

IN THE SUPREME COURT OF THE STATE OF OKLAHOMA

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SUPREME COURT
STATE OF OKLAHOMA
JAN 30 2014
MICHAEL RICHIE
CLERK

SHARLA HELTON,)
)
 Plaintiff/Appellee,)
)
 vs.) Case No. 108,538
)
 ALLERGAN, INC.,)
)
 Defendant/Appellant.)

DEFENDANT/APPELLANT'S PETITION FOR WRIT OF CERTIORARI

James A. Jennings, III, OBA #4647
Linda G. Kaufmann, OBA #14759
JENNINGS TEAGUE, P.C.
204 N. Robinson Avenue, Suite 1000
Oklahoma City, OK 73102
Tel.: (405) 609-6000
Fax: (405) 609-6501

Gregory G. Garre (*pro hac vice*)
Katherine I. Twomey (*pro hac vice*)
Jonathan Y. Ellis* (*pro hac vice pending*)
LATHAM & WATKINS LLP
555 Eleventh Street, NW, Suite 1000
Washington, DC 20004-1304
Tel.: (202) 637-2207
Fax: (202) 637-2201
*Licensed to practice in N.C. only; all work supervised by a member of the D.C. Bar.

GinaMarie Slattery (*pro hac vice*)
SLATTERY PETERSEN, PLLC
111 W. Monroe, Suite 1000
Phoenix, AZ 85003
Tel.: (602) 507-6100
Fax: (866) 323-9593

Ellen L. Darling (*pro hac vice*)
Brendan M. Ford (*pro hac vice*)
K&L GATES LLP
1 Park Plaza, Twelfth Floor
Irvine, CA 92614
Tel.: (949) 253-0900
Fax: (949) 253-0902

Vaughn A. Crawford (*pro hac vice*)
SNELL & WILMER, L.L.P.
One Arizona Center
400 E. Van Buren Street, Suite 1900
Phoenix, AZ 85004
Tel.: (602) 382-6000
Fax: (602) 382-6070

ATTORNEYS FOR DEFENDANT/APPELLANT
ALLERGAN, INC.

January 30, 2014

DEFENDANT/APPELLANT'S PETITION FOR WRIT OF CERTIORARI

Appellant Allergan, Inc., hereby petitions this Court to grant a writ of certiorari to review the decision of the Court of Civil Appeals, Division IV (COCA) in this case.

A. **RELEVANT DATES.** COCA's opinion was filed on September 6, 2013. COCA's order denying Allergan's Petition for Rehearing was filed on January 10, 2014.

B. **REASONS FOR REVIEW.** In allowing the \$15 million damages award in this case to stand, COCA has decided three questions of substance in conflict with applicable decisions of this Court and the plain text of the relevant statutes. Okla. Sup. Ct. Rule 1.178(a). First, in conflict with this Court's decision in *Christian v. Gray*, 2003 OK 10, 65 P.3d 591, COCA eliminated the widely accepted requirement that a plaintiff in a toxic tort case prove general causation—*i.e.*, that the toxin is capable, at a specific exposure level, of causing the type of injury suffered by the plaintiff. Second, in conflict with the plain text of Oklahoma Evidence Code § 2701(3), COCA held that non-treating physicians may offer *lay* opinion testimony based on "their knowledge of medicine" and "their understanding of the technical literature discussing [a] medical issue," without qualifying as *expert* witnesses. And third, in conflict with *DeCorte v. Robinson*, 1998 OK 87, 969 P.2d 358, 361, COCA allowed an internally inconsistent jury verdict—which found no strict liability failure-to-warn, but yet a negligent failure-to-warn—to stand.

C. **STATEMENT OF FACTS.** BOTOX® was first approved by the FDA in 1989 to treat patients with serious and debilitating neuromuscular disorders. This is a pharmaceutical products liability case involving the same drug labeled for sale as BOTOX® Cosmetic (referred to as BOTOX® hereafter), which the FDA approved in 2002 for treating frown lines between the eyebrows. Appellee Dr. Sharla Helton began receiving BOTOX® treatments in 2004. Between 2004 and 2006, Helton received four treatments without experiencing any negative side effects.

But in July 2006, after Helton received her fifth BOTOX® treatment alongside a first-time injection of Restylane, a dermal filler used to plump lips, Helton alleges that she began experiencing joint and muscle pain.

Even though those symptoms were not typical of botulism, in 2009, Helton filed this action against Appellant Allergan, Inc., the manufacturer of BOTOX®, alleging that BOTOX® caused her to develop botulism, small fiber neuropathy, and other problems that precluded her from working as a physician. Helton claimed that Allergan was liable for her injuries (1) under a strict liability theory (manufacturers' products liability) for failing to warn that BOTOX® could cause botulism and other negative side effects, and (2) under a negligence theory for failing to provide sufficient information as to the product's known dangers and risks, including botulism—i.e., negligently failing to warn.

After a trial, the jury returned a split verdict, finding that Allergan was not liable under the manufacturers' products liability failure-to-warn theory, but that it was liable under the negligent failure-to-warn theory. The jury awarded Helton \$15 million in compensatory damages, and found that punitive damages were not warranted.

COCA affirmed. The court first rejected Allergan's argument that it was entitled to judgment because Helton failed to prove general causation—holding that Helton did not need to prove general causation at all. Purporting to apply *Christian*, COCA held, without any explanation, that proof of general causation was not required because this case did not “approach that of mass tort litigation.” Op. 10 (quoting *Christian*, 65 P.3d at 603); see *id.* at 11. And the court found that Helton's treating physician's testimony, which was based primarily on his differential diagnosis of Helton's injuries, established specific causation. *Id.* at 13-16.

COCA also upheld the trial court's ruling that Helton's physician-husband, several of her physician-colleagues, and Helton herself were permitted to testify, based "on their knowledge of medicine [and] understanding of the technical literature," that they believed Helton's BOTOX® treatments caused her injuries, without qualifying as expert witnesses. *Id.* at 17-18. Despite the obviously prejudicial nature of such testimony, COCA held that it was enough that the witnesses were subject to "vigorous cross-examination" and that the jury was instructed that it was the "sole judge of the credibility of the witnesses." *Id.* at 18-19.

Finally, COCA rejected Allergan's argument that the jury's verdict was inconsistent. Inventing a post-hoc rationalization for the verdict, the court theorized that the jury could have found that Allergan was not strictly liable because its warnings were adequate, but was liable for negligence because it encouraged a harmful "off-label" use. *Id.* at 24-25.

