UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

FELICIA DAVIS,

Plaintiff,

v. Case No: 2:17-cv-682-FtM-38CM

BOSTON SCIENTIFIC CORPORATION,

Defendant.
_____/

OPINION AND ORDER[1]

This matter comes before the Court on Boston Scientific's Motion to Dismiss (Doc. 37), which was filed on June 1, 2018. Plaintiff Felicia Davis responded on June 15, 2018. (Doc. 39). The matter is ripe for review.

BACKGROUND

The facts of this products liability case have already been outlined in the Court's previous Order dismissing Davis' Amended Complaint. (Doc. 35). In the interests of brevity, only the salient details will be repeated. This case concerns Boston Scientific's permanent inferior vena cava filter (the "Greenfield Filter), which was created to prevent pulmonary embolisms. (Doc. 36 at ¶¶ 22, 27). A pulmonary embolism occurs when a

[1] Disclaimer: Documents filed in CM/ECF may contain hyperlinks to other documents or websites. These hyperlinks are provided only for users' convenience. Users are cautioned that hyperlinked documents in CM/ECF are subject to PACER fees. By allowing hyperlinks to other websites, this Court does not endorse, recommend, approve, or guarantee any third parties or the services or products they provide on their websites. Likewise, the Court has no agreements with any of these third parties or their websites. The Court accepts no responsibility for the availability or functionality of any hyperlink. Thus, the fact that a hyperlink ceases to work or directs the user to some other site does not affect the opinion of the Court.

blood clot travels through blood vessels to block one of the pulmonary arteries in the lungs. (Doc. 36 at ¶ 19). When clots form in deep leg veins, this condition is called deep vein thrombosis. (Doc. 36 at ¶ 19).

Inferior vena cava filters have been the subject of research over the years. Davis cites two studies from as early as 2008 that found permanent inferior vena cava filters like the Greenfield Filter have comparable complication and protection rates to retrievable filters. (Doc. 36 at ¶¶ 43, 45). And without specifying the dates, she alleges other "cited studies have shown that long-term implantation of [inferior vena cava filters] can cause subsequent [pulmonary embolisms] and [deep vein thrombosis]." (Doc. 36 at ¶ 27). She also alleges that in 2010 and 2014 the United States Food and Drug Administration cautioned against implanting inferior vena cava filters for extended periods of time due to potential adverse health complications. (Doc. 36 at ¶¶ 36-40).

At some point prior to 2009, Davis suffered a pulmonary embolism. (Doc. 36 at ¶ 23). She then had the Greenfield Filter implanted in her right common femoral vein.[2] (Doc. 36 at ¶ 25). In 2015, she was hospitalized for chest pain and diagnosed with bilateral segmental pulmonary emboli. (Doc. 36 at ¶ 27). Almost two years after that, she was hospitalized again and diagnosed with deep vein thrombosis. (Doc. 36 at ¶ 28).

Davis then sued Boston Scientific in state court. (Doc. 2). After the case was removed (Doc. 1), Boston Scientific moved to dismiss. (Doc. 7). Upon review, the Court agreed with Boston Scientific and dismissed the Complaint. (Doc. 19). Davis then filed

[2] It is unclear when the Greenfield Filter was implanted. The Complaint states it was done in September 2009 (Doc. 2 at ¶ 43), while the Amended Complaint claims it happened in 2005 (Doc. 20 at ¶¶ 24, 26, 91, 258, 293, 295, 322). This confusion is compounded by the Second Amended Complaint, which haphazardly uses both the 2005 (Doc. 36 at ¶¶ 174-75, 186, 204, 209, 228, 239) and 2009 dates (Doc. 36 at ¶¶ 23, 25, 81).

an Amended Complaint with claims including negligence, strict liability manufacturing and design defect, breach of warranty, fraudulent misrepresentation, negligent misrepresentation, and fraudulent concealment. (Doc. 20). Boston Scientific again moved to dismiss. (Doc. 21). The Court then agreed with Boston Scientific in part and dismissed the fraud and warranty-based claims. (Doc. 35 at 10-17).

