IBEW - NECA LOCAL 505 HEALTH & WELFARE PLAN v. SMITHKLINE BEECHAM CORPORATION Doc. 436

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

In re: FLONASE ANTITRUST LITIGATION,	:	CIVIL ACTION
	:	NO. 08-CV-3301
THIS DOCUMENT RELATES TO: Indirect Purchaser Action	:	

June __18___, 2012 **Anita B. Brody, J.**

MEMORANDUM

Plaintiffs A.F. of L.-A.G.C. Building Trades Welfare Plan ("AFL"), IBEW-NECA Local 505 Health & Welfare Plan ("IBEW"), Painters District Council No. 30 Health & Welfare Fund ("Painters"), and Andrea Kehoe ("Kehoe"), collectively "Indirect Purchasers," are indirect purchasers of the prescription drug Flonase and its generic equivalent. Flonase is the brand-name version of fluticasone propionate ("FP")—a steroid nasal spray produced by Defendant SmithKline Beecham Corporation, doing business as GlaxoSmithKline PLC ("GSK"). Indirect Purchasers allege that GSK filed sham citizen petitions with the Food and Drug Administration ("FDA") to delay the entry of a cheaper, generic version of Flonase into the market. Indirect Purchasers have moved to certify a class of consumers and third-party payors ("TPPs")[1] under the monopolization, unfair and deceptive trade practices ("UDTP"), and unjust enrichment laws

[1]AFL, IBEW, and Painters are all TPPs that underwrite prescription drugs costs for their plan members, i.e. insured consumers. They will be referred to collectively in this opinion as "named plaintiff TPPs."

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of five states.[2] Also before me are three *Daubert* motions seeking to exclude expert reports and testimony critical to this class certification determination: (1) GSK's Motion to Exclude the Expert Report and Testimony of Gordon Rausser; (2) Indirect Purchasers' Motion to Exclude the Report and Testimony of Bruce Stangle; and (3) Indirect Purchasers' Motion to Exclude the Report and Testimony of Robert Navarro.

GSK asserts that Indirect Purchasers have failed to meet certain requirements for class certification under Federal Rule of Civil Procedure 23—in particular, that common issues do not predominate over individual issues for purposes of establishing antitrust impact and damages. GSK contends that only through individual proof and inquiries can the fact of injury or the extent of damage for each class member's purchase and/or reimbursement of Flonase or its generic equivalent be determined.

I am satisfied that Indirect Purchasers have demonstrated that common issues will predominate and that the Rule 23 requirements have been met. In reaching that conclusion, however, certain adjustments to Indirect Purchasers' proposed class definition will be necessary. As opposed to the larger proposed class, a more limited indirect purchaser class will be certified that excludes those class members who did not purchase a generic equivalent of Flonase after it became available. Furthermore, I will only certify the class under the state laws which Indirect Purchasers have demonstrated standing to invoke. Therefore, I will grant in part and deny in part

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[2] Jurisdiction over this action is proper under the Class Action Fairness Act of 2005, which grants federal district courts original jurisdiction over "any civil action in which the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interests and costs, and is a class action in which . . . any member of a class of plaintiffs is a citizen of a State different from any defendant." 28 U.S.C. § 1332(d)(2); see Kaufman v. Allstate N.J. Ins. Co., 561 F.3d 144, 148 (3d Cir. 2009).

Indirect Purchasers' motion for class certification.

I. BACKGROUND[3]

A. Hatch-Waxman and the Generic Drug Approval Process

In order to market a drug in the United States, a company must obtain FDA approval by filing a "New Drug Application" ("NDA") to demonstrate the safety and efficacy of its product. 21 U.S.C. § 355(b). The NDA process is usually lengthy and expensive, and in 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act") to expedite the approval process for generic drugs. Under Hatch-Waxman, to receive FDA approval for a generic drug, a prospective manufacturer need only file an Abbreviated New Drug Application ("ANDA"), which relies on the safety and efficacy data previously provided in the NDA for its branded equivalent. 21 U.S.C. § 355(j). Instead of clinical trials, an ANDA requires a demonstration of a certain level of bioequivalence[4] to a listed drug. The FDA issues and regularly modifies bioequivalence guidance for various categories of generic drugs in order to inform the public of the bioequivalence standards that ANDAs must meet in order to be approved. Generic drugs certified by the FDA as bioequivalent to the brand drug are completely interchangeable with that branded drug and are referred to as "AB-rated."

While an ANDA is pending before the FDA, any interested party can file a citizen petition with the FDA to register a complaint about the pending application. 21 C.F.R. §§ 10.25(a), 10.30. Until 2007, the FDA was required to consider and respond to every citizen

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[3] The facts are stated based on evidence offered to support Indirect Purchasers' Fourth Amended Complaint.

[4] To establish bioequivalence, the generic version must contain the same active ingredient(s), dosage form, route of administration, and strength.

petition.[5] For this reason, filing a citizen petition necessarily delayed the approval of any pending ANDA—only after the FDA responded to all pending citizen petitions could an ANDA be approved. The citizen petition process often was abused by pharmaceutical companies attempting to prolong their monopoly in the market.

B. Flonase and GSK's Alleged Misconduct

In October 1994, the FDA approved GSK's NDA to treat nasal inflammation caused by seasonal and non-seasonal allergies. GSK released Flonase in the United States in 1995, and it quickly became the most prescribed nasal steroid inhalant in the United States. By 2000, Flonase commanded 38% of brand-name inhaled nasal steroid sales in the United States, resulting in over $600 million in sales. By 2005, the peak year for Flonase sales and the last full year of GSK's market exclusivity, Flonase sales exceeded $1.3 billion.

GSK's single patent on Flonase expired on November 13, 2003. However, GSK obtained a statutory extension of market exclusivity from the FDA to August 2004. By the time Flonase's market exclusivity was set to expire in 2004, GSK had identified a number of generic pharmaceutical manufacturers—including Roxane Laboratories, Inc. ("Roxane")—intent on filing ANDAs and bringing competitive generic FP nasal sprays to the market. This case concerns GSK's alleged "brand maturation strategy," crafted to maintain Flonase's market dominance in the face of inevitable generic competition.

Indirect Purchasers offer evidence that GSK's alleged "brand maturation strategy"

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[5] In 2007, after the citizen petitions at issue in this case were filed, Congress passed a law allowing the FDA to summarily dismiss citizen petitions, in order to prevent pharmaceutical companies from using this process to delay generic entry into the market. See 21 U.S.C. § 355(q)(1)(A)(ii).

included four tactics to delay the entry of generic FP nasal sprays into the market: (1) GSK improperly influenced the FDA's bioequivalence guidance process; (2) GSK filed several frivolous citizen petitions with the FDA regarding pending generic FP ANDAs in order to force the FDA to respond and delay approval; (3) GSK drafted an FP monograph for submission to the United States Pharmacopeia—which lists tests, procedures, and acceptance criteria in order to set standards for the quality, purity, strength, and consistency of the pharmaceutical ingredients in an approved drug—in attempt to raise the bar for FP market entry; and (4) GSK supplemented its original NDA in an attempt to delay the FDA from approving any ANDAs before approving GSK's supplements.

Roxane's generic version of Flonase did not enter the market until March 6, 2006. Indirect Purchasers argue that GSK used each of these four tactics to delay the market entry of AB-rated generic equivanlents of Flonase, and that, absent GSK's exclusionary conduct, generic FP would have entered the market in August 2004. As a result, Indirect Purchasers claim that they were prevented from purchasing and/or reimbursing for less-expensive generic FP between August 2004 and March 2006, and that they were forced to pay inflated prices for generic FP between March 2006 and March 2009.[6]

C. Procedural History

Indirect Purchasers initiated this case in September 2008. In December 2011, they filed their motion for class certification now before me. During this time, as a result of two Third

[6]Indirect Purchasers also allege that consumers and TPPs were forced to pay and/or reimburse for Flonase at a supracompetitive price as a result of GSK's conduct. However, for reasons discussed *infra*, I will exclude the proposed class members proceeding under this "branded overcharge" theory.

Circuit opinions and GSK's filing of several motions to dismiss and motions for summary judgment, the claims and issues presented in this motion for class certification have been narrowed to a significant degree. A review of this procedural history follows.

On September 3, 2008, Indirect Purchasers filed a first amended class action complaint ("FAC") against GSK asserting claims of monopolization, UDTP, and unjust enrichment under numerous state laws. On October 17, 2008, GSK moved to dismiss the FAC. In addressing this motion on April 15, 2009, I concluded that it was appropriate to analyze issues regarding Indirect Purchasers' standing prior to class certification. I granted GSK's motion for two reasons: (1) although Indirect Purchasers could establish standing to bring their claims in the states where they resided or had a principal place of business, they failed to state a claim under any of those state laws; and (2) Indirect Purchasers could not establish standing merely by relying on claims of putative class members. *See In re Flonase Antitrust Litig.*, 610 F. Supp. 2d 409, 413 (E.D. Pa. 2009) ("Unless at least one named Plaintiff can state a claim for relief under each count Plaintiffs do not have standing to bring claims as part of a putative class action."). I dismissed the FAC without prejudice, so that Indirect Purchasers could amend their complaint and, as Indirect Purchasers specifically noted, "named Plaintiffs from additional states could join the case" to address issues of standing. *Id.*

On May 21, 2009, Indirect Purchasers filed a second amended class action complaint ("SAC") asserting state law claims under the laws of seven states and adding Kehoe, an individual consumer from Massachusetts, as a named plaintiff. GSK moved to dismiss the SAC by again contending that Indirect Purchasers had not sufficiently plead an injury to have standing to bring their state law claims, or, alternatively, failed to state a claim under those state laws. On

January 21, 2010, I held that Indirect Purchasers had sufficiently plead standing "in states where they reside, and where they purchased Flonase or reimbursed for purchases of Flonase." *In re Flonase Antitrust Litig.*, 692 F. Supp. 2d 524, 534 (E.D. Pa. 2010). Additionally, *inter alia*, Indirect Purchasers' unjust enrichment claim under Florida law was dismissed because, unlike most unjust enrichment state law, Florida requires that a plaintiff confer a direct benefit upon a defendant in order to state a claim for unjust enrichment. *Id.* at 544.

Indirect Purchasers filed a third amended class action complaint ("TAC") on March 1, 2010, asserting the following state law claims: monopolization under the laws of Arizona, Iowa, North Carolina, and Wisconsin; (2) unfair and deceptive trade practices under the laws of Arizona, Florida, Massachusetts, and North Carolina; and (3) unjust enrichment under the laws of Arizona, Iowa, Massachusetts, and Wisconsin. GSK subsequently filed three different motions for summary judgment in October 2010. I denied GSK's motions for summary judgment on *Noerr-Pennington* and causation grounds in June and July 2010, respectively. GSK's third motion for summary judgment against Indirect Purchasers rested on the following three arguments: (1) Indirect Purchasers failed to provide sufficient evidence to raise a genuine issue of material fact as to whether they have standing to bring their state law claims; (2) choice of law rules require that the Indirect Purchasers' claims be governed by the laws of their home states, rather than the laws of the states in which they purchased and/or reimbursed for purchases of Flonase; and (3) Indirect Purchasers failed to provide sufficient evidence to support several of their state law claims.

