. 14 at 211; R. 15 at 167; R. 18 at 66; R. 20 at 92; R. 22 at 65). Ms. Cody was "in the best position to know whether the air got purged" (R. 14 at 62, 211-13; R. 15 at 59).

Ms. Cody said she said she correctly had purged the system and all tubing (R. 18 at 108-09, 129, 165). In her deposition, however, she admitted she had not purged the transducer with a syringe as required, but had tried to do so by squeezing a saline bag (R. 18 at 144-45). She then went back and changed this answer after watching a training video and reading the Avanta's manual (R. 18 at 153-55). Additionally, she stopped the MPAT's purging process before it had finished, which only was allowable if she "relied on her visualization of the air being completely removed" (R. 12 at 40).

Nurse Stilwell said he watched Ms. Cody purge the saline and contrast lines and catheters and take a syringe and "tap" the SPAT to get air out of it (R. 14 at 226; R. 15 at 77-78). No one expressed any concern about anything, including the Avanta, before the procedure began, and did not observe any defect in the Avanta or crack or hole in the catheters which, if there were, liquid under pressure would have been seen squiring out (R. 10 at 209-11; R. 13 at 151; R. 15 at 31, 33, 35, 82; R. 18 at 65-66, 130-32). Dr. Bajaj said he "would not have" missed any air in any tubing, which he checked (R. 20 at 102).

Then, suddenly, there was an "unusual" "problem" immediately upon the first contrast injection (R. 10 at 178-79; R. 13 at 74-75; R. 14 at 207; R. 18 at 109). Mr.

Bereal "went into ventricular tachycardia," an abnormally high heart rate resulting in "a failure of the heart to adequately profuse the rest of the body," causing his heart rate to drop – a "grave" "medical emergency" (R. 10 at 179-80; R. 15 at 81; R. 20 at 22). On Dr. Bajaj's orders, he was defibrillated – "shocked" – and given antiarrythmic and anti-clotting drugs (R. 10 at 181; R. 14 at 179-80; R. 18 at 110-12; R. 20 at 127). This "stabilized" him (R. 15 at 86; R. 18 at 113). The fact that Mr. Bereal was given an anti-clotting drug could have meant Dr. Bajaj did not think it was air injected into Mr. Bereal, but instead that Mr. Bereal had a clot (R. 14 at 179-80).

The team then unhooked Mr. Bereal from the Avanta, Dr. Bajaj tossed the SPAT away, on Dr. Bajaj's orders the team switched to hand contrast injections, and the procedure went on (R. 12 at 97-98, 100; R. 13 at 24; R. 16 at 91; R. 15 at 60, 85; R. 18 at 115; R. 20 at 25-26, 127, 129). Dr. Bajaj said the switch to hand injections, of which there was no record, was immediately after the first injection using the Avanta to try to "suck the air out" (R. 20 at 36, 70-71). The Avanta's log, however, showed 66 ml of contrast were used during the procedure, and, as one injection only could be 6 ml at most, the device was used for more than one injection (R. 15 at 63).

After the procedure, because of the air injection Mr. Bereal was transferred to intensive care (R. 10 at 186-87; R. 13 at 74; R. 14 at 214; R. 18 at 113-14, 121). He then suffered a stroke, which caused him to be paralyzed (R. 15 at 55; R. 20 at 42). Mr. Bereal remained in inpatient care and then rehabilitation for over two months (R. 13 at 158; R. 17 at 97; R. 20 at 50-51). Dr. Bajaj's discharge summary included a final diagnosis of stroke caused by an air embolism from the heart cath (R. 20 at 53-55).

D. Initial Responses to Mr. Bereal's Injury

Upon the incident, Nurse Willhite called Mr. Lewis and said he needed to come to the cath lab because "the Medrad injector had injected air a [*sic*] patient" (R. 16 at 59-60). Mr. Lewis said he came immediately, while Mr. Bereal was still on the table and Dr. Bajaj and his team "were still in there" performing the end of the procedure (R. 16 at 60-61). Mr. Lewis said he stayed and reviewed images and data with Dr. Bajaj, trying to ascertain what had happened (R. 16 at 63-67; R. 20 at 21, 24-25, 36).

Mr. Lewis said he and Dr. Bajaj focused on "image no. 2" or "the first and second" angiograms, which "showed the air injection" – that "some air had been injected into the aorta" (R. 14 at 215-17; R. 16 at 67). Ms. Cody said she asked Dr. Bajaj what had happened, and "he said it was air" (R. 18 at 125). Ms. Cody and Nurse January said they could see on the images where air came out of the tip of the femoral catheter on the first injection, but Ms. Cody said and told others "there was nothing that I had done or not done that would create this" (R. 6 at 48-49; R. 18 at 127, 129).

These angiograms were "unusual," "abnormal," because contrast comes out like usual into the left coronary artery system, but does not make it all the way through (R. 11 at 134). It should have branched out and elongated like tree roots, but did not (R. 11 at 134-35). The artery filled slowly, rather than rapidly as it should have (R. 11 at 138). The team agreed this meant air was injected into Mr. Bereal's arteries "early on in the procedure," "absolutely" "on the first injection" (R. 11 at 139-40; R. 14 at 35, 53; R. 20 at 20). Dr. Bajaj's expert agreed, too (R. 22 at 30).

After the procedure, no one had asked Nurse January to preserve the SPAT or MPAT, so as usual he disposed of them as "trash," making them impossible to use in any

investigation unless they were dug out, which was not done (R. 10 at 212-14; R. 13 at 71-72, 102, 120; R. 18 at 118-20). The trash is placed in biohazard bags, which are placed in a container and taken to a "soiled utility room," where it is placed in a special trash bin, which then is emptied by environmental services (R. 13 at 101-02; R. 18 at 118-20).

Despite this, at trial, Wesley claimed an item introduced into evidence was the actual SPAT used in Mr. Bereal's procedure (R. 10 at 215; R. 13 at 102-03). Nurse January had no idea how that could be (R. 13 at 103-04). Mr. Lewis said he could not confirm it was the actual SPAT (R. 16 at 84-85, 182). And Nurse Willhite said none of the Avanta's component parts were saved from Mr. Bereal's procedure (R. 18 at 230). Ms. Cody did not see Dr. Bajaj or Mr. Lewis reviewing any materials Nurse January had disposed of in the trash (R. 18 at 125-26). Dr. Bajaj admitted he did not request the evidence from the device needed to be preserved (R. 20 at 38).

Nonetheless, Mr. Lewis claimed he bagged and preserved the SPAT, but did not save anything else, including the transducer and its tubing, and there was nothing "cracked or broken" on the SPAT (R. 16 at 71, 75, 180). Joey Dean, Wesley's risk manager, said Mr. Lewis brought her the SPAT in a biohazard bag, which she "kept" and later transferred to Wesley's attorneys (R. 7 at 20-22; R. 16 at 82)..

Mr. Lewis said that, after all this, he removed all Avanta injectors from the cath labs and stored them in a secure area (R. 16 at 86). He said he then contacted Ms. Dean, Medrad, head of radiology Kathy Reidel, and Wesley's Chief Medical Officer, Dr. Francie Ekengren (R. 7 at 9, 17; R. 16 at 86-87; R. 17 at 248-48). But he admitted he did not contact Wesley's clinical engineering or materials departments to start any investigation on the devices (R. 16 at 86-87).

E. Mechanics of Mr. Bereal's Injury

At trial, all parties agreed Mr. Bereal had suffered an "intravascular air embolism" (R. 12 at 64; R. 15 at 163; R. 22 at 28). Air "enter[ed his] heart and travel[ed] up to his brain" (R. 12 at 129; R. 15 at 168). This was a "serious physical injury" that "disrupt[ed] the flow of blood" and caused his stroke and paralysis (R. 6 at 17; R. 17 at 54).

1. Plaintiff's Medical Experts' Opinions

Both of Mr. Bereal's experts testified "the most important piece of evidence" were the angiograms, specifically the "first image" (R. 12 at 23; R. 14 at 105-06).

His first expert, Karen Harris, a supervising cardiovascular technologist at Massachusetts General Hospital, said "bubbles" are visible on the angiograms, and one "absolutely" "can see the air going in the very first picture before any contrast ever goes in" – "air com[es] out of the catheter first" into the aorta and "then the dye" (R. 12 at 23, 26-27). She estimated it was "less than 6 ccs" of air (R. 12 at 28). She said that means "the first thing out of the catheter was air, so that the air had to be far upstream," "closest to the patient," "and then pushed through," meaning the contrast that was injected pushed the air that was before it out first" (R. 12 at 24, 29).

She said there only were four possibilities for what this means: (1) air came out, and then contrast; (2) blood, which is not radiopaque, came out, then air, then contrast; (3) saline, which is not radiopaque, came out, then air, then contrast; or (4) blood and saline came out together, then air, then contrast (R. 12 at 30-31).

Ms. Harris said this also showed there was no failure in the Avanta, as "the air that was injected was the first thing that came out of the catheter," meaning the air "was much further into the patient than the [Avanta] system. The system injects and pushes

along whatever is in front of it. The air was the first thing to come out. So there was air in the tip of the catheter at the first angiogram," in the femoral catheter (R. 12 at 141).

