No. 15-449

IN THE
# Supreme Court of the United States

JOHNSON & JOHNSON and MCNEIL-PPC, INC.,

*Petitioners*,

v.

LISA RECKIS, RICHARD RECKIS,
AND SAMANTHA T. RECKIS,

*Respondents*.

**On Petition for a Writ of Certiorari to the Supreme Judicial Court of Massachusetts**

## BRIEF IN OPPOSITION


Michael B. Bogdanow
Leo V. Boyle
Bradley M. Henry
Victoria M. Santoro
MEEHAN, BOYLE, BLACK & BOGDANOW, P.C.
Two Center Plaza
Suite 600
Boston, MA 02108
Phone: (617) 523-8300

Robert S. Peck
*Counsel of Record*
CENTER FOR CONSTITUTIONAI LITIGATION, P.C.
777 6th Street, N.W.
Suite 250
Washington, DC 20001
Phone: (202) 944-2874
robert.peck@cclfirm.com

*Counsel for Respondents*

## QUESTION PRESENTED

Whether the Massachusetts Supreme Judicial Court erred when it held, consistently with every court to have answered the question, that Petitioners failed to present clear evidence that, as of 2003, the FDA would have prohibited them from giving plain-language warnings compatible with the FDA's own 2006 requirement that Petitioners warn consumers about symptoms of extremely severe skin reactions but not use the technical names of those reactions?

## TABLE OF CONTENTS

## TABLE OF AUTHORITIES

**Cases**

**Statutes**



**Rules**



**Regulations**

**Other Authorities**

## BRIEF FOR RESPONDENTS IN OPPOSITION

Respondents Lisa, Richard, and Samantha Reckis respectfully request this Court deny the petition for writ of certiorari, seeking review of the decision of the Supreme Judicial Court of Massachusetts here.

In this Petition, a drug manufacturer complains about an adverse verdict after consistent judicial rulings against it under the fact-specific clear-evidence rule for preemption of state causes of action established in *Wyeth v. Levine*, 555 U.S. 555 (2009). The applicable law remains clear, and courts consistently apply it. No conflict exists, not even the manufactured one about interpretation of evidence that Petitioners assert. Simply put, the Petition satisfies none of the criteria this Court utilizes to grant review, and this Court should deny certiorari.

## COUNTERSTATEMENT OF THE FACTS

### A. Underlying Facts.

Samantha Reckis began Thanksgiving weekend 2003 as a happy seven-year-old who "made everyone around her smile." On November 28, she developed a fever and congestion. Her father, Richard Reckis, purchased a bottle of Over The Counter ("OTC") Children's Motrin, read the warnings, administered one dose around 2 p.m. and another around 10 p.m. Pet. App. 3a. She awoke the next morning with redness and a rash on her chest and neck. Several years later, the manufacturers of this comfort drug, which provides temporary relief from pain, swelling, and fever, but no cure for any condition, were ordered by the Food and Drug Administration ("FDA") to warn parents to stop using

Children's Motrin upon signs of redness, rash, and blistering. With no such warning, Richard gave Samantha a third dose.

When Samantha's symptoms persisted, her pediatrician advised Samantha to continue to be treated with three doses a day. However, when she awoke on November 30, her body was covered in blisters. She could not open her eyes or mouth, and her lips were bleeding. She was rushed from one hospital, where she was administered another dose, to another, and, finally, to a third, where she was diagnosed with Toxic Epidermal Necrolysis ("TEN"), a life-threatening skin disorder. Her parents were told that she had a minuscule chance of surviving the night. *Id*. at 4a.

At least 95% of Samantha's body surface was affected by TEN. Bloody secretions led to the top layer of her skin dying and sloughing off in sheets. For weeks, she remained in bed with huge open wounds "moaning in pain." A.13119.[1] To ease her pain, Samantha was placed into a medically induced coma for a month and remained hospitalized for the next six months. During that time, she suffered heart and liver failure, two strokes, one while cradled in her mother's arms, an aneurysm, and a cranial hemorrhage that caused seizures. She underwent brain surgery, and her lung capacity fell to 20%, barely above the 15% threshold that causes death. She became addicted to pain medications and suffered withdrawal symptoms. By the time she left the hospital in May 2004, Samantha weighed thirty-five pounds. Pet. App. 5a.

---

[1] "A.___" refers to the Massachusetts record.

For two years, Samantha needed a feeding tube and oxygen assistance at night. She repeated first grade and required someone to carry her up and down the stairs at school. To eat lunch, she visited the nurse's office, where her feeding tube was administered. She repeatedly suffered from pneumonia, troubled breathing, and bronchitis. Her scarred lungs operated at less than half capacity. *Id*. at 6a.

Samantha is legally blind, had a prosthetic lens implanted, which has now failed, and required more than forty eye surgeries. Her right eye suffers from in-turned eye lashes that rub her scarred cornea, resulting in mucus collecting on the cornea. To read, she uses a projector to enlarge the type and sits very near the screen. She presses her nose to her telephone or television to use them. She requires daily topical antibiotics on her eyes and a specialist to change her protective lens monthly. *Id*. at 6a-7a, App. 40a.

Samantha is now a 19-year-old high-school student, but suffers cognitive limitations. She struggles to retain information. She will never drive an automobile and remains dependent on others for assistance in her daily life. For the remainder of her life, she will face frequent hospitalizations, lung problems such as asthma, and further eye complications, such as glaucoma. She will always have difficulty fighting disease due to her pulmonary deficiencies and low body weight. She will never be able to maintain a pregnancy. *Id*. at 6a-8a.

Her parents' lives were transformed by this tragedy. They stayed with her throughout her initial six-month hospitalization, sleeping in cramped quarters, fearful that any minute could be her last.

Her father quit his job as a chef to work at a local gas station for the shorter hours and proximity to her. The family faces constant and significant challenges for her future. *Id*. at 8a.

### B. Proceedings below.

The present litigation against McNeil-PPC, Inc. and its parent company, Johnson & Johnson (collectively, Petitioners or J&J), was initiated on January 12, 2007. The case did not go to trial until six years later, January 2013, after extensive discovery, a summary judgment motion, and 19 in-limine motions from Defendants. The trial took five weeks. Both parties' expert witnesses testified that ibuprofen (the active ingredient in Children's Motrin) is associated with SJS (Stevens-Johnson Syndrome, a precursor to TEN that covers less of the body) and TEN. *Id.* at 9a. Plaintiffs' theory was that the warning label on Children's Motrin was inadequate. It failed to warn consumers of redness, rash, or blisters, and their significance and potentially dire consequences. *Id*. at 21a, 27a & n.32.

The jury deliberated for four days and concluded that the ingestion of Children's Motrin caused Samantha's TEN and that the warnings were inadequate. With respect to a state-law consumer claim, tried without a jury, the judge found J&J knowingly or willfully engaged in unfair and deceptive acts or practices, but was not liable because of express statutory exceptions. *See id*. at 14a n.20. Nonetheless, he found that, for many years prior to 2003, even prior to submission to the FDA in 1988, J&J was well aware of the science supporting the need for stronger warnings about the signs of life-threatening skin reactions and the "probable causal relationship

between ibuprofen and SJS," having "been warned that the OTC availability of ibuprofen would likely 'place large numbers of potential patients at a substantial risk' rendering the 'need for continued surveillance . . . readily apparent.'" App. 13a. He added,

> Between 1995 and 2003, additional peer-reviewed scientific literature . . . confirmed the prevalence of SJS and TEN caused by ibuprofen. However, the defendants did not provide any discussion or analysis for the FDA about any comprehensive safety assessments of the risks of SJS and TEN with ibuprofen use. . . .
>
> According to . . . McNeil's Vice President of Marketing, no department . . . had a larger operating budget than the marketing department's $450 million annual budget. That marketing budget was used, in part, to "communicate the benefits of the brands" like Children's Motrin . . . [and] not being spent to warn consumers about the risk of SJS and TEN associated with Motrin use . . . [because it] will affect a brand's reputation and . . . cause sales to go down. . . .
>
> [The label failed to warn consumers] that allergic reactions, such as rash or skin redness may . . . be caused by Children's Motrin. . . . As a result, the Reckises [and her doctors] . . . were unable to recognize that the Children's Motrin was causing

> Samantha's condition, and they continued to administer doses of Children's Motrin, thereby exacerbating her condition.

App. 14a-15a, 18a-19a.

The jury determined that Samantha was due $50 million in compensatory damages, while her parents were due $6.5 million each for loss of consortium. Pet. App. 14a.

The judge denied motions for judgment notwithstanding the verdict and for a new trial. In denying a motion for remittitur, the judge found that the total award was "not greatly disproportionate to the injuries proven," *id.* at 38a, and wrote:

> TEN brought Samantha to the doorstep of death . . . almost all of Samantha's skin was burned from her body. . . . She has suffered from acute and chronic respiratory failure, liver problems, nutritional problems, vision problems, and cerebral hemorrhages. TEN devastated not only Samantha's skin, but also all of her mucosal membranes and surfaces, including her throat, mouth, eyes, esophagus, intestinal track, respiratory system, and genitalia

App. 34a-36a, 39a-40a.

On direct appeal to the Massachusetts Supreme Judicial Court ("SJC"), J&J raised three issues: preemption, failure to prove causation, and excessive damages. As for the causation question in which J&J questioned the qualifications of one expert

because he was not a medical doctor, the court found that Dr. Randall Tackett, a professor of pharmacology and toxicology at the University of Georgia's College of Pharmacy with specific relevant research and teaching experience on forensic pharmacy and on NSAIDs[2] such as ibuprofen, App. 29a-30a, to be fully qualified.

The SJC found J&J waived most of its objections to the verdict and had no difficulty finding that the extreme pain and suffering proven warranted damages in the amount awarded or that the difficulties visited upon this family justified the loss of consortium award. *Id*. at 41a, 42a-43a, 44a-45a.

As for preemption, first, it agreed with J&J that the statute's express non-preemption language did not override language embracing conflict preemption or "the ordinary working of conflict preemption principles." *Id*. at 16a-17a (citing 21 U.S.C. § 379r(a) & (e) and *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000)).

Second, it thoroughly analyzed the FDA's review of the Citizen Petition requesting changes to Children's Motrin's OTC status and labeling, accepting J&J's clear-evidence argument that the FDA preempted any claim that SJS or TEN should be expressly identified. *Id*. at 20a. However, it held that "whether Federal law preempts the plaintiffs' claim that the Children's Motrin's label should have warned of redness, rash, or blisters that might lead or be a 'pathway' to a life-threatening disease is another matter." *Id*. at 21a. Quoting the FDA's response to the

---

[2] NSAID stands for nonsteroidal anti-inflammatory drugs, of which ibuprofen is one.

Citizen Petition, the court noted that the FDA "agree[d] that the labeling for OTC NSAIDs, including all ibuprofen products, should be improved to warn consumers about the risks of severe skin reactions." *Id*. at 22a. The FDA response went on to state "'[w]e do not believe that it is useful to include the specific terms SJS, TEN . . . because most consumers are unfamiliar with these terms." *Id*. Instead, a "prominently displayed" "description of symptoms is more appropriate," which would include "skin reddening," "rash," and "blisters." *Id*. at 22a-23a.

The court concluded that "all that we find clear" is that the FDA rejected placing actual names of diseases on the label, but adopted the "proposal to list specific early symptoms of the diseases." *Id*. at 23a. The court found the FDA's treatment of the word "life-threatening" insufficient to satisfy the "demanding defense" of impossibility preemption, and therefore not clearly prohibited. *Id*. at 23a, 26a. It further held that the "jury did not base liability on the defendants' failure to warn of SJS or TEN by name," which would have been impermissible. *Id*. at 27a. As a result, the court unanimously affirmed the judgment.

### C. Statutory and regulatory framework.

This case takes place against the background of the FDA's approach to warnings on OTC drugs and a number of FDA actions with respect to Children's Motrin.

#### *1. Regulation of OTC product labeling.*

The FDA approval process's core objective is to ensure that drugs are both safe and effective. *FDA v.*

*Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 142 (2000). Manufacturers of new drugs conduct clinical trials and submit proposed labeling for the drug, which must identify, *inter alia*, appropriate uses of the product, contraindications, warnings, precautions, and adverse reactions. 21 U.S.C. § 355(b), (d); 21 C.F.R. § 201.56. In particular, the drug's label must bear "such adequate warnings against use . . . as are necessary for the protection of users." 21 U.S.C. § 352(f)(2).

The FDA reviews studies conducted by the manufacturer and the manufacturer's proposed labeling to determine whether the claimed benefits outweigh the drug's known risks for its proposed use. OTC drugs, which do not require a prescription, are regulated with an eye to the risks and understandings of consumers.[3] OTC drug labeling must "be clear and truthful in all respects" and "state the intended uses and results of the product; adequate directions for proper use; and warnings against unsafe use, side effects, and adverse reactions in such terms as to render them likely to be read and understood by the ordinary individual, including individuals of low comprehension, under customary conditions of purchase and use." 21 C.F.R. § 330.10(4)(v).

Pre-marketing clinical trials of branded drugs are typically small, involving only carefully selected patients taking the drug for a limited time. As a

---

[3] The FDA approved ibuprofen for adult prescription use in 1974 and OTC use in 1984. Children's Motrin was approved as a prescription drug in 1989 and as an OTC drug in 1995. *Newman v. McNeil Consumer Healthcare*, No. 10-CV-01541, 2012 WL 39793, at *1 (N.D. Ill. Jan. 9, 2012). OTC Motrin and Children's Motrin are identical. *Id.* at *2.

result, many serious risks are not discovered until the drug has been on the market for years. Karen E. Lasser, *et al.*, *Timing of New Black Box Warnings and Withdrawals for Prescription Medicines*, 287 J.A.M.A. 2215 (2002) (finding half of all black box warnings on drugs introduced after 1975 were added after the drug had been on the market for seven or more years).

Because knowledge about a drug's benefits and risks grow after a drug has begun to be marketed, the drug manufacturers can make changes to a drug's approved labeling. Labeling may be updated through four essential methods, the most common of which are the methods whereby a manufacturer initiates the change.

a. Labeling change initiated by the FDA.

On the basis of reports of adverse reactions, which may be received from consumers, health-care practitioners, and pharmaceutical companies, the FDA, since 2007, has authority to initiate a labeling review and mandate revised labeling. *Wyeth*, 555 U.S. at 571.

b. Labeling change without prior FDA approval.

Because "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times," and because the manufacturer "is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market," *id.* at 570-71, a manufacturer may "add or strengthen a contraindication, warning, precaution, or adverse reaction" or "add or strengthen

an instruction about dosage and administration that is intended to increase the safe use of the drug product," without prior FDA approval. 21 C.F.R. § 314.70(c)(6)(iii)(A), (C). This is accomplished through the "changes being effected" ("CBE") procedure. *Wyeth*, 555 U.S. at 568.

The current CBE regulation provides that a drug manufacturer may change its label to "reflect newly acquired information" and when there is "evidence of a causal association." 21 C.F.R. § 314.70(c)(6)(iii). The FDA recognizes that "'newly acquired information' is not limited to new data, but also encompasses 'new analyses of previously submitted data,' . . . [because] risk information accumulates over time and . . . the same data may take on a different meaning in light of subsequent developments." *Wyeth*, 555 U.S. at 569. The regulation in effect at the time of the underlying injury in this case and prior to 2003 did not include the "newly acquired information" or "causal association" requirements. *See* 21 C.F.R. § 314.70(c)(6) (effective until June 29, 2006).

In response to a manufacturer's label change, the FDA may accept, modify, or reject the CBE change and may bring an enforcement action to stop the manufacturer from using the revised label. 21 C.F.R. § 314.70(c)(7); James T. O'Reilly & Katherine A. Van Tassel, *Food and Drug Administration*, Vol. II, § 15:19, at 36-37 (4th ed. 2015) ("O'Reilly"). Such an enforcement action must show that the "drug is misbranded" in violation of 21 U.S.C. § 352, generally because the label is false or misleading, lacks a warning "necessitated by a potential hazard," or is "'dangerous to health when used in the dosage, or manner, or with the frequency or duration prescribed,

recommended, or suggested in the labeling.'" O'Reilly, Vol. I, § 14:3, at 1092-93. A drug is misbranded if a required warning is not conspicuous and is not written "in such terms as to render it likely to be read and understood by the ordinary individual," and lacks "(1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users." 21 U.S.C. § 352(c), (f).

Even so, this Court has recognized that "the very idea that the FDA would" prohibit a manufacturer from "strengthening a warning pursuant to the CBE regulation is difficult to accept." *Wyeth*, 555 U.S. at 570.

c. Manufacturers' requests to strengthen warnings.

Instead of unilaterally updating its label, a drug manufacturer may submit a "Prior Approval Supplement," which seeks FDA approval to strengthen warnings. 21 C.F.R. § 314.70(b).

d. Citizen Petition seeking FDA label revision.

Citizen Petitions "are a means by which any 'interested person' can request that the FDA . . . 'take or refrain from taking any . . . form of administrative action.'" Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 Cardozo L. Rev. 249, 260 (2012) (citing 21 C.F.R. §§10.25, 10.30). They are primarily used in fights between generic and brand-name drug companies to ward off competition.

*Id*. Others "file petitions to raise safety concerns or to obtain industry guidelines for studies." *Id*. Statistics show that 68% of Citizen Petitions are filed by brand-name companies, 22% by generics, and only 10% by others. *Id*. at 269 & n.102. The "overwhelming majority of citizen petitions are denied," with only 19% granted. *Id*. at 278, 274.

*2. Children's Motrin and the Citizen Petition.*

On February 15, 2005, more than a year after Samantha contracted TEN, a group of physicians, two parents of children adversely affected, and a pharmacologist, who served as an expert for Plaintiffs, petitioned the FDA to "conduct a risk assessment of [SJS] and [TEN] associated with the use of ibuprofen" and require amplified warnings, or withdraw approval of OTC pediatric ibuprofen products. Pet. App. 10a-11a. The requested change first asked for a warning about serious skin reactions that "may progress to more serious and potentially life-threatening diseases, including . . . [SJS] and [TEN]." *Id*. at 11a. Additionally, it asked for a warning to stop use if a skin rash or blister appeared "'because these symptoms may be an early sign of rare and life-threatening reactions including' SJS and TEN." *Id*.

In 2006, after a "comprehensive review of the risks and benefits" of ibuprofen and "based on analyses of data obtained before the petition was submitted," the FDA announced that it "agree[d] that revisions to labeling are necessary to make more explicit the risks associated with SJS and TEN." *Id*. at 11a-12a, 96a-97a n.8, 158a. It further acknowledged that "NSAIDs, including ibuprofen, are known to cause SJS and TEN," and "[p]rompt

recognition of the onset of symptoms, . . . and withdrawal of the suspected drug can minimize the effects of SJS/TEN and improve prognosis." *Id*. at 12a, 147a. It further "agree[d] that the labeling for OTC NSAIDs, including all ibuprofen products, should be improved to warn consumers about the risks of severe skin reactions with OTC ibuprofen products." *Id*. at 161a.

As a result, OTC products were required to add new warnings concerning "skin reddening," "rash," and "blisters." *Id*. at 11a-12a. However, the FDA specified that it was not useful "to include the specific terms SJS, TEN" because "most consumers are unfamiliar with these terms" and because "effective OTC labeling communicates warning information in a manner that consumers can quickly and easily identify and understand." *Id*. at 162a. It thus concluded that a "description of symptoms is more appropriate." *Id*.

Though the FDA declined to request more onto the consumer label, it went further by requiring chemically identical prescription ibuprofen labeling to warn that "NSAIDs . . . can cause serious skin adverse events such as exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal." *Id*. at 158a. An FDA-mandated "Medication Guide" for patients also warned of various "life-threatening skin reactions." *Id*. at 160a. Finally, the "Information for Patients" section in "PRECAUTIONS" warned that "[Children's Motrin], like other NSAIDs, can cause serious skin side effects such as exfoliative dermatitis, SJS, and TEN, which may result in hospitalizations and even death." *Id*. at 159a.

### D. Misstatements of fact and law in the petition.

#### *1. Contrary to the FDA's findings, Petitioners claim Ibuprofen's causal relationship with SJS or TEN remains debatable.*

J&J tells this Court that "medical literature continues to debate whether ibuprofen can cause SJS or TEN" and that the most recent study "found no statistically significant association." Pet. 11. Their own expert, author of the cited study, admitted in testimony here, that one cannot infer from this study that ibuprofen does not cause SJS and TEN. A.9994. On the contrary, a more recent study focused solely on children and confirmed the causal connection. N. Levi, *et al.*, *Medications as Risk Factors of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis in Children: A Pooled Analysis*, 123:2 Pediatrics e297-303 (2009); A.8357-60, 9218, 9291, 9995. The FDA has also unambiguously determined that "NSAIDs, including ibuprofen, are known to cause SJS and TEN." Pet. App. 147a. Moreover, the record in this case demonstrates that, at least since 1988, J&J knew of a "probable causal relationship between ibuprofen and SJS." App. 13a.[4]

[4] The medical community supported Plaintiffs in an amicus brief below filed uniquely on behalf of the Massachusetts Medical Society and Massachusetts Bar Association. Pet. App. 15a, n.21.

*2. Petitioners falsely contend there is no dispute that FDA expressly considered and rejected the warning at issue in this case.*

J&J erroneously asserts that it is "*undisputed* that FDA expressly considered and rejected the very language on which Respondents' claims were based." Pet. 5 (emphasis in original). *See also id.* at 3, 6. Plaintiffs have consistently argued otherwise and every judge to hear this matter has agreed with Plaintiffs.

As both the SJC and the Seventh Circuit held, the FDA expressly rejected inclusion of "the specific terms *SJS*, *TEN*, or *erythema multiforme*, *Stevens-Johnson syndrome*, and *toxic epidermal necrolysis* in the OTC label because most consumers are unfamiliar with these terms." Pet. App. 162a (emphasis in original). Plaintiffs did not premise their inadequate warning claim on use of those terms. The jury was told that Plaintiffs did not contend that the terms SJS or TEN should have been on the label. *Id.* at 27a & n.32.

Nonetheless, the FDA agreed with Plaintiffs that a description of symptoms warranting an immediate stop to usage and immediate medical attention was needed. *Id.* This warning was missing from the Children's Motrin label when Samantha took the drug.

Finally, Plaintiffs' counsel argued that the warning should have alerted parents to redness, rash, and blisters, because those symptoms can lead to a life-threatening condition, but never suggested specific wording, only that the label was inadequate. The jury only determined that the warning was

inadequate. Nothing advocated or decided conflicted with the FDA's expressed rationale for excluding specific mention of the diseases. The SJC found the FDA's response to the petition sufficiently ambiguous as to any other terms. *Id*. at 23a.[5] After all, the FDA did issue an educational tool for consumers about "SJS and potentially life-threatening skin-reactions," and ordered a medication guide be provided directly to consumers of the chemically identical prescription drug, using the term "life-threatening skin reactions." *Id*. at 160a.

In addition, Petitioners misrepresent the FDA's treatment of "life-threatening." Petitioners argue that the term was rejected because the FDA made a "nuanced decision about how best to address the risks of SJS/TEN" based on "the current scientific literature and available risk information." Pet. 6. Besides not expressing any view on "life-threatening" with respect to the OTC label, the FDA used the term in the educational tool and medication guide described above. The FDA's "risk benefit analysis" had nothing to do with its omission of the term, but, rather, was the basis for deciding against withdrawing OTC status for pediatric ibuprofen altogether.

---

[5] Every court reviewing the Citizen Petition for clear evidence regarding Children's Motrin has found only that the FDA prohibited the use of SJS and TEN in a warning label and nothing more. *See*, *e.g.*, *Brown v. Johnson & Johnson,* 64 F. Supp. 3d 717, 720-21 (E.D. Pa. 2014); *Newman*, 2012 WL 39793; *Wolfe v. McNeil Consumer Healthcare*, 6 F. Supp. 3d 694 (E.D. La. 2014).

*3. Petitioners falsely claim Plaintiffs asserted that the label should have warned against TEN by name.*

J&J contends that Plaintiffs claimed that the label should have warned against "Toxic Epidermal Necrolysis," and that a warning that redness, rash, and blisters could lead to life-threatening illness was simply an "alternate theory." Pet. 19, 21. On the contrary, Plaintiffs had one theory: the warning was inadequate, and the jury agreed. Counsel stated explicitly in closing argument that Plaintiffs did not contend that the warning should have mentioned SJS or TEN by name, as consumers do not know what those diseases are. Pet. App. 27a & n.32.

J&J also misleadingly attempts to bolster its claim by stating that Richard testified he would not have given Samantha a third dose if the warning had mentioned TEN. Pet. 19. However, use of that statement conflates a testimonial answer on the stand with Plaintiffs' theory of the case, which did not include naming the disease on a label. Richard testified he had never heard of TEN.

*4. Petitioners falsely portray the subject label as having provided adequate warnings.*

Petitioners convey the impression that the subject label was adequate to alert Richard, because it warned to stop use if an "allergic reaction" or "new symptom" appeared. Pet. 19 n.3. Petitioners failed to note that the 2003 label ***identified only specific allergic reactions to watch for***: hives, facial swelling, asthma (wheezing), shock, and sore throat. Pet. App. 10a. Samantha had none of these reactions.

Her reactions, redness, rash, and blisters, were not identified on the label until three years later, when Petitioners were ordered to provide these necessary warnings. *Id.* at 11a-12a n.10.

*5. Petitioners mischaracterize the Massachusetts decision as creating a per se rule.*

J&J tells this Court that the "SJC's decision establishes a *per se* rule that FDA's prior rejection of a proposed warning is legally irrelevant unless the language was proposed by the drug's manufacturer." Pet. 4. The SJC adopted no such rule, but instead engaged in a careful analysis of whether clear evidence indicated that the FDA would not have approved the proposed change in the warning. As part of that analysis, the SJC concluded that the FDA's express rationale for rejecting an OTC label that specified SJS and TEN as potential outcomes of the use of Children's Motrin, which it called "consumer unfamiliarity," does not apply to "life-threatening." Pet. App. 24a. If J&J were correct that a *per se* rule was adopted, the SJC would have ruled differently than it did on another issue in the case: whether a label mentioning SJS or TEN was preempted by the FDA's action on the Citizen Petition. *Id.* at 20a. At most, the SJC found it relevant, "for the sake of argument," that J&J did not seek the change itself. *Id.* at 24a. It further noted that a determination by the FDA that it would not require specific language advocated in a Citizen Petition is not the same as a determination that the FDA would forbid a manufacturer from adding a different warning that is scientifically valid. *Id.* at 25a. After all, the court stated, "[t]his is not to say that the *Wyeth* standard of clear evidence can be satisfied only by the FDA's

rejection of a manufacturer's request for an additional warning." *Id.* at 25a n.29. Nothing in the discussion of this issue created a *per se* rule.

## REASONS FOR DENYING THE PETITION

Petitioners seek the exercise of this Court's discretion on the basis of a single, alleged conflict between the SJC in this case and one decision of the Seventh Circuit, *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 873 (7th Cir. 2010), about a question immaterial to the disposition of this case. Petitioners assume, even going so far as to claim inaccurately, that it is "undisputed" that the FDA rejected the language Respondents said should have been part of the Children's Motrin warning. It is clear that neither Respondents nor the courts below agree with Petitioners' so-called undisputed assumption. It is equally clear that the FDA limited its rejection to an OTC label that mentioned the diseases SJS and TEN by name. As a result, because those terms are not at issue here, this case cannot present the proffered question about whether rejection of language advocated in a Citizen Petition constitutes clear evidence that a state failure to warn claim based on rejected language is preempted.

The alleged conflict between two courts is entirely manufactured, and subsequent decisions within the Seventh Circuit do not read *Robinson* as Petitioners do. The absence of appellate courts lining up on either side of a divide, as well as the utter dearth of other appellate decisions suggesting a need for this Court to intervene, indicates that the issue is not a recurring one troubling the courts and demanding an immediate definitive resolution by this Court. Even if it were a proper question, at most, it is

one that would benefit from further percolation based on additional appellate decisions where the disposition of the case actually depends on an answer to that question.

Moreover, as any determination of whether clear evidence exists that the FDA would reject a particular drug warning label is entirely fact-specific, the Petition is little more than a claim of error, seeking one more appeal after an adverse result. It presents no unanswered legal question. In fact, the Petition concedes that this Court has already "made clear that the central question is whether FDA would have allowed the manufacturer to issue additional warnings without prior FDA approval." Pet. 24. The clarity of the question a court must answer and the linear result that flows from that answer belies any need for this Court's reconsideration or further articulation of the law.

## I. The Seventh Circuit Decision in *Robinson* Does Not Conflict With the Decision Below.

### A. The petition presents a fact-specific inquiry.

The Question Presented asserts a "direct conflict" between the decision below and that of the Seventh Circuit in *Robinson*. Pet. i. Yet, when J&J explains its claimed conflict it informs this Court that the Seventh Circuit came to a different conclusion on the basis of the "same record evidence at issue here." *Id*. at 25. The difference between the courts, Petitioner thus concedes, is not about a legal question but about interpretation of evidence. Yet, as Supreme Court Rule 10 makes clear, certiorari should rarely, if

ever, be granted "when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law." After all, at least since the Judiciary Act of 1925, this Court has not sat as a court of last resort, concerned primarily with correcting errors and vindicating the rights of particular litigants, but instead resolves conflicts among the circuits and articulates legal rules and principles in cases with broad legal or social significance. *Cf. Stack v. Boyle*, 342 U.S. 1, 13 (1951) (Jackson, J., concurring). There is no warrant to depart from that approach here. This Court has emphasized:

> A federal question raised by a petitioner may be "of substance" in the sense that, abstractly considered, it may present an intellectually interesting and solid problem. But this Court does not sit to satisfy a scholarly interest in such issues. Nor does it sit for the benefit of the particular litigants.

*Rice v. Sioux City Mem'l Park Cemetery*, 349 U.S. 70, 74 (1955) (internal citations omitted).

Rather, "'it is very important that we be consistent in not granting the writ of certiorari except in cases involving principles the settlement of which is of importance to the public, as distinguished from that of the parties.'" *Id.* at 79 (quoting *Layne & Bowler Corp. v. W. Well Works, Inc.*, 261 U.S. 387, 393 (1923)).

### B. The SJC and Seventh Circuit agree on the essential issues.

There is no reason to credit Petitioner's assertion that the Seventh Circuit reached a different

conclusion than did the SJC. In *Robinson*, the Seventh Circuit devotes all of two sentences to "clear evidence,"[6] resolving nothing to do with preemption and not having to. By the time the Seventh Circuit opined about the FDA, it had already determined that the adult woman in the case took Children's Motrin without reading the label and was contributorily negligent under the applicable Virginia law, which "dooms her appeal." 615 F.3d at 867. As a result, she had no cause of action. *Id.* at 871. Any discussion of the FDA and clear evidence was *dicta*.

One district court within the Seventh Circuit, hearing a similar claim, held reliance on *Robinson* on issues of preemption is "misplaced," because the Seventh Circuit only cited the clear evidence standard "to uphold the lower court's refusal to allow the plaintiff, on the eve of trial, to add a breach of implied warranty claim.'" *Newman*, 2012 WL 39793, at *8 (quoting *Schedin v. Ortho-McNeil-Janssen Pharms., Inc.*, No. 08-5743, 2011 WL 834020, at *5 (D. Minn. Mar. 4, 2011) (citing *Robinson*, 615 F.3d at 872-73)). Even if taken to address preemption, *Newman* found that the Seventh Circuit's "explanation of the 'clear

---

[6] Near the end of its opinion, *Robinson* states:

> The "clear evidence" in this case is the agency's refusal to require a reference to SJS/TEN on the label of over-the-counter drugs containing ibuprofen, when it had been asked to do so in the submission to which the agency was responding. And it would be odd to think that McNeil had a legal duty to guarantee against a risk that the FDA thought not worth warning against.

615 F.3d at 873.

evidence' in the case was limited to the FDA's refusal to require references to SJS and TEN on the warning label for OTC ibuprofen products." *Id.* (citing *Robinson*, 615 F.3d at 873).

Thus, the SJC and Seventh Circuit were in complete agreement that the FDA's action on the Citizen Petition only barred claims to put "SJS" and "TEN" on the Children's Motrin label. The *Reckis* Court identically held:

> the defendants are correct that the FDA's explicit rejection of the 2005 citizen petition's proposed inclusion of a specific mention of SJS or TEN by name on OTC ibuprofen drug labels because "most consumers are unfamiliar with these terms" provides the necessary "clear evidence" that the FDA would have rejected the addition of a warning on OTC ibuprofen's labeling that mentioned SJS or TEN by name.

Pet. App. 20a. In support of that proposition the SJC expressly cited and followed *Robinson. Id.* at 20a-21a.

Similarly, another court cited both *Reckis* and *Robinson* as holding the same and exemplary of the "framework from which the Court can apply [*Wyeth*] and its progeny to the facts in this matter," *In re Incretin-Based Therapies Prod. Liab. Litig.*, No. 13MD2452, 2015 WL 6912689, at *7 (S.D. Cal. Nov. 9, 2015), even while finding preemption in that matter.

Simply put, *Robinson* and *Reckis* agree on the applicable legal standard and on the import of the evidence of the FDA's actions.

## II. Courts Are Not Struggling to Apply the "Clear Evidence" Rule Enunciated in *Wyeth*.

Petitioners also attempt to create an issue for this Court by contending that numerous courts have converted the "clear evidence" standard "into a virtual *per se* bar against federal preemption." Pet. 26. They further falsely claim that "[t]hese courts literally demand that companies be subjected to criminal proceedings before a preemption defense can succeed." *Id*. at 32. However, Petitioners fail to corroborate these grossly exaggerated and incorrect assertions and omit or misrepresent the actual grounds for the courts' decisions. All the cases relied upon by Petitioners for these propositions involve prescription drugs, rather than OTC drugs. Moreover, each decision cautiously and properly applied the *Wyeth* clear-evidence standard.

For example, Petitioners cite only the lower court's opinion in *Schilf v. Eli Lilly & Co.*, No. 07-4015, 2010 WL 3909909, at *4 (D.S.D. Sept. 30, 2010), in stating that *Wyeth* establishes that the "lower courts are left to determine what satisfies this 'clear evidence' standard in each case." Yet, the District Court in *Schilf* had little difficulty looking at the proffered evidence and holding that "an email from the FDA" is not clear evidence. *Id*. Petitioners fail to inform this Court that the Eighth Circuit, while reversing the District Court on other grounds, agreed that the defendants had failed to establish "clear evidence" that the FDA would have rejected *any* stronger warnings, as the defendant's "argument—restricted to the one sentence the FDA rejected—would not resolve this case." *Schilf v. Eli Lilly & Co.*, 687 F.3d 947, 950 n.3 (8th Cir. 2012).

Petitioners also entirely omit the primary ground for rejecting preemption in *Wells v. Allergan, Inc.*, No. 12-cv-00973, 2013 WL 389147 (W.D. Okla. Jan. 31, 2013), *cited in* Pet. 31. At issue was a maximum dose warning for Botox. However, the FDA rejected the proposed label because, the proposed warning implied maximum dosage could be used "for cerebral palsy; however, this is not an approved use in the United States." *Id.* at *7 (citation and internal quotation marks omitted). Thus, *Wells* properly concluded that the "FDA's rejection of Allergen's proposal is thus not 'clear evidence' that the FDA would have rejected any warning relating to the 8 U/kg maximum safe dose," other than when it implied a safe dosage for an off-label use. *Id.*

Similarly, *Aaron v. Wyeth*, No. 2:07-CV-927, 2010 WL 653984 (W.D. Pa. Feb. 19, 2010), *cited in* Pet. 31, did not flippantly reject preemption as Petitioners claim[7] but carefully analyzed and applied *Wyeth*, while also granting the defendant summary judgment on other grounds. It denied preemption because "the FDA [only] disagreed with certain changes to the Effexor labeling proposed by Wyeth," and "[s]uch evidence does not definitively show that it was impossible for Wyeth to enhance its safety warnings in place at the time of Aaron's suicide." *Id.* at *6.

Another case cited by Petitioners, *Dorsett v. Sandoz, Inc.*, 699 F. Supp. 2d 1142, 1159 (C.D. Cal.

---

[7] Petitioners claim the court recognized that the FDA "'repeatedly rejected' proposed labeling changes." Pet. 31. However, in using that language, the court was simply stating the defendant's claim and not agreeing with it. *See* 2010 WL 653984, at *5 ("Wyeth argues that preemption applies because the FDA repeatedly rejected efforts to implement different or additional warnings.").

2010), *cited in* Pet. 32, rejected the preemption defense because the defendant "fundamentally" ignored "its burden here" and argued a "mere possibility" of FDA rejection. Petitioners also refer only to a narrow aspect of *Forst v. Smithkline Beecham Corp.*, 639 F. Supp. 2d 948, 954 (E.D. Wis. 2009), *cited in* Pet. 31, and omit the court's careful application of *Wyeth*. In *Forst*, the manufacturer "argue[d] that the FDA would not have approved an enhanced warning regarding suicidality for Paxil's label even if [it] had proposed one." *Id*. at 953. The court correctly rejected that argument on the utter absence of clear evidence supporting it because approval of the manufacturer's earlier label did not constitute rejection of a later enhanced warning. *Id*. at 954. *Cf. Wyeth*, 555 U.S. at 573 ("the mere fact that the FDA approved [the drug]'s label does not establish that it would have prohibited such a change").

The other cases relied upon by the Petitioners were also based on thoughtful applications of *Wyeth*. *See Baumgardner v. Wyeth Pharms.*, No. 06-2519, 2010 WL 3431671, at *2 (E.D. Pa. Aug. 31, 2010) (preemption defense rejected, *inter alia*, because there was evidence that manufacturer "was permitted to unilaterally strengthen Effexor's warnings until a different warning was imposed on antidepressant manufacturers by the FDA"), *cited in* Pet. 28; *Schedin v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F. Supp. 2d 1125, 1133 (D. Minn. 2011), *aff'd in part*, *rev'd in part*, *sub. nom.*, *In re Levaquin Prods. Liab. Litig.*, 700 F.3d 1161 (8th Cir. 2012) (rejecting FDA letter submitted post-trial and not in evidence as clear evidence, in which the FDA, in response to a Citizen Petition, merely stated that the three scientific studies proffered did not show a "robust difference" in risk and did not show that the FDA would have

rejected a label change proposed by" the manufacturer during the relevant time period), *cited in* Pet. 28, without subsequent history. In the subsequent appeal, the defendant did not raise the preemption issue.

In sum, district courts are not struggling with application of the clear-evidence rule and need no further guidance.

## III. Even If the Issue Presented Was Appropriate for This Court's Attention, This Case Is Not the Vehicle to Resolve It.

Because the FDA determined that enhanced warnings were needed and recognized that ibuprofen causes SJS and TEN, this is not a case in which the FDA made one determination and a court made another. On the contrary, the FDA's decision is consistent with the decision below which also found enhanced warnings without mention of SJS/TEN not preempted. Moreover, as demonstrated earlier, the case presents no conflict to resolve. Petitioners are wrong to contend that the FDA's response to the Citizen Petition constitutes clear evidence that the "FDA would have rejected the sort of labeling change at issue here." Pet. 29.

If a future case presents an FDA prohibition of terminology proposed in a Citizen Petition that a court then finds should have been part of a warning label, a result that a diligent search of the caselaw has not unearthed, then the question presented may be of interest to this Court. That issue, however, is not presented by the decision in this case.

Neither the Seventh Circuit nor the SJC lacked clarity on what the underlying law to be applied is or

what the relevant evidentiary record contained or proved. Both courts reached identical conclusions about what, precisely, the FDA rejected, giving that rejection the exact same preemptive effect. On the other hand, an appropriate vehicle would involve a sharply drawn disagreement of the kind absent here and that disagreement would involve more than two appellate courts. Only then, where the issue is actually joined and there is real division among the circuits, would this Court find it necessary to address the constitutional issue and enunciate a new national rule, having had the benefit of more fully developed views among the circuits.

## IV. There Is No Conflict Between the Federal Courts and State Courts in Massachusetts About the Federal Regulatory Process.

Raising an issue not pertinent to their Question Presented, Petitioners add an argument about a supposed conflict between the SJC's decision below and the First Circuit's "Views of the Federal Regulatory Process." Pet. 33. Citing *In re Celexa & Lexapro Marketing & Sales Practices Litigation*, 779 F.3d 34, 41 (1st Cir. 2015), Petitioners state that CBE changes may only be made on the basis of "newly acquired information," 21 C.F.R. § 314.70(c)(6)(iii). They imply that there was no such newly acquired information in 2003 so they could not have strengthened the Children's Motrin warning.

There is no discussion of that issue in the SJC's decision, and it is not presented by this case. This Court has adhered to its declaration that it "generally do[es] not address arguments that were not the basis for the decision below." *Matsushita Elec. Indus. Co. v. Epstein*, 516 U.S. 367, 379 n.5 (1996); *Duignan v.*

*United States*, 274 U.S. 195, 200 (1927) (same). While this limitation on review comprises a prudential consideration, rather than a restriction on jurisdiction, this Court has made plain that it will not depart from that general rule absent "'unusual circumstances.'" *Taylor v. Freeland & Kronz*, 503 U.S. 638, 646 (1992) (citation omitted). No such unusual circumstances are raised or present here.

Still, Petitioners have misstated the relevant facts, laws, and regulations and are simply manufacturing a conflict that does not exist. Citing *In re Celexa*, 779 F.3d at 41-42 (citation omitted), Petitioners quote the First Circuit to the effect that the "CBE procedure is only available to make changes that, among other things, are based on 'newly acquired information.'" Pet. 34. The regulation addressed in *In re Celexa* was promulgated after amendments were enacted in 2008 and thus inapplicable to this dispute. The sole issue here is whether the Defendants should have provided stronger warnings in or prior to 2003. The 2008 version of the CBE regulation relied upon by the Petitioners provides that a drug manufacturer may change its label without prior FDA approval in order to "reflect newly acquired information." 21 C.F.R. § 314.70(c)(6)(iii). The regulation in effect at the time of Samantha Reckis' catastrophic injuries, however, contained no such "newly acquired information" provision or requirement.

Even if the current "newly acquired information" provision were applicable, or if the FDA considered such information important prior to the 2008 regulation, there was overwhelming evidence at trial showing that, by 2003, there was a compelling need for stronger warnings, including those advocated

by the Plaintiffs. *See* App. 12a-16a. Further, as explained in *Wyeth*, 555 U.S. 569-70 (citation omitted), newly acquired information "is not limited to new data, but also encompasses 'new analyses of previously submitted data,'" and manufacturers may analyze such "accumulating data" and add "a stronger warning." In the years leading up to Samantha's near-fatal ingestion of Children's Motrin, Defendants had substantial "accumulating data" that ibuprofen could result in life-threatening diseases like SJS and TEN, that redness, rash, and blisters were the signs of such diseases, and that the OTC drug's label needed strong warnings to stop use upon such signs. *See supra* pp. 4-5, 14-15. Petitioners conceded that they could have changed the label without prior FDA approval. A.5514-16, 5441, 9495, 9692.

In light of Petitioners' failure to provide the necessary warnings, the Citizen Petition seeking stronger warnings was filed. *Wolfe*, 881 F. Supp. 2d at 657. The Petition was "granted in part" as it "persuaded the FDA to strengthen requirements for the ibuprofen warning label." A.11401; *Wolfe*, 881 F. Supp. 2d at 657. The FDA agreed that ibuprofen causes SJS and TEN, that prompt recognition of symptoms such as rash or blisters "and withdrawal of the suspected drug can minimize the effects of SJS/TEN and improve prognosis," and that the label should warn of "the risks of severe skin reactions associated with OTC ibuprofen" and "symptoms associated . . . with SJS and TEN." A.11392-93, 11399. Skin reddening, rash, and blisters are now "prominently displayed" under "Allergy alert" on the Children's Motrin label with a warning that if "an allergic reaction occurs, stop use and seek medical help right away." A.11400. The FDA issued a public health advisory and educational tool that states

"[s]ome NSAIDs have been associated with serious, potentially life-threatening skin reactions, such as Stevens-Johnson syndrome (SJS)." FDA, *Questions and Answers FDA Regulatory Actions for the COX-2 Selective and Non-Selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)* (Apr. 2005), *available at* http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm106148.htm. Tragically, these warnings came too late to help Samantha, but there can be no doubt that Petitioners could have provided them in time to prevent her catastrophic injuries.

Though, before this Court, J&J continues to question "whether ibuprofen can cause SJS or TEN," Pet. 11, the FDA has concluded causal association between the two is not debatable. Pet. App. 147a ("NSAIDs, including ibuprofen, are known to cause SJS and TEN"). Moreover, the record in this case demonstrates that, at least since 1988, J&J knew of a "probable causal relationship between ibuprofen and SJS." App. 13a.

The alleged conflict between state and federal courts within the First Circuit is simply nonexistent.

## V. The Decision Has No Import for the FDA's Regulatory Authority.

Finally, raising a false specter of over-deterrence and impairment of the FDA's regulatory authority, Petitioners claim assumptions and analysis applicable to failure to warn claims involving prescription drugs should be "markedly different in the OTC context." Pet. 36. Of course, this Court recognized otherwise in *Wyeth*, where it noted that in 1997, "Congress pre-empted certain state

requirements concerning over-the-counter medications and cosmetics but expressly preserved product liability actions." 555 U.S. at 575 n.8 (citing 21 U.S.C. §§ 379r(e), 379s(d) ("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.")).

Still, as the FDA has explicitly stated, unlike prescription drugs, "[p]roducts that are marketed under an OTC drug monograph are not required to submit labeling to the agency for preapproval." 64 Fed. Reg. 13254, 13271 (Mar. 17, 1999). The OTC monograph process identifies conditions under which an OTC drug will be "generally recognized as safe and effective." 21 C.F.R. § 330.1. While OTC drug labels must include all warnings required by a final monograph—or risk regulatory action—the inclusion of additional warnings does not render a drug nonconforming or misbranded.

Similarly, 21 C.F.R. § 330.10 (Pet. App. 69a) authorizes FDA to identify in a proposed monograph "labeling claims . . . reviewed and excluded from the monograph on the basis . . . that they would result in the drug's not being generally recognized as safe and effective or would result in misbranding." *Id.* at (a)(5)(ii) & (a)(6)(ii). The FDA has never declared any of the warnings sought by Respondents prohibited or an instance of misbranding.

The FDA made clear that "voluntary warnings" on OTC drug product labels are permitted when it published new labeling requirements for OTC drugs in 1999. 64 Fed. Reg. at 13271. Several OTC manufacturers had sought guidance from the agency about whether such voluntary warnings should be

included under the "Warnings" heading on the label or should be placed elsewhere. The FDA confirmed that such voluntary warnings should be included in the "Warnings" section, thereby eliminating any doubt that OTC manufacturers could add voluntary warnings to their labels. *Id*.

In the absence of a relevant prohibition on warnings proposed by Respondents, Petitioners assert policy reasons that are not clear evidence of a prohibition. Instead, they claim the policies applicable to OTC drugs are intended to prevent abstention from using drugs. Pet. 8. On the contrary, the policy statements relied upon by the Petitioners merely support the use of simple, understandable terms, as sought here, so consumers will understand the warnings, as "the use of less complex terminology, presented in shorter sentences . . . is likely to improve consumer processing of the information." 64 Fed. Reg. at 13255. Specifically, by avoiding dense, scientific-sounding material, "OTC drug product labeling is expected to decrease 'cognitive load' by, among other things, decreasing the memory demands necessary for processing the information" and "provide clear signals regarding important information." *Id*. Specific content and format requirements for OTC drugs are set forth in 21 C.F.R. § 201.66. No provision in that regulation or in the FDA's statements quoted above would prevent a manufacturer from using the well-understood and simple terms of the type that would have prevented Samantha's confrontation with TEN.

Contrary to representations by Petitioners and supporting *amici*, the FDA has never taken the position that the term "life-threatening" would result in cognitive overload or abstention from use, and no court has ever held otherwise. Petitioners' trumped-

up fear that it could have been accused of misbranding by adopting a more adequate warning along the lines Respondents suggested is belied by experience. In fact, it is difficult, if not impossible, to find any example of the "FDA punishing . . . any . . . drug manufacturer for overwarning." *Tucker v. SmithKline Beecham Corp.*, 596 F. Supp. 2d 1225, 1233 (S.D. Ind. 2008). *See also Wyeth*, 555 U.S. at 570 (recognizing that "neither Wyeth nor the United States has identified a case in which the FDA has done so").

Moreover, there is no basis in this case for Petitioners' alleged fear of "over-warning," Pet. 35, which could "deter potentially beneficial uses of the drug by making it seem riskier than warranted and can dilute the effectiveness of valid warnings." *Mason v. Smithkline Beecham Corp.*, 596 F.3d 387, 392 (7th Cir. 2010) (citing 21 C.F.R. § 201.57(e)). The FDA determined the risk was worth warning about and specifically adopted a warning about the symptoms. Its rationale for not requiring the diseases be named on the OTC label, even if it did require them for the prescription version, was limited to speaking in language appropriate to the audience and not about over-warning.

In fact, "prior to 2007, the FDA lacked the authority to order manufacturers to revise their labels," and manufacturers, then and now, retain "ultimate responsibility" for their labels. *Wyeth*, 555 U.S. at 571. The present case involves the Petitioners' duties in and prior to 2003.

In summary, Petitioners regulatory-interference argument lacks merit, would hide information consumers need and the FDA finds necessary, and uses over-warning and over-

deterrence as a weak and inappropriate counterweight to this Court's clear precedents and the express congressional declaration that FDA authority over OTC drugs does not preempt product liability actions. *See* 21 U.S.C. § 379r(e). Preemption does not apply here, and further review is not warranted.

## CONCLUSION

The petition for a writ of certiorari should be denied.

December 9, 2015 Respectfully submitted,

Robert S. Peck
*Counsel of Record*
CENTER FOR CONSTITUTIONAL LITIGATION, P.C.
777 6th Street N.W.
Suite 250
Washington, DC 20001
Phone: (202) 944-2874
robert.peck@cclfirm.com

Michael B. Bogdanow
Leo V. Boyle
Bradley M. Henry
Victoria M. Santoro
MEEHAN, BOYLE, BLACK & BOGDANOW, P.C.
Two Center Plaza
Suite 600
Boston, MA 02108
Phone: (617) 523-8300

*Counsel for Respondents*

# APPENDIX

## TABLE OF CONTENTS

**APPENDIX A:**

**COMMONWEALTH OF MASSACHUSETTS**

**PLYMOUTH, SS.** **SUPERIOR COURT**
**PLCV2007-00064-A**

---

**LISA RECKIS & RICHARD RECKIS, Individually and as Parents and Natural Guardians of their minor child, SAMANTHA T. RECKIS**

**vs.**

**JOHNSON & JOHNSON, MCNEIL-PPC, INC., doing business as MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS**

---

**FINDINGS OF FACT, RULINGS OF LAW, AND ORDER FOR JUDGMENT ON PLAINTIFFS' CAUSE OF ACTION FOR VIOLATION OF GENERAL LAWS CHAPTER 93A**

---

On December 14, 2012, the plaintiffs, Lisa Reckis and Richard Reckis, individually and as parents and natural guardians of their minor child, Samantha T. Reckis (Samantha), filed a first amended complaint against the defendants, Johnson & Johnson and McNeil-PPC, Inc., doing business as McNeil Consumer & Specialty Pharmaceuticals (McNeil). The plaintiffs brought six claims against the defendants: negligence (Count I), breach of warranty (Count II), failure to warn (Count III), violation of the

consumer protection statute, G.L. c. 93A (Count IV), loss of consortium (Count V), and negligent infliction of emotional distress (Count VI). The plaintiffs claimed that after Samantha ingested over-the-counter Children's Motrin (ibuprofen) on November 28, 2003, the medicine caused her to develop Toxic Epidermal Necrolysis (TEN) and that the defendants failed to adequately warn them of this possibility. The plaintiffs filed their original complaint on January 12, 2007.

Nearly six years later, on January 9, 2013, a jury trial commenced before this court. The [*2]evidence presented by the parties was extensive and consisted of approximately twenty-five different witnesses and sixty-two exhibits. The jury heard testimony from medical experts, employees of the defendants, and the plaintiffs themselves, among others. The trial concluded on February 13, 2013 when the jury returned a verdict in favor of the plaintiffs. The plaintiffs prevailed on their claims of negligence and breach of warranty. The jury determined that McNeil and Johnson & Johnson were negligent in failing to provide adequate warnings in connection with Children's Motrin and that this negligence was a cause of harm to the plaintiffs. In addition, the jury determined that Children's Motrin was defective in connection with the warnings provided by McNeil and Johnson & Johnson, rendering Children's Motrin unreasonably dangerous, and that the defective warning was a cause of harm to the plaintiffs. Moreover, the jury found that Samantha's ingestion of Children's Motrin caused her to develop TEN in November of 2003. The jury decided that $50 million would fairly compensate Samantha for all of her injuries and damages, that $6.5 million would fairly compensate Lisa Reckis for her loss of

consortium, and that $6.5 million would fairly compensate Richard Reckis for his loss of consortium. Thus, the jury awarded the plaintiffs a total of $63 million.

Now before the court is the plaintiffs' G.L. c. 93A claim. The parties elected to proceed on this claim through a jury-waived trial. The plaintiffs and the defendants have filed proposed findings of facts and rulings of law, supplemental proposed findings of fact[1] and rulings of law, and trial briefs on the G.L. c. 93A claim. On March 12, 2013, this court conducted a jury-waived trial on the G.L. c. 93A claim and received six exhibits (Exhibits 63-68), which include the [*3]plaintiffs' G.L. c. 93A demand letter, the defendants' response to that letter, various supplemental documents, and a stipulation of the parties.

As discussed below, this court finds that based upon all of the evidence presented at trial, the defendants engaged in unfair and deceptive acts or practices within the purview of G.L. c. 93A and that the defendants' conduct was willful or knowing. However, this court concludes that the defendants have met their burden to demonstrate that the plaintiffs' G.L. c. 93A claim is barred by the permitted practices exemption, and therefore, as a matter of law, judgment must enter for the defendants on the plaintiffs' G.L. c. 93A claim in Count IV of the plaintiffs' first amended complaint.

---

[1] To they [sic] extent such proposed facts are not found by the court, the may be deemed denied.

## FINDINGS OF FACT

Based on the evidence presented at trial and the reasonable inferences therefrom, this court makes the following findings of fact that are applicable only to the plaintiffs' G.L. c. 93A claim that is the subject of this decision.

On March 17, 2006, the plaintiffs served via Federal Express a fifteen-page written demand for relief describing their claims pursuant to the Massachusetts Consumer Protection Act, G.L. c. 93A, upon William C. Weldon, Chairman of the Board and Chief Executive Officer of Johnson & Johnson, and upon Colin F. Watts, President of McNeil. The demand letter referenced exhibits contained in a large binder of materials, which included a timeline of events, photographs, and medical records.

The plaintiffs' c. 93A demand letter informed the defendants that in November of 2003, Samantha (Date of Birth: October 7, 1996) was stricken with TEN caused by Children's Motrin, which her parents gave her for a fever. Samantha was hospitalized for six months at Shriners [*4]Hospitals for Children and Massachusetts General Hospital (MGH) in Boston, Massachusetts during which she suffered almost the complete loss of her skin, respiratory failure, liver failure, cerebral hemorrhages, and the beginning of a life of legal blindness. Prior to November of 2003, Samantha had "vigorously good health" and faced a "bright, promising future." Even though Samantha's parents, Lisa and Richard Reckis, were separated, they "doted on her" and were each actively involved in Samantha's life.

According to the plaintiffs' demand letter, after a post-Thanksgiving event on the morning of November 28, 2003, Samantha, then age seven, showed the first signs of a fever. Samantha and her father, Richard Reckis, left a function at the Church of the Salvation Army in Plymouth, Massachusetts early because Samantha was congested and not feeling well. Richard brought Samantha home and after taking her temperature, determined that she had a low-grade fever. Richard left Samantha in the care of his other daughter and went to a local Tedeschi Food Shops around 2:00 p.m. where he purchased a bottle of original berry flavor, liquid Children's Motrin. The bottle contained a warning label, which included the following warnings: "Allergy alert: Ibuprofen may cause a severe allergic reaction which may include: hives, facial swelling, asthma (wheezing), shock . . . Stop use and ask a doctor if: an allergic reaction occurs. Seek medical help right away . . . [or if] any new symptoms appear." After returning home, Richard gave Samantha the two-teaspoon dose of Children's Motrin, as recommended on the product's packaging.[2] He read Samantha a story and put her to bed.

[*5]When Samantha woke up around 10:00 p.m., Richard gave Samantha a second two- teaspoon dose of Children's Motrin and put her back to bed. On

---

[2] At trial, Richard testified that in 1998, he gave Samantha the prescription drug amoxicillin for an ear infection even though he had read the label on that drug and even though the label warned about the risk of Stevens-Johnson Syndrome (SJS) and TEN. In 2012, Richard gave Samantha doses of the NSAID Aleve, which had a label that advised users to watch for symptoms such as "skin reddening, rash, and blisters."

November 29, 2003 around 5:00 a.m., Samantha was running a fever of about 102-103 degrees and complained that her mouth was hurting. Richard gave Samantha a third dose of Children's Motrin, comforted her with a cool, damp, face-cloth, and put her back to sleep. At this time, Richard noticed "some unusual red blotches" on Samantha's skin and found that she had these blotches on much of her body.[3] Richard called Lisa Reckis about making an appointment with the pediatrician.

Samantha still had a fever, her lips were dry and chapped, and her eyes were tearing when she returned to her mother's house around 12:00 p.m. Lisa took the Children's Motrin with her as well. Both parents believed that Samantha's rash was related to whatever had caused her fever, congestion, and mouth ache.

Lisa called Samantha's pediatrician at Long Pond Pediatrics. At 2:00 p.m. on November 29, 2003, Samantha saw Dr. Anthony Garami. He examined Samantha's rash and questioned whether it might be measles or another viral illness. Dr. Garami learned that Samantha's parents had given her Children's Motrin, and he prescribed Children's Motrin for Samantha, three times a day for the fever. Lisa took Samantha home and gave her another dose of Children's Motrin.

---

[3] Richard noted at trial that this was a "new symptom" and that the label for the Children's Motrin instructed the user to stop use if any new symptoms appeared. As noted below, both Richard and medical professionals continued to give Samantha Children's Motrin.

On the morning of November 30, 2003, Lisa observed that all of the red bumps on Samantha's body were blistering. Lisa found that Samantha's mouth appeared to be "glued shut with crusting mucus." Layers of skin began to peel off of Samantha. Lisa called Richard and Dr. Garami, who instructed the Reckises to meet him at the emergency room at Jordan Hospital in [*6]Plymouth. At around 11:00 a.m., Samantha and her parents arrived at the hospital. She was weak, crying, and in pain. Her lips were blistering, oozing, and cracking, and blisters were beginning to appear on other parts of her body. Dr. Garami told the Reckises that he had never seen anything like this before. No other medical staff at the Jordan Hospital could identify Samantha's illness. Samantha was rushed to MGH in Boston, but before leaving, she was given a 200 mg dose of Children's Motrin.[4]

Samantha arrived at MGH shortly after 2:00 p.m. At least nine separate medical and infectious disease specialists began examining Samantha. By late in the evening, the medical team believed that Samantha had TEN and would need to be transferred to the Shriners Hospitals for Children.

Samantha received extensive medical care that is detailed in three timelines that the plaintiffs included with their demand letter. She had epidermal lesions covering eighty to eighty-five percent of her total body surface. A doctor explained that Samantha

---

[4] Recognition of early symptoms and the discontinuation of all ibuprofen products can prevent adverse drug reactions from progressing to Stevens-Johnson Syndrome (SJS) and TEN. SJS is a milder form of TEN.

had about a twenty percent chance of survival and that TEN was the most serious of severe adverse drug reactions involving the skin. TEN was defined by a skin detachment of more than thirty percent. The doctor explained that TEN "was essentially drug-induced" and most likely brought on in Samantha by the Children's Motrin, a non-steroidal anti-inflammatory drug (NSAID). TEN ravages not only the skin, but all the mucosal membranes and surfaces, including the throat, mouth, eyes, esophagus, intestinal track, respiratory system, and genitalia.

Samantha was placed in a drug induced coma to manage the pain and suffered from acute [*7]and chronic respiratory failure, liver problems, and cerebral hemorrhages. By March 17, 2004, Samantha had recovered enough to be transferred to the Spaulding Rehabilitation Hospital. She began a program of nutritional, physical, respiratory, speech, occupational, and opthamalogical therapies. Samantha was discharged from Spaulding on May 27, 2004, but was repeatedly hospitalized thereafter.

The plaintiffs note in their demand letter that Samantha cannot walk more than one hundred fifty yards without exhaustion, she is now legally blind, and she has a drastically decreased lung capacity, but she can expect a normal life expectancy.

The plaintiffs note in their letter that despite the fact that the association between ibuprofen and TEN has been established in the medical literature since the 1970s, McNeil does not include in its labeling of Children's Motrin any description or information relating to TEN.

The plaintiffs recount that a package insert notes that there is an incidence of less than 1% of skin and appendages, Stevens-Johnson Syndrome (SJS), Lyell's syndrome (Toxic Epidermal Necrolysis). The plaintiffs argued that such technical information did nothing to assist the average consumer to recognize the symptoms of such serious conditions or inform them of the consequences of continuing to use Children's Motrin. They noted that the bottle of Children's Motrin purchased by Richard informed consumers that Children's Motrin could "cause a severe allergic reaction which may include hives, facial swelling, asthma (wheezing) and shock" and if such symptoms appeared, to "consult [a] doctor promptly." According to the plaintiffs, none of these symptoms appeared in Samantha, but because of her rash, eye, and mouth symptoms, Samantha's parents promptly consulted with a pediatrician. The plaintiffs also contend that because the information McNeil provides to physicians inadequately informs or warns them [*8]about serious skin reactions, Samantha's pediatrician and the staff of Jordan Hospital failed to recognize the onset of TEN and prescribed additional Children's Motrin.

In their demand letter, the plaintiffs asserted a claim under G.L. c. 93A for "unfair or deceptive acts or practices in the conduct of any trade or commerce" against McNeil and Johnson & Johnson. The plaintiffs noted that upon a finding of a G.L. c. 93A violation, they would recover their attorney's fees and expenses associated with litigation, and upon a finding that any violation was " willful or knowing," they would recover two or three times the amount of actual damages. The plaintiffs offered to compromise their claims against McNeil and Johnson & Johnson for the amount of $18 million. They deemed the offer

automatically withdrawn upon the commencement of suit and noted that they would provide additional medical documentation and information upon request.

On April 10, 2006, attorneys for McNeil and Johnson & Johnson responded to the plaintiffs' G.L. c. 93A demand letter via certified mail. McNeil stated that it treats the plaintiffs' claims very seriously and that it intended to carefully investigate the circumstances described in the demand letter, particularly the claim that Samantha's injuries were caused by allegedly unfair and deceptive acts or practices on the part of McNeil in the sale of Children's Motrin. McNeil wrote:

> Since the introduction of ibuprofen products into the marketplace in 1967, billions of doses of the drug have been sold worldwide. Its safety and pain-relieving and fever-reducing properties are well-documented and have been extensively analyzed. Children's Motrin was approved for Over The Counter [OTC] sale by the Food and Drug Administration in 1995, and the product has at all times been sold accompanied by labeling drafted consistent with FDA [Food and Drug Administration] mandates and reviewed and approved by that agency. This process was far from a formality and the label with which you take issue was scrutinized by the agency and its contents were revised in response to specific agency mandates.

[*9]Toxic Epidermal Necrolysis ("TEN") is a rare and poorly understood disease affecting the skin and mucous membranes and there is great uncertainty as to how the disease is caused, in part because it is so rare. Assessing causation will require expert review of all relevant medical records. Although the binder you sent with your letter will certainly expedite the process, McNeil accepts your offer to provide additional medical documentation and requests that you provide us with HIPAA compliant releases for each of Ms. Reckis' health care providers and pharmacies (both before and after her TEN hospitalization) to enable us to obtain additional records and to explore in detail the analysis, diagnosis and treatment of Ms. Reckis by her treating physicians, as well as the nature of any other substances to which she may have been exposed. We will of course provide you with copies of any records we obtain pursuant to these releases. In addition, although your letter demands damages in the amount of $18 million for Ms. Reckis and her family, it does not indicate with any specificity how you calculated these damages. This makes it difficult for us to determine, under any circumstances, what a reasonable response to your demand might be. Finally, please send a copy of the full label from the bottle of Children's Motrin purchased by Ms. Reckis' father (the

> photograph in the binder you provided is difficult to read).
>
> While McNeil respectfully disagrees with your assertion that it engaged in unfair and deceptive acts in the labeling of its product, we would be glad to discuss this case with you further.

In May of 2006, at the defendants' request, the plaintiffs provided the defendants with Bates-numbered copies of all medical records obtained to date. From June 2006 to November 2006, at the defendants' request, the plaintiffs provided executed authorizations for the defendants to obtain copies of all medical records to date in anticipation of a meeting between counsel. Also in November 2006, at the plaintiffs' request, the defendants entered into an agreement to toll the statute of limitations to allow a meeting between counsel to take place without filing suit. On December 14, 2006, a meeting between plaintiffs' counsel and the defendants' counsel with assistant general counsel for Johnson & Johnson, John Kim, was held in Boston. The plaintiffs made a video presentation of their claims, clients, and damages. At the conclusion of this meeting, Attorney Kim indicated that he would consider a settlement "in six figures," but not more. On January 7, 2007, the plaintiffs filed this action in the Superior Court [*10]and included a claim under G.L. c. 93A. The defendants have never offered a settlement in the case.

For years, the defendants have been aware of a potential causal relationship between ibuprofen and SJS and TEN. As far back as 1983, McNeil and Johnson & Johnson, together, developed a consumer

products strategy to bring an ibuprofen product to the OTC market.

McNeil and Johnson & Johnson were each aware prior to their submission to the FDA in 1988 of a New Drug Application (NDA) for their pediatric ibuprofen product, first called "Pediaprofen" and, later, prescription Children's Motrin, that there was a probable causal relationship between ibuprofen and SJS. Moreover, the defendants had been warned that the OTC availability of ibuprofen would likely "place large numbers of potential patients at a substantial risk" rendering the "need for continued surveillance . . . readily apparent." The defendants had specifically been warned of the need to monitor the product for previously undescribed toxic effects once the sales patterns changed due to the new OTC availability.

By 1994, when the defendants submitted to the FDA an NDA to affect a switch of their prescription Children's Motrin product to an OTC Children's Motrin product, at least some peer- reviewed scientific literature was available regarding ibuprofen and its probable causal relationship to SJS and TEN.[5] Yet, the defendants had not brought such literature to the FDA's attention by describing, analyzing, or discussing it as it related to the defendants' product under their NDA. At the time OTC Children's Motrin was made available to consumers, at least some peer-reviewed scientific articles had been published that

[5] The chemical make-up and formulation of prescription Children's Motrin and OTC Children's Motrin are identical. The products differ only as to dosage.

showed a causal relationship between [*11]ibuprofen and SJS and TEN.