Davis then filed a Second Amended Complaint. (Doc. 36). She alleges the Greenfield Filter was defectively designed and manufactured. (Doc. 36 at ¶ 55). She further alleges the Greenfield Filter was inadequately tested and had inadequate warnings, instructions, and labeling. (Doc. 36 at ¶ 55). Based on these allegations, Davis claims Boston Scientific is liable for: negligence (Count I), strict liability defective design (Count II), strict liability manufacturing defect (Count III), strict liability failure to warn (Count IV), fraudulent misrepresentation (Count V), fraudulent concealment (Count VI), and negligent misrepresentation (Count VII). (Doc. 36 at ¶¶ 69-242). Now, for the third time, Boston Scientific moves to dismiss. (Doc. 37).

LEGAL STANDARD

Pursuant to Federal Rule of Civil Procedure 8(a)(2), a pleading must contain a short and plain statement of a claim showing the pleader is entitled to relief. Fraud allegations are subject to heightened pleading standards under Federal Rule of Civil Procedure 9(b), which requires a party to "state with particularity the circumstances constituting fraud." To meet this threshold, a pleading must allege

> (1) precisely what statements were made in what documents or oral representations or what omissions were made, and (2) the time and place of each such statement and the person responsible for making (or, in the case of omissions, not making) same, and (3) the content of such statements and the

> manner in which they misled the plaintiff, and (4) what the defendants obtained as a consequence of the fraud.

Ziemba v. Cascade Int'l, Inc., 256 F.3d 1194, 1202 (11th Cir. 2001) (citing *Brooks v. Blue Cross and Blue Shield of Florida, Inc.*, 116 F.3d 1364, 1371 (11th Cir.1997)). But "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." *Brooks*, 116 F.3d at 1371. These standards are intended to "(1) provide defendants with sufficient notice of what the plaintiff complains to enable them to frame a response, (2) prevent fishing expeditions to uncover unknown wrongs, and (3) protect the defendant from unfounded accusations of immoral or otherwise wrongful conduct." *U.S. ex rel. Butler v. Magellan Health Servs., Inc.*, 101 F. Supp. 2d 1365, 1368 (M.D. Fla. 2000).

Under Federal Rule of Civil Procedure 12(b)(6), a court may dismiss a pleading for failure to state a claim upon which relief can be granted. This decision hinges on the *Twombly–Iqbal* plausibility standard, which requires a plaintiff to "plead factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007). At this stage, the Court must accept all factual allegations in a complaint as true and take them in the light most favorable to the plaintiff. *Pielage v. McConnell*, 516 F.3d 1282, 1284 (11th Cir. 2008). But acceptance is limited to well-pleaded factual allegations. *La Grasta v. First Union Sec., Inc.*, 358 F.3d 840, 845 (11th Cir. 2004). A "the-defendant-unlawfully harmed me accusation" is insufficient. *Iqbal*, 556 U.S. at 677. "Nor does a complaint suffice if it tenders naked assertions devoid of further factual enhancement." *Id*. (internal quotations omitted).

DISCUSSION

Boston Scientific argues Counts V, VI, and VII should be dismissed with prejudice because Davis has failed to plausibly plead her claims despite three chances to do so. Davis opposes. The Court will address each count in turn.

A. Fraudulent Misrepresentation

Count V alleges Boston Scientific fraudulently misrepresented the Greenfield Filter's safety and efficacy through a number of avenues including its website, product brochures, product labeling and direct statements to Davis' doctor. The elements of a fraudulent misrepresentation claim in Florida are "(1) a false statement concerning a material fact; (2) the representor's knowledge that the representation is false; (3) an intention that the representation induce another to act on it; and (4) consequent injury by the party acting in reliance on the representation." *Butler v. Yusem*, 44 So. 3d 102, 105 (Fla. 2010). Boston Scientific argues Davis' allegations fail to meet the heightened particularity threshold of Rule 9(b). The Court agrees.

1. The Website

Davis alleges Boston Scientific's website misrepresented that the Greenfield Filter had "[t]rusted performance, [t]imeless design," "[p]roven [s]tability," "[e]stablished [f]ilter [p]erformance," and that "[f]ilter [d]esign [p]romotes [c]lot [l]ysis."[3] (Doc. 36 at ¶¶ 165-66). As a threshold matter, it is unclear whether Davis' claims are based on Boston Scientific's current website, or the version in existence at the time of the implantation. Referring to the current version is problematic because Davis acknowledges it is "not the same as

[3] Though the Court indicates its modification of the quoted materials here, it will use lowercase terminology throughout the remainder of the Order.

