UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISON

KAREN ROBINSON, Plaintiff, v. MCNEIL CONSUMER HEALTHCARE, a Division of MCNEIL-PPC, INC., and JOHNSON & JOHNSON, Defendants.	No. 07 c 5603 Judge Holderman Magistrate Judge Cox

DEFENDANTS' RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW

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DEFENDANTS' RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW

Pursuant to Rule 50 of the Federal Rules of Civil Procedure, Defendants renew their motion for judgment as a matter of law. Plaintiff has not offered a legally sufficient evidentiary basis for her claims, *see* Fed. R. Civ. P. 50(a)(1); instead, when viewed in the light most favorable to Plaintiff, the evidence adduced by both parties "so overwhelmingly favors [Defendants] that no contrary verdict based on that evidence could ever stand." *Cincinnati Ins. Co. v. City of Taylorville*, 818 F.2d 1345, 1348 (7th Cir. 1987) (applying Illinois law).[1]

ARGUMENT

I. NO REASONABLE JURY COULD FIND AGAINST JOHNSON & JOHNSON

Johnson & Johnson is entitled to judgment because Plaintiff had produced no evidence to establish the company's liability either: (1) directly for its actions; or (2) derivatively for the actions of McNeil.

First, Plaintiff offered insufficient evidence to support a theory of direct liability against Johnson & Johnson. It is undisputed that Johnson & Johnson does not design, manufacture, sell, or distribute Children's Motrin; McNeil Consumer Healthcare does. (*See* Pl.'s Ex. Christiansen Deposition Video (replayed at Trial Tr. Vol. 3, 672:7-16, Aug. 25, 2009).) The only evidence connecting Johnson & Johnson to this case is that one of its lawyers, Robert Christiansen, provided certain legal services for McNeil. In particular, Mr. Christiansen reviewed the label to

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[1] Federal courts sitting in diversity look to state law to determine what standard governs a motion for judgment as a matter of law. *See Bilski v. Scientific Atlanta*, 964 F.2d 697, 699 n. 2 (7th Cir. 1992). Where a case poses a choice-of-law issue, the forum state's choice-of-law rules determine which state's standard applies to the motion for judgment. *Sokol Crystal Prods., Inc. v. DSC Commc'ns Corp.*, 15 F.3d 1427, 1432 n.1 (7th Cir. 1994). Illinois's choice-of-law rules, in turn, make clear that the forum state's law applies only if there is an actual conflict. *Townsend v. Sears, Roebuck & Co.*, 879 N.E.2d 893, 898 (Ill. 2007). This principle requires the application of Illinois law to Defendants' motion for judgment, because the standard for granting a motion for judgment does not differ materially between Illinois and Virginia. *Compare Pedrick v. Peoria & E. R.R. Co.*, 229 N.E.2d 504, 513-14 (Ill. 1967) (directed verdict appropriate where "no contrary verdict based on that evidence could ever stand") *with Payne v. Gloeckl*, 374 S.E.2d 32, 35 (Va. 1988) (motion to strike evidence appropriate only where "the trial court would be compelled to set aside any verdict found for the plaintiff as being without evidence to support it").

ensure that it was identical to the label previously approved by the FDA, and he reviewed the label and advertising to ensure that they were consistent with label previously approved by the FDA. (*See id.*) Mr. Christiansen did not have any knowledge about the risks of ibuprofen beyond those described in the label, and he did not have any knowledge about SJS/TEN. (*See id.*)

These record facts cannot possibly support a verdict against Johnson & Johnson on a theory of direct liability. Plaintiff failed to introduce any evidence that (1) Mr. Christiansen was aware of the pertinent risks allegedly posed by Children's Motrin beyond those described in its label or (2) otherwise performed his duties in a negligent manner in any respect. Indeed, under Virginia law, expert testimony is required to determine whether an attorney exercised reasonable care in providing legal services. *See Ripper v. Bain*, 482 S.E. 2d 832, 836 (Va. 1997) ("questions whether an attorney has exercised the required degree of care . . . are to be decided by a fact finder, after considering expert testimony."). Plaintiff not only failed to offer expert evidence concerning Mr. Christiansen's conduct, she failed to produce any evidence to support a theory of direct liability.