ARGUMENTS AMPLIFYING REASONS FOR GRANTING WRIT

I. REVIEW IS WARRANTED BECAUSE COCA ELIMINATED THE REQUIREMENT OF GENERAL CAUSATION IN CONFLICT WITH THIS COURT'S PRECEDENT AND ACCEPTED TORT PRINCIPLES

COCA's holding that a plaintiff in a pharmaceutical products liability case does not need to establish general causation conflicts with this Court's decision in *Christian* and the law of numerous other jurisdictions. In *Christian*, this Court confirmed the default rule that plaintiffs must establish general causation in toxic tort cases. 65 P.3d at 607; *see also id.* at 604. Courts across the country have likewise held that "plaintiffs must show both general and specific causation" in toxic tort cases. Margie Searcy-Alford, *A Guide to Toxic Torts* § 10.02[1] & n.4 (2013); *see, e.g., Blanchard v. Goodyear Tire & Rubber Co.*, 30 A.3d 1271, 1274 (Vt. 2011) (The plaintiff must prove "that (1) he was exposed to the specified chemical at a level that could have caused his physical condition (general causation); and (2) the exposure to that chemical did in fact result in the condition (specific causation)."); *Wright v. Willamette Indus., Inc.*, 91 F.3d

1105, 1106 (8th Cir. 1996) (“[A] plaintiff in a toxic tort case must prove the levels of exposure that are hazardous to human beings generally as well as the plaintiff’s actual level of exposure to the defendant’s toxic substance before he or she may recover.”); *see also Wells v. Smithkline Beecham Corp.*, 601 F.3d 375, 376-78 (5th Cir. 2010) (applying Texas law); *King v. Burlington N. Sante Fe Ry. Co.*, 762 N.W.2d 24, 34 (Neb. 2009); *Terry v. Caputo*, 875 N.E.2d 72, 76-77 (Ohio 2007); *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 881 (10th Cir. 2005); 1 Frank C. Woodside, III, *Drug Product Liability* § 5.01[2][a] & n.6 (2013) (collecting cases).

In *Christian*, this Court recognized a potential, limited exception to the default rule where “circumstances are such that general causation should not be necessary,” such as cases that fit the “sporadic accident model of tort law.” 65 P.3d at 604, 607. As an example, the Court cited a Kansas Supreme Court case, which excused plaintiffs from showing general causation when there was no epidemiological data and no “mass exposure.” *Christian*, 65 P.3d at 603-04 (citing *Kuhn v. Sandoz Pharm. Corp.*, 14 P.3d 1170, 1184-85 (Kan. 2000)). But this Court did not hold that the exception actually applied in *Christian*, and it “decline[d] to list hypothetical controversies where general causation need *not* be shown.” *Id.* at 604 (emphasis added). Importantly, the Court emphasized that the plaintiff would bear the burden of demonstrating that circumstances are such that general causation does not need to be shown. *Id.* at 607.

In the decision below, COCA turned the *Christian* default rule on its head, effectively making general causation the exception rather than the rule. COCA simply stated, “we conclude that the scope of plaintiff[s] case here does not approach that of mass tort litigation,” and “[w]e find no requirement of [plaintiff] to prove general causation.” Op. 10-11 (internal quotation marks omitted). It gave no justification for departing from the default rule, and it did not find that plaintiff satisfied her burden of establishing that general causation need not be shown.

That error is compounded by the fact that this case involves precisely the sort of “mass exposure” for which *Christian* confirmed a general causation showing *is* required. BOTOX® treatments are among the most common cosmetic medical procedures worldwide, with an estimated three million injections per year. According to Helton, she received the same treatments that other patients do every day and her alleged symptoms have been experienced by as many as 60,000 other individuals. Cases like this one, in which plaintiffs claim that their injuries are widely shared and caused by such a common exposure, are properly characterized as “mass tort litigation,” even though they do not flow from the same event. *See, e.g., Ortiz v. Fibreboard Corp.*, 527 U.S. 815, 861 (1999); *Castano v. Am. Tobacco Co.*, 84 F.3d 734, 746 n.23 (5th Cir. 1996). Indeed, such cases are the “most clear-cut examples” of mass exposure cases in which general causation must be shown. Gerald W. Boston, *A Mass-Exposure Model of Toxic Causation*, 18 Colum. J. Envtl. L. 181, 195 (1993).

Furthermore, the effects of BOTOX® have been studied *for decades*, since it was first approved by the FDA to treat serious neuromuscular disorders in 1989. There is plentiful epidemiological data on the effects of BOTOX®. As this Court recognized in *Christian*, “general causation requirements are usually imposed in cases with large existing epidemiological records.” 65 P.3d at 604. This makes sense. “[W]here governmental and public health agencies are likely to undertake the expensive and time-consuming population studies and extensive toxicological studies, the courts should demand that such studies be introduced as evidence in order for a plaintiff to make out a submissible case.” Boston, *supra*, at 191. Yet, far from “demand[ing]” that the plaintiff show general causation to establish liability, COCA *excused* the general causation requirement here (and allowed the plaintiff to ignore that data).

Helton’s evidence of *specific* causation simply confirms the importance of the general

causation requirement in this case. First, Helton relied on her doctor's *differential diagnosis* to establish causation. In a differential diagnosis, a doctor determines "the possible causes for the patient's symptoms and then eliminat[es] each of these potential causes until reaching one that cannot be ruled out." *Christian*, 65 P.3d at 604-05. But, as *Christian* recognized, "where differential diagnosis is used to show specific causation the party has also provided independently reliable evidence that the allegedly dangerous drug or substance had harmful effects; i.e., general causation was also shown." *Id.* at 605 (internal quotation marks omitted). In other words, before a differential diagnosis can be used to rule *out* potential causes, evidence of general causation must be shown to rule *in* a toxin as a potential cause.

Other jurisdictions have similarly recognized the importance of general causation when a differential diagnosis is used to establish specific causation. Indeed, as one commentator noted, "recent opinions seem to be in nearly unanimous agreement that one must 'rule in' the putative cause before 'ruling out' other causes, and that temporal order alone (the cause preceded the effect) is insufficient to support a causal attribution." 3 David L. Faigman et al., *Modern Scientific Evidence* § 21:5 (2013); see, e.g., *Ranes v. Adams Labs., Inc.*, 778 N.W.2d 677, 690 (Iowa 2010) ("differential diagnosis rests on the necessary assumption that the underlying methodology used to rule [the drug] in as a cause is sound"); *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1342 (11th Cir. 2010) ("[Differential diagnosis] assumes the existence of general causation The expert must show ... that the remaining cause ruled in as actually being capable of causing the condition."); *Valentine v. Conrad*, 850 N.E.2d 683, 688 (Ohio 2006) (rejecting differential diagnosis testimony where the plaintiff was "unable to establish that any of the chemicals to which [he] was exposed are capable of causing [his injury]").

Helton also relied on the temporal relationship between her symptoms and her last

BOTOX® treatment to prove causation. Relying on a Third Circuit case that embraced this “temporal relationship” theory, COCA agreed with Helton. Op. 10-11 (quoting *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 154 (3d Cir. 1999)). The majority of jurisdictions, however, have rejected proof of temporal relationship as a substitute for general causation. See Woodside, *supra*, § 5.08 (“Temporal relationship, by itself, does not establish causation.”); *id.* § 5.08 n.1 (collecting cases). And more to the point, *this* Court has rejected that analysis too. In *Christian*, the Court recognized that “a strong temporal relationship and a person being ‘doused’ by a substance” are “facts specific to the exposure of a particular individual and are thus usually presented in the context of *specific causation*.” 65 P.3d at 604 (emphasis added; citations omitted). The Court rejected relying on such a temporal relationship as a substitute for *general* causation. *Id.*

Christian adopts a sensible approach to toxic tort causation. It establishes a general rule that plaintiffs must prove that the substance they claim harmed them is, in fact, *capable* of harming human beings at the dosage they received. At the same time, *Christian* leaves open a potential, limited exception to that requirement where there has been no “mass exposure” or where epidemiological data of the toxin’s effects are unavailable. Excusing the plaintiff *in this case* of the general causation requirement effectively makes *Christian*’s narrow exception the rule. Helton’s negligence claim is a “clear-cut example” of the type of “mass exposure” tort where general causation is required. COCA’s contrary ruling warrants review.

