IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 24-505-JLH
	)	
MSN PHARMACEUTICALS, INC., MSN LABORATORIES PRIVATE LIMITED, AMNEAL PHARMACEUTICALS, INC. and IMPAX LABORATORIES, LLC,	)	REDACTED VERSION
	)	
Defendants.	)	

REPORT AND RECOMMENDATION

Presently pending before the Court in this action is Defendants MSN Pharmaceuticals, Inc., MSN Laboratories Private Limited (together, "MSN"), Amneal Pharmaceuticals, Inc. ("Amneal") and Impax Laboratories LLC's ("Impax" and together with MSN and Amneal, "Defendants") motion ("Motion") seeking: (1) dismissal of Plaintiff Vanda Pharmaceuticals, Inc.'s ("Vanda" or "Plaintiff") Complaint pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6); or (2) alternatively, the stay of this case pending resolution of Plaintiff's then-ongoing actions before the United States Food and Drug Administration ("FDA"). (D.I. 24) For the reasons set out below, the Court recommends that the motion be GRANTED-IN-PART and DENIED-IN-PART in the manner set out below.

I. BACKGROUND

A. Factual Background

1. Plaintiff and its NDA

Plaintiff Vanda is a pharmaceutical company that acquired the compound tasimelteon and developed it into Hetlioz®, a melatonin receptor agonist. (D.I. 2 at ¶¶ 7-8, 17, 27-29) Hetlioz is

a FDA-approved drug that treats two sleep-related health conditions: Non-24-Hour-Sleep-Wake Disorder ("Non-24") and nighttime sleep disturbances in individuals with Smith-Magnis Syndrome. (*Id*. at ¶¶ 8, 27-30) Plaintiff received FDA approval for Hetlioz for the treatment of Non-24, after submission of its New Drug Application ("NDA") Number 205677. (*Id*. at ¶ 31)

2. Defendants and the Submission of the ANDA

Defendants are also pharmaceutical companies. (*Id*. at ¶¶ 18-23) In 2018, MSN, a generic drug manufacturer, submitted Abbreviated New Drug Application ("ANDA") Number 211654 seeking FDA approval of a generic tasimelteon product (also the "generic drug" or "generic product"). (*Id*. at ¶¶ 9, 72) MSN supported its application with study that purported to show that its generic product was bioequivalent to Hetlioz (the "Bioequivalence Study"). (*Id*. at ¶¶ 9, 74-75; *see* D.I. 3, ex. 6) As will be further set out below, according to Plaintiff, MSN's Bioequivalence Study was fundamentally flawed, unreliable and insufficient to support granting the ANDA. (D.I. 2 at ¶¶ 10-11, 14) Also included in MSN's ANDA was a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) stating that MSN's generic product would not infringe Plaintiff's patents relating to tasimelteon for treatment of Non-24 and that those patents are invalid or unenforceable. (*Id*. at ¶ 102)

[redacted]. (*Id*. at ¶ 23) Amneal is an affiliate of Impax. (*Id*.)

3. Related Litigation, Tentative Approval of the ADNA and the License Agreement

On May 7, 2018, Plaintiff filed the first of many related lawsuits against MSN in this Court for patent infringement pursuant to the Hatch-Waxman Act. (*Id*. at ¶¶ 12, 103); *see also Vanda Pharms., Inc. v. MSN Pharms., Inc.*, Civil Action Nos. 18-690-CFC, 19-926-CFC, 20-

235-CFC, 20-318-CFC, 20-1334-CFC, 21-283-CFC (D. Del.). The FDA tentatively approved MSN's ANDA on May 28, 2020. (D.I. 2 at ¶ 98; D.I. 3, ex. 14 (the "Tentative Approval Letter"))

On January 13, 2022, the parties settled the litigation and entered into a license agreement (the "License Agreement"); [redacted] (D.I. 2 at ¶¶ 12, 104-05; *id*., ex. 1) Plaintiff alleges that it would not have entered the License Agreement had it known of the flawed Bioequivalence Study and the distorted conclusions that followed—i.e., that the generic product was not in fact bioequivalent to Hetlioz. (*Id*. at ¶¶ 12, 106-08, 144)

4. Final Approval of the ANDA

On January 12, 2023, the FDA granted final approval of MSN's ANDA with an AB-rating for treatment of Non-24 in patients. (*Id*. at ¶¶ 13, 98-100; D.I. 3, ex. 5 (the "Approval Package")) The related Approval Package included an approval letter (the "Approval Letter"), (D.I. 3, ex. 5 at 3-10), and an FDA-approved label for the generic product, (the "Generic Label"), (*id*. at 11-23). Defendants have since brought the generic drug to market. (D.I. 2 at ¶¶ 13, 111)

Additional facts relevant to resolution of the instant Motion will be discussed in Section III.

B. Procedural Background

Plaintiff commenced this action on April 23, 2024, via which it seeks to rescind the License Agreement, enjoin Defendants from engaging in allegedly false and misleading advertising regarding their generic product, and recover money damages that it has purportedly suffered as a result of Defendants' conduct. (*Id*. at ¶ 16) In the Complaint, Plaintiff asserts six Counts against all Defendants; the Counts allege as follows:

- Count I: False Advertising in violation of § 43(a) of the Lanham Act ("Section 43(a)"), 15 U.S.C. § 1125(a). (*Id.* at ¶¶ 133-41) Here, Plaintiff alleges, *inter alia*, that Defendants engaged in false or misleading advertising when they: (1) identified Hetlioz on Amneal's website as the "Brand Reference" for their generic product, when the reference product used in Defendants' Bioequivalence Study was not actually Hetlioz, or where the study was otherwise so flawed that it undermines any assertion that Defendants' product is bioequivalent to Hetlioz; and (2) inaccurately described their product on Amneal's label, by making false statements about the mean-elimination half-life of the generic and reference drug and about the peak concentration of their drug after oral administration. (*Id.* at ¶¶ 114-18, 125-31);

