UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

JANE DOE,	)	
	)	
Plaintiff.	)	
	)	
v.	)	Civil No. 03-74-B-W
	)	
SOLVAY PHARMACEUTICALS, INC.,	)	
	)	
Defendant.	)	

ORDER ON DEFENDANT'S
MOTION FOR SUMMARY JUDGMENT

Jane Doe[1] sincerely believes her ingestion of the prescriptive medicine Luvox caused her to suffer a severe manic episode, resulting in her involuntary admission to a mental health institution. She sued Solvay Pharmaceuticals, the manufacturer of Luvox, under a number of theories, alleging in essence that Solvay improperly manufactured and distributed Luvox and that it failed adequately to warn her of its risks, specifically the risk of a manic episode. Solvay moved for summary judgment. This Court grants Solvay's Motion, based on Ms. Doe's failure to raise a genuine issue of material fact on her claim that the Luvox she took was defective and based on the application of the learned intermediary rule on the failure to warn question.[2]

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[1] Jane Doe is a pseudonym for the Plaintiff. Ms. Doe understandably considers the information in this law suit "highly confidential, private and sensitive and does not wish the information as to her identity to be available to the public." *Pl.'s Mot. Under Seal to File Jane Doe Complaint* (Docket No. 2). The Court has recited the facts in this case seeking to avoid breaching the Plaintiff's privacy, while at the same time, providing an explanation for its decision.

[2] Ms. Doe has filed two pending motions: 1) a motion dated February 5, 2004, entitled Plaintiff's Objections to Magistrate's Failure to Consider Plaintiff's Request for Rule 37 Sanctions, Objections to Magistrate's Order and Rulings, and Motion to Vacate a Reference of a Civil Matter to Magistrate for Cause; and, 2) a motion dated March 18, 2004, entitled Motion to Supplement Plaintiff's Pending Objections and Motions with Relevant Newly Obtained Evidence. This Court denies both motions. The first motion was addressed by the Magistrate Judge and concerns a discovery issue well within her discretion. There is no indication that either motion addresses issues that would affect the resolution of Solvay's motion for summary judgment.

I. STANDARD OF REVIEW

A. Summary Judgment Standard.

Summary judgment is appropriate only if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); *Santoni v. Potter*, 369 F.3d 594, 598 (1st Cir. 2004). Not every factual dispute is "sufficient to thwart summary judgment; the contested fact must be 'material' and the dispute over it must be 'genuine.'" *Navarro v. Pfizer Corp.*, 261 F.3d 90, 93 (1st Cir. 2001). A "material" fact is one that "might affect the outcome of the suit under the applicable legal standard." *Santoni*, 369 F.3d at 598 (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). An issue is "genuine" if the evidence is such that "a reasonable jury could resolve it in favor of either party." *Santoni*, 369 F.3d at 598 (citation omitted). In deciding whether a genuine issue of material fact exists, the Court "construes the evidence in the light most favorable to the non-moving party." *Id*. (citing *Flowers v. Fiore*, 359 F.3d 24, 29 (1st Cir. 2004)).

B. Local Rule 56.

The evidence the Court may consider in deciding whether genuine issues of material fact exist for purposes of a summary judgment motion is circumscribed by the Local Rules of this District. *See* Local Rule 56. The moving party must first file a statement of material facts that it claims are not in dispute. Local Rule 56(b). Each fact must be set forth in a numbered paragraph and supported by a specific record citation. *Id.* The nonmoving party is then required to submit a responsive "separate, short and concise" statement of facts in which it must "admit, deny, or qualify the facts by

reference to each numbered paragraph of the moving party's statement of material facts." Local Rule 56(c). The nonmovant likewise must support each denial or qualification with an appropriate record citation. *Id.* The moving party may then respond with a reply statement of material facts in similar format. Local Rule 56(d). Failure to comply with the Rule can result in serious consequences: "Facts contained in a supporting or opposing statement of material facts, if supported by record citations as required by this rule, shall be deemed admitted unless properly controverted." Local Rule 56(e).

In general, Local Rule 56 contemplates the Court will discount any statement of material fact or a response containing irrelevant argument or factual assertions unsupported by appropriate record citation. *See* Local Rule 56(e); *Toomey v. UNUM Life Ins. Co.*, 324 F.Supp.2d 220, 222 (D. Me 2004); *Cadle Co. v. Hayes*, 116 F.3d 957, 960 (1st Cir. 1997) (the "evidence illustrating the factual controversy cannot be conjectural or problematic" and "effusive rhetoric and optimistic surmise" is not enough to establish a genuine issue of material fact."). In accordance with these principles, the Court has disregarded unsupported or argumentative portions of Plaintiff's Opposing Statement of Material Facts and Additional Facts.[3]

II. BACKGROUND FACTS

In accordance with "conventional summary judgment praxis," the Court recounts the facts in a light most favorable to Jane Doe's theory of the case consistent with record

[3] Compliance with the local rules in summary judgment practice is occasionally problematic even for counsel. The Plaintiff has made an admirable effort to argue her own case and because she is acting *pro se*, this Court has "read her supporting papers liberally, and will interpret them to raise the strongest arguments that they suggest." *Burgos v. Hopkins*, 14 F.3d 787, 790 (2d Cir. 1994). However, in doing so, she must be held generally to the same standards as an attorney. Otherwise, the Court would apply the rules unevenly, forgiving the Plaintiff for lapses that would be unforgivable if made by the Defendant. *Simpson v. Penobscot County Sheriff's Dep't*, 285 F. Supp. 2d 75, 76-77 (D. Me. 2003)("…*pro se* status does not relieve him of his duty to respond (citation omitted), nor alter the Court's obligation to fairly apply the rules governing summary judgment proceedings.").

support. *Gillen v. Fallon Ambulance Serv.*, 283 F.3d 11, 16 (1st Cir. 2002). The Court has relied either on the uncontested facts or on Ms. Doe's version, if properly placed in conflict.

