IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
ASHEVILLE DIVISION
CIVIL CASE NO. 1:19-cv-00318-MR

EXELA PHARMA SCIENCES, LLC,	)	
	)	
Plaintiff,	)	
	)	**MEMORANDUM OF**
vs.	)	**DECISION AND ORDER**
	)	
SANDOZ, INC.,	)	
	)	
Defendant.	)	
_____	)	

THIS MATTER comes before the Court upon the Plaintiff's Motion for *Ex Parte* Temporary Restraining Order and Preliminary Injunction [Doc. 3], and the Defendant's Motion to Dismiss the Complaint or, in the Alternative, Stay the Case Pending Referral to FDA [Doc. 29].

I. PROCEDURAL BACKGROUND

On November 6, 2019, Exela Pharma Sciences, LLC, (the "Plaintiff"), initiated this action against Sandoz, Inc., (the "Defendant"), asserting claims for unfair and deceptive trade practices in violation of N.C. Gen. Stat. 75-1.1, et seq. ("Chapter 75"); tortious interference with prospective business advantage in violation of North Carolina common law; and false advertising and unfair competition in violation of the Lanham Act, 15 U.S.C. § 1125(a). [Doc. 1]. Along with the Complaint, the Plaintiff filed a motion seeking the

immediate issuance of a temporary restraining order and a preliminary injunction requiring the Defendant to recall and take all necessary steps to recover, remove from interstate commerce, and cease the sale of all the Defendant's L-Cysteine product. [Doc. 3]. In support of its motion, the Plaintiff relies upon the allegations of its Complaint, as verified by the Plaintiff's manager, Phanesh Koneru,[1] as well as several exhibits.

The Court held a hearing on the Plaintiff's request for a temporary restraining order on November 7, 2019. On November 12, 2019, the Court issued an Order denying the Plaintiff's request for a temporary restraining order, finding that the Plaintiff failed to show "its entitlement to such relief." [Doc. 16 at 9]. Nevertheless, the Court held the Plaintiff's request for a preliminary injunction in abeyance pending further presentation of evidence and briefing by the parties. [Id. at 13].

On December 6, 2019, the Defendant filed a Response in Opposition to Plaintiff's Motion for Preliminary Injunction [Doc. 31] and a Motion to Dismiss the Complaint or, in the Alternative, Stay the Case Pending Referral to FDA [Doc. 29]. On December 13, 2019, the Plaintiff filed a Reply in

[1] Mr. Koneru's Verification provides as follows: "That he/she has read the foregoing COMPLAINT; that he/she is the Manager of Exela Pharma Sciences LLC, named Plaintiff in this matter, and that he/she know the contents thereof; that the same is true of his/her own knowledge, *except as to those matters and things stated therein upon information and belief,* and as to those matters and things he/she believes them to be true." [Doc. 1 at 29 (emphasis added)].

Support of Plaintiff's Motion for Preliminary Injunction [Doc. 33]. On December 23, 2019, the Plaintiff filed a Response in Opposition to Defendant's Motion to Dismiss. [Doc. 38].

Having been fully briefed, this matter is ripe for disposition.

II. FACTUAL BACKGROUND

The Plaintiff's Verified Complaint presents the following facts.[2]

The Plaintiff is a North Carolina limited liability company with its principal place of business in Lenoir, North Carolina.[3] [Doc. 1 at ¶ 14]. The Plaintiff develops, manufactures, and markets injectable pharmaceutical products, including an L-Cysteine injection product that is now approved by the FDA. [Id. at ¶¶ 14, 42-43].

L-Cysteine is an amino acid that is administered by parenteral administration (i.e., injection or intravenous infusion) to high-risk patients,

[2] Several allegations in the Complaint are made "on information and belief." Mr. Koneru did not verify such statements (see footnote 1 *supra*), and the Plaintiff provided no affidavits or sworn testimony to support such allegations at the hearing. Conclusory allegations based "upon information and belief" are no substitute for plausible factual allegations that wrongdoing has occurred. See Harman v. Unisys Corp., 356 F. App'x 638, 640 (4th Cir. 2009) (stating that allegations that included the phrase "upon information and belief" were insufficient to defeat a motion to dismiss because the allegations at issue were "conclusory"). As such, the conclusory allegations in the Complaint that are made "on information and belief" will not be considered.

[3] The Plaintiff asserts subject matter jurisdiction in this Court pursuant to the existence of diversity jurisdiction per 28 U.S.C. § 1332 and federal question jurisdiction based on the Lanham Act claim. See 28 U.S.C. § 1331, 15 U.S.C. § 1125(a). The Plaintiff has not presented sufficient allegations to invoke diversity jurisdiction. Nevertheless, the Court will address the Motion to Dismiss based on the existence of federal question jurisdiction.

such as preterm or low-weight newborns and patients with severe liver disease, as part of a nutritional supplement regimen (also known as "total parenteral nutrition" or "TPN"). [Id. at ¶ 26]. Aluminum is a known contaminant of TPN solutions, and aluminum toxicity can cause serious health problems including dementia and impaired neurologic development among others. [Id. at ¶ 27]. High-risk infants who receive TPN are particularly susceptible to harm from excessive, toxic amounts of aluminum, as they have immature kidneys, which impairs the removal of aluminum from the body. [Id. at ¶ 28]. The Defendant manufactures an L-Cysteine product in Canada with a label stating that it contains as much as 5,000 mcg/L of aluminum. [Id. at ¶ 5]. The Defendant's L-Cysteine product is not approved by the FDA. [Id. at ¶ 1].

Beginning in 2014, there was a shortage of L-Cysteine in the United States.[4] [Docs. 1-15, 31-2 at 2]. This led the FDA to approach the Defendant about importing and selling its unapproved L-Cysteine product in the United States under the FDA's "shortage program" without requiring the drug to obtain FDA approval. [Id.; Doc. 1 at ¶¶ 6, 38]. Pursuant to the shortage program and the Defendant's request, the FDA ultimately gave the

[4] Discussions between the FDA and the Defendant regarding the shortage began in 2014. [Doc. 31-2 at 2].

Defendant a "Memorandum of Discretion" on April 12, 2016 [Doc. 31-2 at 38-39], which stated that the FDA would not bring an enforcement action against the Defendant for importing and selling its L-Cysteine product for 6 months if the Defendant followed certain conditions. [Id. at ¶ 40, 44; see also Doc. 31-2 at 6, 13-16, 38-39, 41-59].[5] One such condition was that the Defendant had to distribute a "Dear Healthcare Provider" letter alongside its L-Cysteine product that explained the product, the drug shortage, and the lack of other similar FDA-approved products. [Doc. 1 at ¶ 41; Doc. 1-17; Doc. 1-18; see also Doc. 31-2 at 41-59]. The contents of the letters were pre-approved by the FDA and those letters had to be reviewed by the FDA before distribution. [Doc. 31-2 at 41-50].

[5] The Plaintiff's Complaint does not attach the Memorandum of Discretion or the communications between the FDA and the Defendant related to the issuance of the Memorandum of Discretion and its subsequent renewals. The Defendant, however, attaches the Memorandum of Discretion and those communications to its Response in Opposition to Plaintiff's Motion for Preliminary Injunction. [Doc. 31-2 at 13-16, 38-39, 41-59]. The Court may consider a document submitted by a defendant without converting a Rule 12(b)(6) motion to a summary judgment motion if the document "was integral to and explicitly relied on in the complaint and if the plaintiffs do not challenge its authenticity." Am. Chiropractic Ass'n v. Trigon Healthcare, Inc., 367 F.3d 212, 234 (4th Cir. 2004) (citation and quotations omitted); see also Lee v. City of Los Angeles, 250 F.3d 668, 688 (9th Cir. 2001). The Memorandum of Discretion and the communications surrounding its issuance and renewals are integral documents that were explicitly referenced and relied upon in the Plaintiff's complaint. [Doc. 1]. The Plaintiff does not challenge the authenticity of those documents. As such, the Court will consider the contents of the Memorandum of Discretion and the communications between the FDA and the Defendant when analyzing this Motion. [Doc. 31-2 at 13-16, 38-39, 41-59].

