IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CAREDX, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 19-662-CFC-CJB
	)	
NATERA, INC.,	)	
	)	
Defendant.	)	

REPORT AND RECOMMENDATION

Presently pending before the Court in this suit is Defendant Natera, Inc.'s ("Defendant" or "Natera") motion seeking dismissal of Plaintiff CareDx, Inc.'s ("Plaintiff" or "CareDx") Complaint, filed pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6) (the "Motion"). (D.I. 8) CareDx's Complaint alleges false advertising and "trademark disparagement" under the Lanham Act, common law unfair competition, and violations of the Delaware Unfair or Deceptive Trade Practices Act. (D.I. 1; *see also* D.I. 9 at 1; D.I. 13 at 1-2) With its Motion, Natera argues that this action should be dismissed because: (1) CareDx lacks standing to sue for its false advertising claim pursuant to 15 U.S.C. § 1125(a) ("Section 1125(a)"); and (2) CareDx has failed to plead facts that would plausibly demonstrate the necessary elements of its various claims. For the reasons set out below, the Court recommends that the Motion be GRANTED-IN-PART and DENIED-IN-PART.

I. BACKGROUND

A. Factual Background

CareDx markets and sells AlloSure®, a patented kidney transplant surveillance diagnostic test. (D.I. 1 at ¶¶ 1-2, 10) This non-invasive blood test accurately detects active kidney rejection in kidney transplant patients by measuring levels of cell-free DNA in the

patient's body, with high levels of such DNA originating from the donor kidney indicating that the transplanted kidney may be in the process of being rejected. (*Id.* at ¶¶ 2, 19-20) AlloSure is clinically and analytically validated and Medicare-covered. (*Id.* at ¶ 2)

Prior to launching AlloSure, CareDx conducted a clinical trial (the "DART study"), which involved collecting blood specimens at scheduled intervals at the time of biopsies from 14 clinical sites and comparing the levels of cell-free DNA with the biopsy results. (*Id.* at ¶ 21) The DART study demonstrated that AlloSure "markedly outperformed" the current standard of care for detecting kidney transplant rejection (serum creatinine testing). (*Id.* at ¶¶ 18, 26) The results of the DART Study were published in July 2017 in the *Journal of the American Society of Nephrology* (the "CareDx Study"). (*Id.* at ¶ 21)

Natera has allegedly developed a competing cell-free DNA kidney transplant rejection test, Prospera™. (*Id.* at ¶¶ 3, 27, 51) Natera "is in the midst of launching" Prospera. (*Id.* at ¶ 3) To that end, Natera has "begun significant marketing efforts" with respect to Prospera, such as by making the test available for use in clinical trials and marketing it to major clinical centers. (*Id.* at ¶ 52) Natera also sponsored a clinical study to validate the effectiveness of Prospera (the "Natera Study"). (*Id.* at ¶ 27) The Complaint alleges that the Natera Study involved "retrospectively select[ing] samples that had been collected for unrelated purposes by a single clinical center and archived." (*Id.* at ¶ 28) The results of the Natera Study were published in the December 23, 2018 issue of the *Journal of Clinical Medicine* (the "Natera Study Publication"). (*Id.*)

Natera has made certain statements comparing the Natera Study's results with the results of the CareDx Study (the "Natera Statements"). (*Id.* at ¶¶ 37, 39) CareDx alleges that because

the two studies did not involve "head-to-head clinical trials comparing the two [companies'] products[,]" and because the Natera Study suffers from "substantial material flaws[,]" Natera's statements comparing Prospera's performance to AlloSure's performance are "literally false and entirely misleading." (*Id.* at ¶ 37) As examples of Natera's allegedly "false, misleading and harmful representations" regarding the Natera Study's results, (*id.* at ¶ 39), CareDx points to the following Natera Statements:

- Natera's June 21, 2018 press release and its July 12, 2018 Prospectus Supplement cite to sensitivity-related data from the Natera Study and state that "[t]his sensitivity compares favorably against competition[,] which reported only 59% in a 2017 study [citing to the CareDx Study]." (*Id.* at ¶¶ 40, 42 (internal quotation marks and citation omitted) & exs. 4, 5);

- Natera's June 27, 2018 8K includes a slide entitled "Natera Assay Outperforms Competition" that compares data from the Natera Study and the CareDx Study. (*Id.* at ¶ 41 (internal quotation marks and citation omitted) & ex. 3, slide 10);

- Natera's January 7, 2019 press release states that Prospera "include[s] higher sensitivity and nearly 18% higher area under the curve (AUC) than the competitive [] assay [relating to AlloSure]" and the Natera Study "[r]esults also showed higher sensitivity (89% vs. 59%) and higher AUC (0.87 vs. 0.74) than the competitive [] assay [relating to AlloSure]." (*Id.* at ¶ 43 (internal quotation marks and citation omitted) & ex. 6);

- Natera's January 9, 2019 slide presentation at the J.P. Morgan Healthcare Conference indicates a goal of changing patient care for transplant recipients that is "driven by superior clinical data [i.e., the Natera Study]" and compares data from the Natera Study and CareDx Study, indicating that the Natera Study demonstrates the "[h]ighest area under the curve" and is the "[f]irst test to consistently detect subclinical acute rejection[.]" (*Id.* at ¶ 44 (internal quotation marks and citation omitted) & ex. 7,

slide 12) Further, Natera's CEO gave an oral presentation at this conference in which he compared the performance of Prospera with the performance of "the competitor" AlloSure. (*Id.* at ¶ 45);

- Natera's February 1, 2019, February 22, 2019 and March 28, 2019 press releases contain similar statements comparing results of the Natera Study with the "compet[ing]" AlloSure assay. (*Id.* at ¶¶ 46, 47, 49 (internal quotation marks and citation omitted) & exs. 8-9, 11); and

- Natera provided an advertisement to attendees at the February 2019 American Society of Transplantation CEOT Conference that cited the Natera and CareDx Studies and stated that Natera's performance "compares favorably against competition[.]" (*Id.* at ¶ 48 (internal quotation marks and citation omitted) & ex. 10)

CareDx alleges that the Natera Statements have harmed and will continue to harm CareDx's reputation and have and will cause CareDx to lose sales. (*Id.* at ¶¶ 51, 53)

B. Procedural Background

CareDx filed this case on April 10, 2019. (D.I. 1) The case has now been referred to the Court to hear and resolve all pretrial matters, up to and including expert discovery.

Natera filed the instant Motion in lieu of answering on May 31, 2019. (D.I. 8) The Motion was fully briefed on June 26, 2019. (D.I. 15) After the Motion was thereafter referred to the Court for resolution, (D.I. 17), the Court heard oral argument on the Motion on October 30, 2019, (D.I. 26 (hereinafter, "Tr.")). After oral argument, the Court ordered that Natera could file a supplemental letter brief regarding certain material referenced by CareDx for the first time at oral argument; that letter brief was filed on November 1, 2019. (D.I. 23)

II. STANDARD OF REVIEW[1]

When presented with a Rule 12(b)(6) motion to dismiss for failure to state a claim, a court conducts a two-part analysis. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). First, the court separates the factual and legal elements of a claim, accepting "all of the complaint's well-pleaded facts as true, but [disregarding] any legal conclusions." *Id.* at 210-11. Second, the court determines "whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Id.* at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. In assessing the plausibility of a claim, the court must "'construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief.'" *Fowler*, 578 F.3d at 210 (quoting *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)).