[what was] given to [her] at the time of her implant." (Doc. 36 at ¶ 163). Of course, reliance is a necessary element of a fraudulent misrepresentation claim. *See Butler*, 44 So. 3d at 105. Because Davis could not have relied on the current website at the time of implantation, it provides no assistance. Nevertheless, at this stage the Court is required to take the allegations in the light most favorable to Davis. *Pielage*, 516 F.3d at 1284. As such, the claims will be construed to rest on the version of the website in existence at the time of the implantation.

That resolved, the Court moves into substance. As was explained in a previous Order, all but Boston Scientific's alleged statement that "filter design promotes clot lysis" are opinions. (Doc. 35 at ¶ 13). In Florida, "[a]n action for fraud generally may not be predicated on statements of opinion." *Mejia v. Jurich*, 781 So.2d 1175, 1177 (Fla. 3d DCA 2001). But statements of opinion may support a fraudulent misrepresentation claim where "the person expressing the opinion is one having superior knowledge of the subject of the statement and the plaintiff can show that said person knew or should have known from facts in his or her possession that the statement was false." *Id*.

Here, the most obvious statement of opinion is Boston Scientific's representation that the Greenfield Filter has a "timeless design." (Doc. 36 at ¶ 165). It cannot form the basis for a fraudulent misrepresentation claim because Davis fails to plausibly allege Boston Scientific had a superior knowledge of the timelessness of the design, or that it knew or should have known from facts in its possession that the statement was false. This makes sense because the concept of a product's timelessness is entirely subjective.

The statements about the Greenfield Filter's "trusted performance," "established filter performance," and "proven stability" (Doc. 36 at ¶¶ 165-66), were also opinions.

They too fail to constitute fodder for a fraudulent misrepresentation claim. For starters, Davis does not specify what exactly was trusted or established about the Greenfield Filter's performance, or proven about its stability. And even if she did, the Second Amended Complaint does not allege Boston Scientific had a superior knowledge of the subject. The closest it comes is by alleging that "[i]mportant information regarding the risk of the Greenfield Filter was in the exclusive control of [Boston Scientific] and exclusively known by [Boston Scientific]." (Doc. 36 at ¶ 179). But that allegation does not meet Rule 9(b)'s heightened particularity threshold because it does not detail the contents of Boston Scientific's exclusive knowledge.

Similarly, as she did in the Amended Complaint, Davis fails to plausibly allege the existence of any facts in Boston Scientific's possession to indicate that it knew or should have known its statements about the Greenfield Filter's "trusted" and "established" filter performance, or its "proven stability" were false at the time they were made. Two allegations from the Second Amended Complaint can be read to apply to this statement. First, Davis alleges Boston Scientific "failed to disclose to physicians, patients, or [Davis] in detail that . . . the Greenfield Filter was subject to breakage, collapse, migration, perforation, causing thrombus, and/or the appropriate degree of risk of damage to the vena cava wall and other complications after long-term implantation." (Doc. 36 at ¶ 50) (punctuation omitted). Second, she broadly alleges Boston Scientific "knew . . . its misrepresentations were false regarding the dangers and risks associated with the use of its Greenfield Filter." (Doc. 36 at ¶ 183). These allegations fail because they relate only to Boston Scientific's knowledge of the product's qualities. This differs from the concepts of trust, establishment, or proof, which are third party value judgments.

That leaves only the statement that "filter design promotes clot lysis." (Doc. 36 at ¶¶ 165-66). Lysis is "a process of disintegration or dissolution."[4] Because it is objectively verifiable whether the Greenfield Filter's design contributed toward the dissolution of clots, the statement is one of fact. But even if it could be a viable basis for a fraudulent misrepresentation claim, it fails under Rule 9(b) because it is unclear whether it was made in 2005 (Doc. 36 at ¶¶ 174-75, 186) or 2009 (Doc. 36 at ¶¶ 23, 25, 81). *See Ziemba*, 256 F.3d at 1202 (finding "the time and place of each . . . statement" must be specifically enumerated). Accordingly, all of Davis' website-based allegations do not pass muster.

