UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

IN RE LOESTRIN 24 FE ANTITRUST LITIGATION	MDL No. 13-2472-WES-PAS
	Master File No. 1:13-md-2472
THIS DOCUMENT RELATES TO: ALL ACTIONS	

OPINION AND ORDER

WILLIAM E. SMITH, Chief Judge.

In this putative class action, the Direct Purchaser Plaintiffs ("DPPs") allege that Defendants Warner Chilcott (US), LLC, Warner Chilcott Sales (US), LLC, Warner Chilcott Company LLC, Warner Chilcott plc, and Warner Chilcott Limited (collectively, "Warner Chilcott") and Defendants Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. (together, "Watson"[1], and collectively, with Warner Chilcott, "Defendants") violated federal law through a series of actions intended to delay and suppress generic competition for the oral contraceptive Loestrin 24 Fe ("Loestrin 24").[2] This decision resolves the DPPs' pending Motion for Class

[1] Warner Chilcott and Watson are part of the multinational corporation, Allergan plc. See Direct Purchaser Class Pls.' Third Am. Consolidated Class Action Compl. and Jury Demand ("DPP Compl.") ¶¶ 18-28, ECF No. 380.

[2] Loestrin 24 is an oral contraceptive with 24 tablets containing 1 mg norethindrone acetate and 20 mcg ethinyl estradiol and 4 placebo tablets with iron. DPP Compl. ¶ 109.

Certification.[3] See generally Direct Purchaser Class Pls.' Mot. for Class Certification, ECF No. 513. For the reasons discussed below, the DPPs' Motion for Class Certification is GRANTED, and Defendants' Motion to Exclude the Opinions and Testimony of Dr. Leitzinger, ECF No. 570, is DENIED.

I. Background

The Court constrains its recitation to the factual and procedural background relevant to the Motion for Class Certification.[4]

The DPPs are corporate entities that purchased brand and/or generic Loestrin 24 directly from Warner Chilcott or a non-defendant generic manufacturer. Direct Purchaser Class Pls.' Third Am. Consolidated Class Action Compl. and Jury Demand ("DPP Compl.") ¶¶ 16-18. They allege that Warner Chilcott committed fraud on the Patent and Trademark Office in securing the patent for Loestrin 24 and proceeded to file sham litigation to enforce its patent against potential generic competitors. Loestrin, 261 F. Supp. 3d at 318-21. Plaintiffs further allege that Warner Chilcott then settled its sham patent lawsuits against Watson and

[3] A separate decision on the End-Payor Plaintiffs' Motion for Class Certification, ECF No. 526, is forthcoming.

[4] The curious reader may refer to In re Loestrin 24 Fe Antitrust Litig., 261 F. Supp. 3d 307, 314-25 (D.R.I. 2017) ("Loestrin"), to put more flesh on the bones of the following summary.

Lupin Pharmaceutical, Inc. and/or Lupin Ltd. ("Lupin") by making large and unjustified payments in exchange for their agreement to stay out of the Loestrin 24 market. Id. at 321-23. Right before generic entry was set to occur, Warner Chilcott introduced a drug, Minastrin 24 (a chewable version of Loestrin 24 with added sweetener on the reminder days), to erode the brand Loestrin 24 prescription base. Id. at 323-24. This product hop allowed Warner Chilcott to retain branded sales (in Minastrin 24) once generic Loestrin 24 entered and state automatic-substitution laws kicked in. Id.

This order of events has consequences for the Court's ability to determine — as antitrust law requires — what the world would have looked like but for Defendants' alleged anticompetitive conduct.[5] Because Defendants executed the product hop and pulled brand Loestrin 24 from the market before automatic substitution laws could take hold, there is a dearth of evidence reflecting how the market would have responded to generic entry in a but-for world. See Feb. 11, 2019 DPPs' Mot. for Class Certification Hr'g Tr. ("DPP Hr'g Tr.") 18-20, ECF No. 806. This dearth of evidence means that the DPPs and Defendants, and their respective experts,

[5] Reference to the "but-for world" throughout this decision connotes a hypothetical world in which Defendants did not engage in any of the anticompetitive conduct alleged by the DPPs.

do not agree on the best methodology to use to construct the contours of the but-for world.

II. Defendants' Motion to Exclude Dr. Leitzinger

Defendants have moved to exclude the opinions and testimony of the DPPs' proposed expert, Jeffrey J. Leitzinger, Ph.D.[6] They argue that (1) Dr. Leitzinger's opinions are based on "unsupported assumptions provided to him by counsel" rather than scientific method; (2) he improperly assumes that generic drug prices decrease with additional generic entrants, ignoring evidence specific to Loestrin 24 suggesting otherwise; and (3) his methodology for calculating the alleged aggregate overcharge due to generic delay and related calculations is unreliable. Defs.' Mem. of Law in Supp. of Mot. to Exclude the Opinions and Testimony of DPPs' Expert Jeffrey J. Leitzinger ("Defs.' Mot. to Exclude Leitzinger") 1-3, ECF No. 581.

Before dealing with the DPPs' Rule 23 Motion for Class Certification, the Court must address Defendants' challenge to some of the expert analysis that underpins the DPPs' claims

[6] Dr. Leitzinger has worked as an economist for over forty years and is the president of Econ One Research, Inc., an economic research and consulting firm. He holds master's and doctoral degrees in economics from the University of California Los Angeles and a bachelor's degree in economics from Santa Clara University. Decl. of Jeffrey J. Leitzinger, Ph.D. ("Leitzinger Report") ¶¶ 1-2, ECF No. 518-3. He has testified in many pharmaceutical antitrust cases in federal court, id. ¶ 2 & n.2, and the Court gleans no dispute over his qualifications to provide an opinion in this matter.

regarding what the but for world would look like, who was damaged, and to what extent.

Rule 702 of the Federal Rules of Evidence sets forth the criteria a party must satisfy in order to proffer expert opinion. Rule 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

The Court "serves as the gatekeeper for expert testimony by 'ensuring that [it] . . . both rests on a reliable foundation and is relevant to the task at hand.'" Milward v. Rust-Oleum Corp., 820 F.3d 469, 473 (1st Cir. 2016) (quoting Daubert v. Merrell Dow Pharm., 509 U.S. 579, 597 (1993)). The evidence's proponent "has the burden of establishing both its reliability and its relevance." Id. (citing Daubert, 509 U.S. at 593 n.10; Fed. R. Evid. 702, advisory committee's note). The First Circuit has advised that "Daubert neither requires nor empowers trial courts to determine which of several competing scientific theories has the best provenance." Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling

Co., 161 F.3d 77, 85 (1st Cir. 1998). Instead, "[i]t demands only that the proponent of the evidence show that the expert's conclusion has been arrived at in a scientifically sound and methodologically reliable fashion." Id.

Counsel for the DPPs provided Dr. Leitzinger four baseline scenarios to consider. They assume that: two generic Loestrin 24 products (one manufactured by Watson, the other an authorized generic manufactured by Warner Chilcott) enter the market in September 2009; Minastrin either enters the market in July 2013 (which it did in the actual world) or never enters at all; and Lupin launches its generic Loestrin 24 in either July 2013 or, as it did in the real world, January 2016. See Decl. of Jeffrey J. Leitzinger, Ph.D. ¶ 26 (July 30, 2018) ("Leitzinger Report"), ECF No. 518-3. He made sixteen additional calculations applying his damages model to the four baseline scenarios but assuming later generic entry dates. Ex. 7 to Leitzinger Report, ECF No. 518-3. Dr. Leitzinger did not independently verify the scenarios provided by counsel. Leitzinger Dep. 48:6-50:1, 56:12-63:23 (Aug. 30, 2018), ECF No. 621-34.

