IN THE SUPREME COURT OF THE STATE OF OKLAHOMA

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

STATEMENT OF THE STATE CHAMBER OF OKLAHOMA, THE TULSA REGIONAL CHAMBER, AND THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICI CURIAE* IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

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Pursuant to this Court's February 13, 2014 order granting leave, the State Chamber of Oklahoma, the Tulsa Regional Chamber, and the Chamber of Commerce of the United States of America respectfully submit this statement in support of Allergan, Inc.'s petition for certiorari. *Amici* are leading local, state, and national business advocacy organizations that represent a broad spectrum of businesses of every stripe and size, including ranchers, hospitals, manufacturers, energy companies, and retailers. Reasonable tort law has been a core priority for *amici*, and their members will be significantly impacted by the outcome of this case. Allowing the decision below to stand will make doing business in Oklahoma substantially less attractive.

REASONS FOR GRANTING THE PETITION

In Oklahoma, as in the rest of the country, in cases of "injury resulting from a person's exposure to a harmful substance," a plaintiff ordinarily must show both general causation (is the substance *capable* of causing the injury at issue at a particular level of exposure?) as well as specific causation (did the exposure cause this plaintiff's injury?). *Christian v. Gray*, 2003 OK 10, ¶ 21, 65 P.3d 591, 602. The Court of Civil Appeals excused plaintiff from showing general causation on the rationale that this case does not "'approach that of mass tort litigation.'" Op. 10 (quoting *Kuhn v. Sandoz Pharms. Corp.*, 270 Kan. 443, 465 (2000)). It is not clear what that means. On the one hand, some courts have concluded that an exception to the general causation requirement is appropriate in cases involving one-off exposures to substances that have not been studied, because the epidemiological data needed to evaluate general causation do not exist. But if that is what the Court of Civil Appeals meant, such an exception is strikingly unsuited to this case, because BOTOX® has been widely studied and abundant epidemiological evidence exists concerning whether the

doses that plaintiff received are capable of causing the injury she alleged. On the other hand, the court may have meant simply that this is a single-plaintiff case. The number of plaintiffs, however, is irrelevant to whether there is a valid reason to relax the ordinary requirement to prove general causation.

The Court should grant review to explain what exceptions to the general causation requirement exist under *Christian*. This is a matter of great importance to individuals and businesses operating in Oklahoma, who need clarity in the rules that govern tort liability. And this case is a good vehicle for reaching the issue because the lower court altogether excused plaintiff from the requirement to establish general causation.

I. General Causation Is Required When Epidemiological Data Exists.

Courts around the country agree: general causation is a required element of a plaintiff's claim based on exposure to an allegedly harmful substance. *E.g.*, *Christian*, 2003 OK 10, ¶ 21, 65 P.3d at 602; *King v. Burlington N. Santa Fe Ry. Co.*, 277 Neb. 203, 212-13 (2009); *Parker v. Mobil Oil Corp.*, 857 N.E.2d 1114, 1120-21 (N.Y. 2006); *City of Littleton v. Indus. Claim Appeals Office of State*, __ P.3d ___, 2012 COA 187, ¶ 12 (Colo. Ct. App. 2012); *Parkhill v. Adlerman-Cave Milling & Grain Co. of N.M.*, 245 P.3d 585, 599 (N.M. Ct. App. 2010); *Merrell Dow Pharms., Inc. v. Havner*, 953 S.W.2d 706, 714-15 (Tex. 1997); *Wells v. SmithKline Beecham Corp.*, 601 F.3d 375, 377-78 (5th Cir. 2010) (Texas law); *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 881 (10th Cir. 2005) (Colorado law); *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1239 (11th Cir. 2005) (Alabama law); Am. L. Prod. Liab. 3d § 89:40; Restatement (Third) of Torts: Phys. & Emot. Harm § 28 cmt. c(3).

Courts across the country also agree that plaintiffs bear the burden of presenting sound scientific support for their theory of general causation. This most often comes in the

form of epidemiological studies. "Epidemiology is the field of public health and medicine that studies the incidence, distribution, and etiology of disease in human populations. The purpose of epidemiology is to better understand disease causation and to prevent disease in groups of individuals. . . . [E]pidemiology addresses whether an agent can cause a disease, not whether an agent did cause a specific plaintiff's disease." *Christian*, 2003 OK 10, ¶ 24 n.17, 65 P.3d at 604 n.17 (quoting Federal Judicial Center, *Reference Manual on Scientific Evidence* 381-82 (2d ed. 2000)).

