UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

[redacted] INDIVIDUALLY AND ON BEHALF OF HER MINOR CHILD, M.H.,	
Plaintiffs	**CASE NO: [redacted]**
v.	
MCNEIL CONSUMER HEALTHCARE, a Division of MCNEIL-PPC, INC.; and JOHNSON & JOHNSON,	**JUDGE JANE TRICHE MILAZZO**
Defendants.	**MAGISTRATE KAREN WELLS ROBY**

PRETRIAL ORDER

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1. The date of the Pretrial Conference is Thursday February 20, 2014 at 1:45 PM.

2. The following counsel appeared at the Pretrial Conference:

   a. Representing the Plaintiff:

   [redacted]

   b. Representing the Defendants:

   [redacted]

[redacted]

3. Parties:

   a. The Plaintiff is [redacted], individually and on behalf of her minor child, M.H.

   b. The Defendants are:

      i. McNeil Consumer Healthcare, a Division of McNEIL-PPC, Inc. (Plaintiff also named McNeil Consumer Healthcare, an unincorporated division of McNEIL-PPC, Inc.); and

      ii. Johnson & Johnson.

4. Jurisdiction:

   a. Jurisdiction is based on a complete diversity of citizenship of all parties.

      i. Plaintiff: The plaintiff is a resident of Texas.

      ii. Defendants:

         1. McNEIL-PPC, Inc. is a New Jersey corporation, with its principal place of business in New Jersey (McNeil Consumer Healthcare is an unincorporated division of McNEIL-PPC, Inc.).

         2. Johnson & Johnson is a New Jersey corporation, with its principal place of business in New Jersey.

   b. The parties stipulate that the amount in controversy, exclusive of interest and costs, exceeds $75,000.

5. Motions:

   a. The following motions are pending:

      1. Defendants' Motion *In Limine* No. 2 Concerning the Alleged Inadequacy of FDA's Drug Safety Monitoring;

      2. Defendants' Motion *In Limine* No. 3 Concerning Other Lawsuits, Claims or Settlements Involving Children's Motrin or Other Ibuprofen Products;

3. Defendants' Motion *In Limine* No. 4 Concerning Non-Ibuprofen Products Withdrawn or Removed From The Market;

4. Defendants' Motion *In Limine* No. 5 Concerning McNeil's Voluntary Recalls; and

5. Defendants' Motion *In Limine* No. 6 Concerning the Number of Lawyers Representing Defendants and Whether A Corporate Representative is in the Courtroom.

b. The following additional motions are contemplated concerning special issues appropriate for determination in advance of trial on the merits:

i. Plaintiffs and Defendants intend to file motions *in limine* on various evidentiary issues.

ii. Plaintiff has sued 2 separate defendants. Counsel for the 2 separate defendants intend to each make an opening statement, individually examine and cross-examine witnesses, and make closing arguments. Plaintiffs will object given Plaintiffs' assertion that the Defendants are so closely aligned with respect to Plaintiffs' claims in this case, that such an arrangement would result in duplicative argument and examination.

iii. Pursuant to this Court's Order (Doc. No. 357), the Plaintiff and Defendants have submitted pretrial briefing on the issue of preemption.

6. A brief summary of the material facts claimed by:

a. **Plaintiff:** In the afternoon and evening of February 4, 2010 Plaintiff gave M.H. Children's Motrin for fever. By early the next morning M.H. had developed a rash which progressed rapidly over the course of the morning. Plaintiff immediately sought emergency medical help for M.H. who was admitted to Ochsner Medical Center with a severe "rash" and skin sloughing. At Ochsner M.H. was tested for virus which proved negative. M.H. was ultimately diagnosed with Toxic Epidermal Necrolysis (TEN) a serious, painful, life threatening, disfiguring disease that manifested itself over large areas of M.H.'s body. Because the treatment for TEN is similar to the treatment of severe burn victims, TEN patients, as a matter of the standard of care, are treated in burn units. Once diagnosed with TEN M.H. was transferred to and underwent treatment at the Baton Rouge General Burn Center. M.H. remained at the Burn Center until her ultimate release on March 18, 2010.

Due to her ingestion of Children's Motrin on February 4, 2010, Plaintiff incurred past medical costs in the amount of $ 233,000.00
Due to her ingestion of Children's Motrin on February 4, 2010, M.H. has sustained the following injuries:

1. Occular complications: M.H. suffers epiphora likely from a combination ectropion and scattered entropion with eyelashes irritating the cornea as found by Shriners Hospitals for Children. She has experienced ocular complication, including a fusion of her eyelids and will require ongoing medical care and treatment. In She has experienced a loss of most of the lower lid lashes. Such occular complications are quite common in TEN patients, severely affects the patient's quality of life and his or her functional abilities. [redacted] will incur significant ocular medical expenses in the future.

