UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

ROBERT N. MARKLAND, as the Personal Representative of the Estate of Carolyn S. Markland, Deceased,

Plaintiff,

Case No. 3:16-cv-997-J-34PDB

vs.

INSYS THERAPEUTICS, INC.,

Defendant.
_____/

O R D E R

THIS CAUSE is before the Court on Defendant Insys Therapeutics, Inc.'s (Insys) Amended Motion to Dismiss (Doc. 15; Motion), filed on September 2, 2016. In the Motion, Insys requests that this Court dismiss plaintiff Robert N. Markland's complaint for Damages and Demand for a Jury Trial (Doc. 2; Complaint). Mr. Markland, who files this action as the Personal Representative of the Estate of Carolyn S. Markland, opposes the Motion. See Plaintiff's Response to Defendant's Motion to Dismiss (Doc. 23; Response), filed September 29, 2016. With leave of Court (Doc. 28), Insys filed a Reply in Support of its Amended Motion to Dismiss. See Defendant Insys Therapeutics, Inc.'s Reply in Support of its Amended Motion to Dismiss (Doc. 30; Reply), filed October 25, 2016. Accordingly, this matter is ripe for review.[1]

[1] In his Response, Mr. Markland included a request to amend his complaint in the event the Court found his allegations inadequate. See Response at 23, 27. On September 30, 2017, the Court declined this request without prejudice, see Order at 3 (Doc. 25), noting that a request for affirmative relief, such as a request for leave to amend a pleading, is not properly made when simply included in a response to a motion. See FED. R. CIV. P. 7(b); see also Rosenberg v. Gould, 554 F.3d 962, 965 (11th Cir. 2009) ("Where a request for leave to file an amended complaint simply is imbedded within an opposition memorandum, the issue has not been raised properly.") (quoting Posner v. Essex Ins. Co., 178 F.3d 1209, 1222 (11th Cir. 1999)). The Court

I. STANDARD OF REVIEW

In ruling on a motion to dismiss, the Court must accept the factual allegations set forth in the complaint as true. See Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009); Swierkiewicz v. Sorema N.A., 534 U.S. 506, 508, n 1 (2002); see also Lotierzo v. Woman's World Med. Ctr., Inc., 278 F.3d 1180, 1182 (11th Cir. 2002). In addition, all reasonable inferences should be drawn in favor of the plaintiff. See Omar ex. rel. Cannon v. Lindsey, 334 F.3d 1246, 1247 (11th Cir. 2003) (per curiam). Nonetheless, the plaintiff must still meet some minimal pleading requirements. Jackson v. BellSouth Telecomm., 372 F.3d 1250, 1262–63 (11th Cir. 2004) (citations omitted). Indeed, while "[s]pecific facts are not necessary," the complaint should "'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" Erickson v. Pardus, 551 U.S. 89, 93 (2007) (per curiam) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)). Further, the plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." Twombly, 550 U.S. 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 (citing Twombly, 550 U.S. at 556).

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 (citations omitted); see also BellSouth

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nonetheless advised Mr. Markland that "if he wishes to pursue such relief, he is required to file an appropriate motion, in accordance with the Federal Rules of Civil Procedure and the Local Rules of this Court." Order at 2. Mr. Markland has not done so.

Telecomm., 372 F.3d at 1262 (explaining that "conclusory allegations, unwarranted deductions of facts or legal conclusions masquerading as facts will not prevent dismissal") (citations and quotations omitted). Indeed, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions," which simply "are not entitled to [an] assumption of truth." See Iqbal, 556 U.S. at 679. Thus, in ruling on a motion to dismiss, the Court must determine whether the complaint contains "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Id. at 678 (quoting Twombly, 550 U.S. at 570).

II. BACKGROUND AND ARGUMENTS OF THE PARTIES

This wrongful death action arises from the prescribed use of the drug known as Subsys, a sublingual spray formation of Fetanyl, and the untimely death of Carolyn S. Markland, a resident of Jacksonville, FL. Complaint at ¶¶ 5, 13.

Carolyn Markland, the deceased wife of Mr. Markland, suffered from degenerative disc disease which caused her chronic back pain. Complaint at ¶ 35. Her pain management physician, Dr. Orlando G. Florente, M.D., of Jacksonville, FL, prescribed her a dose of Subsys at his office on July 2, 2014. Id. at ¶ 34. She subsequently suffered from respiratory distress early the following morning and died. Id. at ¶ 36. Reports from the Duval County Medical Examiner noted "drug toxicity" as her cause of death. Id. at ¶. 5.

Subsys is a drug developed and produced by Insys, a Delaware Corporation with its principal place of business in Arizona. Id. at ¶¶ 6, 9.[2] On January 4, 2012, the Food

[2] This case was brought on behalf of the estate of a Florida resident against a Delaware Corporation with its principal place of business in Arizona. Therefore, this Court exercises diversity jurisdiction over the matter. See 28 U.S.C. § 1332. In diversity actions, the Court applies substantive law of the forum state. See Keller v. Miami Herald, Pub. Co., 778 F.2d 711, 714 (11th Cir. 1985) (citing Erie Railroad v. Tompkins, 304 U.S. 64,

and Drug Administration (FDA) specifically approved Subsys for treatment of breakthrough pain in cancer patients. Id. at ¶¶ 6-7. One significant risk associated with the drug, and as noted in the FDA mandated Medical Guide accompanying Subsys, was that the drug could cause respiratory depression and death. Id. at ¶¶ 21, 23-24.[3] Tragically, this appears to have been true for Carolyn Markland.