2. The Product Brochure

Next, Davis alleges Boston Scientific's product brochure misrepresented that the Greenfield Filter's design had been consistent for thirty years, that its design is the most trusted, that it is the most likely to protect from adverse events, and that the Greenfield Filter's "[r]ecurved hooks are designed to provide protection against penetration." (Doc. 36 at ¶¶ 167-68). These claims suffer from the same ambiguity as the website-based allegations in that they seem to be based on both past and current versions of Boston Scientific's product brochure. (Doc. 36 at ¶¶ 161-62). For the same reasons mentioned above, Davis cannot rely on the current product brochure. *See Butler*, 44 So. 3d at 105 (finding reliance is a necessary element of a fraudulent misrepresentation claim).

Assuming the claims stem from a brochure in existence at the time of the implantation, they still fail to the extent they are not based on Boston Scientific's precise statements. *See Ziemba*, 256 F.3d at 1202. Davis seeks to avoid this conclusion by

[4] Lysis, MERRIAM WEBSTER ONLINE DICTIONARY, https://www.merriam-webster.com/dictionary/lysis (last visited on June 22, 2018).

citing the Eleventh Circuit's decision in *Hill v. Morehouse Med. Assocs, Inc.*, which she claims allows her to plead her claims at a lower level of specificity. 2003 WL 22019936 (11th Cir. Aug. 15, 2003). That misreads the law. In *Hill*, the court noted that "Rule 9(b)'s heightened pleading standard may be applied less stringently . . . when specific factual information about . . . fraud is peculiarly within [a] defendant's knowledge or control." *Id.* at *3 (internal quotations omitted). But that only occurs where the information is "in exclusive control of the defendant and cannot be possessed by other entities." *Bray & Gillespie Mgmt. LLC v. Lexington Ins. Co.*, No. 6:07CV222ORL19KRS, 2007 WL 3457585, at *3 (M.D. Fla. Nov. 14, 2007). Even then, a plaintiff must accompany "her legal theory with factual allegations that make her theoretically viable claim plausible." *Hill*, 2003 WL 22019936, at *3. Mere conclusory allegations are insufficient to make a claim plausible. *Id.* Likewise, the difficulty a person faces in securing information as an outsider is not grounds for relaxing Rule 9(b)'s pleading standard. *See id.*

Here, Davis does not plausibly allege Boston Scientific's past brochure is in its exclusive control. To the contrary, she alleges it was once distributed freely enough that she received a copy at the time of her implantation. (Doc. 36 at ¶ 163). Making matters worse, she does not allege there is no viable way for her to obtain past copies of the brochure. The Eleventh Circuit has repeatedly noted that difficulty in obtaining information is not the same as the inability to do so. *See id.; see also U.S. ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1314 n.25 (11th Cir. 2002) (declining to use a lenient pleading standard for a corporate outsider that was "not without avenues for obtaining information" underlying his allegations). Thus, the mere fact that Davis does not possess a copy of Boston Scientific's past brochure is insufficient to lower Rule 9(b)'s pleading

threshold. Therefore, Davis' claims fail to the extent they are not supported with Boston Scientific's precise alleged statements.

That leaves Boston Scientific's purported statement that the Greenfield Filter's "[r]ecurved hooks are designed to provide protection against penetration." (Doc. 36 at ¶¶ 167-68). But Davis does not specify why that statement was false or how it misled her. Nor does she unambiguously state whether she received the brochure in 2005 (Doc. 36 at ¶¶ 174-75, 186) or 2009 (Doc. 36 at ¶¶ 23, 25, 81). Because these details are necessary under Rule 9(b), the allegations fail as well. *See Ziemba*, 256 F.3d at 1202.

3. Labeling

Davis also alleges the Greenfield Filter's labeling fraudulently misrepresented that the product was safe and effective for its intended and reasonably foreseeable use. (Doc. 36 at ¶ 171). But this allegation is insufficient for three reasons. First, Davis does not recite Boston Scientific's precise misrepresentations. *See Ziemba*, 256 F.3d at 1202. Second, it is unclear whether Davis even received the labeling. Count V states only that "[t]he medical community and [Davis'] physicians used this information, including the attending physician Dr. Joseph Creevy, and conveyed to [Davis] sometime prior to her September 9, 2005 surgery." (Doc. 36 at ¶ 174). What exactly Dr. Creevy conveyed to Davis is left to the imagination.