2. Hyperpigmentation: The skin of M.H.'s entire body shows evidence of depigmentation and hyperpigmentation. Examination of he head reveals altered pigmentation, [redacted]s torso shows very irregular, extensive blotchiness due to hyper and hypo pigmentation. Her extremities show the same altered pigmentation as well as a large hypertrophic scar of the right anterior thigh, secondary to a central intravenous line during her hospitalization. It is unclear that this time that any future medical care can improve this condition. The scarring on M.H. neck has recently required surgery to release the skin in her neck to allow her to turn her head and for which she is being evaluated for future surgery

3. Dental: M.H.'s teeth are very irregular with a mix of primary and secondary dentition. These findings are consistent with the authors conclusions as found in the article entitled Severe and Unrecognized Dental Abnormailities After Drug-Induced Epidermal Necrolysis. [redacted] will likely incur significant dental medical expenses in the future.

4. Psychological Counseling: M.H. is currently being treated by for psychological issues often associated with TEN sequelae, and may be experiencing PTSA which is consistent with long term psychological sequelae afflicting many TEN patients. Due to the PTSD and the other psychological injuries one can expect to be associated with her gynecological injuries, it is reasonable to assume that [redacted] will require long term psychological counseling in the future at significant expense.

5. Gynecological Injuries: M.H. has suffered labia minor fusion. Such gynecological complications consistent with the literature regarding vaginal damage resulting from SJS and TEN. Moreover, she is prescribed and uses Premarin cream daily due to the vaginal abnormalities. It is likely that she will require future medical care for her gynecological injuries. Moreover, there may be risk associated with the early and long term use of Premarin, necessitating additional medical treatment and cost.

Prior to giving the Children's Motrin to M.H., Plaintiff read the warnings on the label. Nothing in the label put her on notice that the Children's Motrin could cause a life threatening, life altering reaction such as TEN.

Children's Motrin is a product manufactured by McNEIL-PPC, Inc. (McNeil). McNEIL-PPC, Inc. is a wholly owned subsidiary of Defendant Johnson & Johnson. McNeil Consumer Healthcare is a division of McNEILL-PPC, Inc. Johnson & Johnson retained and exercised control over material matters relating to adverse event reporting, safety signals and warnings associated with Children's Motrin.

Causation: The single active ingredient in Children's Motrin is ibuprofen. Ibuprofen products, such as Children's Motrin, can and do cause SJS and TEN. There is a wealth of peer-reviewed epidemiological data involving case-control studies (SCAR-1995, 2000, 2003, 2007; and Levi, et al. 2009 met analyses), case-series, and case report literature and spontaneous reports of good quality that support a finding that ibuprofen products such as Motrin and Children's Motrin cause SJS and TEN in both adults and children. In fact the prevalent view among researchers is that drugs are, in most cases, the cause of TEN. The only drug ingested by M.H. prior to the onset of TEN, that has been causally associated with TEN, was the Children's Motrin. Plaintiff's dispute the contention that M.H. experienced TEN symptoms prior to her ingestion of Children's Motrin. M.H.'s TEN was, in reasonable medical probability caused by the Children's Motrin. TEN is relatively rare, but the risk and severity of the disease out weights its benefits in the absence of adequate warning, particularly in light of the available alternatives.

Defective Design: When McNeil delivered Children's Motrin into the market place it had a characteristic (ibuprofen) that rendered it unreasonably dangerous under Louisiana law in that there is a feasible safer alternative to the active ingredient ibuprofen and the risk of the very serious injuries associated with ibuprofen clearly outweigh the benefits of ibuprofen. The safer alternative is dexibuprofen which has been demonstrated to be as effective as ibuprofen but which has a much stronger safety profile. M.H.'s injuries were caused by ibuprofen and resulted from a reasonably anticipated use of the ibuprofen. At the time M.H. ingested Children's Motrin it was advertised for use by children as a pain reliever/fever reducer. The risk to M.H. would have been substantially less had dexibuprofen been the active ingredient in Children's Motrin instead of ibuprofen.

Inadequate Warning: When McNeil delivered Children's Motrin into the market place it had a characteristic (ibuprofen) that rendered it unreasonably dangerous under Louisiana law in that the product label failed to adequately warn of the risk of life threatening injury such as TEN. McNeil and J&J are liable since when the Children's Motrin left McNeil's control, it had a characteristic that might cause damage and McNeil and J&J failed to use reasonable care to provide an adequate warning of that characteristic and its danger to users of the product. The injury which M.H. suffered was proximately caused by the ibuprofen, the characteristic of the product which made it unreasonably dangerous and existed at the time the product left the defendant's control. M.H. suffered actual and severe injury and the injury which M.H. suffered arose from a reasonably anticipated use of the children's Motrin. The

warning provided with the Children's Motrin in 2010 was inadequate to lead an ordinary user of Children's Motrin to think about the real danger in using the Children's Motrin, and then have the option of not using it.