- Count II: Fraudulent Inducement under Delaware common law. (*Id.* at ¶¶ 142-51) Here, Plaintiff alleges that Defendants deliberately concealed material facts (i.e., the data discrepancies, study design flaws and labeling inaccuracies discussed above) regarding the equivalence of their product to Hetlioz, and that it wouldn't have entered into the License Agreement if it had known about these facts. (*Id.* at ¶¶ 106, 144-45, 149);

- Count III: Breach of Express Representation under Delaware common law. (*Id.* at ¶¶ 152-59) Here, Plaintiff alleges that Defendants [redacted] they assert that Defendants sale and offer of their generic product violated many laws, including the Lanham Act, state unfair competition laws, the Delaware Deceptive Trade Practices Act ("DDTPA") and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 ("FDCA"). (*Id.* at ¶¶ 153-58; *see also id.*, ex. 1 at § 6.1);[1]

- Count IV: Deceptive Trade Practices in violation of the DDTPA, 6 Del. C. § 2532(a). (*Id.* at ¶¶ 160-68) Here, Plaintiff alleges that the false statements and misrepresentations described as to Count I also amount to deceptive trade practices under the DDTPA. (*Id.* at ¶ 161)

- Count V: Unfair Competition under Delaware common law. (*Id.* at ¶¶ 169-73) Here, Plaintiff asserts that it had a

[1] The Court will refer to Counts II and III herein as the "contract-based claims."

reasonable expectation of entering into business relationships with various purchasers of Hetlioz, and that Defendants wrongfully interfered with those relationships by making the false or misleading representations discussed as to Count I, causing harm. (*Id*.)

- Count VI: Fraud In Connection with Sale or Advertisement of Merchandise in violation of the New Jersey Consumer Fraud Act, N.J. Stat. § 56:8-2. (*Id*. at ¶¶ 174-78) Here, Plaintiff alleges that by violating the Lanham Act, the DDTPA and Delaware's unfair competition law, and by making the misrepresentations discussed as to Count I, Defendants engaged in unlawful practice, causing loss to Plaintiff. (*Id*.)[2]

Defendants filed the instant Motion on July 31, 2024. (D.I. 24) The Motion was fully briefed as of October 14, 2024. (D.I. 34) The Motion was referred to the Court for resolution by United States District Judge Jennifer L. Hall on December 13, 2024. (D.I. 36)

II. DISCUSSION

With the Motion, Defendants seek dismissal of all six Counts in Plaintiff's Complaint, for various reasons. (D.I. 25) The Court will address the merits of certain of these arguments below.

A. Standing

As an initial matter, Defendants challenge Plaintiff's Article III standing to bring all Counts, pursuant to Rule 12(b)(1). (D.I. 25 at 7-8) Below, the Court will first set out the relevant legal standards, and then it will briefly address the merits of Defendants' argument.

1. Legal Standards

Standing "is a constitutional requirement pursuant to Article III [of the United States Constitution] and . . . a threshold jurisdictional issue." *Abraxis Biosci., Inc. v. Navinta LLC*, 625

[2] The Court will refer to Counts I and IV-VI herein as the "false advertising claims" and to Counts IV-VI as the "state law false advertising claims."

F.3d 1359, 1363 (Fed. Cir. 2010) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)). A motion to dismiss for want of standing is properly brought pursuant to Rule 12(b)(1), because standing is a jurisdictional matter. *Ballentine v. United States*, 486 F.3d 806, 810 (3d Cir. 2007); *Samsung Elecs. Co. v. ON Semiconductor Corp.*, 541 F. Supp. 2d 645, 648 (D. Del. 2008). The plaintiff bears the burden of establishing its standing under Article III. *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 & n.3 (2006); *Puma Biotech., Inc. v. AstraZeneca Pharms. LP*, 723 F. Supp. 3d 327, 338 (D. Del. 2024).

To demonstrate constitutional standing, a plaintiff must establish three elements. That is, the plaintiff must show that: (1) it has suffered a concrete and particularized injury in fact that is actual or imminent; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely that the injury will be redressed by a favorable decision. *Lujan*, 504 U.S. at 560-61; *Freedom from Religion Found. Inc. v. New Kensington Arnold Sch. Dist.*, 832 F.3d 469, 476 (3d Cir. 2016).

A party's Rule 12(b)(1) motion regarding lack of standing may present either a facial or factual challenge. *Const. Pty. of Pa. v. Aichele*, 757 F.3d 347, 357-58 (3d Cir. 2014); *Samsung Elecs. Co.*, 541 F. Supp. 2d at 648. A facial challenge, which appears to be what is (or was) at issue here, (D.I. 30 at 3), is based "purely on the sufficiency of the allegations in the complaint and is reviewed under the same standard as a Rule 12(b)(6) motion[,]" *Harrison v. Soroof Int'l, Inc.*, 320 F. Supp. 3d 602, 610 (D. Del. 2018) (internal quotation marks and citation omitted). That is, "the Court must accept well-pled factual allegations as true and may consider only the complaint and any documents referenced therein or attached thereto." *Arneault v. Diamondhead*

Casino Corp., 277 F. Supp. 3d 671, 675 (D. Del. 2017); *see also In re Horizon Healthcare Servs. Inc. Data Breach Litig.*, 846 F.3d 625, 633 (3d Cir. 2017).[3]

2. Discussion

With regard to their standing challenge, Defendants' position appears to be confused, in various ways.

As an initial matter, Defendants' opening brief starts out by suggesting that all three elements of the standing inquiry will be at issue, when it asserts that "[t]here is no concrete and particularized injury-in-fact that is fairly traceable to Defendants' actions and likely to be redressed by a favorable court decision." (D.I. 25 at 7) But then, in the remainder of the portion of their opening brief relating to the standing issue, Defendants only seemed to take up the injury-in-fact element. (*Id*. at 7-8)

But even just focusing on Defendants' injury-in-fact argument, it cannot prevail. That is because it is not really a lack-of-standing argument at all. Indeed, as Plaintiff rightly notes, in "arguing a lack of standing[here, D]efendants confuse the standing inquiry with the merits." (D.I. 30 at 5) To that end, in the relevant portion of their opening brief, Defendants are not articulating why the Complaint fails to allege that Plaintiff suffered a concrete and particularized injury due to Defendants' conduct. Instead, there Defendants are arguing that the relevant allegations against them aren't *plausible* enough or *accurate* enough to support the relevant claims at the pleading stage. For example, Defendants assert that the claims fail here because

[3] On the other hand, a factual challenge to standing attaches no presumption of truthfulness "to plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims." *Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977); *see also Const. Pty. of Pa.*, 757 F.3d at 357-58.

they are premised on "*baseless* allegations" about how the Bioequivalence Study was flawed, or because Plaintiff lacks sufficient "*evidence*" to support "*plausible* allegations" that Defendants "committed any fraudulent acts[.]" (D.I. 25 at 7 (emphasis added)) As to Count II in particular, Defendants say the claim lacks standing because Plaintiff "fail[s] to make any *plausible* allegations for fraudulent inducement" such that that Count "should be dismissed as *implausible* on its face." (*Id.* at 7-8 (emphasis added)) And as to Counts I, III, and IV-VI, Defendants say that the allegations are wanting because they are premised on the fact that Defendants made reference to Hetlioz as the "Brand Reference" drug in their ANDA, or that Defendants made certain statements in their FDA-approved labeling—and in fact, all of those statements were "*true*." (*Id*. at 8 (emphasis added))

These are Rule 12(b)(6) lack-of-plausibility-type arguments—not arguments going to standing. Courts have explained that they must "separate [the] standing inquiry from any assessment of the merits of the plaintiff's claim[s]" and that in a standing inquiry, they must "assume . . . that a plaintiff has stated valid legal claims." *Cottrell v. Alcon Lab'ys*, 874 F.3d 154, 162 (3d Cir. 2017); *see also Davis v. Wells Fargo*, 824 F.3d 333, 348-49 (3d Cir. 2016) ("a district court must take care not to reach the merits of a case when deciding a Rule 12(b)(1) motion") (internal quotation marks and citation omitted). Yet in the "standing" section of their opening brief here, Defendants are wholly focused on arguing why Plaintiff's claims are *not* "valid." (D.I. 30 at 5) Indeed, perhaps Defendants realized this by the time of their reply brief—as therein, they make no more mention of the standing issue. (D.I. 34); *see also In re Seroquel XR (Extended Release Quetiapine Fumarate) Antitrust Litig.*, Master Docket No. 20-1076-CFC, 2022 WL 2438934, at *18 (D. Del. July 5, 2022).

Because Defendants' standing arguments don't really even go to core standing issues at all, the Court recommends that the Motion be denied with regard to the charge of lack of standing.

B. Challenges Brought Pursuant to Rule 12(b)(6)

Defendants additionally make a number of arguments as to why various claims should be dismissed pursuant to Rule 12(b)(6). Below, the Court sets out the relevant standard of review as to such allegations. Thereafter, it will address the merits of one such challenge to Count I, and then it will briefly discuss the status of the remaining state law claims.

1. Standard of Review

When presented with a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6), 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 "'accept all factual allegations as true, 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. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)).[4]

2. Discussion

a. Count I and Preclusion

Count I of the Complaint is a Lanham Act claim for false advertising. To state a clam for false advertising under the Lanham Act, a plaintiff must sufficiently allege: (1) that the defendant has made false or misleading statements in commercial advertising 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 Cir. 2011); *CareDx, Inc. v. Natera, Inc.*, Civil Action No. 19-662-CFC-CJB, 2019 WL 7037799, at *7 (D. Del. Dec. 20, 2019), *report and recommendation adopted,* 2020 WL 401773 (D. Del. Jan. 24, 2020).

[4] Below, the Court will at times rely on or reference information taken from the Approval Package for MSN's ANDA, the Bioequivalence Study, the Generic Label and the product catalog from Amneal's website. The Approval Package is referenced numerous times in the Complaint, (D.I. 2 at ¶¶ 72, 98-100), and is attached thereto as Exhibit 5, (D.I. 3, ex. 5). Defendants' Bioequivalence Study is discussed often in the Complaint, (D.I. 2 at ¶¶ 10-11, 74-97, 117-18, 144), and is attached as Exhibit 6, (D.I. 3, ex. 6). The Generic Label for the tasimelteon product is mentioned throughout the Complaint, (D.I. 2 at ¶¶ 15, 98, 111, 124-131, 137, 157, 161, 164), and is attached as Exhibit 16, (D.I. 3, ex. 16). Lastly, the product catalog from Amneal's website is cited in the Complaint, (D.I. 2 at ¶¶ 13, 106, 112-23, 157, 161, 164), and is attached as Exhibit 17, (D.I. 3, ex. 17). And so the Court may consider these documents in resolving the instant Rule 12(b)(6) motion. *See Buck v. Hampton Twp. Sch. Dist.*, 452 F.3d 256, 260 (3d Cir. 2006).

Defendants' initial challenge to Count I relates to the applicability of an affirmative defense: i.e., that this Lanham Act claim is precluded by the provisions of another federal statute, the FDCA. (D.I. 25 at 8-11) In the Court's view, that challenge has merit.

To explain why, the Court begins by noting that the FDCA and the Lanham Act are two distinct federal statutes that each do or can "regulate the advertising, marketing[] and labeling of drugs." *G&W Lab'ys, Inc. v. Laser Pharms., LLC*, Civil Action No. 3:17-cv-3974-BRM-DEA, 2018 WL 3031943, at *6 (D.N.J. June 19, 2018); *see Belcher Pharms., LLC v. Hospira, Inc.*, 1 F.4th 1374, 1377, 1379-80 (11th Cir. 2021). The Lanham Act was enacted to protect those in the market against unfair competition and prevent fraud and deception in commerce. 15 U.S.C. § 1127; *see Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 131 (2014). It creates a private right of action for competitors injured by another's false statements about their own or the competitor's goods. *Lexmark*, 572 U.S. at 137. The FDCA, on the other hand, "is designed primarily to protect the health and safety of the public at large." *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 108 (2014). Private parties cannot enforce the FDCA; that enforcement authority squarely belongs to the FDA. *Id*. at 109 (citing 21 U.S.C. §§ 333(a), 337). Rather than "focus[ing] on the truth or falsity of advertising claims" in implementing the FDCA, the FDA "protect[s] the public interest by 'pass[ing] on the safety and efficacy of all new drugs[.]'" *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230 (3d Cir. 1990) (quoting *Am. Home Prods. Corp. v. Johnson & Johnson*, 436 F. Supp. 785, 797 (S.D.N.Y. 1977), *aff'd,* 577 F.2d 160 (2d Cir. 1978)).

The fact that Congress delegated enforcement authority to the FDA with regard to certain drug-related matters covered by the FDCA does not categorically preclude Lanham Act claims that are based on the false labeling of food or drugs. *POM Wonderful*, 573 U.S. at 117, 121;

Azurity Pharms., Inc. v. Edge Pharma, LLC, 45 F.4th 479, 502 n.11 (1st Cir. 2022); *Belcher Pharms*, 1 F.4th at 1379, 1381; *Amarin Pharma, Inc. v. Int'l Trade Comm'n*, 923 F.3d 959, 969 (Fed. Cir. 2019). A key case that helps set out the contours of the preclusion doctrine in this regard is *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102 (2014).

In *POM Wonderful*, the plaintiff brought suit under Section 43 of the Lanham Act, alleging that the defendant deceptively and prominently labeled its juice product as "pomegranate blueberry" although the product contained only 0.3% pomegranate juice and 0.2% blueberry juice. 573 U.S. at 105, 110. The defendant, for its part, argued that the FDCA's delegation of enforcement authority to the FDA regarding food and beverage labeling showed Congress' intent to achieve national uniformity in labeling—and, relatedly, served to preclude the plaintiff's Lanham Act claim. *Id*. at 109, 116-17. But the Supreme Court of the United States disagreed. In doing so, it noted that the information at issue on the defendant's food-related product label did not require pre-approval from the FDA—as opposed to information on drug labels, which are subject to the FDA's pre-approval. *Id*. at 109, 116. In the end, the *POM Wonderful* Court concluded that the Lanham Act and the FDCA "complement each other in major respects," and explained that the FDA's exclusive enforcement authority, by itself, did not "indicate that Congress intended to foreclose private enforcement" of the Lanham Act. *Id*. at 115, 117; *see Azurity Pharms.*, 45 F.4th at 488-89. In the Supreme Court's view, there the plaintiff was simply seeking "to enforce the Lanham Act, not the FDCA or its regulations." *POM Wonderful*, 573 U.S. at 117.

Despite the outcome in *POM Wonderful*, the Supreme Court's opinion appeared to leave open the prospect that the FDCA could preclude Lanham Act claims in certain circumstances. For example, as was noted above, the *POM Wonderful* Court twice observed that the FDA's

regulation of drug labels (not at issue in *POM Wonderful*) is more intensive than its regulation of food and beverage labels (which were at issue there). *Id*. at 109, 116. The *POM Wonderful* Court also pointedly noted that, as to the facts of that case, "the FDA ha[d] not made a policy judgment that is inconsistent with POM's Lanham Act suit" and that "[t]his is not a case where a lawsuit is undermining an agency judgment[.]" *POM Wonderful*, 573 U.S. at 120. Noting this, lower courts interpreting *POM Wonderful* have reasoned that because "drug approval is a demanding and complicated process[,] . . . there may be reasons to disallow label challenges involving certain drug claims that call on courts to contradict a conclusion of the FDA or to make an original determination on an issue committed to the FDA's discretion." *Belcher Pharms*, 1 F.4th at 1380 (discussing *POM Wonderful*, 573 U.S. at 116); *see also JHP Pharms., LLC v. Hospira, Inc.*, 52 F. Supp. 3d 992, 998, 1000 n.5, 1004 (C.D. Cal. 2014).

In effect, this commentary in *POM Wonderful* can be said to have left undisturbed the longstanding principle that a party may not use the Lanham Act as a vehicle to enforce the FDCA. *See Sandoz Pharms.*, 902 F.2d at 231 (holding it would be inappropriate "for a court in a Lanham Act case to determine preemptively how a federal administrative agency will interpret and enforce its own regulations"); *see also PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 928 (9th Cir. 2010) (citing cases). Indeed, following *POM Wonderful*, federal courts have continued to distinguish the case by noting that Lanham Act claims are precluded to the extent that they challenge enforcement determinations typically made by the FDA, or to the extent that they challenge FDA decisions where the agency has taken positive regulatory action. *See, e.g.*, *Kurin, Inc. v. ICU Med., Inc.*, Case No. 8:24-cv-00564-FWS-ADS, 2024 WL 5416672, at *9 (C.D. Cal. Nov. 8, 2024) (refusing to permit litigation of "an underlying FDCA violation when the FDA has not made such a determination"); *Exela Pharma Scis., LLC v. Sandoz, Inc.*, 486 F. Supp. 3d

1001, 1024-25 (W.D.N.C. 2020) (concluding that Lanham Act claims challenging the content of healthcare provider letters—letters that were previously approved and mandated by the FDA—were barred by the FDCA); *Hi-Tech Pharms., Inc. v. Hodges Consulting, Inc.*, 230 F. Supp. 3d 1323, 1330 (N.D. Ga. 2016) (ruling that Lanham Act claims are properly precluded when such claims "would require a court to make determinations about safety, legality, and classification of new drugs that are more properly within the exclusive purview of the FDA"); *JHP Pharms.*, 52 F. Supp. 3d at 1003-04 (finding statements that drugs "comply with all applicable laws, including the FDCA[,]" could not proceed before the court "without a clear statement by the FDA" regarding the legality of marketing a particular substance).[5]

With the relevant underlying law set out, the Court now turns to the merits of Defendants' preclusion-related argument for dismissal. According to Defendants, Count I is precluded because it is premised on "issues committed to the FDA's discretion and, even more importantly, [issues] on which the FDA has taken positive action[,]" (D.I. 25 at 9)—in that the claim relates to representations and content in Defendants' ANDA that were previously "FDA-approved[,]" (D.I. 34 at 1-2, 7-9). To examine this argument, the Court turns back to the substance of Count I's Lanham Act claim here.

With Count I, Plaintiff is asserting that Defendants engaged in false, deceptive and misleading advertising in two primary ways:

- First, Plaintiff alleges that on Amneal's website, within its "U.S. Product Catalog" section, Defendants list Hetlioz as the "Brand Reference" for their generic tasimelteon product. This

[5] *See also In re SoClean, Inc., Mktg., Sales Pracs., and Prods. Liab. Litig.*, Master Docket: No. 22-MC-00152-JFC, 2025 WL 974258, at *18-19 (W.D. Pa. Mar. 20, 2025); *Surgical Instrument Serv. Co. v. Intuitive Surgical, Inc.*, 728 F. Supp. 3d 1034, 1046 (N.D. Cal. 2024); *Philips Med. Sys. Nederland B.V. v. TEC Holdings, Inc.*, CIVIL ACTION NO. 1:17-CV-2864-LMM, 2019 WL 11825449, at *5 (N.D. Ga. Jan. 4, 2019).

listing, Plaintiff says, is false and misleading, because either the reference product used in Defendants' Bioequivalence Study was not actually Hetlioz, or because that study was so flawed that it undermines any assertion that Defendants' product is bioequivalent to Hetlioz. (D.I. 2 at ¶¶ 13, 78, 80, 114-19, 130; D.I. 3, ex. 17 at 6; *see also* D.I. 30 at 6-7);

- Second, Plaintiff asserts that Defendants inaccurately described their product on Amneal's label, by making false statements about the mean-elimination half-life of the generic and reference drug and about the peak concentration of their drug after oral administration—statements that differed from what Defendants' Bioequivalence Study data showed regarding those topics. (D.I. 2 at ¶ 125-31; *see also* D.I. 30 at 7-8)

Plaintiff alleged that these statements on Amneal's website and label falsely and wrongly implied that pharmacies and doctors could appropriately switch a patient's existing Hetlioz prescription to MSN's product on the basis of equivalence (and thus that MSN's product was safe and effective to treat Non-24). (D.I. 2 at ¶¶ 119, 129; *see also id*. at ¶ 14)

However, in order for Defendants to have obtained FDA approval for the generic drug, the manufacturer (here, MSN) had to "demonstrate that its drug is bioequivalent to a drug that went through the rigorous NDA approval process" (here, Hetlioz). *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 154 n.28 (3d Cir. 2017). FDA regulations define "bioequivalence" as "the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalent or pharmaceutical alternatives becomes available at the site of a drug action when administered at the same molar dose under similar conditions in an appropriately designed study." 21 C.F.R § 314.3. Additionally, the "Indications and Usage" section of an FDA-approved "label must set forth indications that are supported by 'substantial evidence of effectiveness based on adequate and well-controlled studies.'" *BTG Int'l Ltd. v. Amneal Pharms. LLC*, 352 F. Supp. 3d 352, 391 (D.N.J. 2018) (quoting 21 C.F.R. § 201.57(c)(2)(iv)).

And here, as the Complaint notes, the FDA went through the process of analyzing the evidence regarding bioequivalence that was in MSN's ANDA—and thereafter, it approved the ANDA and MSN's label, providing Defendants' generic product an AB-rating[6] for the treatment of Non-24. (D.I. 2 at ¶¶ 13, 98-99; *see also* D.I. 34 at 4 ("Here, there is no dispute that MSN's ANDA and label for its generic . . . product was, and remains, approved by FDA as an 'AB'-rated therapeutic equivalent of Hetlioz[].")) In so doing, the FDA concluded that the ANDA demonstrated that Defendants' generic product *is* "bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Hetlioz Capsules, 20 mg, of [Plaintiff,]" (D.I. 3, ex. 5 at 4; *see also id*., ex. 14 at 1), and is usable to treat Non-24, (*id*., ex. 5 at 12, 14, 20-21). (*See also* D.I. 2 at ¶ 85 (alleging that MSN's Bioequivalence Study "create[ed] the false impression of bioequivalence between the two products and *ultimately le[d] to FDA approval*") (emphasis added)) And there is no question that as part of its process of reviewing and approving the ANDA, the FDA also considered and approved MSN's label for use in marketing the generic product at issue. (D.I. 2 at ¶¶ 72, 98)

Thus, there can also be no doubt that adjudication of Plaintiff's Lanham Act claim would require the Court to assess—and potentially second-guess—the FDA's decision-making and its enforcement of the FDCA's provisions. Again, examining Plaintiff's specific allegations of false advertising in Count I indicates why this is so:

- For example, with regard to the assertion that Defendants' listing of Hetlioz as the "Brand Reference" for its generic

[6] An AB-rating for a generic drug means the "FDA considers [the generic] to be therapeutically equivalent to other pharmaceutically equivalent products[.]" U.S. Food & Drug Admin., Orange Book Preface: Approved Drug Products with Therapeutic Equivalence Evaluations § 1.7 (Mar. 27, 2025) (emphasis omitted), https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface; *Somaxon Pharms., Inc. v. Actavis Elizabeth LLC*, Civil Action No. 10-1100-RGA, 2020 WL 3470471, at *1 n.4 (D. Del. June 25, 2020).

product is false and misleading, the problem for Plaintiff is that the FDA clearly "determined[,]" after reviewing the Bioequivalence Study, that the generic product was "bioequivalent and therapeutically equivalent" to Hetlioz (which the FDA described as the "reference listed drug (RLD)")—and that Hetlioz was the "[drug] upon which [MSN] based [its] ANDA[.]" (D.I. 3, ex. 5 at 4); *see also* 21 C.F.R. § 314.3 (defining a RLD as "the listed drug *identified by FDA* as the drug product upon which an applicant relies in seeking approval of its ANDA") (emphasis added). Therefore, in listing Hetlioz as the "Brand Reference" drug vis-à-vis Defendants' generic product, it is clear that Amneal's website is merely reiterating the FDA's conclusion in that regard. Similarly, the Complaint's assertions that the compared drug in the Bioequivalence Study was not actually Hetlioz, or that the Bioequivalence Study was so flawed that it could not have supported a decision of bioequivalence, amount to a challenge to the FDA's review and findings—since the FDA did not come to similar conclusions after assessing that same study.

- The situation is the same as to Plaintiff's assertion that Amneal's label inaccurately describes the mean-elimination half-life of the generic and reference drug and the peak concentration of the generic drug after oral administration (i.e., in ways that differ from the data in the Bioequivalence Study). The Generic Label at issue appears to be an exact copy of the "Labeling" Section of the Approval Package. (*Compare* D.I. 3, ex. 5 at 12-22, *with id*., ex. 16 at 1-13) Given that the allegedly incorrect statistics are part the FDA-approved drug label, (*id*., ex. 5 at 18), it is clear that the agency has assessed the content of that label (including the content being challenged in Count I as false and misleading) in light of the administrative record (including the Bioequivalence Study). And it approved that content. As a result, Defendants *must* include the challenged information on their generic label in order to ensure compliance with the FDCA. *See* 21 C.F.R. § 314.94(a)(8)(iv); (D.I. 25 at 15; D.I. 34 at 4 & n.1).[7]

[7] Indeed, it would seem that if Plaintiff's Lanham Act claim was successful, Defendants would be put in a position where they would have to amend MSN's label in order to avoid continuing Lanham Act liability, but yet could not do so without violating the FDCA. *Braintree Lab'ys, Inc. v. Nephro-Tech, Inc.*, No. 96-2459-JWL, 1997 WL 94237, at *7 (D. Kan. Feb. 26, 1997); *cf*. *Exela Pharma Scis.*, 486 F. Supp. 3d at 1024.

Therefore, these sorts of Lanham Act claims are clearly precluded.[8] *See Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 64 (2d Cir. 2016) ("representations commensurate with information in an FDA label generally cannot form the basis for Lanham Act liability"); *Exela Pharma Scis.*, 486 F. Supp. 3d at 1024 ("Because the Plaintiff's Lanham Act claim challenges the letters that were a condition of the [FDA's] 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. . . . Based on the Supreme Court's decision in *POM Wonderful*, such a claim is precluded."); *Wyeth v. Sun Pharm. Indus., Ltd.*, No. 09-11726, 2010 WL 746394, at *6-7 (E.D. Mich. Mar. 2, 2010) (holding that a plaintiff's Lanham Act claim was precluded to the extent that it challenged the defendants' statements on their website to the effect that their product was a generic equivalent of the plaintiff's branded drug, where the FDA had determined that defendants' product was the generic equivalent of Plaintiff's drug, as "[a]llowing the Plaintiff's complaint to proceed necessarily questions the validity of the FDA's decisions").[9]

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[8] This is in line with how courts have described the purpose behind the doctrine of preclusion, which is not to insulate defendants from Lanham Act liability, but instead to honor the scientific findings of the FDA—an entity better suited than a federal court to make such findings. *See GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, CIVIL ACTION: NO. 13-726, 2014 WL 12603224, at *1 n.2 (E.D. Pa. Mar. 10, 2014); *see also Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmBH*, 843 F.3d 48, 73 n.13 (2d Cir. 2016); *Sandoz Pharms.*, 902 F.2d at 231; *Healthpoint, Ltd. v. Ethex Corp.*, 273 F. Supp. 2d 817, 843 (W.D. Tex. 2001).

[9] Defendants also point out that Plaintiff filed a Citizen Petition with the FDA in May 2023. (D.I. 25 at 1 n.1, 2, 4-5, 12 n.9; D.I. 34 at 3); *see also Vanda Pharms. Inc. v. Food & Drug Admin.*, Case No. 23-cv-2812 (CRC), 2024 WL 4133623, at *3-4 (D.D.C. Sept. 10, 2024) (discussing Plaintiff's petition). In that petition, Plaintiff alleged that MSN's Bioequivalence Study was flawed and unreliable for the reasons explained in the instant Complaint, and asked the FDA to vacate its finding of bioequivalence. *See Vanda Pharms.*, 2024 WL 4133623, at *1, 3-4. The content of that petition only seems to underscore the correctness of the Court's conclusion as to the preclusion issue—i.e., that in this suit, Plaintiff is essentially challenging determinations that were previously made by the FDA and are in the FDA's purview. *See Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.*, 547 F. Supp. 2d 939, 947 (E.D. Wis. 2008) (dismissing a claim where resolving it would require the court to determine

Plaintiff disputes this conclusion primarily by invoking the United States Court of Appeals for the Fourth Circuit's decision in *Mylan Lab'ys, Inc. v. Matkari*, 7 F.3d 1130 (4th Cir. 1993). In doing so, it asserts that *Mylan* is a case "allowing Lanham Act claims based on false statements of equivalence to go forward." (D.I. 30 at 11-12 (discussing *Mylan*, 7 F.3d at 1138-39); *see also id*. at 6 (same))

In *Mylan*, the plaintiff alleged that certain defendants violated the Lanham Act by falsely stating and implying in package inserts and brochures that: (1) the defendants' generic drugs had been properly approved by the FDA; and (2) the defendants' drugs were bioequivalent to the plaintiff's drugs. 7 F.3d at 1137-38. The district court had dismissed the Lanham Act claims on the ground that the complaint failed to allege that the defendant's drugs were not, in fact, bioequivalent to the plaintiff's drugs. *Id*. at 1138. The Fourth Circuit overturned the district court's decision as to the Lanham Act claim premised on statements of bioequivalence, concluding that the plaintiff's allegations (i.e., "that a defendant 'falsely represented' that its product was 'bioequivalent to its innovator counterpart and other approved generic equivalents;' that the product was 'entitled to an AB rating'[] from the FDA; or that the product was the 'generic alternative' to the innovator drug") were sufficient to plausibly allege a Lanham Act violation. *Id*.[10] And indeed, some of the factual allegations at issue there in *Mylan* sound similar

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preemptively how the FDA would interpret and enforce its own regulations), *aff'd,* 586 F.3d 500 (7th Cir. 2009). Ultimately, in a 38-page decision issued on June 30, 2025 that denied Plaintiff's petition, the FDA declined to withdraw MSN's ANDA approval and affirmed that the "generic tasimelteon products are bioequivalent to Hetlioz[.]" (D.I. 38, ex. 1 at 35)

[10] As was noted above, the plaintiff in *Mylan* had also raised a Lanham Act claim asserting that the defendants falsely said that their drugs had been "properly approved by the FDA"; as to those allegations, the *Mylan* Court determined that they must fail. In part, that was because "permitting Mylan to proceed on the theory that the defendants violated [the Lanham Act] merely by placing their drugs on the market would, in effect, permit Mylan to use the Lanham Act as a vehicle by which to enforce [the FDCA]." 7 F.3d at 1139. The *Mylan* Court's

to the Plaintiff's allegations here—including the charges that: (1) the defendants had either falsified data used in their bioequivalence studies or used unreliable data; and (2) the studies in question may have been performed on a drug manufactured differently from the one advertised. *Id*.

But a closer look at the facts of *Mylan* indicates why it is not apposite to this matter. To a great degree, that is because the generic drug at issue in *Mylan* was *not* FDA-approved when the plaintiff challenged the defendants' advertisements. Rather, the plaintiff alleged that the FDA's approval had been obtained through fraud and was ultimately withdrawn by the agency. *Id*. at 1138; *see also id*. at 1139 (the plaintiff arguing that placing the generic on the market falsely implied that the drug had been approved by the FDA, when in fact it had not). Therefore, there was no risk that the *Mylan* Court's ruling could conflict with the FDA's judgment to the effect that the drug was bioequivalent—because at the time of the filing of the operative complaint, the FDA *had made no such judgment*. (D.I. 34 at 3); *cf. GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, CIVIL ACTION: NO. 13-726, 2014 WL 12603224, at *1 n.2 (E.D. Pa. Mar. 10, 2014) (permitting false advertising claims founded upon "false public statements as to the bioequivalence and effectiveness of [the generic drug]" to proceed, where the FDA had reversed its earlier findings to hold the drugs were not bioequivalent, and explaining that such claims "may very well have been pre[cluded] under the Lanham Act" had the generic "retained FDA approval"). In contrast, the instant case involves challenges to the appropriateness of

ruling in this regard is understood to preclude Lanham Act claims which require courts to make decisions within the jurisdiction and expertise of the FDA and FDCA. *See, e.g.*, *PhotoMedex*, 601 F.3d at 929 (citing *Mylan*, 7 F.3d at 1139); *Axcan Scandipharm Inc. v. Ethex Corp.*, 585 F. Supp. 2d 1067, 1075 (D. Minn. 2007) (same).

determinations made by the FDA.[11] *See POM Wonderful*, 573 U.S. at 120 (suggesting that a Lanham Act suit that "directly conflict[s] with the agency's policy choice" would be barred, as an attempt to "undermin[e] an agency judgment") (discussing *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 875 (2000)); *Healthpoint, Ltd. v. Ethex Corp.*, 273 F. Supp. 2d 817, 844-45 (W.D. Tex. 2001) ("There is a distinction between respecting the FDA's primary jurisdiction to determine in the first instance whether a drug is lawful, 'generic,' 'bioequivalent,' 'therapeutically equivalent,' or 'pharmaceutically equivalent' and, on the other hand, a Lanham Act claim that a false statement has been made about a product"; determination of the former is "inextricably linked to the determination of whether [the generic drug] is being marketed lawfully[,]" a matter within the domain of the FDA).

[11] Plaintiff cites to a few other district court opinions that discuss *Mylan*, and that purportedly also support the idea that "bioequivalence claims are not preempted by the FDCA[.]" (D.I. 30 at 11-12) But most of these cases involved circumstances where the drugs at issue were non-Orange Book drugs, and no FDA decision on equivalence was required before the drug could enter the market; ultimately, none of these cases help Plaintiff. *See G&W Lab'ys*, 2018 WL 3031943, at *10-11 (citing *Mylan* and finding that claims regarding allegedly false assertions of generic equivalency were not precluded by the FDCA, but where the drugs at issue were not FDA-approved and the allegations did not rely on implicit or explicit FDCA enforcement); *Solvay Pharms., Inc. v. Glob. Pharms.*, 298 F. Supp. 2d 880, 884-85 (D. Minn. 2004) (citing *Mylan* and denying a motion to dismiss false advertising claims on preclusion grounds, but where neither drug at issue was "listed in the Orange Book[,] FDA approval was not required . . . to make a determination of bioequivalence" and no "claims or factual assertions . . . tie[d the plaintiff's] claims to FDA approval"); *Pediamed Pharms., Inc. v. Breckenridge Pharm., Inc.*, 419 F. Supp. 2d 715, 724-25 (D. Md. 2006) (citing *Mylan* and permitting claims including a Lanham Act claim to proceed over an assertion of FDCA preclusion, but explaining that preclusion was not at play in cases (like that one) where the drug at issue "was not listed in the Orange Book and there was no indication that FDA approval is needed to make a claim of equivalency"); *Braintree Lab'ys*, 1997 WL 94237, at *6-7 (citing *Mylan* and holding, in a case where the defendant's drug product was not FDA-approved, that the plaintiff's Lanham Act claim was precluded, because it required a determination as to whether the generic drug product was a "dietary supplement" (a term set out in the FDCA), such that resolving the case would require interpretation of that statutory term and might force the defendant into having to choose between removing the term from its label or violating the FDCA and risking suit from the FDA); *see also* (D.I. 34 at 5-7).

Therefore, for the reasons explained above, the Court finds that Plaintiff failed to plead a plausible claim for false advertising under the Lanham Act—i.e., a claim that is not precluded by the FDCA. And since there is no prospect that amendment could cure this failing, the Court recommends that Count I be dismissed with prejudice.

b. State Law Claims (i.e., Counts II-VI)

With Plaintiff's only federal cause of action dismissed, the Court must assess whether the District Court has jurisdiction over the remaining claims in Counts II to VI, which are all premised on alleged violations of Delaware or New Jersey state law. (D.I. 2 at ¶¶ 142-78) A district court "may decline to exercise supplemental jurisdiction over a claim . . . if . . . the district court has dismissed all claims over which it has original jurisdiction[.]" 28 U.S.C. § 1367(c)(3); *see also Abbott Lab'ys v. Banner Pharmacaps Inc.*, Civil Action No. 07-754 GMS, 2008 WL 11515903, at *1 (D. Del. Nov. 25, 2008). And the Court may raise the subject matter jurisdiction issue *sua sponte*. *See, e.g.*, *Scott v. N.Y. Admin. for Child.'s Servs.*, 678 F. App'x 56, 57 (3d Cir. 2017); *Abbott Lab'ys*, 2008 WL 11515903, at *1; *United States v. Medco Health Sols., Inc.*, Civ. No. 11-684-RGA, 2017 WL 63006, at *13 (D. Del. Jan. 5, 2017).

Where a plaintiff's federal claims have been dismissed, the district court "'*must* decline' to exercise supplemental jurisdiction . . . 'unless considerations of judicial economy, convenience, and fairness to the parties provide an affirmative reason for doing so.'" *Stone v. Martin*, 720 F. App'x 132, 136 (3d Cir. 2017) (citation omitted) (emphasis in original). Although the parties did not address the issue directly in their briefing, the Court can find no affirmative justification to exercise supplemental jurisdiction over the state law claims. This case is still at the initial pleading stage, and our Court has expended few resources on it. Moreover, the parties' License Agreement contemplates lawsuits in "state courts in the State of

Delaware[.]" (D.I. 2, ex. 1 at § 8.6) Consistent with decisions of courts in this Circuit in other similar circumstances, the Court recommends that the District Judge decline to exercise supplemental jurisdiction over Plaintiff's state law claims and dismiss Counts II-VI without prejudice. *See CHW Grp., Inc. v. Better Bus. Bureau of N.J., Inc.*, Civil Action No. 11-3261 (JAP-TJB), 2012 WL 426292, at *5 (D.N.J. Feb. 8, 2012); *Abbott Lab'ys,* 2008 WL 11515903, at *1; *Crown Packaging Tech., Inc. v. Albermarle Corp.*, No. Civ.A. 05-892-JJF, 2006 WL 1652566, at *2 (D. Del. June 8, 2006). It further recommends the remainder of the Motion be denied as moot.[12]

III. CONCLUSION

For the reasons stated above, the Court recommends that: (1) Defendants' Motion be DENIED with respect to Plaintiff's lack of standing under Rule 12(b)(1); (2) the Motion be GRANTED as to Count I with prejudice on Rule 12(b)(6)/preclusion grounds; (3) the Motion be GRANTED as to Counts II-VI without prejudice (i.e., by declining to exercise supplemental jurisdiction over state law claims where no federal claim has been successfully pleaded); and (4) Defendants' other arguments for dismissal under Rule 12(b)(6) and their request for a stay be DENIED as MOOT.

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 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

[12] Defendants also argued, *inter alia*, that the state law false advertising claims in Counts IV-VI would be preempted by federal law. (D.I. 25 at 10-11) That could be so, but in light of the fact that the parties provided so little argument on this front, (*id.*; D.I. 30 at 13), and in light of its decision above, the Court declines to address that issue here.

loss of the right to *de novo* review in the district court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated March 7, 2022, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov.

Because this Report and Recommendation may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the Report and Recommendation. Any such redacted version shall be submitted no later than **August 6, 2025** for review by the Court. It should be accompanied by a motion for redaction that shows that the presumption of public access to judicial records has been rebutted with respect to the proposed redacted material, by including a factually-detailed explanation as to how that material is the "kind of information that courts will protect and that disclosure will work a clearly defined and serious injury to the party seeking closure." *In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Report and Recommendation.

Dated: July 31, 2025

Christopher J. Burke
Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE