IN THE ARIZONA SUPREME COURT

MEDICIS PHARMACEUTICAL CORPORATION, an Arizona corporation, Petitioner/Appellee, vs. AMANDA WATTS, an adult individual, Respondent/Appellant.	No. CV-15-0065-PR Court of Appeals Division One No. 1-CA-CV 13-0358 Maricopa County Superior Court No. CV2012-008081

BRIEF OF PRODUCT LIABILITY ADVISORY COUNCIL, INC., AS *AMICUS CURIAE* IN SUPPORT OF PETITION FOR REVIEW

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STATEMENT OF INTEREST

The Product Liability Advisory Council, Inc. ("PLAC") is a non-profit association with 102 corporate members, a broad cross-section of American and international product manufacturers. See Attachment A. Several hundred leading product liability defense attorneys are non-voting members.

Since 1983 PLAC has filed over 1,000 *amicus curiae* briefs in state and federal courts, including this Court. PLAC seeks to promote the principled development of product liability laws by helping appellate courts understand the perspectives and real-life experiences of companies that design and manufacture products.

STATEMENT OF POSITION

PLAC urges this Court to grant the Petition for Review and join almost every other American jurisdiction in adopting the learned intermediary rule ("Rule") to ensure that warnings for prescription-only products in Arizona pass through physicians with the knowledge and expertise to determine each patient's individual medical needs.

ARGUMENT

The Rule places communication of adequate warnings for prescription medical products where it belongs – with licensed physicians acting within physician-patient relationships. Professionally evaluating individual patients,

physicians should decide how best to share technical medical information with them.

High courts in thirty-five jurisdictions embrace the Rule. Federal courts predict adoption by eight other jurisdictions. The Third Restatement of Torts incorporates the Rule. Before this aberrant decision, the Arizona court of appeals followed the Rule in four cases in which this Court denied review.[1]

I. This Court Should Adopt The Learned Intermediary Rule.

A. The Rule Harmonizes Tort Law With The Heavily Regulated Distribution System For Prescription Medical Products.

Consumers cannot buy prescription medical products without oversight by "learned intermediaries," licensed physicians who "stand in the best position to evaluate a patient's needs and assess the risks and benefits of a particular course of treatment." Vitanza v. Upjohn Co., 778 A.2d 829, 836-37 (Conn. 2001). "The entire system of drug distribution in America is set up so as to place the responsibility of distribution and use upon professional people." Centocor, Inc. v. Hamilton, 372 S.W.3d 140, 155 (Tex. 2012).

[1] "Under the [Rule], 'the manufacturer's duty to warn is ordinarily satisfied if a proper warning is given to the specialized class of people that may prescribe or administer the product.'" Davis v. Cessna Aircraft Corp., 182 Ariz. 26, 38 (App. 1994), review denied (Ariz. April 25, 1995). Accord Piper v. Bear Medical Systems, Inc., 180 Ariz. 170, 178 (App. 1993), review denied (Ariz. Nov. 1, 1994); Gaston v. Hunter, 121 Ariz. 33, 47 (App. 1978), review denied (Ariz. Nov. 21, 1978); Dyer v. Best Pharmacal, 118 Ariz. 465, 469 (App. 1978), review denied (Ariz. May 2, 1978).

A "[p]rescription drug" is "any drug . . . required by Federal law . . . to be dispensed only by a prescription." 21 C.F.R. §203.3(y). All drugs require prescriptions unless the Food & Drug Administration ("FDA") "finds such requirements are not necessary for the protection of the public health." 21 C.F.R. §310.200(b). Similarly a "prescription device" is "[a] device which, because of any potentiality for harmful effect . . . is not safe except under the supervision of a practitioner licensed by law to direct [its] use." 21 C.F.R. §801.109. See Coyle v. Richardson-Merrell Inc., 584 A.2d 1383, 1387 (Pa. 1991) ("a prescription drug [is] a product whose distribution is limited precisely because its benefits and risks are to be assessed only by licensed physicians acting on behalf of particular patients whose individual physical condition and circumstances are known to them"). The Rule thus harmonizes state tort law with governmental regulation; specifically FDA's determination that prescription products have sufficiently severe inherent risks to require professional medical evaluation – as courts have repeatedly recognized. E.g., Vitanza, 778 A.2d at 846; Pittman v. Upjohn Co., 890 S.W.2d 425, 429 (Tenn. 1994).

Further, the Restatement of Torts, which this Court generally follows,[2] recognizes the Rule's predicates: (1) the claim must involve "instructions or

[2] "We have long followed the rule that where not bound by our previous decisions or by legislative enactment, we would follow the Restatement of the Law." In re Krohn, 203 Ariz. 205, 210 ¶18 (2002).

warnings"; (2) the product must require "prescription" by a licensed provider, and (3) this provider must be "in a position" to provide information within a physician/patient relationship. See Restatement (Third) of Torts: Products Liability §6(d) (1998).

This case satisfies all three prerequisites. Watts challenges the adequacy of warnings about a drug prescribed by her long-term "medical provider." Watts v. Medicis Pharmaceutical Corp., 236 Ariz. 511, 513 ¶3 (App. 2015). Consequently, the Rule should apply, recognizing how she actually obtained, and how FDA regulated, this drug.

B. The Rule Advances Patient Safety And Other Practical Benefits.

Beyond harmonizing tort law with government regulation, the Rule advances patient interests by: (1) imparting safety information via physicians best positioned to evaluate individual patient needs; (2) protecting the physician-patient relationship; (3) enabling physicians to decipher technical medical information for patients; and (4) avoiding the frequent infeasibility of direct manufacturer-to-patient warnings.

"The [Rule's] first and best rationale is that the prescribing physician is in a superior position to impart the warning and can provide an independent medical decision as to whether use of the drug is appropriate for treatment of a particular patient." Larkin v. Pfizer, Inc., 153 S.W.3d 758, 763 (Ky. 2004). "[T]he doctor is

in the best position to warn the customer of a given medication's generalized risks." Klasch v. Walgreen Co., 264 P.3d 1155, 1159 (Nev. 2011).

While direct-to-consumer ("DTC") advertising may motivate patients to see doctors, physician are still legally required to decide whether to prescribe – professionally evaluating medical needs within personalized physician/patient relationships. "When the physician-patient relationship does exist . . . [courts] hesitate to encourage, much less require, a drug manufacturer to intervene in it." Swayze v. McNeil Laboratories. Inc., 807 F.2d 464, 471 (5th Cir. 1987). Indeed, direct manufacturer intervention can be dangerous. A patient,

> in a serious medical condition . . . faces unwanted, unsettling and potentially harmful risks if advice, almost inevitably involved and longwinded, from non-physicians, contrary to what the doctor of his choice has decided should be done, must be supplied to him during the already stressful period shortly before his trip to the operating room.

Brooks v. Medtronic, Inc., 750 F.2d 1227, 1232 (4th Cir. 1984).

A manufacturer that adequately warns a doctor "may reasonably assume that the physician will exercise his informed judgment in the patient's best interests." Tracy v. Merrell Dow Pharmaceuticals, Inc., 569 N.E.2d 875, 876 (Ohio 1991). The physician's "duty to disclose relevant risks already exists under the informed consent theory of medical malpractice." Rice v. Brakel, 233 Ariz. 140, 144 ¶12 (App. 2013). Physicians' subsequent inadequate disclosures "do not operate to create, or to extend, a manufacturer's duty to warn third-party family members,

bystanders, or any persons other than the learned intermediary." Ellis v. C.R. Bard, Inc., 311 F.3d 1272, 1283 (11th Cir. 2002). Rather, it remains "the duty of the physician to advise the patient of any dangers or side effects associated with the use of the drug as well as how and when to take the drug." Coyle, 584 A.2d at 1385.

Further, the Rule allows manufacturers to describe product risks for doctors in precise medical terminology, not readily understood by lay patients. FDA-approved warnings are "designed for the physician and not the patient." Oksenholt v. Lederle Laboratories, 656 P.2d 293, 297 (Or. 1982). "Were the patient to be given the complete and highly technical information . . ., he would have no way to evaluate it." Dyer, 118 Ariz. at 469. Patients are not, nor should they be, expected to understand complex medical labeling on their own. E.g., McCombs v. Synthes (U.S.A.), 587 S.E.2d 594, 595 (Ga. 2003); West v. Searle & Co., 806 S.W.2d 608, 613 (Ark. 1991); Humes v. Clinton, 792 P.2d 1032, 1039 (Kan. 1990).

