COMMONWEALTH OF MASSACHUSETTS

Supreme Judicial Court

No. SJC-11677

LISA RECKIS AND RICHARD RECKIS,
INDIVIDUALLY AND AS PARENTS AND NATURAL GUARDIANS OF
THEIR MINOR CHILD, SAMANTHA T. RECKIS,

PLAINTIFFS-APPELLEES,

v.

JOHNSON & JOHNSON AND MCNEIL-PPC, INC. D/B/A
MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS,

DEFENDANTS-APPELLANTS.

ON DIRECT APPELLATE REVIEW

BRIEF OF AMICUS CURIAE
AMERICAN ASSOCIATION FOR JUSTICE
IN SUPPORT OF APPELLEES

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STATEMENT OF AMICUS CURIAE

The American Association for Justice, submits this brief in response to this Court's solicitation of amicus curiae briefing on the following questions:

> Whether the plaintiffs' failure to warn claim—i.e., that the label on the defendants' drug should have instructed the consumer to discontinue usage if certain symptoms manifested—was preempted by Federal law on the theory that the proposed warning would have directly conflicted with Federal requirements, making it impossible for the defendants to comply with both Federal law and a State common law duty to warn; whether the award of $63 million in compensatory damages—$50 million for the injured child and $6.5 million for each of her parents—was, as the defendants argue, unsupported by the evidence, essentially punitive, and subject to the due process limits on punitive damages.

The American Association for Justice is a national voluntary bar association whose trial-lawyer members practice in every state, including Massachusetts. American Association for Justice members primarily represent plaintiffs in personal injury, workers compensation, civil rights, and in other civil actions.

The American Association for Justice is committed to protecting the right of individuals to access to the courts to seek redress for wrongful injury. It believes that unwarranted and expansive application of the doctrine of federal preemption jeopardizes that

fundamental right. In addition, the American Association for Justice believes that the measure of damages appropriate to compensate individuals for wrongful injury is best developed under state law, not federal constitutional strictures.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Court has invited amicus curiae briefing on whether federal law pre-empts this failure-to-warn suit in which a jury determined that Defendants Johnson & Johnson and McNeil-PPC, Inc.'s product, non-prescription Children's Motrin, inadequately warned of the risks of SJS and TEN. Pre-emption is ultimately a question of Congress's intent. Here, that intent is crystal clear: Congress clearly and manifestly expressed an intent to preserve product liability suits like Plaintiff Samantha Reckis's in an explicit non-pre-emption clause. That unambiguous text fully answers the pre-emption issue on appeal.

Even assuming that it does not, however, Defendants simply cannot establish conflict pre-emption based on *Wyeth v. Levine*, 555 U.S. 555 (2009). Defendants argue that it was "impossible" for them to comply with both federal and state law because there is "clear evidence" the FDA would not have approved a change to Children's

Motrin's label to warn of the risks of SJS and TEN. The FDA itself, however, concluded, a few years after Plaintiff was injured, that Children's Motrin's label should be strengthened by adding additional warnings of the risks of SJS and TEN. Defendants, therefore, cannot establish by clear evidence that the FDA would have prohibited it from strengthening this labeling to warn of these risks. Defendants' submission to the contrary misconceives the nature of the clear evidence inquiry, and conflates the elements of failure to warn with its pre-emption defense. Properly understood, the clear evidence inquiry requires Defendants to negate any argument that a stronger warning regarding the risks of SJS and TEN should have been given. Defendants cannot make that demanding showing in this case.

In addition to pre-emption, the American Association for Justice also addresses whether this Court should be the first in the nation to interpret the federal constitution as establishing substantive due process limits on the amount of compensatory damages awarded in this case. In its view, this case is not an appropriate vehicle in which to answer this question. Even were the Court to consider it, however, Defendants' suggestion that the jury's award of compensatory damages

somehow violates substantive due process cannot be taken seriously. Defendants' argument that substantive due process limits on punitive damages should be extended also to limit compensatory damages ignores the legal distinctions between these two very different types of damages. What is more, common-law excessiveness review obviates any need for special due process limitations. Defendants' policy arguments to the contrary are simply misguided.

ARGUMENT

I. PLAINTIFFS' FAILURE-TO-WARN SUIT IS NOT PRE-EMPTED BY FEDERAL LAW.

A. Congress Clearly and Manifestly Expressed an Intent to Preserve Failure-to-Warn Suits in an Explicit Non-Pre-emption Clause.

Because "the purpose of Congress is the ultimate touchstone in every pre-emption case," *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (internal quotation marks omitted), this Court must give effect to the unambiguously expressed intent of Congress that federal law governing non-prescription ("OTC") drugs does not supersede state product liability suits. That Congressional intent is clearly stated in the Food & Drug Administration Modernization Act of 1997 ("FDAMA"), § 412(a), Pub. L. 105-115, 111 Stat. 2296. There, Congress enacted a provision that generally prohibits

States from imposing regulations on non-prescription drugs that differ from federal requirements. 21 U.S.C. § 379r(a). At the same time, however, Congress enacted an exception to that provision to shield state product liability laws from pre-emption: "Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." 21 U.S.C. § 379r(e); *see also* 21 U.S.C. § 379s(d) (same). The U.S. Supreme Court has called this "an express non-pre-emption clause," and has suggested that it is the "sort of 'explicit' expression of congressional intent" that fully answers whether Congress intended to supersede certain state tort suits. *Mutual Pharm. Co., Inc. v. Bartlett*, --- U.S. ----, 133 S. Ct. 2466, 2480 (2013).[1]

[1] The Court in *Bartlett* lamented the absence of any explicit expression of congressional intent in the prescription drug context, because this left the Court in the difficult position of having to "divine Congress' will from the duties the statute imposes." 133 S. Ct. at 2480. *Bartlett* invited Congress to resolve the difficult pre-emption questions that arise in this context, by adopting either an express pre-emption clause (as it has in the vaccine context), or an express non-pre-emption clause (as it has in the non-prescription drug context). *Id*. Defendants' suggestion that this express non-pre-emption clause does not definitively resolve whether, in the non-prescription drug context, federal law in any way modifies or otherwise affects state product liability law is especially curious given that the

Cf. Williamson v. Mazda Motor of Am., Inc., --- U.S. ----, 131 S. Ct. 1131, 1141-42 (2011) (Thomas, J., concurring in judgment) ("[T]he savings clause simply means what it says: [the federal safety standard at issue] does not pre-empt state common-law actions.").

The FDA views 21 U.S.C. § 379r(e) similarly. In a proposed rule governing labeling requirements for non-prescription drugs, issued before FDAMA, the FDA announced that the proposed rules would pre-empt additional or different requirements imposed by state laws or regulations, but would not pre-empt "statutory or common law causes of action in tort, based on the format or content of OTC drug product labeling." 62 Fed. Reg. 9024, 9041 (Feb. 27, 1997).[2] After FDAMA was

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Bartlett Court singled out this federal provision precisely because it does just that.

[2] The proposed pre-emption provision, 21 C.F.R. § 201.66(h), read:

> (h) Preemption. No State or local governing entity may establish or continue in effect any law, rule, regulation, or requirement for OTC drug product labeling format or content that is different from, or in addition to, that required by FDA. This paragraph is not intended to preempt statutory or common law causes of action in tort. 62 Fed. Reg. at 9052 (emphasis added).

enacted, the FDA decided that it was not necessary to promulgate the pre-emption provision in that regulation, because § 379r(e) had addressed "the preemptive effect of the proposed OTC drug product labeling requirements on product liability lawsuits" in a way that paralleled the FDA's proposal. 64 Fed. Reg. 13254, 13272 (Mar. 17, 1999). The agency would, therefore, "rely on the terms of the statute in addressing preemption issues." *Id*.

This express non-pre-emption clause should be dispositive of the pre-emption issue in this case. Congress directly addressed the precise question at issue here, and did so unambiguously: Federal law governing OTC drugs, such as Defendants' Children's Motrin, does not pre-empt product liability suits, such as Plaintiffs' failure-to-warn suit. 21 U.S.C. §§ 379r(e), 379s(d); *see Hunt v. McNeil Consumer Healthcare*, 6 F. Supp. 3d 694, 699 (E.D. La. 2014) (holding that this express non-pre-emption clause establishes that Congress did not intend to pre-empt a failure-to-warn claim based on Louisiana law) ("Congress' intent to preserve state-law product liability actions with respect to non-prescription drugs could not be more clear."); *cf. Williamson*, 131 S. Ct.

at 1131 (Thomas, J., concurring in judgment). That should be the end of the matter.

B. Because the FDA Itself Concluded That Children's Motrin's Label Should Be Strengthened by Adding Additional Warnings of the Risks of SJS and TEN, Defendant Cannot Establish by Clear Evidence That the FDA Would Have Prohibited It from Strengthening This Labeling to Warn of These Risks.

Defendants nonetheless argue that this Court should infer a conflict between federal drug law and the failure-to-warn suit at issue in this case. Relying chiefly on *Wyeth v. Levine*, 555 U.S. 555 (2009), Defendants contend it was "impossible" for them to comply with both federal and state law because there is "clear evidence" the FDA would not have approved a change to Children's Motrin's label to warn of SJS and TEN. Assuming for the sake of argument that the express non-pre-emption clause does not definitely foreclose Defendants' pre-emption defense, Defendants still cannot establish conflict pre-emption based on *Wyeth v. Levine*.

As *Wyeth v. Levine* explains, brand-name prescription drug manufacturers are prohibited by federal *and* state law from selling their products with inadequate warnings. A drug is "misbranded" in violation of federal law when its labeling is false or misleading, or does not provide adequate directions for use or

adequate warnings. *Id*. at 566-67. And a drug may similarly violate state tort law if its labeling is inadequate, false, or misleading. *See id*. In fact, most misbranding claims are resolved by federal juries, not the FDA. *Id*. at 570. When a manufacturer establishes by clear evidence that the FDA would not have accepted *any* labeling change to strengthen warnings, then the labeling is adequate under federal law. In this circumstance, a state-law judgment that this same label is misbranded conflicts with federal law and cannot stand. Absent such clear evidence, however, a state law determination that a label is misbranded does not conflict with federal law. That is because it is possible for brand-name manufacturers to update or strengthen labeling to reflect new information or new analysis of old data, and also to comply with any state-law duty to warn. *Id*. at 572; *see id*. at 583 ((Thomas, J., concurring in the judgment) ("federal law does not give drug manufacturers an unconditional right to market their federally approved drug at all times with the precise label initially approved by the FDA"); *see also MacDonald v. Ortho Pharm. Corp.*, 394 Mass. 131, 139-40 (1985).

In *Wyeth*, the prescription drug manufacturer itself could not make such a showing even though it had submitted to the FDA (though not through the "changes being effected" ("CBE") regulation) revised labeling incorporating proposed changes that Wyeth contended would have warned about the risk of arterial exposure from IV-push administration of its drug.[3] *Wyeth*, 555 U.S. at 561-62, 572. The FDA did not address this submission but instructed the manufacturer to "[r]etain verbiage in current label." *Id*. at 562 (citation omitted). The Court in *Wyeth* nevertheless concluded that the fact that the FDA did not approve *this* warning does not mean it would not have approved *any* stronger warning regarding IV-push administration. *Id*. at 572-73 & n.6. Thus, "'clear

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[3] As the Court in *Wyeth* explained, this regulation

> provides that if a manufacturer is changing a label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval. §§ 314.70(c)(6)(iii)(A), (C).

555 U.S. at 568.

evidence' requires a rejection of a label change actually proposed." *Schedin v. Ortho-McNeil-Janssen*, 808 F. Supp. 2d 1125, 1133 (D. Minn. 2011). This conclusion accords with the Supreme Court's understanding that brand-name drug manufacturers, not the FDA, bear primary responsibility for the adequacy of labeling at all times. *Wyeth*, 555 U.S. at 570-71.

