United States District Court
for the
Southern District Of Florida

Frank Brady, Plaintiff	)	
	)	
v.	)	Civil Action No. 13-cv-62199-RNS
	)	
Medtronic, Inc., *et al.*,	)	
Defendant	)	

Order on Motion to Dismiss

Plaintiff Frank Brady (Brady) has brought several tort claims against Defendants Medtronic, Inc. and Medtronic Sofamor Danek, USA, Inc. (collectively, Medtronic) challenging how Medtronic has produced and promoted a device known as the Infuse® Bone Graft (Infuse). Medtronic has moved to dismiss the complaint in its entirety under Rule 12(b)(6) of the Federal Rules of Civil Procedure arguing that Brady's claims are preempted, inadequately pled, and precluded under Florida law. For the reasons set forth below, the Court **grants** the motion to dismiss (ECF No. 12).

Background

Brady's Complaint is voluminous, consisting of 277 numbered paragraphs, so this background section contains only a brief summary of the facts alleged in the Complaint.

Infuse is a bio-engineered liquid bone graft product. (Compl. ¶1, ECF No. 1.) It is a Class III medical device approved by the Federal Drug Administration (FDA) through the rigorous premarket approval process for specific uses, including for lumbar surgery performed through the abdomen (the anterior approach) and only in combination with an "LT-Cage." (*Id.* ¶¶ 3, 65.) It is not approved for use for any lumbar surgery performed through the back or side of the body (posterior approaches), or without an LT-Cage. (*Id.* ¶ 3.) Studies performed before the approval showed risks associated with using the device in spine surgeries using a posterior approach and other off-label uses. (*Id.* ¶¶ 80-86.) Additional studies continue to warn of the dangers of off-label use of Infuse, that is, a use not indicated on the Food and Drug Administration-mandated label. (*Id.* ¶¶ 87-107.)

Despite knowledge of the studies demonstrating the safety risks of off-label uses of Infuse, Medtronic allegedly promoted off-label uses of Infuse in violation of the Food, Drug, and Cosmetic Act (FDCA). (*Id.* ¶¶ 122-133.) Medtronic directed its sales representatives to promote off-label uses, paid

physicians to promote off-label uses, funded studies and published articles regarding the efficacy and safety of off-label uses, and downplayed studies demonstrating serious and frequent adverse events caused by off-label uses. (*Id.*) As a result, Medtronic was subject to two whistle-blower lawsuits, several adverse regulatory actions by the FDA, and a congressional investigation. (*Id.* ¶124.)

Brady underwent a posterior-approach lumbar fusion in October of 2010 in which Infuse was used in an off-label manner. (*Id.* ¶ 164.) Specifically, Infuse was implanted through a posterior approach, and no LT-Cage was used. (*Id.*) Brady allegedly suffered severe injury and damages resulting from the off-label use of Infuse. (*Id.* ¶ 172.) Brady claims that Medtronic knowingly concealed from Brady and his surgeon the significant rate of injuries and complications resulting from the off-label use of Infuse. (*Id.* ¶ 170.)

Brady brings six causes of action in his Complaint: (1) fraudulent misrepresentation and fraud in the inducement; (2) failure to warn regarding known dangers of off-label use; (3) design defect; (4) making misrepresentations regarding the dangers of off-label use of the product; (5) negligence; and (6) breach of express warranty. Medtronic has moved to dismiss the complaint arguing that the claims are preempted. Medtronic also argues that the fraud claims fail to meet the heightened pleading requirement of Rule 9(b) of the Federal Rules of Civil Procedure, and that Florida law precludes Brady's strict-liability claims. (ECF No. 12.) In a somewhat cavalier and unhelpful response, Brady argues only that his claims are not preempted, and fails to address any of Medtronic's other arguments. (ECF No. 14.)