Dr. Fifer agreed the angiogram showed that, on the very first injection, "air gets into the heart and the aorta before any x-ray dye gets there" (R. 14 at 105). He said it showed the catheter with no dye in it yet, which is improper, and then showed "the very first thing that comes out" of the catheter into Mr. Bereal's heart was "large circles of air" – "fair amounts of air" – that go up the aorta and "into the left coronary artery" (R. 14 at 108, 110, 122). Only after the air already was in Mr. Bereal's heart does contrast dye "finally and belatedly" come out and into the artery (R. 14 at 111). As a result, "most of" Mr. Bereal's heart was "deprived of any blood flow, therefore, any oxygen and, therefore, any glucose," and the air then went up the "aorta to the brain" (R. 14 at 111, 124).

While acknowledging he was "not an expert" in the Avanta and is not a "biomedical engineer," Dr. Fifer agreed with Ms. Harris that the angiograms meant there could not have been a device defect in the Avanta, as "there's much more opportunity for operator error than for device error," that he knew of no "problems with that device," and, "most importantly, the air is there on the very first injection before there's any contrast. So the air has to be closer to the patient than the x-ray dye is to the patient" (R. 14 at 141-42, 180-81). While a device defect was "theoretically possible," Dr. Fifer could not imagine how that would go unnoticed: if there were "a crack in the tubing through which air could be sucked," "under the pressure injection it would be springing a leak and shooting up in the air" like a garden hose with a crack in it (R. 14 at 194).

Ms. Harris explained Mr. Bereal's wave forms recorded from the transducer also showed the air in the femoral catheter before the first injection (R. 12 at 68). She said

they were "dampened," which could be caused by air, a clot, or a kink somewhere in the system, by a lesion in the artery, or by the end of the catheter butting up against the artery wall of the artery (R. 12 at 75, 77). Because there was no evidence of any clot, kink, lesion, or catheter against the artery wall, however, air in the femoral catheter, the SPAT, or the transducer line was the only possible conclusion, which was consistent with the angiogram of the first injection (R. 12 at 75, 78).

Dr. Fifer agreed, explaining that the things that can make a wave form look damped "include blood and clot and air" (R. 14 at 133). Mr. Bereal's initial wave form was "abnormal" and would make a reasonable doctor "want to make absolutely sure that there's no clot or air in the catheter causing the damping," giving "another chance to recognize that there's a problem and to" clear the catheter (R. 14 at 134).

Based on all of this, Ms. Harris testified the only six ways air could have entered Mr. Bereal's system, in order of likelihood, were Ms. Cody: (1) "failing to adequately fill the femoral catheter with saline before insertion into the patient;" (2) failing to close the transducer stopcock; (3) failing properly to purge the transducer; (4) failing to purge the SPAT correctly and visually observe the system to ensure all air has been removed; (5) failing to purge the MPAT correctly and visually observe the system to ensure all air has been removed; or (6) failing "to visualize for air after each step, not repurging when air remains after the initial purging process can allow air to remain in the system" (R. 12 at 125-29). Ms. Harris explained these were the only possibilities, and "if any one of these occurred," it would "be a departure from the standard of care" (R. 12 at 129).

Dr. Fifer reviewed Ms. Harris's conclusions and agreed (R. 14 at 141). He stated this also showed Dr. Bajaj "did not use proper technique to flush the catheter system prior

to taking the first picture and therefore did not ensure that there was no air in the system" (R. 14 at 126, 131-32). Dr. Bajaj also "failed to observe that the arterial wave form prior to the first injection was damp" (R. 14 at 131-32). As "there was obviously air in the system prior to the first injection," Dr. Bajaj's "failure to make sure that there was no air in the system and to recognize the possibility that there was air in the system is a breach of the standard of care" (R. 14 at 139-40). Dr. Fifer concluded these failures caused or contributed to Mr. Bereal's stroke (R. 14 at 141).

2. Defense's Medical Experts' Opinions

At trial, the defendants ensured Dr. Bajaj qualified as an expert on the standard of care and causation (R. 23 at 4-5). He opined that 10-15 ccs of air were injected into Mr. Bereal, but could not explain why he suspected that amount (R. 20 at 125). He believed that, due to this volume, air did not come from the catheter or the SPAT, but had to come from outside the Avanta (R. 20 at 124, 126-27). He claimed the first angiograms showed "air and contrast" coming out together (R. 20 at 135). He said he "met the standard of care in the care and treatment" he provided to Mr. Bereal "very well" (R. 20 at 145).

The defense's other medical expert testified Mr. Bereal's angiograms had "no significance" (R. 22 at 17). He said that, by purging the femoral catheter prior to the wet-to-wet connection but not afterward, and by not filling the femoral catheter with contrast prior to the first injection, Dr. Bajaj met the standard of care (R. 22 at 21-22). He opined that the transducer wave form before first injection was not damped, and Dr. Bajaj met the standard of care in believing that (R. 22 at 24-26). He said Dr. Bajaj had a right to rely on Ms. Cody to make sure the line was clear of air (R. 22 at 27).

F. Wesley's Further Responses to Mr. Bereal's Injury

"[A]t some point," the issue came up" of whether there was a "device or product failure" in the Avanta in Mr. Bereal's procedure (R. 13 at 107). The injury was caused either by operator error or device defect; as Mr. Bereal could not have injected air into himself, these were the only two possibilities (R. 7 at 13, 46; R. 15 at 177; R. 20 at 42).

Dr. Bajaj and Mr. Lewis said they only ever suspected device failure, possibly in the "new tubing" from the Avanta's November upgrade (R. 7 at 14; R. 15 at 174; R. 16 at 70; R. 20 at 37, 44, 46). Though none of Dr. Bajaj's medical records reflect this, he said his "basis" for thinking this was there had been "no issues with air" before the upgrade, and this happened after it (R. 16 at 76; R. 22 at 61). But the same Avanta had been used in many other heart caths for weeks after the upgrade, with no problems (R. 16 at 76).

Wesley's policy for "device or product failures" applied to both physicians and staff (R. 13 at 106; R. 15 at 140-41; R. 17 at 91-92). It required sending reports to the FDA and manufacturer, notifying maintenance, leaving the room untouched, moving the device to a secure location, bagging, preserving, and leaving any soiled or disposable items with the device, downloading or copying the device's memory, notifying the department director, and engaging in an internal investigation (R. 13 at 109, 137-38, R. 15 at 141-42, 144-45, 147, 149, 170). If the Avanta malfunctioned to cause Mr. Bereal's air embolism, this policy would apply (R. 7 at 74; R. 13 at 111; R. 15 at 149-50).

While Mr. Lewis and Dr. Bajaj reported the incident to Dr. Ekengren, this policy was not followed: there was no record of any device defect investigation by Wesley (R. 15 at 150-51, 170, 172-73; R. 17 at 139; R. 20 at 43, 53). Moreover, the Avanta's memory was purged (R. 14 at 56-57; R. 17 at 74).

The only following of the policy was that, the afternoon of the incident, Nurse Stilwell filled out a risk management report on the incident (R. 7 at 52; R. 13 at 122-24, 132). He reported "brand name, Medrad, common device name, BP transducer set" (R. 13 at 132, 138). He was wrong, though: the transducer was not manufactured by Medrad (R. 15 at 105, 109-10, 185). As well, though he never saw any problem with the Avanta's SPAT, Mr. Lewis told him there had been a problem with the SPAT and directed him to note down the SPAT's lot and catalog numbers, which he did (R. 15 at 39-40, 43). Contrary to policy, neither Ms. Cody nor Nurse January filled out any report on Mr. Bereal's injury (R. 15 at 166-67; R. 17 at 238).

Later that day, Ms. Dean sent the FDA a report that a transducer set not manufactured by Medrad caused the air injection (R. 10 at 200-09; R. 11 at 87; R. 13 at 140; R. 17 at 27, 55, 78). She said she did not know what a "transducer" was, and meant the catheter tubing (R. 7 at 32). But Nurse January "threw away" the transducer, it "was not preserved as evidence," and Wesley never had it tested (R. 7 at 59; R. 13 at 138-40).

Additionally, Wesley also was supposed to send a report of this incident to the Joint Commission, its accreditor, but did not (R. 18 at 26). Had it done so, the Joint Commission would have conducted its own investigation (R. 18 at 26-27).

Dr. Ekengren claimed there was an internal investigation, but it did not analyze the root cause of Mr. Bereal's injury and resulted in no conclusion, despite her admission that Wesley's policies and its accreditation required this (R. 7 at 68; R. 17 at 110-11). That "investigation," though, was merely Medrad representatives coming to Wesley on December 15 or 16, 2009, to look at and test the Avanta machine used in Mr. Bereal's procedure, and Wesley relied on this ((R. 7 at 18, 26-28, 46, 68; R. 10 at 217; R. 12 at 53-

55, 138; R. 15 at 56; R. 16 at 15). Ms. Dean said this comprised any "root cause analysis," even though Medrad determined the root cause was *not* equipment defect, and did not analyze further (R. 7 at 28, 30, 46, 48).

When the Medrad representatives came, Ms. Dean, Nurses Stilwell and January, and Ms. Cody were present, and Dr. Ekengren said she was there for part of it (R. 7 at 26; R. 10 at 217; R. 15 at 56-57; R. 17 at 178-80). The representatives "did a full check on the system and the unit was found to be operating to specifications" – "everything tested out fine" (R. 12 at 140-41; R. 13 at 148; R. 16 at 15-16).

The Medrad representatives also gave the Wesley employees, including Ms. Cody, additional training to "re-educat[e them] on the use and function of the machine," including watching them "go through and put everything together like [they] would a normal case" (R. 12 at 53-55; R. 13 at 149; R. 15 at 57; R. 18 at 136-37). Ms. Dean said this satisfied her there was no operator error, but admitted that "just because you watch somebody, after a big problem, do something, doesn't necessarily mean that they did what they were supposed to do correctly when the problem took place" (R. 7 at 73).

