

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK**

JOSEPH HENSON,

Plaintiff,

v.

**5:12-CV-805
(FJS/TWD)**

**WRIGHT MEDICAL TECHNOLOGY,
INC., a Delaware corporation; and WRIGHT
MEDICAL GROUP, INC., a Delaware
Corporation,**

Defendants.

APPEARANCES

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SCULLIN, Senior Judge

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MEMORANDUM-DECISION AND ORDER

I. INTRODUCTION

Currently before the Court is Defendants' motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure. *See* Dkt. No. 16.¹

II. BACKGROUND²

On May 27, 2003, Plaintiff Joseph Henson underwent hip replacement surgery at Pennsylvania Hospital in Philadelphia, Pennsylvania. *See* Dkt. No. 1 at ¶ 12. During the operation, the surgical team implanted a Wright ProFemur Total Hip System (hereinafter the "Prosthesis") that Defendants designed, manufactured, tested, labeled, marketed, distributed, and/or sold. *See id.* at ¶¶ 11, 13. Dr. Jonathan Garino performed the surgery. *See id.* at ¶ 12. The Prosthesis included a Wright ProFemur Z size 3 titanium modular femoral neck (the "Femoral Neck"). Approximately eight years later, the Femoral Neck "suddenly and without warning failed, broke, and/or fractured," causing Plaintiff to have emergency surgery for a total hip replacement on May 18, 2011. *See id.* at ¶¶ 14-15.

Plaintiff thereafter filed this action, asserting various product liability causes of action arising from his alleged injury. *See generally* Dkt. No. 1. Reading the complaint broadly, Plaintiff appears to claim that Defendants (1) failed to warn and/or provide adequate warnings about the Prosthesis' true risks; (2) defectively designed the Prosthesis; (3) misrepresented the Prosthesis' qualities and characteristics; (4) breached their duty of care to provide a safely manufactured product, to notify the Food and Drug Administration ("FDA") of flaws, and to

¹ To avoid confusion, the Court's citations to specific page numbers reference the page numbers that the Court's electronic filing system automatically generates.

² For purposes of ruling on the instant motion to dismiss, the Court accepts as true all well-pleaded allegations in the complaint.

warn the FDA and Plaintiff of the Prosthesis' defective nature; and (5) are negligent *per se* for violations of the Food, Drug, and Cosmetic Act ("FDCA").³ See Dkt. No. 1 at ¶¶ 60-120. On July 27, 2012, Defendants brought this motion to dismiss the complaint. See Dkt. No. 16

III. DISCUSSION

A. Standard of review

1. Motion to dismiss

"A motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure tests the legal sufficiency of the party's claim for relief." *Lyman v. NYS OASAS*, No. 1:12-CV-530, 2013 U.S. Dist. LEXIS 25828, *7 (N.D.N.Y. Feb. 26, 2013) (citing *Patane v. Clark*, 508 F.3d 106, 111-12 (2d Cir. 2007)). In considering the legal sufficiency, a court must accept all well-pleaded factual allegations in the complaint as true and draw all reasonable inferences in the plaintiff's favor. See *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555-56 (2007) (citation omitted). This presumption of truth, however, does not extend to legal conclusions or "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements[.]" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted).

To survive a motion to dismiss, the plaintiff need only plead "a short and plain statement of the claim," see Fed. R. Civ. P. 8(a)(2), with sufficient factual "heft to 'sho[w] that the pleader is entitled to relief.'" *Twombly*, 550 U.S. at 557 (quotation omitted). Under this standard, the

³ Plaintiff also alleges that Defendants (1) breached an express warranty in the third cause of action, see Dkt. No. 1 at ¶¶ 80-87; and (2) defrauded medical personnel and the public to avoid recalling the Prosthesis and incurring liability in the fifth cause of action, see *id.* at ¶¶ 94-104. In his opposition to this motion, however, Plaintiff concedes that the Court should dismiss both claims, with the fifth cause of action being dismissed without prejudice. See Dkt. No. 18 at 6, 15-16. The Court, therefore, dismisses the third cause of action with prejudice and the fifth cause of action without prejudice and grants Plaintiff leave to amend accordingly.