III. DISCUSSION

Natera's Motion seeks dismissal of all Counts of CareDx's Complaint. The Court will first assess the parties' arguments with respect to CareDx's false advertising claim under the Lanham Act, and will then address the remaining claims.

A. False Advertising Under the Lanham Act (Count One)

Count One of CareDx's Complaint alleges false advertising in violation of the Lanham Act, 15 U.S.C. § 1125(a). (D.I. 1 at ¶¶ 54-60) With respect to this claim, Natera first argues that

---

[1] Although Natera moved to dismiss pursuant to both Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), (D.I. 8), as the Court will explain below, Rule 12(b)(1) is not applicable to the Motion. Thus, the Court here sets out the standard for motions filed pursuant to Rule 12(b)(6) only.

CareDx has not established proximate causation, and that it therefore lacks standing under Rule 12(b)(1) as to this claim. (D.I. 9 at 7-10) Natera then argues that even if CareDx has established standing to bring the claim, the Complaint fails to plead sufficient facts necessary to plausibly allege multiple elements of a Lanham Act false advertising claim. (*Id.* at 10-14) The Court takes up these arguments in turn.

1. Proximate Causation

The Lanham Act provides that:

> Any person who [uses any] false or misleading description of fact, or false or misleading representation of fact, which . . . misrepresents the nature, characteristics, [or] qualities . . . of his or her or another person's goods . . . shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a). In *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118 (2014), the Supreme Court of the United States determined that a statutory cause of action under the Lanham Act extends only to plaintiffs whose "injuries are proximately caused by violations of the statute." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 132 (2014).[2]

a. What Standard Applies to Assess Whether CareDx Has Established Proximate Cause?

In order to determine whether CareDx has met its burden with regard to proximate causation, the Court must first confront what standard applies to this inquiry. In its briefing and

---

[2] The *Lexmark* Court also held that a statutory cause of action under the Lanham Act extends only to plaintiffs "whose interests fall within the zone of interests protected by the law invoked" and thus such plaintiffs must allege "an injury to a commercial interest in reputation or sales." *Lexmark*, 572 U.S. at 129, 131-32 (internal quotation marks and citation omitted). Natera has not challenged here whether CareDx meets the "zone of interests" test. (*See* D.I. 13 at 5)

at oral argument, Natera argues that this question—i.e., whether proximate cause has been sufficiently alleged—is one of subject matter jurisdiction. (D.I. 9 at 6-8; *see also* Tr. at 22 ("Proximate causation is a jurisdictional requirement."); Tr. at 34, 38, 68-70) Thus, it brought this portion of its Motion pursuant to Federal Rule of Civil Procedure 12(b)(1). (*See* D.I. 9 at 6) For its part, CareDx retorts that the issue does not implicate Rule 12(b)(1) or subject matter jurisdiction; instead, it argues that the question must be assessed pursuant to the Rule 12(b)(6) standard. (Tr. at 47-50, 67; *see also* D.I. 13 at 4)

The Court agrees with CareDx. The *Lexmark* Court explained that this question (i.e., as to whether a plaintiff has sufficiently established proximate cause regarding its Lanham Act claim at the pleading stage) implicates the concept of so-called "statutory standing"—and that it "does not implicate subject-matter jurisdiction, i.e., the court's statutory or constitutional *power* to adjudicate the case." *Lexmark*, 572 U.S. at 128 n.4, 134 n.6 (internal quotation marks and citations omitted) (emphasis in original); *see also, e.g.*, *Leyse v. Bank of Am. Nat'l Ass'n*, 804 F.3d 316, 320 (3d Cir. 2015) ("Unlike Article III standing, statutory standing is not jurisdictional."). Instead, statutory standing addresses "whether Congress has accorded a particular plaintiff the right to sue under a statute, but it does not limit the power of the court to adjudicate the case." *Leyse*, 804 F.3d at 320 (citing *Lexmark*, 134 S. Ct. at 1388 & n.4).

Here, then, the proximate causation requirement of CareDx's false advertising claim is "an element of the cause of action under the statute" and is thus "subject to the rule that the absence of a valid (as opposed to arguable) cause of action does not implicate subject-matter jurisdiction." *Lexmark*, 572 U.S. at 134 n.6 (internal quotation marks and citation omitted). Nevertheless, proximate cause, like other elements of a cause of action, must be "adequately alleged at the pleading stage in order for the case to proceed." *Id.* To that end, "[i]f a plaintiff's

allegations, taken as true, are insufficient to establish proximate causation, then the complaint must be dismissed; if they are sufficient, then the plaintiff is entitled to an opportunity to prove them." *Id.* As a result, a "dismissal for lack of statutory standing is effectively the same as a dismissal for failure to state a claim, and a motion to dismiss on this ground is brought pursuant to Rule 12(b)(6), rather than Rule 12(b)(1)." *Leyse*, 804 F.3d at 320 (internal quotation marks and citations omitted); *see also, e.g.*, *Lone Star Silicon Innovations LLC v. Nanya Tech. Corp.*, 925 F.3d 1225, 1235 (Fed. Cir. 2019) ("[F]ollowing *Lexmark*, several courts have concluded that motions to dismiss based on 'statutory standing' defects are properly brought under Rule 12(b)(6) rather than Rule 12(b)(1) in recognition of the fact that such defects are not jurisdictional.").[3]

With this having been sorted out, the Court will now assess whether CareDx's allegations are sufficient to establish proximate cause pursuant to Rule 12(b)(6).

b. Has CareDx Sufficiently Pleaded Proximate Cause?

Natera asserts that in order to sufficiently plead proximate cause, a plaintiff must show that there was "'deception of consumers [that] caus[ed] them to withhold trade from the plaintiff.'" (D.I. 9 at 1 (quoting *Lexmark*, 572 U.S. at 133)) The parties agree that when CareDx filed its Complaint, Natera's Prospera product was not yet being sold. (D.I. 13 at 7; *see also* D.I. 9 at 8; Tr. at 13, 54-55) The crux of Natera's argument with respect to proximate cause is that because "Natera *never sold* any product that competes with CareDx's kidney diagnostic product. . . . it is *impossible* that consumers were deceived by Natera and consequently decided to

[3] In its supplemental letter brief filed after oral argument, Natera seemed to all but concede that Rule 12(b)(6) provides the proper standard by which to evaluate its arguments regarding proximate cause. (D.I. 23 at 2)

'withhold trade from' CareDx by selecting another product . . . instead of CareDx's product." (D.I. 9 at 1 (certain emphasis in original, certain emphasis omitted); Tr. at 17-18, 20, 37, 75 (Natera's counsel asserting that there is no proximate cause here, where there has been no sales of Natera's product and no facts pleaded showing a lost sale to CareDx because of Natera's product)) In other words, Natera is arguing that in the absence of being able to plead facts indicating that its product captured sales that would have otherwise gone to CareDx, CareDx cannot sufficiently demonstrate proximate cause, since the law requires a showing of *actual harm* caused by the misrepresentations at issue (and not merely the *possibility of future harm*). (D.I. 15 at 3-5)[4]