Despite the fact that the FDA approved Subsys solely for treatment of breakthrough pain in cancer patients, id. at ¶¶ 6-7, Insys engaged in an "aggressive marketing campaign to get physicians to prescribe Subsys for other uses including relieving chronic back pain." Id. at ¶¶ 26, 28-30. In doing so, Mr. Markland alleges that Insys "negligently convinced physicians, . . . pain management physicians, and doctors specializing in internal medicine that the physicians should and could write prescriptions for Subsys Fetanyl as an off-label use. This was unlawful conduct by Insys and was in violation of federal law." Id. at ¶ 28(d). Mr. Markland describes Insys' marketing scheme as one that "did not consider the safety and wellbeing of patients who were prescribed this extremely dangerous drug and was undertaken only to increase the earnings of Insys. This scheme placed company profits

78 (1938)); Allstate Ins. Co. v. Clohessy, 32 F. Supp. 2d 1328, 1330 (M.D. Fla. 1998). As such, Florida law governs the resolution of Mr. Markland's claims.

[3] Insys attached a variety of exhibits in support of its Motion to Dismiss. Motion, Exs. 9-10. The attached documents appear to be Federal Drug Administration (FDA) records available to the public on the FDA or National Institute of Health websites. Under appropriate circumstances, a court may take judicial notice of and consider documents attached to a motion to dismiss or response, which are public records that are "central" to a plaintiff's claims, without converting the motion to dismiss into a motion for summary judgment. See SFM Holdings, Ltd. v. Banc of Am. Sec., LLC, 600 F.3d 1334, 1337 (11th Cir. 2010). This is so, as long as such documents are "public records that [are] 'not subject to reasonable dispute' because they [are] 'capable of accurate and ready determination by resort to sources whose accuracy [can] not reasonably be questioned.'" Horne v. Potter, 392 F. App'x 800, 802 (11th Cir. 2010) (quoting Fed.R.Evid. 201(b)). Upon review, the Court determines that Insys' exhibits satisfy the foregoing requirements, and therefore, the Court will take judicial notice of the documents. Stanifer v. Corin USA Ltd., Inc., No. 6:14–cv–1192–Orl–37DAB, 2014 WL 5823319, at *3 (M.D.Fla. Nov.10, 2014) ("Courts in this District and elsewhere regularly take judicial notice of public records available on the FDA's website because such document[s] satisfy the requirements of Rule 201.") (collecting cases). In citing Horne, the Court notes that "[a]lthough an unpublished opinion is not binding . . . , it is persuasive authority." United States v. Futrell, 209 F.3d 1286, 1289 (11th Cir. 2000) (per curiam); see generally FED. R. APP. P. 32.1; 11th Cir. R. 36-2 ("Unpublished opinions are not considered binding precedent, but they may be cited as persuasive authority.").

ahead of patients' safety." Id. at ¶ 31. At bottom, Mr. Markland alleges that Insys was "negligent in aggressively promoting the off-label use or prescribing of" Subsys, id. at ¶ 28(e), which resulted in his wife's death.

Based on this conduct, Mr. Markland asserts a single claim of negligent marketing against Insys. Id. at ¶¶ 32-38. Mr. Markland also asserts that as a direct and proximate cause of Insys' negligent marketing, he lost the support, services, comfort, society, companionship, protection, and attention of his deceased wife, along with bearing his own mental pain and suffering. Id. at ¶ 37. Additionally, Mr. Markland asserts that as a direct and proximate cause of Insys' negligent marketing, he individually, and as representative of his deceased wife's estate, incurred funeral expenses resulting from Carolyn Markland's death, along with losing her earnings and net accumulations that she otherwise would have acquired over her natural life span. Id. at ¶ 38.

In the Motion, Insys raises several arguments in support of its request for dismissal of this case. First, Insys asserts that Mr. Markland lacks standing to bring this action on behalf of his wife's estate because his status as Personal Representative ceased when he closed Carolyn Markland's estate in April of 2016. See Motion at 6. Insys argues that when Mr. Markland initiated this action after closing the estate, he could not claim the status of Personal Representative, and therefore lacks standing. Id. at 8. Second, Insys argues that even if Mr. Markland has standing to bring this suit, the tort of negligent marketing is not a recognized cause of action in Florida. Id. at 8. Third, Insys proffers that Mr. Markland's claims are more accurately characterized as violations of the Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301, *et seq.* Id. at 11. In this regard, Insys contends that a private right of action is barred under the statute. Id. at 14-15. Fourth, and allied

with the preceding position, Insys argues that Mr. Markland's action is impliedly preempted by the FDCA. Id. at 15-16. Fifth, Insys contends that in the event the Court nonetheless finds that Mr. Markland is able to assert a claim of negligent marketing, the claim is foreclosed by the learned intermediary doctrine. In support of this contention, Insys asserts that any duty it possessed in terms of ensuring that it delivered a safe product to the market, was discharged because it provided clear and unambiguous warnings regarding dangers associated with Subsys to Carolyn Markland's prescribing physician. Id. at 18-19. Finally, Insys argues that Mr. Markland is judicially estopped from bringing his action. Id. at 26.

