UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

AMY BATOH, as Personal Representative of the Estate of Kyle Kimball, Deceased Plaintiff, v. McNEIL-PPC, INC. and JOHNSON & JOHNSON, Defendants.	No. 3:14-cv-01462 (MPS)

MEMORANDUM OF DECISON

In October, 2010, Kyle Kimball developed rare and extremely painful skin conditions after taking one dose of over-the-counter Motrin. Over a year later, overcome by continued pain and suffering from these conditions and the damage they had done to his life, Kimball killed himself. His mother, Amy Batoh, has sued the manufacturer of Motrin and its parent company in this products liability case, claiming that the Motrin Kimball took contained inadequate warnings and was defective as designed, among other things. On cross-motions for summary judgment, I must decide principally (1) whether there is admissible evidence in the record from which a reasonable juror could find that Kimball would not have taken the Motrin had the label borne the more explicit warnings that Batoh says were required, and (2) whether the defendants have established their defense of "impossibility preemption" with respect to the claim that Motrin harbored a design defect in its chemical composition. The tragic circumstances of this case do not make these decisions easy. Nonetheless, after carefully reviewing the voluminous record and considering the parties' briefs and oral arguments, I conclude (1) that there is no admissible evidence that Kimball would not have taken the Motrin had the label been more explicit and thus that Batoh cannot sustain the causation element of her failure-to-warn claim, and (2) that,

because federal regulations barred the defendants from changing the active ingredient in Motrin without prior approval by the U.S. Food and Drug Administration (the "FDA"), federal law prevented the defendants from complying with the state law duties this lawsuit would impose on them to alter the chemical composition of Motrin. Federal law thus preempts the design defect claim. I therefore grant summary judgment to the defendants.

I. BACKGROUND

A. Relevant Factual Background[1]

The following facts—taken from the Amended Complaint, the parties' Local Rule 56(a) Statements, and their exhibits—are undisputed unless otherwise indicated.

1. The Parties

Batoh, a Connecticut resident, is the mother and personal representative of Kimball's estate. (McNeil's Local Rule 56(a)1 Statement, ECF No. 117 ("McNeil's L.R. 56(a)1 Stmt.") ¶¶ 1-2; Plaintiff's Local Rule 56(a)2 Statement, ECF No. 129 ("Pl.'s L.R. 56(a)2 Stmt.") ¶¶ 1-2.) Defendants McNeil-PPC, Inc. ("McNeil") and Johnson & Johnson ("J&J") (together, "Defendants") are New Jersey Corporations. (McNeil's L.R. 56(a)1 Stmt. ¶¶ 3-4; Pl.'s L.R. 56(a)2 Stmt. ¶¶ 3-4.) J&J "owns all of the stock of Janssen Pharmaceuticals, Inc., which in turn owns all" of McNeil's stock. (McNeil's L.R. 56(a)1 Stmt. ¶ 5; Pl.'s L.R. 56(a)2 Stmt. ¶ 5.) McNeil manufactures and sells Motrin, an FDA-approved over-the-counter ("OTC") medication for the relief of pain and inflammation and the reduction of fever. (McNeil's L.R. 56(a)1 Stmt. ¶ 6; Pl.'s L.R. 56(a)2 Stmt. ¶ 6.)

2. Motrin

[1] Unless otherwise noted, the following facts are recounted in the light most favorable to the nonmovant, with all reasonable inferences drawn in favor of the nonmovant. *Weinstock v. Columbia Univ.*, 224 F.3d 33, 41 (2d Cir. 2000).

The nonsteroidal anti-inflammatory drug ("NSAID") ibuprofen is the active ingredient in Motrin. (McNeil's L.R. 56(a)1 Stmt. ¶ 7; Pl.'s L.R. 56(a)2 Stmt. ¶ 7.) The FDA approved ibuprofen as a prescription medication for adults in 1974, and approved Motrin as an OTC medication in 1984. (McNeil's L.R. 56(a)1 Stmt. ¶¶ 8-9; Pl.'s L.R. 56(a)2 Stmt. ¶¶ 8-9.) The FDA reviewed drug applications for ibuprofen in 1974, 1984, and 1994, and concluded that "the drug is safe and effective for use as recommended in the submitted labeling." (McNeil's L.R. 56(a)1 Stmt. ¶ 10 (*citing* ECF Nos. 117-1, 117-2, 117-3); Pl.'s L.R. 56(a)2 Stmt. ¶ 10.) In 2006, the FDA estimated "that there are more than 100 million users of OTC ibuprofen each year in the United States and approximately 29 million prescriptions dispensed annually in this country." (McNeil's L.R. 56(a)1 Stmt. ¶ 11; Pl.'s L.R. 56(a)2 Stmt. ¶ 11.)

3. SJS and TEN

Stevens Johnson Syndrome ("SJS") and Toxic Epidermal Necrolysis ("TEN") are severe cutaneous adverse reactions ("SCAR events") (Amended Complaint, ECF No. 90 ("Am. Compl.") ¶ 65) "characterized by inflammation of the mucous membranes of the mouth, throat, eyelids, and anogenital region" (*id*. ¶ 9) and "painful and debilitating tissue injury and loss, epidermal blistering, necrosis, and sloughing." (*Id*. ¶ 65) SJS and TEN can "result in massive skin loss, blindness, disfigurement, permanent disability, and death." (*Id*.) "Cases involving skin detachment over less than 10% of total body surface are classified as SJS; cases with 10-30% detachment are referred to as SJS/TEN overlap; and cases over 30% are listed as TEN."[2] (McNeil's L.R. 56(a)1 Stmt. ¶ 12; Pl.'s L.R. 56(a)2 Stmt. ¶ 12.)

[2] Batoh adds that "SJS is characterized by less than ten percent (10%) of skin loss with mortality." (Pl.'s L.R. 56(a)(2) Stmt. ¶ 12.)

SJS and TEN are rare conditions. In 2006, the FDA estimated that the incidence of SJS and TEN, respectively, ranges from 1.2 to 6 per million per year and 0.4 to 1.2 per million per year. (McNeil's L.R. 56(a)1 Stmt. ¶ 13 (*citing* ECF No. 117-4 at 3); Pl.'s L.R. 56(a)2 Stmt. ¶ 13.) In its 1995 medical officer review of OTC Children's Motrin,[3] the FDA stated that, in rare cases, NSAIDs including ibuprofen can cause SJS and TEN. (McNeil's L.R. 56(a)1 Stmt. ¶ 17 (*citing* ECF No. 117-8); Pl.'s L.R. 56(a)2 Stmt. ¶ 17.)

4. Motrin Labeling

On September 30, 1996, McNeil submitted to the FDA revised warning language for Motrin aimed at people with aspirin sensitivity ("Aspirin Sensitivity Warning"), in response to draft language the FDA had sent McNeil several days earlier. (McNeil's L.R. 56(a)1 Stmt. ¶¶ 19-20; Pl.'s L.R. 56(a)2 Stmt. ¶¶19-20.) In March of 1997, the FDA submitted recommended language to McNeil, and in June of 1997, McNeil submitted to the FDA its revised labeling for Children's Motrin. (McNeil's L.R. 56(a)1 Stmt. ¶ 21; Pl.'s L.R. 56(a)2 Stmt. ¶ 21.) Despite this correspondence in 1996 and 1997, the FDA advised McNeil in July of 1997 *not* to implement any changes to the Aspirin Sensitivity Warning because the FDA was evaluating class labeling appropriate for all similar products. (McNeil's L.R. 56(a)1 Stmt. ¶ 22; Pl.'s L.R. 56(a)2 Stmt. ¶ 22.) Nearly a year later, in a letter to the FDA dated June 1, 1998, McNeil proposed a new Aspirin Sensitivity Warning directing users to seek "emergency medical help immediately" if certain allergic reactions occurred. (McNeil's L.R. 56(a)1 Stmt. ¶ 23; Pl.'s L.R. 56(a)2 Stmt. ¶ 23.) On June 4, 1998, the FDA directed McNeil to revise the Aspirin Sensitivity Warning again. (McNeil's L.R. 56(a)1 Stmt. ¶ 24; Pl.'s L.R. 56(a)2 Stmt. ¶ 24.) In a letter dated September 15,

[3] In 1989, the FDA approved McNeil's "Pediaprofen"—later renamed "Children's Motrin"—as the first pediatric ibuprofen product. Its FDA-approved label identified SJS as a possible adverse event. (McNeil's L.R. 56(a)(1) Stmt. ¶ 15; Pl.'s L.R. 56(a)(2) Stmt. ¶ 15.)

1998, the FDA advised McNeil that it had completed its evaluation of class labeling issues, and required, among other things, that McNeil change the Aspirin Sensitivity Warning to an "Allergy Alert" warning. (McNeil's L.R. 56(a)1 Stmt. ¶ 25; Pl.'s L.R. 56(a)2 Stmt. ¶ 25.) Both parties agree that McNeil submitted proposed warning language in a letter to the FDA dated October 23, 1998. (McNeil's L.R. 56(a)1 Stmt. ¶ 26; Pl.'s L.R. 56(a)2 Stmt. ¶ 26.) McNeil characterized its proposed language as "expanded," but Batoh objects to that characterization. (McNeil's L.R. 56(a)1 Stmt. ¶ 26; Pl.'s L.R. 56(a)2 Stmt. ¶ 26.)