Label responsibility: Under the Federal Regulations, responsibility for the adequacy of drug labeling remains with the manufacturer and marketer of a drug, and not with the FDA. With respect to the drugs its manufacturers, including Children Motrin, McNeil has an obligation, under the Federal Regulations, to continuously review and assess all sources of adverse event information, to make comprehensive risk assessments, and to continuously review their labeling (at least annually) to assure that product safety information is correct and adequate. McNeil had this responsibility as long as they continued to manufacture and market the Children's Motrin. The obligation continued beyond the 2006 label change ordered by the FDA. The bottom line is the Federal Regulations impose an independent duty on McNeil and J&J to ensure that the labeling for Children's Motrin is accurate and adequate. The FDA has stated that the responsibility to ensure accurate information on warnings and risks solely rests with the drug company. The evidence is that McNeil failed to review the safety data and literature, and perform an assessment to ensure that their labeling post 2006 remained adequate.

Safety Signals: There was a statistically significant increase in the incidence of SJS/TEN adverse event reporting for ibuprofen products between the date of the Children's Motrin label change in 2006 and the date M.H. ingested Children's Motrin in February 2010. The increase in adverse event reporting constituted a safety signal that the 2006 label was inadequate. The FDA relies on adverse event reporting and requires McNeil and J&J to monitor to McNeil as part of McNeil's ongoing responsibility to monitor its labels. McNeil and not the FDA retains responsibility for the label and for safety. McNeil has the authority and obligation to strengthen its label under the CFR when it should know that the label is inadequate. McNeil was aware of the increased rate of adverse event reporting for ibuprofen and SJS/TEN post he 2006 label change but did not conduct any investigation, study, or label comprehension analysis to determine if the 2006 Children's Motrin label was adequate. McNeil and J&J turned a blind eye to the increased incidence of SJS/TEN reporting and dismissed it as a media phenomenon.

Acetaminophen: Contrary to Defendants' assertions, the 2013 FDA approved label for acetaminophen does not constitute a second rejection by the FDA of Plaintiffs' warnings claims. acetaminophen is a different compound with a better safety profile than ibuprofen.

Louisiana Law: At the time of M.H.'s ingestion of Children's Motion, Plaintiffs were residents of New Orleans, Louisiana and the Children's Motrin was purchased in New Orleans, Louisiana. This is a diversity case and it is undisputed that Louisiana applies to the substantive issues in this case. Under Louisiana law Defendants are liable to Plaintiffs for defective design and inadequate warnings. The evidence will show that is was possible for Defendants to comply with both Federal and Louisiana

state law. Accordingly, Plaintiffs' claims are not preempted under any theory of preemption. Plaintiffs have provided this Court with briefing on the preemption issue.

b. Defendants: McNEIL-PPC, Inc. manufactures Children's Motrin. Johnson & Johnson is a holding company that owns all of the stock of McNEIL-PPC, Inc. Johnson & Johnson does not manufacture or sell Children's Motrin.

SJS/TEN: SJS and TEN are extremely rare and poorly understood diseases. The overall incidence rate is 1-2 cases per million persons per year from all causes. No test exists to identify the cause of an individual patient's SJS or TEN. Certain classes of medications are commonly associated with SJS and TEN, and many drugs can potentially cause these diseases, but there are also other causes – including infections. In many cases, a specific cause cannot be determined. The best available scientific evidence indicates that ibuprofen is unlikely to cause SJS or TEN. There are a number of highly suspect drugs that cause the majority of SJS and TEN cases, and ibuprofen is definitely not one of those highly suspect drugs.

Confounding by Indication: The early (prodromal) symptoms of SJS and TEN are fever, headache and/or malaise. These are the very same symptoms for which consumers take OTC ibuprofen. As a result there are reported cases of SJS and TEN temporally associated with ibuprofen use where ibuprofen was probably taken after the disease had begun.

The FDA Approved the Design and Warning: Children's Motrin is not unreasonably dangerous. The FDA approved both the chemical design of ibuprofen, and the warning label for Children's Motrin, determining that this product is so safe that it can be sold over-the-counter. Ibuprofen is one of the most widely used medications in the world.

