UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

NATALIE S. COPASS, Plaintiff, v. NEW ENGLAND COMPOUNDING PHARMACY INC., d/b/a NEW ENGLAND COMPOUNDING CENTER, AMERIDOSE INC., ALAUNUS PHARMACEUTICALS, GREGORY CONIGLIARO, and BARRY J. CADDEN, Defendants.	)	CAUSE NO: 1:12-cv-1638-WTL-TAB

MEMORANDUM IN SUPPORT OF ALAUNUS PHARMACEUTICAL, LLC'S MOTION TO DISMISS

The Defendant, Alaunus Pharmaceutical, LLC, by and through its counsel, hereby moves the Court to dismiss Plaintiff's Complaint for failure to state a claim upon which relief may be granted pursuant to Fed. R. Civ. P. 12(b)(6).

I. INTRODUCTION

This is a products liability action commenced by Natalie S. Copass ("Copass") against New England Compounding Pharmacy, Inc. ("NECC"), Ameridose, LLC ("Ameridose"), Alaunus Pharmaceutical, LLC ("Alaunus"), Gregory Conigliaro ("Conigliaro"), and Barry Cadden ("Cadden"). Plaintiff's Complaint asserts various causes of action collectively against all Defendants arising out of alleged injuries suffered by Copass purportedly from an injection of a steroid compound that she suspects was contaminated with a fungal agent and that she believes was manufactured and/or distributed by the Defendants. *See Pl. Comp*., ¶ 5. Plaintiff's Complaint asserts five (5) causes of action: Count I – Strict Liability, Failure to Warn; Count II – Strict Liability, Dangerously Defective Product; Count III – Negligence; Count IV – Breach of

Implied Warranty; and Count V – Negligent Infliction of Emotional Distress. *Id*., generally. Plaintiff's Complaint should be dismissed for three (3) reasons. First, Counts I – V of the Complaint are subsumed and pre-empted by the Indiana Product Liability Act ("IPLA"). Second, Plaintiff has failed to plead facts sufficient to establish a viable claim for relief under the IPLA. Third, Plaintiff has failed to plead facts sufficient to give rise to a reasonable inference that Alaunus is liable for the misconduct alleged. Plaintiff has failed to plead facts sufficient to give rise to a reasonable inference that Alaunus manufactured or distributed any defective product into the stream of commerce; that Plaintiff suffered a legally compensable injury; that Plaintiff's alleged injuries were caused by the defective product; or, that the product allegedly consumed by Plaintiff is traceable to Alaunus. Plaintiff's Complaint should be dismissed for failure to state a claim pursuant to Rule 12(b)(6).

II. FACTUAL ALLEGATIONS IN THE COMPLAINT

Plaintiff's Complaint alleges that Alaunus is a manufacturer and/or seller of Methylprednisolone Acetate Product ("MAP"), a prescription steroidal medication which is compounded and provided in liquid form thereby requiring an injection for administration. *See Pl. Comp*., ¶ 5. The Complaint further alleges that that MAP at issue was sold and or distributed, to various hospitals and clinics in several states. *Id*., ¶ 6. The Complaint further alleges that certain vials of MAP were contaminated with a fungus capable of causing fungal meningitis. *Id.*, ¶¶ 7 – 9. The Complaint also asserts that when certain vials of MAP, which did not contain an alcohol preservative, were administered by licensed medical providers into the spine of the patients, "the patients were subjected to infection as a result of potential contact with fungus that had not been eradicated before the solution was injected." *Id.*, ¶¶ 24, 25. The Plaintiff claims that the vials of MAP were defective because they did not contain any alcohol preservative,

thereby increasing the risk of contamination of the product, *id.* at ¶ 37, and that the labeling that accompanied the MAP vials was inadequate for the purposes of warning of the potential adverse effects of administration of MAP injections. *Id.*, ¶ 40. Plaintiff concedes; however, that it is unknown if all of the vials of MAP were actually contaminated with disease causing fungus. *Id.*, ¶ 42.

As to Plaintiff Copass, the Complaint alleges that Copass was referred to Wellspring Pains Solutions Clinic ("Wellspring") in Columbus, Indiana seeking back pain relief, where she received two spinal injections of MAP from Dr. Robertson, on July 31, 2012, and a third spinal injection of MAP on August 22, 2012. *Id.*, ¶¶ 46 – 48. Since receiving the MAP injections, the Complaint alleges that Copass has experienced headaches, episodes of blurred vision and discomfort when lowering her chin to her chest. *Id.*, 49. However, the Complaint does not allege that Copass has contracted spinal meningitis or any other disease from her injections. Nevertheless, Plaintiff asserts, on information and belief, that she is at risk of developing meningitis because she received a letter from Wellspring informing her that "several other patients had developed meningitis following an epidural steroid injection using Defendants' product due to contamination by Aspergillus, a mold" and Dr. Robertson informed her on October 11, 2012 that "she had received three Contaminated Steroid Injections manufactured, sold and distributed by Defendants." *Id.*, ¶¶ 50 – 51.

The Complaint does not specify any facts that might identify the product to sufficiently give rise to a reasonable inference that the product was manufactured by Alaunus. The Complaint does not identify the name of the manufacturer listed on the label of the MAP injection vials that were allegedly distributed to Wellspring; the lot number, production date, and size/volume of the injection vials in Wellspring's inventory; whether the product administered by

Wellspring on the Plaintiff was brand name or generic; or, whether the product used by Wellspring on the Plaintiff was preservative-free or not. Plaintiff's Complaint is devoid of any factual specifics that would sufficiently put Alaunus on notice of a viable claim.