---

[4] In support of Natera's argument that CareDx cannot demonstrate proximate cause, Natera relies in part upon statements made by CareDx's CEO relating to competition; this information amounts to extrinsic evidence that is not referenced in the Complaint or in a document attached thereto. (D.I. 9 at 8-9; Tr. at 5-6) Specifically, Natera points to the transcript of a March 6, 2019 earnings call between CareDx executives and members of the financial services industry, in which CareDx's CEO stated that "I think if there were to be competition we would probably see them really towards the later end of the year." (D.I. 10, ex. A at 13) Natera also cites to the transcript of a May 8, 2019 earnings call in which CareDx's CEO responded "[n]o" when asked if any "competitive noise" was impacting "ordering activity" with respect to AlloSure "at current centers." (*Id.*, ex. B at 12) Natera relies on these statements to assert that as a legal matter, there is no proximate cause here, where: (1) Natera has not yet sold a product; and (2) CareDx's CEO has confirmed that Natera's assay has had no competitive impact on CareDx's business. (D.I. 9 at 8-9; Tr. at 18-19) According to Natera, with CareDx's CEO openly stating that it faces no competition from anyone, CareDx cannot show that Natera ever offered a competing product that actually caused harm to CareDx. (D.I. 9 at 8-9; Tr. at 5-6)

Natera argued that the Court could consider this extrinsic evidence because Natera's standing challenge amounted to a Rule 12(b)(1) "factual challenge" to the Court's subject matter jurisdiction. (D.I. 9 at 6-7; D.I. 15 at 2-3; Tr. at 10) However, as the Court has explained above, Natera's motion does not actually implicate subject matter jurisdiction; instead, Rule 12(b)(6) provides the proper legal standard that must be applied here. And in resolving motions to dismiss under Rule 12(b)(6), courts generally consider only the allegations in the complaint, exhibits attached to the complaint, matters of public record, and documents integral to or explicitly relied upon in the complaint. *See, e.g.*, *U.S. Express Lines, Ltd. v. Higgins*, 281 F.3d 383, 388 (3d Cir. 2002); *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993); *Freed v. St. Jude Med., Inc.*, 364 F. Supp. 3d 343, 349 n.4 (D. Del.

CareDx has a different view of the law. It argues that the Lanham Act can indeed protect against future harm to plaintiffs, including in situations where a competitor's product has not yet been sold on the market. (D.I. 13 at 5-8; Tr. at 52, 59-60) And it asserts that it has sufficiently alleged proximate cause here, where: (1) Natera is CareDx's competitor, as the two parties are "marketing the same type of product to the same audience of consumers[;] and [(2)] Natera is making false statements that its product is superior to CareDx's." (D.I. 13 at 5-6) For the reasons set out below, the Court agrees that CareDx's allegations are sufficient to plead proximate cause.

For one thing, the law does not support Natera's narrow view that a plaintiff cannot demonstrate proximate cause if it has not alleged past harm due to lost sales. After all, the language of the Lanham Act itself, as set out above, demonstrates that it is meant to protect any person "who believes that he or she is *or is likely to be* damaged" by the defendant's false advertising. 15 U.S.C. § 1125(a) (emphasis added).[5]

2019). If a party otherwise relies upon matters outside of the pleadings in a Rule 12(b)(6) motion, a court must either convert the motion into one for summary judgment under Federal Rule of Civil Procedure 56, or exclude the documents in question and continue under Rule 12(b)(6). Fed. R. Civ. P. 12(d). In the former scenario, the court must then give all parties "a reasonable opportunity to present all the material that is pertinent to the motion." Fed. R. Civ. P. 12(d).

The Court exercises its discretion here by taking the latter path. Discovery has not yet occurred, and it is too early in the case to sensibly evaluate any disputed facts that may be implicated by the statements at issue. Moreover, in its moving papers, Natera did not give CareDx notice that this Motion should be converted to a Rule 56 motion. Thus, the Court will not consider the extrinsic evidence attached to Natera's opening brief. (*See* Tr. at 16-17); *see also, e.g.*, *Progressive Freight, Inc. v. Framaur Assocs., LLC*, Civil Action No. 16-9366 (FLW), 2017 WL 3872327, at *3 n.1 (D.N.J. Sept. 5, 2017).

[5] And this statutory language aligns with how "unfair competition" claims were historically viewed, as being concerned "with injuries to business reputation and present *and future sales.*" *Lexmark*, 572 U.S. at 131 (emphasis added).

Moreover, Natera's differing view wrongly hinges on the *Lexmark* Court's statement that a plaintiff suing under Section 1125(a) "ordinarily must show economic or reputational injury flowing directly from the deception wrought by the defendant's advertising; and that that occurs when deception of consumers causes them to withhold trade from the plaintiff." *Lexmark*, 572 U.S. at 133; (*see also* D.I. 9 at 1; D.I. 15 at 4; Tr. at 16). Yet in the Court's view, this one statement cannot be fairly interpreted to mean that a plaintiff can only plead proximate cause if: (1) the defendant has actually sold a product; and (2) the defendant's statements have already caused consumers to buy defendant's product instead of the plaintiff's product. Indeed, the *Lexmark* Court suggested that this would "ordinarily" be the way in which a Lanham Act plaintiff shows proximate cause—thus seeming to leave room for other pathways to proximate cause (i.e., if there was the prospect of likely *future* injury to sales or a plaintiff's economic interests).[6] And further, *Lexmark* additionally emphasizes in another way that prior loss-of-sale-related injury is not the only injury that matters under the Act, when it notes that "[t]o invoke the Lanham Act's cause of action for false advertising, a plaintiff must plead (and ultimately prove)

---

[6] Courts have consistently indicated that a plaintiff has standing to bring a false advertising claim where it sufficiently alleges that it is *likely* to be damaged by a defendant's false representations. *See, e.g.*, *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 595 (3d Cir. 2002) ("[A]s a matter of standing and as a substantive element of a Lanham Act violation, the plaintiff must demonstrate a reasonable basis for the belief that the plaintiff *is likely to be damaged* as a result of the false advertising.") (emphasis added) (internal quotation marks and citations omitted); *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1112 (2d Cir. 1997) ("[A] future 'potential for a commercial or competitive injury' can establish standing[.]"); *Berni v. Int'l Gourmet Restaurants of Am., Inc.*, 838 F.2d 642, 648 (2d Cir. 1988) ("[S]tanding to bring a section 43 claim requires the potential for a commercial or competitive injury."); *De Simone v. VSL Pharms., Inc.*, 395 F. Supp. 3d 617, 628 (D. Md. 2019) (explaining that the proximate cause element of a Lanham Act false advertising claim "does not require proof of actual damages such as lost sales to" the plaintiff as "the statute permits false advertising actions based on the *threat of injury alone*") (emphasis added).

an injury to a commercial interest in sales *or business reputation* proximately caused by the defendant's misrepresentations." *Lexmark*, 572 U.S. at 140 (emphasis added). In sum, in a Lanham Act false advertising case, if a plaintiff pleads facts plausibly indicating that a defendant's statements about the plaintiff's product will likely cause the plaintiff economic harm in the future (or that it has or will otherwise cause the plaintiff reputational harm), that could well satisfy the proximate cause requirement, even if there has been no sales yet lost to the defendant's product.