"While the presence of epidemiology does not necessarily end the inquiry, where epidemiology is available, it cannot be ignored." *Norris*, 397 F.3d at 882; *see also King*, 277 Neb. at 234 ("Courts should normally require more than one epidemiological study showing a positive association to establish general causation . . . ."); *Wells*, 601 F.3d at 380 ("[T]his court has frowned on causative conclusions bereft of statistically significant epidemiological support."); *McClain*, 401 F.3d at 1244, 1251-52 (expert testimony establishing causation inadmissible where expert ignored "thousands of articles" with epidemiological data); *Brock v. Merrell Dow Pharms., Inc.*, 874 F.2d 307, 311 (5th Cir. 1989) ("Undoubtedly, the most useful and conclusive type of evidence in a case such as this is epidemiological studies.").

In *Christian v. Gray*, this Court stated that general causation is presumptively required but left the door open for courts to excuse a plaintiff from carrying that burden in unusual cases. 2003 OK 10, ¶ 26, 65 P.3d at 604 ("We conclude that general causation should be shown unless the particular controversy is inappropriate for general causation."). While the Court declined to list the specific situations that might qualify, the Court's opinion strongly suggests that it had in mind cases where there simply is no epidemiological data one way or the other, or where (as in *Christian* itself) it is unclear what substance or dose the

plaintiff was exposed to. *Id.* To be clear, *amici* do not necessarily agree that the general causation requirement should ever be waived. After all, it is "well established" that plaintiffs bear the burden of proving exposure to and injury from harmful substances by demonstrating both "the levels of exposure that are hazardous to human beings generally" and "the plaintiff's actual level of exposure to the defendant's toxic substance.'" *Mitchell v. Gencorp, Inc.*, 165 F.3d 778, 781 (10th Cir. 1999) (internal quotation marks omitted). If the plaintiff is unable to marshal scientifically valid evidence of general causation, that is no reason to accept scientifically invalid evidence.

That debate, however, is not relevant to this case. BOTOX® has been widely used and rigorously studied for decades, and there is a mountain of scientific data available about its effects—something plaintiff has never disputed. The question here is not whether to excuse plaintiffs from proving general causation in certain cases where there simply is no relevant body of evidence bearing on that question. Rather, the question is whether the lower courts were justified in *ignoring* a wealth of probative epidemiological evidence whose only "deficiency" is that it overwhelmingly refutes plaintiff's theory. Even assuming the lack of any evidence bearing on general causation one way or the other could excuse a showing of general causation, the lack of any support for the plaintiff in a robust body of scientific evidence is not a valid reason to disregard that evidence. When this Court opened the door to an exception, it presumably meant just that: general causation is the default rule, but it may potentially be excused where a valid reason exists to do so.

Limiting the exception in this way would keep Oklahoma in step with the rest of country. *See, e.g.*, *Norris*, 397 F.3d at 882 (where "there was no body of epidemiological evidence demonstrating the absence of a causal relationship," proof of general causation

based on "epidemiological evidence would not necessarily be required"); *Raynor v. Merrell Pharms. Inc.*, 104 F.3d 1371, 1374 (D.C. Cir. 1997) (distinguishing prior case because it involved a drug that "had not been the subject of such a wealth of [epidemiological] studies"); Restatement (Third) of Torts: Phys. & Emot. Harm § 28 cmt. c(3) ("[A]lmost all courts employ a . . . flexible approach to proof of causation—*except in those cases with a substantial body of exonerative epidemiologic evidence*.") (emphasis added).

The decision of the Kansas Supreme Court in *Kuhn v. Sandoz Pharmaceuticals Corp.*, 270 Kan. 443, 465 (2000), which was extensively discussed in *Christian*, 2003 OK 10, ¶ 24, 65 P.3d at 603, is not inconsistent with this position. As *Kuhn* explained, "general causation requirements are usually imposed in cases with large existing epidemiological records." 270 Kan. at 465. In context, *Kuhn*'s reference to "mass exposures" should be seen as shorthand for cases in which relevant epidemiological data is available. *See id.* The court's heavy reliance on a law review article (Gerald W. Boston, *A Mass-Exposure Model of Toxic Causation: The Content of Scientific Proof and the Regulatory Experience*) supports this interpretation. That article recognized that "courts are requiring more scientific evidence" even in isolated-exposure cases, thanks to "the growing availability of toxicological and epidemiological databases that render the causal questions less intractable." 18 Colum. J. Envtl. L. 181, 381-82 (1993).