Second, any theory of derivative liability is equally unsupported by the record facts. Under Virginia law, a parent company is not liable for the conduct of its subsidiary unless the corporate veil can be pierced. *See Glasson v. Children's Surgical Specialty Group, Inc.*, 73 Va. Cir. 480, 481 (Va. Cir. Ct. 2007) (stating that "[o]ther than piercing the corporate veil, [the Court was] not aware of any circumstance under which the Supreme Court of Virginia has ignored the separate existence of a corporation."); *Lane v. Kingsport Armature & Elec.*, 676 F. Supp. 108, 112 (D. Va. 1988) (veil piercing theory applies to hold a parent corporation liable for the torts committed by its subsidiary).

Piercing the corporate veil is "an extraordinary exception and . . . permitted only in cases in which it is necessary in order to promote justice." *Beale v. Kappa Alpha Order*, 64 S.E.2d 789, 797-98 (Va. 1951). "Before the corporate entity may be properly disregarded and the parent corporation held liable for the acts of its subsidiary . . . it must be shown not only that undue domination and control was exercised by the parent corporation over the subsidiary, but also that this control was exercised in such a manner as to defraud and wrong the complainant, and that unjust loss or injury will be suffered by the complainant as the result of such domination unless the parent corporation be held liable." *Id.* at 797. This is a "rigorous standard requiring proof that the defendant used the corporation to 'disguise' some legal 'wrong.' *Perpetual Real Estate Servs., Inc. v. Michaelson Prop., Inc.*, 974 F.2d 545, 548 (4th Cir. 1992); *see also Lane*, 676 F. Supp. at 111 ("Virginia courts are generally protective of the corporate entity"; "in [a] diversity case construing Virginia law, the court should give due deference to the corporate entity."). That is not the case here, where McNeil is already a defendant and can satisfy any judgment. (*See* Trial Tr. Vol. 3 at 380:20-24.)

Plaintiff has offered absolutely no evidence that Johnson & Johnson: (1) exercised undue domination and control over McNeil; and (2) that this control was exercised in such a manner as to defraud and wrong Plaintiff and that unjust loss or injury will be suffered unless Johnson & Johnson is held liable for the acts of McNeil. Accordingly, the Court should enter judgment as a matter of law.

II. DEFENDANTS ARE ENTITLED TO JUDGMENT ON PLAINTIFF'S DESIGN DEFECT CLAIM

Defendants are entitled to judgment on Plaintiff's design defect theory of negligence for two reasons. ***First***, Plaintiff's theory – that ibuprofen products such as Children's Motrin are "unreasonably dangerous for over-the-counter use" (*see, e.g.*, Trial Tr. Vol. 1, 5:19-20, Aug. 19,

2009) – conflicts with the Food and Drug Administration's ("FDA") repeated approval of over-the-counter ibuprofen, and is thus preempted by federal law. ***Second***, Plaintiff has introduced insufficient evidence that Children's Motrin was defectively designed.

A. Plaintiff's Claim Is Preempted

Under the law of conflict preemption, a state-law tort claim is preempted if it, *inter alia*, hinders the "full purposes and objectives" of federal law. *See Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372-73 (2000). Plaintiff's design defect claim is preempted because her theory – that Children's Motrin and other over-the-counter products containing ibuprofen are "unreasonably dangerous" – conflicts with the FDA's decision to approve those products repeatedly as safe, effective, and appropriate for over-the-counter use. Plaintiff asks the jury to reach precisely the opposite conclusion than the FDA in assessing the risks and benefits associated with Children's Motrin and ibuprofen, and her claim thus conflicts with federal law.

Federal law regulates every aspect of the approval of new drugs, and the FDA's authority is both comprehensive and exclusive. *See generally* 21 U.S.C. § 355(a)-(d). At the outset, manufacturers cannot market new drugs without first submitting, and receiving FDA approval for, a New Drug Application ("NDA"). *Id.* § 355(a). The agency will only approve a manufacturer's application if it concludes, among other things, that the drug is safe "for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." *Id.* § 355(d); *see also* 21 C.F.R. §§ 314.105, 314.125. As Plaintiff's expert Dr. Nelson explained, the FDA's approval of an NDA indicates that the agency has deemed the product to be safe and effective. (*See* Trial Tr. Vol. 2, 167:23-168:7, Aug. 24, 2009.) The agency's post-marketing regulation of pharmaceutical approval is likewise wide-ranging; the FDA is empowered to withdraw its approval if it concludes a drug is no longer safe for use. *See* 21 U.S.C. § 355(e).

