SJC-11677

LISA RECKIS & another[1] vs. JOHNSON & JOHNSON & another.[2]

Plymouth. December 1, 2014. - April 17, 2015.

Present: Gants, C.J., Spina, Cordy, Botsford, Duffly, & Lenk, JJ.

Negligence, Pharmaceutical manufacturer, Defective product, Adequacy of warning, Causation, Causing loss of consortium. Consortium. Parent and Child, Consortium. Federal Preemption. Witness, Expert. Evidence, Expert opinion, Qualification of expert witness. Damages, Tort, Future damages, Future earning capacity, Conscious pain and suffering, Loss of consortium.

Civil action commenced in the Superior Court Department on January 12, 2007.

The case was tried before Christopher J. Muse, J., a motion for remittitur was heard by him, and motions for a new trial and for judgment notwithstanding the verdict were considered by him.

The Supreme Judicial Court granted applications for direct appellate review.

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[1] Richard Reckis. Both Lisa and Richard sued individually and as parents and natural guardians of their minor child, Samantha T. Reckis.

[2] McNeil-PPC, Inc., doing business as McNeil Consumer & Specialty Pharmaceuticals.

Joan A. Lukey (Charles C. Lifland, of California, & Justin J. Wolosz with her) for the defendants.

Michael B. Bogdanow (Bradley M. Henry, Leo V. Boyle, & Victoria Santoro with him) for the plaintiffs.

The following submitted briefs for amici curiae:

David C. Spangler, Richard F. Kingham, & Robert A. Long, Jr., of the District of Columbia, & Paul W. Schmidt & Colleen Kelly for Consumer Healthcare Products Association.

Lisa Blue Baron, Andre M. Mura, & Jeffrey R. White, of the District of Columbia, & Anthony Tarricone for American Association for Justice.

Hugh F. Young, Jr., of Virginia, & David R. Geiger & Catherine C. Deneke for Product Liability Advisory Council, Inc.

Martin Healy, Charles Alagero, Jeffrey N. Catalano, & Maria Davis for Massachusetts Bar Association & another.

Charlotte E. Glinka, Elizabeth N. Mulvey, Thomas R. Murphy, & Jeffrey S. Beeler for Massachusetts Academy of Trial Attorneys.

Martha Coakley, Attorney General, & Eric Gold, Assistant Attorney General, for the Attorney General.

BOTSFORD, J. Samantha T. Reckis was seven years old in late 2003, when she developed toxic epidermal necrolysis (TEN), a rare but life-threatening skin disorder, after receiving multiple doses of Children's Motrin. Children's Motrin is an over-the-counter (OTC) medication with ibuprofen as its active ingredient, and is manufactured and sold by the defendants McNeil-PPC, Inc. (doing business as McNeil Consumer & Specialty Pharmaceuticals [McNeil]), and its parent company, Johnson & Johnson. The plaintiffs, Lisa and Richard Reckis, and their child, Samantha,[3] claim that Samantha developed TEN as a result of being exposed to ibuprofen in the Children's Motrin that was

[3] Because all the plaintiffs share a last name, we refer to them by their first names in this opinion.

administered to her, and that the warning label on the Children's Motrin bottle rendered the product defective because it failed to warn consumers adequately about the serious risk of developing a life-threatening disease from it. After a lengthy jury trial in the Superior Court, the jury found in favor of the plaintiffs, awarding general damages to Samantha and loss of consortium damages to each of her parents.

Before us is the defendants' appeal from the Superior Court judgment. They raise three claims: (1) the defendants were entitled to judgment as a matter of law because the plaintiffs' central claim of failure to warn is preempted by the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 et seq., as administered by the Federal Food and Drug Administration (FDA); (2) the defendants also are entitled to judgment as a matter of law because the plaintiffs failed to prove causation as a matter of law -- in the defendants' view, the plaintiffs' causation witness, Randall Tackett, Ph.D., was unqualified to render the opinions on causation that he did, his opinions were not scientifically reliable in any event, and there was no other competent evidence on which the necessary element of causation could be based; and (3) the damages awarded to each of the plaintiffs were "grossly excessive" and unsupported by the record. For the reasons we shall discuss, we affirm the Superior Court judgment.

Background. We summarize the facts from the evidence presented at trial.

1. On the afternoon of November 28, 2003, seven year old Samantha had a fever and sinus congestion and, consequently, her father purchased a bottle of OTC Children's Motrin. The bottle was packaged inside a box, with identical warnings on the outside of the box and on the bottle. Richard read the warnings on each, and administered a dose of Children's Motrin to Samantha around 2 P.M. that day. Samantha then took a nap until approximately 10 P.M., at which point she woke still with a fever and congestion, and Richard gave her a second dose of Children's Motrin.[4]

The next morning, on November 29, Samantha woke with redness and a rash on her chest and neck, and a sore throat; she also had the same fever and congestion as she had had the night before. Richard gave her a third dose of Children's Motrin. Richard testified at trial that he would not have given Samantha the third dose had the drug's label warned that redness, rash, or blisters might lead to a life-threatening disease, or if the label had warned that these symptoms could be signs of Stevens-

[4] Samantha had taken Children's Motrin once before, in October, 2002.

Johnson Syndrome (SJS) or TEN.[5] He further stated that he would have prevented others from administering additional doses of Children's Motrin to Samantha had these warnings been on the drug.

Around 9 A.M. on November 29, Richard telephoned Samantha's mother to tell her about Samantha's rash, and Lisa made an appointment for Samantha to see her pediatrician.[6] When Richard brought Samantha to Lisa's home around noon that day to pick up Lisa on the way to the appointment, Samantha had a fever, nasal congestion, crusty eyes, cracked lips, and a rash. The pediatrician opined that Samantha had the measles, and told Richard and Lisa to treat Samantha with Motrin three times per day. Lisa gave Samantha another dose of Children's Motrin that evening after reading the warning label on the bottle. Lisa testified at trial that she would not have given this dose had the drug's label mentioned rash as a warning signal.

When Samantha woke up the next morning, on November 30, most of her body was covered in blisters. She could not open her eyes or mouth, and her lips were bleeding. Richard and Lisa took Samantha to the emergency room of Jordan Hospital (Jordan)

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[5] Richard also testified, however, that he was not familiar with Stevens-Johnson Syndrome (SJS) or toxic epidermal necrolysis (TEN) at the time.

[6] Richard and Lisa were separated at the time, and were divorced by the time of trial.

where she received another dose of ibuprofen. When Samantha's condition worsened that day, she was transferred to Massachusetts General Hospital (MGH) and, shortly thereafter, to Shriners Hospitals for Children (Shriners) in Boston, where doctors diagnosed Samantha with TEN and informed Lisa and Richard that Samantha had a minuscule chance of surviving through the night. Tests administered at Jordan, MGH, and Shriners essentially ruled out a virus as the cause of Samantha's disease.

Samantha was put into a medically induced coma to ease her pain for approximately one month beginning on December 1, and was hospitalized for the next six months. During her hospitalization, Samantha's TEN resulted in bloody secretions and affected approximately ninety-five per cent of her body's surface area; the top layer of her skin died and sloughed off. She suffered heart and liver failure. At one point, while Lisa cradled Samantha in her arms at the hospital, Samantha suffered a stroke followed shortly thereafter by an aneurysm. She also suffered a cranial hemorrhage that caused seizures, and underwent brain surgery. While in the hospital, she had only twenty per cent of her lung capacity; falling below fifteen per cent of lung capacity puts one at high risk of death. Her eyes were inflamed. Samantha became addicted to pain medications that were given to her to ease her discomfort, and she suffered

visible withdrawal symptoms, shaking and shivering as she was weaned off the medications. Around the time of her release from the hospital in May of 2004, Samantha weighed approximately thirty-five pounds.

The jury heard conflicting expert testimony concerning whether Children's Motrin had caused Samantha's TEN. The plaintiffs' expert witness Randall Tackett testified that the medication did so, as did both Dr. Bonnie Mackool, the director of inpatient dermatology services at MGH and the director of dermatology at Shriners, who treated Samantha during her initial six-month hospitalization, and Dr. Stephen Foster, Samantha's treating ophthalmologist at the time of trial who had treated Samantha since that initial hospitalization. Other experts, including the defense witnesses Dr. Stanford T. Shulman and Dr. Maja Mockenhaupt, testified that ibuprofen had not caused Samantha's TEN.

After being released from the hospital in the spring of 2004, Samantha needed to eat through a feeding tube for two years, and required oxygen assistance at night for two years as well. On occasion, the feeding tube would become dislodged, resulting in pain. She returned to school in the fall of 2004 and repeated first grade; during that school year, Samantha's teacher had to carry her up and down stairs due to her small size, and Samantha needed to visit the school nurse every day to

eat lunch through her feeding tube. At the time of trial in early 2013, Samantha was sixteen years old and weighed eighty-two pounds.

Between her initial release from MGH and Shriners in 2004 and trial, Samantha had been hospitalized several times with pneumonia and for trouble with her breathing, and she had had multiple bouts of bronchitis. She had scarring in her lungs. By 2011, Samantha's lungs had improved but they still functioned at less than half of their capacity, and she could not engage in any athletic activities. Samantha's pediatrician testified that, as a result of Samantha's low lung capacity, she will not be able to maintain a pregnancy.

Since 2004, Samantha has had more than twelve eye surgeries. Before a surgery conducted shortly before trial during which doctors implanted a prosthesis to replace the lens of the cornea in Samantha's left eye, Samantha was legally blind.[7] Following this surgery, Samantha will be required to apply topical antibiotics to her eye often for the remainder of her life, and have her contact lens changed by a specialist each

[7] Although there was a complication deriving from this surgery, the eye surgeon who performed it testified at trial that he was confident this problem could be addressed. However, while not part of the trial record, posttrial filings include an affidavit of the eye surgeon indicating that since trial, Samantha had undergone multiple surgeries to correct the problem, to no avail by that point, and would lose her left eye if surgical correction were ultimately to prove unsuccessful.

month. Samantha's right eye suffers from in-turned eye lashes that rub against her scarred cornea, resulting in mucus stimulation collecting on the cornea. To read, she has used a projector to enlarge the type, and she sits very near to the screen onto which the words are projected. She needs to press her nose to her telephone or the television to see what is on the screen of each.

At the time of trial Samantha was in the ninth grade. She was an honors student, but it took her much longer than other students to complete her homework. She enjoyed her coursework at school, liked to shop at the mall with friends, and often played video games. Samantha was close to her parents before developing TEN and remained so after it. She testified that she wants to attend college and study nursing, and that she hopes to work as a nurse at MGH.

Despite her optimism, Samantha suffers cognitive limitations, and her memory is not as sharp as it was before her illness. Due to her memory loss, she struggles to retain information, which makes completing her schoolwork a constant challenge. She will never be able to drive an automobile, and she remains dependent on others for assistance in her daily life. For the remainder of her life, she will be at increased risk for frequent hospitalizations, lung problems such as asthma and wheezing at a minimum, and further eye complications, such

as glaucoma.[8] She also will always be at a great risk of illness and at a severe disadvantage in terms of fighting disease due to her pulmonary deficiencies and low body weight.

During the acute stage of Samantha's TEN and in the years that followed, her parents devoted themselves to caring for Samantha's many needs. They stayed with her throughout her hospitalization. Richard spent nights in a reclining chair, and Lisa slept in a room the size of a closet. They suffered significant distress in monitoring the progression of Samantha's disease and were often told during Samantha's hospitalization that she would not survive. Since then, Richard, who previously worked as a chef, took a job at a local gasoline station because the shorter hours permitted him to better tend to Samantha. In all, they have not been able to watch Samantha enjoy a normal childhood as a result of the numerous, significant, and constant challenges to her health.

2. The defendants manufacture and market the Children's Motrin brand of ibuprofen, which is a nonsteroidal anti-inflammatory drug (NSAID) used to treat minor aches and pains as well as fever.[9] In 1989, the FDA, which approves and regulates

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[8] See note 7, supra.

[9] At trial, the defendants disputed that Johnson & Johnson played a role in the manufacture of over-the-counter (OTC) Children's Motrin, and Johnson & Johnson moved for a directed verdict on this ground. The judge denied the motion. The jury

prescription and nonprescription medications, approved McNeil to sell pediatric prescription ibuprofen called Pedia Profen, and in 1995, McNeil obtained FDA approval to sell Children's Motrin as an OTC pediatric fever reducer and pain reliever.

TEN and SJS are severe disorders or diseases that attack the skin, resulting in a rash and a diffused eruption of blisters and significant damage to the mucosal membranes throughout the body, particularly the mouth, eyes, and genital and anal areas. SJS occurs where less than ten per cent of the body's surface is affected by the disorder, while TEN occurs where more than thirty per cent of the body's surface is so affected.[10] Both diseases can lead to scarring and infection; with TEN, the top layer of skin dies and the skin sloughs off, leaving raw areas that are predisposed to infection, a condition that can lead to death. SJS and TEN can cause blindness and significant damage to the respiratory and reproductive systems. According to the FDA, SJS has a mortality rate of five per cent, and TEN is fatal in some thirty per cent of cases.[11] The jury

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answered separate special questions finding each defendant equally liable. The defendants do not raise any issue concerning Johnson & Johnson individually on appeal.

[10] If between ten per cent and thirty per cent of the body's surface is affected by the skin reaction, the disease is classified as SJS/TEN.

[11] SJS and TEN are rare disorders or diseases. The Food and Drug Administration (FDA) estimated in 2006 that "the overall

heard testimony from both parties' experts indicating that ibuprofen, the active ingredient in Children's Motrin, is associated with SJS and TEN.

3. When Samantha was given OTC Children's Motrin in 2003, the "warnings" section of the FDA-approved Children's Motrin label contained an "[a]llergy alert" that read as follows:

> "Ibuprofen may cause a severe allergic reaction which may include:
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> - hives
> - asthma (wheezing)
> - facial swelling
> - shock"

The warnings section of the label also alerted consumers to "[s]top use and ask a doctor if . . . an allergic reaction occurs" or if "any new symptoms appear." The label did not mention SJS or TEN, the possibility of skin reddening, rash, blisters, or the onset of a life-threatening disease.[12]

On February 15, 2005, a group that included physicians and Tackett[13] submitted to the FDA a petition concerning the relationship between ibuprofen and SJS and TEN (citizen

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incidences of SJS and TEN range from 1.2 to 6 [cases] per million [persons] per year and 0.4 to 1.2 [cases] per million [persons] per year, respectively."

[12] However, the label of prescription Children's Motrin did warn at this time that Motrin may cause SJS and TEN.

[13] Randall Tackett, Ph.D., is a pharmacologist who was an expert witness for the plaintiffs at trial.

petition).[14] The citizen petition requested the FDA to "conduct a risk assessment of [SJS] and [TEN] associated with the use of ibuprofen products" and to "require manufacturers of ibuprofen to amplify their prescription and [OTC] labeling to adequately warn" of the risks of SJS and TEN.[15] Specifically, the citizen petition requested two alterations to the OTC ibuprofen warning label. The first request was the inclusion of the following language in the "[w]arnings" section of the label:

> "Serious Skin Reactions: Ibuprofen may cause serious skin reactions that begin as rashes and blisters on the skin, and in the areas of the eyes, mouth and genitalia. These early symptoms may progress to more serious and potentially life-threatening diseases, including . . . [SJS] and [TEN]. Seek immediate attention if any of these symptoms develop while taking ibuprofen" (emphasis added).

The second request was for the addition of the following new warning:

> "Stop use and ask a doctor if: a skin rash or blisters on the eyes, mouth or genitalia occur because these symptoms may be an early sign of rare and life-threatening reactions including" SJS and TEN.

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[14] An individual may file a petition with the FDA to request that it "issue, amend, or revoke a regulation or order, or . . . take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.25(a)(2) (1989). See In re Prograf Antitrust Litig., U.S. Dist. Ct., No. 1:11-md-2242-RWZ (D. Mass. Feb. 1, 2012).

[15] The citizen petition included references to studies and literature that, according to the petition, indicated an association between ibuprofen and SJS and TEN. It also incorporated an analysis of reports of adverse reactions to ibuprofen, and a safety assessment of nonsteroidal anti-inflammatory drugs (NSAIDs) performed by the petitioners.

In the alternative, the citizen petition requested that the FDA reconsider its approval of OTC pediatric ibuprofen products.

The FDA responded formally to the citizen petition in 2006. Before doing so, the agency engaged in what it termed "a comprehensive review of the risks and benefits" of ibuprofen, "including the risks of SJS and TEN," and in April of 2005, the FDA announced its request that manufacturers of OTC NSAIDs include warnings regarding symptoms that were associated with SJS and TEN, and specifically, "skin reddening," "rash," and "blisters."[16] In a June, 2005, letter to McNeil, the FDA requested that McNeil revise the "[a]llergy alert" warning on OTC Children's Motrin to add warnings about these three symptoms.

