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

SHEET METAL WORKERS	:	
LOCAL 441 HEALTH & WELFARE	:	
PLAN, et al,	:	
Plaintiffs	:	CIVIL ACTION
	:	
v.	:	NO. 04-5898
	:	
GLAXOSMITHKLINE, PLC, et al,		
Defendants	:	

<u>OPINION</u>

STENGEL, J.

September 30, 2010

The indirect purchaser plaintiffs in this action have filed a motion for certification of a class consisting of all persons and entities in the United States who purchased Wellbutrin SR or its generic equivalent at any time between March 1, 2002, and June 30, 2006. For the reasons discussed below, the motion will be denied.

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I. INTRODUCTION

The named plaintiffs in this purported class action are health and welfare benefit plans seeking to certify a class of end payors for sustained release buproprion, a prescription anti-depressant marketed as Wellbutrin SR. This class could include potentially hundreds of thousands of individual consumers and more than twenty thousand third party payors — health benefit plans, health maintenance organizations, and health insurers, among them — who purchased Wellbutrin SR. Plaintiffs claim the defendants in this action, GlaxoSmithKline, PLC and SmithKlineBeecham ("GSK"), filed sham patent infringement litigation with the goal of preventing generic manufacturers from entering the market for sustained release buproprion. As stated in their second amended class action complaint, the end-payor plaintiffs claim GSK violated the antitrust and consumer protection statutes of a number of states and was unjustly enriched when it filed the allegedly sham patent litigation.¹ They claim that, but for GSK's sham litigation, generic manufacturers would have been able to market sustained release buproprion beginning on or about July 1, 2001, instead of in January 2004, when they actually entered the market.

Plaintiffs' class certification motion has been long pending, in part due to my decision to first address GSK's motion to dismiss plaintiffs' second amended class action

¹ This Memorandum contains an abbreviated version of the facts relevant to the motion for class certification. For a more detailed version of the facts, <u>see In re Wellbutrin SR Antitrust</u> <u>Litigation</u>, No. 04-5525, 2006 WL 616292 (E.D.Pa. Mar. 9, 2006).

complaint. If the named plaintiffs had failed to make valid state claims, the motion for class certification would have been rendered moot. Because I found plaintiffs have stated valid causes of action in some of the states in which they or their members purchased Wellbutrin SR, their motion for class certification is now ripe for consideration.

The end-payor plaintiffs seek to certify the following class:

All persons and entities in the United States who, at any time from March 1, 2002, to June 30, 2006, purchased 100 mg and/or 150 mg Wellbutrin SR and/or their generic equivalents for purposes other than resale. Excluded from the Class are the Defendants, their subsidiaries and affiliates, government entities, and any person or entity that purchased Wellbutrin SR directly from Defendants. For purposes of the class definition, persons and entities "purchased" Wellbutrin SR if they paid all or some of the purchase price.

Second Am. Class Action Compl. ¶ 166.

A direct purchaser class consisting of approximately 100 entities that purchased Wellbutrin SR directly from GSK and then sold it to consumers, hospitals, and third-party payors for the drug has already been certified. That decision is not binding on me, and the issues relevant to the direct purchaser class certification motion are distinct from the issues facing me now. Specifically, the indirect purchaser plaintiffs face a more difficult task than did the direct purchasers. In order for me to certify the class, they must show that common evidence is available to show impact to all class members. Because they have failed to show that certain, substantial groups of buyers in the purported class including "brand loyalists " who would have continued to purchase brand-name Wellbutrin SR even after a generic version became available, and consumers whose

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insurance co-pay would have remained the same whether they were prescribed brandname or generic Wellbutrin SR — would have been impacted by GSK's alleged wrongs, I will deny the motion for class certification.

A. Procedural History

The end-payor plaintiffs filed their original class action complaint against GSK on December 17, 2004.² This case was originally assigned to the Honorable Bruce Kauffman. The accusations set forth by the end-payor plaintiffs remain basically the same even though they have, since initially filing their complaint, amended it twice. An individual indirect purchaser of Wellbutrin SR and a direct purchaser class have also filed claims against GSK for the same alleged conduct.³

On March 23, 2005, GSK filed a motion to dismiss the complaints filed by the direct and indirect purchasers. Judge Kauffman issued a memorandum and order granting that motion in part and denying it in part on March 9, 2006. In relevant part, Judge Kauffman denied the motion to dismiss except as to Count I of the indirect purchaser complaint, which sought declaratory and injunctive relief enjoining GSK from engaging

² Plaintiff IBEW - NECA Local 505 Health & Welfare Plan filed its class action complaint against defendants on May 20, 2005. This complaint was originally docketed as Civil Action Number 05-2405 and was consolidated with the other end-payor class action complaint docketed as Civil Action Number 04-5898 by order of Judge Kauffman on January 12, 2007.

³ <u>See</u> Medical Mutual of Ohio, Inc. v. GlaxoSmithKline PLC, SmithKlineBeecham Corp., Civ. Action No. 05-396; <u>In re Wellbutrin SR Antitrust Litig.</u>, Civ. Action No. 04-5525.

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in further anticompetitive practices. <u>See</u> Document # 21. The end payor plaintiffs filed a motion for class certification on June 29, 2006. <u>See</u> Document #37. They then filed a motion for leave to file a consolidated amended class action complaint on January 7, 2007, in order to withdraw their claims for injunctive relief, dismiss certain state law claims, and assert *Walker Process* claims similar to those initially asserted by the direct purchaser plaintiffs. <u>See</u> Document # 55. Judge Kauffman granted the motion for leave to file a consolidated amended class action complaint, and ordered that the claims of the indirect purchasers be consolidated under Civil Action Number 04-5898. <u>See</u> Document #61.

Discovery proceeded throughout 2007 and into 2008, and Judge Kauffman ordered that the parties file dispositive motions on or before October 20, 2008, which they did. <u>See</u> Second Amended Case Management Order No. 5, Document # 135; Motions for Summary Judgment, Documents ## 178, 180. I ruled on these motions on March 31, 2010, granting one motion in GSK's favor and thereby dismissing all claims relating to the '994 patent, and denying the other motion relating to claims concerning the '798 patent.

Oral argument on the end payor plaintiffs' motion for class certification was held before Judge Kauffman on August 1, 2008. <u>See Minute Entry</u>, Docket # 154. Before a ruling was issued, GSK filed a motion for judgment on the pleadings on May 18, 2009, arguing that the claims asserted by the end payor plaintiffs in the consolidated amended

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class action complaint should be dismissed because the plaintiffs could not state claims in their home states. See Mot. For Judgment on the Pleadings, Document # 221. On July 16, 2009, while that motion, the two summary judgment motions, and the motion for class certification filed in 2006 remained pending, this case was reassigned to me. I granted in part and denied in part the motion for judgment on the pleadings and allowed the end payor plaintiffs leave to file another amended class action complaint in which they could assert claims in the states where they or their members purchased, or into which they sent reimbursements for, Wellbutrin SR. See Mem. & Order, Document # 234. The endpayor plaintiffs filed that complaint, and GSK filed a motion to dismiss it on January 11, 2010. See Mot. To Dismiss, Document # 249. I granted in part and denied in part the motion to dismiss, finding that plaintiffs had asserted valid state antitrust, consumer protection, and unjust enrichment claims in some states and dismissing the claims in other states.

Because the Third Circuit's 2008 decision in <u>In re Hydrogen Peroxide Antitrust</u> <u>Litig.</u>, 552 F.3d 305 (2008) altered the standard courts in this Circuit are to use in resolving motions for class certification filed by antitrust plaintiffs, I directed the parties to address the impact of this decision on the pending motion for class certification. <u>See</u> Order, Document # 230. I resolved the pending motions for summary judgment on March 31, 2010. Although those decisions could not, as a matter of procedure, apply to the indirect purchasers, insofar as they contained rulings on the merits of the underlying

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claims and limited the issues that will be presented to a jury, they were made binding on the indirect purchasers following resolution of the motion to dismiss.

B. The Integral Class Certification Issue

The integral certification issue in dispute is the requirement of Federal Rule of Civil Procedure 23(b)(3)⁴ that common issues of fact and law predominate. Plaintiffs have asserted valid claims under the state antitrust statutes of Arizona, Michigan, Minnesota, Nevada, North Carolina, West Virginia, and Wisconsin and under the state consumer protection laws of Arkansas, California, Florida, Minnesota, Missouri, North Carolina, and Pennsylvania. They have stated valid unjust enrichment claims in the states

- (b) Types of Class Actions. A class action may be maintained if Rule 23(a) is satisfied and if:
 (3) the court finds 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. The matters pertinent to these findings include:
 - (A) the class members' interests in individually controlling the prosecution or defense of separate actions;
 - (B) the extent and nature of any litigation concerning the controversy already begun by or against class members;
 - (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and

(D) the likely difficulties in managing a class action.

FED. R. CIV. PROC. 23(b)(3).

⁴ Federal Rule of Civil Procedure 23(b)(3) provides:

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of Arizona, Iowa, Massachusetts, Michigan, Minnesota, Missouri, Nevada, North Carolina, Pennsylvania, West Virginia, and Wisconsin. These claims are predicated on GSK's alleged filing of sham litigation. The main issue in dispute for purposes of this motion is whether impact resulting from GSK's allegedly anticompetitive conduct is susceptible to proof by common evidence at trial.⁵ The plaintiffs claim they have shown class-wide antitrust impact that is susceptible to common proof. GSK argues the complexities of the class necessitate individual inquiry in order to determine whether each class member was injured. Should proof of antitrust liability require individualized evidence, there is no predominance for Rule 23(b)(3) purposes. <u>See Bell Atl. Corp. v. AT</u> <u>& T Corp.</u>, 339 F.3d 294, 302 (5th Cir.2003) ("[W]here fact of damage cannot be established for every class member through proof common to the class, the need to establish antitrust liability for individual class members defeats Rule 23(b)(3)

⁵ The antitrust and consumer protection statutes under which plaintiffs state their claims all have injury as an element. Further, unjust enrichment claims are based on the theory that "[a] person who has been unjustly enriched at the expense of another is required to make restitution to the other." Restatement of Restitution § 1; see also In re K-Dur Antitrust Litig., No. 01-1652, 2008 U.S. Dist. LEXI 71771, *39 n.13 (D.N.J. March 27, 2008) ("[I]n general, a plaintiff alleging unjust enrichment must show: (1) at plaintiff's expense; (2) defendant received a benefit; (3) under circumstances that would make it unjust for defendant to retain the benefit without paying for it."). "Injury" is not an element of unjust enrichment, but the doctrine requires the plaintiffs to prove that it would be unfair for the defendant to retain the fruits of his alleged anticompetitive conduct. See K-Dur, 2008 U.S. Dist. LEXIS 71771, at *39-40 n.13. Put another way, it would be necessary for the plaintiffs to show that the defendant unlawfully benefitted from plaintiffs' purchases of Wellbutrin SR. As pleaded, this unjust benefit would necessitate proof each plaintiff was compelled to purchase Wellbutrin SR because he was precluded from purchasing the generic substitute or that he paid higher prices for the branded drug. See id. I will not address whether the differences in the state laws under which plaintiffs bring their claims present an insurmountable problem for class certification, because I will deny plaintiffs' motion on the ground that they cannot show class-wide impact.

predominance.").

Because plaintiffs have failed to meet their burden in showing that common evidence is available to show class-wide impact resulting from the delayed market entry of generic buproprion, I will deny plaintiffs' motion.

II. LEGAL STANDARD FOR CLASS CERTIFICATION

Before certifying a class pursuant to Federal Rule of Civil Procedure 23, courts

must undertake a "rigorous analysis" to ensure that all requirements are met. Gen. Tel.

Co. of Southwest v. Falcon, 457 U.S. 147, 161, 102 S.Ct. 2364, 72 L.Ed.2d 740 (1982).

This court may certify a class action only if the end-payor plaintiffs satisfy all four

provisions of Rule 23(a) and at least one provision of Rule 23(b). See, e.g., Amchem

Prods. v. Windsor, 521 U.S. 591, 613-14, 117 S.Ct. 2231, 138 L.Ed.2d 689 (1997). Rule

23(a) provides:

One or more members of a class may sue or be sued as representative parties on behalf of all members only if:
(1) the class is so numerous that joinder of all members is impracticable;
(2) there are questions of law or fact common to the class;
(3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and
(4) the representative parties will fairly and adequately protect the interests of the class.

FED. R. CIV. P. 23(a). To satisfy Rule 23(b)(3),⁶ the End-Payor Plaintiffs must

⁶ Because the End-Payor Plaintiffs seek certification under Rule 23(b)(3), the Court will confine its analysis to that standard and will not consider whether the proposed class meets the

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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).