As in *Wyeth*, there is no reason to credit Defendants' contention that the FDA would have prevented it from adding a stronger warning regarding the risks of SJS and TEN.[4] Defendants attempt to show clear evidence by comparing testimony of Plaintiff's father, who said he would have stopped giving his daughter Children's Motrin if the label had contained additional warnings regarding the risks of SJS and TEN, to the FDA's response

[4] Although Children's Motrin's marketing status is now non-prescription, it was accepted through the New Drug Application process. *See* FDA Approved Drug Products, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=CHILDREN%27S%20MOTRIN (last visited Nov. 3, 2014). Accordingly, its labeling was reviewed and accepted by the FDA. Manufacturers—not the FDA—have the primary responsibility under federal law to maintain their labeling and update the labeling with new safety information. Brand-name manufacturers may do so through CBE. *Wyeth*, 555 U.S. at 570, 579. Nevertheless, because Children's Motrin is a non-prescription drug, and thus is no longer subject to the requirements of 21 U.S.C. § 353(b)(1), it is subject to 21 U.S.C. §§ 379r(a) and 379r(e).

to a Citizen Petition in 2006, in which the FDA declined to require that manufacturers include a specific reference to SJS on labeling. *See* Appellants' Reply Br. 1-2. In Defendants' view, this shows that Plaintiff's father would have stopped giving his daughter Children's Motrin if, and only if, the label had said the one thing the FDA in 2006 concluded it should not say: Steven Johnson Syndrome. This slanted reading of the trial testimony does not fairly reflect what Plaintiff's father said; nor does it consider what he said in the light most favorable to sustaining the verdict.[5] *See Haddad v. Wal-Mart Stores, Inc. (No. 1)*, 455 Mass. 91, 94 n.5 (2009). Equally problematic, Defendants' comparison misconceives the clear evidence inquiry and inappropriately seeks to limit Defendants' "demanding" burden of establishing impossibility pre-emption. *Wyeth*, 555 U.S. at 573.

As discussed, the clear evidence test requires Defendants to negate *any* argument that a stronger warning regarding the risks of SJS and TEN should have been given. *See id*. at 571 ("[A]bsent clear evidence

[5] In fact, Plaintiff's father testified that he had never heard of SJS or TEN and "had no idea that they were life-threatening diseases." Appellees' Br. 15 (citing A.8916).

that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements."). Defendants cannot make that demanding showing here, because about two years after Plaintiff was injured by Children's Motrin, the FDA, in an interim response to a Citizen Petition filed by concerned physicians, indicated that it had "directed manufacturers to make labeling changes to ibuprofen and other non-steroidal anti-inflammatory drugs that include additional warnings regarding the risks of SJS and TEN." FDA Letter to New York Medical College (Preliminary Response to Citizen Petition), at 1 (Aug. 5, 2005).[6] And a year later, in its final response to the Citizen Petition, the FDA reaffirmed this conclusion. FDA Letter to New York Medical College (Final Response to Citizen Petition), at 8-9 (June 22, 2006).[7] It further clarified in 2006 that, although manufacturers are not required to include references to SJS in OTC ibuprofen labels, they should add easily identifiable references to the

[6] *Available at* http://www.regulations.gov/#!documentDetail;D=FDA-2005-P-0130-0003.

[7] *Available at* http://www.regulations.gov/#!documentDetail;D=FDA-2005-P-0130-0010.

symptoms associated with SJS and TEN under the "allergy alert" subheading (such as skin reddening, rash, and blisters); and they should warn that consumers should stop taking the drug and seek medical help right away if an allergic reaction occurs. *See id*. Accordingly, federal district courts have concluded that failure-to-warn suits alleging that ibuprofen labeling inadequately warned of the risks of SJS and TEN are not pre-empted. *Hunt*, 6 F. Supp. 3d at 700-02; *Newman v. McNeil Consumer Healthcare*, No. 10-CV-01541, 2012 WL 39793, at *6-*12 (N.D. Ill. Jan. 9, 2012); *Wolfe v. McNeil-PPC, Inc.*, 773 F. Supp. 2d 561, 568-69 (E.D. Pa. 2011).

Defendants resist that straightforward application of the clear evidence rule and instead focus on whether the FDA would have approved any of the warnings which Plaintiff's father testified would have led him to stop administering the drug. *See* Appellants' Reply Br. 1. These warnings, according to Defendants, differed from the warnings suggested by plaintiffs in other failure-to-warn suits found not to be pre-empted. Appellants' Br. 27 n.9 (calling *Hunt*, *Newman*, and *Wolfe* "inapposite" for this reason). The pre-emption defense, however, requires Defendants to demonstrate that there is clear evidence that the FDA would not have approved any

labeling change. It does not require Plaintiffs to prove which, if any, additional warning the FDA would have allowed. *See Wyeth*, 555 U.S. at 565.

Defendants' approach to pre-emption erroneously conflates the elements of failure to warn with its pre-emption defense. These are distinct inquiries, with different burdens. To establish her tort claim, Plaintiff was required to show that the inadequate label was the cause of her injuries. *See MacDonald*, 394 Mass. at 142. Plaintiff's father's testimony established that a stronger warning would have helped Plaintiff, because he would not have given her a third dose. This is an issue of fact for the jury. *See id*. What is more, the jury verdict in this case established only that Motrin's warning was "insufficient." *See Wyeth*, 555 U.S. at 565 (so characterizing the Vermont jury's verdict). It did not "mandate" a particular warning. *See id*.

To establish pre-emption, by contrast, Defendants must show that the FDA would have rejected any stronger warning proposed to it. *Id*. at 571. This is an issue of law for the court. In this circumstance, clear evidence that the FDA would not have approved a change to Children's Motrin's label to warn of the risks of SJS and TEN is absent *because* the FDA actually determined

that ibuprofen labeling should be strengthened to warn of the risks of SJS and TEN. That the FDA concluded this is best accomplished through a description of symptoms associated with the onset of SJS and TEN rather than by specific reference to SJS does not alter this conclusion. There is simply no basis to infer a clear and manifest intent of Congress to grant Defendants immunity from this tort suit, and to deprive Plaintiff of any compensation for her substantial injuries.