The FDA's formal response to the citizen petition, dated June 22, 2006, acknowledged that "NSAIDs, including ibuprofen,

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[16] The updated warnings were to appear in the "[a]llergy alert" section of the OTC pediatric ibuprofen label, and were to read as follows:

> "Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
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> "▪ hives ▪ facial swelling ▪asthma (wheezing)
> "▪ shock ▪ skin reddening ▪rash ▪ blisters"
>
> "If an allergic reaction occurs, stop use and seek medical help right away."

are known to cause SJS and TEN," and that "[p]rompt recognition of the onset of symptoms, such as the appearance of rash or blisters on the skin, and withdrawal of the suspected drug can minimize the effects of SJS/TEN and improve prognosis." Accordingly, the FDA agreed with the petitioners that the labeling of OTC ibuprofen products such as Children's Motrin "should be improved to warn consumers about the risks of severe skin reactions associated with" such products. The FDA, however, also took the position that it was not useful for OTC ibuprofen labels "to include the specific terms SJS, TEN, . . . Stevens-Johnson syndrome, and toxic epidermal necrolysis" because "most consumers are unfamiliar with these terms." Finally, the FDA declined to reconsider its stance on allowing the sale of OTC pediatric ibuprofen based on the grounds that "the incidence of SJS or TEN is not as great as cited" in the citizen petition, that "the overall benefit versus risk profile for ibuprofen products remains very favorable when they are used according to the labeled instructions," and that it is in the public health's interest "to maintain in the pediatric OTC market a range of therapeutic options for the short-term relief of pain."

4. The plaintiffs filed their complaint in the Superior Court in January, 2007. The amended complaint, filed December 14, 2012, alleges negligence, breach of warranty,

failure to warn of potentially lethal side effects of Children's Motrin, violation of G. L. c. 93A, loss of consortium, and negligent infliction of emotional distress.[17] Prior to trial, the defendants filed a motion for summary judgment claiming they were entitled to judgment because the plaintiffs' central cause of action based on failure to warn was preempted by the FDCA. Hedging their bets, they also filed a motion in limine to exclude evidence or argument at trial that the OTC Children's Motrin label should have warned of SJS or TEN by name, or of the possibility of the onset of a life-threatening disease, on the ground that any claim based on the defendants' failure to include these warnings was preempted. The trial judge denied both of these motions. The trial judge also denied the defendants' motion in limine seeking to exclude Tackett's opinion testimony that ibuprofen caused Samantha's TEN, rejecting the defendants' argument that he lacked the qualifications necessary to offer such an opinion.[18]

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[17] In their amended complaint the plaintiffs effectively withdrew previous claims alleging defective design and manufacturing.

[18] The defendants subsequently challenged Tackett's testimony on the basis that he was not qualified to offer an opinion supporting a finding on specific causation in their motion for a directed verdict at trial. The judge denied the motion.

[18] The defendants subsequently challenged Tackett's testimony on the basis that he was not qualified to offer an opinion supporting a finding on specific causation in their

The case was tried in January and February, 2013. The jury answered special questions to the effect that Samantha's ingestion of Children's Motrin caused her TEN, and that both defendants negligently failed to provide adequate warnings in connection with Children's Motrin, causing harm to Samantha. The jury further found that both Lisa and Richard suffered a loss of consortium as a result of Samantha's injuries.[19] The jury awarded Samantha $50 million in compensatory damages, and awarded $6.5 million to each of Lisa and Richard for their loss of consortium.[20]

Following trial, the defendants filed motions for judgment notwithstanding the verdict and for a new trial in which they renewed their preemption argument, as well as their contention

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motion for a directed verdict at trial. The judge denied the motion.

[19] With regard to breach of warranty, the jury found each defendant liable for rendering Children's Motrin defective due to inadequate warnings, and that this defect caused harm to Samantha. The plaintiffs' negligent infliction of emotional distress claim was withdrawn at trial and not submitted to the jury.

[20] After a jury-waived trial on the G. L. c. 93A claim, the judge found that the defendants knowingly or wilfully engaged in unfair and deceptive acts or practices under c. 93A. Nevertheless, the judge found in favor of the defendants on the ground that the plaintiffs' c. 93A claim was barred by the permitted practices exemption. See G. L. c. 93A, § 3 ("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"). See also Fleming v. Nat'l Union Fire Ins. Co., 445 Mass. 381, 389 (2005).

that Tackett lacked the proper qualifications to opine as to the cause of Samantha's TEN. The judge denied these motions in their entirety. The judge also denied the defendants' motion for remittitur, in which they argued that the jury's damage awards were excessive and unsupported by the evidence. The defendants filed a timely appeal in the Appeals Court, and we granted direct appellate review.[21]

Discussion. 1. Preemption. The defendants renew their argument that the plaintiffs' claim of failure to warn is preempted by the FDCA, and that the trial judge erred in denying them judgment as a matter of law on this ground.[22] Preemption "may be either expressed or implied, and 'is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose.'" Gade v. National Solid Wastes Mgt. Ass'n, 505 U.S. 88, 98 (1992), quoting Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977). Conflict preemption is a type of implied preemption; it occurs

[21] We acknowledge the amicus briefs submitted by The Consumer Healthcare Products Association; American Association for Justice; Product Liability Advisory Council, Inc.; Massachusetts Bar Association and Massachusetts Medical Society; Massachusetts Trial Attorneys; and the Attorney General.

[22] In addition to raising their Federal preemption claim in their summary judgment motion and motion in limine, the defendants advanced the claim again in their motion for a directed verdict at the close of the plaintiffs' case, motion for judgment notwithstanding the verdict, and motion for a new trial, all of which the judge denied.

"where compliance with both federal and state regulations is a physical impossibility, . . . or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" (quotations and citations omitted). Gade, supra. See Wyeth v. Levine, 555 U.S. 555, 588-589 (2009) (Thomas, J., concurring in the judgment). See also In re Fosamax (Alendronate Sodium) Prods. Liab. Litig., 951 F. Supp. 2d 695, 702-703 (D.N.J. 2013) (Fosamax).

The defendants contend that this is a classic case of conflict preemption, in that the warning the plaintiffs say would have made a difference -- difference in the sense of changing the outcome by persuading Richard to cease giving any further doses of Children's Motrin to Samantha once the rash appeared after the second dose[23] -- is one that the FDA has

[23] The defendants point to the following testimony of Richard:

> Q.: "If this label that you had purchased the day before had said to beware of redness and rash because they might -- redness, rash, blisters because they might be the pathway to a life-threatening disease -- . . . [w]ould you have ever given Sammy that third dose of Motrin?"
>
> A.: "Absolutely not."
>
> Q.: "Now if it had said beware and keep an eye out for redness among the other things we've already read but redness, rash, blisters because this could be the warning sign of toxic epidermal necrolysis or Stevens Johnson Syndrome, would you ever have given Sammy that for a third dose?"

expressly rejected, thereby putting the defendants in the impossible position of having to comply with conflicting Federal and State requirements.[24] We disagree that conflict preemption defeats the plaintiffs' claim of failure to warn, but before discussing the reasons why, we consider the plaintiffs' contention that principles of conflict preemption are irrelevant here because a section of the FDCA, 21 U.S.C. § 379r(e) (2012), expressly exempts or saves product liability suits concerning OTC drugs from preemption.

The plaintiffs' argument fails. Section 379r is entitled, "[n]ational uniformity for nonprescription drugs," and it expressly preempts certain State requirements relating to the regulation of OTC drugs. See 21 U.S.C. § 379r(a) (2012) ("no State . . . may establish or continue in effect any requirement . . . that is different from or in addition to, or that is otherwise not identical with, a requirement under [the FDCA]"). The "savings clause" on which the plaintiffs rely, § 379r(e), begins with a heading stating, "[n]o effect on product liability law," and then provides: "Nothing in this section shall be construed to modify or otherwise affect any action or the

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A.: "Absolutely not."

[24] The conflict between Federal and State law would exist because the FDA regulates OTC drug labels as a matter of Federal law, and a State jury verdict and judgment in this case constitutes State law.

liability of any person under the product liability law of any State" (emphasis added). Thus, by its terms, the § 379r(e) savings clause frames its exemption from preemption with a reference to § 379r itself and, as a result, must be read in the context of § 379r as a whole and specifically the express preemption provision set out in § 379r(a).[25] The savings or exemption from preemption provided by § 379r(e), however, does not extend beyond the provisions of § 379r, and in particular does not preclude "the ordinary working of conflict pre-emption principles." See Geier v. American Honda Motor Co., 529 U.S. 861, 869 (2000). That is, even if the savings clause in § 379r(e) "removes tort actions from the scope of [an] express pre-emption clause" such as § 379r(a), the savings clause "does not foreclose . . . the possibility that a federal [law] will pre-empt a state common-law tort action with which it conflicts," see Geier, supra at 869-870, and principles of implicit conflict preemption would still bar the plaintiffs' claim if the result the plaintiffs sought would require the defendants to use a warning label that conflicted with FDA requirements. See id. at 871 (without operation of ordinary preemption principles, "state law could impose legal duties that would conflict directly with federal regulatory mandates").

[25] The additional subsections of 21 U.S.C. § 379r (2012) are not relevant to this discussion.