Scientific accuracy requires that manufacturers draft their warnings for professionals:

> Warnings for prescription drugs are intended for the physician, whose duty it is to balance the risks against the benefits of various drugs and treatments and to prescribe them and supervise their effects. The physician acts as an "informed intermediary" between the manufacturer and the patient.

Martin v. Hacker, 628 N.E.2d 1308, 1311 (N.Y. 1993). As the Fifth Circuit famously described the Rule's function in an early case:

> Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice . . . is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative.

Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1276 (5th Cir. 1974) (applying Texas law). Accord, e.g., Centocor, 372 S.W.3d at 159 (following Reyes).[3]

Finally, feasibility considerations buttress the Rule. Pharmacists routinely repackage drugs, see Ariz. Admin. C. R4-23-658(D)(1)(b), and heightened medical privacy often makes it impractical for manufacturers to warn unknown patients directly. E.g., Larkin, 153 S.W.3d at 764; Craft v. Peebles, 893 P.2d 138, 155 (Haw. 1995); West, 806 S.W.2d at 613; Terhune v. A.H. Robins Co., 577 P.2d 975, 978 (Wash. 1978). No two patients have identical medical needs, education, background, or desire for information. "One-size-fits-all" manufacturer warnings benefit patients far less than one-on-one conversations with their doctors.

Any of these safety and other benefits alone would justify the Rule. Together they present a compelling case.

[3] Numerous jurisdictions approve the Reyes rationale. E.g., Morgan v. Publix Super Markets, Inc., 138 So.3d 982, 989 (Ala. 2013); Gourdine v. Crews, 955 A.2d 769, 761-62 (Md. 2008) (concurring opinion); Larkin, 153 S.W.3d at 763; Freeman v. Hoffman-La Roche. Inc., 618 N.W.2d 827, 841-42 (Neb. 2000); Pittman, 890 S.W.2d at 431.

C. Overwhelming Nationwide Consensus Supports The Rule.

"There is a strong trend in prescription drug failure-to-warn cases to reiterate and apply this well established doctrine." In re Zyprexa Products Liability Litigation, 649 F. Supp.2d 18, 32 (E.D.N.Y. 2009) (applying Arizona law), aff'd, 394 F. Appx. 819 (2d Cir. 2010). "[T]he vast majority of other jurisdictions . . . have overwhelmingly adopted the learned intermediary doctrine." Centocor, 372 S.W.3d at 157-58 & n.17.

Contrary to the Amended Response to Petition for Review ("Amended Response"), at 8-12, the Rule has been recognized by nearly every jurisdiction to consider it. The highest courts of thirty-four states (and the District of Columbia) follow the Rule in prescription medical product cases.

- **Alabama**: Walls v. Alpharma USPD, Inc., 887 So.2d 881, 883 (Ala. 2004).
- **Alaska**: Shanks v. Upjohn Co., 835 P.2d 1189, 1200 & n.17 (Alaska 1992).
- **Arkansas**: West, 806 S.W.2d at 613.
- **California**: Carlin v. Superior Court, 920 P.2d 1347, 1354 (Cal. 1996); Brown v. Superior Court, 751 P.2d 470, 477 n.9 (Cal. 1988).
- **Connecticut**: Vitanza, 778 A.2d at 836-38.
- **Delaware**: Lacy v. G.D. Searle & Co., 567 A.2d 398, 400-01 (Del. 1989).
- **District of Columbia**: Mampe v. Ayerst Laboratories, 548 A.2d 798, 801 & n.6 (D.C. 1988).
- **Florida**: E.R. Squibb & Sons, Inc. v. Farnes, 697 So.2d 825, 827 (Fla. 1997).
- **Georgia**: McCombs, 587 S.E.2d at 595.
- **Hawaii**: Craft, 893 P.2d at 155.
- **Illinois**: Kirk v. Michael Reese Hospital & Medical Center, 513 N.E.2d 387, 393 (Ill. 1987).

- **Kansas**: Humes, 792 P.2d at 1039-40.
- **Kentucky**: Larkin, 153 S.W.3d at 761.
- **Maryland**: Nolan v. Dillon, 276 A.2d 36, 40 (Md. 1971).
- **Massachusetts**: Cottam v. CVS Pharmacy, 764 N.E.2d 814, 820 (Mass. 2002).
- **Michigan**: Smith v. E.R. Squibb & Sons, Inc., 273 N.W.2d 476, 479 (Mich. 1979).[4]
- **Minnesota**: Mulder v. Parke Davis & Co., 181 N.W.2d 882, 885 n.1 (Minn. 1970).
- **Mississippi**: Wyeth Laboratories, Inc. v. Fortenberry, 530 So.2d 688, 691-92 (Miss. 1988).
- **Missouri**: Krug v. Sterling Drug, Inc., 416 S.W.2d 143, 146-47 (Mo. 1967).
- **Montana**: Stevens v. Novartis Pharmaceuticals Corp., 247 P.3d 244, 259 (Mont. 2010).
- **Nebraska**: Freeman, 618 N.W.2d at 841-42.
- **Nevada**: Klasch, 264 P.3d at 1159.
- **New Jersey**: Niemiera v. Schneider, 555 A.2d 1112, 1117 (N.J. 1989).
- **New York**: Martin, 628 N.E.2d at 1311.
- **Ohio**: Seley v. G.D. Searle & Co., 423 N.E.2d 831, 834, 836-37 (Ohio 1981).
- **Oklahoma**: Edwards v. Basel Pharmaceuticals, 933 P.2d 298, 300-01 (Okla. 1997).
- **Oregon**: Oksenholt, 656 P.2d at 296-97.
- **Pennsylvania**: Coyle, 584 A.2d at 1385.
- **South Carolina**: Madison v. American Home Products Corp., 595 S.E.2d 493, 496 (S.C. 2004).
- **Tennessee**: Pittman, 890 S.W.2d at 429.
- **Texas**: Centocor, 372 S.W.3d at 154-59.
- **Utah**: Schaerrer v. Stewart's Plaza Pharmacy, Inc., 79 P.3d 922, 928-29 (Utah 2003).
- **Virginia**: Pfizer, Inc. v. Jones, 272 S.E.2d 43, 44 (Va. 1980).

[4] Although called "dictum" in In re Certified Questions, 358 N.W.2d 873, 877 (Mich. 1984), Michigan courts uniformly follow the Rule. E.g., Mowery v. Crittenton Hospital, 400 N.W.2d 633, 637 (Mich. App. 1986); Knight v. St. Jude Medical, 2011 WL 1230819, at *10 (Mag. W.D. Mich. Jan. 11, 2011), adopted, 2011 WL 1230815 (W.D. Mich. March 31, 2011).

- **Washington**: Washington State Physicians Insurance Exchange & Association v. Fisons Corp., 858 P.2d 1054, 1061 (Wash. 1993).
- **Wyoming**: Rohde v. Smiths Medical, 165 P.3d 433, 436 n.5 (Wyo. 2007).

A thirty-fifth state high court adopted the Rule in a non-prescription product case. Sliman v. Aluminum Co. of America, 731 P.2d 1267, 1270 (Idaho 1986).

Four states codify the Rule.[5] Intermediate appellate courts in four other states follow it.[6] Federal courts have predicted the Rule's adoption in seven more states (and Puerto Rico).[7] A Vermont trial court has also applied the Rule.[8]

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[5] MISS. CODE ANN. §11-1-63(c)(ii); N.C. GEN. STAT. §99B-5(c); N.J. STAT. ANN. §2A:58C-4; OHIO REV. CODE ANN. §2307.76(c).

[6] **Colorado**: O'Connell v. Biomet, Inc., 250 P.3d 1278, 1281-82 (Colo. App. 2010); **Indiana**: Ortho Pharmaceutical Corp. v. Chapman, 388 N.E.2d 541, 548-59 (Ind. App. 1979); **Louisiana**: Kampmann v. Mason, 921 So.2d 1093, 1094 (La. App. 2006); **New Mexico**: Silva v. SmithKlineBeecham Corp., 2013 WL 4516160, at *2-3 (N.M. App. Feb. 7, 2013); Serna v. Roche Laboratories, 684 P.2d 1187, 1189 (N.M. App. 1984).

[7] **Iowa**: Petty v. United States, 740 F.2d 1428, 1440 (8th Cir. 1984); **Maine**: Violette v. Smith & Nephew Dyonics, Inc., 62 F.3d 8, 13 (1st Cir. 1995); **New Hampshire**: Brochu v. Ortho Pharmaceutical Corp., 642 F.2d 652, 656 (1st Cir. 1981); **North Carolina**: Salmon v. Parke, Davis & Co., 520 F.2d 1359, 1362 (4th Cir. 1975); **North Dakota**: Ehlis v. Shire Richwood, Inc., 367 F.3d 1013, 1017 (8th Cir. 2004); **Puerto Rico**: Guevara v. Dorsey Laboratories, 845 F.2d 364, 366 (1st Cir. 1988); **Rhode Island**: Greaves v. Eli Lilly & Co., 503 F. Appx. 70, 71-72 (2d Cir. 2012); **South Dakota**: McElhaney v. Eli Lilly & Co., 575 F. Supp. 228, 231 (D.S.D. 1983), aff'd, 739 F.2d 340 (8th Cir. 1984); **Wisconsin**: Monson v. AcroMed Corp., 1999 WL 1133273, at *20 (E.D. Wis. May 12, 1999).

[8] Estate of Baker v. University of Vermont, 2005 WL 6280644 (Vt. Super. May 5, 2005).

Only one state has rejected the Rule, largely due to DTC advertising. State ex rel. Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899, 900 (W. Va. 2007). The same court subsequently dismissed Karl with a "but see" citation, observing that "the high degree of federal regulation of prescriptive drug products attenuates the effect product marketing has on a consumer's prescriptive drug purchasing decision," White v. Wyeth, 705 S.E.2d 828, 838 (W. Va. 2010), so Karl could well be reconsidered. Karl has not been read to oust the Rule absent DTC advertising. E.g., Tyree v. Boston Scientific Corp., 56 F. Supp.3d 826, 832-33, (S.D.W. Va. 2014).

Thus, contrary to the rhetoric of the Amended Response (at 12), the Rule – not the court of appeals decision here – represents the "forefront" of legal principles. Virtually every other jurisdiction, and the current Restatement of Torts, agrees.

II. UCATA Does Not Displace The Rule.

The Court of Appeals refused to follow the Rule because of supposed conflict with ARIZ. R.S. §12-2506, abolishing joint and several liability. Watts, 236 Ariz. at 518-19 ¶¶36-38.

No conflict exists. In no way does the Rule "protect[] a prescription drug manufacturer from possible liability for its own actions . . . simply because [the prescribing physician] is also expected to act." Id. ¶35. On the contrary, "when the warning to the prescribing physician is inadequate or misleading, the

prescription drug manufacturer remains liable for the injuries sustained by the patient." Centocor, 372 S.W.3d at 157.

"Proximate cause" is "a natural and continuous sequence, unbroken by any efficient intervening cause, [that] produces an injury, and without which the injury would not have occurred." Robertson v. Sixpence Inns, Inc., 163 Ariz. 539, 546 (1990). Ordinary "but for" causation standards are not "fault" within §12-2506(F)(2). Jimenez v. Sears, Roebuck & Co., 183 Ariz. 399, 403 & n.3 (1995). Superseding cause also survives abolition of joint and several liability. E.g., Gipson v. Kasey, 214 Ariz. 141, 147 ¶¶30-31 (2007).[9]

Whether or not a prescription product is involved, failure to read warnings and prior knowledge of risk may break the causal chain. Gosewisch v. American Honda Motor Co., 153 Ariz. 400, 404 (1987); Davis, 182 Ariz. at 38. So too, can a prescribing physician's identical conduct under the Rule − failure to read a warning, or prior knowledge of what an adequate warning would convey.[10]

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[9] Likewise, the Restatement recognizes but for causation as consistent with contribution among tortfeasors. See Restatement (Second) of Torts §875, comment c (1977) (contribution "consistent with" Restatement §§430-453); Restatement (Second) of Torts §433A, comment i (1965) ("misconduct of two or more tortfeasors . . . may depend upon . . . superseding cause").

[10] Many decisions so hold. E.g., Centocor, 372 S.W.3d at 173 (no causation where plaintiff's "prescribing physicians were aware of the potential risks . . . but chose to prescribe [the drug] in spite of those risks"); Ramirez v. Plough, Inc., 863 P.2d 167, 177 (Cal. 1993) (unread drug warning left "no conceivable causal connection between the representations . . . and plaintiff's injury"); Plummer v. Lederle Laboratories, 819 F.2d 349, 359 (2d Cir. 1987) ("no harm could have been

UCATA does not change that. See Hooks SuperX, Inc. v. McLaughlin, 642 N.E.2d 514, 520 (Ind. 1994) (rejecting contention that comparative fault statute abolished superseding cause). The court of appeals' unique misconstruction of UCATA to eliminate the Rule is erroneous and should be reversed.

III. Direct-To-Consumer Advertising Is No Reason To Displace The Rule.

Finally, unlike the court of appeals here, almost every court to consider DTC advertising as an exception to the Rule has rejected it. Indeed, only last month an Illinois court did so, recognizing that such an exception would "swallow" the well-established Rule. Shah v. Forest Laboratories, Inc., 2015 WL 3396813, at *6 (N.D. Ill. May 26, 2015).[11]

FDA reviews all DTC advertising for truthfulness and "balance." Centocor, 372 S.W.3d at 162. Further, "a physician who prescribed a drug to a patient simply based on the patient's request . . . would likely be liable for malpractice." DiBartolo v. Abbott Laboratories, 914 F. Supp.2d 601, 616 (S.D.N.Y. 2012). Regardless, should misleading DTC advertising actually affect a physician's

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caused by failure to warn of a risk already known"); Johnson v. Medtronic, Inc., 365 S.W.3d 226, 232 (Mo. App. 2012) ("adequacy of the instructions . . . made no difference in the outcome . . . because [the prescriber] did not read those materials").

[11] As to DTC advertising "New Jersey law is in direct conflict with the law of every other jurisdiction." In re Norplant Contraceptive Products Litigation, 215 F. Supp.2d 795, 812 (E.D. Tex. 2002); see Mendez Montes De Oca v. Aventis Pharma, 579 F. Supp.2d 222, 228-29 (D.P.R. 2008) ("this approach has not been

prescription, the Rule would allow manufacturer liability. "[A] physician's conduct" does not "automatically act[] as an intervening cause" . . . [i]f [plaintiffs] can produce sufficient evidence to create a triable issue of the question of causation." Eck v. Parke, Davis & Co., 256 F.3d 1013, 1023 (10th Cir. 2001). Thus, a DTC advertising exception adds nothing – except to advance undeserving cases in which such advertising did not affect the actual prescription decision.

IV. This Case's Statewide Importance And Conflict With Prior Court Of Appeals Decisions Warrants Review By This Court.

As in Jimenez and State Farm Insurance Cos. v. Premier Manufactured Systems, Inc., 217 Ariz. 222 (2007), interpretation of UCATA is too important to leave to the court of appeals.

Furthermore, the decision below conflicts with several prior decisions of that court, all of which followed the Rule. See note 1, supra.

Finally, if rejection of the Rule requires "forefront . . . legal reasoning" (Amended Response, at 12), then **this** Court should decide what is actually "forefront," and what is an unwarranted deviation from a Rule accepted in all but one other jurisdiction.

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widely accepted"); Beale v. Biomet, Inc., 492 F. Supp.2d 1360, 1376 (S.D. Fla. 2007) (rejecting exception; observing that no state has followed New Jersey).

CONCLUSION

PLAC respectfully urges the Court to grant review, adopt the Rule, and reverse the court of appeals' holding that the Legislature *sub silentio* abolished the Rule by eliminating joint and several liability.

Dated: June ____, 2015.

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CERTIFICATE OF COMPLIANCE

1. This certificate of compliance concerns an *amicus curiae* brief and is submitted under Rule 16(b)(4).

2. The undersigned certifies that the Brief of The Product Liability Advisory Council, Inc., as *Amicus Curiae* in Support of Petition for Review to which this Certificate is attached uses a proportional font and type of least 14 points, is doubled spaced, and contains _____ words.

3. The Brief to which this Certificate is attached does not exceed the word limit set forth in Rule 23(g)(2) according to the word count feature of the processing system used to prepare this Brief.

Dated: June ____, 2015.

_____
Wayne D. Struble (#027806)

CERTIFICATE OF SERVICE

I hereby certify that on June ____ , 2015, I caused true and correct copies of the foregoing Brief of Product Liability Advisory Council, Inc. as *Amicus Curiae* in Support of Petition for Review to be served by U.S. Mail, postage prepaid, on all parties through their counsel of record, as follows:

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Western Digitial Corporation

Whirlpool Corporation

Yamaha Motor Corporation, U.S.A.

Yokohama Tire Corporation

Zimmer, Inc.