IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KRISTIN L. BROWN and PAUL L. BROWN individually, and RILEY J. BROWN, by and through her natural parents and guardians,	)	CASE NO. 12-4929
Plaintiffs,	)	
v.	)	
JOHNSON & JOHNSON, et al.	)	
Defendants.	)	

PLAINTIFFS' AMENDED PRETRIAL MEMORANDUM

Plaintiffs file this Pretrial Memorandum in accordance with the Court's Scheduling Order and Local Rule 16.1.

I. Nature of Action and Basis for Jurisdiction

This is a strict liability and negligence action in which Plaintiff Riley Brown developed Stevens Johnson Syndrome/toxic epidermal necrolysis ("SJS/TEN")[1] caused by over-the-counter Children's Motrin. Defendants market, manufacture and sell Children's Motrin.

This Court has jurisdiction over this matter based upon diversity of citizenship between the parties and the amount in controversy exceeds $75,000, exclusive of interests and costs,

[1]According to Defendants' SJS/TEN expert, Dr. Maja Mockenhaupt, Stevens Johnson Syndrome ("SJS") and toxic epidermal necrolysis ("TEN") "are characterized by … extensive detachment of epidermis and erosions of mucous membranes. Nowadays SJS and TEN are considered as a single disease entity of different severity but with common causes and mechanisms. The differentiation is made based on the extent of skin detachment …That is limited to less than 10% of the body surface area (BSA) in SJS, widespread with more than 30% of the BSA in TEN and in-between defined as SJS/TEN-overlap. Mucosal erosions are observed in more than 90% of the cases, mainly affecting mouth, nose, genitalia, anus, and eyes, but sometimes also the lower pharynx, trachea and bronchi."

pursuant to 28 U.S.C. § 1332. Plaintiffs are residents of Florida. McNeil has its principal place of business in Pennsylvania and is organized under the laws of New Jersey.

II. Brief Statement of the Case

Plaintiffs are Kristin and Paul Brown, and their daughter Riley Brown, a seven year old little girl who at the age of three years and five months fell victim to the deadly disease of Motrin induced SJS/TEN.[2] There was a consensus amongst Riley's treatment team that Motrin/ibuprofen caused Riley's SJS/TEN. Dr. John W. Sleasman, now the Chief of the Division of Allergy and Immunology at the Duke University School of Medicine, in Durham, North Carolina, treated Riley and unequivocally testified to a reasonable degree of medical certainty that ibuprofen most likely caused Riley's SJS/TEN.[3] Dr. David Mendelblatt, Riley's treating ophthalmologist, concluded to a reasonable degree of medical certainty Riley ingestion of ibuprofen caused her SJS/TEN.[4] Dr. Derek Hess, one of Riley's treating ophthalmologists, testified to a reasonable degree of medical certainty that that the most likely cause of Riley's SJS was ibuprofen.[5] Dr. Scheffer Tseng, Riley's treating ocular surgeon, stated, "Riley Brown's SJS/TEN, consequent blindness, multiple eye surgeries, virtually 100% of her treatment and multiple eye surgeries by Drs. Mendelblatt and myself were caused by her ingestion of Children's Motrin/Ibuprofen well beyond a reasonable degree of medical and scientific certainty."[6] And Dr. Randall Tackett, Plaintiff's expert pharmacologist and toxicologist, stated

[2] Plaintiffs do not intend to waive any claims, pleadings, assertions or prior disclosures, Plaintiffs file this brief statement of the facts of the case, in compliance with the Court's Order.
[3] Sleasman Dep. Tr. at 121:13-124:2; Exhibit C.
[4] Mendelblatt Dep. Tr. at 15:7-17; Exhibit D.
[5] Hess Dep. Tr. at 18:15-19:4; Exhibit E.
[6] Tseng Report at 12; Exhibit F.

Riley Brown's SJS/TEN, to a reasonably degree of pharmacologic and toxicologic certainty was caused by her ingestion of Children's Motrin/ibuprofen.[7]

When a person has SJS/TEN, the body attacks itself, focusing on the body's own skin and mucous membranes. The initial signs of SJS/TEN are often rashes that quickly spread and result in skin sloughing where the top layers of skin essentially fall off of the victim and other organs are attacked. The diagnostic distinction between SJS and TEN is based on the percentage of this skin sloughing. A victim is diagnosed with SJS if he or she has less than 10% of the body suffering from skin sloughing; a person is diagnosed with TEN if he or she has more than 30% body sloughing. The impact of SJS/TEN is not limited to skin however, as the disease attacks the victim's mucous membranes and related organs, including eyes, lips, mouth, anus, genitalia, ears, lungs, bronchial tubes, teeth roots, and other organs and systems.