On December 2, 1998, and again on February 11, 1999, the FDA sent faxes to McNeil, providing labeling revisions and directing McNeil to use the "Allergy Alert" warning that had been drafted by the FDA and sent to McNeil in the letter dated September 15, 1998. (McNeil's L.R. 56(a)1 Stmt. ¶¶ 27-28; Pl.'s L.R. 56(a)2 Stmt. ¶¶ 27-28.) On March 15, 1999, McNeil submitted revised labeling that complied with the language in the FDA's letter of September 15, 1998, and the FDA approved that labeling on August 25, 2000. (McNeil's L.R. 56(a)1 Stmt. ¶ 29; Pl.'s L.R. 56(a)2 Stmt. ¶ 29.)

a. Citizens' Petition

In February 2005, the FDA received a Citizens' Petition (the "Citizens' Petition") that asked the FDA to withdraw its approval of OTC ibuprofen products based on the risks of SJS and TEN (McNeil's L.R. 56(a)1 Stmt. ¶ 39; Pl.'s L.R. 56(a)2 Stmt. ¶ 39), or, at a minimum, require the following warning labels on OTC ibuprofen:

> **Serious Skin Reactions:** Ibuprofen may cause serious skin reactions that begin as rashes and blisters on the skin, and 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.

(McNeil's L.R. 56(a)1 Stmt. ¶ 40; Pl.'s L.R. 56(a)2 Stmt. ¶ 40.) The Citizens' Petition also asked for the following language on OTC ibuprofen, under the heading "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 Erythema Multiforme, Stevens Johnson Syndrome and Toxic Epidermal Necrolysis.

(McNeil's L.R. 56(a)1 Stmt. ¶ 41; Pl.'s L.R. 56(a)2 Stmt. ¶ 41.)

In 2005, the FDA reviewed the labeling on all OTC NSAIDs, including Motrin, and provided McNeil with a template for revisions to the OTC labels. The template added the words "skin reddening," "rash," and "blisters" to the list of symptoms in the "Allergy Alert." (McNeil's L.R. 56(a)1 Stmt. ¶ 32; Pl.'s L.R. 56(a)2 Stmt. ¶ 32.) The FDA asked NSAID manufacturers to implement the revised warnings according to the FDA's template, and advised them that if they proposed different language, they must submit it to the FDA for "review and approval prior to implementation." (McNeil's L.R. 56(a)1 Stmt. ¶ 33; Pl.'s L.R. 56(a)2 Stmt. ¶ 33.) McNeil complied with the FDA's instructions and revised the warning language on its OTC labels. After that revision, the Motrin label included the following language:[4]

> **WARNINGS:**
>
> ***Allergy alert***: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
>
> - hives
> - facial swelling
> - asthma (wheezing)
> - shock
> - skin reddening
> - rash

[4] A different warning was added in 2005 to prescription NSAIDS, including prescription Motrin. (McNeil's L.R. 56(a)(1) Stmt. ¶ 35; Pl.'s L.R. 56(a)(2) Stmt. ¶ 35.) By 2005, McNeil no longer sold prescription Motrin, but it remained the "reference listed drug" for prescription ibuprofen. (McNeil's L.R. 56(a)(1) Stmt. ¶ 36; Pl.'s L.R. 56(a)(2) Stmt. ¶ 36.)

- blisters

If an allergic reaction occurs, stop use and seek medical help right away ….

(McNeil's L.R. 56(a)1 Stmt. ¶ 34; Pl.'s L.R. 56(a)2 Stmt. ¶ 34.) McNeil incorporated the FDA's language on Motrin by 2006 and this language was on the label in 2010, when Kimball ingested Motrin. (McNeil's L.R. 56(a)1 Stmt. ¶¶ 37-38; Pl.'s L.R. 56(a)2 Stmt. ¶¶ 37-38.)

b. FDA's Response to the Citizens' Petition

In its 2006 written response to the Citizens' Petition, the FDA explained that it had "engaged in a comprehensive review of the risks and benefits, including the risks of SJS and TEN, of all approved NSAID products, including ibuprofen." (McNeil's L.R. 56(a)1 Stmt. ¶ 43; Pl.'s L.R. 56(a)2 Stmt. ¶ 43.) The FDA's response stated that it "uses a number of methods to monitor the safety of marketed drugs, including review of clinical trials submitted to FDA for marketing approvals, review of other clinical studies available in the scientific literature, and review of the Adverse Event Reporting Systems (AERS) surveillance database implemented in 1997."[5] (McNeil's L.R. 56(a)1 Stmt. ¶ 43 (*quoting* ECF No. 117-4 at 2); Pl.'s L.R. 56(a)2 Stmt. ¶ 43.) The FDA concluded that "the overall benefit versus risk profile for ibuprofen products remains very favorable when they are used according to the labeled instructions." (McNeil's L.R. 56(a)1 Stmt. ¶ 44; Pl.'s L.R. 56(a)2 Stmt. ¶ 44.) The FDA noted that other OTC drugs used to reduce fever or relieve pain also have risks of severe adverse reactions. (McNeil's L.R. 56(a)1 Stmt. ¶ 45; Pl.'s L.R. 56(a)2 Stmt. ¶ 45.) Finally, the FDA rejected many of petitioners' suggested changes—including specific references to SJS or TEN—"because most consumers are unfamiliar with these terms." The FDA stated that the words "skin reddening," "rash," and

[5] Plaintiff states that "the FDA's postmarketing system has been characterized as a 'woefully underfunded, understaffed, and haphazard system whereby postmarketing information on drug safety and adverse events is gathered, despite marketed drugs causing thousands of deaths each year.'" (Pl.'s L.R. 56(a)(2) Stmt. ¶ 43 (*quoting* Pl.'s Ex. 4, Tackett Report at ¶ 7).)

"blisters," were "more appropriate" than the Petitioners' proposed language—*e.g.* "[s]erious skin reactions," "potentially life threatening diseases," and "rashes and blisters . . . in the areas of the eyes, mouth and genitalia"—because they were words that consumers could easily identify and were symptoms associated with SJS and TEN. (McNeil's L.R. 56(a)1 Stmt. ¶ 47; Pl.'s L.R. 56(a)2 Stmt. ¶ 47.)

In August 2013, the FDA proposed a similar "Allergy Alert" for OTC acetaminophen that included references to "skin reddening," "blisters," and "rash," along with a warning: "[i]f a skin reaction occurs, stop use and seek medical help right away." (McNeil's L.R. 56(a)1 Stmt. ¶ 48; Pl.'s L.R. 56(a)2 Stmt. ¶ 48.) In order to address the risk of conditions such as SJS and TEN, the FDA requested the following changes in labeling for OTC acetaminophen:

> Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:
> - Skin reddening
> - Blisters
> - Rash
>
> If a skin reaction occurs, stop use and seek medical help right away.

(ECF No. 117-33 at 1-2.)

5. Kimball's Injuries

Batoh testified that, on October 3, 2010, Kimball told her that he felt ill, and was suffering from a fever, sore throat, and a stuffy nose. He took one dose of Motrin. (McNeil's L.R. 56(a)1 Stmt. ¶ 53; Pl.'s L.R. 56(a)2 Stmt. ¶ 53.) Batoh testified that Kimball awoke the next morning, October 4, with pain, swelling, and blisters on his lips. Batoh drove Kimball to Bridgeport Hospital emergency room. (McNeil's L.R. 56(a)1 Stmt. ¶ 54; Pl.'s L.R. 56(a)2 Stmt. ¶ 54.) Doctors there believed that Kimball was suffering from a herpes viral infection (McNeil's L.R. 56(a)1 Stmt. ¶ 54; Pl.'s L.R. 56(a)2 Stmt. ¶ 54), and gave him a prescription for the drug Acyclovir. (Am. Compl. ¶ 22.) Kimball was unable to swallow the medication. Batoh testified

that Kimball told her that his symptoms had worsened on October 5, and she drove him to the emergency room again. (McNeil's L.R. 56(a)1 Stmt. ¶ 55; Pl.'s L.R. 56(a)2 Stmt. ¶ 55.) He was suffering from "a severe rash on his chest, hands, forearms, and face, increasing shortness of breath and dyspnea on exertion, generalized muscle pain, cough, sore throat, malaise and fever." (Am. Compl. ¶ 23.) Kimball was admitted to Bridgeport Hospital on October 5, 2010. (McNeil's L.R. 56(a)1 Stmt. ¶ 56; Pl.'s L.R. 56(a)2 Stmt. ¶ 56.) By October 7, 2010, Kimball was diagnosed with SJS and it was recommended that he be transferred to the hospital's burn unit. (Pl.'s Disputed Issues of Material Fact ("Pl.'s DIMF") ¶ 23, ECF No. 129 at 21.) Kimball was later diagnosed with SJS/TEN overlap. (ECF No. 131-3 at 4, Pl.'s Ex. 13, p. 00004). According to Plaintiff's medical expert, Dr. Joseph Glenmullen, when he was discharged from the hospital on October 15, 2010, Kimball had "significant wounds and scarring throughout his body, and damage to his nervous system, eyes, genitals, and feet" and suffered from "severe pain in his feet and legs, making it painful to walk." (Pl.'s DIMF ¶ 25, ECF No. 129 at 21.) Eight months later, Kimball still suffered from difficulty swallowing, constant pain, and impotence. (*Id.* ¶¶ 26-27.)

Batoh testified that, after Kimball's hospitalization in October 2010, Kimball told Batoh that he "was upset the warnings were not 'more specific' and if he would have known, he would not have taken Motrin." (McNeil's L.R. 56(a)1 Stmt. ¶ 60; Pl.'s L.R. 56(a)2 Stmt. ¶ 60.) Kimball's brother, Timothy Kimball, testified that Kimball told him that "if it would have warned him on the bottle that this could have happened to him, he never would have taken it." (Pl.'s Ex. 16, Deposition of Timothy Kimball, ECF No. 132 ("T. Kimball Depo.") at 37.)

Batoh does not know whether Kimball ever saw a Motrin advertisement, but knows that he used Motrin prior to the incident that caused his hospitalization in October 2010. (McNeil's L.R. 56(a)1 Stmt. ¶ 59; Pl.'s L.R. 56(a)2 Stmt. ¶ 59.) Kimball took ibuprofen on multiple

occasions prior to October 2010 and experienced no adverse reactions as a result of those prior uses. (McNeil's L.R. 56(a)1 Stmt. ¶ 51; Pl.'s L.R. 56(a)2 Stmt. ¶ 51.) In fact, prior to his SJS/TEN, doctors had instructed Kimball to take ibuprofen on multiple occasions. (Pl.'s Ex. 33.) In April of 2007, a doctor gave Kimball a prescription for ibuprofen. (*Id*. at 6.)