On September 26, 2011, I granted in part and denied in part GSK's motion. In addressing GSK's standing argument, I again noted that in a class action, [t]he initial inquiry . . . is whether

the lead plaintiff individually has standing." *Winer Family Trust v. Queen,* 503 F.3d 319, 326 (3d Cir. 2007); *see also O'Shea v. Littleton*, 414 U.S. 488, 494 (1974). And although GSK's standing contentions had previously been addressed, at the summary judgment stage the standing inquiry changed because Indirect Purchasers could no longer rely on their allegations; instead, they needed to put forth evidence to establish standing. *See Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 902 (1990). Considering this burden, I granted GSK's motion as to the following named Plaintiffs' claims for lack of standing: (1) IABORI's monopolization and UDTP claims under North Carolina law and (2) Painters' monopolization and unjust enrichment claims under Iowa law; and (3) Painters' UDTP claim under Florida law.[7]

I also conducted a thorough choice of law analysis and concluded that Indirect Purchasers' claims were best considered under the laws of the states in which Flonase or its generic equivalent were purchased (the "purchase states"), as opposed to the states in which Indirect Purchasers resided or had a principal place of business (the "home states"). *In re Flonase Antitrust Litig.*, 815 F. Supp. 2d. 867, 882-85 (E.D. Pa. 2011). Finally, GSK's motion was granted as to Painters' Arizona UDTP claim because no genuine issue of fact had been raised regarding whether GSK had deceived Indirect Purchasers as required under Arizona UDTP law. *Id.* at 885-86.

Indirect Purchasers have since filed a fourth amended class action complaint.[8] The

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[7]As a result of this ruling, named plaintiff International Association of Bridge, Structural, Ornamental and Reinforcing Ironworkers Local No. 79 Health Fund ("IABORI ") was dismissed from this action.

[8]Indirect Purchasers' fourth amended class action complaint includes claims under North Carolina's monopolization statute, N.C. Gen. Stat. § 75-2.1, *et seq.*, and North Carolina's UDTP statute, N.C. Gen. Stat. § 75-1.1, *et seq.* I have already found that none of the named plaintiffs in this case can establish standing to bring an action under these North Carolina statutes. For the

following named Plaintiffs and state law claims remain[9]:

Type of Claim	State	Relevant Plaintiff(s)
Monopolization	Arizona	Painters
Monopolization	Wisconsin	Painters
UDTP	Florida	AFL, IBEW
UDTP	Massachusetts	Kehoe
Unjust Enrichment	Arizona	Painters
Unjust Enrichment	Massachusetts	Kehoe
Unjust Enrichment	Wisconsin	Painters

In December 2011, Indirect Purchasers moved for class certification.[10] On February 22,

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reasons outlined *infra*, I do not find that Indirect Purchasers can seek certification of a class pursuant to the monopolization and UDTP statutes of North Carolina.

Additionally, Indirect Purchasers' fourth amended class action complaint includes a claim under Arizona's UDTP statute, Ariz. Rev. Stat. § 44-1522, *et seq*. However, I previously granted GSK's motion for summary judgment as to Indirect Purchasers' Arizona UDTP claim because Indirect Purchasers had failed to raise a genuine issue of material fact as to whether GSK engaged in deception, as required by the Arizona statute. *In re Flonase Antitrust Litig.*, 815 F. Supp. 2d. 867, 885-86 (E.D. Pa. 2011); *see also Kuehn v. Stanley*, 91 P.3d 346, 351 (Ariz. Ct. App. 2004). At this stage in the litigation, with discovery already closed and without any evidence raising a genuine issue as to whether GSK engaged in deception, I do not find that Indirect Purchasers can now seek certification of a class pursuant to Arizona's UDTP statute.

[9]The remaining state law claims have been outlined in "Appendix A" at the end of this opinion. The statutes at issue are often labeled "*Illinois Brick* repealers" in light of the Supreme Court's decision prohibiting federal antitrust suits by indirect purchasers. *Ill. Brick Co. v. Illinois*, 431 U.S. 720, 728 (1977). Numerous states across the country have subsequently passed "*Illinois Brick* repealers" enabling an indirect purchaser to bring an antitrust claim under state law. Furthermore, in those states with a repealer statute, indirect purchasers are not barred from recovery for unjust enrichment damages.

My previous opinions have detailed *"Illinois Brick* repealers" and the similar theories underlying each of Indirect Purchasers' remaining state law claims. *See In re Flonase Antitrust Litig.*, 815 F. Supp. 2d. 867, 882-85 (E.D. Pa. 2011); *In re Flonase Antitrust Litig.*, 692 F. Supp. 2d 524, 534 (E.D. Pa. 2010); *In re Flonase Antitrust Litig.*, 610 F. Supp. 2d 409, 413 (E.D. Pa. 2009).

[10]Indirect Purchasers first moved for class certification on December 12, 2008. Since that time, I have twice denied Indirect Purchasers' motion for class certification without prejudice to

2012, a hearing was held to establish the parameters of the class sought for certification. In that hearing, Indirect Purchasers generally asserted that: (1) the laws of North Carolina, GSK's home state, should be applied for choice of law purposes, and (2) their proposed class could consist of class members in states where no named plaintiff had established standing.

With regard to choice of law, for the reasons set forth in my September 26, 2011 opinion on GSK's motion for summary judgment and stated on the record in the February 22, 2012 hearing, I find that the Indirect Purchasers' claims are best considered under the laws of the states where they either purchased FP, or where TPP's plan members purchased FP and were reimbursed for those purchases.

Regarding standing and class certification, the Third Circuit has held that "to be a class representative on a particular claim, the plaintiff himself must have a cause of action on that claim." *Zimmerman v. HBO Affiliate*, 834 F.2d 1163, 1169 (3d Cir. 1987). Although Indirect Purchasers are correct that named plaintiffs may generally represent other plaintiffs with common but not identical claims, *see Sullivan*, 667 F.3d at 302, Indirect Purchasers cannot attempt to expand their class to include states in which no named plaintiff has demonstrated injury after the completion of discovery and three rounds of dispositive motions addressing the issue of standing. *See Griffin v. Dugger*, 823 F.2d 1476, 1483 (11th Cir. 1987) ("Each claim must be analyzed separately, and a claim cannot be asserted on behalf of a class unless at least

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re-brief the issue in light of opinions by the Third Circuit, first in *In re Hydrogen Peroxide Antitrust Litigation*, 552 F.3d 305 (3d Cir. 2008), then in *Sullivan v. DB Investments, Inc.*, 667 F.3d 273 (3d Cir. 2011). In December 2011, Indirect Purchasers re-filed their previous two motions for class certification and accompanying memoranda and expert declarations, along with new supplemental memoranda. GSK responded to Indirect Purchasers' motion in the same fashion. All of the re-filed motions, memoranda, and declarations that have been filed since December 2011 have been taken into consideration.

one plaintiff has suffered the injury that gives rise to that claim."); *In re Packaged Ice Antitrust Litig.*, 779 F. Supp. 2d 642, 657 (E.D. Mich. 2011) (detailing the numerous federal district courts that have held that named plaintiffs lack standing to assert claims under the laws of the states in which they do no reside or in which they suffered no injury); *In re Wellbutrin XL Antitrust Litigation*, 260 F.R.D. 143, 156-158 (E.D. Pa. 2009) (reviewing extensively the applicable case law and subsequently rejecting plaintiffs' argument that named plaintiffs with standing in one state may represent absent plaintiffs from states in which the named plaintiff does not have standing).

Therefore, as a result of my choice of law and standing decisions, and as stated on the record in the February 22, 2012 hearing, I find that the indirect purchaser class can only consist of individuals and entities that purchased and/or reimbursed for FP in Arizona, Florida, Massachusetts, and Wisconsin (the "class states")—states in which at least one named plaintiff has demonstrated injury.

From February 27-29, 2012, a hearing was held on Indirect Purchasers' motion for class certification, with both sides offering the testimony of their respective experts, and the three *Daubert* motions lodged against each expert. The parties have since filed post-hearing briefs, particularly focused on whether Indirect Purchasers have demonstrated that common issues predominate over individual issues for purposes of establishing antitrust impact and damages.

III. LEGAL STANDARD

Subsection (a) of Fed. R. Civ. P. 23 lists four prerequisites for any class action: numerosity, commonality, typicality, and adequacy. Fed. R. Civ. P. 23(a). Subsection (b) specifies additional requirements for each type of class action. For certification under subsection

(b)(3), the movant must also show "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). These requirements are called predominance and superiority.

In In re Hydrogen Peroxide, the Third Circuit clarified the standard of review for motions for class certification. The court held that "proper analysis under Rule 23 requires rigorous consideration of all the evidence and arguments offered by the parties." In re Hydrogen Peroxide Antitrust Litig., 552 F.3d 305, 321 (3d Cir. 2008). A district court must "consider carefully all relevant evidence and make a definitive determination that the requirements of Rule 23 have been met before certifying a class." Id. at 320. Further, "the court must resolve all factual or legal disputes relevant to class certification, even if they overlap with the merits . . . [and] [f]actual determinations necessary to make Rule 23 findings must be made by a preponderance of the evidence." Id. at 307, 320. Finally, "[w]eighing conflicting expert testimony at the certification stage is not only permissible; it may be integral to the rigorous analysis Rule 23 demands." Id. at 323. "[A] district court may find it unnecessary to consider certain expert opinion with respect to a certification requirement, but it may not decline to resolve a genuine legal or factual dispute" relevant to class certification. Id. at 324.

IV. DISCUSSION

The following are certified as a class pursuant to Federal Rule of Civil Procedure 23 for the class period of August 2004 through March 2009:

A. With respect to the monopolization and UDTP claims

(1) *For the Class Period from August 2004 through March 2006*
All persons or entities throughout the United States and its territories who from August 2004 through March 2006 purchased, paid for, and/or reimbursed for branded Flonase in any of the following four states—Arizona, Florida, Massachusetts, or Wisconsin. These persons or entities must have also purchased, paid for, and/or reimbursed for an AB-rated generic fluticasone propionate nasal spray equivalent of branded Flonase ("generic FP") from March 2006 to March 2009 in the same designated state in which the Flonase purchase was made.

(2) *For the Class Period from March 2006 through March 2009*
All persons or entities throughout the United States and its territories who from March 2006 to March 2009 purchased, paid for, and/or reimbursed for generic FP in the following states—Arizona, Florida, Massachusetts, or Wisconsin.

B. With respect to the unjust enrichment claims

(1) All persons or entities throughout the United States and its territories who from August 2004 through March 2006 purchased, paid for, and/or reimbursed for branded Flonase in any of the following three states—Arizona, Massachusetts, or Wisconsin. These persons or entities must have also purchased, paid for, and/or reimbursed for generic FP from March 2006 to March 2009 in the same designated state in which the Flonase purchase was made.

C. For purposes of the class definition, the Flonase and/or generic FP drugs must have been intended for consumption by the class members, their families or their members, employees, plan participants, beneficiaries, or insureds.

D. The following are excluded from the class:
(1) GSK and its respective subsidiaries and affiliates;
(2) all governmental entities (except for government funded employee benefit plans);
(3) all persons or entities that purchased FP nasal spray, including Flonase, for purposes of resale or directly from GSK to the extent and solely to the extent of such purpose for resale or as a direct purchase;
(4) insured individuals covered by plans imposing a flat dollar co-pay that was the same dollar amount for generic as for brand name drug purchases;
(5) fully insured health plans, i.e. plans that purchased insurance from another third-party payor covering 100% of the plan's reimbursement obligations

to its members; and

(6) insured individuals who purchased only generic FP (never branded Flonase) and whose health plans imposed a flat dollar co-pay applicable to generic drugs.

E. From August 2004 through March 2009 will be referred to as the "Class Period."

A. Rule 23(a) Requirements

I will first consider the Rule 23(a) requirements of numerosity, commonality, typicality, and adequacy. These prerequisites must be satisfied to bring any class action.