This was the conclusion also reached by the United States District Court for the Northern District of Illinois ("Northern District of Illinois") in *Par Sterile Prods., LLC v. Fresenius Kabi USA LLC*, No. 14 C 3349, 2015 WL 1263041 (N.D. Ill. Mar. 17, 2015). In that case, the parties both manufactured and marketed vasopressin injection products. 2015 WL 1263041, at *1. The defendant's product was not FDA-approved, but it was on the market. *Id.* at *1-2. Meanwhile, the plaintiff developed and obtained FDA approval for its product, which was "fully developed" and "ready for sale." *Id.* at *2-3. The plaintiff filed suit against defendant, alleging that the defendant misrepresented its product as FDA-approved and that sales of the plaintiff's product would likely suffer due to such misrepresentations. *Id.* The defendant moved to dismiss the plaintiff's complaint, arguing that "a Lanham Act claim based on injury to a product that the plaintiff has not yet begun to sell must be dismissed for lack of standing." *Id.* at *2. The Northern District of Illinois Court disagreed. It found that the plaintiff's product was a "concrete competing product to compare with" the defendant's product, and that "[a]llegations that sales of [plaintiff's product] are *likely* to suffer due to misrepresentations made by [the defendant] in advertising or promoting [defendant's product] are sufficient to satisfy the Lanham Act's standing requirement." *Id.* at *3 (emphasis in original).

Natera tries to distinguish *Par Sterile Prods.* by pointing out that there, it was the defendant who was already selling a product and the plaintiff whose product was not yet being sold. (D.I. 15 at 5; Tr. at 31) But in the Court's view, that is a distinction without a meaningful difference. Just as a Lanham Act plaintiff (as in *Par Sterile Prods.*) can demonstrate the likelihood of future injury relating to its own, soon-to-be-sold product (due to a defendant/competitor's allegedly false comparative statements about its own on-the-market product and the plaintiff's product), so too can a Lanham Act plaintiff (as here) demonstrate the likelihood of future injury relating to its own on-the-market product (due to a defendant/competitor's allegedly false comparative statements about its own soon-to-be-sold product and the plaintiff's product). In both scenarios, the likely economic injury is in the future.[7]

Of course, as was noted by the *Par Sterile Prods.* Court, if a plaintiff is asserting that the *likelihood of future economic harm* is what is at issue, then its allegations still have to sufficiently show that the prospect of such harm is concrete and imminent. But here—as with

---

[7] The Court acknowledges that it sounds a little unusual to think about proximate causation in terms of an injury that has not yet occurred. Typically, proximate cause is discussed in terms of a sufficient linkage between an act that has resulted in a currently-felt, tangible injury. Yet in the tort/negligence context, at least according to the law of some states, proximate causation is seen as a concept related to both current and future injury. *See, e.g.*, *Jutzi-Johnson v. United States*, 263 F.3d 753, 763–64 (7th Cir. 2001) ("Under Illinois law, 'proximate cause can only be established when there is a reasonable certainty that the defendant's acts caused the injury' or the increased risk of future injury.") (internal quotation marks and citation omitted). And here, as discussed above, the text of the Lanham Act *requires* that we conceive of proximate causation in this way.

the plaintiff's product in *Par Sterile Prods.*[8]—CareDx's allegations regarding Prospera fit this bill. For example, the Complaint alleges that:

(1) "Natera is *in the midst* of launching" Prospera, (D.I. 1 at ¶ 3 (emphasis added));

(2) "Natera is actively advertising and seeking Medicare coverage for Prospera[,]" (*id.* at ¶ 11); and

(3) "Natera has begun significant marketing efforts for Prospera, including by making Prospera available for use in clinical trials and marketing Prospera to major clinical centers for such use[,]" (*id.* at ¶ 52).

The Complaint thus demonstrates that Prospera is not some speculative, who-knows-if-it-will-ever-be-developed product. And so the comparison of this case to the holding in *Par Sterile Prods.* is an apt one.

In light of all of the above, the fact that CareDx has not pointed to a specific, already-lost sale is not dispositive of CareDx's false advertising claim. CareDx's Complaint alleges that

---

[8] In *Par Sterile Prods.*, the defendant had cited three purportedly similar cases in support of its argument that the plaintiff's basis for statutory standing was insufficiently concrete. The Northern District of Illinois Court distinguished these cases, however, on the ground that they all involved alleged harm that was "remote, speculative and ill-defined." *Id.* at *2-3. For example, in *ITC Ltd v. Punchgini, Inc.*, 482 F.3d 135 (2d Cir. 2007), the United States Court of Appeals for the Second Circuit affirmed the district court's dismissal of the plaintiff's false advertising claim for lack of standing, where the plaintiff's plan to open a new Bukhara restaurant in the United States was "too ill-defined[,]" particularly in light of the plaintiff's abandonment of its registered Bukhara mark for restaurant services. 482 F.3d at 170. In *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105 (2d Cir. 1997), the Second Circuit explained that the defendant's hopes of eventually obtaining FDA approval for its product (which would have required further studies and testing that would cost at least $1,500,000) for a product are "too remote at this stage to confer standing" to bring a false advertising claim. 103 F.3d at 1112 & n.7. And in *Alphamed Pharms. Corp. v. Arriva Pharms., Inc.*, 391 F. Supp. 2d 1148 (S.D. Fla. 2005), the United States District Court for the Southern District of Florida found that the plaintiff lacked standing to make a Lanham Act claim where the plaintiff did not "have a present *or imminent* [] drug on the market"; instead, it only had a "speculative" product, and had only alleged injury through loss of investors (not consumers). 391 F. Supp. 2d at 1161-63 (emphasis added).

Natera is making statements to the effect that CareDx's product is inferior to Natera's product, and that these statements "have harmed and will continue to harm CareDx through loss of goodwill, reputation, profits, and prospective business contracts." (*Id.* at ¶ 51; *see also id.* at ¶ 6; *id.* at ¶ 59 ("Natera's false and misleading statements are material and will affect the purchasing and investment decisions of healthcare providers, patients, and insurance companies."); D.I. 13 at 8; Tr. at 55) That is sufficient here, as CareDx has, at a minimum, credibly alleged that: (1) it is likely to suffer future lost sales because of Natera's allegedly false statements; and (2) it has suffered reputational harm because of such statements. *Cf. Obesity Research Inst., LLC v. Fiber Research Int'l, LLC*, 165 F. Supp. 3d 937, 947 (S.D. Cal. 2016) (finding that plaintiff "sufficiently alleged economic or reputation injury proximately caused by [the defendant's] deception" where plaintiff alleged that it has been injured by a loss of goodwill caused by the defendant's passing off an inferior product as the same as plaintiff's own product).

