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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

LEE KENWORTHY as the Administer for the ESTATE OF SHAYLING KENWORTHY AND LEE KENWORTHY, Individually, Plaintiff, v. LYNDHURST POLICE DEPARTMENT, OFFICER PHILIP REINA, in his individual capacity, LYNDHURST CHIEF OF POLICE JAMES O'CONNOR, in his individual capacity, SERGEANT RICHARD PIZZUTI, in his individual capacity, LYNDHURST TOWNSHIP AMBULANCE SQUAD, TOWNSHIP OF LYNDHURST, ROBERT MARTIN, ANN MARTIN, RICHARD ANDERSON, LAUREN ANDERSON, HOUSING AUTHORITY OF BERGEN COUNTY, and ADAPT PHARMA, INC., Defendants.	CIVIL ACTION NO. 2:18-cv-12822-MCA-CLW

<u>DEFENDANT ADAPT PHARMA, INC.'S BRIEF IN OPPOSITION TO PLAINTIFF'S MOTION FOR LEAVE TO FILE AN AMENDED COMPLAINT</u>

Of Counsel
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On the Brief
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PRELIMINARY STATEMENT

Plaintiff's Motion for Leave to File an Amended Complaint (ECF No. 30) is the most recent step in what has become a pattern of delays and actions that prejudice the parties. Five motions to dismiss have been pending since December 11, 2018 (ECF Nos. 6-7, 14-16). On December 28, 2018, Plaintiff sought, and was denied, an emergency hearing with the Court (ECF Nos. 17-18). On January 7, 2019, Plaintiff filed as his apparent response to the pending motions to dismiss by seeking a continuance (ECF Nos. 19-23). Two days later, he formally filed a motion for a continuance, purportedly to allow an attorney he had apparently retained to enter an appearance and oppose the motions to dismiss (ECF No. 25). The Court granted Plaintiff a thirty-day continuance (ECF No. 27). To date, no attorney has appeared on his behalf.

Rather than address the motions to dismiss, on January 9, 2019, Plaintiff filed a proposed Amended Complaint without having first obtained leave from the Court. The proposed Amended Complaint is not only procedurally improper; it is legally deficient. As to Defendant Adapt Pharma, Inc. ("Adapt"), Plaintiff seeks to re-assert a claim for negligence (Count Eight) and to add claims for Gross Negligence (Count Nine) and Intentional Infliction of Emotional Distress (Count Ten). Even if Plaintiff's allegations against Adapt are accepted as true, he has failed to state a claim upon which relief can be granted. As Adapt argued in its

pending Motion to Dismiss,[1] Plaintiff's common-law claims against Adapt are subsumed by New Jersey's Product Liability Act ("PLA"), which limits Plaintiff to four potential causes of action against a product manufacturer: design defect, manufacturing defect, failure to warn, and express warranty. Further, to the extent the allegations in Plaintiff's proposed gross negligence claim can be read as a claim for fraud, the claim fails for two reasons. First, courts have held that fraud claims are subsumed by the PLA. Second, the Supreme Court has held a claim that a defendant defrauded the Food and Drug Administration ("FDA") is barred under implied preemption principles. Therefore, Plaintiff's Motion for Leave to File an Amended Complaint against Adapt should be denied as futile.

Plaintiff has had the benefit of a continuance, as well as the opportunity to review the motions to dismiss and attempt to cure the deficiencies in the Complaint identified therein. Despite these advantages, Plaintiff has not cured the deficiencies in his claims against Adapt and has succeeded only in causing Adapt and its co-defendants to expend time and money responding to his string of improper filings.

For these reasons, Adapt respectfully requests that Plaintiff's Motion for Leave to File an Amended Complaint should be denied for futility, and the Complaint be dismissed with prejudice as to Adapt.

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[1] A copy of Adapt's Brief in Support of its Motion to Dismiss is attached as Exhibit A to the February 5, 2019 Certification of Beth S. Rose ("Rose Cert.").

STATEMENT OF FACTS

For the factual background of this litigation, Adapt respectfully refers the Court to the Statement of Facts in its Motion to Dismiss. *See* "Rose Cert.", Ex. A, at 3-5.