Accordingly, we interpret the savings clause to spare the plaintiffs' State law claim from express preemption by the FDCA that otherwise would result by virtue of § 379r(a), but the plaintiffs' claim remains susceptible to implicit conflict preemption.[26]

We turn to the defendants' conflict preemption claim. They argue that under the Supreme Court's decision in Wyeth, the plaintiffs' claim of failure to warn is preempted because exceptionally "clear evidence," Wyeth, 555 U.S. at 571, exists that the FDA would not have approved the warning that the plaintiffs argue was called for, thus creating an impossible conflict between State tort law and the Federal regulatory requirements of the FDCA.

In Wyeth, the plaintiff prevailed in a products liability suit that included a claim of failure to warn relating to the warning label on a prescription drug manufactured by the defendant Wyeth. Id. at 559-560, 562. The FDA had approved the

[26] To the extent the plaintiffs construe a footnote in Evans v. Lorillard Tobacco Co., 465 Mass. 411 (2013), to mean this court has determined as a general matter that conflict preemption principles do not come into play in the face of an express preemption savings clause in a Federal statute, the plaintiffs are mistaken. The footnote in question, see id. at 431 n.11, discussed and concerned only the Federal Family Smoking Prevention and Tobacco Control Act. The footnote was not intended to, and did not, establish a general rule to govern the relationship between express statutory savings clauses and Federal principles of conflict preemption.

label when it approved the defendant's supplemental new drug application. Id. at 561-562.[27] The question before the Supreme Court was whether Federal law -- specifically the FDCA -- preempted the plaintiff's State tort law claim of failure to warn concerning the prescription drug's warning label. Id. at 565. Wyeth argued in favor of preemption on the ground that it was "impossible" for it to comply with both the State law warning duties that formed the basis of the plaintiffs' tort claims and the FDA's Federal labeling regulations. Id. at 568. The Court acknowledged that typically a drug manufacturer may change a drug label only upon FDA approval of its supplemental application to do so, but noted that the FDA's "changes being effected" (CBE) regulation "provides that if a manufacturer is changing a label to 'add or strengthen a contraindication, warning, precaution, or adverse reaction," then the manufacturer "may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval." Id., quoting 21 C.F.R. § 314.70(c)(6)(iii)(A). Noting that "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its

[27] The plaintiff's claim was that Wyeth's drug warning label "was defective because it failed to instruct clinicians to use the IV-drip method of intravenous administration" of the drug Phenergan "instead of the higher-risk IV-push method" used in the plaintiff's case. Wyeth v. Levine, 555 U.S. 555, 559-560 (2009).

label at all times," Wyeth, supra at 570-571, the Court concluded that once the risk of the "IV-push" injection method (see note 27, supra) was evident, Wyeth was obligated to warn of that risk, and "the CBE regulation permitted it to provide such a warning before receiving the FDA's approval." Id. at 571. The Court recognized that "the FDA retains authority to reject labeling changes made pursuant to the CBE regulation," but "absent clear evidence that the FDA would not have approved a change to Phenergan's label," it was not "impossible for Wyeth to comply with both federal and state requirements" (emphasis added). Id. at 571. Accordingly, the plaintiff's claim was not preempted. Id. at 572-573.[28]

Wyeth did not "define 'clear evidence,' so 'application of the clear evidence standard is necessarily fact specific.'" Fosamax, 951 F. Supp. 2d at 703, quoting Dobbs v. Wyeth Pharms., 797 F. Supp. 2d 1264, 1270 (W.D. Okla. 2011). In looking at the specific facts of this case, the first step is to identify what

[28] At oral argument in this case, the defendants' counsel noted a disagreement in the drug industry over whether the "changes being effected" (CBE) regulation applies to OTC drugs. Such a controversy was not discussed in the defendants' briefs, and they have not cited any cases or other authorities in support of the point. Because the defendants' preemption argument relies on Wyeth, and Wyeth incorporated the CBE regulation into its reasoning, we consider the CBE regulation as applicable to OTC drugs. Other courts have applied the CBE regulation in cases asserting failure to warn in relation to an OTC drug. See, e.g., Newman vs. McNeil Consumer Healthcare, U.S. Dist. Ct., No. 10-CV-01541 (N.D. Ill. Jan. 9, 2012).

warnings the plaintiffs claim the defendants should have provided to give fair warning of the potentially deadly side-effects from Children's Motrin. The defendants argue that at trial the plaintiffs claimed that the Children's Motrin label should have mentioned SJS and TEN by name; the plaintiffs disagree that they did so, and we address this dispute, infra. However, 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. See Robinson v. McNeil Consumer Healthcare, 615 F.3d 861, 873 (7th Cir. 2010) ("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 [i.e., citizen petition] to which the agency was responding"). See also Fosamax, 951 F. Supp. 2d at 703 (FDA's denial of drug manufacturer's requested change to "[p]recautions" section of label soon after plaintiff's injury provided clear evidence FDA would have rejected change before injury occurred); Dobbs v. Wyeth Pharms., 797 F. Supp. 2d at

1276-1277 (FDA rejected defendant drug manufacturer's proposed expanded cautions on drug label -- "clear evidence" found).

The question 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. The defendants assert the FDA's response to the citizen petition demonstrates that, like the disease names "SJS" and "TEN," the FDA specifically rejected the request to require that OTC ibuprofen labels warn that rashes and blisters may lead to a "life-threatening" disease. We do not read the FDA to have done so. The FDA stated in its response the following:

> "You[, the signers of the citizen petition,] recommend that FDA reconsider the OTC status of the pediatric formulation of ibuprofen or, at a minimum, add the following changes to ibuprofen OTC labeling:
>
> - "In the '<u>Warnings</u>' of the labeling: 'Serious Skin Reactions: Ibuprofen may cause serious skin reactions that begin as rashes and blisters on the skin, and in the areas of the eyes, mouth and genitalia. These early symptoms may progress to more serious and potentially life-threatening diseases, including Erythema Multiforme, Stevens Johnson Syndrome and Toxic Epidermal Necrolysis. Seek immediate attention if any of these symptoms develop while taking ibuprofen.'
>
> - "In the '<u>Stop use and ask a doctor if</u>': 'a skin rash or blisters on the eyes, mouth or genitalia occur because these symptoms may be an early sign of rare and life-threatening reactions including Erythema Multiforme, Stevens Johnson Syndrome and Toxic Epidermonecrolysis.'

> ". . .
>
> "We agree that the labeling for OTC NSAIDs, including all ibuprofen products, should be improved to warn consumers about the risks of severe skin reactions associated with OTC ibuprofen products . . . . As a result, we have requested that manufacturers include under the Allergy alert subheading the symptoms associated specifically with SJS and TEN. We do not believe that it is useful to include 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. In addition, effective OTC labeling communicates warning information in a manner that consumers can quickly and easily identify and understand. Consequently, we believe a description of symptoms is more appropriate. Therefore, prominently displayed under the Allergy alert subheading in the Drug Facts Label, the labeling will include:
>
> - skin reddening
> - rash
> - blisters
>
> "In addition, under the Allergy alert subheading, the labeling will state: 'If an allergic reaction occurs, stop use and seek medical help right away.' We believe that adding these symptoms to the Allergy alert, with advice to stop use and seek medical attention immediately, will alert and educate consumers to the nature of the allergic reactions associated with SJS and TEN. Further, we intend to continue our consumer education efforts regarding the safe and effective use of OTC pain relievers."

As just discussed, this response clearly stated that (1) the FDA rejected the proposal to place the actual names of the diseases mentioned -- Erythema Multiforme, SJS, and TEN -- on any OTC ibuprofen label; and (2) the FDA adopted the citizen petition proposal to list specific early symptoms of the diseases. But that is all that we find clear. The proposed language, "potentially life-threatening diseases," was part of the same

sentence as, and immediately followed by, the names of the three diseases or conditions that the FDA specified it did not think proper for an OTC ibuprofen label. Accordingly, the FDA's decision not to request that manufacturers add a warning about life-threatening diseases could well have been merely a byproduct of its rejection of these requested warnings on the basis that they mentioned Erythema Multiforme, SJS, and TEN by name. Whether the FDA also would consider including a mention of life-threatening diseases, by itself, to be inappropriate and off limits on the OTC label is anybody's guess; certainly the reason specified by the FDA for rejecting use of the disease names -- consumer unfamiliarity -- does not apply to use of such a phrase. See Newman vs. McNeil Consumer Healthcare, U.S. Dist. Ct., No. 10-CV-01541 (N.D. Ill. Jan. 9, 2012) (discussing same portion of FDA response to same citizen petition: "The Citizen Petition did include phrases like 'serious skin reactions' and 'life-threatening diseases' and the FDA did not ultimately require such language, but the agency provided no reasoning for those particular decisions; therefore, conclusions regarding how those phrases and their alleged analogues were considered and evaluated by the FDA are speculative"). See also Lofton v. McNeil Consumer & Specialty Pharms., 682 F. Supp. 2d 662, 677-678 (N.D. Tex. 2010).