Lastly, with respect to Natera's assertion that CareDx cannot sufficiently plead proximate cause because the parties are not "competitors," *see, e.g.*, *supra* n.4, the Court also disagrees. Indeed, the allegations in the Complaint *do* demonstrate competition between the parties. In the Complaint, for example, CareDx alleges that:

> Competitor Natera . . . has begun a false advertising campaign designed to deceive doctors, healthcare professionals, insurance companies, and patients—as well as investors—into believing that Natera's "me too" test is superior to AlloSure. . . .
>
> CareDx is informed and believes that Natera has taken improper advantage of CareDx's pioneering work to develop a competing kidney transplant rejection test. Upon information and belief, Natera is in the midst of launching its competing test, Prospera[.] (D.I. 1 at ¶¶ 1, 3; *see also id.* at ¶ 51)

And as was previously referenced above, the Natera Statements in the Complaint have *Natera* repeatedly referring to the CareDx Study (and the AlloSure assay at issue therein) as the "competition." (*Id.* at ¶¶ 40-49; *see also* D.I. 13 at 7 ("[T]here is no question that Natera is actively making head-to-head comparisons, falsely claiming that Prospera is superior to AlloSure."); Tr. at 28, 51) That this "competition" is of a type where the parties' products are not *both* being sold (but likely will be soon) is not a barrier to setting out proximate cause.[9]

For the above reasons, the Court concludes that the allegations in the Complaint adequately establish proximate cause. The Court will next assess whether the Complaint sufficiently pleads facts necessary to plausibly meet other challenged elements of CareDx's false advertising claim.

2. The Other Elements of a False Advertising Claim

To establish a *prima facie* claim of false advertising under the Lanham Act, a plaintiff must sufficiently allege: (1) that the defendant has made false or misleading statements as to the defendant's own product or another's; (2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience; (3) that the deception is material in that it is likely to influence purchasing decisions; (4) that the advertised goods traveled in interstate commerce; and (5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc. *Pernod Ricard USA, LLC v. Bacardi U.S.A., Inc.*, 653 F.3d 241, 248 (3d

---

[9] During oral argument, Natera's counsel attempted to downplay the relevance of citations to "competition" in the Natera Statements. Counsel asserted that in these statements, Natera was not comparing its *product* with CareDx's *product*; instead, "Natera [was saying] that there are competing *assays*[,]" which are scientific studies undertaken to evaluate products. (Tr. at 14-16 (emphasis added); *see also id.* at 73-74; D.I. 15 at 6) Natera's attempted distinction is not persuasive to the Court, as the assays in question *directly relate to* the parties' respective products. (Tr. at 15, 51-52)

Cir. 2011); *The Reybold Grp. of Cos., Inc. v. Does 1-20*, 323 F.R.D. 205, 209-10 (D. Del. 2017). Natera argues that CareDx's Complaint fails to plead factual allegations in support of four of these five elements necessary to make out a false advertising claim. (D.I. 9 at 10-14; D.I. 15 at 5-8)[10] Below, the Court addresses each of the four disputed elements in turn, explaining why as to each, the Complaint's allegations are sufficient.

a. Element One: False or Misleading Statements

With respect to the first element of a false advertising claim, Natera asserts that CareDx has failed to plead facts showing that any of the Natera Statements were false or misleading. (D.I. 9 at 11-12; D.I. 15 at 6) Natera contends that CareDx fails to allege that any of the study data cited in the Natera Statements was falsely reported; thus, Natera argues that all that is implicated here is "an apparent scientific disagreement about the impact of the" Natera Study. (D.I. 9 at 11) It asserts that raising this type of "disagreement" is not sufficient to establish a valid false advertising claim. (*Id.* at 11-12)

CareDx responds by asserting that the Natera Statements are "establishment claim[s]." (D.I. 13 at 12; CareDx's Motion Presentation, Slide 24; Tr. at 95) Establishment claims are "advertisements that represent explicitly or implicitly . . . that tests or studies prove [a] product superior." *Ferring Pharms. Inc. v. Braintree Labs., Inc.*, 38 F. Supp. 3d 169, 184 (D. Mass. 2014) (internal quotation marks and citations omitted); *see also, e.g.*, *Syncsort Inc. v. Sequential Software, Inc.*, 50 F. Supp. 2d 318, 341 (D.N.J. 1999) (noting that establishment claims make assertions of product superiority based upon measurable tests). A plaintiff may satisfy its burden of showing that an establishment claim is false or misleading under the Lanham Act by proving

[10] The fourth element (that the advertised goods traveled in interstate commerce) is the only element that Natera does not challenge.

that the tests referred to in the advertisement were not sufficiently reliable to permit one to conclude with reasonable certainty that they established the proposition for which they were cited. *See Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc.*, 299 F.3d 1242, 1249 n.6 (11th Cir. 2002); *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997); *Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 62-63 (2d Cir. 1992); *Dyson, Inc. v. Euro-Pro Operating LLC*, Case No. 14 C 9442, 2015 WL 1120006, at *12 (N.D. Ill. Mar. 10, 2015); *Ferring Pharms.*, 38 F. Supp. 3d at 184; *Fed. Express Corp. v. United Parcel Serv., Inc.*, 765 F. Supp. 2d 1011, 1018 (W.D. Tenn. 2010).

To that end, CareDx's Complaint alleges that Natera—by way of the Natera Statements—has made "false, misleading, and harmful representations about the Natera Study's results[.]" (D.I. 1 at ¶¶ 39-49) These Natera Statements refer to data from the Natera Study and state that the performance of the assay related to Prospera compares favorably against the competition (i.e., the assay related to AlloSure). (*Id.*) Critically, the Complaint also includes detailed allegations as to *why* CareDx believes the Natera Study to be flawed and unreliable. For example, CareDx alleges that the Natera Study analyzed unrepresentative samples, included "suspicious" results, improperly mixed population sets and violated well-known criteria for the diagnosis of kidney rejections. (*Id.* at ¶¶ 27-36; CareDx's Motion Presentation, Slides 28-31) Meanwhile, the Complaint alleges how the CareDx Study, in contrast, was robust and reliable. (D.I. 1 at ¶¶ 21, 28-30, 33, 35, 37)

These allegations, taken together, are sufficient to plausibly allege the first element of a false advertising claim under the Lanham Act. Accepting the allegations as true, they establish that the test results upon which the Natera Statements are based are insufficiently reliable. Therefore, when Defendant allegedly compared those test results to the results of the CareDx

Study, it made actionably false and misleading representations of superiority. (*See id.* at ¶ 37; CareDx's Motion Presentation, Slide 32)[11]

In arguing to the contrary, Natera points out that the Natera Statements "involve only the results in the studies" and do not expressly compare "Prospera" and "AlloSure." (D.I. 15 at 6) But while it may be true that the Natera Statements do not expressly compare "AlloSure" and "Prospera," they *do* expressly compare the assays that *directly relate to these products*. It is thus likely that individuals exposed to the Natera Statements will link them to the parties' respective tests (i.e., Prospera and AlloSure), and so CareDx's allegations that "Natera is making various false and misleading claims that Prospera is superior to CareDx's AlloSure based upon [the Natera Study]" are plausible. (D.I. 1 at ¶ 3); *cf. Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497