Thereafter, Medrad reported to Mr. Lewis that their "investigation revealed there was nothing whatsoever wrong with the equipment" (R. 15 at 175; R. 16 at 96-97). Despite Mr. Lewis having claimed he saved the SPAT, the letter stated the actual SPAT was not available for Medrad's testing (R. 16 at 98). Ms. Dean said she did not know why this was, because the SPAT was in her office (R. 7 at 56). The letter recounted that no previous issues related to the SPAT ever had been reported to Medrad (R. 7 at 57).

After this, Wesley took the Avantas out of service and never used them again (R. 6 at 37-39; R. 7 at 43-44; R. 12 at 189; R. 13 at 163-64; R. 14 at 20; R. 16 at 150-51).

G. Formal Device Defect Allegations

1. Medrad's Reports and FDA's Letter

In December 2010, Medrad reported Mr. Bereal's injury to the FDA, explaining its testing found the Avanta "operating to specification" and Wesley would conduct an internal investigation (R. 7 at 59-60; R. 16 at 191-92, 194-95, 197; R. 18 at 10-13; R. 19 at 22, 29). It did not say if user error or device defect caused the injury (R. 16 at 193).

In May 2011, the FDA sent Avanta users a letter mentioning 45 similar reports from before December 2009 of instances in which air possibly had been injected into a patient during use of an Avanta (R. 13 at 15; R. 16 at 171; R. 19 at 22). Like the report about Mr. Bereal, however, none stated a device defect was the cause, which equally could have been user fault (R. 13 at 17; R. 14 at 195; R. 18 at 15). Medrad had not sent these reports to Avanta users, but defense expert Yadin David, a biomedical engineer, said it should have (R. 13 at 17; R. 16 at 186, 172; R. 19 at 25, 34; R. 20 at 98-99).

At the same time, Mr. David agreed the FDA letter did not say "this is an unsafe product that needs to be taken off the market," but was merely "a product safety reminder" about the risk of air embolisms – "to remember to get the air out" (R. 19 at 23-24, 109, 148, 181-82). The letter also stated Medrad was "releas[ing] a new design for" the SPAT's pressure isolation valve to "mak[e] the priming process simpler to perform," and also would change the Avanta's software to make the purging process a "one-touch step" instead of two steps (R. 19 at 23-24, 109-10). Mr. David admitted Medrad already had taken this latter action at Wesley in the November 2009 upgrade (R. 19 at 27, 112).

Thereafter, Medrad instituted a "Class 2" recall of the Avanta (R. 6 at 42-43; R. 17 at 215). But this did not mean it was removed from market or users were advised to

stop using it; instead, Mr. David said it merely was "[t]o remind people that they need to be diligent in removing air from the system" (R. 18 at 23-24; R. 19 at 99, 181-82).

Avantas were in wide use at the time of trial, including at the Massachusetts General Hospital and at another facility where Dr. Bajaj worked and used them, though he said only in emergencies (R. 12 at 17-18; R. 14 at 81; R. 20 at 17-19, 99).

2. Yadin David's Opinions

Mr. David, who was not a medical doctor, testified to two conclusions. First, he said, "Medrad failed to behave as a reasonably prudent manufacturer of medical device by failing to warn the staff and the physicians at Wesley … about problems relating to air injection associated with the Avanta" (R. 19 at 19, 21-22). When asked why he ruled out operator error causing Mr. Bereal's injury, Mr. David responded Dr. Bajaj and the cath lab team testified so, and he believed them (R. 19 at 37-38).

Mr. David was unable to point to any actual defect in the Avanta, but surmised Mr. Bereal's injury must have had something to do with Medrad's later change to the SPAT's pressure isolation valve, or "PIV" (R. 19 at 68-73). He claimed that, if the cath lab team did not err, "the only way to reconcile the facts" was "by determining that the pressure isolation valve was defective" (R. 19 at 75). He said this "defect … made it unreasonably dangerous as marketed and sold by Medrad," but could not explain any specific manner in which that valve was defective, and could not explain why Medrad's testing of the exact Avanta involved in this case showed no defect (R. 19 at 68-75, 85).

Mr. David also sought to support this first conclusion by saying he "found 119" "reports of air injections … associated with the Avanta" on the internet, of which he "looked at about 70" (R. 19 at 37, 144). He admitted, though, that none mentioned any

"device defect," none "even suggest[ed] that there was an air injection problem due either to a problem with the PIV" or a lack of remote air sensors, and some even "reflect[ed] that air injections occurred due to user error," and (R. 19 at 113-24, 133-40).

Mr. David opined that 7-15 ccs, was injected (R. 19 at 54-55). He said the wave form showed there was no air in the tubing prior to the first injection, because its line was not flat, and only went flat on the first injection, showing air in the tubing (R. 19 at 64).

Mr. David said the line stayed flat for 17 seconds, meaning "an additional 17 seconds of air" in the tubing after the first injection (R. 19 at 64-65, 153). He admitted this would be a lot of air, which he would "expect" the cath team to see (R. 19 at 153). Contrary to all other witnesses, he opined that a hole in the pressurized line would not make liquid "spray out," due to a "Venturi effect" in which, "if you have a flow of fluid and there is opening, the air from the atmosphere would be sucked in" (R. 19 at 65-66).

Second, Mr. David also said he concluded "Medrad failed to act as a reasonable manufacturer of medical product by not providing an … air-in-line sensor … following the connection to the blood pressure transducer in the venting part" (R. 19 at 20). He admitted no "standard require[d]" that, but said that, like the Siemens ACIST injector, Medrad could have "moved all the opening into the device and left with a single catheter" subject to a single air sensor, whereas the Avanta had seven openings beyond its air sensor (R. 19 at 80). He said this "probably" "would have prevented Mr. Bereal's injury" (R. 19 at 81). At the same time, Mr. David admitted that the FDA approved the Avanta on the basis that it was "substantially equivalent" to the ACIST (R. 19 at 159-60).

Alternatively, Mr. David said Medrad could have installed a "remote air sensor" (R. 19 at 81). He admitted, though, that no power injector has this (R. 19 at 160, 162).

H. Proceedings Below

On December 9, 2011, Mr. Bereal filed a petition for damages in the District Court of Sedgwick County against Dr. Bajaj, Wesley, Medrad, and Medrad's parents Bayer Healthcare LLC and Bayer Corporation (R. 1 at 68). He alleged claims of medical negligence and lack of informed consent against Dr. Bajaj, and alleged medical and hospital negligence claims against Wesley (R. 1 at 95-99). He also alleged nine claims against Medrad and Bayer, including products liability, negligence, breach of warranty, Kansas Consumer Protection Act, and fraud (R. 1 at 79-95). Finally, he sought damages against all defendants for his wife's loss of consortium (R. 1 at 99).

In their answers, both Dr. Bajaj and Wesley raised affirmative defenses that, if Mr. Bereal suffered any damages, they were the result of the "fault of others," and damages should be apportioned under comparative fault (R. 2 at 44, 49). In March 2013, Mr. Bereal reached a settlement with Medrad and Bayer, and on those defendants' and Mr. Bereal's joint motion, Medrad and Bayer were dismissed from the case, leaving only Dr. Bajaj and Wesley as defendants (R. 10 at 6-27; R. 24 at 1-6).

In December 2013, and on the parties' agreement, the court, through Judge Timothy Lahey, set the defendants' expert disclosure deadline as January 21, 2014 and the plaintiff's rebuttal expert disclosure deadline as February 3, 2014 (R. 24 at 11). On January 21, 2014, the defendants timely filed their expert witness disclosures, among whom was Mr. David (R. 24 at 13, 15, 24).

Then, on February 3, 2014, Mr. Bereal timely served his rebuttal expert disclosure, disclosing Dr. Suzanne Parisian, M.D., as his expert to rebut Mr. David (R. 24 at 17). Dr. Parisian was a former U.S. Public Health Service Commissioned Corps

officer who specialized in hazard and risk assessment for radiological devices at the FDA, who spent four years with the FDA reviewing hundreds of market applications to ensure device safety and efficacy, and thereafter reviewed such devices in the private sector from her company in Arizona (R. 24 at 60-61).

Dr. Parisian would have rebutted Mr. David by, *inter alia*, explaining his "liberal use of various public FDA documents which he obtained from the internet" was flawed, inappropriate, superficial, speculative, misstated, and incomplete, he "failed to create a valid engineering root cause analysis," his "report lacks valid scientific or regulatory methodology and credible evidence to establish that Medrad's device performed defectively," his assumptions about clinical conduct were "unsupported," his brushing away user error was wrong, and he did not engage in any proper design review of the Avanta (R. 24 at 62-63, 67-69, 71-73, 75-76). In short, she would testify Mr. "David's methodology, primarily due to his failure to review critical manufacturing, compliance and regulatory data is unacceptable for a regulatory/safety device analysis and render his opinions speculative at best," and "there is no evidence that the Medrad device or any of the disposables were defective. In fact, the evidence is to the contrary" (R. 24 at 78).

On February 18-19, Wesley and Dr. Bajaj each moved to strike Dr. Parisian, arguing her testimony would be duplicative of both Dr. Fifer and Ms. Harris, who the plaintiff previously had disclosed (R. 1 at 55; R. 24 at 28-29; R. 25 at 69-73). Mr. Bereal opposed this, explaining his disclosure of Dr. Parisian was timely, Dr. Parisian was an authorized rebuttal expert, and her testimony was not duplicative of Dr. Fifer or Ms. Harris, who were not medical device experts (R. 24 at 22-31).

