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*,
MASSACHUSETTS ACADEMY OF TRIAL ATTORNEYS
IN SUPPORT OF APPELLEES

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INTEREST OF AMICUS CURIAE

The Massachusetts Academy of Trial Attorneys (Academy), amicus curiae, is a voluntary, non-profit, state-wide professional association of attorneys in the Commonwealth. The Academy's purpose is to uphold and defend the Constitutions of the United States and the Commonwealth of Massachusetts; to promote the administration of justice; to uphold the honor of the legal profession; to apply the knowledge and experience of its members so as to promote the public good; to reform the law where justice so requires; to advance the cause of those who seek redress for injury to person or property; steadfastly to resist efforts to curtail the rights of injured individuals; and to help them enforce their rights through the courts and other tribunals in all areas of law. The Academy has been actively addressing various areas of tort law in the courts and the Legislature of the Commonwealth since 1975.

The Academy submits that the jurisprudence of the issues under review, correctly understood, calls for affirming the judgment of the trial court.

STATEMENT OF THE ISSUES

I. Federal law articulates a non-preemption provision of product liability law in any State for the liability of one selling over-the-counter drugs. A jury found for the plaintiffs in their claim that these defendants had violated Massachusetts law by failing to warn of risks that inhered in one such drug. Was that claim preempted?

II. A jury awarded a small child $50 million for her catastrophic injuries and $6.5 million to each of her parents for their concomitant losses. The trial judge issued a detailed and reasoned denial of the request for a new trial or remittitur. Did he thereby abuse his ample discretion?

STATEMENT OF THE CASE

The Academy accepts the defendants' statement of the course of proceedings and disposition below.

STATEMENT OF THE FACTS

The Academy accepts the plaintiffs' statement of the facts as supplemented in the Academy's arguments.

SUMMARY OF THE ARGUMENT

I. THE FAILURE-TO-WARN CLAIMS UNDER MASSACHUSETTS PRODUCT LIABILITY LAW WERE NOT PREEMPTED

As the pharmaceutical industry has developed, the players have become experts in marketing as well as science (pp. 10-14). Their advertising budgets promote their products' use to physicians and consumers (pp. 10-14). While there has been an

explosion in marketing both prescription and over-the-counter drugs to consumers, the industry has labored to restrict its tort liability (pp. 10-14).

The manufacturers' first success in that regard was the "learned intermediary" rule (pp. 12-18). It relieved them of liability to the consumer when a prescribing physician had been adequately apprised of the risks of a drug (pp. 12-18). More recently, the industry's efforts have focused on the area of federal preemption, as manufacturers have tried to use the labyrinth of federal regulations to insulate themselves from State law (p. 13). The arguments range from suggestions that governmental approval of a warning establishes its adequacy to contentions that State tort law is preempted because it is "impossible" to comply with both State and federal law (pp. 14-27).

The impossibility claim here is based on the representation that the defendants could not have strengthened their warning to inform parents that symptoms such as redness, rash, or blistering might be a serious side effect requiring immediate medical attention (pp. 18-27). This defense calls for "clear evidence" that the FDA would not have approved such a warning (pp. 18-27). The sole basis for this theory

is that in response to a Citizen's Petition the FDA declined to require the defendants to identify technical names (SJS or TEN), as opposed to the symptoms, though the agency did require a stronger warning (pp. 23-27).

Many courts have rejected this argument; none have accepted it (p. 25). Courts have noted that the FDA did not refuse a warning of the type advocated by these plaintiffs, but instead merely decided that inserting the acronyms on the label would not be helpful (pp. 20-25). The lack of an affirmative requirement to warn of a life-threatening rash does not equate to a rejection of that language (pp. 20-25). Furthermore, the additional warnings were requested by a citizen group and not by the defendants-manufacturers, a significant distinction given the manufacturers' superior knowledge and expertise (pp. 23-24). These defendants have failed to identify a single drug for which the FDA has rejected a manufacturer's request to add a warning based on an adequate scientific foundation.

Deciding that the trial court erred in finding that the defendants had not proved by "clear evidence" that the FDA would have rejected a stronger warning

would be bad law and worse policy (pp. 7-14). Massachusetts consumers are entitled to the full benefit of the manufacturers' knowledge about the dangers and side effects of their products (pp. 7-10). There is no reason to expand the scope of preemption to protect a manufacturer who is in violation of Massachusetts law (pp. 7-10).

II. THE TRIAL JUDGE PROPERLY DENIED DEFENDANTS' MOTION FOR NEW TRIAL OR REMITTITUR

Previously a healthy girl, Samantha Reckis was seven years old when injured. She and her parents have suffered truly horrific injuries at the hands of the defendants (pp. 27-30). They have been through a tremendous ordeal and their future is bleak (pp. 27-30). Samantha's injury was so grave that following the verdict the defendants conceded its severity (pp. 27-30).

A fully-informed and properly-instructed jury are responsible for calculating a compensatory award for the plaintiffs' injury (pp. 29-30). On this record, the pain and suffering components of the case alone warrant an award well into the eight-figure range (pp. 29-30).