1. Numerosity

The first prerequisite in Rule 23(a) requires that the proposed class be "so numerous that joinder of all members is impracticable." Fed. R. Civ. P. 23(a). Although "no minimum number of plaintiffs is required to maintain a suit as a class action," in general sufficient numerosity exists "if the named plaintiff demonstrates that the potential number of plaintiffs exceeds 40 . . . ." *Stewart v. Abraham*, 275 F.3d 220, 226-27 (3d Cir. 2001). This requirement is plainly satisfied as Indirect Purchasers seek to certify a class of tens of thousands of consumer class members and hundreds of TPP class members. *See In re Wellbutrin XL Antitrust Litig.*, No. 08-2433, 2011 WL 3563835, at *7 (E.D. Pa. Aug. 15, 2011) ("*Wellbutrin XL*"). GSK conceded the numerosity requirement. Accordingly, IPPs have established the numerosity requirement of Rule 23(a).

2. Commonality

The second prerequisite in Rule 23(a) requires that "there are questions of law or fact common to the class." Fed. R. Civ. P. 23(a)(2). To establish commonality, plaintiffs must demonstrate that their claims "depend upon a common contention," the resolution of which "will

resolve an issue that is central to the validity of each one of the claims in one stroke." *Wal-Mart Stores, Inc. v. Dukes*, —U.S.—, 131 S. Ct. 2541, 2551 (2011). "However, where an action is to proceed under Rule 23(b)(3), the commonality requirement is subsumed by the predominance requirement" because "it is far more demanding than the Rule 23(a)(2) commonality requirement." *Danvers Motor Co., Inc. v. Ford Motor Co.*, 543 F.3d 141, 148 (3d Cir. 2008) (internal quotation marks omitted). It is therefore appropriate to "analyze the two factors together, with particular focus on the predominance requirement." *In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 528 (3d Cir. 2004).

Although Indirect Purchasers assert state law claims of monopolization, UDTP, and unjust enrichment, proof of the essential elements of these claims will be common across the class and focused on GSK's behavior, not that of the individual class members. The common issues presented in each of the class members' claims include: (1) whether GSK unlawfully monopolized or attempted to monopolize the market for Flonase; (2) whether GSK unlawfully possessed and/or extended its monopoly power over the Flonase market; (3) whether GSK's actions caused the price of FP to be maintained at supra-competitive levels; (4) whether GSK's citizen petitions were intended to prevent generic entry and/or constitute unlawful conduct; (5) whether the class members suffered antitrust injury; and (6) whether GSK was unjustly enriched to the detriment of the class members. Resolving the allegations surrounding GSK's alleged conduct in delaying generic entry will resolve issues that are "central to the validity of each one of the claims in one stroke." Therefore, I find the commonality requirement satisfied here.

3. Typicality

The third prerequisite in Rule 23(a) requires that "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). "Typicality entails an inquiry whether the named plaintiff's individual circumstances are markedly different or the legal theory upon which the claims are based differs from that upon which the claims of other class members will perforce be based." *Hassine v. Jeffes*, 846 F.2d 169, 177 (3d Cir. 1988) (citations and internal quotation marks omitted). "The typicality requirement is intended to preclude certification of those cases where the legal theories of the named plaintiffs potentially conflict with those of the absentees." *Georgine v. Amchem Prods., Inc.*, 83 F.3d 610, 631 (3d Cir. 1996). "The inquiry assesses whether the named plaintiffs have incentives that align with those of absent class members so that the absentees' interests will be fairly represented." *Id.* "Factual differences will not defeat typicality if the named plaintiffs' claims arise from the same event or course of conduct that gives rise to the claims of the class members and are based on the same legal theory." *Danvers Motor Co., Inc.*, 543 F.3d at 150 (emphasis omitted).

In this case, Indirect Purchasers allege that the same unlawful conduct injured both the class representatives and the absent class members. IPPs' state law claims for monopolization, UDTP, and unjust enrichment arise from an identical course of conduct—GSK's allegedly monopolistic "brand maturation strategy." GSK implemented this strategy without reference to individual purchasers, and all members of the proposed class seek to recover for the resulting overcharge injury, or unjust enrichment at their expense, based on the same legal theories. *In re Terazosin Hydrochloride Antitrust Litig.*, 220 F.R.D 672, 688 (S.D. Fla. 2004) ("[I]f one class representative is able to prove that Defendants' alleged anticompetitive acts caused an overcharge for [the brand drug], or that Defendants were unjustly enriched at Indirect Purchaser

Plaintiffs' expense, such proof will likewise prove the case on liability for every other class member."). GSK does not contest the typicality requirement. I find that Indirect Purchasers have satisfied Rule 23(a)(3).

4. Adequacy of Representation

The fourth prerequisite in Rule 23(a) requires that "the representative parties will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). The adequacy determination "depends on two factors: (a) the plaintiff's attorney must be qualified, experienced, and generally able to conduct the proposed litigation, and (b) the plaintiff must not have interests antagonistic to those of the class." *New Directions Treatment Servs. v. City of Reading*, 490 F.3d 293, 313 (3d Cir. 2007). Indirect Purchasers' lead counsel has presented evidence of its extensive experience in complex antitrust actions, including cases involving delayed entry of generic pharmaceuticals. After reviewing Indirect Purchasers' submissions, I find that the first prong of the adequacy inquiry is satisfied, as Indirect Purchasers' counsel are "qualified, experienced, and generally able to conduct the proposed litigation." *New Directions*, 490 F.3d at 313.

The absence-of-conflict requirement "seeks to uncover conflicts of interest between named parties and the class they seek to represent." *Warfarin*, 391 at 532. "A class representative must be part of the class and possess the same interest and suffer the same injury as the class members." *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 625-26 (1997) (internal quotation marks omitted). Adequacy will not be denied simply "because of a potential conflict of interest that may not become actual." *Kohen v. Pac. Inv. Mgmt. Co. LLC*, 571 F.3d 672, 680 (7th Cir. 2009). GSK has not raised any conflicts with the class. Each class member purchased

and/or reimbursed for FP at some point during the Class Period at a supracompetitive price. Each class member holds a strong common interest in establishing GSK's liability for these alleged overcharges.

Because the class suffers from no conflicts and is represented by qualified counsel, I conclude that the class meets both prongs of the adequacy requirement of Rule 23(a)(4).

B. Rule 23(b) Requirements

Once the Rule 23(a) requirements are met, other requirements under Rule 23(b) must be satisfied based on the type of class action. Indirect Purchasers seek certification under section (b)(3), requiring proof of predominance and superiority. Indirect Purchasers must demonstrate "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).

1. Predominance

The parties in this matter directed their arguments regarding certification almost exclusively to the question of predominance. Predominance "'tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation.'" *In re Ins. Broker Antitrust Litig.*, 579 F.3d 241, 266 (3d Cir. 2009) (quoting *Amchem*, 521 U.S at 623). "Issues common to the class must predominate over individual issues." *Hydrogen Peroxide*, 552 F.3d at 311. "Individual questions need not be absent . . . . [Rule 23(b)(3)] requires only that those questions not predominate over the common questions affecting the class as a whole." *Messner v. Northshore Univ. Healthsystem*, 669 F.3d 802, 815 (7th Cir. 2011). "Because the nature of the evidence that will suffice to resolve a question determines whether the question is common or

individual, a district court must formulate some prediction as to how specific issues will play out in order to determine whether common or individual issues predominate in a given case." *Hydrogen Peroxide*, 552 F.3d at 311 (internal quotation marks and citation omitted). "If proof of the essential elements of the cause of action requires individual treatment, then class certification is unsuitable." *Id.* (citing *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 172 (3d Cir. 2001)).

The predominance inquiry "begins, of course, with the elements of the underlying cause of action." *John Fund, Inc. v. Halliburton Co.*, —U.S.—, 131 S.Ct. 2179, 2184, 180 L.Ed.2d 24 (2011). Importantly, the parties agree that the essential elements of Indirect Purchasers' remaining state monopolization and UDTP claims are the same, paralleling their federal counterparts, the Sherman Act and the Federal Trade Commission Act. *See App. A.* (outlining the elements of the monopolization and UDTP state statutes). To satisfy Rule 23(b)(3), Indirect Purchasers must show that common evidence can establish: (1) liability on each of their claims; (2) injury-in-fact, and (3) measurable damages. I will address each of these elements in turn.

a. Common Proof on Liability

Indirect Purchasers have successfully plead, and survived summary judgment on, the following state law claims: (1) monopolization under the laws of Arizona and Wisconsin, (2) unfair and deceptive trade practices under the laws of Florida and Massachusetts, and (3) unjust enrichment under the laws of Arizona, Massachusetts, and Wisconsin. To prove liability on each of these state law claims, each class member will rely on the same evidence focused on GSK's allegedly anticompetitive conduct aimed at preventing a generic version of Flonase from entering the market. The issues relevant to proving liability—relevant market, monopoly power,

exclusionary conduct, and causation—can be proven through class-wide, common evidence because these issues focus on GSK's conduct, not on the actions of the individual class members. *See Warfarin*, 391 F.3d at 528 (explaining that liability for anticompetitive conduct centers on the defendants' conduct, not the actions of individual class members). Although Indirect Purchasers also assert three state unjust enrichment claims, they will utilize the same operative evidence to establish GSK's liability for these claims, as with their monopolization and UDTP claims. *See Sullivan v. DB Investments, Inc.*, 667 F.3d 273, 301 (3d Cir. 2011) (emphasizing that any minor variations between state laws will not defeat class certification "as long as a sufficient constellation of common issues binds class members together"); *Terazosin*, 220 F.R.D. at 697-98 (certifying a class of indirect purchasers in part because "the same common operative facts that form the basis for each of the state classes' antitrust claims form the basis for the unjust enrichment claims").[11] GSK admitted that, with regard to proving liability, the evidence would

[11]I recognize that the elements of the remaining state unjust enrichment claims are not exactly the same as those of the monopolization and UDTP state statutes. In general, to state a claim for unjust enrichment, a plaintiff must show that the defendant received a benefit from the plaintiff, that the defendant accepted and retained the benefit conferred, and that it would be inequitable for the defendant to retain that benefit without paying. *See Powers v. Lycoming Engines*, 245 F.R.D. 226, 231 (E.D. Pa. 2007); *Undoing the Otherwise Perfect Crime—Applying Unjust Enrichment to Consumer Price-Fixing Claims*, Daniel R. Karon, 108 W. Va. L. Rev. 395, 409 (2005). Indirect Purchasers have successfully plead, and survived summary judgment on, unjust enrichment claims under the laws of Arizona, Massachusetts, and Wisconsin. While there are minor variations amongst these claims, *see App. A*, I do not find, nor does GSK assert, that the variation among the remaining state unjust enrichment laws is material to this decision on certification.

To prove their unjust enrichment claims, all class members will rely on common evidence focused on whether: (1) GSK's conduct delayed generic competition; (2) the delay of generic entry enriched GSK as a result of overcharges and monopoly profits in the Flonase market from August 2004 to March 2006; (3) this additional enrichment came at the expense of the class; and (4) whether, as a matter of equity, the retention of this benefit would be unjust. "As is the nature of unjust enrichment claims, this common evidence will focus on the defendant's gain and not on the plaintiff's loss." *Terazosin*, 220 F.R.D. at 698.

be the same for each of Indirect Purchasers' state law claims. Therefore, I find that common issues of fact and law will predominate on this element of Indirect Purchasers' case.

b. Antitrust Impact

Indirect Purchasers next must demonstrate individual injury, i.e. antitrust impact or fact of damage (as opposed to the extent of damage). "In antitrust cases, impact often is critically important for the purpose of evaluating Rule 23(b)(3)'s predominance requirement because it is an element of the claim that may call for individual, as opposed to common, proof." *Hydrogen Peroxide*, 552 F.3d at 311. The Third Circuit has explained plaintiff's burden in establishing antitrust impact at the class certification stage:

> Plaintiffs' burden . . . is not to prove the element of antitrust impact, although in order to prevail on the merits each class member must do so. Instead, the task for plaintiffs at class certification is to demonstrate that the element of antitrust impact is capable of proof at trial through evidence that is common to the class rather than individual to its members. Deciding this issue calls for the district court's rigorous assessment of the available evidence and the method or methods by which plaintiffs propose to use the evidence to prove impact at trial.