The United States Court of Appeals for the Third Circuit recently clarified the legal standard for class certification and explained the meaning of the "rigorous analysis" called for by Rule 23. <u>See Hydrogen Peroxide</u>, 552 F.3d at 316; <u>see also Gen Tel. Co. of Sw. v. Falcon</u>, 457 U.S. at 161 (holding class certification is proper only if the district court concludes, after a *rigorous analysis*, that the prerequisites of Rule 23 are met). <u>Hydrogen Peroxide</u> did not alter substantive law but clarified that the trial court's proper task "in deciding whether to certify a class [is to] resolve factual disputes by a preponderance of the evidence and make findings that each Rule 23 requirement is met or is not met, having considered all the relevant evidence and arguments presented by the parties." <u>Hydrogen Peroxide</u>, 552 F.3d at 320.

Class certification is of paramount significance in large-scale litigation because if denied, it may "sound the 'death knell' of the litigation on the part of the plaintiffs," and if granted, can "create unwarranted pressure to settle nonmeritorious claims on the part of the defendants." <u>Id.</u> at 310 (quoting <u>Newton v. Merrill Lynch, Pierce, Fenner & Smith,</u> <u>Inc.</u>, 259 F.3d 154, 162 (3d Cir. 2001)). The district court may make inquiry into facts

requirements of Rule 23(b)(1) or (b)(2).

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"beyond the pleadings to determine whether the requirements for class certification are satisfied." <u>Id.</u> at 316 (quoting <u>Newton</u>, 259 F.3d at 167 (internal quotations omitted)). Further, "an overlap between a class certification requirement and the merits of a claim is no reason to decline to resolve relevant disputes when necessary to determine whether a class certification requirement is met." <u>Id.</u> at 316; <u>see also Coopers & Lybrand v.</u> <u>Livesay</u>, 437 U.S. 463, 469, 98 S.Ct. 2454, 57 L.Ed.2d 351 (1978) ("[T]he class determination generally involves considerations that are enmeshed in the factual and legal issues comprising the plaintiff's cause of action.").

If an inquiry pertinent to Rule 23 satisfaction does overlap with the merits, the district court's role is not "to predict which party will prevail on the merits." <u>Id.</u> at 318 (quoting <u>Newton</u>, 259 F.3d at 168). Instead the court must "determine whether the alleged claims can be properly resolved as a class action." <u>Id.</u> The district court cannot prematurely grant class certification based on a "party's assurance [] that it intends or plans to meet the requirements." <u>Id.</u> at 318. All Rule 23 requirements must be met *prior to certification*, so "a district court errs as a matter of law when it fails to resolve a genuine legal or factual dispute relevant to determining the requirements." <u>Id.</u> at 320.

Expert opinions do not escape the "rigorous analysis" requirement of Rule 23. <u>Id.</u> at 322. To that end, "resolving expert disputes in order to determine whether a class certification requirement has been met is always a task for the court." <u>Id.</u> at 324. Weighing expert opinions "is not only permissible; it may be integral to the rigorous

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analysis Rule 23 demands." <u>Id.</u> at 323 (citing <u>Blades v. Monsanto Co.</u>, 400 F.3d 562, 575 (8th Cir. 2005)). A district court may, in its discretion, "find it unnecessary to consider certain expert opinions with respect to a certification requirement, but it may not decline to resolve a genuine legal or factual dispute because of an overlap with the merits." <u>Id.</u> at 323; <u>see also West v. Prudential Sec. Inc.</u>, 282 F.3d 935, 938 (7th Cir. 2002) ("Tough questions must be faced and squarely decided, if necessary by holding evidentiary hearings and choosing between competing perspectives.").

The Third Circuit denied that, in an antitrust matter, a "court should relax its certification analysis, or presume a requirement for certification is met." <u>Id.</u> at 321-322 (noting the Supreme Court found predominance to be easily met in cases involving violations of antitrust laws, yet denying that in those cases certification requirements should be relaxed). Predominance should not be presumed, because "[p]rivate damage claims by numerous individuals arising out of concerted antitrust violations may or may not involve predominating common questions." <u>Id.</u> at 322 (quoting <u>Robinson v. Tex.</u> <u>Auto. Dealers Ass'n</u>, 387 F.3d 416, 420-421 (5th Cir. 2004)). Regardless of the area of substantive law, "[i]f proof of the essential elements of the cause of action requires individual treatment, then class certification is unsuitable." <u>Id.</u> at 311 (quoting <u>Newton</u>, 259 F.3d at 172).

III. RULE 23(a) REQUIREMENTS

A. Numerosity

The number of class members present in this case easily satisfies the numerosity requirement. See, e.g., Stewart v. Abraham, 275 F.3d 220, 226-27 (3d Cir. 2001) ("[G]enerally if the named plaintiff demonstrates that the potential number of plaintiffs exceeds 40, the first prong of Rule 23(a) has been met."); Moskowitz v. Lopp, 128 F.R.D. 624, 628 (E.D. Pa. 1989) ("No magic number exists satisfying the numerosity requirement[.]"). The end-payor plaintiffs claim sales of Wellbutrin SR in the United States prior to generic launch totaled approximately \$1.4 billion. Based on this sales volume, they project that consumers number in the hundreds of thousands and that thirdparty payors exceed twenty thousand. The end-payors are dispersed throughout the United States. Accordingly, although the end-payor plaintiffs do not provide an exact number of class members, we can safely say the numerosity requirement is met in this case. See, e.g., In re Remeron End-Payor Antitrust Litig., Nos. 02-2007,04-5126, 2005 U.S. Dist. LEXIS 27011, at *22 (D.N.J. Sept. 13, 2005) (finding that a class of indirect purchasers of the drug Remeron satisfied the numerosity requirement); In re Terazosin Hydrochloride Antitrust Litig., 220 F.R.D. 672, 685 (S.D. Fla. 2004) ("It is undisputed that these thousands of members of the state Classes are geographically dispersed across their jurisdictions and throughout the United States. Further, many of the individual members of the state classes have claims that are far too small to justify bringing

individual suits against the corporate Defendants. For these reasons, joinder of all members of the prospective classes would be highly impracticable.").

B. Commonality

"The commonality requirement will be satisfied if the named plaintiffs share at least one question of fact or law with the grievances of the prospective class." <u>Baby Neal</u> <u>for & by Kanter v. Casey</u>, 43 F.3d 48, 56 (3d Cir. 1994) (citing <u>In re "Agent Orange"</u> <u>Prod. Liab. Litig.</u>, 818 F.2d 145, 166-67 (2d Cir. 1987); <u>Weiss v. York Hosp.</u>, 745 F.2d 786, 808-09 (3d Cir. 1984)). "'However, where an action is to proceed under Rule 23(b)(3), the commonality requirement is subsumed by the predominance requirement' because [the predominance requirement of Rule 23(b)(3)] 'is far more demanding than the Rule 23(a)(2) commonality requirement." <u>McDonough v. Toys R Us, Inc.</u>, 638 F. Supp. 2d 461, 475 (E.D.Pa. 2009). Because this action is to proceed under Rule 23(b)(3), I will not discuss the commonality element further.

C. Typicality

"[T]ypicality 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." <u>Eisenberg v. Gagnon</u> 766 F.2d 770, 786 (3d Cir. 1985) (quoting <u>Weiss</u>, 745 F.2d

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at 809 n.36). As with the commonality requirement, "[t]he threshold for establishing typicality is low." <u>Zlotnick v. Tie Commc'ns, Inc.</u>, 123 F.R.D. 189, 193 (E.D. Pa. 1988). The Third Circuit has noted that "cases challenging the same unlawful conduct which affects both the named plaintiffs and the putative class usually satisfy the typicality requirement irrespective of the varying fact patterns underlying the individual claims." Baby Neal, 43 F.3d at 58.

The end-payor plaintiffs are challenging GSK's alleged filing of frivolous lawsuits to extend the life of its monopoly. While the end-payor plaintiffs may be proceeding under different theories of recovery and possess different economic injuries, the typicality requirement is met because GSK's alleged conduct gives rise to all of their claims. See In re Prudential, 148 F.3d at 311 ("The named plaintiffs, as well as the members of the proposed class, all have claims arising from the fraudulent scheme perpetrated by Prudential. That overarching scheme is the linchpin of the Second Amended Consolidated Complaint, regardless whether each class member alleges a churning claim, a vanishing premium claim, an investment plan claim, or some other injury falling within the category of 'other sales' claims."); In re Relafen, 221 F.R.D. at 267 ("[T]he claims of each of the end payor plaintiffs, including those of the proposed representatives for the class, arise from the same course of conduct: SmithKline's alleged efforts to delay generic competition. Accordingly, the claims of the named plaintiffs are typical of those asserted by other members of the class." (citation omitted)); In re Terazosin, 220 F.R.D.

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at 687 ("[T]he claims of the consumer and the third-party payer class representatives are not only typical of the claims of all class members, they are virtually identical in nature, notwithstanding variations in the amount of damages. Consequently, if one class representative is able to prove that Defendants' alleged anticompetitive acts caused an overcharge for terazosin hydrochloride, 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.").

D. Adequacy of Representation

"The adequacy of representation inquiry has two components intended to assure that the absentees' interests are fully pursued: it considers whether the named plaintiffs' interests are sufficiently aligned with the absentees', and it tests the qualifications of the counsel to represent the class." <u>In re Gen. Motors Corp. Pick-Up Fuel Tank Prods. Liab.</u> <u>Litig.</u>, 55 F.3d 768, 800 (3d Cir. 1995) (citing <u>Weiss</u>, 745 F.2d at 811).

With respect to the qualifications of counsel, GSK has not challenged the adequacy of class counsel to represent the class. Indeed, class counsel have vigorously represented the putative class throughout the course of this litigation, and their submissions and presentations to the court have demonstrated their ability to represent the class members effectively. This prong of the analysis is satisfied.

With respect to the second prong of the analysis, the End-Payor Plaintiffs maintain

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that the class members have no conflicting interests with the named representatives. They argue that all class members have the same interest in this litigation because they all paid supracompetitive prices for Wellbutrin SR, thereby suffering the same injury. <u>See, e.g.</u>, <u>In re Warfarin Sodium Antitrust Litig.</u>, 391 F.3d 516, 532 (3d Cir. 2004) ("As the District Court found, the named parties, who included consumers and [third-party payors], as well as consumers from the indirect purchaser states, all shared the same goal of establishing the liability of DuPont, suffered the same injury resulting from the overpayment for warfarin sodium, and sought essentially the same damages by way of compensation for overpayment."); <u>In re Remeron</u>, 2005 U.S. Dist. LEXIS 27011, at *30 ("The Class Representatives' interests are not antagonistic to those of the absent class members. The central issues in this case are critical to the claims of both groups. In proving these common issues, the Class Representatives further the absent class members' claims no less than their own.").

GSK initially raised two challenges to the adequacy of the named plaintiffs. First, it argued that certain named Plaintiffs lack standing to represent the class because they were not injured by the alleged anticompetitive conduct. Second, it argued that the class requires at least one representative in each state that allows indirect purchaser class actions in monopolization cases. In resolving GSK's motion for judgment on the pleadings, I determined that the plaintiffs may bring claims in each state where they or their members purchased Wellbutrin SR. At the motion to dismiss stage, I granted in part

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and denied in part GSK's motion to dismiss the specific state law claims asserted by the plaintiffs. I will not address these issues again here, as I have concluded that the operative issue is whether the plaintiffs have satisfied Rule 23(b) by showing that common issues of law and fact predominate.

IV. RULE 23(b) REQUIREMENTS

A. The Plaintiffs Must Show Predominance of Common Questions of Law or Fact

To achieve Rule 23(b)(3) class certification, the plaintiffs must establish that "common proof will predominate with respect to each of [the elements of the claim]." <u>Behrend</u>, 264 F.R.D. at 156. In antitrust actions, "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." <u>Hydrogen Peroxide</u>, 552 F.3d at 311 (citing <u>Bogosian v. Gulf Oil Corp.</u>, 561 F.2d 434, 454 (3d Cir. 1977)). In regard to antitrust impact at the class certification stage, the Third Circuit explained:

> In antitrust cases, impact 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.

> Plaintiffs' burden at the class certification stage 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.

Id. at 311-312 (internal citations omitted) (emphasis added).

Applying these principles in Hydrogen Peroxide, the Third Circuit determined class certification may have been improper, because the defendants had proffered empirical evidence and expert testimony calling into question the plaintiffs' 23(b)(3) predominance arguments. The court vacated the district court's order certifying the class and remanded the case for another certification decision. See id. at 325. Other courts in this District to have issued class certification decisions have recognized their increased responsibility for examining expert opinions in the wake of Hydrogen Peroxide. See McDonough, 638 F. Supp. 2d at 467-468 ("In re Hydrogen Peroxide thus teaches that a defendant may successfully challenge class certification by using evidence to undermine the plaintiff's case under Rule 23, and a district court must consider this when deciding class certification."); Behrend, 264 F.R.D. at 155 (quoting Hydrogen Peroxide for the proposition that "[a] district court must not uncritically accept expert opinion testimony "as establishing a Rule 23 requirement merely because [it] holds the testimony should not be excluded[.]").

In order to satisfy this requirement, the plaintiffs must show that every purported class member has been impacted by the foreclosed entry of generic sustained release

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buproprion onto the market. Because plaintiffs' purported class, by definition, includes purchasers of both generic and branded Wellbutrin SR, plaintiffs must show that prices for each of these products were affected during the class period. They must also show that all purported class members actually suffered damages as a result of GSK's allegedly anti-competitive activity.

In support of their class certification arguments, the plaintiffs put forth two expert reports prepared by Dr. Meredith Rosenthal.⁷ Dr. Rosenthal was retained to determine whether end-payor purchasers of branded Wellbutrin SR and generic bupropion SR "were impacted as a class and suffered economic damages as a result of the antitrust violations alleged in this matter." Decl. of Meredith Rosenthal Supp. Certification Class of End-Payor Purchasers, Part I. In response, GSK relies on the expert report of Dr. John P. Bigelow⁸ and the statement of Robert Jagt.⁹ The experts' opinions raise substantial

⁷ Dr. Rosenthal is an Associate Professor of Health Economics and Policy at the Harvard School of Public Health and an Academic Affiliate of Greylock McKinnon Associates, a consulting and litigation support firm. She holds a Ph.D. in Health Policy (Economics Track) from Harvard University and specializes in the economics of the health care industry. Rosenthal Decl. ¶¶ 1-4.

⁸ Dr. Bigelow is a Senior Economist for Princeton Economics Group, Inc., where he analyzes economic and antitrust issues arising out of litigation and regulatory proceedings. He holds a Ph.D. in Economics from the University of Pennsylvania and specializes in Economic Theory and Industrial Organization. He was previously employed as an economics professor at a myriad of different universities, including Yale University. Decl. of Dr. John Bigelow ¶ 1.

⁹ Robert Jagt has been an employee of GlaxoSmithKline and its predecessor companies since 1992 in various sales and marketing capacities. From November 2004 until April 2006, he was the Director of Marketing for Wellbutrin. He currently serves as the Director of Marketing for Valtrex and was previously employed as the Director of Marketing for Advair. While employed as the Director of Marketing for Wellbutrin, Mr. Jagt's primary responsibilities

questions of fact and law that I am required to resolve in deciding the pending motion.

See Hydrogen Peroxide, 552 F.3d at 316 ("[A]n overlap between a class certification

requirement and the merits of a claim is no reason to decline to resolve relevant disputes

when necessary to determine whether a class certification requirement is met.").

1. The Plaintiffs Claim Antitrust Impact Is Susceptible to Common Proof at Trial

Dr. Rosenthal's report states that the plaintiffs can establish antitrust impact on the entire class through common economic proof that:

• Absent GSK's foreclosure, generic entrants would have rapidly captured market share;

• Generic entrants offer substantially discounted prices relative to Wellbutrin SR, so prices paid by class members who would have switched from the brand to the generic, had it been available, were higher than they would have been absent the foreclosure;

• Generic entry drives down the prices of brand name drugs, so prices paid by brand loyal customers were most likely higher than they would have been absent the foreclosure; and

• Sufficient data and well-accepted methods are available to measure and quantify damages on a class-wide basis.

<u>See</u> Rosenthal Decl. ¶¶ 8-9, 16-17.

involved overseeing the planning and implementation of GlaxoSmithKline's marketing efforts for the Wellbutrin branded drug. Decl. of Robert Jagt $\P\P$ 1-2.

a. Dr. Rosenthal claims market conditions would have made generic foreclosure profitable for GSK

Dr. Rosenthal contends "[s]ufficient data and well-accepted methods are available to demonstrate that the impact of Defendant's unlawful delay of generic entry was common to all or substantially all of the members of the proposed class." <u>Id.</u> ¶ 16. Rosenthal's analysis suggests that conditions in the pharmaceutical drug market favored foreclosure of generic entry and that such foreclose would have impacted the entire class. She relies primarily on economic literature in reaching this conclusion. <u>See</u> Rosenthal Decl. ¶ 10-15.

According to Dr. Rosenthal, a number of facts account for this market atmosphere. First, price competition is essentially non-existent for branded drugs prior to patent expiration, because brand name drug manufacturers use marketing campaigns to achieve horizontal differentiation¹⁰ within a therapeutic class. <u>Id.</u> ¶ 11. Second, price competition following generic entry is aggressive due to the FDA's stringent requirements that "generics function in the same way as their brand name drug equivalents." <u>Id.</u> ¶ 12. Third, health insurers/third party payors offer incentives to consumers who choose generic drugs by implementing tiered formularies, generic substitution programs and

¹⁰ Dr. Rosenthal describes two types of so-called horizontal differentiation. The first, "actual differentiation," distinguishes "products within a therapeutic class along non-price dimensions such as the number and types of approved indications and side effect profiles." The other type, differentiation by illusion, distinguishes products solely through "marketing to physicians and consumers." Rosenthal Decl. ¶ 11.

coinsurance rates.¹¹ <u>Id.</u> ¶ 13. Fourth, prescription benefit managers and third party payors collude to encourage consumers to opt for generic drugs by associating the branded drugs with the highest co-pay, marketing generics directly to physicians, and offering pharmacists generous reimbursements for filling prescriptions with the generic version of a drug. <u>Id.</u> ¶ 14. Fifth, the passage of the Hatch-Waxman Act of 1984^{12}

Rosenthal Decl. ¶ 13 (internal citations omitted).

¹² The Drug Price and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, is codified at 21 U.S.C. § 355(j). Under the Act, a would-be generic manufacturer is permitted to file an Abbreviated New Drug Application. The ANDA incorporates FDA findings on the safety and effectiveness of a previously approved list drug given a showing that the new generic drug is bioequivalent to the listed drug. 21 U.S.C. § 355(j).

¹¹ Rosenthal elaborates on the role of health insurers:

During the period relevant to this matter, 2001 to [2006], private third party pay[o]rs covered approximately 44% of all retail prescription drug purchases. Because of double-digit prescription drug spending growth that began in the 1990s, third party pay[o]rs began adopting aggressive cost control mechanisms by the end of that decade. These mechanisms include tiered formularies, generic substitution programs, and coinsurance (copayments that are a percent of the retail price of a drug rather than a fixed dollar amount). Tiered formularies, which were the most common structure of prescription drug benefit in 2003 (57% of enrollees in employer-sponsored plans are now covered by this type of benefit design), provide consumers with incentives to choose lower-cost drugs by requiring higher copayments for certain groups of drugs. In the most common type of three-tiered formulary benefit, generic drugs require the lowest copayment (e.g., \$10), brand name drugs whose manufacturers offer the third party pay[o]r generous discounts and rebates require a somewhat higher copayment (e.g., \$25) and the remaining brand name drugs are associated with the highest copayment (e.g., \$50) or coinsurance (e.g., 50%). Recent studies have documented the effectiveness of tiered formularies as strategies for influencing drug choice and spending.

eliminated certain generic entry barriers, prompting increased and vigorous generic entry and competition. Id. ¶ 15.

b. Dr. Rosenthal claims generic entry would have resulted in decreased market share for and decreased price of Wellbutrin SR

Dr. Rosenthal also offers empirical evidence, in the form of published studies, to bolster her hypothesis that delayed generic entry would have resulted in injury common to all of a majority of class members. She alleges that the studies she consulted, as well as her own research, reflect a consensus "that generic entrants: (1) rapidly capture market share, (2) offer substantial price discounts relative to their brand-name equivalents, and (3) in recent years, have driven down brand name drug prices as well." <u>See id.</u> ¶ 17. Dr. Rosenthal contends that in the years immediately following the passage of the Hatch-Waxman Act, generic drug substitution increased significantly when branded drugs lost patent protection. <u>Id.</u> at ¶ 18. As a result of this increased competition, the average prices of brand drugs declined significantly upon generic entry. <u>Id.</u>

In support of this assertion, she cites a study by Grabowski and Vernon examining the effects of generic entry on eighteen different drugs over a two year period immediately after the Hatch-Waxman Amendments' passage. <u>Id.</u> ¶ 18 (citing H.G. Grabowski & J.M. Vernon, <u>Brand Loyalty and Price Competition in Pharmaceuticals</u> <u>After the 1984 Drug Act</u>, J.L. & Econ., 35(2) (1992)). Grabowski and Vernon found that a "typical brand drug lost around half of its market share to the generic competition two

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years after entry." <u>Id.</u> Additionally, "for each 10 percent market share gain by generics, the authors found an average price (that is, the weighted average of the generic and brand drug prices within a molecule) decline of roughly 6 percent two years after entry." <u>Id.</u>

The second study she cites, by Caves, Whinston, and Hurwitz, examines thirty brand drugs that went off-patent from 1967 to 1987. The authors found "generic producers enter the market by quoting prices much lower than those of their branded competitors, and these prices also decline as the number of generic competitors increases, potentially falling to roughly 17 percent of the branded producer's preentry price." <u>Id.</u> (quoting R.E. Caves, M.D. Whinston & M.A. Hurwitz, <u>Patent Expiration, Entry, and</u> <u>Competition in the U.S. Pharmaceutical Industry</u>, Brookings Papers on Economic Activity, 1991, at 44-45).

Finally, Rosenthal cites a Congressional Budget Office ("CBO") report from 1998 in support of the proposition that occurrence of both price discounting and generic substitution increased in recent years. <u>Id.</u> ¶ 19. The CBO found "the average generic entrant captured about 44% market share in the early 1990s, [but] it is not uncommon for a generic drug launched today to capture 80-90% market share within a year." <u>Id.</u> (citing Cong. Budget Office, <u>How Increased Competition from Generic Drugs has Affected</u> <u>Prices and Returns in the Pharmaceutical Industry</u>, July 1998). Rosenthal also cites the CBO report's finding that one year after generic launch, the retail prices of generic drugs may be up to 25% less than those of their branded equivalents. <u>Id.</u>

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Relying on these three studies, Rosenthal claims there is an inverse relationship between the number of generics that enter a market and the prices of those generics. Id. ¶ 20 & n. 24 ("Numerous studies have demonstrated that the more generics that enter a market, the greater the price competition among those generics and the greater the decline in generic prices overall."). The number of generic entrants is influenced by the attractiveness of the market that is to be entered, which depends on its size as well as the fixed costs of entry versus the expected stream of profits.¹³ Id.

Finally, Rosenthal cites Frank and Salkever to suggest the proportion of the market that is composed of brand-loyalists — customers who are less price-sensitive and would choose to continue purchasing the brand name drug regardless of the availability of a generic alternative — influences how a brand name manufacturer will price its product when faced with generic launch. Id. ¶ 21 (citing R.G. Frank and D.S. Salkever, Pricing, Patent Loss and the Market for Pharmaceuticals, Southern Economic Journal, 59(2) (1992)). Logically, "if brand-loyal customers are a large share of the total market, then the manufacturer of the branded drug may raise its price," whereas if the majority of consumers are "highly price-sensitive, the manufacturer would be better off lowering prices to retain a large market share." Id. ¶ 21.

Based on her review of these studies and pertinent economic literature, Dr.

 $^{^{13}}$ Dr. Rosenthal defines the "expected stream of profits" as the "product of the number of units that the generic entrant can sell (i.e., the generic penetration rate divided by the number of entrants, multiplied by the total units for the molecule) and the profit margin." Rosenthal Decl. ¶ 20.

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Rosenthal concludes the alleged "foreclosed generic entry would have resulted in rapid erosion of Wellbutrin SR's market share and lower prices for both generic switchers and brand-loyal customers." Id. ¶ 22. Dr. Rosenthal claims that in the "but-for world"— the world in which GSK never filed its allegedly sham litigation, the patent for Wellbutrin SR expired, and generic sustained release buproprion entered the market on or about July 1, 2001 — two classes of consumers would have paid less for bupriorion SR during the class period. See Rosenthal Decl. ¶ 7. These consumers are: (1) those who would have switched to the generic version of Wellbutrin SR and would have paid less for the drug than they did in the actual world (in which no generic version was available); and (2) those brand loyal customers who would not have switched to the available generic alternative but would still have paid less for branded Wellbutrin SR than they did in the actual world. See id. ¶ 8.

Dr. Rosenthal claims two factors provide substantial support for her conclusion: (1) the proposed class period "occurred during a time of aggressive efforts by health insurance plans in the U.S. to reduce pharmaceutical spending by encouraging the use of lower-cost generics," and (2) the annual sales of Wellbutrin SR before the generic launch were approximately \$1.4 billion, "making it an attractive target for potential generic entrants." Id. at ¶ 22. According to Dr. Rosenthal, the five new drug applications submitted for generic bupropion SR reveal the Wellbutrin SR market was indeed alluring. Id. ("[A]bsent the unlawful actions of the Defendant, [Rosenthal] would anticipate a

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relatively large number of generic entrants to have launched after the 180 day exclusivity period for the first generic and, consequently, vigorous price competition.").