In his Response, Mr. Markland notes that he has standing to bring his action because he was reappointed Personal Representative of his wife's estate. See Response at 7-8. Further, Mr. Markland contends that his action is recognized under Florida law, because whether framed as "negligent marketing" or simply as "negligence," id. at 8-9, 11, every drug manufacturer has a duty to ensure that its "products will be reasonably safe for consumers in the marketplace." Id. at 8. He asserts that he is not seeking to bring a private right of action under the FDCA, id. at 11-12, but rather, is seeking to use Insys' alleged violation of federal law as evidence to support his negligence claim. Id. Mr. Markland also proffers that his action is not impliedly preempted by the FDCA, id. at 14, nor should the learned intermediary doctrine be applied in this case due to Insys' aggressive over promotion of Subsys. Id. at 20-22. Finally, Mr. Markland asserts that judicial estoppel is not appropriate. Id. at 24-25.

III. DISCUSSION

a. Standing

Insys contends that Mr. Markland lacks standing to bring this action because he was not the Personal Representative of his wife's estate at the time he initiated this lawsuit. In his Response, Mr. Markland acknowledges that he was not the Personal Representative of his wife's estate at the time he filed this wrongful death action, but asserts that because he has since been reappointed as such, he does have standing. In making these arguments, both parties rely on publicly available records from the Circuit Court for Duval County, Florida Probate Division. See Motion, Exhibits 1-8; Response, Exhibits 3-4.

A motion to dismiss based on lack of standing is considered a challenge to the court's subject matter jurisdiction pursuant to Rule 12(b)(1), Federal Rule of Civil Procedure (Rule(s)). Townsend v. U.S. Dep't of Agric., Case No. 2:05-cv-439-FtM-99DNF, 2007 WL 177857, at *1-2 (M.D. Fla. Jan. 19, 2007) (citing Morrison v. Amway Corp., 323 F.3d 920, 924 n.5 (11th Cir. 2003)). Attacks based on a lack of subject matter jurisdiction come in two forms: facial attacks and factual attacks. Lawrence v. Dunbar, 919 F.2d 1525, 1528-29 (11th Cir. 1990) (internal quotations and alternations omitted); see also Jones v. Waffle House, Inc., Case No. 6:15-cv-1637-Orl-37DAB, 2016 WL 3231298, at *3 (M.D. Fla. June 13, 2016). "Facial attacks on the complaint require the court merely to look and see if the plaintiff has sufficiently alleged a basis of subject matter jurisdiction, and the allegations in his complaint are taken as true for the purposes of the motion." Lawrence, 919 F.2d at 1529. "Factual attacks, on the other hand, challenge the existence of subject matter jurisdiction in fact, irrespective of the pleadings, and matters outside the pleadings, such as testimony and affidavits, are considered." Id. Additionally, a court may consider

judicially noticed documents. United States ex rel. Osheroff v. Humana Inc., 776 F.3d 805, 811 (11th Cir. 2015); see also Cair Florida, Inc. v. Teotwawki Inv., LLC, Case No. 15-cv-61541-BLOOM/Valle, 2015 WL 11198249, at *2 (S.D. Fla. Nov. 24, 2015); Gibbs v. U.S., 865 F. Supp. 2d 1127, 1135 (M.D. Fla. 2012) (court may consider extrinsic evidence in resolving a factual attack to subject matter jurisdiction). Therefore, in resolving the issue of standing, the Court will take judicial notice of the publicly filed probate records relied upon by both parties. See FED. R. EVID. 201(b) ("The court may judicially notice a fact that is not subject to reasonable dispute because it: is generally known within the trial court's territorial jurisdiction; or can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.").

Florida law establishes that a wrongful death action "shall be brought by the decedent's personal representative." FLA. STAT. § 768.20 (2015). As such, an individual who is not the decedent's personal representative lacks standing to maintain a wrongful death action. Zaccone v. Ford Motor Co., Case No. 2:15-cv-287-FtM-38CM, 2016 WL 705964, at *1 (M.D. Fla. Feb. 23, 2016); see also Reshard v. Britt, 839 F.2d 1499, 1501 (11th Cir. 1988) (personal representative is the only person who can bring a wrongful death action in Florida on behalf of a decedent's estate) (Tjoflat, J., dissenting on other grounds). However, where the administrator or personal representative of an estate is appointed after the instigation of a wrongful death action, Florida courts have ruled that the appointment relates back to the initiation of the wrongful death proceeding. See Griffin v. Workman, 73 So. 2d 844, 846-847 (Fla. 1954); Univ. of Miami v. Wilson, 948 So. 2d 774, 777-778 (Fla. Dist. Ct. App. 2006); Bermudez v. Florida Power & Light Co., 433 So. 2d 565, 566 (Fla. Dist. Ct. App. 1983). See also FLA. STAT. § 733.601 ("The powers of the personal

representative relate back in time to give acts by the person appointed, occurring before appointment and beneficial to the estate, the same effects as those occurring after appointment.").

With the foregoing in mind, the Court determines that Mr. Markland has standing to bring this action. Carolyn Markland named her husband as the Personal Representative of her estate in her Last Will and Testament. See Motion, Exhibit 3 at 3, Last Will and Testament of Carolyn S. Markland. Upon her death, Mr. Markland was appointed as the Personal Representative, and proceeded to administer his wife's estate. Id., Exhibit 4 at 2-3, Order Admitting Will to Probate and Appointing Personal Representative; id., Exhibit 1, Petition for Administration; id., Exhibit 2, Oath of Personal Representative, and Designation and Acceptance of Resident Agent. In February and March of 2016, Mr. Markland sought leave of the probate court to close the administration of his wife's estate, or in the alternative, to convert the estate to summary administration, and for discharge from his role as Personal Representative. Id., Exhibit 5, Petition to Close Administration and for Discharge of Personal Representative; id., Exhibit 6, Amended Petition to Close Administration, for Discharge of Personal Representative, and Alternatively for Conversion to Summary Administration. The probate court granted his request and closed Carolyn Markland's estate in April of 2016. Id., Exhibit 8, Order Converting to Summary Administration, Discharge of Personal Representative, and Closing Estate.