Between 1995 and 2003, additional peer-reviewed scientific literature was published that confirmed the prevalence of SJS and TEN caused by ibuprofen. However, the defendants did not provide any discussion or analysis for the FDA about any comprehensive safety assessments of the risks of SJS and TEN with ibuprofen use. In 1995, based partly on such scientific findings, the defendants changed their ibuprofen prescription labels, including prescription Children's Motrin, to reflect that TEN was recognized as having a "Probable Causal Relationship" with a known incidence of less than one percent.[6]

From at least 1994 through 2005, Johnson & Johnson maintained an active presence on the Labeling Committee at McNeil, which is responsible for the labeling of Children's Motrin products. A lawyer for Johnson & Johnson sat on that "multi-disciplinary" committee and reviewed all information related to label changes and the safety of the product. Besides that legal representative, the committee was comprised of a representative from McNeil's Medical Affairs group, Regulatory Affairs group, and Marketing groups. According to Ashley McEvoy, McNeil's Vice President of Marketing, no department

---

[6] The 49th Edition of the Physicians' Desk Reference from 1995 lists SJS as having a probable causal relationship with Children's Motrin (precise incidence unknown but less than one percent). TEN is listed as having an unknown causal relationship with Children's Motrin (precise incidence unknown but less than one percent). The most frequent type of adverse reaction occurring with ibuprofen is gastrointestinal.

in the company had a larger operating budget than the marketing department's $450 million annual budget. That marketing budget was used, in part, to "communicate the benefits of the brands" like Children's Motrin. The marketing budget was not being spent to warn consumers about the risk of SJS and TEN associated with Motrin use. According to McEvoy, serious side-effects related to the use of an OTC product that [*12]are warned about or in the public's perception will affect a brand's reputation and, as a general matter, cause sales to go down.

Nonetheless, the label for over-the-counter (OTC) Children's Motrin was subjected to a lengthy review and approval process by the FDA, which included ongoing discussions, negotiation, and communication between McNeil and the FDA. Federal regulations required McNeil to use a label for Children's Motrin approved by the FDA. The FDA and its regulations specified the form and content of the Children's Motrin label, which included warnings, drug facts, and allergy alert sections.

In its 1995 approval letter to McNeil, the FDA enclosed the approved label to be used for OTC Children's Motrin and noted that McNeil was to use that label. The 1995 label did not explicitly mention "skin reddening, rash, and blisters," SJS, TEN, or the risk of a potentially life-threatening reaction. However, in 1995, the FDA knew of an association between TEN and ibuprofen products.[7]

---

[7] FDA approved labeling for prescription ibuprofen products has included references to SJS and TEN as potentially adverse reactions since 1982. Drug labeling designed for physicians on prescription drug products is

The 2003 label for OTC Children's Motrin, like the numerous labels for other OTC ibuprofen products in 2003, did not include the terms SJS, TEN, skin reddening, rash, blisters, or the risk of a potentially life-threatening reaction. The label was identical to the labels used by all other manufacturers of pediatric ibuprofen sold in 2003. The 2003 label for OTC Children's Motrin warned that the drug may cause a "severe allergic reaction" and instructed users and consumers of the drug to, "Stop use and ask a doctor if an allergic reaction occurs . . . [or] any new symptoms appear." In 2005, the FDA mandated changes to the labels of all OTC ibuprofen [*13]products to require manufacturers to warn that consumers should "stop use and seek medical attention immediately" if, after taking the ibuprofen product, the early symptoms of SJS and TEN – "skin reddening, rash [or] blisters" appear. All OTC ibuprofen products, including Children's Motrin, now include warnings about skin reddening, rash, and blisters–certain symptoms of an allergic reaction that were not included on the 2003 label of Children's Motrin.

**RULINGS OF LAW**

The plaintiffs contend that, viewed in its entirety, the evidence in this case shows that McNeil and Johnson & Johnson were aware of the causal connection between the use of Children's Motrin and SJS and TEN for many years prior to 2003, but nevertheless, knowingly failed to provide warnings sufficient to alert parents and physicians to the potentially life- threatening consequences of the

---

more detailed than the labeling for consumers on OTC products.

symptoms of redness, rash, and blistering, and to immediately discontinue use as soon as such symptoms appeared, constituting a knowing violation of G.L. c. 93A. Based on this conduct, the plaintiffs argue that the defendants should pay treble damages under G.L. c. 93A. The defendants deny liability.

**General Laws c. 93A**

Under G.L. c. 93A, § 2, "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful." G.L. c. 93A, § 2. Chapter 93A does not define what constitutes an "unfair or deceptive act or practice," and formulating such a definition would be impossible. *Kattar v. Demoulas*, 433 Mass. 1, 13 (2000). "[U]nfair or deceptive conduct is best discerned 'from the circumstances of each case.'" *Id.* at 14, quoting *Commonwealth v. DeCotis*, 366 Mass. 234, 242 (1974).

Nonetheless, "a practice or act will be unfair under G. L. c. 93A, § 2, if it is (1) within the [*14]penumbra of a common law, statutory, or other established concept of unfairness; (2) immoral, unethical, oppressive, or unscrupulous; or (3) causes substantial injury to competitors or other business people." See *Heller Fin. v. Insurance Co. of N. Am.*, 410 Mass. 400, 408 (1991). See also *Curtis v. Herb Chambers 1-95, Inc.,* 458 Mass. 674, 682 (2011). While Massachusetts cases offer no static definition of the term "deceptive," courts have stated that a practice is "deceptive," for purposes of G.L. c. 93A, if the conduct could reasonably be found to have caused a person to act differently from the way he or she otherwise would have acted. *Aspinall v. Philip Morris Cos., Inc.*, 442

Mass. 381, 394 (2004). Moreover, conduct is deceptive if it possesses "a tendency to deceive." *Id.*

A finding of negligence, by itself, is not sufficient to prove an unfair or deceptive act or practice. See *Darviris v. Petros*, 442 Mass. 274, 278 (2004); *Meyer v. Wagner*, 429 Mass. 410, 424 (1999); *Poly v. Moylan*, 423 Mass. 141, 151 (1996); *Squeri v. McCarrick*, 32 Mass. App. Ct. 203, 207 (1992). However, the Supreme Judicial Court has observed that, generally, a breach of warranty constitutes a violation of G.L. c. 93A. See *Maillet v. ATP-Davidson Co.*, 407 Mass. 185, 190-193 (1990) (acknowledging that defendant's breach of warranty in addition to negligent conduct constitutes a violation of G.L. c. 93A, § 9). The Massachusetts Attorney General, pursuant to G.L. c. 93A, § 2(c), has promulgated a regulation providing that "[i]t shall be an unfair and deceptive act or practice to fail to perform or fulfill any promises or obligations arising under a warranty." 940 Code Mass. Regs. § 3.08(2). See *Aspinall v. Philip Morris Cos., Inc.*, 442 Mass. at 396 n.18.

After considering all of the evidence presented at trial and the verdict returned by the jury, this court concludes that McNeil and Johnson & Johnson violated G.L. c. 93A. This court [*15]recognizes that when Richard Reckis gave Samantha the initial dose of Children's Motrin on November 28, 2013, the label on the bottle informed the consumer that ibuprofen may cause a severe allergic reaction, which may include: hives, facial swelling, asthma (wheezing) and shock and to stop use and seek medical help right away if an allergic reaction occurs or any new symptoms appear. That label, however, failed to specifically warn consumers like the Reckises that allergic reactions, such as rash or skin redness may

also be caused by Children's Motrin.[8] This was an unfair or deceptive act or practice that violated G.L. c. 93A. As a result, the Reckises, Dr. Garami, and other medical professionals at Jordan Hospital were unable to recognize that the Children's Motrin was causing Samantha's condition, and they continued to administer doses of Children's Motrin, thereby exacerbating her condition.

Moreover, the jury determined that McNeil and Johnson & Johnson were negligent in failing to provide adequate warnings in connection with Children's Motrin and that this negligence was a cause of harm to the plaintiffs. In addition, the jury determined that Children's Motrin was defective in connection with the warnings provided by McNeil and Johnson & Johnson, rendering Children's Motrin unreasonably dangerous, and that the defective warning was a cause of harm to the plaintiffs. Also, the jury found that Samantha's ingestion of Children's Motrin caused her to develop TEN in November of 2003. This court accepts the jury's findings in this case (negligence, breach of warranty, medical causation), which further supports this court's determination that McNeil and Johnson & Johnson violated G.L. c. 93A by failing to warn consumers about additional allergic reactions (skin reddening, rash, and blisters) [*16]associated with Children's Motrin. See *Maillet v. ATF-Davidson Co.*, 407 Mass. at 190-193 (noting that generally, a breach of warranty constitutes a violation of G.L. c. 93A). See also 940 Code Mass. Regs. § 3.08(2) (providing that "[i]t shall be an unfair and deceptive

---

[8] For years, McNeil and Johnson & Johnson have been aware of a potential causal relationship between ibuprofen and SJS and TEN.

act or practice to fail to perform or fulfill any promises or obligations arising under a warranty").

**Willful or Knowing Violation**

If the plaintiffs establish a "willful or knowing violation" of G.L. c. 93A, § 2, they are entitled to "up to three but not less than two times" damages. G.L. c. 93A, § 9. See *Computer Sys. Engr., Inc. v. Oantel Corp.*, 571 F. Supp. 1365, 1373-1375 (D. Mass. 1983) (distinguishing the terms "willful" and "knowing" in G.L. c. 93A case); *Shaw v. Rodman Ford Truck Center. Inc.*, 19 Mass. App. Ct. 709, 71 1-712 (1985). See also *Still v. Commissioner of the Dep't of Employment & Training*, 423 Mass. 805, 812-813 (1996) (noting that "decisions construing the multiple damages provisions of G.L. c. 93A [1994 ed.] have imposed such damages for 'wilful' or 'knowing' violations, equating the former with reckless conduct and the latter with intentional acts" ).

Here, the plaintiffs have established a "willful" or "knowing" violation of G.L. c. 93A, § 2, subjecting them to multiple damages. As the court, as trier of fact, is required to consider the credibility of all witnesses (including those appearing through deposition), the court finds that the defendants effectively buried their heads in the sand when it came to acknowledging the connection between ibuprofen and SJS or TEN. The parties designated deposition testimony from various witnesses that was presented to the jury at trial. Particularly, as discussed below, the deposition testimony of Robert Christiansen, Dr. Kenneth Kwong, Dr. Steven Silber, Ashley McEvoy, and Dr. Anthony Temple, in conjunction with other evidence presented at trial, which [*17]is discussed above, reveals that the

defendants were deliberately indifferent to the fact that there was an established causal relationship between ibuprofen and SJS or TEN.

For instance, Robert Christiansen was formerly employed at Johnson & Johnson from 1978 to 2005. He started out in the law department at Johnson & Johnson managing product liability litigation. In December of 2000, Christiansen became director of risk management at Johnson & Johnson. At times, he was on the "copy label committee" that reviewed and vetted advertising and product labels. He acknowledged that Children's Motrin did not include information regarding all of the risks associated with ibuprofen that were set out in a prescription label for the same product because it went through an over-the-counter review process by the FDA, which mandates labeling appropriate for consumers. He would review adverse event reports and was aware that Children's Motrin always had a risk of causing Stevens-Johnson Syndrome. Christiansen acknowledged that Johnson & Johnson has never done an investigation into the connection between SJS and Children's Motrin.

Dr. Kenneth Kwong worked for McNeil from 2001 to 2004 and was head of the pharmacovigilance department. Pharmacovigilance involves monitoring and evaluating safety data regarding drugs. Kwong knew that there was a risk of SJS from Children's Motrin (it was already on the prescription label) and he never went to the safety review board to inform them that there should be additional language regarding SJS in the over-the-counter label.

Dr. Steven Silber served as the vice president of drug development and safety at McNeil between

2003 and 2006. During that time, approximately five or six children reported an injury to McNeil from Children's Motrin. During his time at McNeil, Dr. Silber never personally tried to improve or change the label of Children's Motrin to warn people about the risks of SJS. Dr. [*18]Silber thought the label was adequate and did not require improvement. Moreover, he did not and still does not believe that Motrin is an accepted risk for SJS. Dr. Silber is not aware of anyone at McNeil ever doing a comprehensive review of SJS and Children's Motrin, but he knew that McNeil looked at the issue over the years in conjunction with the FDA.

According to Ashley McEvoy, McNeil's Vice President of Marketing, no department in the company had a larger operating budget than the marketing department's $450 million annual budget. That marketing budget was used, in part, to "communicate the benefits of the brands" like Children's Motrin, but the marketing budget was not being spent to warn consumers about the risk of SJS and TEN associated with Motrin use. According to McEvoy, serious side-effects related to the use of an OTC product that are warned about or in the public's perception will affect a brand's reputation and, as a general matter, cause sales to go down.

Dr. Anthony Temple offered deposition testimony on behalf of McNeil as the person with the most knowledge as to the medical and labeling issues regarding Children's Motrin. He is a senior medical consultant to the medical affairs group at McNeil. Dr. Temple described SJS and TEN as a skin disorder characterized by separation of the superficial layers of the skin on both the dermal and mucosal surfaces of the body. Dr. Temple testified that prior to October of

2003, the medical literature reported an association between ibuprofen and SJS. According to Dr. Temple, McNeil knew that there had been at least three cases of blindness and one case of a visual disturbance in cases involving Children's Motrin and SJS or TEN. Moreover, Dr. Temple was the person most responsible in the medical affairs department at McNeil for determining what information would be put on the label for Children's Motrin, and based on his personal judgment, he felt that the "level of certainty" was such that a warning regarding SJS was not [*19]needed. He believed that more than an association was necessary in order to change the OTC label for Children's Motrin. The jury and this court disagree with Dr. Temple: he should have done more.

Based on this testimony and other evidence, which is discussed above, the plaintiffs have established a "willful" or "knowing" violation of G.L. c. 93A, and they would be entitled to multiple damages, but for the permitted practices exemption discussed below. The defendants knew of a causal relationship between ibuprofen and SJS or TEN and willfully and knowingly decided not to strengthen the label for Children's Motrin.