Riley Brown's SJS/TEN occurred in August 2010, when she was a resident of New Port Richey, Florida. She was ultimately diagnosed with Stevens Johnsons Syndrome with concern of progression to TEN on August 4, 2010, and was hospitalized at All Children's Hospital in St. Petersburg, Florida for 25 days, and suffered immensely. Her SJS/TEN caused in excess of 30% total body surface area ("TBSA") involvement.[8] Riley Brown suffered from SJS/TEN with sloughing over her neck, face, chest, trunk, back and extremities. A detailed summary of Plaintiff Riley's medical history is included in the expert report of Dr. Randall Tackett at pages 141-144, which is incorporated by reference.

As detailed in the damages listed below, Plaintiff has suffered and continues to suffer related to her SJS/TEN, including without limitation, blindness, loss of skin and permanent scarring and disfigurement that will permanently impact her life and affect her future

[7] Tackett Rep. at 143, ¶ 518; Exhibit G.
[8] Exhibit C at 17:1-11.

employment. Riley has no functional vision in her left eye. Riley has undergone over 60 eye surgeries and exams under anesthesia. Riley suffers ocular deficiencies involving her eyelids, eyelashes, and cornea, all related to her SJS/TEN.

Plaintiffs' theories of liability are negligence and strict liability. Defendants were negligent in their failure to warn consumers of Motrin and its dangers and of the consequences of SJS/TEN, and negligent in their failure to use a safer alternative design, or dexibuprofen. Defendants' Children's Motrin product was defective and they are strictly liable because 1) "the danger is unknowable and unacceptable to the average or ordinary consumer, [and/]or that (2) a reasonable person would conclude that the probability and seriousness of harm caused by the product outweigh the burden or costs of taking precautions." *Tincher v. Omega Flex, Inc.*, 17 MAP 2013, 2014 WL 6474923 (Pa. Nov. 19, 2014). The danger of SJS/TEN associated with Children's Motrin is unknowable and unacceptable to average consumers like the Browns. Further, reasonable persons would conclude that the probability and seriousness of SJS/TEN caused by Children's Motrin outweigh the burden or cost of either 1) providing an adequate warning, or 2) using a safer alternative design in dexibuprofen.

SJS/TEN is caused by drugs, in this case the proprionic NSAID – ibuprofen, which was sold to Plaintiffs by Defendants in the form of Children's Motrin. Motrin has long been associated with causing SJS/TEN. A detailed analysis of this is included in the expert reports of Drs. Randall Tackett and Scheffer Tseng. Defendants failed to adequately warn Plaintiffs of the dangers associated with Motrin, and wholly failed to warn of the most serious consequences of SJS/TEN.

The OTC label does not apprise consumers either on the box, in a patient package insert, or in advertisements viewed by Plaintiffs' mother of the fact Motrin causes SJS and TEN, or of

all the symptoms including eye, mouth or genitalia pain, or of the most serious consequences of SJS/TEN, specifically, blindness, hospitalization, and death.

The FDA has posted a McNeil prescription label for Motrin on the FDA website containing the statement "Motrin…can cause … SJS and TEN." Moreover, Plaintiffs will submit evidence that the Defendant knew or should have known for many years prior to Riley Brown's ingestion of Motrin, that its Children's Motrin OTC label was inadequate with regard to the SJS/TEN issue.

There is also a safer formulation of ibuprofen: dexibuprofen. Ibuprofen is a racemic mixture, meaning it has mirror image molecules – dexibuprofen and levoibuprofen. Plaintiffs assert that Defendants have long known that a formula of ibuprofen that only uses the dexibuprofen molecules is both safer and more effective. Indeed, for many years the Defendants have possessed patents for dexibuprofen in both the United States and Europe that assert that dexibuprofen is a safer and more effect version of ibuprofen. Importantly in this case, there is a history of dexibuprofen use in Europe and Latin America that establishes that while racemic ibuprofen causes SJS/TEN, dexibuprofen does not. Accordingly, if Defendant had removed the design defect and sold pure dexibuprofen, Plaintiff would have never suffered SJS/TEN.