The FDA approved ibuprofen for sale in 1974 after conducting this rigorous process and concluding it was safe and effective. (*See, e.g.*, Trial Tr. Vol. 4, 713:5-15, Aug. 26, 2009 (FDA approves ibuprofen after concluding that "the drug is safe and effective for use as recommended in the submitted labeling.").) The agency approved ibuprofen for over-the-counter use in 1984, again concluding that it was safe and effective (*see id.* 730:24-731:11) – a decision that reflected the agency's judgment that it was safe enough to be sold directly to consumers, without the need for a physician's prescription (*see* Trial Tr. Vol. 2, 125:17-24). The same is true for Children's Motrin, whose over-the-counter use was approved after the FDA reviewed a new NDA that McNeil submitted. (*See* Trial Tr. Vol. 4, 773:15-24, Aug. 26, 2009.) The agency has exercised continued authority over Children's Motrin in the years since its approval; for example, it has required multiple label changes due to the FDA's over-the-counter labeling guidance and its ongoing review of risk information. (*See generally id.* 774:16-777:21 (describing FDA letters describing label changes); *id.* 913:12-22 (describing FDA's 1999 over-the-counter labeling guidance).) Ibuprofen products remains on the market and products containing it are used by millions of consumers today. (*See id.* 725:2-7; 725:25-726:6.)

Against this backdrop, Plaintiff asserts that Children's Motrin – which the FDA has approved as safe and effective and which is used by millions of consumers – is nonetheless "unreasonably dangerous for over-the-counter use." (*See* Trial Tr. Vol. 1, 5:19-20.) That claim flatly contradicts the FDA's judgment. It also undermines the FDA's efforts to "achieve a somewhat delicate balance of statutory objectives," *see Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 348 (2001), which include ensuring not only drug safety, but also facilitating the public's access to important drugs. Because Plaintiff's attempt to have over-the-counter ibuprofen declared unreasonably unsafe would "frustrate[] the full effectiveness of federal law,"

her design defect claim is preempted. *Perez v. Campbell*, 402 U.S. 637, 652 (1971); *see also Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 881 (2000) (plaintiff's design defect claim seeking installation of specific automobile safety device was preempted by Department of Transportation rules because it "would have presented an obstacle to the variety and mix of devices that the federal regulation sought").

Wyeth v. Levine is not to the contrary. In *Wyeth*, the Supreme Court considered whether a failure-to-warn claim was preempted, *see* 129 S.Ct. 1187, 1193 (2009); in holding that it was not, the court did not address a design defect theory. For the reasons already explained, Plaintiff's design defect conflicts with and is preempted by federal law. Moreover, because manufacturers cannot alter the design of their drug-delivery systems without prior FDA approval, *see* 21 U.S.C. § 355(j)(2)(C); 21 C.F.R. § 314.70(b), Plaintiff's claim subjects manufacturers to multiple competing regulations with which they could not possibly comply. *See Crosby*, 530 U.S. at 372 (preemption occurs where it is "impossible for a private party to comply with both state and federal law"). And unlike *Wyeth* – where the court relied on the Vermont Supreme Court's finding that the FDA did not give "more than passing attention" to the adequacy of the warning at issue, 129 S.Ct. at 1199 – the FDA here has extensively considered the potential risks of ibuprofen and approved its over-the-counter use anyway (*see, e.g.*, Trial Tr. Vol. 2, 173:8-16 (Dr. Nelson acknowledges that the FDA's Medical Reviewer recommended over-the-counter status for Children's Motrin even though the risk of SJS/TEN was known at the time)). For all of these reasons, Plaintiff's design defect claim is preempted by federal law.

B. Plaintiff Has Not Established That Children's Motrin Was Defectively Designed

In addition, Plaintiff has adduced insufficient evidence to prove that Children's Motrin was defectively designed. Plaintiff's theory – that over-the-counter Children's Motrin is

"unreasonably dangerous," regardless of any warnings on the product – is legally insupportable. Pharmaceutical products, both over-the-counter and prescription, by nature contain both risks and benefits. Because even beneficial drugs pose potentially harmful side effects, they are unreasonably dangerous only if unaccompanied by an adequate warning. *See, e.g., Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 90 (2d Cir. 1980) ("prescription drugs may cause untoward side effects despite the fact that they have been carefully and properly manufactured . . . [they] are not deemed defective or unreasonably dangerous so long as they are accompanied by proper directions for use and adequate warnings as to potential side effects").[2]

Plaintiff also has not made the fundamental showing necessary to support liability under a design defect theory: that the risks of ibuprofen products, such as Children's Motrin, outweigh their benefits. Virginia law does not require a manufacturer to "design and market an accident-proof product," *Turner v. Manning, Maxwell & Moore, Inc.*, 217 S.E.2d 863, 868 (Va. 1975); instead, it imposes liability only on those manufacturers who design unreasonably dangerous products, *see Logan v. Montgomery Ward & Co.*, 219 S.E.2d 685, 687 (Va. 1975). Whether a product is unreasonably dangerous, in turn, depends in part upon a risk-utility analysis that weighs the product's potential risks against its benefits. *See Blevins v. New Holland North America, Inc.*, 128 F. Supp. 2d 952, 960 (W.D. Va. 2001).

While Plaintiff's counsel has offered conclusory assertions that Children's Motrin is "unreasonably dangerous for over-the-counter use" (Trial Tr. Vol. 1, 5:19-20; *see also id.* 6:8 ("this product is unreasonably dangerous")), Plaintiff's experts did not testify ***once*** that the

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[2] While Virginia has not adopted § 402A of the Restatement, its reasoning – that drugs are beneficial and should not be deemed "unreasonably dangerous" if accompanied by adequate warnings, *see* Restatement (Second) of Torts § 402A cmt. k – applies with equal force to a design defect claim sounding in negligence, which imposes an "unreasonably dangerous" requirement. It is also consistent with the Virginia Model Jury Instructions, which provide – in the context of a similar breach of warranty claim – that where a product is "safe for use by most people and yet harmful to others," the product is unmerchantable "unless the manufacturer gave an adequate warning of the danger." *See* Va. Model Jury Instructions 34.080.

drug's risks outweigh its benefits. This is particularly problematic because Plaintiff's theory of defect is not limited to Children's Motrin, but extends to all ibuprofen products (and, in various respects, all propionic acid Non-Steroidal Anti-Inflammatory Drugs ("NSAIDs") and even all NSAIDs). Indeed, Plaintiff's experts conceded that ibuprofen is used to treat a wide variety of serious, debilitating conditions, such as osteoarthritis and rheumatoid arthritis. Absent expert testimony that the risks associated with ibuprofen outweigh those benefits, Plaintiff's design defect theory fails as a matter of law.

Rather than arguing that the product's risks outweigh its benefits, Plaintiff's experts instead posited that other over-the-counter drugs are "safer." (*See* Trial Tr. Vol 2, 230:7-17 (Tylenol); *id.* 245:5-9 (dexibuprofen).) That testimony cannot support a judgment for Plaintiff for two independent reasons. ***First***, Plaintiff's experts did not present any evidence of a safer, alternative ***design*** for this product; rather, they pointed to two entirely different ***products***. But a plaintiff "cannot prove design defect by claiming that defendant should have sold an entirely different product," *Brockert v. Wyeth Pharm., Inc.*, No. 14-07-00445-CV, 2009 WL 997438, at *8 (Tex. Ct. App. Apr. 14, 2009); rather, the proposed alternative "must be one for the product at issue," *id.* at *9 (rejecting design defect claim because plaintiff "[i]n essence . . . argues that the product Prempro should have been a different product"); *see also Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255 (5th Cir. 1999) (per curiam) (rejecting plaintiff's argument that other products should be considered alternative designs, because "[t]he problem with this argument is that it really takes issue with the choice of treatment . . . not with a specific fault of" the product at issue). Because Plaintiff's experts presented no evidence whatsoever of a safer, alternative ***design***, she cannot prevail, as a matter of law, on her design defect claim.

Second, even if Plaintiff had proffered an alternate design (and she has not), the testimony she offered falls entirely short of the evidence needed to show that such a design is a superior alternative. It is not enough to declare, as Dr. Tackett did, that some other design is "safer"; after all, a placebo may also be "safer" than an ingested, active drug. Rather, a plaintiff asserting a design defect claim must establish, through a risk-***benefit*** analysis, that "the proposed device will help more than it hurts." *Tunnell v. Ford Motor Co.*, 385 F. Supp. 2d 582, 586 (W.D. Va. 2005). But Dr. Tackett did not offer that opinion.

With respect to Tylenol, his first proposed alternative design, Dr. Tackett advanced two theories in support of his argument that Tylenol is a safer alternative to ibuprofen: (1) that the American Academy of Pediatrics has recommended Tylenol over Children's Motrin as "a first line" (Trial Tr. Vol. 2, 230:7-13); and (2) that the World Health Organization lists Tylenol as a "better alternative than ibuprofen in most cases" on its list of essential medicines for developing countries (*id.* 15-17). His reliance on the American Academy of Pediatrics is entirely inapposite because Plaintiff is an adult, and because Plaintiff's theory of defect is not confined to Children's Motrin.