Design Claim Preempted by Federal Law: *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013), bars Plaintiff's state law design defect claim as a matter of law. *Bartlett* vacated a product liability judgment predicated on a jury's determination that an FDA-approved drug's active ingredient was unreasonably dangerous in design under state law because it could cause SJS/TEN. The judgment was vacated because it presented an irreconcilable conflict between state and federal law. Deeming a drug's active ingredient "unreasonably dangerous" imposes a duty on a manufacturer to redesign its drug and alter its active ingredient – but any change in the active ingredient renders the reformulated product a "new drug" under federal law which cannot be sold under federal law without prior FDA approval of both the new drug and its label. Thus, a state law requirement to change the formulation of an FDA approved drug conflicts with federal law and is preempted.

Design Claim Fails Under State Law: Under Louisiana state law, Plaintiff must prove there is a feasible alternative design of ibuprofen. LSA-R.S. §9:2800.56. She claims that dexibuprofen is a safer alternative to ibuprofen. However, it is not legal to sell dexibuprofen in the U.S., and, thus, it was not (and is not) an available alternative

design. Second, dexibuprofen is a different drug from ibuprofen, and does not meet the alternative design requirement under the LPLA.

Plaintiff's design defect claims premised specifically on dexibuprofen as a purported safer alternative design are preempted. Plaintiff's proposal requires McNeil to redesign ibuprofen and render it a "new drug" that cannot be sold under federal law without prior FDA approval. Under *Bartlett*, such a state law requirement to change the forumulation of an FDA approved drug conflicts with federal law and is, therefore, preempted.

Warning Claim Preempted by Federal Law: In 2005, the FDA reviewed the risks and benefits of the class of medications known as Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), which includes ibuprofen, to determine what warning language should be used on those drugs. Based on this review, the FDA told McNeil and all other manufacturers of these drugs that they should add a warning to the drug label advising consumers to stop use and see a doctor if skin reddening, rash or blisters appear. In addition, in 2006, the FDA specifically rejected a request that the label for OTC ibuprofen products be required to include a reference to "Stevens-Johnson syndrome" and/or "toxic epidermal necrolysis." The FDA also denied a request that the label include a warning that using the drug could lead to "serious and potentially life-threatening diseases" and/or "rare and life-threatening reactions." McNeil has consistently used the language the FDA told it to use on the Children's Motrin label. Plaintiff's proposed alternative language runs counter to the FDA's directive that the OTC warning should include only easily-identifiable early symptoms of potential side effects, along with an instruction to stop use and see a doctor if they appear.

Plaintiff contends that the Children's Motrin label should have included not just the FDA-specified listing of potential initial symptoms of SJS/TEN ("skin reddening," "rash," and "blisters"), but also warnings about potential severe and permanent injuries such as major skin loss, blindness, scarring, disability, and disfigurement. But the FDA has now twice made clear—in 2005 for NSAIDs (which include ibuprofen products such as Motrin and naproxen products such as Aleve) and in August 2013 for drugs containing acetaminophen (which include Tylenol)—that the only SJS/TEN warnings the agency considers appropriate for the OTC labeling of these widely-used consumer pain and fever medications are warnings about the *initial symptoms*, coupled with instructions to stop use and seek medical attention right away.

Plaintiff's claim that the OTC Children's Motrin label should have specifically warned about "TEN" or of a "life threatening" reaction is preempted. In 2006, the FDA expressly rejected a request that the label for OTC ibuprofen products be required to include a reference to "TEN." The FDA also rejected a request that the label include a warning that using the drug could lead to "serious and potentially life-threatening diseases" and "rare and life-threatening reactions." This is "clear evidence" that the FDA would not approve Plaintiff's proposed warnings. *See Wyeth v. Levine*, 555 U.S. 555, 571 (2009) (holding that federal law preempts state-law

failure-to-warn claims where there is "clear evidence that the FDA would not have approved" unilateral labeling change by manufacturer).

Likewise, any claim that the OTC Children Motrin's label should have included the same warnings as the prescription Motrin label – including an explicit reference to "SJS/TEN" – is preempted. The FDA considered and specifically rejected a warning on OTC ibuprofen products that would have mentioned SJS/TEN. *See id.*

Moreover, under FDA regulations, the standard for an OTC label is materially different from the standard for a prescription label. Over-the-counter drug labels are written to provide consumers with information that will help them use the drug safely. *See* 21 C.F.R. § 330.10 (4)(v) (stating that an OTC label should be "in such terms as to render them likely to be read and understood by the ordinary individual, including individuals of low comprehension, under customary conditions of purchase and use"). Prescription drug labels, by contrast, are written for doctors. They provide information about the drug's risks and benefits that prescribing physicians consider, along with a patient's medical history, when deciding whether the drug is appropriate for a particular individual. *See* 21 C.F.R. § 201.57 (a)(10) (a prescription label should contain "information that would affect decisions about whether to prescribe a drug, recommendations for patient monitoring that are critical to safe use of the drug, and measures that can be taken to prevent or mitigate harm."). Most recently, the FDA reaffirmed the distinction between prescription and OTC labeling when it decided to require a warning on the *early symptoms* of SJS/TEN for *OTC* acetaminophen products — rather than a detailed listing of severe complications the FDA required for *prescription* acetaminophen products — based on its view that OTC warnings about SJS/TEN should simply allow consumers to "recognize and react quickly to the initial symptoms" of those diseases. (Consumer Updates, "FDA Warns of Rare Acetaminophen Risk." Aug. 1, 2013.)