A motion for a new trial or remittitur based on an excessive award rests in the discretion of the judge and is reviewed for abuse of that discretion (pp. 30-31). This award, involving an assessment of intangible and subjective losses as it does, was for the jury to calculate (pp. 31-34).

Defendants' comparison cases of high awards are distinguishable (pp. 31-34). Each involved injuries not nearly as horrific as those suffered by these plaintiffs (pp. 31-34). None involved this magnitude of physical injuries, length of time that the victim had to endure them, nor the emotional toll that these plaintiffs have had (pp. 31-34).

Compensation for the harm to Samantha and her parents was for the jury (pp. 34-37). Since 1808 the law of the Commonwealth has "devolved th[at] power on a jury, as a matter of sentiment and feeling, to be exercised by them according to their sound discretion, duly weighing all the circumstances of the case, and considering the state, degree, quality, trade, or profession, as well of the party injured, as of him who did the injury" (pp. 34-37). There is no formula for a jury to calculate an award; many of its components are entirely subjective (pp. 34-37). The

suggestion that that award was punitive implicitly acknowledges that "[u]nearned suffering is redemptive" (p. 37).

ARGUMENT

I. THE FAILURE-TO-WARN CLAIMS UNDER MASSACHUSETTS PRODUCT LIABILITY LAW WERE NOT PREEMPTED

A. INTRODUCTION

This is a drug case. Defendants ask this Court to apply federal preemption in a way that no other court has: to immunize them from liability for failing to provide consumers with critical warnings about the use of children's Motrin, warnings that would have prevented unspeakable injuries.

This case is but one more battle in the ongoing conflict between the rights of consumers -- and in particular, young children –- and the pharmaceutical industry. On this record, the defendants' immunity claim is without foundation and this Court should reject that claim.

B. HISTORY AND POLICY OF MASSACHUSETTS TORT LAW

1. BACKGROUND

That one is responsible for the cost of injury caused to another has long been a cardinal rule of law. Rodgers v. Boynton, 315 Mass. 279, 280 (1943).

As social relationships have become more complex and technology more sophisticated, courts have expanded the law to reflect those changes. See, e.g., Irwin v. Ware, 392 Mass. 745, 756-757 (1984) (as foreseeable harm changes with evolving societal expectations, so too change the "special relationships" upon which the law imposes liability); George v. Jordan Marsh Co., 359 Mass. 244, 250 (1971) (recognizing a cause of action not fitting pre-existing legal niches). See also, RESTATEMENT (SECOND) OF TORTS, § 402A, cmt. b (1965).

A breach of warranty theory derives "from the tort of deceit." Ora F. Harris and Alphonse M. Squillante, Warranty Law in Tort and Contract Actions 14, citing Karl N. Llewellyn, On Warranty of Quality, and Society, 36 Colum. L. Rev. 699, 712 (1936). What we now know to be products liability claims were originally confined to cases dealing with poison, explosives, and the like. Thomas v. Winchester, 6 N.Y. 397 (1852).

Cardozo brought this area of the law into the modern era holding that if "the nature of a thing is such that it is reasonably certain to place life and limb in peril when negligently made, it is then a thing of danger." MacPherson v. Buick Motor Co., 217

N.Y. 382, 389 (1916). But the actions of the manufacturer, through its "knowledge that the thing will be used...without new tests," were still part of the equation. Id.

It took another thirty years to realize that public policy should "discourage the marketing of products having defects that are a menace to the public" and to hold manufacturers accountable. One is now held to "absolute liability when an article that he has placed on the market" causes injury; "[i]t is needlessly circuitous to make negligence the basis of recovery and impose what is in reality liability without negligence." Escola v. Coca Cola Bottling Co. of Fresno, 24 Cal.2d 453, 461-463 (1944) (Traynor, J. concurring).

A manufacturer's liability for causing harm with its defective products is now a cornerstone of the law. The duty to warn of those dangers is grounded in a manufacturer's superior knowledge. See Vassallo v. Baxter Health Care, Inc., 428 Mass. 1, 23 (1998) (manufacturer held to standard of an expert). As consumer expectations evolved, this principle became embodied in the theory of strict liability for a defective product expressed in RESTATEMENT (SECOND) OF

TORTS, § 402A. Massachusetts never adopted that section, choosing instead to provide an equivalent remedy as a matter of implied warranty law under G.L. c. 106, § 2-314(2)(c). Haglund v. Philip Morris, Inc., 446 Mass. 741, 746 (2006); Back v. The Wickes Corp., 375 Mass. 633, 639-640 (1978).

With that superior knowledge, however, comes a corresponding responsibility to distribute it with the product to the consumers so as to protect them from injury; an essential part of a manufacturer's obligation is to provide adequate instructions and warnings to the product's end user. H.P. Hood & Sons v. Ford Motor Co., 370 Mass. 69, 75 (1976). Indeed, a failure to provide such warning is a breach of the implied warranty of merchantability that accompanies all products. Evans v. Lorillard Tobacco Co., 465 Mass. 411, 439 (2013); Wolfe v. Ford Motor Co., 6 Mass. App. Ct. 346, 358 (1978).