II. REVIEW IS WARRANTED BECAUSE COCA’S OPINION DISRUPTS OKLAHOMA’S RULES OF EVIDENCE GOVERNING EXPERT TESTIMONY

COCA’s decision in this case also eliminates the distinction between lay and expert testimony—and with it the trial court’s important gatekeeping function of policing the reliability of expert testimony. By statute, expert testimony is allowed only when (1) a witness with

“scientific, technical or other specialized knowledge” is “qualified as an expert by knowledge, skill, experience, training or education”; (2) the expert’s testimony is “based on sufficient facts or data” and “the product of reliable principles and methods”; and (3) the expert has “applied the principles and methods reliably to the facts of the case.” 12 Okla. Stat. § 2702. By contrast, when a witness is “not testifying as an expert,” the witness’s lay testimony is limited to opinions and inferences that are “[n]ot based on scientific, technical or other specialized knowledge within the scope of Section 2702.” 12 Okla. Stat. § 2701(3) (emphasis added).

Section 2701(3)’s limitation on lay testimony was recently added for the same reason as Federal Rule of Evidence 701(c): “to eliminate the risk that the reliability requirements set forth in Rule [2]702 will be evaded through the simple expedient of proffering an expert in lay witness clothing.” Fed. R. Evid. 701 advisory committee’s note (2000).¹ The Oklahoma Court of Criminal Appeals has interpreted § 2710(3) to ensure that “[o]nly expert witnesses may give opinion testimony based on scientific, technical, or other specialized knowledge.” *Williams v. State*, 2008 OK CR 19, 188 P.3d 208, 22. COCA’s decision creates a major loophole to that rule.

This Court has not yet interpreted § 2701(3), and it needs to review this “question of substance not heretofore determined by this court,” Okla. Sup. Ct. Rule 1.178(a)(1), because COCA’s decision effectively nullifies this important new provision. Helton offered the testimony of seven doctors to prove that BOTOX® treatments caused her injuries. Six of these doctors consisted of Helton’s husband, four friends and colleagues, and Helton herself. Op. 16. None of the six was “qualified as expert witnesses in the field of toxicology,” none professed any expertise in botulism, and only one had even treated Helton. *Id.* at 16-17. Nevertheless, the trial court allowed them to testify as *lay* witnesses, based “on their knowledge of medicine” and “their

¹ 2002 Okla. Sess. Law Serv. Ch. 468 § 54; see 1 Leo H. Whinery, 1 *Oklahoma Practice Series: Courtroom Guide to the Oklahoma Evidence Code*, Ch. 5, § 2701 (2013).

understanding of the technical literature discussing this medical issue,” that they believed Helton had contracted iatrogenic botulism as result of her BOTOX® treatments. *Id.* at 17. Rather than subject this testimony to the reliability requirements for expert testimony based on “scientific, technical or other specialized knowledge,” *see* 12 Okla. Stat. § 2702, the court allowed the physicians to offer purported *lay* testimony without any such safeguards. The cumulative effect of this testimony was highly prejudicial.

In affirming the trial court, COCA reasoned that the jury was instructed that it was the “sole judge of the credibility of the witnesses” and that the witnesses were subjected to “vigorous cross-examination.” Op. 18-19. But that reasoning eviscerates § 2701(3) and is incompatible with the trial judge’s role under Oklahoma law as the gatekeeper of the evidentiary process. The purpose of § 2701(3) is to ensure that testimony like that offered here is subjected to the *trial judge’s* determination of its reliability before it is submitted to the jury. *See Cities Serv. Co. v. Gulf Oil Corp.*, 1999 OK 14, 980 P.2d 116, 132. As a federal court interpreting Federal Rules of Evidence 701 and 702 recently held, “trial courts [must] be vigilant in ensuring that the reliability requirements set forth in Rule 702 not be evaded through the simple expedient of proffering an expert in lay witness clothing.” *Williams v. Mast Biosurgery USA, Inc.*, 644 F.3d 1312, 1317 (11th Cir. 2011) (internal quotation marks omitted)). This Court’s review is warranted to ensure that § 2701 performs its statutorily intended role.

III. REVIEW IS WARRANTED BECAUSE COCA AFFIRMED A JUDGMENT BASED ON AN INTERNALLY INCONSISTENT JURY VERDICT

This Court’s review is also warranted because COCA affirmed a judgment based on a split verdict that is internally inconsistent. Under this Court’s precedent, a jury verdict may be upheld only when it is “supported by competent evidence.” *DeCorte v. Robinson*, 1998 OK 87, 969 P.2d 358, 361. Here, the jury’s verdict in favor of Allergan on strict liability and in favor

Helton on negligence is hopelessly inconsistent. By reaching a verdict in favor of Allergan on the strict liability failure-to-warn claim, the jury necessarily found either that Allergan provided an adequate warning or that any failure to warn was not the cause of Helton's injuries—or both. *See Kirkland v. Gen. Motors Corp.*, 1974 OK 52, 521 P.2d 1353, 1363. The jury therefore necessarily negated at least one essential element of the negligent failure-to-warn claim. *See Vicki Lawrence MacDougall*, 8 *Oklahoma Practice Series: Oklahoma Product Liability Law* 31 (2006). The verdicts cannot be reconciled—and COCA did not even try.

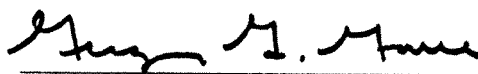
Instead, COCA theorized that the jury could have found that Allergan's warnings were sufficient but that irrespective of those warnings, Allergan negligently encouraged "off-label" use in a manner that could harm Helton. Op. 24-25. But that is not a *failure-to-warn* theory, and that post-hoc rationalization fails. Helton did not advance such distinct theories at trial and her evidence does not support them. From the outset, Helton's manufacturers' products liability and negligence claims were simply alternate legal avenues for the same *failure-to-warn* theory. In his opening statement, Helton's counsel explained that "this case is about ... was there adequate warnings." Tr.Vol.2A at 32. And in his closing, counsel again argued that "[t]he warning was inadequate." Tr.Vol.15 at 30-31. The trial court itself instructed the jury that—as to both claims—its task was to determine whether "Defendant provided inadequate warnings regarding the side effects of BOTOX® Cosmetic." Jury Instruction #1, R.1582 at 1583.