In its August 2013 announcement of the new warnings required for OTC acetaminophen products—which also expressly references the agency's earlier-mandated warnings for NSAIDs including OTC ibuprofen and naproxen—the FDA explained its rationale. The FDA was well aware of the severe potential consequences of SJS/TEN, and indeed cited the severity of the disease as the reason for requiring the warnings. But the FDA also recognized, as it had recognized for NSAIDs when it previously rejected a stronger SJS/TEN warning for NSAIDs, that acetaminophen was a widely-used and beneficial consumer medication, and the incidence of SJS/TEN associated with its use was both rare and unpredictable. The OTC labeling changes therefore were "not intended to worry consumers or health care professionals, nor . . . to encourage them to choose other medications," but to allow consumers to "recognize and react quickly to the *initial symptoms* of these rare[,] but serious, side effects, which can be fatal." As this explanation makes plain, the FDA's decision to warn only about the potential initial symptoms of SJS/TEN on OTC labeling reflects a considered regulatory judgment balancing the competing objectives of providing adequate information for safe use while avoiding alarmist descriptions of rare and unpredictable potential side effects that might deter

beneficial use. This is clear evidence that the FDA would have rejected the warnings about severe and permanent injuries that Plaintiff alleges should have been on the OTC Children's Motrin label.

Warning Claim Fails Under State Law: The label used for OTC Children's Motrin is the same label used by all OTC ibuprofen manufacturers. The language at issue in that label was written and approved by the FDA. McNeil did not act unreasonably when it used the warnings that the FDA told it, and every other ibuprofen manufacturer, to use.

M.H.'s TEN was Not Caused by Children's Motrin: M.H. had the prodromal symptoms of TEN before she was allegedly given Children's Motrin. Furthermore, the time to onset between when she was reportedly given that drug and when she experienced mucocutaneous signs and symptoms was only an hour – not the typical 3-4 days that would be expected.

[redacted] Individual Claims are Prescribed: [redacted] filed this lawsuit on February 24, 2011, more than one year after February 5, 2010 – the date her daughter had clearly developed SJS and/or TEN and also the date that Plaintiff learned what may have caused that disease. After M.H. awoke with rash/hives-like bumps all over her face and neck at 3-4 AM on February 5, 2010, Plaintiff called her sister, and her sister told her that M.H.'s condition might be a reaction to medication. Therefore, Plaintiff did not give her daughter any more medication. On that same day, the ER physician at Ochsner Medical Center told Plaintiff that M.H.'s TEN may have been caused by medication. Further, prior to M.H.'s discharge from Ochsner on February 8, 2010, a second physician told Plaintiff that her daughter's TEN may have been caused by medication.

Plaintiff's Claims Preempted Under *Buckman*: To the extent Plaintiff bases any of her claims on McNeil's alleged failure to provide relevant or complete safety information about ibuprofen to the FDA, such claims are preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348 (2001) (holding that state-law claims that allege that the defendant withheld from or otherwise misrepresented information to the FDA are preempted).

Therefore, under *Buckman*, Plaintiff's claims are preempted to the extent they are based on any allegation that McNeil failed to report information it was required to report to the FDA, including any adverse event reports.

7. A single listing of all uncontested material facts:

   a. McNEIL-PPC, Inc. is the "manufacturer" of Children's Motrin, as the term "manufacturer" is used in the Louisiana Products Liability Act.

   b. M.H. awoke with bumps on her face and neck in the early morning hours of February 5, 2010.

c. [redacted] called her sister early in the morning on February 5, 2010, and her sister told her that M.H.'s condition might be a reaction to the medication

d. After speaking with her sister early in the morning on February 5, 2010, [redacted] did not give M.H. any more medication on February 5, 2010.

8. A single listing of the contested issues of fact:

a. Whether M.H. was given Children's Motrin on February 4, 2010?

b. If M.H. was given Children's Motrin on February 4, 2010, did that occur before or after her prodromal symptoms of TEN were already present?

c. If M.H. was given Children's Motrin on February 4, 2010, did that occur before or after her rash appeared?

d. Whether M.H.'s SJS/TEN was caused by Children's Motrin?

e. Whether Children's Motrin is unreasonably dangerous in design?

f. Whether Children's Motrin is unreasonably dangerous due to an inadequate warning?

g. The nature and extent of the injuries sustained by M.H. and any alleged disability?

h. The nature and extent of general damages sustained by M.H.?

i. The nature and extent of M.H.'s special damages pre-majority?

j. The nature and extent of M.H.'s special damages post-majority?

k. The nature and extent of general damages sustained by [redacted] as a result of her daughter's TEN?

l. Whether [redacted]' individual claims are barred by prescription because this lawsuit was not filed timely?

m. The extent to which TEN is attributable primarily to drug ingestion.

n. Whether ibuprofen can cause TEN.

o. Whether Children's Motrin can cause TEN.

p. Whether dexibuprofen is a safer alternative to ibuprofen.

q. Whether dexibuprofen is a feasible alternative to ibuprofen.

r. Whether it is technically, scientifically and economically feasible to manufacture ibuprofen in a single molecule version isolating the active molecule of ibuprofen known as dexibuprofen from the inactive molecule known as levoibuprofen and whether the result is a purer form of ibuprofen.

s. Whether McNeil and J&J had authority to strengthen the warnings in its 2006 label prior to the time M.H. ingested Children's Motrin.

t. Whether McNeil and J&J had the responsibility to strengthen the warnings in its 2006 label prior to the time M.H. ingested Children's Motrin.

u. Whether Defendants' ignored safety signals impacting the adequacy of the Children's Motrin label in 2010.

v. Whether there was an increase in the rate of SJF/TEN adverse event reports related to ibuprofen ingestion between the label change for Children's Motrin in 2006 and the ingestion of Children's Motrin by M.H. in February 2010.

w. Whether Acetaminophen has a better safety profile than ibuprofen.

x. Whether [redacted] read the warnings on the Children's Motrin label prior to giving the Children's Motrin to M.H.

y. Whether McNeil and J&J have never sought FDA approval for dexibuprofen.

z. Whether as early as 1993 Defendants filed a patent related to an application of dexibuprofen to its Pepcid and Mylicon products. In this patent, Defendants stated that compared to regular/racemic ibuprofen that dexibuprofen is more effective: 1) dexibuprofen works faster for head and stomach ache relief; (2) dexibuprofen provides enhanced relief of aches and pains; (3) dexibuprofen offers faster onset of pain-relief and inflammation relief. Defendants' patents further state that compared to regular racemic ibuprofen, dexibuprofen is safer in that (1) it has a lower risk of allergic reaction; (2) it produces a lower metabolic load on the body; it produces less deposits in the body's fatty tissues; (3) and that dexibuprofen has a lower incidence rate of adverse reactions that were significantly lower.

aa. Whether, in spite of any action on the part of the FDA, McNeil and J&J retain responsibility for the safety of its products and the adequacy of its labels.

9. A single listing of the contested issues of law:

a. Whether the recent U.S. Supreme Court decision of *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013), bars Plaintiff's state law claim that there is an inherent risk of SJS or TEN associated with ibuprofen and that Louisiana law

therefore imposes a duty on the Defendants to redesign Children's Motrin by changing the formulation of the active ingredient from ibuprofen to dexibuprofen?

b. Whether, as a matter of law, Louisiana state law permits recovery for damages allegedly caused by an unreasonably dangerous design when the product at issue is an OTC drug that is one of the most widely used medications in the world that has been approved as both safe and effective by the FDA for decades, when the Plaintiff's proposed alternative design, dexibuprofen, is:

   i. A different drug from ibuprofen; and

   ii. Was not (and is not) legally available for sale in the United States?

c. Whether Plaintiff's state law claim that the warning on OTC Children's Motrin is inadequate is preempted because, under the U.S. Supreme Court's decision in *Wyeth v. Levine*, 555 U.S. 555 (2009), there is "clear evidence" that the FDA would not have approved the changes to the Children's Motrin warning label proposed by Plaintiff?

d. Whether, as a matter of law, Louisiana state law permits recovery for damages allegedly caused by an inadequate warning if the product at issue is an OTC medication regulated by the FDA and the language at issue in the warning was written and approved by the FDA?

e. Whether, as a matter of law, [redacted] individual claims, including those for medical expenses incurred by M.H. during her minority, are barred by prescription because this lawsuit was not filed until February 24, 2011?

f. Whether, as a matter of law, Plaintiff's claims based on McNeil's alleged failure to provide relevant or complete safety information about ibuprofen to the FDA are preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348 (2001)?

10. A list and description of the exhibits that each party intends to introduce at trial are attached as *Appendices 1 and 2* to this Pretrial Order. The list first describes those exhibits that are to be admitted without objection. It then describes those to which there will be an objection, noting by who the objection is made and the nature of the objection.