Jane Doe is a resident of Maine, and Solvay Pharmaceuticals, Inc. ("Solvay") is a Georgia corporation with a principle place of business in Marietta, Georgia.[4] (DSMF ¶¶ 1, 24). In 1994, Ms. Doe was treated for obsessive-compulsive disorder ("OCD") by a Maine psychiatrist. (DSMF ¶ 23). After moving in 1997, Ms. Doe again sought treatment for OCD from her psychiatrist. (DSMF ¶ 27). Ms. Doe began to take Luvox on July 21, 1997 to treat her OCD. (DSMF ¶ 27; POSMF ¶ 27). A prescriptive medication, Luvox, or fluvoxamine maleate, a selective serotonin reuptake inhibitor ("SSRI"), was used to treat obsession and compulsive behavior. (DSMF ¶¶ 3, 4, 11; POSMF ¶ 11). On September 3, 2003, the U.S. Food and Drug Administration (FDA) withdrew its approval of the New Drug Application for Luvox, noting possible inaccuracies in the chemical, manufacturing, and controls (CMC) section of the application. (POSMF ¶ 11, Exhibit 1 at 1). In withdrawing Luvox's application, the FDA noted that although the findings in the CMC section "raised concerns about the drug product as manufactured by Solvay, they do not affect the safety or efficacy of fluvoxamine maleate in treating obsessive compulsive disorder." (POSMF ¶ 11, Exhibit 1 at 2).

Based on his professional judgment and information from Solvay, Ms. Doe's psychiatrist considered Luvox to be a safe and appropriate medication to prescribe to treat her OCD. (DSMF ¶¶ 28-32; POSMF ¶ 28-32). He discussed with Ms. Doe potential adverse side effects of the drug, particularly that the drug can cause mania in

[4] This Court's jurisdiction is based on diversity of citizenship. 28 U.S.C. § 1332.

some patients. (DSMF ¶¶ 33-44). The Physicians Desk Reference (PDR), which he consulted, confirms Luvox has been prescribed for treatment of OCD and sets forth the following warning:

> [d]uring premarketing studies involving primarily depressed patients, hypomania or mania occurred in approximately 1% of patients treated with fluvoxamine. Activation of mania/hypomania has also been reported in a small proportion of patients with major affective disorder who were treated with other marketed antidepressants. As with all antidepressants, LUVOX Tablets should be used cautiously in patients with a history of mania.

(DSMF ¶ 32). In addition, Ms. Doe and her physician read the label and package insert that accompanies Luvox, which states in premarketing studies involving primarily depressed patients, "hypomania or mania occurred in approximately 1% of patients treated with fluvoxamine." (DSMF ¶ 15). There is no indication Ms. Doe has ever been diagnosed with depression. (POSMF ¶ 22).

After taking Luvox for approximately five months, Ms. Doe became delusional and manic. (POSMF ¶ 36). While in the manic state, Ms. Doe came to believe there were no longer any diseases in the world, and therefore felt there was no longer any need to take medication, including Luvox. (POSMF ¶ 37). Ms. Doe's manic episode caused her to experience high energy, delusions, an inability to sleep, reduced appetite, and weight loss. *Id.* As a result, Ms. Doe was involuntarily committed to a Maine state mental institution on January 27, 1998. (POSMF ¶ 38). She was diagnosed with bipolar disorder, another term for manic depression. (POSMF ¶ 39). After discharge five weeks later, she was placed on Zoloft, which she continues to take for her OCD, and she has experienced no adverse effects. (POSMF ¶ 41). However, she now suffers from post

traumatic stress disorder resulting from her manic episode and its sequelae. (POSMF ¶ 39).

On April 23, 2003, Ms. Doe filed a complaint against Solvay, alleging she suffered the severe manic reaction as a consequence of taking Luvox. The Complaint contains eight counts. Count I alleges negligent manufacture and delivery of a defective product. Count II alleges a violation of the Deceptive Trade Practices Act, 10 M.R.S.A. § 1212. Count III alleges a violation of the Unfair Trade Practices Act, 5 M.R.S.A. § 207, et seq. Count IV alleges a breach of implied warranty of fitness for a particular purpose, 11 M.R.S.A. § 2-315. Count V alleges a violation of Maine's strict liability law, 14 M.R.S.A. § 221, et seq. Count VI claims a failure to warn, alleging that Solvay knew or should have known that Luvox was dangerous and that adults with obsessive compulsive disorder could experience a manic reaction when taking Luvox. Count VII alleges fraudulent misrepresentation. Finally, Count VIII[5] seeks punitive damages, alleging Solvay acted with malice in the design, manufacture, sale, and distribution of Luvox.

III. DISCUSSION.

As a preliminary matter, the Court notes Ms. Doe consistently confuses argument with evidence. There is no doubt Ms. Doe is extremely knowledgeable about the factual issues in this case. She has thoroughly researched Solvay, Luvox, OCD, FDA filings, and the scientific literature and she has impressively marshaled these facts in her memoranda. Despite her commanding level of understanding, there is no evidence she is qualified by virtue of knowledge, skill, experience, training or education to express expert opinions under Rule 702 on these matters. Fed. R. Evid. 702. Some documents

[5] Count VIII is mislabeled as a second Count VII in the Plaintiff's Complaint.

she has submitted in response to Solvay's motion for summary judgment have sufficient indicia of authenticity and reliability to be considered under Rule 803(8), Fed. R. Evid. 803(8), *see Stewart v. Waldo County*, 2004 WL 2397403, *3 n.1 (D. Me. 2004); however, the vast bulk has been attached without any attempt at authentication and cannot be considered. Moreover, Ms. Doe's extrapolations from these documents are expert opinions in the guise of legal argument. Her sole designated expert in this claim is her treating psychiatrist and he fails to provide expert corroboration on many of the critical issues in this case, leaving the Court with an expansive argument in an evidentiary void.[6]

Secondly, Solvay categorizes Ms. Doe's complaints into two broad types: 1) the medicine was defective (Counts I, IV and V); and, 2) the warnings were inadequate (Counts II, III, V, VI, and VII).[7]

A. Whether The Medicine Was Defective.

1. Negligent Manufacture and Delivery (Count I).

Ms. Doe alleges Solvay negligently manufactured and delivered Luvox, and her use of the drug caused her manic episode. In its motion for summary judgment, Solvay asserts there is no evidence supporting negligent manufacture or delivery. Alternatively,

[6] The Court does not imply any criticism of Ms. Doe personally. Self representation is commonly fraught with difficulty, all the more so in a case as potentially complex as this action.