Moreover, because the defendants were not involved in the submission of the citizen petition, the absence of the FDA's explicit rejection of the phrase "life-threatening diseases" or any rationale for the decision not to request that manufacturers add such a warning takes on increased significance. That is, even assuming for sake of argument that we could predict the FDA would have rejected a citizen petition proposal to add only this warning, that would not answer whether the FDA would have rejected the warning had it been sought by the defendants themselves. See Schedin v. Ortho-McNeil-Janssen Pharms., Inc., 808 F. Supp. 2d 1125, 1133 (D. Minn. 2011) (FDA's decision not to seek label change "in the face of a Citizen's Petition, not supported by the [drug] manufacturer does not constitute clear evidence that the FDA would have rejected a label change proposed" by manufacturer [emphasis in original]). Cf. Dorsett v. Sandoz, Inc., 699 F. Supp. 2d 1142, 1157 (C.D. Cal. 2010) (FDA's rejection of warning requests in citizen petitions "constituted determinations that the warnings should not be mandated; they were not determinations that manufacturers could not choose to add warnings that they believed were scientifically substantiated" [emphasis in original]). This is so in part because "the very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a

warning pursuant to the CBE regulation is difficult to accept." Wyeth, 555 U.S. at 570.[29,30]

In sum, "[i]mpossibility pre-emption is a demanding defense," id. at 573, and we cannot glean from the FDA's response to the citizen petition, or from any other source in this record, clear evidence that the FDA would not have approved

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[29] The Court in Wyeth specifically suggested that "clear evidence" could be established by the FDA's rejection of a drug maker's attempt to give the warning underlying a claim of failure to warn, see Wyeth, 555 U.S. at 572, but there was no evidence of such a rejection here. Contrast, e.g., In re Fosamax (Alendronate Sodium) Prods. Liab. Litig., 951 F. Supp. 2d 695, 703 (D.N.J. 2013). This 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. Clear evidence that the FDA would have rejected a new warning can be shown in other ways, as indicated in this case: as discussed, the FDA's response to the 2005 citizen petition plainly rejected warnings that mentioned SJS and TEN by name.

[30] The Court in Wyeth also pointed out that the "FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge." Wyeth, 555 U.S. at 578-579 & n.11. In light of the burden on the FDA, we are reluctant to infer that its response to the citizen petition conclusively rejected a warning regarding a life-threatening disease in the absence of a direct statement on the subject. This view is supported by the observation in Wyeth that claims of failure to warn under State law "uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly," and that they "also serve a distinct compensatory function that may motivate injured persons to come forward with information." Id. at 579. Moreover, the savings clause in 21 U.S.C. § 379r(e) (2012) that exempts from express preemption products liability actions brought under State law, although not dispositive on the issue of conflict preemption, supports the general notion that products liability suits remain an important avenue for relief and indicates congressional intent that such actions are not to be prevented lightly.

a warning on OTC ibuprofen labels stating that redness, rash, and blisters may lead to a life-threatening disease, so if an allergic reaction occurs, stop use and seek medical help right away. But because we have concluded that principles of conflict preemption would bar any claim of failure to warn advanced by the plaintiffs on the premise that the OTC Children's Motrin label should have warned of SJS or TEN by name, we must consider, and therefore turn to, the defendants' argument that the jury may have based its finding of liability on this preempted theory.

The defendants contend that the jury were free to decide liability on the basis of the preempted theory of failure to warn because (1) Richard testified he would have stopped administering Children's Motrin to Samantha once her rash appeared if the label had warned that a rash could be a sign of TEN, and (2) the trial judge declined to instruct the jury that they could not find the warning label inadequate for failing to mention SJS or TEN by name.[31] This argument is unavailing.

Certainly, where multiple theories were before a jury, at least one of which was improper, a new trial would be necessary if there is "no way of knowing on which basis the jury reached

[31] The defendants proposed that the judge instruct the jury that they could not find the defendants liable for failing to warn of SJS or TEN by name or for failing to warn of life-threatening diseases; the judge declined to give the instruction as proposed.

its verdict." Rosado v. Boston Gas Co., 27 Mass. App. Ct. 675, 678 (1989). See Slate v. Bethlehem Steel Corp., 400 Mass. 378, 384 (1987). Cf. Evans v. Lorillard Tobacco Co., 465 Mass. 411, 445 (2013) ("Where we cannot ascertain on which theory the jury relied in finding causation, the jury's finding of liability as to negligence cannot stand"). This is not a case in which there is "no way of knowing" the basis for the jury's verdict; we are reasonably confident that the jury did not base liability on the defendants' failure to warn of SJS or TEN by name. For one, Richard testified that he had never heard of SJS or TEN when he gave Children's Motrin to Samantha, making it unlikely the jury would have credited his subsequent testimony that he would have stopped administering the drug to Samantha if the label had warned that a rash could be a sign of TEN. In addition, Lisa testified that if the warning label had mentioned rash as a warning signal, she would not have given Samantha the additional dose of Children's Motion when Richard brought Samantha to Lisa's house on November 29; Lisa did not mention SJS or TEN in connection with a warning. Moreover, the plaintiffs' trial counsel stated explicitly to the jury in his closing argument that the plaintiffs did not contend that the warning should have mentioned SJS or TEN by name;[32] he argued solely that the warning

[32] Counsel told the jury: "Now, just to be clear, I mean, just to be clear what we say the label should have said, we

should have mentioned the possibility that redness, rash, or blisters could lead to a life-threatening disease. In these circumstances, although it is theoretically possible that the jury reached their verdict on the basis of the defendants' failure to warn about the possible occurrence of SJS and TEN, the likelihood appears very slim, and we find no reason to disturb the jury's verdict on preemption grounds.

2. Expert testimony. The defendants argue that they were entitled to judgment as a matter of law on the ground that the causation evidence essential to the plaintiffs' case came from Dr. Randall Tackett, a pharmacologist, who offered the testimony without the necessary qualifications or a proper foundation.

We start on common ground with the defendants: expert testimony is required to establish medical causation.[33] See Canavan's Case, 432 Mass. 304, 316 (2000). "'The crucial issue,' in determining whether a witness is qualified to give an expert opinion, 'is whether the witness has sufficient "education, training, experience and familiarity" with the

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don't take the position that it had to have the technical names of the diseases. That stuff. That doesn't happen because most people don't know what they are."

[33] Medical causation has two components, both of which require expert opinion evidence. See Kerlinsky v. Sandoz Inc., 783 F. Supp. 2d 236, 240 (D. Mass. 2011) ("an expert opinion on medical causation must contain two elements -- general causation, i.e., that the drug can cause the injury, and specific causation, i.e., that the drug did cause the injury in this case" [emphasis in original]). Specific causation is the focus of the defendants' challenge here.

subject matter of the testimony.'" Commonwealth v. Frangipane, 433 Mass. 527, 533 (2001), quoting Commonwealth v. Richardson, 423 Mass. 180, 183 (1996). With regard to the adequacy of the methodology supporting expert testimony, a "party seeking to introduce scientific evidence may lay an adequate foundation either by establishing general acceptance in the scientific community or by showing that the evidence is reliable or valid through an alternate means." Canavan's Case, supra at 310. See Commonwealth v. Lanigan, 419 Mass. 15, 26 (1994). In the end, a "trial judge has wide discretion to qualify an expert witness and to decide whether [a] witness's testimony should be admitted," and we will reverse a judge's decision to admit expert testimony "only where it constitutes an abuse of discretion or other error of law." Frangipane, supra. See Canavan's Case, supra at 312. The defendants contend that Tackett was unqualified to render an opinion as to specific medical causation in Samantha's case because as a pharmacologist rather than a medical doctor, he has never diagnosed or treated a patient with TEN. The trial judge concluded otherwise, and we find no abuse of discretion in his doing so.

Tackett testified that he is a professor of pharmacology and toxicology at the University of Georgia's College of Pharmacy, and a former chair of its department of pharmacology and toxicology; he has taught these subjects there for three

decades. Pharmacology, Tackett explained, involves the study, at the molecular level, of how a drug is metabolized and absorbed by the body, including how the drug is distributed once ingested and how particular dosages of drugs may lead to certain side effects. Toxicology, in turn, is primarily concerned with the adverse, or toxic, effects of a drug.