The Defendant sought several extensions of the Memorandum of Discretion and the FDA granted each of the Defendant's requests, with each renewal providing the Defendant with six additional months to import and distribute its unapproved product. [Doc. 1 at ¶ 40]. The FDA approved the last Dear Healthcare Provider letter on June 21, 2019, instructing the Defendant to ensure that the "previously reviewed Dear Healthcare Provider letter continues to accompany [the Defendant's] L-Cysteine in distribution" in shipments thereafter. [Doc. 31-2 at 50]. Every version of the letter stated that "there are currently no FDA-approved L-Cysteine Hydrochloride Injection products in the United States." [Doc. 1 at ¶ 41; Doc. 1-18; see also Doc. 31-2 at 41-59].

Beginning in 2017, the Plaintiff undertook extensive efforts to tackle the aluminum problem in TPN solutions and develop an L-Cysteine product with low aluminum levels. [Doc. 1 at ¶ 31]. In May 2017, the Plaintiff filed a New Drug Application (NDA) with the FDA for an L-Cysteine product that contained a maximum of 1,400 mcg/L of aluminum. [Id.]. In July 2017, however, the FDA informed the Plaintiff that this proposed level of aluminum was unacceptably high, and that the product should have less than or equal to 145 mcg/L of aluminum in order to gain permanent approval. [Id. at ¶ 32]. The Plaintiff ultimately succeeded in reducing the aluminum levels in its L-

Cysteine product to less than 120 mcg/L and submitted its new data to the FDA for its redeveloped product in July 2018. [Id. at ¶ 33]. On April 16, 2019, the FDA approved the Plaintiff's NDA under Fast Track designation and Priority Review. [Id.]. The Plaintiff branded its L-Cysteine product ELCYS. [Id.].

After ELCYS received FDA approval, the Plaintiff's marketing and sales teams began communicating with health systems regarding its availability. [Id. at ¶ 34]. By late May 2019, the Plaintiff had manufactured sufficient inventory to meet the entire market demand for L-Cysteine.[6] [Id.].

In late May 2019, the Defendant's executives reached out to the Plaintiff's executives to inquire whether the Plaintiff would be willing to license its "recently approved products," including ELCYS, to the Defendant. [Id. at ¶ 43]. The Plaintiff declined the Defendant's offer. [Id.].

After the FDA approved the Plaintiff's product, the Plaintiff made numerous efforts to get the Defendant to stop selling its unapproved product. Starting in May 2019, the Plaintiff repeatedly asked the FDA to remove L-Cysteine hydrochloride injection from its drug shortage list and prohibit any further importation and distribution of the Defendant's unapproved product.

[6] Notwithstanding its approval of the Plaintiff's ELCYS product, the following month the FDA approved the Defendant's continued distribution of its product along with the previously approved Dear Healthcare Provider letter. [Doc. 31-2 at 50].

[Doc. 1 at ¶ 49; Doc. 1-23]. Receiving no relief from the FDA, the Plaintiff sent letters to the CEO and Chairman of the Board of Defendant Sandoz's parent company, Novartis, A.G., on August 20, 2019. [Doc. 1-24]. Copying the FDA on the letter, the Plaintiff told Novartis about the allegedly improper and unethical conduct and asked that Novartis immediately stop importation and distribution of the L-Cysteine product. [Doc. 1 at ¶ 50; Doc. 1-24].

On September 3, 2019, the FDA declared an end to the L-Cysteine drug shortage. [Id. at ¶ 50; Doc. 1-25]. Around the same time, the FDA asked the Defendant to stop importing its L-Cysteine product. [Doc. 1-21]. The Defendant's stopped importing its L-Cysteine product in response to the FDA's request. [Doc. 1 at ¶ 45]. On September 25, 2019, the Plaintiff sent a letter to its customers stating that although "there is now an FDA approved L-Cysteine available in the US market[,]" the "FDA is allowing Sandoz to continue distributing its existing inventory . . . ." [Doc. 1-21 at 2].

On September 24, 2019, the Defendant responded to the Plaintiff's August 20 letter, acknowledging that the Plaintiff's ELCYS product had been approved by the FDA and that "the drug shortage has abated." [Doc. 1 at ¶ 51; Doc. 1-15]. The Defendant nevertheless confirmed that it had the FDA's permission to sell the product that it had already imported and expressed its intention to do so. [Id.]. The Plaintiff's marketing team claims to have

observed customers buying or committing to buy up to a year's supply of the Defendant's product even after ELCYS received FDA approval. [Doc. 1 at ¶ 53].

On October 8, 2019, the FDA directed the Defendant to stop distribution distributing its L-Cysteine product. [Doc. 1-20]. The Defendant immediately complied with the FDA's request. [Doc. 1 at ¶ 45; Doc. 1-20]. Despite being the only FDA-approved L-Cysteine product on the market and having low aluminum levels, the Plaintiff's ELCYS has attained less than 20% of the L-Cysteine market while the Defendant "maintain[s] over" 80%.[7] [Id. at ¶¶ 35, 58].

III. STANDARD OF REVIEW

To survive a motion to dismiss pursuant to Rule 12(b)(6), "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 Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007)).

[7] The Plaintiff's allegation in Paragraph 58 of the Complaint appears to facially contradict its allegation in Paragraph 45. If the Defendant discontinued sales of this product by October 8, 2019, then as of the date of the Plaintiff's filing (November 6, 2019), the Defendant no longer had *any* share of the market. [Doc. 1 at ¶¶ 45, 58]. Giving the Plaintiff the benefit of a very generous inference, this may mean that 80% of the *use* (rather than sales) of an L-Cysteine product in the United States as of November 6, 2019 was of the Defendant's product that had been sold prior to October 8, 2019.

To be "plausible on its face," a plaintiff must demonstrate more than "a sheer possibility that a defendant has acted unlawfully." Iqbal, 556 U.S. at 678.

In reviewing the complaint, the Court must accept the truthfulness of all factual allegations but is not required to assume the truth of "bare legal conclusions." Aziz v. Alcolac, Inc., 658 F.3d 388, 391 (4th Cir. 2011). "The mere recital of elements of a cause of action, supported only by conclusory statements, is not sufficient to survive a motion made pursuant to Rule 12(b)(6)." Walters v. McMahen, 684 F.3d 435, 439 (4th Cir. 2012).

Determining whether a complaint states a plausible claim for relief is "a context-specific task," Francis v. Giacomelli, 588 F.3d 186, 193 (4th Cir. 2009), which requires the Court to assess whether the factual allegations of the complaint are sufficient "to raise the right to relief above the speculative level," Twombly, 550 U.S. at 555. As the Fourth Circuit has explained:

> To satisfy this standard, a plaintiff need not forecast evidence sufficient to prove the elements of the claim. However, the complaint must allege sufficient facts to establish those elements. Thus, while a plaintiff does not need to demonstrate in a complaint that the right to relief is probable, the complaint must advance the plaintiff's claim across the line from conceivable to plausible.

Walters, 684 F.3d at 439 (citations and internal quotation marks omitted).

IV. DISCUSSION

In its Motion to Dismiss the Complaint or, in the Alternative, Stay the Case Pending Referral to FDA, the Defendant argues that the Plaintiff's Chapter 75 and tortious interference with prospective business advantage claims are preempted by the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., and that the Plaintiff's Lanham Act claim fails because it is inconsistent with the FDCA. [Doc. 29-1]. Specifically, the Defendant argues that the FDCA does not contain a private right of action to enforce its provisions and that the Plaintiff's state-law claims interfere with the federal regulatory regime because they are allegedly predicated on unenforced FDCA violations. [Id.]. The Defendant, therefore, argues that the Plaintiff's Complaint , as a matter of law, fails to state a claim upon which relief can be granted. The Plaintiff responds that the Complaint contains sufficient facts to support the Chapter 75, tortious interference with prospective business advantage, and Lanham Act claims and that those claims are not preempted by or inconsistent with the FDCA. [Doc. 38].