Batoh testified that Kimball was in the habit of reading the labels on medication carefully, but that she had never actually witnessed him reading a medication label:

> Q. So your guidance to your children, including Kyle, was to read the labels carefully when they were using medication and read the instructions and warnings?
> A. Absolutely.
> Q. Do you know whether that, in fact, was his habit when he used medications?
> A. Yes, to my knowledge.
> Q Did he ever talk to you about that?
> . . .
> A. Yes. I mean, he -- I think maybe once or twice.
> Q. And what would he say about that, if you remember?
> . . .
> A. I don't recall.
> Q. Did you ever actually see him with a medication bottle or medication paperwork in his hand reading the label, reading the warnings, ever witness it yourself?
> A. No.

(Pl.'s Ex. 19, Deposition of Amy Batoh, ECF No. 135-1 ("Batoh Depo.") 43:4–18.)

6. Kimball's Suicide

In early December 2011, Kimball told his brother (Timothy Kimball) and his uncle (Craig Kimball) that he planned to commit suicide "because he did not feel he could continue to tolerate the symptoms that he believed he was suffering as a result of his earlier development of SJS or TEN." (McNeil's L.R. 56(a)1 Stmt. ¶ 61; Pl.'s L.R. 56(a)2 Stmt. ¶ 61.) Kimball took his own life on December 20, 2011. (McNeil's L.R. 56(a)1 Stmt. ¶ 62; Pl.'s L.R. 56(a)2 Stmt. ¶ 62.) He left a suicide note in his apartment that listed "pros" and "cons" of life. (McNeil's L.R. 56(a)1 Stmt. ¶ 63; Pl.'s L.R. 56(a)2 Stmt. ¶ 63.)

B. Relevant Disputed Facts

Batoh disputes Defendants' statement that "[f]ederal law prohibited McNeil from selling Dexibuprofen." (McNeil L.R. 56(a)1 Stmt. ¶ 50; Pl.'s L.R. 56(a)2 Stmt. ¶ 50.) Although the FDA denied McNeil's New Drug Application ("NDA") for dexibuprofen in 1994, Plaintiff's expert, Dr. Randall Tackett, stated that "[t]he FDA considers dexibuprofen to be safe and effective." (Pl.'s L.R. 56(a)2 Stmt. ¶ 50 (*quoting* Pl.'s Ex. 4, Tackett Report at ¶¶ 197-198).)

Tackett "opined that from at least 1995 through 2005 the Motrin OTC label was false or misleading" because it failed to: provide any information about SJS and TEN; identify symptoms of SJS and TEN; identify the risk of SJS and TEN; and warn about increased risk in certain subpopulations. (Pl.'s DIMF ¶ 9, ECF No. 129 at 17-18 (*citing* Pl.'s Ex. 4, Tackett Report, ECF No. 129-4 ¶¶ 221-232).) Moreover, from 2006 through at least 2010, McNeil did not approach or inquire of the FDA about adding any terms to the label (*e.g.* blindness, tongue swelling, widespread skin pain, etc.). (Pl.'s DIMF ¶ 18, ECF No. 129 at 19 (*citing* Pl.'s Ex. 10).) Tackett also reported that "[f]rom 1988 through 2006, McNeil also failed to cite numerous reports of SJS and TEN which appeared in the scientific literature in its annual reports to the FDA." (*Id*. (*citing* Pl.'s Ex. 4, Tackett Report at ¶ 137, ECF No. 129-4 at 44.).) According to Tackett, "McNeil violated FDA regulations and failed to comply with industry standards by not having a written procedure for the systematic collection, reporting, and safety signal analysis that would lead to a uniform procedure to assess safety signals by a Safety Review Committee, which was not established until 2003." (*Id*. (*citing* Pl.'s Ex. 4, Tackett Report at ¶ 157, ECF No. 129-4 at 53.).) Despite knowing that ibuprofen could result in SJS and TEN, McNeil failed to warn users, and failed to tell them that TEN carries a 30-80% mortality rate in some populations. Tackett also

states that McNeil provided stronger warnings on non-prescription ibuprofen in foreign countries by 2000, but not in the U.S. (Pl.'s Ex. 4, Tackett Report, ECF No. 129-4 ¶¶ 243-46.)

C. Procedural Background

Batoh brought her original complaint in the Pennsylvania Court of Common Pleas for Philadelphia County against McNeil-PPC, Inc., McNeil Consumer Healthcare Division of McNeil PPC, Inc., Johnson & Johnson, Janssen Pharmaceutical Research and Development, LLC, and Janssen Pharmaceuticals, Inc. (ECF No. 1-1 at 4-5.) On October 25, 2013, these defendants, alleging diversity jurisdiction, removed the action to the Federal District Court for the Eastern District of Pennsylvania. (Notice of Removal, ECF No. 1 at 4-5.) On April 11, 2014, the parties filed a stipulation of dismissal of McNeil Consumer Healthcare Division of McNeil-PPC, Inc., Janssen Pharmaceuticals, Inc., and Janssen Research and Development, LLC, without prejudice. (ECF Nos. 22 and 23.) The district court *sua sponte* transferred the case to the District of Connecticut on October 2, 2014. (ECF Nos. 52 and 53.) Batoh filed her amended complaint on November 14, 2014. (ECF No. 90.)

In Count One of the operative complaint, Batoh alleges that the remaining defendants, McNeil and J&J,[6] are liable under the Connecticut Product Liability Act ("CPLA"), Conn. Gen. Stat. § 52–572m, *et seq.*, based on the following theories: (a) failure to warn, (b) defective design, (c) negligence, (d) negligent design, (e) negligence *per se*, (f) fraud, misrepresentation and concealment, (g) negligent misrepresentation, (h) breach of express warranty, and (i) breach

[6] Defendants are now known as Johnson & Johnson Consumer, Inc. (ECF No. 144 at 1), but I will continue to refer to them separately as "McNeil" and "J&J" in this ruling. There has been no motion to change the name of McNeil or substitute a party.

of implied warranty.[7] In Count Two, Batoh alleges that the Defendants are liable for financial injuries under the Connecticut Unfair Trade Practices Act ("CUTPA"), Conn. Gen. Stat. § 42-110a *et seq*.[8] Batoh also alleges a separate count entitled "punitive damages" (Count Three).

In July of 2015, Batoh moved for partial summary judgment on four of Defendants' affirmative defenses (ECF No. 112), and the Defendants also moved for summary judgment on Batoh's claims. (ECF Nos. 115 and 118). The parties have also filed notices of supplemental authority and responses (ECF Nos. 144, 145, 146, and 153.) The Court heard oral argument on March 3, 2016.

II. STANDARD

Summary judgment is appropriate only when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party bears the burden of demonstrating that no genuine issue exists as to any material fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323–25 (1986). If the moving party carries its burden, "the opposing party must come forward with specific evidence demonstrating the existence of a genuine dispute of material fact." *Brown v. Eli Lilly & Co.*, 654 F.3d 347, 358 (2d Cir. 2011) (citation omitted). "A dispute regarding a material fact is genuine if the evidence is such that a reasonable jury could return a verdict for the nonmoving party."

[7] In her brief, Batoh withdrew her claims for (e) negligence *per se*, (h) breach of express warranty, and (i) breach of implied warranty. (ECF No. 140 at 1-2; ECF No. 128 at 2.) Accordingly, I grant Defendants summary judgment on those claims. (ECF No. 140 at 1-2; ECF No. 128 at 2.)

[8] As Plaintiff's counsel acknowledged at oral argument, Plaintiff abandoned this claim by not addressing it in her brief opposing summary judgment. Therefore, it is dismissed. *See Jackson v. Fed. Exp.*, 766 F.3d 189, 196 (2d Cir. 2014) ("Generally . . . a partial response [to a motion for summary judgment] reflects a decision by a party's attorney to pursue some claims . . . and to abandon others. . . . Where abandonment by a counseled party is not explicit but such an inference may be fairly drawn from the papers and circumstances viewed as a whole, district courts may conclude that abandonment was intended.").

Williams v. Utica Coll. of Syracuse Univ., 453 F.3d 112, 116 (2d Cir. 2006) (internal quotation marks and citation omitted). "The mere existence of a scintilla of evidence in support of the [non-movant's] position will be insufficient; there must be evidence on which the jury could reasonably find for the [non-moving party]." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986) (internal citations and quotation marks omitted). "[T]he court must assess the record in the light most favorable to the non-movant and . . . draw all reasonable inferences in [the non-movant's] favor." *Weinstock v. Columbia Univ.*, 224 F.3d 33, 41 (2d Cir. 2000) (internal quotations and citations omitted).

III. DISCUSSION

A. McNeil's Motion for Summary Judgment

The United States District Court for the Eastern District of Pennsylvania decided that Connecticut law applies to the substantive claims in this action. (ECF No. 52 at 2.) Neither party has contested that ruling in the summary judgment briefs. Therefore, I apply Connecticut law as well.

1. Failure-to-Warn: Causation

Under the CPLA, Batoh must prove (1) that Motrin "was defective in that adequate warnings or instructions were not provided" and (2) "that if adequate warnings or instructions had been provided, [Kimball] would not have suffered the harm." Conn. Gen. Stat. § 52-572q(a), (c). Batoh alleges that Motrin product labels were inadequate because, among other things, they did not: (1) contain a warning for potentially fatal SCAR events; (2) identify other potential SCAR event hazards that might occur from exposure to the drug, including massive skin loss, blindness, disfigurement, and permanent disability; (3) disclose the frequency of all clinically significant adverse reactions and the approximate mortality and morbidity rates for patients

experiencing SCAR events; (4) disclose that the risk of SCAR events was significantly higher in the first weeks of the products' use; (5) reveal that certain patient populations may be at higher risk for SCAR adverse events; and (6) instruct individuals to stop ingesting Motrin immediately and seek medical attention if any skin rash, blistering, or mucosal lesions developed as well as fever or malaise symptoms. (Am. Compl. ¶¶ 134-39.) With respect to the second element, causation, Batoh alleges that had these warnings and instructions been on the label in 2010, Kimball would not have ingested the product.