Tackett has a bachelor's degree in biology, and a master's degree and doctorate in pharmacology and toxicology. He has written numerous peer-reviewed or refereed publications, primarily on pharmacology and toxicology. He has taught courses (forensic pharmacy and advanced therapeutics) that focus on the interactions of drugs with the human body. He has taught courses on NSAIDs as well. He also is experienced in reviewing medical records to determine the effects of a drug because doing so is a component of pharmacology and toxicology, and he has served as a peer-reviewer of papers written by physicians. He has not treated a patient with SJS or TEN or published an article on these diseases, but he was instructed on TEN during his training, and at the time of trial he had read a majority of the scientific literature concerning the causes of SJS and TEN.

The judge was entitled to credit Tackett's testimony about the depth and scope of his education, training, and experience in determining the manner in which drugs adversely affect the human body, and could also credit Tackett's testimony that he

has considerable experience in reviewing patient medical records in order to determine the effects of a drug on the body. In light of the evidence of Tackett's qualifications, we find no error in the judge's ruling that Tackett was qualified to render an opinion on whether ibuprofen specifically caused Samantha's TEN despite the fact that he was not a physician treating TEN patients. See Allen v. Martin Surfacing, 263 F.R.D. 47, 57-58 (D. Mass. 2009) (neurotoxicologist qualified to offer expert testimony as to specific medical causation despite lacking medical degree). See also Frangipane, 433 Mass. at 533-535.[34,35]

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[34] The defendants rely on Commonwealth v. Frangipane, 433 Mass. 527 (2001), for the proposition that Tackett was unqualified to testify as to specific causation, but the reliance is misplaced. In that case, a prosecution for rape of a child, we concluded that the trial judge had acted within his discretion in permitting a social worker called as an expert witness by the Commonwealth to offer opinion evidence on dissociative memory loss, recovered memory, and delayed disclosure among sexually abused children, based on the witness's extensive training, education and experience in the field; that she was not a medical doctor or psychologist did not "alter this conclusion." See id. at 527, 530-531, 533-535. We also concluded, however, that the witness was not competent, and should not have been permitted, "to testify about how a trauma victim stores and retrieves, or dissociates, a traumatic memory because the witness's testimony on these issues involved pronouncements concerning the physical functioning of the brain, a scientific and medical matter on which the Commonwealth failed to establish that the witness was qualified to testify" (emphasis in original). Id. at 535. Unlike the social worker witness in Frangipane, however, Tackett's education, training, and experience as a pharmacologist and toxicologist did encompass the science of how a drug, such as ibuprofen, produces adverse effects on the body.

[35] Our conclusion that Tackett was qualified to testify as to specific medical causation is in accord with other courts

We note also that Tackett's specific causation opinion was in accord with that of Samantha's treating physicians who testified at trial. Dr. Bonnie Mackool, a dermatologist, and Dr. Stephen Foster, an ophthalmologist, each of whom treated Samantha and examined her extensively, testified that ibuprofen had caused her to develop TEN. In addition, the jury heard evidence that the medical resident who examined Samantha upon her initial admission to MGH in 2003 indicated that Samantha's disease was caused by ibuprofen.

We turn to the defendants' argument that Tackett had no foundation for what the defendants refer to as his "third dose" opinion -- that is, according to the defendants, the opinion that Samantha would not have contracted SJS or TEN if, once her rash appeared, she had not received the third dose of Children's Motrin.[36] The defendants contend that the "third dose" theory

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that have considered his qualifications to testify to an opinion that Motrin caused SJS or TEN. See Wolfe v. McNeil-PPC, Inc., 881 F. Supp. 2d 650, 659 (E.D. Pa. 2012) (finding Tackett qualified to testify as to causation on basis of his experience as pharmacologist, "notwithstanding his lack of a medical degree"); Lofton vs. McNeil Consumer & Specialty Pharms., U.S. Dist. Ct., No. 3:05-CV-1531-L (N.D. Tex. July 25, 2008).

[36] The plaintiffs assert that the defendants did not object at trial to the foundation for Tackett's opinion that Samantha would not have contracted TEN had she not received any ibuprofen after suffering a rash. Accordingly, they argue, the defendants have waived this issue on appeal. The trial judge, however, recognized the defendants' continuing objection to, among other things, a lack of foundation for Tackett's testimony regarding specific medical causation. In the circumstances, we decline to find a waiver.

was an essential component of causation in the plaintiffs' claim of failure to warn, but was not medically or scientifically valid and not supported by medical literature.[37]

It is true that the plaintiffs' claim of failure to warn was premised in substantial part on Richard's testimony that he would not have given Samantha more Children's Motrin once her rash appeared had the drug's label warned that redness, rash, or blisters might lead to a life-threatening disease.[38] That is, the omitted warning underlying the plaintiffs' claim became relevant to those caring for Samantha only once she woke up with a rash on the morning of November 29, the same morning that Richard gave her the third dose of Children's Motrin. To prevail on their claim of failure to warn, the plaintiffs had to establish that the lack of this warning caused Samantha's harm because its omission resulted in Samantha receiving more ibuprofen than she otherwise would have, resulting, ultimately, in TEN. See Laaperi v. Sears, Roebuck & Co., 787 F.2d 726, 729

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[37] As we discuss infra, this "third dose" theory is more accurately described as a "second dose" opinion because Tackett's testimony primarily conveyed an opinion that Samantha would not have contracted TEN had she received only the first two doses of Children's Motrin, and not the three subsequent doses. To avoid quibbles about numbers, we will refer to this as Tackett's "dose opinion."

[38] Richard also testified that he would have prevented others from giving Children's Motrin to Samantha once her rash appeared had the drug's label warned of the significance of a rash.

(1st Cir. 1986) ("the failure to warn of hazards associated with foreseeable uses of a product is itself negligence, and if that negligence proximately results in a plaintiff's injuries, the plaintiff may recover"; applying Massachusetts law); Jones v. Walter Kidde Portable Equip., 16 F. Supp. 2d 123, 125 (D. Mass. 1998) (claim of failure to warn requires establishing causation through evidence indicating that if additional "warnings had been given and heeded, the outcome would have been different"; applying Massachusetts law). Accordingly, we agree with the defendants that Tackett's dose opinion, coupled with Richard's testimony, was an important step in establishing that an adequate warning on the Children's Motrin label about the significance of a rash would have prevented Samantha from receiving more ibuprofen and developing a full-blown case of TEN.

We are not convinced, however, that to establish liability it was essential for the plaintiffs to show that the third dose of Children's Motrin administered to Samantha, as opposed to the fourth or fifth dose, caused her to develop TEN. In 2003, when the warning on the Children's Motrin label that the plaintiffs argue should have been present was not, there appears to have been a general unfamiliarity about the significance of Samantha's rash. Thus, in addition to the third dose of Children's Motrin administered by Richard, Samantha's

pediatrician ordered continued treatment with the Children's Motrin despite the presence of her rash, resulting in Lisa administering a fourth dose to Samantha,[39] and Samantha was administered a fifth dose of ibuprofen the next day in the Jordan Hospital emergency department. Therefore, the plaintiffs could prevail on the issue of causation through evidence that any or all of the three doses administered to Samantha after she contracted a rash caused her to develop TEN and, thus, that an adequate warning to stop administering the drug upon the presence of a rash more likely than not would have resulted in a different outcome. See Jones, 16 F. Supp. 2d at 125. In this regard, Dr. Foster, Samantha's treating ophthalmologist, testified that Samantha did not have TEN after receiving the first two doses of Children's Motrin, but that her TEN symptoms materialized after the administration of the third dose. And Dr. Stanford T. Shulman, an expert witness of the defense, testified that "one or two doses of a drug like Motrin" cannot "trigger such a severe disease" as Samantha's TEN.

In any event, we cannot agree with the defendants that Tackett's dose opinion was incompetent and therefore inadmissible. Tackett based his testimony, generally, on his

[39] As previously mentioned, Lisa testified that she would not have given Samantha the fourth dose of Children's Motrin had the label warned to discontinue use upon the appearance of a rash.

review of Samantha's medical records, including those from MGH and Shriners, as well as his awareness and working knowledge of relevant scientific literature. See Canavan's Case, 432 Mass. at 314-315 (expert scientific opinion must be based on relevant literature or other indicia of reliability). After opining that ibuprofen caused Samantha's TEN, Tackett testified that had Samantha received only two doses of Children's Motrin, her illness would not have progressed to TEN. It is true, as the defendants note, that Tackett agreed that the scientific literature does not specifically support an opinion that had Samantha ingested only two doses of Children's Motrin, she probably would not have contracted TEN. However, Tackett's opinion testimony appeared to vary somewhat during his lengthy appearance as a witness and, although he did testify at one point that the third dose of Children's Motrin caused the disease, the thrust of his opinion testimony, as we read it, was that Samantha would not have contracted TEN had she received only the first two doses of Children's Motrin, and not the third, fourth, and fifth doses after her rash appeared. This opinion appears to find some support, as Tackett stated, in the literature, which recognizes that prompt withdrawal of the drug causing TEN symptoms leads to a better prognosis for the patient.[40] Tackett's testimony indicated as much, in that he

[40] The FDA recognized in its response to the citizen

stated that a "basic pharmacology tenet" holds that "if you keep giving a drug that's producing a toxic effect, it's going to amplify or make that toxic effect worse," and that stopping the

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petition that "[p]rompt recognition of the onset of symptoms [of SJS and TEN], such as the appearance of rash or blisters on the skin, and withdrawal of the suspected drug can minimize the effects of SJS/TEN and improve prognosis" (emphasis added). Furthermore, one of the defendants' expert witnesses in this case, Dr. Maja Mockenhaupt, has written that with regard to treating SJS and TEN the causative drug "should be rapidly identified and withdrawn." Mockenhaupt, Severe Drug-Induced Skin Reactions: Clinical Pattern, Diagnostics and Therapy, 7 JDDG 142, 142 (2009).