III. Plaintiffs Response to Issues Raised in Defendant's Amended Pretrial Memorandum

A. McNeil's Amended Exhibit List

Plaintiffs do not object procedurally to Defendants' Amended Exhibit List, provided Defendants agree to the same consideration for the Plaintiffs; Plaintiffs preserve the right to raise substantive and evidentiary objections to these new exhibits.

B. Issues Relating to Plaintiffs' Exhibit List

Plaintiffs have served upon Defendant an amended Exhibit List. Plaintiffs withdrew exhibits to conform with the Court's rulings. Plaintiffs also eliminated duplicative exhibits although some remain due to use in multiple settings. All documents listed in Plaintiffs' Exhibit List were previously provided to Defendants, but Defendant brought to Plaintiffs' counsel's attention today that while the exhibits are listed by number, the numbers are not affixed to the documents and some of the exhibits still contained multiple documents. Accordingly, Plaintiffs are tomorrow reproducing all exhibits with the exhibit numbers affixed, and correcting any multi-document exhibits. Finally, Plaintiffs will provide to Defendant each day before Court a binder of hard copy exhibits containing what Plaintiffs intend to use that day. Further, Plaintiffs trust Defendant's issue with Plaintiffs' Exhibit List is now moot.

AMENDED SECTION 7(B) – SPECIAL COMMENTS REGARDING LEGAL ISSUES

A. Preemption of the Design Defect Claims

Design defect claims against branded drug manufacturers are not barred by preemption. The savings clause in section 379(r) is relevant; conflict preemption analysis is completely unnecessary because Congress has explicitly stated product liability suits like this one are exempted from preemption. 21 U.S.C. 379r.

1. The *Bartlett* Generic Drug Case Does Not Extend to Design Defect Claims for Brand Name Drugs

This Court properly held that *Bartlett* does not address design defect claims and that Defendants failed to meet their demanding preemption burden:

> Defendants have not made out federal preemption. *See Wyeth v. Levine*, 555 U.S. 555, 565, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009) ("[I]n all pre-emption cases, ... we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." (internal citation and quotation marks omitted)). **The Supreme Court has not addressed whether federal law can preempt state law design defect claims brought against manufacturers of brand-name or non-prescription**

> **drugs. I conclude that its preemption cases do not extend to the manufacturers of these products.** *See Mut. Pharm. Co. v. Bartlett*, —— U.S. ——, 133 S.Ct. 2466, 2475, 186 L.Ed.2d 607 (2013) (preempting claims against generic drug manufacturers because generic drugs are required to have the same design as their brand-name counterparts); *id.* at 2480 (emphasizing that the federal statute governing prescription drugs "includes neither an express pre-emption clause ... nor an express non-pre-emption clause (as in the over-the-counter drug context)"); *Hunt v. McNeil Consumer Healthcare*, 6 F.Supp.3d 694, 704 (E.D.La.2014) ("Congressional intent to preserve products liability actions against manufacturers of nonprescription drugs could not be more clear."). Defendants have also failed to demonstrate that the FDA would have rejected a proposed change to Children's Motrin's chemical composition. (*See* Steffey Decl., Ex. 42 at 12; Ex. 10 at 109 (suggesting that the FDA's initial rejection of dexibuprofen was based on the lack of clinical trials).) In these circumstances, Defendants *722 have failed to meet their "exacting burden."

Brown v. Johnson & Johnson, 64 F. Supp. 3d 717, 721-22 (E.D. Pa. 2014).

Numerous other court have reached the same conclusion that *Bartlett* "cases do not extend to the manufacturers of [branded] products."[9] *Id. See, e.g., Estate of Cassel v. Alza*