Defendants argue that even if the Motrin warning was defective, Batoh cannot prove—as a matter of law—that the defective warning caused Kimball's injuries. (ECF No. 116 at 16.) "Generally, questions regarding the existence of a causal link are reserved for the trier of fact. [H]owever, the issue becomes one of law 'when the mind of a fair and reasonable [person] could reach only one conclusion. . . .'" *Haesche v. Kissner*, 229 Conn. 213, 218, 640 A.2d 89, 92 (1994) (citations and internal quotation marks omitted). Specifically, Defendants argue that no admissible evidence shows that Kimball would not have taken Motrin if the warnings on the label had been different. (ECF No. 116 at 17.)

Batoh submits the following as evidence of causation: (1) testimony from Kimball's family that he was a cautious person who was careful with medications and had a habit of checking their warnings; (2) Kimball's statements to his mother and brother that he would not have taken Motrin if it had borne a different warning; and (3) Defendants' failure to warn Kimball's physicians of Motrin's risks. (ECF No. 128 at 13-22.) Defendants argue that the first two pieces of evidence are not admissible, and that McNeil had no duty to warn physicians. Batoh bears the burden of establishing the admissibility of evidence on which she seeks to rely in opposing summary judgment. Fed. R. Civ. P. 56(c)(2) ("A party may object that the material

cited to support or dispute a fact cannot be presented in a form that would be admissible in evidence."); Advisory Cmte. Note to 2010 Amendment to Fed. R. Civ. P. 56(c) (following objection under Rule 56(c)(2), "[t]he burden is on the proponent to show that the material is admissible as presented or to explain the admissible form that is anticipated.").

a. Evidence of Kimball's Cautious Nature

The testimony from Kimball's family about his personality and habits requires an examination of two evidentiary categories: character evidence and habit evidence. The Federal Rules of Evidence distinguish between these two types of evidence. While "[e]vidence of a person's character or character trait is not admissible to prove that on a particular occasion the person acted in accordance with the character or trait," Fed. R. Evid. 404, "[e]vidence of a person's habit . . . may be admitted to prove that on a particular occasion the person . . . acted in accordance with the habit or routine practice." Fed. R. Evid. 406.

> Difficulty arises in drawing the line between inadmissible character evidence and admissible habit evidence. For this reason, courts have been cautious in allowing evidence that attempts to prove a pattern of conduct as habit, because of the risk that such evidence will be used to establish a party's propensity to act in conformity with his general character, which is specifically prohibited by Fed. R. Evid 404.

Loussier v. Universal Music Grp., Inc., No. 02CV2447KMW, 2005 WL 5644420, at *2 (S.D.N.Y. Aug. 30, 2005) (citations and footnotes omitted). Habit evidence is more specific than character evidence. *Id*. Consequently, for evidence to be admissible to demonstrate habit, the offering party must establish "the degree of specificity and frequency of uniform response that ensures more than a mere tendency to act in a given manner, but rather, conduct that is semi-automatic in nature." *Zubulake v. UBS Warburg LLC.*, 382 F. Supp. 2d 536, 542 (S.D.N.Y. 2005) (internal quotation marks and citations omitted). "It is only when the examples offered to establish such a pattern of conduct or habit are sufficiently numerous to permit the inference of

systematic conduct, that such examples are admissible." *Loussier*, 2005 WL 5644420, at *2 (citations omitted). The only evidence Batoh provides in support of Kimball's habit of checking warning labels is from her deposition testimony:[9]

> Q. So your guidance to your children, including Kyle, was to read the labels carefully when they were using medication and read the instructions and warnings?
> A. Absolutely.
> Q. Do you know whether that, in fact, was his habit when he used medications?
> A. Yes, to my knowledge.
> Q Did he ever talk to you about that?
> . . .
> A. Yes. I mean, he -- I think maybe once or twice.
> Q. And what would he say about that, if you remember?
> . . .
> A. I don't recall.
> Q. Did you ever actually see him with a medication bottle or medication paperwork in his hand reading the label, reading the warnings, ever witness it yourself?
> A. No.

(Batoh Depo. at 43:4–18.) Batoh offers no examples of which she has personal knowledge of Kimball's reading the label or warnings for a medication to establish a pattern of conduct. Thus, Plaintiff's evidence is insufficient to show admissible habit evidence. *See U.S. Football League v. Nat'l Football League*, 842 F.2d 1335, 1373 (2d Cir. 1988) (district court "correctly found that this testimony was not admissible 'habit' evidence under Fed. R. Evid. 406, because testimony as to 'three or four episodes over a 20–year period' was hardly sufficient to 'conclude that a pattern of behavior exists with respect to the conduct at issue here.'") (citation omitted).

[9] Plaintiff cites Kimball's brother's testimony that Kimball "didn't trust medications. . . . even before he got sick." (T. Kimball Depo. at 59.) Batoh states in an affidavit that, "[b]ased upon my knowledge of my son Kyle's personality, cautious temperament, upbringing with regard to drug warnings, and his actions both before and after his diagnosis [of SJS/TEN] it is my opinion that Kyle Kimball would not have taken Motrin had he been sufficiently warned of the risks of [SJS]." (Pl.'s Ex. 37, Batoh Affidavit, ECF No. 137-6.) This is inadmissible character evidence. Although the affidavit also refers to "actions" of Kimball, it does not specify what those actions were or otherwise provide a basis to qualify them as habit evidence.

b. Kimball's Statements to his Mother and Brother

Kimball told his mother that if the warning label "had been more specific and he'd had more information than what was on [the label] . . . he would not have taken it." (Batoh Depo. at 119:12–14.) He also told his brother, Timothy Kimball, that "if it would have warned him on the bottle that this could have happened to him, he never would have taken it." (T. Kimball Depo. At 37.) [10] Defendants argue that these statements are inadmissible hearsay and "cannot be relied on to defeat summary judgment." (ECF No. 116 at 17.) Batoh argues that these statements are admissible under the "residual exception" to the hearsay rule, which states that a hearsay statement is not excluded if: (1) "the statement has equivalent circumstantial guarantees of trustworthiness"; (2) "it is offered as evidence of a material fact"; (3) "it is more probative on the point for which it is offered than any other evidence that the proponent can obtain through reasonable efforts"; (4) "admitting it will best serve the purposes of these rules and the interests of justice"; and (5) the opposing party has reasonable notice. Fed. R. Evid. 807(a) and (b); *see also Parsons v. Honeywell, Inc.*, 929 F.2d 901, 907 (2d Cir.1991). "These five indicia of reliability are to be examined to see whether the four classes of risk peculiar to hearsay evidence, which are insincerity, faulty perception, faulty memory and faulty narration, are minimized. Hearsay statements, however, 'need not be free from all four categories of risk to be admitted under Rule 807.'" *Steinberg v. Obstetrics-Gynecological & Infertility Grp., P.C.*, 260 F. Supp. 2d 492, 495 (D. Conn. 2003) (*citing Schering Corp. v. Pfizer Inc.*, 189 F.3d 218, 232-233 (2d Cir. 1999) (citation omitted)). The "residual hearsay exception" is to "be used very rarely, and

[10] Kimball also told his brother Timothy that he would not have taken Motrin "if he had known it could almost kill him." (T. Kimball Depo. at 86:19–20.) Even construed in the light most favorable to Batoh, this statement is insufficient to establish causation because it does not suggest that Kimball read the Motrin warnings at any time.

only in exceptional circumstances." *Parsons*, 929 F.2d at 907 (internal citations and quotations omitted).

Kimball's statements are offered as evidence of causation, which is a material issue in this case. Because he is dead and unable to testify, and because the Court has determined that evidence of his cautious character is inadmissible, the statements are the most probative of any other evidence concerning whether Kimball would have taken Motrin had the warning label been different. "The most important requirement of Rule 807 is that the hearsay evidence have 'circumstantial guarantees of trustworthiness'" that are "equivalent" to those reflected in the other hearsay exceptions. *Brown ex rel. Estate of Brown v. Philip Morris Inc.*, 228 F. Supp. 2d 506, 512 (D.N.J. 2002); Advisory Cmte. Note to Paragraph (24), Fed. R. Evid. 803 ("The committee believes that there are certain exceptional circumstances where evidence which is found by a court to have guarantees of trustworthiness equivalent to or exceeding the guarantees reflected by the presently listed exceptions, and to have a high degree of pro[b]ativeness and necessity could properly be admissible.").[11] The proponent of the statement bears the burden of establishing that the statement is especially trustworthy. *See Jacobson v. Deutsche Bank,* A.G., 206 F. Supp. 2d 590, 595 (S.D.N.Y. 2002); *United States v. Washington*, 106 F.3d 983, 1001-02 (D.C. Cir. 1997), cert. denied, 522 U.S. 984 (1997). I find that Batoh has not satisfied that burden in this case.

There is little evidence in the record about the circumstances under which Kimball made the statements to his mother and brother. In her deposition, Batoh testified that the conversation occurred "within several months after he got out of the hospital," and that the only thing that was said in the conversation was Kimball's statement that "if [the label] had been more specific and

[11] In 1997, the contents of Rule 803(24) and its analogue in Rule 804(b)(5) were combined and transferred to a new Rule 807.

he'd had more information than what was on there, that he would not have taken [the Motrin]." (Batoh Depo. at 119:12–17.) As for the statement reported by Kimball's brother, there is no evidence of the circumstances other than that it occurred sometime after Kimball developed SJS/TEN. (T. Kimball Depo. at 36-38.) There is no evidence about Kimball's mood or demeanor when he made these statements, the time of day the conversations took place, the location at which the conversations occurred, the presence of any other witnesses, or any circumstances that might have prompted him to discuss the Motrin label. Further, what little evidence there is in the record about other subjects Kimball was discussing around the same time, if anything, weighs against a finding of trustworthiness: Batoh testified that "a couple months after his October 2010 hospitalization," Kimball brought up the possibility of bringing a lawsuit based on his condition and told her that "he had called a lawyer." (Batoh Depo. at 116-17.) This is at least a suggestion that the statement was made in the context of conversations about possible litigation – a suggestion of untrustworthiness. *See Greco v. Nat'l R.R. Passenger Corp.*, 2005 WL 1320147 *6 (declining to admit under Rule 807 written statement created by decedent "at the prompting of the attorney for his estate").

At oral argument, Plaintiff's counsel was unable to point to any other evidence in the record about the circumstances of Kimball's statement to his mother that he would not have taken the Motrin had the label been more specific. Plaintiff's counsel did point to places in the record indicating that Kimball spoke with Batoh about his health. But there is no evidence that his statements about reading the Motrin label, which themselves do not describe his condition or solicit health-related advice, were part of those conversations. Further, most of the conversations about Kimball's health that Batoh described in her deposition occurred after Kimball's hospitalization and concerned his ongoing health problems from SJS/TEN. (Batoh Depo. at 103,

106-7.) Those conversations are insufficient to demonstrate a longstanding pattern of dialogue between Kimball and his mother regarding his health, and, even if they did show such a pattern, they would not amount to circumstantial guarantees of trustworthiness for a statement made on a separate occasion about reading a medication label.[12]

Plaintiff also argues that Kimball's statements "were made soon after he took Motrin and suffered from SJS/TEN" and analogizes the statements to state-of-mind evidence admissible under Fed. R. Evid. 803(3). (Pl.'s Opp. Br. at 20, ECF No. 128 at 28.) As noted, however, the only evidence in the record about the timing of the statements is that the statement to Batoh was made "several months after he got out of the hospital" (Batoh Depo. at 119)—which, on its face, could mean anything from two months after he left the hospital until shortly before his death—and that possibly around the same time, *i.e.*, "a couple" or a "a few" months after he left the hospital, he spoke with a lawyer about the possibility of litigation. (*Id*. at 116-17.) This evidence, coupled with the fact that the statements concerned Kimball's belief about what he would have done in the past, places the statements well outside the state-of-mind exception: "A statement of the declarant's *then-existing* state of mind (such as motive, intent, or plan) or emotional, sensory, or physical condition (such as mental feeling, pain, or bodily health), *but not including a*

[12] If there were evidence that Batoh served as Kimball's health provider or advisor, it might, by analogy to Rule 803(4), render admissible statements made for purposes of diagnosis or treatment. But a freestanding statement about what Kimball would have done in the past had a drug label been more explicit cannot be characterized as one made for diagnosis or treatment. Nor can it be characterized as a statement that describes past or present symptoms or their cause. *See* Fed. R. Evid. 803(4); Advisory Cmte. Note to Paragraph (4) (describing "the patient's strong motivation to be truthful" as a rationale for admitting statement of patient's present condition to physician, and noting that "[t]he same guarantee of trustworthiness . . . . extends to statements as to causation, *reasonably pertinent to the [purposes of diagnosis and treatment]"* but that "[s]tatements as to fault would not ordinarily qualify . . . ." (emphasis added)).There is nothing in the record suggesting that Kimball's statements about the label to his mother and brother were for a reason "reasonably pertinent to" diagnosis or treatment.

statement of memory or belief to prove the fact remembered or believed unless it relates to the validity or terms of the declarant's will." Fed. R. Civ. P. 803(3) (emphasis added).

Batoh argues further that the statements are trustworthy because Kimball died before this litigation began and therefore "had no reason to lie about reading the Motrin label, or in stating that an adequate warning would have altered his behavior." (ECF No. 128 at 19.) First, having "no reason to lie" does "not amount to a circumstantial guarantee of trustworthiness." *United States v. Ashburn*, No. 11-CR-303 NGG, 2015 WL 5098607, at *45 (E.D.N.Y. Aug. 31, 2015) (citation omitted); *United States v. Wilson*, 281 F. App'x 96, 99 (3d Cir. 2008) ("Before the District Court, Wilson's primary argument in favor of admission of the private investigator's testimony was that Renee Russell had 'no reason to lie,' and he now argues that a person 'speaking to a stranger about a matter in which they have no involvement or interest, will generally make truthful statements.' This is not an 'exceptional guarantee of trustworthiness.'"). Second, while the evidence of timing is vague on this point, too, the suggestion that the statement to Batoh was made around the same time that Kimball was contemplating litigation is at least some evidence of a motive, if not to lie, then to shape his memories to fit the contours of a legal claim. *See Greco*, *supra.*

In short, Batoh has failed to identify any circumstances in the record that make the statements Kimball made to Batoh and Timothy Kimball especially trustworthy. And when the statements are measured against the factors that some courts have considered to determine trustworthiness under Rule 807, they do not fare well. Those factors include "whether the declarant was under oath; the voluntariness of the statement; whether the statement was based on personal knowledge; whether the statement contradicted any previous statement; whether the statement was preserved on videotape to provide the jury an opportunity to evaluate the

declarant's demeanor; the declarant's availability for cross-examination; the statement's proximity in time to the events described; whether the statement is corroborated; the declarant's motivation to fabricate; whether the statement was prepared in anticipation of litigation; the statement's spontaneity; and whether the declarant's memory or perception was faulty." *Brown ex rel. Estate of Brown*, 228 F. Supp. 2d at 512 (citation omitted). In this case, when the scant evidence about the statements is viewed in the light most favorable to Batoh, it would permit a finding that the statements were voluntary, based on personal knowledge, and not contradictory. But virtually none of the other factors cited would support their admission. The statements were not under oath or video-taped; they were made either "several months" or at some other unspecified time after the events described; they are not corroborated; there was at least a motivation to shape the statements, if not to fabricate; there was no opportunity to cross-examine; and there is some suggestion that the statements were made in anticipation of litigation.

Batoh's final argument is that excluding these types of statements will effectively insulate drug manufacturers from failure-to-warn liability in cases in which OTC drugs cause death, because the decedent will generally be the only one able to testify whether or not he would have heeded a more explicit warning. (ECF No. 128 at 29.) If this is so, however, it is a consequence inherent in the operation of the residual hearsay rule, which will often lead to the exclusion of critical evidence.[13] The rule applies only when the hearsay evidence is both material and "more probative on the point … than any other evidence that the proponent can obtain through reasonable efforts." Fed. R. Evid. 807. The rule also requires an independent finding that the

[13] There are steps that can be taken to avoid this outcome—such as noticing and taking the deposition of a plaintiff or potential plaintiff where there is a risk that he or she will perish before trial. I point this out only to show that application of Rule 807 need not always have the effect of foreclosing a successful lawsuit in death cases; I am not suggesting that this option occurred or should have occurred to Kimball or his family, especially under the tragic circumstances of this case.

statement has equivalent circumstantial guarantees of trustworthiness. *Id*. Thus, evidence that satisfies the materiality and probativeness requirements but not the independent requirement of trustworthiness will be excluded, meaning that frequently the rule will bar essential proof and lead to the entry of judgment against the proponent of the evidence. It is thus no surprise that other courts that have found a decedent's statement inadmissible under the residual exception in wrongful death cases have granted summary judgment for the defendant. *See, e.g., Brown ex rel. Estate of Brown*, 228 F. Supp. 2d at 513 (granting summary judgment to defendant cigarette manufacturer because, among other things, videotaped statement by decedent in his attorney's office—made years after the relevant events and in anticipation of litigation—lacked circumstantial guarantees of trustworthiness and was inadmissible); *Land v. Am. Mut. Ins. Co.*, 582 F. Supp. 1484, 1487 (E.D. Mich. 1984) (granting summary judgment to the defendant because, although decedent's unsworn written statement was made shortly after accident, both parties who were present during the statement had interests adverse to the defendant, and the statement itself was self-serving).

Preservation of the opportunity to cross-examine is a key purpose of the hearsay rule. The "purposes of [the Federal Rules of Evidence] and the interests of justice" Fed. R. 807(a)(4), require the court to consider not only the prospect that one party will lose a case because it could not introduce a piece of evidence but also the prospect that another party will lose a case because it could not cross-examine a piece of evidence. Because Batoh has failed to demonstrate that the proffered statements fall within any exception to the hearsay rule, the statements are inadmissible and do not provide competent proof of causation.

c. Failure to Warn Physicians

Kimball was instructed to take—or was prescribed—ibuprofen by physicians on several occasions before taking the Motrin that caused his SJS/TEN in 2010. (ECF No. 128 at 22 (*citing* Pl.'s Ex. 33, ECF 137-2).) Batoh argues "that Defendants' failure to warn physicians about the full extent of the risks of . . . Motrin kept [him] from being informed about those risks prior to his 2010 injuries." (ECF No. 128 at 22.) Batoh seems to argue that if McNeil had properly warned Kimball's physicians of the risks of SJS/TEN, then Kimball would have been aware of such risks before 2010, and would not have ingested Motrin at that time. Neither the evidence in the record nor the law supports this argument. First, while a doctor did prescribe ibuprofen to Kimball 2007 (Pl.'s Ex. 33 at 6), McNeil did not manufacture or sell that ibuprofen. Kimball's physician prescribed generic prescription ibuprofen, which the parties agreed at oral argument was not a McNeil product. McNeil owed no duty under the CPLA to warn Kimball's physician about a product that it did not make or sell. Second, manufacturers of non-prescription drugs—the product that allegedly caused the injuries that are the subject of this lawsuit—have no duty to warn physicians about the risks associated with those drugs. *See, e.g, Brown v. Johnson & Johnson*, 64 F. Supp. 3d 717, 721 (E.D. Pa. 2014); *Hurley v. Heart Physicians, P.C.*, 278 Conn. 305, 316, 898 A.2d 777, 783 (2006) ("a manufacturer's duty to warn of dangers associated with its products . . . runs to the ultimate user or consumer of those products."). Even if McNeil had manufactured the prescription product taken by Kimball in 2007, that would not have created a duty to warn Kimball's physicians about the nonprescription Motrin he took in 2010. Thus, Batoh has failed to raise a genuine dispute of material fact about whether McNeil's failure to warn Kimball's physicians about the dangers of ibuprofen caused his injuries.

* * *

Because there is no admissible evidence showing that Kimball would not have taken Motrin if the warnings on the label had been different, Batoh cannot prove that a defective warning caused Kimball's injuries, an essential element of her failure-to-warn claim under the CPLA. Therefore, I grant Defendants' motion for summary judgment on Batoh's failure-to-warn claim and design defect claim based on inadequate warnings.[14]

2. Negligence and Negligent Design

Batoh alleges that Defendants are liable under the CPLA for the negligent designing, testing, manufacturing, labeling, advertising, marketing, packaging, promoting, selling, and distributing of Motrin. (Am. Compl. ¶ 161.) Batoh submits no evidence of a manufacturing defect in the Motrin that Kimball ingested. Besides Motrin's label, Batoh also submits no evidence that Kimball was exposed to any advertising, marketing, or promotions for Motrin. In fact, the parties agree that Batoh does not know whether Kimball ever saw a Motrin advertisement. (McNeil's L.R. 56(a)1 Stmt. ¶ 59; Pl.'s L.R. 56(a)2 Stmt. ¶ 59.) Batoh also submits no evidence in support of her negligent selling and distributing claims. Finally, Batoh fails to put forth evidence that any failure to test Motrin caused Kimball's injuries. As Defendants point out, she "has no evidence to show that additional testing likely would have revealed something that is pertinent to this injury, and that McNeil (and the FDA) did not already know." (ECF No. 141 at 15.) Therefore, the Court grants the Defendants summary judgment on Batoh's negligent testing, manufacturing, advertising, marketing, packaging, promoting, selling, and distributing claims. Because, as discussed above, Batoh has failed to raise a genuine issue of

[14] Batoh brings a failure-to-warn claim and a design defect claim based on the Motrin label. *See Fraser v. Wyeth, Inc.*, 992 F. Supp. 2d 68, 90 (D. Conn. 2014) (allowing the plaintiff to submit to the jury both a design defect claim and a negligent failure-to-warn claim based on improper labeling). While both claims are recognized, they amount to the same claim for failure to warn in this case.

material fact as to whether Kimball read and relied on the Motrin warnings, Batoh cannot show that Defendants' negligence with respect to labeling caused his injuries. Further, as explained below, Batoh's negligent design claims based on the chemical composition of Motrin are preempted. Therefore I grant Defendants summary judgment on these claims.

3. Fraud, Misrepresentation and Concealment

Batoh alleges that Defendants are liable under the CPLA for their misrepresentations, concealment, and "fraudulent behavior regarding the safety of" Motrin. (Am. Compl. ¶ 197.) Specifically, Batoh alleges that the packaging of Motrin in October 2010 contained an incomplete list of symptoms of the "severe allergic reaction," failing to list symptoms such as conjunctivitis and malaise. (*Id*. at ¶ 202). Batoh's expert, Dr. Tackett, "opined that Defendant misrepresented the safety of Motrin by failing to disclose that Motrin can cause serious skin reactions that are fatal in ten to eighty percent of cases." (ECF No. 128 at 40.) Finally, Batoh alleges that McNeil failed to disclose severe skin reactions such as SJS and TEN on its website as risks associated with using Motrin. (ECF No. 128 at 40; Am. Compl. ¶ 203.)

The elements of fraudulent misrepresentation are: "(1) that a false representation was made as a statement of fact; (2) that it was untrue and known to be untrue by the party making it; (3) that it was made to induce the other party to act on it; and (4) that the latter did so act on it to his injury." *Updike, Kelly & Spellacy, P.C. v. Beckett*, 850 A.2d 145, 166 (Conn. 2004). Negligent misrepresentation claims require proof of the same elements, except the plaintiff must also prove that defendants made a false representation of fact that they knew or should have known was false. *Fraser v. Wyeth, Inc.*, 992 F. Supp. 2d 68, 85 (D. Conn. 2014) (internal citations and quotations omitted). Claims for negligent and fraudulent misrepresentation depend on McNeil's making or failing to make statements in the Motrin warning label. Because, as

discussed above, Batoh has failed to raise a genuine issue of material fact as to whether Kimball read and relied on the Motrin warnings, Batoh cannot show that Kimball acted on any false misrepresentations to his injury. Therefore, Batoh's claims for fraudulent and negligent misrepresentation also fail as a matter of law, and I grant Defendants summary judgment on these claims.

4. Impossibility Preemption

Defendants argue that the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* preempts Batoh's failure to warn and design defect claims. The defense of preemption emanates from the Supremacy Clause, which provides that the laws and treaties of the United States "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., Art. VI, cl. 2. Preemption may occur when: "(1) Congress expressly indicated that [the federal law] preempts state law; (2) [the federal law] is a comprehensive regulatory scheme such that it creates a reasonable inference that the state cannot supplement it; or (3) state law directly conflicts with [the federal law]." *Niagara Mohawk Power Corp. v. Chevron U.S.A., Inc.*, 596 F.3d 112, 138 (2d Cir. 2010) (internal citations and quotation marks omitted). This case involves the third species of preemption—conflict preemption. "[S]tate laws that conflict with federal law are without effect." *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2472-73 (2013) (internal citations and quotation marks omitted). Conflict preemption occurs when "compliance with both state and federal law is impossible, or when the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Niagara Mohawk Power Corp.*, 596 F.3d at 138 (internal citations and quotation marks omitted). Defendants invoke impossibility preemption in this case.

"Impossibility pre-emption is a demanding defense." *Wyeth v. Levine*, 555 U.S. 555, 573 (2009). As in any preemption case, the court "start[s] 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." *Id.* at 565 (internal quotation marks and citations omitted). The court then examines Defendants' duties under state law to determine whether compliance with both state and federal law is impossible. I find that while federal law does not preempt Batoh's failure-to-warn claim, it does preempt her design defect claim based on the chemical composition of Motrin.[15]

a. Failure to Warn[16]

As noted, Batoh alleges that the Motrin product label was inadequate because it did not contain more specific warnings about SCAR events. McNeil argues that it was impossible to change the warnings on Motrin's label without prior FDA approval, and even if it could change the warnings, the FDA would have rejected such changes. (ECF No. 116 at 18-23.) Generally, a drug "manufacturer may only change a drug label after the FDA approves a supplemental application." *Levine*, 555 U.S. at 568 (2009). Under the FDA's "changes being effected" regulation, however, McNeil could have strengthened the warnings on Motrin prior to receiving

[15] Batoh argues that Congress preserved Batoh's state-law claims by specifically exempting state product liability suits from preemption. (ECF No. 128 at 23-24.) But as Defendants point out, the statute at issue, which states that "*[n]othing in this section* shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State," 21 U.S.C. § 379r(e) (emphasis added), does not foreclose the possibility that conflict preemption may arise from other sources of federal law. *See Reckis v. Johnson & Johnson*, 471 Mass. 272, 284 (2015) ("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.'") (*quoting Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000)).

[16] Although I have granted summary judgment to the Defendants on the failure-to-warn claim, I address this issue in the event that the Court of Appeals, should there be an appeal, reaches a different conclusion on the causation issue.

FDA approval for the changes without violating federal law. "Among other things, this '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' . . . it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval." *Levine*, 555 U.S. at 568 (*quoting* 21 C.F.R. §§ 314.70(c)(6)(iii)(A)).

Defendants argue that the CBE regulation was amended in 2008 "to clarify that changes to warnings without prior FDA approval applied *only* on prescription drugs." (ECF No. 116 at 20.) But nowhere does the CBE regulation suggest that it applies only to prescription drugs. To the contrary, the regulation addresses changes to "approved [drug] applications," which are applicable to OTC drugs as well as prescription drugs.[17] The provision of the CBE regulation governing the strengthening of warnings makes no reference to prescription drugs either. It states that manufacturers may "add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c) of this chapter." 21 C.F.R. § 314.70(c)(6)(iii)(A). Defendants apparently argue that the FDA's 2008 addition of a reference in the just-quoted language to the standard for causation evidence set forth in another regulation, § 201.57(c), was intended to import into the CBE regulation the restricted scope of that other regulation, which applies only to prescription drugs. *See* 21 C.F.R. § 201.57 ("[t]he requirements in this section apply only to prescription drug products . . . .").

[17] The CBE regulation, 21 C.F.R. § 314.70(c)(6)(iii)(A), is in the same subpart ("Applications") as 21 C.F.R. § 314.50(a), which states that "the applicant shall submit a completed and signed application form that contains . . . [a] statement whether the applicant proposes to market the drug product as a prescription or an over-the-counter product."

