UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 16-CV-60471-GAYLES

DENNIS GODELIA, et al.,

Plaintiffs,

v.

ZOLL SERVICES, LLC, et al.,

Defendants.
_____/

ORDER

THIS CAUSE came before the Court upon Defendant Zoll Services, LLC's Motion to Dismiss Second Amended Complaint [ECF No. 26]. The Court has reviewed the Motion and the record and is otherwise fully advised. For the reasons that follow, the Motion is granted.

FACTUAL BACKGROUND[1]

I. The LifeVest

Defendant Zoll Services, Inc. ("Zoll") designs, manufactures and markets the LifeVest, a wearable defibrillator for patients at risk for sudden cardiac arrest. The LiveVest is made to detect life-threatening heart rhythms and automatically deliver a shock to restore the rhythm. The LifeVest is a Class III medical device, initially approved for sale in 2001 by the Food and Drug Administration ("FDA"), and must be prescribed by a medical doctor.

[1] On a motion to dismiss, the court takes the plaintiff's factual allegations as true. *Brooks v. Blue Cross v. Blue Shield of Florida, Inc.*, 116 F.3d 1364, 1369 (11th Cir. 1997).

II. Debra Godelia's LifeVest

In November, 2013, Debra Godelia was in the hospital recovering from a cardiac operation. Following a review of her medical records, Zoll determined that Mrs. Godelia was a candidate for the LifeVest and sent Defendant Samantha Orsini ("Orsini"), a Zoll employee, to visit Mrs. Godelia to explain the benefits of and how to use the LifeVest. Mrs. Godelia expressed her concerns that the LifeVest would either administer a shock when one was not needed or fail to administer a shock when one was needed. Orsini represented to Mrs. Godelia that (1) the LifeVest would never administer a shock when one was not needed, (2) the LifeVest would administer a shock if a treatable heart event was detected, (3) LifeVest's success rate in detecting and administering a treating shock was higher than 98%, and (4) the LifeVest has a 98% first treatment shock success rate for resuscitating patients from sudden cardiac arrest. Based on Orsini's representations, Mrs. Godelia agreed to use the LifeVest and did not inquire about alternative options.

Mrs. Godelia remained concerned about the LifeVest working as promised. As a result, Zoll sent Defendant Ana Cecilia Masters ("Masters"), also a Zoll employee, to visit the Godelias to further explain the benefits of the LifeVest. Masters reassured the Godelias that their concerns were unwarranted and made the same or substantially similar representations as Orsini.

III. LifeVest Fails to Administer a Lifesaving Shock

On November 18, 2013, Mrs. Godelia experienced a defibrillation event[2] and lost consciousness. Mrs. Godelia's LifeVest detected her defibrillation event and made an audible alarm, but did not administer the requisite shock. As Zoll instructed, Plaintiff Dennis Godelia did not touch his unconscious wife and waited for the LifeVest to work. At the same time, Plaintiff

[2] A defibrillation event is either ventricular tachycardia ("VT") (150 beats per minute) or ventricular fibrillation ("VF") (200 beats per minute).

Sterling Youmas, Mrs. Godelia's minor child, called 911. After he realized that the LifeVest was not administering a shock, Youmas, pursuant to instructions from a 911 operator, administered CPR on his mother to no avail. Mrs. Godelia remained unconscious until she died in the hospital on November 20, 2013.

IV. The Warning Letter

From May 22, 2014, through June 20, 2014, the FDA inspected the Zoll facility that manufactures and distributes LifeVest devices. On September 23, 2014, the FDA issued a warning letter informing Zoll that "the methods used in, or the facilities or controls used for, their manufacture, processing, packing or installation are not in conformity with the current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) Regulation found at Title 21, Code of Federal Regulations (CFR), Part 820." [ECF No. 23 at ¶ 21]. The Warning Letter also informed Zoll that the FDA found various violations during the inspection, including a "failure to document results for corrective and preventive actions, as required by 21 CFR 820.100(b) . . . as a result of a high noise artifact and/or vibration causing the LifeVest device to inappropriately ***deliver*** shock treatments to patients." [*Id.* Ex. A, at 23] (emphasis added).

V. Zoll's Marketing Statements

Zoll markets that the LifeVest (1) allows its users to return to their activities of daily living, while having the peace of mind that they are protected from sudden cardiac arrest and (2) detects life-threatening heart rhythms and automatically delivers a treatment shock, usually in less than a minute, to restore the normal heart rhythm. Zoll represents that the LifeVest has a first treatment shock success rate of 98% for resuscitating patients, dependent on a patient receiving a timely and appropriate treatment shock.