Especially in light of the other errors discussed above, COCA's decision allowing this inconsistent verdict to stand warrants this Court's review.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,



James A. Jennings, III, OBA #4647
Linda G. Kaufmann, OBA #14759
JENNINGS TEAGUE, P.C.
204 N. Robinson Avenue, Suite 1000
Oklahoma City, OK 73102
Tel.: (405) 609-6000
Fax: (405) 609-6501

Gregory G. Garre (*pro hac vice*)
Katherine I. Twomey (*pro hac vice*)
Jonathan Y. Ellis* (*pro hac vice pending*)
LATHAM & WATKINS LLP
555 Eleventh Street, NW, Suite 1000
Washington, DC 20004-1304
Tel.: (202) 637-2207
Fax: (202) 637-2201
*Licensed to practice in N.C. only; all work supervised by a member of the D.C. Bar.

GinaMarie Slattery (*pro hac vice*)
SLATTERY PETERSEN, PLLC
111 W. Monroe, Suite 1000
Phoenix, AZ 85003
Tel.: (602) 507-6100
Fax: (866) 323-9593

Ellen L. Darling (*pro hac vice*)
Brendan M. Ford (*pro hac vice*)
K&L GATES LLP
1 Park Plaza, Twelfth Floor
Irvine, CA 92614
Tel.: (949) 253-0900
Fax: (949) 253-0902

Vaughn A. Crawford (*pro hac vice*)
SNELL & WILMER, L.L.P.
One Arizona Center
400 E. Van Buren Street, Suite 1900
Phoenix, AZ 85004
Tel.: (602) 382-6000
Fax: (602) 382-6070

ATTORNEYS FOR DEFENDANT/APPELLANT
ALLERGAN, INC.

CERTIFICATE OF MAILING TO ALL PARTIES

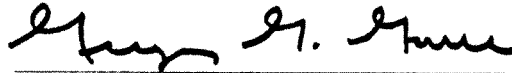
I hereby certify that a true and correct copy of this Petition for Rehearing and Brief in Support was sent this 30th day of January, 2014, by Certified Mail, return receipt requested, to:

Ray Chester
Carlos R. Soltero
MCGINNIS, LOCHRIDGE & KILGORE, LLP
600 Congress Avenue, Suite 2100
Austin, TX 78701

-and-

Richard C. Ford
Anton J. Rupert
CROWE & DUNLEVY, P.C.
20 N. Broadway Avenue, Suite 1800
Oklahoma City, OK 73102-8273

ATTORNEYS FOR PLAINTIFF/APPELLEE
SHARLA HELTON



Gregory G. Garre

APPENDIX

TO

**DEFENDANT/APPELLANT ALLERGAN, INC.'S
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Case No. 108,538

APPEAL FROM THE DISTRICT COURT OF
OKLAHOMA COUNTY, OKLAHOMA

HONORABLE BARBARA G. SWINTON, TRIAL JUDGE

AFFIRMED

Ray Chester
Carlos R. Soltero
Jessica B. Palvino
MCGINNIS, LOCHRIDGE & KILGORE, LLP
Austin, Texas

and

Richard C. Ford
CROWE & DUNLEVY, P.C.
Oklahoma City, Oklahoma

For Plaintiff/Appellee

Vaughn A. Crawford
Todd E. Lundell
Richard A. Derevan
SNELL & WILMER L.L.P.
Phoenix, Arizona

and

Ellen L. Darlings
SNELL & WILMER L.L.P.
Costa Mesa, California

and

James A. Jennings
Linda G. Kaufmann
JENNINGS COOK & TEAGUE
Oklahoma City, Oklahoma

For Defendant/Appellant

OPINION BY JERRY L. GOODMAN, JUDGE:

Allergan, Inc., (Allergan) appeals the trial court's June 28, 2010, judgment in favor of Dr. Sharla Helton, a medical doctor, hereinafter referred to as "Consumer," following a jury verdict rendered in her favor. Based on our review of the facts and applicable law, we affirm.

FACTS

Consumer specializes in obstetrics and gynecology. She received Botox injections four times between 2004 and 2006 without incident. Botox is a purified, vacuum-dried botulinum toxin type A used for therapeutic purposes since 1989. It is manufactured by Allergan and FDA approved for treating eyebrow wrinkles. Warning labels provided with the product warn of possible side effects, including death. However, in 2006, the label did not warn of the risk of botulism.

In July 2006, after previous injections, Consumer obtained another injection of Botox and an injection for Restylane, a dermal filler used to plump lips and

minimize lip lines. Restylane is not manufactured by Allergan. Both products were injected by a nurse.¹

The day after the injections, Consumer began experiencing symptoms of joint and muscle pain. Over a period of time, the symptoms became worse to the extent Consumer finally became debilitated. Her initial symptoms were atypical of botulism poisoning, in that she had none of the classic symptoms of botulism. As a result, she was not diagnosed with botulism poisoning for a substantial period of time. After such time, Consumer was finally diagnosed with iatrogenic botulism—botulism attributed to therapeutic or cosmetic use of botulinum toxin. Treatment for botulism can be effective, if done within days of the onset of the symptoms. However, by the time Consumer was diagnosed, the window of opportunity for effective treatment had long since closed.

Consumer filed her cause of action against Allergan based on two theories of recovery. In her first theory—manufacturer’s product liability (MPL)—Consumer contended the warning labels included with the product were insufficient to warn her of the risk of contracting botulism from use of the product. Her second theory, based on negligence, alleged Allergan’s practice of encouraging physicians to use the product “off label,” *i.e.*, in a manner and in dosages not approved by the FDA, was negligent.

¹ Suit was filed against the nurse, but later dismissed prior to trial. There are no issues regarding the nurse before us.

The matter was tried to a jury over a period of sixteen days. Thirty-eight witnesses testified. The jury was twice deadlocked. It ultimately returned a verdict in favor of Allergan on the MPL theory, but returned a verdict in favor of Consumer on the negligence theory, awarding damages of \$15,000,000.00. A journal entry of judgment was entered June 28, 2010, for that amount, interest, and costs. Allergan appeals, raising legal and evidentiary issues.

STANDARD OF REVIEW

Jury Verdict

As set out in *Badillo v. Mid Century Ins. Co.*, 2005 OK 48, 121 P.3d 1080:

In *Florafax International, Inc. v. GTE Market Resources, Inc.*, 1997 OK 7, 933 P.2d 282, this Court set forth the general appellate standard of review concerning actions at law tried to a jury. This Court said in *Florafax*:

In an action at law, a jury verdict is conclusive as to all disputed facts and all conflicting statements, and where there is any competent evidence reasonably tending to support the verdict of the jury, this Court will not disturb the jury's verdict or the trial court's judgment based thereon. Where such competent evidence exists, and no prejudicial errors are shown in the trial court's instructions to the jury or rulings on legal questions presented during trial, the verdict will not be disturbed on appeal. In an appeal from a case tried and decided by a jury an appellate court's duty is not to weigh the evidence and determine which side produced evidence of greater weight, i.e. it is not an appellate court's function to decide

where the preponderance of the evidence lies—that job in our system of justice has been reposed in the jury. In a jury-tried case, it is the jury that acts as the exclusive arbiter of the credibility of the witnesses. Finally, the sufficiency of the evidence to sustain a judgment in an action of legal cognizance is determined by an appellate court in light of the evidence tending to support it, together with every reasonable inference deducible therefrom, rejecting all evidence adduced by the adverse party which conflicts with it.

Id. at ¶ 3, at 287. (citations omitted).

In plain language, we are not allowed to substitute our judgment for that of the jury merely because we would have decided or viewed disputed material fact questions differently than the jury. Where competent evidence was presented at trial to support reasonable findings as to those material fact questions relating to the claim in suit and no reversible error is otherwise shown, an appellate court must affirm a judgment based on a jury verdict, not second-guess such judgment or the jury verdict upon which it is based. These general principles guide our review here.

Badillo, at ¶¶ 2, 3, at 1088 (footnote omitted).

[] We must affirm a jury verdict if there is any competent evidence reasonably tending to support it, evidence which is relevant and material to the issue to be determined. *Jos. A. Coy Co. v. Younger*, 1943 OK 160, 136 P.2d 890. We do not weigh the evidence. We consider all the evidence tending to support the verdict, together with every reasonable inference from it, and must affirm unless there is an entire absence of proof on a material issue.

Covel v. Rodriguez, 2012 OK 5, ¶ 11, 272 P.3d 705, 710.

ISSUES

I. Causation

We reject Allergan's first proposition of error. Allergan argues Consumer failed to establish causation, a crucial element of proof in a negligence action. Allergan contends Consumer failed to prove either general or specific causation. Allergan argues the trial court erred when it denied its motion for directed verdict made following submission of all the evidence to the jury.

Our standard of review of a denial of a motion for directed verdict is whether there is any evidence that reasonably tends to support a judgment for the party against whom the motion was made. *Thomason v. Pilger*, 2005 OK 10, ¶ 7, 112 P.3d 1162, 1165; *Trent v. Oklahoma Gas & Electric Co.*, 1989 OK 54, ¶ 6, 775 P.2d 275, 277; *Myers v. Maxey*, 1995 OK CIV APP 148, ¶ 17, 915 P.2d 940, 947. In ruling on such a motion the trial court must consider as true all the evidence and all the inferences reasonably drawn therefrom favorable to the party against whom the motion is made and any conflicting evidence favorable to the movant must be disregarded. *Woods v. Fruehauf Trailer Corp.*, 1988 OK 105, ¶ 8, 765 P.2d 770, 772.

Discussion:

McKellips v. Saint Francis Hosp., Inc., 1987 OK 69, 741 P.2d 467, states:

The three elements essential to a prima facie case of negligence are: (1) a duty owed by the defendant to protect the plaintiff from injury, (2) a failure to properly exercise or perform that duty and (3) the plaintiff's injuries are proximately caused by the defendant's failure to exercise his duty of care.

Id. at ¶ 8, at 470 (footnote omitted).

Proximate cause consists of two elements: cause in fact and legal causation. Legal causation concerns a determination whether legal liability should be imposed as a matter of law where cause in fact is established and depends upon considerations of common sense and policy. Cause in fact, on the other hand, deals with the "but for" consequences of an act. "The defendant's conduct is a cause of the event if the event would not have occurred but for that conduct."... Generally, the question of cause in fact is for the jury. It is only when there is no evidence from which the jury could reasonably find a causal nexus between the negligent act and the resulting injury it becomes a question of law for the court.

Id. at ¶ 9, at 470, 471 (footnotes omitted).

Consumer's burden was to prove cause in fact, *i.e.*, she would not have contracted botulism but for the injection of Botox. Her burden of proof is clear:

The sufficiency of the evidence to show cause in fact presents a question of law for the court. Sufficiency of evidence is the "legal standard which is applied to determine whether the case may go to the jury." A plaintiff's burden of proof of causation is twofold. First, a plaintiff has the burden of producing evidence, satisfactory to the judge, that a reasonable person could believe in the existence of the causal link and that the evidence should be weighed by the jury. A verdict will be directed for the defendant if a plaintiff fails to carry

this burden. Secondly, a plaintiff bears the burden of persuasion should the evidence be allowed to reach the jury. The standard for sufficiency of proof of evidence, related to a plaintiff's first burden, should not be confused with the standard of proof, associated with a plaintiff's second burden, which is applied by the jury in reaching a final verdict. Generally, in civil cases the standard of proof means a preponderance of the evidence. The certified questions concern the burden of production and sufficiency of proof of causation standard as to whether the causation issue should be submitted to the jury.

In Oklahoma, the general principles of proof of causation in a medical malpractice action are the same as an ordinary negligence case. The reasonable probability standard for sufficiency of proof of causation is applied although it has been stated in varying language, such as “[t]he circumstances proved must lead to the conclusion with reasonable certainty and probability” or “[w]hen such lay and expert testimony is considered together, it must warrant the conclusion that a preponderance of the evidence discloses facts and circumstances establishing a reasonable probability that defendant’s negligence was the proximate cause of the injury.” Absolute certainty is not required, however, mere possibility or speculation is insufficient. As stated above, if a plaintiff fails to meet his burden of sufficiency of proof of evidence to establish a prima facie issue of causation where the probabilities are evenly balanced or less, a defendant may be entitled to a directed verdict.

Id. at ¶¶ 10, 11, at 471.

The concept of two types of causation—general and specific—was addressed in *Christian v. Gray*, 2003 OK 10, 65 P.3d 591. There, the plaintiff

alleged respiratory injuries arising out of exposure to airborne chemicals while attending a circus.

Christian noted that:

Causation is now often divided into general causation and specific causation in **some** controversies involving allegations of injury resulting from a person's exposure to a harmful substance. General causation is whether a substance is capable of causing a particular injury or condition in the general population, while specific causation is whether that substance caused the particular individual's injury... .

Id. at ¶ 21, at 602 (footnotes omitted, emphasis in original).

When, as here, an expert's testimony is challenged on the issue of causation, the *Christian* Court noted that the proponent of that testimony may show evidence of general causation **or** show that general causation is not necessary for the admissibility of the expert's testimony. *Id.* at ¶ 23, at 603. The *Christian* Court quoted *Kuhn v. Sandoz Pharmaceuticals Corp.*, 14 P.3d 1179 (Kan. 2000), for the premise that:

general causation requirements (requiring plaintiffs to present confirming epidemiological evidence to make out a prima facie case) have typically been applied in cases involving mass exposures

as opposed to:

Cases that have not imposed this requirement [general causation] typically involve injuries that may be placed in the 'sporadic accident model of tort law.' In [these] cases, where only a single plaintiff or a few plaintiffs

have allegedly suffered an injury due to some exposure, a medical doctor will be permitted to render an opinion as to whether the exposure caused the plaintiff's injury solely on an examination of the plaintiff and a differential diagnosis of the source of the plaintiff's injury, sometimes supplemented with toxicological evidence... .

Id. at ¶ 24, at 603.