2. THE PHARMACEUTICAL INDUSTRY

Drug companies have long availed themselves of the "unavoidably unsafe" exception to RESTATEMENT § 402A in cmt. k, permitting a manufacturer to avoid strict liability for harm caused by products which, "in the

present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." The same characteristics that make a product unavoidably unsafe often form the foundation for a failure-to-warn claim.

This principle is perhaps nowhere more important than in the field of pharmaceuticals; adequate instructions and warnings are critical to the safe use of those products. While many drugs bestow tremendous benefits on society by preventing and curing diseases or simply making life more enjoyable, they also have an eerie and uncanny ability to harm, sicken, maim, disfigure, or even kill.

Because of this enormous potential for harm, the manufacturer's duty to warn of dangers that inhere in their wares is a vital feature of pharmaceutical law. See, e.g., Garside v. Osco Drug, Inc., 976 F.2d 77 (1st Cir. 1992); MacDonald v. Ortho Pharmaceutical, Inc., 394 Mass. 131 (1985). In fact, questions surrounding the risks in the use of drugs were deemed so important that this area now has its own RESTATEMENT comment. RESTATEMENT (SECOND) OF TORTS, § 402A, cmt. k (1965); see also, RESTATEMENT (THIRD) OF TORTS, PRODUCT LIABILITY, § 2(c) (1998).

But imposing liability on defective-product manufacturers is not only in recognition of their superior knowledge; it is a burden that corresponds with their ability to prevent harm through proper design and adequate warnings. Courts and commentators have recognized that public policy favors such liability in at least two respects, both grounded in the realities of the marketplace.

First, exposure to liability induces manufacturers to devote their ample resources to safe design, adequate testing, and improved practices. Second, manufacturers are in the best position to bear the cost of injuries caused by products from whose sales they profit. See RESTATEMENT (THIRD) OF TORTS, PRODUCT LIABILITY § 2, cmt. a (1998).

Another attempt by this industry to reduce its liability is the "learned intermediary" rule. It states that a manufacturer's duty to warn of potential adverse effects of prescription medications runs only to the prescribing physician. See, e.g., Garside, supra, at 80. In describing the rule, this Court has said "that physicians have the duty to inform themselves about the drug and warn their patients as

they deem necessary." Cottam v. CVS Pharmacy, 436 Mass. 316, 321 (2002).

Thus, a manufacturer can discharge its duty by properly warning the doctors who, in turn, are responsible for forwarding that information to the consumers. Although some exceptions arose for drugs where patient choice was a prominent feature — most notably certain birth control products, see, e.g., McDonald v. Ortho Pharmaceutical Corp., supra, at 137-39 — this rule has continued to insulate manufacturers in many cases. See, e.g., Cottam at 321.

Sadly, the industry has continued to affect changes in basic tenets of tort law, tenets once thought unassailable. Converting federal preemption from a tool to a weapon, the industry has brought about an anti-consumer sea change in the law. Consumers of generic drugs have already become a casualty of this war, as federal law now holds generic drug manufacturers have no liability for inadequate warnings on their products. See, e.g., Mutual Pharmaceutical Co., Inc. v. Bartlett, --- U.S. ---, 133 S. Ct. 2466 (2013) (patient who suffered from use of generic drug could not recover on theory that drug should not have been sold given federal law

prohibiting manufacturer from changing warnings); PLIVA, Inc. v. Mensing, --- U.S. ---, 131 S. Ct. 2567 (2011) (federal law preempts state law from imposing duty to change label on generic drug); see also, Bruesewitz v. Wyeth LLC, --- U.S. ---, 131 S. Ct. 1068 (2011) (National Childhood Vaccine Injury Act preempts design defect claims); Riegel v. Medtronic, Inc., 552 U.S. 312 (2008) (FDA's premarket approval process preempts State product liability law). Increasingly, these preemption decisions leave injured consumers with no remedy. See PLIVA, 131 S. Ct. at 2581.

C. PREEMPTION: HISTORY, POLICY, AND LIMITATIONS

1. THE SAVINGS CLAUSE IN THE STATUTE PRESERVES PRODUCT LIABILITY CLAIMS UNDER STATE LAW

As the scope of the federal government's regulatory authority has expanded, so too preemption has become increasingly important in product liability law. Many decisions have focused on whether and to what extent federal law prohibits consumers from asserting claims against manufacturers under State law. See Wyeth v. Levine, 555 U.S. 555 (2009); Altria Group, Inc. v. Good, 555 U.S. 70, 77 (2008).

But there is a presumption against preemption, and manufacturers bear a heavy burden before securing its protection. Altria Group, Inc. v. Good, 555 U.S. 70, 77 (2008) (quoting Rice v. Sante Fe Elevator Corp., 331 U.S. 218, 230 (1947)). A State's interests in its citizens' health and welfare are not superseded by federal law absent clear Congressional purpose. Rice, 331 U.S. at 230; see also Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005). Preemption is disfavored and State law will control absent a conflict with federal law. Sawash v. Suburban Welders Supply Co., Inc., 407 Mass. 311, 314-15 (1990); Arthur D. Little, Inc. v. Commissioner of Health & Hospitals of Cambridge, 395 Mass. 535 (1985).

Parties may claim either express preemption, where a federal statute specifically prohibits State regulation, or implied conflict (or field) preemption where there is a question whether one can simultaneously operate under federal and State law. The latter version asks whether Congress intended to "occupy the field," thus removing the area from the reach of State regulation. Sawash, 407 Mass. at 314-15.

The federal statute here is in the Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 321 et seq. It expressly preserves a consumer's right to bring product liability claims under State law. Section 379r(e) of the FDCA states:

> **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) (emphasis added). Nothing means precisely that: no thing.

The non-preemption provision in § 379r(e) is abundantly clear. It reflects a congressional intent to allow consumers to bring product liability suits under State law –- there simply is no "direct and positive conflict" with the FDCA here. See Wyeth, 555 U.S. at 567; see also Evans, 465 Mass. at 431 n.11 (2013) (noting "liability of any person under product liability law of any State" preserved despite FDA authority over tobacco).

This portion of 21 U.S.C. § 379r(e), and the absence of a similar "carve-out" for prescription drugs, is consistent with the development of pharmaceutical liability. As discussed above, manufacturers of prescription drugs have traditionally

avoided liability by invoking the learned intermediary rule. Unlike § 379r(e), 21 U.S.C. § 355 which regulates prescription drugs does not provide an express savings clause. This omission stands in stark contrast to § 379r(e) and its unequivocal statement ("Nothing in this section...") that State product liability law controls these matters. See Hunt v. McNeil Consumer Healthcare, 6 F.Supp.3d 694, 699 (E.D.La. 2014) ("Congress' intent to preserve state-law product liability actions with respect to non-prescription drugs could not be more clear.").

The Food and Drug Administration (FDA) also weighed in on the scope of preemption when it proposed its OTC labeling requirements in light of the FDA Modernization Act: "As proposed, the scope of this preemption would exclude 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.

While the FDA Modernization Act does preempt State laws regulating non-prescription drugs under § 379a, it specifically carves out from preemption product liability under State laws. Mills v. Warner-

Lambert Co., 581 F.Supp.2d 772, 780 (E.D.Tex., 2008); see 21 U.S.C. § 379a; 21 U.S.C. § 379r.

The distinction between § 355 and § 379 in Title 21 reflects Congress's choice as to how these different types of drugs end up with consumers. While prescription-drug users interact with health care providers who are familiar with the product and owe a duty to warn of the risks of the drug's use, consumers purchase non-prescription drugs with no professional advice. Without a learned intermediary, non-prescription drug users must rely on the manufacturers to instruct them on the proper use of the product and warn of possible dangers attendant to that use.

2. THE DEFENDANTS HAVE FAILED TO CARRY THEIR HEAVY BURDEN OF ESTABLISHING CONFLICT PREEMPTION

a. The Defendants Failed to Establish Impossibility By Clear Evidence

There are exceptions to preserving product liability claims under State law. One is when there is a direct conflict between State and federal law such that a manufacturer could not possibly comply with both. See Roberts v. Southwestern Bell Mobile Sys., Inc., 429 Mass. 478, 491 (1999). But this is not that case.

Referred to as “impossibility” preemption, it is a difficult and demanding defense to maintain. “Absent clear evidence that the FDA would not have approved a change to [a drug’s label, the Supreme Court] will not conclude that it was impossible for [a manufacturer] to comply with both federal and state requirements.” Wyeth v. Levine, 555 U.S. at 570-71. This defense carries an “exacting burden” on these defendants, one that cannot be met “simply by showing that the FDA approved the label which was in place at the time of the plaintiff’s injury.” Wolfe v. McNeil-PPC, Inc., 773 F.Supp.2d 561, 568 (E.D. Pa. 2011), citing Forst v. Smithkline Beecham Corp., 639 F.Supp.2d 948, 953–54 (E.D.Wis. 2009).

Defendants “impossibility” claim hangs by a thin reed. Namely, that the FDA rejected a proposed warning in a Citizens Petition (Petition) for labeling on the defendants’ product and, so the argument goes, that rejection is “clear evidence” of their inability to comply with both State and federal law. A.6360, 6649, 11014. This theory ignores both the content of the Petition and the FDA’s response to it, to say nothing of the growing body of law in this regard.

In February, 2005 a group of health care professionals together with parents whose children had died from ibuprofen-induced TEN petitioned the FDA. They wanted stronger warnings on OTC ibuprofen so as to alert consumers to the risks of life-threatening reactions that might result from using the drug. A.7456-66, 19062-63, 19084.