In his report, Dr. Leitzinger concludes that there is evidence common to the proposed class that demonstrates "with high likelihood" that all DPP class members were injured by Defendants' alleged wrongdoing. Leitzinger Report ¶¶ 9(b), 27, 50. This common evidence includes: literature showing that generic

competition converts upwards of 90% of the brand prescription base to generics at prices substantially below the brand price, and increasingly so as more generics enter; Defendants' and generic manufacturers' forecasts predicting that Loestrin 24 generic competition would lead to high rates of generic substitution at well below the brand price; evidence of the actual market following generic entry in 2014; and that DPP class members serve a wide range of prescription needs. Id. ¶ 27.

The DPPs can be broken into three subgroups of direct purchasers: (1) brand Loestrin 24 purchasers that later bought generic Loestrin 24 once it entered the market ("Brand-Generic Purchasers"); (2) brand Loestrin 24 purchasers that never ultimately purchased generic Loestrin 24 during the class period, even after it became available ("Brand-Only Purchasers"); and (3) generic Loestrin 24 purchasers that never purchased brand Loestrin 24 from Defendants during the class period, and made all their relevant purchases from generic-manufacturer Amneal[7] ("Generic-Only Purchasers"). With respect to Brand-Generic Purchasers, Dr.

[7] Watson divested its Loestrin Abbreviated New Drug Application ("ANDA") to Amneal when it acquired Warner Chilcott. Defs.' Mem. of Law in Opp'n to Direct Purchaser Class Pls.' Mot. for Class Certification ("Defs.' Opp'n to Class Cert.") 14, ECF No. 582. As a result, Amneal agreed to delayed entry of generic Loestrin 24 per Watson's alleged unlawful reverse payment to Warner Chilcott. See Reply in Further Supp. of Direct Purchaser Class Pls.' Mot. for Class Certification ("DPPs' Further Supp. for Class Cert.") Ex. 14 ¶ 2.4, ECF No. 621-3.

Leitzinger concludes that the high rate of generic penetration that would have taken hold if generic Loestrin 24 had entered earlier, coupled with the discount on the wholesale acquisition cost ("WAC")[8] that generic purchasers enjoy, would have led Brand-Generic Purchasers to substitute more of their brand purchases with lower-priced generic Loestrin 24. Leitzinger Report ¶ 50. As a result, Defendants' anticompetitive conduct caused them to incur overcharges. Id.

Dr. Leitzinger similarly concludes that the Brand-Only Purchasers were injured. In his view, they suffered antitrust injury because, had there been sustained, robust generic competition in the Loestrin 24 market, these purchasers would have responded to their customers' demands and substituted some of their brand Loestrin purchases for cheaper generic Loestrin. Id. ¶¶ 28-32, 50-51; Rebuttal Decl. of Jeffrey J. Leitzinger, Ph.D. ("Leitzinger Rebuttal Report") ¶¶ 28-29, ECF No. 621-1.

[8] The wholesale acquisition cost ("WAC") of a prescription drug refers to the list price of the branded drug. Leitzinger Report 28 n.83; see also DPP Hr'g Tr. 16. As discussed below, Dr. Leitzinger conceptualizes generic drug price in terms of its discount from the brand's WAC. See Leitzinger Rebuttal Report ¶ 15 ("While generic suppliers compete with one another, they are also engaged collectively in competing with and diverting sales from the brand. The key metric in this regard is the level of the generic price relative to brand prices, often summarized as the generic discount from brand WAC."); see also Expert Report of Pierre-Yves Cremieux ("Cremieux Report") ¶ 32 n.41, ECF No. 582-1 ("The WAC is the manufacturer's list price to wholesalers before considering discounts, rebates, and other price concessions.").

Generic-Only Purchasers, in Dr. Leitzinger's view, also suffered antitrust injury at Defendants' hands. In forming this opinion, he uses the benchmark experiences of Minastrin and Ovcon-35 (another oral contraceptive) to demonstrate that as the number of generic competitors increase, the generic discount off the brand WAC increases over time as the market starts to operate more effectively. Leitzinger Rebuttal Report ¶¶ 8, 15, 27; DPP Hr'g Tr. 118-19. Dr. Leitzinger concludes that, in the but-for world, generic Loestrin would have cost less and thus its purchasers were injured by overcharges caused by Defendants' unlawful conduct. Leitzinger Rebuttal Report ¶¶ 25-27; DPP Hr'g Tr. 118-19. In reaching this conclusion, he determines the brand WAC at each point in time along with the generic discount expected based on forecasts, actual experience, and the number of generic competitors presumed to have been in the market at the time. DPP Hr'g Tr. 118-20; Dr. Jeffrey Leitzinger Slides from DPP Hr'g 9-13, ECF No. 987-3.

A. Dr. Leitzinger's Methodology and Reliance on DPP Counsel's Scenarios

The First Circuit has held that "[t]he use of aggregate damages calculations is well established in federal court and implied by the very existence of the class action mechanism itself." In re Pharm. Indus. Average Wholesale Price Litig., 582 F.3d 156, 197 (1st Cir. 2009). Indeed, Dr. Leitzinger's proffered

methodology has been accepted as reliable for proving class-wide impact by many courts. See Leitzinger Report ¶ 53 (citing his extensive past work analyzing aggregate overcharges associated with delayed generic entry for direct purchaser plaintiff classes); see also Direct Purchaser Class Pls.' Opp'n to Defs.' Mot. to Exclude the Opinions & Testimony of Jeffrey J. Leitzinger, Ph.D. ("DPPs' Opp'n") 1 n.3, ECF No. 620 (listing cases in which Dr. Leitzinger provided expert opinion). The Court is satisfied that here, as in other cases, Dr. Leitzinger's methodology calculates damages using common evidence and analysis that does not vary by class member, and leaves room for a range of jury findings. See infra Part III.E.2.

Nor is the Court troubled by Dr. Leitzinger's reliance on but-for scenarios provided by counsel. "Objections [to] the factual underpinnings of an expert's investigation[] often go to the weight of the proffered testimony, not to its admissibility." Crowe v. Marchand, 506 F.3d 13, 18 (1st Cir. 2007) (citing Microfinancial, Inc. v. Premier Holidays Int'l., Inc., 385 F.3d 72, 81 (1st Cir. 2004); Int'l Adhesive Coatings Co. v. Bolton Emerson Int'l, Inc., 851 F.2d 540, 545 (1st Cir. 1988)). Dr. Leitzinger opines that the DPPs were all impacted by Defendants' alleged anticompetitive conduct, that this impact resulted in antitrust damages, and that both may be proven with evidence common to the class. Leitzinger Report ¶¶ 9, 50. In reaching that

opinion, Dr. Leitzinger relied upon class counsel's but-for scenarios, which in turn, class counsel will venture to establish at trial with their fact witnesses and merit experts' reports and testimony. See DPPs' Opp'n 7 ("Dr. Leitzinger concludes that if the jury finds that Defendants unlawfully delayed and suppressed generic competition as Plaintiffs allege, then there is a high likelihood that all Class members suffered antitrust injury in the form of overcharges."). The Court discerns no reason to throw out Dr. Leitzinger's opinion and testimony on the basis that he has relied upon scenarios based upon facts and opinions elicited from other witnesses; it is common for experts to rely on such in formulating their opinions, and Defendants may probe their quality and reliability on cross-examination.

What is more, Dr. Leitzinger's model can be adjusted to account for a variety of jury findings during the liability phase – for example, a jury determination that Warner Chilcott would have launched Minastrin 24 earlier in the but-for world can be incorporated into the model and reflected in the damages calculation. See Leitzinger Rebuttal Report ¶ 56 (explaining that his models may be adjusted to respond to various findings by a jury). At this juncture, however, Defendants have not demonstrated that any of Dr. Leitzinger's assumptions are sufficiently problematic to render his opinions and testimony unreliable.

Defendants' criticisms, instead, go to the weight of the evidence. See Crowe, 506 F.3d at 18.

B. Dr. Leitzinger's Impact Analysis

Defendants take issue with Dr. Leitzinger's conclusion that additional generic entrants would have driven down prices because, in their words, Dr. Leitzinger "relies on generalized evidence and averages" and his opinion "is not grounded in the facts of the case." Defs.' Mot. to Exclude Leitzinger 11. Defendants contend that the Generic-Only and Brand-Only Purchasers were not injured by Defendants' alleged unlawful actions. Id. at 10-16.