On August 4, 2016, Mr. Markland filed this wrongful death action against Insys. Given that Carolyn Markland's estate was closed and Mr. Markland was no longer the Personal Representative for the estate, he lacked standing at that time. See Zaccone, 2016 WL 705964, at *1 (an individual who is not the decedent's personal representative

lacks standing to bring a wrongful death action). However, in September of 2016, the probate court reappointed Mr. Markland as the Personal Representative for the estate. See Reply, Exhibit 3, Order Appointment Personal Representative; id., Exhibit 4, Letters of Administration. Pursuant to Florida law, the probate court's September 2016 reappointment of Mr. Markland as Personal Representative of Carolyn Markland's estate relates back to Mr. Markland's initial filing of the wrongful death action. See FLA. STAT. § 733.601 ("The powers of the personal representative relate back in time to give acts by the person appointed, occurring before appointment and beneficial to the estate, the same effects as those occurring after appointment."); see also Griffin, 73 So. 2d at 846-847; Univ. of Miami, 948 So. 2d at 777-778; Bermudez, 433 So. 2d at 566. Therefore, Mr. Markland has standing to pursue this action, and the Court rejects Insys' argument that this matter should be dismissed for lack of standing.

b. Failure to state a claim upon which relief can be granted

Having resolved the matter of standing, the Court turns to the substantive arguments raised in the Motion to Dismiss. Generally, Insys contends that regardless of how the Court decides to read Mr. Markland's complaint, he has failed to state a claim upon which relief can be granted. The parties' competing arguments on this matter overlap and intertwine, rendering a discrete analysis of each individual position counterproductive. Rather, the viability of Mr. Markland's complaint is best evaluated through the lens of federal preemption, which by its very nature, takes into account Mr. Markland's assertions regarding the validity of his state law claims and Insys' reliance on the learned intermediary doctrine.

The concept of preemption broadly addresses the balance of powers between the state and federal governments. The Supremacy Clause of the United States Constitution provides that "the Laws of the United States . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST., art. VI, cl.2. "In accordance with that principle, when state law conflicts with federal law, state law must give way." Guarino v. Wyeth, LLC, 719 F.3d 1245, 1248 (11th Cir. 2013). This type of preemption, known as "conflict preemption," applies where "'(1) compliance with both federal and state regulations is a physical impossibility, or (2) the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" Id. (quoting Fresenius Med. Care Holdings, Inc. v. Tucker, 704 F.3d 935, 939 (11th Cir. 2013)).

In this context, it is generally accepted that the states are vested with broad authority to protect and promote the health, welfare, and safety of their citizens. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 475 (1996). Nonetheless, "in recent decades the Federal Government has played an increasingly significant role in the protection of the health of our people." Id. This is evidenced by Congress's broad regulation in the area of drugs and medical devices. Id.; see also 21 U.S.C. § 301 *et seq*. However, when competing sovereigns have fashioned laws to serve the public and those laws abut and conflict, one must make way for the other. When faced with such a contest, the Supreme Court has explained that a court's analysis is guided by two presumptions.

> First, because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action. In all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, we start with the assumption that the historic police

> powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.

Id. at 485 (internal citations and quotations omitted). Second, "the purpose of Congress is the touchstone in every pre-emption case." Id. (internal citations and quotations omitted). To discern Congressional intent, a court must consider the language of the statute and statutory framework. Id. at 486. Also, relevant "is the structure and purpose of the statute as a whole as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." Id. (internal citations and quotations omitted). As such, the Court's admonition that courts should begin with a presumption against pre-emption does not foreclose a contrary conclusion after careful consideration of the competing principles.

Here, Mr. Markland brings a state tort claim of negligent marketing against Insys, where he repeatedly asserts that the company's off-label marketing of Subsys violated federal law. While it is not unlawful for a doctor to prescribe a drug for purposes other than those approved by the FDA, see Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350 (2001); United States v. Caronia, 703 F.3d 149, 153 (2nd Cir. 2012), it is generally accepted that a manufacturer's off-label promotion of a drug runs afoul of federal law. Doing so represents a form of misbranding. See 21 U.S.C.A. § 331(a) (prohibiting the "introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded."). While the

> FDCA and its accompanying regulations do not expressly prohibit the "promotion" or "marketing" of drugs for off-label use[] . . . [t]he regulations do recognize that promotional statements by a pharmaceutical company or its representatives can serve as proof of a drug's intended use. Off-label promotional statements could thus presumably constitute evidence of an

> intended use of a drug that the FDA has not approved. The FDA, however, has concluded that an approved drug that is marketed for an unapproved use (whether in labeling or not) is misbranded because the labeling of such drug does not include adequate directions for use.

Caronia, 703 F.3d at 154-55 (internal citations and quotations omitted). Moreover, the "the government has repeatedly prosecuted – and obtained convictions against – pharmaceutical companies and their representatives for misbranding based on their off-label promotion." Id. at 154; see also id. (listing cases).[4] In light of Mr. Markland's reliance on the FDCA prohibitions to assert his negligent marketing claim, the Court must address Insys' contention that the negligent marketing claim is preempted by the FDCA. Id. at 154-55.

In examining whether federal law preempts Mr. Markland's state negligence claim, the Court's analysis is informed by the Supreme Court's decision in Buckman, 531 U.S. at 347-53. In Buckman, the plaintiffs sued a medical device manufacturer under state tort law for injuries they suffered from the manufacturer's product. The plaintiffs alleged that the defendant made fraudulent representations to the FDA regarding the product's safety

[4]The courts have not reached a consensus regarding the scope of the federal prohibitions against off-label promotion. See e.g., United States v. Caronia, 703 F.3d 149, 152 (2nd Cir. 2012) (criminal prosecution under FDCA misbranding provisions violates the First Amendment); Jones v. Medtronic, Inc., 89 F. Supp. 3d 1035, 1048 nn. 16, 17 (D. Ariz. 2015) (noting differing interpretations by courts); Hawkins v. Medtronic, Inc., 62 F. Supp. 3d 1144, 1151-52 (E.D. Cal. 2014) (noting discord on matter of off-label promotion but concluding that false or misleading off-label promotion is prohibited); Travelers Indem. Co. v. Cephalon, Inc., 32 F. Supp. 3d 538, 544 (E.D. Pa. 2014) (FDA regulations generally prohibit off-label promotion); Schouest v. Medtronic, Inc., 13 F. Supp. 3d 692, 701-03 (S.D.Tex. 2014) (noting lack of clarity on whether only false or misleading off-label promotion violates federal law, or whether truthful off-label promotion is also prohibited); Ramirez v. Medtronic, Inc., 961 F. Supp. 2d 977, 990 (D. Ariz. 2013) (FDA prohibits off-label promotion).

Decisions from the Florida district courts reflect that courts have recognized off-label promotion claims, but have not settled as to the breadth of the FDCA prohibition against off-label promotion. See Byrnes v. Small, 60 F. Supp. 3d 1289, 1297-98., id. at n. 2 (M.D. Fla. 2015) (addressing both truthful and misleading or false off-label promotion); Wilson v. Danek Med., Inc., Case No. 96-2460-CIT-T-17B, 1999 WL 1062129, at *2 (M.D. Fla. Mar. 29, 1999) (addressing harms allegedly suffered by plaintiff as a result of defendant's off-label promotion that included misrepresentations regarding safety and efficacy of product); see also Hosler v. Alcon Lab., Inc., Case No. 12-60025-CIV, 2012 WL 4792983, at *12 (S.D. Fla. October 9, 2012) (evaluating cause of action based on defendant's alleged untruthful off-label promotion of a medical treatment).

in the process of obtaining federal approval to market the device. Id. at 343. The plaintiffs further asserted that absent the defendant's false statements, the FDA would not have approved the device. Id. Without such approval, the device would not have been available on the market, and consequently the plaintiffs would not have suffered harm. Id. Upon review of the plaintiffs' claims, the Court determined that their action was impliedly preempted by the FDCA. Id. at 348.

Labeling the plaintiffs' state tort actions as "fraud-on-the-FDA claims," id. at 347, the Court noted that "[p]olicing fraud against federal agencies is hardly a field which the states have traditionally occupied such as to warrant a presumption against finding federal preemption of a state-law cause of action." Id. (internal citation omitted). The Court reasoned that the plaintiffs' action was based entirely on the defendant manufacturer's dealings with the FDA as required by federal law, and that the "very subject matter of the [manufacturer's] statements were dictated by [the law's] provisions." Id. at 347-48. On those facts, the Court determined that the

> plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law. The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law.

Id. at 348. The Court also noted that by the statute's terms, Congress intended any violations of the FDCA be "enforced exclusively by the Federal Government." Id. at 352. Indeed, § 337(a) of the statute provides that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C.A. § 337(a).

Despite concluding that the specific "fraud-on-the-FDA" state tort claims before it were preempted under federal law, the Court clarified that not all state tort claims relating to a drug or device otherwise regulated by the FDCA would be preempted. In doing so, the Court recognized a distinction between two of its previous decisions where it found the plaintiffs' claims not preempted, Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984), and Medtronic, 518 U.S. 460, and cases like Buckman where the claim would be preempted. Id. at 352-53. The Court explained that in both Silkwood and Medtronic, the plaintiffs' claims were based "on traditional state tort law principles of the duty of care owed" by the defendants, id. at 352, and "not [drawn] solely from the violation of FDCA requirements." Id. In contrast, the Court viewed the Buckman plaintiffs' claims as singularly focused on the defendant's alleged fraudulent statements to the FDA. Therefore, the Buckman case differed from Silkwood and Medtronic because "were [the Buckman] plaintiffs to maintain their fraud-on-the-agency claims, they would not be relying on traditional state tort law which had predated the federal enactments in question. On the contrary, the existence of these federal enactments is a critical element in their case." Id. at 353. On these differentiated grounds, the Court ruled the Buckman plaintiffs' claims preempted.

The Eleventh Circuit Court of Appeals recently discussed Buckman's implied preemption analysis in Mink v. Smith & Nephew, Inc., 860 F.3d 1319 (11th Cir. 2017). There, the court first instructed that § 337 of the FDCA, which it referred to as the "no-private-right-of-action clause," governs implied preemption. Id. at 1327. Next, the court recognized that relying on § 337, the Supreme Court determined that the plaintiff's state law fraud claims based on misrepresentations to the FDA were impliedly preempted. Id.

However, the court also recognized that not all state law claims would be preempted. Rather, the Eleventh Circuit observed:

> . . . the Court made the distinction between the "fraud-on-the-agency" claims in Buckman and "traditional state tort law [that] predated the federal enactments in question[ ]." [Buckman, 531 U.S.] at 353. Thus, the Supreme Court told us that traditional state-law tort claims survive implied preemption so long as they don't seek to privately enforce a duty owed to the FDA.

Id. (textual alteration in original).

Applying Buckman's preemption analysis to the claims the Mink plaintiff asserted, the Eleventh Circuit concluded that the plaintiff's "failure to report" claim was impliedly preempted because it was premised on a failure to fulfill a duty owed to the FDA. Id. at 1330. But, the plaintiff's manufacturing defect claim was not preempted. Id. This was so, the court explained, because the manufacturing defect claim was based on the traditional state law duty of care in manufacturing that both predated the applicable federal law, and was a duty owed to the plaintiff, not to the FDA. Id. Mink therefore instructs that implied preemption prohibits state law claims that seek to privately enforce duties owed to the FDA pursuant to the FDCA. Id. at 1327 (citing Buckman, 531 U.S. at 348). However, traditional state law claims that predated the FDCA remain viable. Id. at 1330.

Other courts considering claims of implied preemption have similarly concluded that claims based on allegations that a defendant violated the FDCA are impliedly preempted. See Elliott v. Sandoz, Inc., Case No. 2:16-cv-861-RDP, 2016 WL 4398407, at *6 (N.D. Ala. Aug. 18, 2016) (claim preempted because "although . . . couched . . . under a negligence standard, granting relief would essentially hold Defendant liable for not following federal law and regulations"); Blankenship v. Medtronic, Inc., 6 F. Supp. 3d 979, 991 (E.D. Mo. 2014) ("While plaintiff couches her claim as a state negligence claim, this claim is, in

substance, a claim for violating the FDCA."); Fulgenzi v. Pliva, Inc., 711 F.3d 578, 586 (6th Cir. 2013) (state tort suits impliedly preempted because the FDCA excludes a private right of action); In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Lit., 623 F.3d 1200, 1204 (8th Cir. 2010) (noting Buckman's construction of § 337(a) as barring suits by private litigants); Riley v Cordis Corp., 625 F. Supp. 2d 769, 777 (D. Minn. 2009) ("a private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA – that is, when the state claim would not exist if the FDCA did not exist."). Conversely, courts considering claims based on traditional state law theories which predated the federal law have found such claims are not impliedly preempted. See Mink, 860 F.3d at 1330 (plaintiff's manufacturing defect theory "falls into the category of traditional state tort law"); Fulgenzi, 711 F.3d at 586-86 (plaintiff's suit "not even premised on violation of federal law, but rather on an independent state duty"); Stengel v. Medtronic, Inc., 704 F.3d 1224, 1233 (9th Cir. 2013) (traditional state tort law cause of action for failure to warn is not preempted); Bass v. Stryker Corp., 669 F.3d 501, 514 (5th Cir. 2012) (case was based on state-tort law claims "rather than any duties independently created by FDA regulations"); Hughes v. Boston Scientific Corp., 631 F.3d 762, 775 (5th Cir. 2011) (plaintiff asserted a state tort claim based on the "underlying state duty to warn about dangers or risks" of the product); Desiano v. Warner-Lambert Co., 467 F.3d 85, 94-95 (2d Cir. 2007) (plaintiff's claims are based on traditional duties between a product manufacturer and consumers rather than deriving from "a newly-concocted duty between a manufacturer and a federal agency").[5]

[5] The Court notes that many of the cases cited here on the issue of implied preemption address claims related to medical devices rather than drugs, and as a result, also discuss express preemption, and the "narrow gap" through which a plaintiff must travel to plead a viable claim. See Mink, 860 F.3d at 1327. However, the express preemption provision of the Medical Device Amendments to the FDCA applies only to medical

With this framework in mind, the Court turns to Mr. Markland's claim against Insys. Mr. Markland's claim can be summarized as follows: Insys promoted Subsys to "medical specialists who did not treat cancer patients but treated other chronic pain problems . . . ." Complaint at ¶ 8. In so doing, Insys enticed doctors, such as Carolyn Markland's physician, to subscribe Subsys for off-label use. Consequently, Carolyn Markland was subject to the substantial, and in this deeply unfortunate case, deadly risks associated with Subsys. Significantly, throughout his complaint, Mr. Markland repeatedly refers to Insys' alleged violations of the FDCA. For example, in referencing that the company marketed the drug to physicians treating individuals with migraines and chronic back pain, he asserts "[t]his off-label use was never approved by the FDA." Id. at ¶ 8. Similarly, Mr. Markland claims that "Insys[ ] negligently convinced physicians, such as family practice physicians, pain management specialists, and doctors specializing in internal medicine that the physicians should and could write prescriptions to Subsys Fentanyl as an off-label use. This was unlawful conduct by Insys and was in violation of federal law." Id. at ¶ 28(d). Additionally, he states that Insys

> intentionally violated the requirements imposed by the FDA regarding the condition that this drug should be utilized to treat cancer patients with breakthrough cancer pain. At all times material hereto, this Defendant, Insys, violated the provisions of the Medical Guide approved by the FDA regarding the specific use of Subsys Fentanyl which limited approval for use and treating cancer patients with breakthrough pain.