Additionally, Tackett referenced in his testimony a study that examined the effect of the withdrawal of a causative drug on patients who were diagnosed with SJS or TEN. See Garcia-Doval, Le Cleach, Bocquet, Otero, & Roujeau, Toxic Epidermal Necrolysis and Stevens-Johnson Syndrome: Does Early Withdrawal of Causative Drugs Decrease the Risk of Death?, 136 Arch. Dermatol. 323 (2000). This study selected patients diagnosed with SJS or TEN who had taken a drug believed to have caused their disease. Id. at 324. For purposes of the study, patients "were determined to have stopped [causative] drug administration early if the last dose of the causative drug was administered no later than the same day that a definite sign of TEN or SJS appeared," such as a blister or skin erosion. Id. The study revealed a better mortality rate among patients who stopped ingesting the causative drug early as opposed to those who stopped after the day on which a sign of SJS or TEN appeared. Id. at 324-325. The defendants contend that because each patient in this study was diagnosed with SJS or TEN at the outset, the study cannot support Tackett's opinion that ceasing administration of ibuprofen to Samantha after the second dose would have prevented her disease from worsening into TEN. We agree that the study cannot explicitly support Tackett's opinion, but the study's conclusion that "early withdrawal of the causative drug(s) is associated with a better prognosis for patients with TEN or SJS," id. at 327, provides general support for the notion that ceasing administration of Children's Motrin to Samantha sooner rather than later would have improved her prognosis.

causative drug allows the body to metabolize it and rid itself of the drug.[41]

Based on the state of the knowledge in the field concerning early withdrawal of causative drugs, see note 40, supra, the judge did not abuse his discretion in determining that Tackett's testimony was reliable and admissible. See Palandjian v. Foster, 446 Mass. 100, 111 (2006) (trial judge "has broad discretion to determine how to assess the reliability of expert testimony"). Cf. Vassallo v. Baxter Healthcare Corp., 428 Mass. 1, 12-13 (1998) (judge did not err in admitting expert testimony that implants cause disease, despite lack of epidemiological study specifically supporting testimony, where causation opinion was based on, among other things, other relevant studies).

In any event, we have found Tackett qualified to testify as to specific medical causation. The defendants' criticisms of his dose opinion essentially go to the basis of his opinion, and affect the weight of the opinion rather than its admissibility.[42]

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[41] Tackett's dose opinion also must be considered in light of his unchallenged testimony that a diagnosis of TEN simply represents a determination that over thirty per cent of a person's body has been affected by the adverse skin disorder; an opinion that Samantha's condition would not have developed into TEN if only two doses of Children's Motrin had been administered in effect states a view that over thirty per cent of her body would not have become affected -- not an opinion that Samantha would not have been ill.

[42] Accordingly, the judge appropriately instructed the jury that they had the prerogative to determine whether to accept the

See generally Commonwealth v. Crouse, 447 Mass. 558, 569 (2006). The defendants extensively cross-examined Tackett as to the basis of his dose opinion, and specifically as to whether the literature on which Tackett relied for his opinion was, in fact, supportive. See Higgins v. Delta Elevator Serv. Corp., 45 Mass. App. Ct. 643, 648 (1998), quoting Lanigan, 419 Mass. at 26 ("The judge's ruling 'is not final on the reliability of the [expert] opinion evidence, and the opponent of that evidence may challenge its validity before the trier of fact'").

3. Damages. Last, the defendants challenge the jury's awards of damages. The jury awarded a total of $50 million in compensatory damages to Samantha as a general award of damages; although instructed on pain and suffering, future medical expenses, and loss of future earning capacity as categories of damages Samantha was entitled to have them consider, the jury were not asked to itemize or specify what portion, if any, of the total award represented damages for each or any of these categories. The jury also awarded $6.5 million to each of Samantha's parents for loss of consortium. As noted at the outset, the defendants moved for remittitur on the ground that the awards of damages were not supported by evidence in the record. The judge denied the motion, concluding that the

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opinions of expert witnesses. See Higgins v. Delta Elevator Serv. Corp., 45 Mass. App. Ct. 643, 648-649 (1998).

evidence at trial supported the jury's total award, which, in the judge's view, was "not greatly disproportionate to the injuries proven."

"[A]n award of damages must stand unless . . . to permit it to stand was an abuse of discretion on the part of the court below, amounting to an error of law." Labonte v. Hutchins & Wheeler, 424 Mass. 813, 824 (1997), quoting Mirageas v. Massachusetts Bay Transp. Auth., 391 Mass. 815, 822 (1984). "It is an error of law if 'the damages awarded were greatly disproportionate to the injury proven or represented a miscarriage of justice.'" Labonte, supra, quoting doCanto v. Ametek, Inc., 367 Mass. 776, 787 (1975). Damages are also excessive when they are "so great . . . that it may be reasonably presumed that the jury, in assessing them, did not exercise a sound discretion, but were influenced by passion, partiality, prejudice or corruption." Bartley v. Phillips, 317 Mass. 35, 41 (1944), quoting Coffin v. Coffin, 4 Mass. 1, 43 (1808). However, "[a]buse of discretion in granting or refusing a new trial" on the ground of excessive damages "can so seldom be found that actual instances in which this court has set aside the action of the trial judge . . . are almost nonexistent, and it has repeatedly been stated that occasions when this court can do so are exceedingly rare." Loschi v. Massachusetts Port Auth., 361 Mass. 714, 715 (1972), quoting Hartmann v. Boston

Herald-Traveler Corp., 323 Mass. 56, 61 (1948). See Blake v. Commissioner of Correction, 403 Mass. 764, 771 (1989) ("We do not substitute our judgment for that of the trial judge who saw the witnesses").

a. Award of damages to Samantha. As a general matter, Samantha was "entitled to compensation for all damages that reasonably are to be expected to follow, but not to those that possibly may follow" the injuries she suffered. Donovan v. Philip Morris USA, Inc., 455 Mass. 215, 223 (2009), quoting Pullen v. Boston Elevated Ry., 208 Mass. 356, 357 (1911). Although they did not request the jury to be asked to specify separate amounts for future medical expenses, impairment of future earning capacity, and pain and suffering, the defendants' challenge on appeal focuses on each of these categories separately, and we consider them separately.

i. Future medical expenses.[43] The defendants assert that the trial evidence here (1) presented for the most part possibilities, not probabilities, of types of future medical expenses Samantha might incur, and possibilities are an insufficient basis for an award, see Donovan, 455 Mass. at 223; and (2) in any event, even with probable future medical expense categories, failed to present any evidence -- "dollars and cents

[43] The parties stipulated to approximately $810,000 in past medical expenses.

evidence" -- of what the future medical expenses were reasonably likely to be.

The defendants' argument suffers from two fatal flaws. The first is the defendants' failure to request that the jury be instructed to consider the discrete categories of damages separately. Since there is no way of knowing whether the jury did, in fact, include any amount for future medical expenses in their award, a claim premised on the assumption that they did can go nowhere; certainly the defendants' way around the problem of the missing information, which is to assume that the entire award of $50 million was for future medical expenses and then to assert that there was insufficient evidence to support such an award, does not provide a permissible solution. See Dalessio v. Dalessio, 409 Mass. 821, 830 (1991), S.C., 413 Mass. 1007 (1992) (where jury returned general verdict it was unknown "exactly how the jury calculated their award or exactly how much of the total award was meant to compensate" for pain and suffering as opposed to other compensatory damages). Second, central to the defendants' argument is the assertion that there was insufficient evidence introduced at trial on which the jury could permissibly fashion an award to cover future medical expenses. But the defendants never challenged the absence or insufficiency of such evidence through a motion for a directed verdict on this ground and did not include this ground in their

motion for judgment notwithstanding the verdict. The plaintiffs argue correctly that the defendants have waived this claim. See Shafir v. Steele, 431 Mass. 365, 371 & n.13 (2000) (defendant waived objection to damages awarded for claim of interference with contract where he had not raised objection in motion for directed verdict; defendant also waived claim that judge erred in allowing jury to consider particular theory of measuring damages where he had not objected to instruction on this ground).[44]

[44] We note that the record does contain evidence, such as the testimony of treating doctors, as to Samantha's reasonably expected future medical expenses -- e.g., medical expenses for monitoring her pulmonary system, monthly ophthalmologist appointments, periodic eye surgeries necessitated by her in-turned eyelashes, and likely hospitalizations due to her reduced lung function and low body weight. There was testimony that Samantha's medical concerns will follow her for her life, which, at the time of trial, was expected to last some sixty-six more years. That future medical expenses "cannot always be foretold with exactness is a fact which the jury have to deal with in determining what . . . expense reasonably will follow as distinguished from what possibly may follow." Donovan v. Philip Morris USA, Inc., 455 Mass. 215, 223 (2009), quoting Pullen v. Boston Elevated Ry., 208 Mass. 356, 357-358 (1911).