[9] Case law Defendants rely on for the proposition design defect cases are preempted, are at best, inapposite, at worst, misleading. The first case Defendant argues for the proposition *Bartlett* preempts design defect claims for brand named drugs is *Shah v. Forest Labs*., Inc., 10 C 8163, 2015 WL 3396813, at *5 (N.D. Ill. May 26, 2015), which does not even *mention* "*Bartlett*," let alone contain any analysis. In *Shah*, Plaintiffs had *no evidence* of design defect. *Id.* Defendants rely on *Amos v. Biogen* that recognized *Bartlett* held "***warning[s]-based design-defect cause[s] of action*** [are] pre-empted with respect to FDA-approved drugs sold in interstate commerce." *Amos v. Biogen Idec Inc*., 28 F. Supp. 3d 164, 169 (W.D.N.Y. 2014). In that case the plaintiffs withdrew their design defect claims and conceded preemption, because they had *no non-warnings based design defect* causes of action. *Id.* The Southern District of New York clarified this fact and held the *Amos* court would not have ruled as it did but for plaintiffs conceding preemption. *Sullivan v. Aventis, Inc.*, 14-CV-2939-NSR, 2015 WL 4879112, at *6 (S.D.N.Y. Aug. 13, 2015). Defendant cites *Yates v. Ortho-McNeil Pharm. Inc.*, 76 F. Supp. 3d 680, 686 (N.D. Ohio 2015) applying New York law, that followed *Amos* wherein the plaintiffs had no non-warnings based design defect case. The Ohio Court's primary reason for finding preemption of design defect was that it did not want to contradict the holding in *Amos*, and "creat[e] a conflict in the jurisprudence of New York tort law." *Id.* Such is not an issue here. Defendants cite *Booker v. Johnson & Johnson*, 54 F. Supp. 3d 868, 875 (N.D. Ohio 2014), another Ohio federal court case that follows *Yates*, which follows *Amos*, all relating back to an

Corp., No. 12–771, 2014 WL 856023 (W.D.Wis. Mar. 5, 2014); *Dopson–Troutt v. Novartis Pharm. Corp.*, No. 06–1708, 975 F.Supp.2d 1209, 2013 WL 5330463 (M.D.Fla. Sept. 23, 2013); *Trahan v. Sandoz, Inc.*, 3:13-CV-350-J-34MCR, 2015 WL 2365502, at *5 (M.D. Fla. Mar. 26, 2015); *Sullivan v. Aventis, Inc.*, 14-CV-2939-NSR, 2015 WL 4879112, at *6 (S.D.N.Y. Aug. 13, 2015).

One court applying *Bartlett* was "not persuaded that it was impossible for [a generic manufacturer] to use a safer [design of its] container," reasoning in part that in *Bartlett*, there was no way to re-redesign sulindac. *Trahan v. Sandoz, Inc.*, 3:13-CV-350-J-34MCR, 2015 WL 2365502, at *5 (M.D. Fla. Mar. 26, 2015). Unlike Ms. Bartlett, the *Trahan* plaintiff proffered a safer alternative design to the generic drug's packaging (a non-defective glass packaging.) *Id*. The *Trahan* court acknowledged that some courts (the same cases Defendant relies on):

> have relied on *Bartlett* to find preemption in design defect cases against brand-name manufacturers because the manufacturer could not redesign the drug without FDA approval. Those cases do not address whether the brand-name manufacturer was required to use the allegedly defective design in the first place. *See Yates v. Ortho–McNeil Pharm., Inc.*, No. 3:09 oe 40023, 2015 WL 66423, at *5–6 (N.D.Ohio Jan.5, 2015) (citing *Amos v. Biogen Idec Inc.*, 28 F.Supp.3d 164, 169 (W.D.N .Y.2014)); *Booker v. Johnson & Johnson*, No. 3:12 oe 40000, 2014 WL 5113305, at *4–5 (N.D.Ohio Oct.10, 2014); *see also Thompson v. Allergan USA, Inc.*, 993 F.Supp.2d 1007 (E.D.Mo. Jan.28, 2014). **It follows from the reasoning in these cases that once a drug has received FDA approval, it is shielded from any future liability because the drug cannot later be altered without FDA permission. <u>If this is the correct interpretation of</u>**

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instance wherein the plaintiffs conceded preemption because they had no true design defect case, like in *Bartlett*. Plaintiffs in this case have a true design defect case against a branded manufacturer.

> ***Bartlett*, then it appears virtually all design defect cases against generic and brand-name prescription drug manufacturers alike would be preempted.** *See Estate of Cassel*, 2014 WL 856023, at *5; *see also Hunt v. McNeil Consumer Healthcare*, 6 F.Supp.3d 694, 703 & n. 8 (E.D.La.2014) (acknowledging the debate on the scope of *Bartlett* and noting that if the broader interpretation is correct "it would effectively foreclose all design-defect claims, since manufacturers are prohibited from unilaterally altering a drug's composition"). In support of this broader interpretation, courts cite the statement in *Bartlett* that "[o]nce a drug-whether a generic or brand-name-is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.' " *See Bartlett*, 133 S.Ct. at 2476–77. The *Bartlett* Court went on to hold that "state-law design-defect claims ... that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling." *Id.* at 2479. However, in the next sentence, the ***Bartlett* Court reaffirms that "federal law establishes no safe-harbor for drug companies-but it does prevent them from taking certain *remedial* measures." *Id.* (emphasis added). Indeed, the Supreme Court previously recognized that Congress's failure to enact an express preemption provision in the 70–year history of the FDCA, "coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness**." *See Wyeth*, 555 U.S. at 574–75. The *Wyeth* Court further explained that "[s]tate tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information." *Id.* at 579. As such, this ***Court does not interpret the Bartlett decision to change course and foreclose all design defect claims against prescription drug manufacturers in the absence of an express statement that it was doing so***. To the contrary, **because the Bartlett Court stated its express understanding that it was not providing a safe-harbor for drug companies, the Court declines to interpret Bartlett in such a way as to preempt [design defect] claims** on the current limited record.