Third, even if the Court were to overlook Davis' failure to precisely restate Boston Scientific's statement and assume she received the labeling, her allegations still fail because the Second Amended Complaint lists contradictory dates for her implantation – and therefore for her reception of the labeling. On the one hand, Count V states the information was "conveyed" to Davis prior to her surgery in 2005 (Doc. 36 at ¶ 174), but

other parts of the Second Amended Complaint allege the surgery occurred in 2009. (Doc. 36 at ¶¶ 23, 25, 81). The Eleventh Circuit has been clear that a Plaintiff must plead "the time and place of each . . . statement." *Id*. By pleading two surgery dates that are four years apart, Davis has failed to meet that standard.[5] As such, the claim fails.

4. Statements from Dr. Creevy

Next, Davis alleges Boston Scientific made false statements to Dr. Creevy, the medical community, and the FDA. (Doc. 36 at ¶ 171). She then alleges Dr. Creevy communicated those misrepresentations to her. (Doc. 36 at ¶ 175-77). The Court need not wade into the content of those statements to find them wanting. To hold Boston Scientific liable for Dr. Creevy's statements, Davis would need to allege the existence of an agency relationship. *See Palm Beach Roamer, Inc. v. McClure*, 727 So. 2d 1005, 1007 (Fla. 5th DCA 1999)*; see also Great Fla. Bank v. Countrywide Home Loans, Inc.*, No. 10-22124-CIV, 2011 WL 382588, at *4 (S.D. Fla. Feb. 3, 2011). But she does not.

Davis argues this is not the case. She cites to an opinion from the Southern District of Florida, *Brady v. Medtronic, Inc.*, to contend that a plaintiff may have a plausible fraudulent misrepresentation claim where a defendant's misrepresentations induce a doctor into reliance, and the doctor repeats the misrepresentations to the plaintiff. No. 13-62199-CIV, 2015 WL 11181971 (S.D. Fla. Mar. 30, 2015). Indeed, *Brady* does make such a finding. *Id*. at *5. But it does so without first considering whether the defendant's liability hinged on the existence of an agency relationship with the third-party doctor. That

[5] These problems are largely what can be expected when filing multiple cases with cookie-cutter complaints. *See* Second Am. Compl., *Kendall v. Boston Sci. Corp.*, No. 6:17-CV-1888 (M.D. Fla. May 1, 2018); *see also* Second Am. Compl., *Douse v. Boston Sci. Corp.*, 2:17-CV-599 (M.D. Fla. May 21, 2018).

makes this case distinguishable.

Here, Florida law seems clear that where a defendant makes misrepresentations to a third party, who then makes the same misrepresentations to a plaintiff, the liability of the original defendant depends on the existence of an agency relationship. *See Palm Beach Roamer, Inc.*, 727 So. 2d at 1007. Because Davis does not allege the existence of an agency relationship, her claims fail.

5. Statement of Unknown Origin

Finally, Davis alleges Boston Scientific represented its Greenfield Filters had been adequately tested in clinical trials and found to be safe and effective for long term implantation. (Doc. 36 at ¶ 182). But this allegation also fails under Rule 9(b) for multiple reasons. First, Davis does not cite the specific statement made by Boston Scientific. Second, she does not allege how Boston Scientific made the allegation. And third, Davis does not allege when Boston Scientific made the allegation. In other words, Davis failed to include even the most basic information about the representation. Rule 9(b) requires more. *Ziemba*, 256 F.3d at 1202. Thus, Count V will be dismissed.

B. Fraudulent Concealment

Count VI alleges Boston Scientific fraudulently concealed material information about the Greenfield Filter's safety. Fraudulent concealment is similar to fraudulent misrepresentation except that the defendant conceals facts instead of misrepresenting them. *Kish v. A.W. Chesterton Co.*, 930 So. 2d 704, 707 (Fla. 3d DCA 2006). Like fraudulent misrepresentation claims, fraudulent concealment claims are subject to the heightened pleading requirements of Rule 9(b). *Grills v. Philip Morris USA, Inc.*, 645 F. Supp. 2d 1107, 1123 (M.D. Fla. 2009). Boston Scientific argues Count VI fails to state a

viable claim. The Court agrees.