In pressing this argument as to the Generic-Only Purchasers, Defendants say there "is no proof that Amneal's generic would have had a lower price in a but-for world where generic competitors entered earlier." Id. at 13 (quoting Cremieux Report ¶ 11). Indeed, the analysis of Defendants' rebuttal expert, Dr. Pierre-Yves Cremieux, suggests that the Generic-Only Purchasers experienced flat prices in the actual world after generic entry, and the actual prices paid by many Generic-Only Purchasers did not decline with additional generic entrants. Cremieux Report ¶¶ 11, 53. Because of this, he says, one must look at individualized evidence (the underlying contract, for example) to determine how each purchaser's price reacts to generic entry in the oral contraceptive space where branded generics abound. DPP Hr'g Tr. 221, 245 (testimony of Dr. Cremieux); Defs.' Mot to Exclude

Leitzinger 12.

With respect to the Brand-Only Purchasers, Defendants argue that Dr. Leitzinger's opinion that common evidence can be used to demonstrate injury is "fundamentally flawed." Defs.' Mot. to Exclude Leitzinger 14. They reason that, in the actual world, none of the six[9] Brand-Only Purchasers in fact purchased generic Loestrin 24 – or any other Loestrin product - after it became available in January 2014. Id. at 14-15. At least in part, this can be attributed to wholesalers choosing not to carry generic drugs because many of their retailer customers purchase generics directly from the generic manufacturers.[10] Id. at 14 (citing Cremieux Report ¶ 69 n.92).

[9] One of the six Brand-Only Purchasers, King Drug Company of Florence, Inc., went out of business in November 2010, and has submitted a declaration stating that, considering its business model, it would have purchased generic Loestrin 24 had it been available earlier. Leitzinger Rebuttal Report ¶¶ 28-29; Decl. of Keith Elmore (Nov. 23, 2018), ECF No. 621-25.

[10] This phenomenon is referred to as "generic bypass". Following generic entry, some wholesalers' customers shift their buying practices to purchase the generic drug directly from generic manufacturers, thereby "bypassing" the wholesaler. Leitzinger Report ¶ 68. As a result, wholesalers may lose volume in their sales. Id. ¶¶ 68-70.

The weight of the authority on this issue sides with the DPPs, and the Court adopts those courts' reasoning that, consistent with Hanover Shoe, Inc. v. United Shoe Mach. Corp., 392 U.S. 481 (1968), purchasers are injured at the point in time they incur the overcharge. Thus, even if generic bypass may have occurred in a but-for world, this does not negate injury. See Illinois Brick v. Illinois, 431 U.S. 720, 724 (1977) (holding that direct purchasers may recover the full amount of overcharges (citing Hanover Shoe,

In response, the DPPs marshal Dr. Leitzinger's analysis to argue that Dr. Cremieux, along with other missteps, "ignores that, in the but-for world, more generics would have been on the market earlier, and the years of robust competition would have driven prices down." DPPs' Opp'n 14. Also, they contend, even if a jury determines there are some uninjured class members, Dr. Leitzinger's model allows for the exclusion of those class members from the aggregate damages calculation. See Leitzinger Rebuttal Report ¶ 56.

The DPPs, through Dr. Leitzinger, have set forth sufficient, reliable evidence supporting the conclusion that Generic-Only and Brand-Only Purchasers would have purchased cheaper generic Loestrin 24 in a but-for world with sustained and robust generic competition. See id. ¶¶ 28-29. While Defendants fashion a colorable argument on this score, the DPPs have satisfied their burden to produce a "scientifically sound and methodologically reliable" opinion. Ruiz-Troche, 161 F.3d at 85. It will be up to the jury to determine which party's theory wins the day.

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392 U.S. at 494)); see also In re Nexium (Esomeprazole) Antitrust Litig., 296 F.R.D. 47, 55 (D. Mass. 2013) ("Nexium II")("The Supreme Court has 'long recognized [overcharges] as the principal measure of damages for plaintiffs injured as customers.'") (quoting In re Relafen Antitrust Litig., 218 F.R.D. 337, 344 (D. Mass. 2003)).

C. Dr. Leitzinger's Damages Analysis

Defendants argue that aggregate damages cannot be accurately and readily calculated without reliance on individualized inquiry as to each class member. Specifically, they take issue with Dr. Leitzinger's reliance on unreliable forecasts; failure to account for the effects of generic bypass; inclusion of uninjured purchasers in his calculation of damages; and disregard for what Defendants term "key facts." Defs.' Mot. to Exclude Leitzinger 16.

Dr. Leitzinger's reliance on pre-launch forecasts of generic manufacturers does not render his damages analysis unreliable. Dr. Leitzinger determined that the forecasts were reliable because the "internal documents were used, among other things, for strategic planning and budgeting, and for production planning[,]" and, additionally, because they "predicted the same type of market-wide impact from AB-rated generic competition described in the literature." Leitzinger Report ¶ 33. It goes without saying that industry manufacturers have a lot of interest in maintaining the accuracy of their forecasts, and such forecasts reflect their "own study of the . . . market and analogous experiences of other drugs." In re Namenda Direct Purchaser Antitrust Litig., 331 F. Supp. 3d 152, 181-82 (S.D.N.Y 2018) ("Namenda"); see also id. at 182 ("The use of Defendants' own forecasts to model a but-for world has been held to be a sound economic methodology."); In re Solodyn

(Minocycline Hydrochloride) Antitrust Litig., No. CV 14-MD-02503, 2017 WL 4621777, at *8-9 (D. Mass. Oct. 16, 2017) ("Solodyn") (rejecting Daubert challenge to Dr. Leitzinger's reliance on forecasts in an antitrust pharmaceutical case). Moreover, Dr. Cremieux acknowledged that he has no reason to believe that the twenty-two forecasts Dr. Leitzinger considered were cherry-picked to skew the analysis in the DPPs' favor. See DPPs' Opp'n Ex. 5 at 94-95, ECF No. 620-5.

As discussed above, consistent with the Supreme Court's pronouncement in Hanover Shoe, generic bypass does not affect the DPPs' damages award. See In re Niaspan Antitrust Litig., No. 13-MD-2460, 2015 WL 4197590, at *1 (E.D. Pa. Jul. 9, 2015) (holding that damages award should not be "offset by the amount of any purchases . . . that would not have been made in a 'but for' world"); In re Lidoderm Antitrust Litig., No. 14-MD-02521-WHO, 2017 WL 679367, at *14 n.21 (Feb. 21, 2017) ("Courts have also rejected attempts to decrease damages under [a generic bypass] theory."); In re Prograf Antitrust Litig., No. 11-md-2242-RZW, 2014 WL 7641156, at *4 (D. Mass. Dec. 23, 2014) (holding that "reducing damages to plaintiff wholesalers under a bypass defense is inconsistent with Hanover Shoe"); In re Skelaxin (Metaxalone) Antitrust Litig., No. 12-md-2343, 2014 WL 2002887, at *4-5 (E.D. Tenn. May 15, 2014) ("Skelaxin") (rejecting generic bypass theory for offsetting damages).

As discussed above, that Dr. Leitzinger's damages model may include a purchaser that was uninjured does not render his analysis unsound. It is for the jury to determine whether the Generic-Only and Brand-Only Purchasers were injured, and if so, to what extent; and if the jury concludes they were not, these subgroups will be extracted from Dr. Leitzinger's damages model. See Leitzinger Rebuttal Report ¶ 56 (explaining that his models may be adjusted to respond to various findings by the jury); see also Leitzinger Report ¶ 67 (noting that, to the extent the Court or jury renders legal or factual determinations inconsistent with the assumptions underlying his calculations, an "adjustment can be readily incorporated within the class-wide overcharge formulas, and such an adjustment will be class-wide in nature").

Finally, the key facts with which Defendants take issue are all within the realm of facts the jury may or may not accept during trial and, accordingly, Defendants' criticisms go to the weight, and not the admissibility, of Dr. Leitzinger's opinion. However, the jury is free to accept, based on Dr. Leitzinger's robust analysis based on sound methodology, that the actual world was too tainted by Defendants' unlawful conduct to give credence to how prices in this market responded to generic entry. See DPPs' Opp'n 14.

Plaintiffs have satisfied their burden by demonstrating that Dr. Leitzinger's opinions and testimony "rest[] on a reliable

foundation and [are] relevant to the task at hand." Milward, 820 F.3d at 473 (quoting Daubert, 509 U.S. at 597). Now it is for the trier of fact to weigh the DPPs' evidence, with the aid of cross-examination and Defendants' rebuttal expert evidence. Accordingly, the Court DENIES Defendants' Motion to Exclude the Opinions and Testimony of Dr. Leitzinger, ECF No. 570.

III. DPPs' Motion for Class Certification

A. Legal Standard for Class Certification

To certify a class, the Court "must undertake a 'rigorous analysis' to determine whether" the putative class satisfies each of the four prerequisites set forth in Rule 23(a) of the Federal Rules of Civil Procedure: numerosity, commonality, typicality, and adequacy of representation. In re Nexium Antitrust Litig., 777 F.3d 9, 17 (1st Cir. 2015) ("Nexium III") (quoting Comcast Corp. v. Behrend, 569 U.S. 27, 33 (2013); Wal–Mart Stores, Inc. v. Dukes, 564 U.S. 338, 351 (2011); Gen. Tel. Co. of Sw. v. Falcon, 457 U.S. 147, 161 (1982)). In addition, the putative class must also demonstrate that it satisfies one of the requirements set forth in Rule 23(b), Nexium III, 777 F.3d at 18; in this case, the putative class argues that "the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). To meet this requirement,

the putative class must demonstrate "that 'the fact of antitrust impact can[] be established through common proof' and that 'any resulting damages would likewise be established by sufficiently common proof.'" Nexium III, 777 F.3d at 18 (quoting In re New Motor Vehicles Can. Exp. Antitrust Litig., 522 F.3d 6, 20 (1st Cir. 2008) ("New Motor Vehicles")).

The Supreme Court has explained that "Rule 23 does not set forth a mere pleading standard" but rather, a plaintiff "must affirmatively demonstrate [its] compliance with the Rule." Dukes, 564 U.S. at 350. To do so, a plaintiff has the burden to demonstrate by a preponderance of the evidence that Rule 23's prerequisites to class certification are satisfied. Nexium III, 777 F.3d at 27. "Merits questions may be considered to the extent – but only to the extent – that they are relevant to determining whether the Rule 23 prerequisites for class certification are satisfied." Amgen Inc. v. Conn. Ret. Plans and Tr. Funds, 133 S. Ct. 1184, 1195 (2013); see also Comcast, 569 U.S. at 35 (stating that the Court must determine whether the plaintiff's burden is satisfied under Rule 23 "even when that requires inquiry into the merits of the claim").

The DPPs move to certify a class of 47 members,[11] as defined

[11] In the DPPs' Further Support for Class Certification Memorandum, they adjust the putative class from comprising 48 to 47 members. DPPs' Further Supp. for Class Cert. 3 & n.7, ECF No. 621.

as:

> All persons or entities in the United States and its territories who purchased brand or generic Loestrin 24 directly from Warner [Chilcott] or Amneal at any time during the period from September 1, 2009, through and until June 3, 2015, and all persons or entities in the United States and its territories who purchased brand Minastrin 24 directly from Warner at any time during the period from September 1, 2009, through and until March 14, 2017 (the "Class Period").
>
> Excluded from the Class are defendants, and their officers, directors, management, employees, subsidiaries, or affiliates, and, all federal governmental entities. Also excluded from the class are educational institutions such as universities and colleges.

DPPs' Mem. of Law in Supp. of Mot. for Class Certification ("DPPs' Mot. for Class Cert.") 4, ECF No. 518-1.

B. Numerosity

Under Rule 23(a)(1), to certify a class, a court must determine that "the class is so numerous that joinder of all members is impracticable." Fed. R. Civ. P. 23(a)(1). While there is no strict minimum number of plaintiffs required to demonstrate impracticability, there is a general presumption that "if the named plaintiff demonstrates that the potential number of plaintiffs exceeds 40, the first prong of Rule 23(a) has been met." García-Rubiera v. Calderón, 570 F.3d 443, 460 (1st Cir. 2009) (quoting Stewart v. Abraham, 275 F.3d 220, 226-27 (3d Cir. 2001)); see also

In re Relafen Antitrust Litig., 218 F.R.D. 337, 342 (D. Mass. 2003) ("Relafen"); Solodyn, 2017 WL 4621777, at *4.[12]

In determining whether joinder would be impracticable, district courts may consider the following non-exhaustive factors, in addition to the size of the class: "judicial economy, the claimants' ability and motivation to litigate as joined plaintiffs, the financial resources of class members, the geographic dispersion of class members, the ability to identify future claimants, and whether the claims are for injunctive relief or for damages." In re Modafinil Antitrust Litig., 837 F.3d 238, 253 (3d Cir. 2016), as amended Sept. 29, 2016 ("Modafinil") (citing 5 Moore's Federal Practice § 23.22; 5 Newberg on Class Actions § 3.12); accord Solodyn, 2017 WL 4621777, at *4 ("The Court may also take into account such 'subjective factors' as the 'geographic location of proposed class members, the nature of the action, and matters of judicial economy.'" (quoting In re Nexium (Esomeprazole) Antitrust Litig., 296 F.R.D. 47, 52 (D. Mass. 2013) ("Nexium II")). Moreover, "courts have certified smaller classes in generic suppression cases where judicial economy favors

[12] As a general matter, a class of 20 or fewer tends to carry the presumption that it is not sufficiently numerous; a class of 41 or more carries a presumption that it is sufficiently numerous; and "[c]lasses with between 21 and 40 members are given varying treatment," depending on the facts of the specific case. Modafinil, 837 F.3d at 250 (quoting 5 James Wm. Moore, et al., Moore's Federal Practice § 23.22)).

proceeding as a class action." Solodyn, 2017 WL 4621777, at *4 (citing Nexium II, 296 F.R.D. at 53 (certifying class of twenty-four or twenty-nine); Dale Elecs., Inc. v. R.C.L. Elecs., Inc., 53 F.R.D. 531, 535-36 (D.N.H. 1971) (certifying class of thirteen)).

The DPPs contend they satisfy the numerosity requirement under Rule 23, arguing that their proposed class comprises forty-seven members, for which they have adduced common evidence of injury, and that joinder would be impractical. DPPs' Mot. for Class Cert. 20-21; Reply in Further Supp. of Direct Purchaser Class Pls.' Mot. for Class Certification ("DPPs' Further Supp. for Class Cert.") 3 & n.7. Defendants counter that, at most, the DPPs' class is made up of 16 members. Defs.' Opp'n to Class Cert. 11-12. First, they argue that 27 members of the proposed class (viz., the Brand-Only and Generic-Only Purchasers) must be excluded because they lack standing and/or a plausible claim of injury-in-fact. Id. at 12. Second, they argue that nine putative class members (or five more[13]) must be consolidated because they are no longer stand-alone companies, but rather corporate affiliates of other class members. Id.

1. Generic-Only and Brand-Only Purchasers

Defendants argue that the Generic-Only Purchasers lack antitrust standing under Illinois Brick v. Illinois, 431 U.S. 720,

[13] Four of these overlap with parties that Defendants allege have no direct injury. Defs.' Opp'n to Class Cert. 19.

724 (1977), and its progeny, because they never directly purchased brand or generic Loestrin 24 and/or Minastrin from Defendants during the class period. Defs.' Opp'n to Class Cert. 13-17. Illinois Brick, however, is inapposite. See Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application ¶ 347 (3d & 4th eds. 2019 Cum. Supp.). Illinois Brick holds that an indirect purchaser – one who purchases product from a defendant's customer rather than the defendant itself (like an End-Payor Plaintiff in this case) – may not recover antitrust damages under federal antitrust law. 431 U.S. at 724. But these Generic-Only Purchasers did not purchase indirectly – or otherwise - from Defendants.[14]

Instead, the DPPs' theory of injury for the Generic-Only Purchasers is that Defendants, by delaying and suppressing generic competition, caused the Generic-Only Purchasers to pay more for generic Loestrin from non-Defendant Amneal than they would have absent Defendants' anticompetitive conduct. Leitzinger Rebuttal Report ¶ 25. To this point, the DPPs offer evidence of class-wide injury, including: studies observing that generic prices decline after generic entry; business planning documents of Defendants and

[14] Indeed, but for the no-authorized-generic agreement between Warner Chilcott and Watson, the DPPs' theory posits, Generic-Only Purchasers would have made their generic purchases directly from Warner Chilcott. Only because Warner Chilcott had agreed not to market an authorized generic did generic purchasers need to look elsewhere. DPPs' Further Supp. for Class Cert. 13, 15-16.

Loestrin 24 generic manufactures predicting that inter-generic competition would lower prices; and the actual experience of class savings once the first generic entered the market, with additional savings as competition increased. Leitzinger Report ¶¶ 9(a), 29, 39, 49, 60.

The Generic-Only Purchasers also have established that they have antitrust standing under the considerations set forth by the Supreme Court and enumerated by the First Circuit as:

> (1) the causal connection between the alleged antitrust violation and harm to the plaintiff; (2) an improper motive; (3) the nature of the plaintiff's alleged injury and whether the injury was of a type that Congress sought to redress with the antitrust laws . . .; (4) the directness with which the alleged market restraint caused the asserted injury; (5) the speculative nature of the damages; and (6) the risk of duplicative recovery or complex apportionment of damages.

Sullivan v. Tagliabue, 25 F.3d 43, 46 (1st Cir. 1994) (citing Assoc. Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters, 459 U.S. 519, 537-45 (1983)). As to the first three factors, Dr. Leitzinger's analysis plainly demonstrates that the overcharges incurred by the Generic-Only Purchasers were the result of Defendants' unlawful conduct aimed at suppressing generic competition; an inference can readily be drawn that Defendants intended both to suppress generic competition and to cause prices to increase market-wide; and the Generic-Only Purchasers' injury (overcharges from an anticompetitive scheme) is the type the Sherman Act intends to redress.

The crux of Defendants' argument is that their alleged conduct did not directly cause the Generic-Only Purchasers' injury and, therefore, the damages calculation would be too speculative. But the Court is unconvinced. Defendants' alleged unlawful conduct is plainly the proximate cause of the Generic-Only Purchasers' alleged antitrust injury. While Amneal could have charged less for generic Loestrin 24 than the market would have dictated absent robust and sustained generic competition, where Defendants have foreclosed an entire market from additional generic competition, this purported break in causation is not sufficient to save Defendants from liability. See Areeda & Hovenkamp, Antitrust Law ¶ 347 ("[W]e should allow recovery by the umbrella plaintiff purchasing the 'self-same' product the defendants sold in the same clearly defined . . . market."). The Generic-Only Purchasers' alleged injuries are "the direct result of the asserted antitrust violation – they allege they paid higher prices for generic [Loestrin 24] because Defendants intentionally restricted and manipulated generic competition." See Namenda, 331 F. Supp. 3d at 213; see also In re Lower Lake Erie Iron Ore Antitrust Litig., 998 F.2d 1144, 1168-69 (3d Cir. 1993) (stating, in a market-exclusion case, where there are "no missing links in the causation chain," plaintiffs have standing); Modafinil, 837 F.3d at 264-65 (permitting recovery in a pharmaceutical antitrust case where defendants have engaged in "market exclusion, as it concerns

conduct that prevents a competitive market from forming at all"); Solodyn, 2017 WL 4621777, at *10 (certifying a class in a reverse payment and product hop case that included generic purchasers). But see Mid–West Paper Prods. Co. v. Cont'l Grp., 596 F.2d 573, 583-84 (3d Cir. 1979) (holding that a non-conspiring competitor of a defendant supplier did not have antitrust standing because of the "tenuous line of causation between [the] defendants' price-fixing and the prices paid by [the plaintiff]").

And, finally, as to the sixth consideration, the Generic-Only Purchasers, as direct purchasers vis-à-vis Amneal, do not present issues of "apportionment" or "burdens of duplicative recovery," in the way indirect purchasers may. Areeda & Hovenkamp, Antitrust Law ¶ 347.[15] The Generic-Only Purchasers are the only purchasers in a position to prove injury and recover damages for the alleged

[15] This Court respectfully disagrees with the conclusion reached on this issue in Skelaxin, 2014 WL 2002887, at *11. There, the court held that the plaintiffs did not have standing to pursue antitrust damages for "generic overcharges". Id. at *1, 11. It reasoned that the causal connection between the defendant's alleged antitrust violation and the plaintiff-generic purchaser's harm was too attenuated. See id. at *11 (citing In re Vitamins Antitrust Litig., No. 99CIV5134, 2001 WL 855463, at *4 (D.D.C. July 2, 2001)). Moreover, the Court reasoned that, because it was satisfied that the defendants did not intend the plaintiff's harm, they had not satisfied the standing inquiry set forth by the Supreme Court in Assoc. Gen. Contractors of Cal., Inc., 459 U.S. at 537-45. Skelaxin, 2014 WL 2002887, at 8-9. The Court, consistent with its reading of Areeda & Hovenkamp, concludes that in a market exclusion case like the one at bar, as opposed to a price fixing case, intervening pricing decisions of the non-defendant manufacturer do not require the same level of searching inquiry into causation.

overcharges on their purchases of generic Loestrin 24 from Amneal during the class period under federal antitrust law.

2. Corporate Subsidiaries

Defendants also argue that nine putative class members should not be treated as separate entities for purposes of the numerosity analysis because other members of their corporate families are also direct purchasers. Defs.' Opp'n to Class Cert. 19-20. This argument gets no traction. The entities are separately incorporated companies, are separately listed in Warner Chilcott's transactional sales data, and are distinct from their corporate affiliates. DPPs' Further Supp. for Class Cert. Exs. 37-44. Because they each suffered independent injury, as reflected in their separately tracked purchases of brand and/or generic Loestrin 24, they are separate for purposes of this analysis. See Solodyn, 2017 WL 4621777, at *4; Namenda, 331 F. Supp. 3d at 207; Celebrex, 2017 WL 3669604, at *8.

Defendants' remaining attempts to exclude the Generic-Only Purchasers and the Brand-Only Purchasers[16] are intertwined with their attacks on Dr. Leitzinger's methodology and analysis, as

[16] Defendants argue that the Brand-Only Purchasers should be excluded from the class because there is no proof that they would have purchased generic Loestrin had it been available. See Defs.' Opp'n to Class Cert. 17-18. For the reasons stated above, see supra Part II.B. (discussing this argument in connection with Defendants' Motion to Exclude Dr. Leitzinger's Expert Report), this argument fails.

well as on whether the DPPs have established that common issues predominate under Rule 23(b). As discussed in more detail above and below, the Court concludes that all forty-seven members are properly included in this class, and thus, the class presumptively satisfies Rule 23(a)(1)'s numerosity requirement. García-Rubiera, 570 F.3d at 460. Moreover, the Court is further satisfied that joinder is impracticable after considering the non-exhaustive list of considerations, especially judicial economy; the class members' incentives to bring suit individually against their supplier(s); and the geographic dispersion of class members. See Solodyn, 2017 WL 4621777, at *4 (citing Nexium II, 296 F.R.D. at 52). Thus, Rule 23(a)(1) is satisfied.

C. Commonality

Under Rule 23(a)(2), "[c]ommonality requires the plaintiff to demonstrate that the class members 'have suffered the same injury[.]'" Dukes, 564 U.S. at 349–50 (quoting Falcon, 457 U.S. at 157). A plaintiff's "claims must depend upon a common contention . . . ." Id. at 350. And, "that common contention . . . must be of such a nature that it is capable of classwide resolution — which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke." Id. The Court concludes that commonality under Rule 23(a)(2) is easily met for this putative class. Each putative class member alleges that Defendants caused

overcharges by engaging in an anticompetitive scheme to delay and suppress generic competition.

D. Typicality and Adequacy

Under Rule 23(a)(3), a court may certify a class only where "the claims or defenses of the representative parties are typical of the claims or defenses of the class[.]" Fed. R. Civ. P. 23(a)(3). Courts have noted some uncertainty as to the independent significance of Rule 23's typicality requirement. See 7A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1764 (rev. 4th ed. 2018). "[M]any courts have found typicality if the claims or defenses of the representatives and the members of the class stem from a single event or a unitary course of conduct, or if they are based on the same legal or remedial theory." Id. (citations omitted). Other courts have used Rule 23(a)(3) "to screen out class actions in which the legal or factual position of the representatives is markedly different from that of other members of the class even though common issues of law or fact are present." Id. (citations omitted).

Moreover, Rule 23(a)(4) provides for certification only where "the representative parties will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). The moving party is tasked with demonstrating that "the interests of the representative party will not conflict with the interests of any of the class members . . . ." Andrews v. Bechtel Power Corp., 780

F.2d 124, 130 (1st Cir. 1985). But interests need not be identical; only fundamental conflicts that "go to the heart of the litigation prevent a plaintiff from meeting the Rule 23(a)(4) adequacy requirement." Matamoros v. Starbucks Corp., 699 F.3d 129, 138 (1st Cir. 2012).

Defendants argue that the DPPs do not satisfy Rule 23's typicality and adequacy of representation prerequisites. Defs.' Opp'n to Class Cert. 27-34. Specifically, Defendants challenge the DPPs' class representative Ahold USA, Inc.'s ("Ahold") typicality and ability to adequately represent the class on the basis that: Ahold has no stake in the product hop allegations; Ahold's partial assignment from McKesson only gives it an interest in proving a generic entry date back to March 2011, while other class members' interest reaches back to September 2009; Ahold's purchasing habits are affected differently by the entry of generic products because it is a retailer and not a wholesaler; and Ahold is the only member of the class with an assignment. Id. at 27-29.

Here, as noted above, the putative class members' claims plainly stem from a unitary course of conduct. Ahold's status as a retailer with an assignment does not render its interest in pursuing these claims "markedly different." See Modafinil, 837 F.3d at 251 (holding that, "no matter how intuitively appealing this argument may be, it lacks legal support" and "partial

assignees are appropriately considered to be members of a class"); Meijer, Inc. v. Warner Chilcott Holdings Co. III, 246 F.R.D. 293, 296 (D.D.C. 2007) (noting that the defendants, including Warner Chilcott, admitted that "an assignee stands in the shoes of his assignor, deriving the same but no greater rights and remedies than the assignor then possessed." (quoting Fox–Greenwald Sheet Metal Co. v. Markowitz Bros., 452 F.2d 1346, 1358 n.69 (D.C. Cir. 1971)). Moreover, the assignment gives Ahold a stake in the product hop allegations and purchases of Minastrin 24, as it encompasses "claims [that] relate to those acts alleged against Warner Chilcott in" litigation "to recover allegedly illegal overcharges imposed on purchasers of Loestrin 24." Defs.' Opp'n to Class Cert. Ex. 4; see also DPPs' Further Supp. for Class Cert. 64; DPP Compl. ¶¶ 257-96 (setting forth product hop allegations).

Establishing an earlier generic entry date is also plainly in Ahold's interest: the earlier the entry date for generic Loestrin, "the longer the delay period established, the sooner generic competition ensues, and the lower prices would have been at the start of Ahold's assignment and at the time of Ahold's direct purchases of generic Loestrin 24." DPPs' Further Supp. for Class Cert. 68. Ahold has already filed a Third Amended Complaint that covers the full class period (back to 2009), see DPP Compl. ¶ 297, and it has filed expert reports addressing and seeking damages for the full class period. See Leitzinger Report ¶ 5 n.4. In blunt,

strategic terms, counsel for the DPPs explained that it is in Ahold's individual interest to pursue the whole claim period "[b]ecause the bigger the claim, the bigger the leverage on [Defendants] and hopefully the bigger the settlement [the DPPs will] try to get out of them before we go to trial or while we're in trial". DPP Hr'g Tr. 95:8-12. The Court sees how this would be motivating.

In sum, the Court concludes that Ahold's claims and defenses are typical of the class and is confident Ahold will fairly and adequately protect the interests of the class. Its status as a retailer pursuing claims with an assignment does not render it "markedly different" from the other class members, does not create a conflict with the class, and does not impair its ability to adequately represent the putative class. Indeed, Ahold has been named class representative in many pharmaceutical antitrust class actions, and no court has ever found Ahold to be atypical or inadequate due to its status as an assignee or for any other reason. See, e.g., Solodyn, 2017 WL 4621777; Nexium II, 296 F.R.D. 47; Meijer, Inc., 246 F.R.D. 293. Ahold satisfies Rule 23's typicality and adequacy requirements.

E. Rule 23(b)(3)

As stated above, the DPPs seek certification under Rule 23(b)(3), which requires a putative class to demonstrate that "the questions of law or fact common to class members predominate over

any questions affecting only individual members . . . ." Fed. R. Civ. P. 23(b)(3). This "inquiry tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation." Amchem Prods. Inc. v. Windsor, 521 U.S. 591, 623 (1997). To meet this requirement, the putative class must demonstrate "that 'the fact of antitrust impact can[] be established through common proof' and that 'any resulting damages would likewise be established by sufficiently common proof.'" Nexium III, 777 F.3d at 18 (quoting New Motor Vehicles, 522 F.3d at 20)). "An individual question is one where members of a proposed class will need to present evidence that varies from member to member, while a common question is one where the same evidence will suffice for each member to make a prima facie showing [or] the issue is susceptible to generalized, class-wide proof." Tyson Foods, Inc. v. Bouaphakeo, 136 S. Ct. 1036, 1045 (2016) (internal quotation marks omitted).

1. Predominance: Common Proof of Injury-in-Fact

In order to satisfy Rule 23(b)(3)'s predominance requirement, the DPPs must "include some means of determining that each member of the class was in fact injured." New Motor Vehicles, 522 F.3d at 28; see also In re Asacol Antitrust Litig., 907 F.3d 42, 51 (1st Cir. 2018) ("Asacol") ("Proof of injury, also called 'injury-in-fact,' is a required element of a plaintiff's case in an action such as this one." (quoting New Motor Vehicles, 522 F.3d at 19

n.18). At this stage, "plaintiffs must only show that 'antitrust impact is capable of proof at trial through evidence that is common to the class rather than individual members." Nexium III, 777 F.3d at 24 n.20 (quoting In re Hydrogen Peroxide Antitrust Litig., 552 F.3d 305, 311 (3d Cir. 2008)).

DPPs' common theory of injury is that "every Class member would have purchased at least some lower-priced generic Loestrin [24] instead of higher-priced branded Loestrin 24, Minastrin 24 or generic Loestrin 24 that it did buy." DPPs' Mot. for Class Cert. 16 (quoting Leitzinger Report ¶ 50). Accordingly, in order to prevail on their motion for class certification, the DPPs must satisfy the Court that Dr. Leitzinger's model demonstrates, using common evidence, that each of the DPPs would have substituted some of their purchases of brand Loestrin 24 or Minastrin from Warner Chilcott, or generic Loestrin 24 from Amneal, for cheaper generic Loestrin 24 but for Defendants' allegedly unlawful generic suppression efforts.

Defendants, in turn, argue that individualized inquiry is required for twenty-seven of the forty-eight members of the proposed class to determine injury-in-fact. Defs.' Opp'n to Class Cert. 3. They take issue, specifically, with Dr. Leitzinger's model establishing injury-in-fact for the Generic-Only and Brand-Only Purchasers. Id. at 3-4. They say that Dr. Leitzinger improperly relies on aggregate trends and averages that do not

account properly for the facts of this case and hide the need for individualized inquiry. Id. at 36.

a. Assumptions Regarding Early Minastrin Entry and an Authorized Generic

Defendants challenge Dr. Leitzinger's assumptions relating to whether Warner Chilcot would have launched Minastrin 24 earlier and/or an authorized generic in the but-for world. Defs.' Opp'n to Class Cert. 37-39; Cremieux Report ¶¶ 101-04.[17] But as discussed above, Dr. Leitzinger's sound methodology and analysis cannot be otherwise faulted for accepting reasonable assumptions supported by Plaintiffs' other experts and fact witnesses. See supra Part II.A. Whether Warner Chilcott would have launched Minastrin earlier and/or whether Warner Chilcott would have launched an authorized generic if generics had entered earlier goes to the heart of the merits of this case and is a classic fact question best suited for decision by a jury. See Solodyn, 2017 WL 4621777, at *10 (holding that whether the product hop led the plaintiffs to purchase more of the expensive brand product over the cheaper generic product was a fact question for the jury, not to be

[17] For what it's worth, as the kids say, Dr. Leitzinger has now performed, in response to Defendants' criticisms, the calculations necessary for jury findings that the product hop was lawful, that the product hop was unlawful, and that the product hop occurred six months before a non-delayed Watson generic entry. See Leitzinger Report ¶¶ 62-65; Leitzinger Rebuttal Report ¶¶ 35-41.

determined on class certification).

b. Brand-Only Purchasers

Defendants argue that the DPPs cannot demonstrate that the Brand-Only Purchasers incurred overcharges, because they did not purchase generic Loestrin 24, even after it became available. Defs.' Opp'n to Class Cert. 17-18. The DPPs counter that Dr. Leitzinger's analysis clearly demonstrates that most brand purchases would have been converted to generic Loestrin 24 purchases after generic entry. This, coupled with evidence that the Brand-Only Purchasers are wholesalers in the business of responding to their retail customers' demands, is strong evidence that most Brand-Only Purchasers would have converted at least one brand prescription into a generic prescription in the but-for world. See DPPs' Further Supp. for Class Cert. 33; Leitzinger Rebuttal Report ¶ 29.

The Court acknowledges that the Brand-Only Purchasers' failure to purchase generic Loestrin 24 once it was available "casts doubt on the fact that these entities would have purchased the generic earlier had it been available to them[;]" however, Defendants have not earned "the benefit of the doubt when the very reason we cannot know the answer to that question is because of their alleged wrongdoing." Namenda, 331 F. Supp. 3d at 209 (citing In re DDAVP Direct Purchaser Antitrust Litig., 585 F.3d 677, 689 (2d Cir. 2009)). The Court reiterates the discussion on this score

in relation to Defendants' Motion to Exclude Dr. Leitzinger's Report. See supra Part II.B. The Court is fully satisfied that Dr. Leitzinger's report and testimony establish that the Brand-Only Purchasers each likely would have purchased at least a single prescription of generic Loestrin 24 during the class period in a market with robust, sustained generic competition, given their business interests in meeting their customers' demand. As noted above, it will be for the jury to decide whether Dr. Leitzinger's theory wins the day, in whole or in part; but for present purposes – class certification – his theory more than suffices.

c. Generic-Only Purchasers

Defendants further argue that there is no common proof of injury for the Generic-Only Purchasers, and thus, individual issues predominate. Defs.' Opp'n to Class Cert. 39. Twenty-one of the putative class members purchased generic Loestrin 24 from non-defendant generic manufacturer Amneal and made no brand Loestrin 24 purchases from Defendants. Defs.' Opp'n to Class Cert. 13, 39. The DPPs allege that Defendants' conduct created market conditions that allowed other sellers, like generic-manufacturer Amneal, to charge higher prices than the market would have allowed absent the unlawful conduct. Leitzinger Report ¶ 49. Dr. Leitzinger's model demonstrates that purchasers obtained greater discounts relative to brand WAC as more generics entered the market. Leitzinger Rebuttal Report ¶¶ 25-27. In reaching this

conclusion, Leitzinger relies upon economic literature regarding sustained generic entry; Defendants' and generic manufactures' own forecasts; market-wide sales data showing that prices fell substantially when generic entry finally occurred; and evidence that class members supply brand and generic Loestrin 24 to a broad cross-section of customers. DPPs' Further Supp. for Class Cert. 19-20 (citing Leitzinger Report ¶¶ 28-52).

Defendants retort that branded generics compete differently than generics generally and the actual data demonstrate "meaningful variation in generic prices and no common injury-in-fact/impact as to" the Generic-Only Purchasers. Defs.' Opp'n to Class Cert. 39-42. First, Defendants argue that the price for generic Loestrin 24 did not uniformly decline as additional generics entered the market. Instead, "the average prices paid for the generic products continued to vary" as generic competition became more robust later in the class period. Id. at 40 (quoting Cremieux Report ¶ 41 & Ex. 5).

But the DPPs do not dispute that the generic Loestrin 24 market did not respond in unison as additional generics entered. To the contrary, Dr. Leitzinger's methodology incorporates the "variation across Class members in the actual prices they paid and in the prices they would have paid", providing averages that "correctly summarize the combined effects of all of these Class members in a single classwide overcharge measure." Leitzinger

Rebuttal Report ¶ 45. As discussed throughout, aggregating damages in this way is well accepted.

Second, Defendants argue that the data reveal that generic purchasers showed brand loyalty to their branded generics and did not just shift to the cheapest option. Defs.' Opp'n to Class Cert. 41. But this does not undercut DPPs' allegation that Generic-Only Purchasers would have paid less for the generics they were purchasing. Dr. Leitzinger's model demonstrates that Generic-Only Purchasers would have paid less for their purchases in a but-for world with robust, sustained generic competition; it does not purport to show that they shifted to the cheapest generic available. Leitzinger Rebuttal Report ¶¶ 25-27.

Third, Defendants point to individual data suggesting that some purchasers that bought generic Loestrin 24 from Amneal did not pay less once additional generic manufactures entered. Defs.' Opp'n to Class Cert. 42. Defendants' analysis, however, focuses in on the actual price a few months following generic entry with two and three generic competitors on the market, thereby failing to consider the effect of sustained, robust generic competition. Leitzinger Rebuttal Report ¶¶ 9-12. In particular, Dr. Leitzinger explains, the effects of manufacturer price concessions (viz., chargebacks and rebates) are often recorded in the data later than the original sale transitions. Id. As a result, Dr. Cremieux's data arguably overstates generic prices by understating the

generic discounts. Id.; see also id. ¶ 13 (noting that some of the pricing data used by Dr. Cremieux did not provide any data on manufacturer price concessions). To combat this concern, Dr. Leitzinger uses a combination of transactional data and manufacturers' forecasts to predict prices in the but-for world. Leitzinger Report ¶ 27; see also id. ¶ 61; Table 1, Leitzinger Rebuttal Report (calculating discount off WAC with one through five generic entrants in the market). At trial, the jury will sort out the details, but for now, the Court is satisfied that the DPPs have evidence common to the class that the Generic-Only Purchasers sustained injury-in-fact.

In sum, the DPPs have sufficiently shown that damages may be "demonstrated by a 'common methodology' applicable to the class as a whole." In re Nexium (Esomeprazole) Antitrust Litig., 297 F.R.D. 168, 182 (D. Mass. 2013) ("Nexium I"), aff'd sub nom. Nexium III, 777 F.3d 9 (quoting Comcast 569 U.S. at 30)). While it may be borne out through the evidence at trial that there are a couple uninjured members of the DPP class, it would be a "very small absolute number of class members . . . picked off in a manageable, individualized process at or before trial." Asacol, 907 F.3d at 53-54. The prospect that a handful of identifiable class members may be uninjured is not a barrier to class certification. Cf. id. (holding that class should not be certified in pharmaceutical antitrust case where "any class member may be uninjured, and there

are apparently thousands who in fact suffered no injury").

2. Predominance: Common Proof of Damages

Rule 23(b)(3) carries with it the additional requirement that a putative class demonstrate that damages can be calculated on a class-wide basis. Comcast, 569 U.S. at 35. The damages model must be "consistent with [the putative class's] liability case," id.; that is, "the defendants cannot be held liable for damages beyond the injury they caused." Nexium III, 777 F.3d at 18. That said, "it is well-established that '[t]he individuation of damages in consumer class actions is rarely determinative under Rule 23(b)(3).'" Id. at 21 (quoting Smilow v. Sw. Bell Mobile Sys., Inc., 323 F.3d 32, 40 (1st Cir. 2003)). Rather, "where . . . common questions predominate regarding liability, . . . courts generally find the predominance requirement to be satisfied even if individual damages issues remain." Id. (quoting Smilow, 323 F.3d at 40).

In his Declaration and Rebuttal Report, Dr. Leitzinger establishes a "formulaic approach to class-wide overcharges [that] does not require individualized analysis for each Class member." Leitzinger Report ¶ 67. Dr. Leitzinger develops a benchmark demonstrating (1) the prices that direct purchasers would have paid in a but-for world, and (2) the number of Loestrin 24 and Minastrin 24 purchases that would have instead been generic Loestrin 24 purchases in a but-for world. Id. ¶¶ 54, 57, 62. This

allows him to calculate overcharges or, the "difference between the amounts actually paid for [generic and brand] Loestrin 24 . . . and Minastrin 24, and the amounts that would have been paid absent illegal conduct." Leitzinger Report ¶ 57.

Dr. Leitzinger's approach to calculating class-wide overcharges using evidence common to the class involves: (1) using generic manufacturers' own forecasts predicting the effect of genetic Loestrin 24 entry, along with the literature on the pharmaceutical industry, to calculate a generic entry rate, id. ¶¶ 58-59; (2) using pricing data from the actual experience of generic Loestrin 24 entry, coupled with the forecasts from generic Loestrin 24 manufacturers to calculate the discount off the brand price (i.e., discount off WAC) that would have been available in a but-for world, id. ¶¶ 60-61; (3) calculating the but-for volumes of Loestrin 24, Minastrin 24, and generic Loestrin 24 using generic penetration rates over time applied to actual purchase volumes over time, id. ¶¶ 62-64; and (4) multiplying the per unit overcharge by the actual sales volume to determine the aggregate class-wide overcharges incurred by the DPPs, id. ¶ 66, Table 1. Importantly, Dr. Leitzinger's calculations can be adjusted to account for whichever (if any) anticompetitive conduct the jury finds Defendants liable for, as well as when and how many generic competitors would have entered earlier in the but-for world. Id. ¶¶ 26, 66, 71-72. He further notes that additional adjustments

could be made to account for additional or different determinations altering the calculations used in his model (e.g., generic entry dates). Id. ¶ 67.

Defendants contend that the DPPs, using Dr. Leitzinger's methodology and analysis, fail to establish that "damages are capable of measurement on a classwide basis." Defs.' Opp'n to Class Cert. 43 (quoting Comcast, 569 U.S. at 34-35). They argue that Dr. Leitzinger's model is "highly aggregated" and thus inaccurate and unreliable; it ignores Brand-Only and/or Generic-Only Purchasers that may not be injured; and it fails to separate out overcharges from the alleged generic delay and the alleged product hop. Id. at 43-45. In addition, they continue to take issue with Dr. Leitzinger's assumptions regarding Minastrin entry and his failure to account for decreased volume caused by generic bypass in his damages calculation. Id. at 45-47.

Most of these arguments have been addressed above at length. As stated, the DPPs have satisfied the Court that Dr. Leitzinger's analysis is based on sound and reliable methodology. For this reason, the Court is satisfied that Dr. Leitzinger's damages model does not ignore uninjured purchasers, nor does it improperly assume facts about the Minastrin entry. Moreover, as discussed, see supra Part II.C., the Court sides with the weight of authority in holding that a direct purchasers' damages model need not — and, indeed, should not — offset its damages calculation with any anticipated

decrease in volume that may have occurred in a but-for world due to changes in buying practices.

Moreover, the Court rejects Defendants' plaint that Dr. Leitzinger's aggregated model of damages is unreliable. In an attempt to undermine Dr. Leitzinger's model, Dr. Cremieux disaggregated Dr. Leitzinger's calculations and determined that it yielded purchases of Minastrin for class members that never purchased Minastrin and, when the disaggregated overcharges were added back together for one but-for scenario, the result was $56 million less than Dr. Leitzinger's class-wide estimate of $625.2 million. Defs.' Opp'n to Class Cert. 44; see also Leitzinger Rebuttal Report ¶ 43. Dr. Leitzinger's methodology, as discussed above, involves calculating class-wide averages (including those of actual prices paid, but-for generic penetration rates, but-for brand prices, and but-for generic prices) and plugging them into his aggregate overcharge model. The output is a "single classwide overcharge measure." Id. ¶ 45. This methodology is widely accepted and does not purport to calculate individual damages for any one purchaser. See, e.g., Solodyn, 2017 WL 4621777, *9-10 (certifying a class of direct purchasers based upon Dr. Leitzinger's aggregated damages model). But it is nonsensical to disaggregate the model by taking the class-wide averages for certain measures and applying them to each class member.

This is easily illustrated by considering the application of

the average generic penetration rate to Generic-Only Purchasers. By definition, Generic-Only Purchasers should have a one-hundred-percent generic penetration rate in the actual and but-for worlds. Leitzinger Rebuttal Report ¶ 47. If one were to disaggregate Dr. Leitzinger's model and apply the average generic penetration rate to the Generic-Only Purchasers, it results in the assignment of Minastrin 24 purchases to class members who never purchased a brand product. Id. The Court remains confident in Dr. Leitzinger's model sufficient to send it to a jury — indeed, Dr. Cremieux's alternative calculation, even with its weaknesses, produced a total overcharge damages number that is only 9% lower than Dr. Leitzinger's. Id. ¶ 44.

The DPPs have satisfied the Court that "damages may be demonstrated by a 'common methodology' applicable to the class as a whole." See Solodyn, 2017 WL 4621777, at *10 (quoting Nexium I, 297 F.R.D. at 182) (internal quotation omitted).

3. Superiority

To earn certification, a putative class must establish that a class action is "superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). In undertaking this analysis, the Court examines four factors:

> (A) The class members' interests in individually controlling the prosecution or defense of separate actions; (B) the extent and nature of any litigation

> concerning the controversy already begun by or against class members; (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and (D) the likely difficulties in managing a class action.

Id.

Defendants do not seriously dispute that superiority is met here, but rather regurgitate their arguments that joinder is not impracticable and common issue do not predominate. See Defs.' Opp'n to Class Cert. 48-50. The Court disagrees, for the reasons stated above, and concludes that a class action is the superior method for fairly and efficiently adjudicating this matter. With that, the DPPs have carried their burden in establishing that their proposed class should be certified under Rule 23(a)(1) and (b)(3) under the Federal Rules of Civil Procedure.

IV. Conclusion

For the reasons stated above, the DPPs' Motion for Class Certification (ECF No. 513) is GRANTED and Defendants' Motion to Exclude (ECF No. 570) is DENIED. The Court further APPOINTS as class representative Ahold USA, Inc., and APPOINTS Hagens Berman Sobol Shapiro LLP, Berger & Montague, P.C., Faruqi & Faruqi LLP, and Kessler Topaz Meltzer & Check LLP as Co-Lead Counsel for the

DPP Class.

IT IS SO ORDERED.

William E. Smith
Chief Judge
Date: July 2, 2019