Contrary to Defendants' recounting, Plaintiff's father was asked how he would have reacted to the very language the FDA concluded in 2005 and 2006 should be added to Children's Motrin's label. For example, he was asked if would have stopped administering Children's Motrin if he had been warned that certain symptoms, such as skin reddening, rash, and blisters, were a sign of a "life-threatening disease" or "Steven Johnson Syndrome." A.8924-25. Defendants' quibble with the precise wording of this questioning borders on the silly. Defendants appear to be suggesting that the use of the term "Steven Johnson Syndrome" in this questioning triggered pre-emption. Defendants thus fault Plaintiffs for mentioning "life-threatening disease" (a phrase never addressed by the FDA in its response to the Citizen Petition) or

"Steven Johnson Syndrome" (a medical term the FDA declined to require on the label)—as if pre-emption here rises or falls on the mere incantation of these phrases.[8] As already discussed, these questions were relevant to causation, not pre-emption.[9] And insofar as causation is concerned, the issue was not whether Plaintiff's father would have stopped administering the drug if skin reddening, rashes, and blisters were a sign of: skin reddening, rashes, and blisters. The relevant question was whether a warning that told Plaintiff's father that skin reddening, rashes, and blisters were a sign of a *serious ailment* would have changed his behavior. The question merely described symptoms that the FDA and jury understood were associated with the onset of SJS and TEN, because that was the serious ailment at issue.

[8] As discussed above, *Wyeth* did not find pre-emption despite a manufacturer's proposal to change the label, which the FDA never specifically addressed. That the FDA did not address whether Children's Motrin's label should include a reference to life-threatening disease similarly cannot support pre-emption.

[9] Again, because a plaintiff seeking to prove failure to warn is not required to establish what an adequate warning would look like, and because a jury's judgment that a manufacturer is liable for failure to warn establishes only that a label is inadequate, this testimony should not be read as evidence that the jury has made a judgment that any particular label is adequate.

Plaintiff's father's answer—Yes—supported causation. What supported the legal conclusion of non-pre-emption, by contrast, was the fact that the FDA itself determined that the label needed to be updated to warn of the risks of SJS and TEN.

* * *

Impossibility pre-emption is a demanding defense because "respect for the States as 'independent sovereigns in our federal system' leads us to assume that 'Congress does not cavalierly pre-empt state-law causes of action.'" *Wyeth*, 555 U.S. at 565-66 n.3 (quoting *Lohr*, 518 U.S. at 485); *see generally Nw. Cent. Pipeline Corp. v. State Corp. Comm'n*, 489 U.S. 493, 515 (1989) ("conflict-pre-emption analysis must be applied sensitively in this area, so as to prevent the diminution of the role Congress reserved to the States while at the same time preserving the federal role"). Its demands should be particularly weighty here, given the longstanding co-existence of state tort liability and federal drug-safety law, which requires courts to presume that state law is not pre-empted; and given that pre-emption would leave injured persons such as Plaintiff without a remedy. *Bruesewitz v. Wyeth LLC*, --- U.S. ----, 131 S. Ct. 1068, 1080 (2011) (recognizing

the Court's longstanding "doubt that Congress would quietly preempt product-liability claims without providing a federal substitute").

Defendants cannot satisfy this stringent test in this case. They can readily comply with both state and federal law obligations not to sell Children's Motrin with inadequate labeling. Defendants' belief that it was the clear and manifest purpose of Congress to wipe out longstanding product-liability suits for failure to warn therefore cannot be credited—especially given Congress's unambiguous conclusion to the contrary, made explicit in an express non-pre-emption clause.

II. THERE IS NO LEGITIMATE CONSTITUTIONAL REASON TO DISTURB THE JURY'S AWARD OF COMPENSATORY DAMAGES.

This Court has also invited *amici* to address the question "whether the award of $63 million in compensatory damages . . . was, as the defendants argue, unsupported by the evidence, essentially punitive, and subject to the due process limits on punitive damages." Plaintiffs have persuasively marshalled the record evidence supporting the jury's award. Appellees' Br. 38-47. The American Association for Justice respectfully submits that the award is not punitive and should not be subject to the due process limits on punitive damages.

In Massachusetts, and in every state, courts exercise the common-law authority to review damage awards for excessiveness. *See Honda Motor Co., Ltd. v. Oberg*, 512 U.S. 415, 425-26 (1994) (citing this Court's decision in *Coffin v. Coffin*, 4 Mass. 1, 41 (1808)). But no court has held that an award of compensatory damages is subject to federal due process limits as well. *TXO Prod. Corp. v. Alliance Res. Corp.*, 509 U.S. 443, 471 (1993) (Scalia, J., concurring) ("[N]o one would claim (or at least no one has yet claimed) that a substantively correct determination of . . . reasonableness of compensatory damages is a federal constitutional right."). This Court should not venture into that uncharted territory in this case.

A. This Case Is Not an Appropriate Vehicle for This Court to Consider Due Process Limits on Compensatory Damages.

1. The compensatory damages award in this case is not a "de facto punitive damages award."

Defendants contend that the jury in this case "used its verdict not merely to redistribute wealth but to punish, transforming the verdict into an unauthorized de facto punitive damages award." Appellants' Br. 53. There is, however, no indication that the jury did so.

The trial court instructed the jury explicitly that they were not to award damages for the purpose of punishing the Defendants. Mem. of Decision & Court Order on Defendants' Mot. for Remittitur (hereinafter "Remittitur Order") 4-5. Defendants do not suggest that the trial court's instructions were erroneous, nor do they point to any admissible evidence that might suggest that the jury was motivated by a desire to punish, rather than the desire to compensate a horribly injured child and her family. Indeed, Defendants quote one juror's statement to a newspaper reporter that her own feeling was that Defendant, as "a Fortune 50 company" could afford to compensate the Reckis family.[10]

[10] Defendants asked the trial court to consider Boston Globe articles containing information from various jurors that might impeach the verdict in this case. In a decision dated March 18, 2013, the trial court "addressed and denied the defendants' request for a post-verdict voir dire and now declines to revisit the issue." Court Order 4 n.3. Defendants nevertheless have inserted into their merits brief the juror's statement quoted in the article—"they're a Fortune 50 company; this is chicken feed to them." Appellants' Br. 52. The American Association for Justice points out that in the immediately preceding sentence, that juror "said she felt a need to order Johnson & Johnson to pay a large sum *that could help compensate the Reckis family* for their struggle." Zachary T. Sampson, "For Jurors, Child's Motrin Case May Have a Lasting Impact," *Boston Globe*, Feb. 16, 2013 (emphasis added).