VI. The Second Amended Complaint

On July 17, 2016, Plaintiffs filed their Second Amended Complaint asserting claims under Florida law for (1) strict liability manufacturing defect, (2) negligent manufacturing defect, (3) fraudulent misrepresentation, (4) fraudulent omission/concealment, (5) fraudulent marketing/promotion, (6) breach of express warranty, (7) negligent misrepresentation, and (8) negligent infliction of emotional distress.[3] Plaintiffs allege that Defendants knew or should have known that (1) the number of inappropriate shocks administered by LifeVest devices were equal or almost equal to the number of appropriate shocks administered, (2) the LifeVest devices were not adequately validated under actual and simulated use conditions to ensure that they conformed to defined user needs and intended uses, (3) Zoll was not adequately identifying, investigating, and remedying non–conformities with the LifeVest devices, (4) Zoll was not adequately reviewing, evaluating and investigating incidents where LifeVest devices may have caused or contributed to a death or serious injury, and (5) normal day to day activities would create noise artifact and/or vibration that would result in the LifeVest devices administering inappropriate shocks. On July 27, 2016, Defendants moved to dismiss arguing that the Medical Device Amendment ("MDA") of the Food, Drug, and Cosmetic act ("FDCA") preempts all of Plaintiffs' claims.

LEGAL STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Although this pleading standard "does not require 'detailed factual allegations,' . . . it demands more than

[3] In their response to the Motion to Dismiss, Plaintiffs conceded that their claim for fraudulent omission/concealment should be dismissed. *See* Plaintiff's Response at pg. 12, n. 10.

an unadorned, the defendant-unlawfully-harmed-me accusation." *Id*. (alteration added) (quoting *Twombly*, 550 U.S. at 555). Pleadings must contain "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 (citation omitted). Indeed, "only a complaint that states a plausible claim for relief survives a motion to dismiss." *Iqbal*, 556 U.S. at 679 (citing *Twombly*, 550 U.S. at 556). To meet this "plausibility standard," a plaintiff must "plead[ ] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678 (citing *Twombly*, 550 U.S. at 556).

When reviewing a motion to dismiss, a court must construe the complaint in the light most favorable to the plaintiff and take the factual allegations therein as true. *See Brooks v. Blue Cross & Blue Shield of Florida, Inc.*, 116 F.3d 1364, 1369 (11th Cir. 1997). However, pleadings that "are no more than conclusions are not entitled to the assumption of truth. While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." *Iqbal*, 556 U.S. at 678.

ANALYSIS

I. Background on Class III Medical Devices

Medical devices, like the LifeVest, are regulated by the FDCA, 21 U.S.C. §§ 301–399f. In 1976, Congress enacted the MDA, 21 U.S.C. § 360c, which amended the FDCA and "swept back some state obligations and imposed a regime of detailed federal oversight" for medical devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). Under the MDA, medical devices are divided into three classes with the most federal oversight imposed upon devices in Class III. *Id.* at 317. A Class III device is "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of

human health," or "presents a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii).

Before a Class III device is introduced to the market, "the manufacturer must provide the FDA with 'reasonable assurance' that the device is both safe and effective" through a process known as the "premarket approval" or "PMA." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996) (quoting 21 U.S.C. § 360e(d)(2)). Once a device is granted premarket approval, the manufacturer may not change the design, manufacturing, labeling or any other element that would affect safety or effectiveness of the device without FDA permission. § 360e(d)(6)(A)(i). Furthermore, the manufacturer of approved devices must provide reports of, among other things, "incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred." *Riegel*, 552 U.S. at 319 (citing § 803.50(a)). The FDA retains the power to withdraw approval and must do so if a device is unsafe. *Id.* at 320.

II. Preemption

Defendants argue that the MDA preempts all of Plaintiffs' state law claims and, therefore, must be dismissed.

A. Express Preemption

The MDA includes an express preemption provision for medical devices that provides:

> 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). The Supreme Court has interpreted this language to preempt all state-law claims relating to "the design, testing, inspection, distribution, labeling, marketing and sale of" PMA devices. *Riegel*, 552 U.S. at 320. Accordingly, state law claims are preempted to the extent that they are different from or in addition to federal law. *Id.*