The FDA agreed. The labeling needed improvement; consumers needed to be warned about the risks of severe skin reactions associated with these products. It then requested that manufacturers include a warning. A.11400.

But the FDA did not, as argued, reject the notion that consumers be warned that the appearance of blistering, rash, or redness might be signs of a fatal disease requiring immediate medical attention. A.10286-87. To the contrary, the government requested that those symptoms be added to the OTC Motrin label. A.11401, 11392-93, 11399, 11400. The only "rejection" was to the proposal that the label include SJS and TEN, something the FDA reasoned (and plaintiffs conceded at trial) would be meaningless and not lead to safer use of the product. A.11014.

Mistaking those facts as "clear evidence" that the FDA would not have approved the language suggested to the jury, defendants posit that the absence of an explicit FDA response to the proposal that the newly-listed symptoms be described as life-threatening is an express rejection of that language. Hardly clear and barely evident, that makes no sense at all; one simply does not follow from the other.

The defendants are to be forgiven for failing to cite any cases supporting their theory that no response to a suggestion is a rejection of it: there are none. Indeed, the converse is true. See, e.g., Motus v. Pfizer, Inc., 127 F.Supp.2d 1085, 1096 (C.D.Cal. 2000) (distinguishing between FDA's failure to require warnings and prohibition against including warnings); Sprietsma v. Mercury Marine, 537 U.S. 51, 63 (2002) ("quite wrong" to treat Coast Guard's decision not to require propeller guards as functional equivalent of prohibiting State from adopting such a regulation [emphasis added]); compare Freightliner Corp. v. Myrick, 514 U.S. 280, 286 (1995) (rejecting argument that the "absence of regulation itself constitutes regulation," where lack of regulation did not result from affirmative decision of officials to

refrain from regulation) with Ray v. Atlantic Richfield Co., 435 U.S. 151, 176-77 (1978) (all authority over the regulated area was centralized in one decision maker, the federal government).

Each court to which these defendants have presented this chimera about the Petition has rejected it out of hand. As noted in Hunt, the FDA did not expressly reject the warnings the plaintiffs advocated, as the agency had requested manufacturers to strengthen their warnings by including the enumerated symptoms. 6 F.Supp.3d at 700-01; accord, Newman v. McNeil Consumer Healthcare, No. 10–CV–1541, 2012 WL 39793, at *6–11 (N.D. Ill. 2012); Wolfe v. McNeil-PPC, Inc., 773 F.Supp.2d 561, 568-569 (E.D. Pa. 2011) (FDA's refusal to require addition of technical disease names to OTC labeling was not "clear evidence" that FDA would have rejected manufacturer's proposal to add warning about rash or blistering); Johnson & Johnson v. Superior Court, 192 Cal.App.4th 757, 766-767 (2011), (FDA's response to Petition supports argument that FDA felt stronger warnings about symptoms of SJS and TEN were necessary); Lofton v. McNeil Consumer & Specialty Pharm., 682 F.Supp.2d 662, 677–78 (N.D. Tex. 2010) (court cannot say as a matter

of law that FDA would have not have changed label to require warning of early symptoms of SJS and TEN).

As in Hunt, the plaintiffs maintained that the defendants' label should have warned against redness, rash, or blistering and the need to seek medical attention for those reactions. Plaintiffs did not claim that the labeling should have identified SJS or TEN, agreeing with the FDA that those terms would be meaningless to most consumers. A.10084, 10179-80, 10622.[1]

Rather, this trial was about the absence of warnings that Samantha's symptoms -- redness, rash, blisters -- required stopping the medication and getting medical attention. Cf. Robinson v. McNeil Consumer Healthcare, 615 F.3d 861, 873 (7th Cir. 2010) (plaintiff's claim was that labeling should have included reference to SJS and TEN). Those changes, in essence, are what the FDA later suggested and the defendants implemented. A.11400.

[1] In closing argument counsel said "to be clear...we don't take the position that [the label] had to have the technical names of the diseases... because most people don't know what they are." A.10413. "What matters is that when you get something that's over the counter and that it's for children, you get a heads-up...Be alert folks, watch for X, Y, and Z, redness, rash, blisters, because these could be signs, early signs of a fatal disease." A.10286-87.

b. A Partial Rejection of the Petition is Not Clear Evidence that the FDA Would Have Rejected the Updated Warnings Put to the Jury

Defendants overlook the critical fact that the FDA's partial rejection of the requested labeling change was in response to a request from a third-party, not the defendants-manufacturers. Moreover, they simultaneously disparage the source of the request as "plaintiff's side litigation experts",[2] Brief of Petitioner-Appellant at 10, while suggesting that the request would carry the same weight with the FDA as one they -- the defendants -- might submit. This is pretzel logic; it cannot be the law.

Surely the source of a proposal and accompanying data in a manufacturer's possession are important in assessing the FDA's reaction. If the defendants had requested this label change, they would have submitted data and research with their request, including information to which they alone have access. And had

[2] Candidly, this characterization of the petitioners reflects the defendants' overriding concern for their profit margin while disrespecting the clinical experience and scientific research that led these well-respected professionals to opine that consumers needed additional information about the fatal consequences of a common and seemingly innocuous product.

they sought strengthening of their warnings and been rebuffed by the FDA, then their argument for "clear evidence" of impossibility might be more convincing. But as the Wyeth Court noted, "the very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a warning pursuant to the CBE regulation is difficult to accept -- neither [the manufacturer] nor the United States has identified a case in which the FDA has done so." 555 U.S. at 570.

Nor have these defendants identified such a case. See, e.g., Schedin v. Ortho-McNeil-Janssen Pharmaceuticals, Inc., 808 F.Supp.2d 1125, 1133 (D. Minn. 2011), rev'd in part on other grounds sub nom. In re Levaquin Prod. Liab. Litigation, 700 F.3d 1161 (8th Cir. 2012) (FDA's failure to require a label change based on a Citizen's Petition not supported by the manufacturer does not constitute clear evidence that the FDA would have rejected a label change proposed or supported by manufacturer).

Indeed, few courts have found "clear evidence" that the FDA would not have approved a label change. Those cases are limited to situations where the proposed warning was unsupported by the evidence.

See, e.g., In re Fosamax Prod. Liab. Litigation, 951 F.Supp.2d 695, 698-699 (D.N.J. 2013) (rejecting proposal to add language to Precautions section where scientific evidence did not support addition); Dobbs v. Wyeth Pharmaceutical, 797 F.Supp.2d 1264, 1272-1280 (W.D.Okla. 2011) (discussing lack of scientific basis for causal connection between Effexor and suicide in decedent's age group).

These situations are inapposite to this case. Here the connection between ibuprofen and SJS/TEN is scientifically well-established; it is identified in the labeling for prescription Motrin. The FDA's partial rejection of the Petition was based on a concern for consumer confusion, not on a lack of scientific evidence.

Like the Wyeth defendant who did "not argue that it attempted to give the kind of warning required by the Vermont jury but was prohibited from doing so by the FDA," 555 U.S. at 572, these defendants do not claim that they requested strengthening their warnings. Had they done so, no doubt the FDA would have approved the request. Unlike the few cases where the FDA's rejection of a manufacturer's proposal constituted clear evidence of impossibility, the

scientific evidence about the dangers of ibuprofen supports the proposed warning.

The FDA had approved a "Medication Guide" which warned of life threatening skin reactions and was distributed with defendants' prescription version of Motrin. A.11399. If the government approved a warning accompanying a prescription drug, does it make any sense at all that the FDA would reject such a warning for OTC drugs?

Similarly, the defendants had always provided physicians with specific references to SJS and TEN as part of the labeling for prescription Motrin. A.9491-92, 9615-16. Thus, it is undisputed that both the symptoms of SJS and TEN and the potential for ibuprofen to cause them is well-supported by scientific evidence, and that that science was known in 2003 when Samantha was given the OTC version of the drug. See Vassallo, 428 Mass. at 20-23 (noting duty to warn extends to risks that were reasonably foreseeable at the time of the sale).

II. THE TRIAL JUDGE PROPERLY DENIED DEFENDANTS' MOTION FOR NEW TRIAL OR REMITTITUR

Previously a healthy girl, Samantha Reckis was seven years old when the defendant's over-the-counter product caused her condition. A.7325-28, 8905-06, 11323-35. The permanent injuries she and her parents sustained were truly horrific: descriptors such as catastrophic and devastating only begin to tell the tale. Indeed, the life that Samantha and her parents have had to endure and will endure might well leave most people hopeless.

But these plaintiffs have hope, though the future will not be kind to the Reckis family. The girl is legally blind and is threatened with the loss of her remaining eye. A.2464, 2544-59, 7340, 8730-34, 8733-39, 8750-52, 8740, 9307, 9400, 17060, 18568. With each blink, her inward-facing eyelashes scrape that eye; an eye which has and will go through numerous surgeries as her physicians try to maintain what sight she has. See Respondent-Appellee at 40 (citing record).

She cannot bear children (nor beget grand-children) and should she become pregnant, that condition would likely be her end because of her

inability to maintain the weight necessary to carry a child and her reduced pulmonary function. See A.9024. Her breathing will not improve unless she has a lung transplant, an unlikely event because of her many limitations. See A.8518-22, 8526, 9022, 9024, 17693, 17705, 18502. Her weight and nutritional deficits are not likely to improve due to her damaged taste buds and compromised gastrointestinal tract.

These facts are a constant source of anxiety. A.8512, 9018-19, 12111, 18471, 8518-26, 9027-29, 16741, 17693, 17705. Samantha's life and education have been repeatedly disrupted by medical appointments, including as many as forty surgeries thus far. A.7350-51, 8516-19, 8910, 9016, 9025-26, 16075, 16170. At the time of trial she had a sixty-six year life expectancy and her future is grim to say the least. A.9026-27.

Indeed, her injury was so grave that following the verdict, the defendants conceded that: (1) Samantha's injuries were "severe" (2) that she endured "significant pain and suffering" and (3) that her impaired pulmonary function and blindness were "probably permanent[]." Brief of Petitioner-Appellant

at 48. How does one determine a fair compensation for those injuries?

It is an animating principle of law that a fully-informed and properly-instructed jury are charged with making that calculation. On this record, and given the extent and duration of Samantha's injuries -- physical and emotional -- together with her medical treatment which itself was painful and disruptive, see Respondent-Appellee at 37-41, the pain and suffering components of the case alone warrant an award well into the eight-figure range. Indeed, the jury would have been warranted in concluding that the defendants destroyed the plaintiffs' lives. The award was commensurate with the harms and losses caused by the defendants' breach.

A. STANDARD OF REVIEW

Cases are legion for the proposition that "the allowance of a motion for a new trial based on an inadequate or excessive award of damages, and the direction of an addition or remittitur, rests in the sound discretion of the judge." Loschi v. Mass. Port Auth., 361 Mass. 714, 715 (1972) (citing cases). Indeed, reversal is only appropriate when the award is

"greatly disproportionate to the injury proved...or where it appears to the judicial conscience...that otherwise a miscarriage of justice will result." Id. citing Bartley v. Phillips, 317 Mass. 35, 41 (1944). "Abuse of discretion in granting or refusing a new trial can so seldom be found that actual instances in which this court has set aside the action of the trial judge...are almost nonexistent, and it has repeatedly been stated that occasions when this court can do so are exceedingly rare." Hartman v. Boston Herald-Traveler Corp., 323 Mass. 56, 61 (1948).

An award such as here, involving an assessment of intangible and non-economic losses as it does, was "a matter 'peculiarly within the jury's ken.'" Smith v. Kmart Corp., 177 F.3d 19, 30 (1st Cir. 1999) (citations omitted); accord Velazquez v. Figueroa-Gomez, 996 F.2d 425, 428 (1st Cir. 1993).

B. DEFENDANTS' CASE COMPARISONS DO NOT JUSTIFY DISTURBING THE JURY AWARD

Defendants rely on a line of cases to support their claim that the jury award was too high. Brief of Petitioner-Appellant at 49-50. A close look at each, however, shows that the injuries in those

matters were not as horrific as those suffered by these plaintiffs.

In Gath v. M/A-Com, Inc., 440 Mass. 482 (2003), a jury awarded $14.25 million to a man who sustained brain injuries and paralysis requiring around-the-clock care for life. Id. at 483-484. Both he and Samantha will require extensive future care and treatment, but that is where their similarities end.

At the time of his injury Mr. Gath was twenty-four years older than Samantha was at the time of hers. See Gath, 440 Mass. at 482. He was into middle age when his life changed while she was but a child; she lost most of her childhood and all of her young-adult years. The life tables teach us that Jeff Gath will not have to live with his injuries nearly as long as Samantha will with hers.

Defendants also point to two unpublished opinions: O'Meara v. Argenbright, Inc., 2008 Mass. App. Unpub. LEXIS 112, 2-3 and Mackesy v. Mass. Bay Transp. Auth., 2010 Mass. App. LEXIS Unpub. 155 at 1-5. Preliminarily, these Appeals Court summary dispositions were issued under Rule 1:28. Such a decision typically begins with a warning that it may be "cited for its persuasive value but, because of the

limitations noted above, not for binding precedent." See generally, Hart v. Massanari, 266 F.3d 1155 (9th Cir. 2001) (Kozinski, J.) (as to citing unpublished opinions).

But comparisons between O'Meara, Mackesy, and Samantha's situation are at best unreliable and at worse impossible because of the lack of relative information about the injuries, suffering, and future damages in each. See O'Meara, at 2-3; Mackesy at 1-5. What is clear is that the injured party in Mackesy was older than Samantha as shown by her having a high school transcript and a child. Id.

Finally, defendants offer up another drastic injury case: Rhodes v. AIG Domestic Claims, 461 Mass. 486 (2012). Similarly, the Rhodes plaintiff was a grown woman with a husband and daughter; she too suffered serious injuries requiring extensive care and treatment, both at the time of the accident and ongoing. Id. at 489. Her compensatory award was $7.412 million. Id. at 493. Though we do not know her age, she had a daughter and a husband at the time of the accident, so we do know she was an adult. Id. at 487.

None of the defendants' comparison cases involves the same magnitude of physical injuries, the length of time that the victim had to endure the injuries, nor the emotional toll that Samantha's condition has inflicted on all three plaintiffs. See Brief of Petitioner-Appellant at 49-50.

At bottom, case comparisons can only take a reviewing court so far. As the First Circuit noted, "simply showing that the damage award was generous in comparison to other hand-picked cases is insufficient to warrant relief." Bielunas v. F/V Misty Dawn, Inc., 621 F.3d 72, 82 (2010). The injuries in this record are many and varied; together, they are truly unique. Placing a fair value on the harm to Samantha and her parents was for the jury whose "function [is] to make the difficult and uniquely human judgments that defy codification and that 'buil[d] discretion, equity, and flexibility into a legal system.'" Aleo v. SLB Toys USA, Inc., 466 Mass. 398, 413 (2013) (internal citations omitted).

C. THE AWARD WAS NOT DISPROPORTIONATE TO THE HARM

Little has changed in more than 200 years in the jurisprudence on this issue. "That a verdict may be

set aside for excessive damages, there can be no doubt; and it may be done in two cases: one case is where the law recognizes some fixed rules and principles in measuring the damages, whence it may be known that there is an error in the verdict." Coffin v. Coffin, 4 Mass. 1, 41 (1808) (Parsons, C.J.). Then, as now, this class of cases included contract actions and disputes over liquidated damages.

> The other case includes actions for personal injuries, where no rules are prescribed by law for ascertaining the damages, but from the exorbitancy [sic] of them the Court must conclude that the jury acted from passion, partiality, or corruption -- causes which naturally produce error or injustice. But to enable the Court to draw this conclusion, it is not enough, that in their opinion the damages are too high, or that much less damages would have been a sufficient satisfaction to the plaintiff; for the law has not intrusted [sic] the Court with a discretion to estimate the damages, but has devolved the power on a jury, as a matter of sentiment and feeling, to be exercised by them according to their sound discretion, duly weighing all the circumstances of the case, and considering the state, degree, quality, trade, or profession, as well of the party injured, as of him who did the injury. Judges, therefore, should be very cautious how they overthrow verdicts, given by twelve [people] on their oaths, on the ground of excessive damages.

Id. That is, overturning an award was then as it is now, only appropriate if "in a case where the damages are monstrous and enormous indeed, and such as all

mankind will be ready to exclaim against it at first blush." Id. at 41-42. Not so here.

Fast-forward to today, an overriding theme of the law of torts is "that presumptively there should be recourse for a definite injury to a legitimate interest due to a lack of the prudence or care appropriate to the occasion." Diaz v. Eli Lilly & Co., 364 Mass. 153, 165 (1973).

Lastly, Bartlett v. Mutual Pharmaceutical Co., Inc., 678 F.3d 30 (1st Cir. 2012), rev'd on other grounds, Mutual Pharmaceutical Co., Inc. v. Bartlett, --- U.S. ---, 133 S. Ct. 2466 (2013) reviewed an award to a fifty-year-old TENs victim with a life expectancy of more than thirty years. See Bartlett v. Mutual Pharmaceutical Co., Inc., 760 F.Supp.2d 220, 262 (D.N.H. 2011). Finding a prescription drug was defectively designed, the jury's $21.06 million award broke down thus: $1.25 million for past medical expenses, $2.377 million for future medical expenses, $933,000 for lost wages, and $16.5 million for pain, suffering, and loss of enjoyment of life. Id. at 261. Noting that Bartlett's injuries were "truly horrific," the court concluded that "[t]he outcome of this case, at least on this record, is not surprising or, with

respect to [the drug], patently alarming." Bartlett, 678 F.3d at 43-44. Judgment affirmed.

Nor does the law require a formulaic correlation between special damages and a compensatory award; many components of the award are intangible and subjective. But the defendants nonetheless challenge the amount of the verdict likening it to a punitive award. Perhaps it seems punitive because "[u]nearned suffering is redemptive." Martin Luther King, I Have a Dream, Address at the Lincoln Memorial (Aug. 28, 1963).

In any event, this "prophylactic" factor is important to the law of torts. It does not make a compensatory award penal. See W. Page Keeton, PROSSER AND KEETON ON TORTS, § 4 at 25 (5th ed. 1984) (citing Williams, THE AIMS OF THE LAW OF TORT, 4 Curr. Leg. Prob. 137 (1951)).

In light of the plaintiffs' lot -- a sentence imposed by the defendants' breach -- an objective and emotionally uninvolved fact finder could have properly compensated Samantha with $50 million and $6.5 million to each of her parents. The verdict was neither disproportionate to the injury nor a miscarriage of justice.

CONCLUSION

For these reasons, the Court should affirm the judgment of the trial court.

Respectfully submitted,

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Dated: November 17, 2014

MASS. R. A. P. 16(k) CERTIFICATION

I hereby certify that this brief complies with the rules of Court including but not limited to Mass. R. A. P. 16, 18, and 20.

/s/ Thomas R. Murphy
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CERTIFICATE OF SERVICE

I hereby certify that I served two (2) copies of this brief on counsel of record in this matter by priority mail, postage prepaid, on this 17th day of November, 2014.

/s/ Thomas R. Murphy
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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*, MASSACHUSETTS ACADEMY OF TRIAL ATTORNEYS IN SUPPORT OF APPELLEES

BATEMAN & SLADE, INC. BOSTON, MASSACHUSETTS