Trahan v. Sandoz, Inc., 3:13-CV-350-J-34MCR, 2015 WL 2365502, at *6 (M.D. Fla. Mar. 26, 2015) (em. added). Sixteen days ago from the filing of this paper, in light of the Western District of New York *Amos* decision and its Ohio progeny, the *Amos's* sister court ruled:

> **A [brand-name] manufacturer choosing among alternative designs for a brand-name drug *is not* subject to the federal "equivalence" restrictions that apply to generic drugs.**

Sullivan v. Aventis, Inc., 14-CV-2939-NSR, 2015 WL 4879112, at *6 (S.D.N.Y. Aug. 13, 2015). (em. added). Plaintiffs have viable design defect claims against Defendant in connection with their branded drug product.

2. The Savings Clause in Relevant and Applicable

The United States Supreme Court has repeatedly held that when Congress decides to tolerate whatever tension lies between its interest and state law – there can be no preemption:

> **The case for federal pre-emption is *particularly weak* where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to "stand by both concepts and to tolerate whatever tension there [is] between them."** *Silkwood v. Kerr–McGee Corp.*, 464 U.S. 238, 256, 104 S.Ct. 615, 625, 78 L.Ed.2d 443 (1984).

Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 166-67, 109 S. Ct. 971, 986, 103 L. Ed. 2d 118 (1989).

In this case, Congress has made clear its decision to tolerate whatever tension exists between its intent and state law. The Federal Food Drug and Cosmetic Act at 21 U.S.C. 379r, a provision related to uniformity in the regulation of OTC drugs, provides a savings clause that specifically exempts state product liability suits from preemption. 21 U.S.C. 379r(e). In that provision Congress explicitly specified, "Nothing in this section shall be construed to modify or otherwise affect any actions or the liability of any person under the **product liability law of any State**." *Id*. In *Levine*, the Court interpreted this provision to mean that Congress "expressly preserved product liability actions" for OTC medications. 129 S. Ct. at 1200 n.8; *see also Orso v. Bayer Corp.*, No. 04 C 0114, 2006 WL 2794975, at *4-*5 (N.D. Ill. Sept. 27, 2006) (considering the savings clause for OTC drugs and holding that state law claims for design defect

are not preempted). It is completely unnecessary to undertake the conflict preemption analysis if the federal statute "expressly preempts or expressly preserves otherwise applicable state law duties." *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 475 (4th Cir. 2014). In *Bartlett*, the United States Supreme Court reaffirmed the validity the preemption exclusion for OTC drugs set out at §379r. *Mutual Pharmaceutical Co., Inc. v. Bartlett*,133 S.Ct. 2466 (2013).

This Court correctly found that "Congressional intent to preserve products liability actions against manufacturers of nonprescription drugs could not be more clear." *Brown v. Johnson & Johnson*, 64 F. Supp. 3d 717, 721 (E.D. Pa. 2014), *citing Hunt v. McNeil Consumer Healthcare*, 6 F.Supp.3d 694, 704 (E.D.La.2014). Plaintiffs' claims are not preempted, and Defendants do not cite a single binding, authoritative, or persuasive piece of case law to the contrary.[10]

B. Plaintiffs' Failure to Warn Claims are Not Preempted

The CBE process could have been used in this case and applies to OTC products. Clear evidence shows the FDA would approve the warnings Plaintiffs seek.

1. McNeil Could Have Used the CBE Process to Change the OTC Children's Motrin Label

i. The FDA Did Not Prohibit a CBE Change for Motrin

This issue was briefed extensively in Defendant's summary judgment papers and Plaintiffs' response and Defendant raises nothing new before the Court. Plaintiffs' incorporate herein their Response to Defendants' Motion for Summary Judgment. The reasons why the language the FDA letter upon which Defendant relies for the proposition that they were prohibited from using the CBE on Motrin does not carry the day, as previously stated in part, are:

[10] Defendants cite two state law cases that are neither binding nor authoritative. Plaintiffs incorporate herein their Response to Defendant's Motion for Summary Judgment wherein they responded to all federal jurisprudence Defendant's rely in their motion for reconsideration, titled Defendant's Amended Pretrial Memorandum.

- *First*, Defendants conflate 1) complying with a request to incorporate the FDA's proposed templates on their product packaging, and 2) a preclusion from providing additional information separate from such templates, in or even outside the corners of the templates. In fact, in the very letters Defendants refer to, the FDA reminds Defendants of their ability to include a package insert.[11] Defendants elected not to include a package insert and provide additional and crucial safety information. Defendants were free to include additional safety information on the principal display panel in the areas outside the four corners of the template for the principal display panel. Defendants elected not to. Defendants could have provided additional information on the top flap or lid to its packaging. Defendants elected not to provide additional safety information. Defendants had the ability to fully comply with the FDA's requests as set forth in the FDA's letters, and still provide the supplemental warning information Plaintiffs seek. Defendants chose not to and it cost Riley Brown her sight.
- *Second*, this newfound argument, developed nine years after the letters were disseminated, is completely contrary to the testimony three months ago of Defendant's former director of regulatory affairs, and corporate representative in this case, and witness in virtually all Motrin-induced SJS/TEN cases tried to date, Ms. Lynn Pawelski, who just testified that McNeil *can* unilaterally change their label through the CBE process, in a case involving the exact same 2010 Children's Motrin label as in this case.[12]
- *Third*, the letters request that "changes be made in accordance with the [CBE] requirements of 21 C.F.R. § 314.70."[13] The FDA did not intend to take away a drug manufacturer's congressionally enacted CBE supplement process rights to strengthen its warnings, the requested changes and inclusion of the templates were intended to be in accordance with them – and Defendants cite no authority for such an unsupportable assertion.
- *Fourth*, under 21 CFR 314.70, all postapproval CMC (chemistry, manufacturing and controls) changes beyond the variations provided for in an approved NDA and ANDA are categorized into one of three reporting categories: major, moderate, or minor.[14] If a change is considered to be major, an applicant must submit and receive FDA approval of a supplemental application to the NDA or ANDA before the product made with the manufacturing change is distributed (also known as a prior approval supplement (PAS)).[15] If a change is considered to be moderate, an applicant must submit a supplement at least 30 days before the product is distributed (CBE-30 supplement) or, in some cases, submit a

[11] *Id.*
[12] *Hunt v. McNeil, et al.*, Trial Tr. Excerpts (3/27 AM Trial Tr. 1233:12-23); Exhibit H.
[13] *Id.*
[14] Guidance for Industry: CMC Postapproval Manufacturing Changes to be Documented in Annual Reports at 2; Exhibit I.
[15] *Id.*

> supplement at the time of distribution (CBE-0 supplement).[16] If a change is considered to be *minor*, **an applicant may proceed with the change**, and simply notify FDA of the change in an annual report.[17] Minor changes are those that "will likely have a minimal potential effect on product quality, …*i.e.* drug product identity, strength, quality, or potency."[18] The warnings Plaintiffs seek would have zero effect on product identify, strength, quality, or potency. Defendants at all times could have implemented the language Plaintiffs seek, and reported the same in an annual report.[19]

- *Fifth*, and alternatively, the templates the FDA requested that McNeil use were the product of negotiations relating to "previous revisions that were *agreed upon* in [McNeil's] most recently approved labeling."[20] McNeil could have proposed and reached agreement with the FDA relating to the warnings Plaintiffs seek, though the CBE supplement process – Defendants elected not to, caused the FDA to agree to the inadequate warnings they proposed. The FDA's REQUEST TO McNeil to incorporate the agreed upon changes does not preclude Defendants from strengthening their warnings and does not insulate them from liability.

Defendant was not prohibited from making a CBE change.

ii. The CBE Regulation Applies to OTC Medications

Plaintiffs acknowledge that since September 22, 2008, Part A of 21 C.F.R. § 314.70(c)(6)(iii) relates to prescription drugs. There is nothing that precluded Defendants from changing the label pursuant to part A in 2006, 2007, or up until September of 2008.

Part C of 21 C.F.R. § 314.70 continues to apply to OTC drugs as it was not modified in 2008:

> (C) To add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product.

21 C.F.R. § 314.70(c)(6)(iii)(C). Plaintiffs allege Defendants should have strengthened their instruction about administration to provide explicit instruction to discontinue Motrin use at the

[16] *Id.*
[17] *Id.* (emphasis added).
[18] *Id.* at 1.
[19] *Id.* at 1.
[20] Exhibits J and K, (Temple Decl. Exs. 10 and 11).

first sign of hypersensitivity and not to resume Motrin use unless SJS/TEN was rule out. Defendants were not prohibited from making these changes.

iii. Adverse Event Reports Constitute Newly Acquired Information

Defendant, at least twice recently, in *Hunt* and *Newman*, have made these arguments before, and failed:

> Second, the FDA's response in 2006 to the Citizen Petition is not clear evidence the agency would have rejected *in 2010* the stronger warnings Plaintiff proposes. *See Newman*, 2012 WL 39793, at *9–11; *accord Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 395 (7th Cir.2010). As the Supreme Court explained in *Wyeth*, manufacturers are required by federal law to update their labels in response to "newly acquired information," which encompasses both new data and new analyses of old data. 555 U.S. at 568–69, 129 S.Ct. 1187 (internal quotation marks omitted); *Newman*, 2012 WL 39793, at *9. When the FDA responded to the Citizen Petition, it noted that a search of the U.S. adverse event report database ("AER") retrieved only forty-nine reports of SJS/TEN cases related to ibuprofen. Of those forty-nine cases, only thirteen reported the use of non-prescription ibuprofen. The FDA ultimately concluded the risk of SJS/TEN associated with the use of ibuprofen was not nearly as high as that asserted in the Citizen Petition. **Subsequent to the FDA's 2006 response, however, Defendants have received over one-hundred AERs regarding ibuprofen-related SJS/TEN cases.** *See id.* at *9. At least fifty-one of those reports were received between the time the FDA responded to the Citizen Petition and February 4, 2010—the date on which Plaintiff ingested Children's Motrin. **"This newly acquired information yields the conclusion that even if there was clear evidence that the FDA would not have approved a change to the Motrin labels at some point in the past, such evidence is no longer sufficiently obvious for preemption purposes."** *Id.* at *11.

Hunt v. McNeil Consumer Healthcare, 6 F. Supp. 3d 694, 701 (E.D. La. 2014), *citing Newman v. McNeil Consumer Healthcare*, 10-CV-01541, 2012 WL 39793, at *11 (N.D. Ill. Jan. 9, 2012). In addition to the over 100 AERs Defendant received regarding ibuprofen and SJS and TEN, the World Health Organization recorded 228 cases of ibuprofen induced SJS and TEN. Exhibit G (Tackett Rep. at 79, ¶ 286.) This is a doubling of the incidence *after* the FDA assessed the risk and *after* the purportedly effective label was implemented. *Id*. From 1969-2005 WHO only

recorded 234 cases of ibuprofen induced SJS/TEN case. The incidence rate of SJS/TEN has clearly doubled since the FDA assessed the data. Defendant cannot bury their head in the sand to this data. Defendants cite no authority for the proposition that they can. Plaintiffs' claims are not preempted.

C. The Evidence Shows the FDA Would Have Approved the Warnings Proposed By Plaintiffs

In August, 2013, the FDA issued a Drug Safety Communication to consumers of OTC acetaminophen, which informed consumers two times, once in a blow up heading, in plain and unambiguous, enlarged 23 point font, that "SJS and TEN…are the two most serious skin reactions…[that] usually require **hospitalization** and can cause **death.**"[21] The FDA advised consumers that "[r]ecovery [from SJS and TEN] can take weeks or months, and possible complications include **scarring, changes in skin pigmentation, blindness and damage to internal organs.**"[22] The FDA advised consumers that SJS and TEN, "in the **worst case**, [can cause] **widespread damage to the surface of this skin.**"[23] The FDA advised consumers "it is important that people recognize and react quickly to the initial symptoms of these rare but serious, side effects [of SJS and TEN], which are potentially **fatal.**"[24] These are the explicit words of the FDA to consumers on the effects SJS/TEN. The FDA considered, approved, and disseminated precisely the warning language for acetaminophen induced SJS/TEN Plaintiffs advocate here for Children's Motrin induced SJS/TEN. This FDA Consumer Update leaves little doubt and makes near certain the FDA would approve all the warnings plaintiffs seek. In fact, the FDA recently stated:

