UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF IDAHO

GEORGE PATRICK WILSON,

Plaintiff,

v.

AMNEAL PHARMACEUTICALS, L.L.C., a New Jersey Corporation, and JOHN and JANE DOES I through X, whose true identities are presently unknown,

Defendants.

Case No. 1:13-cv-00333-CWD

MEMORANDUM DECISION AND ORDER

INTRODUCTION

This matter is before the Court on Defendant Amneal Pharmaceuticals, L.L.C.'s Motion for Judgment on the Pleadings (Dkt. 11) and its Motion to Take Judicial Notice (Dkt. 18), as well as Plaintiff George Wilson's Motion to Conduct Discovery Pursuant to Fed. R. Civ. P. 56(d) (Dkt. 15).[1] The Court conducted a hearing on all pending motions on December 20, 2013. For the reasons that follow, the Court will grant Amneal's motion for judgment on the pleadings in part, and grant its motion for judicial notice. Wilson's motion to conduct discovery will be denied.

[1] Plaintiff's response to Defendant's motion (Dkt. 14) is identical to his Motion to Conduct Discovery (Dkt. 15). The Clerk of Court required the identical filing because Plaintiff's response brief requested affirmative relief under Rule 56(d).

BACKGROUND

Wilson filed his complaint in the District Court of the Fourth Judicial District for the State of Idaho, in Ada County, on April 12, 2013. Amneal removed the action to this Court on July 30, 2013, based on diversity of citizenship. According to the pleadings, Wilson was seen by his physician and prescribed an antibiotic, Bactrim, which was filled with a generic product manufactured by Amneal. Wilson took the drug for over one week.[2] Wilson developed a reaction, and was treated for Stevens-Johnson syndrome, a condition that causes blisters and a rash. Stevens-Johnson syndrome can result in severe disfigurement and death. TABER'S CYCLOPEDIC MEDICAL DICTIONARY, 18th Ed. p. 1833 (1997).[3]

Wilson alleges seven causes of action under Idaho state law against Amneal. In his first cause of action for strict liability, Wilson alleges that Amneal manufactured Bactrim; Wilson expected the drug to reach him without substantial change from the condition in which it was sold; the drug did reach him without substantial change from the condition in which it was sold and had been manufactured; and that the drug was unsafe for its foreseeable use and was otherwise defective and unreasonably dangerous. Second, Wilson alleges defective design in that the drug Bactrim was unreasonably dangerous and in a defective condition when put to its reasonably anticipated use. He further contends Amneal failed to use ordinary care in the manufacture and testing of the drug Bactrim,

[2] Wilson does not allege the dates upon which these events occurred. At the hearing, Wilson represented the events giving rise to the Complaint occurred in April of 2011.

[3] Stevens-Johnson syndrome is a "systemic form of erythema multiforme involving fever and lesions of the oral, conjunctival, and [other] mucous membranes, and marked by a cutaneous rash that is often widespread and severe. Skin loss may lead to dehydration and infection."

thereby creating an unreasonable risk of foreseeable injury to Wilson. Third, Wilson alleges negligent manufacture, contending that the drug Bactrim was unreasonably dangerous and in a defective condition when put to its reasonably anticipated use, and that Amneal failed to use ordinary care in the manufacture of the drug Bactrim. Fourth, Wilson alleges failure to warn on the basis that Amneal failed to give proper notice and instructions as to the defects and dangers of the drug Bactrim. Fifth, Wilson alleges Amneal negligently failed to warn Wilson of the dangers associated with taking the drug Bactrim, which dangers included blisters in his mouth and a rash on his lower extremities, and onset of Stevens-Johnson syndrome. And finally, in Counts Six and Seven, Wilson alleges breach of express and implied warranty.

In its Answer, filed on August 6, 2013, Amneal admits that it manufactures and sells to pharmacies the generic form of Brand Name Bactrim, known as "Sulfamethoxazole and Trimethorprim" (Generic Bactrim), and that it has manufactured and sold Generic Bactrum since June 23, 2008. The antibiotic must be prescribed by a health care professional.

Amneal denies the allegations of liability in the complaint, and affirmatively asserts that Wilson's claims are barred, either by the statute of limitations; lack of privity; or preemption. Attached to Amneal's answer are three additional documents supporting Amneal's defenses. The first is an FDA approval letter dated January 27, 2005, approving Interpharm's Abbreviated New Drug Application (ANDA) for Generic Bactrim. (Ans. Ex. A, Dkt. 6.) Next, on January 22, 2010, the FDA issued a letter to Amneal acknowledging Interpharm, Inc.'s transfer of ownership of the ANDA for various drugs

to Amneal, including rights to Generic Bactrim. (Ans. Ex. B, Dkt. 6.) Finally, Amneal attached its label (aka "Package Insert") for its Generic Bactrim, both the current version and two prior versions. (Ans. Ex. C, Dkt. 6.) In each of the versions, the label has identified Stevens-Johnson syndrome and other severe skin reactions as potentially life threatening side effect of Generic Bactrim.[4]

Amneal filed its motion seeking judgment on the pleadings on November 26, 2013. In support of its motion, Amneal asks the Court to take judicial notice of the three exhibits attached to its Answer, and also of three additional FDA documents. (Request for Judicial Notice, Dkt. 18.) These additional documents include an October 17, 2002 approval letter from the FDA to Mutual Pharmaceuticals, the brand name drug manufacturer of Bactrim, together with the approved label; a July 27, 2010 letter from the FDA to Mutual Pharmaceuticals together with the revised label for Brand Name Bactrim; and an August 29, 2012 letter from the FDA to Mutual Pharmaceuticals together with a revised label for Brand Name Bactrim.

Amneal argues that Wilson's first five causes of action asserting product liability claims against it are preempted by federal law, because Amneal, a generic drug manufacturer, has a mandatory federal duty of "sameness." In other words, Amneal is required by federal law to manufacture and sell Generic Bactrim with the same chemical

[4] Exhibit C attached to Amneal's answer includes a warning in all caps and bold that "fatalities associated with the administration of sulfonamides, although rare, have occurred due to severe reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, agramulocytosis, aplastic anemia and other blood dyscrasias. Sulfonamides, including Sulfonamide-containing products such as Sulfamethoxazole/Trimethoprim, should be discontinued at the first appearance of skin rash or any sign of adverse reaction." (Dkt. 6-3 at 1.) The label indicates it was "rev. 01-2013." It is difficult to read the text on the other two versions; however Amneal represents that the labels included a similar warning. Def.'s Mem. at 10 (Dkt. 11-1.)

equivalency and bioequivalency as Brand Name Bactrim, and to use the exact same label approved by the FDA for Brand Name Bactrim. Thus, Amneal is prohibited by federal law from altering the design, composition, or label of Generic Bactrim unless Brand Name Bactrim's design, composition, or label has been changed first. Central to Amneal's argument are two recent decisions of the United States Supreme Court, both of which held that state law is preempted by federal law when it is impossible for a private party to comply simultaneously with state and federal requirements. See Mut. Pharm. Co., Inc. v. Bartlett, 133 S. Ct. 2466 (2013), affirming its earlier decision in Pliva, Inc. v. Mensing, 131 S. Ct. 2567 (2011).

In response, Wilson filed a motion requesting permission to conduct discovery under Fed. R. Civ. P. 56(d), and contending that the Court is required to convert Amneal's motion for judgment on the pleadings into a motion for summary judgment because Amneal attached to its Answer FDA-approved documents, as well as Amneal's Generic Bactrim labels. If the Court considers the motion under Rule 56, Wilson contends he is entitled to conduct discovery to oppose Amneal's motion. Alternatively, Wilson argues that the federal preemption analysis under Bartlett and Pliva does not apply to his product liability claims (counts one through five), and that Count Four, for failure to warn, should be interpreted as a failure to update package inserts and warnings, which claim does survive preemption.

Amneal argues also that Wilson's sixth and seventh causes of action for breach of express and implied warranty are subject to dismissal because Idaho does not recognize the causes of action absent privity of contract. Wilson concedes his seventh claim, for

breach of implied warranty, may be dismissed based upon lack of privity, but argues that privity of contract is not required to support a claim for breach of express warranty.

Lastly, Wilson opposes Amneal's request for judicial notice on the grounds that, while notice may be taken of the existence of the FDA documents, the Court may not consider the accuracy of their contents. Amneal, on the other hand, urges the Court to consider the documents. Amneal argues the warning label (Exhibit C to Amneal's Answer) is referred to and therefore incorporated by reference into Wilson's Complaint, and the remaining documents are publically accessible on the internet and published by a federal agency as matters of public record.

DISCUSSION

1. Standard of Review

According to Federal Rule of Civil Procedure 12(c), a judgment on the pleadings is properly granted when, "taking all allegations in the pleading as true, the moving party is entitled to judgment as a matter of law." McGann v. Ernst & Young, 102 F.3d 390, 392 (9th Cir. 1996). In determining whether a complaint states a cognizable claim under Rule 12(c), courts apply the same legal standards applicable to motions brought under Rule 12(b)(6). Cafasso, U.S. ex rel. v. General Dynamics C4 Systems, Inc., 637 F.3d 1047, 1054, n. 4 (9th Cir. 2011) ("we have said that Rule 12(c) is functionally identical to Rule 12(b)(6) and that the same standard of review applies to motions brought under either rule.").

A Rule 12(b)(6) motion to dismiss tests the sufficiency of a plaintiff's claim for relief. The relevant inquiry is whether the plaintiff's allegations are sufficient under

Federal Rule of Civil Procedure 8(a), which sets forth the minimum pleading requirement, i.e., that the plaintiff provide a "short and plain statement of the claim showing that the pleader is entitled to relief," and "give the defendant fair notice of what the ... claim is and the grounds upon which it rests." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007).

When reviewing a motion to dismiss, the court must accept as true all nonconclusory, factual (not legal) allegations made in the complaint, Ashcroft v. Iqbal, 556 U.S. 662, 679 (2009); Erickson v. Pardus, 551 U.S. 89 (2007), and draw all reasonable inferences in favor of the plaintiff, Mohamed v. Jeppesen Dataplan, Inc., 579 F.3d 943, 949 (9th Cir. 2009). "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires 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. In addition, "[f]actual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." Id. Dismissal may therefore be based on the lack of a cognizable legal theory or on the absence of sufficient facts alleged under a cognizable legal theory. Navarro v. Block, 250 F.3d 729, 732 (9th Cir. 2001); Balistreri v. Pacifica Police Dep't, 901 F.2d 696, 699 (9th Cir. 1988).

Further, the Court may not consider any evidence contained outside the pleadings without converting the motion to one for summary judgment. See Fed. R. Civ. P. 12(b); United States v. Ritchie, 342 F.3d 903, 907–908 (9th Cir. 2003). "A court may, however,

consider certain materials–documents attached to the complaint, documents incorporated by reference in the complaint, or matters of judicial notice–without converting the motion to dismiss into a motion for summary judgment." Id. at 908 (citing Van Buskirk v. CNN, 284 F.3d 977, 980 (9th Cir. 2002); Barron v. Reich, 13 F.3d 1370, 1377 (9th Cir. 1994); 2 James Wm. Moore et al., MOORE'S FEDERAL PRACTICE § 12.34[2] (3d ed. 1999)).

As a threshold matter, the Court must consider Amneal's Request for Judicial Notice, and Wilson's corresponding argument that judicial notice is improper. Related to that argument is whether the motion should be considered under Fed. R. Civ. P. 56, and whether Wilson's motion to engage in discovery under Fed. R. Civ. P. 56(d) should be granted.

2. Matters Submitted Outside the Pleadings

A. Request for Judicial Notice

Amneal's challenges to the sufficiency of the complaint rest upon matters submitted outside the pleadings. As a general rule, "a district court may not consider any material beyond the pleadings in ruling on a Rule 12(b)(6) motion." Lee v. City of Los Angeles, 250 F.3d 668, 688 (9th Cir. 2001) (quoting Branch v. Tunnell, 14 F.3d 449, 453 (9th Cir. 1994)). If matters outside the pleading are presented to and not excluded by the court, "the motion shall be treated as one for summary judgment and disposed of as provided in Rule 56, and all parties shall be given reasonable opportunity to present all material made pertinent to such a motion by Rule 56." Fed. R. Civ. P. 12(b)(6).

However, as mentioned, a court may consider "material which is properly submitted as part of the complaint" on a motion to dismiss without converting the motion

to dismiss into a motion for summary judgment. Lee, 250 F.3d at 688 (quoting Branch, 14 F.3d at 453 (citation omitted)). If the documents are not physically attached to the complaint, they may be considered if the documents' "authenticity ... is not contested" and "the plaintiff's complaint necessarily relies" on them. Id. (quoting Parrino v. FHP, Inc., 146 F.3d 699, 705–06 (9th Cir. 1998)). Second, under Fed. R. Evid. 201, a court may take judicial notice of "matters of public record." Id. at 689 (quoting Mack v. South Bay Beer Distrib., 798 F.2d 1279, 1282 (9th Cir. 1986)). Records of administrative bodies such as the Food and Drug Administration constitute such materials. Barron v. Reich, 13 F.3d 1370, 1377 (9th Cir. 1994) (considering a policy contained in a handbook published by the Wage and Hour Division of the Department of Labor).

Further, it is appropriate to take judicial notice of information if it is made publicly available by government entities on the internet, and neither party disputes the authenticity of the websites or the accuracy of the information displayed on the website. Daniels-*Hall v. Nat'l Education Assoc.*, 629 F.3d 992, 999 (9th Cir. 2010) (citing In re Amgen Inc. Sec. Litig., 544 F.Supp.2d 1009, 1023-24 (C.D. Cal. 2008) (taking judicial notice of drug labels taken from the FDA's website); and County of Santa Clara v. Astra USA, Inc., 401 F.Supp.2d 1022, 1024 (N.D. Cal. 2005) (taking judicial notice of information posted on a Department of Health and Human Services website)).

Nevertheless, judicial notice has its limitations. There is a distinction between taking judicial notice of undisputed, versus disputed, factual matters. For example, in Lee, the court took judicial notice of court documents and other public records, including declarations. The United States Court of Appeals for the Ninth Circuit, in ruling upon the

propriety of the lower court's decision to take judicial notice, explained that the court could take judicial notice of the fact that a hearing was conducted, and the fact that the defendant signed a waiver of extradition, but that it was error to take judicial notice of disputed facts that were attributed to the defendant and contained within the records. Lee, 250 F.3d at 690.

Amneal argues that Exhibit C to its Answer, its Generic Bactrim labels, may be considered because the complaint refers to the warning labels and Count Four is based upon what warnings were given, while the other five documents are publically available on the FDA's website. Wilson does not distinguish between Exhibit C, Amneal's Generic Bactrim labels and not found on the internet, versus the other exhibits, which are easily accessible on the internet.[5] And, Wilson does not object to the authenticity of any of the documents, or the websites where they were obtained. In short, Wilson did not object to the Court's taking judicial notice of and considering all six documents, including the labels for Generic Bactrim. (Brief at 2-3, Dkt. 23.)[6]

The Court therefore finds it proper to grant Amneal's request for judicial notice as to Exhibits A and B attached to its Answer, and the three additional FDA documents attached to its motion for judicial notice. These documents are taken from the FDA website, are capable of accurate and ready determination, and not subject to reasonable dispute. See Funk v. Stryker Corp., 631 F.3d 777, 783 (5th Cir. 2011) (affirming judicial

[5] The Court had no difficulty accessing the FDA's website and finding the documents. The website is publically accessible at:
http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#labelinfo

[6] Wilson's brief states, "judicial notice of these six documents as to their existence can be taken. . . ."

notice of FDA documents and transcripts granting premarket approval for a medical device manufacturer); In re Amgen Sec. Litigation, 544 F.Supp.2d at 1023 (granting the defendants' request to take judicial notice of labels for two drugs found on the FDA's website). Pursuant to the incorporation by reference doctrine, the Court takes judicial notice of Exhibit C, Amneal's labels for Generic Bactrim. Wilson's fourth cause of action for failure to warn is dependent upon the label, and referenced by Wilson's statement that Amneal failed to give proper notice and instructions as to the defects and dangers of the drug.

Wilson's objection to the Court's consideration of the documents' contents, however, is illogical in this context. While the Court recognizes there is a valid distinction between taking judicial notice of undisputed facts— such as the fact that it was not raining on a given date according to weather data—versus taking judicial notice of disputed facts—such as the effect of the lack of rain—this is not such a case.

Wilson relies substantially upon an unpublished case, Fellner v. Tri-Union Seafoods, LLC, No. 06-CV-0688-DMC, 2010 WL 1490927 (D. N.J. Apr. 13, 2010), for the proposition that it is improper for the Court to take judicial notice of the content of the FDA's and Amneal's Generic Bactrim label here. In Fellner, the plaintiff sued a seafood company alleging she contracted mercury poisoning from eating its canned tuna. Mercury is a naturally occurring element in tuna, and the FDA has established tolerance levels of mercury in fish through nutritional guidelines. Fellner, 2010 WL 1490927 at *1. The plaintiff alleged that the defendant's tuna product was defective because the company failed to warn consumers about the presence of mercury in the tuna.

The defendants argued warning labels were not required because the company was in compliance with FDA requirements, and asked the court to take judicial notice of several documents to establish its common knowledge defense, including magazine articles about the dangers of mercury, an FDA advisory on mercury in fish, and a letter responding to a health claim petition about the correlation between Omega-3 fatty acids and reduced risk of coronary heart disease. The court judicially noticed all three documents, not for the truth of the contents, but as evidence of the information provided by the federal government to individuals and industry participants. Id. at *6 n. 8.[7] See also Lee, 250 F.3d at 690, discussed supra.

The documents and resultant facts judicially noticed in Fellner, and the other cases cited in Wilson's opposition brief (Dkt. 23), are distinguishable. Here, Wilson does not dispute the veracity of the facts contained in the documents. Nor could he. For instance, Exhibit A is the letter from the FDA approving Interpharm's drug application for Generic Bactrim. This fact is capable of ready determination on the FDA's website, and is not capable of any other interpretation. With respect to Exhibit B, the letter from the FDA acknowledging the transfer of ownership to Amneal of the ANDAs for the drug products listed, including Generic Bactrim, Wilson alleges Amneal manufactured the drug he ingested. Amneal admits it manufactured Generic Bactrim.

[7] Wilson misconstrues Fellner in his opposition brief. (See Dkt. 23 at 3). Wilson states that judicial notice of the FDA warning labels was taken, and the notice was not taken for the truth of the contents but only for the evidence provided by the federal government to the public. But, in Fellner, the defendant argued it did not have to provide warning labels, because there is a rebuttable presumption no warnings are required if the company is in compliance with FDA requirements and it was "common knowledge" that mercury was in tuna. The documents the court judicially noticed were not the warning labels---they were an FDA article in its consumer magazine, a talk paper, and a letter responding to a health claim about Omega 3 Fatty Acids.

As to Exhibit C, Amneal's labels for the relevant time period, Wilson has not produced an affidavit of his own indicating that the Generic Bactrim he purchased and ingested had a different label, which would be necessary to dispute the authenticity and contents of Amneal's submitted label. See, e.g., Lee, 250 F.3d at 689 (finding it was error to consider the contents of public records containing statements allegedly made by the plaintiff when the plaintiff submitted affidavits denying he made the statements). Similarly, the three additional documents attached to Amneal's motion to take judicial notice are simply approval letters of Brand Name Bactrim's labels, with the attached labels. See Miller v. Mylan Inc., No. 12-11684, 2012 WL 5300721 (E.D. Mich. Oct. 25, 2012) (court may consider letters that constitute decisions of a government agency) (citing Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 2499, 2509 (2007)).

It is difficult to conceive in this context why the Court is unable to consider the undisputed facts contained in the letters, or the contents of the labels, when the facts under consideration and contained therein are not stating opinions. Moreover, Wilson has not come forward with a persuasive argument or contrary facts disputing the contents of the FDA letters or the authenticity of Amneal's labels. Although Wilson argues that the Court may not take judicial notice of the contents of the letters because they reference other events, papers, or documents, the Court is not relying upon the entirety of the letters' contents. Rather, the Court is being asked to take judicial notice of when certain approvals occurred, and what was being approved---whether it was the transfer of the ANDA for Generic Bactrim, or the labels for Brand Name Bactrim and what those labels

stated. These are proper facts not subject to reasonable dispute of which the Court may take judicial notice, and the Court will do so.[8]

B. Request for Discovery

Wilson's briefs and affidavit, (Dkt. 14, 23), do not address the exceptions to Rule 12's conversion requirement discussed above, only that by virtue of the attachment of the documents to the motion and to the answer, it is necessary to conduct discovery. But, because the Court may judicially notice all six documents, the motion for judgment on the pleadings is not converted into a motion for summary judgment, and Wilson's request for discovery under Rule 12(d) and Rule 56(d) lacks support.

Alternatively, Wilson argues that his fourth claim for relief, for failure to warn, should be construed as a failure to update claim, and he should be permitted limited discovery. The Court will discuss this issue later in the opinion, in conjunction with Amneal's preemption argument.

3. Preemption

A. *Idaho's Product Liability Act*

Idaho has adopted the RESTATEMENT (SECOND) OF TORTS § 402A as the basis for imposing strict liability upon the sellers of products. Rindlisbaker v. Wilson, 519 P.2d 421, 428 (Idaho 1974). Further, Idaho consistently has adhered to § 402A and to its

[8] Wilson argues that the Court cannot take judicial notice of the relationships between Interpharm, Mutual Pharmaceutical Company, and Amneal. Wilson's point is well taken. However, the Court need not consider the relationship between the three companies. It is enough for the Court to consider the basic facts---Interpharm obtained approval to manufacture and sell Generic Bactrim. The FDA acknowledged that Amneal later acquired the right to do so. The FDA approved Mutual Pharmaceutical's labels for Brand Name Bactrim. And Amneal's labels are identical to the FDA required label for Brand Name Bactrim. It is unnecessary for the Court to construe the facts beyond these, which are confirmed by documents accessible via the FDA's website.

accompanying comments. Toner v. Lederle Laboratories, 732 P.2d 297, 304 (Idaho 1987). Generally speaking, there are three general categories of strict liability in product liability cases---manufacturing flaws, design defects, or failure to warn. Toner, 732 P.2d at 306 (Idaho 1987); Mortensen v. Chevron Chemical Co., 693 P.2d 1038, 1041 (Idaho 1984).

Whether a cause of action is based upon negligence or strict liability, the plaintiff must show that (1) the product in question was defective, (2) the defect existed at the time the product left the manufacturer's control, and (3) that the defective product was the proximate cause of the plaintiff's injuries. Pucket v. Oakfabco, Inc., 979 P.2d 1174, 1179 (Idaho 1999) (citing Corbridge v. Clark Equip. Co., 730 P.2d 1005, 1007 (1986)); Mortensen, 693 P.2d at 1041 (citing Restatement §402A as the basis for finding strict liability for a manufacturing, design defect, or failure to warn) *Farmer v. Internat'l* Harvester Co., 553 P.2d 1306, 1310 (Idaho 1976) (elements of prima facia case are the same regardless of negligence theory or strict liability theory).

Count One alleges an independent cause of action for "strict products liability." However, this claim is not differentiated in Wilson's briefing from the three theories recognized under a claim for strict products liability. Rather, as discussed above, Idaho recognizes a claim for strict product liability which can be proven under three alternate theories. Strict product liability is not considered a separate cause of action. Toner, 732 P.2d at 306 (Idaho 1987). Therefore, Count One is not properly pleaded, and will be dismissed.

Next, under a theory of design defect, the design of the product is at issue. The product must be designed "so as to eliminate unreasonable risks of foreseeable injuries." Puckett, 979 P.2d at 1179. (citing Zimmerman v. Volkswagen of America, Inc., 920 P.2d 67, 70 (1996)). Similarly, a product is defective when it exposes a user or bystander to an unreasonable risk of physical injury. Id. A plaintiff may prove a design defect by presenting evidence of feasible alternative designs, available to the manufacturer, that would have lessened the risk associated with the product. Nepanuseno v. Hansen, 104 P.3d 984, 988 (Idaho Ct. App. 2004).

Wilson urges that a distinction should be made between his theory of design versus manufacturing defect. Brief at 7 (Dkt. 14.) However, even though Idaho courts distinguish between the three theories of strict liability, "[t]here is no rational distinction between design and manufacture, since a product may be equally defective and dangerous if its design subjects protected persons to unreasonable risk as if its manufacture does so. 'A manufacturer of a chattel made under a plan or design which makes it dangerous for the uses for which it is manufactured is subject to liability to others whom he should expect to use the chattel or to be endangered by its probable use for physical harm caused by his failure to exercise reasonable care in the adoption of a safe plan or design.'" Rindlisbaker v. Wilson, 519 P.3d 421, 429 (Idaho 1974) (quoting RESTATEMENT (SECOND) OF TORTS § 398.

In jurisdictions or cases that recognize a distinction between design and manufacture, the plaintiff must establish that the particular product at issue was not manufactured in conformity with the precise specifications for making the product. See

Snell v. Bell Helicopter Texton, Inc., 107 F.3d 744, 749 (9th Cir. 1997) (applying California law in a manufacturing defect claim against the maker of helicopters). In such a case, the alleged defect must exist "independently of the design itself," Getz v. Boeing Co., 654 F.3d 852, 864 (9th Cir. 2011), and the product must "fail to conform to specifications," Harduvel v. Gen. Dynamics Corp., 878 F.2d 1311, 1321 (11th Cir. 1989).

Alternatively, failure to warn can be a basis for recovery in a products liability action, whether alleged under a theory of strict liability in tort or negligence. Puckett, 979 P.2d at 1181; Toner, 732 P.2d at 305 n.7 ("[T]here generally is little difference in the requirements and analysis of the duty to warn under either a negligence or strict liability theory."). Under the theory of failure to warn, a "product is defective if the defendant has reason to anticipate that danger may result from a particular use of his product and fails to give adequate warnings of such danger." Puckett, 979 P.2d at 1181. A product sold without such a warning is in a defective condition. Watson v. Navistar Intern. Transp. Corp., 827 P.2d 656, 673 (Idaho 1992).

B. Impossibility Preemption

The Court's analysis begins with two recent decisions of the United States Supreme Court, Pliva, Inc. v. Mensing, 131 S.Ct. 2567 (2011), and Mut. Pharmaceutical Co. v. Bartlett, 133 S.Ct. 2466 (2013). Both matters involved "impossibility" preemption, which is what Amneal argues applies here. Impossibility preemption occurs when it is "impossible for a private party to comply with both state and federal requirements." In re Fosamax Products Liability Litigation, No. 06 MD 1789, 2013 WL 4306434 *1 (S.D.N.Y. Aug. 15, 2013) (quoting Freightliner Corp. v. Myrick, 514 U.S. 280, 287

(1995)). Put another way, where state law and federal law directly conflict, state law must yield. Mensing, 131 S.Ct. at 2577.

Under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq., drug manufacturers must gain approval from the United States Food and Drug Administration (FDA) before marketing any drug in interstate commerce. 21 U.S.C. § 355(a). In the case of a new brand-name drug, FDA approval can be secured only by submitting a new-drug application (NDA). An NDA is a compilation of materials that must include "full reports of [all clinical] investigations," § 355(b)(1)(A), relevant nonclinical studies, and "any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source," 21 C.F.R. §§ 314.50(d)(2) and (5)(iv) (2012).

The NDA must also include "the labeling proposed to be used for such drug," 21 U.S.C. § 355(b)(1)(F); 21 C.F.R. § 314.50(c)(2)(i), and "a discussion of why the [drug's] benefits exceed the risks under the conditions stated in the labeling," 21 C.F.R. § 314.50(d)(5)(viii); § 314.50(c)(2)(ix). The FDA may approve an NDA only if it determines that the drug in question is "safe for use" under "the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(d). For the FDA to consider a drug safe, the drug's "probable therapeutic benefits must outweigh its risk of harm." FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 140 (2000), quoted in Bartlett, 133 S.Ct. at 2471.

To provide a faster route for approval of generic drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, commonly

known as the "Hatch–Waxman Act." Bartlett, 133 S.Ct. at 2471. Under this Act, a generic drug may be approved without the same level of clinical testing required for approval of a new brand-name drug, provided the generic drug is identical to the already-approved brand-name drug in several key respects. Id. See also 21 U.S.C. § 355(j)(2)(A).

The proposed generic drug must be chemically equivalent to the approved brand-name drug: it must have the same "active ingredient" or "active ingredients," "route of administration," "dosage form," and "strength" as its brand-name counterpart. 21 U.S.C. §§ 355(j)(2)(A)(ii) and (iii). Second, a proposed generic drug must be "bioequivalent" to an approved brand-name drug. § 355(j)(2)(A)(iv). That is, it must have the same "rate and extent of absorption" as the brand-name drug. § 355(j)(8)(B). Third, the generic drug manufacturer must show that "the labeling proposed for the new drug is the same as the labeling approved for the [approved brand-name] drug." § 355(j)(2)(A)(v).

Once a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the "qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application." 21 C.F.R. § 314.70(b)(2)(i). Generic manufacturers are prohibited as well from making any unilateral changes to a drug's label. See 21 U.S.C. §§ 355(j)(2)(A)(v) & (j)(4)(G); 21 C.F.R. §§ 314.94(a)(8)(iii), 314.150(b)(10) (approval for a generic drug may be withdrawn if the generic drug's label "is no longer consistent with that for [the brand-name] drug.").The FDA interprets these regulations as imposing an ongoing duty for generic manufacturers to update their product labels to ensure the sameness of the generic and name-brand drug labels. Mensing, 131 S.Ct. at 2575; 57 Fed.

Reg. 17961 (1992) ("Abbreviated New Drug Application (ANDA) product's labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for ANDA approval.").

(1) *Wilson's Failure to Warn Clai*m is Preempted by Mensing

In Mensing, the two plaintiffs brought separate failure to warn claims under Minnesota and Louisiana state law against several generic manufacturers of the drug metoclopramide, a drug commonly used to treat digestive tract problems. Mensing, 131 S.Ct. at 2573. The plaintiffs alleged that the generic manufacturers violated state tort laws by failing to change the labels for metoclopramide to adequately warn of the risk of a severe neurological disorder. Id. The applicable tort laws of Minnesota and Louisiana required manufacturers that are "or should be aware of [their] product's danger to label that product in a way that renders it reasonably safe." Id. But, because of the federal requirement imposed upon generic manufacturers requiring the warning labels of a brand-name drug and its generic copy to be the same, the Supreme Court held that the plaintiff's failure to warn claims under state law were preempted; "it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same." Id. at 2578.

Wilson argues that Mensing should be interpreted narrowly, and that defective design claims that "do not rise or fall on the adequacy of the manufacturer's warnings are not implicated by" Mensing. However, Mensing expressly found that claims based upon a demand that a generic drug manufacturer change its warnings, strengthen its warnings, or communicate new warnings directly to physicians, were all preempted. Mensing, 131

S.Ct. at 2575—2578. See also In re Fosamax, 2013 WL 4306434 at *5 (joining majority of other courts considering the issue in holding that claims stemming from generic defendants' alleged failure to communicate additional warnings through some method other than their package inserts are preempted).

Mensing involved only a failure to warn claim, and squarely foreclosed such claims based upon impossibility. Mensing, 131 S.Ct. at 2577-78. Because labeling is so broadly defined that it "encompasses nearly every form of communication with medical professionals….generic drug defendants are not allowed to alter the labeling adopted by the brand manufacturers in any way." In re Fosomax, 2013 WL 4306434 at *5 (quoting Del Valle v. Pliva, Inc., 2011 WL 7168620 at *6 (S.D. Tex. Dec. 21, 2011)). See also Bartlett, 133 S.Ct. at 2473 ("it was impossible for Mutual to comply with both its state-law duty to strengthen the warnings on sulindac's label and its federal-law duty not to alter sulindac's label. Accordingly, the state law is pre-empted.").

Wilson appears to concede that Mensing impacts both his fourth and fifth causes of action, which allege failure to warn under a strict liability theory and alternatively under a negligence theory. However, as discussed above, Idaho does not differentiate between negligence and strict liability, and considers the concepts together. Pucket, 979 P.2d at 1179. Both causes of action, however pleaded, are foreclosed under Mensing.

(2) *Wilson's Failure to Update Claim is Implausible*

Alternatively, Wilson argues that his fourth cause of action should be interpreted as a "failure to update" claim. A failure to update claim is premised upon a generic drug manufacturer's failure to timely update its warning label once the FDA has approved a

change to the brand name manufacturer's submission of a label update. See In re Fosamax Prods. Liab. Litig., No. 06 MD 1789, 2013 WL 4306434 (S.D.N.Y. Aug. 15, 2013) (holding that the plaintiff's claim against a generic drug manufacturer for failure to timely update its labels to match the brand name labels was not subject to dismissal). Failure to update claims are not preempted. In re Fosamax, 2013 WL 4306434 at *3. A plaintiff must show, however, that the updated warning label contained a new warning, that the generic manufacturer failed to update its label to include the change, and the cause of the harm was directly related to the change in the warning. See Couick v. Wyeth, Inc., No. 3:09–CV–210–RJC–DSC, 2012 WL 79670 *3-4 (W.D.N.C. Jan. 11, 2012) (plaintiff permitted to proceed where she pleaded that brand name drug manufacturer's label changed, and generic drug manufacturer's label did not, with respect to a specific warning cautioning that drug therapy should not exceed twelve weeks).

Wilson argues he has adequately pleaded a failure to update claim within Count Four. He further contends he has made the requisite showing under Fed. R. Civ. P. 56(d) to conduct discovery concerning the specific dates when Amneal amended its warnings and package inserts for Generic Bactrim; the specific dates when the manufacturer of Brand Name Bactrim amended its warnings and package inserts; the reasons why Amneal amended its warnings and package inserts for Generic Bactrim; the product reviews and investigations performed by Amneal prior to amending its warnings and package inserts for Generic Bactrim; correspondence and letters between Amneal and the manufacturer of Brand Name Bactrim regarding the warnings and package inserts; and Amneal's

knowledge and notice of the amendments to the warnings and package inserts for Brand Name Bactrim.

Amneal argues all of the above information is either irrelevant or available on the FDA's website. For example, Amneal argues the specific dates when the manufacturer of Brand Name Bactrim amended its warnings and package inserts can be found on the FDA's public website, and that it submitted the three FDA approvals for changes to the Brand Name Bactrim label as part of its request for judicial notice. Further, Amneal notes that federal law requires a generic drug manufacturer to have the same label as the brand name drug manufacturer. 21 U.S.C. § 355(j)(2)(A)(v); 21 C.F.R. § 314.94(a)(8)(iii), 314.150(b)(10), cited in Mut. Pharmaceutical Co., Inc. v. Bartlett, 133 S.Ct. 2466, 2470 (2013) . And finally, Amneal noted in its brief, and in Exhibit C attached to its answer, that at all times relevant to the claims made in the complaint,[9] the label for Generic Bactrim included a warning of the risk of Stevens-Johnson syndrome in two different locations. (Ans. Ex. C; Def.'s Brief at 9—10, Dkt. 11-1.) Thus, the Court is not convinced as to what would be gained if the discovery Wilson requested was allowed.

A claim against Amneal for failure to update its warning to reflect labeling changes made by the brand name manufacturer was not sufficiently pleaded. Count Four, for failure to warn, does not specifically state that Amneal failed to update its warnings and instructions, the lag between the updates, how the lag damaged Wilson, or any of the

[9] Wilson does not aver when the events occurred that caused him to take Generic Bactrim, or when he sought medical treatment for the rash that developed thereafter. Amneal notes that a two-year statute of limitations applies to product liability actions in Idaho. Idaho Code § 6-1403(3), 5-219(4). Therefore, Amneal attached to Exhibit C copies of FDA-approved labeling in existence from the date of Wilson's complaint and for three years prior to that date. At the hearing, Wilson's attorney represented the events occurred in April of 2011.

specifics required to satisfy Fed. R. Civ. P. 8. Rather, Count Four claims only that Amneal failed to adequately warn consumers of the dangers from taking the drug. As such, Count Four does not satisfy the pleading standard under Rule 8 for pleading a failure to update claim.

Although the general rule is that the Court must grant the plaintiff leave to amend even if no request to amend the pleading was made, the Court can deny leave to amend if it determines that the pleading "could not possibly be cured by the allegation of other facts." Cook, Perkiss & Liehe, Inc. v. N. Cal. Collection Serv., Inc., 911 F.2d 242, 247 (9th Cir. 1990). Indeed, a dismissal without leave to amend is improper unless it is beyond doubt that the complaint "could not be saved by any amendment." Harris v. Amgen, Inc., 573 F.3d 728, 737 (9th Cir. 2009).

The Court will not permit Wilson to file an amended complaint. Here, all three versions of the drug label submitted by Amneal contain the very warning at issue—the warning that Wilson, by taking the drug, could develop a severe and life threatening skin rash, or Stevens-Johnson syndrome. This aspect of the warning label did not change, and was required since 2002. Even assuming Wilson amended his Complaint to assert when the events occurred, which his counsel represented was April of 2011, it would not save his failure to update claim when the same warning was on the label and did not change after that time.[10] Wilson will not be granted leave to amend and conduct discovery with respect to his failure to warn claim.

[10] The March 2011 label is included in the record at page 5 of Dkt. 6-3, and includes the same warning as the previous label, warning against the risk of Stevens-Johnson syndrome.

(3) *Wilson's* Design Defect Claim is Preempted by Bartlett

Next, Wilson argues that his state law design defect claim (Count Two) is not preempted under Bartlett. In Bartlett, the issue presented was whether state law design defect claims are also preempted under Mensing. The plaintiff suffered side effects from taking a generic drug, and brought a design-defect claim and a failure to warn claim under New Hampshire state law. New Hampshire, like Idaho, follows § 402A of the Restatement (Second) of Torts. Bartlett, 133 S.Ct. at 2473. The plaintiff's failure to warn claim was dismissed before trial. After a two-week trial, the plaintiff won a 21 million dollar verdict, which the court of appeals affirmed. The Supreme Court reversed, discussing New Hampshire's product liability law at length, and finding the plaintiff's design defect claim was preempted.

New Hampshire law provides that a product is defectively designed when "the design of the product created a defective condition unreasonably dangerous to the user." Id., 133 S.Ct. at 2474 (citation omitted). To determine whether a product was "unreasonably dangerous," the New Hampshire Supreme Court employs a "risk-utility approach" under which a product is defective "if the magnitude of the danger outweighs the utility of the product." Id., 133 S.Ct. at 2466. Accordingly, the Supreme Court determined that a manufacturer of a generic drug can only escape liability for defective design if the generic manufacturer could have redesigned the drug or changed the label to add a stronger warning. See id. at 2470.

Because a generic manufacturer cannot unilaterally change their label, as established in Mensing, the Supreme Court analyzed whether a generic manufacturer can

redesign the drug. Id. at 2470–71. The Court determined a drug's usefulness and its risk of danger are directly correlated with its chemical design and, more importantly, its active ingredients. Id. at 2475. Nonetheless, the Supreme Court held redesign is not possible because of the FDCA's requirements that generic drugs be chemically equivalent to the brand-name drug. Id. Had the generic manufacturer changed the composition of its drug, the altered chemical would be a new drug. See 21 U.S.C. § 355(j)(2)(A)(ii)-(v) and (B); 21 C.F.R. § 320.1(c). Therefore, the Supreme Court held it is impossible for generic manufacturers to comply with both state and federal law. Id. at 2477. And, following from that conclusion, the only way for a generic drug manufacturer to ameliorate the drug's "risk-utility" profile and escape liability was to strengthen the drug's warning, which it could not do under Mensing. Bartlett, 133 S.Ct. at 2476—77.

Wilson contends that Bartlett was narrow in its scope, because the design defect claim depended upon the adequacy of the drug's warning. Wilson tries to distinguish his design defect claim, contending that it does not depend upon Generic Bactrim's warning. Brief at 8 (Dkt. 14.) But Bartlett is not that narrow, and must be read in the context in which it was decided. Although Bartlett held that state-law design defect claims that turn on the adequacy of a drug's warnings are pre-empted by federal law under Mensing, 133 S.Ct. at 2470, the Supreme Court discussed how it arrived at that conclusion.

Because generic drug manufacturers are precluded from changing the chemical design of the generic drug, the only other way to balance the risk is to change the warning. Therefore, under Bartlett, if a balancing of the risks under state law would require the generic drug manufacturer to change the chemical composition of the drug,

which it cannot do under federal law, then it necessarily follows that updating the label is the only way to escape liability. Thus, Bartlett inextricably links design defect claims against generic drug manufacturers with failure to warn claims, a link that Wilson does not discuss and attempts to explain away instead.

Idaho, like New Hampshire, follows the Restatement, and therefore the holding in Bartlett is directly applicable here. Because Idaho adheres to the risk-utility approach under the Restatement, the Court finds no basis to deviate from the holding in Bartlett. Wilson has failed to show how his state law claim under Count Two varies from the New Hampshire product liability claim at issue in Bartlett. Bartlett held that it was impossible for generic drug manufacturers, under Federal law, to change the design, or chemical makeup, of their drugs. Therefore, the Court finds, pursuant to Bartlett, Wilson's design defect claim is preempted and judgment should be entered for Amneal on Count Two.

(4) Negligent Manufacture

Finally, apart from generally asserting that his cause of action for negligent manufacture is a "separate" cause of action, Wilson has not adequately pleaded or explained how this cause of action exists separate and apart from his negligent design and failure to warn theories. As discussed, in cases that recognize a separate cause of action for manufacturing defect, the alleged defect must exist "independently of the design itself," and the product must "fail to conform to specifications." No such allegations appear in the complaint. The complaint alleges that Amneal "failed to use ordinary care in the manufacture and testing of the drug," created an unreasonable risk of injury, and Amneal's acts were the cause of Wilson's injuries. However, Amneal, under federal law,

did not perform any testing of Generic Bactrim---that was the duty of the brand-name manufacturer when it submitted its NDA.

Next, it is undisputed based upon Amneal's label (Ans., Ex. C) that the label warned of Stevens-Johnson syndrome, which is what Wilson alleges he acquired. To maintain a cause of action, it will be Wilson's burden to prove that the drug he ingested was manufactured incorrectly, and the side effect suffered was directly caused by the manufacturing defect. Wilson must be able to adequately plead, and then establish, causation. If the product Wilson ingested was different in chemical composition or was tampered with during the manufacturing process, he must show that the manufacturing defect was the cause of contracting a harm warned about on the drug label, a harm that could be caused even if the product was manufactured according to its specifications. Wilson has not satisfactorily explained these legal stumbling blocks, nor has he pleaded them with specificity.

Mindful, however, of the Ninth Circuit's liberal amendment standard, and that neither Bartlett nor Mensing discussed a manufacturing defect claim, Wilson will be permitted leave to amend his complaint.[11]

4. Warranty Claims

Wilson's sixth and seventh causes of action pleaded breach of express and implied warranties. Wilson concedes that, under Idaho law, he may not bring an action for breach of implied warranty absent privity of contract between a manufacturer of a product and an injured party. (Pl.'s Mem. at 12, Dkt. 14.) However, Wilson contends there is no such

[11] The Court cautions Wilson's counsel to be mindful of his obligations under Rule 11.

requirement for Wilson to be compensated for a breach of express warranty, citing Green v. A.B. Hagglund & Soner, 634 F.Supp.790 (D. Idaho 1986).

In Green, a government employee was injured during a test drive of an all-terrain vehicle. The vehicle was being considered for purchase by the plaintiff's employer. The defendant argued that the warranty claims should be dismissed, because neither the plaintiff nor her employer was in privity of contract with the vehicle manufacturer. The court, in a conclusory fashion, simply stated that it found that the plaintiff "need not be in privity of contract" with the manufacturer to maintain an action for breach of warranty in the context of personal injury. Green, 634 F.Supp. at 796. The court so concluded on the basis of an assumption that the Idaho Supreme Court would rule that way if it had the opportunity. Green, 634 F.Supp. at 796 ("If the Idaho Supreme Court has indicated a willingness to remove privity from the context of economic loss, it can safely be concluded that the court will not require privity in the context of personal injury.").

Wilson fails to reconcile Green with Oats v. Nissan Motor Corp., 879 P.2d 1095 (Idaho 1994), decided by the Idaho Supreme Court after Green, and holding that claims for personal injury under theories of breach of express and implied warranties may not be maintained absent privity of contract. 879 P.2d at 1102—1105. The court explained that a breach of warranty action "in tort to recover for personal injuries caused by a defective product is essentially an action for strict liability in tort," and should be considered as such. Id. at 1105. Accordingly, the court held that when a plaintiff brings a non-privity breach of warranty action against a manufacturer to recover for personal injuries allegedly sustained as a result of a defective product, that action is governed by Idaho's

product liability act, not the Uniform Commercial Code. Id. In other words, even though the plaintiff pleaded a claim for breach of express and implied warranties, his claim would be treated as one alleging strict liability for product liability. See RESTATEMENT (SECOND) OF TORTS § 402A(2) (strict liability of a product manufacturer applies even though the consumer has no contractual relationship with the seller).

This Court, in Elliott v. Smith & Nephew, Inc., No. 1:12-cv-070-EJL-MHW, 2013 WL 1622659 at *8 (D. Idaho Apr. 15, 2013), recently followed the holding in Oats, dismissing the plaintiffs' breach of express and implied warranty claims in a personal injury action arising from an alleged defective medical device. The Court recognizes the holding in Oats, and the holding in Green that privity of contract is not required for personal injury product liability actions is no longer good law. See also Puckett v. Oakfabco, Inc., 979 P.2d 1174, 1183 (Idaho 1999) (in a product liability action, "UCC warranties apply only to those in privity of contract with the manufacturer" and citing Oats, 879 P.2d at 1102).[12]

Wilson has not alleged the existence of a contract between himself and Amneal. And, based upon his concession that his breach of implied warranty claim is subject to dismissal because there is no privity of contract, the Court can conclude that privity of contract is lacking on both counts. Accordingly, Amneal is entitled to judgment as a matter of law against Wilson on his sixth and seventh claims for relief.

[12] Puckett cited Green with approval, but only for the proposition that an injured plaintiff who is an agent or employee of the corporation that purchased the allegedly defective product is a person to whom warranties, if any, could be extended. Puckett, 979 P.2d at 1183.

CONCLUSION

After reviewing Wilson's complaint, hearing oral argument, and being fully advised in the matters before the Court, the Court finds that judgment is appropriately entered in favor of Amneal on Counts One, Two, Four, Five, Six, and Seven. To the extent that Wilson can amend his complaint to allege facts constituting defective manufacture, Wilson may file an amended complaint.

ORDER

NOW THEREFORE IT IS HEREBY ORDERED:

1) Defendant's Motion for Judgment on the Pleadings (Dkt. 11) is **GRANTED** as to Counts One, Two, Four, Five, Six, and Seven. However, Plaintiff shall have up to and including **January 31, 2014**, to file an amended complaint consistent with the Court's opinion regarding Count Three, for negligent manufacture.
2) Plaintiff's Motion to Conduct Discovery (Dkt. 15) is **DENIED**.
3) Defendant's Motion to Take Judicial Notice (Dkt. 18) is **GRANTED.**

Dated: **December 31, 2013**

Honorable Candy W. Dale
United States Magistrate Judge