In the case under review, as in *Kuhn*, we conclude that the “scope of plaintiffs’ case here does not approach that of mass tort litigation.” *Id.* at ¶ 24, at 603.

Christian continues:

We conclude that general causation should be shown unless the particular controversy is inappropriate for general causation. We decline to list hypothetical controversies where general causation need not be shown. We thus decline to make a first-instance assessment of the application of general causation to this controversy in the absence of the parties having developed the issue in the trial court. We do note that [*Heller v. Shaw Industries, Inc.*, 167 F.3d 146 (3d Cir. 1999)] discusses a strong temporal relationship and a person being “doused” by a substance. *Id.* 167 F.3d at 154. These are facts specific to the exposure of a particular individual and are thus usually presented in the context of specific causation.

Id. at ¶ 26, at 604.

Heller, infra, involved a claim of respiratory illness allegedly caused by chemicals in a carpet which were released following its installation in the plaintiff's home.

A number of courts, including our own, have looked favorably on medical testimony that relies heavily on a temporal relationship between an illness and a causal event. *See, e.g., Zuchowicz v. United States*, 140 F.3d 381, 385 (2d Cir.1998); *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 809 (3d Cir.1997). The temporal relationship will often be (only) one factor, and how much weight it provides for the overall determination of whether an expert has “good grounds” for his or her conclusion will differ depending on the strength of that relationship. For example, if there was a minor oil spill on the Hudson River on the same day that Heller began experiencing her symptoms in West Chester, Pennsylvania, and she recovered around the time the oil was cleaned up, a proper differential diagnosis and temporal analysis by a well-qualified physician such as Dr. Papano could not possibly lead to the conclusion that the oil spill caused Heller's illness. *See, e.g., Paoli*, 35 F.3d at 745 (both the methodology and the application of that methodology must be reliable). Conversely, “if a person were doused with chemical X and immediately thereafter developed symptom Y, the need for published literature showing a correlation between the two may be lessened.” *Cavallo v. Star Enter.*, 892 F.Supp. 756, 774 (E.D.Va.1995), *aff'd in relevant part*, 100 F.3d 1150, 1159 (4th Cir.1996), *cert. denied*, 522 U.S. 1044, 118 S.Ct. 684, 139 L.Ed.2d 631 (1998).

Heller v. Shaw Industries, Inc., 167 F.3d 146 at 154.

We find no requirement of Consumer to prove general causation. Proof of specific causation is sufficient under these facts. *Christian* speaks to this:

What have the courts had to say about specific causation? Two issues often discussed are (1) the appropriateness of a differential diagnosis, and (2) the temporal, or time-based, relationship between the exposure and a plaintiff's injury.

Differential diagnosis, or differential etiology, is a standard scientific technique which identifies the cause of a medical problem by eliminating the likely causes until the most probable one is isolated. . . . A reliable differential diagnosis typically is performed after ‘physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests,’ and generally is accomplished by determining the possible causes for the patient’s symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out, or determining which of those that cannot be excluded is the most likely.”

Magistrini v. One Hour Martinizing Dry Cleaning, 180 F.Supp.2d 584, 609 (D.N.J. 2002), (citation omitted).

Courts have not been uniform in applying *Daubert* when assessing the methodology of clinical medicine to prove causation. In *Hollander v. Sandoz Pharmaceuticals Corp.*, 289 F.3d 1193 (10th Cir. 2002), the Tenth Circuit declined to decide, in general terms, the reliability of differential diagnoses and case reports. However, it then stated that where differential diagnosis is used to show specific causation the party has also provided “independently reliable evidence that the allegedly dangerous drug or substance had harmful effects;” i.e., general causation was also shown. *Id.* 289 F.3d 1210-1211.

Id. at ¶¶ 27, 28, at 603, 604 (footnotes omitted).

Finally, *Christian* states:

In Oklahoma a physician treating a patient may use a medical history provided by the patient when making an opinion on causation of the patient’s injury. In *Sneed v. Beaverson*, 1964 OK 191, 395 P.2d 414, 416, we said that “it was incumbent upon the trial court to consider the history plaintiff had given doctor, as correct” when the trial court ruled on defendant’s demurrer to plaintiff’s evidence. In *Chicago, R.I. & P. Ry. Co. v. Jackson*, 1917 OK 145, 162 P. 823, we said that:

. . . [T]he correct rule, it would appear, should permit a physician to testify to a statement or narrative given him by his patient in relation to his condition, symptoms, sensations, and feelings, both past and present, when made in connection with his own opinion as to the cause of the injury, though the statement may not be received as independent evidence to establish the fact of the injury.

Id. 162 P. at 826.

A physician using a patient's history is part of a **method** to determine causation of an injury. *See A & A Checker Cab Operating Co. v. Fritzshall*, 1953 OK 321, ¶ 14, 264 P.2d 322, 324, *quoting*, *Danner v. Chandler*, 1951 OK 246, 236 P.2d 503.

Id. at ¶ 29, at 605 (emphasis in original).

We therefore review the record to determine whether there is evidence supporting specific causation. We need not look further than the testimony of Dr. Beson.

Dr. Beson, a triple-board certified medical physician specializing in neuromuscular disease, was one of Consumer's treating physicians. He testified that though he originally did not believe that 50 units of Boxtox could cause the symptoms for which he was treating Consumer, after further study, he later came to the conclusion that "there's a direct correlation with any level of injection of Botulinum toxin, that it can cause significant problems." (Tr. May 3, 2010, p. 16,

l. 16.) He further noted the scarcity of scientific papers discussing iatrogenic botulism (11) versus food-borne botulism (257).² After much discussion of his treatment, research, and conclusions, Dr. Beson was asked:

Q. [] do you have an opinion as to whether or not Dr. Sharla Helton suffered from iatrogenic botulism as a result of her Botox injections on July 14, 2006.

A. Yes, I do.

Q. And what is that opinion, Dr. Beson?

A. That she had iatrogenic botulism and subsequently small fiber peripheral neuropathy related to it.

R. Tr. *id.* p. 58, ll. 19-25, p. 59, l. 1.

Dr. Beson was then subjected to a lengthy and vigorous cross-examination.

On redirect, he again was asked:

Q. [] Final Question: the small fiber neuropathy, based on those objective tests at Cleveland Clinic, any doubt that she's got that?

A. No.

Q. And whether it's immune mediated or a toxic response or some other direct effect, is it your opinion that that small fiber neuropathy was caused by her Botox injections?

A. Yes. And I can't make it any better.

R. Tr. *id.*, p. 146, ll. 17-25.

² (Tr. *id.*, p. 24, ll. 1-5.)

An expert's opinion need not be correct; only reliable. *Christian*, at ¶ 23, at 603.

[] In *Christian v. Gray*, 2003 OK 10, 65 P.3d 591, we explained the application of *Daubert* in circumstances involving an allegation that injury resulted from a person's exposure to a toxic substance. *We noted that where there is evidence of instantaneous onset of injury following a certain occurrence and expert testimony that the injury could have been caused by the occurrence, this methodology is sufficient to present the issue of causation to the jury although there is evidence of other possible causes. Id.* at ¶ 32, 65 P.3d at 605-606, and quoting *Martin v. Stratton*, 1973 OK 124, 515 P.2d 1366, 1371. ...

Scruggs v. Edwards, 2007 OK 6, ¶ 20, 154 P.3d 1257, 1265 (emphasis added).

Finally, when reviewing the admissibility of an expert witnesses' testimony,

First, the clear abuse of discretion appellate standard applies when we review a decision on the admissibility of expert testimony. In the context of a ruling on the relevance of proffered evidence we have said that "a judgment will not be reversed based on a trial judge's ruling to admit or exclude evidence absent a clear abuse of discretion." *Myers v. Missouri Pacific R. Co.*, 2002 OK 60, ¶ 36, 52 P.3d 1014, 1033. We have applied this standard to an expert witness. *Gabus v. Harvey*, 1984 OK 4, 678 P.2d 253, 258. In *Cities Service Co. v. Gulf Oil Corp.*, 1999 OK 14, ¶ 32, 980 P.2d 116, 132, we applied this standard to an expert witness, and relied upon the U.S. Supreme Court opinion that applied the abuse of discretion standard to *Daubert* rulings. *Cities Service Co. v. Gulf Oil Corp.*, at ¶ 32, 980 P.2d at 132, citing, *General Elec. Co. v. Joiner*, 522 U.S. 136, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997). The Court of Criminal Appeals uses the standard of clear abuse of

discretion for reviewing a *Daubert* decision. *Gilson v. State*, 2000 OK CR 14, n. 5, 8 P.3d 883, 908.

Christian, at ¶ 42, at 608.

In this case, Dr. Beson's testimony was admissible, supports Consumer's burden of proof regarding the issue of specific causation, and the weight to be given this testimony was up to the jury. We therefore reject Allergan's assertion of error. We hold the evidence of specific causation in the record was sufficient to survive a motion for directed verdict. That same evidence was also sufficient to support the jury's verdict. Therefore, we conclude no trial court error occurred.

II. Improper Witness Testimony

Allergan next contends the trial court erred by permitting Consumer, her physician-husband, her fellow physicians, and her treating physicians, to testify regarding their observations and opinions of the cause of her illness, though none were qualified as expert witnesses in the field of toxicology or had ever treated a patient with botulism. All in all, five of these doctors testified in her behalf.

Allergan contends these witnesses were experts "in lay witness clothing" and thus their testimony was prejudicial to Allergan and therefore, a new trial is merited.

We find no reversible error occurred.

Discussion:

Allergan accurately outlined the substance of the witnesses' testimony in its appellate brief-in-chief. Consumer's husband, an anesthesiologist who had never treated his wife or encountered a case of botulism, admitted his goal was to prove his wife contracted botulism from Botox. Other physicians who were friends and colleagues of Consumer, only one of whom treated her, all testified that even though they had never seen botulism cases before, they believed that Botox caused the botulism suffered by Consumer. These doctors based their opinions on their knowledge of medicine, their observations of Consumer, the temporal connection between the date of injection and date of onset of symptoms, and their understanding of the technical literature discussing this medical issue. Allergan contends these were "experts in lay-witness clothing." It argues the trial court erred in allowing these witnesses to testify as to causation over its objections, that such testimony was prejudicial, and therefore the judgment should be reversed.

Allergan also filed a motion in limine to restrict Consumer's opinion that, as a result of her self-diagnosis, she contracted botulism from Botox. That issue was resolved in a pretrial hearing in which the trial court noted that "as long as she's testifying to her individual knowledge and opinion based on that knowledge, any witness can do that. So I don't see how I can limit her other than on cross-

examination when you all determine the limit of the knowledge that she has.”³

The court went on to permit Allergan to extensively cross-examine these witnesses to show their lack of expertise in treating and diagnosing Botox-induced botulism.

We find no reversible error occurred.

We first note the jury, being properly instructed, is the sole judge of the credibility of the witnesses. The jury was given OUI instruction No. 3.13, which told them they were the sole judges of the witnesses’ believability, and should consider their biases, prejudices, or interest in the outcome of the trial. The jury was given OUI Instruction No. 3.21, telling them that the expert’s opinions were to be given whatever weight the jury felt appropriate; but that the jury was not required to surrender their judgment to that of the expert.

The fact that the witnesses used by Consumer to assist her in shouldering her burdens of proof and persuasion were educated and trained as medical doctors presents no basis for reversal. It would be difficult to instruct a well-educated witness, in whatever field, to forget years of training, experience, and knowledge before being permitted to testify regarding matters with which they have familiarity, or proffering opinions of which they have knowledge. Further, to disqualify a witness simply because they have an advanced education would be erroneous. While it is unusual for there to be so many doctors testifying about

³ R. 1570, TT. April 10, 2010, p. 83, ll. 14-18.

Consumer's condition, it is not unlikely, given her profession, and certainly not reversible error. The witnesses were subject to vigorous cross-examination, and their biases and lack of expertise in botulism cases was amply demonstrated both in their direct and cross-examination. The jury was properly instructed, and was free to accept or disregard their testimony as it saw fit.

Finally, even Allergan concedes that, even if all of the physician's witnesses' testimony was stricken, there remained the opinions of the two experts used by Consumer to make her case. Though Allergan contends those expert opinions were flawed and should be disregarded, we have already determined there was sufficient evidence based on those experts' testimony to support the jury's decision.

Therefore, we conclude the jury had before it ample testimony, both expert and lay, from which it could arrive at its verdict. No reversible error occurred.

III. Psychiatric Exam

Allergan sought to compel Consumer to submit to a psychiatric exam in an effort to prove that Consumer was suffering from a "somatoform disorder," defined by Allergan as "a disorder which manifests itself in bodily complaints caused by a psychiatric illness."⁴ Allergan sought to show the jury that there was

⁴ Appellant's Brief in Chief, p. 23

an alternate cause of Consumers' symptoms.⁵ As stated in its appellate brief, "In the absence of an alternative cause of Helton's injury, the jury was left to wonder 'if not BOTOX,[®] then what caused Helton to get sick?'"⁶ To this end, Allergan sought to introduce the testimony of two of its experts who would testify regarding their conclusions based on a psychiatric examination of Consumer and her medical records.

Consumer filed a motion in limine to protect her from such an examination and to prohibit Allergan's experts from testifying regarding their theory. The trial court granted the motion and prohibited the testimony be given to the jury, but offered Allergan the opportunity to submit its evidence outside the presence of the jury. This offer was declined, and the witnesses were not permitted to testify regarding their alternative theory. Allergan now contends the exclusion of the witnesses' testimony was error.

We disagree. First, we hold Allergan has waived this error. This Court has held in *Clark v. Turner*, 2004 OK CIV APP 69, 99 P.3d 736:

Motions in limine are recognized by Oklahoma case law. *Messler v. Simmons Gun Specialities, Inc.*, 1984 OK 35, ¶ 15, 687 P.2d 121, 127. A motion in limine is a motion preliminary to trial to preclude the

⁵ Consumer contends Allergan's defense theory was that Consumer was psychosomatic or a malingerer. Allergan rejected those terms, preferring instead to use the phrase "somatoform disorder."

⁶ Appellant's Brief in Chief, p. 23 (Italics in original).

introduction of prejudicial matters to the jury, and is advisory until finally determined at trial. *Christian v. Gray*, 2003 OK 10, n.22, 65 P.3d 591 (citing *Myers v. Missouri Pac. R. Co.*, 2002 OK 60, n.66, 52 P.3d 1014). See also *Middlebrook v. Imler, Tenney & Kugler M.D.'s, Inc.*, 1985 OK 66, ¶ 12, 713 P.2d 572, 579 (in limine rulings are preliminary and advisory in nature until point in trial at which evidence would have been admitted but for the motion). Consequently, liminal rulings are not appealable, *Myers*, 2002 OK 60 at n.66, 52 P.3d 1014, and only evidentiary rulings during trial remain subject to review. *Hartford Ins. Co. v. Dyer*, 2002 OK CIV APP 126, ¶ 15, 61 P.3d 912, 914. See also *Messler*, 1984 OK 35 at ¶ 15, 687 P.2d at 127 (appeal from the granting of a motion in limine is actually an appeal from the rejection of evidence offered, not from the granting of the motion).

If evidence is excluded by an in limine ruling, the proponent must, at the appropriate time during trial (and out of the hearing of the jury), make an offer of proof for the record explaining what the evidence will show and why it is admissible. *Middlebrook*, 1985 OK 66 at ¶ 12, 713 P.2d at 579. The Oklahoma Supreme Court has explained that the party against whom a liminal ruling is made must re-press the issue at trial and obtain a final order. *Myers*, 2002 OK 60 at n.66, 52 P.3d 1014. The Court cautioned litigants regarding how they must satisfy these requirements:

Since . . . any error must be predicated upon the exclusion of evidence, litigants would be well-advised to assist in appellate review by making sure the record includes a clear offer of proof in which the appellate court can readily determine the precise evidence which was offered and that the trial court makes a ruling as to the admissibility of the precise evidence offered, not a general category of evidence.

Messler, 1984 OK 35 at n.7, 687 P.2d 121.

Clark, at ¶¶ 23, 24, at 741 (emphasis in original).

We further reject Allergan’s call for a review for fundamental error for the reason that it is not the jury’s duty to determine all possible causes, or eliminate other possible causes, of Consumer’s injury. Rather, it is the jury’s duty to determine if Consumer proved her chosen theory of recovery. Had Consumer failed to prove that theory, the jury’s duty would end with a verdict in favor of Allergan.⁷ It would not be the jury’s continued duty to ask: “If not Botox, then What?” Nor is it Allergan’s duty to prove what caused Consumer’s illness.⁸ Allergan’s sole duty to obtain a favorable verdict is to show that Consumer did not meet her burdens of proof and persuasion. Allergan’s attempt to shift the burden is rejected.

The jury obviously found that Consumer met her burdens of proof and persuasion. There was no need for it to inquire further. The trial court did not err in excluding this evidence. We find no merit to this proposition of error.

IV. Irreconcilable Verdicts

Allergan contends the trial court erred when it entered judgment on the jury’s verdict, which Allergan contends was inconsistent. Consumer pled two

⁷ Which, we note, it did just that on the MPL theory.

⁸ Allergan stated in its appellate reply brief, at p. 16, “So Allergan was never permitted to explain to the jury what was causing Helton’s medical problems.”

theories of recovery: Manufacturer's Products Liability and Negligence. The jury was instructed on both theories, and returned a verdict in favor of Allergan on the MPL theory, but found in favor of Consumer on the negligence theory. The trial court then entered judgment against Allergan on the jury's negligence-based verdict. Allergan contends this was erroneous. We hold the jury's verdict is not inconsistent under these facts, find no error, and reject this proposition of error.

A. Standard of Review

It is within this context that we must consider whether the jury's verdict was inconsistent. The long-standing rule of this Court is that a verdict will be affirmed if there is any theory, supported by competent evidence, which could serve as the basis for the verdict. *Eversole v. Okla. Hosp. Founders Ass'n*, 1991 OK 80, 818 P.2d 456, 458 (Okla. 1991); *Pine Island RV Resort Inc. v. Resort Management Inc.*, 1996 OK 83, 922 P.2d 609 (Okla. 1996). Even when the award itself or amount of damages appears inconsistent with a finding of liability, the jury's verdict will be affirmed if there is a theory under which the damages (or lack thereof) could be supported. *Wright v. Central Oklahoma Milk Producers Ass'n*, 1973 OK 15, 509 P.2d 464 (Okla. 1973)(verdict affirmed where plaintiff was awarded damages for injury but no damages for pain and suffering because jury could have determined that pain suffered arose from a preexisting condition); *Essary v. Fitts*, 1970 OK 58, 467 P.2d 173 (Okla. 1970)(Court upheld a verdict in which the defendant was found responsible for automobile accident but plaintiff was awarded no damages); *Higginbotham v. Hartman*, 1970 OK 25, 465 P.2d 478 (Okla. 1970).

Decorte v. Robinson, 1998 OK 87, ¶ 9, 969 P.2d 358, 361.

B. Discussion

Allergan argues the jury's verdict was irreconcilable. Allergan suggests that the jury's failure to find all the elements necessary to reach a verdict on MPL means that those elements could not be met on the negligence claim.

We disagree. The theories are separate. *See Kirkland v. General Motors Corporation*, 1974 OK 52, 521 P.2d 1353. Contrary to Allergan's argument in its brief, we are not confronted with identical causes of action being defended on the same grounds. Consumer pled two different theories of recovery, one (MPL) focusing on the potential danger of the product, and the other (negligence) focusing on the behavior of the corporate actor in the manner in which it marketed the product. These are separate concepts.

All that remains is to review the jury's instructions for plain error. The jury was given Instruction No. 17, which states:

Since this lawsuit is based on the theory of negligence, you must understand what the terms "negligence" and "ordinary care" mean in the law with reference to this case.

"Negligence" is the failure to exercise ordinary care to avoid injury to another's person or property. For Defendant Allergan, Inc., "ordinary care" is the care which a reasonably careful pharmaceutical company would use under the same or similar circumstances. The law does not say how a reasonably careful pharmaceutical company would act under those circumstances. That is for you to decide. Thus, under the facts in evidence in this case, if Allergan, Inc., failed

to do something which a reasonably careful pharmaceutical company would do, or did something which a reasonably careful pharmaceutical company would not do, Allergan, Inc., would be negligent.⁹

We have reviewed the voluminous record and find it supports the trial court's instructions. The jury, now properly instructed, could determine that, in fact, the product manufactured by Allergan was not defective, yet that because of Allergan's marketing campaign and encouragement of "off-label" use, that use of the product in such a manner could harm Consumer.

We find no error.

CONCLUSION

We affirm the trial court's order.

AFFIRMED.

RAPP, J., and BARNES, V.C.J. (sitting by designation), concur.

September 6, 2013

⁹ Modified OUJI 9.2, made case-specific.