

UNITED STATES COURT OF APPEALS
TENTH CIRCUIT

DEC 3 2003

PATRICK FISHER
Clerk

CARLA GRAY,

Plaintiff-Appellant,

v.

HOFFMAN-LA ROCHE, INC.;
ROCHE LABORATORIES, INC.;
ROCHE PHARMACEUTICALS,

Defendants-Appellees.

No. 02-7079
(E.D. Okla.)
(D.Ct. No. 01-CV-493-S)

ORDER AND JUDGMENT*

Bill V. Wilkinson of Wilkinson Law Firm, Tulsa, Oklahoma, for Plaintiff-Appellant.

Michael X. Imbroscio (Mark H. Lynch and Lanny A. Breuer of Covington & Burling, Washington, D.C.; Harry A. Woods, Jr., of Crowe & Dunlevy, P.C., Oklahoma City, Oklahoma; Mary Morrissey Sullivan of Sullivan, Sullivan & Nahigian, L.L.P., Boston, Massachusetts, with him on the brief) of Covington & Burling, Washington, D.C., for Defendants-Appellees.

Before **BRISCOE** and **McWILLIAMS**, Circuit Judges, and **BRORBY**, Senior Circuit Judge.

* This order and judgment is not binding precedent except under the doctrines of law of the case, *res judicata* and collateral estoppel.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.

Appellant Carla Gray claims the prescription drug Accutane caused her to experience severe depression. She sued Hoffman-La Roche, Inc., the drug's manufacturer, and Roche Laboratories, Inc., the drug's distributor (collectively "Roche"),¹ in federal court. The suit resulted in a jury verdict in favor of Roche. This appeal followed. Exercising jurisdiction under 28 U.S.C. § 1291, we affirm.

Roche manufactures and distributes Accutane, a prescription drug commonly used to treat acne. Ms. Gray took Accutane to treat acne for a number of years and claims to have suffered from severe depression during that time. Believing Accutane caused her depression, Ms. Gray filed a complaint against Roche based on diversity jurisdiction in the United States District Court for the Eastern District of Oklahoma. She alleged Roche was liable because it failed to adequately warn either her or her doctor about Accutane's possible psychiatric side effects. Ms. Gray proceeded under three Oklahoma state law causes of action: (1) manufacturer's products liability; (2) negligence; and (3) breach of express and implied warranties. A jury returned a verdict in favor of Roche.

¹ Ms. Gray also named Roche Pharmaceuticals as a defendant in her complaint. However, according to Roche's answer, "no corporate entity named Roche Pharmaceuticals exists."

On appeal, Ms. Gray raises five arguments. She believes the trial court: (1) erred in a number of evidentiary rulings during her examination of Dr. McCauley, her treating physician; (2) erred in a number of evidentiary rulings during her cross-examination of one of Roche's expert witnesses, Dr. Gudas; (3) erred in excluding evidence of Ms. Gray's daughter's experience with Accutane and depression; (4) erred in excluding evidence relating to Roche's alleged profit motive for not issuing a stronger Accutane warning; and (5) erred in rejecting a jury instruction she proposed.

We review a trial court's evidentiary rulings and jury instructions for an abuse of discretion. *Hinds v. Gen. Motors Corp.*, 988 F.2d 1039, 1046-47 (10th Cir. 1993). We will only find an abuse of discretion if the trial court's decision "was based on a clearly erroneous finding of fact or an erroneous conclusion of law or manifests a clear error of judgment." *Cartier v. Jackson*, 59 F.3d 1046, 1048 (10th Cir. 1995). Even if we find an abuse of discretion, we will disturb the jury's verdict only if the error affected "a substantial right of the party." Fed. R. Evid. 103(a). *See also* Fed. R. Civ. P. 61. Under these standards, we consider Ms. Gray's arguments in turn.

I. EXAMINATION OF DR. MCCAULEY

Ms. Gray claims the trial court committed a number of evidentiary errors during her examination of her treating physician, Dr. McCauley. Ms. Gray hoped to prove Roche should have warned Dr. McCauley of Accutane's alleged psychological side effects "[a]nd, in turn, these warnings should have been given by Dr. McCauley to [Ms. Gray]." To establish Roche proximately caused her alleged injuries, Ms. Gray needed to demonstrate that "had [Roche] issued a proper warning to [Dr. McCauley], he would have altered his behavior and the injury would have been avoided." *Eck v. Parke, Davis & Co.*, 256 F.3d 1013, 1018 (10th Cir. 2001). Ms. Gray believes the trial court prevented her from making this showing by: (a) sustaining objections during her examination of Dr. McCauley, and (b) granting (in part) Roche's motion in limine to exclude "evidence regarding changes made to Accutane product warnings and communications after the conclusion of Ms. Gray's treatment with Accutane."

a. Sustained Objections

First, Ms. Gray claims the trial court erred in sustaining Roche's "asked and answered" objections. Ms. Gray described two specific warnings she believes Roche should have issued, and asked Dr. McCauley whether he would have followed them. Dr. McCauley responded, "it depends." He went on to explain:

“[W]e don’t rotely just follow instructions from drug companies. There are a lot of other things that go into evaluation of drugs with known and unknown side effects. So we would have taken this into account, but we also temper it with the experience that the patient is relating to us; also in regards to what other, what our own experience is with other patients....

And also in regard to other literature that we may be reading, and the experiences that we have, our shared experiences that we had with colleagues. So we don’t just rote do what the drug companies tell us. We do it, we take this certainly into consideration, and we put it into the rest of the equation in regards to the information that we visit with our patients about and also counsel them in regards to the medications.

Apparently dissatisfied with his response, Ms. Gray immediately repeated her question. Roche objected on grounds the question had been asked and answered, and the trial court sustained. Throughout the remainder of her examination of Dr. McCauley, Ms. Gray repeatedly asked slight variations of this same question. The trial court sustained a number of Roche’s objections on grounds the question had been asked and answered.²

Trial courts may prohibit litigants from asking witnesses repetitive

² In the instances the trial court allowed Dr. McCauley to respond to Ms. Gray’s question, he indicated he “may or may not have done anything differently,” he was “not sure that at this particular point it would have made any difference in the way that [he] would have advised [Ms. Gray],” and he “may or may not have acted upon this any differently.”

questions. Fed. R. Evid. 611(a) (instructing courts to “exercise reasonable control ... so as to ... avoid needless consumption of time”); Fed. R. Evid. 403 (recognizing courts’ discretion to exclude evidence “if its probative value is substantially outweighed ... by considerations of undue delay, waste of time, or needless presentation of cumulative evidence”). *See, e.g., Bragg v. Foretravel, Inc.*, 652 F.2d 39, 40 (10th Cir. 1981) (holding a “trial court properly exercised its discretion in order to prevent repetitive questioning and needless consumption of judicial time”). Here, Dr. McCauley obviously did not provide the answer Ms. Gray hoped to elicit. However, he did reply to the question with an appropriate answer. The trial court did not abuse its discretion by prohibiting the repetitive questions.

Ms. Gray next complains the trial judge should have permitted her to ask Dr. McCauley, in regard to part of a warning she asserts Roche should have issued, “what those two sentences mean to him.” The sentences state: “Follow-up visits during Accutane treatment should include specific questioning regarding psychiatric signs and symptoms. Patients should be specifically warned to immediately discontinue Accutane use and seek medical evaluation if depression

or mood change occurs.”³ The district court excluded the question on the ground it called for Dr. McCauley to interpret the sentences.

We have held, “where ... expert testimony is offered on an issue that a jury is capable of assessing for itself, it is plainly within the trial court’s discretion to rule that testimony inadmissible.” *Thompson v. State Farm Fire & Cas. Co.*, 34 F.3d 932, 941 (10th Cir. 1994). Although Dr. McCauley testified as a lay witness, the same reasoning applies here. Lay opinions, like expert opinions, are only admissible if they are helpful to the jury. Fed. R. Evid. 701, 702. The sentences Ms. Gray asked Dr. McCauley to interpret were not technical or confusing; the jury was capable of understanding them without Dr. McCauley’s assistance. The trial court did not abuse its discretion in sustaining Roche’s objection.

³ Ms. Gray also asked Dr. McCauley whether he disagreed with these two sentences. Dr. McCauley responded he would like to see the rest of the document to view the sentences in their context. Ms. Gray immediately repeated the question, and the trial court sustained Roche’s objection on the ground it had been asked and answered. Ms. Gray believes the court erred in sustaining the objection because Dr. McCauley did not answer her question. Again, we see no abuse of discretion. Although Dr. McCauley may not have provided the answer Ms. Gray hoped for, his response was within the realm of appropriate answers. Thus, the trial court did not abuse its discretion in sustaining Roche’s objection.

Ms. Gray next argues the trial court improperly interrupted her when she asked Dr. McCauley if he would have altered her treatment had he “received a warning from Roche that he considered to constitute a significant change in the warnings involving side effects for Accutane.” Troubled by the word “significant,” the trial court ruled it would only allow Dr. McCauley to answer if Ms. Gray clarified “what changes.” Ms. Gray argues “[i]t is up to the witness to inform the Court if he cannot answer the question.” We disagree.

Trial courts bear the responsibility of “mak[ing] the interrogation ... effective for the ascertainment of the truth.” Fed. R. Evid. 611(a)(1). Here, the court found Ms. Gray’s question vague, thus not helpful to the jury. We see no abuse of discretion in its *sua sponte* interruption. *See, e.g., United States v. Head*, 697 F.2d 1200, 1210 (4th Cir. 1982) (noting trial court’s prerogative to interrupt witness examinations *sua sponte*). Moreover, the court gave Ms. Gray the opportunity to clarify her question.

Finally, Ms. Gray complains the trial court erroneously limited her redirect examination of Dr. McCauley, finding her questions unrelated to Roche’s cross-examination. She points out Roche had asked whether Dr. McCauley’s other patients taking Accutane reported depression. Accordingly, Ms. Gray argues the

court should not have prevented her from asking if “whether [his] patients report psychiatric side effects ... [has] anything to do ... with whether the patient understands that Accutane might cause the psychiatric side effects,” because this question was related to Roche’s questioning on reported depression of other patients.

“The scope of redirect examination is committed to the sound discretion of the trial court” and is normally limited to the scope of cross-examination. *United States v. Hodges*, 480 F.2d 229, 233 (10th Cir. 1973). Here, the trial court reasonably determined Ms. Gray’s question went beyond the scope of cross-examination. Roche’s inquiry was limited to whether any of Dr. McCauley’s other Accutane patients reported depression. Ms. Gray’s question, on the other hand, delves into what factors might motivate his patients to report side effects. The trial court acted within its discretion by curtailing this line of questioning.

b. Subsequent Remedial Measures

Ms. Gray also asserts the trial court erred by excluding evidence Roche changed Accutane’s warnings after she stopped taking the drug. Ms. Gray sought to introduce Roche’s revised “informed consent/patient agreement” form through Dr. McCauley. This form, modified after Ms. Gray discontinued treatment,

addresses possible psychological side effects associated with Accutane, and requires patients to initial the form acknowledging their understanding of the possible side effects. The trial court granted (in part) Roche's motion in limine to exclude the form as evidence of a subsequent remedial measure.

In diversity actions involving a products liability claim, the admissibility of subsequent remedial measures is a matter of state law. *Wheeler v. John Deere Co.*, 862 F.2d 1404, 1410 (10th Cir. 1988). Under Oklahoma law, "evidence of subsequent measures" taken after an "event" is inadmissible "to prove negligence or culpable conduct." Okla. Stat. Ann. tit. 12, § 2407 (1993). However, we found no Oklahoma law indicating whether this exclusion applies to products liability suits. We must therefore turn to Rule 407 of the Federal Rules of Evidence. *Herndon v. Seven Bar Flying Serv., Inc.*, 716 F.2d 1322, 1326 (10th Cir. 1983) (holding where no state rule of evidence is available, the federal rule should be applied).

Federal Rule of Evidence 407's subsequent remedial measures exclusion applies to products liability cases. *See* Fed. R. Evid. 407 advisory committee's note. In relevant part, it excludes evidence of measures taken after "an injury or harm" occurred "that, if taken previously, would have made the injury or harm

less likely to occur ... to prove ... a need for a warning and instruction.” Fed. R. Evid. 407. However, such evidence may be admitted for other purposes, notably for impeachment and for proving the “feasibility of precautionary measures, if controverted.” *Id.* Roche’s revised patient informed consent form fits squarely within the category of evidence Rule 407 bars. Therefore, the trial court properly excluded the form as evidence Roche should have issued a stronger warning.

Because Rule 407 does not exclude subsequent remedial measures taken by non-parties, *Mehojah v. Drummond*, 56 F.3d 1213, 1215 (10th Cir. 1995), Ms. Gray asserts the trial court should have admitted the evidence because she offered it to show Dr. McCauley, a non-party, took the remedial measure of using Roche’s revised form. We disagree.

Evidence admissible under Rule 407 still faces Rule 403 scrutiny. Courts must exclude evidence if “the dangers of prejudice or confusion substantially outweigh the probative value of the evidence.” Fed. R. Evid. 407 advisory committee’s note (1997 Amendments). Here, the form’s danger of prejudice to Roche ran high. Because the form not only established Dr. McCauley’s subsequent remedial measure, but Roche’s, as well, the jury might have used the form against Roche for the very purpose Rule 407 prohibits – as evidence there

was “a need for a warning.” Additionally, the form’s probative value was minimal. As to Dr. McCauley’s remedial action, the form merely bolstered his testimony that he now specifically questions his Accutane patients about psychiatric side effects. The form’s potential for prejudice thus substantially outweighed its probative value. The trial court acted within its discretion by ordering it excluded.⁴

1. Impeachment Exception

Ms. Gray next argues the trial court should have allowed her to introduce the form to impeach Dr. McCauley’s testimony. As discussed above, Dr. McCauley testified he “may or may not have” followed instructions had Roche issued them during Ms. Gray’s treatment. Ms. Gray contends she could have impeached this testimony with the form because she claims Dr. McCauley’s deposition testimony indicates, “*as soon as* he received the revised informed patient consent form from [Roche], he *immediately* began using it.” (Emphasis

⁴ Ms. Gray also believes the court should have allowed her to introduce Roche’s revised consent form because Roche failed to cite Oklahoma law mandating its exclusion. She claims *Meller v. Heil Co.*, 745 F.2d 1297 (10th Cir. 1984) places the burden of demonstrating the evidence’s inadmissibility under state law upon the party seeking its exclusion. However, the principle in *Meller* Ms. Gray refers to is our interpretation of a Colorado statute excluding post-injury scientific advancements. *Id.* at 1302. The statute in *Meller* does not apply to this case.

added.) According to Ms. Gray, the deposition testimony shows Dr. McCauley “responds directly and immediately to such warnings and instructions from the drug manufacturer.” She believes she could have proved Dr. McCauley would have altered her treatment had the trial court permitted her to introduce the form.

Both Oklahoma law and Rule 407 permit litigants to introduce subsequent remedial measures evidence for impeachment purposes. Fed. R. Evid. 407; Okla. Stat. Ann. tit 12, § 2407 (1993). Here, the informed consent form itself did not contradict Dr. McCauley’s testimony that he does not “rotely” follow instructions from drug companies, or that he would have altered Ms. Gray’s treatment had Roche issued warnings while she was taking Accutane. Furthermore, we are unconvinced the form would have allowed Ms. Gray to elicit further testimony to impeach Dr. McCauley.

First, and contrary to Ms. Gray’s assertions, we found no indication in Dr. McCauley’s deposition testimony that he began using the consent form immediately after receiving it. On the contrary, Dr. McCauley testified he could not remember when he received the informed consent form or when he began using it. Second, the informed consent form differs in both form and content from the warning Ms. Gray claims Roche should have issued years earlier. The

fact he currently uses the form does not prove he would have followed a different warning several years earlier. Indeed, Dr. McCauley's deposition testimony indicates he attained new information about Accutane's possible side effect around the time Ms. Gray stopped taking Accutane and before he adopted the form. In light of these facts, we doubt Ms. Gray could have used the form to demonstrate that, contrary to his testimony, Dr. McCauley would have proceeded differently had Roche issued the two warning sentences. The trial court properly excluded the form for impeachment purposes.

2. Feasibility Exception

Next, Ms. Gray argues the trial court should have admitted the form under the feasibility exception to the rules barring subsequent remedial measures. She believes feasibility was controverted at trial. Ms. Gray first explains she controverted feasibility when she attempted to show Roche's former method of informing doctors about Accutane's possible side effects was infeasible, whereas the revised patient informed consent form would have been feasible. Ms. Gray also claims Roche controverted feasibility when its representative testified the company "didn't think to put" warnings on patient brochures and blister packs, and testified it would not have been easy for Roche to revise the informed consent form.

Neither the Oklahoma statute nor Rule 407 bars subsequent remedial measures to prove the “feasibility of precautionary measures, *if controverted*.” Fed. R. Evid. 407; Okla. Stat. tit. 12, § 2407 (emphasis added). The “if controverted” requirement “allows the opposing party to lay the groundwork for exclusion by making an admission.” Fed. R. Evid. 407 advisory committee’s note. Here, in a pretrial brief, Roche stated it did not contest feasibility. Although the trial court indicated its order excluding the form was “subject to reconsideration at trial,” during the trial Ms. Gray never argued Roche’s representative’s testimony controverted feasibility. Because she raises this argument for the first time on appeal, we decline to review it. *See Tele-Communications, Inc. v. Commissioner*, 12 F.3d 1005, 1007 (10th Cir. 1993). In addition to waiving appellate review, Ms. Gray’s omission also deprived Roche of the opportunity to make an admission regarding feasibility.

Ms. Gray further suggests her efforts to controvert feasibility satisfy the “if controverted” requirement irrespective of Roche’s response. We believe the advisory committee’s note to Rule 407 forecloses this argument by reiterating the parties must present a “genuine issue,” and by recognizing the opposing party’s opportunity to “lay the groundwork for exclusion by making an admission.” Fed. R. Evid. 407 advisory committee’s note. We affirm the trial court’s exclusion of

the form to prove feasibility.

3. “Other purposes” exception

Finally, Ms. Gray argues the form was admissible to demonstrate she was not guilty of contributory negligence. We have upheld the admission of subsequent remedial measures to demonstrate a plaintiff was not contributorily negligent. *See, e.g., Rimkus v. Northwest Colo. Ski Corp.*, 706 F.2d 1060, 1065-66 (10th Cir. 1983). However, because Roche did not raise contributory negligence as a defense at trial, the trial court properly excluded the evidence.

In sum, the trial court did not abuse its discretion in excluding evidence pertaining to Roche’s subsequent remedial measure under Oklahoma law and Rule 407.

II. CROSS-EXAMINATION OF DR. GUDAS

Roche called as an expert witness Dr. Lorraine Gudas, chairman of the Pharmacology Department at Cornell Medical College. Based on her research and background, Dr. Gudas opined there is no evidence Accutane causes depression. Ms. Gray believes the trial court committed a number of errors that “substantially interfered” with her cross-examination of Dr. Gudas.

First, Ms. Gray believes the trial court abused its discretion by preventing Dr. Gudas from answering a hypothetical question she posed. Ms. Gray attempted to discount Dr. Gudas's opinion by suggesting the studies she relied upon (which were designed to determine whether Accutane prevents cancer) could not accurately determine whether the drug causes depression. Ms. Gray presented a hypothetical scenario involving a study designed to "determine whether left-handed people are smarter than right-handed people." Attempting to analogize the hypothetical study to Dr. Gudas' cancer study, she asked Dr. Gudas, "that study would not automatically tell you whether left-handed people grow bald quicker than right-handed people; would it?" The trial court sustained Roche's objection on grounds the question was too speculative.

Expert opinions are admissible only if they help the jury understand the evidence or resolve a factual issue. Fed. R. Evid. 702. The opinion must be "based upon sufficient facts or data." *Id.* Ms. Gray's hypothetical scenario lacked sufficient facts and data necessary for Dr. Gudas to form a valid opinion. In fact, in response to a similar question based on this hypothetical study, Dr. Gudas stated the scenario was "too vague" and not "posed in a way that a scientist [could] answer." For these reasons, it also was not helpful to the jury. The trial court acted within its discretion in sustaining Roche's objection.

Second, Ms. Gray believes the trial court committed reversible error in preventing her from asking “whether, as part of the cancer study, the participants were ever specifically interviewed regarding psychiatric side effects.” She claims the judge likewise erred in preventing her from exploring this topic through a hypothetical question. Our review of the record revealed these alleged errors were later cured when Ms. Gray elicited the answer to her questions. Dr. Gudas testified the cancer study participants had, in fact, been interviewed about depression specifically. Accordingly, the alleged errors do not warrant reversal.⁵

Third, Ms. Gray claims the trial court committed reversible error by preventing her from having Dr. Gudas confirm the \$30,000 she had already received from Roche, combined with \$30,000 she could earn during the trial, would total \$60,000. In response to Roche’s objection, the trial court commented: “Well no need to ask the question because we can add.” We agree with the trial court that the jury was capable of confirming counsel’s arithmetic. To the degree the trial court’s comment may have been misplaced, we find such error harmless.

⁵ Ms. Gray also complains during this portion of her examination the trial court made a “caustic remark” – a comment that both the witness and Ms. Gray’s counsel “like to talk” – that devastated her cross-examination of Dr. Gudas. Because Ms. Gray did not make a contemporaneous objection, we review the comment for plain error. *See Glenn v. Cessna Aircraft Co.*, 32 F.3d 1462, 1464 (10th Cir. 1994). Under this standard, we conclude the district court did not err.

Fourth, Ms. Gray claims the trial court abused its discretion by sustaining Roche's objection when she asked whether Dr. Gudas realized "two completely conflicting opinions" had been offered as to the importance of MedWatch reports. This question misstated Dr. Gudas's testimony and was potentially misleading to the jury. Although Dr. Gudas had testified the reports are not "valid scientifically," she had not commented on whether they are "important." The trial court acted within its discretion in sustaining the objection.

Ms. Gray's remaining complaints arise from the trial court's refusal to allow her to ask questions that appear harassing and argumentative in tone. Specifically, Ms. Gray asked Dr. Gudas if she expected the jury to "take this leap" with her, and if Dr. Gudas was curious about whether Accutane "caused pain and death" in the thousands of Accutane users in the MedWatch reports. "The trial court sits in a far better position to resolve disputes over the tone of examination than we do looking at the lifeless pages of a transcript." *United States v. Carter*, 973 F.2d 1509, 1516-17 (10th Cir. 1992). We believe the trial court acted within the bounds of its discretion in prohibiting these questions.

In sum, we see no reversible errors in the trial court's rulings pertaining to Ms. Gray's examination of Dr. Gudas.

III. DAUGHTER'S ACCUTANE USE

Ms. Gray believes the trial court committed reversible error by excluding her daughter's testimony. Ms. Gray's pretrial brief indicates her daughter would have testified she took her mother's Accutane for a few weeks to "clear up" her skin before a formal dance, and experienced feelings of depression during this time which subsided when she quit taking the medication.

As previously discussed, trial courts may exclude otherwise admissible evidence if it finds the "danger of ... confusion of the issues" or considerations of "undue delay, waste of time, [and] needless presentation of cumulative evidence" substantially outweigh its probative value. Fed. R. Evid. 403.

Here, to prove Accutane causes depression, Ms. Gray introduced reports from at least 2,000 patients who experienced psychiatric side effects while taking Accutane. Testimony indicated one third of those patients "got better once the drug was stopped." While Ms. Gray's daughter's experience with Accutane may have buttressed the reports, the proposed testimony offered substantively little to the evidence already before the jury. Moreover, we believe it likely the testimony would have resulted in a "trial within a trial," thereby confusing the issues and needlessly wasting time. Roche undoubtedly would have contested whether Ms.

Gray's daughter actually experienced depression and whether the alleged depression could have been attributed to another source. These questions may have required a substantial digression into her medical and psychiatric history, as well as additional expert witness testimony. Therefore, the trial court did not abuse its discretion in excluding the evidence under Rule 403.

IV. LOST SALES EVIDENCE

Ms. Gray also contends the trial court erred in excluding evidence relating to whether profit concerns motivated Roche's failure to issue a stronger warning about Accutane's possible psychiatric side effects. Specifically, she sought to have her expert witness (a former Roche employee) testify "[Roche's] failure to warn was attributable to [Roche's] concern for loss of sales." Ms. Gray also attempted to introduce documents she claims demonstrated Accutane sales in fact decreased when Roche issued stronger warnings. The trial court excluded the evidence, concluding profit motive was "not an issue," and evidence relating to profit motive would be "more prejudicial than probative."

Trial courts may only admit "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R.

Evid. 401, 402. Roche's alleged motive for failing to issue a stronger warning is immaterial to any element of Ms. Gray's three causes of action,⁶ and is therefore inconsequential to the determination of the case. Our review of the trial indicates Roche's liability turned on whether the jury found: (1) Accutane caused Ms. Gray to suffer from depression; (2) Roche's warning was inadequate; and (3) Dr. McCauley would have altered Ms. Gray's treatment had Roche issued a stronger warning. The trial court acted within its discretion under Rule 402 in determining profit motive evidence bore no relevance to the issues posed to the jury.

Arguing a Roche representative gave "incorrect" testimony, Ms. Gray

⁶ Under Oklahoma law, to recover under a manufacturer's products liability claim, "[a] plaintiff must prove the product was the cause of the injury, that the product was defective when it left the control of the manufacturer, and that the defect made the product unreasonably dangerous to an extent beyond which would be contemplated by the ordinary consumer who purchases it." *Johnson v. Ford Motor Co.*, 45 P.3d 86, 91 n.12 (Okla. 2002). To recover under a negligence claim, "a plaintiff must establish the concurrent existence of: a duty on the part of the defendant to protect the plaintiff from injury; a failure of the defendant to perform that duty; and an injury to the plaintiff resulting from the failure of the defendant." *Johnson v. Hillcrest Health Ctr., Inc.*, 70 P.3d 811, 816 (Okla. 2003). To recover for breach of warranty, a plaintiff must prove "the existence of the warranty[,] ... the warranty was broken[,] and that the breach of the warranty was the proximate cause of the loss sustained." *Am. Fertilizer Specialists, Inc. v. Wood*, 635 P.2d 592, 595 n.10 (Okla. 1981). Further, when a cause of action is based on a failure to warn claim, a plaintiff "must prove that the drug caused the injury and that the manufacturer breached a duty to warn of possible detrimental reactions." *McKee v. Moore*, 648 P.2d 21, 23-24 (Okla. 1982). None of these elements require an inquiry into the defendant's subjective knowledge, intent, or motive.

apparently believes evidence of Accutane sales was also admissible for impeachment purposes. Without record support, Ms. Gray claims the representative testified she was “unaware of any harm [to Roche] which would result from compliance with the [warning the Food and Drug Administration recommended].” Even under Ms. Gray’s description of the testimony, the evidence she sought to offer impeaches the testimony only remotely, if at all. Neither the proposed expert testimony nor Accutane’s sales history reflect on the witness’ knowledge of whether any harm to Roche might have occurred. Due to its minimal probative value, the trial court acted within its discretion in excluding the evidence under Rule 403.

V. JURY INSTRUCTION

Ms. Gray argues the trial court erred by not submitting to the jury one of her requested instructions. The instruction states, in significant part:

If you believe that the [Food and Drug Administration] required Defendants to provide direct warnings to the users of Accutane, then you are instructed that these circumstances constitute an exception to the Learned Intermediary Doctrine. If the Defendants failed to warn the consumer, you may consider this evidence that the drug is unreasonably dangerous.

As a preliminary matter, Ms. Gray did not provide record proof that she preserved this issue for appellate review by objecting at trial, as required by

Federal Rule of Civil Procedure 51. *See also* 10th Cir. R. 28.2(C)(3)(b) (requiring appellants to “cite the precise reference in the record where a required objection was made and ruled on, if the appeal is based on ... [the] refusal to give a particular jury instruction.”). We therefore review her claim for plain error. *Telecor Communications, Inc. v. Southwestern Bell*, 305 F.3d 1124, 1142 (10th Cir. 2002), *cert. denied*, 123 S. Ct. 2073 (2003). Under the plain error standard, we will reverse “only in exceptional circumstances where the error was patently plainly erroneous and prejudicial.” *Reed v. Landstar Ligon, Inc.*, 314 F.3d 447, 453 (10th Cir. 2002) (quotation marks and citations omitted).

Litigants are entitled to jury instructions “only if they are supported by ... the evidence presented at trial.” *FDIC v. Clark*, 978 F.2d 1541, 1550 (10th Cir. 1992). Here, Ms. Gray’s requested instruction applies only “when the [Food and Drug Administration] requires warnings be given directly to the patient.” *Edwards v. Basel Pharm.*, 933 P.2d 298, 303 (Okla. 1997) (emphasis added). Ms. Gray made no attempt to demonstrate the Food and Drug Administration *required* such a warning. We will not “sift through” the record to find support for her argument. *See SEC v. Thomas*, 965 F.2d 825, 827 (10th Cir. 1992). Accordingly, the alleged error is not “patently plainly erroneous and prejudicial.” *Reed*, 314 F.3d at 453 (quotation marks and citations omitted). Ms. Gray has not established

the trial court committed plain error by refusing to submit her instruction to the jury.

Conclusion

For the foregoing reasons, we **AFFIRM** the trial court's rulings.

Entered by the Court:

WADE BRORBY
United States Circuit Judge