III. STANDARD OF REVIEW

Pursuant to Federal Rule of Civil Procedure 12(b)(6), a motion to dismiss for failure to state a claim may be granted if a plaintiff fails to plead any set of facts that would support a state of claim for relief. *See Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955 (2007); *Holman v. Indiana*, 211 F.3d 399, 402 (7th Cir. 2000). In ruling on a motion to dismiss, this Court must accept as true all facts asserted in the Complaint and draw all reasonable inferences from them in plaintiff's favor. *Id*. However, to survive a motion to dismiss, plaintiff must allege "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. Plaintiff's factual allegations are required to show that his claim for relief is more than "speculative" or merely "conceivable;" her claim must be "plausible on its face." *Id*. at 570 ("[b]ecause the plaintiffs here have not nudged their claims across the line from conceivable to plausible, their complaint must be dismissed").

To have facial plausibility, the complaint must contain "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937 (2009). The *Twombly-Iqbal* plausibility standard implicates a two-step analysis. *Iqbal*, 129 S.Ct. at 1950. First, the court must separate the complaint's factual allegations (which must be accepted as true) from its conclusory legal allegations (which need not be credited). *Iqbal*, 129 S.Ct. at 1950, citing *Twombly*, 127 S.Ct. 1955. Second, the court must determine whether the well-pleaded, non-conclusory factual allegations give rise to a plausible inference that the defendant is liable for the misconduct

alleged. *See Iqbal*, 129 S.Ct. at 1950, *citing Twombly*, 127 S.Ct. 1955. Where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint should be dismissed because it has alleged – but it has not "shown" – "that the pleader is entitled to relief." *Iqbal*, 129 S.Ct. at 1950.

IV. ARGUMENT

A. Plaintiff's Complaint Asserts Only Conclusory Assertions against Alaunus Which Should be Disregarded by the Court.

On a motion to dismiss, "a plaintiff's obligation to provide the 'grounds' of [his] 'entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 127 S.Ct. at 1965. A court need not accept as true "legal conclusions or threadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Brooks v. Ross*, 578 F. 3d 574, 581 (7th Cir. 2009) (citing *Iqbal*).[1] When a plaintiff alleges a fact "upon information and belief," the assertion signifies that the "allegations are based on secondhand information that [the asserting party] believes to be true." *Pirelli Armstrong Tire Corp. Retiree Med. Benefits Trust v. Walgreen Co.*, 631 F.3d 436, 442 (7th Cir. 2011) (quoting Black's Law Dictionary 783 (7th ed. 1999); *Zuk v. E. Pa. Psychiatric Inst. of the Med.Coll. of Pa.*, 103 F.3d 294, 299 (3d Cir. 1996).

In the absence of factual allegations of secondhand information that the plaintiff believes to be true which logically compels or supports an allegation that is made "upon information and belief," such an allegation is merely a conclusory assertion that should not be deemed to be true by the court on a motion to dismiss. *See Twombly*, 127 S.Ct. at 1962-1963, 1970. "Conclusions"

[1] *See also Maldonado v. Fontanes*, 568 F.3d 263, 266 (1st Cir. 2009) (naked assertions devoid of further factual enhancement need not be accepted on a 12(b)(6) motion); *Barrington Cove Ltd. Partnership v. Rhode Island Housing and Mortg. Finance Corp.*, 246 F.3d 1 (1st Cir.2001) (ruling that the court should not credit "conclusory assertions, subjective characterizations, or outright vituperation").

only become "facts" for pleading purposes when conclusions are logically compelled, or at least supported, by the stated facts, as well as the reasonable inferences drawn therefrom. *Iqbal*, 129 S.Ct. at 1950 (conclusions are not entitled to the assumption of truth where they are not supported by factual allegations); *Brooks*, 578 F. 3d at 581; *The Dartmouth Review v. Dartmouth College*, 889 F.2d 13, 16 (1st Cir. 1989) (same).

The conclusion that Alaunus was jointly involved in the manufacture, marketing, distribution, and sale of MAP, *Pl. Comp.*, ¶¶ 5, 26, and that Alaunus is merely an alter-ego of NECC and/or Ameridose, *id.* at ¶ 20, is not supported by any specific factual allegations in the Complaint and therefore must be disregarded. Ostensibly, Plaintiff bases these conclusions on scant allegations which are predominately made upon information and belief. The Complaint asserts that Alaunus has a principal place of business next door to that of NECC's, *id.*,¶ 15; that NECC, Alaunus and Ameridose share common officers and managers, *id.*, ¶¶ 16, 19, and therefore Alaunus holds itself out as a pharmaceutical developer and distributor for NECC and Ameridose. *Id.*, ¶ 15.

The allegation that Alaunus holds itself out as a pharmaceutical developer and distributor for NECC and Ameridose must be disregarded as it is not supported by any facts in the Complaint. *See Maldonado v. Fontanes*, 568 F.3d 263, 266 (1st Cir. 2009) (naked assertions devoid of further factual enhancement need not be accepted on a 12(b)(6) motion); *Barrington Cove Ltd. Partnership v. Rhode Island Housing and Mortg. Finance Corp.*, 246 F.3d 1 (1st Cir.2001) (ruling that the court should not credit "conclusory assertions, subjective characterizations, or outright vituperation"). Even assuming for the purposes of a motion to dismiss that there was common ownership and management between Alaunus, NECC, and Ameridose, such facts do not logically compel or even support an inference that Alaunus was the

alter-ego of another entity and therefore jointly involved in the manufacture and distribution of MAP. *See United States v. Bestfoods*, 524 U.S. 51, 69 (1998) (overlap in directors or officers among affiliated corporate entities is not unusual, and is widely held to be insufficient to establish alter ego liability alone); *Steven v. Roscoe Turner Aeronautical*, 324 F.2d 157, 161 (7th Cir. 1963) ("[w]hile stock control and common directors and officers are generally prerequisites for application of the instrumentality rule, yet, they are not sufficient by themselves to bring the rule into operation").[2]

There are simply no ***factual allegations*** which remotely support that theory that Alaunus is merely an alter-ego of NECC or that Alaunus was jointly involved in the manufacturing, distribution, and sale of MAP. There are only conclusory assertions masquerading as factual allegations which should not be taken as true on a motion to dismiss. *See Twombly*, 127 S. Ct. at 1966 (refusing to accept conspiracy allegation as true because "an allegation of parallel conduct and a bare assertion of conspiracy will not suffice"); *Brooks*, 578 F. 3d at 582 (refusing to accept as true allegations of malicious prosecution since they were merely a formulaic recitation of the cause of action and nothing more); *Resolution Trust Corp. v. Driscoll*, 985 F.2d 44, 48 (1st Cir. 1993) (affirming dismissal of claims against corporate defendant because naked assertion of alter ego liability was not supported by sufficient factual allegations).[3] These formulaic, conclusory

[2] In determining whether a corporation is merely an alter-ego of another corporation, the courts consider whether (1) similar corporate names were used; (2) the corporations shared common principal corporate officers, directors, and employees; (3) the business purposes of the corporations were similar; (4) the corporations were located in the same offices and used the same telephone numbers and business cards; (5) there was intermingling of business transactions, functions, property, employees, funds, records, and corporate names in dealing with the public. *See Ziese & Sons Excavating, Inc. v. Boyer Constr. Corp.*, 965 N.E.2d 713, 719 (Ind. Ct. App. 2012).

[3] *See also De Jesus v. Sears, Roebuck & Co.*, 87 F.3d 65, 70 (2d Cir. 1996) (granting 12(b)(6) motion to dismiss since complaint was "devoid of any specific facts or circumstances supporting" liability of an individual on a veil piercing theory); *Lovely Peoples Fashion, Inc. v. Magna Fabrics, Inc.*, 95 CIV. 8450 AGS, 1996 WL 732634, *5 (S.D.N.Y. Dec. 19, 1996) (granting motion to dismiss against individual shareholders for failure to "state some basis in fact for piercing the corporate veil" where complaint's sole allegation was that shareholders "control and operate the [corporation] as their alter egos for the benefit of themselves and their families"); *Centrifugal Air Pumps Australia v. TCS Obsolete, LLC*, 610-CV-820-ORL-31DAB, 2010 WL 3584948 at *2 (M.D. Fla. Sept. 9, 2010)

allegations should be disregarded by the Court.

B. Counts I – V of Plaintiff's Complaint Are Subsumed by the IPLA and Must be Dismissed.

The Indiana Products Liability Act ("the IPLA") governs ***all*** product liability actions brought by a user or consumer,[4] against a manufacturer[5] or seller,[6] for physical harm caused by a product, ***regardless of the substantive legal theory of theories upon which the action has been brought***. Ind. Code § 34-20-1-1 (emphasis added); *Stegemoller v. ACandS, Inc.*, 767 N.E.2d 974, 976 (Ind. 2002); *Campbell v. Supervalu, Inc.*, 565 F.Supp.2d 969, 976 (N.D. Ind. 2008) (plaintiff's "attempt to cast [defendant]'s action as one of 'simple negligence,' and therefore somehow falling outside the reach of the Indiana Product Liability Act, clearly fails"); *Cincinnati Ins. Cos v. Hamilton Beach/Proctor-Silex, Inc.*, 2006 U.S. Dist. LEXIS 9807, at *2 (N.D. Ind. Feb. 7, 2006); *Ryan v. Philip Morris USA, Inc.*, 2006 U.S. Dist. LEXIS 9077, at *9 (N.D. Ind. Feb. 22, 2006); *Conley v. Lift-All Co.*, 2005 U.S. Dist. LEXIS 15468, 12-13 (S.D. Ind. July 25, 2005) ("[t]he IPLA effectively supplants [] common law claims because all [] claims are brought by a user or consumer against a manufacturer for physical harm caused by a product. Plaintiff's common law claims will therefore be treated as merged into the IPLA claims.").

(plaintiff's failure to plead facts in support of its conclusory veil piercing allegations required dismissal of individual LLC members from action).

[4] The IPLA defines a user or consumer, in relevant part, as "a purchaser, or any individual who uses or consumes the product." Ind. Code § 34-6-2-29.

[5] A manufacturer is defined as "a person or an entity that designs, assembles, fabricates, produces, constructs, or otherwise prepares a product or a component part of a product before the sale of the product to a user or consumer." Ind. Code § 34-6-2-77. The definition of a manufacturer includes a seller who (1) has actual knowledge of a defect in the product; (2) creates and furnishes a manufacturer with specifications relevant to the alleged defect for producing the product or who otherwise exercises some significant control over all or a portion of the manufacturing process; (3) alters or modifies the product in any significant manner after the product comes into the sellers possession and before it is sold to the ultimate user or consumer; (4) is owned in whole or significant part by the manufacturer; or, owns in whole or significant part the manufacturer. Ind. Code § 34-6-2-77(a).

[6] A seller is defined as "a person engaged in the business of selling or leasing a product for resale, use, or consumption." Ind. Code § 34-6-2-136.

Plaintiff's Complaint predicates its manufacturing defect and failure to warn claims under theories of strict liability, negligence, breach of implied warranties, and negligent infliction of emotional distress. Even putting aside the conclusory assertions in the Complaint, Plaintiff's common law claims for strict liability, negligence and negligent infliction of emotional distress claim (Counts I – III and V) are pre-empted or subsumed by the IPLA as a matter of law. *See Atkinson v. P & G-Clairol, Inc*. 813 F.Supp.2d 1021 (N.D. Ind. 2011) (negligence and strict liability claims subsumed); *Ganahl v. Stryker Corp.*, No. 1:10-cv-1518-JMS-TAB, 2011 WL 693331, at *3 (S.D. Ind. Feb. 15, 2011) (negligence and strict product liability claims subsumed); *American Intern. Ins. Co. v. Gastite*, 2009 WL 1383277, *2 (S.D. Ind. 2009); (negligence and strict liability claims subsumed under IPLA); *Ryan v. Philip Morris USA, Inc.*, No. 1:05CV162, 2006 WL 449207 (N.D. Ind. 2006) (negligence and fraud claims subsumed under IPLA); *Henderson v. Freightliner*, LLC, 2005 WL 775929 (S.D. Ind. 2005) (negligence claim subsumed); *McGookin v. Guidant Corp.*, 942 N.E.2d 831 (Ind. App. January 21, 2011 (observing that trial court merged claims for negligence, negligence *per se*, actual and constructive fraud, intentional and negligent infliction of emotional distress, and the Indiana Deceptive Consumer Sales Act, into a single cause of action under the Indiana Products Liability Act).

Plaintiff's claims for breach of implied warranties (Count IV) are also subsumed by the IPLA. "The Indiana Court of Appeals and several federal district courts sitting in Indiana have all held that tort-based breach of warranty claims have been subsumed into the [I]PLA." *Hathaway v. Cintas Corporate Services*, No. 1:10 CV 195, 2012 WL 4857828, at *2 (N.D. Ind. Oct. 11, 2012) (Moody, J.).[7] Because Copass's claim for breach of implied warranty is based in

[7] *See also Atkinson v. P&G-Clairol, Inc*., 813 F. Supp. 2d 1021, 1025 (N.D. Ind. 2011); *Cincinnati Ins. Cos. v. Hamilton Beach/Proctor–Silex, Inc.*, No. 4:05 CV 49, 2006 WL 299064, at *3 (N.D. Ind. Feb.7, 2006); *N.H. Ins. Co. v. Farmer Boy AG, Inc.*, No. IP 98–0031–C–T/G, 2000 WL 33125128, at *3 (S.D. Ind. Dec.19, 2000); *Condon v. Carl J. Reinke & Sons, Inc.*, 575 N.E.2d 17, 18 (Ind.Ct.App.1991).

tort, the IPLA provides the exclusive remedy, thereby barring any common law cause of action for breach of warranty. *Id.*, at *3 (holding that plaintiff's common law claims for breach of express and implied warranties arising out of severe burn injuries from spark created by machine used to cut metal were subsumed under IPLA); *Atkinson v. P&G-Clairol, Inc.*, 813 F. Supp. 2d 1021, 1025 (N.D. Ind. 2011) (warranty claim based in tort supplanted by IPLA).

Copass's breach of implied warranty claim is further pre-empted by the IPLA because the claim is based in tort, and Plaintiff has not sought recovery for damage to the product itself or any economic loss arising from the failure of the product to work as expected. *See Hathaway, supra*, 2012 WL 4857828 at *2, citing *Gunkel v. Renovations, Inc.*, 822 N.E.2d 150, 153 (Ind. 2005) ("Indiana law under the Products Liability Act and under general negligence law is that damage from a defective product or service may be recoverable under a tort theory if the defect causes personal injury or damage to other property, but contract law governs damage to the product or service itself and purely economic loss arising from the failure of the product or service to perform as expected").

Indiana's IPLA, as well as the case law interpreting the Act, clearly instruct that claims involving allegedly defective products are exclusively governed by the IPLA, thereby precluding all other tort claims. Accordingly, Counts I – V of Plaintiff's Complaint asserting common law claims are subsumed by the IPLA and must be dismissed. Additionally, because Plaintiff has failed to assert a claim under the IPLA, each common law claim is subject to dismissal. *See Kirksey v. R.J. Reynolds Tobacco Co.*, 168 F.3d 1039, 1042 (7th Cir. 1999) ("a claim that does not fit into an existing legal category requires more argument by the plaintiff to stave off dismissal, not less, if the defendant moves to dismiss on the ground that the plaintiff's claim has no basis in law").

C. Plaintiff's Complaint Fails to State a Claim Under the IPLA

Even if this Court were to indulge the Plaintiff by treating the Complaint as if it pled a claim under the IPLA – which it does not – the Complaint nevertheless fails to state a viable claim for relief under the IPLA. When Indiana Code sections 34-20-1-1 and 34-20-2-1 are read together, there are five (5) unmistakable threshold requirements for IPLA liability: (i) a claimant who is a user or consumer and is also in the class of persons that the seller should reasonably foresee as being subject to the harm caused; (ii) a defendant that is a manufacturer or a seller engaged in the business of selling a product; (iii) physical harm caused by a product; (iv) a product that is in a defective condition unreasonably dangerous to a user or consumer or to his property; and, (v) a product that reached the user or consumer without substantial alteration in its condition. *See* Ind. Code 34-20-1-1; 34-20-1-2. Plaintiff's Complaint falls short of satisfying any of these elements. *Williams v. REP Corp.*, 302 F.3d 660 (7th Cir. 2002).

First, Copass does not meet the "physical harm" requirement under the statute. To recover under the IPLA, a plaintiff must show that her use of a product caused her "physical harm." IND. CODE § 34-20-2-1; *Doerner v. Swisher Intern., Inc.*, 272 F.3d 928, 931 (7th Cir. 2001). Physical harm is defined as "bodily injury, death, loss of services, and rights arising from any such injuries, as well as sudden, major damage to property." IND. CODE § 34-6-2-105; *Doerner*, 272 F.3d at 931. "Mental distress does not qualify as a 'physical harm' under the IPLA." *Doerner*, 272 F.3d at 932.

Plaintiff's Complaint alleges symptoms such as "headaches, blurred vision, and discomfort when lowering her chin to her chest," which according to the FDA-approved labeling are known side effects of ***non-contaminated*** methylprednisolone acetate.[8] Notably, clinical

[8] This Court may consider the contents of the FDA-approved labeling for methylprednisolone acetate on a motion to dismiss under Rule 12(b)(6) without converting the motion to one for summary judgment because it is an official

administration of brand-name**,** non-contaminated methylprednisolone acetate has been associated with various adverse reactions including, among other things, moderate to severe headaches, chest/neck/back pain, flu-like symptoms, meningitis and various neurological and psychiatric conditions.[9]

Moreover, although the Plaintiff does not claim that she has been diagnosed with spinal meningitis or any other disease as a result of her MAP injections, the FDA-approved labeling of for the brand-named ***non-contaminated version*** of MAP also lists meningitis as a serious adverse reaction associated with ***non-contaminated*** product. Therefore, it is insufficient to suggest that the MAP injection Copass allegedly received was contaminated simply because "other patients developed meningitis following an epidural steroid injection using the Defendants' products." *See Pl. Comp*., ¶ 50.

Plaintiff's Complaint does not plead anything more than a possibility that Copass ***might*** have been exposed to fungal contamination and that she ***might*** contract some disease in the future. Fear of contracting a disease is not sufficient to demonstrate an actual injury. *See In re Bridgestone/Firestone, Inc.*, 288 F.3d 1012, 1017 (7th Cir. 2002) (noting that "most states would not entertain" no-injury products liability cases); *Martin v. American Medical Systems, Inc.*, 1995 WL 680630 (S.D. Ind. Oct. 25, 1995) (risk of implant failure is insufficient injury); *R.E.G.*

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public record susceptible to judicial notice under Federal Rule of Evidence 201 and/or a document central to the Plaintiff' claim. *See Watterson v. Page*, 987 F.2d 1, 3 (1st Cir. 1998); *City of Sausalito v. O'Neill*, 386 F.3d 1186, 1223 n.2 (9th Cir. 2004) ("We may take judicial notice of a record of a state agency not subject to reasonable dispute"); *O'Toole v. Northrop Grumman Corp.*, 499 F.3d 1218, 1225 (10th Cir. 2007) ("It is not uncommon for courts to take judicial notice of factual information found on the world wide web"); *New Mexico ex rel. Richardson v. Bureau of Land Management*, 563 F.3d 683 (10th Cir. April 28, 2009) (No. 06-2352, 06-2353, 06-2354) (taking judicial notice of releases which were referred to on the websites of two federal agencies because it was not subject to reasonable factual dispute and is capable of determination using sources whose accuracy cannot reasonably be questioned).

[9] *See* U.S. FDA, MedWatch: The FDA Safety Information and Adverse Event Reporting Program, Safety Information – Depo-Medrol/S-085 Label (brand named methylprednisolone acetate injectable suspension, USP), available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/011757s085s086lbl.pdf (accessed Jan. 3, 2013).

v. L.M.G., 571 N.E.2d 298 (Ind. Ct. App. 1991) (wife cannot recover against husband due to possible exposure to HIV merely because he was at high risk for contracting disease).[10]

Second, the Complaint does not sufficiently allege that Defendant Alaunus is a "manufacturer" or a "seller" engaged in the business of selling MAP. The Complaint asserts no factual allegations showing[11] that Alaunus designed, assembled, fabricated, produced, constructed, or otherwise prepared MAP or any of its components prior to its sale. Plaintiff's Complaint does not specify the name of the manufacturer listed on the labeling of the product, the lot number or product code of any product used or consumed, whether the product was brand name or generic, or the type and strength of the drug or compound. As set forth above, all of the allegations that Alaunus was jointly involved in the manufacture and sale of MAP are nothing more than unsupported conclusory assertions that must be disregarded by this Court.

Because the Plaintiff has failed to show that Alaunus is a "manufacturer" or "seller," the Complaint does not state a plausible claim under the IPLA. *See Williams v. REP Corp.*, 302 F.3d 660, 666 (7th Cir. 2002) (defendant that did not sell, lease or otherwise put into the stream of commerce the machine that caused plaintiff's injury could not be held liable under IPLA);

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[10] *See also Rothschild v. Tower Air, Inc.*, 1995 WL 71053 (E.D. Pa 1995) (refusing recovery for fear of HIV because the plaintiff failed to show that the needle she was accidentally pricked by was contaminated with HIV); *Mink v University of Chicago*, 460 F. Supp. 713 (N.D. Ill. Mar. 17, 1978) (increased risk and/or fear of future serious disease from exposure to DES is not sufficient injury); *Burk v. Sage Products, Inc.*, 747 F. Supp. 285 (E.D. Pa. Sept. 27, 1990) (fear of AIDS from needlestick was not sufficient injury, without proof of actual exposure); *Watkins v. Omni Life Science Inc.*, 2010 WL 809820, slip op. (D. Mass. March 9, 2010) (fear of future harm from potential failure of hip implant is not sufficient injury); *Aberbach v. Biomedical Tissue Services, Ltd.*, 854 N.Y.S.2d 143 (N.Y. App. Div. Feb. 26, 2008) ("potential" for infection by bone paste is not sufficient injury); *Plummer v. Abbott Laboratories*, 568 F. Supp. 920 (D.R.I. July 1, 1983) (same); *Hagepanos v. Shiley, Inc.*, 846 F.2d 71 (unpublished), 1988 WL 35752 (4th Cir. Apr. 18, 1988) (applying Maryland law) (increased risk/fear of heart valve failure is not sufficient injury to recover under theories of negligence, strict liability, express warranty, and implied warranty); *In re Louie*, 213 B.R. 754, 758 (N.D. Cal. 1997) (stating a plaintiff cannot just suspect he has a disease or have been exposed to a disease); *Kerins v. Hartley*, 27 Cal. App. 4th 1062 (Cal. App. 1994) (fear of contracting AIDS not sufficient); *Barrett v. Danbury Hosp.*, 654 A.2d 748 (Conn. 1995) (no recovery for AIDS phobia).

[11] Where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint should be dismissed because it has alleged – but it has not "shown" – "that the pleader is entitled to relief." *Iqball*, 129 S.Ct. at 1950.

Chappey v. Ineos USA L.L.C., No. 2:08-CV-271, 2009 U.S. Dist. LEXIS 24807 (N.D. Ind. Mar. 23, 2009) (dismissing IPLA claim concluding that the plaintiff had "not alleged that INEOS was a manufacturer or a seller of any product" and that she likewise had "failed to specifically identify a product").[12]

Third, Plaintiff's Complaint does not sufficiently allege that the MAP injection Copass allegedly received suffered from a manufacturing defect by virtue of fungal contamination. While the Complaint alleges that contaminated MAP was distributed into interstate commerce, it does plead facts sufficient to give rise to a reasonable inference that this product was manufactured and/or distributed by Alaunus. The Complaint does not identify the lot numbers of the injection vials that were distributed to Copass's medical providers; the lot number or product code of the injection vial that was used to treat Copass; the name of the manufacturer listed on the injection vial that was allegedly given to Copass; the volume of the injection vial, or whether Copass received preservative-free formula or not. Plaintiff's Complaint does not establish any connection between the allegedly contaminated product distributed into the stream of commerce and the product that Copass allegedly received. Accordingly, the Complaint does not give rise to a reasonable inference that Copass received an injection of contaminated product simply because other people claim to have received injections of contaminated MAP. *See Smith v. Michigan*

[12] *See also Patterson v. Novartis Pharmaceuticals Corp.*, 451 Fed. Appx. 495 (6th Cir. Aug. 23, 2011) (affirming dismissal for failure to state a claim because Massachusetts law requires that a plaintiff suing a manufacturer in a product-liability action be able to prove that his or her injury can be traced to that specific manufacturer and the factual allegations in the complaint only permitted the Court to infer the possibility that the plaintiff received infusions of the name-brand drug, Aredia, manufactured by Novartis, as opposed to the generic equivalent manufactured by some other manufacturer); *In re Fosamax Products Liability Litigation*, 2010 WL 1654156 (S.D.N.Y. April 9, 2010) (dismissing all product liability claims on grounds that plaintiff's complaint failed to allege sufficient facts to identify manufacturer of product observing that statement in the complaint that "Defendants, either directly or through [their] agents, apparent agents, servants, or employees, at all relevant times, designed, tested, developed, manufactured, labeled, marketed, distributed and sold Fosamax and Boniva" was conclusory since the complaint did not provide any specifics to support such a conclusion); *Johnson v. Moog, Inc.*, 2011 WL 719600 (E.D. Tex. Feb. 22, 2011) (all claims in medical device case dismissed under *Twombly-Iqbal* because the pleading asserted only that unknown "defendants" committed actions and failed to state sufficient facts to identify defective product).

Beverage Co., 495 F.2d 754, 757 (7th Cir. 1974) ("[j]ust as it is the general rule that the mere fact of injury will not create an inference of negligence, the mere fact of the accident cannot create an inference of a defect in a products case") (applying Indiana law); *Gaskin v. Sharp Electronics Corp.*, 2007 WL 2819660, *5 (N.D. Ind. Sept. 26, 2007) ("the mere fact that an accident occurred does not create an inference of a defect in a products liability case").[13]

Plaintiff's Complaint also does not plead sufficient facts to identify Alaunus as the manufacturer of the allegedly defective MAP injection. Given that the Complaint does not establish ***any*** connection between the allegedly contaminated product and the product Plaintiff supposedly received from her physician, the Complaint does not give rise to a reasonable inference that Plaintiff received an injection of a contaminated product from Alaunus, or that Alaunus is liable for the alleged misconduct**.** *See Iqball*, 129 S.Ct. at 1950 (where the well pleaded facts do not permit the court to infer more than a mere possibility of misconduct the complaint should be dismissed because it has alleged but not shown that the pleader is entitled to relief.)

In sum, Plaintiff has woefully failed to plead sufficient facts to give rise to a reasonable inference that Alaunus may be held liable under the IPLA. Consequently, Counts I – V of Plaintiff's Complaint should be dismissed for failure to state a claim pursuant to Fed.R.Civ.P. 12(b)(6). Plaintiff's Complaint is subject to dismissal based on the IPLA alone; however, even without the IPLA, Plaintiff's Complaint fails for additional reasons discussed below.

D. Plaintiff's Failure to Warn Claim (Count I) Fails Under the Learned Intermediary Doctrine and Should be Dismissed for Failure to State a Claim

Even if this Court were to find that Plaintiff's failure to warn claim (Count I) is not

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subsumed by the IPLA – which it is – the claim nevertheless fails under the learned intermediary doctrine. *See Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E.2d 541, 548-549 (Ind. Ct. App. 1979) (since drugs are available only by prescription, a manufacturer's duty to warn extends only to the medical profession, not the ultimate users); *Phelps v. Sherwood Med. Indus*., 836 F.2d 296, 303 (7th Cir. 1987); *Menges v. DePuy Motech, Inc*., 61 F.Supp.2d 817, 830 (N.D. Ind. 1999).

In *Phelps*, the Seventh Circuit (applying Indiana law) held that the "duty to warn of hazards associated with prescription drugs is part and parcel of the physician-patient relationship." *Phelps*, 836 F.2d at 303, *citing Ingram v. Hook's Drugs, Inc.*, 476 N.E.2d 881, 886 (Ind. Ct. App. 1985). The duty of drug manufacturers is initially to warn of risks by alerting the doctors who then use their training to determine whether to prescribe the drug. *Phelps*, 836 F.2d at 303 (internal citations omitted). A manufacturer of prescription drugs discharges its duty to warn by warning the physician's patient who then has the duty to inform himself of the drug's propensities before using them on his patients. *Id.*, *citing Ortho Pharmaceutical Corp., supra*.[14]

Plaintiff's claim that Alaunus beached a duty to warn by failing to provide adequate warnings to the Plaintiff fails as a matter of law under the learned intermediary doctrine. Plaintiff's Complaint acknowledges that the MAP injection Copass received was administered by Dr. Robertson. *See Pl. Compl*., ¶¶ 47, 48. Therefore, the manufacturer's duty to warn of the potential adverse reactions associated with the use of MAP was to Dr. Robertson, not Plaintiff. *See Phelps*, 836 F.2d at 303 (manufacturer of catheter had no duty to warn users of the catheter other than the operating surgeon who installed the catheter); *Ziliak v. AstraZeneca LP*, 324 F.3d

[14] The duty of a pharmacist is the same as that as of a manufacturer in these circumstances. *See Peters v. Judd Drugs, Inc.*, 602 N.E.2d 162 (Ind. Ct. App. 1992) (pharmacy that had no direct contact with patient had no duty to warn patient of adverse drug effects); *Hook's SuperX, Inc. v. McLaughlin*, 642 N.E.2d 514 (Ind. 1994) (duty to warn patients of adverse effects of drugs generally lies with physician, not pharmacist); *Allberry v.Parkmore Drug, Inc*., 20A03-0503-CV-125, (Ind. Ct. App. Sept. 16, 2005) (finding no pharmacist duty to warn patient of side effects nor a pharmacist duty to give patient the manufacturer's product information, containing warnings, that wasn't included in prescription itself).

518 (7th Cir. 2003) (applying Indiana law) (inhaler manufacturer absolved of strict liability in products liability action brought by asthma patient where the prescribing doctor was aware of the inhaler's warnings and the doctor took the risks that patient would develop adverse side effects into account when prescribing the inhaler).

E. Plaintiff's Negligent Infliction of Emotional Distress Claim (Count V) Should Also be Dismissed for Failure to State a Claim

Similarly, even if Plaintiff's negligent infliction of emotional distress claim (Count V) was not subsumed by the IPLA – which it is – this claim still fails to state a claim for emotional distress. In *Spangler v. Bechtel*, 958 N.E.2d 458 (Ind. 2011), the Indiana Supreme Court explained Indiana's negligent infliction of emotional distress jurisprudence:

> "[I]ndependent, stand-alone actions for negligent infliction of emotional distress are not cognizable in Indiana. But actions seeking damages for emotional distress resulting from the negligence of another are permitted in two situations: where the plaintiff has (1) witnessed or come to the scene soon thereafter the death or severe injury of certain classes of relatives (i.e., the bystander rule) or (2) suffered a direct impact (i.e., the modified impact rule).

Spangler, 958 N.E.2d at 466 (citations omitted). The "modified impact rule" is "properly understood as being 'physical' in nature." *Ross v. Cheema*, 716 N.E.2d 435, 437 (Ind. 1999). In order to succeed under the modified impact rule, Plaintiff must show that she sustained a direct impact as a result of Alaunus's alleged negligence and that as a result of this "direct impact" she suffered an emotional trauma "which is serious in nature and of a kind and extent normally expected to occur in a reasonable person. . . " *Shuamber v. Henderson*, 579 N.E.2d 452, 456 (Ind.1991), citing *Webb v. Jarvis*, 575 N.E.2d 992, 995 (Ind. 1991).

As set forth above, Plaintiff's Complaint is woefully devoid of any ***factual allegations*** to give rise to a reasonable inference that the MAP injection Plaintiff received was actually manufactured by Alaunus. Therefore, it is even more tangential to suggest that Plaintiff was

"directly impacted" by a harm she has not even established is attributable to Alaunus. To survive a motion to dismiss, Plaintiff's factual allegations must be more than "speculative" or merely "conceivable;" her claim must be "plausible on its face." *Twombly*, 550 U.S. at 570. To have facial plausibility, the complaint must contain "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. Plaintiff's Complaint has not satisfied the *Twombly-Iqbal* standard. Plaintiff's negligent infliction of emotional distress claim fails because Copass has not alleged sufficient ***facts*** to give rise to a reasonable inference of Alaunus's negligence.

F. Plaintiff's Breach of Warranty Claim (Count IV) Should Also be Dismissed for Failure to State a Claim Due to Lack of Privity and Lack of Causation

Similarly, even if Plaintiff's breach of warranty claims (Count IV) were not subsumed by the IPLA – which they are – these claims still fail because Plaintiff has not pled facts showing the existence of vertical privity. Vertical privity is required for claims of breach of express warranty. *Davidson v. John Deere & Co.*, 644 F. Supp. 707, 713 (N.D. Ind. 1986) (finding that the plaintiff did not have a claim for breach of express warranty because "[p]rivity has not been abrogated as a requirement in contract actions for breach of warranty"). "Simply put, vertical privity exists only between immediate links in a distribution chain. A buyer in the same chain who did not purchase directly from a seller is 'remote' as to that seller." *Hyundai Motor Am., Inc. v. Goodin*, 822 N.E.2d 947, 952 (Ind. 2005). Vertical privity "typically becomes an issue when a purchaser files a breach of warranty action against a vendor in the purchaser's distribution chain who is not the purchaser's immediate seller." *Id.*

Here, Plaintiff's claim for breach of implied warranty of fitness for a particular purpose fails for lack of vertical privity. Not only is the claim subsumed by the IPLA, it also fails because the Complaint does not plead any facts showing the existence of vertical privity between

Alaunus and Compass. *Hunt v. Unknown Chem. Mfr. No. One*, No. IP 02-389-C, 2003 U.S. Dist. 20138, at *34-35 (S.D. Ind. Nov. 5, 2003). Plaintiff's Complaint does not plead any facts to suggest that Alaunus directly sold the MAP injection to Copass. In *Hunt*, this District Court held that "a plaintiff bringing a breach of implied warranty of fitness for a particular purpose claim under Ind. Code § 26-1-2-315 must show privity of contract." *Id*. at*34-35; s*ee also Atkinson v. P & G-Clairol, Inc*., 813 F.Supp.2d 1021, 1025 (N.D. Ind. 2011) (contract-based claim for breach of implied warranty of fitness for a particular purpose dismissed because plaintiff did not state from whom she purchased the produce of that she entered into any type of bargain or purchase agreement with the defendant).

Plaintiff's breach of warranty claims also fail due to lack of causation. As set forth above, the Complaint does not plead sufficient facts to show that the MAP injection Copass allegedly received was defective. Nor does it show that Plaintiff suffered an injury as a result of a breach of an implied warranty by Alaunus. The failure to plead facts showing causation is fatal to Plaintiff's implied warranty claims. *See Frantz v. Cantrell*, 711 N.E.2d 856, 859 (Ind. Ct. App. 1999) (an action based on breach of warranty requires evidence showing not only the existence of the warranty but also that the warranty was broken and that the breach was the proximate cause of the loss).[15]

G. Plaintiff's Claims Against Alaunus Should Also be Dismissed Because Plaintiff Impermissibly "Lamps" the Allegations Such they Are Indistinguishable As Between Defendants NECC, Ameridose, and Alaunus

Finally, Plaintiff's Complaint is also subject to dismissal because the Complaint

[15] *See also Pennsylvania Employees Benefit Trust Fund v. Astrazeneca Pharmaceuticals LP*, 2009 WL 2231686 (M.D. Fla. July 20, 2009) (express warranty claims dismissed under *Twombly-Iqbal* due to failure, in relevant part, to plead any facts in drug case showing proximate cause between breach of warranty and Plaintiff' alleged injuries); *Mitchell v. Proctor & Gamble*, 2010 WL 728222 (S.D. Ohio March 1, 2010) (all product liability claims in drug case dismissed under *Twombly-Iqbal* due to failure to plead causation).

impermissibly "lumps" all Defendants together as one, such that it is impossible to distinguish what conduct is alleged against which Defendant. Per Rule 12(b)(6), a complaint is subject to dismissal where the complaint fails to provide an adequate factual basis to distinguish the conduct of particular defendants. *Goren v. New Vision Intern., Inc.*, 156 F.3d 721, 730 (7th Cir. 1998) (affirming dismissal of complaint where complaint treated defendants as one, "lumping" them together); *Bagheri v. Galligan*, 160 Fed. Appx. 4, 5 (1st Cir. 2005) (upholding district court's dismissal of action where the original complaint did not "state clearly which defendant or defendants committed each of the alleged wrongful acts.

"By lumping all the defendants together in each claim and providing no factual basis to distinguish their conduct, [plaintiff]'s complaint failed to satisfy [the] minimum standard" of pleading under Fed.R.Civ.P. 8(a)." *Atuahene v. City of Hartford*, 10 Fed. Appx. 33, 34 (2d Cir.2001). *See also Vanzandt v. OK Dep't Human Serv's.*, 276 Fed. Appx. 843 (10th Cir. 2008) ("To carry their burden, plaintiffs under the *Twombly* standard must do more than generally use the collective term 'defendants' . . . This is because the purposes of plausibility, notice, and gate keeping are best served by requiring plaintiffs to directly link an actual individual with the alleged improper conduct").

Here, Plaintiff's Complaint impermissibly "lumps" Defendants NECC, Ameridose, and Alaunus together because it merely refers to them collectively as "Defendants" of "Defendants, NECC" and fails to plead any basis to distinguish the conduct of Alaunus from that of NECC and Ameridose. *See Pl. Comp.* ¶¶ 2 – 4 and generally. Plaintiff's Complaint impermissibly "lumps" Alaunus together with NECC and Ameridose and there is no basis to distinguish or separate the allegations against Alaunus from the allegations against the other Defendants. Plaintiff's Complaint should be dismissed pursuant to *Twombly-Iqbal* because the allegations in

the pleading fail to give adequate notice to Alaunus as to what it did wrong and therefore fails to meet the pleading standards of Rule 8. *See Goren*, 156 F.3d at 730; *Bagheri*, 160 Fed. Appx. at 5 (1st Cir. 2005); *Atuahene*, 10 Fed. Appx. at 34 (2d Cir.2001); *Vanzandt*, 276 Fed. Appx. at 843.[16]

V. CONCLUSION

Plaintiff's Complaint as to Alaunus must be dismissed for failure to state a claim pursuant to Rule 12(b)(6). Plaintiff's Complaint fails under the *Twombly-Iqball* standard to assert sufficient factual allegations beyond non-conclusory formulaic recitations of various causes of action. In addition, Counts I – V of Plaintiff's Complaint are pre-empted by the IPLA – the exclusive remedy for personal injury claims involving allegedly defective products. Even if Plaintiff's claims were not pre-empted by the IPLA – which they are – Plaintiff's Complaint fails to plead facts sufficient to create an reasonable inference of liability against Alaunus. For these reasons, Plaintiff is not entitled to conduct any discovery to cure the defects in their pleading.[17] Plaintiff's Complaint, as to Alaunus, must be dismissed pursuant to Fed.R.Civ.P. 12(b)(6).

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[16] *See also Jackson v. Federal Bureau of Investigation*, 2007 WL 433143, at *3 (N.D. Ill. Jan. 31, 2007) (dismissing complaint under Rule 8 because it "fails to properly identify which of the multiple defendants engaged in the alleged conduct"); *Nagel v. ADM Investor Serv.'s, Inc.*, 995 F. Supp. 837, 845 (N.D. Ill. 1998) (dismissing complaint under Rule 8 because it fails to properly identify which of the multiple defendants engaged in the alleged conduct).

[17] *See Twombly*, 127 S. Ct. at 1966 (rejecting arguments that a plaintiff should be permitted to proceed with discovery and that case management techniques may be used by defendants to weed out baseless claims in an anti-trust case ruling that one of the main goals of the plausibility standard is the avoidance of unnecessary discovery and discovery would be massive since the Plaintiff represents a putative class of at least 90 percent of all subscribers to local telephone or high-speed Internet service in the continental United States in an action against America's largest telecommunications firms, Supreme Court); *Dura Pharmaceuticals, Inc. v. Broudo*, 125 S.Ct. 1627 (2005) ("something beyond the mere possibility of loss causation must be alleged, lest a plaintiff with `a largely groundless claim' be allowed to `take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value").

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CERTIFICATE OF SERVICE

This is to certify that a copy of the foregoing has been filed with the Clerk of the Court on February 6, 2013 using the CM/ECF system which sent notification of this filing to the following:

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