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[21] *Id.* at 2 (emphasis added).
[22] *Id.*
[23] *Id.* at 1 (emphasis added).
[24] *Id.*

> **The U.S. Food and Drug Administration (FDA) is informing the public [of] a risk of rare but serious skin reactions. These skin reactions, known as Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP), can be fatal.**

Exhibit L (2015 Questions and Answers: FDA warns of rare but serious skin reactions with the pain reliever/fever reducer acetaminophen). There is no reason to believe the FDA would tell consumers this for acetaminophen, and then prohibit communication of the same information for ibuprofen, a drug with a higher incidence of SJS/TEN. The FDA further told consumers and the public:

> **If you develop a skin rash or reaction while using a drug product containing acetaminophen, stop using the drug product and seek medical attention right away. A health care professional will evaluate you to determine if you are experiencing a serious skin reaction such as acute generalized exanthematous pustulosis (AGEP), Stevens Johnson Syndrome (SJS), or toxic epidermal necrolysis (TEN).**

This is precisely the information that Plaintiffs allege should have been conveyed to them – through any of the means Defendant communicates with consumers. Had Defendants warned of these symptoms, Riley would not be partially blind.

Plaintiffs submit Defendant could have used the CBE process to strengthen their warning. The Defendant could have included a package insert and provide additional and crucial safety information. Defendant could have included additional safety information in the template itself, or in the areas outside the four corners of the template. Defendants could have provided additional information on the top flap or lid to its packaging. Defendants could have added a warning flag directing the consumer to additional warnings. Additionally Defendant could have warned in the advertisements viewed by Riley's mother. Defendants cannot forever live in 2005. The "FDA's response to the 2005 Citizen Petition is not "clear evidence" that the FDA would have rejected stronger warnings, including blindness warning." *Brown v. Johnson & Johnson*,

64 F. Supp. 3d 717, 720 (E.D. Pa. 2014) Plaintiffs respectfully submit the evidence is clear that the FDA would have approved the warnings Plaintiffs seek.

IV. Damages to Plaintiffs

Plaintiffs incorporate their expert reports which detail the injuries to Plaintiff Riley Brown in a much greater clinical and medical detail. As a result of her ingestion of Motrin, Plaintiff Riley Brown has suffered, *inter alia*, the following injuries as a result of her ingestion of Motrin:

1. **Vision**: Riley Brown is partially blind. She will never have functional vision in her left eye and she has residual deficiencies in her right eye including light sensitivity;
2. **Pain and suffering** - During the acute phase of her SJS/TEN Riley's pain and suffering was immense, and post SJS/TEN Riley continues to endure pain in her eyes and related headaches;
3. **Permanent disfigurement** – Riley has permanent scarring as a result of her SJS/TEN;
4. **Loss of Enjoyment of Life, Mental Anguish and Disfigurement –** Riley Brown endured immense pain, suffering, medical injuries, physical limitations, and loss of enjoyment of life, as a direct and proximate cause of her Motrin induced SJS/TEN.
5. **Medical and Life Care expenses in the past and in the future –** detailed in Plaintiffs' expert reports, Plaintiff has suffered and will continue to suffer detailed medical and life care needs.
6. **Reduced Earning Capacity** – Riley will have reduced earning capacity as a result of SJS/TEN.

7. **Loss of Consortium, Mental Anguish and Vicarious Damages –** as the responsible parties for her minor child, Plaintiffs Paul and Kristin Brown are eligible to recover their own separate damages for mental anguish or otherwise.

8. **Summary of Economic Damages by category**:

   A. Past medical expenses total **$1,003,729.76.**

   B. Future lost earnings as evaluated by Economist Royal Bunin range from **$213,647 to to $1,277,700.**

   C. Future medical expenses as evaluated by Economist Royal Bunin range from **$1,406,336 to $3,412,406.**

   D. Total economic damages range from **$2,613,365 to $5,683,488.**

V. Witness List

Plaintiffs' Witness list is attached as Exhibit A.

VI. Exhibit List

Plaintiffs' Exhibit List is attached as Exhibit B.

VII. Anticipated Length of Trial

Three weeks.

Respectfully Submitted,

Dated: September 1, 2015

/s/Rosemary Pinto

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CERTIFICATE OF SERVICE

The Undersigned certifies that this document was served on Defendants by and through their attorneys of record via the Court's ECF system on the day of filing.

/s/Rosemary Pinto
Rosemary Pinto