552 F.3d at 311-12.

Indirect Purchasers contend that class members were injured through overcharges for purchases and/or reimbursements of FP during the Class Period, as a result of delayed generic entry into the market. To support their argument on common impact and damages, Indirect Purchasers present expert declarations and testimony from Gordon Rausser, Ph.D., an economics

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The class proceeding under unjust enrichment claims will only be limited to the extent that (1) "generic only" class members (March 2006—March 2009 generic FP purchasers only) and (2) class members who only purchased and/or reimbursed for FP in the state of Florida cannot recover damages based on a theory of unjust enrichment. *See In re Flonase Antitrust Litig.*, 692 F. Supp. 2d 524, 544 (E.D. Pa. 2010) (dismissing Indirect Purchasers' unjust enrichment claim under Florida law because Florida requires that a plaintiff confer a direct benefit upon a defendant in order to state a claim for unjust enrichment).

professor at the University of California-Berkeley.[12] Rausser opines that general economic principles and actual market data establish common impact in this case, and that through a "yardstick" methodology—comparing prices in the actual world with prices in a hypothetical "but-world" without GSK's misconduct—he can demonstrate that across all types of end-payors and all distribution channels, injury and damages occurred in this case as a result of GSK's delaying generic entry.

This common evidence is capable of establishing two types of injury in the purchase of FP during the Class Period: (1) "switcher overcharge," from August 2004 through March 2006, that applies to class members who purchased Flonase before generic entry and would have switched to the less expensive generic FP if it had been available; and (2) "generic overcharge," from March 2006 to March 2009, that applies to class members who purchased generic FP at a supracompetitive price because delayed generic entry prevented earlier generic price competition and a lower initial generic price. I will refer to the first group of class members as "switchers" and to the second group of class members as "generic only."

GSK challenges Indirect Purchasers' claim that antitrust impact is capable of proof at trial through evidence that is common to the class rather than individual to each class member. Specifically, GSK raises three arguments: (1) Rausser's methodology, which relies on aggregated data, masks considerable variation in the actual prices paid by class members, the purchasing patterns of class members, and the prescription drug formularies possessed by TPP class members, and therefore cannot determine whether a given class member was in fact injured; (2)

[12]Rausser's opinions can be found in three separate expert declarations (January 2010, May 2010, and October 2010 Declarations), two depositions (March 2010, January 2012), and his testimony at Indirect Purchasers' class certification hearing on February 27-29, 2012.

uninjured class members remain in the class; and (3) complex and individualized inquiries are necessary to prove impact, as well as damages. In rebutting Dr. Rausser, GSK relies on the expert opinions of Dr. Robert Navarro, a trained pharmacist and expert in pharmacy benefit programs, and Dr. Bruce Stangle, an economist.[13]

I will first discuss how Indirect Purchasers have demonstrated that impact to the class is capable of proof through their common evidence. Then I will address how GSK's arguments fail to show that individual inquiries will predominate in determining impact to this class.

(1) Impact to All Class Members

To meet their burden in demonstrating impact to purchasers of generic FP, Indirect Purchasers must show that generic FP prices would have been lower absent GSK's conduct through common evidence. Rausser described how certain general principles demonstrate that impact for generic FP purchasers occurs through basic market mechanisms, and how the actual market data confirms that these market mechanisms were present in this case. First, he explained that by delaying generic entry, GSK can capture an extended exclusivity period for a brand drug like Flonase during which time large numbers of consumers are willing to pay elevated prices because the drug is effective for them and less expensive alternatives are unavailable. In this case, the price per unit of Flonase showed a steady increase from the beginning of the Class Period until just prior to generic entry, moving from around $60/bottle to $70/bottle. When the first generic drug then enters the market, that generic drug is invariably priced at a discount to the

[13]Stangle's opinions can be found in three expert declarations (April 2010, June 2010, February 2012) and one deposition (May 2010). Navarro issued one expert declaration in April 2010 and was deposed in May 2010. Both Stangle and Navarro testified during the class certification hearings on February 27-29, 2012.

brand drug's price at that same time. Upon generic entry in March 2006, both Roxane and GSK introduced generic FP drugs at a price 25% below the price of Flonase. While the initial generic price was lower than the brand price, absent GSK's conduct it would have been even lower because it would have been discounted off the brand price in August 2004, not the higher brand price in March 2006.

Rausser further explained that by delaying generic entry, GSK prevented generic price competition that would have resulted in lower generic FP prices for those class members purchasing generic FP between March 2006 and March 2009 in this case. Specifically, he noted that after its initial discount off the brand price, the generic FP price steadily declined over the first eighteen months after entry with only two generic drugs on the market. Rausser explained that this decline was consistent with extensive historical data and academic studies detailing how generic price declines, while spurred on by new generic drug entries, are not dependent on additional generic drugs entering the market. As more drug manufacturers launch additional generic drugs, competition intensifies and drives the generic price down further. In 2007, when a third generic drug (Apotex) launched, the generic price dropped even further; a fourth generic drug (Hi-Tec) arrived on the market in 2009 initiating yet another generic price decrease.

These basic market principles, confirmed by historical data and actual market data in this case, demonstrate how class members would have paid less for generic FP "but-for" GSK's exclusionary conduct.

To meet their burden in establishing "switcher overcharge," Indirect Purchasers must show through common evidence not only that generic FP prices would have been lower than Flonase prices between August 2004 and March 2006 (the period during which GSK prevented

generic entry), but also that those class members who purchased Flonase prior to generic entry would have switched to the generic product if it had been available. Many of the same market mechanisms described above explain the cost differential that existed between brand and generic FP. Upon generic entry, the first generic drug is invariably priced at a significant discount to the brand. Two years after generic entry, as a result of generic drug competition, Rausser stated that the generic price is on average 70% less than the brand price. In this case, although the average price of Flonase decreased after generic entry—dropping to approximately the same price as the generic three months after entry—from that point on, the generic price stayed consistently and significantly below the price of Flonase.

For the "switcher" class members that actually purchased and/or reimbursed for generic FP after entry in March 2006, it is reasonable to assume—based on their observed decisions between the brand and generic—that if the generic had been available earlier, they would have purchased and/or reimbursed for it over the higher-priced brand drug. *See In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 326, 343 (E.D. Mich. 2001) ("Evidence that class members have purchased a generic [drug] after it became available gives rise to the inference that they would have similarly done so in the 'but-for' world at the 'but-for' price. There is no need for individual analysis of switching behavior as to these putative class members."); *see also Wellbutrin XL*, 2011 WL 3563835, at *14 (making similar finding regarding TPPs that purchased and/or reimbursed for a generic drug after it became available). This inference is further supported by the rapid conversion to generic drugs that occurred in this case. Rausser stated that one month after generic entry in March 2006, Flonase had lost 88% of the total bottle sales of FP at pharmacies. Within the first year following entry, 95% of the FP sales became generic. By the

end of the Class Period, Flonase made up only 1% of the FP market, as the generic captured the remaining 99%. The erosion of brand-name Flonase was even faster than GSK had initially expected, and was one of the most rapid Rausser had ever examined.

Such rapid conversion can be explained not only by the purchase price differential between the drugs, but also by state generic substitution laws that make the substitution of generic drugs for prescribed brand drugs either mandatory or within the discretion of a pharmacist. Furthermore, TPPs offer prescription drug formularies, i.e. tiered pricing, with lowers co-pays and coinsurance to encourage insured consumers to purchase a generic equivalent over the brand drug.

This common evidence is capable of demonstrating that the "switchers" would have purchased the generic drug over Flonase prior to March 2006 absent GSK's exclusionary conduct. It further shows the price of generic FP would have been lower than that of Flonase.[14]

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[14]Indirect Purchasers repeatedly emphasize that this evidence of general economic principles and actual market data is the same evidence that a group of direct purchasers relied on in seeking certification in a related action, alleging injury through overcharges as a result of delayed generic entry into the market. *See American Sales Co., Inc. v. SmithKline Beecham Corp.*, 274 F.R.D. 127 (E.D. Pa. 2010). Because in November 2010 I granted that motion for class certification, Indirect Purchasers claim that their proposed class should be certified. However, this motion for class certification presents certain issues and complexities that were absent in my certification of a direct purchaser class. For one, GSK neither contested that motion nor asserted a *Daubert* challenge against the direct purchaser plaintiffs' two certification experts. More importantly, though, the issues of antitrust impact and damages are different in the context of an indirect purchaser class, largely as a result of the cost and payment structure present in the pharmaceutical industry and the fact that the indirect purchaser class is much larger than thirty member direct purchaser class.

To the extent Indirect Purchasers assert that impact can be proven based solely on GSK's alleged exclusionary conduct, in accordance with the presumption of impact established in *Bogosian v. Gulf Oil Co.*, 561 F.2d 434 (3d Cir. 1977), I do not find such a presumption compatible with the record of this case. *See In re OSB Antitrust Litig.*, No. 06-826, 2007 WL 2253425, at *6-7 (E.D. Pa. Aug. 3, 2007) (noting that courts in the Third Circuit apply the *Bogosian* doctrine almost exclusively in direct, not indirect, purchaser actions, and explaining

(2) Rausser's Yardstick Methodology

To further demonstrate impact, as well as damages, Rausser proposes to utilize a "yardstick" methodology through which he can compare prices paid for FP in the actual world (i.e. with GSK's alleged misconduct delaying generic entry until March 2006) with the prices paid in a hypothetical "but-for" world (i.e. with generic entry nineteen months earlier in August 2004).

To construct the actual world of FP prices in each class state, Rausser utilized monthly nationwide data on the actual volume and dollar sales of Flonase and generic FP that took place within each distribution channel throughout the Class Period. These distribution channels are pharmacy (or retail), mail order, long-term care, clinics, HMOs, home health care, non-federal hospitals, and miscellaneous. He then computed the average brand and generic price each month within each channel by simply dividing the dollar sales with the volume data.

Rausser subsequently constructed a "but-for world" to estimate how the prices paid for FP would have changed if generic entry had not been delayed. In doing this, he used the market data of what actually occurred in the FP market after generic entry, along with generic economic

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that even in direct purchaser actions "the Third Circuit also requires proof of actual classwide economic injury - a 'belt and suspenders' approach to establishing impact."). In addition, the continued existence of the *Bogosian* presumption appears uncertain within the Third Circuit. *See Hydrogen Peroxide*, 552 F.3d at 326 ("We emphasize that actual, not presumed, conformance with the Rule 23 requirements is essential.").

Regardless, Indirect Purchasers do not rely exclusively on general economic principles and GSK's alleged anticompetitive conduct to demonstrate impact. As discussed *infra*, Rausser utilizes a yardstick methodology and sensitivity analysis, relying on available industry nationwide and state-specific data, to show that impact to these class members is capable of proof through common evidence.

principles and historical studies in generic pricing and entry. Rausser first assumed that, as in the actual world, GSK's generic product (Par) would have launched simultaneously with Roxane's generic FP drug because historically brand drug companies usually decide to launch their own authorized generic alongside the first non-authorized generic as a means to offset any losses inevitably resulting from generic entry. He conservatively assumed that the launch dates for the third and fourth generic FP drugs—Apotex in October 2007 and Hi-Tech in February 2008—would not be accelerated in the "but-for" world.

Rausser explained that his analysis of the rhinitis drug market revealed no other substantial differences between the markets before and after generic entry that would have caused a material change in the pricing of Flonase or its generic substitutes. The competitive therapies available were substantially the same, consumer demand did not materially change, and reimbursement practices were essentially the same.

To construct the "but for" price of Flonase and generic FP across the Class Period, Rausser used the price changes, discounts and conversion rates observed in the actual market data after March 2006 as a yardstick for estimating what the effect of generic entry would have been in 2004. Rausser explained that he set the initial "but-for" generic price at 25% below the Flonase price in August 2004; this discount is consistent with industry practice and with the initial price discount set in this case. Rausser then used price data observed in the available industry market data to map out the generic prices in the "but-for" world. Generic prices eventually leveled out in the actual world in March 2009 at $20, and Rausser used this same price in his "but for" world as a benchmark for the end of the Class Period

From this yardstick analysis, Rausser showed that the "but-for" generic prices would have

been lower than the actual generic FP prices between March 2006 and March 2009, as well as the actual Flonase prices between August 2004 and March 2006.

However, within the prescription drug market, Rausser noted that two characteristics might be thought to distinguish the price experience of one class member from another: (1) type of end-payor, i.e. uninsured consumer, insured consumer, or TPP; and (2) sales channel (i.e., retail/pharmacy, mail order) through which the class member paid and/or reimbursed for FP. Rausser contends that available market data enables him to examine each of these distinctions and conclude that there is no significant group of class members who were not impacted as a result of GSK's conduct.

To test the robustness of his methodology considering these distinctions, Rausser conducted a sensitivity analysis. First, he analyzed the uninsured consumers' prices across each sales channel and for each generic manufacturer (Roxane, Par, Apotex, Hi-Tech). Rausser concluded that his average was robust for this group of consumers—of course, uninsured consumers capture the entire price difference between Flonase and generic FP across all sales channels.

Next, Rausser analyzed the insured consumers, whose cost burden for an FP purchase derives from the contractual arrangement with their TPP. As a result of this contractual arrangement, an insured consumer may pay a percentage of a drug's purchase price (coinsurance), a flat dollar amount of the purchase price (co-pay), or the full purchase price (if they have not met their deductible or have exceeded their annual benefit maximum). The payment amount can also vary between brand and generic drug purchases, as set by a TPP's formulary or tiers. For example, a three tier formulary could include generic, preferred brand,

non-preferred brand tiers, each with different co-pay or coinsurance amounts. Generally, Rausser noted, co-pay and coinsurance rates are lower for generic drugs than for brand drugs, as TPPs often place brand drugs on a less favorable formulary status than generic drugs.

In testing the impact of plan provisions in each class state, Rausser separated out insured consumer cost-sharing by state by using data on the net consumer contribution for commercial and Medicare third-party payer plans. This data showed that, in each of the four class states, insured consumers contributed more money per claim for brand purchases prior to generic entry than for generic purchases. In each class state, the difference was greater than eight dollars per claim. Moreover, because this data revealed net consumer contributions, it took into account all the complexities of a plan's provisions, i.e. co-pay, coinsurance, deductible. Rausser noted that his analysis of insured consumer contributions excluded two groups of consumers whose plan provisions do not allow for injury—specifically, insured consumers with the same flat dollar co-pay for brand and generic drug purchases ("one-tier plans"), and insured consumers with a flat dollar co-pay for generic drug purchases and who only purchased generic FP, not Flonase, during the Class Period.[15]

Finally, Rausser analyzed the robustness of his yardstick methodology for TPPs, whose net cost for FP purchases during the Class Period is determined by subtracting the applicable consumer contribution (i.e. co-pay, coinsurance) and drug manufacturer rebates from the gross

[15]In a similar delayed generic entry case, the presence of these consumers in a proposed class of consumers and TPPs was a critical reason behind the court's denial of class certification. *See Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, No. 04-5898, 2010 WL 3855552, at *26 (E.D. Pa. Sept. 30, 2010). At the early stages of this litigation, Indirect Purchasers' proposed class included these consumers. Stangle and Navarro pointed out the existence of these uninjured parties in their initial expert declarations. Indirect Purchasers subsequently amended their class definition to exclude these consumers.

drug cost.[16] As the literature and actual market data indicated, generic entry has the following effect on each of these three variables: lowers the gross FP price, lowers the co-pay/coinsurance rate, and reduces the number of manufacturer rebates. Therefore, Rausser explained, the effect of generic entry on the net cost to TPPs depends on whether the decline in gross FP drug price exceeds the reductions in co-pays, coinsurance, and manufacturer rebates.

Rausser tested whether TPPs still suffer injury when extreme values are used for the reduction in co-pay/coinsurance rates and manufacturer rebate rates. For example, the average difference in the co-pay/coinsurance amount between brand and generic drugs averaged $15. Rausser analyzed whether impact still occurred for a TPP if that differential was actually $40. The average rebate price reduction for Flonase after generic entry was 12%. Rausser examined whether TPPs were still injured if the rebates offered were 50% of the gross drug price. Even using these extreme values, Rausser stated that TPPs still suffer monetary loss during the Class Period as a result of GSK's conduct.[17]

Additionally, Rausser examined the actual transaction data from the named Plaintiff

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[16]Rausser explained that rebates are offered by manufacturers of branded drugs to create incentives for moving volume. Rebates, of course, offset the net cost of a brand drug; therefore, they only make sense economically if the revenue decrease GSK experiences is more than outweighed by the volume increase that they are able to capture as a result. Because generic entry triggers a steady decrease in brand drug volume, drug manufacturers typically reduce the number of rebates offered after generic entry. This case was no different, as Rausser reviewed internal GSK data demonstrating such a reduction in rebates after generic entry.

[17]It must be noted that Rausser's analysis of TPPs does not include fully-insured TPPs, which have been excluded from the class because they do not bear the cost burden for an FP purchase. At the early stages of this litigation, Indirect Purchasers' proposed class included these TPPs—one named plaintiff, in fact, was a fully-insured TPP. Again, Stangle and Navarro explained the presence and uninjured nature of these TPPs in their initial declarations. Indirect Purchasers subsequently amended their class definition to exclude these TPPs. All of the remaining named plaintiff TPPs are self-insured plans.

TPPs. Utilizing his yardstick methodology, Rausser demonstrated that each of the TPPs suffered at least some injury in each of the class states in which it purchased and/or reimbursed for Flonase or generic FP.

Through this common evidence and Rausser's methodology, Indirect Purchasers have demonstrated that they can establish impact to this class of consumers and TPPs through class-wide evidence. GSK raises several objections to Rausser's methodology and Indirect Purchasers' assertions, which are addressed below.

(3) GSK's Objections: Aggregated Data and its Effect on TPP Cost-Sharing Provisions

GSK attacks the reliability of Dr. Rausser's methodology for its use of aggregated data sources, which this section addresses, that allegedly mask the presence of injury and exaggerate the extent of damages for the class. According to GSK, this aggregated data, particularly concerning pricing and distribution of purchases, fails to represent the actual FP prices paid by class members in the class states or the actual distribution of purchases reimbursed by TPP class members in the class states. As a result, GSK argues that Rausser's methodology cannot adequately assess injury or measure damages for TPPs at the state level.

In addressing the argument regarding the use of aggregated data and its effect on TPP cost-sharing provisions, GSK relies on the expert opinions and declarations of Dr. Robert Navarro, a trained pharmacist and expert in pharmacy benefit programs, and Dr. Bruce Stangle, an economist. Dr. Navarro explained that TPPs and prescription benefit managers ("PBMs") offer widely variable prescription drug programs. Several commonly used mechanisms and incentives can influence the amount of cost-sharing and price for any given prescription drug

transaction. Navarro outlined each of these, including patient copayment/coinsurance, deductibles, benefit caps, drug formularies, participating pharmacy networks, and use of mail service. Each of these provisions is highly varied among the named Plaintiff TPPs, and, Navarro opined, this variation is consistent with that seen among TPPs across the country. Furthermore, Navarro explained that each of these plan features can alter the cost burden imposed on insured consumers and TPPs.

As a result of this variation in the structure of prescription drug benefit programs, Stangle opined that it was impossible for Rausser's class-wide methodology to assess fact of injury. He explained that the various plan provisions detailed by Navarro (i.e. co-pays, deductibles, benefit maximums) must be considered in the impact analysis. Stangle opined that only through an analysis of individual transactions, considering each TPP's provisions, could impact be established.

Rausser's sensitivity analysis, though, tested his methodology against each of these various plan provisions. Using state-specific data, Rausser showed that even considering all the various plan provisions that determine an insured consumer's cost burden for an individual FP purchase, insured consumers' net contribution per claim would have been much lower in each class state absent GSK's conduct. GSK ignores the fact that this data takes into account more than simply co-pays and coinsurance. By looking at the net contribution per claim, this data factors in all the plan provisions—including deductibles—that Stangle and Navarro highlighted as factors that could alter the price experience for consumers and undermine Rausser's analysis.[18]

[18]Moreover, some of these plan provisions, though present in a particular TPP prescription drug program, are unlikely to effect this analysis because they are rarely triggered. For instance, Stangle admitted that it is unlikely that benefit maximums will ever affect an

Rausser additionally analyzed whether extreme drug formularies—in particular, a co-pay/coinsurance differential of $40 between brand and generic drugs, as opposed to the average $15 differential—could alter impact to TPPs in this case.[19] He concluded that TPPs still suffered impact. He also examined whether impact would still occur for TPPs if GSK offered extreme rebates (50% off the gross Flonase price as opposed to the average 12%), contrary to pharmaceutical industry practice. Again he found that his methodology did not mask injury, as the TPPs continued to be impacted.

In response, GSK grasps onto the possibility that certain TPPs might be uninjured—even benefitted—by delayed generic entry if they only reimbursed for a few FP purchases. Specifically, GSK points to the following testimony by Rausser: "[I]n the early part of the 'but for' period, because the [TPP] is losing the rebates and there is a more favorable co-pay for generics in the early part of the damage period . . . it takes a while before the [TPPs] catch up with what . . . they have foregone . . . in the first part of the period." (2/28 AM H'rg Tr. 31-32). Rausser noted that if a TPP only had a couple transactions in the first nineteen months of the Class Period you could not show injury for them. GSK asserts that many TPPs could potentially exhibit this same reimbursement pattern because many class member TPPs, like the named plaintiff TPPs, may be from outside the class states and may have made only a few

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individual plan member. Named plaintiff Painters utilizes a participating pharmacy network, requiring its plan members to absorb more of a drug's cost if purchased outside that network. In reviewing all of Painters' actual claims data, Rausser noted that no prescriptions were filled in non-participating pharmacies during the Class Period.

[19]Stangle challenged the sufficiency of Rausser's sensitivity analysis by claiming that it only accounted for a two-tier drug formulary. However, Rausser explained that by using such an extreme value ($40 differential in consumer contribution between brand and generic drugs), his sensitivity analysis encompassed more than a two-tier prescription drug plan.

reimbursements for FP purchases during the Class Period. Stangle emphasized that Rausser's methodology could not account for these TPPs because he applied an average distribution of purchases/reimbursements for TPPs across the Class Period.

It is apparent that underlying GSK's contention is its belief that the Third Circuit's decision in *Hydrogen Peroxide* requires Indirect Purchasers to demonstrate, by a preponderance of the evidence, that impact can be established for *every* class member through common proof. GSK cites to a statement, however, that concerns plaintiffs' burden at the *merits* stage of the litigation—"individual injury (also known as antitrust impact) is an element of the cause of action; to prevail on the merits, every class member must prove at least some antitrust impact resulting from the alleged violation." *Hydrogen Peroxide*, 552 F.3d at 311; *see In re Neurontin Antitrust Litig.*, No. 02-md-1390, 2011 WL 286118, at *8 n.23 (D.N.J. Jan. 25, 2011) (considering a similar argument by defendants and noting that this passage relates to plaintiffs' burden at the merits stage of the litigation).

The Seventh Circuit has explained this distinction regarding uninjured class members in the following manner:

> [A] class will often include persons who have not been injured by the defendant's conduct . . . . Such a possibility or indeed inevitability does not preclude class certification, despite statements in some cases that it must be reasonably clear at the outset that all class members were injured by the defendant's conduct. Those cases focus on the class definition; if the definition is so broad that it sweeps within it persons who could not have been injured by the defendant's conduct, it is too broad.

Kohen v. Pacific Inv. Management Co. LLC, 571 F.3d 672, 677 (7th Cir. 2009) (citations omitted). I agree with the analysis in *Kohen* and with other courts that "have routinely observed that the inability to show injury as to a few does not defeat class certification where the plaintiffs

can show widespread injury to the class." *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 297, 320-21 (E.D. Mich. 2001) (citing *In re NASDAQ Market-Makers Antitrust Litig.*, 169 F.R.D. 493, 523 (S.D.N.Y. 1996)); *see also Meiher, Inc. v. Warner Chilcott Holdings, Co. III, Ltd.*, 246 F.R.D. 293, 309-310 (D.D.C. 2007) (same); *In re K-Dur Antitrust Litig.*, No. 01-1652, 2008 WL 2699390, at *18 (D.N.J. April 14, 2008) (same).

GSK's speculative concern does not undermine the ability of Rausser's methodology and the available common evidence to demonstrate widespread injury to the class. For one, Rausser has shown that all named plaintiff TPPs—who fit a similar profile, i.e. out-of-state TPP with a select number of FP reimbursements—suffered injury as a result of GSK's alleged misconduct. Additionally, by removing from the class all TPPs and consumers that only purchased and/or reimbursed for Flonase, never generic FP, during the Class Period, *see infra*, this concern largely disappears. Therefore, I am satisfied that the class definition is not so overly broad as to defeat certification.

GSK also asserted that Rausser's methodology was flawed because its use of aggregated data masked varied pricing at the end-payor level in each of the class states. With regard to pricing, Stangle criticized Rausser's use of a national average price for both the actual and "but-for" FP prices. Stangle labeled these national average prices as "synthetic prices"—computations derived from national data on FP volume and sales dollars—that mask the actual transaction prices paid by class members in the class states.[20]

[20]Rausser does not argue with the notion that he uses an average price. As he explained: "It's a price that's used throughout the pharmaceutical industry. I look at the total dollars, I look at the extended units, and I've got a price for which those extended units moved through the market. It is an average price, there is no question about that." (H'rg Tr. 33.)

Stangle spent significant time comparing the actual state price data of named plaintiff TPPs with Rausser's national average generic price, both in the actual and "but-for" worlds. However, Stangle only offered one concrete example of Rausser's national average generic price masking injury—named plaintiff AFL. Stangle looked at the actual transaction prices for AFL in Florida for generic FP after generic entry in March 2006 to construct his own "but for" generic price lines for assessing impact to AFL. Based on this analysis, he concluded that AFL actually benefitted from the alleged delay of generic entry in the state of Florida. Yet, as Rausser explained, Stangle's analysis was lacking in two critical respects: (1) Stangle failed to consider that earlier generic entry in August 2004 would typically mean a lower initial generic price, because the generic price in August 2004 would be discounted off the Flonase price at that same time, not the higher Flonase price in March 2006; and (2) Stangle failed to account for the full price decline that occurred over the first nineteen months after generic entry.[21] Instead, he averaged the generic prices that occurred for the first year after generic entry and applied that same average price across the first nineteen months of the "but-for" world. By making these two corrections, Rausser showed that AFL suffered injury in Florida during the Class Period.[22]

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[21]Rausser pointed out a third mistake in Stangle's analysis: the inclusion of a transaction that fell outside the Class Period. While correcting for this mistake also changed the calculation such that AFL was injured in Florida, this mistake/correction does not carry the same weight as the other two corrections noted above in attempting to ascertain whether Rausser's methodology is capable of establishing impact to this class.

[22]GSK and Stangle repeatedly note the significant variation between the actual generic prices paid in a given state and Rausser's "but-for" generic price. For example, they noted that although Rausser's "but-for" generic price never exceeds $50/bottle, named plaintiff Painters reimbursed for generic FP purchases in 2006 at prices as high as $63.97/bottle. Therefore, GSK appears to argue that the "but-for" prices in 2004 should match up more closely with the actual prices paid in the class states in 2006. However, this contention again fails to recognize that earlier generic entry in 2004 would allow for a lower generic entry price than in 2006.

Stangle also compared Rausser's national average generic price to the prices actually paid for the FP generic in ten states, based on data from the named plaintiff TPPs.[23] Although Stangle demonstrated that the prices exhibited some level of variation around Rausser's national average generic FP price, GSK fails to explain how any price variation that may exist for FP purchases is masking injury, i.e. that class members would have actually paid and/or reimbursed more for FP absent GSK's conduct. In fact, in analyzing the state-specific prices paid by AFL and IBEW during specific time increments, Rausser demonstrated that the price variation across the states was less than 1%. Much of the price variation is merely a reflection of the changes in brand and generic prices over time.[24] And because Rausser computed average prices for each month—he did not compute average prices over time—his analysis factored in price variation across the Class Period.

Rausser also testified that although he lacked state-specific FP pricing data, he did consider what differential between state prices and national prices would need to exist for his national average to mask injury. He explained that prices would have to move outside the realm of the data outliers to reach a point where there was no injury. Furthermore, as noted above, Rausser conducted a sensitivity analysis, using state-specific data, to test whether his national

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[23]The ten states are Alabama, Arizona, Florida, Illinois, Indiana, Kentucky, Mississippi, New Mexico, Tennessee, and Wisconsin.

[24]The rest of the price variation, as Rausser explained, existed because Stangle included prices from the mail-order distribution channel, all of which were found in named plaintiff Painters' internal data. Rausser demonstrated that these prices also exhibited little price variation. Furthermore, although the prices in the mail-order channel do not exactly parallel those seen in the retail channel, Rausser analyzed each of the distribution channels for FP and found that consumers of FP were injured by GSK's exclusionary conduct. Unlike Rausser's average brand price for Flonase after generic entry, discussed *infra*, I do not find that Rausser's average generic price is masking the absence of injury for class members purchasing FP in certain distribution channels.

average price masked injury for TPPs or insured consumers.

Courts, under certain circumstances, have found averaged data to be unreliable on the question of common impact and class-wide damages. *See Reed v. Advocate Health Care*, 268 F.R.D. 573, 591 (N.D. Ill. 2009) (explaining that "averaging by definition glides over what may be important differences") (internal quotation marks and citation omitted); *In re Graphics Processing Units Antitrust Litig.* 253 F.R.D. 478, 502 (N.D. Cal. 2008) (same).[25] Regarding the use of averages in econometric analyses, the American Bar Association has noted:

> Sometimes the prices used by economists are averages of a number of different prices charged to different customers or for somewhat different products. Using such averages can lead to serious analytical problems. For example, averages can hide substantial variation across individual cases, which may be key to determining whether there is common impact. In addition, average prices may combine the prices of different package sizes of the same product or of somewhat different products. When this happens, the average price paid by a customer can change when the mix of products that the customer buys changes-even if the price of the single product changed.

ABA Section of Antitrust Law, *Econometrics: Legal, Practical, and Technical Issues* 220 (2005). It is critical to note that this case does not involve several different products or different markets of supply and demand. The allegations in this case involve two bioequivalent substitutable drugs with a supply and demand market that exhibited no significant changes during the relevant time periods. Within this homogenous market, Rausser has demonstrated through

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[25]GSK cites to *Reed*, in particular, where plaintiffs relied on Rausser's expert testimony, and the court did not find that he had applied his econometric principles and methods reliably to the particular facts of that case. Yet this case and *Reed* are simply inapposite. *Reed* involved allegations of wage-suppression by a class of hospital-based registered nurses. The court noted that numerous factors could affect the wages of an individual nurse—age, nurse performance and merit, sign-on or retention bonuses, and non-wage compensation (i.e. employee benefits, overtime). Defendants presented evidence that, because of these various factors, the wages paid varied greatly and, more importantly, certain nurses actually received pay increases during the class period. Although Dr. Rausser's methodology failed to control for all the relevant factors in *Reed*, I find Rausser's methodology to be sufficient for the facts of this case.

common evidence that between March 2006 and March 2009, after generic FP became available, the actual price for generic FP was higher than the corresponding generic FP price would have been in the "but-for" world, and that between August 2004 and March 2006, the "but-for" generic FP prices would have been lower than the actual Flonase prices.

I recognize, though, that certain variables—in particular co-pay/coinsurance and deductibles—can alter the FP price experience for a given class member, such that an average price differential by itself may not answer the question of impact for the class members under all circumstances. *See Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, No. 04-5898, 2010 WL 3855552 (E.D. Pa. Sept. 30, 2010) (*"Wellbutrin SR"*) ("Just because an average price was increased or decreased by the alleged foreclosure does not mean that all members of the proposed class paid supracompetitive prices or that any damage for an individual end-payor or that any damage for an individual end-payor could be calculated in any formulaic way by common proof."). But as I have already thoroughly discussed above, Rausser did much more than simply compare a monthly average FP price in the actual and "but-for" worlds to demonstrate common impact. He conducted a sensitivity analysis to test whether his methodology was robust in assessing impact for all three types of class members. He also showed that each named plaintiff TPP was injured during the Class Period, applying the available common data and his yardstick methodology. I am satisfied that the data variation in this case is not so extreme as to mask the absence of injury for a significant number of class members.[26]

[26]In *Weiss v. AstraZeneca*, No. BC323107 (Ca. Sup. Ct. 2008), Rausser criticized the usefulness of similar aggregated data from third-party vendors to establish impact and class-wide damages to a class of uninsured consumers, insured consumers, and third-party payors. Much of the testimony, admittedly, appears contradictory to that set forth by Rausser in the instant case. Rausser explained that *Weiss* required a different analysis because the class was alleging that a

Finally, GSK contests whether Indirect Purchasers must show that the overcharges for FP had been "passed through" to the indirect purchaser class, as opposed to merely demonstrating that the actual FP prices paid by the class were greater than the prices it would have paid but-for GSK's delaying generic entry. Rausser testified that in a case alleging foreclosed competition like this one, conducting a formal pass-through analysis to trace the economic damages throughout the distribution chain was unnecessary. Rather, he explained that by comparing the actual and "but-for" FP prices as he did in his yardstick methodology, he could observe the clear price differential in the actual and "but-for" worlds that shows impact. He further stated that unlike a price-fixing case, where an end-payor can mitigate or even avoid the prices increases through various measures, in a foreclosed competition case, impact can be measured in terms of what product the end-payor was actually forced to buy because of the delayed entry, versus what product(s) they would have purchased, absent the forestalling of competition. I agree that in the instant case Indirect Purchasers need not conduct a formal pass-through analysis, and that Rausser's methodology is sufficient. *See In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 326, 344 (E.D. Mich. 2001) ("[A]n indirect purchaser must estimate only the 'but-for' price that it should have paid, which is a far less exacting exercise than apportioning the overcharge throughout the entire chain of distribution") (quoting Roger D. Blair & Jeffrey L. Harrison,

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drug manufacturer issued misleading advertisements concerning the effectiveness of one drug compared to another drug with a chemically different makeup, different dosage requirements, and a relatively similar price. On the other hand, this case concerns allegations of foreclosed generic competition, involving two bioequivalent substitutable drugs with vastly different prices. I am satisfied that the market dynamics of the two cases are sufficiently different so as not to undermine Rausser's testimony in this case.