2. GSK Argues the Plaintiffs' Purported Class is Overbroad Because It Includes Uninjured Consumers

GSK counters the plaintiffs' arguments with its own expert report from Dr. Bigelow, who faults Dr. Rosenthal's economic analysis for failing to identify uninjured class members for exclusion. Bigelow also claims Rosenthal's methodology is unsuitable to establish class-wide damages primarily because the class and analysis include uninjured end-payors.

a. Dr. Bigelow claims each class member would not have been injured in Rosenthal's but-for world

Dr. Bigelow believes Dr. Rosenthal's but-for world is improperly broad because it includes consumers who would not have purchased sustained release bupropion absent GSK's extensive marketing campaign. Both Dr. Bigelow and Dr. Rosenthal acknowledge that it is routine practice for brand name drug manufacturers to invest considerably in marketing and promotion efforts prior to generic entry. <u>See</u> Bigelow Decl. ¶ 32; <u>see also</u> Rosenthal Decl. ¶ 11. Producers of brand name drugs have strong incentives to differentiate their drug from therapeutically similar brand name drugs by raising awareness about the benefits unique to their specific product. <u>See</u> Bigelow Decl. ¶ 32; <u>see also</u> Rosenthal Decl. ¶ 11.

Dr. Bigelow bases his conclusions in part on the statement of Robert Jagt, the former Director of Marketing for Wellbutrin, affirming GSK engaged in extensive marketing efforts for Wellbutrin SR. Jagt explains that in 2001, GSK began Direct-To-Consumer ("DTC") media advertisements that emphasized the lower incidence of sexual side effects in Wellbutrin SR as compared to comparable antidepressants. Jagt Decl. 20-21; see also Defs.' Mem. Law Opp'n End-Payor Pls.' Mot. Class Certification at 15. The DTC campaign proved successful, and internal GSK analyses estimated it led to a 7 to 12% increase in new prescriptions from January to May of 2001. Jagt Decl. ¶ 22. Launching a DTC marketing campaign, Jagt asserts, is not the result of a spontaneous decision but requires careful analysis, given it is an "expensive and time-consuming process" and must "comply with exacting FDA regulatory requirements." Id. ¶ 6. DTC advertising also requires a substantial period of time to cultivate results, so Jagt maintains that GSK would evaluate the situation very thoroughly before investing in a DTC campaign for a drug nearing the end of its patent term.¹⁴ Id. Jagt opines that promotional

Jagt Decl. ¶ 6 (emphasis added).

¹⁴ Jagt explains:

DTC advertising requires a period of time to have an effect on prescriptions since it takes time to both build awareness through DTC and for patients who see the DTC ads to discuss the product with their healthcare provider and obtain a prescription from their [healthcare provider] if deemed appropriate. *Therefore, we would very carefully evaluate the decision to begin or continue an investment in expensive DTC media advertising for a product that was nearing the end of its patent life.*

spending was of particular importance in the case of Wellbutrin SR. Id. ¶ 14 ("While Wellbutrin SR did grow to become a very successful product for GSK, its success was not preordained."). GSK's advertising campaign proved instrumental in "differentiating the product in a crowded antidepressant market based on [Wellbutrin] SR's side effect profile." Id.

Jagt provides a number of reasons for GSK's decision to engage in the DTC campaign for Wellbutrin SR. First, he notes that the antidepressant market is highly competitive in terms of promotional spending, in part because of what GSK has observed to be a positive correlation between antidepressant prescription sales and promotional spending. Id. ¶ 9.

As of early 2005, approximately \$1.2 billion was being spent on an annual basis by all companies having a branded antidepressant on professional and consumer promotion of antidepressant products, *exclusive* of the cost of sampling. Six antidepressants... were ranked in the top 55 promoted products in the United States based on dollar spend [sic]. The antidepressant category is one in which prescription sales are highly responsive to promotional spending. In general, promotional spending is important in the crowded antidepressant category to build awareness of product differentiation, including with respect to a product's efficacy or side effect profile.

Id. Second, GSK considered Wellbutrin SR an ideal candidate for DTC advertising

because it was an improvement on its predecessor drug¹⁵ and possessed unique

¹⁵ Wellbutrin SR's predecessor, Wellbutrin IR, required administration three-times-daily and carried with it the risk of seizure as a potential side effect. Wellbutrin SR, however, required only a twice-daily dosing regimen and had an improved side effect profile. <u>See</u> Jagt. Decl. ¶¶ 15, 17.

characteristics as compared to other antidepressants. <u>Id.</u> ¶ 17.¹⁶

In light of the fierce competition in the antidepressant market and GSK's perceived ability to effectively differentiate Wellbutrin SR with respect to its side effect profile, GSK decided to invest substantially in a DTC campaign. <u>Id.</u> ¶¶ 18-20. Had the patent been close to expiration, "GSK would have been more cautious in deciding whether to begin a DTC media campaign . . . and would not have likely begun such an effort." <u>Id.</u> ¶

20. In sum, Jagt explained:

I believe that had a generic entered the market in 2002 or earlier, promotional support for branded Wellbutrin SR would have been significantly reduced. Given the fact that GSK did not begin branded DTC for Wellbutrin SR until 2001, the time it takes for DTC to have an impact, and the considerable expense of both the planning and the implementation of a DTC media campaign, *it is unlikely we would have launched a DTC media campaign for Wellbutrin SR at all in such a situation*. Indeed, if a generic had entered as early as July 1, 2001, it would have been difficult to justify launching the 2001 branded DTC campaign for Wellbutrin SR given the 24-month [return on investment] period . . . that the company looks at to evaluate such spend[ing]. *Instead, we would have only carried out very limited promotional activities to bridge the period until the launch of Wellbutrin XL*.

Id. ¶ 30 (emphasis added).

Jagt maintains that had generic entry been on the horizon, GSK would have

curtailed its marketing entirely, as was common practice. See Jagt Decl. ¶¶ 28-29 ("[I]t is

¹⁶ Clinical studies showed that Wellbutrin SR was of comparable efficacy to other antidepressants, particularly Zoloft, yet presented a lower incidence of sexual dysfunction and no measured impact on weight. <u>Id.</u> at ¶ 17.

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GSK's standard course to terminate active promotion for a brand name drug once its generic version enters the market."). Because promotion would have ended sooner, purchases that were influenced by that promotion would be lost.

The plaintiffs' but-for world is flawed, according to Dr. Bigelow, because GSK would not have conducted such capacious promotion, including but not limited to the DTC campaign, in the but-for world. See Bigelow Decl. ¶ 33; see also Jagt Decl. ¶ 30. Certain consumers who actually purchased branded Wellbutrin SR could have purchased the drug solely because of GSK's advertisements, i.e. the purchases would not have been made but for the alleged generic entry foreclosure because the DTC campaign caused those purchases. Id. In other words, purchasers of Wellbutrin SR at the allegedly lower prices would not have been purchasers at all. Bigelow asserts that even if Rosenthal could show "that prices would have been lower but for the alleged generic entry foreclosure, these consumers would have enjoyed no benefit from those lower prices because they would not have purchased sustained release bupropion at the lower prices." Bigelow Decl. ¶ 33. Individual inquiry is necessary, Dr. Bigelow concludes, to investigate the incentives driving each individual purchaser so as to determine whether each would have been impacted in the absence of GSK's extensive marketing. Id. ¶ 36.

Identifying customers who purchased Wellbutrin SR [] based on GSK's marketing and promotion will necessarily require an individualized inquiry and cannot be made on a class-wide basis using common or class-wide information. Merely knowing that the consumers did purchase sustained release bupropion would not identify which consumers were influenced to purchase by

GSK's promotion. At a minimum, an inquiry would need to be made of all consumers who began consuming Wellbutrin SR for the first time in 2001 – which is the date the plaintiffs allege generic entry would have occurred but for the alleged generic entry foreclosure – and before generic entry actually took place in 2004.

Id.

b. Dr. Bigelow claims brand loyalists would not have been injured in Rosenthal's but-for world

Dr. Bigelow also faults Rosenthal's premise that generic entry would have reduced the prices paid for Wellbutrin SR by brand-loyalists. <u>See</u> Rosenthal Decl. ¶ 11 ("Prices paid by brand loyal customers were most likely higher than they would have been absent the foreclosure."). First, Bigelow notes that it remains in dispute, among the studies on which Rosenthal bases her conclusions, whether generic competition reduces the prices of branded products. Bigelow Decl. ¶ 22. Bigelow criticizes these studies, including the CBO report, because each analyzes the trends of average prices rather than how these changes in average prices impact individuals.¹⁷ Bigelow Decl. ¶ 23. Individual impact,

Bigelow Decl. ¶ 23 n.20 (internal citations omitted).

¹⁷ Dr. Bigelow provides a brief description of each of the following studies cited by Dr. Rosenthal:

Both Caves *et al.* and Grabowski and Vernon analyze the determinants of the ratio of the average (within a market at a point in time) generic price to the average brand price. Similarly, the CBO studies the relationship between the average price paid by retail pharmacies for generic drugs and the average price they pay for brand name drugs. Frank and Salkever's econometric analysis studies the determinants of average prices for generic and brand name drugs.

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not average price changes, Bigelow contends, is what "needs to be addressed in order to determine if *all* members of the proposed class would have been injured if GSK had delayed generic entry." Id.

Second, Dr. Bigelow avers GSK actually *increased* the price of Wellbutrin SR in 2004, the year following generic market entry. <u>Id.</u> ¶ 27. In support of this contention, he relies on two empirical models.¹⁸ The first, Exhibit 3, illustrates the price increase by charting the estimated weighted average net prices¹⁹ to hospitals and managed care organizations for Wellbutrin SR 100mg and 150mg kits and refills, organized by quarter and trade group, for 2003 and 2004. <u>Id.</u> ¶ 28. Although the hospitals and managed care organizations do not typically buy the drugs directly from GSK, many have rebate or discount contracts with GSK. <u>Id.</u> Exhibit 3, presented in four parts, shows uniformly higher weighted average net prices in the quarters following generic entry for both trade

¹⁹ Dr. Bigelow explains:

Bigelow Decl. ¶ 28 n.30.

¹⁸ Dr. Bigelow included data on the branded drug Zyban in both Exhibits 3 and 4. As Zyban is not pertinent to my analysis, I will exclude it from my discussion. Similarly, Exhibit 4 contains data on the 200mg dosage of Wellbutrin SR, which is also irrelevant to the class certification discussion and will be excluded.

Weighted average net prices for a trade group are estimated by reducing the weighted average [wholesaler acquisition cost] in each quarter by that trade group's average discount percentage for that quarter. Weighted average quarterly WAC is calculated by dividing quarterly gross sales dollars by quarterly gross sales units. Discount percentages for each trade group are calculated by dividing each trade group's total discount amount by its contracted sales total (calculated at WAC).

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groups.²⁰ <u>Id.</u> The second model, Exhibit 4, charts the progression of average retail prices, measured in retail dollars per tablet, for Wellbutrin SR 100 mg and 150 mg doses. <u>Id.</u> ¶ 29. Exhibit 4 presents Verispan data – the total price paid to the retail pharmacy – from January 2000 to March 2006, with generic entry marked at January 2004. <u>Id.</u> According to Dr. Bigelow, Exhibit 4 shows "the pattern of continued retail price increases after generic entry." Id.

The models, according to Dr. Bigelow, affirm empirically that "the price of brand name sustained release bupropion *increased* with the advent of generic competition." <u>Id.</u> ¶ 27. Additionally, the lack of consensus among relevant studies as to the effect of generic competition on brand prices, as well as the studies' use of average prices, discredits Rosenthal's exclusive reliance on scientific literature in drawing her conclusions about brand loyalists. <u>Id.</u> Because the plaintiffs have failed to establish that brand loyalists would have been injured if GSK had foreclosed generic entry, Dr. Bigelow claims, the class includes members unaffected by the alleged antitrust violations.

Bigelow Decl. ¶ 28.

²⁰ Dr. Bigelow notes that the data exhibit an exception to the showing of uniformly higher weighted average net prices:

For Managed Care entities there was some fluctuation during 2004, but weighted average net prices to this group for Wellbutrin SR 150 mg ended 2004 at a higher level than they had been during any quarter of 2003. Exhibit 3.b also shows that occasional fluctuation has pre generic-entry precedents in [the third and fourth quarters of 2003], so it is unlikely to have been caused by generic entry.

Bigelow also estimates that the percentage of the class that would have remained brand

loyal is not insubstantial. Identifying who in the class would have remained a brand

loyalist if generic entry had occurred earlier would require individualized inquiry. Id. ¶

30.

The uninjured Brand Loyalists can not be identified from common information or by the application of a common Individual consumers might remain brand loyal formula. because of their perception of the relative quality of brand and generic drugs, because of the nature of their health insurance coverage, or for some other reason. Whatever those reasons are, they will not be evident in data that show the amount and prices of Wellbutrin SR [] purchased when generic versions were not available. When one looks at data from the period between July 2001, when the plaintiffs allege that generics would have entered but for the alleged generic entry foreclosure, and January 2004, those consumers who would have remained brand loyal if generics had entered and those who would have switched to the generic are indistinguishable from one another. Identifying the brand loyal subset among the group will require an inquiry into individual circumstances and even attitudes toward generic versus branded drug purchases.

<u>Id.</u>

c. Dr. Bigelow claims end-payors with certain insurance coverage would not have been injured in Rosenthal's but-for world

Finally, Dr. Bigelow asserts that there are several subsets of consumers who,

because of their insurance coverage, would not have been affected by the delayed entry of

generic buproprion. Generally, prescription drug insurance plans charge consumers a co-

payment cost per prescription filled, with a possible a co-insurance rate addition

calculated as a percentage of the retail drug price. Id. ¶ 42. But consumers who do not

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pay a co-insurance rate and whose co-payment for generic bupropion SR would be unaffected whether or not generic entry was delayed would not be injured. <u>Id.</u> Recognizing this, Dr. Bigelow identifies three subsets of bupropion SR consumers included in the proposed class who would not have sustained damages: (1) generic only consumers with health insurance; (2) generic switchers with single tier insurance; and (3) brand loyal consumers with 1 or 2 tier insurance.

First, Dr. Bigelow faults Dr. Rosenthal's premise that insured consumers who purchased bupropion SR for the first time after generic entry in January 2004 and only purchased a generic version would be injured by the defendant's alleged antitrust conduct. Bigelow Decl. ¶ 44. Rosenthal claims these first time, generic only purchasers were injured because the price at which they bought the generic version would have been lower but for the alleged foreclosure. Rosenthal Decl. ¶ 27. Bigelow contends that for these same purchasers, who have health insurance and do not pay a co-insurance rate, their only cost would be the co-payment. Bigelow Decl. ¶ 44. The co-pay would remain the same, as it is a fixed cost charged per prescription filled and invariant to any price effects resulting from delayed generic entry. <u>Id.</u>

Second, Dr. Bigelow contends purchasers of Wellbutrin SR who would have switched to the generic but have health insurance under which they pay the same co-pay and no co-insurance for both generic and branded drugs would not have been injured. <u>Id.</u> ¶ 46. Generic entry would not affect the fixed co-payment, so these generic-switcher

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consumers with single-tier insurance would not have been injured. Id.

Third, Dr. Bigelow asserts that insured brand loyalists who are required to pay the same co-payment and no co-insurance rate whether or not a generic version is available are also not impacted. Id. ¶ 48. Assuming that absent foreclosed generic entry, the brand prices of Wellbutrin SR would have been lower than the price the consumer actually paid, the co-payment would remain fixed. Id. The brand loyalists with 1 or 2 tier insurance would pay the same co-pay regardless of the alleged antitrust violations, so this subset of consumers would also be uninjured. Id.

The class definition, as proposed by the plaintiffs, fails to exclude these endpayors, who would not have paid any overages given their individual insurance plans. Dr. Bigelow asserts that in order to identify the consumers who would be uninjured, it would be necessary to determine "not only the amounts of sustained release bupropion [each class member] actually purchased, but also the amounts and type (brand or generic) of sustained release bupropion they would have purchased but for the alleged generic foreclosure, and the detailed terms of their health insurance policies." <u>Id.</u> ¶ 52. Dr. Bigelow concludes individualized evidence is necessary to show class-wide antitrust impact (or the lack thereof). <u>Id.</u> ¶ 53.

Further, in her deposition, Dr. Rosenthal admits that her yardstick methodology for calculating damages does not "exclude individuals that may or [] may not have sustained

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zero injury because of their co-payment arrangement."²¹ Deposition of Meredith

Rosenthal 180:14-181:5, 182:4-24. The import of Rosenthal's statements and the

structure of certain class members' insurance arrangements, according to Dr. Bigelow, is

that Rosenthal's proposed methodology is incapable of proving each class member

²¹ Dr. Rosenthal testified as follows at her deposition:

<u>Q. So it</u> is not a predicate to use a yardstick or a common methodology to calculate damages that everyone in the class has been injured?

A. The class is defined as narrowly here for those members who consume Wellbutrin SR. Of course there's certain class members who won't be included in the yardstick analysis and won't be included in the ultimate damage analysis. Those might include, for example, government payors. So they would not be included here. But the class members that we talked about before, all consumers and third-party payor who purchased as end payors Wellbutrin SR or Zyban, they're included in this analysis. *There's no part of the analysis that tries to exclude individuals that may or – may not have sustained zero injury because of their co-payment arrangement, for example.*

. . .

A. As we talked about before, there may be some consumers or third-party payors, because of payment arrangements, did not actually sustain impact. My analysis won't be able to identify them. So they may be in the analysis.

Q. So essentially those people who haven't been injured would be getting certain damages based on your theory?

A. I believe that's a question of allocation. Again, the estimate of aggregate impact will be accurate, and that's the question I've addressed here, is how do we accurately assess aggregate impact to the class.

Q. Including those people who we've already agreed have suffered no injury?

A. We've sort of agreed that *there are hypothetical people who may have suffered no injury*. *They aren't identified, can't be identified here to be excluded. They're included in the class definition.*

Rosenthal Deposition 180:17-181:5, 182:4-24 (emphasis added).

sustained individual injury. Because Rosenthal's analysis does not show class-wide damages, Dr. Bigelow reasons that it fails to satisfy the plaintiffs' burden of proof in showing that antitrust impact is susceptible to proof by common evidence at trial.

3. The Plaintiffs Fail To Address Adequately the Concerns Raised by GSK

In response to the defendant's criticisms of her methodology, Dr. Rosenthal submitted a reply declaration addressing certain points raised by Dr. Bigelow.

a. Uninjured Class Members

Dr. Rosenthal dismisses Bigelow's arguments concerning subsets of uninjured class members as "commonly presented and rejected in pharmaceutical antitrust cases such as this one." Reply Decl. of Professor Meredith Rosenthal Decl. ¶ 3. Rosenthal also faults Bigelow's premise that the inclusion of potentially uninjured consumers frustrates class certification because "his analysis only demonstrates that the magnitude of overcharges would vary across [c]lass members, not that aggregate damages could not be accurately estimated." Id. Finally, she theorizes that even if there are certain class members who would not have sustained injury, Dr. Bigelow "has failed to identify how the methods of applied microeconomics are inadequate to provide the Courts with information and tools by which to address differences." Id.

b. Brand Loyalists

Rosenthal maintains that her economic market analysis competently assesses

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"common impact and [c]lass wide damages." Id. ¶ 5. First, she asserts Bigelow neglected to address the evolution of pharmaceutical competition in his analysis. Substantial efforts to encourage generic substitution, including "laws, regulations and public and private pay[o]r business practices and benefit strategies," intensified around the turn of the century, rendering earlier studies unpersuasive. Id. In recent years, Rosenthal alleges, branded drug prices have tended to either decline or to increase at the pre-generic entry rate even *after* generic market entry. Id. (citing Cong. Budget Report). Nonetheless, Rosenthal states the impact generic entry would have had on Wellbutrin SR pricing is, in the end, an empirical question that her analysis will address. Further, she contends that her analysis "will explicitly model GSK's pricing strategy based on actual pricing trends observed after the launch of [generic bupropion SR]." Id.

Second, Dr. Rosenthal faults the two models submitted by Dr. Bigelow for inadequately addressing the impact of generic entry on Wellbutrin SR prices. With respect to Exhibit 3, she claims it is inaccurate because it uses pricing data from the period immediately preceding and following the generic launch rather than historic pricing data. <u>Id.</u> ¶ 6. According to Rosenthal, injury to brand loyalists "is a function of the difference in the actual *trend* in prices compared to the but-for *trend* in prices before and after the but-for entry date[,] not a simple before/after comparison of price levels." <u>Id.</u> Additionally, she claims that because Dr. Bigelow utilized the "manufacturer's net prices" as opposed to the "end-pay[o]r prices," in formulating Exhibit 3, that model reflects GSK's net profits rather than what the end-payors actually paid. Id.

Dr. Rosenthal also criticizes Exhibit 4, arguing that although it plots the prices of Wellbutrin SR over a period of many years, it relies on "retail pharmacy sales data," commonly known as "scanner data." Rosenthal Reply Decl. ¶ 7. She claims "scanner data" fails to take into account rebates paid by drug companies to pharmacy benefit managers and managed care organizations. <u>Id.</u> In his deposition, Dr. Bigelow acknowledged that Exhibit 4 represents pricing at the retail level.²² Rosenthal contends that retail sales data "fail[s] to account for a major area of price concessions, rebates that are paid by drug companies to pharmacy benefit managers and managed care organizations." <u>Id.</u> ¶ 7. Accordingly, Dr. Rosenthal indicates that neither of Dr. Bigelow's models "establish that prices to end-pay[o]rs increased, decreased or remained the same after the entry of [generic bupropion SR]."

Q. Are you aware of the phenomenon that when, or at least the argument, put it that way, are you aware of the argument that when a retail branded drug goes generic that the branded company will increase the amount of rebates that are paid to PBMs and/or managed care entities which are not reflected at the retail pharmacy level?

A. I don't believe I recall hearing that suggestion before.

²² Dr. Bigelow testified at his deposition as follows:

A. What Exhibit 4 represents, as I said, is the total dollars that the retail pharmacy receives for the prescription from the various sources from which it receives it. That may include – that will include pharmacy benefits management companies, or other entities that get rebates from the manufacturer. To the extent that the rebates, those parties receive in turn reflect their negotiations with the pharmacy, they'll be a reflection of that in the numbers you see here on Exhibit 4. *But Exhibit 4 doesn't purport to represent pricing at some other level of this business. Exhibit 4 represents pricing at the retail level.*

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Third, Dr. Rosenthal faults Dr. Bigelow for failing to account for what she terms the "exogenous influence of the launch of Wellbutrin XL on brand prices of Wellbutrin SR." Id. ¶8. GSK launched Wellbutrin XL in September of 2003, and Rosenthal gathers from GSK internal forecast documents that "GSK sought to convert subscribers from Wellbutrin SR to Wellbutrin XL during the months preceding anticipated generic entry." Id. To that end, GSK intended to introduce Wellbutrin XL at a price "at or slightly below Wellbutrin SR, a 'cannabalization' strategy that has been observed in other second-generation drug launches." Id. Accordingly, Rosenthal avers "GSK had an economic incentive to maintain high prices for Wellbutrin SR in order to further the incentives for conversion to Wellbutrin XL." Id. She claims that had generic buproprion entered the market in 2001, this incentive would not have been a factor. Id.

Finally, Rosenthal asserts that even if GSK can show that brand loyalists would have paid the same or higher prices before and after generic market entry, "a determination of aggregate damages to the Class is wholly feasible using standard methods of applied microeconomics and [] determination of membership within that Class could be accomplished through claims submissions and documentation procedures." Rosenthal Reply Decl. ¶ 9.

B. The Plaintiffs Fail to Show that Common Proof is Available to Show Antitrust Impact to All Class Members

The plaintiffs allege that GSK's monopolistic conduct foreclosed generic market

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entry and the ensuing delay caused *direct purchasers* to pay supra-competitive prices²³ for Wellbutrin SR. The plaintiffs theorize that the direct purchasers, in turn, passed the injury on to *indirect purchasers*, or end-payors who purchased Wellbutrin SR from direct purchasers. It follows that in order to show antitrust impact to indirect purchasers, the plaintiffs must show: (1) that *direct purchasers* paid supra-competitive prices for Wellbutrin SR and (2) that some or all of the inflated cost paid by direct purchasers was *passed through to indirect purchasers*. See In re Flash Memory Antitrust Litig., No. 07-0086, 2010 U.S. Dist. LEXIS 59491, *44 (N.D. Cal. March 31, 2010); <u>see also In re</u> <u>Graphics Processing Units Antitrust Litig.</u>, 253 F.R.D. 478, 502 (N.D. Cal. 2008) ("By definition, indirect purchasers must prove that an overcharge was levied on *direct* purchasers of defendants' products, who then passed all or some of that overcharge through to the indirect purchasers.").

The Third Circuit has yet to explicitly articulate the same sequential, two-step inquiry for antitrust impact to indirect purchasers, but at least one court in this Circuit has relied on the same reasoning.²⁴ In <u>American Seed</u>, the court denied certification to a class of indirect purchasers who failed to show injury to direct purchasers and instead had relied on a presumption of impact. <u>Am. Seed Co. v. Monsanto Co.</u>, 238 F.R.D. 394, 402

²³ For the purposes of this memorandum, "supra-competitive prices" means "prices higher than the prices which would obtain in a competitive regime." <u>McDonough</u>, 638 F. Supp. 2d at 483 n.13 (internal quotations omitted).

²⁴ No decision has been cited, nor can I find one, in this or any Circuit, in which the court explicitly held that *indirect purchaser* plaintiffs are *not* required to show impact to *direct purchasers* through common, formulaic proof.

(D. Del. 2006), <u>aff'd</u>, 271 Fed. Appx. 138, (3d Cir. 2008) ("Even assuming overcharges were in fact passed through *in toto* in all cases, negating any need for individualized inquiry, the premise of plaintiffs' theory . . . rests upon the presumption of impact on the direct purchasers."). In asking for certification of the class of end-payor purchasers, the plaintiffs necessarily expect this court to make the leap from direct injury to indirect injury. However, the plaintiffs must demonstrate that common evidence is available to show that at least some of the direct purchaser injury *passed through* to each indirect purchaser.²⁵ See Hydrogen Peroxide, 552 F.3d at 316 n.14 ("The burden of proof rests on the movant.") (citing <u>Unger v. Amedisys Inc.</u>, 401 F.3d 316, 320 (5th Cir. 2005) ("The party seeking certification bears the burden of establishing *all* requirements of Rule 23 have been satisfied.").

1. Certification of the Direct Purchaser Class Does Not Mandate Certification of the Indirect Purchaser Class

The plaintiffs rely heavily on the role of direct purchaser class certification in making their own case. The plaintiffs argue, through the declaration of Dr. Rosenthal, that GSK's alleged anticompetitive conduct altered the "the sequence of events and the

²⁵ "Indirect-purchaser plaintiffs, like direct-purchaser plaintiffs, must demonstrate that they paid a higher price . . . than they would otherwise have paid absent a conspiracy. However, 'the problem of proof in an indirect purchaser case is intrinsically more complex, because the damage model must account for the actions of innocent intermediaries who allegedly passed on the overcharge.''' <u>In re Graphics Processing</u>, 253 F.R.D. at 499 (quoting William H. Page, <u>The Limits of State Indirect Purchaser Suits: Class Certification in the Shadow of Illinois Brick</u>, 67 Antitrust L.J. 4, 12 (1999-2000)).

timing of actual generic entry in the market for Wellbutrin SR." Rosenthal Decl. ¶ 7(f). Dr. Rosenthal's analysis evaluates "(1) whether economic proof can be used to demonstrate common impact of the alleged foreclosure of generic competition on the members of the proposed class, and (2) whether such impact can be quantified using standard methods." Rosenthal Decl., Part I. Although injury to *indirect purchasers* is necessarily dependent on impact to the direct purchasers who sold to them, Dr. Rosenthal fails to address *direct purchasers* a single time in her declaration, reply, or damages estimate.

However, the end-payor plaintiffs — and Dr. Rosenthal — essentially ask this court to presume impact to the indirect purchasers based on its earlier certification of a separate class of direct purchasers. <u>See</u> Tr. Oral Argument (July 31, 2008) at 6:9-19. At oral argument, counsel for the plaintiffs stated:

First, because this Court has already ruled on the direct purchasers' claims and certified a class, the issues that are relevant to this proceeding are only those that are unique to the indirect purchaser class . . . The fact that there's a layer of common impacts to the wholesalers, you've already determined that.

Id.

I am not persuaded this is correct. The burden of proof is on the end-payor plaintiffs to show common impact to the purported class. The end-payor plaintiffs cannot avoid this burden by relying on the work of the direct purchaser plaintiffs. <u>See In re</u> <u>Graphics Processing</u>, 253 F.R.D. at 503 ("Even if this order had certified an entire,

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massive class of direct purchasers, indirect purchasers would still carry a burden all their own for the former might settle out and leave the latter holding a bag of presumptions.").

In asserting that the only issues material to their motion are those "that are unique to the indirect purchasers," Tr. Oral Argument at 6:20-22, the indirect purchasers essentially argued that this court (1) presumed impact to direct purchasers; and (2) that a presumption of impact could therefore be applied to them. The Third Circuit has recognized that in limited circumstances, courts considering a class certification motion may presume antitrust impact. <u>See Bogosian v. Gulf Oil Corp.</u>, 561 F.2d 434, 454 (3d Cir. 1977). Specifically, Bogosian provides:

If ... a nationwide conspiracy is proven, the result of which was to increase prices to a class of plaintiffs beyond the prices which would obtain in a competitive regime, an individual plaintiff could prove fact of damage simply by proving that the free market prices would be lower than the prices paid and that he made some purchases at the higher price. If the price structure in the industry is such that nationwide the conspiratorially affected prices at the wholesale level fluctuated within a range which, though different in different regions, was higher in all regions than the range which would have existed in all regions under competitive conditions, it would be clear that all members of the class suffered some damage, notwithstanding that there would be variations among all dealers as to the extent of their damage.

<u>Id.</u> at 455.

It is undisputed that it is "immensely difficult to determine class-wide economic impact in indirect purchaser antitrust actions." <u>In re OSB Antitrust Litig.</u>, No. 06-826, 2007 U.S. Dist. LEXIS 56617, *17 (E.D. Pa. Aug. 3, 2007) (citing <u>Illinois Brick Co. v.</u>

Ill., 431 U.S. 720, 741-742 (1977)). Recognizing this inherent hurdle, the Bogosian court found that "when an antitrust violation impacts upon a class of persons who do have standing, there is no reason in doctrine why proof of the impact cannot be made on a common basis so long as the common proof adequately demonstrates some damage to each individual." Bogosian, 561 F.2d at 454. The Third Circuit applies the Bogosian short cut only "when it is clear the violation results in harm to the entire class." Newton, 259 F.3d at 179 n.21. The presumption "does not support class certification where there is no additional evidence of class-wide impact." Am. Seed, 238 F.R.D. at 398 (citing In re Linerboard Antitrust Litig., 305 F.3d 145, 153 (3d Cir. 2002)); see also In re OSB, 2007 U.S. Dist. LEXIS 56617 at *7 ("Thus, Plaintiffs must show, exclusive of any short cut, that they can prove actual class-wide impact at trial."). Further, the presumption is permitted "almost exclusively in *direct purchaser* antitrust actions." Id. at *16; see, e.g., Linerboard, 305 F.3d at 152; In re Mercedes-Benz Antitrust Litig., 213 F.R.D. 180, 188 (D. N.J. 2003).

Judge Kauffman did not rely on the <u>Bogosian</u> short cut in certifying the direct purchaser class, instead finding that the expert report of Dr. French was sufficient to establish that the direct purchasers suffered class-wide impact and that individual damages did not predominate their antitrust claim. Therefore, there is no basis from the decision in the direct purchaser litigation for reliance on the <u>Bogosian</u> presumption here. Nor have the plaintiffs supplied any expert testimony or empirical evidence as to direct

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purchaser impact. Further, even if some of the market conditions detailed by Dr. Rosenthal are instructive as to direct purchasers, market data alone is insufficient to justify application of the <u>Bogosian</u> presumption. <u>See In re Graphics Processing</u>, 253 F.R.D. at 502-503 (declining to presume impact where the plaintiffs relied exclusively on market data and economic theory to prove common impact). Therefore, I am not prepared to presume impact on this record.

The issue here is essentially analogous to that in American Seed, where the court decided not to apply the Bogosian short cut. In American Seed, the indirect purchasers sought class certification, arguing that common proof of injury to them could be established based on the direct purchasers' showing of price overcharges. Am. Seed, 238 F.R.D. at 402. The court found that even if injury passed through for every indirect purchaser, their arguments were premised exclusively on a presumption that direct purchasers had incurred injury. Id. Here, the Bogosian presumption is inappropriate for direct purchasers, and the indirect purchasers have inherently premised their own arguments exclusively on an improper presumption of direct purchaser impact. I am not satisfied the plaintiffs showed that common evidence can be used to establish class-wide impact, because they have not even attempted to demonstrate injury to direct purchasers. See In re Graphics Processing, 253 F.R.D. at 503 ("In order to even begin to demonstrate widespread injury to the indirect-purchaser class, however, plaintiffs must first demonstrate that there is a way to prove injury to direct purchasers on a common,

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formulaic basis.").

More importantly, the facts facing Judge Kauffman in deciding whether to certify the direct purchaser class were entirely different from the facts before me. The direct purchasers sought to certify a smaller class, consisting of only non-governmental entities that purchased Wellbutrin SR directly from GSK. The direct purchasers relied on a different expert, and therefore a different expert report from that relied on by the indirect purchasers here.²⁶ Finally, the direct purchaser plaintiff class certification decision was issued prior to the Third Circuit's decision in <u>Hydrogen Peroxide</u>, which undoubtedly raised the standard for plaintiffs seeking to certify a class in an antitrust action such as this one.

GSK has convinced me that significant flaws in the plaintiffs' expert evidence necessitate that I deny their class certification motion. Although the rigorous analysis of the end-payor plaintiffs' expert reports demanded by <u>Hydrogen Peroxide</u> was not, and should not have been, undertaken by Judge Kauffman in considering certification of the direct purchasers, I do not necessarily believe the outcome would have been any different if it had. Many of the flaws in the indirect purchasers' argument — including their inability to show that brand loyalists would have paid lower prices in the but-for world, and their failure to account for the effect insurance plan terms have on the prices paid by

²⁶ Plaintiffs relied on the expert report of Dr. Gary French in arguing that common evidence is available to show that all class members were adversely impacted on their purchases of Wellbutrin SR and generic buproprion.

indirect purchaser consumers — are not applicable to the direct purchaser claims. GSK did not raise these claims in relation to the direct purchaser class. Nor did GSK move for reconsideration of the direct purchaser class certification decision following issuance of the decision in <u>Hydrogen Peroxide</u>. Nothing in this opinion should be interpreted to invite them to do so now.

2. The Plaintiffs Fail to Provide an Independent Method for Showing Class-wide Impact to Their Purported Class

Plaintiffs must demonstrate, independently of any finding relating to the direct purchasers, that a common, formulaic method exists to show antitrust injury to the purported class. I am not satisfied the plaintiffs have shown class-wide antitrust impact is susceptible to proof by common evidence at trial.

The plaintiffs initially asked the court to accept a threshold showing of antitrust impact or to presume impact to the end-payors. <u>See</u> End-Payor Pls.' Mem. Supp. Class Certification at 17 (asserting that predominance is easily shown in antitrust actions and that the "[p]laintiffs need only make a threshold showing that common proof will predominate at trial with respect to the essential elements of the claims"); <u>see also</u> Reply Mem. Supp. Of End-Payor Pls.' Mot. Class Certification at 5 ("Courts evaluating anticompetitive conduct routinely presume common impact for purposes of class certification."). As noted, the Third Circuit explicitly rejected the position that the Rule 23(b)(3) predominance requirement should be abandoned in an antitrust action. Hydrogen Peroxide, F.3d at 321-322.

We recognize that the Supreme Court has observed that predominance is a test readily met in certain cases alleging consumer or securities fraud or violations of the antitrust laws. But it does not follow that a court should relax its certification analysis, or presume a requirement for certification is met, merely because a plaintiff's claims fall within one of those substantive categories.

Id. (internal citations and quotations omitted).

To show antitrust impact resulting from GSK's actions, the plaintiffs must be able to prove that their injury was causally linked to a violation of antitrust laws, and that their injury was of the type those antitrust laws were designed to prevent. <u>See McDonough</u>, 638 F. Supp. 2d at 483. It is well-accepted that "higher consumer prices because of an antitrust violation obviously constitute antitrust injury." <u>Id.</u> at 483 n.12. However, the plaintiffs still must show "that they can use common evidence to prove the impact of the Defendants' alleged anti-competitve conduct with a fair degree of certainty as to the proposed class[], without resorting to lenghy individualized examinations." <u>Terazosin</u>, 220 F.R.D. at 696. More specifically, they must be able to show, on a class-wide basis, (1) that GSK's anti-competitive conduct caused supra-competitive prices for buproprion SR and (2) that every end-payor bought buproprion SR at a supra-competitive price. <u>McDonough</u>, 638 F. Supp. 2d at 483.

a. Plaintiffs fail to show that GSK's conduct affected the price of both branded and generic buproprion SR

The first prong of the inquiry requires a showing that GSK's conduct caused supra-competitive prices for the end-payors. In the indirect purchaser scenario, assuming impact to direct purchasers was shown, causation is satisfied by demonstrating that some or all of the supra-competitive prices were passed on by the direct purchasers to the end-payors.²⁷

Dr. Rosenthal contends that generic drugs enter the market at a substantially lower price than their branded predecessors, and that the branded drug manufacturers are, in turn, compelled to lower their prices as they lose the majority of their sales to the generics.²⁸ A "rigorous analysis" of the record and economic literature reveals it does not follow from Dr. Rosenthal's theory that the brand prices necessarily decreased with generic entry. <u>See In re New Motor Vehicles Canadian Export Antitrust Litig.</u>, 522 F.3d 6, 29 (1st Cir. 2008) ("There is intuitive appeal to this theory, but intuitive appeal is not

²⁷ "Recovering in an Indirect-Purchaser case under state law requires a demonstration that a defendant overcharged its Direct-Purchasers for the product at issue, and that those Direct-Purchasers *then passed on* the overcharges to indirect purchasers." <u>In re Flash Memory</u>, 2010 U.S. Dist. LEXIS 59491, *53-54.

²⁸ No part of Rosenthal's report acknowledges direct purchasers are necessary intermediaries in the chain of liability from GSK to the end-payor plaintiffs. I have already addressed and found fault with Dr. Rosenthal's silence on the issue of impact to direct purchasers. But, for the purposes of the indirect purchasers section, I will disregard this broken link in the causal chain and independently evaluate Rosenthal's theories of causation and liability.

enough.").

The first conceptual flaw with Dr. Rosenthal's approach is a lack of basis in economic literature, as noted by Dr. Bigelow. Rosenthal inaccurately asserts there is a consensus among published literature that generic entry decreases the price of branded drugs.²⁹ Rosenthal Decl. ¶ 17. She relies primarily on four studies in formulating this theory.³⁰ Taken together, the studies do not offer any concrete conclusions regarding the impact of generic launch on branded prices. Specifically, the CBO report prominently cited by Dr. Rosenthal actually substantiates GSK's contention that there is no scholarly consensus that generic market entry reduces the prices of brand name drugs or causes them to increase at a rate slower than they would have absent generic entry.³¹ Cong.

³¹ The CBO reported the following equivocal results:

Several economists have studied what happens to the prices of innovator drugs when generic copies enter the market. All of the studies agree that the effect on innovators' prices is very small, although there is some dispute about the direction of that effect.

²⁹ When a price is said to "decrease," this means prices were lower *or* continued to increase, but at a slower rate.

³⁰ <u>See</u> Rosenthal Decl. ¶ 17 n.18 (citing Cong. Budget Office; Frank and Salkever; Grabowski and Vernon; and Caves, Whinston, and Hurwitz). Rosenthal also submits that her own research confirms her conclusions here and explains that she has "either submitted testimony and/or consulted on the launches of approximately 10 generics over the last 7 years." <u>Id.</u> ¶¶ 18, 18 n.19. I do not doubt Dr. Rosenthal's qualification as an expert, but as she has not provided specific references to any of her own prior research, I cannot consider it as corroborative.

Overall, brand-name prices frequently continue to rise after generic entry. Whether they rise more quickly or more slowly than would be the case without competition from generic drugs, however, is unclear based on these studies.

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Budget Office at 30. The CBO report evaluated the very same studies Dr. Rosenthal cites in her market analysis. The CBO, however, found these studies provided irreconcilable conclusions with no consensus as to the effect of generic entry on brand prices. Id.

GSK articulated many of the same points in rebutting Rosenthal's market analysis, and she herself retreats from the position that generic entry causes brand prices to decrease. In her reply, Rosenthal avoids addressing the criticisms raised by dismissing "whether the prices of Wellbutrin SR would have declined, or would not have risen at previous rates of increase after entry of generic sustained release bupropion hydrochloride," claiming that this is an "ultimately [] empirical question that the proposed analysis *will* address." Rosenthal Reply Decl. ¶ 5 (emphasis added). Her proposed analysis, Rosenthal avers, "*will* explicitly model GSK's pricing strategy based on actual pricing trends observed after the launch of [bupropion SR]." <u>Id.</u> (emphasis added). This is in stark contrast to Rosenthal's original conclusion that common data and methods were at her immediate disposal to show the "[p]rices paid by brand loyal customers were most likely higher than they would have been absent the foreclosure."³² Rosenthal Decl. ¶ 8(c).

Cong. Budget Office at 30.

 $^{^{32}}$ Dr. Rosenthal also appears to base her conclusion that all class members sustained economic injury on her ability to show that common proof will demonstrate prices for bupropion SR were higher than they would have been absent the generic entry delay for both generic switchers and brand loyalists. Rosenthal Decl. ¶ 9(b).

As the case matured and new discovery emerged, including data from the actual launch of generic buproprion SR, Dr. Rosenthal abandoned her previous assertion that brand prices in the but-for world would decrease with generic entry. In her calculation of aggregate damages, Rosenthal uses prices and quantities collected from the actual generic bupropion SR market entry to evaluate what would have occurred but for GSK's alleged anticompetitive conduct. Rosenthal Damages Decl. ¶ 28. Rosenthal expressly concedes "[b]rand prices . . . continue[d] to increase after generic launch."³³ Id. ¶ 37. Nothing in her report suggests that the actual brand prices increased at a slower rate after generic entry. At oral argument before Judge Kauffman, however, plaintiffs' counsel represented that in general and therefore in this case, brand prices after generic entry go up at a slower rate than before generic entry. Tr. Oral Argument 24:24. Further, the tables attached to Dr. Rosenthal's damages calculation reveal that brand prices for Wellbutrin SR 100mg

³³ Even if Dr. Rosenthal's arguments regarding Dr. Bigelow's models cast doubt on his price data, this does not obscure the fact that her own damages declaration confirms that brand prices were higher post generic entry. For that reason, I will decline to address Rosenthal's early criticisms of Dr. Bigelow's models, because she has now confirmed his ultimate assertion, that brand prices increased, with her own data. I would like to note though, that Rosenthal's own models suffer from the same defects for which she faulted Dr. Bigelow. In her graphs tracing the generic price change, generic penetration rate, and brand price change of her but-for statistics as compared to her comparison yardsticks, Rosenthal admittedly uses Verispan data. Rosenthal Damages Decl. Exs. C.1-C.3. In criticizing Bigelow's exhibit showing the Verispan prices of Wellbutrin SR over many years, Rosenthal claimed Verispan data reflect retail pharmacy prices and fails to account for "rebates that are paid by drug companies to pharmacy benefit managers and managed care organizations." Rosenthal Reply Decl. ¶ 7. Accordingly, she concludes that the model using this Verispan data does not establish "prices to end-pay[o]rs increased, decreased, or remained the same after the entry of sustained release generic bupropion hydrochloride." Rosenthal's criticisms are a double-edged sword, and her own damages calculations use the very data she criticized Bigelow for using.

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and 150mg tablets would have been higher in almost every quarter of the but-for world.³⁴ <u>See</u> Rosenthal Damages Decl. Ex. D.4, D.5. Put another way, in those quarters, the purchasers of branded Wellbutrin SR paid nothing in overcharges.³⁵ <u>Id.</u> ¶ 40 ("[O]vercharge damages to Brand Loyalists are calculated as zero for most quarters.").

Faced with her own admissions that brand prices were lower in the actual rather than the but-for world, Dr. Rosenthal attempts to justify this price differential with GSK's launch of Wellbutrin XL. Because GSK released another improved formulation of bupropion hydrocholoride in September of 2003, Rosenthal avers "GSK had an economic incentive to maintain high prices for Wellbutrin SR in order to further the incentives for conversion to Wellbutrin XL." Rosenthal Reply Decl. ¶ 8. The only nexus Rosenthal draws between Wellbutrin XL and antitrust impact is a vague suggestion that had Wellbutrin XL entered the market *after* generic bupropion SR, GSK would not likely have had an economic incentive to keep Wellbutrin SR prices high. <u>Id.</u> ¶ 8. In an earlier submission, Rosenthal asserted that whether a branded drug manufacturer chooses to raise, lower, or maintain pre-generic launch prices depends on what percent of the drug's market it estimates to be less price-sensitive, or brand loyal. Rosenthal Decl. ¶ 21. GSK

³⁴ Exhibit D.4 – "Wellbutrin SR 100 mg Overcharge Damages Assuming But-For Generic Launch on March 1, 2002" – represents that but-for brand prices were lower than actual brand prices only in the third and fourth quarters of 2002. <u>See</u> Rosenthal Damages Decl. Ex. D.4. Similarly, Exhibit D.5 – "Wellbutrin SR 150 mg Overcharge Damages Assuming But-For Generic Launch on March 1, 2002" – shows but-for brand prices were lower than actual brand prices in 2002, the first two quarters of 2003, and the first quarter of 2004.

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has not disagreed with this, nor with Rosenthal's contention that generic drugs typically capture up to 80-90% of the market within a year of entry. <u>Id.</u> ¶ 20. I am unsure how the launch of a successor drug would disrupt economic principles propounded by Dr. Rosenthal and supported by empirical evidence. Rosenthal asks this court to accept, without evidence, that delaying generic entry encouraged GSK to maintain high prices for Wellbutrin SR in order to facilitate a transition to Wellbutrin XL, and as a result, brand loyalists incurred no damages. Although it is a creative argument, I am not swayed by Rosenthal's effort to salvage her contention that injury to brand loyalists is susceptible to common proof.

The plaintiffs must demonstrate they can use common proof to show that prices were supra-competitive for each end-payor purchaser of branded Wellbutrin SR. They have not done this. See <u>Hydrogen Peroxide</u>, 552 F.3d at 314 n.12 (quoting <u>ABA Section</u> <u>of Antitrust Law</u>, Econometrics 210 (2004) ("Generally, when the prices for some customers are going up while the prices of other customers are not, there is reason to doubt that the different customers (class members) are experiencing a common impact.)". At the certification stage, "[t]he relevant question is not whether each element can be proved but whether such proof will require evidence individual to class members." <u>McDonough</u>, 638 F. Supp. 2d, at 479. I cannot fathom, and the plaintiffs have not put forth, a method for identifying which individual purchasers would remain brand loyal through analysis of common information. I agree with Dr. Bigelow's assertion that

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"identifying the brand loyal subset . . . [would] require an inquiry into individual circumstances and even attitudes toward generic versus branded drug purchases." Bigelow Decl. ¶ 30. Mindful that "impact is a question unique to each particular plaintiff and one that must be proved with certainty," I do not believe the plaintiffs have demonstrated that common proof is available to show that supra-competitive prices passed through to purchasers of both branded and generic bupropion SR. <u>Alabama v.</u> <u>Blue Bird Body Co., Inc.</u>, 573 F.2d 309, 327 (5d Cir. 1978); <u>see also Story Parchment Co.</u> <u>v. Paterson Parchment Paper Co.</u>, 282 U.S. 555, 562, 51 S.Ct. 248, 75 L.Ed. 544 (1931).

b. Plaintiffs fail to show that all end-payor purchasers paid supra-competitive prices despite variations in insurance plan terms

Even assuming the plaintiffs can show on a basic level that prices for both generic and branded buproprion SR increased as a result of GSK's allegedly anti-competitive conduct, they must also demonstrate that *all* the end-payor purchasers made a purchase at a supra-competitive price. If some direct purchasers absorbed any GSK price increase, there would be no pass through injury to certain indirect purchasers. If only some endpayors paid increased prices, this would suggest the plaintiffs will have to prove economic impact customer-by-customer. <u>See In re OSB</u>, 2007 U.S. Dist. LEXIS 56617, at *21.

The impact of variable insurance plans affects whether many of the consumer plaintiffs suffered an injury. The defendant asserts, and I agree, that there are presumably

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significant numbers of third party payors and consumer plaintiffs, who, as a result of their applicable co-payment and co-insurance structures, did not suffer any out-of-pocket losses.³⁶

I find GSK's criticism of the plaintiffs' inability to exclude certain uninjured insured consumers is valid. GSK claims three subsets of consumers in the proposed class would not be injured because of the nature of their respective insurance plans: (1) consumers who first purchased bupropion SR in generic form and who do not pay coinsurance; (2) generic switchers who pay the same co-payment and no co-insurance for both generic and branded drugs; and (3) brand loyalists who pay the same co-payment and no co-insurance whether or not a generic version is available. In a shallow rebuttal, Dr. Rosenthal dismisses Bigelow's identification of uninjured subclasses of end-payors as "arguments with which [she is] familiar as they are commonly presented and rejected in pharmaceutical antitrust cases such as this one." Rosenthal Reply Decl. ¶ 3. She argues his analysis only demonstrates that the amount of overcharge would vary across the purported class; but it is clear Dr. Bigelow has demonstrated that certain class members would have suffered *no* injury. <u>Id.</u>

³⁶ It is immaterial that out-of-pocket losses are not the equivalent of antitrust injury, because the third-party payors will bear the loss in some situations and the consumers in other situations. <u>K-Dur</u>, 2008 U.S. Dist. LEXIS 71771, at *49 ("Since antitrust injury is not the same as out-of-pocket-loss, on some transactions, the third-party payor will bear the out-of-pocket loss (for example where there are fixed or no co-pays), and on others the consumer will bear the loss (where the difference in the co-pay exceeds the difference between the supra-competitive and but-for price.")).

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The plaintiffs deny having ever conceded that the class as pleaded includes consumers who have suffered no injury. Pls.' Reply Mem. at 11 n.27. They have not proffered sufficient evidence, either empirical or theoretical, from which I can adduce a showing that the three subsets of insured plaintiffs identified would have incurred injury or are excluded from the class. Additionally, when questioned about her proposed yardstick methodology, Dr. Rosenthal *did* admit that "there may be some consumers or third-party payors, because of payment arrangements, [who] *did not actually sustain impact.* My analysis *won't be able to identify them.*" Rosenthal Deposition 182:4-24 (emphasis added).

The plaintiffs cite one case, <u>Warfarin Sodium</u>, to support their assertion that determination of injury in fact is unrelated to a consumer's particular insurance coverage and co-payment. See Pls.' Reply Mem. at 9 (citing In re Warfarin Sodium Antitrust Litig., 212 F.R.D. 231, 252 (D. Del. 2002)). In <u>Warfarin Sodium</u>, consumers and thirdparty payors who purchased branded warfarin sodium alleged the defendant pharmaceutical company's anticompetitive conduct and dissemination of false and misleading information caused the purchasers to overpay for the branded version of the drug. <u>Id.</u> at 236. The district court granted the indirect purchasers final approval of a nationwide class settlement agreement that resolved pending class actions in both state and federal court. <u>Id.</u>

Warfarin Sodium is distinguishable from this case, and the plaintiffs are mistaken

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in their characterization of its holding. The district court there noted that "some class members argue that fixed co-pay consumers have not suffered any damages, because they pay the same for warfarin sodium regardless of whether [it is the brand name or generic version]" and should be excluded from the settlement class. Id. at 259. The court acknowledged that this "argument has merit," but decided that "excluding the fixed copay consumers at this point in the litigation cannot be justified." Id. (emphasis added). Prominent among the court's concerns was that exclusion of "fixed co-pay consumers [] would require sending additional notice and a new more complicated claim form to the consumers who have already filed claims." Id. This procedure, the court determined, would only "further delay distribution to the rest of the class and result in additional administrative costs." Id. Concerns about timely settlement distribution taken with the near certainty that class members with recognized damages would see a complete return on their losses "persuade[d] the court that fixed co-pay consumers should be allowed to share in the distribution of the settlement fund." Id. The court's decision in Warfarin Sodium to include fixed co-payment consumers in the settlement class was a matter of convenience and in furtherance of settlement distribution.³⁷ It did not make any blanket

³⁷ The Third Circuit recently acknowledged that where certification of a *settlement class* is at question, predominance is decided in light of imminent settlement:

Unlike in *In re Hydrogen Peroxide Antitrust Litigation*, where the certification inquiry was set against the backdrop of an impending trial, here we are not as concerned with formulating some prediction as to how this element of [an antitrust act] violation will play out at trial for the proposal is that there be no trial, and instead our inquiry

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assertion about injury to fixed co-pay consumers, as the plaintiffs would now like this court to accept.³⁸

It appears the subset of brand loyalists with a fixed co-pay and no co-insurance is the most significant of the uninjured subclasses. The brand loyalists made their purchases in an effectively competitive market, given their preference for branded buproprion. The only competition that would affect brand loyalists with no co-insurance is non-price related horizontal competition from other therapeutically similar, brand-name drugs. The plaintiffs do not claim that the defendant's antitrust conduct constrained horizontal competition. Hence, this group likely has no antitrust claim.³⁹ See <u>Sullivan v. DB Invs.</u>

In re Insurance Brokerage Antitrust Litig., 579 F.3d 241, 269 (3d Cir. 2009).

³⁸ The District of New Jersey has distinguished <u>Warfarin Sodium</u> on the same grounds. <u>See</u> K-Dur, 2008 U.S. Dist. LEXIS 71771, at *51-52.

[I]t is apparent that the *Warfarin* court's decision to include the [third party payors] and the fixed co-pay consumers in the settlement class had far more to do with the convenience of, or the potential benefits derived from including them in the settlement class, or the inconvenience of extracting them from it, *not recognition of or concerns about any shared injury*.

Id. (emphasis added).

³⁹ This argument really pertains to standing to bring an antitrust claim, but it also underscores that these brand loyalists were not injured. Class members who have no antitrust injury whatsoever would have no viable antitrust claims." <u>See Sullivan</u>, 2010 U.S. App. LEXIS 14375, at *52-53 (citing <u>Angelico v. Lehigh Valley Hosp., Inc.</u>, 184 F.3d 268, 273-274 (3d Cir. 1999) (requiring plaintiffs to show they have suffered an antitrust injury as a prerequisite to obtaining standing to bring an antitrust claim)).

is solely for the purpose of ensuring that issues common to the class predominate over individual ones.

Inc., Nos. 08-2784/08-2785/08-2798/08-2799/08-2818/08-2819/08-2831/08-2881, 2010 U.S. App. LEXIS 14375, at *52 (3d Cir. Jan. 28, 2010) (noting the indirect purchasers who made acquisitions when [the defendant] "allowed market forces to dictate pricing, likely have no antitrust claim because they made their purchases in a competitive market.").

A "rigorous analysis" of Dr. Rosenthal's reports and testimony reveals it does not show that *all* class members paid supra-competitive prices for generic or branded sustained release bupropion, or that this determination can be made with common proof. Dr. Bigelow discredits the plaintiffs by providing evidence there are at least three subsets of uninjured end-payors included in their class definition. Not only do I believe these uninjured groups would be substantial in size, but the plaintiffs did not show they can address this inquiry with common proof. I am not satisfied that the plaintiffs have met their burden of demonstrating that questions common to the class predominate over individual ones.

Class certification is not precluded by the "possibility or indeed inevitability" that the class includes members uninjured by the defendant's conduct. <u>Kohen v. Pacific Inv.</u> <u>Mgmt. Co.</u>, 571 F.3d 672, 677 (7th Cir. 2009) ("[A] class will often include persons who have not been injured by the defendant's conduct; indeed this is almost inevitable because at the outset of the case many of the members of the class may be unknown, or if they are known still the facts bearing on their claims may be unknown."). However, "a class

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should not be certified if it is apparent that it contains a great many persons who have

suffered no injury at the hands of the defendant." Id. It is appropriate to consider:

When the potential liability created by a lawsuit is very great, even though the probability that the plaintiff will succeed in establishing liability is slight, the defendant will be under pressure to settle rather than to bet the company, even if the betting odds are good. For by aggregating a large number of claims, a class action can impose a huge contingent liability on a defendant....[The defendant] has good reason not to want to be hit with a multi-hundred-million-dollar claim that will embroil it in protracted and costly litigation--the class has more than a thousand members, and determining the value of their claims, were liability established, might thus require more than a thousand separate hearings.

<u>Id.</u> at 678.

I am satisfied the defendant has shown there are a great number of uninjured class members, that it would therefore take many mini-trials to determine which of the class members are uninjured. Plaintiffs have failed to show they can exclude these uninjured consumers.

c. Plaintiffs fail to show that GSK's direct-to-consumer marketing campaign had no effect on consumers

Finally, GSK claims there are hundreds of thousands of individuals who actually purchased Wellbutrin SR due to GSK's advertising but would not have purchased it in the plaintiffs' but-for world, absent the same promotion. I have already identified flaws fatal to certification, specifically that the plaintiffs cannot show that *all* of the class members

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bought bupropion SR at a supra-competitive price resulting from GSK's allegedly anticompetitive conduct. However, I will briefly address GSK's argument that sales GSK would not have made but for its alleged antitrust conduct can now act in its favor to preclude class certification.

In response to GSK's argument about the effect of the DTC advertising campaign, the plaintiffs counter that they "will present evidence that the decrease in the average price for the drug that accompanies a generic launch prevents a decrease in the number of prescriptions, notwithstanding the brand manufacturer's termination or reduction of promotional and detailing activities." Pl.'s Reply Memo. In Support of Class Cert., 6-7. This assertion speaks only to the average price and the average quantity of prescriptions and does nothing to show impact to individual end-payors. In her damages calculation, Rosenthal contends that the total molecule sales actually decreased by approximately 10% after generic entry rather than remaining the same. Rosenthal Damages Decl. ¶ 27. She attempts to justify this drop in the quantity of prescriptions with a highly speculative claim that they decreased because the launch of Wellbutrin XL preceded the generic launch. Id. Rosenthal continues that "[i]f the generics had entered before Wellbutrin XL, the trend in Wellbutrin SR total molecule sales would almost surely have been higher." Id. Rosenthal's rebuttal is speculative at best and at worst provides nothing instructive about which individual purchasers would have switched to Wellbutrin XL (and thus incurred no injury).

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At oral argument, the plaintiffs presented an appeal to justice to counter GSK's

marketing arguments:

There is then this argument GSK raises that we wouldn't promote the product in the but-for world, therefore, there are sales that occurred that wouldn't otherwise have occurred. That's their argument. Now, that doesn't hold up for a variety of reasons. But first, let's just look at how bizarre the argument is. The argument says if we weren't making all this money through our illegal conduct, we wouldn't have the money to market it. If we weren't marketing it, then we would have sold it to less people. Therefore, because we were using our marketing to undertake – we were marketing with the illegal profits means that there should be no class at all. So, it's bizarre. I mean, basically it says that any antitrust situation where you use the profits in order to market, you can defeat class certification. Makes no sense.

Tr. Oral Argument at 26:23—27:12.

The plaintiffs' counter-arguments are poorly drawn. At oral argument, plaintiffs' counsel seemed to misunderstand the record, because the DTC marketing campaign was not the product of purely economic considerations. More importantly, plaintiffs fail to establish they can show through common evidence whether individual consumers would not have purchased bupropion SR in the but-for world absent the defendant's extensive promotional efforts. Despite plaintiffs' failure to present evidence that GSK's DTC campaign did not produce consumers of Wellbutrin SR who otherwise would not have purchased the drug, I am not prepared to rule that the campaign (which was made possible by GSK's alleged antitrust violation), is sufficient in itself to bar class

certification. Because the other flaws in plaintiffs' evidence *are* sufficient to preclude class certification, I need not consider the DTC argument further.

C. The Plaintiffs Fail to Show That Antitrust Damages Are Susceptible to Common Proof

Dr. Rosenthal proposes a "yardstick" comparison as a standard methodology for calculating damages, both overcharge and unjust enrichment, suffered by members of the proposed class from the alleged foreclosure of generic entry. Rosenthal Decl. ¶ 24-48; see also Rosenthal, Damages Decl. The "yardstick approach" involves a comparison of the "actual prices and quantities in the market of interest" to the "prices and quantities that occur in a similar market that is untainted by the alleged foreclosures." Rosenthal Decl. ¶ 24. Appropriate yardsticks, Dr. Rosenthal opines, could be selected after considering "(1) the therapeutic class of the comparison drug, (2) the number of generic entrants, and (3) the nature of formularies and other aspects of benefit design that were in effect [during the class period]." Id. ¶ 31. In her actual calculation of damages, Rosenthal uses data garnered from the actual market entry of bupropion SR in 2004, concluding it "reasonably approximate[s] what would have occurred but-for the alleged market foreclosure by GSK." Rosenthal Damages Decl. ¶ 28. To validate her yardstick choice, Dr. Rosenthal conducted a comparison with yardsticks derived from "other antidepressants that were subject to generic entry near the but-for entry dates," namely

Prozac, Paxil, and Remeron. Id. ¶ 29.

The yardstick methodology employs simple econometric equations whose input values include both actual and but-for prices and quantities — the but-for values are derived from the comparison yardsticks. <u>See id.</u> The method utilizes the average prices of Wellbutrin SR, generic bupropion SR, and the yardstick drugs in computing overcharge damages. <u>See id.</u> ¶¶ 33-34. Similarly, in computing the unjust enrichment damages, the price inputs are "the average manufacturer price of brand name Wellbutrin SR" and "the average manufacturer price that would have been charged for brand name Wellbutrin SR." <u>Id.</u> ¶ 44.

The plaintiffs contend, and GSK disputes, that Dr. Rosenthal's yardsticks provide a common method capable of showing damages across the class. The court does not need to resolve this issue, having already decided certification is inappropriate given the plaintiffs' failure to demonstrate that GSK's conduct caused supra-competitive prices for both generic and branded bupropion SR and that all class members purchased bupropion SR at a supra-competitive price. That being said, I believe the plaintiffs' methodology is insufficient because the calculations were made using *average* prices. This evidence says nothing about the actual price paid by each purported class member. Average prices falter as a method for proving class-wide injury, because "averaging 'by definition glides over what may be important differences.'" <u>Reed v. Advocate Health Care</u>, No. 06-3337, 2009 WL 3146999 at *17 (N.D. Ill. Sep. 28, 2009) (quoting <u>In re Graphics Processing</u>,

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253 F.R.D. at 494).

Further, with respect to using averages, the American Bar Association has

highlighted certain inherent problems:

Sometimes the prices used by economists are averages of a number of different prices charged to different customers or for somewhat different products. Using 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.*

ABA Section of Antitrust Law, Econometrics: Legal, Practical, and Technical Issues 220 (2005) (emphasis added).

The evidence presented shows there are substantial variations in the prices paid by individual class members. Different class members purchased different forms of the drug, either branded or generic. End-payors bought the burpropion SR at different times. Insurance plans vary across the class. Certain class members are less price sensitive than others. The plaintiffs' use of average prices masks these individual variations. Just because an average price was increased or decreased by the alleged foreclosure does not mean that all members of the proposed class paid supra-competitive prices or that any damage for an individual end-payor could be calculated in a formulaic way by common proof.

Neither am I persuaded by the plaintiffs' insistence that the yardstick methodology Dr. Rosenthal proposes is commonly accepted in antitrust cases. The fundamental "issue

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is not whether [the] techniques are generally accepted; it is whether they are appropriate when applied to the facts and data *in this case*." <u>Reed</u>, 2009 WL 3146999, at *20 (emphasis in original). I am not persuaded that they are.

The plaintiffs have failed to meet their burden of establishing that common proof concerning the fact of antitrust injury will predominate.

V. CONCLUSION

Certification of the end-payor class is not warranted because plaintiffs have failed to meet their burden of showing "that the questions of law or fact common to class members predominate over any questions affecting only individual members." FED. R. CIV. P. 23(b)(3). Rather, I find that proof of antitrust impact and damages resulting from GSK's allegedly anti-competitive conduct will require evidence individual to class members. Therefore, plaintiffs' motion for class certification is denied.