Analysis

A. Motion-to-dismiss standard

When considering a motion to dismiss under Rule 12(b)(6), the Court must accept all of a complaint's well-pled factual allegations as true, construing them in the light most favorable to the plaintiff. *Pielage v. McConnell*, 516 F.3d 1282, 1284 (11th Cir. 2008). Under Rule 8(a)(2) of the Federal Rules of Civil Procedure, a pleading need only contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Though the Rule does not require detailed factual allegations, it does require "sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (brackets, internal citation, and internal quotation marks omitted). "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." *Id.* (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007)).

"Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* So a pleading that offers mere "labels and conclusions" or "a formulaic recitation of the elements of a cause of action" will be dismissed. *Id.*

Faced with a motion to dismiss, a court should therefore "(1) eliminate any allegations in the complaint that are merely legal conclusions; and (2) where there are well-pleaded factual allegations, assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Am. Dental Assoc. v. Cigna Corp.*, 605 F.3d 1283, 1290 (11th Cir. 2010) (internal quotation marks omitted). Moreover, "courts may infer from the factual allegations in the complaint obvious alternative explanations, which suggest lawful conduct rather than the unlawful conduct the plaintiff would ask the court to infer." *Id.* (brackets and internal quotation marks omitted). "This is a stricter standard than the Supreme Court described in *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957), which held that a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Mukamal v. Bakes*, 378 F. App'x 890, 896 (11th Cir. 2010) (internal quotation marks omitted). These precepts apply to all civil actions, regardless of the cause of action alleged. *Kivisto v. Miller, Canfield, Paddock & Stone, PLC*, 413 F. App'x 136, 138 (11th Cir. 2011).

Where a cause of action sounds in fraud, however, Federal Rule of Civil Procedure 9(b) must be satisfied in addition to the more relaxed standard of Rule 8. Under Rule 9(b), "a party must state with particularity the circumstances constituting fraud or mistake," although "conditions of a person's mind," such as malice, intent, and knowledge, may be alleged generally. Fed. R. Civ. P. 9(b). "The 'particularity' requirement serves an important purpose in fraud actions by alerting defendants to the precise misconduct with which they are charged and protecting defendants against spurious charges of immoral and fraudulent behavior." *W. Coast Roofing & Waterproofing, Inc. v. Johns Manville, Inc.*, 287 F. App'x 81, 86 (11th Cir. 2008) (citations omitted). "When a plaintiff does not specifically plead the minimum elements of their allegation, it enables them to learn the complaint's bare essentials through discovery and may needlessly harm a defendant's goodwill and reputation by bringing a suit that is, at best, missing some of its core underpinnings, and, at worst, [grounded on] baseless allegations used to extract settlements." *U.S. ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1313 n.24 (11th Cir. 2002). Thus, the Rule's "particularity" requirement is not satisfied by "conclusory allegations that certain statements were fraudulent; it requires that a complaint plead facts giving rise to an inference of

fraud." *W. Coast Roofing & Waterproofing*, 287 F. App'x at 86. To meet this standard, the Complaint needs to identify the precise statements, documents, or misrepresentations made; the time and place of, and the persons responsible for, the alleged statements; the content and manner in which the statements misled the plaintiff; and what the defendant gained through the alleged fraud. *Id.*

B. The regulatory framework under the Medical Device Amendments of 1976

The Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug, and Cosmetic Act (FDCA) established a method of federal oversight of the introduction of new medical devices into the market. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315-16 (2008). The MDA created three categories of devices, each receiving an increasing level of regulatory scrutiny. Devices receiving the most federal oversight are those in Class III. *Id.* at 316. "In general, a device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is 'purported or represented to be for a use in supporting or sustaining human life or for use which is of substantial importance in preventing impairment of human health,' or presents a potential unreasonable risk of illness or injury.'" *Id.* (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)).

The MDA established a "rigorous" premarket approval process for Class III devices. *Id.* 317-18. To obtain approval, a manufacturer must submit a detailed application that contains "specimens of labeling proposed to be used for such device." 21 U.S.C. § 360c(a)(1)(C)(ii). The FDA evaluates the safety and effectiveness of a device with respect to the use proposed by the manufacturer, "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." *Id.* §§ 360c(a)(2), 360e(c)(1). The FDA also reviews the device's labeling to evaluate "safety and effectiveness under the conditions of use set forth on the label." *Riegel*, 552 U.S. at 318. The FDA only grants approval for the device if it finds that there is a "reasonable assurance" of the device's "safety and effectiveness." 21 U.S.C. § 360e(d).

Once a device has received premarket approval, the FDA takes substantial control of how the device is designed, manufactured, and labeled—"the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). If the manufacturer wishes to modify the

labeling, design, or indications for use of the device, it must submit an application for supplemental premarket approval to the FDA. *Id.*

C. An overview of express preemption, parallel claims, and implied preemption

The MDA includes an express preemption provision:

> Except as provided in subsection (b) of this section, no 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 chapter 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 chapter.

21 U.S.C. § 360k(a). Courts employ a two-step analysis to determine whether a state-law claim is preempted under this section. First, a court must determine whether the federal government has established requirements applicable to the device. *Riegel*, 355 U.S. at 321-22; *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300-01 (11th Cir. 2011). Premarket approval imposes device-specific requirements. *Riegel*, 355 U.S. at 322-23.

Once the first step of the express preemption analysis is met, as it is here, the court must then determine whether the state-law claims would impose a requirement that is different from, or in addition to the federal requirements, and that relates to the safety and effectiveness of the device. *Riegel*, 355 U.S. at 321-22; *Wolicki-Gables*, 634 F.3d at 1301. The express preemption provision does not, however, "prevent a State from providing damages remedies for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330. A state requirement is parallel to a federal requirement, and thus not expressly preempted, if the plaintiff "shows that the requirements are '*genuinely* equivalent.' State and federal requirements are not generally equivalent if a manufacturer should be held liable under the state law without having violated federal law." *Wolicki-Gables*, 634 F.3d at 1300 (quoting *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005)) (emphasis in original).

The MDA also impliedly preempts certain claims brought by private litigants. The FDCA states that an action for "enforcement or to restrain violations," of the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court has stated that this language is "clear

evidence that Congress intended that the MDA be enforced exclusively by the Federal Government." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001).

Together, express preemption and implied preemption provide a "narrow gap" through which a plaintiff's claims must fit in order to survive. *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013). The Eighth Circuit has described the "narrow gap" through which a state-law claim must fit to escape preemption: "The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *In re Medtronic*, 623 F.3d 1200, 1204 (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)).

D. Preemption analysis applies to Brady's claims of off-label promotion

District Courts differ in applying the Supreme Court's preemption rulings to off-label marketing claims regarding Infuse, and Brady argues that preemption analysis does not apply to his claims of off-label promotion. *See, e.g., Scovil v. Medtronic, Inc.*, No. 13-cv-02093, 2014 WL 502923 (D. Ariz. Feb. 7, 2014) (applying the traditional preemption analysis and finding that some of plaintiffs' claims survived the preemption analysis); *Ledet v. Medtronic, Inc.*, No. 13-cv-200, 2013 WL 6858858 (S.D. Miss. Dec. 30, 2013) (applying the traditional preemption analysis and finding that plaintiffs' claims were preempted); *Ramirez v. Medtronic Inc.,* No. 13-cv-00512, 2013 WL 4446913 (D. Ariz. Oct. 24, 2013) (finding that the traditional analysis of whether state-law claims qualify as parallel claims does not apply to claims of off-label marketing and finding that claims of off-label marketing are neither expressly or impliedly preempted); *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1026 (W.D. Okla. 2013) (applying the traditional preemption analysis and finding that the plaintiff's claims were preempted). The Court finds that that the language of § 360k and the relevant case law require the Court to conduct the traditional preemption analysis to Brady's off-label marketing claims.

The language of § 360k(a) is extremely broad. There is nothing in the provision that suggests that the applicability of the preemption analysis turns on either how the device was used or marketed, or on the conduct of the manufacturer. *See Gavin v. Medtronic, Inc.*, No. 12-cv-0851, 2013 WL 3791612, at *11 (E.D. La. July 19, 2013). Instead, the statute requires preemption analysis if there are federal requirements applicable "to the *device*." 21 U.S.C. § 360k(a). Because the premarket approval process imposes requirements on Infuse, the Court must analyze whether state-law claims would impose requirements different from or in addition to those federal

requirements. *Caplinger*, 921 F. Supp. 2d at 1218 (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 779 (D. Minn. 2009)).

Although the FDCA does not expressly prohibit off-label marketing, it does prohibit the "adulteration or misbranding" of any device. 21 U.S.C. § 331(b). A Class III device may be misbranded if its "labeling is false or misleading in any particular," or if it uses "false or misleading advertising." *Id.* § 352(a), (q). A device can also be mislabeled if it does not bear "adequate directions for use," defined by the FDA as "directions under which the layman can use [the] device safely and for the purposes for which it is intended." *Id.* § 352(f)(1); 21 C.F.R. § 801.5. The intended use of a device is determined on the basis of the objective intent of the manufacturer responsible for labeling the device, and can be demonstrated by the manufacturer's advertisements or marketing. 21 C.F.R. § 801.4. Manufacturers are subject to criminal and civil penalties where they are found to have violated the FDCA's prohibition against misbranding. 21 U.S.C. §§ 333(a), (f); *Carson v. Depuy Spine, Inc.*, 365 Fed. App'x 812, 815 (9th Cir. 2010)("[W]hile doctors may use a drug or device off-label, the marketing and promotion of a Class III device for unapproved use violates Section 331 of the FDCA."). The Court finds no evidence that it should ignore the preemption analysis when a Complaint has alleged conduct governed by the FDCA—false and misleading advertising—and addressed by FDA regulations.

In each of the cases involving preemption that are binding upon this Court, the focus was on comparing the federal requirement with the state requirement to determine whether the claims fall within the scope of § 360k. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996); *Riegel*, 552 U.S. 312; *Buckman*, 531 U.S. 341; *Wolicki-Gables*, 634 F.3d 1296. Nothing in the case law or in the text of the statute itself suggests that the Court should deviate from traditional preemption analysis simply because of how the plaintiff framed his claim. To be clear, this does not mean that Brady's claims are categorically preempted. Rather, it means that the Court must conduct the traditional analysis for determining whether each claim in the Complaint is, in fact, preempted.

E. Brady's strict-liability claims are dismissed

Before turning to analyzing whether Brady's claims are preempted, the Court first addresses Medtronic's argument that Brady's strict-liability claims are precluded by Florida law.

The Florida Supreme Court has adopted Section 402A of the Restatement (Second) of Torts, which imposes strict liability upon "[o]ne who sells any product in a defective condition unreasonably dangerous to the user or

consumer[.]". *West v. Caterpillar Tractor Co., Inc.*, 336 So. 2d 80, 87 (Fla. 1976); Restatement (second) of Torts § 402A (1965). Comment k to Section 402A creates an exception for "unavoidably unsafe products." Restatement (second) of Torts § 402A, cmt. k; *Zanzury v. G.D. Searle & Co.*, 784 F. Supp. 1511, 1518-19 (S.D. Fla. 1990) (Hoeveler, J.) (noting that Florida has adopted comment k to Section 402A of the Restatement (Second) of Torts). Comment k "applies to products which current knowledge and technology cannot make safe for their ordinary use, but for which society has a need great enough to justify using the product despite its dangers." *Adams v. G.D. Searle & Co., Inc.*, 576 So. 2d 728, 733 (Fla. App. 2d Dist. 1991).

Citing *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466 (W.D. Pa. 2010), Medtronic argues that, as a matter of law, Class III medical devices like Infuse are unavoidably unsafe products. In *Gross v. Stryker Corp.*, the court found that a medical device that received FDA approval through the premarket approval process fell within the scope of comment k. 858 F. Supp. 2d at 481-82. The court noted that "the inherently rigorous nature of the premarket approval process" and the product's accompanying warnings supported its conclusion that the product is "unavoidably unsafe," and falls within the scope of comment k. *Id.*

Brady effectively concedes that his strict product liability claims must be dismissed; he fails to address this argument in his opposition to the Motion to Dismiss. "The premise of our adversarial system is that . . . courts do not sit as self-directed boards of legal inquiry and research, but essentially as arbiters of legal questions presented and argued by the parties before them." *Carducci v. Regan*, 714 F.2d 171, 177 (D.C. Cir. 1983). Generally, a "litigant who fails to press a point by supporting it with pertinent authority, or by showing why it is sound despite a lack of supporting authority or in the face of contrary authority, forfeits the point. The court will not do his research for him." *Phillips v. Hillcrest Med. Ctr.*, 244 F.3d 790, 800 n. 10 (10th Cir. 2001) (internal quotation marks omitted). Moreover, the allegations in his Complaint appear to place Infuse within the exception for unavoidably unsafe products: Brady alleges that "Class III devices pose the greatest risk of death or complications . . . . Infuse® is a Class III device." (ECF No. 1, ¶ 64.)

Based on the Florida law and case law provided by Medtronic, the allegations in Brady's Complaint, and Brady's waiver of any argument that this exception does not apply, the Court finds that Infuse is an unavoidably unsafe product that falls within the purview of comment k. Counts II, III, and IV are dismissed with prejudice.

F. Application of the preemption framework to Brady's claims

The Court now turns to Brady's remaining claims—Count I for fraudulent misrepresentation and fraud in the inducement, Count V for negligence, and Count VI for breach of express warranty—to determine whether these claims survive preemption analysis. Brady's response is entirely unhelpful in this analysis; Brady summarily argues that his "claims in this case are not different from or in addition to Federal requirements." (Resp. at 4, ECF No. 14.)

1. Fraudulent misrepresentation and fraud in the inducement

Brady's claim for fraudulent misrepresentation and fraud in the inducement alleges that Medtronic "fraudulently and intentionally misrepresented material and important health and safety product risk information" to Brady and his physician. (ECF No. 1, ¶ 182.) Brady alleges three grounds for his claim each of which he alleges is sufficient to independently establish Medtronic's liability:

a. MEDTRONIC fraudulently concealed and misrepresented the health and safety hazards, symptoms, constellation of symptoms, disease and/or health problems associated with the off-label use of Infuse®;
b. MEDTRONIC fraudulently concealed and misrepresented their practice of promoting and marketing to physicians, including Plaintiff's physician, the off-label practice of using Infuse without an L T-Cage™ and placing it posteriorly or laterally;
c. MEDTRONIC fraudulently concealed and misrepresented information about the known comparative risks and benefits of the use of Infuse® and the relative benefits and availability of alternate products, treatments and/or therapies.

(*Id.* ¶ 184.)

To the extent that this claim is based upon alleged misrepresentations and omissions contained in the FDA approved warning, the claim is expressly preempted. In order to prevail, Brady would need to show that Medtronic was required to include warnings beyond those in the FDA-approved label. This would impose a requirement "different from or in addition to" the federal requirements.

To the extent, however, that this claim is based upon alleged misrepresentations and omissions made in promoting off-label use of Infuse, it survives preemption. Brady's claim that Medtronic made affirmative misrepresentations to promote off-label uses of Infuse parallels federal requirements, which prohibit false or misleading advertisements. *See Houston*,

957 F. Supp. 2d at 1179; *Blankenship v. Medtronic, Inc.*, No. 13-cv-1087, 2014 WL 1226491, at *10 (E.D. Mo. 2014); *Eidson v. Medtronic, Inc.*, No. 13-cv-02049, 2013 WL 5533081, at *10 (N.D. Ca. 2013). So, Brady's fraud claim is "genuinely equivalent" to federal law because there is no likelihood that Medtronic could be liable under Florida law without having violated federal law. *Wolicki-Gables*, 634 F.3d at 1300. This claim is also not impliedly preempted because it sounds in traditional state common law that exists independently from the FDCA and not solely by virtue of the FDCA. *Eidson*, 2013 WL 5533081, at *11.

Brady, however, has failed to plead Count I with particularity, as required by Rule 9(b). The Complaint alleges that Medtronic "actively promoted the off-label procedures to [Brady's] spine surgeon." (ECF No. 1, ¶131.) Brady has not alleged with specificity when, where, and by whom these representations were made, or the content of those misrepresentations. Count I is dismissed without prejudice.

2. Negligence

Brady's negligence claim asserts that Medtronic breached duties to Brady in four respects: (1) improper promotion and marketing of Infuse to physicians, including marketing Infuse for off-label use; (2) failure to warn physicians and Brady of the dangers associated with off-label uses of Infuse; (3) failure to exercise reasonable care by not complying with federal law and regulations applicable to the sale and marketing of Infuse; and (4) failure to exercise reasonable care to prevent Infuse from creating an unreasonable risk of harm to Brady. (ECF No. 1, ¶ 248.)

To the extent Brady's negligence claim is premised on a failure to warn or dangerous design (grounds 2 and 4), these claims are expressly preempted. These claims proceed on the theory that state law required Medtronic to issue warnings about the risks of off-label uses or modify the design in a manner "different from or in addition to" federal requirements.

Any negligence claim based on failure to comply with federal law or solely on illegal off-label promotion (grounds 1 and 3) is impliedly preempted. Permitting this claim to proceed would essentially allow Brady, a private litigant, to attempt to enforce the FDCA. *Buckman* prohibits this.

The Court can conceive of negligence claims that survive preemption, but Brady has not pled one here. Count V is dismissed without prejudice.

3. Breach of express warranty

Brady's final claim is for a breach of express warranty. He alleges that Medtronic used journal articles, advertisements, sales representatives, and

opinion leaders to promote the off-label use of Infuse and expressly warranted that off-label uses were safe and effective. (ECF No. 1, ¶ 258.) Federal law "already requires [Medtronic] to ensure that any warranty statements it voluntarily makes are truthful, accurate, not misleading, and consistent with applicable federal and state law." *Riley*, 625 F. Supp. 2d at 788; 21 U.S.C. § 331(b). So, a state law requirement that holds manufacturers to voluntary warranties made during off-label promotion does not require something "different from or in addition to" federal requirements. Moreover, Brady's claim for breach of express warranty would exist in the absence of the FDCA and MDA. It is therefore not preempted.

Nonetheless, Count VI is dismissed without prejudice because it is inadequately pled. An express warranty is "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes a basis of the bargain[.]" Fla. Stat. § 672.313(1)(a). Brady has not alleged (other than in a conclusory fashion) the specific express warranties made to him or his physician.[1]

Conclusion

For the reasons stated above, the Court **grants** the motion to dismiss (ECF No. 12). Counts II, III, and IV are dismissed with prejudice. Counts I, V, and VI are dismissed without prejudice. Brady may file an Amended Complaint by **April 29, 2014**.

Done and ordered in chambers, at Miami, Florida, on April 8, 2014.

Robert N. Scola, Jr.
United States District Judge

[1] In a footnote, Medtronic also argues that, consistent with Florida law, it disclaimed any express warranties in connection with sales of Infuse. (ECF No. 12, 29 n. 32.) "A footnote is the wrong place for substantive arguments on the merits of a motion." *First Advantage Background Servs. Corp. v. Private Eyes, Inc.,* 569 F.Supp.2d 929, 935 (N.D.Cal.2008). The Court will not consider the arguments raised in Medtronic's 33 footnotes.