A. State Law Claims

The Supremacy Clause of the Constitution makes evident that "state laws that conflict with federal law are 'without effect.'" Altria Grp., Inc. v. Good, 555 U.S. 70, 76 (2008) (citation omitted). There are three types of

preemption under the Supremacy Clause: (1) express preemption, (2) field preemption, and (3) conflict preemption. Id. at 76–77. Conflict preemption, the only type of preemption relevant here, exists where "there is an actual conflict between state and federal law," id, and the "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985) (citations and quotations omitted). For example, the Supreme Court has held that a state-law claim contrary to the FDCA is barred by conflict preemption because "the federal statutory scheme . . . used by the [FDA] to achieve a somewhat delicate balance of statutory objectives" would be "skewed by allowing" a plaintiff to bring state-law claims. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 348 (2001). In evaluating whether federal law has preempted state law, the Court must look to "the purpose of Congress [as] the ultimate touchstone," while also "start[ing] with the assumption that the historic police powers of the States were not to be superseded . . . unless that was the clear and manifest purpose of Congress." Wyeth v. Levine, 555 U.S. 555, 565 (2009).

The FDCA charges the FDA with "promot[ing] the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner." 21 U.S.C.

§ 393(b)(1). In the FDCA, Congress required the FDA to "protect the public health" by making sure that "drugs are safe and effective." Id. § 393(b)(2)(B). The FDCA also empowers the FDA to combat drug shortages, See, e.g., id. at §§ 356c-1(a)(5), 356d, 356(e)(4).

If a drug is marketed without prior FDA approval, the FDA may bring an enforcement action under the FDCA. See 21 U.S.C. §§ 332–34 (1982). The FDCA gives the FDA "complete discretion" to "decide how and when [it] should be exercised." Heckler v. Chaney, 470 U.S. at 835. The FDCA provides that "all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." As such, "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance . . . ." Buckman, 531 U.S. at 349 n. 4.

The FDCA's prohibition on private actions, however, would be "thwarted if savvy plaintiffs can label as arising under a state law for which there exists a private enforcement mechanism a claim that in substance seeks to enforce the FDCA." Loreto v. Procter & Gamble Co., 515 F. App'x 576, 579 (6th Cir. 2013). As such, "private litigants may not 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." Id. (citations and internal

quotation marks omitted); see also American Home Products Corp. v. Johnson & Johnson, 436 F. Supp. 785, 797 (S.D.N.Y.1977) (noting that "state unfair competition laws [are] not the proper legal vehicle in which to vindicate the public's interest in health and safety."). Likewise, "[t]here can be no state law cause of action if a plaintiff's true goal is to privately enforce alleged violations of the FDCA." Borchenko v. L'Oreal USA, Inc., 389 F.Supp.3d 769, 773 (C.D. Cal. 2019) (citation and quotations omitted).

"The test for determining whether a state law claim is impliedly preempted is whether or not the claim would exist in the absence of the FDCA." Evans v. Rich, No. 5:13-CV-868-BO, 2014 WL 2535221, at *2 (E.D.N.C. June 5, 2014) (citing Loreto, 515 Fed. App'x at 579). "As the Sixth Circuit has explained, any claim that relies on the FDCA or its implementing regulations '[a]s a critical element' is barred by § 337(a).'" Agee v. Alphatec Spine, Inc., No. 1:15-CV-750, 2017 WL 5706002, at *3 (S.D. Ohio Mar. 27, 2017) (quoting Marsh v. Genentech, Inc., 693 F.3d 546, 553 (6th Cir. 2012)); see also In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig., 756 F.3d 917, 936 (6th Cir. 2014) ("claims" premised on "a violation of the FDCA" are impliedly preempted "because the FDA has the exclusive power to enforce the FDCA" and there is "no private right to enforce the statute"). For example, "a state-law claim that the defendant made misrepresentations to

the FDA is preempted because such a claim would not exist absent the federal regulatory scheme established by the FDCA." Riley v. Cordis Corp., 625 F. Supp. 2d 769, 777 (D. Minn. 2009) (citing Buckman, 531 U.S. at 352-53). Similarly, courts have found implied preemption applies to claims like "breach of warranty, negligence per se, design defect, and failure to warn." Evans, 2014 WL 2535221, at *2 (citing in re Medtronic, Inc. Sprint Fidelis Leads Products Liab. Litig., 592 F.Supp.2d 1147, 1159–64 (D. Minn. 2009)).

With this preemption framework in mind, the Court now turns to each of the Plaintiff's state law claims.

1. Chapter 75 Claim

A Chapter 75 claim requires (1) an unfair or deceptive act or practice; (2) in or affecting commerce; which (3) proximately caused actual injury to the claimant or its business. N.C. Gen. Stat. § 75-1.1. An act is deceptive "if it has a tendency or capacity to deceive." Rahamankhan Tobacco Enterprises Pvt. Ltd. v. Evans MacTavish Agricraft, Inc., 989 F.Supp.2d 471, 477 (E.D.N.C. 2013). An act is unfair "if it offends established public policy," "is immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers," or "amounts to an inequitable assertion of . . . power or position." Id. A deceptive practice is one that has "the capacity or tendency to deceive the average consumer, but proof of actual deception is not

required." Spartan Leasing, Inc. v. Pollard, 101 N.C. App. 450, 461, 400 S.E.2d 476, 482 (1991). "What is an unfair or deceptive trade practice usually depends upon the facts of each case and the impact the practice has in the marketplace." Durling v. King, 146 N.C. App. 483, 489, 554 S.E.2d 1, 4 (2001) (citing Pan American World Airways, Inc. v. United States, 371 U.S. 296 (1963)).

The Plaintiff generally claims that the Defendant violated Chapter 75 through its "unfair and deceptive actions to import, sell, and stuff the distribution channels with its unapproved product." [Doc. 1 at ¶ 1]. Specifically, the Plaintiff alleges that the Defendant acted unlawfully by (1) importing and selling an illegal product, [id. at ¶¶ 6, 8, 36, 37, 66, 67, 69, 77, 79]; (2) seeking a "Memorandum of Discretion," and numerous extensions of that Memorandum, to import an illegal product, [id. at ¶¶ 40, 69]; (3) failing to update its 2018 Dear Healthcare Provider letter after the FDA approved ELCYS, [id. at ¶ 69]; (4) failing to warn its customers about its product's aluminum content, [id.]; and (5) misusing "its incumbent status in the market and its huge market power and reach to block hospitals and distributors from switching" to the Plaintiff's L-Cysteine product. [Id.].

a. Importing and Selling an Illegal Product

The Plaintiff claims that the Defendant violated Chapter 75 by importing and selling its L-Cysteine product because such conduct is the type of "'immoral, unethical, [and] unscrupulous behavior'" that Chapter 75 "deems as 'unfair.'" [Doc. 1 at ¶ 68 (quoting State ex rel. Cooper v. NCCS Loans, Inc., 174 N.C. App. 630, 640 (2005)]. The crux of the Plaintiff's Chapter 75 claim is that the Defendant's L-Cysteine product was unlawful, dangerous, and unfit for importation or sale, and that the FDA acted unlawfully by letting the Defendant import and sell that product.[8] Stated differently, the Plaintiff's state-law claim challenges the FDA's decision not to bring enforcement proceedings against the Defendant under the FDCA for importing and selling an unapproved and unsafe drug.

The Plaintiff's Chapter 75 claim related to the Defendant's sale and importation of the L-Cysteine product is preempted. The FDCA contains no private right of action and gives the FDA "complete discretion" to decide whether to bring enforcement proceedings. Heckler, 470 U.S. at 835. As such, the "FDA has power to determine whether particular drugs require an approved NDA [New Drug Application] in order to be sold to the public."