Defendants' argument, for which they cite no cases or regulatory history, runs counter to the principles courts use to interpret regulations, which mirror those they use to interpret statutes. *See, e.g., Bonkowski v. Oberg Indus., Inc.*, 787 F.3d 190, 199 (3d Cir. 2015) ("In interpreting a federal regulation, we look to well-established principles of statutory interpretation"); *Bergmann v. C.I.R.*, 552 F. App'x 673, 674 (9th Cir. 2014) ("the principles of statutory interpretation apply equally to regulatory interpretation") (*citing Boeing Co. v. United States*, 258 F.3d 958, 967 (9th Cir.2001), *aff'd*, 537 U.S. 437 (2003)). It is common for drafters of statutes and regulations to use cross references to standards and definitions in other statutes and regulations as a shorthand for incorporating specific, previously adopted rules. Such borrowing of bits and pieces of other laws does not, by itself, connote an intent to incorporate all of the other rules set forth in those laws. *See Keller v. C.I.R.*, 568 F.3d 710, 725 (9th Cir. 2009) ("Ertz Taxpayers point to no authority for interpreting the applicable version of § 6621 to include a good faith exception. To read the statute this way would require us to hold that a statutory provision that explicitly cross-references one part of another provision also implicitly incorporates another part of that other provision. We decline to do this."). Further, the presence of an *express* limitation to prescription drugs in § 201.57(c), and the absence of any such limitation in the CBE regulation, is an indication that the FDA deliberately chose not to limit the CBE regulation to prescription drugs. Finally, at least two other district court cases involving OTC drugs ingested after 2008 have found (without analyzing this issue) that the CBE regulation allows manufacturers to change warning labels on OTC drugs prior to FDA approval. *See Hunt v. McNeil Consumer Healthcare*, 6 F. Supp. 3d 694, 698-702 (E.D. La. 2014) (plaintiff ingested Children's Motrin in 2010); *Newman v. McNeil Consumer Healthcare*, No. 10-CV-01541, 2012 WL 39793, at *5-12 (N.D. Ill. Jan. 9, 2012) (plaintiffs ingested Children's Motrin in 2009).

Defendants also argue that "[s]ubsection (c)(6)(iii) has always allowed preapproval changes in warnings *only* to 'reflect newly acquired information,' and the reported risk of SJS or TEN associated with ibuprofen, as well as the potential consequences of SJS and TEN, were not 'new information' at the relevant time here." (ECF No. 116 at 21 (*citing* § 314.70(c)(6)(iii)).) As other courts have recognized in rejecting this argument, however, "'newly acquired information' is not limited to new data, but also encompasses 'new analyses of previously submitted data.'" *Levine*, 555 U.S. at 569 (*citing* 73 FR 49603-01 at 49604). In its 2006 response to the Citizens' Petition, the FDA reviewed the AER database, and found that there were forty-nine reports of SJS/TEN related to ibuprofen between 1975 and March 2005, thirteen of which were related to non-prescription ibuprofen. (Def.'s Ex. 4, ECF No. 114-4.) Analyses of additional AERs from March 2005 until 2010, especially if the incidence of SJS and TEN increased or decreased substantially, "might change the FDA's analysis." *See Newman*, 2012 WL 39793, at *10 ("there were eighty-seven such AERs from 2005 through 2009"); *Hunt*, 6 F. Supp. 3d at 701.

Defendants next argue that even if they could have changed the warnings, the FDA would have rejected such changes. Here, however, their impossibility defense faces a high hurdle: "absent clear evidence that the FDA would not have approved a change to [the drug's] label, [a court] will not conclude that it was impossible for [the drug manufacturer] to comply with both federal and state requirements." *Levine*, 555 U.S. at 571. Defendants have failed to provide such "clear evidence." First, Defendants point to the language in the FDA's letters of June and July 2005, which asked McNeil and all other OTC NSAID manufacturers to use the FDA's new warning language, and "instructed manufacturers that if they wanted to use different language they were *required* to submit it to the FDA for 'review and approval *prior to implementation*.'" (McNeil's L.R. 56(a)1 Stmt. ¶ 33; Pl.'s L.R. 56(a)2 Stmt. ¶ 33.) This

instruction refers to "[t]hese labeling revisions," which suggests that the requirement of prior approval applies specifically to the changes identified in those letters. The July letter stated:

> These labeling revisions should be submitted to FDA in the form of a "Supplement- Changes Being Effected" within 30 days from the date of this letter in accordance with the requirements of 21 C.F.R. § 314.70. . . . If you deviate from the attached templates you must submit a prior approval supplement for our review and approval prior to implementation.

(Letter from FDA to McNeil, dated July 18, 2005, ECF No. 117-27 at 3.) The June letter differed slightly, requiring "a prior approval supplement for our review and comment." (Letter from FDA to McNeil, dated June 20, 2005, ECF No. 117-26 at 2-3.) There is no indication in these letters that the FDA intended to require McNeil to obtain prior approval from the FDA for *future* changes to the Motrin label based on newly acquired information using the CBE regulation. Further, such a reading of the letters would amount to saying that the FDA had, without notice or comment and by means of letters from its employees, abrogated a rule set forth in its own duly promulgated regulation, *i.e.*, the CBE regulation. I am unaware of any authority that would permit the agency to rescind its own regulations in this manner.

Defendants also argue that "clear evidence" exists because in 2006, the FDA specifically rejected proposals from the Citizens' Petition that OTC ibuprofen should refer to SJS and TEN by name, or warn of "[s]erious skin reactions," "potentially life threatening diseases," and "rashes and blisters . . . in the areas of the eyes, mouth and genitalia." (McNeil's L.R. 56(a)1 Stmt. ¶ 47; Pl.'s L.R. 56(a)2 Stmt. ¶ 47.) This argument fails for the same reasons it failed in *Hunt*. First, in its 2006 response to the Citizens' Petition, the FDA did not reject the specific warnings that Batoh alleges were required. *See Hunt*, 6 F. Supp. 3d at 700 (citing cases). Batoh's Amended Complaint goes beyond the requests of the Citizens' Petition, alleging, among other things, that the warning label should have identified other potential SCAR event hazards that

might occur from exposure to the drug, including massive skin loss, blindness, disfigurement, and permanent disability. (Am. Compl. ¶¶ 134-39.) Second, "the FDA's response in 2006 to the Citizen's Petition is not clear evidence the agency would have rejected *in 2010* the stronger warnings Plaintiff proposes." *Hunt*, 6 F. Supp. 3d at 701. Several years later, after obtaining more information about incidents of SJS and TEN, the FDA might have decided to implement stronger warnings like those suggested in the Citizens' Petition—or at least the Defendants have not produced "clear evidence" to the contrary. Moreover, the FDA's rejection of the suggestions in a Citizens' Petition does not provide clear evidence that it would reject similar warnings proposed by a *manufacturer*. *See Reckis v. Johnson & Johnson*, 471 Mass. 272, 289 (2015) ("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"); *Dorsett v. Sandoz, Inc.*, 699 F. Supp. 2d 1142, 1157 (C.D. Cal. 2010) ("the FDA's rejection of those 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"). It is the manufacturer, not the FDA, that is responsible for ensuring that its warnings are adequate and reflect the latest scientific information available to it. *Levine*, 555 U.S. at 570-71 ("Yet through many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market.").

Finally, Defendants argue that the fact that the FDA's 2013 "Allergy Alert" for OTC acetaminophen is very similar to the FDA's mandated language in 2005 is clear evidence that the

FDA would have rejected Batoh's proposed changes to the Motrin label. Much like the FDA's OTC ibuprofen label, the 2013 Allergy Alert for OTC acetaminophen included references to "skin reddening," "blisters," and "rash," along with a warning to "stop use and seek medical help right away" if such a reaction occurs. (McNeil's L.R. 56(a)1 Stmt. ¶ 48; Pl.'s L.R. 56(a)2 Stmt. ¶ 48.) The 2013 alert is not "clear evidence" for the same reasons stated in *Hunt.* "Acetaminophen is not ibuprofen. Defendants offer no evidence as to chemical similarity between the two drugs, the comparative safety profile of acetaminophen, the nature, number, and extent of acetaminophen-related AERs, and the specific factors considered by the FDA in ordering stronger warnings." *Hunt*, 6 F. Supp. 3d at 702. In fact, Batoh presents evidence that, in 1984, McNeil claimed that the risk of fatal adverse reactions to ibuprofen was substantially greater than with acetaminophen at recommended doses. (Pl.'s DIMF ¶ 7, ECF No. 129 at 17 (*citing* Pl.'s Ex. 8, ECF No. 130-3 at 1).)

Because Defendants have failed to provide "clear evidence" that the FDA would not have approved a change to the Motrin label, I "will not conclude that it was impossible for [McNeil] to comply with both federal and state requirements." *Levine*, 555 U.S. at 571. Thus, Batoh's failure-to-warn claim is not preempted by federal law.

b. Defective Design[18]

Batoh alleges that McNeil is liable for the innocent, negligent, or willful failure adequately to design Motrin (Am. Compl. ¶ 146), and that Motrin is "unreasonably dangerous for normal use due to its defective design . . . ." (*Id*. ¶ 150.) Defendants argue that federal law preempts Batoh's design defect claims because "risk is alleged to be inherent in the use of

[18] Batoh has two design defect claims: one based on Defendants' failure to provide adequate warnings and another based on the chemical composition of Motrin. Because the Court has already addressed the failure-to-warn claim, in order to avoid confusion, I refer to the "defective design" claim in this section as the claim based on altering the chemical composition of Motrin.

ibuprofen," and "McNeil could not render the design non-defective . . . by any means other than removing ibuprofen," the sole active ingredient. (ECF No. 116 at 25-26.) Therefore, "McNeil would have to remove the product from the market or replace ibuprofen with a different active ingredient," but federal law prohibits McNeil from substituting a different ingredient prior to FDA approval. (*Id*.) I agree that Batoh's design defect claim based on altering the chemical composition of Motrin is preempted.

In *Bartlett*, the Supreme Court held 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." *Bartlett*, 133 S. Ct. at 2479. Batoh argues that federal law cannot preempt her state law design defect claim because "*Bartlett* turned on a law only applicable to generic drug manufacturers, not to branded OTC manufacturers."[19] (ECF No. 128 at 32.)

In applying impossibility preemption, the court first determines the manufacturer's duties under Connecticut law. Connecticut applies the "consumer expectations" test to design defect claims. In order to prevail on a strict liability claim, the plaintiff must prove that the product is "unreasonably dangerous." The definition of "unreasonably dangerous" derives from comment

[19] Batoh also argues that "Congress has expressed its intention **not** to preempt state law claims with regard to OTC drugs." (ECF No. 128 at 30 (emphasis in original).) I have already rejected this argument because the saving clause on which Batoh relies, 21 U.S.C. § 379r(e), does not affect conflict preemption arising from other sources of federal law. *See, supra* n.15. Although Batoh cites several cases in which courts have concluded that *Bartlett* applies only to manufacturers of generic prescription drugs, *see, e.g., Brown v. Johnson & Johnson*, 64 F. Supp. 3d at 721; *Hunt*, 6 F. Supp. 3d at 704; I do not agree that *Bartlett* is so limited. The *Hunt* court reached this conclusion in large part on the basis of the "non-preemption clause" in the "statute governing non-prescription drugs," *i.e.*, 21 U.S.C. § 379r(e). As shown above, however, that provision only limits the scope of the express preemption clause in § 379r(a). It does not purport to limit the preemptive effect of other sources of federal law, including FDA regulations, that conflict with state law requirements.

(i) to the Restatement (Second) of Torts § 402A, which provides that "the article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." *Potter v. Chicago Pneumatic Tool Co.*, 241 Conn. 199, 214-15 (1997) (*quoting* 2 Restatement (Second), Torts § 402A (1965), cmt (i)). For cases "involving complex product designs in which an ordinary consumer may not be able to form expectations of safety" *Potter*, 241 Conn. at 219, a jury[20] may consider "risk-utility factors," under a "modified consumer expectations test." These factors include:

> the usefulness of the product, the likelihood and severity of the danger posed by the design, the feasibility of an alternative design, the financial cost of an improved design, the ability to reduce the product's danger without impairing its usefulness or making it too expensive, and the feasibility of spreading the loss by increasing the product's price.

Id. at 221 (citations omitted). Connecticut has recognized that, "certain products, by their very nature, cannot be made safe." *Vitanza v. Upjohn Co.*, 257 Conn. 365, 375 (2001). Defendants argue that Motrin, which contains ibuprofen, is such an "unavoidably unsafe" product. (ECF No. 141 at 13.) "A manufacturer of an unavoidably unsafe product can avoid strict liability if the product is 'properly prepared, and accompanied by proper directions and warning. . . .'" *Vitanza*, 257 Conn. at 375 (*quoting* 2 Restatement (Second), *supra*, § 402A, cmt. (k)). "Brand-name drug manufacturers can thus avoid liability . . . by choosing a safer design for the drug" or "by strengthening the drug's warning label." *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 297 (6th Cir. 2015) (internal citations and quotations omitted).

[20] The issue of whether a product is unreasonably dangerous is for the jury. *Potter*, 241 Conn.at 225 ("[w]hether a product is unreasonably dangerous is a question of fact to be determined by the jury. . . .") (citation and internal quotation marks omitted).

As discussed above, federal law does not preempt Batoh's claim that McNeil could have strengthened Motrin's warning label. But it does preempt her claim that Defendants could have altered the chemical composition of Motrin. Batoh does not argue that Defendants should have used dexibuprofen rather than ibuprofen *before* Motrin received FDA approval. Instead, Batoh alleges that Defendants "never switched to an alternatively designed drug called dexibuprofen, despite indications that it would have been safer" than ibuprofen. (ECF No. 128 at 1.) Batoh disputes Defendants' statement that "[f]ederal law prohibited McNeil from selling dexibuprofen." (McNeil L.R. 56(a)1 Stmt. ¶ 50; Pl.'s L.R. 56(a)2 Stmt. ¶ 50). Although the FDA denied McNeil's New Drug Application ("NDA") for dexibuprofen in 1994, Batoh's expert, Dr. Randall Tackett states that "[t]he FDA considers dexibuprofen to be safe and effective." (Pl.'s L.R. 56(a)2 Stmt. ¶ 50 (*quoting* Pl.'s Ex. 4, Tackett Report at ¶¶ 197-198).) But Batoh has submitted no evidence that the FDA has ever approved dexibuprofen for consumer use.

Motrin is subject to the NDA process. "Once a drug—whether 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'" without prior approval by the FDA. *Bartlett*, 133 S. Ct. at 2471 (*quoting* 21 C.F.R. § 314.70(b)(2)(i)). Thus, changing the active ingredient from ibuprofen to dexibuprofen qualifies as a "major change" requiring prior approval from the FDA. If Defendants had unilaterally changed the active ingredient of Motrin from ibuprofen to dexibuprofen to satisfy their state law duty, they would have violated federal law. "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2579 (2011). "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and

assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id*. at 2581.

Because it would have been impossible for Defendants to comply both with any state law duty to substitute dexibuprofen for ibuprofen and with federal requirements, federal law preempts Batoh's claim that Defendants should have altered the chemical composition of Motrin.

B. Johnson & Johnson's Motion for Summary Judgment

J&J is entitled to summary judgment for the same reasons McNeil is, but it moves separately for summary judgment because it is the corporate parent of McNeil, and unlike McNeil, it did not make or sell Motrin. (ECF No. 118 at 4.) It is entitled to summary judgment on this ground as well.

"[I]t is a fundamental principle of corporate law that the parent corporation and its subsidiary are treated as separate and distinct legal persons even though the parent owns all the shares in the subsidiary and the two enterprises have identical directors and officers. Such control, after all, is no more than a normal consequence of controlling share ownership." *SFA Folio Collections, Inc. v. Bannon*, 217 Conn. 220, 232, *cert. denied*, 501 U.S. 1223 (1991) (internal quotation marks and citations omitted). "Ordinarily the corporate veil is pierced only under exceptional circumstances, for example, where the corporation is a mere shell, serving no legitimate purpose, and used primarily as an intermediary to perpetuate fraud or promote injustice." *Naples v. Keystone Bldg. & Dev. Corp.*, 295 Conn. 214, 233 (2010) (internal citations and quotation marks omitted). In analyzing corporate veil-piercing issues, Connecticut applies "either the instrumentality rule or the identity rule." *Id*. at 232.

> The instrumentality rule requires, in any case but an express agency, proof of three elements: (1) Control, not mere majority or complete stock control, but complete domination, not only of finances but of policy and business practice in respect to the transaction attacked so that the corporate entity as to this transaction

> had at the time no separate mind, will or existence of its own; (2) that such control must have been used by the defendant to commit fraud or wrong, to perpetrate the violation of a statutory or other positive legal duty, or a dishonest or unjust act in contravention of [the] plaintiff's legal rights; and (3) that the aforesaid control and breach of duty must proximately cause the injury or unjust loss complained of. . . .
>
> The identity rule has been stated as follows: If [the] plaintiff can show that there was such a unity of interest and ownership that the independence of the corporations had in effect ceased or had never begun, an adherence to the fiction of separate identity would serve only to defeat justice and equity by permitting the economic entity to escape liability arising out of an operation conducted by one corporation for the benefit of the whole enterprise.
>
> Courts, in assessing whether an entity is dominated or controlled, have looked for the presence of a number of factors. Those include: (1) the absence of corporate formalities; (2) inadequate capitalization; (3) whether funds are put in and taken out of the corporation for personal rather than corporate purposes; (4) overlapping ownership, officers, directors, personnel; (5) common office space, address, phones; (6) the amount of business discretion by the allegedly dominated corporation; (7) whether the corporations dealt with each other at arm's length; (8) whether the corporations are treated as independent profit centers; (9) payment or guarantee of debts of the dominated corporation; and (10) whether the corporation in question had property that was used by other of the corporations as if it were its own.

Id. at 232-33 (citations and internal quotation marks omitted). Although "[w]hether the circumstances of a particular case justify the piercing of the corporate veil 'presents a question of fact,'" *id*. at 234 (internal citations omitted), Batoh has submitted no evidence of with respect to *any* of these factors.

Batoh alleges that J&J controls "what Motrin products were placed on and removed from store shelves . . . . and all communications to consumers related to Motrin." (ECF No. 133 at 4.) Batoh's cites two pieces of evidence in support of J&J's control: (1) a speech by Edolphus Towns, Chairman of the House Committee on Oversight and Government Reform, on September 20, 2010, in which he referred to e-mails from McNeil executives concerning the "phantom recall" of certain Motrin products in 2008-2009 and stated that J&J had "the legal and moral obligation to do the right thing and they did not"; and (2) the statement of J&J's former CEO,

William Weldon, that he "accept[s] full accountability for the problems at McNeil" related to the "phantom recall." (ECF No. 133 at 4-5.) As Defendants point out, the congressional speech has nothing to do with the events in this case, the congressperson's statements are not based on personal knowledge, and the statements themselves refer to the actions of McNeil executives—not J&J. (ECF No. 142 at 2-4.) Neither statement provides a basis for finding that J&J controls Motrin's product placement and communications to consumers. And even if J&J had such control, it is not sufficient to pierce the corporate veil and hold J&J liable in light of Batoh's failure to provide evidence that McNeil is a "mere shell." Because I find that there is no genuine dispute as to any material fact concerning piercing the corporate veil, I grant J&J's motion for summary judgment.

IV. CONCLUSION

After Defendants withdrew their defense of abstention (ECF No. 126 at 2) and Plaintiff withdrew her *negligence per se* claim, two affirmative defenses remain in Batoh's partial motion for summary judgment (ECF No. 112): federal preemption and punitive damages. (ECF No. 140 at 1-2; ECF No. 128 at 2.) Because Batoh's CPLA claims fail, the issue of punitive damages is moot, and I deny Plaintiff's motion for summary judgment on this affirmative defense. For the reasons set forth above, I find that federal law preempts Batoh's design defect claim, but not her failure-to-warn claim. Thus, I GRANT in part and DENY in part the Plaintiff's motion for summary judgment on Defendants' affirmative defense of preemption.

I GRANT Defendant McNeil's motion for summary judgment (ECF No. 115), I GRANT defendant J&J's motion for summary judgment (ECF No. 118), and I GRANT in part and DENY in part Plaintiff's motion for summary judgment (ECF No. 112). I also GRANT McNeil's

consent motions (ECF Nos. 114 and 139) and Batoh's consent motion (ECF No. 125) for leave to file excess pages. The Clerk is directed to close this case.

IT IS SO ORDERED.

/s/
Michael P. Shea, U.S.D.J.

Dated: Hartford, Connecticut
March 10, 2016