More fundamentally, at no point did Dr. Tackett testify that Tylenol possesses all the same ***benefits*** that Children's Motrin and ibuprofen provide. To the contrary, Dr. Nelson acknowledged that ibuprofen was first approved to treat rheumatoid arthritis, which he deemed "a very serious" condition. (*Id.* 168:20-25). Tylenol, by contrast, "is a different kind of drug than ibuprofen," and lacks the anti-inflammatory properties needed to treat conditions such as rheumatoid arthritis. (*See* Trial Tr. Vol. 4, 714:9-13 (testimony of Dr. Anthony Temple).) Without testimony that the overall risk-***benefit*** profile of Tylenol is superior to ibuprofen, Plaintiff's theory fails as a matter of law. Dr. Tackett also did not testify that Tylenol works for

all patients, and that the beneficial effect of the availability of Children's Motrin as another option for patients is outweighed by the risks associated with its use.

Dr. Tackett also identified dexibuprofen as a purportedly safer alternative, but that testimony was also insufficient; he asserted only that because the drug "is being sold in other countries . . . it seems to be a safer alternative in my opinion." (Trial Tr. Vol. 2, 245:8-9.) Not only is the fact that a drug is "sold" in other countries legally insufficient to establish that it is safer than another drug, but here, too, Dr. Tackett provided no evidence that dexibuprofen's "benefits truly outweigh its risks." *Tunnell*, 385 F. Supp. 2d at 586. As a result, the evidence adduced by Plaintiff is insufficient to demonstrate that Children's Motrin is defective or that a safer alternative – whose benefits outweigh its risks and which treats the same conditions as ibuprofen – exists. For this reason, too, Defendants are entitled to judgment on Plaintiff's design defect claim.

III. DEFENDANTS ARE ENTITLED TO JUDGMENT ON PLAINTIFF'S PUNITIVE DAMAGES CLAIM

Defendants are also entitled to judgment on Plaintiff's punitive damages claim, because Plaintiff failed to demonstrate that Defendants acted with the type of malicious, willful, or wanton conduct needed to sustain an award of punitive damages.

Punitive damages are similar to criminal penalties and are permissible only in those cases "involving the most egregious conduct," *Bowers v. Westvaco Corp.*, 419 S.E.2d 661, 668 (Va. 1992); they may be imposed only upon a showing that a defendant acted with actual malice, or exhibited willful and wanton conduct that "evince[d] a conscious disregard of the rights of others," *id.*; *see also Simbeck, Inc. v. Dodd Sisk Whitlock Corp.*, 508 S.E.2d 601, 604 (Va. 1999). For this reason, a plaintiff cannot recover punitive damages where she provides no evidence that a manufacturer acted with malice or conscious disregard of the public safety. *See Ford Motor*

Co. v. Bartholomew, 297 S.E.2d 675, 684 (Va. 1982) (affirming trial court's decision to strike punitive damages because the "plaintiff failed to carry her burden of showing that Ford 'had made a decision that [was] wanton, willful, malicious or in conscious disregard of the rights of others'").

Against this backdrop, Plaintiff has adduced no evidence that the Defendants acted with actual malice, displayed willful or wanton conduct, or consciously disregarded the rights of Plaintiff. Rather, the evidence at most shows that SJS/TEN is an extremely rare condition that scientists continue to study (*see, e.g.*, Trial Tr. Vol. 2, 160:16-22); as a result, Plaintiff cannot show that Defendants' decision to continue an FDA-approved product that benefits millions of people (*see* Trial Tr. Vol. 4, 725:2-7 (billions of doses of ibuprofen sold)), and which other manufacturers likewise market, was done with actual malice, willfulness, or wantonness.

Plaintiff cannot possibly establish, in light of this evidence, that Defendants acted with malice, willfulness, or wantonness. It is well-established that compliance with government regulations and industry custom is evidence that a manufacturer acted reasonably. *See Turner*, 217 S.E.2d at 869; *Redman v. John D. Brush & Co.*, 111 F.3d 1174, 1177-78 (4th Cir. 1997). If compliance with FDA regulations suggests that Defendants acted reasonably, it is even stronger evidence that they did not act with the type of malice or wantonness needed to sustain an award of punitive damages. *See, e.g.*, *Richards v. Michelin Tire Corp.*, 21 F.3d 1048, 1059 (11th Cir. 1994) (judgment as a matter of law on punitive damages claim proper where defendant complied with applicable federal standards).[3] For these reasons, Defendants' conduct falls far short of that which any reasonable jury could conclude warrants punitive damages.