At a hearing on February 27, 2014, the trial court, through Judge Eric Yost, granted the defendants' motions and struck Dr. Parisian, reasoning that because Mr. Bereal originally brought products liability claims against Medrad, and the defendants' affirmative defenses of products liability were against Medrad, "whatever you had to say about the equipment you needed to say it in your original disclosure," and could not in a rebuttal (R. 4 at 21). The pretrial order, entered that same day, contains a variety of affirmative defenses by Wesley and Dr. Bajaj as to products liability claims against Medrad (R. 2 at 60-61, 64-65).

Mr. Bereal moved the court to reconsider (R. 25 at 1-14). At another hearing, it refused, stating, "I agree with you you have the right to do rebuttal expert reports. I just don't think this particular report should have been a rebuttal report. I think you should have offered this as part of your initial wave of plaintiff's disclosures" (R. 5 at 20).

Before the final pretrial conferences, Mr. Bereal filed a motion in limine to exclude the defendants' products liability comparative fault claims against Medrad and any evidence or testimony as to those claims, because Mr. David's report failed to designate any specific defect found in the Avanta, failed to inspect or test it, was just "personal opinion" testimony, and did not meet the *Frye* standard, and as a result the defendants had no actual evidence required under the Kansas Products Liability Act that any device defects caused Mr. Bereal's stroke, paralysis, and other damages (R. 30 at 44-84). The court, now through the trial judge, Judge William Wooley, ruled that the Kansas Products Liability Act did apply to the defendants' products liability claims, but refused to exclude them or evidence relating to them (R. 8 at 60-64).

The court said Mr. David was the defense's expert "as to products liability" (R. 10 at 35). It did, however, grant Mr. Bereal's motion in limine excluding Mr. David from giving standard of care opinions (R. 11 at 4-5).

The case then proceeded to a jury trial over 21 days in March and April, 2014 (R. 1 at 64-66). When Mr. David testified, Mr. Bereal again objected to the admission of his testimony at all, which was denied, and also again requested to have Dr. Parisian testify as a rebuttal expert, which was denied (R. 19 at 165-79, 183-86). When the defense rested its case-in-chief, Mr. Bereal once again requested to have Dr. Parisian testify as a timely rebuttal expert to rebut Mr. David, formally proffering the discovery scheduling order, Mr. Bereal's notice of compliance, and Dr. Parisian's report and CV (R. 22 at 67-69). The court denied the proffer (R. 22 at 69). Mr. Bereal had no rebuttal (R. 22 at 71).

Thereafter, Mr. Bereal moved for judgment as a matter of law under K.S.A. § 60-250 as to all of Wesley's and Dr. Bajaj's claims against Medrad (R. 22 at 121-83). The court denied this as to each claim (R. 22 at 134, 142, 159, 170, 182). The jury then was instructed on the defendants' six comparative fault allegations against Medrad, and the definitions for the standards of fault as to them under the Kansas Products Liability Act (R. 2 at 97, 99, 104-09; R. 22 at 211-13).

After one-and-a-half hours of deliberation, the jury reached a unanimous verdict finding neither Dr. Bajaj nor Wesley were at fault for Mr. Bereal's injuries (R. 3 at 1-2; R. 23 at 43-46). Once the trial court entered its journal entry of judgment for the defendants, Mr. Bereal timely appealed to this Court (R. 3 at 3, 10).

Argument and Authorities

I. The trial court erred in striking and then excluding the plaintiff's rebuttal expert witness, Dr. Suzanne Parisian, M.D. Disclosure of Dr. Parisian was timely, she was qualified to testify as an expert on the subjects in her report rebutting the defense's products liability expert, and her testimony would not have duplicated that of either of the plaintiff's other two expert witnesses, neither of whom gave or were qualified to give products liability opinions. As a result of Dr. Parisian's exclusion, the plaintiff had no ability to counter the defense's products liability expert and was left with only two experts, whereas the defense was allowed three.

Standard of Appellate Review

Decisions to strike or exclude an expert witness will be reversed only upon a showing of "abuse of discretion." *Walder v. Board of Comm'rs of Jackson Cnty.*, 44 Kan.App.2d 284, 286, 236 P.3d 525 (2010) (striking); *Nold ex rel. Nold v. Binyon*, 272 Kan. 87, 96, 31 P.3d 274 (2001) (excluding).

A judicial action constitutes an abuse of discretion if it (1) is arbitrary, fanciful, or unreasonable; (2) is based on an error of law; or (3) is based on an error of fact. *State v. Ward*, 292 Kan. 541, Syl. ¶ 3, 256 P.3d 801 (2011). Whether an exercise of judicial discretion is based on an error of law is a question of law, which is subject to unlimited review. *State v. Garcia*, 295 Kan. 53, 61, 283 P.3d 165 (2012).

* * *

K.S.A. § 60-226 provides a plaintiff must be allowed to have a rebuttal expert as long as she is qualified, would solely rebut a defense expert, and is timely disclosed. Here, the plaintiff timely disclosed his rebuttal products liability expert, who was qualified and, unlike the plaintiff's medical standard of care experts, solely would rebut the defense's products liability expert. Nonetheless, the trial court struck the rebuttal expert and excluded her from testifying. Did this violate § 60-226?

A. K.S.A. § 60-226 allowed the plaintiff to have a timely disclosed, qualified rebuttal expert to rebut the defense's products liability expert.

K.S.A. § 60-226(b) provides that, generally, "Parties may obtain discovery regarding any nonprivileged matter that is relevant to the subject matter involved in the action, whether it relates to any party's claim or defense …." This expressly includes procuring and deposing expert witnesses. § 60-226(b)(5).

To activate the right to an expert witness, a "party must disclose to other parties the identity of any witness it may use at trial to present expert testimony," which "must state" both the subject matter on which the expert will testify and the substance of her facts and opinions. § 60-226(b)(6)(A). As well, "if the witness is retained or specially employed" as an expert, the disclosure also must "state a summary of the grounds for" her opinion." If a party fails to adhere to these rules, the witness cannot testify "unless the failure was substantially justified or is harmless." K.S.A. § 60-237(c)(1).

Section 60-226(b)(6)(C)(ii) specifically provides for a party to procure a rebuttal expert, if her "evidence is intended solely to contradict or rebut evidence on the same subject matter identified by another party."

No Kansas case law, published or unpublished, yet has discussed the propriety and admissibility of rebuttal experts under § 60-226, except to hold merely that disclosure of a rebuttal expert must be timely and, if not, he may not testify. *See In re Marriage of Sinks*, No. 110,316 at *2-4, 333 P.3d 204 (Kan. App. 2014) (unpublished). Still, numerous decisions confirm that allowing timely, competent, rebuttal expert testimony is proper and routine. *See, e.g.*, *In re Tallgrass Prairie Holdings, LLC*, 50 Kan.App.2d 635, 637, 333 P.3d 899 (2014); *State v. Carr*, 300 Kan. 1, 293, 331 P.3d 544 (2014).

Section 60-226, though, is substantially the same as Fed. R. Civ. P. 26, and Kansas courts follow federal authority interpreting that rule to interpret the statute. *See, e.g., Berst v. Chipman*, 232 Kan. 180, 185-86, 653 P.2d 107 (1982) (following interpretation of Fed. R. Civ. P. 26 in *Herbert v. Lando*, 441 U.S. 153, 177 (1979), as to § 60-226). Indeed, the rebuttal expert language in § 60-226(b)(6)(C)(ii) is identical to Fed. R. Civ. P. 26(a)(2)(D)(ii): experts presenting evidence "intended solely to contradict or rebut evidence on the same subject matter identified by another party …."

While, like 60-226(b)(6)(C)(ii), the federal rule concerns disclosure timing, federal courts widely have observed and applied it as providing a party the substantive ability to procure an expert witness to rebut an opposing party's expert – as the trial court agreed, "the right to do rebuttal expert reports" (R. 5 at 20). *See, e.g., Panasonic Comms. Corp. of Am. v. United States*, 108 Fed.Cl. 412, 414 (2013) (rule "allows the filing of a rebuttal expert report"); *1-800 Contacts, Inc. v. Lens.com, Inc.*, 755 F.Supp.2d 1151, 1167 (D.Utah 2010), *aff'd in part, rev'd in part on other grounds*, 722 F.3d 1229 (10th Cir. 2013) (same); *New York v. Solvent Chem. Co.*, 685 F.Supp.2d 357, 414 (W.D.N.Y. 2010), *rev'd in part on other grounds*, 664 F.3d 22 (2d Cir. 2011) (same).

Thus, rebuttal expert testimony must be timely disclosed, must be from a qualified expert, and must rebut an opposing expert and not simply introduce new theories:

> Rebuttal expert testimony must relate to and rebut evidence or testimony on the same subject matter identified by another party …. Such evidence is not tied to any particular witness; it is tied to whether the party with the affirmative burden has presented evidence and/or testimony from a duly disclosed expert on the same subject matter as that which will be rebutted by the disclosed rebuttal expert.

Bleck v. City of Alamosa, No. 10–cv–03177, 2012 WL 695138 at *4 (D.Colo. 2012).

Therefore, as a plaintiff has the burden to prove his cause of action, and a defendant has the burden to prove his affirmative defenses, a plaintiff must "have an opportunity to respond to Defendants' expert reports in their rebuttal reports, including theories relied upon by Defendants' experts with respect to their affirmative defenses." *Plumbers & Pipefitters Local 572 Pension Fund v. Cisco Sys., Inc.*, No. C 01-20418 JW, 2005 WL 1459572 at *2 (N.D.Cal. 2005).

"Rebuttal evidence is properly admissible when it will explain, repel, counteract or disprove the evidence of the adverse party." *Crowley v. Chait*, 322 F.Supp.2d 530, 551 (D.N.J. 2004). "[A]rchetypal rebuttal testimony … identifies a flawed premise in an expert report that casts doubt on both that report's conclusions and its author's expertise." *Scientific Components Corp. v. Sirenza Microdevices, Inc.*, No. 03 CV 1851, 2008 WL 4911440 at *2 (E.D.N.Y. 2008). While rebuttal expert testimony "is not an opportunity for the correction of any oversights in the plaintiff's case in chief," *Crowley*, 332 F.Supp.2d at 551, the phrase "same subject matter" in Fed. R. Civ. P. 26 (and, thus, § 60-226), "allow[s] rebuttal experts to use a different methodology to analyze the same facts considered by the expert in chief." *Scientific Components*, 2008 WL 4911440 at *2.

As a result, it is proper for a plaintiff's rebuttal expert to testify to "technical information … that was not previously the subject of expert testimony in this litigation, and without which a non-[expert] would be unable to evaluate [the rebuttal expert]'s criticism of [the defendant's expert]'s report." *Id.*

Therefore, under § 60-226(b)(6)(C)(ii), as long as a plaintiff's rebuttal expert is timely disclosed, is qualified, and will testify solely to contradict or rebut evidence on the

same subject matter a defense expert identified, the law of Kansas is that the plaintiff must be allowed that rebuttal expert.

In this case, to support their products liability affirmative defenses, the defendants disclosed Yadin David, their expert "as to products liability" (R. 10 at 35). The court already had entered a scheduling order allowing the plaintiff rebuttal experts. Pursuant to that order, the plaintiff disclosed Dr. Suzanne Parisian, M.D, to rebut Mr. David.

Dr. Parisian was timely and properly disclosed, was qualified, and her report solely rebutted Mr. David's products liability conclusions. She identified numerous flawed premises in Mr. David's report, casting doubt on both his conclusions and expertise. Her expertise and methodology were different than the plaintiff's medical experts in chief, none of whom had any medical device expertise, and none of whom could have rebutted or did rebut Mr. David's products liability conclusions.

Nonetheless, the trial court struck Dr. Parisian and excluded her from trial, reasoning the plaintiff had to disclose her as an initial expert, not in rebuttal. This was error. This Court should reverse the judgment below and remand this case for a new trial.

B. The trial court violated § 60-226 in striking and then excluding the plaintiff's timely disclosed, qualified rebuttal expert, Dr. Parisian, who, unlike either of the plaintiff's medical experts, would have rebutted the defense's products liability expert.

1. The plaintiff timely disclosed Dr. Parisian.

A rebuttal expert must be timely disclosed, or else cannot be allowed to testify. *Sinks*, No. 110,316 at *2-4, 333 P.3d at 204 (reversing judgment following trial involving untimely rebuttal expert). Section 60-226(b)(6)(C)(ii) provides that, "Absent a stipulation or court order," a rebuttal expert must be disclosed "within 30 days after the other party's disclosure" of the expert to be rebutted.

Here, there was both a stipulation and an order. On December 10, 2013, on the parties' agreement the court ordered the defendants to disclose any experts by January 21, 2014, and the plaintiff to disclose any rebuttal experts by February 3, 2014 (R. 24 at 11).

Pursuant to this, the defendants timely and properly disclosed all their experts, including Mr. David, on January 21, 2014, providing the plaintiff with all their experts' reports (R. 24 at 13, 15, 24). Mr. David's report is in the record on appeal (R. 24 at 48-58), as well as the appendix to this brief (Appx. A28-38). Then, on February 3, 2014, the plaintiff timely and properly disclosed Dr. Parisian as a rebuttal expert to Mr. David, providing the defendants with her report (R. 24 at 17). Dr. Parisian's report also is in the record on appeal (R. 24 at 59-78), as well as the appendix to this brief (Appx. A8-27).

Therefore, the plaintiff's disclosure of Dr. Parisian met § 60-226(b)(6)(C)(ii).

2. Dr. Parisian was qualified to testify in rebuttal to the defense's products liability expert's opinions.

Dr. Parisian also was eminently qualified to testify to her conclusions. Under K.S.A. § 60-456(b), an expert only may testify to "scientific, technical or other specialized knowledge" when she "is qualified as an expert by knowledge, skill, experience, training or education." She "must possess special training as an expert in that" topic and "the professional qualifications" appropriate thereto. *State v. Willis*, 256 Kan. 837, 847, 888 P.2d 839 (1995).

Dr. Parisian would have rebutted Mr. David's conclusions that supported the defendants' affirmative defense theories that a product defect in the Avanta or its associated tubing was responsible for the injection of air into Mr. Bereal (R. 24 at 59-78; Appx. A8-27). She especially would have rebutted Mr. David's methodology and assumptions (R. 24 at 59-78; Appx. A8-27).

This was scientific and technical knowledge for which Dr. Parisian was qualified by knowledge, skill, experience, training, and education. A former U.S. Public Health Service Commissioned Corps officer specializing in hazard and risk assessment for radiological devices at the FDA, she spent four years with the FDA reviewing hundreds of market applications to ensure device safety and efficacy of radiological devices like the Medrad Avanta, thereafter reviewing them in the private sector (R. 24 at 60-61).

As a result, Dr. Parisian "qualif[ied] as an expert" on whether the Avanta was defective. *Willis*, 256 Kan. at 847.

3. Dr. Parisian would have rebutted the defense's products liability expert, and her testimony would have been unlike anything to which either of the plaintiff's two medical experts did or could have testified.

The defendants' only argument to support striking Dr. Parisian was that her testimony would have duplicated that of the plaintiff's two experts, Dr. Fifer and Ms. Harris (R. 1 at 55; R. 24 at 28-29; R. 25 at 69-73). They argued she thus was inappropriate as a rebuttal expert, and instead should have been disclosed earlier.

The trial court agreed and struck Dr. Parisian, reasoning that, because Mr. Bereal's original petition brought products liability claims against Medrad, and the defendants' products liability defenses of were against Medrad, "whatever you had to say about the equipment you needed to say it in your original disclosure," and could not do so in rebuttal (R. 4 at 21). It "agree[d the plaintiff had] the right to do rebuttal expert reports," but opined "this particular report should have been a rebuttal report. I think you should have offered this as part of your initial wave of plaintiff's disclosures" (R. 5 at 20). Essentially, the trial court struck Dr. Parisian because it believed that, under § 60-226(b)(6)(C)(ii), she was not a "rebuttal expert."

This was error. First, by the time of the expert disclosures, Medrad had not been a party to the case for nearly a year (R. 10 at 6-27; R. 24 at 1-6). From its dismissal in March 2013 onward, the plaintiff had no products liability claims at all. His only claims were medical malpractice against Dr. Bajaj and Wesley (R. 1 at 95-99).

Indeed, until receiving Mr. David's report in January 2014, *after* the disclosure time for the plaintiff's initial experts already had passed, the plaintiff had no idea what contentions, if any, Dr. Bajaj or Wesley were going to allege regarding any defect in the Avanta. Throughout the discovery process, even before Medrad was dismissed, Dr. Bajaj and Wesley never disclosed to the plaintiff any problems, defects, or malfunctions in the Avanta they believed caused or contributed to cause Mr. Bereal's injuries (R. 25 at 2-5).

Medrad itself never answered any party's discovery, propounded any discovery, or participated in any discovery (R. 25 at 2-5). In their responses to the plaintiff's interrogatories, both before and after Medrad's dismissal, the defendants repeatedly did not disclose any claims about defects in the Avanta, but merely reserved the right to disclose any such claims later – which they never then supplemented (R. 25 at 2, 4). In their responses to the plaintiff's requests for production of documents, Dr. Bajaj and Wesley further stated they had no documents related to any such claims (R. 25 at 2-5).

Therefore, at the time the court issued the final scheduling order in December 2013, setting the actual expert disclosure deadlines, the plaintiff *had no idea* what claims the defendants would make about defects in the Avanta, *or if they even would make any at all*. For all the plaintiff knew, based on the defendants' failure to supplement their interrogatory responses and their failure to conduct any discovery concerning the Avanta, the defendants were not going to allege any comparative fault against Medrad at all.

As a result, and as none of the plaintiff's claims against Dr. Bajaj and Wesley on which he bore the burden of proof had anything to do with products liability, the plaintiff had no reason to procure any products liability expert witness in his initial expert disclosures, and therefore procured and disclosed only medical standard of care and causation experts to prove his medical malpractice claims against the defendants. The trial court's conclusion that the plaintiff's initial, long-dismissed claims against Medrad had any impact on his initial expert disclosures in any way was error.

Second, *all of that changed for the first time* on January 21, 2014, when, at long last, the defense finally disclosed, through Mr. David's report, their supposed evidence to support what, ultimately, became their six affirmative defenses making claims under the Kansas Products Liability Act ("KPLA"),[1] K.S.A. §§ 60-3301, *et seq.*: that problems, defects, or malfunctions in the Avanta caused or contributed to cause Mr. Bereal's injuries for comparative fault purposes (R. 2 at 97; R. 24 at 13, 15, 24, 48-58).

Under elementary civil procedure, the defense had the burden to prove those affirmative defenses. *Wooderson v. Ortho Pharm. Corp.*, 235 Kan. 387, 412, 681 P.2d 1038 (1984). Under the KPLA, the defense had the additional burden to rebut a variety of technical presumptions to do so. *See, e.g.*, K.S.A. § 60-3304 (device is presumed not defective if, at time of manufacture, it complies with regulatory standards).

So, to rebut Mr. David's products liability expert report, the plaintiff then procured and disclosed Dr. Parisian, whose testimony solely would have rebutted Mr. David's conclusions. She would not have duplicated any of the plaintiff's prior medical

[1] Over the defense's objection, the trial court expressly held the KPLA governed each and every one of the defendants' products liability affirmative defenses (R. 8 at 60-64). As the defendants did not cross-appeal, they cannot now challenge this adverse decision. *Mangus v. Stump*, 45 Kan.App.2d 987, 990-91, 260 P.3d 1210 (2011).

standard of care and causation experts' testimony, who did not and could not have rebutted Mr. David's products liability conclusions.

The defendants' products liability defenses against Medrad were: (1) "Manufacturing the Avanta … with an unreasonably dangerous and defective condition that allowed air to enter;" (2) "Designing the Avanta … with an unreasonably dangerous and defective condition that allowed air to enter;" (3) "Failing to provide adequate warnings and inform Dr. Bajaj and Wesley Medical Center regarding an unusual number of air injection events associated with use of the Avanta;" (4) "Failing to conduct an adequate risk assessment of the Avanta … and its components, both before and after multiple reports of air injections with the device;" (5) "Failing to design the Avanta … with a down-the-line remote air sensing detector;" and (6) "Failing to adequately train hospital employees and physicians regarding setup and use of the Avanta … in light of the number of air injection problems associated with the System" (R. 2 at 97).

Mr. David's report, disclosed on January 21, 2014, was the first inkling the plaintiff had that the defendants would raise these defenses. Among Mr. David's conclusions were: (1) the Avanta was unsafe for its intended use; (2) the Avanta had a history of unintended air injections and regulatory noncompliance; (3) Medrad failed to act as would a prudent, reasonable manufacturer by not providing the Avanta with remote air sensing detector; and (4) Medrad failed to communicate potential air injection problems associated with the Avanta to its users, providing an unsafe product to the defendants instead of removing it from use (R. 24 at 48-58; Appx. A28-38).

These conclusions were brand new in the case as of January 21, 2014, solely supporting the defendants' affirmative defenses, and not in any way responding to

anything the plaintiff's two, already disclosed standard of care and causation experts, Dr. Fifer and Ms. Harris, had concluded to support the plaintiff's medical malpractice claims.

Dr. Fifer and Ms. Harris opined that, based on the wave forms and angiograms from Mr. Bereal's procedure, Ms. Cody's and Dr. Bajaj's errors in operating the Avanta and failing to follow proper patient safety care standards caused Mr. Bereal's injury (R. 24 at 33-47). But neither was qualified to testify (or testified) whether the Avanta was safe, had a history of air injections, or had a history of regulatory noncompliance, or whether Medrad acted reasonably or failed to communicate necessary information to Avanta users. Neither was a biomedical device expert, and neither had any experience in medical device safety or compliance. Neither could testify as to the propriety either of Mr. David's theories or the proper methodology and documents that a qualified, unbiased biomedical device expert requires to evaluate alleged device defects properly.

Simply put, as to Mr. David's products liability opinions, neither Dr. Fifer nor Ms. Harris was "qualified as an expert by knowledge, skill, experience, training, or education." § 60-456(b). Neither "possess[ed] "special training as an expert in that" topic or "the professional qualifications" appropriate thereto. *Willis*, 256 Kan. at 847.

As a result, the plaintiff procured and disclosed Dr. Parisian, who *was* qualified, and could and did rebut each and every one of Mr. David's products liability conclusions. She did not duplicate Dr. Fifer's or Ms. Harris's opinions, and did not discuss the standard of care or causation. She solely rebutted Mr. David.

Dr. Parisian would have explained Mr. David's "liberal use of various public FDA documents which he obtained from the internet" was flawed, inappropriate, superficial, speculative, misstated, and incomplete, he "failed to create a valid

engineering root cause analysis," his "report lacks valid scientific or regulatory methodology and credible evidence to establish that Medrad's device performed defectively," his assumptions about clinical conduct were "unsupported," his brushing away user error was wrong and unscientific, and he did not engage in any proper design review of the Avanta (R. 24 at 62-63, 67-69, 71-73, 75-76).

In short, Dr. Parisian would have testified Mr. "David's methodology, primarily due to his failure to review critical manufacturing, compliance and regulatory data is unacceptable for a regulatory/safety device analysis and render his opinions speculative at best," and also that "there is no evidence that the Medrad device or any of the disposables were defective. In fact, the evidence is to the contrary" (R. 24 at 78).

Plainly, Dr. Parisian's testimony was "intended solely to contradict or rebut evidence on the same subject matter identified by" the defense's products liability expert, Mr. David. § 60-226(b)(6)(C)(ii). The defense had the "affirmative burden" to "presen[t] evidence … from a duly disclosed expert" on its KPLA defenses, and did so through Mr. David, which was "the same subject matter as that which w[ould] be rebutted by" Dr. Parisian. *Bleck*, 2012 WL 695138 at *4.

As a result, Dr. Parisian's testimony was "properly admissible" because it would "explain, repel, counteract or disprove" Mr. David's testimony. *Crowley*, 322 F.Supp.2d at 551. Indeed, her testimony was "archetypal rebuttal testimony," which "identifie[d] a flawed premise in [Mr. David's] expert report" and "cast[ed] doubt on both that report's conclusions and its author's expertise." *Scientific Components*, 2008 WL 4911440 at *2. Whereas the plaintiff's medical experts analyzed the facts from a medical standard of care methodology so as to prove the plaintiff's medical malpractice claims, Dr. Parisian

properly "use[d] a different methodology," products liability and device compliance, "to analyze th[ose] same facts" so as to rebut the defense's products liability expert. *Id.*

But for Mr. David, the defense's products liability allegations were "not previously the subject of expert testimony in this litigation, and without" Ms. Parisian's expert testimony, "a non-[expert] would be unable to evaluate [her] criticism of [Mr. David]'s report." *Id.* As a result, the law of Kansas is the plaintiff had to "have an opportunity to respond to [Mr. David's report] in [Dr. Parisian's] rebuttal repor[t]" as to "theories relied upon by [Mr. David] with respect to [defendants'] affirmative defenses." *Plumbers*, 2005 WL 1459572 at *2. The trial court erred in holding otherwise.

4. The trial court's decision unfairly left the plaintiff with only two medical experts and no products liability expert, whereas the defense was allowed two medical experts as well as a products liability expert.

Compounding this error, the trial court's decision to strike and exclude Dr. Parisian left a glaring imbalance in the parties' expert testimony at trial. The defense was allowed three experts: two medical standard of care experts, Drs. Bajaj and Reusser (R. 22 at 4-66; R. 23 at 4-5), and one "as to products liability," Mr. David (R. 10 at 35; R. 19 at 7-168). Conversely, the plaintiff only was allowed his two medical standard of care experts, Dr. Fifer and Ms. Harris (R. 12 at 11-203; R. 13 at 6-48; R. 14 at 78-206).

But § 60-226 should not be applied to "create an imbalance in the number of experts" allowed to each party." *EEOC v. JBS USA, LLC*, No. 10–cv–02103, 2014 WL 2922625 at *6 (D.Colo. 2014). Striking Dr. Parisian left the plaintiff with no one to rebut Mr. David, and this plainly would have been apparent to any reasonable juror.

The trial court abused its discretion in striking and excluding Dr. Parisian. This Court should reverse the trial court's judgment and remand this case for a new, fair trial.

II. The trial court erred in allowing the defendants' products liability expert, Yadin David, to testify to conclusions outside the scope of his disclosed pretrial report, which conclusions formed the whole of two of the defendants' affirmative defenses. As the plaintiff was disallowed from having his own products liability expert, the plaintiff had no possibility of countering Mr. David's surprise, undisclosed evidence, prejudicing the plaintiff and denying him a fair trial.

Standard of Appellate Review

The admission of evidence is within the trial court's discretion, and will be reversed only for an abuse of that discretion. *Haley ex rel. Haley v. Brown*, 36 Kan.App.2d 432, 440, 140 P.3d 1051 (2006).

A judicial action constitutes an abuse of discretion if it (1) is arbitrary, fanciful, or unreasonable; (2) is based on an error of law; or (3) is based on an error of fact. *State v. Ward*, 292 Kan. 541, Syl. ¶ 3, 256 P.3d 801 (2011). Whether an exercise of judicial discretion is based on an error of law is a question of law subject to unlimited review. *State v. Garcia*, 295 Kan. 53, 61, 283 P.3d 165 (2012). "[W]hen exclusionary rules are involved" in determining whether evidence erroneously was admitted, "the existence of" the rule "is a question of law" subject "to de novo review," as a "court [does] not have discretion to admit evidence" if a rule prohibits it. *Haley*, 36 Kan.App.2d at 440.

* * *

The law of Kansas limits testimony by a retained expert only to opinions contained in his disclosed pretrial report. In this case, however, the trial court allowed defense expert Yadin David to testify to two and products liability conclusions that were nowhere in his pretrial report, surprising and prejudicing the plaintiff. Was this error?

K.S.A § 60-226(b)(6)(A) requires a party to "disclose to other parties the identity of any witness it may use at trial to present expert testimony," as well as both the "subject

matter on which the expert is expected to testify" and "the substance of facts and opinions to which the expert is expected to testify." Section 60-226(b)(6)(B) then requires that, "if the witness is retained or specially employed to provide expert testimony," the disclosure "must also state a summary of the grounds for each opinion."

These "disclosures are often the centerpiece of discovery in litigation that uses expert witnesses," because they allow the opposing party "to properly prepare" for cross-examination. *S. States Rack & Fixture, Inc. v. Sherwin-Williams Co.*, 318 F.3d 592, 595 (4th Cir. 2003); see also Fed. R. Civ. P. 26, 1993 Comm. Note, ¶ 2 (purpose is to give opposing party "a reasonable opportunity to prepare for effective cross examination").

As such, generally, "expert testimony should be excluded when it exceeds the scope of the pretrial report …." *Hill v. Reederei F. Laeisz G.M.B.H., Rostock*, 435 F.3d 404, 425 (3d Cir. 2006) (Rendell, J., concurring). A trial court's decision to allow it anyway is reversible when: (1) it unfairly surprised and prejudiced the opposing party; (2) the opposing party was unable to cure the prejudice; (3) allowing the testimony affected the trial of the case; (4) the proponent of the testimony introduced it willfully; and (5) the testimony was important to the overall case. *Id.* (citing *Quinn v. Consol. Freightways Corp.*, 283 F.3d 572, 577 (3d Cir. 2002)).

To avoid this, in this case, as is customary in Kansas, *see, e.g., Estate of Mills ex rel. Mills v. Mangosing*, 44 Kan.App.2d 399, 415, 238 P.3d 293 (2010), in the pretrial order the trial court ordered, "Opinions of expert witnesses shall be limited to the substance of those opinions reasonably disclosed in their written disclosures, and answers to interrogatories" (R. 2 at 85). Before defense expert Yadin David testified, on the parties' agreement the trial court reiterated this by prohibiting Mr. David from "get[ting]

into medical opinions" including standard of care and causation, and ruled his "report is the only thing he can testify to" (R. 19 at 4-5).

Nonetheless, the trial court then allowed Mr. David to testify to two crucial conclusions on direct examination that did not appear anywhere in his report. Compounded by the trial court's earlier ruling disallowing the plaintiff from having his own expert to rebut Mr. David, *supra* at 27-39, the plaintiff had no effective ability whatsoever to attack these unreported, undisclosed conclusions in cross-examination.

First, Mr. David sought to testify that the volume of air he believed was in the Avanta's line after the first injection meant "the air that we know to be entered into Mr. Bereal is larger than that, then it's obvious that there is external source of air not only expendable by the volume was in the catheter" (R. 19 at 54-55) – i.e., that the cause of the air being in the line had to be it entering the Avanta from outside, not being in the line already. The plaintiff objected, explaining this opinion appeared nowhere in Mr. David's expert report, and also went to causation of Mr. Bereal's injury, which was outside the scope of Mr. David's non-medical expertise (R. 19 at 55-60). The trial court overruled the objection, reasoning that this was not "a causation opinion" (R. 19 at 59-60).

Second, Mr. David sought to testify to an actual defect in the Avanta, stating "the only way to reconcile the facts … is by determining the pressure isolation valve was defective" (R. 19 at 75). The plaintiff immediately objected again, stating, "There's no opinion about the PIV valve in his report" (R. 19 at 75). Without any argument by the defense and with no explanation, the trial court overruled the objection (R. 19 at 75).

Both decisions were error. Plainly, Mr. David's written report *did not disclose any opinion at all* as to the meaning of any volume of air or from where any air would

have come (R. 24 at 48-58; Appx. A28-38). The notion that Mr. David's new conclusion that the cause of the air injection was air being sucked into the Avanta, and not already being in the line, was not "a causation opinion" is mind-bogglingly unreasonable.

More glaringly, Mr. David's written report mentioned *nothing whatsoever* about the Avanta's SPAT's pressure isolation valve (R. 24 at 48-58; Appx. A28-38). The terms "isolation," "valve," and "PIV" do not appear anywhere in his report. His report did not conclude there was any actual defect in the Avanta at all.

Indeed, Mr. David's report concluded only four things: (1) FDA reports of air injections involving Avantas meant Medrad marketed products that were unsafe, which risks Medrad unreasonably failed to communicate to its users; (2) Dr. Bajaj and his team set up the Avanta correctly; (3) the transducer wave forms did not show air in the line before the first injection; and (4) Medrad failed to act as a reasonable manufacturer by failing to include a down-the-line remote air sensor (R. 24 at 50-58; Appx. A30-38). *Nothing* about translating the meaning of volumes of air into the cause of the air injection. *Nothing* about any defective valve.

Plainly, Mr. David's brand new, surprise conclusions prejudiced the plaintiff. The plaintiff was ready to attack Mr. David's four reported conclusions on cross-examination. Indeed, he had been laying his preparation for it throughout trial, eliciting testimony that FDA reports are not routinely sent to users, the reports at issue for the Avanta did not mention device defects, Avantas remained in routine use, Mr. Bereal's transducer wave forms showed air in the line before the first injection, and down-the-line air sensors did not exist on any power injection system (R. 10 at 147-48; R. 12 at 17-18, 68-77; R. 13 at 15; R. 14 at 81, 132-34, 195; R. 16 at 44-45, 171; R. 18 at 15, 234).

But the plaintiff was prejudiced by being denied any ability effectively to cross-examine Mr. David on these two new opinions willfully elicited by the defendants for the first time on direct examination. As the plaintiff was prohibited from having any rebuttal witness to rebut Mr. David, he was unable otherwise to cure that prejudice in any way.

Finally, Mr. David's undisclosed conclusions about the source of the air based on its volume and the defective valve were crucial to the defendants' ultimate affirmative defenses. The first two of the defendants' claims against Medrad on which the jury was instructed were strict liability claims specifically regarding the pressure isolation valve:

> 1. Manufacturing the Avanta Fluid Injection System with an unreasonably dangerous and defective condition that allowed air to enter into the system. (**PIV valve**, strict liability, instruction 13, 14)
>
> 2. Designing the Avanta Fluid Injection System with an unreasonably dangerous and defective condition that allowed air to enter into the system. (**PIV valve**, strict liability, instruction 13, 14)

(R. 2 at 97) (emphasis added).

Thus, without Mr. David's undisclosed conclusions that: (1) air was caused to be in the Avanta by coming from outside of it; and (2) this was due to a defective pressure isolation valve, there would have been *no evidence* for these first two defenses!

The law of Kansas requires parties to disclose *all of their expert's conclusions* pretrial to avoid exactly this kind of surprise and prejudice. The trial court violated that law by allowing defense expert Yadin David to testify for the first time on direct examination at trial to undisclosed conclusions that became essential to the defense's case. This fundamentally denied the plaintiff a fair trial. It evidently was not enough that the plaintiff was prohibited from having his own products liability expert to rebut Mr.

David. Mr. David then was allowed to testify to conclusions reached for the first time at trial, on which the plaintiff could not even cross-examine him.

If this Court were to allow this, the Legislature might as well repeal the expert disclosure requirements in § 60-226 and allow an expert witness free-for-all. The plaintiff is confident the Court knows well that the ends of justice cannot allow that.

The Court should reverse the trial court's judgment and remand this case for a new, truly fair trial at which, as is proper, customary, and required by law, expert witnesses only will be allowed to testify to matters within the scope of their reports.

III. The trial court erred in denying the plaintiff judgment as a matter of law on the defendants' six affirmative defenses of products liability against Medrad under the KPLA. The only evidence introduced in support of those defenses, the testimony of expert Yadin David, was purely surmise and conjecture, and was insufficient to meet the defendants' burden under the KPLA. Mr. David never tested the Avanta or any of its components and was unable to identify any specific defect, none of the reports on which he relied identified any defect, and he admitted no power injector contains a remote air sensor.

Standard of Appellate Review

This Court uses the same analysis as the trial court "when reviewing the grant or denial of a motion for" judgment as a matter of law: "the trial court is required to resolve all facts and inferences reasonably to be drawn from the evidence in favor of the party against whom the ruling is sought. Where reasonable minds could reach different conclusions based on the evidence, the motion must be denied." *Bussman v. Safeco Ins. Co. of Am.*, 298 Kan. 700, 706-07, 317 P.3d 70 (2014).

* * *

The law of Kansas is that mere surmise, conjecture, or speculation is not evidence. In this case, the defendants had the burden to introduce sufficient evidence to prove their six products liability affirmative defenses against Medrad under the KPLA.

All they introduced, though, was the testimony of their "expert," Yadin David, who never tested an Avanta, was unable to identify any specific defect or report of any defect in the Avanta system, and merely surmised that the Avanta system *must have had* some unidentified defect in a valve. Was the defendants' evidence as to at least one of their affirmative defenses under the KPLA insufficient?

The defendants brought six affirmative defenses under the KPLA, K.S.A. §§ 60-3301, *et seq.*, memorialized to the jury as this:

> 1. Manufacturing the Avanta … with an unreasonably dangerous and defective condition that allowed air to enter into the system. (PIV valve, strict liability, instruction 13, 14)
>
> 2. Designing the Avanta … with an unreasonably dangerous and defective condition that allowed air to enter into the system. (PIV valve, strict liability, instruction 13, 14)
>
> 3. Failing to provide adequate warnings and inform Dr. Bajaj and Wesley Medical Center regarding an unusual number of air injection events associated with use of the Avanta …. (negligence, duty to warn, instructions 10 & 12)
>
> 4. Failing to conduct an adequate risk assessment of the Avanta … and its components, both before and after multiple reports of air injections with the device. (negligence, duty to warn, instructions 10 & 12)
>
> 5. Failing to design the Avanta … with a down-the-line remote air sensing detector. (negligence, design defect, instruction 10, 11)
>
> 6. Failing to adequately train hospital employees and physicians regarding setup and use of the Avanta … in light of the number of air injection problems associated with the System. (negligence, instruction 10)

(R. 2 at 97).

As with all comparative fault defenses, the defendants had the burden to produce sufficient evidence to prove these claims to the jury. *Wooderson v. Ortho Pharma. Corp.*, 235 Kan. 387, 412, 681 P.2d 1038 (1984). This is true regardless of the fact that

the defendant's affirmative defenses were against Medrad, a third party. *McGraw v. Sanders Co. Plumbing & Heating, Inc.*, 233 Kan. 766, 772, 667 P.2d 289 (1983).

Therefore, if the defendants failed to introduce sufficient evidence of any one of their respective claims against Medrad, the jury cannot be instructed on that defense and the plaintiff would be entitled to judgment as a matter of law on it. *Wooderson*, 235 Kan. at 412. And if the trial court erred in its determination that there was sufficient evidence and submitting the claim to the jury anyway, the plaintiff would be entitled to a new trial.

It is well-established though, that mere surmise, conjecture, guesses, assumptions, and speculation *are not evidence*. "[R]easonable inferences … cannot be drawn from facts or conditions merely imagined or assumed." *Duncan v. Atchison, Topeka & Santa Fe Ry. Co.*, 86 Kan. 112, Syl., 119 P. 356 (1911). "Permissible presumptions or inferences, as understood in the law of evidence, must have substantial probative force as distinguished from surmise. While reasonable inferences may be drawn from the facts and conditions shown they cannot be drawn from facts merely imagined or assumed." *State v. Lloyd*, 299 Kan. 620, 649, 325 P.3d 1122 (2014) (citations omitted).

Thus, even where it is "proper to use expert testimony," the "opinion of the expert" must be "based upon adequate facts and … not based upon evidence which is too uncertain or speculative." *Farmers Ins. Co. v. Smith*, 219 Kan. 680, 689, 549 P.2d 1026 (1976). Simply put, "rumors, guesses, and assumptions" by an expert are "speculative," and not evidence. *Olathe Mfg., Inc. v. Browning Mfg.*, 259 Kan. 735, 768, 915 P.2d 86 (1996). *See also Jones v. Hittle Serv., Inc.*, 219 Kan. 627, 633, 549 P.2d 1383 (1976) (expert whose opinion was contrary to all known industry standards and government regulation was nothing more than "personal opinion"); *Unified Sch. Dist. No. 285 v. St.*

Paul Fire & Marine Ins. Co., 6 Kan.App.2d 244, 250, 627 P.2d 1147 (1981) (testimony of cost expert who did not evaluate actual damaged structure was "purely speculative" and not evidence).

In this case, the defendants wholly failed to introduce anything other than pure speculation to prove any of their affirmative defenses against Medrad. All they introduced was the testimony of their "expert," Yadin David, who did not test the Avanta, failed to designate any specific defect in the Avanta, admitted that the Avanta conformed to all regulatory specifications, and could not testify that any defect actually caused Mr. Bereal's injury. Under the KPLA, the defendants did not meet their burden, and the trial court erred in allowing their defenses to go to the jury.

The KPLA covers all of the defendants' product liability defenses against Medrad, including both "strict liability in tort" and negligence, including "claims involving … personal physical injuries …." *Fennesy v. LBI Mgmt., Inc.*, 18 Kan.App.2d 61, 65, 847 P.2d 1350 (1993) (in part quoting K.S.A. § 60-3302(c)). Essentially, the defendants had to introduce evidence that would have been sufficient for a jury to reach a verdict for them against Medrad if they were suing Medrad for their claims.

Therefore, as a prerequisite to all their claims, the defendants first had to establish: (1) that Medrad put the Avanta "on the market … in a defective condition unreasonably dangerous to the consumer;" and (2) that "the defective product was the cause of or contributed to cause" Mr. Bereal's injury. P.I.K. 128.17. They specifically had to "identif[y] what aspect of [the Avanta] was defectively designed," or otherwise "cannot prevail." *Jenkins v. AmChem Prods., Inc.*, 256 Kan. 602, 634-37, 886 P.2d 869 (1994). Simply inferring a defect because an injury resulted is impermissible. *Id.* at 635.

The defendants also had to overcome the KPLA's express presumption that a product "in compliance with legislative regulatory standards or administrative regulatory safety standards" is not defective. K.S.A. § 60-3304. As to "failure to warn" claims, they had to show the user did not know of any danger from their experience, knowledge, education, and training, or that the danger was not open and obvious. K.S.A. § 60-3305.

Mr. David's testimony failed these burdens. First, his testimony failed the first KPLA prerequisite when *he was entirely unable to point to <u>any</u> actual defect in the Avanta*, instead merely *surmising* Mr. Bereal's injury *must have* had *something* to do with Medrad's later change to the SPAT's pressure isolation valve, or "PIV" (R. 19 at 68-73). Even then, *he could not explain any specific manner in which the PIV was defective* (R. 19 at 68-75, 85). He admitted he never actually tested an Avanta, could not explain why Medrad's testing of the exact Avanta involved in this case showed no defect, and said his only basis for concluding there was this unidentified defect was his assumption that the cath lab team did not err (R. 19 at 68-75). And his only basis for waiving away operator error was he believed the team's testimony that they did not err (R. 19 at 37-38). Plainly, these personal opinions were insufficient to constitute evidence of a *specific* defect, and merely (impermissibly) inferred a defect from the fact that an injury occurred.

Second, Mr. David's testimony failed to overcome the statutory presumption that, as the Avanta complied with regulations, it was not defective. He attempted to bolster his testimony by pointing to his having "looked at about 70" reports on the FDA's website of "air injections … associated with the Avanta" (R. 19 at 37, 144). But this equally merely *assumed* or *surmised* that those reports meant anything to do with a dangerous condition: Mr. David openly admitted none of the reports mentioned any "device defect," none

"even suggest[ed] that there was an air injection problem due either to a problem with the PIV" or any other conditions, and some even "reflect[ed] that air injections occurred due to user error" (R. 19 at 113-24, 133-40). Mr. David admitted that the FDA licensed and approved the use of the Avanta (R. 19 at 113-24, 133-40, 159-60).

Third, Mr. David failed to show that Dr. Bajaj and Ms. Cody, who he admitted were sophisticated users with special experience, knowledge, education, and training, and who he admitted knew well the dangers of air injection (R. 19 at 37-38), could not have known of that danger. He claimed "an additional 17 seconds of air" remained in the Avanta's tubing after the first injection, but *openly admitted he would "expect" the cath lab team to have been able to see this* (R. 19 at 64-65, 153).

Finally, Mr. David failed to show that the lack of an air-in-line sensor in any way made Medrad an unreasonable manufacturer. He admitted that no "standard require[d]" that, could not point to any existing device with such a sensor, and admitted the FDA approved the Avanta on the basis that it was "substantially equivalent" to the one power injector he said was better-built (R. 19 at 80-81, 159-60, 162).

Mr. David's testimony was "full of sound and fury," but "signif[ied] nothing." WILLIAM SHAKESPEARE, THE TRAGEDY OF MACBETH act 5, sc. 5. His mere speculation, assumptions, surmise, and conjecture *were not evidence*. The defendants failed to introduce sufficient evidence to support any of their affirmative defenses against Medrad. The trial court therefore erred in sending those defenses to the jury, requiring a new trial.

Conclusion

The Court should reverse the trial court's judgment and should remand this case for a new trial.

Respectfully submitted,

Jonathan Sternberg, Attorney, P.C.

by_____
Jonathan Sternberg, Kan. # 25902
2323 Grand Boulevard, Suite 1100
Kansas City, Missouri 64108
Telephone: (816) 292-7000
Facsimile: (816) 292-7050
E-mail: jonathan@sternberg-law.com

WARNER LAW OFFICES, P.A.

Thomas M. Warner, SCID #12004
Anne H. Pankratz, SCID #12941
310 West Central, Suite 110
Wichita, Kansas 67202
(316) 269-2500
tom@warnerlawoffices.com

COUNSEL FOR APPELLANT
EDWARD M. BEREAL

Certificate of Service

I hereby certify that, on May 4, 2015, I mailed two true and accurate copies of this Brief of the Appellant to each of the following:

Mr. David S. Wooding
Martin, Pringle, Oliver, Wallace & Bauer, L.L.P.
100 North Broadway, Suite 500
Wichita, Kansas 67202
Telephone: (316) 265-9311
Facsimile: (316) 265-2955
dswooding@martinpringle.com

Counsel for Appellee
Ravi K. Bajaj, M.D.

Mr. John Gibson
Gilliland & Hayes
301 North Main, Suite 1300
Wichita Kansas 67202
Telephone: (316) 264-7321
Facsimile: (316) 264-8614
jgibson@gh-ks.com

Counsel for Appellee
Wesley Medical Center, L.L.C.

_____
Attorney

Appendix