11. A list of all deposition testimony that each party intends to offer into evidence at trial is attached as *Appendices 3 and 4* to this Pretrial Order.

12. A list and brief description of any charts, graphs, models, schematic diagrams, and similar objects which, although not to be offered in evidence, respective counsel intend to use in opening or closing arguments:

a. Plaintiff: In addition to blowups of those documents and things identified on the Exhibit List, Plaintiff may use an easel and writing pad, computer projection, monitors/screens.

b. Defendants: In addition to those documents and things identified on the Exhibit List, Defendants may use an easel and writing pad.

13. Witnesses:

a. A list of witnesses for all parties, including the names, addresses, and statement of the general subject matter of their testimony (it is not sufficient to designate the witness simply "fact," "medical," or "expert"), and an indication in good faith of those who will be called in the absence of reasonable notice to opposing counsel to the contrary:

i. Plaintiff:

I. Witnesses Plaintiffs Will Call

WITNESS	ADDRESS	SUBJECT MATTER	L/D
[redacted] **Ph.D.**	Department Of Clinical And Administrative Sciences College Of Pharmacy, University Of Georgia Athens, Georgia 30602-2354	Dr. [redacted] will testify regarding the matters set forth in his expert report and disclosures, including his qualifications and general causation of SJS/TEN by ibuprofen products, including Children's Motrin; causation of M.H.'s TEN; sequelae of TEN; FDA regulations regarding labeling and post label pharmacovigilance; scope of safety investigations by the FDA; the temporal relationship between the administration of ibuprofen, including Children's Motrin and the onset of SJS/TEN; knowledge and investigation of Defendants and FDA regarding the risk of SJS/TEN; adequacy of Children's Motrin label.	Live
[redacted], **Ph.D.**	Columbia University Department of Statistics [redacted]	Dr. [redacted] will testify regarding the matters set forth in his expert report, disclosures and deposition regarding his findings concerning AERs/MedWatches and other reports reflected in the drug safety	Live

WITNESS	ADDRESS	SUBJECT MATTER	L/D
		and the sequelae of M.H.'s TEN.	
R. [redacted] Ph.D.	University of California San Francisco School of Pharmacy [redacted]	Dr. [redacted] will testify regarding the matters set forth in his report, deposition and disclosures including his qualification, his label comprehension studies methodology and results, label comprehension studies in general.	Live
[redacted] **M.D.**	Loyola University of Chicago, Strich School of Medicine [redacted]	Dr. [redacted] will testify regarding his qualifications to treat SJS/TEN patients; the treatment in burn units of SJS/TEN patients; the care and treatment of M.H.	Live
[redacted]	[redacted]	Mother of M.H. will testify about the events surrounding M.H.'s ingestion of Children's Motrin, her resulting TEN and the course of treatment for the TEN, M.H.'s injuries and concerns.	Live
[redacted]	[redacted]	Sister of [redacted] will testify regarding the report of M.H.s ingestion of Children's Motrin on February 4, 2010	Live
[redacted]	[redacted]	Family friend of the [redacted]'s will testify regarding her observations as to M.H.s injuries and limitations.	Live
M.H.	c/[redacted]	Her experience with TEN and her ongoing issues with the sequelae of TEN.	Live

II. Witnesses Plaintiffs May Call

WITNESS	ADDRESS	SUBJECT MATTER	L/D
[redacted]	[redacted]	Mother of [redacted] will testify regarding her observation of the medications consumed by M.H. on	Live

WITNESS	ADDRESS	SUBJECT MATTER	L/D
[redacted] MD	Children's Choice Pediatrics [redacted]	The care and treatment of M.H.	Live
[redacted] MD	Children's Medical Center [redacted]	The care and treatment of M.H.	Live
Dr. [redacted]	[redacted]	The care and treatment of M.H.	Live
[redacted] M.D., Ph.D.	[redacted]	Dr. [redacted] may be called as a rebuttal witness to rebut the testimony and/or computations and/or report of Dr. [redacted], including but not limited to his calculations regarding "multivariate relative risk" (regardless of who testifies regarding those computations) and the testimony and/or report of Dr. [redacted] regarding causation, including the ALDEN score relied on by Dr. [redacted] and its relationship to EuroSCAR.	Live
Plaintiffs also identify any individuals, including but not limited to records custodians, who may be needed to authenticate documents for all treating physician offices and hospitals involved in the care and treatment of M.H..			Live, by Deposition or by Affidavit
Plaintiff may call any witness identified by Defendants.			Live or Deposition

ii. Defendants:

I. Witnesses Defendants Will Call

WITNESS	ADDRESS	SUBJECT MATTER	L/D
[redacted] MD	[redacted]	Will testify as an expert regarding (a) principles of pediatric infectious	Live

II. Witnesses Defendants May Call

WITNESS	ADDRESS	SUBJECT MATTER	L/D
[redacted]	c/o McNeil [redacted]	Former McNeil employee, testimony regarding adverse event reporting and medical communications.	Live
[redacted]	c/o McNeil [redacted]	Current McNeil employee, testimony regarding medical communications and marketing issues.	Live
[redacted]	[redacted]	The care and treatment of M.H..	Live
[redacted] MD	[redacted]	The care and treatment of M.H..	Live
[redacted], MD	[redacted]	The care and treatment of M.H..	Live or deposition
[redacted], PhD	[redacted]	May testify as an expert, from a statistical perspective, on the results concerning the association between SJS/TEN and exposure to ibuprofen (among other drugs) reported in two peer-reviewed epidemiological studies – SCAR and EuroSCAR. *See* expert report. He may also rebut evidence presented by Plaintiff's experts.	Live
[redacted], MD	[redacted]	The care and treatment of M.H..	Live
[redacted] MD	[redacted]	The care and treatment of M.H..	Live
[redacted] MD	[redacted]	The care and treatment of M.H..	Live
[redacted]	c/o McNeil [redacted]	Testimony regarding pharmacovigilance processes and analysis.	Live
[redacted]	c/o McNeil [redacted]	Testimony regarding pharmacovigilance processes and analysis.	Live

WITNESS	ADDRESS	SUBJECT MATTER	L/D
		Plaintiff's experts.	
[redacted]	[redacted]	The care and treatment of M.H..	Live or deposition
[redacted] MD	[redacted]	The care and treatment of M.H..	Live
[redacted] MD	[redacted]	The care and treatment of M.H..	Live
Defendants also identify any individuals, including but not limited to records custodians, who may be needed to authenticate documents for all treating physician offices and hospitals involved in the care and treatment of M.H..			Live
Defendants may call any witness identified by Plaintiff.			Live or Deposition

b. Witnesses were identified in accordance with Rule 26 Pretrial Disclosures and written discovery propounded by the parties, in accordance with the Federal Rules of Civil Procedure and prior court orders. No other witnesses shall be allowed unless agreeable to all parties and their addition does not affect the trial date. This restriction will not apply to rebuttal witnesses or documents whose necessity cannot be reasonably anticipated.

In the case of expert witnesses, counsel certifies that they have exchanged expert reports in accordance with the Federal Rules of Civil Procedure and prior court orders. Expert witnesses whose reports have not been furnished to opposing counseled shall not be permitted to testify nor shall experts be permitted to testify to opinions not included in the reports timely furnished.

c. Except for good cause shown, the Court will not permit any witness to testify with respect to such witness there has been complete compliance with all provisions of the pre-trial order and prior court orders.

d. Counsel shall not be allowed to ask questions on cross-examination of an economic expert which would require the witness to make mathematical calculations in order to frame a response unless the factual elements of such questions shall have been submitted to that expert witness not less than three full working days before trial.

14. This is a jury case.

    a. The jury trial is applicable to all aspects of this case.

       Proposed jury instructions, special jury interrogatories, and trial memoranda shall be electronically filed with the Court not later than **ten** working days prior to the trial date; and any special questions that the Court is asked to put to prospective jurors on voir dire shall be electronically filed with the Court not later than **five** working days prior to the trial date unless specific leave to the contrary is granted by the Court.

    b. A trial memorandum shall be required only when and to the extent ordered by the Court. However, any party may in any event file such memoranda not less than **five** working days prior to trial and should accomplish this with respect to any anticipated evidentiary problems which require briefing and jury instructions requiring explanation beyond mere citation to authority.

15. Defendants propose that the issue of liability should be tried separately from that of quantum. Plaintiffs object and assert that the issues should be tried together.

16. Other matters that might expedite a disposition of the case:

17. Trial shall commence on March 17, 2014 at 8:30 AM. The Defendants estimate that trial will take 15 trial days. Plaintiffs essentially concur that the trial will take 10-15 trial days.

18. This pretrial order has been formulated after conference at which counsel for the respective parties have appeared in person. Reasonable opportunity has been afforded counsel for corrections, or additions, prior to signing. Hereafter, this order will control the course of the trial and may not be amended except by consent of the parties and the Court, or by order of the Court to prevent manifest injustice.

19. Possibility of settlement of this case was considered.

THIS THE 18th day of February, 2014.

[redacted]

Attorneys for Plaintiffs

[redacted] INDIVIDUALLY AND
ON BEHALF OF HER MINOR CHILD, M.H.

[redacted]

Attorneys for Defendants
MCNEIL CONSUMER HEALTHCARE
DIVISION OF MCNEIL-PPC, INC.; and
JOHNSON & JOHNSON

UNITED STATES DISTRICT JUDGE