**Permitted Practices Exemption**

The defendants argue that the plaintiffs' G.L. c. 93A claim is foreclosed by the "permitted practices" exemption. The plaintiffs, however, contend that the defendants' position on this issue ignores case law governing the respective roles of the FDA and the manufacturers of regulated drugs, namely *Wyeth v. Levine*, 129 S. Ct. 1187, 1196 (2009). The defendants argue, and this court agrees, that *Wyeth v. Levine* is

"off point" because it is a preemption decision and "has nothing to do with the Section 3 exemption."[9]

General Laws c. 93A, § 3, provides: "Nothing in this chapter shall apply to transactions or actions otherwise permitted under laws as administered by any regulatory board or officer acting under statutory authority of the commonwealth or of the United States. For the purpose of [*20]this section, the burden of proving exemptions from the provisions of this chapter shall be upon the person claiming the exemptions." General Laws c. 93A, § 3 must be read together with G.L. c. 93A, § 2. That section "created new substantive rights," and thus "[t]he fact that particular conduct is permitted by statute or by common law principles should be considered, but it is not conclusive on the question of unfairness." *Schubach v. Household Fin. Corp.*, 375 Mass. 133, 137 (1978), quoting *Commonwealth v. DeCotis*, 366 Mass. at 244 n.8. A defendant's burden in claiming the permitted practices exemption is heavy and a difficult one to meet. *Commonwealth v. Fremont Investment & Loan*, 452 Mass. 733, 750 (2008) (citation omitted). See *Aspinall v. Philip Morris, Inc.*, 453 Mass. 431, 433 (2009) (concluding that defendants had not met their burden of showing that the Federal Trade Commission (FTC) affirmatively permitted use of

---

[9] Navigation of this issue, defined by the Tenth Amendment, among the points of Federal Preemption, state court action, and the permitted practices exemption, at first blush, is a "Bermuda Triangle" adventure. However, as defendants concede, denial of their Federal Preemption claim is not inconsistent with the allowance of a permitted practice exemption. (See fn 1, p. 2, of the defendants' response to the plaintiffs' first supplemental proposed conclusions of law).

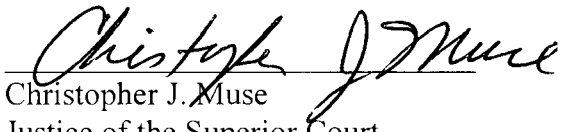
descriptors such as " light" and " lower tar and nicotine" on cigarette packages). To sustain this heavy burden, a defendant must show more than the mere existence of a related or even overlapping regulatory scheme that covers the transaction. *Commonwealth v. Fremont Investment & Loan*, 452 Mass. at 750. Rather, a defendant must show that such scheme affirmatively permits the practice which is alleged to be unfair or deceptive. *Id*.

Here, the defendants have met their heavy burden of showing that the permitted practices exemption applies under the facts of this case. Cf. *Aspinall v. Philip Morris, Inc.*, 453 Mass. at 436 (emphasizing requirement of affirmative permission and noting that "[i]nferences cannot be the basis for satisfying the defendants' heavy burden under the statute"). *Aspinall v. Philip Morris, Inc.* is instructive on the issue of the permitted practices exemption. See *id*. There, the court found that G.L. c. 93A § 3 is not a shield for fraud or misrepresentation, referencing the similar case and U.S. Supreme Court ruling in *Altria Group, Inc. v. Good*, 129 S. Ct. 538 (2008). [*21]*Id*. at 432-435. The Federal Cigarette Labeling and Advertising Act "does not encompass the more general duty not to make fraudulent statements." See *Altria Group, Inc. v. Good*, 129 S. Ct. 538, 549 (2008), quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 509 (1992) "The FDA's premarket approval of a new drug application includes the approval of the exact text in the proposed label . . . Generally speaking, a manufacturer may only change a drug label after the FDA approves a supplemental application." *Wyeth v. Levine*, 129 S. Ct. at 1 196. The 2003 label for OTC Children's Motrin, like the numerous labels for other OTC ibuprofen products in 2003, did not include the terms SJS, TEN, skin reddening, rash, blisters, or the

risk of a potentially life-threatening reaction. The label was identical to the labels used by all other manufacturers of pediatric ibuprofen sold in 2003. Moreover, the label for OTC Children's Motrin was subject to a lengthy review and approval process. In this case, McNeil and Johnson & Johnson provided a label that was accurate, but not adequate. Thus, the label for Children's Motrin at issue in this case was affirmatively permitted and approved by the FDA, and the plaintiffs are barred from recovering under G.L. c. 93A based on the permitted practices exemption.

[*22]**ORDER FOR JUDGM ENT**

For the foregoing reasons, it is hereby **ORDERED** that judgment enter in favor of the Defendants, Johnson & Johnson and McNeil-PPC, Inc., doing business as McNeil Consumer & Specialty Pharmaceuticals, on the Plaintiffs' G.L. c. 93A claim in Count IV of the Plaintiffs' First Amended Complaint.



Christopher J. Muse
Justice of the Superior Court

Dated: June 26, 2013

**APPENDIX B:**

**COMMONWEALTH OF MASSACHUSETTS**

**PLYMOUTH, ss.** **SUPERIOR COURT**
**PLCV2007-00064-A**

---

**LISA RECKIS & RICHARD RECKIS, Individually and as Parents and Natural Guardians of their minor child, SAMANTHA T. RECKIS**

vs.

**JOHNSON & JOHNSON, MCNEIL-PPC, INC., doing business as MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS**

---

**MEMORANDUM OF DECISION AND ORDER ON DEFENDANTS' MOTION FOR REMITTITUR**

---

On December 14, 2012, the plaintiffs, Lisa Reckis and Richard Reckis, individually and as parents and natural guardians of their minor child, Samantha T. Reckis (Samantha), filed a first amended complaint against the defendants, Johnson & Johnson and McNeil-PPC, Inc., doing business as McNeil Consumer & Specialty Pharmaceuticals (McNeil). The plaintiffs brought six claims against the defendants: negligence (Count I), breach of warranty (Count II), failure to warn (Count III), violation of the consumer protection statute, G.L. c. 93A (Count IV), loss of consortium (Count V), and negligent infliction of emotional distress (Count VI). The plaintiffs claimed that after Samantha ingested Children's

Motrin (ibuprofen) on November 28, 2003, the medicine caused her to develop Toxic Epidermal Necrolysis (TEN) and that the defendants failed to adequately warn them of this possibility. The plaintiffs filed their original complaint on January 12, 2007.

Nearly six years later, on January 9, 2013, a jury trial commenced before this court. The evidence presented by the parties was extensive and consisted of approximately twenty-five [*2]different witnesses and sixty-two exhibits. The jury heard testimony from medical experts, employees of the defendants, and the plaintiffs themselves, among others. The trial concluded on February 13, 2013 when after a lengthy period of deliberations, the jury returned a verdict in favor of the plaintiffs. The plaintiffs prevailed on their claims of negligence and breach of warranty. The jury determined that McNeil and Johnson & Johnson were negligent in failing to provide adequate warnings in connection with Children's Motrin and that this negligence was a cause of harm to the plaintiffs. In addition, the jury determined that Children's Motrin was defective in connection with the warnings provided by McNeil and Johnson & Johnson, rendering Children's Motrin unreasonably dangerous, and that the defective warning was a cause of harm to the plaintiffs. Moreover, the jury found that Samantha's ingestion of Children's Motrin caused her to develop TEN in November of 2003. The jury decided that $50 million would fairly compensate Samantha for all of her injuries and damages, that $6.5 million would fairly compensate Lisa Reckis for her loss of consortium, and that $6.5 million would fairly compensate Richard Reckis for his loss of consortium. Thus, the jury awarded the plaintiffs a total of $63 million.

On April 5, 2013, the defendants filed a motion for remittitur. The defendants are moving to remit the jury's damages award of $63 million or, in the alternative, they are moving for a new trial on damages. They contend that the jury's compensatory damages award is not supported by the evidence and that the record does not support so large of an award for pain and suffering or loss of consortium. Moreover, the defendants argue that the jury's award is excessive compared to verdicts in similar cases, which suggests that the jury's deliberations were overtaken by passion and prejudice. On May 1, 2013, the plaintiffs filed a written opposition to [*3]the defendants' motion. On May 17, 2013, the defendants filed a reply memorandum. On June 10, 2013, the plaintiffs filed a surreply memorandum. On June 12, 2013, this court held a hearing on the defendants' motion.[1] For the following reasons, the defendants' motion for remittitur is **DENIED.**

## DISCUSSION

Remittitur is the process by which a court requires either that the case be retried, or that the damages awarded by the jury be reduced. Black's Law Dictionary 1409 (9th ed. 2009). Under Mass. R. Civ. P. 59(a), "[a] new trial shall not be granted solely on the ground that the damages are excessive until the prevailing party has first been given an opportunity to remit so much thereof as the court adjudges is excessive." See Mass. R. Civ. P. 59(a). Moreover, the

[1] At the hearing, the defendants suggested that Samantha is entitled to reasonable damages in the amount of $5 million to $10 million and that Lisa Reckis and Richard Reckis are each entitled to $250,000 for their loss of consortium in connection with this case.

allowance of a motion for a new trial based upon an excessive award of damages, and the direction of a remittitur, rests in the sound discretion of the trial judge. See *Loschi v. Massachusetts Port Authority*, 361 Mass. 714, 715-716 (1972). See also *Baudanza v. Comcast of Massachusetts I, Inc.*, 454 Mass. 622, 630 (2009) (noting that appellate court shall not substitute judgment for that of the trial judge who saw the witnesses). On a motion for remittitur, this court is not obliged to make the smallest modification possible; rather, this court has discretion "to bring the verdict anywhere within the range of verdicts supported by the evidence." *D'Annolfo v. Stoneham Hous. Auth.*, 375 Mass. 650, 662 (1978). In addition, "[u]nless the damages awarded were greatly disproportionate to the injury proven or represented a miscarriage of justice, an appellate court will not find an abuse of discretion in the judge's refusal to grant a new [*4]trial." *doCanto v. Ametek. Inc.*, 367 Mass. 776, 787 (1975). See *Evans v. Lorillard Tobacco Co.*, 2013 WL 2462140 at *31 (Mass. 2013) (concluding that trial judge's remittitur award was not disproportionate to injuries suffered and did not represent a miscarriage of justice).

First, the defendants argue that the jury's award of compensatory damages in the amount of $63 million is not supported by the evidence. They argue that: (1) the record is devoid of any reasonable basis for calculating future medical expenses[2]; (2) the record is sparse in terms of evidence supporting a substantial award for impairment of Samantha's future earning capacity; (3) the compensatory damage

[2] At trial, the parties stipulated to Samantha's past medical expenses in the amount of approximately $840,000.

award does not reasonably relate to Samantha's pain and suffering; (4) the jury's award for loss of consortium was unreasonable.[3] This court does not agree with the defendants.

This court provided the jury with thorough instructions on how to calculate damages, which the jury presumably followed. See *Mailman's Steam Carpet Cleaning Corp. v. Lizotte*, 415 Mass. 865, 870 (1993) (noting that "[w]e presume that the jury followed the judge's instructions"); *O'Connor v. Raymark Indus., Inc.*, 401 Mass. 586, 590 (1988). See also *Commonwealth v. Degro*, 432 Mass. 319, 328 (2000) (recognizing that "[t]he jury are presumed to follow the judge's instructions"); *Commonwealth v. Watkins*, 425 Mass. 830, 840 (1997). This court instructed the jurors that the purpose of awarding damages is to compensate an injured [*5]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[4] and not to engage in guess work or speculation. The court instructed the jury to take into consideration three areas of damages: pain and suffering, medical expenses, and loss of earning

---

[3] The defendants also ask this court to consider newspaper articles from the Boston Globe containing information from various jurors who decided this case. In a decision dated March 18, 2013, this court addressed and denied the defendants' request for a post-verdict jury voir dire and now declines to revisit the issue or consider the articles in the Boston Globe in deciding the defendants' motion for remittitur.

[4] Sympathy must not be confused with empathy and understanding.

capacity. As to pain and suffering, this court noted that the jurors should take into consideration past, present, and future physical pain and suffering and mental pain and suffering. Also, the jurors were to consider and allow a reasonable sum for any permanent condition caused or resulting to the plaintiff as a result of the defendants' wrongful conduct. As to medical expenses, the jury was to consider a fair, reasonable sum for damages that the plaintiff may expect in the future. As to loss of earning capacity, this court instructed the jury that each person has an ability to earn money and that the capacity to earn money varies from individual to individual depending on a number of factors. This court explicitly instructed the jury not to take into account anything that is merely possible, speculative, or imaginative, and that the award for loss of earning capacity must be based on reasonable probability. Finally, this court instructed the jury to add up the damages for each of these areas to arrive at a final total damages award and cautioned the jury that there must not be any overlapping of the various elements constituting the damages.[5] The jurors knew that the total sum of damages must be fair compensation for the entire injury, no more and no less.

[*6]The evidence presented at trial thoroughly supports the thoughtful and reasonable total damage

---

[5] In their proposed verdict forms, neither the plaintiffs nor the defendants proposed that the damages question be broken down into specific categories. The defendants wanted one question that asked, "Please state in words and numbers the amount of money you find will fully and reasonably compensate the Plaintiffs for their injuries."

award that the jurors calculated in this case.[6] As to future medical expenses, the jury could reasonably determine that the costs associated with Samantha's future medical care will be high.[7] Based on the evidence presented at trial, Samantha's future medical expenses will likely include, among other things: treatment for her vision problems, treatment for her reduced lung capacity and the damage to her lungs, hospitalizations when she gets relatively minor common colds, and regular medical appointments to monitor her overall health. Since she cannot drive, Samantha will have to hire someone to take her to and from medical appointments or anywhere else she has to go. As to Samantha's future earning capacity, it was reasonable for the jury to award a substantial amount of damages to Samantha for this category of damages.[8] While Samantha and Lisa Reckis were hopeful that one day Samantha could pursue a career as a nurse, the evidence presented at trial reasonably suggests that such a career path is unlikely and that Samantha's future earning capacity has been dramatically reduced as a result her suffering from TEN. Based on their common knowledge, the jurors

---

[6] This court specifically finds that throughout the trial, all of the jurors paid close attention to the evidence presented by the parties and to the court's jury instructions.