The MDA's express preemption provision, however, is not absolute. In *Riegel*, the Supreme Court held that § 360k "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* at 330 (quoting *Lohr*, 518 U.S. at 495). Courts must apply a two-pronged test to determine if a claim is parallel: (1) has the Federal Government established requirements applicable to the device and (2) are the claims based on state-law requirements that are "'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." *Riegel*, 552 U.S. at 321–22 (quoting 21 U.S.C. § 360(k)(a)(1)). Class III medical devices, having gone through the PMA process, automatically satisfy the first prong. *Id*. The second prong requires the plaintiff to "show that the requirements are 'generally equivalent.' State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law." *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300 (11th Cir. 2011) (quoting *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005)). In addition, "[a] plaintiff must allege that "[the] defendant violated a particular federal specification referring to the device at issue," and must allege a link between the defendant's violation of the FDA regulation and the alleged injury. *Id.* at 1301-1302 (citing *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008)). Florida courts have consistently held that "'common law products liability or negligence actions – i.e., actions not based on a "parallel" requirement adopted by the state – are preempted by the MDA.'" *Mink v.*

Smith & Nephew, Inc. ("Mink II"), 169 F. Supp. 3d 1321, 1333 (S.D. Fla. 2016) (quoting *Wheeler v. DePuy Spine, Inc.*, 706 F. Supp. 2d 1264, 1270 (S.D. Fla. 2010)).

B. Implied Preemption

Even if a plaintiff is able to properly plead a parallel claim, the Court must determine if the claim is impliedly preempted. Pursuant to the FDCA, all actions to enforce FDA requirements "shall be by and in the name of the United States." 21 U.S.C. § 337(a). In *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n. 4 (2001), the Supreme Court, citing § 337, noted that "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions. . ." *Id.*. Pursuant to this holding, § 337 impliedly preempts claims involving Class III medical devices if brought by private litigants. *Id.* The Eleventh Circuit has yet to address implied preemption. *See Wolicki-Gables*, 634 F.3d at 1302 ("Because the Gableses' claims are preempted, we do not address Arrow's assertion that private actions brought for violations of the FDA regulations are barred pursuant to 21 U.S.C. § 337(a)."). However, several district courts in Florida have found private litigants' claims impliedly preempted by § 337. *See Mink II*, 169 F. Supp. 3d at 1334 (plaintiff's claims for failure to comply with FDCA requirements impliedly preempted); *McClelland v. Medtronic, Inc.*, 944 F. Supp. 2d 1193, 1200 (M.D. Fla 2013) (holding that § 337 impliedly preempts suits by private litigants); *Kaiser v. Depuy Spine, Inc.*, 944 F. Supp. 2d 1187, 1192 (M.D. Fla. 2013) (dismissing the plaintiff's claims because "Florida law does not allow Plaintiff to bring a private cause of action to enforce FDA regulations"); *Brown v. DePuy Orthopaedics, Inc.*, 978 F. Supp. 2d 1266, 1274 (M.D. Fla. 2013).

Courts addressing the application of both express and implied preemption have held that there is a "narrow gap through which a plaintiff's state-law claim must fit if it is to escape

express or implied preemption." *McClelland*, 944 F. Supp. 2d at 1200 (quoting *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010). "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*)." *Id. cf. Mink II*, 169 F. Supp. 3d at 1335 ("Admittedly, the Court is mildly perplexed as to what manner of claim would make it through the 'narrow gap' described by the Eighth Circuit . . . Nevertheless, after canvassing the binding and persuasive authority submitted in support of S&N's Motion, it is clear that Mink's claim cannot fit.") It is through this narrow window that the Court reviews Plaintiffs' claims.

III. Plaintiffs' Claims are Preempted

A. Strict Products Liability and Negligent Manufacturing

Plaintiffs' claims for strict products liability and negligent manufacturing are expressly preempted by the MDA. "Since *Riegel* and *Wolicki-Gables*, trial courts within Florida, and within this District, have dismissed strict liability and negligence claims at the pleadings stage because Florida state-law on these causes of action 'clearly impose[] requirements which are "different from, or in addition to" the federal requirements.'" *Mink v. Smith & Nephew (Mink I)*, 145 F. Supp. 3d 1208, 1216 (S.D. Fla. 2015) (quoting *Stokes v. I-Flow Corp.* No. 6:12-cv-991-Orl-36DAB, 2013 WL 1715427, at *7 (M.D. Fla. Apr. 8, 2013); *see Kaiser*, 944 F. Supp. 2d 1187 at 1190-91 (state law tort claims are preempted by MDA). To permit Plaintiffs to proceed on their strict liability and negligence claims presents the possibility of conflicting results. Indeed, a jury could find that the LifeVest had a manufacturing defect despite FDA pre-market approval. This result runs afoul of the MDA preemption provision. *See Brown*, 978 F. Supp. 2d at 1272-73 ("Because the state law claims require a determination that the product is defective or

unreasonably dangerous, it is also possible that 'a fact finder could find liability under [the] Florida . . . laws even if the manufacturer had completely complied with the FDA regulations.'") (citations omitted).

Plaintiffs point to the warning letter in an attempt to establish a parallel claim. Plaintiffs' reliance on the warning letter is misplaced. The warning letter, issued after Mrs. Godelia's death, relates to some LifeVests inappropriately delivering shocks to patients when a shock was not warranted, due to noise and/or outside vibration. Mrs. Godelia's LifeVest allegedly failed because it did not deliver a shock when necessary. Accordingly, there is no nexus between the warning letter, Mrs. Godelia's LifeVest, and her injuries. *See Brown*, 978 F. Supp. 2d at 1274 (finding plaintiff failed to show how warning letters related to her medical device and the injuries she alleged resulted from the device). *See also Wolicki-Gables*, 634 F.3d at 1301-02 ("These allegations do not set forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged.") (internal quotation omitted). Accordingly, Counts I and II are expressly preempted and must be dismissed.

B. Remainder of Claims Sound in Manufacturing Defect

Plaintiff's remaining claims for fraudulent misrepresentation, fraudulent marketing/promotion, breach of express warranty, negligent misrepresentation, and negligent infliction of emotional distress are all based on Defendants' representations regarding the efficacy of the LifeVest. Simply stated, Plaintiffs allege that Defendants' represented that the LifeVest would work properly when it did not. Although couched in terms of misrepresentations and inaccurate statements, at base, Plaintiffs claims only survive if the factfinder determines the LifeVest was defective.

Fraudulent Misrepresentation and Negligent Misrepresentation Claims

To establish their misrepresentation claims, Plaintiffs need to establish that Defendants' representations regarding the LifeVest's ability to administer a life-saving shock were false, in part because Mrs. Godelia's LifeVest malfunctioned. Like Plaintiffs' strict products liability and negligent manufacturing claims, these claims potentially conflict with the FDA's findings regarding the LifeVest. As a result, the claims are expressly preempted.[4] *See e.g. Mink II*, 169 F. Supp. 3d at 1335 ("plaintiff may not 'attempt to recast a claim for violation of the FDCA as a state-law negligence claim' simply by pleading it as such.") (quoting *McClelland* 2012 WL 5077401, at *6); *Parks v. Howmedica*, Case No. 8:15-cv-0075-MSS-MAP, 2016 WL 7220707 at *10 (M.D. Fla. March 11, 2016) ("Plaintiffs' claims for Fraud by Concealment, Fraudulent Misrepresentation, and Negligent Misrepresentation are expressly preempted as they are derivative of Plaintiffs' claims for inadequate design, manufacturing, and warnings.")

Breach of Express Warranty

Similarly, Plaintiffs' breach of express warranty, as pled, is preempted. Plaintiffs' allege that Defendants' warranties regarding whether the LifeVest works were inaccurate. The only way to prove this claim would be to establish that, contrary to the FDA's findings, the LifeVest was defective. *See Parks*, 2016 WL 7220707 at * 12; *Allen v. Zimmer Holdings*, Case No. 3:15-CV-00341-LRH-VPC, 2015 WL 6637232 at *4 (D. Nev. Oct. 30, 2015) ("Courts have held claims for breach of express warranty to be preempted primarily where the warranty directly

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[4] Plantiffs rely heavily on *Byrnes v. Small*, 142 F. Supp. 3d 1262 (M.D. Fla. 2015) and *Brady v. Medtronic, Inc.*, Case No. 13-cv-62199-RNS, 2014 WL 1377830 (S.D. Fla. Apr. 8, 2014) for the proposition that, in some circumstances misrepresentation claims involving an MDA approved device will not be expressly preempted. Plaintiffs' reliance is misplaced as both *Byrnes* and *Brady* deal with a defendant's marketing of an off-label use of a device or drug – a use that was not approved by the FDA. Mrs. Godelia's use of the LifeVest was in accordance with the FDA-approved use of the device.

relates to the safety or effectiveness of the device."); *Cooley v. Medtronic*, Case No. 09-30-ART, 2012 WL 1380265 at * 5 (E.D.K.Y. April 20, 2012) ("since the MDA preempts the manufacturing defect claim, Cooley's emotional distress claims are also preempted").

Plaintiffs' breach of express warranty claim is also subject to dismissal for failure to state a claim. Under Florida law, "warranty-based claims, including breach of express warranty, require privity of contract between the parties . . . No privity exists, and a breach of warranty claim fails, where plaintiff did not purchase the product from the defendant." *Kaiser*, 944 F. Supp. 2d at 1193. Plaintiffs allege that Mrs. Godelia required a prescription to obtain the LifeVest. As such, Mrs. Godelia could not purchase the device directly from Defendants. Therefore there is no privity between Mrs. Godelia and Defendants. *See Id.* ("Because medical devices . . . are available to Plaintiff only through prescription use from a licensed physician or healthcare provide" there can be no privity). *See also Cubbage v. Novartis*, Case No. 5:16-cv-129-Oc-30PRL, 2016 WL 3595747 at * 7 (M.D. Fla. 2016) (no breach of express warranty under Florida law for prescription medication where Plaintiff was not in privity with drug manufacturer).

Negligent Infliction of Emotional Distress

Plaintiffs' claim for negligent infliction of emotional distress, even if not preempted, are subject to dismissal for failure to state a claim. To properly allege a negligent infliction of emotional distress claim under Florida law, a plaintiff must establish (1) a physical injury; (2) caused by the psychological trauma; (3) the plaintiff must be involved in some way in the event causing the negligent injury to another; and (4) the plaintiff must have a close personal relationship to the directly injured person. *Zell v. Meek*, 665 So. 2d 1048, 1054 (Fla. 1995). A plaintiff generally may not recover damages for emotional distress caused by the negligence of

another, unless the emotional distress injuries suffered flow from the plaintiff's physical injuries sustained in an impact. *Langbehn v. Pub. Health Tr. Of Miami-Dade Cty.*, 661 F. Supp. 2d 1326, 1339 (S.D. Fla. 2009).

In lieu of a physical impact, "recovery of damages for negligent infliction of emotional distress is not permitted unless the plaintiff manifests some physical injury as a result of the emotional trauma." *Gonzalez-Jimenez de Ruiz v. United States*, 231 F. Supp. 2d 1187, 1200–01 (M.D. Fla. 2002). The Florida Supreme Court explained that "such psychological trauma must cause a demonstrable physical injury such as death, paralysis, muscular impairment, or similar objectively discernible physical impairment before a cause of action may exist." *Brown v. Cadillac Motor Car Div.*, 468 So. 2d 903, 904 (Fla. 1985). "[B]odily injury including hypertension, pain and suffering, mental anguish, loss of capacity for the enjoyment of life, and the reasonable expense for medical care and attention" are "insufficient to meet the physical injury required under the impact rule." *R.J. v. Humana, Inc.*, 652 So. 2d 360, 364 (Fla. 1995).

Here, Plaintiffs' allegations fail to allege a discernable physical injury. Mr. Godelia alleges that due to Zoll's negligence, he experienced "insomnia, depression, short-term memory loss, inability to stop reliving the Debra Godelia's death, muscle and stomach pain." [ECF No. 23 at ¶ 111]. Without more, Mr. Godelia's injuries are not the type of "discernable physical injuries" for which he may recover. Likewise, Youmas alleges that due to Zoll's negligence, he experienced "inability to stop reliving the event, depression, short-term memory loss, muscle and other pain." [*Id.* at ¶ 112]. These ailments as well do not compare to "death, paralysis, muscular impairment, or similar objectively discernable physical impairment" as articulated by the Florida Supreme Court. *Brown*, 468 So. 2d at 904. Accordingly, Count VIII must also be dismissed for failure to state a claim.

C. Implied Preemption

Even if Plaintiffs' claims were not subject to express preemption, they would likely be impliedly preempted. To survive express preemption, Plaintiffs' claims must be based on Defendants' violations of the FDCA. However, such claims are impliedly barred by § 337(a). "No private right of action exists for a violation of the FDCA." *McClelland,* 944 F. Supp. 2d at 1201 (quoting *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1284 n. 10 (11th Cir. 2002)). Indeed, Florida courts consistently hold that Florida does not recognize private causes of action for violations of FDA regulations. *See Parks*, 2016 WL 7220707 at *11; *Kaiser,* 944 F. Supp. 2d at 1192 ("Florida law does not allow Plaintiff to bring a private cause of action to enforce FDA regulations.").

CONCLUSION

Based on the foregoing, it is

ORDERED AND ADJUDGED that the Motion to Dismiss [**ECF No. 26**] is **GRANTED**. Plaintiffs' Complaint is **DISMISSED**. This action is **CLOSED**

DONE AND ORDERED in Chambers at Miami, Florida this 18th day of January, 2017.

DARRIN P. GAYLES
UNITED STATES DISTRICT JUDGE