Reexamining the Role of Illinois Brick in Modern Antitrust Analysis, 68 Geo. Wash. L. Rev. 1, 29 (1999)); *see also Wellbutrin XL*, 2011 WL 3563835, at *15 (finding pass-through unnecessary to establish antitrust impact).

I find that Indirect Purchasers have shown that impact is capable of proof at trial through evidence that is common to the class rather than individual to its members for "generic only" and "switcher" overcharges.

(4) Proposed Class Members That Never Purchased Generic FP

Indirect Purchasers proposed class included certain types of consumers and TPPs that either were not impacted by GSK's conduct, or will be unable to show impact through the class-wide evidence presented. These include the following class members: (1) uninsured consumers who purchased Flonase after generic entry; (2) all consumers who purchased Flonase prior to generic entry and did not purchase Flonase or generic FP after entry; and (3) TPPs that only purchased and/or reimbursed for Flonase, never generic FP, during the Class Period. Each of these class members possesses a common attribute—they never purchased and/or reimbursed for generic FP during the Class Period. For the reasons detailed below, I am unwilling to certify these class members.

(i) Uninsured Consumers Who Purchased Flonase After Generic Entry

Consumers purchasing Flonase after generic entry are known as "brand loyalists." Indirect Purchasers' proposed class excludes "brand loyal consumers," defined as insured consumers who purchased only the branded version of Flonase after generic entry. GSK pointed out that this exclusion failed to include uninsured consumers who purchased only the branded

version of Flonase after generic entry, i.e. uninsured "brand loyal consumers."

The only plausible theory by which "brand loyalists" can show damage in a delayed generic entry case is "branded overcharge"—paying supracompetitive prices for Flonase because earlier generic entry would have lowered Flonase prices. Stangle declared that according to Dr. Rausser's own data, brand prices actually increased in some distribution channels—in particular, the retail/pharmacy channel—after generic entry, even though Rausser's national average brand price exhibited a decrease in brand prices after generic entry. The limited data from Indirect Purchaser TPPs—showing only twenty purchases of Flonase after generic entry—further confirmed this trend as the large majority of those purchases were at a price equal to or greater than the price of Flonase just prior to generic entry. Rausser admitted that Flonase prices within the retail channel stayed high and increased slightly over the course of the damage period. Rausser further admitted that such uninsured consumers would not have been injured as a result of GSK's conduct. He also acknowledged that Flonase prices may have risen in at least one other channel during certain periods after generic entry.

In this particular instance, therefore, Rausser's national average Flonase price after generic entry does mask price increases, and in turn fact of injury, across certain distribution channels for uninsured consumers. Because his methodology is not reliable in establishing injury for uninsured consumers that purchased Flonase after generic entry, I excluded these members from Indirect Purchasers' proposed class.

(ii) Consumers Who Purchased Flonase Before Generic Entry and Made No Brand or Generic Purchases After Generic Entry

A select number of consumers who purchased Flonase before generic entry made no drug purchases, either brand or generic, after generic entry. For these consumers, there were no observed transactions in which they chose between the brand and the generic drug.[27] Indirect Purchasers argue that nearly all of these consumers would have switched to generic FP if generic entry had occurred in August 2004. GSK contends that, without resorting to individualized proof of a consumer's personal medical-decisionmaking, Indirect Purchasers cannot establish which class members would have switched to generic FP and which class members would have continued purchasing Flonase.

To demonstrate that these consumers would have converted to generic FP in the "but-for" world, Rausser points out that 91% of FP volume switched from brand to generic after generic entry. He also noted that each of the four class states have generic substitution laws that facilitate conversion to the generic drug, either by mandate or at a pharmacist's discretion. Finally, given the cost difference between the generic and brand drugs, whether in co-pay/coinsurance rates for insured consumers or full purchase price for uninsured consumers, general economic principles hold that in choosing between equivalent products, consumers will choose the less-expensive one.

This common evidence, however, is cannot establish which of these consumers would

[27]Both Stangle and Rausser agreed that approximately 21.5% of insured consumers fit this purchasing pattern. Neither expert offered an estimate as to how many uninsured consumers only purchased Flonase before generic entry and made no purchases after generic entry.

have switched to the generic. Indirect Purchasers attempt to transpose a volume statistic—generic conversion rate of FP prescriptions—on a group of entirely different customers, who did not exhibit a preference for the generic during the Class Period. Rausser acknowledged that this data only concerned volume conversion and failed to display the number of individuals who switched to the generic.

Regardless of what other features might exist to encourage generic conversion, I do not find that injury is capable of being established for these individual through evidence common to the class. An individual consumer might continue to purchase Flonase for various reasons, i.e. the nature of her health insurance coverage, a perceived difference in the relative quality between Flonase and generic FP, or some other personal reason. Only through knowledge of an individual consumer's personal medical decision-making can this determination be made. For these reasons, I have excluded these consumers from the class.

(iii) TPPs That Never Purchased and/or Reimbursed for Generic FP

GSK has repeatedly stressed that, based on the difficulties noted above with regard to consumers that only purchased Flonase, Indirect Purchasers have failed to meet their burden to show that impact is capable of proof through common evidence for TPPs that only paid and/or reimbursed for Flonase during the Class Period.[28] Indirect Purchasers, meanwhile, have continually ignored any explanation as to why TPPs that never paid for and/or reimbursed for

[28]Navarro and Stangle noted that it is quite possible that TPPs may have only reimbursed for Flonase purchases during the Class Period; for example, a TPP may have shut down in the period between May 2004 and May 2006, or it may only have a few reimbursements in a class state during the Class Period, all concentrated between May 2004 and May 2006, because it is an out-of-state TPP.

generic FP remain in the class. Asked about a TPP's burden regarding brand loyal consumers, Rausser stated that a TPP is going to end up paying exactly what it paid in both the actual and "but-for" world in reimbursing for those insured consumers' purchases. He explained that the injury for a TPP derives from the cumulative effect on the TPP across all its reimbursed transactions—in other words, transactions that produce "switcher" or "generic only" overcharges in the "but-for" world.

For a TPP that only paid and/or reimbursed for Flonase during the Class Period, this argument rests on the underlying assumption that in the "but-for" world, at least some of the TPP's reimbursements would be for purchases of the generic product. Whether a TPP would have continued to reimburse for Flonase, or would have switched to make some reimbursements for generic FP, turns on the personal medical decision-making of its plan members, who decide to make the purchases underlying those reimbursements. Therefore, the same significant individual issues are present in the impact analysis for TPPs that only reimbursed for Flonase, as they are for consumers that only bought Flonase prior to generic entry. *See Wellbutrin XL,* 2011 WL 3563835, at *13-14 (rejecting plaintiffs' argument that a probability analysis can establish impact for TPPs that never reimbursed for generic purchases because significant individual issues concerning a plan member's purchasing behavior undermine the reliability of the analysis).

For the foregoing reasons, I find that Indirect Purchasers have failed to establish that impact is capable of proof through common evidence for class members that never purchased and/or reimbursed for generic FP during the Class Period.

c. Measurable Damages

The last prong of the predominance inquiry is whether Indirect Purchasers "have demonstrated by a preponderance of the evidence that they will be able to measure damages on a class-wide basis using common proof." *Behrend v. Comcast Corp.*, 655 F.3d 182, 204 (3d Cir. 2011) (citing *Hydrogen Peroxide*, 552 F.3d at 325). "Some variation of damages among class members does not defeat certification." *Id.* (citing 7AA Charles Alan Wright, et al., *Federal Practice and Procedure* § 1781 (3d ed. 2005) (noting that for antitrust class certification "it uniformly has been held that differences among the members as to the amount of damages incurred does not mean that a class action would be inappropriate.")). "Complex and individual questions of damages, however, weigh against finding predominance." *Id.* (citations omitted).

"The usual measure in an overcharge case is the difference between the illegal price that was actually charged and the price that would have been charged 'but for' the violation multiplied by the number of units purchased." *Behrend*, 655 F.3d at 203. Due to the "inherent difficulty of identifying a 'but-for world,'" the Third Circuit has explained that such damages need not be "measured with certainty," but rather may be "demonstrated as 'a matter of just and reasonable inference.'" *Id.* at 203-204 (quoting *Story Parchment Co. v. Paterson Parchment Paper Co.,* 282 U.S. 555, 563 (1931)); *see also Rossi v. Standard Roofing, Inc.*, 156 F.3d 452, 483 (3d Cir. 1998) (holding that for class certification purposes, "[i]t is not necessary to show with total certainty the amount of damages sustained"); *In re Lower Lake Erie Iron Ore Antitrust Litig.*, 998 F.2d 1144, 1176 (3d Cir. 1993) (noting that a "relaxed measure of proof is afforded to the amount" of damages).

i. Monopolization and UDTP Overcharge Damages

To measure class-wide damages, Rausser relies on the same "yardstick" methodology he utilized to establish common impact. Through the use of "yardsticks," Rausser compares the prices actually paid by purchasers of FP to what prices would have been paid in the "but-for" world. The model is relatively straightforward as aggregate class-wide damages equal the difference between the costs paid by class members for FP in the actual world versus the costs class members would have paid for FP in the "but-for" world; Rausser calculates these costs and isolates certain sales because of the class exclusions (i.e. federal facilities, Medicare reimbursements, HMO direct purchasers, GSK rebates) through the use of available industry data.[29]

The before-and-after "yardstick" methodology has been accepted by courts as a means to measuring damages in both indirect and direct purchaser antitrust actions. GSK does not attack the validity of the methodology generally, but instead attacks the data on which Rausser relies to implement his methodology—specifically, again, that the data is not representative of state-specific pricing. To calculate damages within each of the class states, Rausser utilized state-specific data on FP prescriptions in retail and mail-order channels to allocate the nationwide data on FP unit sales and dollars to each of the class states. GSK is correct that through this allocation, Rausser is essentially implementing nationwide prices in measuring state damages. However, Rausser did utilize certain state-specific data to more precisely calculate damages in

[29]Rausser also explained that common data was available to enable him to "back out" of his damages calculation transactions by consumers purchasing only Flonase during the Class Period.

the class states (i.e. co-pay data, prescription data by payer type). He also demonstrated, based on the named plaintiff TPPs' transaction data in several class states, that FP prices exhibited minimal variance from state to state. Although, as Stangle pointed out, Rausser's national average generic price is consistently below the state prices observed in the named plaintiff TPPs' data, Rausser explained that named plaintiff TPPs' data comes from a small set of individual transactions, and is not representative of the full volume of FP purchases in the class states that will drive the damages calculation. While of course Rausser's methodology would have been even more reliable had he been provided with state-specific FP pricing, "it is important not to let a quest for perfect evidence become the enemy of good evidence." *Messner*, 669 F.3d at 808.

GSK's other challenges to Rausser's methodology "are concerns that relate primarily to the allocation of damages among individual class members, not to the computation of aggregate damages on a class-wide basis. Assuming the jury renders an aggregate judgment, allocation will become an intra-class matter accomplished pursuant to a court-approved plan of allocation, and such individual damages allocation issues are insufficient to defeat class certification." *Terazosin*, 220 F.R.D. at 699; *see also In re Potash Antitrust Litig.*, 159 F.R.D. 682, 697 (D. Minn. 1995) ("The amount of damages largely involves individualized questions. This is typically true in antitrust actions, however, and does not preclude certification.").[30]

[30]Both Rule 23(c)(1)(C), which allows for the amendment of class certification orders at any time before final judgment, and Rule 23(d), which authorizes courts to make appropriate orders to facilitate class action proceedings, provide adequate methods through which I can address any potential difficulties associated with damage allocations as they may arise.

I am satisfied that although the magnitude of overcharges will vary across class members, Indirect Purchasers have set forth a just and reasonable estimate of the class-wide overcharge damages in each of the four class states.

ii. Unjust Enrichment Damages

In addition to his yardstick methodology measuring damages resulting from the anticompetitive overcharge, Rausser has also proposed a methodology to calculate unjust enrichment damages for the class by comparing GSK's actual profits to what its profits would have been in the "but-for" world. This methodology would rely on common evidence in the form of profit and loss statements for Flonase possessed by GSK. Rausser further explained that this data could be adjusted to calculate state-specific damages by relying on available state-specific data on FP prescriptions and their penetration in the class state markets.

Neither of GSK's experts challenged the reliability of Rausser's proposed methodology to calculate unjust enrichment damages in Arizona, Massachusetts, and Wisconsin. GSK asserts that because Rausser has failed to show an actual calculation of unjust enrichment damages, based on his proposed methodology, his methodology is unreliable and incapable of measuring class-wide damages. However, at this stage of the litigation, this bare contention is simply insufficient. *See In re Wellbutrin SR Direct Purchaser Antitrust Litig.*, 2008 WL 1946848, at *9 (E.D. Pa. May 2, 2008) (explaining that the court's inquiry is "limited to whether or not the proposed methods are so insubstantial as to amount to no method at all") (quoting *Potash*, 159 F.R.D. at 697); *In re Vitamins Antitrust Litig.*, 209 F.R.D. 251, 268 (D.D.C. 2002) ("At the certification stage, the preliminary inquiry in assessing the proposed methods of proving damages

is limited: The inquiry is not whether the methods are valid, but is only to assess whether the methods are available to prove damages on a class-wide basis."). I find that, based on Rausser's testimony and declarations and the available common data possessed by GSK, that Indirect Purchasers have demonstrated that unjust enrichment damages can be calculated on a class-wide basis using common evidence.

2. Superiority

Rule 23(b)(3) also requires that a class action be "superior to other available methods for the fair and efficient adjudication of the controversy." Fed. R. Civ. P. 23(b)(3). Assessing superiority requires a court "to balance, in terms of fairness and efficiency, the merits of a class action against those of 'alternative available methods' of adjudication." *Georgine v. Amchem Prods., Inc.*, 83 F.3d 610, 632 (3d Cir. 1996). The Supreme Court explained in *Amchem* that, similar to the predominance requirement, the requirement of superiority ensures that resolution by class action will "'achieve economies of time, effort, and expense, and promote . . . uniformity of decision without sacrificing procedural fairness or bringing about other undesirable results.'" *Amchem*, 521 U.S. at 615 (quoting Advisory Committee's Note on Fed. R. Civ. P. 23).

GSK reiterates its arguments regarding predominance in contending that a class action is not superior to other available methods of adjudication. However, both fairness and efficiency dictate that I certify the class in this case; otherwise, the numerous individual class members would be forced to file suit individually, producing numerous identical issues in each case that would waste judicial resources and leave all parties vulnerable to unfair inconsistencies. I agree with the vast majority of district courts that in a delayed generic entry case such as this, class

action treatment is superior to other available methods of adjudication. Therefore, I find that the requirements of Rule 23(b)(3) have been met.

C. *Daubert* Motions

Both Indirect Purchasers and GSK moved to exclude the other party's respective expert(s) (Rausser, Stangle, Navarro) on class certification issues. The party offering an expert must demonstrate, by a preponderance of the evidence, that the expert's qualifications and opinions comply with Federal Rule of Evidence 702. *See Daubert v. Merrel Dow Pharms., Inc.*, 509 U.S. 579, 592-93 (1993) (citation omitted). Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. Rule 702 has "a liberal policy of admissibility." *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (citation omitted).

The Third Circuit has explained that to survive a *Daubert* challenge, an expert must satisfy three "restrictions on expert testimony: qualification, reliability, and fit." *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003) (citations omitted). The qualification inquiry examines whether a witness possesses specialized expertise. The Third Circuit "has interpreted this requirement liberally, holding that a broad range of knowledge, skills, and training qualify an expert." *Id.* (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994)).

For an expert's testimony to be reliable, it "must be based on [] methods and procedures . . . rather than subjective belief or speculation." *In re TMI Litig.*, 193 F.3d 613, 670 (3d Cir. 1999). "[T]he admissibility inquiry thus focuses on principles and methodology, not on the conclusions generated by principles and methodology." *Id.* at 665. Furthermore, an "expert's testimony must be accompanied by a sufficient factual foundation before it can be submitted to the jury." *Elcock v. Kmart Corp.*, 233 F.3d 734, 754 (3d Cir. 2000) (citation omitted).

Finally, Rule 702 requires that the expert testimony fit the issues in the case. Testimony "fits" a case when it is "relevant for the purposes of the case and . . . assist[s] the trier of fact." *Schneider*, 320 F.3d at 404.

The Third Circuit has not explicitly addressed the question of whether expert testimony must satisfy *Daubert* at the class certification stage. Nevertheless, the Supreme Court has strongly suggested that a full *Daubert* examination may be necessary at class certification. *See Dukes*, —U.S.—, 131 S. Ct. at 2553-54 ("The District Court concluded that *Daubert* did not apply to expert testimony at the certification stage of class-action proceedings. We doubt that is so . . . ." (internal citation omitted)). Furthermore, in *Hydrogen Peroxide*, the Third Circuit explained that "opinion testimony should not be uncritically accepted as establishing a Rule 23 requirement merely because the court holds the testimony should not be excluded, under *Daubert* or for any other reason." 552 F.3d at 323. "Inherent in that statement is the conclusion that a court could, at the class certification stage, exclude expert testimony under *Daubert*." *Behrend*, 665 F.3d at 215 n.18 (Jordan, J., concurring in the judgment in part and dissenting in part).

Regardless, I will not exclude any of the expert testimony and declarations on class certification, even making a full *Daubert* examination. Both parties concede the issue of expert qualification and focus their arguments on the reliability and fit of each expert's testimony and declarations. From a review of this opinion, it is clear that the expert opinions of Rausser, Stangle, and Navarro were reliable, relevant, and significant contributions to the issues raised by Indirect Purchasers' class certification. Therefore, I will deny all of the following *Daubert* motions: (1) GSK's Motion to Exclude the Expert Report and Testimony of Gordon Rausser; (2) Indirect Purchasers' Motion to Exclude the Report and Testimony of Bruce Stangle; and (3) Indirect Purchasers' Motion to Exclude the Report and Testimony of Robert P. Navarro.

V. CONCLUSION

For the reasons explained above, I conclude that Indirect Purchasers have carried their burden under Rules 23(a) and (b)(3). In reaching that conclusion, however, the indirect purchaser class was limited to class members that purchased/or reimbursed for generic FP during the Class Period. I will therefore grant in part and deny in part Indirect Purchasers' motion for class certification. Additionally, I will deny the three *Daubert* motions that seek to exclude each party's respective expert(s) on class certification.

s/Anita B. Brody

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ANITA B. BRODY, J.

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APPENDIX A

State Monopolization Claims	
Arizona	Arizona's monopolization statute, Ariz. Rev. Stat. § 44-1401, *et seq.*, permits any "person threatened with injury or injured in his business or property" to sue for redress of a violation of the statute." Ariz. Rev. Stat. § 44-1408(b). The statute includes a federal guidance clause, which notes that it is "the intent of the legislature that in construing this article, the courts may use as a guide interpretations given by the federal courts to comparable federal antitrust statutes." *Id.* § 44-1412. Indirect purchasers have standing to sue under this statute. *Bunker's Glass Co. v. Pilkington, PLC*, 75 P.3d 99 (Ariz. 2003).
Wisconsin	Wisconsin's monopolization statute, Wis. Stat. § 133.01, *et seq*., aims to prohibit "unfair and discriminatory business practices which destroy or hamper competition," *id.*, and provides for penalties against every person "who monopolizes, or attempts to monopolize." *Id.* § 133.03. Section 133.18 permits any person injured directly or indirectly by an antitrust violation to seek treble damages. *Id*. § 133.18. The statute was also "intended as a reenactment of the first two sections of the federal Sherman Antitrust Act . . . ." *Grams v. Boss*, 294 N.W.2d 473, 380 (Wisc. 1980).
State UDTP Claims	
Florida	Florida's Deceptive and Unfair Trade Practices Act ("FDUTPA"), Fla. Sta. § 501.201, *et seq*., declares unlawful any "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce." Fla. Stat. § 501.204(1). A "claim for damages under FDUTPA has three elements: (1) a deceptive act or unfair practice; (2) causation; and (3) actual damages." *Rollins, Inc. v. Butland*, 951 So.2d 860, 869 (Fla. Dist. Ct. App. 2006). To ascertain whether a FDUTPA violation has occurred, a court may utilize rules promulgated "pursuant to the Federal Trade Commission Act" and the "standards of unfairness and deception set forth and interpreted by the Federal Trade Commission or the federal courts." Fla. Stat. § 501.203(3). While Florida bars indirect purchasers from asserting claims under its antitrust act, they may state claims under FDUTPA. *See Mack v. Bristol-Myers Squibb Co.*, 673 So.2d 100, 103, 107-08 (Fla. Dist. Ct. App. 1996).
Massachusetts	Massachusetts UDTP statute, Mass. Gen. Laws ch. 93A, *et seq*., provides that "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are ... unlawful. *Id.* § 2.

	The claim has three elements, as a plaintiff "must establish (1) that the defendant has committed a violation of [Mass. Gen. Laws ch. 93A, § 2]; (2) injury; and (3) a causal connection between the injury suffered and the defendant's unfair or deceptive method, act, or practice." *Herman v. Admit One Ticket Agency LLC,* 912 N.E.2d 450, 454 (Mass. 2009). Although Massachusetts bars indirect purchasers from bringing claims under its antitrust law, it does not bar indirect purchaser standing under its UDTP act. *See Claire v. F. Hoffmann-La Roche Ltd.*, 762 N.E. 2d 303, 308-10 (Mass. 2002).
State Unjust Enrichment Claims	
Arizona	"In Arizona, five elements must be proved to make a case of unjust enrichment: (1) an enrichment; (2) an impoverishment; (3) a connection between the enrichment and the impoverishment; (4) absence of justification for the enrichment and the impoverishment and (5) an absence of a remedy provided by law." *Trustmark Ins. Co. v. Bank One*, 48 P.3d 485, 492 (Ariz. Ct. App. 2002).
Massachusetts	To state a claim for unjust enrichment in Massachusetts, a plaintiff must give proof of "some misconduct, fault or culpable action on the part of the defendant as 'wrongdoer' which renders his retention of a benefit at the expense of another contrary to equity and good conscience." *DeSanctis v. Labell's Airport Parking Inc.*, 1991 Mass App. Div. 37, 40, 1991 WL 71921 (Mass. Dist. Ct. 1991).
Wisconsin	In Wisconsin, "[t]o recover on a claim for unjust enrichment, three elements must be proven: (1) a benefit conferred upon the defendant by the plaintiff; (2) an appreciation or knowledge by the defendant of the benefit; and (3) the acceptance or retention by the defendant of the benefit under circumstances that makes its retention inequitable." *Tri-State Mechanical, Inc. v. Northland College*, 681 N.W.2d 302, 306 (Wis. Ct. App. 2004).