Despite being dismissed as inadequate on a previous occasion, Davis has changed remarkably little about Count VI. She alleges Boston Scientific "had sole access to material facts concerning the defective nature of the [Greenfield Filter], and its propensity to cause serious and dangerous side effects." (Doc. 36 at ¶ 201). And that Boston Scientific used this exclusivity of control to conceal a range of information including "the risks of adverse events with the Greenfield Filters," that the "Greenfield Filters were not safe", and "that the Greenfield Filter was manufactured negligently." (Doc. 36 at ¶ 199(a)-(j)). These allegations fail for two main reasons. First, whether a product is safe is an opinion. Similarly, whether a product was manufactured negligently is a legal conclusion. Because fraudulent concealment only applies to suppressed facts, rather than opinions or legal conclusions, the allegations are wanting.

Second, Davis does not allege a single fact that was specifically concealed by Boston Scientific. To avoid this glaring insufficiency, she again argues *Hill* allows her to plead at a lower standard of particularity because Boston Scientific has factual knowledge that is peculiarly within its knowledge or control. But Davis does not cite any specific information exclusively possessed by Boston Scientific or provide any specific facts to show that such information was concealed. Therefore, her claims are subject to Rule 9(b). *See Bray*, 2007 WL 3457585, at *3. Because she does not cite any specific materials that would substantiate her claims, Count VI must be dismissed.

C. Negligent Misrepresentation

Count VII alleges Boston Scientific negligently misrepresented that the Greenfield Filter was safe and effective. To establish negligent misrepresentation in Florida, a

plaintiff must allege

> (1) [a] misrepresentation of material fact; (2) the representor . . . ma[d]e the representation without knowledge as to its truth or falsity, or . . . under circumstances in which he ought to have known of its falsity; (3) the representor . . . intend[ed] that the misrepresentation induce another to act on it; (4) injury must result to the party acting in justifiable reliance on the misrepresentation.

Souran v. Travelers Ins. Co., 982 F.2d 1497 (11th Cir.1993) (quoting *Hoon v. Pate Constr. Co., Inc.*, 607 So.2d 423, 427 (Fla. 4th DCA1992)). Boston Scientific argues that Count VII claim should be dismissed with prejudice because Davis has failed to plead a plausible claim after three opportunities. The Court agrees.

Negligent misrepresentation claims must meet Rule 9(b)'s heightened pleading threshold. *Lamm v. State St. Bank & Tr.*, 749 F.3d 938, 951 (11th Cir. 2014). Count VII relies on the same alleged misrepresentations alleged in Count V. The outcome will be the same as well. Because none of the statements allegedly made in Count VII can viably support a negligent misrepresentation claim, Count VII will be dismissed.

D. Dismissal With Prejudice

In general, a district court's discretion to dismiss a complaint without leave to amend is subject to the directives of Rule 15(a)(2), which states that "[t]he court should freely give leave when justice so requires." "A district court need not, however, allow an amendment (1) where there has been . . . [a] repeated failure to cure deficiencies by amendments previously allowed; (2) where allowing amendment would cause undue prejudice to the opposing party; or (3) where amendment would be futile." *Bryant v. Dupree*, 252 F.3d 1161, 1163 (11th Cir. 2001). Here, Davis has received three opportunities to plead her claims viably. Yet she has failed to cure her deficiencies. As

such, Counts V, VI, and VII will be dismissed with prejudice.

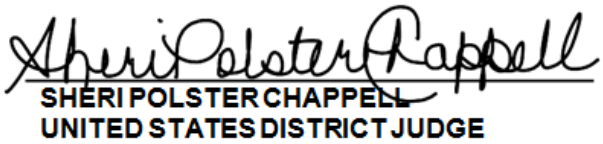
Accordingly, it is now

ORDERED:

1. Boston Scientific's Motion to Dismiss (Doc. 37) is **GRANTED**.

2. Counts V, VI, and VII are **DISMISSED with prejudice**.

DONE and **ORDERED** in Fort Myers, Florida this 28th day of June, 2018.



SHERI POLSTER CHAPPELL
UNITED STATES DISTRICT JUDGE

Copies: All Parties of Record