---

[11] *See, e.g.*, *Clorox Co. v. Reckitt Benckiser Grp. PLC*, 398 F. Supp. 3d 623, 641 (N.D. Cal. 2019) ("Because Clorox has alleged a factual basis for putting into doubt whether [the strength tests in advertisements showing Clorox wipes ripping when trying to support a kettlebell while Lysol wipes remain intact for much longer are] sufficiently reliable to permit one to conclude with reasonable certainty that [they] established the claim made, it has done enough to plead that the test is literally false.") (internal quotation marks and citation omitted); *Biolase, Inc. v. Fotona Proizvodnja Optoelektronskih Naprav D. D.*, Case No. SACV 14-0248 AG (ANx), 2014 WL 12577153, at *3 (C.D. Cal. Sept. 15, 2014) (finding that the plaintiff adequately stated a claim for false advertising where the complaint alleged that the defendant falsely advertised its lasers as superior to the plaintiff's lasers, and that some of the tests the defendant relied upon "were performed in settings inapplicable to clinical use, and therefore do not support clinical superiority claims"); *Fed. Express Corp.*, 765 F. Supp. 2d at 1020 (finding that plaintiff set forth sufficient facts to state a claim for literal falsity based on unreliability of the survey that was the basis of defendant's advertisement, where the plaintiff alleged that the "margin of error was too high, the sample size was insufficient, the participants were not sufficiently screened, the questions and responses were too narrow, and the structure, execution, and methodology were flawed"); *Syncsort Inc.*, 50 F. Supp. 2d at 342-43 (finding that defendant pleaded the essential elements of false advertising counterclaim under the Lanham Act where the plaintiff's advertisements referred to benchmark tests as establishing that plaintiff's product was the fastest sort product in the world, but accepting the defendant's allegations as true, the test results upon which plaintiff based its claims of superiority may prove to be an inaccurate measure of the speed of sort products).

F.3d 144, 162 (2d Cir. 2007) (in assessing whether the plaintiff was likely to suffer irreparable harm in connection with a motion for preliminary injunction under the Lanham Act, finding that the fact that the commercial at issue "does not name plaintiff's product is not necessarily dispositive[,]" as it would be obvious to consumers that the defendant's claims of superiority are "aimed at diminishing the value of cable[, which is] synonymous with" plaintiff's product).

Natera also argues that CareDx's allegations fail "as a matter of law" because a false advertising claim cannot be premised on matters about which there is legitimate ongoing "scientific disagreement[.]" (D.I. 9 at 11; Tr. at 79-80) In support, Natera relies on *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490 (2d Cir. 2013) and *Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc.*, 299 F.3d 1242 (11th Cir. 2002).

The Court is not persuaded. In *ONY*, the plaintiff alleged that a published, peer-reviewed scientific paper contained false and misleading statements, and that it therefore constituted false advertising. 720 F.3d at 496-97. The district court granted the defendant's motion to dismiss, finding that the article's statements were statements of opinion protected under the First Amendment and thus were not actionable under the Lanham Act. *Id.* The United States Court of Appeals for the Second Circuit affirmed, explaining that "to the extent a speaker or author draws conclusions from non-fraudulent data, based on accurate descriptions of the data and methodology underlying those conclusions, on subjects about which there is legitimate ongoing scientific disagreement, those statements are not grounds for a claim of false advertising under the Lanham Act." *Id.* at 498. Yet whatever the merit of the Second Circuit's legal conclusions in *ONY*, (D.I. 13 at 10; Tr. at 104), at a minimum, this case is not like that one. Here, unlike in *ONY*, CareDx does not challenge statements made in the Natera Study Publication itself. Instead, CareDx challenges statements made in Natera's press releases and other advertising

materials that compare the results of the Natera Study with the results of the CareDx Study. (D.I. 13 at 10); *see also, e.g.*, *Eastman Chem. Co. v. Plastipure, Inc.*, 775 F.3d 230, 236 (5th Cir. 2014) (distinguishing *ONY* from the facts before it where "Eastman did not sue Appellants for publishing an article in a scientific journal. Rather, Eastman sought to enjoin statements made in commercial advertisements and directed at customers"). Advertisements are not immune from Lanham Act protection just because their claims may have some relation to areas of scientific debate. *See Eastman*, 775 F.3d at 237 ("The First Amendment ensures a robust discourse in the pages of academic journals, but it does not immunize false or misleading commercial claims."); *see also, e.g.*, *PAX Water Techs., Inc. v. Medora Corp.*, Case No. LA CV18-09143 JAK (AGRx), 2019 WL 4390567, at *6 (C.D. Cal. Aug. 5, 2019) (finding that plaintiffs' complaint adequately alleged that an advertisement contained false statements of fact, where it alleged the study discussed therein was based on a flawed premise, leading to the incorrect conclusion that the defendant's mixer outperformed the plaintiff's mixer).

And *Johnson & Johnson* too is inaopposite. There, the plaintiff did not contest the reliability of the survey cited in the advertisement at issue. *Johnson & Johnson*, 299 F.3d at 1249 n.6. Here, meanwhile, the alleged unreliability of the Natera Study constitutes the entire basis for CareDx's claim.

For all of these reasons, CareDx has sufficiently pleaded the first element of a Lanham Act false advertising claim.

b. Elements Two and Three: Deception and Materiality

With respect to elements two and three of a false advertising claim under the Lanham Act, Natera argues that CareDx has failed to plead any facts showing that: (1) Natera's

statements actually deceived anyone; or (2) the statements materially influenced a purchasing decision. (D.I. 9 at 12-13; D.I. 15 at 7-8) CareDx's Complaint alleges that:

- "Natera's false and misleading statements likely have (and, unless stopped, will continue to) deceive healthcare providers, insurance companies, patients, and the general public about the capabilities and accuracy of AlloSure." (D.I. 1 at ¶ 58); and

- "Natera's false and misleading statements are material and will affect the purchasing and investment decisions of healthcare providers, patients, and insurance companies." (*Id.* at ¶ 59)

With regard to Natera's argument regarding alleged deception, CareDx retorts that it need not identify a specific individual who was actually deceived at this stage. (D.I. 13 at 13) Instead, CareDx argues that because it has alleged that the Natera Statements are literally false, it is entitled to a presumption of deception under the law. (*Id.*); *see, e.g.*, *Syncsort*, 50 F. Supp. 2d at 341 ("If a complaint sufficiently alleges literal falsehood, it need not also allege the buying public was misled."); *see also, e.g.*, *Rimini Street, Inc. v. Oracle Int'l Corp.*, Case No. 2:14-cv-1699-LRH-CWH, 2017 WL 4227939, at *8 (D. Nev. Sept. 22, 2017) ("Oracle has plead sufficient facts in its third amended counterclaims demonstrating that Rimini Street's statements were literally false and thus, Oracle is entitled to a presumption of materiality and consumer deception."); *Genzyme Corp. v. Shire Human Genetic Therapies, Inc.*, 906 F. Supp. 2d 9, 17-18 (D. Mass. 2012) ("At the pleading stage[,] Genzyme is entitled to the benefit of a presumption of consumer deception because it has alleged the dissemination of literally false statements."); *cf. Pernod Ricard*, 653 F.3d at 248 ("[A]ctual deception or a tendency to deceive is presumed if a plaintiff proves that an advertisement is unambiguous and literally false.").