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[3] Courts in jurisdictions across the country are in accord. *See, e.g.*, *Welch v. Gen. Motors Corp.*, 949 F. Supp. 843, 845 (N.D. Ga. 1996) (although a jury could find the defendant "negligent, or perhaps even grossly negligent," summary judgment on plaintiff's punitive damages claim was appropriate because "the record indicates that defendant complied with the applicable federal regulations"); *Sloman v. Tambrands, Inc.*, 841 F. Supp. 699, 703

Because the evidence is entirely insufficient, as a matter of law, to establish that Defendants acted with malice or wantonness, Defendants are entitled to judgment on Plaintiff's punitive damages claim.

IV. PLAINTIFF HAS NOT ESTABLISHED THAT DEFENDANTS' WARNINGS PROXIMATELY CAUSED HER INJURIES

For several reasons, there is also no evidence from which a reasonable jury to conclude that Plaintiff Karen Robinson would not have taken Children's Motrin if the label had contained an adequate warning. Because a plaintiff must show that an allegedly inadequate warning proximately caused her injury, *see Butler v. Navistar Intern. Transp. Corp.*, 809 F. Supp. 1202, 1207-08 (W.D. Va. 1991), Defendants are entitled to judgment for this reason alone.

First, there is no evidence from which a jury could conclude that a different label would have led Mrs. Robinson to stop taking Children's Motrin after her symptoms developed. The record evidence shows that:

- Plaintiff never read the label – other than the dosage – the three times that she took Children's Motrin in September, 2005. Indeed, she admitted that she was not considering the label at all during those days. She also did not remember what the label said, and did not remember the warnings it included. (Trial Tr. Vol. 3, 596:10-14; 610:9-11; 610:17-19.)

- Plaintiff failed to heed to the symptoms of a known allergic reaction. In 1992, Plaintiff used an antibiotic called Cipro, which resulted in a rash and blotchy skin. (*Id.* at 600:19-601:15.) The Children's Motrin label instructs to stop use and ask a doctor if an allergic reaction occurs. (*Id.* at 604:2-4.) However, Plaintiff did not stop the use of Children's Motrin even after the appearance of a rash.

- Plaintiff also failed to follow other instructions on the existing label. The Children's Motrin label instructs to call a doctor if an allergic reaction or fever occurs or if any new symptoms appear, yet she continued to take Children's Motrin even when

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n.8 (D. Md. 1993) ("Since defendant successfully proved that it complied with federal regulations, the Court concludes that Tampax did not act with malice in its TSS warning and thus plaintiff is not entitled to punitive damages."); *Chrysler Corp. v. Wolmer*, 499 So. 2d 823, 826 (Fla. 1986) (reversing district court's decision to reinstate punitive damages where it was undisputed that "Chrysler tested its product and . . . the fuel system in the [vehicle] satisfied" the regulatory standard); *see also* W. Page Keeton, et al., Prosser & Keeton on the Law of Torts 233, n.41 (5th ed. 1984) ("In most contexts…compliance with a statutory standard should bar liability for punitive damages.").

symptoms of rash, blisters, fever and itching appeared after she first took Children's Motrin. (*Id.* at 596:10-14; 610:9-11; 610:17-19.)

As a result, no reasonable jury could conclude that a different warning on the product would have led Karen Robinson to stop ingesting the product after she developed symptoms of SJS/TEN.

Second, no reasonable jury could conclude that Karen Robinson never would have ingested Children's Motrin to begin with if the product contained an allegedly adequate warning. Plaintiff's theory is based on the assertion that Karen Robinson would never have purchased the drug to begin with if she knew that it "could cause an extraordinarily dangerous reaction." (Trial Tr. Vol. 3, 542:16-543:4.) But no expert testified that it should have included such a warning; indeed, the Court granted the Defendants' Motion *In Limine* on that issue. Rather, the only expert evidence was that the label should have included more specific information about the symptoms of SJS/TEN. As just described, however, Karen Robinson was not aware of the symptoms already listed on the label, so more detailed information about those symptoms would not have mattered.

More fundamentally, the Children's Motrin label already warned that "ibuprofen may cause a severe allergic reaction which may include hives, facial swelling, asthma, and shock" (*id.* at 628:19-21), and Mrs. Robinson was aware that such reactions could be dangerous or even life-threatening (*id.* at 604). Despite the fact that she read those warnings months before September 2005, she purchased the product, gave it to her son, and ingested it herself, under the assumption that the benefits the drug provided outweighed the small chance of a severe allergic reaction. (*Id.* at 605:8-13.) No reasonable jury could conclude that the addition of language describing the symptoms of SJS/TEN would have changed Karen Robinson's decision to purchase Children's Motrin.

Based on this record, no reasonable jury could conclude that a different warning would have prevented Karen Robinson from taking Children's Motrin.

V. PLAINTIFF HAS NOT ESTABLISHED MEDICAL CAUSATION

It is axiomatic that "[u]nder any theory of tortious injury, one requisite element of a claim is a causal connection between defendant's conduct and plaintiff's injury." *Hartwell v. Danek Medical, Inc.*, 47 F. Supp. 2d 703, 707 (W.D. Va. 1999) ("The law of products liability in Virginia does not permit recovery where responsibility is conjectural.") (internal citations and quotation marks omitted). Because Plaintiff has not adduced sufficient evidence to show either that Children's Motrin causes SJS/TEN in general or that it caused Karen Robinson's injuries, Defendants are entitled to judgment on both her theories of negligence.

A. Plaintiff Has Not Established That Children's Motrin Causes SJS/TEN

Plaintiff's expert, Dr. Nelson, relies on one epidemiologic study and some case reports – which he admits do not establish causation – to support his opinion that ibuprofen is capable of causing SJS/TEN. This scientific evidence is insufficient under the law to establish general causation.

To date, there have been only two epidemiologic studies – the SCAR study and the EuroSCAR study – and three associated papers investigating the causal relationship between ibuprofen and SJS/TEN. (Trial Tr. Vol. 3, 501:21-502:1.) The findings of these epidemiologic studies do not support a finding of general causation. While the SCAR study found a statistically significant relative risk for ibuprofen associated with SJS/TEN (Trial Tr. Vol. 2, 104:23-106:13), the latest epidemiologic study – the EuroSCAR – prepared by the same authors as the SCAR study, came to the opposite conclusion: that there was *no* statistically significant relative risk for ibuprofen associated with SJS/TEN. (*See id.* at 185:1-16.) Dr. Nelson characterized EuroSCAR as a "very well done" study. (*Id.* at 178:14.) The mixed results of these studies do not support

general causation. *See, e.g., Merrell Dow Pharms. v. Havner*, 953 S.W.2d 706, 727 (Tex. 1997) (stating that "if scientific methodology is followed, a single [epidemiologic] study would not be viewed as indicating that it is 'more probable than not' that an association exists).

Dr. Nelson also relied on many non-epidemiologic studies to support his opinion. But as Dr. Nelson admitted, these studies cannot establish causation. (Trial Tr. Vol. 2, 163:10-15 (non-epidemiologic papers discussed earlier "didn't have the controls that would be needed to try to assess the risk for an particular drug or class of drugs"); *id.* at 155:10-18 (Sharma article could not determine whether ibuprofen causes SJS/TEN); *id.* at 158:17-23 (same conclusion while discussing Raksha article); *id.* at 159:13-16 (stating that, as a general rule, causation cannot be determined from a case report).) That is particularly true here, where the drug at issue is frequently used to treat the ***symptoms*** associated with the underlying disease.

Finally, Plaintiff's expert, Dr. Salisbury, gave an opinion that ibuprofen causes SJS or TEN based on his clinical experience of seeing patients. (Trial Tr. Vol. 3, 395:19-396:1.) That testimony likewise cannot prove causation, as Dr. Salisbury conceded. *See In re Breast Implant Litig.*, 11 F. Supp. 2d 1217, 1230, 1231 (D. Colo. 1998) (clinical experience is "equivalent [to] a series of case reports, or observations made about a particular patient," which are "universally . . . regarded as an insufficient scientific basis for a conclusion regarding causation.").

B. Plaintiff Has Not Established That Children's Motrin Caused Karen Robinson's Injuries

Plaintiff also fails to meet the causation requirement because she has not produced competent scientific evidence that ibuprofen caused her SJS/TEN. Dr. Nelson did not offer a specific causation opinion. Plaintiff's second expert, Dr. Randall Tackett, testified that "ibuprofen is known to cause SJS and TEN, which [Karen Robinson] had . . . [and][the]time course [was] ***consistent with*** what's in the literature associated with ibuprofen induced SJS and

TEN [and] there were no infectious secondary causes which could be attributed." (Trial Tr. Vol. 2, 259:4-9 (emphasis added).) But the question in this case is not whether her injuries were "consistent with" injuries caused by ibuprofen, but whether they were actually caused by the drug. Dr. Tackett, who is not a medical doctor and cannot perform a differential diagnosis, cannot and did not offer sufficient specific causation testimony. Likewise, Dr. Salisbury testimony that, in his opinion, Children's Motrin caused Karen Robinson's SJS/TEN is legally insufficient. That testimony was based on his belief, based on his clinical experience, that SJS/TEN is always caused by drugs, a belief that is unsupported by science.

VI. DEFENDANTS ARE ENTITLED TO JUDGMENT ON PLAINTIFF'S FAILURE-TO-WARN CLAIM

As set forth above, Plaintiff's inability to establish that Defendants' warning proximately caused her injury precludes her from prevailing on her failure-to-warn theory of negligence. Defendants are entitled to judgment on Plaintiff's failure-to-warn claim for two additional reasons as well. ***First***, Plaintiff has not established that the warning on Children's Motrin was legally inadequate. ***Second***, because there is clear evidence that the FDA would not have approved the label changes Plaintiff seeks, her failure-to-warn claim is preempted by federal law.

A. Plaintiff Has Not Established That The Children's Motrin Warning Was Inadequate

The evidence Plaintiff adduced was insufficient to demonstrate that Defendants failed their duty to give a reasonable warning. *See Pfizer, Inc. v. Jones*, 272 S.E.2d 43, 45 (Va. 1980) (manufacturers must give a reasonable warning, not the best possible one). Plaintiff's expert, Dr. Tackett, stated that the warning on Children's Motrin did not specifically mention SJS/TEN (*see* Trial Tr. Vol. 2, 241:10-14); neither he nor Plaintiff's other witnesses, however, in any way established that the failure to specifically mention SJS/TEN rendered Defendants' label inadequate. And while Dr. Salisbury – who conceded that he never testified before the FDA,

consulted with the agency on labeling decisions, or had any other involvement in drug labeling (*see* Trial Tr. Vol. 3, 466:8-23) – opined that Defendants' label was "incomplete" (*id.* at 426:22-427:1), he likewise failed to offer any evidence that it was legally inadequate. Nor could he; indeed, it is well-established that manufactures need not give the "best possible" warning. *See Pfizer*, 272 S.E.2d at 45.

In *Pfizer*, the Virginia Supreme Court set aside a jury verdict in a failure-to-warn case where the plaintiff had argued that a drug manufacturer's warning – which gave physicians "explicit instructions as to how the drug should be administered" – was nonetheless inadequate because the label did not also mention a specific condition that might result if the instructions were not followed. *See id.* at 44. The court held that the warning was adequate, and that the defendant did not have a duty "to explain[] exactly how the danger against which [the plaintiff] had been warned might operate." *Id.* at 45 (citing *Sadler v. Lynch*, 64 S.E.2d 664 (Va. 1951)). The same is true here. As set forth above, Plaintiff herself conceded that the Children's Motrin label warned consumers to stop use and consult a doctor if an allergic reaction occurred. (*See, e.g.*, Trial Tr. Vol. 3, 604:2-4.) That the label did not explain "exactly how the danger . . . might operate" by specifically mentioning SJS/TEN does not render its warning inadequate as a matter of law.

Because Plaintiff did not present sufficient evidence that Defendants' label was inadequate, Defendants are entitled to judgment on this basis alone.

B. Plaintiff's Failure-to-Warn Claim Is Preempted By Federal Law

Even if Plaintiff had adduced sufficient evidence to support her failure-to-warn claim, Defendants would still be entitled to judgment because that claim is preempted by federal law. As set forth above, state law is preempted if it frustrates the "full purposes and objectives of Congress" or, most relevant here, if it would be impossible to comply with both laws at once.

See Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 372-73 (2000). As set forth in more detail in Defendants' Motion for Summary Judgment, Plaintiff's claim is preempted because there is clear evidence that the FDA would not have approved the labeling changes she seeks. *See Wyeth v. Levine*, 129 S.Ct. 1187, 1198 (2009). For this reason, too, Defendants are entitled to judgment on her failure-to-warn claim.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court enter judgment in their favor.

Dated: August 27, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 27, 2009, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following:

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