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IN THE
SUPREME COURT OF MISSOURI

No. SC96151

MIASIA BARRON, *et al.*,
Plaintiff/Respondents

v.

ABBOTT LABORATORIES INC.,
Defendant/Appellant.

Appeal from the Circuit Court of the City of St. Louis
Hon. Steven R. Ohmer

Brief of *Amicus Curiae* Pharmaceutical Research and Manufacturers of America Supporting Defendant/Appellant

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STATEMENT OF AMICUS CURIAE

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association comprised of the leading pharmaceutical research and technology companies. PhRMA members are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. In 2015 alone, PhRMA members invested $58.8 billion in discovering and developing new medicines.[1]

This case presents a question of critical importance to the members of PhRMA: whether a manufacturer may face liability for punitive damages when it has complied with the direction of the Food and Drug Administration ("FDA") to include the most significant form of warning – a so-called "black box" warning – that addresses the very risk alleged in the lawsuit. PhRMA's members have a vital interest in having clear and fair liability standards that account for the rigorous federal regulatory scrutiny to which black box warnings are subjected, and the imposition of punitive damages in the face of a black box warning is both unprecedented and unjust.

[1] *See* PhRMA, *2016 Profile: Biopharmaceutical Research Industry*, http://phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf.

Amicus also adopts the jurisdictional statement as set out in the brief of Appellant Abbott Laboratories Inc.

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STATEMENT OF FACTS

Amicus adopts the Statement of Facts as set out in the brief of Appellant Abbott Laboratories Inc.

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SUMMARY OF THE ARGUMENT

Each prescription medicine that enters the U.S. market has been subject to extensive regulatory scrutiny by the Food and Drug Administration ("FDA"). FDA is tasked with the great responsibility to ensure that each prescription medicine is both safe and effective for its intended uses as set forth in the product's full prescribing information for physicians, generally referred to as a medicine's "labeling." Because a medicine's labeling is the "centerpiece of [its] risk management," *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006), FDA plays a central role in determining and approving the content, format, and placement of risk information in a medicine's label.

"Boxed" warnings, often referred to as "black box" warnings, occupy an exceptional position in FDA's regulatory framework. Black box warnings are reserved for those medicines with particularly serious risks that warrant special highlighting as the first information presented in the labeling. FDA controls the issuance, format, and content of a black box warning, and a manufacturer is not free to alter the content of such a warning without prior FDA approval.

Because punitive damages function to regulate discretionary conduct that is willful in nature, they are uniquely ill-suited in the context of the most strictly regulated and proscribed warnings available for prescription medicines. Under

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Minnesota law, which the parties agree is applicable here, a jury may consider the imposition of punitive damages only where there exists "clear and convincing evidence" that a defendant "show[ed] deliberate disregard for the rights or safety of others." Minn. Stat. § 549.20 subd. 1(a). Where a medicine's label specifically describes a precise risk at issue – here, birth defects – in the most prominent of available warnings, the pharmaceutical manufacturer cannot be said to have shown "deliberate disregard" for the consumer's rights and safety. To hold otherwise would be unjust and run contrary to well-established law across the country.

ARGUMENT

I. Labeling for Prescription Medicines is Subject to Extensive Federal Oversight.

A. FDA Closely Regulates the Content and Format of All Medicine Labeling.

FDA exercises an exclusive gatekeeping function in the U.S. prescription pharmaceutical market. No medicine may enter interstate commerce until, after rigorous scientific scrutiny, FDA determines that the medicine is safe and effective for its proposed uses as set forth in its approved labeling. 21 U.S.C. § 355. In making such a determination, FDA relies on its extensive scientific and policy expertise, considering "not only complex clinical issues related to the use of the product in study populations, but also important and practical public health issues

pertaining to the use of the product in day-to-day clinical practice." *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) ("*2006 FDA Labeling Rule*").

Because "[f]ew if any drugs are completely safe in the sense that they may be taken by all persons in all circumstances without risk," *United States v. Rutherford*, 442 U.S. 544, 555 (1979), prescription medicines must bear "labeling" designed for healthcare providers that accurately and fairly communicates their intended uses and potential risks. *See* 21 U.S.C. § 355(d). FDA strictly regulates both the content and format of prescription pharmaceuticals labeling, dictating mandatory categories, the precise content for each of those categories, and exact formatting standards. *See* 21 C.F.R. §§ 201.56–201.57, 201.80. FDA must approve all labeling before a medicine can be marketed.

Prescription labeling "reflects thorough FDA review of the pertinent scientific evidence and communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively." *2006 FDA Labeling Rule*, 71 Fed. Reg. at 3934. Indeed, FDA's unique expertise and discretion in communicating complex risk and benefit information is well-established: "There are . . . a number of sound reasons why FDA may prefer to limit warnings on product labels. Warnings about dangers with less basis in science or fewer hazards could take attention away from

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those that present confirmed, higher risks . . . . Space on product labeling material is also a factor, and the most effective labels are those with large, bold warnings and a simple design." *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 796 (8th Cir. 2001); *see also* H.R. Rep. No. 86-1861 (1960), as reprinted in 1960 U.S.C.C.A.N. 2833, 2837 (speculative warnings "invit[e] indifference to cautionary statements on packages of substances presenting a real hazard of substantial injury or illness"); *Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices*, 73 Fed. Reg. 49603, 49605–06 (Aug. 22, 2008) (final rule) (unfounded statements in FDA labeling may cause "more important warnings" to be "overshadow[ed]"); *Supplemental Applications in Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices*, 73 Fed. Reg. 2848, 2851 (proposed Jan. 16, 2008) ("Exaggeration of risk, or inclusion of speculative or hypothetical risks, could . . . decrease the usefulness and accessibility of important information by diluting or obscuring it.").

Even after a medicine enters the marketplace, FDA continues to scrutinize its labeling. A manufacturer generally may not introduce new labeling for an existing product prior to obtaining FDA approval through the submission of a "prior approval supplement" ("PAS") to its New Drug Application. *See* 21 C.F.R. § 314.70(b)(4). In some limited circumstances, manufacturers may add or strengthen a warning to reflect "newly acquired information" prior to receiving

FDA approval of the change, *see id.* § 314.70(c)(6)(iii)(A), but must first submit a "changes being effected" ("CBE") supplement to FDA. *See id.* § 314.70(c)(3). Unless FDA finds that "the evidence of a causal association satisfies the standard for inclusion in the labeling," *id* § 314.70(c)(6)(iii)(A), it must retroactively reject the change and require the manufacturer to stop distributing products with the new labeling, *see id.* § 314.70(c)(6)–(7); 73 Fed. Reg. at 2851 ("[Manufacturers] should seek to utilize §§ 314.70(c)(6)(iii)(A) . . . only in situations when there is sufficient evidence of a causal association between the drug . . . and the information sought to be added."). FDA also independently monitors the adequacy of existing labeling. Once it "becomes aware of new safety information" that it "believes should be included in the labeling," FDA must notify the manufacturer, which must either propose a change or explain why no change is warranted. *See* 21 U.S.C. § 355(o)(4)(A)–(C).

Finally, and as especially relevant here, FDA has developed specific procedures and regulations to describe the potential risk of medicines if used by women who are pregnant. Indeed, for more than three decades, FDA had used a methodology whereby a medicine would be assigned a letter associated with particular level of potential fetal risk, referred to as a "pregnancy category." *See, e.g.*, 21 C.F.R. § 201.57(c)(9)(i)(A) (2014); *see also Labeling and Prescription Drug Advertising; Content and Format for Labeling for Human Prescription*

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Drugs, 44 Fed. Reg. 37434, 37451 (1979). Such classifications ranged from Category A, which indicated that studies failed to demonstrate a risk of birth defects, to Category X, which indicated significant risk of fetal injury such that the risks of prescribing the medication to pregnant women outweighed the potential benefits. *See* 21 C.F.R. §§ 201.57(c)(9)(i)(A)(1)-(5) (2014). In each instance, the FDA dictated precise language that must be included based on the applicable pregnancy category. *Id.* The FDA required Depakote to bear "Category D" pregnancy risk, the second highest risk category behind Category X and the highest risk permitted to be prescribed to pregnant women. *See* 21 C.F.R. § 201.57(c)(9)(i)(A)(4) (2014). ("Pregnancy Category D" applicable "[i]f there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential risks . . . .").[2]

[2] In 2014, the FDA overhauled the manner in which it requires companies to describe pregnancy risks for medicines, demonstrating the Agency's continued attention to the careful regulation of medicines which might present the risk of birth defects. *See Content and Format of Labeling for Human Prescription Drug and Biological*

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B. "Black Box" Warnings Are Subject to the Highest Level of Regulatory Scrutiny by FDA.

Medicines that present particularly serious or life-threatening risks or contraindications are subject to even additional regulatory scrutiny. In such cases, FDA may dictate that a medicine's labeling include a "boxed warning." Also called a "black box warning" because the warning is literally contained within a box drawn around it, the boxed warning draws special attention to the most important warnings that health care providers should be aware of when prescribing the medicine. *See* Guidance for Industry, Warnings and Precautions, Contraindications, and Boxed Warning Sections for Labeling for Human Prescription Drugs and Biological Products — Content and Format, at 11-12 (Oct. 2011).

A boxed warning is the strongest warning available under FDA's regulations. *Franzman v. Wyeth LLC*, 451 S.W.3d 676, 681 (Mo. Ct. App. 2014). The "FDA imposes [boxed warnings] in order to convey life-and-death information to the prescribing doctor . . . ." Judith E. Beach, Ph.D. *et al.*, Black Box Warnings in Prescription Drug Labeling: Results of A Survey of 206 Drugs,

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Products; Requirements for Pregnancy and Lactation Labeling, 79 Fed. Reg. 233 (Dec. 4, 2014).

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53 Food & Drug L.J. 403, 410 (1998). "Black box warnings provide physicians with important insights as to how to prescribe a drug that may be associated with serious side effects in a way that maximizes its benefits and minimizes its risks." Black Box Warning Added Concerning Long-Term Use of Depo-Provera Contraceptive Injection, MedWatch, U.S. Food and Drug Administration (November 17, 2004).

In light of the severity of risk implicated, black box warnings are subjected to the most stringent regulatory control. Indeed, FDA maintains exclusive control over the institution and content of black box warnings. *See* 44 Fed. Reg. 37434, 37448 (1979) (boxed warnings may be issued "only when specifically required by FDA"). FDA justifies its complete control over the implementation of black box warnings as preserving the "significance" of boxed warnings and preventing a dilutive effect. *Id.; see also Sulfiting Agents; Labeling in Drugs for Human Use; Warning Statement*, 51 Fed. Reg. 43900, 43902 (December 5, 1986) ("The agency's policy is to use restraint in requiring warnings to be boxed because overuse of the box will ultimately lead to reducing its effect.").

FDA has expressly prohibited manufacturers from adopting black box warnings without prior FDA approval. *See* 44 Fed. Reg. at 37448. Indeed, there are many instances where FDA has declined to allow manufacturers to adopt a boxed warning because the agency believed they were not appropriate. By way of

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only a few examples, in the case of Effexor, FDA forbade Wyeth in January 2002 from adding a black box to address the risk of suicide. *See Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 211 n. 12 (5th Cir. 2008) (explaining that "'[t]o ensure the significance of boxed warnings in drug labeling, they are permitted in labeling only when specifically required by FDA'" (citing 44 Fed. Reg. 37434 at 37448 (June 26, 1979))). Likewise, in the late 1980s, consumers and manufacturers both asked that certain oral contraceptives carry boxed warnings to address the risk of breast cancer, but, "[a]fter reviewing all pertinent studies . . . the FDA panel voted unanimously that 'the existing data do not support a change in the prescribing practices of physicians or the use of oral contraceptives.'" Raymond G. Mullady, Jr., Everything You Needed and Wanted to Know About Black Boxed Warnings, 68 Def. Couns. J. 50, 56 (2001).

In addition to controlling the implementation of black box warnings, FDA also closely regulates the content and format of such warnings. "It is imperative that the prominence of a warning be proportionate to the risk and supported by data. If the seriousness of the information in the boxed warning is exaggerated, practitioners and pharmacists may become skeptical so that their confidence and reliance on such information will diminish." Judith E. Beach, Ph.D. et al., Black Box Warnings in Prescription Drug Labeling: Results of A Survey of 206 Drugs, 53 Food & Drug L.J. 403, 409 (1998).

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To begin, FDA requires each boxed warning to be prominently displayed in a box with bolded text, in a location determined by the agency. 21 C.F.R. § 201.57(a)(4), (c)(1); 21 C.F.R. § 201.80(e). FDA regulations mandate that each boxed warning contains a header with the word "WARNING" in all capital letters and a statement "convey[ing] the general focus of the information in the box." 21 C.F.R. § 201.57(c)(1). A boxed warning must then briefly explain the serious risk implicated by the medicine and "refer to more detailed information in the 'Contraindications' or 'Warnings and Precautions' section, accompanied by the identifying number for the section or subsection containing the detailed information." *Id*. The black box warning must be "based on clinical data," or "serious animal toxicity . . . in the absence of clinical data." *Id*.[3]

[3] Black box warnings subject pharmaceutical manufacturers to additional regulatory restrictions, including limits on the nature of direct-to-consumer advertising that is permissible. 21 C.F.R. §§ 202.1(e)(2)(i).

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II. Punitive Damages Should Not Be Available Where the Manufacturer Has Warned About the Specific Risk at Issue in a Black Box Warning.

A. Punitive Damages Are Inappropriate Under Minnesota Law Absent a "Clear and Convincing" Showing of the Requisite Intent to Do Harm.

It is universally accepted that the threshold for the imposition of punitive damages is substantial. As this Court as expressed, "[t]he test for punitive damages in a product liability case is a strict one. In numerous cases awards of punitive damages have been set aside." *Bhagvandoss v. Beiersdorf, Inc.*, 723 S.W.2d 392, 397 (Mo. 1987). "Punitive damages are 'an extraordinary remedy to be allowed with caution and within narrow limits.'" *Kruszka v. Novartis Pharm. Corp.*, 19 F. Supp. 3d 875, 898 (D. Minn. 2014), as amended (May 19, 2014) (citations omitted).

Under Minnesota law, punitive damages may only be awarded upon "clear and convincing evidence that the acts of the defendant show deliberate disregard for the rights or safety of others." Minn. Stat. § 549.20 subd. 1(a). A defendant has shown such "deliberate disregard" if the defendant "ha[d] knowledge of facts or intentionally disregard[ed] facts that create a high probability of injury to the rights or safety others and deliberately proceed[ed] to act: [(1)] in conscious or intentional disregard of the high degree of probability of injury to the rights or

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safety of others . . . [or (2)] with indifference to the high probability of injury to the rights and safety of others." Minn. Stat. § 549.20 subd. 1(b). "Punitive damages require 'a maliciousness, an intentional or willful failure to inform or act,' and are not proper [in failure-to-warn cases] where the defendant 'actively sought ways to prevent the dangers associated with its product.'" *In re Levaquin Prod. Liab. Litig.*, 700 F.3d 1161, 1169 (8th Cir. 2012) (citing *Beniek v. Textron, Inc.*, 479 N.W.2d 719, 723 (Minn. Ct. App. 1992)).

B. A Specific Warning of the Very Risk Suffered by Plaintiff, Especially When Located in a Black Box, Precludes a Showing that the Manufacturer Acted With Deliberate Disregard.

Punitive damages should not be available in failure-to-warn cases where a plaintiff alleged an injury from a medicine that is specifically and prominently highlighted in the medicine's labeling. In such cases, there can be no possible showing that a manufacturer has acted with such "deliberate disregard" as to warrant the imposition of the ultimate penalty in civil litigation. To the contrary, the presence of the precise risk at issue in the labeling demonstrates as a matter of law that the manufacturer "actively sought ways to prevent the dangers associated with its product." *In re Levaquin*, 700 F.3d at 1169 (citation omitted). And absent clear and convincing evidence that the defendant acted with "deliberate disregard," the question of punitive damages may not be submitted to a jury. *See, e.g.*,

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Donahue v. Phillips Petroleum Co., 866 F.2d 1008, 1013–14 (8th Cir. 1989) (punitive damages not available when facts did not support a finding of requisite intent); *Bhagvandoss*, 723 S.W.2d at 398 ("Here the defendant gave serious attention to the problem and issued a warning. Even if there are grounds for criticizing its procedures, the finding of complete indifference is not supported by the record.").

Indeed, courts across the country have held that punitive damages are not available as a matter of law when the product manufacturer had provided a warning concerning the very injury alleged by the plaintiff. The provision of such a warning precludes a finding that the manufacturer acted with the requisite ill intent and conscious disregard to impose punitive damages. *See, e.g.*, *In re Levaquin*, 700 F.3d at 1169 ("By warning of that risk in its package insert, [the defendant] 'actively sought ways to prevent the dangers associated with its product.'"); *Toole v. McClintock*, 999 F.2d 1430, 1436 (11th Cir. 1993) ("[T]he issue of punitive damages should not go to the jury when a manufacturer took steps to warn plaintiff of the potential danger that injured him; those facts bar a finding that defendant was 'consciously indifferent.'"); *DeLuryea v. Winthrop Labs., a Div. of Sterling Drug, Inc.*, 697 F.2d 222, 230-31 (8th Cir. 1983) (noting that because "warnings were given," "there was no evidence to support punitive damages" and "no indication of malice, wantonness, or reckless indifference to the

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consequences from which malice could be inferred"); *Heston v. Taser Int'l, Inc.*, 431 F. App'x 586, 589 (9th Cir. 2011) (vacating plaintiff's punitive damage award when the defendant "made efforts, albeit insufficiently, to warn its customers about the risks posed by prolonged TASER deployment"); *Dudley v. Bungee Int'l Mfg. Corp.*, 76 F.3d 372 (4th Cir. 1996) ("[S]ince Bungee warned of the potential danger that injured Dudley, it exhibited some care for his safety. Because Bungee exercised some care for the safety of others, an award of punitive damages was not warranted under a failure to warn theory."); *Richards v. Michelin Tire Corp.*, 21 F.3d 1048, 1059 (11th Cir. 1994) ("We have repeatedly held that the issue of punitive damages should not go to the jury when a manufacturer takes steps to warn the plaintiff of the potential danger that injured him; such acts bar a finding of wantonness."); *Jone v. Coleman Corp.*, 183 S.W.3d 600, 610-11 (Mo. App. 2005) ("warning indicate[d] that [defendant] did not willfully or consciously disregard the safety of the consumers"), *transfer denied* (Mo. Feb. 28, 2006); *Salvio v. Amgen Inc.*, No. 2:11-cv-00553, 2012 WL 517446, at *8 (W.D. Pa. Feb. 15, 2012) ("[P]unitive damages are unfounded where a manufacturer-defendant warns of the potential danger that resulted in injury to a plaintiff. . . . [E]ven if Plaintiff could show that '[m]ore could have been done or said,' the Defendants did not display indifference toward the public's safety and therefore punitive damages are not warranted." (citations omitted)); *Tyler Enterprises of Elwood, Inc.*

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v. Skiver, 633 N.E.2d 1331, 1339 (Ill. App. 1994) (noting that while "[t]here is a fact question as to the adequacy of the warnings," the defendant did provide a warning and thus "we cannot conclude that [defendant] acted with a conscious disregard for, or indifference to, the safety of [plaintiff]").

This rule should be especially applicable in the case of a black box warning where the manufacturer has such limited discretion in its content or issuance. Boxed warnings occupy an exceptional position in the FDA's regulatory framework. Indeed, courts overwhelmingly conclude that the existence of a black box in a medicine's labeling precludes any liability at all, let alone liability for punitive damages. *See, e.g., In re Chantix (Varenicline) Products Liability Litigation*, 881 F. Supp. 2d 1333, 1342-43 (N.D. Ala. 2012) (holding that "black box warning [wa]s adequate as a matter of law to warn of the risk of neuropsychiatric complications in patients taking Chantix," even when label did not specify that Chantix should not be used as a first line treatment); *Gentile v. Biogen Idec, Inc.*, No. 11-3500, 2016 WL 4168942, at *7 (Mass. Super. July 28, 2016) (Black box warning was adequate as a matter of law when "the warnings unmistakably conveyed the seriousness of [the plaintiff's injury] and its association with Tysabri treatment."); *Hain v. Johnson & Johnson*, No. ATL-L-8568-11 MT, slip op. (N.J. Super. L.D. June 20, 2013) (holding that boxed warning was adequate as a matter of law and "the single argument that the label did not state

that some studies have associated Levaquin with a higher tendon toxicity compared to other fluoroquinolones . . . does not change the fact that the warning[] regarding tendon injuries was clear, strong, and prominent").

To subject manufacturers to the risk of substantial punitive liability in failure-to-warn cases when a plaintiff suffers the very injury detailed in a black box warning would fail to appreciate the intense regulatory scrutiny devoted the issuance and content of each black box warning. "The purposes of punitive damages are to punish the perpetrator, to deter repeat behavior and to deter others from engaging in similar behavior." *Jensen v. Walsh*, 623 N.W.2d 247, 251 (Minn. 2001). Punishing a manufacturer because of some perceived deficiency in the warnings so carefully scrutinized by FDA would be manifestly unjust and serve no deterrence function.

Indeed, the imposition of punitive damages in this situation would run afoul of the Supreme Court's articulated concerns regarding fair notice and profoundly implicate the "procedural and substantive constitutional limitations" to the award of punitive damages. *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 416 (2003). "Elementary notions of fairness enshrined in our constitutional jurisprudence dictate that a person receive fair notice not only of the conduct that will subject him to punishment, but also of the severity of the penalty that a State may impose." *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 574 (1996). To impose

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punitive damages here – where the company cooperated extensively with the duly-delegated federal agency responsible for the regulation of prescription medicines, where the company and that Agency worked together to craft a comprehensive label using the most prominent risk-communication tools available, and where that warning label addressed the precise risk alleged by plaintiff in the lawsuit – would be irreconcilable with the principles of fairness and due process that the Supreme Court has instructed provide an essential Constitutional check on punitive damages.

CONCLUSION

This Court should recognize that punitive damages are improper as a matter of law where, as here, a medicine's label includes a black box warning that specifically identifies the risk of the very injury suffered by the plaintiff. In such circumstances, there cannot be any finding of deliberate disregard, and any conclusion to the contrary would violate the due process rights of the manufacturer.

February 28, 2017

Respectfully Submitted,

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CERTIFICATION

The undersigned hereby certifies, pursuant to Missouri Supreme Court Rule 84.06(c), that this brief complies with Rule 55.03 and the length limitations contained in Eastern District Rule 360 in that there are 4,671 words in the brief (except the cover, signature block, certificate of service, certificate of compliance, and appendix) according to the word count of the Microsoft Word word-processing system used to prepare the brief.

/s/ Bart C. Sullivan
Bart C. Sullivan
Counsel for Amicus Curiae Pharmaceutical Research and Manufacturers of America and Biotechnology Innovation Organization

Dated: February 28, 2017

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on February 28, 2017, the foregoing was filed electronically with the Clerk of the Court to be served by operation of the court's electronic filing system on all counsel of record.

/s/ Bart C. Sullivan
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