IN THE COURT OF APPEALS OF THE STATE OF NEW MEXICO

Opinion Number: 2020-NMCA-020

Filing Date: December 30, 2019

No. A-1-CA-36565

MICHAEL BRIAN MCDONALD, PH.D,

Plaintiff-Appellee,

v.

ZIMMER INC., and ZIMMER HOLDINGS INC.,

Defendants-Appellants,

and

LAMORRIS RICHARD HERRIN, JR. and RK ORTHOPEDICS, LLC,

Defendants.

APPEAL FROM THE DISTRICT COURT OF BERNALILLO COUNTY
Nan G. Nash, District Judge

Released for Publication May 5, 2020.

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OPINION

VANZI, Judge.

{1} Zimmer Inc. and Zimmer Holdings Inc. (collectively, Defendants) appeal the district court's finding of strict liability for a design defect in the hip prosthetic implanted in Brian McDonald (Plaintiff). Following a bench trial, the district court concluded that the design of the prosthetic was unreasonably dangerous, in that it shed excessive metal debris, causing poisoning and death of the soft tissue in Plaintiff's hip joint, requiring Plaintiff to have additional hip surgeries and ongoing (potentially lifelong) antibiotic treatment. Defendants argue on appeal that (1) the district court erred in its findings and conclusions concerning a design defect; and (2) the hip prosthetic is an unavoidably unsafe product, for which adequate warnings were given, such that Defendants are not subject to strict liability, pursuant to comment k to the Restatement (Second) of Torts § 402A (1965). Defendants seek judgment as a matter of law, or a new trial. For the reasons set forth below, we affirm the district court.

BACKGROUND

I. Procedural History

{2} Plaintiff filed a lawsuit against Defendants, and co-defendants Lamorris Richard Herrin, Jr., and RK Orthopedics, LLC, on May 9, 2013. The complaint arose from Plaintiff's injuries in connection with the failure of his hip implant, a prosthetic device designed and manufactured by Defendants. The claims tried before the district court in December 2016, in a bench trial, sounded in strict liability (design defect and failure to warn), negligence, breach of express and implied warranties, and punitive damages. The district court found Defendants strictly liable for a design defect in the prosthetic device, and dismissed all other claims, including those against co-defendants Herrin and RK Orthopedics.[1]

II. Facts Presented at Trial

1The co-defendants were dismissed pursuant to a motion under Rule 1-041(B) NMRA, granted by the district court following the bench trial.

A. Plaintiff's Hip Surgeries

{3} In 2010 Plaintiff was diagnosed with severe osteoarthritis with flattening of the femoral head, osteophyte formation, and cystic formation. Plaintiff consulted with orthopedic surgeon Joshua Carothers, M.D., and elected to have total hip replacement surgery.[2] Dr. Carothers had originally planned to use a single-modular prosthetic device for Plaintiff's hip replacement—a Zimmer brand "M/L Taper with VerSys head." "Single-modular" describes a device with a fixed or solid neck-stem[3] component (the component anchored to the femur) coupled with an artificial head (replacing the "ball" of the natural hip joint). Zimmer's device, which included a titanium alloy neck-stem component, and a cobalt-chromium alloy (CoCr) head component, was (at the time) considered the "gold standard" in total hip replacement. However, during the surgery in June 2010, Dr. Carothers had to make certain adjustments to accommodate Plaintiff's anatomy, and decided to use a dual-modular device instead: the Zimmer brand "M/L Taper Hip Prosthesis with Kinectiv Technology" (MLTK).[4] The MLTK is a "dual-modular" device because the neck and stem components of the prosthetic are separate and can be adjusted, both in relationship to the head and to one another, to account for variations in joint configuration (e.g., leg length, offset, and version, which refers to the forward or backward rotation of the hip joint). In Plaintiff's case, these options allowed Dr. Carothers to choose an anteverted neck (one with a forward rotation) for Plaintiff's implant. Like the traditional M/L Taper, the MLTK's neck and stem are made of titanium alloy. The MLTK can be used with either a CoCr head (such as the VerSys) or a ceramic head. Dr. Carothers used the CoCr head.

{4} Plaintiff initially recovered well, but by early May 2011, Plaintiff was experiencing hip pain, groin pain, and loss of flexibility. Dr. Carothers commenced an established series of tests to determine the cause of Plaintiff's pain, which showed, inter alia, that Plaintiff had elevated levels of C-reactive protein (indicating tissue necrosis, or tissue death), and a pseudotumor[5] forming in the hip joint. Plaintiff then saw Christopher Beauchamp, M.D., at the Mayo Clinic in Phoenix, Arizona, on September 2, 2011, where Dr. Beauchamp diagnosed Plaintiff with an adverse reaction to metal debris, associated with the MLTK implant, and scheduled Plaintiff for revision surgery. Dr. Beauchamp ordered a blood serum test, which revealed slightly elevated chromium levels, and significantly elevated (tenfold the normal level) cobalt levels. Dr. Beauchamp performed a revision surgery on Plaintiff's right hip joint on October 4, 2011, during which he discovered corrosion[6] and metal debris at the taper junction of Plaintiff's MLTK

2Also known as "total hip arthroplasty."

3Also called a "monoblock taper."

4Dr. Carothers noted in his testimony that, at the time, Presbyterian Hospital (where Plaintiff's surgery was performed) had a sole-source contract with Defendants, and therefore Dr. Carothers was restricted to using a Zimmer product for Plaintiff's total hip replacement.

5A pseudotumor is metal-related pathology consisting of a large fluid collection in the joint.

6Corrosion is a reduction-oxidation reaction at the surface of a metal. It may occur where two metals with differing electro-potentials are in contact with one another, and the more active metal (i.e., the metal that more readily loses electrons) oxidizes, or corrodes. This is known as galvanic corrosion. Corrosion may also occur through micro-motion or fretting—that is, wear to a metal surface induced by rubbing (on metal or another surface). With fretting corrosion (also known as tribocorrosion), surface wear removes the metal's natural oxide coating and

prosthetic, as well as burnishing on the neck component at the second (neck-stem) junction, necrotic (dead) tissue, and turbid (cloudy) joint fluid. Dr. Beauchamp's pre-operative and post-operative diagnoses were failed total hip replacement secondary to adverse reaction to metal debris caused by the CoCr head on the hip prosthetic articulating with the titanium trunnion (the top of the neck, where it couples with the head). Such adverse reaction is also known as metallosis or adverse local tissue reaction.

{5} Dr. Beauchamp revised the hip by exchanging the CoCr head for a ceramic head; he also replaced the Kinectiv neck component and the polyethylene liner (which rests between the head and the cup). Dr. Beauchamp was unable to remove all of the necrotic tissue around Plaintiff's right hip, because removing too much tissue leaves a patient at risk for joint dislocation; however, retaining necrotic tissue poses a risk of infection, given the lack of blood circulation to the dead tissue. In fact, Plaintiff developed an infection following this revision surgery, requiring a second revision surgery, performed by Dr. Carothers. Dr. Carothers performed an irrigation and debridement for the infection and replaced the Kinectiv neck and polyethylene liner. He also replaced the ceramic head from the first revision surgery with a new ceramic head.[7] Plaintiff has required and may permanently require antibiotic therapy due to his continued risk for infection. It is probable that Plaintiff will require a third, more complicated revision surgery in the future to eradicate the infection.

B. Development of the MLTK

{6} Single-modular hip prostheses have been widely used since the early 1980s, but dual-modular prostheses were not developed until approximately twenty years later. Indeed, when Defendants launched the development of the MLTK in 2001 (through a project known as "G2"), it was a new design and a "new frontier" for Defendants. Defendants employed multiple engineers and approximately twenty consulting surgeons on the design team. The MLTK was intended to be minimally invasive, to offer a wider range of adjustments to surgeons, and to provide greater flexibility within the joint. Defendants designed the titanium neck and stem components to be used with either a CoCr or a ceramic head component. The MLTK offers a total of sixty possible configurations.

{7} Hip implants fail for a variety of reasons, including but not limited to dislocation, fracture, loosening, infection, and metallosis. Some degree of corrosion occurs in all modular hip implants. Although there is no consensus as to why some patients with a

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exposes it to a new chemical environment. In the junction of a modular hip prosthetic, wear is created by the micro-motion of one component against the other, and small volumes of joint fluid exchanged within the junction facilitate the corrosive reaction, carrying oxides and metal ions outside of the joint, and generally altering the electro-chemical environment around and within the joint. This phenomenon has been described as mechanically-assisted crevice corrosion.

7Dr. Carothers testified that, for Plaintiff's primary surgery, he believed the benefits of using the MLTK with the CoCr head outweighed the risks, but at the time, he did not know that the MLTK with CoCr head presented a risk of metallosis.

corroding implant develop metallosis, while others do not, it is well understood that more corrosion/metal debris increases the risk of developing metallosis. Defendants were aware the particular characteristics of the MLTK would increase the risk of micro-motion, and therefore corrosion and liberated metal debris from junctions of the prosthetic. Specifically, the MLTK features (1) two modular junctions, and therefore an additional location where corrosion may occur; (2) a junction between two dissimilar metals (known to generally pose a higher risk of corrosion than junctions between similar metals); (3) a neck that is thinner in two planes and more flexible[8] than a traditional neck (increasing the likelihood of fretting corrosion); and (4) optional adjustments in length and version that may increase the bending moment[9] in the neck (further increasing the likelihood of fretting corrosion).

{8} Accordingly, one of the design goals for the MLTK was to minimize corrosion at the head-neck and neck-stem junctions, with the goal that the metal debris released by the device would be within "known acceptable levels." However, no reasonable level for wear debris was, in fact, known. Defendants elected to define "known acceptable level[s]" through a "clinically proven" predicate device: the traditional M/L taper with a CoCr (VerSys) head, and six-inch tapered titanium neck (a single-modular device). This device, according to Defendants' research report on the MLTK, had a "long clinical history of exhibiting some debris generation without adverse clinical effects." Defendants therefore designed a test (known as an accelerated corrosion fatigue test[10]) that would quantify the "worst case" metal debris released by the predicate device, which was determined to be 5.62 milligrams. Defendants reasoned that, if the debris generated by the "worst case" orientation of the MLTK in a similar environment was below 5.62 milligrams, the MLTK would, like the predicate device, avoid adverse clinical effects.[11]

{9} At trial Defendants explained that they ran corrosion fatigue testing on the two MLTK junctions "separately," in order to isolate and measure the worst-case metal debris generated at the head-neck, and neck-stem junctions, respectively. In effect, the Defendants tested the entire MLTK device with a ceramic head, but never tested the entire device with CoCr head. Defendants' explicit rationale for this was that utilization

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8The MLTK neck is in the top third of flexibility among hip prosthetic necks.

9The "moment" is the product of force times distance. In the neck of the MLTK, for instance, the longer the neck, the greater the moment. A greater moment induces greater bending (and consequently, greater micro-motion in the junction).

10Accelerated corrosion fatigue testing is calculated to mimic and accelerate the corrosive conditions in the human body, to measure a prosthetic's loss of debris under such conditions and to ascertain the fatigue strength of the components. Fatigue strength refers to resistance to cracking or fracture under corrosion stress. In this case, such testing entailed immersing the relevant prosthetic components in a solution with a PH slightly more acidic than the human body, at a temperature somewhat higher than the temperature of the human body, and subjecting the components to loads analogous to the weight borne by the joint over a period of approximately five years.

11Defendants initially ran corrosion fatigue testing on a design featuring a CoCr neck, as CoCr is an alloy superior in strength to titanium. However, this combination generated too much metal debris, and was therefore abandoned in favor of a design that replaced the CoCr neck with a titanium neck. This change in materials extended the time-frame of the G-2 project (from three to five years) and resulted in additional costs for Defendants.

of the ceramic head would minimize the debris generated at the head-neck junction, thus allowing Defendants to isolate the debris generated at the neck-stem junction. Defendants then separately tested the head-neck junction using a CoCr head and titanium neck, but did not use the Kinectiv neck, instead using a titanium neck of similar geometry (a 12/14 Taper) anchored in bone cement. Defendants added together the metal debris released in each test,[12] which totaled 4.4 milligrams. Because this total was less than the 5.62 milligrams released by the predicate device, Defendants determined that the debris generated by the MLTK in vivo would be within "known acceptable levels."

{10} Nothing prevented Defendants from performing corrosion fatigue testing on the entire MLTK device with a CoCr head. Spectrum Accelerated Corrosion Fatigue (SACF) testing, which would have applied side loads in a variable manner more similar to a patient's use of his or her joint, was also considered by the G2 design team in 2006, but Defendants elected not to pursue it. Although the best evaluation of a device would include clinical information, in addition to laboratory testing, and one of Defendants' consulting surgeons, Joshua Jacobs, M.D., proposed clinical studies in 2003 (and 2011, after the device had been marketed), Defendants never conducted one prior to launching the MLTK. Again, evidence showed that Defendants deemed a clinical study unnecessary, reasoning that the clinical predicate device used in the corrosion fatigue testing provided sufficient information regarding the device's risk of corrosion in patients. Ultimately, the MLTK, configured with the CoCr head or the ceramic head, passed Defendants' testing for fatigue strength and stability.

C. Marketing and Use of the MLTK

{11} The MLTK was cleared for marketing by the Food and Drug Administration (FDA) on January 24, 2007. The MLTK is a "Class III" medical device—meaning one that either "presents a potential unreasonable risk of illness or injury" or which is "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[.]" 21 U.S.C. § 360c(a)(1)(C) (2018). Although such devices are ordinarily required to undergo a rigorous premarket approval process, the Medical Device Amendments Act of 1976, Pub. L. No. 94-295, 90 Stat. 539 (the Act), permitted devices that are "substantially equivalent" to devices already on the market to avoid the premarket approval process. *See* 21 U.S.C. § 360e(b)(1)(B) (2018). Courts have observed that this truncated route (known as the "510k process," under a prior version of the Act) is "focused on equivalence, not safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996) (emphasis, internal quotation marks, and citation omitted). Whereas the premarket review process (which requires 1,200 hours to complete) is a federal safety review, the on-average 20-hour review process for devices marketed under 510k "requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly." *Id.* at 479 (internal quotation marks and citation omitted).

12Defendants actually tested five different constructs for the neck-stem junction and averaged them.

{12} Manufacturers are required to internally track adverse events in connection with medical devices and to report them to the FDA; these are made public through the Manufacturer and User Facility Device Experience (MAUDE) database. However, because such data is primarily controlled by the manufacturers, and because not all doctors report adverse events to manufacturers, statistical data from MAUDE may not be used to justify or prove a device's safety. At trial, evidence was presented that, per Defendants' internal reporting, 47 MLTK devices were revised due to metallosis between July 9, 2009 and June 20, 2016. It is unknown whether, or how many of these devices were configured in the same manner as Plaintiff's, because Defendants do not track reported revisions with sufficient detail to ascertain this information. Dividing this number by the number of devices sold worldwide through 2016 (148,470), .032 MLTK devices were revised due to metallosis, for every thousand sold.[13] The traditional M/L Taper (the predicate device in testing for the MLTK) had a lower metallosis revision rate (.025 per thousand) during the same period.

{13} At trial, evidence was also presented regarding the MLTK's performance as reported through independent registries in Australia and the United Kingdom (UK).[14] It appears that the MLTK had a significantly higher overall revision rate,[15] and a nine-times higher rate of revision due to metal-related pathology, compared to all other hip implant systems being used in Australia as of 2013. In the UK, the revision rate between 2006 and 2016 was 23 for 1,074 MLTK units implanted, for a revision rate of only .021, but the number of MLTKs sold in the UK has also dropped precipitously since 2012; zero were sold in 2016. No explanation for this was offered in evidence at trial.[16]

{14} In 2010 Dr. Jacobs submitted a research proposal to study fretting corrosion in the MLTK. The proposal sought to utilize corrosion fatigue and other wear testing of the entire device (both junctions) with a CoCr head, in multiple configurations. The rationale for this was that, "presently, the amount of metal released from newer dually modular head-neck total arthroplasty components is not well characterized and thus the biological impact of this is not known." Dr. Jacobs explained that fretting corrosion in modular junctions "appears to be a major or primary source of metal released in vivo in total joint arthroplasty patients" and that "[t]he issue of metal release from modular prosthetic devices is becoming increasingly urgent due to an increasing prevalence of implant modularity associated with new Kinectiv joint replacement surgery techniques." Defendants' lead engineer in the design of the MLTK, Steven Meulink, met with Dr. Jacobs, and agreed with his concerns, but Defendants did not fund the proposed research because they "did not have funding for the project at [the] time."

13Units sold does not reflect the units actually implanted in a patient, further limiting the usefulness of this data.
14George Kantor, M.D., retained by Plaintiff as an expert in orthopedic surgery, explained that the registry data is problematic in terms of relying on it to communicate reasons for revision of a given prosthetic device, because the data is limited in specificity, and the causes of implant failure are complex. For instance, revisions reported as caused by loosening of the prosthetic, fracture, infection, and osteolysis (bone loss), may have been caused by metallosis or metal-related pathology, but not reported as such. Dr. Kantor felt that this data's best function, then, is as a "canary in the mine-shaft."
15Dr. Kantor testified that, per National Institutes of Health consensus on hip prosthetic performance, the five-year revision rate for survival should be 2.0; per the Australian data; the MLTK's rate was 5.1 at five years.
16It appears that fewer than one-third of the MLTKs implanted in the UK used cobalt-chromium heads.

{15} Dr. Jacobs then reported on ten cases in which head-neck taper corrosion was "observed at the time of revision[,]" and in which adverse local tissue reactions were observed in a subset of several patients, leading Defendants to conduct a Quality Investigation Report (QIR-12014) in 2011. QIR-12014 noted a substantial rise in "corrosion complaint rates" in the past five years, among which the majority had "in-vivo times of less than four years." Moreover, the highest number of complaints were regarding CoCr heads on MLTK devices or CoCr heads on a fixed CoCr stem (the VerSys Beaded Full Coat Stem).

{16} Soon thereafter, in 2012, Paul J. Diwelius, M.D., another of Defendants' consulting surgeons for the MLTK, published a short-term study on a large cohort of patients, some of whom received a traditional M/L Taper implant, and some of whom received the MLTK implant, with the aim of understanding whether the advantages of the MLTK outweigh its disadvantages. He concluded that the advantages of the MLTK's modular neck configuration did not translate to better outcomes, and that the benefits of using the MLTK over the M/L Taper did not outweigh the risks. In a group of three patients with the MLTK components, he observed corrosion and adverse local tissue reactions at the junction of the CoCr head and titanium neck. He also noted the risk of corrosion at the titanium neck-stem junction. Dr. Diwelius "now almost exclusively uses nonmodular stems and ceramic femoral heads to decrease the possibility of corrosion." Dr. Beauchamp, who performed Plaintiff's first revision surgery, no longer uses the Zimmer CoCr head in his total hip arthroplasty practice. He has switched to ceramic heads, to "eliminate cobalt-chromium from the equation," and reduce the risks to his patients. Indeed, Dr. Beauchamp testified that the Mayo Clinic in Arizona has largely shifted to use of ceramic heads, only, to avoid the metal debris generated by CoCr heads. Dr. Kantor testified that he has performed approximately 5,000 hip surgeries, and that he never uses dual-modular implants in his primary procedures. Moreover, although the prevalence of metallosis is not yet well understood, Dr. Kantor sees cases of metallosis on a monthly basis.

{17} In a 2016 article, Dr. Jacobs recommended, to prevent adverse local tissue reactions, minimizing the micro-motion of modular junctions, and "optimizing material selection," noting that "many surgeons have abandoned CoCr heads entirely" in favor of ceramic heads. Dr. Jacobs also noted that serum cobalt levels differentially elevated over chromium levels have become a "hallmark" diagnosis for adverse local tissue reaction. At trial, Dr. Jacobs testified that he has never seen a case of adverse local tissue reaction in a patient with a ceramic head component and is only aware of a case report or two documenting such a reaction in a patient with a ceramic head on a CoCr stem (not a titanium stem, used in the MLTK). Although Dr. Jacobs testified that ceramic heads present risks—including a risk of fracture—he felt that these risks are exceedingly low. Dr. Jacobs was also aware that ceramic head technology was available in 2010 (when Plaintiff received his primary MLTK implant).

{18} Finally, Jeremy Gilbert, Ph.D., a biomedical engineering expert retained by Defendants, authored a 2016 study investigating the material loss associated with use of a ceramic head, versus a CoCr head, on a group of modular hip prosthetics including

the MLTK. Dr. Gilbert found that use of the ceramic head resulted in reduction of material loss by an order of magnitude (a factor of ten), and that the study's findings "support the hypothesis that the use of ceramic heads mitigates metallic material loss from taper junctions." At trial, Dr. Gilbert acknowledged that the use of ceramic heads should eliminate the release of cobalt-chromium entirely. He also testified that a "constant" in patients who develop adverse local tissue reactions is the presence of modular junctions, where at least one component in those junctions is fabricated from cobalt alloy. A 2015 study by Brian J. McGrory, M.D., noted that, while minimal titanium corrosion still occurs with the use of a ceramic head, it does not seem to cause metallosis.

{19} In 2010, 90 percent of the femoral heads sold by Zimmer were CoCr, and ten percent were ceramic. By the time of trial in 2016, 50 percent of the femoral heads sold by Zimmer were CoCr, and 50 percent were ceramic.

D. Risk of Injury

{20} Plaintiff's expert biomechanical engineer, Albert Burstein, Ph.D., testified that earlier generations of single-modular hip implants did not generate fretting corrosion/metal debris at toxic levels in meaningful clinical quantities. However, the MLTK introduced a risk of fretting corrosion well beyond that seen in earlier devices. According to Dr. Burstein, Defendants did not perform adequate testing with respect to the risk of corrosion in the MLTK. Specifically, Dr. Burstein opined, Defendants failed to test the cobalt-chromium head on the full Kinectiv device, even though the Kinectiv neck-stem is more flexible than a titanium neck anchored in bone cement, and greater flexibility is known to increase micro-motion, and therefore corrosion. Furthermore, Defendants' test of the neck-stem junction did not include a CoCr head, nor the multiple geometric configurations available to surgeons (such as the anteverted orientation of Plaintiff's implant), despite the fact that the version of the neck (in addition to the length) is known to impact fretting corrosion. Defendants' failure to adequately test resulted in the marketing of an unreasonably dangerous and defective device—one that, when used with a CoCr head, in the configuration seen in Plaintiff's implant, allowed the liberation of excessive, toxic quantities of cobalt debris.[17]

{21} Dr. Gilbert testified that, in his opinion, the MLTK as configured in Plaintiff is not unreasonably dangerous. In his view, Defendants effectively tested the worst-case configurations of the MLTK, and separate testing of each junction was appropriate under a principle of mechanical engineering known as "Saint Venant's [p]rinciple," such that motion at one of the MLTK junctions should not affect motion at the other. However, Dr. Gilbert later conceded that corrosion at one location affects other locations of corrosion, under principles of electrochemistry, as he had previously testified when presenting to the FDA. Dr. Gilbert stated that the corrosion observed on Plaintiff's device was moderate. However, when asked at trial: "If a device is throwing off or

17Dr. Burstein noted that Plaintiff's configuration was a more "extreme" case within the system of sixty possible configurations of the MLTK. He explained that, in order to predict performance, an adequate number of configurations at certain extremes need to be tested (and, in the case of the MLTK, they were not).

creating so much metal debris and corrosion that it causes metallosis or adverse local tissue reaction, that is not an acceptable risk of harm, is it?" Dr. Gilbert responded, "No, it's not."

III. Findings and Conclusions on Strict Liability for Design Defect

{22} Based on the evidence presented at trial, the district court found (in relevant part) that "Plaintiff developed metallosis around his implant and his implant failed due to the corrosion caused by the cobalt chromium femoral head articulating with the titanium trunnion." The district court reasoned that "[a]lthough a small amount of non-toxic corrosion or metal debris may occur with a hip implant, an implant that causes an excessive amount of corrosion or metal debris sufficient to cause toxic metal poisoning creates an unreasonable risk of injury." It further found that the MLTK device, when configured with a CoCr head, as in Plaintiff's case, may generate metal debris sufficient to cause toxic metal poisoning. Accordingly, the MLTK, as configured in Plaintiff's case, was defective.

DISCUSSION

I. Standard of Review

{23} We review de novo the district court's application of law to the facts. *TPL, Inc. v. N.M. Taxation & Revenue Dep't*, 2003-NMSC-007, ¶ 10, 133 N.M. 447, 64 P.3d 474. Moreover, where a district court enters conclusions of law following a bench trial, those conclusions must find support in one or more findings of fact. *Chavez v. S.E.D. Labs.*, 2000-NMSC-034, ¶ 19, 129 N.M. 794, 14 P.3d 532 (*Chavez II*). "Findings are sufficient if, taken together and construed in support of the judgment, they justify that judgment." *Id.* We review a district court's factual findings as we would the verdict of a jury—for substantial evidence. *See Bustos v. Hyundai Motor Co.*, 2010-NMCA-090, ¶ 27, 149 N.M. 1, 243 P.3d 440; *see also Giant Cab, Inc. v. CT Towing, Inc.*, 2019-NMCA-072, ¶ 6, ___P.3d ___.[18] "Substantial evidence is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Clovis Nat'l Bank v. Harmon*, 1984-NMSC-119, ¶ 7, 102 N.M. 166, 692 P.2d 1315 (internal quotation marks and citation omitted). Moreover, "we resolve all disputed facts in favor of the successful party, indulge all reasonable inferences in support of a verdict, and disregard all evidence and inferences to the contrary." *Id.* ¶ 7 (noting also that we do not re-weigh the evidence).

II. Analysis

{24} Defendants' first argument on appeal is that the district court effectively held Defendants "absolutely liable" for Plaintiff's injuries, both through misapplication of the

18Defendants assert that "[w]hether the evidence presented at trial is sufficient to support the trial court's decision" is a question of law subject to de novo review. This is incorrect. The case cited by Defendants for this proposition, *Couch v. Astec Indus., Inc.*, 2002-NMCA-084, ¶¶ 56-57, 132 N.M. 631, 53 P.3d 398, is addressed to the standard of review for entry of a directed verdict, not entry of a judgment following trial.

law, and because there were insufficient findings or evidence of a design defect in the hip prosthetic. Defendants specifically assert that, in its assessment of risk of injury, the district court failed to make sufficient findings under the seven factors required by *Brooks v. Beech Aircraft Corp.*, 1995-NMSC-043, ¶ 32 n.2, 120 N.M. 372, 902 P.2d 54 (citing UJI 13-1407 NMRA, comm. cmt.). Defendants also suggest that the findings, such as they are, were not supported by sufficient evidence.[19]

{25} Defendants' second argument on appeal is that the district court should have found strict liability inapplicable to Plaintiff's claims under comment k to the Restatement (Second) of Torts Section 402A, pursuant to which "unavoidably unsafe products" are exempt from strict liability, provided (as here) the product was properly prepared and marketed and adequate warnings were given. We address each argument in turn.

A. The District Court Did Not Err in Finding a Design Defect

{26} Defendants first contend that the district court identified no defect in the MLTK, and instead erroneously "based its conclusion that the MLTK was defective in design on its finding that the implant was 'unreasonably dangerous.' " However, this is precisely what is required under New Mexico law. "[A]n unreasonable risk of injury resulting from a condition of the product or from a manner of its use . . . makes the product defective." UJI 13-1406 NMRA; *see Rudisaile v. Hawk Aviation, Inc.*, 1979-NMSC-015, ¶ 11, 92 N.M. 575, 592 P.2d 175 (noting that "[c]ourts have generally equated 'defective' with 'unreasonably dangerous' "), *abrogated on other grounds by Livingston v. Begay*, 1982-NMSC-121, ¶ 24, 98 N.M. 712, 652 P.2d 734. An unreasonable risk of injury is "a risk which a reasonably prudent person having full knowledge of the risk would find unacceptable. This means that a product does not present an unreasonable risk of injury simply because it is possible to be harmed by it." UJI 13-1407; *see id.*, comm. cmt. (further explaining that "a product is defective if it is unreasonably dangerous as marketed. It is unreasonably dangerous if a reasonable person would conclude that the magnitude of the scientifically perceivable danger as it is proved to be at the time of the trial outweighed the benefit of the way the product was so designed and marketed" (alteration, internal quotation marks, and citation omitted)). In determining whether a product design poses an unreasonable risk of injury, the fact-finder conducts a risk-benefit analysis, and considers "the ability to eliminate the risk without seriously impairing the usefulness of the product or making it unduly expensive." UJI 13-1407.

{27} While a "defect" may be considered a separate element of the cause of action in the sense that an unreasonable danger must result "from a condition of the product or from a manner of its use," the concept is broad. *See Brooks*, 1995-NMSC-043, ¶ 31 ("Our 'unreasonable-risk-of-injury' test [has] allowed for proof and argument under any rational theory of defect."); *id.* ¶ 32 (holding that UJI 13-1406 and 13-1407 "adequately define 'defect' " by focusing the fact-finder's attention to evidence of the relative risks and benefits of a product's design); *see also Rudisaile*, 1979-NMSC-015, ¶ 11 (relying

19Throughout Defendants' briefs, it is unclear whether they are challenging the district court's factual findings, or the evidence in support of those findings, or both. We have endeavored to address both contentions where it appears they are raised, but the overlapping nature of the arguments has made our review more difficult.

on other state court holdings that "[i]f a product is unreasonably dangerous, it is necessarily defective[,]" and that separate proof of defectiveness and unreasonable danger is not required (internal quotation marks and citation omitted)). The cases cited by Defendants do not offer any meaningful alternative definition of "defect." For instance, in *Tenney v. Seven-Up Co.*, 1978-NMCA-090, ¶ 7, 92 N.M. 158, 584 P.2d 205, we noted that a defect was an element of proof in a strict liability case, but held that the product in that case was defective only in the sense that it was unfit for its intended purpose, and not unreasonably dangerous. We emphasized that strict liability is only imposed where "the product involves a risk of death or serious personal injury or substantial damage." *Id.* ¶ 6. Similarly, *Trujillo v. Berry*, 1987-NMCA-072, ¶ 12, 106 N.M. 86, 738 P.2d 1331, only states that a defective product is an element of a products liability claim. In *Pacific Indemnity Co. v. Therm-O-Disc, Inc.*, 476 F. Supp. 2d 1216, 1229 (D.N.M. 2006) (applying New Mexico law), the federal district court held that "the mere fact that a failure or accident occurred is insufficient to support a strict products liability claim[,]" and that [t]here must be evidence of a defect[,]" but did not offer any definition of "defect."

{28} Here, it was virtually undisputed that significant corrosion and metal debris generated by the MLTK, as configured with a CoCr head, was a substantial cause of Plaintiff's serious injury (i.e., metallosis) and failed implant. The question for the district court was, then, whether the MLTK so configured posed an unreasonable risk of metallosis, taking into account the relative risks and benefits of its design. *See* UJI 13-1406, -1407. The district court found that the MLTK's dual modularity and flexible neck, its multiple possible configurations, and its CoCr-titanium head-neck junction, offers a number of benefits, but also a risk of corrosion greater than the risk posed by earlier, single-modular designs. The court further found that, although patients respond differently to corrosion, greater corrosion increases the associated risks, such as metallosis. Consistent with the foregoing, the court cited evidence that the MLTK configured with a CoCr head poses a greater risk of metallosis than other devices. Defendants' own consulting expert biomechanical engineer, Dr. Gilbert, testified that it was not an acceptable risk of harm for a device to generate metal debris sufficient to cause metallosis. Dr. Beauchamp, who performed Plaintiff's revision surgery at the Mayo Clinic, agreed that a safely- designed hip prosthetic should not generate metal debris sufficient to cause metallosis. The MLTK, including as configured with a ceramic head, had passed Defendants' internal product testing/design goals for strength, corrosion fatigue and junction stability. The court found that *Defendants' own alternative design*—the MLTK with a ceramic head—was being used by Defendants' own consulting surgeon and others to avoid the risk of metallosis posed by the CoCr head. The above findings were sufficient to support the district court's conclusion that the MLTK with a CoCr head, as configured in Plaintiff, presented an unreasonable risk of metallosis, rendering it defective.

{29} Defendants argue that, even if the district court made a broad connection between the MLTK and an unreasonable risk of injury, it did not adequately connect any particular feature of the MLTK with the mechanism of injury or the degree of risk, and therefore erred in finding a design defect. Defendants cite, inter alia, *Bustos*, 2010-

NMCA-090, ¶ 23, for the proposition that a design defect, and the risk posed thereby, must be precisely described and quantified. In that case, the "steep rake of [the] support pillar for the car roof" was identified by expert testimony as the defect that created the unreasonable risk of injury. That expert based his opinion on the damage to and measurements of the vehicle at issue, and a calculation that filling the support pillar with foam would add 10-20 percent structural strength. *Id.* Here, by contrast, no expert quantified the amount of corrosion necessary to cause metallosis, and thus no expert could quantify the "excessive" corrosion allegedly caused by the MLTK in Plaintiff, nor did any expert describe whether all, or only some of configurations of the MLTK with a CoCr head were defective.

{30} To the extent Defendants argue that the district court misapplied the law by failing to require adequate quantification of the risks posed by the MLTK, the defendants in *Bustos*, an enhanced injury case,[20] also argued that the plaintiffs were required to show the unreasonableness of the risk through precise data: namely that, but for the defective design, the roof would have crushed only to a certain number of inches. *Id.* ¶ 30. We disagreed, as testimony in the record reflected various ways that the strength of the roof could have been improved without undue cost (including but not limited to altering the rake of the support pillar), and the expert opined that, as a result of the failure to undertake any of these improvements, the roof did not provide adequate survival space in a slow rollover accident. *Id.* ¶¶ 30-32. Thus, there was evidence from which a jury could reasonably infer that the roof could and should have been designed not to crush to a level "way below what would be considered necessary to provide rollover protection[.]" *Id.* ¶ 32. Similarly, here, the findings supported the district court's reasonable inference that the MLTK could and should have been designed to minimize corrosion and metal debris to levels that do not cause metallosis.

{31} We further note the following: Defendants elected to market the MLTK without a precise understanding of what degree of corrosion or volume of metal debris presents a risk of metallosis. The district court concluded that Defendants' testing was inadequate to measure the quantity of corrosion and debris liberated by the MLTK with a CoCr head. Defendants identify no law that would require Plaintiff to conduct the research and clinical trials omitted by Defendants in order to establish a precise quantification of the risks posed by the MLTK. Indeed, we read the district court's findings regarding the inadequacies of Defendants' testing of the MLTK as an explanation for the presence of an unreasonable risk that could have been better understood and earlier identified, but was not.

{32} To the extent Defendants argue that there was insufficient evidence to support the district court's findings,[21] Defendants' brief overlooks significant portions of the

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20*Bustos* requires a plaintiff in an enhanced injury case to present evidence as to the *degree of enhancement*, and in that sense requires some quantification of the properties affecting risk. 2010-NMCA-090, ¶¶ 35-46. We agree with Plaintiff that this does not equate to a requirement that risks be precisely quantified in every design defect case.

21In their reply brief, Defendants state that they do not focus "primarily" on the sufficiency of the evidence, which is of little assistance.

evidentiary record—including key testimony from Dr. Gilbert (Defendants' own consulting expert), Dr. Jacobs, Mr. Meulink, Dr. Beauchamp, Dr. Kantor and exhibits such as research articles and Zimmer's own internal data. Defendants focus almost exclusively on Dr. Burstein's testimony, and the language of the findings themselves, rather than on the sufficiency of the entire record under the applicable legal standards. Under our appellate rules, "[a] contention that a verdict, judgment, or finding of fact is not supported by substantial evidence shall be deemed waived unless the summary of proceedings includes the substance of the evidence bearing on the proposition[.]" Rule 12-318(A)(3) NMRA. This rule is intended to ensure that we are fully apprised of the fact-finder's view of the facts and its disposition of the issues, particularly given that we "resolve all disputed facts in favor of the successful party, indulge all reasonable inferences in support of a verdict, and disregard all evidence and inferences to the contrary." *Harmon*, 1984-NMSC-119, ¶ 7; *see Martinez v. Sw. Landfills, Inc.*, 1993-NMCA-020, ¶ 15, 115 N.M. 181, 848 P.2d 1108 (stating that the purpose of Rule 12-318 is to ensure that the appellate court is fully apprised of the "fact finder's view of the facts and it's disposition of the issues"). The district court's findings are binding on Defendants, who failed to set forth the substance of the evidence (favorable or unfavorable) bearing on those findings. *See Maloof v. San Juan Cty. Valuation Protests Bd.*, 1992-NMCA-127, ¶ 19, 114 N.M. 755, 845 P.2d 849; *see also Chavez v. S.E.D. Labs.*, 2000-NMCA-034, ¶ 26, 128 N.M. 768, 999 P.2d 412 (*Chavez I*), *aff'd in part, rev'd in part on other grounds by Chavez II*, 2000-NMSC-034, ¶ 24.

{33} Defendants' next argument on appeal is that, in reaching its determination that the MLTK as configured in Plaintiff posed an unreasonable risk of injury, the district court failed to consider the seven factors set forth in *Brooks*, 1995-NMSC-043, ¶ 32 n.2, and the committee commentary to UJI 13-1407. But we find no support for the contention that all seven factors must be considered for every design defect claim. Rather, UJI 13-1407 states in the committee commentary that "[c]riteria for determining whether a risk of injury is unreasonable have not been provided in the instruction because the committee feels this falls within the unique domain of advocacy under the circumstances of proof in each case." The commentary then lists the seven risk-benefit criteria *suggested* by Professor John W. Wade in his article "*The Nature of Strict Tort Liability for Products*," 44 Miss. L. J. 825, 837-38 (1973):

> (1) the usefulness and desirability of the product . . . ; (2) the availability of other and safer products to meet the same need . . . ; (3) the likelihood of injury and its probable seriousness, i.e., "risk" . . . ; (4) the obviousness of the danger . . . ; (5) common knowledge and normal public expectation of the danger (particularly for established products) . . .; (6) the avoidability of injury by care in use of the product (including the effect of instructions or warnings) . . . [;] and (7) the ability to eliminate the danger without seriously impairing the usefulness of the product or making it unduly expensive.

We considered these factors in *Bustos*, where the defendants argued (citing *Brooks*) that the jury was improperly instructed on the plaintiffs' design defect claim because the

jury should have been required to consider whether there was a showing of a reasonable alternative design. *Bustos*, 2010-NMCA-090, ¶¶ 50-51. This Court held that, "[w]hile a jury is required to make risk-benefit calculations, consideration of alternative designs is but one of several risk-benefit considerations that a jury *may* balance in determining whether a product created an unreasonable risk of injury." *Id.* ¶ 54 (emphasis added). We then referred to the seven risk-benefit considerations set forth in UJI 13-1407's committee commentary. *See Bustos*, 2010-NMCA-090, ¶ 54. This Court reasoned that only the seventh factor (the ability to eliminate the danger without seriously impairing the usefulness of the product or making it unduly expensive) contains language included in the actual jury instruction as something the jury "should" consider. *Id.* Defendants conceded this point at oral argument.

{34} Here, the district court's conclusions of law included consideration of the manufacturer's ability to eliminate the danger without seriously impairing the usefulness of the product or making it unduly expensive. It is unclear from Defendants' brief whether they challenge the sufficiency of the findings on this point, or the sufficiency of the evidence to support those findings. Again, Defendants' argument flatly ignores the district court's findings concerning the use of a ceramic head, Defendants' own alternative component part, in order to avoid the risk of metallosis. In other words, Defendants already market a design that avoids the risk of metallosis without impairing the product's functionality. Such findings suffice to demonstrate that the district court considered the ability to eliminate the danger without impairing the usefulness of the product or rendering it unduly expensive. *See Chavez II*, 2000-NMSC-034, ¶ 19. To the extent Defendants raise an argument regarding the sufficiency of the evidence to support these findings, Defendants' brief again disregards the majority of the evidentiary record. There was evidence that use of a ceramic head on the MLTK virtually eliminates the risk of metallosis; evidence that the MLTK with a ceramic head met Defendants' internal strength and stability requirements; and evidence that sales of the ceramic head, versus the CoCr head, have gone from ten percent to 50 percent of the market share since 2010. Defendants presented no evidence that any risk of injury from the use of their alternative design outweigh the benefits of avoiding metallosis. In any event, we again hold that the district court's findings are binding on Defendants, who failed to set forth the substance of the evidence bearing on those findings. *See* Rule 12-318(A)(3); *Chavez I*, 2000-NMCA-034, ¶ 26; *Maloof*, 1992-NMCA-127, ¶ 19.

B. Defendants' Argument Under Comment K Was Not Preserved

{35} Defendants' second argument on appeal is that the district court should have found the doctrine of strict liability to be inapplicable to Plaintiff's claims, under comment k to the Restatement (Second) of Torts, Section 402A. Section 402A provides that a supplier should not be held strictly liable for the provision of an unavoidably unsafe product, provided the product was properly prepared and marketed, and adequate warnings were given.

{36} Specifically, Section 402A comment (1) provides that a seller in the business of supplying a product "who sells any product in a defective condition unreasonably

dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer[.]" However, comment k to this Section provides, in part, as follows:

> *Unavoidably unsafe products*. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many . . . drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. . . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

{37} New Mexico has incorporated the strict liability standards set forth in the Restatement (Second) of Torts, Section 402A, with some exceptions and modifications. *See, e.g.*, UJI 13-1406, use note (providing that the instruction is to be used together with UJI 13-1407 "in every strict products liability case based upon Restatement (Second) of Torts § 402A"); UJI 13-1406, comm. cmt. (noting that the language in Section 402A "has less than the universal application which these instructions are intended to have for strict products liability relating to production flaw defects, unsafe design or formulation, warning inadequacies, safety options and products which are unavoidably unsafe, with a risk of harm not justified by usefulness or desirability of the product"). New Mexico's "unavoidably unsafe products" exception is set forth in UJI 13-1419 NMRA, which provides, in part, as follows:

> There are some products which, even when properly prepared and labeled, cannot be made safe for their intended and ordinary use. Because of the nature of ingredients or natural characteristics of the products, use of these products involves substantial risk of injury, and some users will necessarily be harmed. Such products are said to be unavoidably unsafe.
>
> Unless the product unreasonably exposes users to risk of injury, there is no liability for supplying an unavoidably unsafe product. Whether users are unreasonably exposed to risk of injury turns upon a balancing of the dangers and benefits resulting from the product's use.

The use note of this UJI provide that it "must be given only in cases in which the generic condition of the product gives rise to the risk of injury, for example, certain chemicals and drugs. The risk arises from the nature of the product and not from inadequacies of design, manufacture, or labeling." UJI 13-1419, use note. The Committee Commentary,

in turn, provides that "[w]hether a risk is reasonable is a question for the jury, balancing the benefits and hazards of the product." UJI 13-1419, comm. cmt.

{38} We must first address whether Defendants preserved for our review their argument that the MLTK is an unavoidably unsafe product under comment k of Section 402A and UJI 13-1419. We hold that they did not.

{39} In general, an issue is not preserved unless the appellant "fairly invoked a ruling of the trial court on the same grounds argued in the appellate court." *Benz v. Town Ctr. Land, LLC*, 2013-NMCA-111, ¶ 24, 314 P.3d 688 (internal quotation marks and citation omitted). Defendants concede that they did not seek a finding that the MLTK was "unavoidably unsafe," nor did they otherwise refer to comment k or UJI 13-1419 in motion practice, at trial, in written closings, or in their requested findings of fact and conclusions of law. At oral argument, defense counsel identified only Defendants' affirmative defenses, set forth in the answer to the complaint, as explicitly raising comment k of Section 402A or UJI 13-1419. "We require parties to assert the legal principle upon which their claims are based and to develop the facts in the trial court primarily for two reasons: (1) to alert the trial court to a claim of error so that it has an opportunity to correct any mistake, and (2) to give the opposing party a fair opportunity to respond and show why the court should rule against the objector." *State v. Gomez*, 1997-NMSC-006, ¶ 29, 122 N.M. 777, 932 P.2d 1. Thus, an affirmative defense is not preserved for our review unless it is litigated before the district court and a ruling is invoked on the issue. *See, e.g.*, *Rodriguez ex rel. Rodarte v. Sanchez*, 2019-NMCA-065, ¶¶ 25-26, 451 P.3d 105 (holding that the defendant's statute of limitations argument, while raised as an affirmative defense in the answer, was not litigated before the district court; therefore, it was not preserved for appellate review).

{40} Defendants argue, in reply, that their proposed findings and conclusions are predicates for the application of comment k; therefore, Defendants constructively sought the trial court's ruling on the issue, preserving their argument. Specifically, Defendants sought a conclusion of law that the MLTK did not present an unreasonable risk of harm, and a conclusion that the MLTK was not defectively designed. Moreover, Defendants proposed, and the district court adopted the following findings: zero risk of corrosion is unattainable; some corrosion may occur in any modular implant device; there is no consensus as to why patients react differently to corrosion; and Defendants' warnings for the MLTK were adequate. We hold that, while these points would be relevant to a Section 402A comment k/UJI 13-1419 analysis, they do not amount to a comment k analysis.

{41} UJI 13-1419 (New Mexico's iteration of comment k) is only applicable where a product "cannot be made safe" for its intended use, and where the nature of a product, or its "generic condition . . . gives rise to the risk of injury." UJI 13-1419, use note. It is inapplicable where the risk arises "from inadequacies of design[.]" *Id.* Furthermore, New Mexico's UJI expressly adopts a case-by-case inquiry, as it contains a caveat that there may be strict liability even for an unavoidably unsafe product, where the product "unreasonably exposes users to risk of injury[.]" UJI 13-1419. In other words, even an

unavoidably unsafe product may present dangers so unreasonable that the imposition of strict liability is appropriate. This risk-benefit determination is a question of fact for the jury (or in this case, the district court). *Id.*, comm. cmt. Other jurisdictions have adopted comment k in a similar manner; Oklahoma holds (in a case cited by Defendants) that the unavoidably unsafe exception does not apply unless the product was incapable of being made safer at the time of its distribution, and its benefits justify its risks. *Tansy v. Dacomed Corp.*, 890 P.2d 881, 885-86 (Okla. 1994). On appeal, Defendants cite cases holding that an FDA-approved medical device is covered by comment k and exempt from strict liability. *See, e.g.*, *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 481-82 (W.D. Pa. 2012). However, at least one jurisdiction has addressed the distinction between drugs/devices approved through the premarket process, and those approved through the 510k process, holding that the latter are subject to a more rigorous case-by-case analysis. *See, e.g.*, *Burningham v. Wright Med. Tech., Inc.*, 2019 UT 56, ¶ 39, 448 P.3d 1283 (holding that "when an implanted medical device enters the market through the 510(k) process . . . the manufacturer must prove by a preponderance of the evidence that (1) when the product was made, it could not be made safe for its intended use even applying the best available testing and research, and (2) the benefits of the product justified its risk").

{42} As the evidence in this case makes clear, a finding that all modular hip implants present some risk of corrosion is not a finding that all modular hip implants present an unavoidable risk of metallosis. Indeed, notably, Defendants did not pose this equivalency to the district court. Defendants proposed no finding that the risk of metallosis arose from the nature of the MLTK, and not from an inadequacy in design. Defendants proposed no finding that the MLTK was incapable of being made safe for its intended use. Defendants ignore the district court's finding that "[t]he FDA 510(k) process cannot be used as evidence that the MLTK was safe for use[,]" but their arguments here suggest that they are entitled to the "blanket" exemption afforded by some jurisdictions to all prescription drugs and medical devices. In sum, the cited findings and conclusions would not have alerted the district court, or Plaintiff, that Defendants were seeking a finding that the MLTK was unavoidably unsafe under comment k and UJI 13-1419, and accordingly, Defendants have failed to establish that we can review their comment k argument on appeal.[22]

CONCLUSION

{43} For the foregoing reasons, we conclude that the district court properly applied the law of strict liability for design defect. Moreover, the district court's findings supported its conclusion that the MLTK as configured in Plaintiff was defective. Those findings are

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22At oral argument, Defendants referred to our holding in *Davila v. Bodelson*, 1985-NMCA-072, ¶¶ 25-28, 103 N.M. 243, 704 P.2d 1119, for the proposition that an argument is preserved if there was evidence in the record supporting a theory, and the theory was tried on implied consent of the parties. But in *Davila*, the district court gave an instruction under UJI 13-1419 at trial; the question on appeal was whether the instruction had been given in error. *Davila*, 1985-NMCA-072, ¶ 25. The issue was not, as here, whether the district court's ruling had been fairly invoked, such that the court and the plaintiff were able to address the theory presented. *See Gomez*, 1997-NMSC-006, ¶ 29. Accordingly, *Davila* is inapposite.

binding, given that Defendants failed to set forth the substance of the evidence bearing on them. Defendants also failed to preserve their argument under comment k to the Restatement (Second) of Torts Section 402A, and we do not address it here. Accordingly, we affirm.

{44} IT IS SO ORDERED.

LINDA M. VANZI, Judge

WE CONCUR:

J. MILES HANISEE, Chief Judge

JACQUELINE R. MEDINA, Judge