Natera fights back by asserting that while CareDx has "merely label[ed]" the Natera Statements as literally false in its Complaint, this label is clearly inaccurate, since none of the allegations suggest that Natera has "misstated the published findings" found in the Natera Study. (D.I. 15 at 7) And in the context of establishment claims like this one, to be sure, the line between literal falsity and misleading statements can seem a fine one. *See, e.g.*, *Riddell, Inc. v. Schutt Sports, Inc.*, 724 F. Supp. 2d 963, 971–72 (W.D. Wis. 2010). However, courts reviewing such establishment claims have repeatedly determined that when a defendant makes comparative statements based on testing that is flawed and unreliable, those statements (e.g., here, that Natera's product "compares favorably" to CareDx's product, or is supported by "superior" data, or "outperforms" the CareDx product) are appropriately viewed as literally false statements. *See, e.g.*, *Clorox Co.*, 398 F. Supp. 3d at 641; *Genzyme Corp.*, 906 F. Supp. 2d at 17-18; *Fed. Express Corp.*, 765 F. Supp. 2d at 1018-19. The Court cannot say that this is an incorrect way to view the statements at issue in this case.

As for the materiality element of a false advertising claim, a plaintiff must show that the defendant's misrepresentation is "material, in that it is likely to influence [a] purchasing decision." *U.S. Healthcare, Inc. v. Blue Cross of Greater Phila.*, 898 F.2d 914, 922 (3d Cir. 1990) (internal quotation marks and citation omitted). Natera asserts that since Prospera is not yet on the market, there are no "'purchasing decisions' to affect[.]" (D.I. 15 at 8)

However, the Court is not persuaded that Natera must make a sale before CareDx can sufficiently plead materiality. Natera cites to no support for that proposition. And, as explained above, the Lanham Act is intended to protect not only plaintiffs that have been previously damaged by false advertisements, but also plaintiffs that are *likely* to be damaged by such advertisements. Indeed, courts generally do not require that a plaintiff demonstrate an actual

effect on purchasing decisions; rather, a "likely" effect on consumer choice is sufficient. *See, e.g.*, *U.S. Healthcare*, 898 F.2d at 922; *e-ImageData Corp. v. Dig. Check Corp.*, Case No. 15-CV-658, 2018 WL 1411226, at *3 (E.D. Wis. Mar. 21, 2018).

Here, CareDx alleges that Natera's false and misleading statements represent that the Natera Study demonstrated Prospera's superiority over AlloSure, including because Prospera detects kidney rejection better than AlloSure, because the Natera Test is reliable, and because the results of the Natera Test can be used to support claims comparing Prospera and AlloSure. (D.I. 1 at ¶ 55) And CareDx alleges that these statements are "material and will affect the purchasing and investment decisions of healthcare providers, patients, and insurance companies." (*Id.* at ¶ 59) Accepting these allegations as true, it does seem plausible that the Natera Statements will, *inter alia*, likely affect future purchasing decisions by consumers to whom the Prospera test is now or will be marketed. After becoming aware of the Natera Statements, it stands to reason that such consumers needing to test kidney transplant rejection would desire the supposedly superior Prospera test over AlloSure. (D.I. 13 at 13-14); *see, e.g.*, *10X Genomics, Inc. v. Celsee, Inc.*, Civil Action No. 19-862-CFC-SRF, 2019 WL 5595666, at *6 (D. Del. Oct. 30, 2019) (finding that the complaint adequately alleged that the false or misleading statements made by the defendant regarding the cell capture rate of its product were material because they are likely to influence the purchasing decisions of a consumer, since cell capture rate is an important criterion of system performance and efficiency); *Telebrands Corp. v. Ragner Tech. Corp.*, Civil Action No. 16-3474 (ES) (MAH), 2019 WL 1468156, at *4 (D.N.J. Apr. 3, 2019) (finding that the plaintiff sufficiently pleaded materiality as "[a]t the motion-to-dismiss stage, the Court cannot say that allegedly false advertisements touting a product's high strength would not influence purchase decisions").

For these reasons, CareDx has sufficiently pleaded elements two and three of a false advertising claim under the Lanham Act.

c. Element 5: Likelihood of Injury to CareDx

With regard to the fifth element of a Lanham Act false advertising claim, Natera argues that CareDx does not allege any facts that show that CareDx has suffered injury due to the Natera Statements. (D.I. 9 at 13-14; D.I. 15 at 8) Yet again, the Court disagrees that CareDx's allegations are lacking.

As CareDx points out, (D.I. 13 at 14; CareDx's Motion Presentation, Slide 45), the United States Court of Appeals for the Third Circuit has held that as a substantive element of a Lanham Act violation, a plaintiff must establish only "a reasonable basis for the belief that the plaintiff is *likely to be damaged* as a result of the false advertising[,]" *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 595 (3d Cir. 2002) (emphasis added) (internal quotation marks and citations omitted);[12] *cf. Accu-Sort Sys., Inc. v. Lazerdata Corp.*, 820 F. Supp. 928, 931 (E.D. Pa. 1993) (finding that the plaintiff carried its burden regarding the injury element of a Lanham Act claim at the summary judgment stage, where a reasonable jury could conclude that the plaintiff was "likely" to be injured if the defendant's assertions are false). And as the Court explained above when assessing proximate cause, CareDx's Complaint alleges that it is likely to suffer future lost sales because of Natera's

---

[12] Natera retorts that *Novartis* had to do with a preliminary injunction motion and that it is thus inapposite. (D.I. 15 at 8 & n.6) While it is true that the *Novartis* Court was reviewing the district court's decision in issuing a preliminary injunction, the *Novartis* Court differentiated between the standard for evaluating whether a plaintiff seeking a preliminary injunction would suffer irreparable harm in the absence of an injunction (i.e., potential harm that cannot be redressed following trial) and the standard applicable to the fifth element of a Lanham Act false advertising claim (i.e., a reasonable basis to believe a plaintiff is likely to suffer injury). *Novartis*, 290 F.3d at 595. CareDx applies the right standard here.

allegedly false statements, and that it has been harmed by damage to its reputation because of such statements. These allegations are sufficient to establish the fifth injury-related element of a Lanham Act false advertising claim. *See, e.g.*, *Krupa v. Platinum Plus, LLC*, Case No. 8:16-cv-3189-T-33MAP, 2017 WL 1050222, at *4 (M.D. Fla. Mar. 20, 2017) (finding that the plaintiffs' allegations gave rise to a plausible claim to relief with respect to the injury element of a Lanham Act false advertising claim, where the plaintiffs alleged damage to their respective brands, which in turn negatively affects future earning capacity).