pleading's "[f]actual allegations must be enough to raise a right of relief above the speculative level," *id.* at 555 (citation omitted), and present "enough facts to state a claim to relief that is plausible on its face[.]" *id.* at 570. "A claim has facial plausibility when the plaintiff pleads 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 (citation omitted). Indeed, "[w]here a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" *Id.* (quotation omitted). Ultimately, "when the allegations in a complaint, however true, could not raise a claim of entitlement to relief," *Twombly*, 550 U.S. at 558, or where a plaintiff has "not nudged [its] claims across the line from conceivable to plausible, the[] complaint must be dismissed[.]" *id.* at 570.

B. Failure to warn claim (first cause of action)

1. Sufficiency of the pleading

Under New York law, a plaintiff advancing a failure to warn claim must demonstrate that "(1) a manufacturer has a duty to warn (2) against dangers resulting from foreseeable uses about which it knew or should have known, and (3) that failure to do so was the proximate cause of the harm." *Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 575 (E.D.N.Y. 2012) (quoting *State Farm Fire & Cas. Co. v. Nutone, Inc.*, 426 F. App'x 8, 10 (2d Cir. 2011)) (other citation omitted); *see also Tompkins v. R.J. Reynolds Tobacco Co.*, 92 F. Supp. 2d 70, 90 (N.D.N.Y. 2000) (stating "New York courts consider a negligence claim for failure to warn and a strict liability claim for failure to warn to be equivalent" (citation omitted)). "[A] failure to warn cause of action is appropriately dismissed if a plaintiff does not plead facts indicating how the provided warnings were inadequate." *Reed*, 839 F. Supp. 2d at 575 (citations omitted).

At the outset, the Court notes Plaintiff's misguided claim that, "[a]t this early stage of the litigation, all [he] is required to plead in his failure to warn claim is that the defendants had a duty to warn the plaintiff, that the defendants breached its duty to warn the plaintiff, and that the breach of duty was a substantial factor or proximate cause of plaintiff's injury." *See* Dkt. No. 18 at 10 (citations omitted). The Supreme Court has clearly declared that "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice[;]" and "[w]here a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of 'entitlement to relief.'" *Iqbal*, 556 U.S. at 678 (quotation omitted).

It follows that Plaintiff has insufficiently pled a failure to warn claim because his allegations lack facts as to "how or why the acknowledged warning was inadequate, that is, about what risk of harm, or in what way, the acknowledged warning failed to warn." *Reed*, 839 F. Supp. 2d at 577; *see also Bravman v. Baxter Healthcare Corp.*, 984 F.2d 71, 75 (2d Cir. 1993) (stating that "[a] plaintiff proceeding under a failure-to-warn theory in New York must demonstrate that the failure to warn adequately of the dangers of a product was a proximate cause of his or her injuries" (citation omitted)). Plaintiff alleges, in part, that Defendants failed to (1) warn health care professionals and the public of the risks associated with the Prosthesis, including fretting and fracturing; and (2) provide adequate warnings about the Prosthesis' safe and effective use. *See* Dkt. No. 1 at ¶¶ 62, 64; *see also Reed*, 839 F. Supp. 2d at 576 (dismissing a failure to warn claim where the plaintiff merely alleged, "(1) 'the drug was not accompanied by adequate warnings;' and (2) the drug was promoted 'without sufficient disclosure of its dangerous propensities'" (quotation omitted)). Not only are these allegations merely legal conclusions

unsupported by factual content, but they also demonstrate nothing more than "a sheer possibility that [D]efendant[s] ha[ve] acted unlawfully." *Ashcroft*, 556 U.S. at 678 (citation omitted).

Accordingly, the Court grants Defendants' motion to dismiss this claim but grants Plaintiff leave to amend.⁴

2. "*Learned intermediary*" doctrine

Given Plaintiff's claims that Defendants failed to provide adequate warnings, and this case involves a medical product, the learned intermediary doctrine applies. *See Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 259 (E.D.N.Y. 1999) (finding that "plaintiff's 'failure to warn' claim, whether sounding in negligence or strict liability, is barred under the informed intermediary doctrine" (citation omitted)). Under the learned intermediary doctrine, a defendant manufacturer has an obligation to inform the treating physician of the risks of a medical device. *See Glucksman v. Halsey Drug Co., Inc.*, 553 N.Y.S.2d 724, 726 (1st Dep't 1990) (citation omitted); *see also Steinman v. Spinal Concepts, Inc.*, No. 05-CV-774S, 2011 U.S. Dist. LEXIS 107286, *26 (W.D.N.Y. Sept. 22, 2011) (stating that "[i]t is well settled with respect to prescription drugs and medical devices that a manufacturer's duty to warn is owed not [to] the patient, but to the treating physician as the 'learned intermediary'" (quotation and other citation omitted)). This doctrine is based on the notion that a physician serves as a learned intermediary "between the manufacturer and the patient, evaluating the patient's needs, assessing the risks and benefits of available drugs, and prescribing and supervising their use." *Glucksman*, 160 A.D.2d

⁴ To the extent Plaintiff also asserts his failure to warn claim under the theory of negligence, the Court dismisses such a claim because, "[w]here liability is predicated on a failure to warn, New York views negligence and strict liability claims as equivalent." *Martin v. Hecker*, 8 N.Y.2d 1, 8 n.1 (1993) (citation omitted).

305, 307 (1st Dep't 1990) (citations omitted). A manufacturer's liability, therefore, is related directly to the adequacy of the warning provided. *See id.*

In this case, the Prosthesis is a medical device that only physicians may implant and that is only available to the public via a prescription, meaning that Defendants distribute information about the Prosthesis to physicians, not to patients. Although Plaintiff does not appear to deny that Defendants provided a warning to physicians, he disputes the warnings' adequacy in conveying the Prosthesis' known or knowable risks. *See* Dkt. No. 18 at 6. The Court, however, cannot determine the adequacy of the warnings on a motion to dismiss. Thus, at this pleading stage, Defendants have not proven that the learned intermediary doctrine bars Plaintiff's claim. *See Smith v. St. Luke's Roosevelt Hosp.*, No. 08 Civ. 4710, 2009 U.S. Dist. LEXIS 69995, *30 (S.D.N.Y. Aug. 11, 2009) (stating that, in deciding a motion to dismiss, the court's role ""is merely to assess the legal feasibility of the complaint, not to assay the weight of the evidence which might be offered in support thereof"" (quotation and other citation omitted)).

C. Misrepresentation claim (fourth cause of action)

New York General Business Law ("GBL") §§ 349 and 350 make unlawful deceptive acts, practices, and false advertising "in the conduct of any business, trade or commerce or in the furnishing of any service[.]" N.Y. Gen. Bus. Law §§ 349(a), 350. Although Plaintiff does not cite to GBL §§ 349 and 350 in the complaint, he does so in his memorandum of law in opposition to Defendants' motion to dismiss. *Compare* Dkt. No. 1 *with* Dkt. No. 18. Even if the Court were to construe Plaintiff's complaint as alleging causes of action pursuant to §§ 349 and 350, it is clear that these claims are meritless.

To state a claim under §§ 349 and 350, the plaintiff must show that the act, practice, or advertisement was (1) consumer-oriented; (2) misleading in a material respect; and (3) caused his injury. *See Levine v. Landy*, 832 F. Supp. 2d 176, 192 (N.D.N.Y. 2011) (quotation omitted). In addition, for § 350, "the plaintiff must "point to [a] specific advertisement or public pronouncement" upon which [the consumer] relied." *Medisim Ltd. v. BestMed LLC*, No. 10 Civ. 2463, 2012 U.S. Dist. LEXIS 169042, *22 (S.D.N.Y. Nov. 28, 2012) (footnote omitted).

In the present matter, Plaintiff neglects to plead the necessary elements of §§ 349 and 350 violations, let alone allege sufficient factual allegations "to raise a right of relief above the speculative level." *Twombly*, 550 U.S. at 555 (citation and footnote omitted). Indeed, Plaintiff merely alleges that (1) Defendants represented the Prosthesis as safe for its intended uses but knew it was defective and caused "dozens of similar injuries," *see* Dkt. No. 1 at ¶ 90; (2) they knew the falsity of their representations about the Prosthesis' safety, which Plaintiff justifiably relied upon to his detriment, *see id.* at ¶ 91; and (3) their misrepresentations proximately caused his injuries, *see id.* at ¶¶ 92-93. Beyond these flat assertions and conclusory statements, Plaintiff advances no sufficient allegations regarding how Defendants' alleged deceptive or misleading business practices harmed consumers. *See Stadt v. Fox News Network LLC*, 719 F. Supp. 2d 312, 324 (S.D.N.Y. 2010) (finding no GBL § 349 violation where the complaint lacked allegations that the defendant "harmed consumers or the public interest in any material respect" (footnote omitted)). He also neglects to identify any specific advertisement or public pronouncement on which he relied. *See* N.Y. Gen. Bus. Law § 350.

Accordingly, the Court finds that Plaintiff has failed to state a cause of action for violations of GBL §§ 349 and 350 and grants Defendants' motion to dismiss this claim.

D. Negligence claim (sixth cause of action)⁵

In the sixth cause of action Plaintiff alleges that Defendants (1) "had a duty and continue to owe a duty to plaintiff to provide a safely manufactured product, to notify the FDA of flaws, and to warn the FDA and plaintiff of the defective nature" of the Prosthesis, *see* Dkt. No. 1 at ¶ 106; and (2) "breached their duty of reasonable care to [him] by failing to promptly and adequately notify the FDA . . . of known deficits" with the Prosthesis, *id.* at ¶ 109. Defendants argue that, to the extent Plaintiff is stating a negligence claim related to wrongdoings on the FDA, federal law preempts such a claim. *See* Dkt. No. 16 at 17-18.

Section 360k(a) of the Medical Device Amendments Act ("MDA") to the FDCA states,

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--(1) which is different from, or in addition to, any requirement applicable under this Act to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

21 U.S.C. § 360k(a). However, "[t]he MDA does not preempt state-law claims based on medical devices that received pre-market approval through the FDA's 'substantial-equivalence' review under § 510(k)." *Aaronson v. Am. Med. Sys., Inc.*, No. 09-CV-2487, 2010 U.S. Dist. LEXIS 92879, *5 n.2 (E.D.N.Y. Sept. 7, 2010) (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 492-94, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996)); *see also Sita*, 43 F. Supp. 2d at 261 (explaining that the § 510(k) clearance process allows "[a] manufacturer [to] circumvent the lengthy pre-market approval process by establishing that the medical device sought to be marketed is 'substantially

⁵ Defendants contend that the Court should dismiss the eighth cause of action, which alleges that they breached their duty to Plaintiff, causing him emotional and physical harm, because it is merely a claim for damages and is duplicative of the sixth cause of action. *See* Dkt. No. 16 at 10; Dkt. No. 1 at ¶¶ 119-20. The Court agrees and, therefore, dismisses the eighth cause of action.

equivalent' to a device that existed on the market prior to the enactment of the FDCA in 1976" (citing 21 U.S.C. § 360e(b)(1)(B)). Consequently, because the Prosthesis in this case received § 510(k) clearance from the FDA on December 13, 2000, the MDA does not preempt Plaintiff's negligence claim. *See* Dkt. No. 1 at ¶¶ 21, 23.

Accordingly, the Court denies Defendants' motion to dismiss this claim.

E. Negligence *per se* claim (seventh cause of action)

Plaintiff alleges that Defendants are negligent *per se* for violating §§ 331(a) and 333(a)(1) of the FDCA. *See* Dkt. No. 1 at ¶ 115. Specifically, Plaintiff contends that Defendants unlawfully adulterated and/or misbranded the Prosthesis by advertising, marketing, and selling its product as safe and similar to those on the market without providing warnings about its known risk of fracturing. *See* Dkt. No. 18 at 17.

Section 331(a) prohibits, in relevant part, "[t]he introduction or delivery for introduction into interstate commerce of any . . . device . . . that is adulterated or misbranded." 21 U.S.C. § 331(a). Second, § 333(a)(2) sets forth criminal consequences for misbranding. *See* 21 U.S.C. § 333(a)(2) (providing, in relevant part, that "if any person commits [] a violation [of section 301] after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three year or fined not more than \$10,000 or both"); *see also United States v. Caronia*, 703 F.3d 149, 154 (2d Cir. 2012) (stating that "[p]harmaceutical manufacturers and their representatives can face misdemeanor charges for misbranding or felony charges for fraudulent misbranding" (citations omitted)). Additionally, although the FDCA does not provide an express or implied private cause of action, "the Second Circuit has expressly recognized that a private cause of

action for per se negligence arises under New York State law upon violation of the FDCA." *Sita*, 43 F. Supp. 2d at 262 (citing *Ezagui v. Dow Chemical Corp.*, 598 F.2d 727, 733 (2d Cir. 1979)) (other citations omitted). Thus, Plaintiff is entitled to recovery under a theory of *per se* negligence, despite Defendants' contention otherwise. *See id.*

In addition, a defendant is negligent *per se* if the plaintiff establishes that "(1) [he] is among the class of people for whose particular benefit a statute had been enacted; (2) recognition of a private right of action would promote the legislative purpose behind the statute; and (3) creation of the right would be consistent with the overall legislative scheme. *See Prohaska v. Sofamor, S.N.C.*, 138 F. Supp. 2d 422, 448 (W.D.N.Y. 2001) (citation omitted).

The Court finds that, although Plaintiff is plainly a member of the class for whose benefit Congress passed the FDCA, his bare allegations do not plausibly set forth violations of §§ 331(a) and 333(a)(2). First, Plaintiff's factual allegation that the Prosthesis received § 510(k) clearance from the FDA on December 13, 2000, contradicts his claim that it is adulterated. *See* Dkt. No. 1 at ¶ 23; *see also* 21 U.S.C. § 351 (stating, "[a] . . . device shall be deemed adulterated . . . if it is a class III device" which, with respect to an intended use, has not received premarket approval or § 510(k) clearance). Second, with respect to misbranding, the complaint is void of allegations that Defendants provided inadequate directions for the Prosthesis' intended use, "including relevant hazards, effects and side effects, indications and contraindications, and warnings to medical practitioners cautioning them on how to make use of the device safely and in the manner in which it is intended to be used." *Sita*, 43 F. Supp. 2d at 261 (citing 21 U.S.C. § 352(f); 21 C.F.R. §§ 801.4, 801.109 (1993)). Third, it follows that Plaintiff's failure to allege plausible facts that Defendants violated § 333(a)(2) is fatal to any claim of criminal misbranding in violation of § 333(a)(1). *See* 21 U.S.C. § 333(a)(2).

Accordingly, the Court grants Defendants' motion to dismiss this claim.

F. Unavoidably unsafe exception to strict liability

Restatement (Second) of Torts § 402A, comment k ("Comment k"), as adopted in New York, imposes strict liability on manufacturers of unreasonably dangerous products. *See* Restatement (Second) of Torts § 402A, cmt. K. However, it also provides an exception to the imposition of strict liability for "unavoidably unsafe products." *Id.* Per the unavoidably unsafe exception, a manufacturer is not strictly liable for injurious side effects from properly manufactured prescription drugs, provided they include adequate warnings about potential side effects and proper directions for use. *See Wolfgruber v. Upjohn Co.*, 72 A.D.2d 59, 61 (4th Dep't 1979).

In this case, Defendants argue that the unavoidably unsafe defense enumerated above bars all of Plaintiff's non-negligence claims. *See* Dkt. No. 16 at 1, 3, 5-6. Although Comment k traditionally applies to prescription medication, Defendants assert that the Prosthesis is unavoidably unsafe because it is a sophisticated, prescription medical device available only to physicians. *See id.* at 5; Dkt. No. 21 at 1-2. To the contrary, Plaintiff argues that Defendants have insufficiently demonstrated that the unavoidably unsafe exception applies to medical devices, as they fail to provide supporting legal authority.⁶ *See* Dkt. No. 18 at 5.

⁶ The Court notes the Second Circuit's decision in *Bravman v. Baxter Healthcare Corp.*, 984 F.2d 71 (2d Cir. 1993). In *Bravman*, the plaintiffs appealed the district court's decision to dismiss his claim that his heart valve implant, which the defendant manufactured, suffered product and design defects and that the defendant violated its duty to warn. *See id.* at 76. Contrary to the plaintiffs' arguments, the Second Circuit found that the heart valve "may be treated, at least at the time of [the plaintiff's] surgery, as an unavoidably unsafe product." *Id.* (citing *McPheron v. Searle Lab., Inc.*, 888 F.2d 31, 33 (5th Cir. 1989) (listing courts following majority rule that medical devices that must be prescribed and inserted by a physician are unavoidable unsafe products)). Although the Second Circuit ultimately affirmed the dismissal, it

Notably, "[t]he fact that a product is sold only to physicians or by prescription is significant only insofar as it may qualify a product as 'unavoidably unsafe. . .[.]' The manufacturer still must show that the warning provided specific and detailed information on the potential hazards of the product . . . [.]" *Varveris v. Orthopaedic & Sports Assocs. of Long Is., P.C.*, No. 023193/10, 2011 N.Y. Misc. LEXIS 5042, *6-*7 (N.Y. Sup. Ct. Oct. 21, 2011) (internal and other citation omitted). Consequently, assuming, without deciding, that the Prosthesis is an unavoidably unsafe product, Defendants' defense hinges on the adequacy of the warnings it provided to the medical community, including Plaintiff's physician. *See id.* at *6 (stating that, "a manufacturer of an 'unavoidably unsafe' product cannot escape liability without demonstrating that its product was accompanied by proper directions and adequate warnings"). For the reasons previously set forth, the Court cannot determine the adequacy of such warnings at this stage of the proceedings.

Accordingly, the Court denies Defendants' motion to dismiss on this ground.

IV. CONCLUSION

After carefully reviewing the entire record in this matter, the parties' submissions, and the applicable law, and for the above-stated reasons, the Court hereby

ORDERS that Defendants' motion to dismiss is **GRANTED** and the third, fourth, seventh and eighth causes of action are **DISMISSED WITH PREJUDICE**; and the Court further

stated that "the district court findings on the product and design defect claims did not depend upon th[e] determination" of the heart valve being an unavoidably unsafe product. *Id.*

ORDERS that Defendants' motion to dismiss is **GRANTED** and the first, fifth, and sixth causes of action are **DISMISSED WITHOUT PREJUDICE** and **WITH LEAVE TO AMEND**; and the Court further

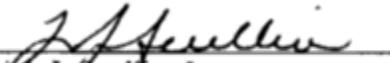
ORDERS that Defendants' motion to dismiss is **DENIED** with regard to the second cause of action;⁷ and the Court further

ORDERS that Plaintiff shall file and serve his amended complaint within **ten (10) days** of the date of this Memorandum-Decision and Order;⁸ and the Court further

ORDERS that this matter is referred to Magistrate Judge Dancks for all further pretrial matters.

IT IS SO ORDERED.

Dated: March 28, 2013
Syracuse, New York


Frederick J. Scullin, Jr.
Senior United States District Court Judge

⁷ To the extent that Defendants assert the unavoidably unsafe defense to Plaintiff's first and second causes of action, the Court denies their motion to dismiss those claims on that ground.

⁸ Consistent with this Memorandum-Decision and Order, any amended complaint that Plaintiff files shall include only those causes of action that he enumerated as the first, second, fifth, and sixth causes of action in his original complaint.