Nor does counsel's mention of Defendants' sales and revenue figures during closing argument transform an award of compensatory damages into a "de facto punitive damages award." Defendants themselves claim that the size of the award and references to Defendants' wealth indicate that the jury acted out of passion and prejudice against large or wealthy corporations, rather than to punish Defendants. Appellants' Br. 51-52. Defendants did not object to Plaintiffs' counsel's closing argument and the trial court itself did not observe any appeal to passion or prejudice. Remittitur Order 9 n.11.

Even if Defendants were correct that the jury acted out of bias, the size of the award would not warrant review under constitutional due process standards. As Defendants acknowledge, the "passion or prejudice" standard is the common-law standard for judicial review of jury awards for excessiveness under Massachusetts law. Appellants' Br. 51 (citing *Bartley v. Phillips*, 317 Mass. 35, 41 (1944)). Defendants received the benefit of common-law excessiveness review in this case. As the U.S. Supreme Court has pointed out, review of a jury's award in the exercise of common law authority is more restrictive than "than the outer limit allowed by due process," and so "precedes and should obviate any

application of the constitutional standard." *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 502 (2008).

Defendants give very little attention in their merits brief, and none in their reply brief, to their argument that a large compensatory damages award should be subject to the due process limits of punitive damages. Nor did Defendants raise the issue to the court below. For that reason alone, this Court should not undertake a constitutional analysis of the jury's verdict.

2. The lump sum verdict requested by Defendants precludes the Court from imposing a mathematical limit on general damages.

Defendants do not define for this Court the specific limit on compensatory damages they would have this Court apply under the due process clause. They do suggest, however, that a proper limit might be based on the ratio between general damages for pain and suffering and proven damages for medical expenses. *See* Appellants' Br. 48-49 ("The pain and suffering award here, which is sixty times Samantha's past medical expenses, is not reasonably related to her injuries."); *Id*. at 54 (The "stipulated sum for past medical expenses is one-sixtieth of the total" award.); *Id*. at 46 (Medical

expenses "through January 2013 totaled $811,372.25—one-sixtieth of the jury's award.").

Even if this Court were persuaded that due process requires some maximum ratio of general damages to past medical expenses, the award in this case does not permit such a calculation.[11] First, the award of $50 million included not only damages for pain and suffering, but also the jury's award for future medical expenses over Samantha's expected lifespan of 60 years as well as her lost income for that period of time. Defendants did not seek a verdict form that broke damages into specific categories, but specifically asked the trial court to ask the jury for lump sum awards for Samantha and each of her parents. Remittitur Order 5 n.5. Second, the amount of past medical expenses which Defendants proffer as representing the value of Samantha's injury, $811,372.25, was not a finding by the jury. It was a stipulation by the parties that greatly understates the cost of Samantha's injuries because it does not include

[11] Defendants cite *Mejias-Quiros v. Maxxam Property Corp.*, 108 F.3d 425, 428 (1st Cir. 1997), where the court ruled that plaintiff could recover no more than $4,000 in medical costs for injuries in a fight. Appellants' Br. 46. At the same time, however, the court upheld an award for pain and suffering of $200,000, a ratio of 50 to 1.

her treatment at Shriners Hospital, which did not charge the Reckis family. *Id*. 20 & n.8. Thus any due process ratio cannot be applied in this case because neither the numerator nor the denominator is knowable. This case is therefore a poor vehicle to consider such a limit on compensatory damages.

B. The Basis for Substantive Due Process Limits on Punitive Damages Does Not Apply to Compensatory Damages.

1. The U.S. Supreme Court has imposed limits on punitive damages because they function as quasi criminal punishments imposed without the due process protections afforded to criminal accuseds.

Defendants contend that large compensatory damage awards should be "subject to the constitutional limits established in *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996), *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), and *Labonte* [*v. Hutchins & Wheeler*, 424 Mass. 813], at 826-827." Appellants' Br. 53. However, the U.S. Supreme Court made clear in those decisions that due process limits are appropriate for punitive damages precisely because they are fundamentally different from compensatory damages.

The U.S. Supreme Court has consistently referred to punitive damages as "quasi-criminal," and as "private fines," intended to punish the defendant. *Cooper Indus.,*

Inc. v. Leatherman Tool Grp., Inc., 532 U.S. 424, 432 (2001). *See also Gertz v. Robert Welch, Inc.*, 418 U.S. 323, 350 (1974) ("[Punitive damages] are not compensation for injury. Instead, they are private fines levied by civil juries to punish reprehensible conduct and to deter its future occurrence."). Jurors assess punitive damages based on "the enormity of [the] offence rather than the measure of compensation to the plaintiff." *Exxon Shipping Co.*, 554 U.S. at 492 (quoting *Day v. Woodworth*, 54 U.S. (13 How.) 363, 371 (1852)). As this Court has stated, punitive damages serve to vindicate "the Commonwealth's legitimate interests in condemnation and deterrence." *Aleo v. SLB Toys USA, Inc.*, 466 Mass. 398, 420-21 (2013) (citing *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 568 (1996)).

The Court in *State Farm Auto. Ins., Co. v. Campbell*, 538 U.S. 408 (2003) began its analysis by underlining that distinction:

> [I]n our judicial system compensatory and punitive damages, although usually awarded at the same time by the same decisionmaker, serve different purposes. Compensatory damages "are intended to redress the concrete loss that the plaintiff has suffered by reason of the defendant's wrongful conduct." By contrast, punitive damages serve a broader function;

> they are aimed at deterrence and retribution. . . "to further a State's legitimate interests in punishing unlawful conduct and deterring its repetition."

Id. at 416 (internal citations omitted). This Court has likewise recognized this fundamental difference.

Yet, the Court in *State Farm* observed, although punitive damages "serve the same purposes as criminal penalties, defendants subjected to punitive damages in civil cases have not been accorded the protections applicable in a criminal proceeding." *Id*. at 417. The Court noted in particular the constitutional protections against excessive punishments, including, "the Eighth Amendment's prohibition against excessive fines and cruel and unusual punishments applicable to the States." *Cooper Indust., Inc.*, 532 U.S. at 433-34 (citing *Coker v. Georgia*, 433 U.S. 584, 592 (1977) (sentence of death as excessive punishment for rape); *Solem v. Helm*, 463 U.S. 277, 279, 303 (1983) (life imprisonment without parole "significantly disproportionate" punishment for nonviolent crimes); *United States v. Bajakajian*, 524 U.S. 321, 324 (1998) (punitive forfeiture for violating reporting requirement held "grossly disproportional" to the gravity of the offense)). Because punitive damages are *intended* to function as criminal penalties, the

Court concluded that "[t]he Due Process Clause of the Fourteenth Amendment prohibits the imposition of grossly excessive or arbitrary *punishments* on a tortfeasor." *State Farm*, 538 U.S. at 416 (emphasis added).

In short, the U.S. Supreme Court has determined that added constitutional limits on punitive damages are warranted by the principles that support such safeguards in contests between an individual and the state. *Id.* at 428 ("Great care must be taken to avoid use of the civil process to assess criminal penalties that can be imposed only after the heightened protections of a criminal trial have been observed.").

By contrast, compensatory damages are not awarded to vindicate the state's own interest. They are a matter between an individual wrongdoer and an individual victim. In that contest, the individual is entitled to be made whole. If the defendant is liable, justice and public policy require that the wrongdoer, not the victim, bear the risk of uncertainty as to the measure of damages.

2. A plaintiff who has been injured by the misconduct of a defendant is entitled to a jury determination of the amount of compensatory damages.

The U.S. Supreme Court has held that the jury's assessment of punitive damages is not a finding of fact, but "an expression of its moral condemnation." *Cooper Indus., Inc.*, 532 U.S. at 432. Judicial review that takes away all or part of the jury's award of punitive damages does not violate the plaintiff's right to have the jury make that determination. As the Court explained:

> Unlike the measure of actual damages suffered, which presents a question of historical or predictive fact, *see, e.g.*, [*St. Louis, I.M. & S.R. Co. v. Craft*, 237 U.S. 648 (1915)], the level of punitive damages is not really a 'fact' 'tried' by the jury." *Gasperini v. Center for Humanities, Inc.*, 518 U.S. 415, 459, 116 S. Ct. 2211, 135 L.Ed.2d 659 (1996) (SCALIA, J., dissenting). Because the jury's award of punitive damages does not constitute a finding of "fact," appellate review of the district court's determination that an award is consistent with due process does not implicate the Seventh Amendment concerns.

Id. at 437.[12]

[12] Significantly, in *St. Louis, Iron Mountain & Southern Railway, Co. v. Craft*, 237 U.S. 648 (1915) (cited by the Court in *Cooper Industries, Inc.*) the U.S. Supreme Court rejected the railroad's argument that "the

In support of their argument for closer scrutiny of "de facto" punitive damages, Defendants cite two cases in which appellate courts set aside compensatory awards as punitive and entered judgment for an amount the court deemed proper. Appellants' Br. 53. Neither case supports such judicial intrusion into the jury's domain under Massachusetts law. *Davis v. Pena*, 222 So. 2d 595 (La. Ct. App. 1969), is an idiosyncratic case in which the reviewing court held that awards of $5,450 to each of two bar waitresses slightly injured in a shoving incident with the bar owner were excessive; the court entered judgment for $833 and $547 instead. *Id*. at 598. The court's authority to intrude into an area generally entrusted to the jury's wide discretion was not the due process guarantee, but rather Louisiana's unique constitutional provision that vests appellate courts with jurisdiction over both law and facts. La. Const. art. 5, § 10. That provision, "resulting from

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award of $5,000 as damages for pain and suffering, even though extreme, for so short a period as approximately thirty minutes, is excessive." *Craft*, 237 U.S. at 661. That award for pain and suffering, if expanded to one year, would exceed $87 million. *Compare Toczko v. Armentano*, 341 Mass. 474, 482 (1960) (holding that award of $7,500 for 85 minutes of pain was not so excessive as to require a new trial). That award amounts to about $43 million per year in 1960 dollars.

Louisiana's history as a civilian jurisdiction, has been interpreted as giving an appellate court the power to decide factual issues de novo." *Rosell v. Esco*, 549 So. 2d 840, 844 n.2 (La. 1989). *Davis* is not persuasive on "closer" judicial scrutiny of damage awards by the courts of Massachusetts, whose constitution provides that the "right to a trial by jury . . . shall be held sacred." M.G.L.A. Const. pt. 1, art. 15.

New York State Department of Correction Services v. State Division of Human Rights, 207 A.D.2d 587(N.Y. App. Div. 1994), likewise provides no persuasive authority for more stringent review of jury awards. In that case, the Appellate Division reduced an award of $10,000 rendered by an administrative law judge for plaintiff's mental anguish caused by employment discrimination to $2,500. *Id*. at 587. There was no jury in the case and the right to trial by jury was not implicated.

By contrast a jury's determination of the proper compensation for personal injury, including compensation for pain and suffering, has long been deemed the province of the jury. As the U.S. Supreme Court observed:

> "[T]he common law rule as it existed at the time of the adoption of the Constitution" was that "in cases where the amount of damages was uncertain[,] their assessment was a

> matter so peculiarly within the province of the jury that the Court should not alter it."

Feltner v. Columbia Pictures Television, Inc., 523 U.S. 340, 353 (1998) (quoting *Dimick v. Schiedt*, 293 U.S. 474, 480 (1935)). Nor does uncertainty in the measure of such damages warrant judicial intervention:

> When the suit is brought by the party for personal injuries, there cannot be any fixed measure of compensation for the pain and anguish of body and mind, nor for the permanent injury to health and constitution, but the result must be left to turn mainly upon the good sense and deliberate judgment of the tribunal assigned by law to ascertain what is a just compensation for the injuries inflicted.