On the issue of what anticipated future medical expenses might cost, although a plaintiff may offer evidence of future medical expenses through expert testimony, see Harlow v. Chin, 405 Mass. 697, 714-715 (1989), we have held that "[h]ospital records and the testimony of physicians" as to "anticipated future services permit[] the jury to use their judgment to award more than nominal amounts" as future medical expenses. Bencosme v. Kokoras, 400 Mass. 40, 44-45 (1987). See VanAlstyne v. Whalen, 15 Mass. App. Ct. 340, 347 n.1 (1983), S.C., 398 Mass. 1004 (1986).

ii. Impairment of future earning capacity. For the same reasons, the defendants' arguments concerning damages for impairment of future earning capacity also must be rejected: the jury's award of general damages offers no insight into whether they awarded any amount for loss of future earning capacity and, if they did, what that amount was; and the absence of any challenge (e.g., a motion for a directed verdict) to the purported insufficiency of the evidence on this issue serves to waive the defendants' claims in any event.[45]

iii. Pain and suffering. As they did with the future medical expenses, the defendants again assume that the jury's entire award of $50 million in general damages represented pain and suffering damages, and they again assert that such a sum is excessive and "greatly disproportionate to the injury proven." See Labonte, 424 Mass. at 824. For reasons previously stated,

[45] Insofar as the jury may have included some damages for loss of future earning capacity in their award, we add the following. Although, as the defendants point out, Samantha and her parents testified that she plans to attend college and become a hospital nurse, the jury could reasonably infer that despite Samantha's commendable optimism, her health will not allow her to pursue her chosen career in nursing or in any number of other occupations. See Halnan v. New England Tel. & Tel. Co., 296 Mass. 219, 222 (1936). Instead, the evidence at trial regarding Samantha's lasting injuries and her appearance on the witness stand allowed the jury, "with their knowledge of practical affairs," to "measure the probable extent of the impairment of [Samantha's] earning capacity." See Cross v. Sharaffa, 281 Mass. 329, 331 (1933). The "assessment of damages for impairment of earning capacity rests largely on the common knowledge of the jury, sometimes with little aid from evidence." Griffin v. General Motors Corp., 380 Mass. 362, 366 (1980).

we do not accept the defendants' governing assumption, but even were we to do so, we would disagree with their claim of excessiveness. It is unnecessary to recount again a full litany of Samantha's injuries, but the most severe of her injuries bear repeating in evaluating the amount of the award. As a result of having TEN, the seven year old Samantha suffered lesions (blisters) all over her body and lost the top layer of her skin (over ninety-five percent of it), substantially the same as for a severe burn victim; she was hospitalized for six months, where she needed to be placed in a medically induced coma for a full month to deal with the pain; while in the hospital, she suffered liver and heart failure, a stroke, seizures, and a cranial hemorrhage, and had only twenty per cent of her lung capacity; upon discharge she was required to eat through a feeding tube for two years and required oxygen every night for the same period of time; at the time of trial, she weighed just eighty-two pounds as a sixteen year old; she is legally blind;[46] her short-term memory is damaged; her lung capacity remains significantly impaired, and she will never be able to carry a child as a result; and she faces hospitalizations and limitations for the remainder of her life.

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[46] As mentioned, see note 7, supra, the corneal implant Samantha received has required many surgeries to try to correct problems interfering with the implant's success, so far unsuccessfully.

To be sure, Samantha's parents testified about her remarkable ability to endure these injuries while maintaining a positive outlook and prospects for the future. Samantha herself testified to her belief that she will lead a "great life." The jury could applaud this optimism but nevertheless reasonably infer from the significant extent of Samantha's past pain and suffering, and the state of her health, that she will likely experience pain and suffering throughout her life. See Pemberton v. Boas, 13 Mass. App. Ct. 1015, 1018 (1982) (upholding damages award where "[f]actors which would have warranted a lesser amount of damages were fully explored before the jury and apparently rejected by them"). Accordingly, we cannot say that the jury's award is "greatly disproportionate" to Samantha's grave injuries. See Labonte, 424 Mass. at 824. See also Bartley, 317 Mass. at 40 (damages may be "incapable of computation" and, thus, dependent on "judgment of the fact-finding tribunal in appraising suffering and deprivation and translating them into a compensatory sum").[47]

b. Loss of consortium damages. Finally, we decline to disturb the jury's awards to Lisa and Richard for loss of

[47] We decline the invitation of the parties to engage in the "dangerous game" of comparing the verdict in this case to that in other personal injury cases. See Griffin v. General Motors Corp., 380 Mass. 362, 371 (1980).

consortium.[48] In explaining the parameters of loss of consortium of a child, we have stated that parents may recover for "loss of filial society if they can show that [their child's] injuries are of such severity and permanence as to render [her] physically, emotionally, and financially dependent on them and that, as a result, their lives have been significantly restructured and their expectations of enjoying those experiences normally shared by parents and children have been seriously impaired." Monahan v. Methuen, 408 Mass. 381, 388-389 (1990), quoting Norman v. Massachusetts Bay Transp. Auth., 403 Mass. 303, 316 (1988) (Liacos, J., dissenting). It is difficult to imagine how Lisa and Richard's lives could have been more "significantly restructured" as a result of Samantha's illness than they have been. Despite being employed at the time, Lisa stayed at the hospital with Samantha throughout her six-month hospitalization; Rick did so as well. Both slept at the hospital every night, and each testified to the distress caused by the pain Samantha endured and by her devastating prognosis. During this time, they suffered many "close calls" when it appeared that Samantha would not survive. In the years that followed, both parents devoted their time to caring for

[48] "The parents of a minor child or an adult child who is dependent on his parents for support shall have a cause of action for loss of consortium of the child who has been seriously injured against any person who is legally responsible for causing such injury." G. L. c. 231, § 85X.

Samantha's myriad needs, including feeding her through a tube for two years. A chef by trade, Richard has since taken employment at a local gasoline station because the shorter hours allow him to attend to Samantha's medical problems. He lamented at trial that due to Samantha's injuries and ongoing medical treatment, he is unable to see her enjoy a normal life. Cf. Norman, 403 Mass. at 315 (Liacos, J., dissenting) (one's child is valued because he or she "is a source of emotional sustenance and joy").

Based on the evidence before them, the jury could reasonably infer that Samantha would remain dependent upon her parents, "physically, emotionally, and financially," for the indefinite future. Monahan, 408 Mass. at 389. We recognize that the awards to Lisa and Richard are generous, but the evidence warrants the jury's finding that their lives have been "significantly restructured" in a manner justifying these awards.[49] See id. See also Smith v. Kmart Corp., 177 F.3d 19,

[49] Finally, we find unavailing the defendants' argument that the size of the jury's award indicates that their purpose was to punish the defendants rather than to fairly compensate the plaintiffs. See Bartley v. Phillips, 317 Mass. 35, 41 (1944). The defendants imply that remarks in the plaintiffs' counsel's closing argument concerning the defendants' wealth and resources may have led to a verdict based on passion or prejudice. The defendants do not contend that these remarks, alone, require reversal, and we agree with the plaintiffs that the remarks were not without an evidentiary basis. Moreover, the judge explicitly instructed the jury that the purpose of damages in this case was "not to reward the plaintiffs" and "not to punish

30 (1st Cir. 1999), quoting Wagenmann v. Adams, 829 F.2d 196, 215 (1st Cir. 1987) ("Translating legal damage into money damages is a matter 'peculiarly within a jury's ken' . . .").

Judgment affirmed.

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the defendants." He added that the jury were to "put aside [their] personal feelings" during deliberations, and that they were "not to be swayed by sympathy" in awarding damages. We presume that the jury followed these instructions in rendering their verdict. See O'Connor v. Raymark Indus., Inc., 401 Mass. 586, 590 (1988).