[7] Samantha is expected to have a normal life expectancy and should live for at least sixty more years.

[8] The defendants argue that there was no evidence one way or the other on the issue of Samantha's future earning capacity and that nobody knows what she would have been or earned. However, based on all of the evidence presented at trial, the jury could have reasonably inferred that Samantha's future earning capacity has been severely limited as a result of the TEN.

could reasonably infer that nurses are required to quickly read electronic medical records, read fine print on medications, visually evaluate patients, and record readings from various instruments, often during long and strenuous [*7]days. The evidence at trial revealed that Samantha has poor vision and can only read books with the help of a projector that greatly magnifies the text of whatever she is trying to read. She tires easily as a consequence of her reduced lung capacity. It was reasonable for the jury to determine that despite her future ambitions, Samantha will never be able to earn any salary as a nurse. Thus, it was reasonable for the jury to award Samantha a substantial amount of monetary damages for future medical expenses and loss of earning capacity.

Moreover, it is reasonable to conclude that the vast majority of the jury's damage award to Samantha was based on past, present, and future physical pain and suffering and mental pain and suffering. As to this category of damages, the jury's award was amply supported by the evidence presented at trial. TEN brought Samantha to the doorstep of death. As a result of the TEN, almost all of Samantha's skin was burned from her body when she was only seven years old. The pain was so intense that Samantha was placed in a drug induced coma to manage the pain. She has suffered from acute and chronic respiratory failure, liver problems, nutritional problems, vision problems, and cerebral hemorrhages. TEN devastated not only Samantha's skin, but also all of her mucosal membranes and surfaces, including her throat, mouth, eyes, esophagus, intestinal track, respiratory system, and genitalia. Samantha struggled through months of physical therapy. She has had approximately forty surgeries. The jury could

reasonably determine that Samantha suffered an incredible amount of physical and mental pain and suffering that almost killed her.

How does one translate such an immense amount of physical and mental pain and suffering into monetary damages? That was for the jury to determine, and after carefully hearing the evidence presented at trial for over one month, the jury believed that $50 million was an [*8]amount of money that would fairly compensate Samantha for all of her injuries and damages.[9] Samantha unquestionably suffered "extensive and painful injuries" as a result of the TEN that the jury reasonably concluded was caused by Children's Motrin. Cf. *Baudanza v. Comcast of Massachusetts I, Inc.*, 454 Mass. at 630 & n.9 (noting that "judge might permissibly determine, in his discretion, that a jury did include both pain and suffering and reasonable medical expenses in their damage award even though the award and the medical bills happened to be the same amount"). After hearing all of the evidence presented at trial, this court declines to disturb the jury's damage award because it is not greatly disproportionate to the injuries proven and reasonably and fairly compensates Samantha for all of her injuries and damages. [10]

---

[9] Throughout the trial, the jury heard hours of testimony about Samantha's injuries and the pain and suffering she experienced as a result of the TEN. Translating Samantha's myriad of injuries into monetary damages was the jury's task, and their final monetary damage award was thoroughly supported by the record.

[10] In addition, this court declines to disturb the jury's determination that $6.5 million would fairly

Moreover, the defendants argue that the compensatory damages award is excessive when compared to verdicts in similar cases and that the "sheer size of the jury's award in this case [*9]shocks the sense of justice and immediately invites skepticism regarding the jury's motives."[11] The

---

compensate Lisa Reckis for her loss of consortium, and that $6.5 million would fairly compensate Richard Reckis for his loss of consortium. This court instructed the jurors that they could award Lisa Reckis and Richard Reckis damages for the loss of society and companionship that they have suffered as a result of the defendants' negligence. They were to consider loss of comfort, solace, or moral support, any restrictions on social or recreational life, and any deprivation of the full enjoyment of the parent-child relationship. However, this court noted that there is no special formula or rule to measure a fair amount for loss of consortium and that the jurors were to use their own common sense, good judgment, experience, and conscience in awarding damages for loss of consortium. The evidence at trial established that since November of 2003, Lisa Reckis and Richard Reckis have devoted almost all of their attention to caring for Samantha-financially, emotionally, and medically. TEN robbed the Reckises of their chance at enjoying a normal parent-child relationship with their daughter. Under the facts of this case, the jury's decision to award Lisa Reckis and Richard Reckis a total of $13 million for their loss of consortium was reasonable and supported by the evidence at trial.

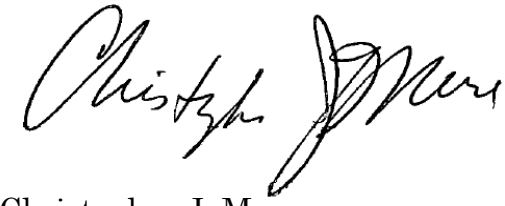
[11] The defendants argue that certain aspects of the plaintiffs' attorney's closing argument were improper and invited an excessive damage award. Nonetheless, the defendants never objected to the plaintiffs' attorney's closing argument during the trial, and this court never felt that it should have interrupted the plaintiffs' attorney's closing argument, *sua sponte*, for any reason. Hence, the plaintiffs' closing argument does not provide this court with a reason to order a remittitur.

defendants report that after reviewing reported case law, they have uncovered no verdict in a products liability or personal injury action not involving a wrongful death in Massachusetts that exceeded $20 million in compensatory damages. The defendants have attached a chart to their motion for remittitur that evaluates damages in eight separate cases. In their surreply memorandum, the plaintiffs cite verdicts in Stevens-Johnson Syndrome or TEN cases from various jurisdictions in support of their claim that the jury's verdict in this case should not be disturbed. Yet, this court should not compare the jury's award of damages in the instant case with damage awards in unrelated cases. See *Griffin v. General Motors Corp.*, 380 Mass. 362, 370-371 (1980) (emphasizing that in concluding that a remittitur was required, Supreme Judicial Court did not rely on comparisons of similar cases in arriving at conclusion). See also *Labonte v. Hutchins & Wheeler*, 424 Mass. 813, 825-826 & n.17 (1997). In *Griffin v. General Motors Corp.*, the defendant admitted that the plaintiff s injuries were unquestionably severe, but argued that the $1 million damages awarded were "so greatly disproportionate to the injuries proven that they represent a miscarriage of justice," and that the judge abused his discretion by failing to order a remittitur or a new trial. *Griffin v. General Motors Corp.*, 380 Mass. at 370-371. The defendants submitted an affidavit to the trial judge describing eighteen bum cases in which verdicts of $1 million or more were returned and argued that in each of those cases, the injuries [*10]were more severe than those in *Griffin v. General Motors Corp*. The Supreme Judicial Court determined that the trial judge did not abuse his discretion in declining to order a remittitur or a new trial and noted that comparing verdicts from various jurisdictions "is a dangerous game to say the

least." *Id.* at 731. This court declines to play this dangerous game of comparing the verdict in this case with verdicts from other unrelated cases. [12] As discussed above, the jury's total damage award of $63 million was not excessive, was reasonably and thoroughly supported by the evidence that was presented at trial, and does not represent a miscarriage of justice. See *Griffin v. General Motors Corp.*, 380 Mass. at 370-371; *D'Annolfo v. Stoneham Hous. Auth.*, 375 Mass. at 662. Accordingly, the defendants' motion for remittitur is denied.

**ORDER**

For the foregoing reasons, it is hereby **ORDERED** that the Defendants' Motion for Remittitur is **DENIED**.



Christopher J. Muse
Justice of the Superior Court

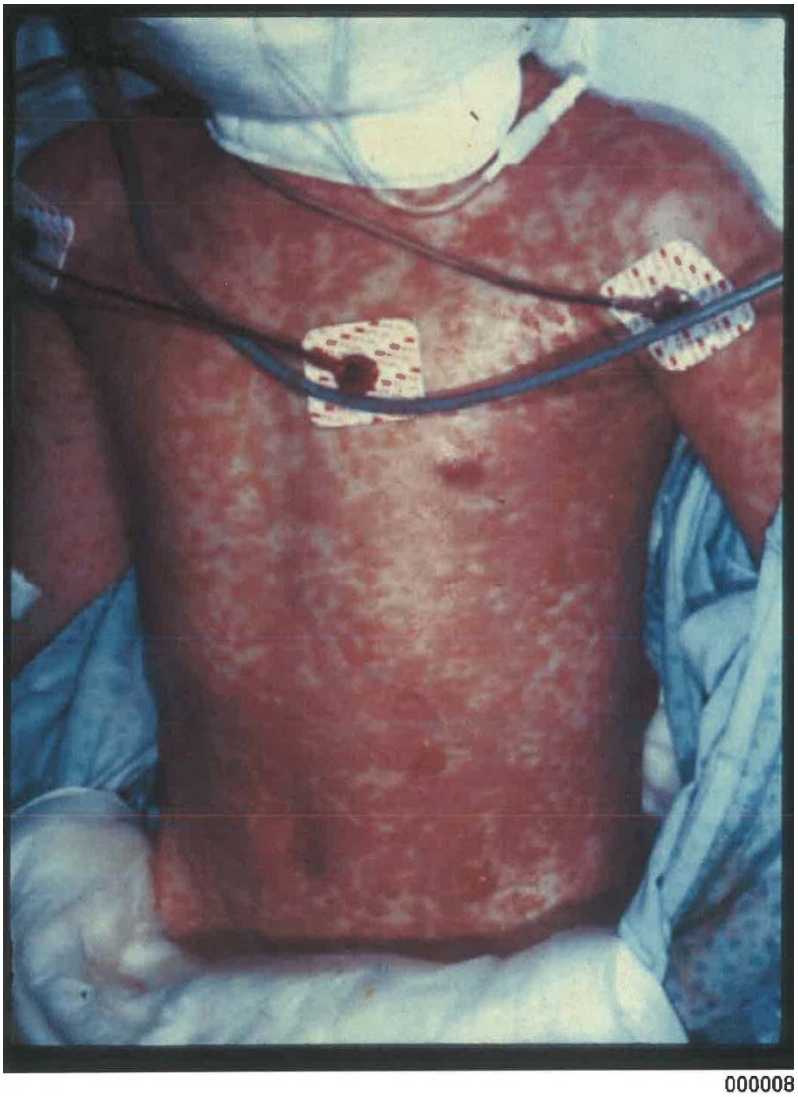
Dated: June 26, 2013

---

[12] Similarly, the court declines to consider the recent affirmation of the multiple millions of dollars awarded for personal injury and loss of consortium in the case of *Evans v. Lorillard Tobacco Co.*, 2013 WL 2462140 at *31 (Mass. 2013).

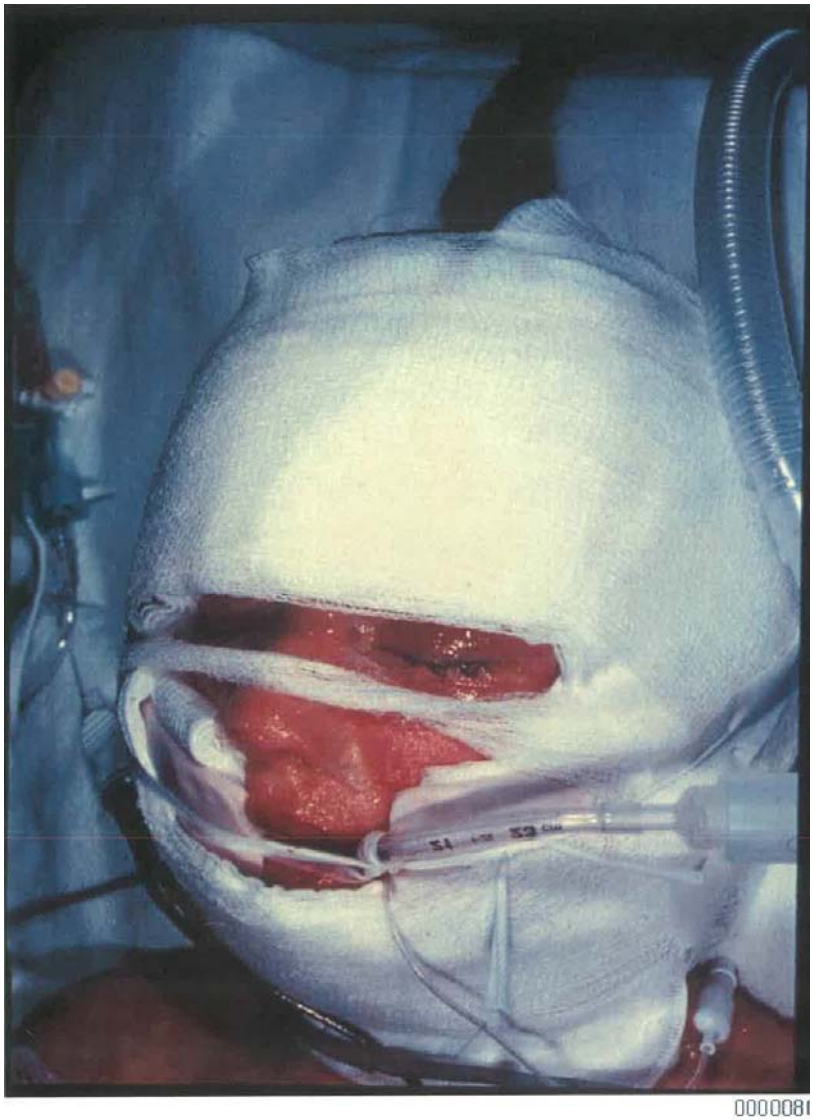
## APPENDIX C:

Excerpted from Appendix in Massachusetts Supreme Judicial Court, Volume 24, Exhibit 24: Photographs of Samantha Reckis



000008

**A. 11359**



0000081

A. 11367