The City of Panama, 101 U.S. 453, 464 (1879). *See also Barry v. Edmunds*, 116 U.S. 550, 565 (1886) ("nothing is better settled than [the principle] that, in . . . actions for torts where no precise rule of law fixes the recoverable damages, it is the peculiar function of the jury to determine the amount by the verdict".)

3. Unlike punitive damages, compensatory damages are limited by the court's instructions.

Another reason the U.S. Supreme Court imposed substantive due process limits on punitive damage awards is the danger of arbitrary deprivations where juries are

instructed to punish the defendant but are told "little more than . . . to do what they think is best" and are "left largely to themselves" in assessing the amount of punishment. *Browning-Ferris Indus. of Vermont, Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 281 (1989) (Brennan, J., concurring); *see also TXO Prod., Corp.*, 509 U.S. at 474 (O'Connor, J., dissenting) (noting that in punitive damage instructions "juries sometimes receive only vague and amorphous guidance"). The Court in *State Farm,* recognized that punitive damage instructions "typically leave the jury with wide discretion in choosing amounts." 538 U.S. at 417, while providing only "[v]ague instructions . . . [that]. . . do little to aid the decisionmaker." *Id*. at 418. The Court therefore reaffirmed and refined its judicial review of punitive damage awards in light of the three "guideposts" it had adopted in *BMW*. 538 U.S. at 418-28.

This case does not present a problem of vague instructions. The jury was expressly instructed not to punish the Defendants, based on wealth or any other reason, and was afforded no discretion to do so. Instead, the trial court,

> instructed the jurors that the purpose of awarding damages is to compensate an injured person for the

> losses incurred because of another's conduct and that the purpose of damages is not to reward the plaintiffs or punish the defendants. Moreover, this court explicitly instructed the jury not to be swayed by sympathy and not to engage in guesswork or speculation.

Remittitur Order 4-5.

These instructions gave the jury the appropriate guidance in their assessment of compensatory damages and protected Defendants from arbitrary awards. Defendants do not contend that the instructions were too vague or gave the jury too little guidance. As one federal district court has pointed out, there are "systematic safeguards" designed to ensure juror compliance with the court's instructions, including probing voir dire, the juror's oath, and clear instructions that the jury is to base their verdict solely on the evidence presented to them. *Shillcutt v. Gagnon*, 602 F. Supp. 1280, 1283 (E.D. Wis. 1985), *aff'd*, 827 F.2d 1155 (7th Cir. 1987). "While not infallible, these checks minimize prejudice without undermining the integrity of the jury system." *Id*. The clear and precise instructions given to the jury in this case do not provide any justification for due process review of the award.

C. Review of Jury Awards Under Common-law Excessiveness Standards Obviates Any Need for Imposing Due Process Limitations.

This Court's jurisprudence regarding judicial review of a jury's award of damages dates to Chief Justice Parson's seminal opinion in *Coffin v. Coffin*, 4 Mass. 1, 43 (1808). Drawing upon the leading cases at common law, Chief Justice Parsons laid down the standard for setting aside a verdict for excessive damages in an action for a personal injury:

> When the damages are so great, that it may be reasonably presumed that the jury, in assessing them, did not exercise a sound discretion, but were influenced by passion, partiality, prejudice, or corruption, the court may set aside the verdict, and send the cause to another jury.

Id.

This Court reaffirmed that standard in *Bartley v. Phillips*, 317 Mass. 35, 44 (1944). On appellate review of a denial of a new trial motion, "an award of damages must stand unless to make it [sic] or permit it to stand was an abuse of discretion on the part of the court below, amounting to an error of law." *Mirageas v. Mass. Bay Transp. Auth.*, 391 Mass. 815, 822 (1984) (quoting *Bartley*, 317 Mass. at 43). Such an error of law requires a finding that '"no conscientious judge, acting

intelligently, could honestly' have permitted the verdict to stand." *Giblin v. Lincoln Park Amusement Co.*, 318 Mass. 781, 781 (1945) (internal quotation omitted). An appellate court shall not substitute its judgment for that of the trial judge, who saw the witnesses. *Baudanza v. Comcast of Mass., Inc.*, 454 Mass. 622, 630 (2009). Nevertheless, if "the damages awarded were greatly disproportionate to the injury proven or represented a miscarriage of justice, an appellate court [may] find an abuse of discretion in the judge's refusal to grant a new trial." *doCanto v. Ametek, Inc.*, 367 Mass. 776, 787 (1975).

Defendants received the benefit of the trial court's review of the award using that standard. The court found the jury's assessment of damages "thoughtful and reasonable." Remittitur Order 6 & n.6. That determination is reviewable by this Court for abuse of discretion. Defendants offer very little justification for adoption of an additional, constitutional, standard of review.

Defendants nevertheless would prefer "closer judicial review of large compensatory damage awards," using a standard that eliminates "extreme deference to the jury." Appellants' Br. 54. Their proposed standard

appears to be that "a general damages award must 'relate reasonably' to the plaintiff's injuries." *Id*. at 48 (quoting *Labonte v. Hutchins & Wheeler*, 424 Mass. 813, 825 (1997)). *See also id*. at 48-49 ("The pain and suffering award here . . . is not reasonably related to her injuries."); *id*. at 52 (characterizing the verdict as "disproportionate to reasonable compensatory damages"); and *id*. at 55 (Award "is orders of magnitude greater than reasonable compensation for plaintiffs' damages.").

However, the due process limit on punitive damages that Defendants would apply to large compensatory awards does not look to a "reasonable relationship." The outer limit imposed by the Due Process Clause prohibits "grossly excessive" punitive damages. *BMW,* 517 U.S. at 562; *Cooper Indus., Inc.*, 532 U.S. at 433-34; *State Farm*, 538 U.S. at 417. *Aleo*, 466 Mass. at 412-13.

In *Labonte*, reviewing an award for emotional distress damages unaccompanied by physical injury, this Court looked to "whether the size of the verdict so shocks the sense of justice as to compel the conclusion that the jury was influenced by partiality, prejudice, mistake or corruption." 424 Mass. at 825. This Court deemed that standard to be similar to that of "grossly

and manifestly excessive." *Id*. at n.16. Defendants have provided no justification for imposing a federal limit on damages that is substantially the same as the common-law standard under Massachusetts law.

D. Defendants' Policy Arguments Do Not Support Application of Federal Due Process Limits to Large Compensatory Damage Awards.

In seeking "closer judicial review of large compensatory damage awards," Defendants urge this Court to consider a list of societal concerns that are more properly addressed to the legislative branch: "Excessive damages, whether punitive or compensatory, can lead to higher consumer prices, layoffs, plant closures, product withdrawals, and less research and innovation," as well as higher insurance costs. Appellants' Br. 52-53. However, the works cited by Defendant in support of this argument are particularly inapposite and should not persuade this Court to impose further restrictions on jury awards of compensatory damages.

At the outset, many of the works cited deal solely with punitive damages. *See*, *e.g.*, W. Kip Viscusi, *The Social Costs of Punitive Damages Against Corporations in Environmental and Safety Torts*, 87 Geo. L.J. 285, 311, 314 (Nov. 1998).

Others simply do not support Defendants' proposition. For example, in W. Kip Viscusi, *et al.*, *A Statistical Profile of Pharmaceutical Industry Liability, 1976-1989*, 24 Seton Hall L. Rev. 1418 (1994), the authors found that research and development actually increased steadily during the period, despite a sharp increase in the number of product liability lawsuits and size of awards in 1982-1986. *Id.* at 1432-34. More importantly, they state, "Although liability awards may be greatest for innovative firms, liability also affects innovation by encouraging safety innovation and discouraging risky product innovations." *Id.* at 1432. Similarly, in Rochelle Chodock, *et al.*, *'Insuring' The Continued Solvency of Pharmaceutical Companies in the Face of Product Liability Class Actions*, 40 Tort Trial & Ins. Prac. L.J. 997 (2005), the authors stated that drug companies' insurance costs were rising, not because of excessive jury awards, but because "the FDA has almost completely abdicated its role in ensuring the safety of drugs already on the market, in favor of new-drug reviews," leading to the injuries and deaths of thousands Americans. *Id.* at 1004-05. Patrick A. Gaughan, *The Economics of Punitive Damages*, *at* http://economatrix.com/the-economics-of-punitive-

damages.php (last visited Nov. 7, 2014), does not address excessive awards at all. The author states that "drug prices are higher in a more active litigation environment" like the United States compared to Canada.

Finally, some of the assertions relied upon by Defendants have dubious factual support. For example, Defendants cite (White House) Council of Economic Advisers, *Who Pays for Tort Liability Claims?: An Economic Analysis of the U.S. Tort Liability System* 12 (2002). The cited passage claims that "concerns over liability have resulted in withdrawals of certain medicines, and halted the production of vaccines such as smallpox and DPT." However, as the CDC explains, small pox vaccines are not in production because "the disease is now eradicated after a successful worldwide vaccination program. . . . The last naturally occurring case in the world was in Somalia in 1977. . . . [R]outine vaccination against smallpox among the general public was stopped because it was no longer necessary for prevention." Centers for Disease Control & Prevention, *Smallpox Disease Overview*, http://www.bt.cdc.gov/agent/smallpox/overview/disease-facts.asp (last visited Nov. 3, 2014).

As for DPT, which is no longer available in the United States due to serious vaccine injuries, liability concerns have prompted the development of safer versions. Centers for Disease Control & Prevention, *Vaccine Information Statements* (2007), http://www.cdc.gov/vaccines/hcp/vis/vis-statements/dtap.html. *See also* World Health Organization, *Information Sheet: Observed Rate of Vaccine Reactions* (2014), *available at* http://www.who.int/vaccine_safety/initiative/tools/DTP_vaccine_rates_information_sheet.pdf (noting that five different formulations are in use globally).

In sum, this Court should not take the unprecedented step of applying the federal constitutional limits on punitive damages to large compensatory awards. Because the jury returned a lump sum verdict combining damages for lost future income, future medical costs, and pain and suffering, this case is a poor vehicle for the Court to consider proposed limits on pain and suffering damages. In addition, the U.S. Supreme Court imposed due process limits on punitive damages precisely because they are fundamentally different from compensatory damages. Punitive damages are quasi-criminal penalties designed to vindicate the state's interest in punishing

reprehensible misconduct; compensatory damages are intended to make the wrongly injured individual whole and that individual has a right to a jury determination of their amount. Moreover, due process of "grossly excessive" damages is unnecessary where the common-law standard applied by Massachusetts courts is at least as protective of defendants. Finally, the policy arguments raised in favor of constitutional limits on compensatory damages are unpersuasive.

CONCLUSION

For the foregoing reasons, this Court should affirm the judgment of the court below.

Date: November 11, 2014 Respectfully submitted,

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CERTIFICATION OF COMPLIANCE

I certify that this brief complies with the rules of court that pertain to the filing of briefs, including, but not limited to: Mass. R.A.P. 16(a)(6) (pertinent findings or memoranda of decision); Mass. R.A.P. 16(e) (references to the record); Mass. R.A.P. 16(f) (reproduction of statutes, rules, regulations); Mass. R.A.P. 16(h) (length of briefs); Mass. R.A.P. 18 (appendix to the briefs); and Mass. R.A.P. 20(form of briefs, appendices, and other papers).

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AFFIDAVIT OF MAILING

Pursuant to Mass. R. A. P. 13(a)(ii), I hereby attest that the foregoing Brief for the American Association for Justice as Amicus Curiae was mailed on November 11, 2014 within the time fixed for filing.

_____
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CERTIFICATE OF SERVICE

I hereby certify under the penalties of perjury that on November 11, 2014, two copies of the foregoing Brief for the American Association for Justice as Amicus Curiae was served on the following counsel of record by United Parcel Service 2nd Day Delivery:

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