Id. at ¶¶ 29-30.

devices, not to drugs. Cartwright v. Pfizer, Inc., 369 F. Supp. 2d. 876, 885 (E.D. Tex. 2005) (". . . Congress and the FDA has chosen not to include an express preemption clause in the statutes and regulations for prescription drugs. Clearly, Congress knows how to enact FDA legislation that contains a preemption clause. Thus, the absence of any such clause with respect to prescription drugs demonstrates an implied intent not to [expressly] preempt cases, such as this.").

Accepting as true the factual allegations set forth in Mr. Markland's complaint and drawing all reasonable inferences in his favor, see Iqbal, 556 U.S. at 678; Lotierzo, 278 F.3d at 1182; Omar ex. rel. Cannon, 334 F.3d at 1247, the Court nonetheless reads the substance of Mr. Markland's complaint as alleging that Insys violated federal law. Mr. Markland asserts that Carolyn Markland's tragic and unnecessary death stemmed from Insys' off-label promotion of Subsys, rather from Insys' failure to satisfy an independent state law duty of care. Hence, Mr. Markland's action against Insys, while framed in the language of negligence, appears to derive from Insys' alleged off-label promotion of Subsys. Indeed, a number of courts considering similar claims of off-label promotion have concluded that such claims are impliedly preempted because the very concepts of off-label use and off-label marketing are born out of the FDCA. See Hafer v. Medtronic, Inc., 99 F. Supp. 3d 844, 857 (W.D. Tenn. 2015) (claim based solely on off-label promotion preempted); Brady v. Medtronic, Inc., Case No. 13-cv-62199-RNS, 2014 WL 1377830, at *8 (S.D. Fla. Apr. 8, 2014) ("Any negligence claim based on failure to comply with federal law or solely on illegal off-label promotion . . . is impliedly preempted."); Blankenship, 6 F. Supp. 3d at 990-91 (plaintiff's negligence claim preempted where such claim was based on conduct that would not give rise to recovery under state law in the absence of FDCA regulations); Houston v. Medtronic, Inc., 957 F. Supp. 2d 1166, 1178 (C.D. Cal. 2013) ("any negligence claim based solely on illegal off-label promotion is impliedly preempted"); Caplinger v. Medtronic, Inc., 921 F. Supp. 2d 1206, 1219-20 (W.D. Okla. 2013) ("The conduct plaintiff complains of . . . is governed by the FDCA. To determine whether said conduct is improper would require reliance on the requirements of the FDCA. Further, even the concept of 'off-label use' is a creature of the FDCA . . . .").

Here, the premise of Mr. Markland's claim is that Insys' statements and actions in promoting Subsys were improper because they violated the FDCA. In other words, it is only because of the existence of the FDCA's restrictions on off-label marketing that Mr. Markland claims Insys' actions were improper or otherwise violated a duty. Because the "existence of [off-label promotion] . . . is a critical element in [his] case," Buckman, 531 U.S. at 353, Mr. Markland's claim is preempted.

Mr. Markland's reliance on this Court's decision in Trahan v. Sandoz, Inc., Case No. 3:13-cv-350-J-34MCR, 2015 WL 2365502 (M.D. Fla. Mar. 26, 2015), is misplaced. In Trahan, this Court examined whether "federal law preempts state-tort claims against the manufacturer of a generic prescription drug based on the purported design and/or manufacturing defect in the packaging for the drug." Id. at *3. The drug at issue was packaged in glass vials. Due to glass delamination, small pieces of glass separated from the vial interiors, and allegedly caused "serious injuries, including multiple lung collapses and several strokes" from the glass flakes. Id. at *1. The plaintiff sued the drug manufacturer for strict liability defective design and/or manufacture and negligence, id. at *2, alleging that the defendant "negligently failed to conduct adequate inspections, test, and/or post-distribution tests for the possibility of delamination" in the vials containing the drug. Id. at *7.

In response, and as relevant here, the defendant contended that the claims were impliedly preempted because the plaintiff was seeking to privately enforce FDCA regulations relating to drug inspection, testing, and packaging. Id. at *8. This Court disagreed, noting that none of the plaintiff's claims rested solely on the defendant's violation of a federal statute or regulation. Rather, the plaintiff's complaint asserted that

defendant's inadequate testing demonstrated negligence because it "should have detected a defective condition in the glass vials, removed the defective product from the marketplace and used a different container." Id. at *7. As such, the plaintiff's complaint alleged that the defendant "breached its duty of care under Florida law when it failed to conduct reasonable tests or inspections of [its product] to ensure that the product was reasonably safe to use." Id. at *8. That the defendant's actions might have also violated federal law did not preclude the plaintiff's claim. Id. Citing to the Supreme Court's decision in Buckman and its discussion of the Medtronic decision, id. at *8, this Court recognized the distinction between claims arising "from the manufacturer's alleged failure to use reasonable care in the production of a product," id. (quoting Buckman, 531 U.S. at 352), and claims based solely on violations of FDCA requirements. Id. Based on the facts presented in Trahan, this Court was persuaded that at the motion to dismiss stage of proceedings, the plaintiff stated a plausible claim under a Florida negligence theory, rather than emanating from federal law.

The same cannot be said of Mr. Markland's complaint. While he couches his claim in the language of negligence, he cannot escape the fact that crucial to his allegations against Insys is that the company violated federal regulations regarding off-label promotion. Rather than pointing to Insys' violation of federal law as potential evidence of negligence, see Fla. Dep't of Corr. v. Abril, 969 So. 2d. 201, 205 (Fla. 2007) ("The Courts of Florida have long recognized that the violation of a statute may be utilized as evidence of negligence."), Mr. Markland is using Insys' violation of federal law to substantiate the existence of a state tort claim, see e.g., Mink, 860 F.3d at 1330 ("failure to report" claim preempted because asserted duty based on federal law requirements). This he cannot do.

Notably, even if this Court were to read Mr. Markland's complaint as grounded in Florida state tort principles of negligence,[6] he would nonetheless be stymied by Florida law which bars plaintiffs from using state negligence actions to seek recovery for FDCA violations. See Wolicki-Gables v. Doctors Same Day Surgery Ctr., Ltd., 216 So. 3d 665, 673 (Fla. Dist. Ct. App. 2017) ("Florida law does not permit a private action to enforce violation of FDA requirements.").[7] See also Marmol v. St. Jude Med. Ctr., 132 F. Supp. 3d 1359, 1367-68 (M.D. Fla. 2015) (same); Kaiser v. Depuy Spine Inc., 944 F.Supp.2d 1187, 1192 (M.D. Fla. 2013) (same); Brown v. DePuy Orthopaedics, Inc., 978 F. Supp. 2d 1266, 1275 (M.D. Fla. 2013) ("Florida law does not allow a plaintiff to bring a private cause of action to enforce FDA regulations."); McClelland v. Medtronic, Inc., Case No. 6:11-CV-1444-Orl-36KRS, 2012 WL 5077401, at *4-5 (M.D. Fla. Sept. 27, 2012) ("Plaintiff cannot assert a negligence per se claim based on violations of the FDCA or the FDA's implementing regulations."); Metz v. Wyeth, LLC, 872 F. Supp. 2d 1335, 1343 (M.D. Fla. 2012) ("Plaintiff's negligence per se claim is subject to dismissal because Florida law does not recognize a claim upon a theory of negligence per se for an alleged violation of the FDCA."); Rounds v. Genzyme Corp., Case No. 8:10-cv-2479-T-23TBM, 2010 WL 5297180, at *3 (M.D. Fla. Dec. 20, 2010) (plaintiff cannot bring negligence per se claim for FDCA violations); Blinn v. Smith & Nephew Richards, Inc., 55 F. Supp. 2d 1353, 1361 (M.D. Fla. 1999) ("Under Florida law . . . Plaintiff cannot use a negligence per se claim to create a private cause of action for Defendant's alleged violations of the FDCA."); Stevens

[6] Because the Court reads Mr. Markland's claim as asserting a violation of federal law, it is unnecessary for the Court to address Insys' assertion that Mr. Markland's potential state based negligent marketing claim is undermined by the learned intermediary doctrine, or Mr. Markland's over promotion counter argument.

[7] In Mink, the Eleventh Circuit criticized portions of the Wolicki-Gables decision, particularly its interpretation of federal law. See Mink, 860 F.3d at 1328. However, the court did not take issue with the Wolicki-Gables court's conclusion that Florida law does not recognize a cause of action to enforce FDA regulations. See id.

v. Danek Med., Inc., Case No. 95-14293-CIV-PAINE, 1999 WL 33217282, at *5-6 (S.D. Fla. Apr. 16, 1999) ("Florida courts have refused to recognize a private right of action for negligence per se based on an alleged violation of a federal statute that does not provide for a private right of action."); Baker v. Danek Med., Inc., 35 F. Supp. 2d 875, 878 (N.D. Fla. 1998) (plaintiff's negligence per se action alleging violations of the FDCA was barred).

The Court does not question for a moment the grievous nature of Carolyn Markland's death, nor the deep sadness Mr. Markland must face on a daily basis as a result of his wife's untimely passing. Nonetheless, the Court must act within the bounds of the law. In his action against Insys, Mr. Markland focuses on the company's illegal off-label promotion of Subsys as evidence of Insys' breach of a duty of care toward his wife, Carolyn Markland. Florida law prohibits such an action.

In consideration of the foregoing, the Court must dismiss Mr. Markland's claim because the FDCA does not permit private rights of action for violations of the statute, see 21 U.S.C. § 337(a); a claim asserting unlawful off-label promotion is in itself a creature of federal and not state law, see e.g., Buckman, 531 U.S. at 353; Caplinger, 921 F. Supp. 2d at 1219-20; and Florida law bars a plaintiff from seeking to enforce FDCA violations under standard tort actions, Wolicki-Gables, 216 So. 3d at 673.[8]

ORDERED:

1. Defendant Insys Therapeutics, Inc.'s Amended Motion to Dismiss (Doc. 15) is **GRANTED.**

[8] In their motion to dismiss, Insys also asserted that Mr. Markland's action should be dismissed under the doctrine of judicial estoppel. See Motion at 26-32. Because this Court has determined there are other grounds to support Insys' motion to dismiss, it is unnecessary to address the judicial estoppel argument. Additionally, Mr. Markland, who is represented by counsel, did not file a motion seeking leave to amend or otherwise make any attempt to remedy the pleading deficiencies identified in the Motion. See Wagner v. Daewoo Heavy Indus. Am. Corp., 314 F.3d 541, 542 (11th Cir. 2002) (en banc).

2. The Clerk of the Court is directed to enter **JUDGMENT** in favor of Defendant Insys, Therapeutics, Inc.
3. The Clerk of the Court is further directed to terminate all remaining pending motions and deadlines as moot, and close the file.

DONE AND ORDERED at Jacksonville, Florida, this 15th day of September, 2017.

MARCIA MORALES HOWARD
United States District Judge

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Copies to:

Counsel of Record
Pro Se Parties