B. CareDx's Other Claims

The Court now assesses Natera's arguments for dismissal of CareDx's remaining claims.

1. "Trademark Disparagement" or Trade Disparagement (Count Two)

Count Two of CareDx's Complaint seeks relief for "Trademark Disparagement Under Lanham Act 15 U.S.C. § 1114(1)." (D.I. 1 at ¶¶ 61-66) Natera moves to dismiss this claim because the Lanham Act "does not contemplate a cause of action for trademark 'disparagement[.]'" (D.I. 9 at 14-15) In response, CareDx explains that it intended to state a cause of action for "trade disparagement" under the Lanham Act and that it mistakenly cited to the wrong portion of the Lanham Act in doing so. (D.I. 13 at 15-16; Tr. at 119); *see also Parker v. Google, Inc.*, 242 F. App'x 833, 838-39 (Fed. Cir. 2007) (noting that a plaintiff can bring a claim for trade disparagement under the Lanham Act).

As of now, Count Two is decidedly unclear on its face as to what type of claim it actually means to plead (or how that claim, whatever it is, meaningfully differs from the false advertising Lanham Act claim set out in Count One). And a plaintiff cannot amend its complaint by way of arguments set out in a brief opposing a motion to dismiss. *See, e.g.*, *Mason v. Delaware*, Civ. No. 15-1191-LPS, 2017 WL 4070741, at *3 (D. Del. Sept. 14, 2017) (citing cases). For these

reasons, the Court recommends that the Motion be granted with respect to Count Two, and that CareDx be given an additional opportunity to clearly and properly plead this claim. *See* Fed. R. Civ. P. 15(a)(2).

2. Unfair Competition Under Delaware Law (Count Three)

Count Three of CareDx's Complaint alleges common law unfair competition; in its briefing, CareDx explained that this claim is brought pursuant to Delaware law. (D.I. 1 at ¶¶ 67-72; D.I. 13 at 16) The parties agree that Delaware courts recognize such a cause of action. (D.I. 13 at 16; D.I. 15 at 9-10) Under Delaware law, a plaintiff alleging this cause of action must plead facts showing "a reasonable expectancy of entering a valid business relationship, with which the defendant wrongly interferes, and thereby defeats the plaintiff's legitimate expectancy and causes him harm." *Agilent Techs., Inc. v. Kirkland*, C.A. No. 3512-VCS, 2009 WL 119865, at *5 (Del. Ch. Jan. 20, 2009) (internal quotation marks and citation omitted).

Here, while they certainly could have been more factually robust, CareDx's allegations sufficiently establish that: (1) it had a reasonable expectancy of entering into business relationships with patients and healthcare providers; (2) Natera's allegedly false and misleading statements likely have and will continue to deceive patients and healthcare providers (as well as insurance companies and the general public); and (3) harm has and will result by preventing CareDx from earning revenue and building goodwill. (D.I. 13 at 17 (citing D.I. 1 at ¶¶ 68-72)); *cf. GPNE Corp. v. Fleetmatics USA, LLC*, Civil Action No. 13-2049-SLR-SRF, 2015 WL 730046, at *9 (D. Del. Feb. 20, 2015) (denying the defendant's motion to dismiss plaintiff's common law claim for unfair competition where "Fleetmatics has pleaded that it had a reasonable expectancy of entering and continuing its valid business relationships with its customers, that GPNE interfered with those business relationships by wrongfully sending letters

to Fleetmatics' customers, and that GPNE's actions defeated Fleetmatics' expectancy and caused harm by preventing Fleetmatics from earning revenue"). The Court thus recommends that the Motion be denied with respect to Count Three.

3. Delaware Unfair or Deceptive Trade Practices Act (Count Four)

Count Four of the Complaint alleges that the Natera Statements violate the Delaware Unfair or Deceptive Trade Practices Act ("UDTPA"), Del. C. tit. 6, §§ 2531-36. (D.I. 1 at ¶¶ 73-81) Natera argues that CareDx's claim for relief under the UDTPA should be dismissed because the Complaint alleges violations of *every section* of the UDTPA, which is essentially the same as identifying no *particular* section. (D.I. 9 at 17-18; D.I. 15 at 10)

The Court agrees with Natera that Count Four is insufficiently pleaded. This is not only because CareDx did not specifically identify the statutory subsections that it means to put at issue. *See, e.g.*, *Kimberly-Clark Worldwide, Inc. v. Cardinal Health 200, LLC*, Civil Action No. 11-1228-RGA, 2012 WL 3063974, at *4 (D. Del. July 27, 2012) (explaining that defendant's counterclaim "ought to assert, at a minimum, a violation of a particular state's deceptive trade practices act, *including allegations of which subsection is violated*") (emphasis added).[13] It is also because the allegations in the Count are so bare-bones that they do not provide the Court with enough to go on, in order to figure out whether the Complaint's pleaded facts actually

[13] The Court can see how the language of certain paragraphs in Count Four tracks some of the language of certain subsections of Del. C. tit. 6, § 2532. Perhaps if the failure to identify by number the relevant subsections was the only flaw as to the Count, dismissal could be staved off. *See 10X Genomics*, 2019 WL 5595666, at *7 (denying a motion to dismiss the plaintiff's UDTPA claim where, even though the complaint did not expressly recite the numerical subsections of the statute at issue, the language of the complaint tracked the language of two subsections, thus providing sufficient notice to defendant of the relevant subsections of the statute).

substantiate the allegation. By way of one example of many, Count Four alleges that Natera made "false and misleading statements [that] represent that Prospera has uses or benefits that it does not have." (D.I. 1 at ¶ 76) But the Court is unsure about exactly what "uses or benefits" of Prospera are being referred to here, or which particular "statements" CareDx is referring to. The Court therefore recommends that the Motion be granted with respect to Count Four and that Plaintiff be given leave to re-plead the Count. If CareDx does so, it should then: (1) make clear which statutory subsections it means to invoke; and (2) provide more factual allegations in the Count as to which of the pleading's allegations are relevant to which statutory subsection.[14]

IV. CONCLUSION

For the foregoing reasons, the Court recommends that Natera's Motion be GRANTED-IN-PART and DENIED-IN-PART. More specifically, the Court recommends that the Motion be DENIED with respect to CareDx's false advertising claim under the Lanham Act and also with respect to CareDx's unfair competition claim under Delaware law. The Court recommends that the Motion be GRANTED without prejudice with respect to CareDx's claim for trademark disparagement, and with respect to its claim under the UDTPA. As to those latter two claims, the Court also recommends that if the District Court affirms its decision, CareDx be given 14 days to file an amended complaint.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections

---

[14] Natera also argues that CareDx's claim under the UDTPA is deficient because CareDx has failed to plead facts that show that the alleged statements reference (let alone misrepresent) any CareDx *product* (since the statements do not explicitly refer to AlloSure). (D.I. 15 at 10) However, as explained above with respect to CareDx's false advertising claim under the Lanham Act, the Court is not persuaded that the statements' failure to expressly refer to products absolves Natera from liability.

within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987); *Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006).

The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov.

Dated: December 20, 2019

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE