**F I L E D**
**United States Court of Appeals**
**Tenth Circuit**

**August 8, 2006**

**Elisabeth A. Shumaker**
**Clerk of Court**

**UNITED STATES COURT OF APPEALS**

**FOR THE TENTH CIRCUIT**

WENDIE H. TINGEY,

Plaintiff-Appellant,

v.

RADIONICS, a division of Tyco Health Care Group LP, a Utah corporation,

Defendant-Appellee.

No. 04-4216
(D.C. No. 2:02-CV-710-TS)
(D. Utah)

**ORDER AND JUDGMENT**[*]

Before **KELLY**, **SEYMOUR**, and **MURPHY**, Circuit Judges.

After examining the briefs and appellate record, this panel has determined unanimously that oral argument would not materially assist the determination of this appeal. *See* Fed. R. App. P. 34(a)(2); 10th Cir. R. 34.1(G). The case is therefore ordered submitted without oral argument.

[*] This order and judgment is not binding precedent, except under the doctrines of law of the case, res judicata, and collateral estoppel. The court generally disfavors the citation of orders and judgments; nevertheless, an order and judgment may be cited under the terms and conditions of 10th Cir. R. 36.3.

This is a products liability action alleging that plaintiff-appellant, Wendie H. Tingey, suffered injury from a defective product manufactured by defendant Radionics. Ms. Tingey appeals from the district court's order striking the affidavit of her expert witness; striking the second deposition of her physician; denying her motion for summary judgment; and granting Radionics' motion for summary judgment. We affirm in part, reverse in part, and remand for further proceedings.

## FACTS

### 1. Ms. Tingey's back problems

Ms. Tingey suffered from long-standing back pain, exacerbated by a previous surgical fusion of her lower vertebrae. She sought treatment from an anesthesiologist, Dr. Richard Rosenthal. After treatment with pain medication and anesthetic nerve blocks proved unsatisfactory, Ms. Tingey agreed to undergo a "nerve ablation procedure" designed to isolate and destroy the nerves causing her pain.

### 2. The radiofrequency device

This procedure was performed by Dr. Rosenthal, accompanied by a nurse, using a radiofrequency lesion generator, model RFG-3C+ (the "device" or "radiofrequency device") manufactured by Radionics. Dr. Rosenthal was well-experienced in use of the radiofrequency device, as was the nurse who

assisted him. The device is designed to therapeutically destroy painful nerve tissue by creating lesions in the tissue.

The Radionics radiofrequency device used by Dr. Rosenthal on Ms. Tingey required him to insert a hollow needle into her back. An electrode was then inserted into the needle to produce the radiofrequency waves. The device was designed to operate in two basic modes, lesioning and stimulation mode.

**3. Lesioning vs. stimulation mode**

In its high-voltage, lesioning mode (also known as the "pulse mode"), the device destroys nerve tissue. In order to locate the precise nerve tissue to be destroyed, however, the device also has a lower-voltage, nerve stimulation mode (sometimes called "stim mode"). When operating in the stim mode, the device delivers a low-voltage current to nerve tissue so that the patient can feel the tingle it produces in the nerves and advise the physician when he has positioned the needle adjacent to the painful nerve tissue to be lesioned. The usual procedure is to use the stim mode to locate the tissue to be lesioned, and then to switch over to pulse mode to actually destroy nerve tissue.

**a. High and low frequency stimulation**

The stim mode, in turn, requires the use of two settings, which are controlled by a rate-select button. The higher-frequency setting (50 Hz) is used to stimulate the sensory part of the nerve. A lower-frequency setting (2 Hz) is used to stimulate the motor portion of the nerve.

**b. Voltage adjustments**

There are also voltage adjustments to be made within the stim mode. These adjustments allow the operator to position the needle as close as possible to the affected nerve. The closer the needle is to the affected tissue, the less voltage is required to detect the nerve. The physician can tell that the needle is positioned correctly when only a small amount of voltage is needed to produce a tingling sensation on the affected nerve. If a higher voltage is required to produce sensation, he may need to reposition the needle closer to the nerve before beginning to lesion it.

The voltage is controlled by two switches located on the front panel of the device. One switch is a rheostat or potentiometer similar to a dimmer switch for a light fixture, which allows the operator to increase the output voltage in slow increments. The other is a toggle switch that immediately increases the voltage ten-fold, from a range of zero to one volt to a range of one to ten volts.

High-frequency sensory stimulation (50 Hz) is performed uniquely at a low voltage (zero to one volt maximum), while low-frequency motor stimulation (2 Hz) is done only at a higher voltage (one to ten volts). When the operator wants to switch from stimulating the sensory portion of a nerve to stimulating the motor portion of the nerve, he must activate two switches: the rate select switch (stepping down the frequency from 50 Hz to 2 Hz), and the voltage toggle switch (stepping up from the zero to one volt mode to the one to ten volt mode). The

same is true in reverse, when switching from motor to sensory mode. There, the operator would step up the frequency from 2 Hz to 50 Hz, and step down the voltage range to zero to one volt.

**c. Potential dangers and safety mechanisms provided**

The frequency switch, but not the voltage-toggle switch, has a fail-safe mechanism. If the operator attempts to switch between frequencies and the voltage control knob has not been set to zero, the machine shuts itself down. The voltage toggle switch, however, contains no such fail-safe device.

If the voltage is not set at zero when the voltage toggle switch is flipped, it allows for a sudden, ten-fold spike in electrical current into the patient, without automatic shutoff. The operator can avoid this sudden, ten-fold increase in voltage in one of two ways. First, he can reset the voltage control to zero before switching the toggle switch. In fact, operators are trained to reset to zero voltage before making changes to the device's output. Second, if he forgets to do that, but if he activates the switches in the order frequency first, voltage second, the fail-safe mechanism associated with the rate select switch will shut the device down. In fact, any attempt to change frequency while the voltage knob is not at zero results in the device immediately shutting down.

**d. Ms. Tingey's operation**

In Ms. Tingey's case, she alleges that the nurse operating the device made two crucial errors, when the physician told her to switch from sensory to motor stimulation. First, she did not turn the voltage control to zero. Second, she immediately switched the toggle switch, to increase the voltage ten-fold, rather than the rate-select switch, to adjust the frequency. Because of this, the fail-safe mechanism that would have engaged had she activated the rate-select switch with a non-zero current did not prevent an instant ten-fold increase in the amount of electricity flowing through the needle.

As a result, Ms. Tingey received an electrical shock of approximately seven volts, at a frequency of 50 Hz. She jumped and screamed out in pain. Later that day, she found that she was unable to urinate and defecate normally. Her fecal incontinence resolved soon thereafter, but she was left with an apparently permanent form of urinary incontinence known as "neurogenic bladder." This means that she cannot sense when her bladder is full, and that her bladder does not empty properly. As a result, she must self-catheterize to empty her bladder.

**4. The district court's summary judgment decision**

Ms. Tingey's complaint alleged causes of action for strict products liability, negligence, and failure to warn. The parties filed cross motions for summary judgment. The district court (1) struck the affidavit of Ms. Tingey's expert witness, Dr. McKay Platt; (2) struck the second deposition of Dr. Rosenthal, the

physician who performed the lesioning procedure; (3) denied Ms. Tingey's motion for summary judgment; and (4) granted Radionics' motion for summary judgment.

The district court gave two reasons for granting Radionics' motion as to Ms. Tingey's strict liability cause of action. First, there was no evidence to support Ms. Tingey's claim that the device caused her injuries. Second, Ms. Tingey did not meet her burden of coming forward with evidence that the device was unreasonably dangerous or that an alternative safer design was practicable. The district court also rejected her failure to warn claim, finding that the nurse who operated the device had been properly trained and knew how the switch in question operated. Finally, the district court found no credible evidence that Radionics breached any duty owed to Ms. Tingey that would support her negligence claims.

## STANDARD OF REVIEW

> We review the district court's order granting summary judgment under the same standard employed by the district court under Rule 56(c) of the Federal Rules of Civil Procedure. Summary judgment is proper only if there is no genuine issue of material fact for determination, and the moving party is entitled to judgment as a matter of law. We review the entire record on summary judgment de novo in the light most favorable to the party opposing summary judgment.

*Durham v. Herbert Olbrich GMBH & Co.*, 404 F.3d 1249, 1250 (10th Cir. 2005) (quotation omitted). "In cases such as this, where the nonmoving party will bear

the burden of proof at trial on a dispositive issue[,] that party must go beyond the pleadings and designate specific facts so as to make a showing sufficient to establish the existence of an element essential to that party's case in order to survive summary judgment." *Garrett v. Hewlett-Packard Co.*, 305 F.3d 1210, 1216 (10th Cir. 2002) (quotations omitted).

## ANALYSIS

### 1. Strict liability – design defect

To prove her strict product liability claim based on defective design, Ms. Tingey must show

> (1) that the [device] was unreasonably dangerous due to a defect or defective condition, (2) that the defect existed at the time the product was sold, and (3) that the defective condition was a cause of the plaintiff's injuries.

*Brown v. Sears, Roebuck & Co.*, 328 F.3d 1274, 1279 (10th Cir. 2003) (quotation omitted). The district court concluded that she failed to establish the first and third elements. We begin with the first element, whether the Radionics device was defectively designed, and therefore unreasonably dangerous. We address causation in a separate section of this order and judgment, because it impacts each of Ms. Tingey's claims.

#### a. Objective and subjective tests–overview

A plaintiff alleging that a product is "unreasonably dangerous" must satisfy both an objective and a subjective component. *Id.* at 1282. The objective

component asks whether the product is "dangerous to an extent beyond which would be contemplated by the ordinary and prudent buyer, consumer or user of that product in that community considering the product's characteristics, propensities, risks, dangers and uses." Utah Code Ann. § 78-15-6(2). "The issue, roughly speaking, is whether an ordinary person would think the product is less dangerous than it is." *Brown*, 328 F.3d at 1280.

The subjective component requires the court to consider "any actual knowledge, training, or experience possessed by that particular buyer, user or consumer." Utah Code Ann. § 78-15-6(2). Since the subjective component involves knowledge that *increases* a particular buyer, user or consumer's ability to understand the dangers associated with the product, it can only *raise* the standard that the plaintiff must meet in a particular case. *Brown*, 328 F.3d at 1282. If the particular buyer, user or consumer has no specialized knowledge, of course, the plaintiff has no additional burden to meet for this element.

**b. Objective test–analysis**

Ms. Tingey contends that the Radionics device is unreasonably dangerous from an objective standpoint because "an ordinary and prudent Anaesthesiologist would have no meaningful way of knowing the toggle switch could be flipped-up into the 'high' position (0 to 10 volts), and the Device would **instantly** deliver to the patient a continuous electrical impulse **10-times** greater than intended." Aplt. Opening Br. at 26 (emphasis in original). Radionics counters, first, that the

device has been approved by the Food and Drug Administration (FDA), and second, that an ordinary and prudent user of the device would have appreciated the dangers of improperly activating the toggle switch without turning down the power knob. Radionics further notes that the device has been widely used for twenty years without any complaint that its design or the design of its toggle switch is in any way dangerous or defective.

**(1.) Statutory presumption**

Radionics contends that it is entitled to a presumption created by Utah's Product Liability Act, which sets limits on suits for product defects. That statute reads in pertinent part:

> In any action for damages for personal injury, death, or property damage allegedly caused by a defect in a product:
>
> [. . .]
>
> (3) There is a rebuttable presumption that a product is free from any defect or defective condition where the alleged defect in the plans or designs for the product or the methods and techniques of manufacturing, inspecting and testing the product were in conformity with government standards established for that industry which were in existence at the time the plans or designs for the product or the methods and techniques of manufacturing, inspecting and testing the product were adopted.

Utah Code Ann. § 78-15-6.

Radionics cites a letter ruling it obtained from the FDA permitting it to market the device. *See* Aplt. App., Vol. I, at 70-71. It contends that this letter ruling entitles it to the rebuttable presumption in § 78-15-6(3) that the device "is

free from any defect or defective condition." Ms. Tingey responds that Radionics is not entitled to the presumption because the FDA never tested the device, and because there were no FDA requirements regarding the labeling of devices of this type.

In *Slisze v. Stanley-Bostitch*, 979 P.2d 317 (Utah 1999), the Utah Supreme Court indicated that § 78-15-6(3) should be read in light of the Restatement (Second) of Torts § 285 (1965), which permits courts to determine the standard of reasonable care to be followed by reference to an administrative regulation. *See id.* at 321. Section 286 of the same Restatement provides specific guidelines for the use of administrative regulations to establish the standard of care. It states that a court may adopt the standard contained in an administrative regulation whose purpose is "(a) to protect the class of persons which includes the one whose interest was invaded, and (b) to protect the particular interest which is invaded (c) to protect that interest against the kind of harm which has resulted, and (d) to protect that interest against the particular hazard from which the harm results." An administrative regulation that meets these requirements can be used to establish the presumption of non-defectiveness under § 78-15-6(3). *Slisze*, 979 P.2d at 321.

The question before us, therefore, is whether the FDA approval that Radionics received satisfied the standards identified in the Restatement test, and, hence, those required for the application of § 78-15-6(3). The FDA letter ruling

at issue granted Radionics' "Section 510(k)" application to market the radiofrequency device that allegedly injured Ms. Tingey. The section referenced is part of the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act (MDA), codified at 21 U.S.C. § 360(k). Section 510(k) requires persons seeking to introduce into interstate commerce a device intended for human use to report to the Secretary of Health and Human Services the class under which the device is classified and the person's actions taken to comply with requirements under 21 U.S.C. § 360d or 360e.

With regard to the "class under which the device is classified," the Supreme Court has explained that

> [t]he Act classifies medical devices in three categories based on the risk that they pose to the public. Devices that present no unreasonable risk of illness or injury are designated Class I and are subject only to minimal regulation by "general controls." 21 U.S.C. § 360c(a)(1)(A). Devices that are potentially more harmful are designated Class II; although they may be marketed without advance approval, manufacturers of such devices must comply with federal performance regulations known as "special controls." § 360c(a)(1)(B). Finally, devices that either "presen[t] a potential unreasonable risk of illness or injury," or which are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," are designated Class III. § 360c(a)(1)(C).

*Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476-77 (1996).

Before the device was introduced into interstate commerce, therefore, Radionics would ordinarily have had to comply with the requirements for a Class

II device noted in 21 U.S.C. § 360d. These requirements are much less rigorous than the requirements for obtaining premarket approval (PMA) for a Class III device.[1] And in this case, Radionics received additional relief from the regulatory requirements, because the FDA determined that the device was substantially equivalent to devices marketed in interstate commerce on or before May 28, 1976, and therefore entitled to be "grandfathered" in as safe. Therefore, Radionics was only required to comply with the general controls provisions of the Act before marketing the device. Aplt. App., Vol. I, at 70.

These general controls do incorporate a safety rationale. The statutory definition of Class I General Controls specifically includes any combination of such controls "sufficient to provide reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. § 360c(a)(1)(A). Moreover, the regulations dealing with the content and format of a § 510(k) summary require a person intending to use the device for a different purpose than that prescribed for its equivalent to explain "why the differences do not affect the safety and effectiveness of the device when used as labeled." 21 C.F.R. § 807.92(a)(5). *See also Medtronic*, 518 U.S. at 491 (stating "primary issue motivating the MDA's enactment" was "the safety of those who use medical devices").

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[1] "In contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours." *Medtronic*, 518 U.S. at 479.

On the other hand, as the Supreme Court has explained in the preemption context, the § 510(k) process is focused on equivalence rather than safety, and therefore "provide[s] little protection to the public." *Id.* at 493. While the FDA examines § 510(k) applications with a general concern for safety and effectiveness, it does not require devices approved under that section to take any particular form; the device must merely be substantially equivalent to one that existed before 1976, "marketed without running the gauntlet" of MDA. *Id.* at 494. *Cf. also Talley v. Danek Medical, Inc.*, 179 F.3d 154, 161 (4th Cir. 1999) (holding, in negligence per se context, that requirement for pre-market approval under the MDA "lacks any independent substantive content," failure to comply is "analogous to the failure to have a drivers license," and MDA does not establish the standard of care). Because the MDA approval Radionics received, that of substantial equivalence to a pre-1976 device, did not result from its compliance with a regulatory standard meeting the Restatement test, we conclude that Radionics is not entitled to the presumption in § 78-15-6(3) that the device "is free from any defect or defective condition."

**(2.) Actual vs. perceived dangers of device**

Ms. Tingey notes that the device is designed so that it automatically shuts off if any change in output *other than that created by operation of the toggle switch* is made without first adjusting the power knob to zero. While the nurse who operated the device testified that she was trained to turn the voltage down to

zero before changing the output on the device, Radionics fails to point us to any evidence that she was aware that the toggle switch was not protected by the automatic shutoff safety mechanism, or that failing to zero out the voltage would result in a harmful shock to the patient.[2] For this reason, we believe that Ms. Tingey has at least demonstrated a genuine factual issue concerning whether the device was "more dangerous than an ordinary user would anticipate." *Brown*, 328 F.3d at 1277.

**c. Subjective test-analysis**

Radionics emphasizes the specialized training and experience that both Dr. Rosenthal and the nurse had with the device, and the specific training that the nurse received to zero out the voltage before changing inputs. While this training does raise the bar somewhat in terms of Ms. Tingey's burden, we nevertheless conclude that she has met her burden of showing unreasonable dangerousness for purposes of summary judgment. Even given their specialized training, Radionics fails to point to anything in the training Dr. Rosenthal and the nurse received that would have alerted them to the danger that resulted in Ms. Tingey's injuries.

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[2] Radionics argues that the nurse "knew . . . that she needed to turn down the power prior to engaging the toggle switch *to prevent the patient from receiving a shock*." Aplee Br. at 4 (emphasis added). The record citation it provides for this statement, however, does not support Radionics' contention that the nurse knew that Ms. Tingey would receive a harmful shock if the power switch were not zeroed out when the toggle switch was activated.

**d. Practicability of safer design**

Because Ms. Tingey asserts that the Radionics device is defectively designed, she must also satisfy a "risk-utility balancing test." *Brown*, 328 F.3d at 1279. She does this by proving the practicability of a safer design. *Id.* More specifically, in response to Radionics' assertion that no evidence exists to satisfy the "risk-utility balancing test," Ms. Tingey was responsible for coming forward with evidence that "there was an alternative, safer . . . design [for the device], practicable under the circumstances, [that] was [technically] feasible" and that would have prevented the accident that allegedly caused the injury to her bladder nerves. *Allen v. Minnstar, Inc.*, 8 F.3d 1470, 1479 (10th Cir. 1993).

Radionics asserts that an alternative design would not have been feasible, because the toggle switch, unlike other switches on the device that control its output, operates mechanically rather than being controlled by computer circuitry. The toggle switch achieves its ten-fold differential by activating a series of resistors that step the current down to the lower voltage. An engineer deposed in the case opined that this use of a mechanical rather than computer-controlled voltage adjustment would require a re-design of the entire unit to develop a fail-safe mechanism that is digitally controlled. Aplt. App., Vol. II, at 520. It is unclear whether such a re-design would even be feasible.

Ms. Tingey presented evidence, however, that the device could still perform its essential functions, even if the toggle switch were eliminated. *Id.* at

521. The toggle switch was provided primarily as a matter of convenience, to permit fine tuning when the device operates in stim mode. *Id.* Dr. Rosenthal testified that in his opinion, there was no medical reason why the toggle switch could not be eliminated. *Id.*, Vol. I, at 190.[3] Radionics represented to the government, in support of its 510(k) application, that the device's microprocessor design made the unit safer than its predecessors. *See id.*, Vol. II, at 357. If the additional measure of safety afforded by the microprocessor failsafe design could not in fact be achieved in the case of the toggle switch, a jury could find that a safer alternative would be to eliminate the switch altogether. We conclude that Ms. Tingey has made a sufficient showing of the practicability of a safer design to survive summary judgment on this element of her strict liability claim.

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[3] In such a case, apparently, the entire voltage range would be accessible and controlled using the potentiometer. Fine voltage gradiations might be lost. Also, it is unclear how the use of the frequency setting knob would be coordinated with a single voltage control. Nevertheless, given Dr. Rosenthal's extensive experience with the device, and the other testimony of record that it operates primarily as a convenience, we believe Ms. Tingey has made a sufficient showing on the "safer design" issue.

**2. Duty to warn claim**

Under Utah law, a manufacturer may also "be held strictly liable for any physical harm caused by its failure to provide adequate warnings regarding the use of its product." *House v. Armour of Am., Inc.*, 929 P.2d 340, 343 (Utah 1996).[4] "Where a manufacturer knows or should know of a risk associated with its product, the absence or inadequacy of warnings renders that product unreasonably dangerous, subjecting the manufacturer to strict liability." *Id.* (quotation omitted). Moreover, "[a] manufacturer . . . may have a duty to warn of latent dangers even if there is no feasible way to produce a safer product; the purpose of the warning is to enable the user to take appropriate steps to avoid the hazard." *Wankier v. Crown Equipment Corp.*, 353 F.3d 862, 867 (10th Cir. 2003).

In order to evaluate whether summary judgment was appropriate on Ms. Tingey's "duty to warn" claim, we consider three questions: (1) Was there a duty to warn? (2) Was the warning given adequate? and (3) Did the failure to give the warning cause the plaintiff's damages? *See generally* 2 Louis R. Frumer &

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[4] Utah follows the "learned intermediary doctrine," whereby it is the manufacturer's duty to warn the doctor of the dangers associated with a dangerous drug, rather than the patient. *See, e.g., Barson ex rel. Barson v. E.R. Squibb & Sons*, 682 P.2d 832, (Utah 1984). Courts have applied this doctrine to claims involving medical devices, *see Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 762 (Ky. 2004) (citing cases), and we assume Utah would do so as well. We therefore look, as the parties do, to the warnings provided to Dr. Rosenthal and/or the nurse, rather than Ms. Tingey.

Melvin I. Friedman, *Products Liability* §§ 12.01 - 12.04 (2005); *House*, 929 P.2d at 343-48 (analyzing three elements of duty to warn claim). While there is limited authority in Utah dealing with these issues, case law from other jurisdictions that recognize duty to warn claims, as well as commentary in the Restatement (Third) of Torts – Products Liability,[5] provide useful guidance.

**a. Was there a duty to warn?**

Radionics contends that it had no duty to warn because the danger was not reasonably forseeable. No previous incidents of shock resulting in bladder incontinence from use of the device had been reported. Moreover, the particular output that harmed Ms. Tingey was unintended and resulted only when the nurse failed to follow proper operating directions. Ms. Tingey responds that Radionics was aware that unwanted output of the device could cause adverse and potentially dangerous health effects. The danger from such outputs is demonstrated as a general matter, she claims, by the shutoff mechanisms Radionics had installed on other controls that changed the output from the device, which were absent in the case of the toggle switch.

A manufacturer has a duty to warn of potential dangers from both reasonably forseeable use and misuse of a device. *See, e.g., Huber v. Niagara*

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[5] While Utah has not formally adopted the Third Restatement, the principles contained therein are similar but more fully developed than those described in the Restatement (Second) of Torts § 402A, on which Ms. Tingey's "duty to warn" cause of action is based.

*Machine & Tool Works*, 430 N.W.2d 465, 467-68 (Minn. 1988). "[L]iability for failure to instruct or warn attaches only if the risks presented by the product could have been reduced by the adoption of reasonable instructions or warnings . . . . The post-sale conduct of the user may be so unreasonable, unusual, and costly to avoid that a seller has no duty to design or warn against them." Restatement (Third) of Torts – Products Liability § 2, cmt. "p" (1998). Radionics makes much of the multiple errors committed by the nurse in this case in her operation of the device, contrary to her training. Courts have, however, extended the concept of forseeable misuse even to accidents involving a combination of factors, such as the accident resulting in Ms. Tingey's alleged injury.

In *Palmer v. Hobart Corp.*, 849 S.W.2d 135 (Mo. Ct. App. 1993), for example, the court upheld a verdict for the plaintiff on a duty to warn claim, after the plaintiff was injured while cleaning a meat grinder. A label on the meat grinder warned that it should not be operated without the guard over the cylinder opening and the electric interlock in place. *Id.* at 137. The plaintiff was injured after he left a wall switch on, "placed the adjusting ring on top of the grinder, which inadvertently depressed the interlock device, thereby overriding the interlock system; and . . . unintentionally pressed the foot pedal which started the grinder." *Id.* at 138. Thus, the operator made three separate mistakes, all of which were required for the accident to have occurred, even though warned

specifically about at least one of them. Notwithstanding his multiple errors, he prevailed on his failure to warn claim.

We think Ms. Tingey has demonstrated a question for a trier of fact concerning Radionics' duty to warn of the potential hazards associated with flipping the toggle switch without first zeroing out the voltage on the device.

**b. Was the warning adequate?**

Radionics contends that it provided an adequate warning because the nurse who operated the device was trained that she must zero out the voltage before activating the toggle switch. Ms. Tingey argues, however, that the real issue is not whether the nurse knew how to operate the device, but whether she knew that the toggle switch, alone among all devices adjusting output, was not designed so that the device would automatically shut off if it was switched when the voltage had not been previously adjusted to zero. She argues that this is a "hidden danger" of the device's toggle switch.

The training the nurse received about zeroing out the voltage was an instruction in proper use of the device, rather than a warning of the consequences of misuse. "[T]here is a distinction between instructions and warnings . . . . Warnings signal danger while instructions serve principally to provide the user with information necessary to make proper and efficient use of the product." *Palmer*, 849 S.W.2d at 140-41(quotation omitted). Merely instructing a user on how to use a product, without informing him or her of the dangers inherent in

misuse, may constitute an inadequate warning of the product's inherent dangers. *Scheman-Gonzalez v. Saber Mf'g Co.*, 816 So. 2d 1133, 1140 (Fla. Ct. App. 2002). While the nurse here was instructed to zero the voltage before engaging the toggle switch, Radionics has pointed to no evidence that she was informed of the consequences of failing to follow this instruction.[6] We conclude that Ms. Tingey has made an adequate showing to survive summary judgment on whether the warning or instruction given in this case was adequate.

**c. Did the failure to warn cause Ms. Tingey's injuries?**

We discuss causation generally in the last section of this order and judgment. The causation issue in this case basically concerns whether Ms. Tingey presented sufficient evidence to survive summary judgment that the shock she received from the radiofrequency device caused her neurogenic bladder. In the "duty to warn" context, however, a separate causation question is presented: Could an adequate warning have prevented Ms. Tingey's injury? "In any failure to warn claim, a plaintiff must show that the failure to give an adequate warning in fact caused the injury; i.e., that had warnings been provided, the injured party would have altered his use of the product or taken added precautions to avoid the

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[6] Dr. Rosenthal was aware that the purpose of the fail-safe feature on other output controls of the device was to prevent an unwanted shock, that could at very least frighten the patient. *See* Aplt. App., Vol. I, at 189. He was surprised, however, when Ms. Tingey received the shock from the improper application of the toggle switch. *Id.* He indicated that he had read the operator's manual for the device, and that nothing in it warned him of this hazard. *Id.* at 193.

injury." *House*, 929 P.2d at 346. Radionics relies on the training the nurse received to attempt to refute Ms. Tingey's claim that the lack of a warning caused her injuries. As we have noted, however, this training did not substitute for an adequate warning of the hidden dangers associated with the device.

Utah law applies a heeding presumption. "[I]n cases in which it cannot be demonstrated what the plaintiff would have done had he or she been adequately warned, the plaintiff should be afforded a rebuttable presumption that he or she would have followed an adequate warning had one been provided." *Id.* at 347 (quotation omitted). The injury here resulted from a confessed mistake by the nurse operating the controls of the Radionics device. Had she been adequately warned of the dangers associated with the device, as opposed to merely being taught how to operate it, we must presume that she would not have made the error. Radionics has failed to rebut the heeding presumption applicable to this case. We conclude that Ms. Tingey has adequately established each of the elements of her "duty to warn" claim in a fashion sufficient to survive summary judgment.[7]

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[7] To the extent that Ms. Tingey has stated a claim for "negligent failure to warn" in addition to a failure to warn claim sounding in strict liability, our analysis also requires reversal of summary judgment on that claim.

### 3. Negligence

Utah law permits a plaintiff simultaneously to bring both strict products liability and negligence claims. *Slisze*, 979 P.2d at 319. To establish a negligence claim, the plaintiff must show: "(1) that the defendant owed the plaintiff a duty, (2) that the defendant breached that duty, (3) that the breach of duty was the proximate cause of the plaintiff's injury, and (4) that the plaintiff in fact suffered injuries or damages." *Webb v. Univ. of Utah*, 125 P.3d 906, 909 (Utah 2005). The district court found that Ms. Tingey failed to show that Radionics had breached any duty owed to her. Radionics contends that there is no duty because the device was not defective. Specifically, Radionics argues that "under Utah law a manufacturer does not have a duty to refrain from marketing a non-defective product [even though] an alternative safer design was available." Aplee. Br. at 6. As we have already determined, however, Ms. Tingey has established the existence of a jury question concerning whether the device contained a design defect that made it unreasonably dangerous. We must therefore reverse summary judgment on her negligence claim.

### 4. Causation

Finally, we consider whether Ms. Tingey presented sufficient evidence to survive summary judgment that the shock she received from the radiofrequency device caused her neurogenic bladder. Such a showing on causation is a necessary element of each of her claims. To establish causation, Ms. Tingey

relied on circumstantial evidence based in part on her own testimony, and in part on medical testimony. The district court struck her medical expert testimony concerning causation, finding it unreliable under Fed. R. Civ. P. 56(e) and Fed. R. Evid. 702. It then concluded that Ms. Tingey had failed to present evidence to support the causation element of her claims.

Because medical testimony was necessary on the causation issue, the evidentiary issues under Rule 702 are closely intertwined with the ultimate summary judgment issue. Both federal and state law play a role in the summary judgment determination. While federal law governs the issue of whether the non-moving party in a diversity case has presented evidence sufficient to establish a genuine issue of material fact concerning causation, *see Burnette v. Dow Chemical Co.*, 849 F.2d 1269, 1274 (10th Cir. 1988), "the underlying cause of action, with its attendant elements and requirement of proof in a diversity case, is governed by state law." *Moe v. Avions Marcel Dassault-Breguet Aviation*, 727 F.2d 917, 932 (10th Cir. 1984). We thus look to state law to determine what theories of causation are permissible and the general means permitted to establish causation.

Before turning to an analysis of Utah law on the subject of proof of causation, we will first discuss the evidence presented on the causation issue. In addition to Ms. Tingey, four doctors and two lay witnesses provided evidence on

this issue. After summarizing this evidence, we will analyze it under Utah law concerning differential diagnosis and circumstantial evidence.

**a. The evidence**

**(1.) Tingey affidavit**

Ms. Tingey stated in her affidavit that prior to the procedure on March 10, 2000, she had never had any problems with her bladder or bowels, and had not been diagnosed with a neurogenic bladder. During the procedure, she received a painful shock from the device. Later that day, she began having problems urinating normally and could not defecate. Her normal bowel function eventually returned, but her urinary incontinence persists.

**(2.) Medical testimony**

The medical testimony was as follows:

**(A) Dr. Landau**

Dr. Stuart T. Landau is a urologist, who Dr. Rosenthal asked to examine Ms. Tingey. He diagnosed Ms. Tingey with a "sensory-type neurogenic bladder." Aplt. App., Vol. I, at 110. He stated, however, that "[w]hether this [condition] is related to this procedure in the L5 region is impossible to know for sure." *Id.* The reason for this is that the nerve roots for the bladder are not located in the L5 region. Thus, the current would have had to move along the spinal cord to produce Ms. Tingey's bladder injury, a possibility the likelihood of which Dr. Landau characterized as "unknown." *Id.* In a later letter to Dr. Rosenthal,

Dr. Landau reiterated that he did "not have a good explanation for the bladder situation." *Id*. at 111.

**(B) Dr. Platt**

Ms. Tingey was also examined by another urologist, Dr. McKay L. Platt. Dr. Platt stated, in a letter to Ms. Tingey's attorney:

> It is my opinion that [the] events of 13 May resulted in the neurogenic bladder. The patient's voiding pattern before this time was normal and the patient had no previous urinary retention. The procedure done on the above date is the cause of the patient's urinary retention in my opinion. I cannot even postulate any reasonable alternative explanation.

*Id*. at 127.

Dr. Platt later reiterated this opinion in an affidavit, stating that in his opinion, "the cause of Wendie's neurogenic bladder was the inadvertent electrical shock Wendie received during the radiofrequency procedure on March 10, 2000." *Id*., Vol. II, at 451. Dr. Platt's opinion thus supports Ms. Tingey's theory that the procedure caused her neurogenic bladder.

**(C) Dr. Miska**

Ms. Tingey's counsel also retained a neurologist, Dr. Robert M. Miska, to provide an opinion concerning the cause of her injuries. His opinion, however, proved unfavorable to her position on causation. In a letter to Ms. Tingey's counsel, Dr. Miska stated: "I continue to have a complete lack of understanding as to why an attempted radio frequency lesion of the L5 dorsal root ganglion

should produce isolated urinary sphincter incontinence." *Id.* at 540. He continued:

> While I understand that there appears to be a cause and effect relationship between the procedure in question and the subsequent complaint of urinary incontinence . . . there is still a considerable "leap" to associate the two, especially when the recognized physiologic implications of dorsal rhizotomy are so benign, and there are no reported cases of inadvertent injury to lower sacral nerve roots.

*Id.*

Dr. Miska stated that he could not "reasonably explain Ms. Tingey's current difficulties on the basis of what I know." *Id.* He further noted the lack of evidence of a visible lesion through lumbar MRI scanning, but noted "it is still, of course, possible that a very limited type of injury to the conus medullaris might produce sphincter incontinence, though even then, some incontinence of the anal sphincter would also be expected, and there has been none." *Id.* at 541.[8]

**(D) Dr. Rosenthal**

Dr. Rosenthal was the physician who performed the procedure that Ms. Tingey believes caused her injuries. He was deposed twice in connection with Ms. Tingey's injuries, with dramatically different results. Not surprisingly, Radionics focuses its attention on his first deposition, which is favorable to its

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[8] It is unclear whether Dr. Miska was speaking of permanent anal sphincter incontinence, as it must be recalled that Ms. Tingey did complain about transient inability to control bowel function after the procedure, which later resolved itself.

position in this case. Ms. Tingey relies heavily on the views expressed in his second deposition.

**(i.) First deposition**

At the time Dr. Rosenthal gave his first deposition, as part of this federal court action against Radionics, Ms. Tingey had sued him in a separate action in state court for medical malpractice. He was adamant during his first deposition that the procedure he performed had *not*, indeed *could not have*, caused Ms. Tingey's injuries.

Dr. Rosenthal was asked, for example, about an opinion he had expressed early on in his treatment notes. At the time, he had suggested that although he had been using the device on the L5 nerve root, the electrical energy could have spread to other nerves. When asked if he still believed in that possibility, he replied:

> Absolutely not. [ . . . ] [L]et me say it this way. I sleep very well at night. I have no question in my mind that – that I did not damage this person in any way, and, you know, it would really bother me if I had. And what's happened here unfortunately is it scared her, she's angry, she's a person who abuses medications, she's probably run through a bunch of money and she wants more money.

*Id.* at 703 (Dep. p. 147).

Later in the deposition, Dr. Rosenthal repeated his opinion on the causation issue:

> And whether or not she truly does have a neurogenic bladder is in question, but what's not in question is [whether] this procedure

> caused it. There's no doubt that this procedure did not cause that finding.

*Id*. at 704 (Dep. p. 149).

Dr. Rosenthal further expressed his opinion that Ms. Tingey's symptoms may have been caused by drug abuse, and that her desire for money to fuel her drug addiction could explain her motivation for bringing this suit.

**(ii.) Second deposition**

After his first deposition, counsel for Dr. Rosenthal contacted Ms. Tingey's counsel, stating that "Dr. Rosenthal had information that would be helpful in proving the Radionics machine was subject to a design defect, and that basically this unfortunate event was the result of this design defect, not any fault of Dr. Rosenthal." Aplt. App., Vol. IV, at 972. Ms. Tingey's counsel then suggested a second deposition of Dr. Rosenthal, to be conducted in the state case.

Radionics was not a party to the state case against Dr. Rosenthal. It received no notice of this second deposition, and unlike the first deposition, it did not have a representative present. At the second deposition, Dr. Rosenthal had a very different opinion about the causation issues than the opinion he gave at his first deposition.

Dr. Rosenthal began his second deposition by undermining the suggestion that he had made in his first deposition, that chronic opiate abuse might have caused Ms. Tingey's bladder symptoms. While noting that "urology is not within

my specialty," *id.* at 862, he suggested that the type of injury that Ms. Tingey had, a sensory neurogenic bladder, was not the kind of neurogenic bladder that would be expected from opiate abuse. *Id.* at 864-65. Instead, her type of bladder injury was more consistent with damage to the sacral nerve roots.

At his first deposition, Dr. Rosenthal had been adamant that such damage to the nerve roots that control bladder function could not have been caused by an electric shock at the L5 location, where the device's probe had been located at the time of the alleged injury. Now, he was not so sure. He suggested that "retrograde conduction" might explain Ms. Tingey's injuries:

> A. Okay. When the shock was delivered, a nerve is a conductive tissue, so it causes the nerve to depolarize. In other words, she got a shock down her leg, certainly.
>
> Q. Uh-huh.
>
> A. However, the nerve . . . when an external shock is delivered doesn't know, you know, that it needs to just go down the leg. It also probably went up.
>
> Q. Okay.
>
> A. That's what they call retrograde conduction. Well, if you look, as the fibers travel up they become in close proximity to one another.
>
> Q. Uh-huh.
>
> A. And so it's possible, and this is the best that I can come up with, that these – that this retrograde conduction caused either – probably I think what may have happened is that to really explain this, it probably went into – to the spinal cord and caused that population of neurons to fire.

Q. Uh-huh.

A. And somehow that resulted – that maybe the – the thing that resulted in this damage.

*Id.* at 868-69.

Dr. Rosenthal next considered medical evidence that seemingly posed a challenge to his theory. An electromyelogram (EMG) performed by a neurologist had failed to reveal any damage to Ms. Tingey's sacral nerve roots. He explained the lack of evident damage as follows:

A. And the answer is that EMG – there's four fiber types . . . . [T]wo of them are covered with this myelin sheath, and those are the types that EMG is able to detect. The smaller fiber types, A delta and C fibers, and EMG is not able to – to detect or sense damage to those fibers. Well, it turns out that those are the fiber types that go to the bladder.

*Id.* at 869. Dr. Rosenthal also stated that nerves without myelin sheathing, such as those running to the bladder, are more vulnerable to electric shock, though he did not know why.[9]

Counsel then asked him a key question:

Q. Okay. Based upon all you now know and what you studied, do you have an opinion as to . . . more probably than not what caused her neurogenic bladder?

A. This has been a difficult case because it's very hard to come to, you know, to come to a conclusion.

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[9] Myelin is a form of fatty sheath that surrounds and protects certain nerve fibers. Aplt. App., Vol. IV, at 869.

Q. Uh-huh.

A. But after doing some further studying and looking at the chart again and comparing what I learned in this studying to Dr. Landau's report, I would have to conclude that the – the procedure that I performed did have a – was the cause of her – of her bladder problem.

*Id.* at 875.

Perhaps the most difficult statement from Dr. Rosenthal's first deposition for his new theory lay in his previous deposition testimony that a mere seven-volt shock could not have produced Ms. Tingey's injuries. When asked about this at his second deposition, Dr. Rosenthal explained that in the stim mode, the radio frequency current oscillates very quickly. *Id.* at 885.

**(3.) Other testimony concerning causation**

In addition to Ms. Tingey's testimony and that of various physicians, there was testimony from two engineers familiar with the device who had worked with Radionics. Ray Fredricks testified that Radionics had never had a complaint about the toggle switch. *Id.*, Vol. III, at 785. He also stated that a mere seven volts could not lesion nerves; it would merely cause discomfort. *Id.*, Vol. II, at 523. Gerald Gagon testified that Ms. Tingey was the only patient he had ever heard of being shocked as a result of activation of the toggle switch. *Id.* at 530. He was aware of no injuries from the device in stim mode. *Id.* at 539.

**b. Application of causation test to the evidence**

Ms. Tingey argues that causation may be proved by circumstantial evidence; that is, that an inference of causation may be drawn based on "the strong temporal relationship between the shock and the immediate onset of Wendie's injury." Aplt. Opening Br. at 30, 33. The Utah courts have recognized that a temporal relationship between exposure to a hazardous substance and injury can provide circumstantial evidence of causation. *Alder v. Bayer Corp.*, 61 P.3d 1068, 1085-90 (Utah 2002).[10] Where the cause of an injury is obvious (for example, where a cyclist breaks his arm in a fall), the sequence of condition followed by event followed by altered condition may by itself provide sufficient evidence of causation. *Id.* at 1090. Where causation would not be obvious to an unaided finder of fact, however, plaintiff must also present some documented proof or expert medical testimony that exposure to the harmful substance could have been a cause of the type of injury that plaintiff received. *See id.* at 1087, 1089.

The primary difficulties with causation under the facts of this case are that the voltage was administered to Ms. Tingey's sacral nerves, not those going to the bladder, and that only seven volts or so of electricity was applied by the shock.

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[10] Although *Alder* concerned hazardous chemical fumes, the same sort of analysis has been applied where a plaintiff alleges permanent physical injury due to shocks received from ambient electricity. *See Easum v. Miller*, 92 P.3d 794, 801-04 (Wyo. 2004).

*Adler*, however, does not require a plaintiff to provide direct proof through medical studies of the mechanism of the illness or to quantify the harmful exposure necessary to have produced the harm alleged by the plaintiff. Instead, a plaintiff may establish causation circumstantially through the use of differential diagnosis. Quoting language in *Zuchowicz v. United States*, 140 F.3d 381 (2d Cir. 1998) that it called "a thoughtful review of the theory of causation," the *Alder* court explained that

> [I]t is well established that causation "may be proved by circumstantial evidence," . . . and that "[t]he causal relation between an injury and its later physical effects may be established by the direct opinion of a physician, by his deduction by the process of eliminating causes other than the traumatic agency, or by his opinion based upon a hypothetical question.

*Alder*, 61 P.3d at 1090 (quoting *Zuchowitz*, 140 F.3d at 389) (further quotation omitted).

**(1.) General principles**

*Alder* involved hospital employees who asserted that an improperly installed, poorly ventilated x-ray processing machine caused them various illnesses, including fibromyalgia and chronic fatigue syndrome. The manufacturer argued on appeal that "there must be a basis for generally 'ruling in' an agent as a known cause of the relevant class of injury before admitting differential diagnosis expert testimony." *Alder*, 61 P.3d at 1084. The Utah Supreme Court did not disagree with this analysis. It observed, however, that

"[t]he record in the instant case . . . contains ample documentation that exposure to x-ray processing chemicals causes the types of harm alleged by [plaintiffs]." *Id*. The absence of quantitative laboratory-based testing would not, therefore, vitiate the proof offered by differential diagnosis, "one of the oldest and most widely used and recognized of all the methods." *Id.*

Ms. Tingey primarily relies on differential diagnosis to establish causation. "Differential diagnosis . . . is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999). "In performing a differential diagnosis, a physician begins by 'ruling in' all scientifically plausible causes of the plaintiff's injury. The physician then 'rules out' the least plausible causes of injury until the most likely cause remains." *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001).

Radionics asserts that there are two problems with Ms. Tingey's use of differential diagnosis, given the facts of this case. First, her evidence fails to "rule in" the shock she received as a known cause of her injuries. Second, she fails to "rule out" other possible causes. As both requirements in fact were met, we conclude that summary judgment was inappropriate on the causation issue.

### (2.) Application to evidence

#### (A.) Dr. Rosenthal

The district court struck Dr. Rosenthal's second deposition, for two independent reasons. First, Ms. Tingey failed to provide notice of the deposition, which was taken in a separate state proceeding, to Radionics. Second, it found that Dr. Rosenthal's opinion was not reliable.

Concerning the first reason, the district court stated that "[u]nder Rule 32 of the Federal Rules of Civil Procedure, the deposition cannot be used against Defendant in this case as Defendant had no notice of the deposition and as a result was not afforded the opportunity to be present at the deposition and [to] cross-examine the witness." *Id.*, Vol. IV, at 1013. Rule 32(a) states that a deposition "may be used against any party who was present or represented at the taking of the deposition or who had reasonable notice thereof." As the case law reveals, the rule is primarily applied as a limitation on introducing deposition testimony *at trial*. While a few courts have applied Rule 32(a) to deposition testimony introduced in summary judgment proceedings, *see, e.g.*, *Nippon Credit Bank, Ltd. v. Matthews*, 291 F.3d 738, 750-51 (11th Cir. 2002), in our view this application represents an overly-expansive view of the Rule, given the purpose of the rule and the mechanics of summary judgment procedure.

Parties may file affidavits in support of summary judgment without providing notice or an opportunity to cross-examine the affiant. *See* Fed. R. Civ.

P. 56(c). The "remedy" for this non-confronted affidavit testimony is to file an opposing affidavit, not to complain that one was not present and permitted to cross-examine when the affidavit was signed. For this reason, the Ninth Circuit has permitted a party to introduce deposition testimony for summary judgment purposes against a party who was not present at the deposition, by construing the deposition *as an affidavit*. *Hoover v. Switlik Parachute Co.*, 663 F.2d 964, 966-67 (9th Cir. 1981). A similar reasoning applies here. If Radionics wished to controvert Dr. Rosenthal's testimony for summary judgment purposes, it could either have noticed an additional deposition of Dr. Rosenthal, or presented additional testimony from its own expert to cast doubt on his conclusions.[11] Therefore, the district court should not have struck Dr. Rosenthal's deposition under Rule 32(a).

Alternatively, the district court found the testimony contained in Dr. Rosenthal's second deposition unreliable and therefore inadmissible, stating:

> Plaintiff failed to demonstrate that Dr. Rosenthal is qualified to determine issues of causation in this matter and by Dr. Rosenthal's own admission he is not. The Court finds that the materials Dr. Rosenthal testified he reviewed prior to stating his opinion did not support Dr. Rosenthal's opinion on causation. The Court further finds that there is nothing in the record to demonstrate that Dr. Rosenthal's theory of causation is reliable and that Dr. Rosenthal's own testimony shows that his new explanation about how the injury might or could have occurred is mere supposition.

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[11] We express no opinion concerning the use of either of Dr. Rosenthal's depositions in a trial of this case.

> While the Court acknowledges that causation can be established in some cases through a differential diagnosis, Dr. Rosenthal failed to adequately address any of the other possible causes of the injury and also failed to "rule in" the surgical procedure at issue in this case as a potential known cause.

Aplt. App., Vol. IV, at 1014.

Federal Rule of Evidence 702 provides that

> [i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589-90 (1993), the Supreme Court made it clear that the touchstone of admissibility under Rule 702 is whether the scientific evidence presented is reliable. Specifically, "[u]nder Rule 702, expert testimony is admissible if it will assist the trier of fact and if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." *Lantec, Inc. v. Novell, Inc.*, 306 F.3d 1003, 1024 (10th Cir. 2002) (quotation omitted). This court may only reverse the district court's application of the *Daubert* standards for an abuse of discretion. *Lantec*, 306 F.3d at 1024. This means that "[w]e will not . . . disturb a district court's ruling absent our conviction that it is arbitrary, capricious, whimsical, manifestly unreasonable, or clearly erroneous."

*Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1232 (10th Cir. 2004), *cert. denied*, 126 S.Ct. 395 (2005).

We will consider each of the reasons given by the district court for excluding Dr. Rosenthal's testimony:

(1) Dr. Rosenthal's qualifications to determine issues of causation

The district court concluded that Ms. Tingey had failed to demonstrate that Dr. Rosenthal was qualified to determine issues of causation. Dr. Rosenthal admitted that he was not a urologist. Aplt. App., Vol. IV, at 862. He relied, however, on his general training and experience as well as his study of published authorities dealing with the specific issues presented in this case. Dr. Rosenthal studied several texts concerning types of neurogenic bladder problems and nerve damage. *Id.* at 862-65. He also correlated his research to clinical findings made by other doctors who had examined Ms. Tingey. *Id.* at 865-68. He adequately demonstrated his qualifications to express an opinion on causation in this matter, and the district court abused its discretion in concluding to the contrary.

(2) Dr. Rosenthal's use of supporting materials

The district court found that the materials on which Dr. Rosenthal relied did not support his opinion on causation. Dr. Rosenthal testified that he reviewed two medical treatises, primarily in an effort to rule out drug abuse as a cause for Mr. Tingey's bladder dysfunction. His review of these materials convinced him that Ms. Tingey's bladder problems had resulted from a traumatic injury to her

sacral nerve roots, rather than her abuse of opiates. His description of these materials does appear to support his theory of causation.

Dr. Rosenthal also reviewed Dr. Landau's report, which he concluded further supported his conclusion that Ms. Tingey's injury resulted from sacral nerve root damage. While Dr. Miska's report tended to contradict Dr. Rosenthal's impression concerning traumatic nerve damage, because his electromyography (EMG) did not uncover any evidence of acute or chronic denervation changes of the L5 nerve, and no evidence of damage to the S1 nerves on either side, Dr. Rosenthal did not believe that this ruled out his theory of causation. Rather, he explained that the EMG would not detect damage to small nerve fibers of the type that go to the bladder. These non-myelinated nerve fibers would also be more vulnerable to damage from an electric shock. Thus, the materials from Ms. Tingey's other doctors, which Dr. Rosenthal reviewed, did not contradict his theory of causation.

Dr. Rosenthal also stated that he was unaware of any report in the medical literature that identified bladder nerve damage as a possible consequence of the lesioning procedure. He did not rely on this medical literature, however, as a basis for his opinion. We conclude that the district court erred in concluding that the materials on which Dr. Rosenthal relied did not support his theory of causation.

(3) Lack of record evidence for Dr. Rosenthal's theory of causation

The district court also stated that there was nothing in the record to demonstrate that Dr. Rosenthal's theory of causation was reliable. The district court appears to have relied on lack of corroboration, beyond Dr. Rosenthal's own testimony. As we have already pointed out, however, in reaching his conclusions regarding causation, Dr. Rosenthal relied on treatises, medical tests and laboratory findings. Moreover, "disputes as to the strength of his credentials, faults in his use of differential etiology as a methodology, or lack of textual authority for his opinion, go to the weight, not the admissibility of his testimony." *Zuchowicz*, 140 F.3d at 387 (quotation omitted).

(4) Speculative nature of Dr. Rosenthal's causation theory

The district court opined that "Dr. Rosenthal's own testimony shows that his new explanation about how the injury might or could have occurred is mere supposition." Aplt. App., Vol. IV, at 1014. The court did not refer to specific examples in the summary judgment record to support its conclusion, but our review of the record convinces us that whatever the ultimate merit of Dr. Rosenthal's opinion, it is not based on mere supposition. While Dr. Rosenthal did use such phrases as "here's how I might explain it," *id.* at 868, or "what seems to have happened," *id.*, he ultimately provided a scientific basis to describe the mechanism of Ms. Tingey's injury.

Specifically, Dr. Rosenthal testified that (1) Ms. Tingey has a hypotonic bladder, consistent with an injury to the sacral nerve roots; (2) during the

procedure, a shock was delivered to her L5 nerve, near the dorsal root ganglion; (3) the shock probably caused retrograde conduction through the spinal cord causing damage to the sacral nerve roots; and (4) this damage was not visible on an EMG because the nerves damaged were small, unmyelinated nerves leading to the bladder, which are more vulnerable to electric shock. This theory represents more than mere supposition, and the district court erred in excluding it for that reason.

(5) Dr. Rosenthal's use of differential diagnosis

The district court concluded that "Dr. Rosenthal failed to adequately address any of the other possible causes of the injury and also failed to 'rule in' the surgical procedure at issue in this case as a potential known cause." *Id.* at 1014. This conclusion is incorrect. A careful review of Dr. Rosenthal's deposition testimony shows that he took great pains to show that Ms. Tingey's injuries were inconsistent with opiate abuse, the only other possible cause discussed in any detail in the record. Also, as we have discussed, his testimony provided a detailed mechanism to "rule in" the procedure as a cause of the injury. Any doubts about the validity of his theory, as we have emphasized, go to the weight, rather than the admissibility, of Dr. Rosenthal's testimony.

**(B.) Dr. Platt**

The district court struck Dr. Platt's affidavit, finding it "so lacking in foundation and therefore unreliable that it does not meet the requirements of

Rule 56(e) of the Federal Rules of Civil Procedure or Rule 702 of the Federal Rules of Evidence." *Id.*, Vol. IV, at 1013. The district court gave three reasons for rejecting Dr. Platt's affidavit. First, "[t]he Affidavit does not contain specific facts to support a direct or circumstantial case of causation." *Id.*, Vol. IV at 1013. The affidavit does, however, contain specific facts describing the nature of Ms. Tingey's injuries and detailing a circumstantial case for causation. Specifically, Dr. Platt stated that: (1) he had conducted an examination of Ms. Tingey's medical records and had found no evidence in these records prior to March 10, 2000, that Ms. Tingey had experienced any bladder problems; (2) her complaints of bowel and bladder incontinence had begun after she underwent a radiofrequency surgical procedure on March 10, 2000 at Orem Community Hospital; (3) he conducted a bulbocavernous reflux test on Ms. Tingey with negative results, from which he determined that the nerves going to her bladder had been damaged; (4) she continues to suffer from a mixed sensory and neurogenic bladder dysfunction; and (5) in his opinion, "the cause of [Ms. Tingey's] neurogenic bladder was the inadvertent electrical shock [she] received during the radiofrequency procedure on March 10, 2000." *Id.*, Vol. II, at 451. We conclude that the district court abused its discretion in determining that the affidavit contained insufficient facts to establish causation.

Second, the district court stated that the affidavit was deficient because it did not set forth that Dr. Platt had "the necessary qualifications to opine on how

injury could have occurred to Plaintiff or rule out other possible causes for Plaintiff's alleged injuries." *Id.*, Vol. IV, at 1013. Various exhibits were attached to the affidavit, including letters on Dr. Platt's letterhead stationery, where he is identified as a Diplomate of the American Board of Urology. *Id.*, Vol. II, at 452. Other exhibits detailed the medical tests Dr. Platt performed on Ms. Tingey, and the conclusions he drew from the test results, particularly in light of his experience with other patients. This is clearly a case where "the doctor's training and experience placed his report and testimony well above the Rule 702/*Daubert* bar." *Feliciano-Hill v. Principi*, 439 F.3d 18, 25 (1st Cir. 2006); *see also Bitler*, 400 F.3d at 1237 ("In the medical context, differential diagnosis is a common method of analysis, and federal courts have regularly found it reliable under *Daubert*.").

Finally, the district court found Dr. Platt's affidavit deficient because it did not discuss the evidence from Dr. Miska, a neurologist who found no evidence that Ms. Tingey had incurred nerve damage. Dr. Platt specifically found, from a urological standpoint, that "the nerves going [Ms. Tingey's] bladder have been damaged." Aplt. App., Vol. II, at 450. Dr. Miska stated that the neurological tests he performed had not revealed nerve damage. *See id.* at 540. The apparent disagreement between these two physicians, however, goes to the weight and not the admissibility of Dr. Platt's opinion. *See Feliciano-Hill*, 439 F.3d at 25 (holding that "[t]he mere fact that two experts disagree is not grounds for

excluding one's testimony."). Dr. Platt's failure to refute, or even to discuss, Dr. Miska's opinion does not make his opinion inadmissible under Rule 702 or *Daubert*.

Radionics further argues that the procedure itself, rather than the shock, could have been the cause of Ms. Tingey's injuries. Radionics did not present expert testimony to substantiate a theory that the procedure itself caused the injuries, nor did it develop a legal argument that expert testimony is not necessary to factor in the pre-shock lesioning as a potential cause necessary for consideration in a differential diagnosis analysis. As a consequence, for purposes of this appeal we deem the absence of such expert testimony fatal to Radionics' position.

We conclude that the district court erred in striking Dr. Rosenthal's second deposition and in excluding Dr. Platt's affidavit. With these two items of evidence included, Ms. Tingey has made a sufficient showing on the causation issue to survive summary judgment on her claims.

**5. Ms. Tingey's cross-motion for summary judgment**

Ms. Tingey also appeals from the district court's denial of her motion for summary judgment. In her motion, she requested summary judgment on the following issues: (1) that the Radionics device was unreasonably dangerous as a matter of law; (2) that its defect existed at the time the device left Radionics' control; (3) that the defect in the device caused her neurogenic bladder injury;

(4) that an alternative, safer design was available at the time Radionics placed the device into the stream of commerce; and (5) that Radionics failed to warn users and consumers about the hidden dangers posed by the device's toggle switch. As our foregoing analysis makes clear, while Radionics is not entitled to summary judgment on these issues, neither is Ms. Tingey. Genuine issues of fact remain as to each of the listed issues, precluding the entry of summary judgment in favor of either party. We therefore affirm the district court's denial of Ms. Tingey's motion for summary judgment.

## CONCLUSION

We AFFIRM the order of the district court denying Ms. Tingey's motion for summary judgment. We REVERSE the district court's order granting summary judgment to Radionics, striking the affidavit of Ms. Tingey's expert witness, and striking the second deposition of her physician Dr. Rosenthal, and we REMAND for further proceedings.

Entered for the Court

Paul J. Kelly, Jr.
Circuit Judge