LEGAL ARGUMENT

I. PLAINTIFF'S MOTION FOR LEAVE TO AMEND SHOULD BE DENIED AS FUTILE BECAUSE THE PROPOSED AMENDED COMPLAINT FAILS TO STATE A CLAIM

Leave to amend should be denied when the proposed amendment is futile. *See generally In re Burlington Coat Factory Sec. Litig*., 114 F.3d 1410, 1434-35 (3d Cir. 1997). In this context, futility "means that the complaint, as amended, would fail to state a claim upon which relief could be granted. In assessing 'futility,' the district court applies the same standard of legal sufficiency as applies under Rule 12(b)(6)." *Id*. at 1434 (citations omitted). *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'") (citations omitted); *see also Travelers Indem. Co. v. Dammann & Co*., 594 F.3d 238, 256 n.14 (3d Cir. 2010) (holding that a denial of a motion to amend on futility grounds was proper where it was "based on a finding that the proposed claim would be subject to dismissal under Rule 12(b)(6)").

A. Plaintiff's Proposed Amended Complaint Would Be Futile Because The Claims Of Negligence (Count Eight), Gross Negligence (Count Nine), and Intentional Infliction of Emotional Distress (Count Ten) Are Subsumed By The PLA

Plaintiff's proposed Amended Complaint fails to state a claim upon which relief can be granted as to Adapt. As Adapt argued in its Motion to Dismiss, due to the fact this case involves claims that Decedent suffered personal injuries as a result of a product (or products), Plaintiff may only assert claims that are authorized by the PLA: design defect, manufacturing defect, failure to warn, and breach of express warranty. *See N.J.S.A.* 2A:58C-1(b)(3) (allowing express warranty claims); *N.J.S.A.* 2A:58C-2 (identifying design defect, manufacturing defect, and failure to warn as the only other claims available under the PLA). The New Jersey Supreme Court has repeatedly held that the PLA provides the sole and exclusive remedy for individuals who claim they were physically injured by a product. *In re Lead Paint Litigation ("In re Lead Paint")*, 191 N.J. 405, 436-37 (2007). All other potential theories of recovery, including those for negligence and breach of implied warranties, are subsumed by the PLA and cannot be asserted in a traditional product liability action such as this one.

In *In re Lead Paint*, the New Jersey Supreme Court addressed whether plaintiffs could assert a nuisance cause of action against lead paint manufacturers that allegedly caused plaintiff's personal injuries. The Court analyzed the language of the PLA, and its legislative history, and held that "[t]he language

chosen by the Legislature in enacting the PLA is both expansive and inclusive, encompassing virtually all possible causes of action relating to harms caused by consumer and other products." *In re Lead Paint*, 191 N.J. at 436-37. Because lead paint was a product covered by the PLA, and because the personal injuries at issue in the case were squarely within the scope of the PLA, the Court held that the PLA precluded plaintiffs from asserting common law claims. *Id.*

The District of New Jersey has applied the holding of *In re Lead Paint* in the context of a common law negligence claim related to a pharmaceutical product. *Clements v. Sanofi-Aventis, U.S., Inc.*, 111 F. Supp. 3d 586, 596 (D.N.J. 2015). In *Clements*, the plaintiff asserted state common law claims for negligence, strict liability, and breach of warranty stemming from her use of an injectable dermatological product. *Id.* The defendant manufacturer moved to dismiss, arguing that the plaintiff could not assert common law claims in a product liability action. The Court, relying on *In re Lead Paint*, granted the motion as to the common law claims. *Id.* The Court ruled that the plaintiff's negligence claim was subsumed by the PLA and "must be dismissed as a matter of law." *Id.* at 598. The Court also noted that courts consistently dismiss product liability claims based on common law causes of action. *Id.* at 597 n.5 (citing *Port Auth. of N.Y. & N.J. v. Arcadian Corp.*, 189 F.3d 305, 313 (3d Cir. 1999) (dismissing negligence claim, stating that "[u]nder New Jersey law negligence is no longer viable as a separate

claim for harm caused by a product"); *Repola v. Morbark Indus., Inc.*, 934 F.2d 483, 489-94 (3d Cir. 1991) (dismissing claims of negligence and negligent failure to warn); *Thomas v. Ford Motor Co.*, 70 F. Supp. 2d 521, 528-29 (D.N.J. 1999) (dismissing common-law claim for negligent manufacture); *Reiff v. Convergent Techs.*, 957 F. Supp. 573, 583 (D.N.J. 1997) (dismissing negligence and breach of warranty claims); *McWilliams v. Yamaha Motor Corp. USA*, 780 F. Supp. 251, 262 (D.N.J. 1991) (dismissing claims of negligence and breach of implied warranty), *aff'd in part, rev'd in part on other grounds*, 987 F.2d 200 (3d Cir. 1993); *Tirrell v. Navistar Int'l, Inc.*, 248 N.J. Super. 390, 399 (2007) (dismissing negligence claim); *see also, e.g.*, *Green v. Gen. Motors Corp.*, 310 N.J. Super. 507, 517, 709 A.2d 205 (App. Div. 1998) (stating that "causes of action for negligence, strict liability and implied warranty have been consolidated into a single product liability cause of action" under the PLA); *Ramos v. Silent Hoist & Crane Co.*, 256 N.J. Super. 467, 473, 607 A.2d 667 (App. Div. 1992) (stating that the "Legislature has consolidated the negligence, breach of warranty and strict liability theories for product liability claims" into single product liability action under PLA)).

In assessing whether a cause of action is subsumed by the PLA, a court must look at the nature of Plaintiff's alleged claim and injuries and determine whether they represent a traditional product liability claim. Here, there can be no doubt that Plaintiff's claims against Adapt present a classic product liability case that clearly

falls within the confines of the PLA. "A product liability action is statutorily defined as 'any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except for actions for harm caused by a breach of an express warranty.'" *Indian Brand Farms v. Novartis Crop Prot., Inc.*, 890 F. Supp. 2d 534, 540 (D.N.J. 2012) (quoting *N.J.S.A.* 2A:58C-1(b)(3)). Plaintiff's central allegation is that Decedent suffered fatal physical injuries following the administration of naloxone. This allegation is the basis of a traditional product liability claim.

Plaintiff's proposed Amended Complaint states a claim for negligence. Specifically, Plaintiff alleges Adapt had a duty to use reasonable care in the development and sale of Narcan, and in the training of the product's users *See* Rose Cert., Ex. B, *Proposed Amended Complaint*, ¶¶ 258-62. Plaintiff further alleges that Adapt breached that duty, which resulted in his injuries. *Id.* ¶¶ 265, 267. The elements of a negligence claim are "a duty of care, a breach of that duty, and that the breach proximately caused the harm." *Olivo v. Exxon Mobil Corp.*, 377 N.J. Super. 286, 292 (App. Div. 2005). A negligence claim is barred under the PLA. *See Clements, Inc.*, 111 F. Supp. 3d at 596 ("New Jersey law no longer recognizes breach of implied warranty, negligence, and strict liability as viable separate claims for harm deriving from a defective product.") Consequently, New

Jersey state courts, the Third Circuit, and this Court have "consistently dismissed product liability claims based on those common-law theories." *Id.* at 596-97.

Likewise, Plaintiff's claim for gross negligence would also be subsumed by the PLA. *Kuhar v. Petzl Co.*, 2016 U.S. Dist. LEXIS 94279, *8 (D.N.J. Jul. 19, 2016), Rose Cert., Ex. C, (dismissing plaintiff's claims for negligence and gross negligence as subsumed by the PLA). Under New Jersey law, the elements of negligence and gross negligence are the same, and gross negligence differs only in the degree to which the tortfeasor is culpable. *Monaghan v. Holy Trinity Church*, 275 N.J. Super. 594, 599 (App. Div. 1994). Here, Plaintiff alleges that Adapt was not merely negligent but that its actions were "aggravated by malice fraud and grossly negligent disregard for the rights of others, the public, and the Plaintiff." Rose Cert., Ex. B, ¶ 271. Plaintiff's gross negligence claim would be subsumed by the PLA just as his negligence claim would be, and the amended claim is therefore futile.

Finally, Plaintiff's proposed claim for intentional infliction of emotional distress is also a common-law claim that is subsumed by the PLA. *See Rivera v. Valley Hosp., Inc.*, 2017 U.S. Dist. LEXIS 33203, *8 (D.N.J. Mar. 7, 2017), Rose Cert., Ex. D, (dismissing plaintiff's negligent infliction of emotional distress claim as subsumed by the PLA); *Chester v. Boston Sci. Corp.*, 2017 U.S. Dist. LEXIS 26676 (D.N.J. Feb. 27, 2017), , Rose Cert., Ex. E, (dismissing plaintiff's common-

law claims, including intentional infliction of emotional distress, as subsumed by the PLA); *see also Walus v. Pfizer, Inc.*, 812 F. Supp. 41, 45 (D.N.J. 1993) (granting summary judgment to defendant in product liability action on all claims, including intentional infliction of emotional distress). "New Jersey treats all product liability actions the same, regardless of the theory asserted." *Walus*, 812 F. Supp. at 45 (citing *N.J.S.A.* § 2A:58C-1b(3)). Plaintiff's proposed claim for intentional infliction of emotional distress would be subsumed by the PLA, and the proposed claim is therefore futile.

B. To The Extent Plaintiff Seeks To Assert A Fraud Claim, Such A Claim Would Be Futile

To the extent that Plaintiff's proposed gross negligence claim can be read as a claim for fraud, such a claim would also fail. First, the causes of action of common-law fraud and claims under the New Jersey Consumer Fraud Act ("CFA") are subsumed by the PLA. Second, insofar as Plaintiff alleges Adapt withheld information from the FDA, the Supreme Court has held that such "fraud on the FDA" claims are precluded as a matter of law under implied preemption principles. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

Plaintiff's proposed gross negligence claim alleges that Adapt's actions were "aggravated by malice, *fraud*, and grossly negligent disregard for the rights of others." Rose Cert, Ex. B ¶ 271 (emphasis added). Plaintiff further alleges that Adapt "intentionally and fraudulently misrepresented facts and information to both

the medical community and the general public . . . by making intentionally false and fraudulent misrepresentations about the safety of Narcan." *Id.* ¶ 275. While Adapt denies the allegations, even if Plaintiff's allegations were accepted as true they would fail to state a claim upon which relief could be granted.

Several courts have held that the PLA subsumes common-law fraud claims like that which Plaintiff asserts in the proposed Amended Complaint. *See, e.g.*, *Bailey v. Wyeth, Inc.*, 2008 N.J. Super. Unpub. LEXIS 3004, *92-98 (Law Div. July 1, 2008), Rose Cert., Ex. F, (holding that common-law fraud and misrepresentation claims were subsumed by the PLA); *Brown v. Phillip Morris, Inc.*, 228 F. Supp. 2d 506, 517 (D.N.J. 2002) (same); *cf. Sinclair v. Merck & Co., Inc.*, 195 N.J. 51, 65 (2008) (holding that the PLA precluded product liability plaintiffs from asserting claims under the New Jersey Consumer Fraud Act ("CFA")); *see also McDarby v. Merck & Co., Inc.*, 401 N.J. Super. 10, 94-99 (App. Div. 2008) (holding that plaintiffs' CFA claims seeking the recovery of payments made for prescription drugs that allegedly injured plaintiff were subsumed by the PLA).

Insofar as Plaintiff alleges Adapt withheld information from the FDA, the claim would also fail. The Supreme Court has held that the Food, Drug and Cosmetic Act ("FDCA") does not provide plaintiffs with a private right of action, that the FDA has the exclusive authority to enforce its disclosure laws and

regulations, and that allowing "fraud on the FDA" claims would conflict with the FDA's regulatory authority. *Buckman*, 531 U.S. at 349 and n.6. Since *Buckman* was decided, numerous courts have dismissed claims where they are based on allegations that the manufacturer failed to provide information to or withheld information from the FDA. *See, e.g., Miller v. DePuy Spine, Inc.*, 2009 U.S. Dist. LEXIS 49602 *11-12 (D. Nev. May 1, 2009), Rose Cert., Ex. G, (holding that "any claim by Mr. Miller based on a contention that DePuy Spine provided inaccurate or incomplete information to the FDA would be preempted … under the implied preemption principles stated in *Buckman* … ."); *Wheeler v. DePuy Spine, Inc.*, 2010 U.S. Dist. LEXIS 48524, *11 and n.4 (S.D. Fl. March 8, 2010), Rose Cert., Ex. H, (dismissing plaintiff's negligence claim under *Buckman* because it was based on plaintiff's assertion that the defendant failed to disclose product safety information to the FDA).

Plaintiff's proposed Amended Complaint fails to state a claim as to Adapt. Accordingly, the Motion for Leave to File an Amended Complaint should be denied as to Adapt. Plaintiff has had two opportunities to assert a claim against Adapt and has failed to do so. Despite numerous filings with the Court, he has ignored the substantive arguments supporting Adapt's Motion to Dismiss. The Court granted Plaintiff a thirty-day continuance in response to Plaintiff's assurances that an attorney would appear on his behalf. No attorney has appeared,

which makes one question whether Plaintiff has, in fact, retained counsel. Adapt has expended time and money to respond to baseless allegations and procedurally improper filings. Adapt respectfully requests that the Court dismiss the claims against it with prejudice.

CONCLUSION

Based on the foregoing reasons, Adapt respectfully requests that the Court deny Plaintiff's Motion for Leave to File an Amended Complaint and dismiss Plaintiff's Complaint with prejudice as to Adapt.

Respectfully submitted,
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By: *s/ Beth S. Rose*
BETH S. ROSE

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Dated: February 5, 2019