[7] This Court accepts this categorization. Count I – the negligence count - alleges Solvay "negligently manufactured and delivered a defective product"; Count IV – the breach of implied warranty of fitness for a particular purpose count – alleges Ms. Doe "relied upon Defendant Solvay to manufacture and furnish a suitable and defect-free product". Counts I and IV are premised on a defective product. Count II – Deceptive Trade Practices – alleges the Luvox did not "meet the standard, grade or quality represented by Defendant Solvay"; Count III – Deceptive Trade Practices - alleges the Luvox "was not of the standard, grade or quality represented by Defendant Solvay"; Count VI – failure to warn – obviously alleges the warnings were inadequate; and, Count VII – fraudulent misrepresentations – alleges Solvay's failure to disclose "constitutes a false misrepresentation of a material fact." Counts II, III, VI, and VII are premised on a failure to warn. Count V – strict liability – is a hybrid. It alleges Luvox was "unreasonably dangerous to the user." Although the allegations alone appear to address the design and manufacture of Luvox, in the context of prescriptive drugs, strict liability law includes a failure to warn element. Count VIII – the punitive damages count – depends upon the validity of one or more of the underlying theories of primary liability.

Solvay argues even if the product were negligently manufactured, Ms. Doe has not produced any evidence of causation, *i.e*. that any defect caused her manic episode.

In Maine, as elsewhere, a prima facie case of negligence requires a plaintiff to establish four elements: duty, breach, causation, and damages. *Mastriano v. Blyer*, 2001 ME 134, 779 A.2d 951, 954. There is "little to distinguish a negligence action predicated upon negligence in the manufacture or design of a product from other types of negligence actions well known to the common law." *Adams v. Buffalo Forge Co*., 443 A.2d 932, 938 (Me. 1982).

A duty is "an obligation, to which the law will give recognition and effect, to conform to a particular manner of conduct toward another." *Budzko v. One City Ctr. Assocs. Ltd. P'ship*, 2001 ME 37, P 10, 767 A.2d 310, 313. A manufacturer or seller owes a duty to exercise reasonable care to foreseeable users of its products and to persons who are foreseeably endangered by the use of those products. *Adams*, 443 A.2d at 939; Donald N. Zillman et al, Maine Tort Law § 12.12. The degree of care depends on the nature of the item and "a manufacturer must exercise a higher degree of care when manufacturing an automobile or drug than when manufacturing a notebook," since there is a great risk of harm if such an item is negligently manufactured. Zillman at §12:13 (citing Restatement (Second) of Torts § 388, cmts. a, d; §395 cmt. g.). Solvay owed this duty of reasonable care to foreseeable patients, including Ms. Doe, in manufacturing Luvox.

However, even viewing the evidence in a light most favorable to Ms. Doe, there is no evidence of a breach of that duty in the manufacturing and distribution process. In support of its Motion, Solvay has asserted that it is unaware of "any instances in which

Luvox distributed in 1997 failed to comply with product specifications." DSMF ¶ 8. It has also alleged that Luvox was "distributed, marketed, packaged, and labeled in accordance with all applicable FDA regulations." DSMF ¶ 10. Ms. Doe posited extensive denials of each statement.

Denying paragraph 8, Ms. Doe cites the FDA Enforcement Report dated July 31, 2002 in which the FDA informed Solvay that all strengths of Luvox were being recalled from the United States market, because of "inaccuracies in data submitted to the New Drug Application by Solvay (stability)." POSMF ¶ 8, Ex. 2. Pointing to the 2002 recall for stability problems, Ms. Doe, who has clearly thought about these matters, contends these problems reach back to at least 1997, when Solvay manufactured the Luvox she ingested. *Id.* She notes Solvay admitted that in September 1997, it was "placed under the Application Integrity Policy (AIP)" and as a result, a "thorough audit and validity assessment" of Luvox was conducted, revealing "instances where inaccurate or unsubstantiated chemistry, manufacturing and controls (CMC) data had been submitted to the FDA. . . " *Id.* She also refers to an audit by Biotechnical Services, Inc. (BSI) completed in 2000, which concluded Solvay's records "contained inaccurate and insufficient documentation ...selective reporting, and (data manipulation)." *Id.* Finally, she makes note of an audit by Lamar Furr of Lamar Furr Consulting, covering the time period from 1986 through 1999. She contends Mr. Furr concluded Solvay had made "retrospective changes to batch production records for several Luvox batch lots" and in April 1997, Solvay had made 19 changes to the batch records. *Id.* Referencing these audits and FDA records, Ms. Doe argues there are genuine issues of material fact as to whether Solvay improperly manufactured Luvox in 1997, whether she ingested

improperly manufactured Luvox, and whether the improperly manufactured Luvox then caused the untoward consequences she has suffered.

The Achilles' heel in Ms. Doe's argument is the absence of any expert testimony on the issues of defect and causation. The Court is left with a number of critical unanswered questions. What is the significance of these audits within the context of this case? Are the Solvay recordkeeping miscues evidence of a particular defect? Do they support the later withdrawal for "stability" problems? Even assuming *arguendo* she has raised a factual question about whether some Luvox manufactured in 1997 had stability problems, was her array of symptoms in 1997-98 caused by whatever occurred during the manufacturing process? The record before the Court contains no direct evidence of: 1) the nature of the defect in 1997; 2) whether the defect, if it existed, was present in the medication she ingested; and, 3) whether the symptoms she experienced would have been consistent with or caused by the defect. Further, the record does not allow inferences that would fill these gaps. To the contrary, her treating psychiatrist, who is her only expert, testified he has no reason to believe the Luvox she took was negligently manufactured, much less that there was a manufacturing defect that caused her difficulties in 1998.[8]

Even when viewed in a light most favorable to Ms. Doe, there is just simply no evidentiary basis to conclude Solvay breached its duty to exercise reasonable care in the manufacture of Luvox, that a defect from improper manufacture existed in any of the Luvox she ingested, or that this defect caused her any injuries. This Court grants Solvay's motion for summary judgment on Count I.

[8] Her treating psychiatrist agreed he had "no reason to think" the Luvox Ms. Doe took was: 1) "negligently manufactured"; 2) "negligently tested or marketed"; or 3) "negligently distributed". DSMF ¶ 46. *Psychiatrist's Deposition* at 96, ln. 21-25; 97, ln. 1-6.

2. Breach of Implied Warranty of Fitness for Particular Purpose (Count IV).

Solvay contends Doe has failed to establish a claim for breach of implied warranty of fitness for a particular purpose, since the law requires more than fitness for the ordinary purpose for which the goods were sold. Solvay argues since the ordinary purpose of Luvox was for treatment of OCD and Ms. Doe took Luvox for OCD, there is no claim of a breach of a warranty for a particular purpose. In response, Doe claims although Luvox was approved for treatment of OCD, Solvay breached the implied warranty of fitness as the drug was marketed, since Luvox was improperly manufactured and Solvay failed to provide adequate warnings for its use.

Maine's implied warranty of fitness for a particular purpose provides, unless modified or excluded in the contract, "where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is . . . an implied warranty that the goods shall be fit for such purpose." 11 M.R.S.A. § 2-315. The Maine Supreme Judicial Court has held § 2-315 requires the following elements:

> (1) the purchaser have a particular purpose *outside* the scope of ordinary purposes;
> (2) the seller at the time of contracting has reason to know of the particular purpose;
> (3) the seller has reason to know that the purchaser is relying on the seller's skill or judgment to furnish appropriate goods; and,
> (4) the purchaser must, in fact, rely upon the seller's skill or judgment.

Lorfano v. Dura Stone Steps, Inc., 569 A.2d 195, 197 (Me. 1990) (emphasis in original) (citing White & Summers, *Uniform Commercial Code* § 9-7 at 358 (1980)). In Maine,

> A "particular purpose" differs from the ordinary purpose for which the goods are used in that it envisages a specific use by the buyer which is peculiar to the nature of his business whereas the ordinary purposes for which goods are used are those envisaged in the concept of merchantability and go to uses which are customarily made of the goods in question. For example, shoes are generally used for the purpose of walking upon ordinary ground, but a seller may know that a particular pair was selected to be used for climbing mountains.

11 M.R.S.A.§ 2-315, cmt 2.

Here, Ms. Doe admits she was prescribed Luvox specifically for obsessive compulsive disorder; she also admits Solvay developed, selected, and provided Luvox to treat persons with OCD. Thus, she was taking Luvox for its intended ordinary purpose. There is no evidence Solvay knew or had reason to know of a *particular* purpose, other than for the treatment of obsessive compulsive disorder.[9] This Court grants summary judgment on Count IV of the complaint.

3. Maine's Strict Liability Law (Count V)-Defective Design and Manufacturing.

Solvay argues summary judgment should be granted on Count V because, when marketed with proper warnings, prescription drugs are exempt under Maine's strict liability law and the Restatement (Second) of Torts § 402A.[10] Further, Solvay contends

[9] Even if Ms. Doe had a particular purpose in mind, she would have to demonstrate she intended to or, in fact relied on the skill or judgment of Solvay to select an appropriate drug to treat her condition. Although the issue is not settled in Maine, in some jurisdictions, the warranty of fitness for a particular purpose does not run to the manufacturer of prescription drugs, but runs instead to the physician. *See, e.g. Heindel v. Pfizer, Inc.*, 2004 WL 1398024, *7, *16 (D. N.J. 2004) (finding that under Pennsylvania law, the very nature of prescription drugs themselves precludes the imposition of a warrant of fitness for "ordinary purposes," to bar breach of implied warranty of fitness for ordinary purposes claims against pharmaceutical manufacturers and that the manufacturer's negligence is the only recognized basis of liability."); *Beaman v. Schwartz*, 738 S.W.2d 632, 634 (Tenn. Ct. App. 1986) (under Tennessee law, "[w]here a drug manufacturer sells a [prescriptive] drug designed for a specific purpose ... and warns the medical profession of possible side effects in some users, the warranty of fitness for a particular purpose is not breached where one of those side effects occurs" when the drug was prescribed by a physician.)

[10] Restatement (Second) of Torts § 402A reads:

the foreseeable therapeutic benefits of Luvox outweigh any foreseeable risks of harm. It points out that Ms. Doe's psychiatrist continues to prescribe Luvox to his patients. Doe counters by citing Restatement (Third) of Torts § 6(d), and argues a prescriptive drug can be defective under § 402A if there is a failure to warn. She also contends Solvay manufactured and distributed Luvox in a defective condition, with a defective design, and failed to provide adequate warnings and instructions to foreseeable users of Luvox, and thus strict liability should apply.

a. Strict Liability – General Principles.

Maine's strict liability statute reads:

> One who sells any goods or products in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to a person whom the manufacturer, seller or supplier might reasonably have expected to use, consume or be affected by the goods, or to his property, if the seller is engaged in the business of selling such a product and it is expected to and does reach the user or consumer without significant change in the condition in which it is sold. This section applies although the seller has exercised all possible care in the preparation and sale of his product and the user or consumer has not bought the product from or entered into any contractual relation with the seller.

14 M.R.S.A. § 221. Strict liability claims can be premised on manufacturing defects, design defects, or by the failure to warn of a product hazard. *See, e.g., Bernier v. Raymark Indus., Inc.*, 516 A.2d 534, 537 n.3 (Me. 1996) (quoting Keeton, *The Meaning*

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(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
   (a) the seller is engaged in the business of selling such a product, and
   (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although
   (a) the seller has exercised all possible care in the preparation and sale of his product, and
   (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

of Defect in Products Liability Law -- A Review of Basic Principles, 45 Mo. L. Rev. 579, 586-87 (1980)). In a strict liability action, "no liability will be imposed unless the product is defective," and in actions based on product design defects, "negligence and strict liability theories overlap in that under both theories the plaintiff must prove that the product was defectively designed thereby exposing the user to an unreasonable risk of harm." *Guiggey v. Bombardier*, 615 A.2d 1169, 1171 (Me. 1992) (quoting *Stanley v. Schiavi Mobile Homes, Inc.*, 462 A.2d 1144 (Me. 1983)).

To determine whether a product is defective and unreasonably dangerous, Maine applies the danger/utility test. *Guiggey*, 615 A.2d at 1172. The utility of the product is weighed against the danger it presents. *Violette v. Smith & Nephew Dyonics, Inc*., 62 F.3d 8, 12 (1st Cir. 1995); *Guiggey*, 615 A.2d at 1172; *St. Germain v. Husqvarna Corp*., 544 A.2d 1283, 1285 (Me. 1988). The process involves "an examination of utility, risk, and the feasibility of safer alternatives." *Violette*, 62 F.3d at 13.

b. Strict Liability – Prescriptive Drugs and the Restatements of Law.

Prescriptive drugs pose a singular challenge to the conventional application of strict liability principles. To be a candidate for a drug, a patient must suffer a condition or disease which, if left untreated, presents a set of inherent risks. Yet, few, if any, drugs are risk free and occasionally the known risks of a particular drug can be dire. The patient is often faced with a Hobson's choice: whether the cure is worse than the disease. To assist a knowing decision, the law requires the drug manufacturer to warn of the medically recognizable risks; however, even when fully informed, the patient cannot know whether she will fall outside the subcategory of unfortunate patients.

Comment k of § 402A uses the example of the rabies vaccine:

> An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous.

The application of products liability to prescriptive medications was further explained in the Restatement of the Law, Third:

> § 6. Liability of Commercial Seller or Distributor for Harm Caused by Defective Prescriptive Drugs and Medical Devices.
> (a) A manufacturer of a prescriptive drug…who sells or otherwise distributes a defective drug… is subject to liability for harm to persons caused by the defect. A prescription drug… is one that may be legally sold or otherwise distributed only pursuant to a health-care provider's prescription.
> (b) For purposes of liability under Subsection (a), a prescription drug or medical device is defective if at the time of sale…the drug…;
> (1) contains a manufacturing defect as defined in § 2(a); or,
> (2) is not reasonably safe due to a defective design as defined in Subsection (c); or
> (3) is not reasonably safe due to inadequate instructions or warnings as defined in Subsection (d).
> (c) A prescription drug… is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug … are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug… for any class of patients.
> (d) A prescription drug… is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:
> (1) prescribing or other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or
> (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

Restatement (Third) of Torts: Products Liability § 6 (1998).

The Maine Supreme Judicial Court has not directly faced the application of strict liability principles to prescriptive drugs; however, because the Maine Legislature

modeled its strict liability statute on § 402A of the Restatement (Second) of Torts, Maine courts have looked to the Restatement for interpretive guidance. *Bernier*, 516 A.2d at 534. Other jurisdictions addressing prescriptive drug products liability claims have adopted the Restatement analytic framework. *See, e.g, Vitanza v. Upjohn Co.*, 214 F.3d 73, 78 (2d Cir. 2000); *Coursen v. A.H. Robins Co*., 764 F.2d 1329, 1337 (9th Cir. 1985) (citing *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1274-75 (5th Cir.) (oral polio vaccine unavoidably unsafe under Comment k), *cert. denied*, 419 U.S. 1096 (1974); *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 425 (2nd Cir. 1968) (applying Connecticut law); *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 656 (1st Cir. 1981)(quoting *Thibault v. Sears, Roebuck & Co.,* 395 A.2d 843, 846 (N.H. 1978)(applying New Hampshire law));. *Davis v. Wyeth Laboratories, Inc.,* 399 F.2d 121, 127 (9th Cir. 1968). *Fellows v. USV Pharmaceutical Corp.*, 502 F. Supp. 297, 300 (D. Md. 1980) (prescription drug constituted unavoidably unsafe product)). Prescriptive drugs are products that "consumers for a long time have lived with and accepted the risks inherent in their use." *Basko*, 416 F.2d at 425 (citing Kessler, Products Liability, 76 Yale L.J. 887, 930-31 (1967)).

c. Defective Design or Manufacture.

Two sources of strict liability in this case may arise from either defective design or defective manufacture. § 6(b)(1),(2). This Court has already ruled there is no probative evidence that Solvay's manufacture of Luvox was defective or that any manufacturing defect caused her injuries. Similarly, there has been no evidence that Luvox was defectively designed or, if defectively designed, the design defect caused her injuries. Finally, Ms. Doe has produced no evidence from which this Court could apply

Maine's danger/utility test: that the risks of the drug's design outweigh by its therapeutic benefits. Even when viewed in a light most favorable to Ms. Doe, Solvay is entitled to summary judgment on the issues of defective design and manufacture.

B. Whether There Was A Failure to Warn: Counts II, III, V, VI and VII.

At its heart, Ms. Doe's claim is a failure to warn claim. She raises this overriding issue under a number of legal theories: Count II – Deceptive Trade Practices Act; Count III – Unfair Trade Practices Act; Count V – Maine's Strict Liability Law; Count VI – Failure to Warn; and Count VII – Fraudulent Misrepresentation. The pith of Ms. Doe's contention can be extracted only by an exegesis of the precise language Solvay used to characterize the risks Luvox presented.

1. Ms. Doe's Contentions: Failure to Warn.

Ms. Doe focuses on three paragraphs in the packing insert label and PDR entry for Luvox. Under the heading, **PRECAUTIONS – General**, the following language appears:

> **Activation of Mania/Hypomania:** During premarketing studies involving primarily depressed patients, hypomania or mania occurred in approximately 1% of patients treated with fluvoxamine. Activation of mania/hypomania has also been reported in a small proportion of patients with major affective disorder who were treated with other marketed antidepressants. As with all antidepressants, LUVOX Tablets should be used cautiously in patients with a history of mania.

Second, Ms. Doe points out the label addresses **INDICATIONS AND USAGE** with the following reference:

> The efficacy of Luvox Tablets was established in two 10-week trials with obsessive compulsive outpatients with the diagnosis of (OCD) as defined in DSM-III-R.

The label refers to the clinical trials section, which further explains:

Clinical Trials

> The effectiveness of Luvox Tablets for the treatment of (OCD) was demonstrated in two 10-week multicenter, parallel group studies of adult outpatients. Patients in those trials were titrated to a total daily fluvoxamine maleate dose of 150 mg/day over the first two weeks of the trial, following which the dose was adjusted within a range of 100-300 mg/day (on a **bid** schedule) on the basis of response and tolerance. Patients in these studies had moderate to severe OCD (DSM-III-R)… Patients receiving fluvoxamine maleate experienced mean reductions of approximately 4 to 5 units on the Y-BOCS total score, compared to a 2 unit reduction for placebo patients.

Third, under the heading "**Other Events Observed During the Premarketing Evaluation of LUVOX Tablets,"** the following warning appears:

> During premarketing clinical trials conducted in North America and Europe, multiple doses of fluvoxamine maleate were administered for a combined total of 2737 patient exposures in patients suffering OCD or Major Depressive Disorder. Untoward events associated with this exposure were recorded by clinical investigators using descriptive terminology of their own choosing. Consequently, it is not possible to provide a meaningful estimate of the proportion of individuals experiencing adverse events without first grouping similar types of untoward events into a limited (i.e. reduced) number of standard nonevent categories.

Turning to the first warning, Ms. Doe fixes on the words, "primarily depressed patients," "major affective disorder," and "antidepressants." Ms. Doe agrees this language would place people with primary depression on notice of a risk of hypomania or mania from the use of Luvox. However, she reads this warning as limited to patients with primary depression, a condition she does not have and never has had. In other words, since the label discusses the manic reaction only in patients with primary depression, Ms. Doe concluded she would not be at risk for a manic episode.

The second and third warnings combine, in Ms. Doe's view, to misinform the patient. Ms. Doe says the reference in the second warning to the two studies is to the studies the FDA used to evaluate the safety of Luvox: 5529 and 5534, which do not

disclose the mania rate for OCD patients. However, Ms. Doe introduced two other published clinical studies in her response to Solvay's motion for summary judgment, but did not offer either in the summary judgment record. She reads both as confirming a high incidence of mania among patients whose primary diagnosis was OCD. The first study, referred to in a letter to the editor of a medical journal, found that 2 patients became manic and 3 hypomanic, a "switch rate" of 25%. James W. Jefferson et al., *Letter to the Editor, Fluvoxamine-Associated Mania/Hypomania in Patients with Obsessive-Compulsive Disorder,* 11 J. Clin. Psychopharmacol. 391 (1991). The second study found "a substantial proportion of OCD patients… in our sample… develop. . . hypomania. . . " J.Rihmer et al., *Antidepressant-induced Hypomania in Obsessive-Compulsive Disorder,* 11 Int'l Clin. Psychopharmacology 203, 204 (1996). It concluded that "the 25% hypomanic/manic switches in (fluvoxamine) treated OCD patients… is much higher than the 1% switchover incidence in patients with depression on the same treatment." *Id.* (actual drug quoted in study was fluoxetine.) She says Solvay failed to reveal these studies and, therefore, the patient with a primary diagnosis of OCD was left without any warning of the true potential for a manic episode.

She is also critical of the third warning, which discusses clinical trials involving 2,737 patients. She says the warnings mix OCD and major depressive disorder patients, who have markedly distinct conditions, and the OCD patient is consequently never informed what the specific risks Luvox poses for her condition.

2. Solvay's Response.

In Solvay's Reply Memorandum, it suggests Doe has engaged in a "willful misreading of undisputed text" in its Luvox label. Regarding the "activation of

mania/hypomania" warning, Solvay says this warning is expressly limited to a study involving patients with primarily depressed patients. It says this implies nothing about those whose primary diagnosis is OCD.

Solvay responded that Ms. Doe's complaints about the second warning misrepresent the facts. Solvay says the incidence rate for mania among all Luvox patients is approximately 1% and there is no separate OCD mania rate. It claims adverse events did not differ in their incidence when comparing patients with OCD and a larger pool of patients with either OCD or depression.

It also disputes Doe's interpretation of the two studies. It contends the Jefferson study was described by the authors as an anomaly when compared with other published studies. They explained the anomaly by the fact "3 of our 5 patients had a history consistent with bipolar disorder." By contrast, most of the other studies had excluded patients with bipolar disorder. Regarding the second study by Rihmer et al., Solvay asserts Doe misquoted the paper. Solvay says the Study uses the term, "fluoxetine," a different antidepressant, not fluvoxamine, and claims Ms. Doe misrepresented the Rihmer study findings.

3. The "Learned Intermediary" Rule.

The point – counterpoint between Ms. Doe and Solvay on the adequacy of the warning would commonly generate a genuine issue of material fact requiring resolution by a jury. *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E. 2d 65, 71 (Mass. 1985) ("Whether a particular warning measures up to (the legal) standard is almost always an issue to be resolved by a jury."). However, Ms. Doe's failure to warn claim is constrained by the application of the "learned intermediary" rule. The learned

intermediary rule was first described by the Eighth Circuit in *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966). Applying Massachusetts law, the First Circuit addressed the rule in *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 80 (1st Cir. 1992):

> "… a product may be unreasonably dangerous if the manufacturer fails to warn of a non-obvious risk associated with the normal use of the product about which the manufacturer knows or has reason to know. (citations omitted) In a typical strict products liability case, the manufacturer's duty to warn extends to the consumer of the product. Where the product is a prescription drug, however, it is widely accepted that the manufacturer's duty to warn runs to the physician rather than the patient. (citation omitted)."

The First Circuit explained the reasoning for the rule:

> "The rationale underlying the prescription drug rule is that the prescribing physician, as the 'learned intermediary' standing between the manufacturer and consumer/patient is generally in the best position to evaluate the potential risks and benefits of ingesting a certain drug and to advise the patient accordingly. Under this doctrine, the manufacturer's duty is fulfilled once it adequately warns the physician."

Id. As *Garside* noted, the learned intermediary rule is "widely accepted." *Id.*; *see Knowlton v. Deseret Medical, Inc.*, 930 F.2d 116, 120 n.2 (1st Cir. 1991)(medical device); *Brochu*, 642 F.2d at 656 (applying New Hampshire law); *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 811 (5th Cir.), *cert. denied*, 504 U.S. 956 (1992); *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992)(applying South Carolina law); *Phelps v. Sherwood Med. Indus.*, 836 F. 2d 296, 303 (7th Cir. 1987)(applying Indiana law); *Kirsch v. Picker Int'l, Inc.*, 753 F.2d 670, 671 (8th Cir. 1985)(applying Missouri law); *Lindsay v. Ortho Pharmaceutical Corp.*, 637 F.2d 87, 91 (2d Cir. 1980)(applying New York law); *Timm v. Upjohn Co.*, 624 F.2d 536, 538 (5th Cir. 1980), *cert. denied*, 449 U.S. 1112 (1981)(applying Louisiana law); *Skill v. Martinez*, 91 F.R.D. 498, 507 (D.N.J. 1981) aff'd, 677 F.2d 368 (3d Cir. 1982); *Goodson v. Searle Laboratories*, 471 F.

Supp. 546, 549 (D. Conn. 1978); *Lareau v. Page,* 840 F. Supp. 920, 931-33 (D. Mass. 1993); *Dunkin v. Syntex Laboratories, Inc.,* 443 F. Supp. 121, 123 (W.D. Tenn. 1977); *Chambers v. G.D. Searle & Co.,* 441 F. Supp. 377, 381 (D. Md. 1975), aff'd per curiam, 567 F.2d 269 (4th Cir. 1977); *Carmichael v. Reitz,* 17 Cal. App. 3d 958, 989 (1971); *Hamilton v. Hardy,* Colo. App. 375, 387 (1976) (overruled on other grounds, *State Bd. of Medical Examiners v. McCroskey*, 880 P.2d 1188 (Colo. 1994)); *Mahr v. G.D. Searle & Co.,* 72 Ill. App. 3d 540, 561 (1979); *Ortho Pharmaceutical Corp. v. Chapman,* 388 N.E. 2d 541, 548 (Ct. .App. Ind. 1979); *Seley v. G.D. Searle & Co.,* 423 N.E.2d 831, 838 (Ohio 1981); *McEwen v. Ortho Pharmaceutical Corp.,* 528 P.2d 522, 529 (Or. 1974); *Leibowitz v. Ortho Pharmaceutical Corp.,* 307 A.2d 449, 457 (Sup. Ct. Pa. 1973). The rule is also incorporated into the Restatement (Third):

> A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to: (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or (2) the patient when the manufacture knows or has reason to know that health-care provider will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

Restatement (Third) of Torts § 6(d).

a. Maine and the Learned Intermediary Rule.

Although the Maine Supreme Judicial Court has never directly addressed the learned intermediary rule, one Maine Superior Court case has applied the rule, citing "overwhelming" national authority. *Tardy v. Eli Lily and Co.,* CV-03-538, 2004 WL 1925536, *2 (Me. Super. Ct. 2004)(Crowley, J.). In *Violette v. Smith & Nephew Dyonics*, 62 F.3d 8, 13 (1st Cir. 1995), the First Circuit applied the learned intermediary rule to a

medical device case on the assumption Maine would adopt the rule. The conclusion is inescapable: if presented with the issue, Maine would adopt the learned intermediary rule.

b. "The Pill" Exception: *McDonald v. Ortho.*

In her memorandum, Ms. Doe cites *McDonald v. Ortho*, a Massachusetts Supreme Judicial Court decision involving oral contraceptives. *McDonald* created an exception to the learned intermediary rule, but only for oral contraceptives. It concluded that the oral contraceptive "stands apart from other prescriptive drugs." *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65, 70 (Mass. 1985). It pointed to the following unique factors: 1) the heightened participation of patients in decisions relating to use of "the pill"; 2) the substantial risks affiliated with the product's use; 3) the feasibility of direct warnings by the manufacturer to the user; 4) the limited participation of the physician (annual physical); and, 5) the possibility that oral communications between physicians and consumers may be insufficient or too scanty standing alone fully to apprise consumers of the product's dangers at the time the initial selection of a contraceptive method is made as well as at subsequent points. *Id.* This Court agrees with Judge Young, who predicted "the Supreme Judicial Court will not further limit the learned intermediary defense, especially in cases… wherein the judgment and skill of the (physician) are paramount." *Lareau*, 840 F. Supp. at 932 n.13.

In this case, this Court concludes the *McDonald* exception does not apply. The psychiatrist in Ms. Doe's case was required to call upon considerable training, judgment, and skill in assessing her condition, reaching a recognized DSM diagnosis, preparing a treatment plan, engaging in ongoing psychotherapy, and prescribing appropriate medications. Even when viewed in a light most favorable to Ms. Doe, the record does

not support the conclusion that it would have been feasible to present the complex set of risks directly to the typical Luvox patient, that her psychiatrist's participation in the selection and risk assessment of Luvox was in any way limited, or that oral communications between psychiatrists and their patients prior to and after the initial selection was insufficient or scanty.

c. Application of the Learned Intermediary Rule.

One escape hatch from the application of the learned intermediary rule is if the Plaintiff can demonstrate it "was reasonably foreseeable that physicians, despite awareness of the dangers of (the drug), would be consciously or subconsciously induced to prescribe the drug when it was not warranted, (the manufacturer) cannot be relieved of liability because of the intervening act of (the doctor) in prescribing the drug while cognizant of its dangers." *Hamilton*, 37 Colo. App. at 387 (quoting *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 664 (1973)). In *Garside*, the First Circuit addressed two presumptions applicable to these cases: (1) a presumption that if an adequate warning is given the physician, it will be read and heeded; and, (2) a rebuttable presumption that if no warning is given or if the warning is inadequate, the failure to adequately warn was a proximate cause of the Plaintiff's ingestion of the drug. *Garside*, 976 F.2d at 80-81 (quoting *Seley*, 423 N.E. 2d at 838. The First Circuit commented that such presumptions are "consistent with the principle followed in this Circuit that a physician's carelessness, even if it takes an unanticipated form, should not relieve a drug manufacturer of liability if the manufacturer's failure to warn adequately may have contributed to that carelessness." *Garside*, 976 F.2d at 81 n.4 (quoting *Brochu*, 642 F.2d at 660).

In *Thomas*, the Fifth Circuit shed additional light on the proper analysis by describing the Plaintiff's burden in failure to warn cases involving prescriptive medicine. *Thomas* said the burden is to produce "either objective evidence of how a reasonable physician would have responded to an adequate warning, or subjective evidence of how the treating physician would have responded. But, to create a jury question, the evidence must be of sufficient weight to establish, by the preponderance of the evidence, at least some reasonable likelihood that an adequate warning would have prevented the plaintiff from receiving the drug." *Thomas*, 949 F.2d at 812.

Application of the learned intermediary rule is fatal to Ms. Doe's failure to warn claim. The record establishes Solvay provided a warning with Luvox and, therefore, under *Thomas*, a warning was given. The remaining question is whether the warning was adequate. On this point, her own treating psychiatrist, who is her only designated expert, testified: 1) before he prescribed Luvox for Ms. Doe, he read the package insert for Luvox (DSMF ¶ 30); 2) he was familiar with the 1997 PDR entry for Luvox when he prescribed it to her (DSMF ¶¶ 32, 57); 3) his practice was to review the PDR entry on any newly prescribed drug with his patients and he discussed potential side effect with Ms. Doe (DSMF ¶ 33); 4) specifically, he discussed with Ms. Doe that Luvox may cause mania in some patients (DSMF ¶ 34); 5) he knows of no potentially adverse consequences not disclosed to him (DSMF ¶ 50); 6) Ms. Doe's reaction was the kind of adverse reaction that Solvay described and disclosed in the Luvox product literature (DSMF ¶ 52); 7) he had no reason to believe Solvay was deceptive or inaccurate in any way in describing Luvox or in its warnings of the risks associated with Luvox (DSMF ¶ 55); 8) then and now, he considered Luvox to be entirely safe and appropriate to

prescribe to patients (DSMF ¶¶ 28, 56); 9) when he prescribed Luvox to Ms. Doe, there was nothing he needed to know about the medication he did not already know (DSMF¶ 58); and, 10) he continues to prescribe Luvox to his patients (DSMF ¶ 60).[11]

An adequate warning is one reasonable under the circumstances. *Brochu*, 642 F.2d at 657. Based on this evidence, there is no genuine issue as to whether her treating physician considered the Solvay warning sufficient. He did. Solvay has the benefit of the *Garside* presumption that the warning was read and heeded, a presumption fully consistent with the record. Further, under *Thomas,* there is no evidence that if the warning had been adequate, she would not have received Luvox, since her treating physician considered the warning adequate and she received Luvox. Finally, there is no objective evidence in the record of how a reasonable physician would have responded, apart from the treating psychiatrist's own response. Despite Ms. Doe's arguments to the contrary, the record evidence in this case, bolstered substantially by the testimony of her treating psychiatrist, compels the conclusion the Luvox warning to her treating doctor, was adequate, that the learned intermediary rule applies, and that Solvay is entitled to

[11] Ms. Doe has entered qualified responses to each of these Statements of Material Fact; she has not denied any of them. The Court has traced each statement to its record citation and has confirmed each statement is properly supported by the record citations. In each case, either her psychiatrist testified directly on point or there is other evidence in the record substantiating the point. None of Ms. Doe's qualified responses disputed that the Statement was corroborated by evidence in the record, but rather challenged its significance. To use a typical example, Ms. Doe made a qualified admission to Solvay's Statement of Material Fact ¶ 30, which states: "(Her psychiatrist) read the package insert for Luvox." Solvay's record citation was to her physician's deposition and her own deposition. In her deposition, she recalled her physician finding the Luvox label: "He got up looked around, found it, sat down, took 15 minutes to read it over completely while I waited. Then we began to discuss it." *Doe Deposition* at 66, ln. 23-24. Ms. Doe made a qualified admission, noting that although her psychiatrist read the label, 1) he was mislead by it; 2) he did not have accurate adverse rates for side effects for OCD patients; 3) Solvay failed to submit study reports to the FDA; 4) he was misled because the label mixed depressed and OCD patient trial results; 5) Luvox was FDA approved only to treat OCD; 6) Solvay included depression data to confuse, mislead and dilute the side effect rates for OCD patients; 7) Solvay violated FDA regulations by including depressed patient data on the label; 8) adverse reactions to Luvox are different between depressed and OCD patients; and, 9) Solvay failed to disclose in the United States label that adverse reactions to Luvox differ between depressed and OCD patients. To comply with the Local Rules, Ms. Doe should have admitted the statement and raised its significance in argument. This Court has taken as admitted the statements 1-10 set forth above because the statements are fully supported by record citations.

summary judgment on Counts II, III, V, VI and VII, since each count is premised on a failure to warn.[12]

C. Count VIII – Punitive Damages.

The failure of Plaintiff's underlying claims causes the failure of her claim for punitive damages. In Maine, punitive damages "will not lie unless the plaintiff receives compensatory or actual damages based on the defendant's tortious conduct." *Jolovitz v. Alfa Romeo Distrib. of N. Am.*, 2000 ME 174, ¶ 11, 760 A.2d 625, 629; *DiPietro v. Boynton*, 628 A.2d 1019, 1025 (Me. 1993).

IV. CONCLUSION

This Court orders that the Defendant's Motion for Summary Judgment be GRANTED.[13]

SO ORDERED.

/s/ John A. Woodcock, Jr.
JOHN A. WOODCOCK, JR.
UNITED STATES DISTRICT JUDGE

Dated this 21st day of December, 2004.

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[12] See footnote 6 above. Since Counts II, III, VI, and VII were based on a failure to warn, summary judgment to each is required. Since Count V is premised on both defective design and manufacture and on failure to warn and this Court has ruled against Ms. Doe on the defective design and manufacture, the Court's ruling on the failure to warn theory mandates judgment in favor of Solvay on that count as well.

[13] Count II – Deceptive Trade Practices Act, Count III – Unfair Trade Practices Act, and Count VII - fraudulent misrepresentation are subject to summary judgment on separate bases. The Deceptive Trade Practices Act provides solely for injunctive relief, which Ms. Doe is not seeking. 10 M.R.S.A. § 1213; *see, e.g., L.L. Bean, Inc. v. Drake Publishers, Inc.*, 629 F. Supp. 644, 647 (D. Me. 1986)("(The DTPA) by its own terms, only provides for injunctive relief and does not support a legal claim."); *Sebago Lake Camps, Inc. v. Simpson*, 434 A.2d 519, 521-22 (Me. 1981). The Unfair Trade Practices Act provides a remedy for "actual damages, restitution and for such other equitable relief, including an injunction, as the court determines to be necessary and proper." 5 M.R.S.A. § 213(1); *see Bartner v. Carter*, 405 A.2d 194, 203 (Me. 1979)("…that language appears to rule out recovery, under the statute, of several kinds of non-restitutionary damages, such as damages for personal injury, mental distress or loss of time."). Ms. Doe does not appear to be making a claim for damages that would be compensable under either the DTPA or the UTPA. The fraudulent misrepresentation claim, based on the evidentiary record before the Court, is grounded on argument, not evidence. However, in view of this Court's determination that summary judgment must be granted on each count for other reasons, it will not engage in a separate analysis as to whether summary judgment would have been otherwise appropriate.

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