[8] The Plaintiff concedes that the Defendant's "misconduct originated in a violation of the FDCA–the import and sale of the unapproved product." [Doc. 1-38 at 7].

Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 624 (1973). The Plaintiff does "not have the authority to stand in the shoes of the FDA to determine whether [the defendant's] sale of the products at issue amounts to the sale of an unapproved drug under the FDCA. This enforcement authority [lies] exclusively with the FDA." Allergan, Inc. v. Athena Cosmetics, Inc., 738 F.3d 1350, 1359 (Fed. Cir. 2013); see also Agee, 2017 WL 5706002, at *5 (stating that if "the distribution of [the product] was in violation of the FDCA and relevant FDA regulations . . . it is the sole responsibility and privilege of the federal government, and not private plaintiffs, to bring a suit to enforce those violations."). The crux of the Plaintiff's Chapter 75 claim is a challenge to whether the importation and sale of the Defendant's L-Cysteine product are lawful under the FDCA. As such, the Plaintiff is preempted from making that claim.

The Plaintiff's claim related to the Defendant's importation and sale of its L-Cysteine product is also preempted because it would stand "as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Hillsborough Cnty., 471 U.S. at 713 (citations omitted). The FDCA empowers the FDA to combat drug shortages, see, e.g., 21 U.S.C. §§ 356c-1(a)(5), 356d, 356(e)(4), while also ensuring "that any product regulated by the FDA is 'safe' and 'effective' for its intended use."

FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000) (citing 21 U.S.C. § 393(b)(2). As such, the FDA "must evaluate the risks associated" with a drug shortage when deciding to bring an enforcement action under the FDCA. 21 U.S.C. § 356d(c). Allowing a state-law claim challenging the FDA's discretionary refusal to bring an enforcement action under the FDCA against the Defendant would therefore thwart the FDA's purpose. Hillsborough Cnty., 471 U.S. at 713 (citations omitted). Other courts have rejected similar claims. See Loreto, 515 F. App'x at 579 (stating that "[a] plaintiff cannot use a state-claim to argue that a defendant's product was "'illegal,' and had [consumers] known it, they wouldn't have purchased the products" because that "theory of liability depends entirely upon an FDCA violation.").

Allowing a Chapter 75 claim based on the safety of the Defendant's L-Cysteine product would also skew "the federal statutory scheme . . . used by the [FDA] to achieve a somewhat delicate balance of statutory objectives." Buckman, 531 U.S. at 348. Here, the record shows that the FDA engaged in a prolonged effort to balance those objectives, as well as the various interests, before deciding to let the Defendant to distribute its L-Cysteine product. That decision necessarily involved balancing the risks inherent in a drug shortage with the safety risks of allowing the importation and sale of an

unapproved product. After ELCYS received FDA approval, the FDA still had to account for the risk that ELCYS might not be able to meet the entire market demand for L-Cysteine, the risk of supply chain issues during the transition from the Defendant's L-Cysteine product to ELCYS, and other associated risks.[9] Allowing state-law claims would disrupt the delicate and considered balance that the FDA struck. In short, the FDA was charged with addressing a shortage of a critical medical product. The FDA made its determination of the best solution of the problem. For the Plaintiff to now second guess the FDA's decision in a civil action based on state law would render the FDA's authority to be a nullity.

The Plaintiff's claim related to the Defendant's importation and sale of its L-Cysteine product presents a similar issue to the one addressed in Drager v. PLIVA USA, Inc., 741 F.3d 470, 479 (4th Cir. 2014). In Drager, a consumer injured by a drug brought state-law claims alleging that the manufacturer's label that was approved by the FDA was inadequate. The Fourth Circuit held that the state-law claims were preempted by federal law because they would force the manufacturer to either "leave the market or

[9] The FDA also had to balance the competing interests of these parties, each of whom sought and advocated for different outcomes. While the Plaintiff wanted the FDA to remove the Defendant's L-Cysteine product from the market almost immediately after ELCYS received FDA approval, the Defendant wanted a chance to sell the inventory *it* created in response to the FDA's requests to help with the drug shortage.

accept tort liability" despite the manufacturer's compliance with the FDA's edicts. Id. The Fourth Circuit explained that the Hobson's choice presented in such a situation illustrates how allowing a state-law claim can subvert the federal regulatory scheme, thus requiring the preemption of such state claims. Id.

The logic of Drager is applicable to this case. Here, the FDA issued a Memorandum of Discretion, and several renewals of that Memorandum, allowing the Defendant temporary permission to import and sell its L-Cysteine product. [Doc. 1 at ¶¶ 40, 44]. Notwithstanding the Defendant's permission from the FDA, a viable Chapter 75 claim related to the import and sale of the L-Cysteine product would have nonetheless forced the Defendant "to leave the market or accept tort liability." Id. This is precisely the type of claim that the Fourth Circuit held in Drager must be preempted.

This case, just like Drager, is unlike the failure-to-warn cases that the Plaintiff cites. [See Doc. 38 at 11]. For example, in Wyeth v. Levine, the Supreme Court explained that a state-law claim was not preempted by the FDCA's labeling requirements because those "requirements create a floor, not a ceiling, for state regulation." 555 U.S. 555, 563 (2009). As such, the Court in Wyeth found that the state-law claim did not "stand as an obstacle to the accomplishment of Congress' purposes in the FDCA" because the

defendant could have remained in the market by adding additional warnings that would comply with both the state-law and federal-law requirements. Id. at 581. That is not the case here, where the Plaintiff asserts that the only way to comply with state law would have been for the Defendant to leave the market, notwithstanding the Defendant's compliance with the FDA's directives. Drager, 741 F.3d at 479. Likewise, Wyeth was a claim by an injured patient against a drug company related to a purportedly deficient label, not a claim by a competitor seeking to prevent the distribution of a purportedly unsafe drug. That distinction is important because removing a product that the FDA expressly allowed in the market to address a drug shortage interferes with federal objectives in a way that changing a product's label does not. See Zogenix, Inc. v. Patrick, No. CIV.A. 14-11689-RWZ, 2014 WL 1454696, at *2 (D. Mass. Apr. 15, 2014) (stating that "Wyeth is a drug labeling case, and defendant present no evidence of persuasive argument that its reasoning should control" when determining whether a state law can contravene the FDA's decision to allow the sale of a drug.).

The Plaintiff also relies on Allergan, [Doc. 38 at 12], where the Federal Circuit found that a state-law claim based on the marketing, sale, and distribution or an unapproved drug was not preempted by the FDCA. Id. In that decision, however, the Federal Circuit focused on the fact that the state-

law requirements paralleled the FDCA requirements, in a situation where the FDA had *not* given the defendant explicit permission to market, sell, or distribute the drug at issue. Allergan, 738 F.3d at 1355. That case has no application here, because the FDA gave explicit permission to the Defendant to distribute its product. The Plaintiff's state-law claim would entirely undercut the FDA's decision and authority.

Instead, Zogenix, Inc. v. Patrick, No. CIV.A. 14-11689-RWZ, 2014 WL 1454696, at *2 (D. Mass. Apr. 15, 2014) is more instructive. In that case, Massachusetts' ban on the sale of an FDA-approved drug was preempted because allowing the state to "countermand the FDA's determinations and substitute its own requirements [would] undermine the FDA's ability to make drugs available to promote and protect the public health." Id. As such, the state-tort claim would interfere with "'the accomplishment and execution of' an important federal objective." Id. (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)). Like the plaintiff in Zogenix, the Plaintiff herein seeks to overturn the FDA's decision to allow the importation and sale of a product. While the Plaintiff argues that Zogenix is distinguishable because that case involved an FDA-approved drug, rather than drug allowed to be imported and sold under a Memorandum of Discretion, [Doc. 38 at 12], that distinction matters little for preemption purposes. The outcome of the FDA's decision

in both instances, whether made through its approval process or through an exercise of discretion to address a shortage, was to allow the drug to be imported and sold. The Plaintiff cannot use a state-law claim to contravene the FDA's decision and remove that drug from the market because that would interfere with the federal objective of allowing that drug to remain available. See id. at *2-3. This is particularly true in a case such as this one where the FDA was trying to address a crucial shortage.