And limiting the exception in this way—restricting it to cases with no ready epidemiological data—makes it abundantly clear that no general causation exception can govern this case. Plaintiff's argument hinges on the fact that Allergan's Medication Guide warns that the drug "may affect areas of the body away from the injection site and cause symptoms of a serious condition called botulism." Pet. Resp. at 5-6 (quoting PX89, p. 089-

001). But that misses an essential link: whether the doses plaintiff received are capable of causing the injuries she alleged. The Medication Guide does not indicate what dosage would place patients at risk for the described symptoms. Connecting her dose to her injury was plaintiff's burden to carry, and she cannot do so simply by citing general language in a warning that does not address this critical issue. Even in plaintiff's response to the petition, she entirely ignores the critical requirement to link her dose to her injury in a scientifically valid way—consistent with her failure to address this requirement at trial.

This case is nothing like *Christian*. Here, the precise number of units of BOTOX® that plaintiff received is known. Therefore, plaintiff was required to present scientific data showing that BOTOX®, *in the dose she received*, is capable of causing the injuries she alleged. Plaintiff has never contended that no relevant epidemiological data exist. Indeed, such a contention would not have been credible given how widely BOTOX® has been studied and used. Instead of presenting scientific evidence to link her dose to her injury, plaintiff relied chiefly on her doctor's testimony that he could not identify any other potential cause of her alleged injuries and therefore believed that BOTOX® was likely the cause. *See* Pet. 6. But such a differential diagnosis puts the cart before the horse. Without a scientific basis to consider BOTOX® a potential cause of plaintiff's injuries in the first place, ruling out other potential causes cannot rule *in* BOTOX®.

The fact that plaintiff relied on a differential diagnosis in her attempt to show *specific* causation thus heightens the importance of requiring plaintiff first to show *general* causation. If the dose she received was not capable of causing the injuries with which she was later diagnosed, her doctor's inability to identify some other cause is irrelevant. This is, again, a matter of well-settled law around the country. *E.g.*, *Norris*, 397 F.3d at 885 (plaintiff's

doctors' "reliance on differential diagnosis without supporting epidemiological evidence is misplaced and demonstrates the unreliable nature of the testimony"); *id.* at 885-86 ("We are unable to find a single case in which differential diagnosis that is flatly contrary to all of the available epidemiological evidence is both admissible and sufficient to defeat a defendant's motion for summary judgment."); *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1413 (D. Or. 1996) ("[D]ifferential diagnosis does not by itself prove the cause, even for the particular patient. Nor can the technique speak to the issue of general causation. Indeed, differential diagnosis *assumes* that general causation has been proven for the list of possible causes it eliminates."); *see also McClain*, 401 F.3d at 1253 (a differential diagnosis is inadmissible when general causation is not proven); *Raynor*, 104 F.3d at 1374 (same); *Parkhill*, 245 P.3d at 599 (same).

When this Court decided *Christian*, it gave no hint that it meant to mark a dramatic departure from tort-law principles that are well-settled across the country. Recognizing that there may be a narrow exception to the need to prove general causation in unusual cases is one thing, but dispensing more broadly with that basic requirement would move Oklahoma out of step with the nation as a whole. This Court should grant review to clarify that Oklahoma adheres to the longstanding requirement that a plaintiff must prove general causation with scientifically valid evidence, at least in cases like this one where relevant epidemiological evidence exists.

II. The Court Should Grant Review to Clarify This Important Area of Law.

The Court of Civil Appeals provided essentially no explanation for its conclusion that general causation need not be shown in this case. As explained above, *Christian* teaches that general causation may be dispensed with only in cases where there is no way to conduct a general causation inquiry. The Court of Civil Appeals did not suggest that conducting a

general causation inquiry was impracticable in this case, and (as explained above) such a suggestion would be plainly incorrect. Nor did the Court of Civil Appeals attempt to articulate a clear or meaningful standard by which it judged whether to require general causation. Instead, it announced an opaque, one-sentence conclusion: "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.'" Op. at 10 (quoting *Kuhn*, 270 Kan. at 465).

The reference to "mass tort litigation" is ambiguous. Perhaps the Court of Civil Appeals meant simply that there is only one plaintiff in this case and it is not a class or mass action with multiple plaintiffs suing about the same event. That is true but irrelevant. There is no logical relationship between the number of plaintiffs and the amount of scientific knowledge available about the allegedly causative agent. This Court in *Christian* did not suggest that whether general causation is required turns on how many plaintiffs there are. Nor did *Kuhn*. 270 Kan. at 465. Instead, as explained above, *Kuhn* discussed "mass exposures" in the context of explaining the difficulty of proving general causation where "'there is relatively little epidemiological data'" about the substance at issue. *Id.* (quoting 2 Faigman, Keye, Saks & Sanders, Modern Scientific Evidence: The Law and Science of Expert Testimony: The Role of Epidemiological Evidence in Toxic Tort Cases § 28-1.3.2, at 307-08 ("Faigman")). And *that* is what the exception is really about. "On the other hand, when there is a substantial body of negative epidemiological evidence, this *by itself* may defeat the plaintiff's claim." 3 Faigman, *supra*, § 23.4 (emphasis added).

The critical question is thus whether relevant epidemiological evidence exists that bears on whether the substance and dose at issue are capable of causing the injury at issue. Perhaps in some unusual, one-off exposure cases there will be no such evidence. For that

matter, perhaps there could be "mass exposure" cases involving many plaintiffs where there likewise is no such evidence. For instance, *Christian* dealt with an alleged exposure to airborne chemicals at a circus. 2003 OK 10, ¶ 1, 65 P.3d at 594. Presumably many people at the circus were exposed to whatever was in the air, but the number of people exposed could not change the fact that the identity and exposure level of the airborne chemicals were unknown. *Id.* ¶¶ 16, 19, 65 P.3d at 604. For present purposes, the key point is that, whatever the precise contours of an exception for cases where conducting a general causation inquiry is impracticable, this case falls far outside of any such exception. *See supra* pp. 4-5.

Equally fundamentally, if there are to be cases where general causation is not required, it is essential that there be a clear standard so that litigants and lower courts can determine which cases fall on which side of the line. Certainly *Christian* does not suggest that courts have a free-ranging discretion to require general causation, or not, as they see fit for any particular reason. *Cf.* 2003 OK 10, ¶ 24, 65 P.3d at 604. Yet the Court of Civil Appeals' failure to articulate a reason for its conclusion portends just such a standardless, ad hoc approach.

That would be a recipe for arbitrariness and unpredictability that would make doing business in Oklahoma more uncertain and less attractive. In a 2006 Harris Poll, 69% of businesses respondents said that a state's litigation environment is "likely" to impact where to do business. Harris Interactive Inc., 2006 State Liability Systems Ranking Study, at 8 tbl.2, http://www.instituteforlegalreform.com/uploads/sites/1/Exec_Summary-_FINAL.pdf. In addition to making it more difficult for companies to predict and manage litigation risks, sanctioning a broad exception to the well-established general causation requirement could encourage a new wave of potentially frivolous lawsuits where, as here, a vast body of

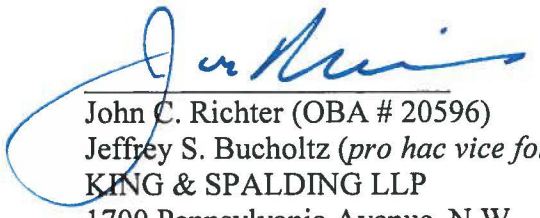
epidemiological evidence shows that the plaintiff could not have been harmed by the defendant. In deciding whether to grant review, this Court should weigh policy factors such as the impact of unpredictable liability rules on business location decisions, or the possibility that Oklahoma courts could become "magnet jurisdictions" for meritless lawsuits.

The lower court's standardless approach would negatively impact not only the Oklahoma business environment. It would be in *no one's* interest, as it would leave everyone in a position of uncertainty, including plaintiffs and the courts themselves. If parties do not know whether general causation will be required in any given case, they will not be able to make intelligent decisions about settlement, much less adopt reasonable approaches to litigation in trial or appellate courts. The Court therefore should grant review and clarify that the exception suggested in *Christian* is confined to cases where there simply is no way to conduct a general causation inquiry, through epidemiological studies or otherwise.

CONCLUSION

Companies spend hundreds of millions of dollars each year to fund scientific studies about the effects of products like BOTOX®. *See* FDA, Obligation of User Fee Revenues, http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/FinancialReports/PDUFA/ucm262847.htm. Such studies are conducted for important public health reasons, not for tort-defense purposes, and the epidemiological data they generate is science's gold standard for assessing important issues like causation. Where such scientific evidence exists, courts should respect it. This Court should grant the petition and should reverse the Court of Civil Appeals' holding that plaintiff was not required to prove general causation.

Respectfully submitted.



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CERTIFICATE OF SERVICE

On February 27, 2014, a true and correct copy of the foregoing Statement was mailed to:

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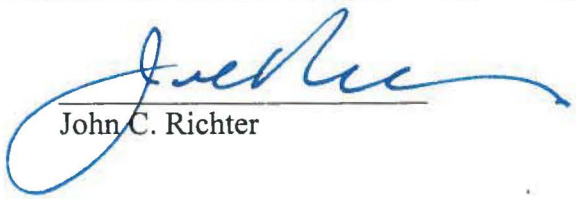

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