The Plaintiff next argues that the FDA's Memorandum of Discretion allowing the Defendant to import and sell its L-Cysteine product was illegitimate because the FDA's entire shortage program was declared illegal by the D.C. Circuit in Cook v. FDA, 733 F.3d 1 (D.C. Cir. 2013). [Doc. 1 at ¶ 39]. The claim in Cook was brought under the Administrative Procedures Act against the FDA regarding the importation of sodium thiopental from unregistered foreign laboratories for use in lethal injections. 733 F.3d at 10. Cook held that the FDA is required to examine samples of imported drugs manufactured in unregistered facilities to determine if those drugs violate FDCA requirements. Id. at 9 ("We do not say the FDA must sample and examine every article under its jurisdiction that is offered for import but only that it must sample and examine drugs manufactured . . . in an *unregistered*

establishment.").[10] Cook specifically allowed the FDA to "exercise enforcement discretion to allow the domestic distribution of a misbranded or unapproved new drug" and "invoke its express statutory authority to permit the importation of an unapproved new drug." Id. at 10. Contrary to the Plaintiff's argument, Cook did not go as far as to hold that the FDA's shortage program is illegal. Id. at 10.

Cook is simply inapposite here. Unlike Cook, the Plaintiff did not bring this action against the FDA seeking judicial review of agency action (or inaction) under the Administrative Procedures Act. The FDA is not even a party to this case. Instead, this case presents a dispute between two drug manufacturers. Moreover, the Plaintiff cites no authority for the proposition that the FDA's refusal to bring enforcement proceedings would even be reviewable under the circumstances found here as it was in Cook. See Heckler v. Chaney, 470 U.S. 821, 832-33 (1985) (stating that "an agency's decision not to take enforcement action should be presumed immune from judicial review" unless the "substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers."). While the presumption against judicial review did not apply in Cook because the FDCA

[10] While Cook involved importation from an unregistered facility, this case involves importation from a registered facility. [Doc. 1-22 at 5]; Cook, 733 F.3d at 9.

"provided guidelines for the agency to follow in exercising its enforcement powers" concerning unregistered foreign facilities, Cook, 733 F.3d at 6, the Plaintiff identifies no such guidelines that apply to the registered facility at issue here. As such, the FDA's enforcement decisions concerning registered laboratories appear to be immune from judicial review because the FDCA's enforcement provisions commit "complete discretion to the FDA to decide how and when they should be exercised." Heckler, 470 U.S. at 835.

For all these reasons, the Plaintiff's Chapter 75 claim based on the Defendant's sale or importation of its L-Cysteine product must be dismissed as preempted.

b. Seeking a Memorandum of Discretion

The Plaintiff next claims that the Defendant violated Chapter 75 by seeking a renewal of the Memorandum of Discretion in June 2019 after ELCYS received FDA approval to continue selling its L-Cysteine product. [Doc. 1 at ¶¶ 40, 69]. In this sense, however, the Plaintiff's true quarrel is with the FDA *granting* the Defendant's June 2019 request for a renewal of the Memorandum of Discretion, not with the Defendant's *seeking* the renewal. The FDA did not declare the end of the drug shortage until September 3, 2019. [Id. at ¶ 50; Doc. 1-25]. It was not unfair or deceptive

for the Defendant to ask if it could continue importing and selling its L-Cysteine product while the drug shortage continued. That is particularly true considering that it was this drug shortage that originally led the FDA to ask the Defendant to import and sell its L-Cysteine product. [Doc. 1-15].

Moreover, the Plaintiff has failed to plausibly allege that the Defendant's requests for the Memorandum of Discretion or the subsequent renewals of that Memorandum involved any unfairness or deception. The FDA was fully aware of the development of ELCYS, its approval status and production status, the differences in the aluminum content between the ELCYS and the Defendant's L-Cysteine product, as well as the state of the L-Cysteine market when it renewed the Memorandum of Discretion in June 2019. Despite that knowledge, the FDA rebuffed the Plaintiff's requests to end the drug shortage until September 3, 2019, waited until that time to halt importation of the Defendant's L-Cysteine product, and waited until October 8, 2019 to halt sales of that product. [Docs. 1-23, 1-20, 1-21].

Though the FDA is not a party to this case, it has issued guidance explaining that it generally weans unapproved products off the market once a competing product has been approved. See FDA, Marketed Unapproved Drugs – Compliance Policy Guide: Sec. 440.100, Marketed New Drugs without Approved NDAs or ANDAs (Sep. 2011) at 7-8 ("When a company

obtains approval to market a product that other companies are marketing without approval, FDA normally intends to allow a grace period of roughly 1 year from the date of approval of the product before it will initiate enforcement action (*e.g.*, seizure or injunction) against marketed unapproved products of the same type." "To assist in an orderly transition to the approved product(s), in implementing a grace period, FDA may identify interim dates by which firms should first cease manufacturing unapproved forms of the drug product, and later cease distributing the unapproved product."). That guidance explains the FDA's actions here. In fact, rather than allowing the Defendant a one-year grace period per its regulations, it gave the Defendant only six months (April to October 2019) to continue importing and selling its L-Cysteine product before halting importation of the product and then halting sales of the product.[11]

The Plaintiff does not allege that the FDA's guidance-based decisions were a result of any false or misleading actions on the part of the Defendant. The Plaintiff only alleges that the Defendant committed an unfair or deceptive act by merely seeking renewal. That is insufficient to support a Chapter 75

[11] Notably, the Plaintiff did not have sufficient production to satisfy the market for a significant portion of that six-month period. The Plaintiff makes no allegations regarding the adequacy of its distribution network to distribute what it was able to manufacture during that time.

claim. For these reasons, the Plaintiff's Chapter 75 claim based on the Defendant seeking a renewed Memorandum of Discretion in June 2019 is without merit, and that claim must be dismissed.

c. Failing to Update Dear Healthcare Provider Letter

The Plaintiff next claims that the Defendant violated Chapter 75 by failing to update the Dear Healthcare Provider letter that accompanied its L-Cysteine product to inform customers that ELCYS had received FDA approval. [Doc. 1 at ¶¶ 9, 41, 69]. Specifically, the Plaintiff alleges that the Defendant sent out Dear Healthcare Provider letters in March 2016, [Doc. 1-17], and September 2018 [Doc. 1-18], stating that "there are currently no FDA-approved L-Cysteine Injection products in the United States" and failed to send a new letter to update that statement until six months after ELCYS received FDA approval. [Doc. 1 at ¶ 9, 41, 46, 69; Doc. 1-21].[12]

[12] The Plaintiff's Complaint fails to identify the particular communication that provides a basis for the alleged Chapter 75 violation. The Plaintiff alleges, *on information and belief*, that the Defendant sent Dear Healthcare Provider letters with incorrect information regarding ELCYS' FDA approval status after it had received FDA approval on April 16, 2019. [Doc. 1 at ¶¶ 9, 46]. The Plaintiff's Complaint, however, only attaches Dear Healthcare Provider letters sent on March 1, 2016, and September 1, 2018. [Doc. 1-17; 1-18]. The Plaintiff provides no communication from after April 16, 2019, where the Defendant falsely states that its L-Cysteine product is the only L-Cysteine product available in the United States. The only communication that the Plaintiff provides from that period is from September 25, 2019, when the Defendant informed customers that "there is now an FDA approved L-Cysteine available in the US market." [Doc. 1-21].

The Defendant argues that the Plaintiff's claim is preempted because the Dear Healthcare Provider letters were mandated, overseen, and preapproved by the FDA as part of its decision to grant a Memorandum of Discretion to the Defendant under the FDCA. [Doc. 29-1 at 17]. The Defendant also argues that it did not violate Chapter 75 because it sent a new letter to tell customers that "there is now an FDA approved L-Cysteine available in the U.S. market" roughly five months after ELCYS received FDA approval. [Doc. 29-1 at 18 (citing Doc. 1 at ¶¶ 46)].

"Manufacturers and distributors of drugs and the Food and Drug Administration occasionally are required to mail important information about drugs to physicians and others responsible for patient care" in so-called Dear Healthcare Provider letters. See 21 C.F.R. § 200.5. The FDA can mandate and oversee the distribution of Dear Healthcare Provider letters in conjunction with its oversight of drug shortages. [Doc. 29-1 at 17]; Center for Drug Evaluation and Research, Drug Shortage Management, Manual of Policies and Procedures 4190.1 at 10 ("When a potential or actual shortage might be resolved by obtaining a drug from an alternate source," the FDA will "[c]oordinate issuance and clearance of a Dear Healthcare Provider Letter . . . ."). While no explicit statutory or regulatory provisions set forth the circumstances under which a drug manufacturer must issue a Dear

Healthcare Provider letter, the FDA has brought enforcement actions under the FDCA where Dear Healthcare Provider letters contained "false or misleading" statements. State ex rel. McGraw v. Johnson & Johnson, 226 W. Va. 677, 682, 704 S.E.2d 677, 682 (2010).

Here, the Memorandum of Discretion and the subsequent renewals of that Memorandum show that the Defendant distributed the Dear Healthcare Provider letters at the FDA's direction and with the FDA's approval. [Doc. 31-2 at 41-59]. The distribution of those letters was one of the FDA's conditions for not exercising its enforcement authority against the Defendant's L-Cysteine product. [Id.]. Under those conditions, the FDA explicitly approved the language contained in the Defendant's Dear Healthcare Provider letters and any revisions of those letters required FDA approval. [Doc. 31-2 at 41, 43, 46-50].

Notably, the last Memorandum of Discretion renewal occurred on June 21, 2019, after the FDA approved ELCYS, after the Plaintiff had produced sufficient ELCYS for the entire market, and after the Plaintiff had started shipping ELCYS. [Id. at 50; Doc. 1 at ¶ 33, 34]. The FDA, however, did not require the Defendant to update its Dear Healthcare Provider letter after ELCYS was approved. Instead, the June 21, 2019 renewal mandated (under threat of enforcement action) that "*[t]he previously reviewed Dear Healthcare*

Provider letter continues to accompany" the Defendant's product. [Doc. 31-2 at 50 (emphasis added)]. That previously reviewed letter stated that "there are currently no FDA-approved L-Cysteine Injection products in the United States." [Doc. 1-18]. Accordingly, the FDA not only approved the statement in the Dear Healthcare Provider letter about which the Plaintiff complains, but *required* the Defendant to make that statement.

Nevertheless, the Plaintiff argues that the Defendant should face state tort liability for failing to ask the FDA for permission to update the Dear Healthcare Provider letter after the FDA approved ELCYS. [Id. at ¶ 69]. The Memorandum of Discretion and its subsequent renewals prohibited the Defendant from unilaterally changing the statements contained in the letter, including the statement about which the Plaintiff complains. [Doc. 31-2 at 50; see also Doc. 31-2 at 43 (stating that "if Sandoz makes further edits to this letter, [the FDA] requests the opportunity to review before the letter is printed and distributed")]. The Supreme Court has held that "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." PLIVA, Inc. v. Mensing, 564 U.S. 604, 623-24 (2011). That is because "[t]he only action the [Defendant] could

independently take—asking for the FDA's help—is not a matter of state-law concern." Id. at 624. To the extent that the Plaintiff's Chapter 75 claim is based on the Defendant's failure to update its Dear Healthcare Provider letter, that claim is preempted because the FDA controlled the contents of the Dear Healthcare Provider letters and the Defendant could not unilaterally update those letters without the FDA's involvement and approval, which is not a matter of state-law concern. Therefore, the failure to change the contents of the letter cannot be a basis for a state law claim.

While the Plaintiff asserts that the Defendant "failed to inform its customers of the FDA-approved status of Exela's product at least until September 25, 2019[,]" [Doc. 1 at ¶ 69], that allegation also cannot support a Chapter 75 claim. As discussed above, the FDA's scheme for controlling the risks associated with the Defendant's product required the Defendant to communicate with customers through Dear Healthcare Provider letters. That arrangement and process would have been undermined if the Defendant sent other communications to customers contradicting the contents of the FDA-approved Dear Healthcare Provider letters. The Defendant's failure to subvert the FDA's scheme and risk enforcement action by sending a communication other than a Dear Healthcare Provider letter cannot give rise to a Chapter 75 claim.

d. Failing to Warn Customers About Aluminum Content

The Plaintiff next claims that the Defendant violated Chapter 75 by failing to warn its customers that its L-Cysteine product had a higher aluminum content than the standard that the FDA required ELCYS to meet and by failing to tell its customers about the difference in aluminum content between the two products. [Doc. 1 at ¶ 69]. The Plaintiff also alleges that the Defendant did not update its Dear Healthcare Provider letters or "distribute any other formal communication to the field to inform its customers that the aluminum levels of its unapproved product far exceed" the standard that the FDA required ELCYS to meet to receive approval. [Id. at ¶ 9].[13]

To begin, what the Plaintiff refers to as "FDA standards" are not standards at all. The relevant regulations do not set any upper limit on aluminum content for small volume parenteral drug products like the Defendant's L-Cysteine product. See 21 C.F.R. § 201.323. Moreover, the letter where the Plaintiff contends that the FDA provided its aluminum content standard "does not constitute an official agency determination." Schering-Plough Healthcare Prod., Inc. v. Schwarz Pharma, Inc., 547 F. Supp. 2d 939, 947 (E.D. Wis. 2008), amended, No. 07-CV-642, 2009 WL

[13] Regarding the Plaintiff's allegations concerning the Dear Healthcare Provider letter, see Part IV.A.1.c, supra.

151573 (E.D. Wis. Jan. 22, 2009) (collecting cases); see also Dietary Supplement Coal., Inc. v. Sullivan, 978 F.2d 560, 563 (9th Cir.1992) (stating that "regulatory letters do not constitute final agency action."). Indeed, the FDA later explained to the Plaintiff that the Defendant's L-Cysteine product had aluminum levels that were "well within the standards agreed upon with FDA" and that "[i]t is thus inappropriate to suggest that the Sandoz product is somehow unsafe." [Doc. 1-15]. As such, the fact that the FDA required the Plaintiff's ELCYS product to meet a certain aluminum level to *receive FDA approval* did not create a binding limitation on other drugs, especially ones that do not seek FDA approval like the Defendant's. In this argument, the Plaintiff conflates the level that needed to be met to receive temporary permission with the level for permanent approval.

The Plaintiff further argues that the Defendant violated Chapter 75 by failing to tell its customers about the difference in aluminum content between the Defendant and the Plaintiff's products. [Doc. 1 at ¶ 69]. The Plaintiff has cited no authority for the proposition that a merchant's failure to inform its customers as to how its product compares unfavorably to a competitor's product constitutes a deceptive trade practice. There is no basis to conclude that the law imposes such obligation.

The Plaintiff's dispute appears to be with the FDA for temporarily permitting importation and sale of a drug that did not meet the same aluminum levels that the FDA required ELCYS to meet for permanent approval. The Plaintiff cannot, however, use a state-law claim against a competitor to "countermand the FDA's determinations and substitute its own requirements" regarding the permissible aluminum content of the Defendant's L-Cysteine product. Zogenix, 2014 WL 1454696, at *2. If the Plaintiff were allowed to bring such a claim, it would stand "in the way of 'the accomplishment and execution of' an important federal objective" by undermining "the FDA's ability to make drugs available to promote and protect the public health." Id. (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)). "The Constitution does not allow it to do so." Id.

As such, to the extent that the Plaintiff's Chapter 75 claim is based on the Defendant failing to meet the same aluminum content level that ELCYS was required to meet or on the Defendant failing to affirmatively advertise the differences between the two products, that claim must be dismissed as preempted and as failing to state a claim upon which relief can be granted.

e. Oversupplying Customers

The Plaintiff next argues that the Defendant violated Chapter 75 by "oversupplying customers and flooding distribution channels with its

unapproved product to prevent them from purchasing [ELCYS]." [Doc. 1 at ¶ 69]. In short, the Plaintiff bases this claim on the fact that the Defendant imported, marketed, and sold a product that it was permitted by the FDA to import, market, and sell, and in quantities that did not exceed that permission.

As discussed previously, the Plaintiff is preempted from bringing a state-law claim to challenge the FDA's decision to allow the Plaintiff to import and sell its L-Cysteine product because there is no private right of action in the FDCA and the FDA is the sole entity that can bring enforcement actions to halt the sale and importation of drugs. In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig., 756 F.3d 917, 936 (6th Cir. 2014) As such, the Plaintiff is preempted from bringing a Chapter 75 claim against the Defendant based on the volume of its L-Cysteine product sales.

f. Misusing Incumbent Status

Finally, the Plaintiff argues that the Defendant violated Chapter 75 by misusing "its incumbent status in the market and its huge market power and reach to block hospitals and distributors from switching" to ELCYS. [Id. at ¶ 70]. It bears repeating that the Plaintiff's claims cannot be based merely on the Defendant's importation or sale of its L-Cysteine product because those claims are preempted.

The Defendant's sales were permitted by the FDA and the Plaintiff does not identify any act, other than the sales themselves, that constituted an unfair or deceptive act or an inequitable assertion of power. The volume of the sales, and the timing of those sales, as permitted by the FDA, are not suitable bases for a Chapter 75 claim. Moreover, an incumbent market competitor's sale of its inventory does not become an unfair or deceptive act simply because those sales come at the expense of a smaller market competitor. The Plaintiff has cited no authority for this proposition. As such, the Plaintiff cannot base its Chapter 75 claim on the Defendant's incumbent status in the market or its volume of sales before exiting the market.

For all these reasons, the Plaintiff's Chapter 75 claim is dismissed.

2. Interference with Prospective Economic Advantage Claim

The Plaintiff next claims that the Defendant illegally interfered with its prospective economic advantage by continuing to sell its unapproved L-Cysteine product after ELCYS received approval from the FDA. [Doc. 1 at ¶¶ 75-81].

Tortious interference with prospective economic advantage "arises when a party interferes with a business relationship 'by maliciously inducing a person not to enter into a contract with a third person, which he would have entered into but for the interference, . . . if damage proximately ensues, when

this interference is done not in the legitimate exercise of the interfering person's rights.'" Beverage Sys. of the Carolinas, LLC v. Associated Beverage Repair, LLC, 368 N.C. 693, 701, 784 S.E.2d 457, 463 (2016) (quoting Spartan Equip. Co. v. Air Placement Equip. Co., 263 N.C. 549, 559, 140 S.E.2d 3, 11 (1965)). Because the interference must be done outside of the legitimate exercise of the interfering person's rights, "[i]nterference with a contract is justified if it is motivated by a legitimate business purpose, as when the plaintiff and the defendant . . . are competitors." Id., 368 N.C. at 700, 784 S.E.2d at 463 (citations and quotations omitted). To survive dismissal, a complaint alleging tortious interference "must admit of no motive for interference other than malice." Pinewood Homes, Inc. v. Harris, 184 N.C. App. 597, 605, 646 S.E.2d 826, 832–33 (2007).

The Plaintiff tries to meet this element of the tort of intererence by alleging that the Defendant's "actions were not an exercise of any legitimate right of its own" because "it is illegal to introduce" an unapproved drug into interstate commerce. [Doc. 1 at ¶ 79 (citing 21 U.S.C. §§ 331(d), 355(a); Cook, 733 F.3d at 9-10)]. Again, the cornerstone of the Plaintiff's claim is this assertion that it is somehow "illegal" for the Defendant to do precisely what the FDA gave the Defendant permission to do. As such, this claim again attempts to enforce the FDCA against the Defendant for importing and

selling an illegal drug. The FDA, however, is the only entity that can bring a claim against the Defendant for its alleged introduction of an illegal drug into interstate commerce. See Allergan, Inc. v. Athena Cosmetics, Inc., 738 F.3d 1350, 1359 (Fed. Cir. 2013). The Plaintiff is preempted from bringing a claim based on the Defendant having no legal right to make the sales.

The Plaintiff's allegations also show that the Defendant was merely a competitor motivated by a legitimate business purpose when it imported and sold its L-Cysteine product. Beverage Sys. of the Carolinas, 368 N.C. at 701, 784 S.E.2d at 463. The Plaintiff's own allegations show that the crux of the Defendant's alleged wrongdoing is that it "schemed to stay, *compete*, and dominate the L-Cysteine market for months" and thereby prevent "the vast majority of customers from buying [the Plaintiff's] FDA-approved product." [Doc. 41 at ¶ 78] (emphasis added). Those allegations, however, simply show a market competitor motivated by a legitimate business purpose—selling its existing inventory. The Plaintiff has failed to plausibly allege that the Defendant, as its competitor, had no legitimate business purpose for selling its inventory after ELCYS had been approved. As such, the Plaintiff's allegations concerning interference with prospective economic advantage fail to state a claim upon which relief can be granted and must be dismissed.

B. Lanham Act Claim

The Plaintiff next claims that the Defendant violated the Lanham Act by making "false and misleading representations in the course of selling its unapproved L-Cysteine product." [Doc. 1 at ¶ 84]. According to the Plaintiff, those false and misleading representations

> include, but are not limited to failing to update its Dear Healthcare Provider letter to inform customers of the FDA approved status and availability of [the Plaintiff's] product; providing a link on its product website to a database that says nothing about the aluminum content of [the Defendant's] product while clearly indicating the low aluminum content of FDA-approved ELCYS; failing to inform customers that the aluminum levels of [the Defendant's] unapproved product exceed FDA standards; and failing to inform customers of the much lower aluminum content of [the Plaintiff's] approved product.

[Id.].

To state a claim for false advertising under the Lanham Act, a plaintiff must allege that: (1) the defendant made a false or misleading description of fact or representation of fact in a commercial advertisement; (2) the misrepresentation is material, in that it is likely to influence the purchasing decision; (3) the misrepresentation actually deceives or has the tendency to deceive a substantial segment of its audience; (4) the defendant placed the false or misleading statement in interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the misrepresentation, either

by direct diversion of sales or by a lessening of goodwill associated with their product. Scotts Co. v. United Indus. Corp., 315 F.3d 264, 272 (4th Cir. 2002). Unless the omission of a statement would render an affirmative statement false or misleading, the Lanham Act "imposes no affirmative duty of disclosure." MDM Grp. Assocs., Inc. v. Emerald Isle Realty, Inc., No. 2:07-CV-48 D, 2008 WL 2641271, at *5 (E.D.N.C. July 1, 2008) (citation and quotations omitted); see also Casper Sleep, Inc. v. Mitcham, 204 F. Supp. 3d 632, 638 (S.D.N.Y. 2016).

1. Failing to Update Dear Healthcare Provider Letter

The Plaintiff asserts that the Defendant violated the Lanham Act by continuing to send Dear Healthcare Provider letters stating that "there are currently no FDA-approved L-Cysteine Hydrochloride Injection products in the United States" even after ELCYS received FDA approval on April 16, 2019. [Doc. 1 at ¶ 41; Doc. 1-18; see also Doc. 31-2 at 41-59]. The Plaintiff does, however, allege that the Defendant updated its customers on September 25, 2019, when it told them that "there is now an FDA approved L-Cysteine available in the US market." [Doc. 1-21 at 2].[14] The Defendant

[14] While the Defendant argues that the Dear Healthcare Provider letters do not constitute commercial advertising, another court has held that Dear Healthcare Provider letters are "disseminated in a manner sufficient to constitute commercial advertising placed in interstate commerce[.]" De Simone v. VSL Pharm., Inc., 395 F. Supp. 3d 617, 624 (D. Md. 2019).

moves to dismiss, arguing that the Plaintiff's Lanham Act claims fail as a matter of law. [Doc. 29-1 at 16- 32].

In POM Wonderful LLC v. Coca–Cola Co., the Supreme Court held that "the FDCA and the Lanham Act complement each other" and the FDCA does not categorically bar Lanham Act suits. 134 S. Ct. 2228, 2241 (2014). POM Wonderful, nevertheless, preserved "the possibility that *some* Lanham Act suits might be precluded by the FDCA." JHP Pharm., LLC v. Hospira, Inc., 52 F. Supp. 3d 992, 998 (C.D. Cal. 2014) (citing id.). Specifically, the Court in POM Wonderful said that a Lanham Act claim may be precluded by the FDCA if "it turns on the content" of something that has been "previously preapproved by the FDA." Id. at 998; see also Church & Dwight Co. Inc. v. SPD Swiss Precision Diagnostics, GmbH, 104 F. Supp. 3d 348, 352 (S.D.N.Y. 2015) (stating POM Wonderful held that "in essence, that Lanham Act claims might be precluded if the FDA had authorized the challenged name and label."). Moreover, POM Wonderful suggested that a Lanham Act claim might be precluded by the FDCA if it conflicts "with an affirmative policy judgment by the FDA." JHP Pharm., 52 F. Supp. 3d at 998 (citing POM Wonderful, 134 S. Ct. at 2241). Likewise, other courts have found that Lanham Act claims which "involve an issue on which the FDA has taken 'positive regulatory action' are all likely precluded by the FDCA." Allergan

USA Inc. v. Imprimis Pharm., Inc., No. SACV171551DOCJDEX, 2017 WL 10526121, at *7 (C.D. Cal. Nov. 14, 2017) (quoting JHP Pharm., 52 F. Supp. 3d at 1000 n.5, 1004)).

Here, the Plaintiff's Lanham Act claim regarding the Dear Healthcare Provider letters "turns on the content" of something that was "previously preapproved by the FDA." JHP Pharm., 52 F. Supp. 3d at 998. Because the Plaintiff's Lanham Act claim challenges the letters that were a condition of the Memorandum of Discretion, it thereby also challenges the FDA's policy judgment and implicates an issue upon which the FDA has taken positive regulatory action. Imprimis Pharm., 2017 WL 10526121, at *7. Based on the Supreme Court's discussion in POM Wonderful, such a claim is precluded.

Examining the practical effects of allowing such a claim to proceed further demonstrates that preclusion is appropriate here. If the Plaintiff were correct that the FDA approved and mandated Dear Healthcare Provider letters could serve as the grounds for a Lanham Act violation, the Defendant would have had three options once ELCYS received FDA approval in April 2019: (1) face Lanham Act liability for continuing to distribute its L-Cysteine product with the FDA-approved Dear Healthcare Provider letter; (2) face FDA enforcement action for violating the Memorandum of Discretion by

sending a new Dear Healthcare Provider letter that had not been approved by the FDA; or (3) withdraw its product from the market completely while it negotiated a new Dear Healthcare Provider letter with the FDA. It is unreasonable to interpret the Lanham Act to impose such a Hobson's choice, particularly when the FDA has taken and continues to take positive regulatory action to address something as critical and sensitive as a drug shortage. As such, this is not an instance where "the FDCA and the Lanham Act complement each other . . . ." POM Wonderful, 134 S. Ct. 2228, 2241 (2014). Accordingly, the Plaintiff's Lanham Act claim based on the Defendant's failure to send a new Dear Healthcare Provider letter after ELCYS received FDA approval fails to state a claim upon which relief can be granted.

2. Failing to Disclose Aluminum Content Difference

The Plaintiff's Lanham Act claim also fails to the extent it is based on the Defendant's failure to affirmatively advertise the aluminum content of its L-Cysteine product. The Plaintiff, however, concedes that the Defendant never affirmatively "told its customers the respective aluminum levels of the [Plaintiff and the Defendant's] products." [Doc. 1 at ¶ 9]. The Plaintiff makes no allegation that the Defendant made any statement that would be rendered false or misleading by failing to affirmatively provide information regarding its

product's aluminum content or ELCYS's aluminum content. The Defendant had no duty to provide such a statement under the Lanham Act. Therefore, the Plaintiff cannot state a Lanham Act claim based on the Defendant's failure to affirmatively advertise the difference between the aluminum content in its L-Cysteine product and ELCYS. Emerald Isle Realty, 2008 WL 2641271, at *5; see also Casper Sleep, 204 F. Supp. 3d at 638.

3. Failing to Disclose FDA "Standards"

The Plaintiff also asserts that the Defendant failed to inform customers that the aluminum levels of its "unapproved product exceed FDA standards." [Doc. 1 at ¶ 84]. What the Plaintiff refers to as FDA "standards," however, are not actual FDA standards at all. (See, Part IV.A.1.c., supra.). As such, Plaintiff's allegations are based on a false premise. Moreover, the Plaintiff's own allegations show that the Defendant never made any statement regarding the aluminum content of its L-Cysteine product or whether its product met any FDA "standards." The Lanham Act "imposes no affirmative duty of disclosure." Emerald Isle Realty, 2008 WL 2641271, at *5; Casper Sleep, 204 F. Supp. 3d at 638.

This claim is a thinly veiled attempt by the Plaintiff to step into the shoes of the FDA to enforce the FDCA based on an underlying assumption that the Defendant's product is unsafe due to its aluminum levels. Such a claim is

precluded. PhotoMedex, Inc. v. Irwin, 601 F.3d 919, 924 (9th Cir. 2010) ("Because the FDCA forbids private rights of action under that statute, a private action brought under the Lanham Act may not be pursued when, as here, the claim would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation."); American Home Products Corp. v. Johnson & Johnson, 436 F. Supp. 785, 797 (S.D.N.Y.1977) (stating that "an action under the Lanham Act and state unfair competition laws is not the proper legal vehicle in which to vindicate the public's interest in health and safety."). Accordingly, the Plaintiff's Lanham Act claim cannot be based on the Defendant's failure to disclose that its product does not meet FDA "standards."

For all these reasons, the Plaintiff's Lanham Act claim will be dismissed.

V. CONCLUSION

In 2014 the FDA determined that there was a shortage of L-Cysteine product needed for medical treatments in the United States. The FDA approached the Defendant and worked out a program to *temporarily* allow the Defendant to import and sell its L-Cysteine product in the United States to meet this shortage. The Plaintiff meanwhile developed a competing L-

Cysteine product for which the Plaintiff sought full FDA approval to sell in the U.S. market. Regarding the brief (less than six-month) period of the overlap of the availability of both the Plaintiff's and the Defendant's product, the Plaintiff complains that the FDA should not have allowed the Defendant to continue to sell its product. The Plaintiff brings this action, however, against the Defendant, not the FDA. Because of the exclusivity of the FDCA and the authority of the FDA regarding such sales, the Plaintiff's claims against the Defendant fail both under the Lanham Act and pursuant to state law. For this reason, the Defendant's Motion to Dismiss will be granted.

ORDER

IT IS, THEREFORE, ORDERED that the Defendant's Motion to Dismiss the Complaint or, in the Alternative, Stay the Case Pending Referral to FDA [Doc. 29] is **GRANTED,** and this action is **DISMISSED WITH PREJUDICE**.

IT IS FURTHER ORDERED that the Plaintiff's Motion for Preliminary Injunction [Doc. 3] is **DENIED.**

The Clerk of Court is directed to close this civil action.

IT IS SO ORDERED.

Signed: September 15, 2020

Martin Reidinger
Chief United States District Judge