

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

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<b>IN RE: SUBOXONE (BUPRENORPHINE</b>	:	
<b>HYDROCHLORIDE AND NALAXONE)</b>	:	
<b>ANTITRUST LITIGATION</b>	:	<b>MDL NO. 2445</b>
	:	<b>13-md-2445</b>
<b>THIS DOCUMENT APPLIES TO</b>	:	
<b>ALL ACTIONS</b>	:	

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**Goldberg, J.**

**September 26, 2019**

**MEMORANDUM**

The Plaintiffs in this multi-district litigation case allege anticompetitive conduct by Defendant Reckitt Benckiser, Inc. (“Reckitt”)<sup>1</sup> in connection with their Suboxone product—a drug used to combat opioid addiction. Plaintiffs’ claims focus on a relatively new theory of antitrust liability, referred to as a “product hop,” pursuant to the unique regulatory and statutory scheme that governs the marketing and distribution of pharmaceutical drugs. Under this theory, a pharmaceutical company makes modest reformulations to a brand-name drug prior to the expiration of its market exclusivity for the purpose of stymieing generic competition and preserving monopoly profits.

The Plaintiffs are the Direct Purchasers of Suboxone (“Direct Purchasers” or “DPPs”) and the End Payors of Suboxone (“End Payors” or “EPPs”), who claim that Reckitt switched from sublingual Suboxone tablets to a sublingual Suboxone film for the purpose of foreclosing generic competition. According to Plaintiffs, this switch (the “product hop”) was accompanied by Reckitt disparaging the tablet through fabricated safety concerns and ultimately removing Suboxone tablets

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<sup>1</sup> Reckitt is currently known as Indivior, Inc. In December 2014, Reckitt Benckiser Pharmaceuticals, Inc. was demerged from its prior parent, the Reckitt Benckiser Group PLC, into Indivior PLC. Although Indivior is technically the named defendant in this case, the pleadings and many of the relevant exhibits use the name “Reckitt.” To avoid confusion, I will refer to Defendant as “Reckitt.”

from the market just as generic Suboxone tablets were able to begin competing. Reckitt is also alleged to have manipulated FDA regulations to delay the entry of generic Suboxone onto the market, thereby unlawfully maintaining a monopoly in violation of Section 2 of the Sherman Act. According to all Plaintiffs, Reckitt's conduct foreclosed competition and resulted in the overpayment for Suboxone. Reckitt acknowledges the product switch, but strenuously asserts that the switch was done to market and sell an improved and superior product.

Both the DPPs and the EPPs have now sought class certification. For the following reasons, I will certify the DPP class under Federal Rule of Civil Procedure 23(b)(3), deny certification of the EPP class under Federal Rule of Civil Procedure 23(b)(2), and grant certification of the EPP class under Federal Rule of Civil Procedure 23(c)(4).

## **I. FACTUAL BACKGROUND**

To fully understand the basis of Plaintiffs' antitrust theories and their requests for class certification, a review of the regulatory background and the alleged anticompetitive conduct is necessary. The pertinent facts alleged by Plaintiffs are as follows:<sup>2</sup>

### **A. Regulatory Framework – Hatch-Waxman Act**

#### **1. Generic Drug Approval Process**

Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–92 (“FDC Act”), a manufacturer who creates a new drug must obtain the approval of the Food and Drug Administration

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<sup>2</sup> Although a court should go beyond the complaint to determine whether a class should be certified, a plaintiff has no obligation to establish the merits of the case at the certification stage. *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 311, 316 (3d Cir. 2008). For the sole purpose of understanding the premise of the present case, I will take the allegations of the operative complaints as true, but will engage in a more “rigorous assessment” of the available evidence when conducting class certification review.

The Direct Purchasers' and the End Payors' Complaints contain almost identical allegations. To avoid confusion, the facts recited herein will be derived from the Direct Purchasers' consolidated Amended Complaint. Where the allegations in the complaints differ, I will distinguish accordingly.

(“FDA”) to sell the new drug by filing a New Drug Application (“NDA”). An NDA must include submission of specific data concerning the safety and efficacy of the drug, as well as any information on applicable patents. (Direct Purchaser Plaintiffs’ (“DPP”) Sec. Am. Compl. ¶ 43.)

In an effort to speed the entry of generic drugs into the market, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984 (“Hatch-Waxman”), 12 U.S.C. § 355. Hatch-Waxman provides brand-name manufacturers with several means, in addition to traditional patent rights, to obtain protection from generic competition for set, and specifically limited, periods of time. For example, for truly new and innovative pioneer drugs, the FDA may grant a brand manufacturer a “new chemical entity” (“NCE”) exclusivity period of five years. (*Id.*) If an NDA drug treats a rare condition, the FDA may grant seven years of orphan drug exclusivity during which time no corresponding generic drug may be approved or commercialized. (*Id.* ¶¶ 44–45.)

The Hatch-Waxman Act also simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to duplicate the clinical studies used to obtain approval for the brand-name counterpart drug. Under the Act, generic manufacturers may file and gain approval for their drugs through filing an Abbreviated New Drug Application (“ANDA”), which relies on the scientific findings of safety and efficacy included by the brand-name drug manufacturer in the original NDA. The ANDA filer must scientifically establish that the generic drug it intends to market is just as safe and effective as the corresponding brand-name drug through demonstrations of bioequivalence, *i.e.*, that the generic product delivers the same amount of active ingredient into a patient’s blood stream for the same amount of time as does the corresponding brand-name drug, and hence has the same clinical effect. (*Id.* ¶¶ 46–47.)

Oral drugs proven to be both bioequivalent and pharmaceutically equivalent—meaning the generic drug has the same active ingredient as the branded oral drug—receive an “AB” rating from the FDA, indicating they are therapeutically equivalent to other drugs with the same rating in the

same category. In most cases, only oral generic drugs with an AB rating may be substituted by pharmacists for a physician's prescription of a brand-name drug without the physician's approval. Once the FDA approves an ANDA and determines that the generic drug is AB-rated to the branded drug, state laws govern how the generic may be substituted for the brand-name drug prescribed by physicians. In most states and under most health plans, a pharmacist may, and in many cases must, substitute an AB-rated generic drug for a prescribed brand-name drug. (Id. ¶¶ 48–49, 55.)

Competition from low cost AB-rated generic drugs saves consumers billions of dollars a year. When an AB-rated generic drug enters the market, the brand-name company often suffers a rapid, steep decline in sales. AB-rated generic competition enables direct and indirect purchasers to obtain both the generic drugs and the brand-name drugs at substantially lower prices. (Id. ¶¶ 56–58.)

## 2. The SSRS/REMS Process

Under the FDA Amendments Act of 2007, the FDA has the authority to require Risk Evaluation and Mitigation Strategies (“REMS”) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks. A REMS can include a medication guide, a package insert, and potential restrictions on the distribution of the drug. If a REMS is required for a particular generic product, the FDA will withhold ANDA approval until such time that an appropriate REMS has been created by the ANDA sponsor. The FDA can also require that ANDA sponsors coordinate with the manufacturer of the branded counterpart drug for the purposes of creating a Single Shared REMS program (“SSRS”), which is a single REMS program to be used by both the sellers of the brand drug and AB-rated generic equivalents. Congress has specifically prohibited brand-name drug manufacturers from using REMS “to block or delay approval of” ANDAs. (Id. ¶¶ 62–65.)

### 3. Citizen Petitions

Pharmaceutical companies have multiple avenues and opportunities through which to communicate their views to the FDA. One such avenue is by filing a “Citizen Petition,” which provides a forum for individuals or businesses to express and support genuine concerns about the safety, scientific, or legal issues regarding a product at any time before, or after, market entry. To move the FDA to take action regarding drug approval requirements, the petition must include supportive, clinically meaningful data, and the requested relief must be consistent with the Hatch-Waxman statutory and regulatory framework. The FDA must respond to each Citizen Petition within 180 days after the date on which the petition was submitted, and the response may approve the request in whole or in part, or deny the request. A response to a Citizen Petition may be appealed under the Administrative Procedures Act. (Id. ¶¶ 66–70.)

Plaintiffs claim that abusive and anticompetitive Citizen Petitions have become an increasingly common problem in the last several years and, in some cases, are filed with the intended effect of delaying the approval of generic drugs while the FDA evaluates the Citizen Petition. To deal with the potential anticompetitive abuse of the citizen petition process, Congress passed the Food and Drug Administration Amendments Act (“FDAAA”), enacted on September 27, 2007, which adds new section 505(q) to the FDC Act. This section provides that the FDA may not delay approval of an ANDA application because of a requirement to take action related to the pending Citizen Petition unless the delay is necessary to protect the public health. (Id. ¶¶ 73, 75, 77.)

#### **B. FDA Approval of Suboxone Tablets**

Defendant Reckitt developed two buprenorphine products for the treatment of opioid addiction: (a) a single-entity buprenorphine product, Subutex, intended for a brief induction stage, and (b) Suboxone, a buprenorphine-naloxone combination for post-induction maintenance treatment. At the time of their introduction, Subutex tablets and Suboxone tablets were the only

pharmaceuticals on the market that provided maintenance treatment for patients suffering from opioid addiction that could also be prescribed in an office setting for the patient's home use. All other opioid addiction maintenance treatments, such as methadone, could only be dispensed at a clinic. (Id. ¶ 82.)

Although the FDA approved Reckitt's NDA for Suboxone tablets in 2002, Reckitt had no patent protection and relied primarily on seven years of orphan drug exclusivity. Orphan drug designation is granted where (a) a product is intended to treat a disease or condition that has a U.S. prevalence of less than 200,000 persons; or (b) where the sponsor can show that there is no reasonable expectation that the costs of developing and making the drug will be recovered from U.S. sales, despite the fact that the product treats a disease or condition that has a U.S. prevalence of 200,000 or more individuals. FDC Act § 526(a)(2)(A & B). Suboxone's orphan drug exclusivity expired on October 8, 2009. (Id. ¶ 84.)

### **C. Alleged Anticompetitive Conduct**

#### **1. Product-Hopping: Development of Suboxone Film and the Alleged Destruction of the Tablet Market**

In early 2006, in an effort to avoid generic competition with its Suboxone product, Reckitt allegedly began searching for a way to replace Suboxone tablets with a product not subject to automatic generic substitution. Reckitt opted to develop a Suboxone sublingual film, which, even though bioequivalent to tablets, would not be AB-rated to tablets—and thus not automatically substitutable by pharmacists due to a difference in dosage form. Although Suboxone film cost more to make, Reckitt allegedly started exploring a strategy in the United States to coerce doctors to prescribe and pharmacists to dispense film in lieu of tablets. (Id. ¶¶ 86–87, 89.)

The NDA for Suboxone film was submitted on October 20, 2008, and was approved on August 30, 2010. The three-year exclusivity for Suboxone film extended to August, 2013. In

addition, the film is covered by patent 8,017,150 (“the ’150 patent”), which will not expire until September 2023. (Id. ¶¶ 91–92.)

Plaintiffs allege that there are few differences between Suboxone film and Suboxone tablets, and that film is not superior to tablets. Plaintiffs point out that the two products are so similar that Reckitt submitted safety and efficacy studies performed on Suboxone tablets when seeking approval of the Suboxone film NDA. The tablets and film are alleged to have equivalent bioavailability, meaning that the products release the same amount of active ingredients into a patient’s bloodstream. (Id. ¶ 93.)

Although Reckitt indicated in its NDA that the film’s individual packaging reduced the risk for accidental pediatric exposure to the drug, Plaintiffs assert that the evidence provided by Reckitt on this issue was flawed. Indeed, the FDA expressed concerns that the film may present increased risk for accidental pediatric exposure because the filmstrip dissolves more quickly than the tablet and, therefore, may be more difficult for a child to spit out in the event of exposure. The FDA also had concerns that film had a higher risk of abuse than tablets because film is easier to conceal, dissolve, and inject. Finally, the FDA informed Reckitt that it did “not agree that the packaging for [Suboxone film] provides meaningful incremental protection against pediatric exposure.” (Id. ¶¶ 94–97.)

Once the FDA approved Suboxone film NDA in 2010, Reckitt allegedly launched a fraudulent sales and marketing campaign against the tablet for the purpose of diverting sales from the tablet, which would soon face generic competition, to the patent-protected film. After Suboxone was originally launched in 2002, Reckitt spent several years building the market by (a) generating public acceptance/demand for office-based treatment; and (b) building a network of doctors that were able and willing to offer Suboxone treatment to addicts. This network of doctors had more influence over the product selection than is usually the case because only 12,800 doctors have

government certification to treat Suboxone patients, and even fewer actually treat Suboxone patients. Moreover, there are limits on how many Suboxone patients a doctor can treat at any one time. These factors make it difficult for patients to find and/or switch doctors. (Id. ¶¶ 102, 105, 109–110.)

Understanding the crucial role doctors played in the distribution of Suboxone, Reckitt allegedly began creating economic disincentives to penalize doctors who did not push their patients to film. Reckitt also developed a program providing economic incentives to doctors who did push their patients to use film. Even though tablets were purportedly cheaper to produce, Reckitt priced tablets higher than film. (Id. ¶¶ 111–115, 120.)

According to Plaintiffs, Reckitt then implemented a massive fraudulent sales and marketing campaign to advance the conversion of all Suboxone prescriptions from tablets to film. This “product-hopping marketing campaign” included several tactics, including: (a) a wide-ranging fraudulent marketing campaign in which Reckitt’s sales representatives promoted only the film formulation and discouraged physicians from writing prescriptions for the original tablet formulation under the pretext of alleged safety concerns with the tablet; (b) publicly announcing that Reckitt was pulling Suboxone tablets from the market due to the false safety issues; and (c) publicly seeking an FDA determination that Suboxone tablets were voluntarily pulled from the market by Reckitt due to “safety” issues (even though Reckitt had not actually pulled the tablets from the market). On September 25, 2012, Reckitt publicly announced that it would discontinue selling branded Suboxone tablets in the U.S. based on purported safety reasons. Yet, Reckitt continued selling the tablets until early March 2013, while it implemented the conversion to film. (Id. ¶¶ 130–132.)



2. Abuse of the SSRS/REMS Process

Aside from the product switch and concurrent attempted destruction of the tablet market, Reckitt purportedly engaged in a series of actions to delay generic competition, one of which was abuse of the SSRS/REMS process. (Id. ¶ 134.)

In 2009 and 2011, Actavis, Inc. (“Actavis”) and Amneal Pharmaceuticals, LLC (“Amneal”) (collectively, the “Generics”), respectively, filed ANDAs for generic Suboxone tablets. On December 22, 2011, the FDA approved a REMS performed by Reckitt on the issue of the risk of pediatric exposure to Suboxone tablets. Through the REMS, the FDA required that Reckitt address pediatric exposures via FDA-approved labeling. On January 6, 2012, the FDA sent all sponsors of pending ANDAs for Suboxone tablets a notification letter stating that all branded and generic Suboxone products would be subject to a Single Shared REMS program (“SSRS”). ANDA filers were directed to contact Reckitt to collaborate on the creation of an SSRS program. The FDA set a compliance date of May 6, 2012 for the SSRS. The FDA gave a short turn-around time, assuming that the recently approved REMS performed by Reckitt would simply be amended to add the bioequivalent generic products. (Id. ¶¶ 135–138, 140.)

Plaintiffs allege that Reckitt used the SSRS as a means to undermine and delay generic entry by feigning cooperation in the SSRS development process. During the next six months, ANDA applicants for generic Suboxone Tablets sought to negotiate the SSRS process in good faith, but Reckitt allegedly delayed by making unreasonable demands on the generic companies as a precondition of Reckitt’s cooperation in the SSRS, despite the fact that such delay tactics are expressly prohibited by 21 U.S.C. § 355-1(f)(8). Reckitt reportedly turned down numerous invitations to participate in meetings with the Generics, and refused to engage in substantive discussions until the Generics agreed to a number of conditions, including “an upfront agreement that all manufacturers would share the costs of product liability for future potential lawsuits.”

Plaintiffs further allege that Reckitt refused to share non-public information from its REMS program until its demands were met. (Id. ¶¶ 142–145.)

The Generics complained to the FDA about Reckitt’s alleged delay tactics, and a meeting was held on June 18, 2012. The FDA acknowledged during this meeting that it could not compel Reckitt to share its non-public REMS program, and suggested that the Generics develop a new SSRS without using Reckitt’s information. Although the FDA implored Reckitt and the Generics to work together in good faith and not attempt to block or delay, Plaintiffs claim that Reckitt’s obstructionist actions continued, and that Reckitt refused to cooperate unless the Generics agreed to provide Reckitt veto authority or a super-majority vote on all issues relating to the SSRS. Two days before the SSRS was submitted, Reckitt allegedly argued, for the first time, that an important element of the REMS had been omitted, and it refused to sign the SSRS. In mid-September 2012, the FDA provided comments regarding the proposed new SSRS, and Reckitt maintained that it desired to continue collaborating. Ultimately, on October 3, 2012, given Reckitt’s intransigence, the Generics sought a waiver for approval of their Generics-only SSRS on October 3, 2012. (Id. ¶¶ 145–150.)

### 3. Sham Citizen Petition

Reckitt learned that the FDA planned to grant final approval to several generic tablets in the fall of 2012. By that time, Reckitt had not converted all of its Suboxone unit sales from tablet to film. (Id. ¶ 151.)

On September 25, 2012, Reckitt formally announced its intent to permanently withdraw Suboxone tablets from the U.S. market for purported reasons of safety. That same day, Reckitt filed a Citizen Petition with the FDA to block approval of all pending Suboxone ANDAs on alleged safety grounds. The Citizen Petition requested that the FDA take three actions: (a) refrain from approving any buprenorphine NDA or ANDA for the treatment of opioid addiction that did not include a targeted pediatric exposure education program; (b) refrain from approving applications for

buprenorphine for opioid addiction that lacked unit-dosage packaging; and (c) refrain from approving any buprenorphine/naloxone ANDA for addiction treatment until the FDA determined whether the reference listed drug, Suboxone tablets, had been discontinued for safety reasons. (Id. ¶¶ 152–154.)

As to the first requested action, Plaintiffs allege that it was baseless since Reckitt was well aware (a) that its “targeted pediatric exposure education program” was not part of the FDA-approved REMS or labeling for Suboxone tablets, and (b) that the FDA-approved REMS and labeling for Suboxone tablets already contained the substantive material that had to be mimicked by ANDA filers in order for them to gain final FDA approval. Thus, the FDA had no statutory or regulatory ability to require ANDA filers to mimic non-approved labeling and REMS materials in order to obtain approval. As to the third request, Plaintiffs allege that it was baseless because Reckitt had not actually discontinued its sale of Suboxone tablets, and the FDA had no authority to engage in advisory opinions about the reasons why a drug had been discontinued when, in fact, it had not actually been discontinued. Finally, as to the second request, Plaintiffs allege that it was baseless because Reckitt had successfully sold Suboxone tablets in bulk containers for over ten years, the tablets were sold in child-resistant bottles, the tablets had FDA-approved labeling and REMS, the FDA did not believe that unit-dose packaging was superior to child-resistant bottles, and Reckitt did not present clinically significant, well-controlled studies demonstrating that Suboxone tablets in bulk containers were unsafe. (Id. ¶¶ 157, 162–163.)

In short, according to Plaintiffs, Reckitt failed to provide well-controlled, statistically-significant scientific support for its call for the FDA to refuse to approve ANDAs for generic Suboxone tablets, which made the Citizen Petition a sham. Indeed, Reckitt was aware of pediatric exposure issues regarding Suboxone as early as 2002, having sold Suboxone tablets in blister packaging in Canada and Europe for years, yet purportedly used the packaging issue to delay the

launch of generic competitors by raising the safety issues at the last possible moment. (Id. ¶¶ 171, 173–74.)

Ultimately, on February 22, 2003, the FDA denied the Citizen Petition, noting the lack of evidentiary support and acknowledging the inconsistency between Reckitt’s Citizen Petition and its prior behavior. It referred Reckitt’s conduct to the Federal Trade Commission (“FTC”) for antitrust investigation. In the interim, however, Reckitt made millions in additional Suboxone sales. (Id. ¶¶ 155, 182.)

4. The Tablet Withdrawal

Immediately after the denial of Reckitt’s Citizen Petition, the FDA granted final approval to the ANDAs of two generic manufacturers, Amneal and Actavis, for generic versions of Suboxone tablets. Three weeks later, on March 18, 2013, Reckitt withdrew its Suboxone tablets from the market. As a result, a patient would receive the generic Suboxone tablets only if a doctor specifically prescribed the generic tablets, which doctors were less likely to do because of Reckitt’s disparagement of generic tablets. (Id. ¶¶ 184–185.)

**D. Effects on Competition and Damages**

Plaintiffs allege that Reckitt’s actions had the effect of substantially destroying demand for Suboxone tablets before generic tablets entered the market. Absent Reckitt’s actions, the generic Suboxone tablets would theoretically have entered the market and competed with branded Suboxone tablets, resulting in migration from the more expensive brand to the less-expensive generic. Both the Direct Purchaser Class and the End Payor Class allege that this conduct has caused their members to pay inflated prices for co-formulated buprenorphine/naloxone products. (Id. ¶¶ 186–187, 189.)

### **E. Causes of Action**

In their Second Amended Complaint, the Direct Purchasers bring claims under § 2 of the Sherman Act for: (1) unlawful maintenance of monopoly power through an overarching scheme to prevent or delay generic competition (“Count I”); (2) unlawful maintenance of monopoly power by conversion of the market from tablet to film formulation (“Count II”); (3) unlawful maintenance of monopoly power by intentionally delaying the SSRS process and violating 21 U.S.C. § 355-1(f)(8) (“Count III”); (4) unlawful maintenance of monopoly power by filing a sham Citizen Petition (“Count IV”); and (5) unlawful maintenance of monopoly power by fraudulently delaying the filing of the Citizen Petition until the eve of generic ANDA approval (“Count V”).

The End Payors assert the following causes of action in their Second Amended Complaint: (1) monopolization and monopolistic scheme under state law (“Count I”); (2) attempted monopolization under state law (“Count II”); (3) unfair and deceptive trade practices under state law (“Count III”); (4) injunctive and declaratory relief under section 16 of the Clayton Act for Reckitt’s violations of section 2 of the Sherman Act (Count IV), and (5) unjust enrichment under state law (“Count V”).<sup>3</sup>

## **II. MOTION TO EXCLUDE RUSSELL LAMB’S EXPERT REPORT**

The Direct Purchaser Plaintiffs’ (“DPPs”) Motion for Class Certification relies, in large part, on the expert report of Dr. Russell Lamb. Dr. Lamb opines that the DPPs can prove—using evidence common to the class—that the direct purchasers of Suboxone Tablets suffered antitrust injury on a class-wide basis. Dr. Lamb has also calculated damages the class incurred as a result of Reckitt’s hard switch scheme. Reckitt argues that Dr. Lamb’s opinions and report are fundamentally unsound

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<sup>3</sup> Aside from the Direct Purchasers and the End Payors, a group of States Attorneys General have pressed similar claims against Reckitt. As they do not require class analysis, I do not include them in the discussion here.

and should be excluded from consideration. The DPPs respond that Reckitt's Motion is nothing more than an attack on the merits of Plaintiffs' claims rather than a legitimate Daubert challenge to Dr. Lamb's methodology.

The United States Supreme Court has strongly suggested that a full examination pursuant to the decision in Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993), is necessary prior to class certification. See WalMart Stores, Inc. v. Dukes, 564 U.S. 338, 354 (2011) ("The District Court concluded that Daubert did not apply to expert testimony at the certification stage of class-action proceedings. We doubt that is so . . ." (internal citation omitted)). Interpreting Dukes, the United States Court of Appeals for the Third Circuit has held that "a plaintiff cannot rely on challenged expert testimony, when critical to class certification, to demonstrate conformity with Rule 23 unless the plaintiff also demonstrates, and the trial court finds, that the expert testimony satisfies the standard set out in Daubert." In re Blood Reagents Antitrust Litig., 783 F.3d 183, 187 (3d Cir. 2015).

Because my ruling on Reckitt's Daubert motion affects the outcome of my class certification decision, I will address that issue at the outset.

**A. Standard of Review**

Federal Rule of Evidence 702 provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) The expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) The testimony is based on sufficient facts or data;
- (c) The testimony is the product of reliable principles and methods;  
and
- (d) The expert has reliably applied the principles and methods to the facts of the case

Fed. R. Evid. 702. Rule 702 places district courts in the role of “gatekeeper,” requiring courts to “ensure that any and all [expert] testimony . . . is not only relevant, but reliable.” Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 147 (1999) (quoting Daubert, 509 U.S. at 589). The party offering an expert must demonstrate, by a preponderance of the evidence, that the expert’s qualifications and opinions comply with Federal Rule of Evidence 702. See Daubert, 509 U.S. at 592–93 (citation omitted). Rule 702 has “a liberal policy of admissibility,” Pineda v. Ford Motor Co., 520 F.3d 237, 243 (3d Cir. 2008) (citation omitted), and “embodies a trilogy of restrictions on expert testimony: qualification, reliability, and fit.” Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003) (citations omitted).

Reckitt does not challenge either Dr. Lamb’s qualification or the “fit” of his testimony, but rather focuses solely on the reliability of his methodology.

The reliability restriction requires that the testimony be based upon “the ‘methods and procedures of science’ rather than on ‘subjective belief or unsupported speculation’” and that the expert have “‘good grounds’ for his or her belief.” Calhoun v. Yamaha Motor Corp., U.S.A., 350 F.3d 316, 321 (3d Cir. 2003) (quotations omitted). In that respect, reliability mandates an examination into the expert’s conclusions in order to determine “whether [the conclusions] could reliably flow from the facts known to the expert and [the] methodology used.” In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prod. Liab. Litig., 706 F.3d 217, 225 n.7 (3d Cir. 2013) (quoting Oddi v. Ford Motor Co., 234 F.3d 136, 146 (3d Cir. 2000) (internal quotation marks omitted)).

The Third Circuit has identified the following non-exhaustive factors to be taken into consideration when evaluating the reliability of a particular methodology: (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the

technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put. Elcock v. Kmart Corp., 233 F.3d 734, 745–46 (3d Cir. 2000).

Importantly, the rule does not require the party proffering the expert to demonstrate the “correctness” of the expert’s opinion. In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 744 (3d Cir. 1994) (concluding that the “evidentiary requirement of reliability” amounts to a lower burden “than the merits standard of correctness”). Rather, the party need only demonstrate “by a preponderance of the evidence” that the expert’s opinion bears adequate indicia of reliability. Id. Indeed, “[a] judge will often think that an expert has good grounds to hold the opinion . . . even though the judge thinks the opinion otherwise incorrect.” Id. Therefore, “[t]he focus . . . must be solely on principles and methodology, not on the conclusions that they generate.” Daubert, 509 U.S. at 595. “When the methodology is sound, and the evidence relied upon sufficiently related to the case at hand, disputes about the degree of relevance or accuracy (above this minimum threshold) may go to the testimony’s weight, but not its admissibility.” i4i Ltd. P’ship v. Microsoft Corp., 598 F.3d 831, 852 (Fed. Cir. 2010), aff’d, 564 U.S. 91 (2011).

## **B. Discussion**

The challenged portion of Dr. Lamb’s report analyzes whether the DPPs can prove that the direct purchasers of Suboxone Tablets suffered an antitrust injury on a class-wide basis using evidence common to the class. Dr. Lamb considers the DPPs’ claim that Reckitt’s scheme involved three major anticompetitive components: inflation of the brand tablet prices paid by all class members, delay of generic entry, and inflation of the film’s share of the Suboxone market that prevented generic tablets from being dispensed. These practices, according to the DPPs, helped Reckitt shift the market from tablet to film. Assuming these facts, Dr. Lamb concludes that all class



members suffered three types of aggregate classwide damages corresponding to the above effects: (1) overcharges relating to Reckitt's increase of brand tablet prices before generic tablets launched; (2) overcharges relating to Reckitt's delay of the entry of generic tablets into the market; and (3) overcharges relating to the hard switch of the market from tablets to film, meaning that when lower-priced generic tablets came on the market, prescriptions were already being written for film.

Reckitt presses five challenges to the reliability of Dr. Lamb's report: (1) Dr. Lamb's methodology improperly attributes damages to lawful, pro-competitive pricing practices; (2) Dr. Lamb's but-for price calculations reflect "chargeback" sales revenue that has no place in a calculation of alleged overcharges; (3) Dr. Lamb's report fails to show a link between the alleged "hard switch scheme" and the "but-for" market share of generic products; (4) Dr. Lamb's calculation of but-for market share using analogs is arbitrary; and (5) Dr. Lamb's methodology does not account for generic bypass. I address each argument separately.

1. Whether Dr. Lamb's Improperly Attributes Damages to Lawful Pro-Competitive Pricing Practices

Reckitt first argues that Dr. Lamb's methodology for determining class-wide injury and damages is flawed because it relies upon the assumption that Plaintiffs can claim antitrust injury from Reckitt's practice of selling Suboxone film at a lower price than Suboxone tablets. Reckitt reasons that unilateral above-cost pricing is lawful, unless there are allegations of predatory pricing. According to Reckitt, there is no legal basis to conclude that Suboxone film pricing was excessively low, as even Dr. Lamb concedes that Reckitt was not selling film below its cost. Reckitt also posits that there is no legal basis to conclude that it was required to price tablets at parity with film. Thus, Reckitt urges that Dr. Lamb's faulty assumption of antitrust injury due to pricing practices invalidates all elements of his damages and injury analysis.

In support of this argument, Reckitt relies heavily on the Supreme Court decision in Comcast Corp. v. Behrend, 569 U.S. 27 (2013). There, the plaintiffs sought to certify an antitrust class of Comcast subscribers, under Rule 23(b)(3), and proposed four theories of antitrust impact. Id. at 30. On class certification review, the district court certified only one of the theories for class treatment. Id. at 36. In calculating damages, however, the plaintiffs’ expert assumed the validity of all four theories of antitrust impact initially advanced by the plaintiffs and sought to establish a “but for” baseline to show what competitive prices would have been if there had been no antitrust violations. The expert admitted that his model calculated damages resulting from “the alleged anticompetitive conduct as a whole” and did not attribute damages to any one particular theory of competitive impact. Id. at 36–37. The Third Circuit found no problem in this methodology, stating that “[a]t the class certification stage we do not require that Plaintiffs tie each theory of antitrust impact to an exact calculation of damages, but instead that they assure us that if they can prove antitrust impact, the resulting damages are capable of measurement and will not require labyrinthine individual calculations.” Id. at 37.

The Supreme Court rejected the Third Circuit’s reasoning, holding that “such assurance is not provided by a methodology that identifies damages that are not the result of the wrong.” Id. at 37. It found that “at the class-certification stage . . . any model supporting a plaintiff’s damages case must be consistent with its liability case, particularly with respect to the alleged anticompetitive effect of the violation.” Id. at 35 (quotations omitted). The Court went on to note that the expert’s methodology might have been sound and produced commonality of damages if all four of the alleged antitrust theories remained in the case. Id. at 37. But because only one of the theories was certified as appropriate for class treatment, the plaintiffs’ model could not reliably demonstrate impact to the class from the sole remaining theory. Id. Rather, in order for the plaintiffs’ model to provide any probative evidence of antitrust impact or damages from the single theory found appropriate for class

treatment, the model needed to have been able to isolate that single theory's effect from the effects of the three theories not suitable for class treatment. Id. at 38.

Here, similar to Comcast, the DPPs have multiple theories of antitrust impact. The DPPs contend that the entirety of Reckitt's "hard switch" scheme resulted in the antitrust injury at issue. That conduct included not only the increase in the price of tablets and decrease in the price of film, but also the introduction of Suboxone film onto the market, the removal of Suboxone tablets from the market several months prior to generic approval, the dissemination of false safety concerns with Suboxone tablets, and the disparagement of Suboxone tablets. Dr. Lamb relies on the combination of those theories to set forth his model of antitrust damages. Reckitt presses that because one of these theories—the pricing of Suboxone film and/or Suboxone tablets—is not actionable under antitrust law, Dr. Lamb's report, which is premised on the cumulative anticompetitive conduct, cannot reliably show antitrust damages.

Reckitt's argument disregards the distinction between this case and Comcast. Here, notwithstanding Reckitt's challenge to the DPPs' pricing allegations, none of the DPPs' theories has been invalidated or deemed unsuitable for class determination. Indeed, considering the validity of these allegations at the motion to dismiss stage, I previously found that Plaintiffs' allegations, considered collectively, stated a plausible claim of exclusionary conduct as required for an antitrust violation. And I reached this conclusion even though the pricing practices allegations alone could not give rise to such a claim. In re Suboxone, 64 F. Supp. 3d 665, 683–84 n.9 (E.D. Pa. 2014); see also ZF Meritor, LLC v. Eaton Corp., 696 F.3d 254, 277 (3d Cir. 2012) (holding that, even absent allegations of predatory pricing, an antitrust plaintiff may rely on the exclusionary effect of prices together with other forms of anticompetitive conduct in order to state a plausible antitrust claim), cert denied, 569 U.S. 958 (2013).

Reckitt’s challenge to Dr. Lamb’s reliance on Reckitt’s pricing practices for Suboxone film would require a broad inquiry into the merits of the DPPs’ antitrust allegation—an inquiry in which I need not engage at this stage of the litigation. The recent decision of In re Processed Egg Products Antitrust Litigation, 312 F.R.D. 171 (E.D. Pa. 2015) is instructive on this point. There, the plaintiffs sought class certification of several classes, relying in part on expert testimony that assumed the viability of plaintiffs’ theory of liability. Id. at 190–91. Citing Comcast, the defendants sought to exclude the expert’s opinions because of alleged legal defects in plaintiffs’ theory on which the expert’s damages model was premised. Id. at 191. The district court rejected this argument, noting that the “posture of [the] case is different from Comcast, because none of the alleged [antitrust theories] have been found inappropriate for class treatment.” Id. at 192. The court went on to explain:

Defendants would have it that Plaintiffs must, at this stage, disaggregate each alleged anticompetitive action and isolate its effect. Such a requirement, Defendants argue, is the only way to ensure that the Court does not face the same difficulties that arose in Comcast—that is, “[i]f one or more modes of challenged conduct are found to be lawful, [the expert’s] damage model . . . becomes entirely useless, as did the damage model in Comcast.” . . . But Comcast does not stand for the broad proposition Defendants ascribe to it. Although the Court must engage with the merits of the case when they weigh upon the Court’s analysis of Rule 23, the Court must not engage in “free-ranging merits inquiries at the certification stage.” . . . Here, Defendants’ proposed disaggregation requirement is based on hypotheticals that the Court has no basis to consider at this moment, as there was no argument at the class certification stage from Defendants that any disaggregated part of the alleged conspiracy should be found lawful or otherwise incapable of common proof. Defendants nevertheless assert that because “*now* is the time to demonstrate compliance with Rule 23,” the Court should refuse certification because of the possibility that some conduct that [the expert] included in his damages measurement will be found to relate to “damages” ultimately held to be unrecoverable. But Defendants are asking the Court to do more than ensure compliance with Rule 23—Defendants ask the Court to ensure that compliance with Rule 23 will withstand any possible development moving forward. That is not what Comcast required, as implied by the Supreme Court’s note

that the plaintiffs' methodology in Comcast "might have been sound . . . if all four of those alleged distortions remained in the case." Id. . . . That is, likewise, not what Rule 23 requires as Rule 23(c)(1)(C) provides that "[a]n order that grants or denies class certification may be altered or amended before final judgment"—such a provision would have little utility if the Court had to ensure that a class certification ruling could withstand any potential future developments in a case. The Court would, under Defendants' reading of Rule 23, need to determine not just that common issues are likely to predominate over individual ones, but that Plaintiffs have indeed proven the merits of every aspect of their case, such that no development in the case could threaten the initial decision on certification of the class. Class certification is not such a free-ranging inquiry.

In re Processed Egg Prods., 312 F.R.D. at 192–93.

This case falls into a similar posture. While the parties debate whether Reckitt's increase in the price of Suboxone tablets and concurrent sale of Suboxone film at a lower price constitutes unlawful antitrust activity, this dispute is not at issue in either this Daubert motion or the Motion for Class Certification. "Daubert does not require a plaintiff to prove causation of damages 'twice—they do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are *correct*, they only have to demonstrate by a preponderance of evidence that their opinions are reliable' and fit the facts of the case." In re Linerboard Antitrust Litig., 497 F. Supp. 2d 666, 675 (E.D. Pa. 2007) (emphasis in original) (quoting In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 744 (3d Cir. 1994)). Indeed, "the standard for admitting expert testimony on antitrust damages is lower than a plaintiff's burden of proof in establishing antitrust damages."<sup>4</sup> Id. at 676.

Here—where the DPPs' theory is not that any one act itself was unlawful, but that all the acts taken together constituted an antitrust violation—an expert need not segregate and attribute a

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<sup>4</sup> The Third Circuit has admitted expert testimony on antitrust damages, while concurrently finding that the assumptions underlying the expert's damages calculations were unfounded and insufficient to support a finding of actual damage. See Stelwagon Mfg. Co. v. Tarmac Roofing Sys., Inc., 63 F.3d 1267, 1275 (3d Cir. 1995).

fixed amount of damages to any one act. Rather, “[i]n constructing a hypothetical world free of defendants’ exclusionary activities, the plaintiffs are given some latitude in calculating damages, so long as their theory is not wholly speculative.” Bonjorno v. Kaiser Aluminum & Chem. Corp., 752 F.2d 802, 812 (3d Cir. 1984). Once a jury finds that some unlawful activity by the defendant caused the antitrust injury, the damages may be determined without strict proof of which act caused the injury, so long as the damages calculation is free from speculation or guesswork. Id. at 813.

In LePage’s Inc. v. 3M, 324 F.3d 141 (3d Cir. 2003), the Third Circuit addressed a similar attack on an expert damage report. The defendant, challenging a jury’s verdict for the plaintiff under § 2 of the Sherman Act, contended that “a plaintiff cannot succeed in a § 2 monopolization case unless it shows that the conceded monopolist sold its product below cost.” Id. at 144. As part of the defendant’s argument, it claimed that the plaintiff’s damages expert opinion was based on improper assumptions and should have been excluded, and that the expert’s theory failed to disaggregate the damages based on lawful versus unlawful conduct by defendant. Id. at 164–65. Finding no error in the admissibility of the expert, the Third Circuit remarked that “[t]he relevant inquiry is the anticompetitive effect of [defendant’s] exclusionary practices considered together,” and not the legality of its individual actions.” Id. at 162. Because the jury found that defendant’s actions as a whole violated § 2 of the Sherman Act, the expert’s disaggregation of damages—*i.e.*, separating damages arising from defendant’s lawful conduct or other facts from damages arising from defendant’s unlawful conduct—was “unnecessary, if not impossible.” Id. at 166. In turn, the Court found no error in the trial court’s admission of the expert testimony.<sup>5</sup> Id.

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<sup>5</sup> Numerous courts have, since Comcast, declined to exclude an antitrust damages expert under Daubert, even where the expert’s damages calculation relies on assumptions that could eventually be proven legally or factually inaccurate. See, e.g., In re Domestic Drywall Antitrust Litig., 322 F.R.D. 188, 234 (E.D. Pa. 2017) (holding that plaintiffs need not disaggregate each alleged anticompetitive action and isolate its effect; rather the defendants were free to argue at trial that damages were not attributable to a particular form of alleged anticompetitive action); Dial Corp. v.

In short, unlike in Comcast, where three of the four theories on which the expert relied were deemed inappropriate for class treatment, the DPPs’ pricing allegations here remain a viable part of their overall antitrust theory.<sup>6</sup> The relevant inquiry here requires that I “look to the monopolist’s conduct taken as a whole rather than considering each aspect in isolation.” Philadelphia Taxi Assoc., Inc. v. Ubert Techs., Inc., 886 F.3d 332, 339 (3d Cir. 2018) (quoting LePage’s, 324 F.3d at 162); see also In re Niaspan Antitrust Litig., No. 13-mdl-2460, 2019 WL 3816829, at \*15 (Aug. 14, 2019) (admitting expert damages model premised on the entire anticompetitive scheme and declining to require expert to parse each type of conduct). Under such a theory, “it would be extremely difficult, if not impossible, to segregate and attribute a fixed amount of damages to any one act as the theory was not that any one act in itself was unlawful, but that all the acts taken together showed a [Sherman Act] violation.” LePage’s, 324 F.3d at 166. Dr. Lamb’s measurement of “class-wide damages” relies on the totality of this alleged exclusionary conduct. (Lamb Report ¶¶ 125–167.) Accordingly, I will deny Reckitt’s Daubert Motion to Exclude Dr. Lamb’s Opinions on this ground.

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News Corp., 165 F. Supp. 3d 25, 38 (S.D.N.Y. 2016) (“And if a jury were to find News Corp.’s actions taken as a whole to be a violation of Section Two of the Sherman Act, disaggregating the monopolist’s lawful actions from its unlawful actions for the purpose of calculating damages may be ‘unnecessary, if not impossible.’”); Univac Dental Co. v. Dentsply Int’l, Inc., No. 07-493, 2010 WL 1816745, at \*3 (M.D. Pa. Apr. 27, 2010) (“[I]t is perfectly acceptable for an expert to calculate an estimated amount of damages without regard to causation or any other elements of liability. Indeed, in the antitrust context, plaintiffs enjoy a considerable amount of leeway in ‘constructing a hypothetical world free of the defendant[’s] exclusionary activities[.]’”).

<sup>6</sup> In his rebuttal report, Dr. Lamb clarified that in the event Reckitt’s pricing practices are deemed to be an improper part of the alleged anticompetitive scheme, he can recalculate aggregate class damages using actual generic prices paid by the class instead of the lower generic prices that would have been paid in the absence of Reckitt’s scheme. (Lamb Rebuttal Report ¶¶ 165–66.)

2. Whether Dr. Lamb's But-For Price Calculations Improperly Reflect "Chargeback" Sales Revenue

Reckitt next challenges Dr. Lamb's use of "chargebacks" in his attempts to calculate the real-world price of generic tablets.

Chargebacks are "payments wholesalers [direct purchasers] receive from manufacturers when they sell at a discounted price to downstream customers [end payors] – as a price discount to the direct purchaser class." (Report of Reckitt's Expert Parker Normann ("Normann Expert Report") ¶ 133.) Chargebacks arise when a manufacturer has an arrangement with a downstream purchaser to sell a drug at a specific price, often below the price paid by the wholesaler. The wholesaler/direct purchaser sells the drug to the downstream purchaser at the lower price and then "charges back" to the manufacturer the difference between the price it paid and the price at which it sold the drug in order to be made whole on the transaction. (Lamb Dep. 276:13–277:3.)

According to Reckitt, chargebacks are a type of sales revenue and not part of the purchase transaction—*i.e.*, it is only through a potential subsequent sale to a downstream purchaser that chargebacks are properly understood as part of the sales transaction—and thus they should only be considered in a lost profits analysis, not an overcharge analysis. It asserts that Dr. Lamb's damages calculation purports to be an "overcharge" analysis, but is, in actuality, a "lost profits" analysis due to his consideration of "chargebacks" in determining the but-for generic tablet price. More specifically, in calculating what direct purchasers paid for generic tablets, Dr. Lamb subtracts out the amount the direct purchasers received in chargebacks from the manufacturers, thus creating the appearance that direct purchasers paid less for generic tablets than they actually did. Reckitt posits that such chargebacks cannot be part of the overcharge analysis because their inclusion "substantially understate[s] generic pricing, resulting in grossly inflated 'overcharge' calculations." (Reckitt's Reply Br. 8.) Reckitt's expert, Dr. Normann, opines that a chargeback is "not a discount



on the purchase price paid, but a reimbursement from the generic manufacturer to the wholesaler for a separate service,” making it “irrelevant as a matter of definition, to an ‘overcharge’ damages methodology that seeks to compare the *prices paid* to the prices that would have been paid in the but-for world.” (Normann Report ¶¶ 137–138 (emphasis in original).)

Dr. Lamb responds that Dr. Normann is mistaken as “chargebacks constitute reductions in the prices paid by direct purchasers of branded Suboxone tablets and film and generic Suboxone tablets.” (Lamb Rebuttal Report ¶ 170.) He acknowledges that his damages analysis focuses on whether proposed class members were overcharged as a class and does not calculate lost profits. (Dep. Of Charles Lamb (“Lamb Dep.”) 155:22–156:24.) He explains, however, that an “overcharge” analysis in an antitrust context looks at the price paid in the actual world compared with the price that would have been paid in a but-for world free of the alleged misconduct. (*Id.* at 157:19–158:3, 159:22–160:3.) Dr. Lamb then notes numerous sources which define the net price of a generic as including chargebacks received from wholesalers. (Lamb Rebuttal Report ¶¶ 170–174.)

The conflicting opinions on the soundness of including chargebacks in an overcharge analysis bear not on the reliability of Dr. Lamb’s analysis, but rather on the correctness of his opinion. When conducting a Daubert analysis, a court may not “evaluate the credibility of opposing experts or the persuasiveness of their conclusions. Walker v. Gordon, 46 F. App’x 691, 695 (3d Cir. 2002); see also In re Chocolate Confectionary Antitrust Litig., 289 F.R.D. 200, 210 (M.D. Pa. 2012) (“Obviously, Defendants vigorously dispute Dr. Tollison’s conclusions, but the court finds that these disputes go to the weight, and not the admissibility, of Dr. Tollison’s expert testimony.”). Rather, it is enough to find that the methodology used by the expert is reliable. Walker, 46 F. App’x at 695.

Reckitt has not cited any case law establishing that Dr. Lamb’s methodology is inherently unscientific or unreliable. “When calculating damages, [t]he usual measure in an over-charge case is the difference between the illegal price that was actually charged and the price that would have been charged ‘but for’ the violation . . . .” In re Chocolate Confectionary, 289 F.R.D. at 222 (quoting Comcast, 655 F.3d at 203 (further quotations omitted)). “Because of the practical difficulties in calculating damages based on an illusory ‘but-for’ world, courts do not require damages to be reduced to a mathematical certainty. Rather courts require that damages be established ‘as a matter of just and reasonable inference.’” Id. (quoting Comcast, 655 F.3d at 203–04). In other words, at the class certification stage, district courts need not search for “hard factual proof, but [instead] for a more thorough explanation of *how* the pivotal evidence behind plaintiff’s theory can be established.” In re New Motor Vehicles Canadian Export Antitrust Litig., 522 F.3d 6, 29 (1st Cir. 2008) (emphasis in original).

As Dr. Lamb’s report provides a plausible method for calculating damages, and as credibility disputes between experts cannot be resolved at this stage, I decline, under Daubert, to exclude Dr. Lamb’s opinions on the chargeback issue.

3. Whether Dr. Lamb’s Failure to Show a Link Between the Alleged “Hard Switch Scheme” and the “But-for” Market Share of Generic Products Requires Exclusion of His Report

Reckitt next contends that Dr. Lamb’s methodology contains a fundamental disconnect. On one hand, the alleged anticompetitive conduct all occurred prior to generic entry in March 2003, and was designed to switch potential prescriptions of branded Suboxone tablets to film. On the other hand, Dr. Lamb’s largest category of damages calculates injury flowing from the decisions of physicians—made after the end of the allegedly anticompetitive course of conduct—to prescribe film instead of generic tablets. According to Reckitt, Dr. Lamb leaves unanswered the question of what, after generic entry, prevented doctors from prescribing generic tablets as opposed to branded

film. Moreover, Reckitt alleges that Dr. Lamb gives no reason to conclude that pre-2013 “Hard Switch Conduct” (prior to generic entry) continues to affect market prices and shares today. As such, Reckitt asserts that Dr. Lamb’s calculation—which assumes that the anti-competitive conduct is responsible for the current high price and low market share of generics—is unsupported.

Reckitt’s argument is effectively a challenge to causation. “A consumer alleging antitrust violations cannot obtain damages without showing that he actually paid more than he would have paid in the absence of the violation.” City of Pittsburgh v. West Penn Power Co., 147 F.3d 256, 265 (3d Cir. 1998) (citing Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law, at 200 (1995)). Thus, “one pursuing antitrust recovery must establish that the damages suffered were caused by the defendant’s participation in a scheme repugnant to the antitrust laws.” In re Lower Lake Erie Iron Ore Antitrust Litig., 998 F.2d 1144, 1176 (3d Cir. 1993) (citing Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477 (1977)). “Once causation is determined, . . . the actual amount of damages may result from a reasonable estimate, as long as the jury verdict is not the product of speculation or guess work.” Id. at 1176 (internal quotation marks and quotations omitted).

A challenge to causation is premature in a Daubert motion. “The standard for admitting expert testimony on antitrust damages is lower than a plaintiff’s burden of proof in establishing antitrust damages.” Linerboard, 497 F. Supp. 2d at 675. As noted above, “Daubert does not require a plaintiff to prove causation of damages ‘twice—they do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are *correct*, they only have to demonstrate by a preponderance of the evidence that their opinions are reliable’ and fit the facts of the case.” Id. at 675 (quoting Paoli, 35 F.3d at 744). As such, the failure of a plaintiff to adequately prove the causation theory on which the damages expert relies does not mean that the expert opinion is inadmissible under Daubert.

This distinction was addressed in Stelwagon Manufacturing v. Tarmac Roofing Systems, Inc., 63 F.3d 1267 (3d Cir. 1995). There, the Third Circuit faced a similar causation challenge and agreed that plaintiff's damages expert "failed to sufficiently link" any decline in the plaintiff's sales to the alleged anticompetitive conduct. Id. at 1275. The Court found that while the expert's opinions did not support a finding of actual damages, the district court properly rejected a challenge to the expert's admissibility. Id.; see also Callahan v. A.E.V., Inc., 182 F.3d 237, 256 (3d Cir. 1999) (summarizing Stelwagon's holding).

Reviewing the admissibility of Dr. Lamb's report under these standards, I find that his reliance on Plaintiffs' causation theory does not render his report unreliable. Dr. Lamb explains that the entire "hard switch" campaign was a generic defense strategy launched by Reckitt in order to "prolong the life of the Suboxone franchise in the face of this expected generic competition." (Lamb Report ¶ 71.) Dr. Lamb opines that Reckitt's own November 2007 "Strategy Overview," regarding how to "fill the gap" in Suboxone net revenue expected to be caused by generic entry, described the strategy of launching a Suboxone film product in order to "[p]revent loss of brand share to generic." (Lamb report ¶ 71 n.205.) He reasons that, as part of Reckitt's hard switch scheme, Reckitt "planned to prepare the market generally, and MCOs in particular, for the eventual withdrawal of Suboxone tablets prior to its launch of Suboxone film," noting that Reckitt identified one of the "[c]ritical success factors" as an "[e]ffective tablet withdrawal communication strategy to pharmacists, patients, and physicians." (Lamb Report ¶ 37.) Relying on this theory, Dr. Lamb then attributes damages to Reckitt's alleged movement of the market from tablet to film, the effect of which continued after generic entry.

Reckitt remains free to offer its countervailing view that "generics' lagging share can be entirely explained by the fact that film was preferred by patients and doctors . . . and it was less expensive than the generic tablet entrants." (Reckitt Reply Br. 6.) This argument, however,

“implicates the weight a jury may give [Dr. Lamb’s report], not its admissibility.” In re Blood Reagents Antitrust Litig., No. 09-2081, 2015 WL 6123211, at \*12 (E.D. Pa. Oct. 19, 2015). Accordingly, I will deny the Daubert motion on this ground.

4. Whether Dr. Lamb’s Calculation of But-For Market Share is Arbitrary

Reckitt’s next argument again attacks the viability of Dr. Lamb’s “Branch-Generic (Film)” damages calculation, which requires the calculation of actual and but for prices of the products at issue. Reckitt notes that Dr. Lamb measured the market share of Suboxone film but-for the allegedly anticompetitive conduct by averaging the market share gained by four “analog” comparator products. An analog or “yardstick” approach is where a model is constructed based upon analogous markets that are not subject to the anticompetitive conduct. See Castro v. Sanofi Pasteur, Inc., 134 F. Supp. 3d 820, 838 (D.N.J. 2015). According to Reckitt, however, Dr. Lamb made no effort to determine whether the analogs were similar to each other or to Suboxone film in any metric that would successfully predict market share. In other words, Reckitt claims that Dr. Lamb failed to determine what factors tend to make a product line extension more or less successful, or to locate analogs that share significant characteristics with Suboxone film. Ultimately, Reckitt posits that Dr. Lamb’s assertion that film would have achieved less than half its actual share but for alleged anticompetitive conduct ignores evidence that film was simply a cheaper and preferred product.

In response, Plaintiff explains that Dr. Lamb used analogs to estimate both the share of the Class’s purchases that would have been film and the share of the Class’s purchases that would have been tablets but for Reckitt’s hard switch scheme. In calculating these shares, Dr. Lamb identified drugs that could be used as analogs for Suboxone film. (Lamb Rebuttal Report ¶ 116.) To identify these analogs, Dr. Lamb used a set of objective selection criteria.<sup>7</sup> For each of the identified drugs,

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<sup>7</sup> These criteria included: (1) drugs for which there is a brand originator and a line extension marketed by the same manufacturer where the brand originator and the line extension are both

he calculated the percentage of the total share that the line extension captured thirty months and twenty-four months after the launch of the line extension, and then took the average across each of the drugs for the thirty-month time period and the twenty-four-month time period. (Lamb Rebuttal Report ¶ 119.) He then applied those percentages to the Suboxone line extension. (Id.)

Such an analysis is a well-accepted scientific method and implicates no reliability concerns. “The before-and-after ‘yardstick’ methodology has been accepted by courts as a means to measuring damages in both indirect and direct purchaser actions.” In re Flonase Antitrust Litig., 284 F.R.D. 207, 232 (E.D. Pa. 2012); see also Nichols v. SmithKline Beecham Corp., No. 00-6222, 2003 WL 302352, at \*4 (E.D. Pa. Jan. 29, 2003) (upholding expert’s use of benchmark at class certification stage as a “generally accepted methodology for determining impact”); In re Rubber Chems. Antitrust Litig., 232 F.R.D. 346, 354 (N.D. Cal. 2005) (noting that “yardstick” approach is a “reasonable and commonly-used approach”). The approach “is especially useful in cases where the pre-conspiracy prices are unreliable predictors of future prices—that is, in cases where the before-and-after approach is unavailing. IIA Phillip E. Areeda et al., Antitrust Law ¶ 395b3 (3d ed. 2007). Nonetheless, “[i]t is also necessary that the yardstick market be as comparable as possible in all respects.” Id.

“The selection of comparators will seldom approach the ‘Utopian ideal’ of identifying the perfect clone.” Celebrity Cruises Inc. v. Essef Corp., 434 F. Supp. 2d 169, 189 (S.D.N.Y. 2006). “Arguments about what factors an expert should have controlled for in conducting a yardstick

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orally-administered, solid, and small molecule prescription medications; (2) drugs for which the brand originator and the line extension share the same active ingredients; (3) drugs for which the line extension was launched between 2007 and 2012; (4) drugs for which the line extension was on the market without AB-rated generic competition for at least thirty months after its launch; and (5) drugs for which the line extension is not an orally-disintegrating tablet or chewable (to eliminate remaining instances where the line extension is for a different target population than the brand originator). (Lamb Rebuttal Report ¶ 117.)

analysis generally go to the weight, rather than the admissibility, of the expert's testimony." Tawfilis v. Allergan, Inc., No. 15-307, 2017 WL 3084275, at \*6 (C.D. Cal. June 26, 2017); see also In re Prograf, No. 2014 11-2242, WL 7641156, at \*3 (D. Mass. Dec. 23, 2014) (same).<sup>8</sup>

In short, Reckitt's challenge to Dr. Lamb's selection of analogs has no place in a Daubert analysis. To the extent Reckitt believes that Dr. Lamb's methodology fails to adequately account for a range of factors that affect market shares, those issues are properly raised on cross-examination.

#### 5. Whether Dr. Lamb Failed to Account for Generic Bypass

Reckitt's final attack on Dr. Lamb's expert report argues that he failed to account for generic bypass. Reckitt explains that while wholesalers' customers, such as pharmacies and other retailers, tend to purchase the *brand* products exclusively from the wholesalers, many downstream customers prefer to buy their *generic* products directly from generic manufacturers, bypassing the wholesalers, *i.e.*, generic bypass. Reckitt contends that this "generic bypass" phenomenon held true for buprenorphine products where the wholesaler members of the putative DPP class bought 100% of all branded Suboxone tablets, but they purchased less than half of all generic tablets. Reckitt contends that because Dr. Lamb did not make any adjustments to account for generic bypass, he

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<sup>8</sup> Reckitt's contrary cases are distinguishable. For example, in Loeffel Steel Products, Inc. v. Delta Brands, Inc., 387 F. Supp. 2d 794 (N.D. Ill. 2005), an expert in a breach of contract and breach of warranty case sought to offer an opinion on lost profits based on a model using comparable businesses in the area. Id. at 811-12. The expert admitted that he knew nothing about the respective geographic or product markets or customer bases of the eight comparator companies or the quality of service or any other relevant factor that would bear upon the question of comparability, other than spending some time on the internet. Id. at 814-15. Finding that expert's report was "junk science," the court excluded the opinion. Id. at 817.

Eleven Line, Inc. v. North Texas State Soccer Ass'n, Inc., 213 F.3d 198 (5th Cir. 2000) involved antitrust issues, but did not address the admissibility of expert testimony. Rather, the Fifth Circuit admitted and considered the expert's testimony, but found that the plaintiffs had not satisfactorily proven damages because the expert's projections were not based on a satisfactory yardstick of performance by closely comparable businesses. Id. at 207-08. Ultimately, after allowing the expert to testify, the Court concluded that "[d]amage assumptions that find no support in the actual facts of the case cannot support a verdict." Id. at 209. The case does not stand for the proposition that such expert testimony should be excluded under Daubert.

improperly inflated the volume of purchases to the direct purchaser class and therefore inflated damages.

“Generic bypass refers to the phenomenon in which retail pharmacies buy their brand drugs from wholesalers, . . . but purchase some or all of their generic drugs directly from generic manufacturers, thereby ‘bypassing’ the wholesaler. In such a situation, the wholesalers lose sales volume, and thus do not need to stock the generic drug at the same inventory level as the brand.” In re Neurontin Antitrust Litig., No. 02-1390, 2011 WL 286118, at \*8 (D.N.J. Jan. 25, 2011); see also In re Wellbutrin XL Antitrust Litig., No. 08-2431, 2011 WL 3563385, at \*15 (E.D. Pa. Aug. 11, 2011) (“Generic bypass refers to the situation whereby direct purchasers may lose sales volume because end purchasers often buy generics directly from the generic manufacturer and ‘cut out the middle man’ or ‘bypass’ the wholesaler.”) “At its most extreme, generic bypass may result in a wholesaler not making any purchases of the generic.” In re Neurontin, 2011 WL 286118, at \*8.

Repeatedly, courts have held that a generic bypass deduction need not be done at the class certification stage. Because the plaintiff’s burden at this stage is to demonstrate a reliable methodology to estimate class wide damages, deductions for generic bypass can be accomplished at later stages of the case. See, e.g., In re Loestrin 24 Fe Antitrust Litig., No. 13-2472, 2019 WL 3214257, at \*6 (D.R.I. July 2, 2019) (declining, in a product hop antitrust case, to exclude expert for failing to account for generic bypass in damages analysis); In re Lidoderm Antitrust Litig., No. 14-2521, 2017 WL 679367, at \*12 (N.D. Cal. Feb. 21, 2017) (finding that the expert’s failure to account for generic bypass did not impact the class certification analysis where the model could be adjusted to account for bypass); King Drug Co. of Florence, Inc. v. Cephalon, Inc., 309 F.R.D. 195, 209 (E.D. Pa. 2015) (“Insofar as Defendants argue that Plaintiffs’ damages calculations would vary based upon generic bypass, ‘[s]uch hypothetical conflicts regarding proof of damages are not sufficient to defeat class certification at this stage of the litigation.’”), vacated on other grounds, In



re Modafinial Antitrust Litig., 837 F.3d 238 (3d Cir. 2016); In re Wellbutrin, 2011 WL 3563385, at \*16 (finding that plaintiffs had adequately shown a reliable method to prove damages on a class-wide basis even though expert had not accounted for generic bypass); In re K-Dur Antitrust Litig., No. 01-1652, 2008 WL 2699390, at \*15 (D.N.J. Apr. 15, 2008) (“Defendants’ arguments regarding the effects of generic bypass relate to the quantum of damages, rather than the fact of injury.”).

Here, Dr. Lamb’s lack of accounting for generic bypass has no impact on either the admissibility of his report under Daubert or on whether damages can be proven with evidence common to the class. Moreover, in his rebuttal report, Dr. Lamb states that he “could apply the same damages methodology” as contained in his initial report and “simply adjust (reduce) purchase volumes to account for bypass. That is, [he] could simply reduce the Class’s share of the but-for volumes by the amount of the bypass (to account for volume that is purchased directly by entities that buy generic Suboxone tablets directly from manufacturers but are not Class members because they did not buy branded Suboxone tablets directly from Reckitt).” (Lamb Rebuttal Report ¶ 176.) As Dr. Lamb’s report offers a judicially-recognized method for calculating damages and has shown that the data needed to account for generic bypass is available and can be accommodated by the methodology, I decline to exclude his report on this basis.

6. Conclusion as to *Daubert* Motion to Exclude Dr. Lamb’s Opinions

In light of the foregoing, I will deny Reckitt’s Motion to Exclude Dr. Lamb in its entirety. The alleged deficiencies in Dr. Lamb’s report go not to its admissibility, but rather to its weight. Although Reckitt is free to raise such alleged problems during summary judgment briefing or at trial, they do not require exclusion of the report under Daubert.

### **III. MOTIONS FOR CLASS CERTIFICATION**

#### **A. Standard of Review**

To obtain certification, a class must satisfy the requirements of Federal Rule of Civil Procedure 23(a) and 23(b). Rule 23(a) sets forth four prerequisites to class certification:

- (1) the class is so numerous that joinder 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).

Following consideration of these four prerequisites—often referred to as numerosity, commonality, typicality, and adequacy of representation—the court must examine whether the class falls within one of the three categories of class actions set forth in Federal Rule of Civil Procedure 23(b). In re Cmty. Bank of N. Va., 418 F.3d 277, 302 (3d Cir. 2005).

The DPPs move for class certification under Rule 23(b)(3), which provides for certification when:

[T]he 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. P. 23(b)(3).

The EPPs, by contrast, seek certification under Federal Rule of Civil Procedure 23(b)(2), which provides for certification when:

[T]he party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole[.]

Fed. R. Civ. P. 23(b)(2).

The EPPs also seek limited certification of an “issues class” under Federal Rule of Civil Procedure 23(c)(4). Rule 23(c)(4) provides that, “[w]hen appropriate, an action may be brought or maintained as a class action with respect to particular issues.” Fed. R. Civ. P. 23(c)(4). Certification of particular issues under Rule 23(c)(4) is only proper if the other requirements of Rule 23(a) and (b) are first met. Romero v. Allstate Ins. Co., 52 F. Supp. 3d 715, 724 (E.D. Pa. 2014).

The proponent of certification bears the burden of proving both the prerequisites of a class action under Rule 23(a), and that the class fits within one of the Rule 23(b) categories. Marcus v. BMW of N. Am., LLC, 687 F.3d 583, 591 (3d Cir. 2012). Although the plaintiff need not establish the merits of his case at this stage, the Third Circuit has held that “[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.” In re Hydrogen Peroxide Antitrust Litig., 552 F.3d 305, 316 (3d Cir. 2008). “It may be necessary for the court to probe behind the pleadings before coming to rest on the certification question.” Id. at 319 (quotations omitted). In other words, “[i]n deciding whether to certify a class under [Rule] 23, the

district court must make whatever factual and legal inquiries are necessary and must consider all relevant evidence and arguments presented by the parties,” including expert testimony. Id.

Ultimately, a court’s class certification analysis must be “rigorous.” Wal-Mart Stores, Inc. v. Dukes, 564 U.S. 338, 350–51 (2011). “[T]he decision to certify a class calls for findings by the court, not merely a ‘threshold showing’ by a party, that each requirement of Rule 23 is met,” and that “[f]actual determinations supporting Rule 23 findings must be made by a preponderance of the evidence.” Hydrogen Peroxide, 552 F.3d at 307. Thus, “to certify a class the district court must find that the evidence more likely than not establishes each fact necessary to meet the requirements of Rule 23.” Id. at 320. “A party’s assurance to the court that it intends or plans to meet the requirements is insufficient.” Id. at 318.

#### **B. Direct Purchaser Plaintiffs’ Motion for Class Certification**

The DPPs move for certification of the following class:

All persons or entities in the United States and its territories who purchased branded Suboxone tablets directly from Reckitt at any time during the period January 1, 2012 through March 14, 2013 (the “Class”). Excluded from the Class are Reckitt, its officers, directors, management, employees, subsidiaries, and affiliates, and all federal governmental entities.

(DPPs’ Mem. Supp. Class. Cert. 2.)

Reckitt responds that class certification is not appropriate on multiple grounds. For purposes of ensuring the “rigorous” review required by the Supreme Court, I will address all of the Rule 23 requirements.

##### 1. Rule 23(a) Requirements

###### *a. Numerosity*

A plaintiff seeking certification must first demonstrate that the class is so numerous that joinder of all members is impracticable. Fed. R. Civ. P. 23(a)(1). “In recent years, the numerosity

requirement has been given ‘real teeth.’” Mielo v. Steak ‘n Shake Operations, Inc., 897 F.3d 467, 484 (3d Cir. 2018). Third Circuit precedent demands that a court “make a factual determination, based on the preponderance of the evidence, that Rule 23’s requirements have been met.” Id. (quoting Marcus v. BMW of N. Am., LLC, 687 F.3d 583, 596 (3d Cir. 2012)).

The first part of the numerosity inquiry is the size of the class. “No magic number exists satisfying the numerosity requirement, nor must plaintiff allege the exact number or identity of class members.” Moskowitz v. Lopp, 128 F.R.D. 624, 628 (E.D. Pa. 1989); see also Chakejian v. Equifax Info. Servs., LLC, 256 F.R.D. 492, 497 (E.D. Pa. 2009). As a general rule, “if the named plaintiff demonstrates that the potential number of plaintiffs exceeds 40, the first prong of Rule 23(a) has been met.” Stewart v. Abraham, 275 F.3d 220, 226–27 (3d Cir. 2001). On the other hand, a class of fifteen to twenty is likely too small to meet the numerosity requirement. In re Modafinil Antitrust Litig., 837 F.3d 238, 250 (3d Cir. 2016). Classes with between twenty-one and forty members are given varying treatment, depending on the circumstances of each case. Id.

The second half of the numerosity inquiry looks at the impracticability of joinder. Whether joinder of all of the class members would be impracticable depends on the circumstances surrounding the case and not merely on the number of class members. In re Modafinil, 837 F.3d at 249. The Third Circuit has enumerated a non-exhaustive list of factors to consider, including: judicial economy, the claimants’ ability and motivation to litigate as joined plaintiffs, the financial resources of class members, the geographic dispersion of class members, the ability to identify future claimants, and whether the claims are for injunctive relief or for damages. Id. at 253. Of those factors, both judicial economy and the ability to litigate as joined parties are of primary importance. Id.

In cases involving alleged antitrust violations, courts have certified classes of direct payor plaintiffs involving anywhere from thirty to fifty geographically-dispersed members. See, e.g., In

re Mushrooms Direct Purchaser Antitrust Litig., 319 F.R.D. 158, 173 (E.D. Pa. 2016); In re Processed Egg Prods., 312 F.R.D. at 178; In re K-Dur Antitrust Litig., No. 01-1652, 2008 WL 2699390, at \*3 (D.N.J. Apr. 14, 2008).

Here, the proposed class is larger than forty, as it includes seventy-one members identified by Reckitt's sales data as direct purchasers. (Lamb Expert Report, Ex. C, ¶ 30.) Moreover, as reflected by the evidence of record, these direct purchasers are dispersed throughout the United States, making joinder impracticable. Reckitt does not dispute that the numerosity prong has been met. Finding no evidence in the record to undermine the DPPs' showing, I conclude that the first Rule 23(a) element has been satisfied.

*b. Commonality*

Rule 23(a)(2) next requires Plaintiffs to demonstrate that “there are questions of law or fact common to the class.” Fed. R. Civ. P. 23(a)(2). “[C]ommonality does not require perfect identity of questions of law or fact among all class members. Rather, ‘even a single common question will do.’” Reyes v. Netdeposit, LLC, 802 F.3d 469, 486 (3d Cir. 2015) (quoting Dukes, 564 U.S. at 359). “The focus of the commonality inquiry is not on the strength of each plaintiff’s claim, but instead is on whether the defendant[s]’ conduct was common as to all of the class members.” Rodriguez v. Nat’l City Bank, 726 F.3d 372, 382 (3d Cir. 2013) (internal quotation and citations omitted). All plaintiffs need not suffer the same injury; rather, the fact that the plaintiffs were subjected to the injury or faced the immediate threat of these injuries suffices for Rule 23. Baby Neal for and by Kanter v. Casey, 43 F.3d 48, 57 (3d Cir. 1994); see also Rodriguez, 726 F.3d at 383 (“[T]here may be many legal and factual differences among the members of a class, as long as all were subjected to the same harmful conduct by the defendant.”). “Even where individual facts and circumstances do become important to the resolution, class treatment is not precluded.” Baby Neal, 43 F.3d at 57. Ultimately, the commonality bar is not a high one. Rodriguez, 726 F.3d at 382.

The Rule 23(a)(2) “language is easy to misread, since “[a]ny competently crafted class complaint literally raises common questions.” Dukes, 564 U.S at 349 (quotations omitted). Thus, to satisfy Rule 23(a)(2), the resolution of the common question of law or fact must “resolve an issue that is central to the validity of each one of the claims in one stroke.” Id. at 350.

The DPPs set forth several “core issues” that they allege are common to the class:

- a. Whether Reckitt’s alleged scheme violates the antitrust rule of reason;
- b. Whether, as a result of the scheme, Reckitt suppressed generic competition to Suboxone;
- c. Whether Reckitt’s scheme was for the purpose of suppressing and delaying generic competition to Suboxone;
- d. Whether the scheme suppressed generic competition to Suboxone by improperly reducing the volume of Suboxone Tablets prescriptions that were subject to automatic substitution by generic Suboxone Tablets;
- e. Whether the scheme suppressed generic competition to Suboxone by delaying Actavis’s and Amneal’s generic launches, thereby preventing prices for buprenorphine hydrochloride/naloxone hydrochloride (“BPN/NLX”) from dropping;
- f. Whether Reckitt’s scheme was for a procompetitive purpose, and, if so, whether the scheme was reasonably necessary to achieve that procompetitive purposes;
- g. Whether (and when), absent Reckitt’s scheme, Actavis and Amneal would have launched their generic versions of Suboxone earlier than they actually did;
- h. Whether, on balance, Reckitt’s scheme harmed competition in the BPN/NLX market;
- i. Whether Reckitt maintained or attempted to maintain its market and/or monopoly power in the BPN/NLX market;
- j. Whether Reckitt had market or monopoly power in the BPN/NLX market;

- k. To the extent a relevant market must be defined, what that definition is;
- l. Whether Reckitt’s activities substantially affected interstate commerce;
- m. Whether, and to what extent, the challenged conduct caused antitrust injury to the business or property of DPPs and the Class in the nature of overcharges; and
- n. The quantum of overcharges paid by the Class in the aggregate.

(DPPs’ Mem. Supp. Class Cert. 1–2.)

On a fundamental level, these issues appear to set forth at least one basic, common question on behalf of all of the proposed class members—whether Reckitt committed an antitrust violation that resulted in delayed generic entry and, in turn, higher prices of branded Suboxone tablets. “Generally, antitrust plaintiffs are found to have satisfied [the commonality] requirement . . . as an allegation of conspiracy or monopolization will generally be treated as a ‘central’ or ‘single overriding’ issue . . . sufficient to establish a common question.” Brown v. Cameron-Brown Co., 92 F.R.D. 32, 38 (E.D. Va. 1984); see also In re Loestrin 24 Fe Antitrust Litig., No. 13-2472, 2019 WL 3214257, at \*11 (D.R.I. July 2, 2019) (finding that “[e]ach putative class member alleges that Defendants caused overcharges by engaging in an anticompetitive scheme to delay and suppress generic competition).

Reckitt does not directly address this commonality element, but rather focuses on the predominance requirement of Rule 23(b)(3). (See Reckitt’s Opp’n DPPs’ Class Cert. 11 (arguing that “there is no ‘glue’ allowing for a common answer to the question of whether they purchased Film as a result of coercion or deception”; “[h]aving failed to show commonality, DPP’s have likewise failed to establish common issues predominate, as required by Rule 23(b)(3)’’).)

Rule 23(a) commonality and Rule 23(b)(3) predominance are often discussed in tandem. “Parallel with Rule 23(a)(2)’s commonality element, which provides that a proposed class must



share a common question of law or fact, Rule 23(b)(3)'s predominance requirement imposes a more rigorous obligation upon a reviewing court to ensure that issues common to the class predominate over those affecting only individual class members." Sullivan v. DB Invs., Inc., 667 F.3d 273, 297 (3d Cir. 2011). Thus, the Third Circuit has noted that the Rule 23(a) commonality requirement is "incorporated into the more stringent Rule 23(b)(3) predominance requirement" and has deemed it "appropriate to analyze the two factors together, with particular focus on the predominance requirement." Id. (internal quotation marks omitted); see also In re Ins. Brokerage Antitrust Litig., 579 F.3d 241, 266 (3d Cir. 2009).

Given this standard, I will discuss both commonality and predominance together under the Rule 23(b)(3) standards, as set forth later in this Memorandum.

*c. Typicality*

The third Rule 23(a) factor considers typicality. "Typicality" aids a court in determining whether "maintenance of a class action is economical and whether the named plaintiff's claim and the class claims are so interrelated that the interests of the class members will be fairly and adequately protected in their absence." Marcus, 687 F.3d at 597–98 (citing Gen. Tel. Co. of the Sw. v. Falcon, 457 U.S. 147, 158 n.13 (1982)). Typicality "screen[s] out class actions in which the legal or factual position of the representatives is markedly different from that of other members of the class even though common issues of law or fact are present." Id. at 598. To determine whether a named plaintiff is markedly different from the class as a whole, the court must address three distinct concerns: "(1) the claims of the class representative must be generally the same as those of the class in terms of both (a) the legal theory advanced and (b) the factual circumstances underlying that theory; (2) the class representative must not be subject to a defense that is both inapplicable to many members of the class and likely to become a major focus of the litigation; and (3) the interests and incentives of the representative must be sufficiently aligned with those of the class." Id. at 598

(quoting In re Schering Plough Corp. ERISA Litig., 589 F.3d 585, 599 (3d Cir. 2009)). The Third Circuit has set a “low threshold” for typicality, such that “[e]ven relatively pronounced factual differences will generally not preclude a finding of typicality where there is a strong similarity of legal theories or where the claim arises from the same practice or course of conduct.” In re Nat’l Football League Players Concussion Injury Litig., 821 F.3d 410, 428 (3d Cir. 2016) (internal quotation marks omitted).

Reckitt does not dispute typicality. Indeed, the claims of the named Plaintiffs and the absent class members rely on the same legal theories and arise from the same “core pattern” of alleged conduct by the Defendants, *i.e.*, that Reckitt’s “hard switch” scheme combined with the “sham” citizen petition and Reckitt’s actions during the SSRS process delayed generic entry and resulted in direct purchasers allegedly paying higher prices for Subxone tablets. See In re Linerboard Antitrust Litig., 203 F.R.D. 197, 207 (3d Cir. 2001) (holding that, “in instances it is alleged that the defendants engaged in a common scheme relative to all members of the class,” typicality is generally satisfied). Accordingly, I find that the DPPs have met their burden as to typicality.

*d. Adequacy of Class Representative*

The last Rule 23(a) factor considers adequacy of representation. “The principal purpose of the adequacy requirement is to determine whether the named plaintiffs have the ability and the incentive to vigorously represent the claims of the class.” In re Cmty. Bank of N. Va. Mortg. Lending Practices Litig., 795 F.3d 380, 393 (3d Cir. 2015). The adequacy requirement has two components: (1) the interests and incentives of the representative plaintiffs; and (2) the experience and performance of class counsel. Dewey v. Volkswagen Aktiengesellschaft, 681 F.3d 170, 181 (3d Cir. 2012) (citation omitted).

Reckitt challenges the DPPs’ ability to satisfy the first prong, which focuses primarily on whether the class representatives have conflicts of interest with the putative class members.

Williams v. Sweet Home Healthcare, LLC, 325 F.R.D. 113, 122 (E.D. Pa. 2018) (citing New Directions Treatment Servs. v. City of Reading, 490 F.3d 293, 313 (3d Cir. 2007)). Only a “fundamental” conflict of interest will be sufficient to impact the adequacy analysis. Id. (citing Dewey, 681 F.3d at 183). “A fundamental conflict exists where some [class] members claim to have been harmed by the same conduct that benefitted other members of the class.” Dewey, 681 F.3d at 183 (internal quotation marks omitted).

Reckitt argues that named Plaintiff Burlington Drug Corporation (“Burlington”) is an inadequate representative because it “has abdicated its obligation to ‘control the litigation’ and ‘make decisions regarding settlement.’” (Reckitt’s Mem. Supp. Opp’n DPPs’ Class Cert. 23.) Specifically, Reckitt posits that, based on the testimony given at the Rule 30(b)(6) deposition of Burlington’s representative, Burlington has no control over the lawyers representing the DPPs, and that class counsel are making all pertinent decisions relating to the litigation, including which substantive allegations to include in the complaint, which parties to sue, the course of mediation, which settlement offers to make, and whether to accept any settlement offers proffered. (Reckitt’s Opp’n DPPs’ Class Cert, Rule 30(b)(6), Ex. 25, Dep. of John Mitiguy (“Mitiguy Dep.”), 150:23–154:12.) Although Reckitt does “not dispute class counsel’s diligence or skill,” it asserts that Burlington cannot serve as a class representative due to its total surrender of independence to the judgment of its lawyers. (Reckitt’s Mem. Supp. Opp’n DPPs’ Class Cert. 24.)

Reckitt’s argument sets too high a bar. “A class representative must have some minimal knowledge about the case and be able to make the requisite decisions required of a plaintiff.” Allen v. Holiday Universal, 249 F.R.D. 166, 184 (E.D. Pa. 2008). Nonetheless, a class representative’s lack of knowledge about his case does not make him an inadequate representative. Rather, the adequacy inquiry focuses primarily on whether the class representatives have conflicts of interest with the putative class members; it does not require that the representatives possess more than “a

minimal degree of knowledge.” New Directions Treatment Servs., 490 F.3d at 313. “Indeed, [a named plaintiff] may even ‘[display] a complete ignorance of the facts concerning the transaction that he was challenging.’” Shamberg v. Ahlstrom, 111 F.R.D. 689, 695 (D.N.J. 1986) (quoting In re Data Access Sys. Secs. Litig., 103 F.R.D. 130, 140 (D.N.J. 1984)); see also Gwiazdowski v. Cty. of Chester, 263 F.R.D. 178, 188 (E.D. Pa. 2009) (holding that the fact that the plaintiff was not familiar with the allegations in the complaint or the relevant documents turned over by the defendant did not impact his adequacy as a class representative).

Here, although experienced class counsel are controlling the litigation decisions, Burlington’s Rule 30(b)(6) deponent, John Mitiguy, explicitly testified that Burlington had the requisite minimal degree of knowledge necessary to meet the adequacy standard:

Q. What role does Burlington Drugs play in this litigation?

A. We are class representative—representative, and as a result I’m being deposed as class representative. We have a fiduciary responsibility to the class to work for the best interests of the class as opposed to our own individual interests, and that’s a role that we’re happy to fulfill. Even dragged me out of retirement for it.

Q. What efforts specifically have you or others at Burlington Drug done to fulfill your obligations as class representative?

A. Well, a number of things. Number one, my willingness to be deposed and testify on behalf of the class; my and our former compliance officer’s and regulatory officer’s willingness to maintain contact with attorneys and keep up-to-date on what’s going on in the case and—and be familiar with the basics—those would probably be the two main areas—and be as cooperative as we can in this process.

(Mitiguy Dep. 150:16–151:5.)

Although Mr. Mitiguy admitted that Burlington did not specifically direct litigation or mediation decisions, he testified that Burlington was kept apprised about the ongoing mediation sessions. (Id. at 152:10–153:18.) Moreover, Mr. Mitiguy was able to articulate the basis for the claimed injury to the class. (Id. at 144:2–10.) Finally, it is undisputed that Burlington’s interests

are aligned with the members of the class. Accordingly, I find that the adequacy prong of Rule 23 has been satisfied.<sup>9</sup>

## 2. Rule 23(b)(3) Predominance

Having found that the Rule 23(a) requirements are met, I must next consider whether the DPPs have met one of the Rule 23(b) categories. Here, the DPPs have moved for certification under subsection (b)(3), which requires that common questions of law or fact “predominate” over questions affecting only individual class members, and that a “class action is superior to other available methods for fairly and efficiently adjudicating the controversy.” Fed. R. Civ. P. 23(b)(3). The plaintiff must satisfy both the predominance and the superiority elements of Rule 23(b)(3). Reckitt’s opposition to class certification focuses solely on the predominance element of Rule 23(b)(3).

The predominance requirement is similar to commonality and “tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation.” Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 623 (1997). While commonality and predominance present similar considerations, the predominance standard is “far more demanding.” In re Hydrogen Peroxide Antitrust Litig., 552 F.3d 305, 311 (3d Cir. 2008), as amended (Jan. 16, 2009) (quotations omitted).

The plaintiff need not be required to prove his claims for purposes of the predominance inquiry. He must only show that he can establish the elements of his claim at trial by common, and not individualized, proof. Sullivan v. DB Invs., Inc., 667 F.3d 273, 305 (3d Cir. 2011). “Rule 23(b)(3)

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<sup>9</sup> The cases cited by Reckitt are inapposite. See In re Gen. Motors Corp. Pick-Up Fuel Tank Prods. Liabl. Litig., 55 F.3d 768, 784–85 (3d Cir. 1995) (generally discussing certification of a *settlement* class and noting that “the protection of the absentees’ due process rights depends in part on the extent the named plaintiffs are adequately interested to monitor the attorneys”); Clair v. DeLuca, 232 F.R.D. 523 (W.D. Pa. 2006) (finding that although lead plaintiff’s interests did not clearly align with the class, inasmuch as he could not recover his losses in the suit, court determined that based on his statements regarding his experience, education, and motivation to pursue the matter diligently on behalf of the class, he satisfied the adequacy prong of Rule 23).

requires a showing that *questions* common to the class predominate, not that those *questions* will be answered, on the merits, in favor of the class.” Amgen, Inc. v. Connecticut Retirement Plans and Trust Funds, 568 U.S. 455, 459 (2013) (emphasis in original). The merits underlying the cause of action need be considered only to the extent that they are “enmeshed” with the certification inquiry. Comcast Corp. v. Behrend, 569 U.S. 27, 34 (2013) (citations omitted). “Put another way, what matters for purposes of the predominance determination is whether there are common questions, not common answers.” In re Mushroom Direct Purchaser Antitrust Litig., 319 F.R.D. 158, 187–88 (E.D. Pa. 2016). As such, to decide whether class-action treatment is appropriate, the court must “give careful scrutiny to the relation between common and individual questions in” the litigation. Tyson Foods, Inc. v. Bouaphakeo, 136 S. Ct. 1036, 1045 (2016). Common questions are those “where the same evidence will suffice for each member to make a prima facie showing or the issue is susceptible to generalized, class-wide proof.” Id. (quotation and alterations omitted). Individual questions are those “where members of a proposed class will need to present evidence that varies from member to member . . . .” Id. (quotation omitted).

To assess predominance, a court at the certification stage must examine each element of the asserted legal claim “through the prism” of Rule 23(b)(3). Marcus, 687 F.3d at 600 (quoting In re DVI, Inc. Sec. Litig., 639 F.3d 623, 630 (3d Cir. 2011)). The plaintiff must “demonstrate that the element of [the legal claim] is capable of proof at trial through evidence that is common to the class rather than individual to its members.” Marcus, 687 F.3d at 600 (quoting Hydrogen Peroxide, 552 F.3d at 311). Thus, a court must predict how specific issues will play out at trial “in order to determine whether common or individual issues predominate in a given case.” Malack v. BDO Seidman, LLP, 617 F.3d 743, 746 (3d Cir. 2010) (quoting Hydrogen Peroxide, 552 F.3d at 311).

The United States Supreme Court has noted that “[p]redominance is a test readily met in certain cases alleging consumer [ ] fraud or violations of antitrust laws.” Amchem, 521 U.S. at 625; see also In re Warfarin Sodium Antitrust Litig., 391 F.3d 516, 528 (3d Cir. 2004) (holding, in a consumer fraud and antitrust case, that liability depended on the conduct of the defendant and not on the conduct of the individual class members); In re Flat Glass Antitrust Litig., 191 F.R.D. 472, 483–84 (W.D. Pa. 1999) (noting that the predominance test is met in an antitrust case because “consideration of the conspiracy issue would, of necessity, focus on defendants’ conduct, not the individual conduct of the putative class members.”).

Here, the DPPs set forth antitrust violations. As such, they must show that common issues predominate with respect to their ability to prove: (1) a violation of the antitrust laws; (2) antitrust impact from the violation, *i.e.* causation; and (3) measurable damages. See Hydrogen Peroxide, 552 F.3d at 311. I consider whether Plaintiffs have met their Rule 23(b)(3) burden on each element.

*a. Antitrust Violation*

As a general rule, liability for anticompetitive conduct focuses on the defendants’ actions, not the conduct of individual class members. In re Warfarin, 391 F.3d at 528. The DPPs’ theory of antitrust liability is premised on what is known as a “product hop,” which occurs “when a brand-name drug manufacturer tweaks the drug ‘to prevent pharmacists from substituting a generic equivalent when presented with a prescription for the newly modified brand-name drug.’” In re Loestrin 24 Fe Antitrust Litig., 261 F. Supp. 3d 307, 350 (D.R.I. 2017) (quoting In re Asacol Antitrust Litig., No. 15-12730, 2016 WL 408333, at \*2 (D. Mass. July 20, 2016)). “[T]he combination of withdrawing a successful drug from the market and introducing a reformulated version of that drug, which has the dual effect of forcing patients to switch to the new version and impeding generic competition, without a legitimate business justification,” violates § 2 of the

Sherman Act. New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638, 659 (2d Cir. 2015); see also In re Suboxone, 64 F. Supp. 3d 665, 682 (E.D. Pa. 2014).

Here, the common question among the class is whether Reckitt’s alleged product-hopping or “hard-switch” strategy—consisting of efforts to undermine tablet sales, raise false safety concerns about tablets, withdraw branded tablets, raise branded tablet prices, and then ultimately switch the market to Suboxone film—had a “legitimate business justification” or whether it constituted anticompetitive conduct. As described below, Plaintiffs have pointed to common evidence that will establish that these allegations are susceptible to common proof.<sup>10</sup>

- According to the DPPs, Reckitt actively began searching, in 2006, for a way to “increase the commercial barriers to entry” by investigating the possibility of changing the method of administering buprenorphine to patients. (DPP’s Mot. Class Cert., Ex. 7, at RBP-00704376; see also DPPs’ Mot. Class Cert, Ex. 12, at slide 3.) Reckitt was aware that the generic tablet would not be AB-rated with film, and thus not automatically substitutable. (DPPs’ Mot. Class Cert., Ex. 14, at RBP-01602417–18.) Moreover, Reckitt conceded that it was looking for film not to be safer, but rather to be “equally as safe” as sublingual tablets. (DPPs’ Mot. Class Cert. Ex. 15, RBP-01887095.)
- Thereafter, in 2009, Reckitt began to put its strategy into place and “[p]repare the payer market for potential tablet withdrawal” and offer only film. (DPPs’ Mot. Class Cert., Ex. 17, at Slide 5; see also Ex. 19, at Slide 13.) Reckitt began discussions with Managed Care Organizations (“MCO”s) to end or “sunset” rebates on tablets, in favor of adding film rebates in order to provide an incentive for payers to make the switch. (DPPs’ Mot. Class Cert., Exs. 20, 21.)
- According to the DPPs’ evidence, by May 2011, Reckitt’s President, Gary Phillips, expressly stated that Reckitt would “be moving to discontinue the Suboxone tab[let] by year end.” (DPPs’ Mot. Class Cert., Ex. 24, at RBP-00006199.) Indeed, payers were told that the tablet was coming off the market in early 2012. (DPPs’ Mot. Class Cert., Ex. 26, at Slide 10.) In the meantime, “Tablet price increases ha[d] exposed payers without rebate relief and price stabilization.” (*Id.*) In connection with this plan, Reckitt indicated its intent to “no longer . . . promot[e] SUBOXONE Tablets,” and to promote “only SUBOXONE Film to certified providers and recommend[] that they switch to the new formulation.” (*Id.*) In addition, Reckitt sent letters to doctors and patients indicating that, “[p]atients currently participating in the [Here to Help Patient Assistance Program (PAP)] and receiving SUBOXONE

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<sup>10</sup> This recitation of the evidence does not account for any contrary evidence Reckitt may have to dispute these facts. That is because the sole inquiry here is whether Plaintiffs can adduce class-wide evidence in support of their claims.



sublingual tablets will need to be transitioned to SUBOXONE Film prior to December 31, 2010.” (DPPs’ Mot. Class Cert., Ex. 30.)

- The DPPs’ point to evidence that, in conjunction with the introduction of film and the withdrawal of the tablet, Reckitt understood that in order to “justify withdrawal of the tablets from the markets,” it had to demonstrate the safety benefits of film over tablet. (DPPs’ Mot. Class Cert., Ex. 15, at RBP-01887096.) To that end, Reckitt commented, “[i]f we can build a safety story with the strip it would appear almost unethical to not take the tablet off the market.” (DPPs’ Mot. Class Cert., Ex. 34.) At the same time, and inconsistent with its planned safety campaign, Reckitt seemed to understand that some patients “may have adverse events due to the polymers in the strip which are not existent in the tablet.” (Id.)
- In 2008, Reckitt recognized that the FDA had a high level of interest in the potential for unintentional childhood exposure to buprenorphine. (DPPs’ Mot. Class Cert. 35, at RBP-01322565.) It understood that it could leverage this concern to its advantage by getting the FDA to mandate that all addiction-treatment drugs have a dose wrapped in its own child-proof pack. (Id.) Although Reckitt was originally going to develop a blister-pack for tablets, Reckitt recognized that it would have “limited value” once the film was launched because the objective was to drive patient switch and new patients to film, and withdraw the tablet on grounds of safety for lack of child-resistant packaging. (DPPs’ Mot. Class Cert. Ex. 36, Schmidt Dep., 131:1–132:24.)
- According to the DPPs’ evidence, the FDA found no evidence to compare the safety profile of the Suboxone film to the Suboxone tablet. (DPPs’ Mot. Class Cert., Ex. 40, Reuter Dep. Ex. 2, at 2.) Indeed, it recognized “the significant risks of abuse and diversion from the Suboxone strip.” (Id.) The FDA found that the safety study was “poorly designed and conducted and was not useful for demonstrating any difference in the safety profile or abuse potential of the two formulations.” (Id. at 3.) Yet, according to the DPPs’ evidence, Reckitt’s announcement of the approval of film touted it as “discourag[ing] misuse and abuse.” (DPPs’ Mot. Class Cert., Ex. 29, at RBPMDL-10040172.) Indeed, when meeting with doctors who were resistant to the switch, Reckitt sales representatives stated that the film would curtail “diversion, misuse and abuse.” (DPPs’ Mot. Class Cert., Ex. 43, at RBP-01798919; see also Id., Exs. 44, 47.) Moreover, sales representatives were instructed to advise physicians that tablets “intrinsicall[ly] ha[ve] a higher risk of treatment failure, unintended pediatric exposure, diversion and misuse” over the “safer” film version. (DPPs’ Mot. for Class Cert., Ex. 47, at RBP-02248439.)
- The DPPs also point out that film was originally launched at the same price as tablets, but, after two months, Reckitt increased tablet prices to “drive cost differential for Film with payers and patients to accelerate conversion and protect [Reckitt’s] market position.” (DPPs’ Mot. Class Cert., Ex. 53, slide 1.) Reckitt then began giving higher rebates on film, which widened the price difference between tablets and film. (DPPs’ Mot. Class Cert., Ex. 66, at RBPMDL-10677408.) As argued by the DPPs, this price differential made no economic sense because “[t]he [cost of goods] for the film are . . . higher than the tablet as the manufacturing supply chain involves a 3<sup>rd</sup> party manufacturer and a secondary packers as opposed to complete in house production per tablets.” (DPPs’ Mot. Class Cert., Ex. 55, at RBP-02916129.)

- In the Spring of 2011, the film share began to flatten, in part because many physicians were not “on board” with film. (DPPs’ Mot. Class Cert, Ex 58 & 60 at RBPMDL-11199641.) The most common “adverse events” were far more prevalent in the film version as opposed to the tablet. (DPPs’ Mot. Class Cert., Ex. 59, at Slides 9–11.) As such, Reckitt continued its campaign of pushing the film over tablet. (DPPs’ Mot. Class Cert., Ex. 62, at RBPMDL-11077711.)
- According to the DPPs, in order to buy additional time to convert the market to film, Reckitt engaged in further delay tactics. First, Reckitt allegedly feigned participation in a collaborative REMS process with the generic companies, while actually working to delay the process. Second, on the day that Reckitt formally announced its discontinuation of tablets, Reckitt filed a Citizen Petition with the FDA seeking, in part, to have the FDA not approve any generic tablets. (DPPs’ Mot. Class Cert., Ex. 38, at RBP-01172662.) That Petition was denied on February 22, 2013. (DPPs’ Mot. Class Cert., Ex. 33.)

Viewing this evidence as a whole creates a question, common to all class members, of whether Reckitt engaged in an anticompetitive nationwide and market-wide product switch scheme to move prescriptions from tablet to film. Put another way, if each class member were required to pursue its claims individually, such class member would have to prove the same antitrust violations using the same evidence. “The issues of relevant market, monopoly power, and exclusionary conduct can be proven using common, class-wide evidence because such issues focus on the defendants’ conduct rather than individual class members.” In re Wellbutrin XL Antitrust Litig., 282 F.R.D. 126, 140 (E.D. Pa. 2011). I therefore find that the DPPs have met their burden of producing class-wide evidence that Reckitt engaged in an anticompetitive scheme, thus satisfying their Rule 23(b)(3) burden on this element.

*b. Antitrust Impact/Causation*

The DPPs must next show that they can prove by common evidence that the class members suffered an injury—or antitrust impact—from the antitrust violation. In re Processed Egg Prods., 312 F.R.D. at 183. The Third Circuit has clarified a class plaintiff’s burden on this element at the certification stage:

In antitrust cases, impact often is critically important for the purpose of evaluating Rule 23(b)(3)'s predominance requirement because it is an element of the claim that may call for individual, as opposed to common, proof. 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.

In re Hydrogen Peroxide, 552 F.3d at 311–12 (citations omitted). In adducing common proof of antitrust impact, “a plaintiff is only required to show that alleged illegal conduct is ‘a material cause of the [antitrust] injury; a plaintiff need not exhaust all possible alternative sources of injury in fulfilling his burden of proving compensable injury.’” In re Namenda Direct Purchaser Antitrust Litig., 331 F. Supp. 3d 152, 179 (S.D.N.Y. 2018) (quotations omitted).

Here, as to common impact, the DPPs propose to show that every member of the proposed class—regardless of individual circumstances—paid more for Suboxone tablets because of Reckitt's scheme. As detailed above, the DPPs' evidence suggests that the alleged scheme was implemented by executives at Reckitt on a nationwide basis and throughout the entire market. The DPPs explain that film was originally launched at the same price as tablets, but, after two months, Reckitt increased tablet prices to “drive cost differential for Film with payers and patients to accelerate conversion and protect [Reckitt's] market position.” (DPPs' Mot. Class Cert., Ex. 53, slide 1.) Dr. Lamb, the DPPs' expert, notes that Reckitt dramatically increased tablet prices at a much higher rate than previous Suboxone price increases—60% over a 30-month period as compared to only 17% for film over the same period. (Lamb Rebuttal Report ¶ 107.) Dr. Lamb opines that Reckitt implemented the higher tablet prices in furtherance of its anticompetitive scheme to drive sales away from branded Suboxone tablets and achieve a greater market share for film. (Id. ¶ 108.) He explains

that “the question of whether all or nearly all Class members were injured by Reckitt’s anticompetitive scheme can be answered with a showing that all or nearly all Class members paid higher prices for branded Suboxone tablets than they would have absent Reckitt’s anticompetitive scheme.” (Lamb Rebuttal Report ¶ 56.) He goes on to reason that:

[A]s a matter of economics, given that Suboxone film was costlier to produce (and less profitable) than Suboxone tablets, and given the common evidence demonstrating that Reckitt in fact increased the price of the brand Suboxone tablets as part of its anticompetitive scheme, Reckitt would have priced Suboxone tablets at least as low as Suboxone film was actually priced, as it was when Suboxone film first launched, absent its anticompetitive scheme, thus supporting my conclusion that all or nearly all Class members were injured by Reckitt’s anticompetitive scheme, since they paid higher prices for Suboxone tablets they purchased than they otherwise would have absent Reckitt’s anticompetitive scheme.

(Lamb Rebuttal Report ¶ 56.)

Dr. Lamb further concludes that “[t]he common evidence . . . demonstrates that all Class members were very likely impacted by Reckitt’s Hard Switch Scheme and/or Hard Switch Scheme Plus Delay in that they paid inflated prices for at least some of their BPN/NLX [buprenorphine/naloxone] purchases.” (Lamb Rebuttal Report ¶ 49.) He identifies five categories of common proof. First, he reviews empirical economic research showing that when AB-rated generic products enter the market, they typically do so at lower prices than their brand-name counterparts and capture a significant share of the total unit sales for the drug. (Lamb Report ¶ 73a.) Second, he cites to documents and testimony from Reckitt and the generics (Actavis and Amneal) forecasting the effects of generic competition in the market for buprenorphine-naloxone, which (a) confirm his conclusion that generic Suboxone tablets would have been priced at a lower price than brand Suboxone tablets, and (b) demonstrate that Reckitt implemented price increases for branded Suboxone tablets relative to Suboxone film in order to drive greater conversion to Suboxone film. (Lamb Report ¶ 73b.) Third, he considers transaction-level data on the actual and but-for prices for

branded tablets and film, and for generic Suboxone tablets showing that class members paid more for branded Suboxone tablets than they would have absent the hard switch scheme. (Lamb Report ¶ 73c.) Fourth, Dr. Lamb points to Reckitt documents and testimony regarding its own expectations and projections of the market share that Suboxone film would achieve, and then performs an analog analysis of the but-for Suboxone film market share which would have prevailed in the “No Hard Switch But-For World.” (Lamb Report ¶ 73d.) Finally, Dr. Lamb, cites to Reckitt’s documents and testimony demonstrating that price increases for Suboxone tablets relative to prices for Suboxone film implemented by Reckitt as part of its hard switch scheme caused class members to be overcharged for branded Suboxone Tablets. (Lamb Report ¶ 73e.) Importantly, Dr. Lamb opines that all of this evidence is common to the proposed class. (Lamb Report ¶ 73f.)

In an effort to defeat this predominance showing, Reckitt counters with two arguments. First, it posits that individualized issues predominate among the mix of clinics and wholesalers that comprise the class. Second, Reckitt asserts that the only theory of antitrust impact that can be proven through common evidence is not cognizable and does not predominate. I address each argument individually.

i. Whether Individualized Issues Predominate

Reckitt first avers that the DPPs seek certification of “an unusual kind of class—a mixture of methadone clinics and wholesalers.” (Reckitt’s Opp’n Class Cert. 10.) It contends that “[l]ooking at the actual evidence shows there is no common evidence that the class members were exposed to or reacted to the alleged misconduct in any common way—that is to say, there is no ‘glue’ allowing for a common answer to the question of whether they purchased Film as a result of coercion or deception.” (*Id.* at 11.) Given this lack of commonality, Reckitt asserts that individual, rather than that common issues predominate (a) among the clinics in the class, (b) between the clinics as a group and the wholesalers as a group; and (c) among the wholesalers in the class. In support of this

argument, Reckitt identifies a series of distinctions that allegedly permeate the class and prevent the DPPs from producing common evidence to establish the key allegations in the case.

Reckitt's alleged individualized questions are summarized as follows:

*Alleged Individualized Questions Among the Clinics*

- Were class members “cocerced” into purchasing film? Reckitt contends that significant differences among the clinic class members preclude attempts to collectively explain their purchasing decisions through common evidence. Reckitt explains that different clinics stocked different drugs.<sup>11</sup> Some class members never purchased film, some increased or decreased film purchases after generic tablets became available, and other clinics' film purchases varied with no pattern.<sup>12</sup> Thus, whether any clinic purchased film as a result of coercion or deception is, according to Reckitt, an individualized inquiry.
- Were Reckitt's efforts to avoid pharmacy substitution laws the genesis of its scheme? Reckitt argues that many of the clinics purchased Suboxone products directly and dispensed them directly to their patients.<sup>13</sup>
- Did Reckitt signal tablet withdrawal before and after film launch? Reckitt contends that no evidence, common or otherwise, exists for the proposition that any direct purchaser clinic was informed about the tablet withdrawal and that it acted on the information. Thus, according to Reckitt, the question of which clinics may have chosen film over tablets due to the potential withdraw of tablets requires individualized inquiry.

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<sup>11</sup> (See, e.g. Def.'s Oppn' DPPs' Class Cert., Ex. 50, 27:16–28:25 (Esper Treatment Center in Pennsylvania stocks Methadone, Subutex, and Zubsolv); Ex. 49, 20:3–25); Phoenix Health in Maryland stocks Suboxone Film, Zubsolv, Vivitrol, Sublocade, and Methadone); Ex. 51 (Acadia with clinics in ten stages stocks multiple different types of products including Suboxone).)

<sup>12</sup> (*Id.*, Ex. 1 (“Norman Report”) ¶ 112.) Testimony from these clinics shows that each clinic employed different criteria for purchasing decisions. (See, e.g., *Id.*, Ex. 49, 50:13–52:9 (Phoenix Health Center's prescribing decision has nothing to do with the individual, but rather whatever the state is willing to pay for); Ex. 48, 31:16–25 (purchasing decisions for Acadia is made at the local or regional level based on consumer demand, demographics, and what the community needs).)

Notably, the representative for Acadia also testified decisions regarding what specific medications are purchased are made at the national level based on pricing concerns and what proposals they are given from various suppliers. (Def.'s Opp'n DPPs' Class Cert., Ex. 48, 44:4–19.)

<sup>13</sup> (See, e.g., Def.'s Opp'n DPP's Class Cert., Ex. 48, 24:6–25:17 (Acadia Clinics); Ex. 49, 58:19–59:18 (Phoenix Clinic); Ex. 50, 19:12–21:13.)

- Did Reckitt engage in a market-wide campaign to deceive the market into thinking that tablets were more dangerous and film was superior? Reckitt notes that the FDA concluded that Suboxone film in unit-dose packaging posed a lower overall risk of accidental pediatric exposure than Suboxone tablets in multi-dose packaging.<sup>14</sup> Thus, according to Reckitt, there were no false statements or communications about film. Moreover, even if the DPPs could show common false safety claims, Reckitt contends that there is no evidence showing either (a) what precisely the clinics were told, or (b) that concerns about accidental pediatric exposure, abuse, or diversion had any impact on a clinic, where patients were supervised when taking their medication.<sup>15</sup>
- Did Reckitt coerce the customers to switch to film by raising tablet prices and offering larger rebates and copay coupons? Reckitt argues that the DPPs presented no evidence regarding which clinic direct purchasers could obtain rebates from or which clinics allowed their patients to use copay coupons. According to Reckitt, no evidence is presented regarding which clinics made purchasing decisions as a result of Reckitt’s alleged pricing practices.
- Did Reckitt delay generic purchases by approximately five months by sabotaging the shared REMS process? Reckitt contends that twenty-five out of seventy-one class members never purchased generic tablets and, without individualized inquiry, it would be impossible to determine what they would have purchased had there been an earlier generic launch.

*Alleged Individualized Questions Between the Clinics and Wholesalers*

- Is the purchasing process for clinics and wholesalers susceptible to common proof? According to Reckitt, clinics are healthcare providers that treat patients with opioid use disorder. Reckitt explains that these clinics perform an on-site dispensation of drugs that they purchase, and the most common treatment drug is methadone. By contrast, wholesalers function as pharmaceutical suppliers to downstream buyers in the healthcare industry.<sup>16</sup> The demand that the wholesaler has for the purchases of Suboxone tablets or film is “derived from what is happening downstream in the end user market where patients are receiving prescriptions or treatment using Suboxone tablet or Suboxone film,” and this is not susceptible to common proof.<sup>17</sup>

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<sup>14</sup> (Def.’s Opp’n DPPs’ Class Cert., Ex. 12, 44:9–45:4, Ex. 52.)

<sup>15</sup> (See, e.g., Def.’s Opp’n DPPs’ Class Cert., Ex. 48, 42:22; Ex. 49, 15:14–17:12; Ex. 50, 22:10–23:7.) Reckitt further notes that one of the clinics stopped buying film and started buying a different branded product when a staff member heard a rumor that patients were scraping the coat of the film off of their tongues and selling it. (*Id.* Ex. 50, 28:17–29:9.)

<sup>16</sup> (Def.’s Opp’n DPPs’ Class Cert., Ex. 25, 15:8–19:14.)

<sup>17</sup> (Def.’s Opp’n DPPs’ Class Cert. Ex. 2, 140:24–141:10, 142:9–16.)

*Alleged Individualized Questions Among Wholesalers*

- Is the purchasing process among the wholesalers proven by different evidence? Wholesalers are regional players and operate only in a single state. (Norman Report ¶ 121.) Thus, according to Reckitt, determining the factors affecting the relative demand for brand Suboxone film or for brand or generic tablets in each state requires an “individualized inquiry for that purchaser based on the insurance coverage status, pricing at retail level, preferences of doctors and patients, . . . [and] analysis of the effect of the alleged conduct.” (*Id.*) The DPPs allege that Reckitt—through communications about withdrawal of branded tablets, false safety claims, and offers of a rebate structure making film less costly—induced MCOs and other third-party payors to make formulary structures. According to Reckitt, however, such conduct could only have had a common impact across all regions if the third-party payors all responded to Reckitt’s efforts in a common manner, which the evidence shows that they did not.<sup>18</sup>
- Did doctors react uniformly to the signal that tablets would be withdrawn? Reckitt notes that, in a marketing study regarding physicians’ prescribing decisions, doctors listed discontinuation of the tablet as the least important factor influencing their decisions.<sup>19</sup>

Reckitt presses that these multiple distinctions and individual questions among the various class members preclude any finding of predominance. Careful scrutiny of Reckitt’s arguments, however, reveals that these questions pertain to the merits of the DPPs’ overall case and have little bearing on the common issues regarding antitrust impact. As set forth above, the element of antitrust impact in this case requires a showing that every member of the proposed class, regardless of their status as a wholesaler or a clinic, paid more for branded Suboxone tablets as a result of Reckitt’s allegedly unlawful anticompetitive behavior. Such an inquiry is subject to common proof.

The Third Circuit’s holding in In re Warfarin Sodium Antitrust Litigation, 391 F.3d 516 (3d Cir. 2004) supports my conclusion. In re Warfarin involved alleged efforts by a brand manufacture to preclude generic drug entry onto the market. The plaintiffs, a group of end-payors, alleged that the defendant’s anticompetitive behavior—involving the dissemination of false and misleading

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<sup>18</sup> (Compare DPPs’ Mot. Class Cert., Ex. 32, 94:20–96:10 (Highmark adds Suboxone film to the formulary because tablets would soon be withdrawn); Def.’s Opp’n DPPs’ Class Cert., Ex. 54, 81:12–16 (Prime Therapeutics adds film to the formulary to “alleviat[e] member confusion.”)

<sup>19</sup> (See Def.’s Opp’n DPPs’ Class Cert., Ex. 56.)



information about the safety and equivalence of a lower-priced generic competitor—caused the plaintiffs to purchase the higher-priced, brand-name drug instead of the generic drug. Id. at 522–23. The alleged misrepresentations were aimed at health care professionals, government agencies, pharmacy boards, and formularies. Id. The plaintiffs asserted that the misrepresentations led consumers to believe that the branded drug was superior to the generic equivalents, causing millions of prescriptions to be filled with the brand that would have otherwise been filled with less expensive generic drugs, and allowing the defendant to maintain supracompetitive prices. Id. at 523. The parties and the putative class representatives settled and the district court certified a settlement class. Id. at 525–27.

On appeal, several objectors argued, like Reckitt does here, that Rule 23(a) commonality and Rule 23(b)(3) predominance were not satisfied because of the variations in the claims and injuries of the plaintiffs, specifically between consumers and third-party payors. The objectors also pointed to differences in the laws of the fifty states which formed the basis of several of the class claims. Id. at 527. The Third Circuit disagreed noting that “proof of liability does not depend on evidence that [defendant] made deceptive communications to individual class members or of class members’ reliance on those communications; to the contrary, [the defendant’s] alleged deceptive conduct arose from a broad-based, national campaign conducted by and directed from corporate headquarters, and individual reliance on the misrepresentations was irrelevant to liability.” Id. at 528–29. The Court further noted that because the plaintiffs alleged purely an economic injury in the form of overpayment for the drug at issue—and not any physical injury—a finding of commonality and predominance was warranted. Id. at 529. The facts and issues in In re Warfarin are remarkably similar to the case before me.<sup>20</sup>

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<sup>20</sup> The fact that In re Warfarin involved certification of a settlement class rather than a litigation class is irrelevant because the Rule 23(b)(3) predominance standard applies equally to both

Repeatedly, district courts have taken a similar approach and rejected contentions, similar to Reckitt's, that differences in purchasing decisions defeated class certification on the issue of antitrust impact. See, e.g., In re Processed Egg Prods., 312 F.R.D. at 180 ("Differing purchasing methods and prices do not necessarily defeat a finding of typicality and adequacy, provided that the alleged misconduct applies across the array of methods, and prices."); Meijer, Inc. v. Warner Chilcott Holdings Co. III, Ltd., 246 F.R.D. 293, 309 (D.D.C. 2007) (rejecting defendants' argument that plaintiffs could not show predominance on antitrust injury because "the heterogeneous business models, purchasing practices, and pricing among putative class members"); In re Cardizem Antitrust Litig., 200 F.R.D. 297, 319 (E.D. Mich. 2001) ("[N]either a variety of prices nor negotiated prices is an impediment to class certification if it appears that plaintiffs may be able to prove at trial that the price range was affected generally.") (quoting In re NASDAQ Market Makers Antitrust Litig., 169 F.R.D. 493, 523 (S.D.N.Y. 1996)); In re Vitamins Antitrust Litig., 209 F.R.D. 251, 266 (D.D.C. 2002) ("It is not unprecedented that courts have found common impact in cases alleging price-fixing despite individual negotiations, varied purchase methods and different amounts, prices, and types of products purchased."); In re Lorazepam and Clorazepate Antitrust Litig., 202 F.R.D. 12, 30 (D.D.C. 2001) (finding that plaintiffs could prove, through common evidence and despite the existence of individualized issues, that defendants' anticompetitive conduct allowed them to hike and sustain high prices of drug causing antitrust injury).

Here, to meet their burden in demonstrating impact to direct purchasers of branded Suboxone, the DPPs must show, through common evidence, that brand Suboxone prices would have been lower absent Reckitt's conduct. As set forth above, the DPPs have pointed to evidence that Reckitt engaged in a campaign designed to simultaneously introduce Suboxone in film form,

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settlement and litigation classes. See AmChem Prods, Inc. v. Windsor, 521 U.S. 591, 622–23 (1997).

withdraw branded Suboxone tablets from the market, falsely disparage the safety of Suboxone tablets, and delay entry of generic tablets through both the shared REMS process and the filing of a baseless citizen petition. The DPPs also offer common evidence that Reckitt's actions caused the DPPs to pay supracompetitive prices for branded Suboxone.

While there are undoubtedly distinctions within the class, class members need not have exhibited identical purchasing patterns in order for them to have been injured by Reckitt's alleged anticompetitive scheme. Indeed, the class definition includes only those direct purchasers that actually purchased branded Suboxone tablets directly from Reckitt during a particular time period, making it irrelevant whether some of them also bought film or generic tablets. Thus, many of the individualized purchasing decisions will have no bearing on common proof antitrust impact in the form of overcharges.<sup>21</sup>

ii. Whether the Above-Cost Pricing Portion of the Class Definition is Cognizable

In an alternative argument, Reckitt contends that, even assuming that the DPPs could prove antitrust impact through a theory premised on supracompetitive pricing of Suboxone tablets, that theory is violative of antitrust laws. Relying substantially on the assertions raised in its Motion to Exclude the Opinions of Dr. Lamb, Reckitt contends that "above-cost pricing (including price increases that plaintiffs may view as excessive or coercive) is not subject to attack under the antitrust

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<sup>21</sup> Reckitt also points to precedent which states that the predominance requirement cannot be met in cases founded on alleged misrepresentations that are not shown to be "standard, uniform, [or] scripted." In re LifeUSA Holding, Inc., 242 F.3d 136, 146 (3d Cir. 2001) (holding, in case asserting class claims for fraudulent nondisclosures and misrepresentations regarding annuity contracts, that absence of any uniform misrepresentation made to plaintiffs precluded a finding of commonality or predominance).

This argument is irrelevant here. In LifeUSA, the claims were for fraudulent nondisclosures and misrepresentations, which require, as an element of proof, that each of the class members relied on the misrepresentations. Id. at 145 n.9. Here, the claims are for antitrust violations, which have no reliance element, but simply require a showing that the anticompetitive conduct caused injury to the class members.

laws.” (Reckitt’s Reply Opp’n DPP Class Cert. 7.) It posits that although the DPP class’s claims arise from a multifaceted scheme to maintain Reckitt’s monopoly, the only aspect of their claims that can be proven through common evidence is the pricing aspect, which, absent claims of predatory pricing, is not legally cognizable.

Again, Reckitt seeks to improperly characterize this case as one premised solely on allegations of predatory pricing. The Third Circuit confronted a similar situation in ZF Meritor, LLC v. Eaton Corp., 696 F.3d 254 (3d Cir. 2012). The plaintiffs, competitors of the defendant, brought an antitrust action against the manufacturer of heavy-duty transmissions, alleging that the manufacturer used long-term agreements with direct-purchaser truck manufacturers to foreclose competition. Id. at 264–66. Following a trial, and a denial of the defendant’s renewed motion for judgment as a matter of law, the district court entered an injunction against the defendant. Id. at 268.

On appeal the defendant argued that the plaintiffs’ claims could not constitute actionable predatory, or below-cost, pricing. Id. at 275. The Third Circuit acknowledged that had the sole allegation at issue been predatory pricing, the plaintiff’s claims would not have been cognizable. Id. at 276–77. It noted, however, that the plaintiffs “did not rely solely on the exclusionary effect of [defendant’s] price, and instead highlighted a number of anticompetitive provisions in the [long-term agreements]” and “price itself was not the clearly predominant mechanism of exclusion.” Id. at 277. The Third Circuit remarked that “[n]othing in the case law suggests, nor would it be sound policy to hold, that above-cost prices render an otherwise exclusive dealing agreement lawful,” because to do so “would place a significant portion of anticompetitive conduct outside the reach of the antitrust laws without adequate justification.” Id. at 278. The Court recognized that “conduct that does not result in below-cost pricing may nevertheless be anticompetitive.” Id. at 279. Ultimately, it found that because the pricing allegations were not the clearly predominant method

of exclusion, but rather were only one of the alleged exclusionary tools used by the defendant, they were actionable. *Id.* at 279.

Similarly here, the DPPs' theory of liability is not that Reckitt's pricing of brand tablets individually caused harm. Rather, the DPP's theory is that the *combination* of the alleged exclusionary conduct—including the increase in the price of brand tablets and decrease in the price of film, combined with the introduction of Suboxone film onto the market, the removal of Suboxone tablets from the market several months prior to generic approval, the false safety concerns with Suboxone tablets, the disparagement of Suboxone tablets, and the efforts to delay entry of the generics—resulted in antitrust injury.<sup>22</sup>

Moreover, and contrary to Reckitt's argument, the DPPs need not put forth any proof of individualized antitrust impact arising from each of the separate forms of alleged anticompetitive conduct. "The relevant inquiry is the anticompetitive effect of [defendant's] exclusionary practices considered together," and the court "must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation." *LePage's Inc. v. 3M*, 324 F.3d 141, 162 (3d Cir. 2003) (citing *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962)). Numerous cases from within the Third Circuit have reached the same conclusion. *See, e.g., In re Neurontin Antitrust Litig.*, No. 02-1390, 2009 WL 2751029, at \*16–17 (D.N.J. Aug. 28, 2009) (noting that, where plaintiffs pled a comprehensive multifaceted scheme to monopolize the market, the relevant inquiry is the anticompetitive effect of the defendant's exclusionary practices considered together and not whether the underlying elements of the plaintiffs' alleged scheme are violations of antitrust laws in their own right); *SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686, 702–03

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<sup>22</sup> In my prior opinion denying Reckitt's motion to dismiss, I found this theory to state a plausible claim for relief. *In re Suboxone Antitrust Litig.*, 64 F. Supp. 3d 665, 683 n.9 (E.D. Pa. 2014).

& n.10 (E.D. Pa. 2004) (holding that even plaintiffs cannot prove injury from one element of a larger antitrust scheme, antitrust impact must be determined by looking at the anticompetitive effect of the defendant's acts as a whole).

In sum, I find that the DPPs have met their burden of demonstrating the existence of common evidence to prove antitrust impact. Accordingly, I conclude that the predominance element has been satisfied on this issue.

*c. Aggregate Damages*

The last element at issue is aggregate damages. “The predominance requirement applies to damages as well, because the efficiencies of the class action mechanism would be negated if “[q]uestions of individual damage calculations . . . overwhelm questions common to the class.” In re Modafinil, 837 F.3d at 260 (quoting Comcast, 569 U.S. at 35). Plaintiffs therefore need to demonstrate that common issues predominate as to the element of “measurable damages” on a classwide basis. Hydrogen Peroxide, 552 F.3d at 311–12 (citing 15 U.S.C. § 15). Nonetheless, “[a]t the class certification stage, the plaintiffs are not required to prove damages by calculating specific damages figures for each member of the class, but rather they must show that a reliable method is available to prove damages on a class-wide basis.” In re Wellbutrin, 282 F.R.D. at 144. That is, Plaintiffs must show that there is a reliable means for measuring damages with reasonable accuracy in the aggregate. In re Processed Egg Prods., 312 F.R.D. at 202. Variation of damages between and among class members does not necessarily defeat predominance. Id. at 180; see also In re Vitamins, 209 F.R.D. at 268 (“At the certification stage, the preliminary inquiry in assessing the proposed methods of proving damages is limited: The inquiry is not whether the methods are valid, but is only to assess whether the methods are available to prove damages on a class-wide basis.”); In re Loestrin 24 Fe Antitrust Litig., No. 13-2472, 2019 WL 3214257, at \*15 (D.R.I. July

15, 2019) (“[I]t is well-established that ‘[t]he individuation of damages in consumer class actions is rarely determinative under Rule 23(b)(3).’”) (quotations omitted).<sup>23</sup>

Reckitt contends that the DPPs have not established predominance as to damages on two bases. First, it repeats its argument, made in connection with the Motion to Exclude Dr. Lamb’s expert report, that all aspects of Dr. Lamb’s calculations depend on the assumptions that it was unlawful to raise tablet prices and to encourage film sales by lowering film prices through rebates and discounts. Reckitt contends that because these are not viable antitrust theories, Dr. Lamb’s damages model is improper.

As discussed both with respect to the Motion to Exclude Dr. Lamb and the predominance showing of antitrust impact, I find no merit to this argument. Dr. Lamb’s reliance on these assumptions in order to calculate damages does not require exclusion of his opinions under Daubert.

Reckitt’s second argument posits that the DPPs have failed to propose a mechanism for determining the damages of each class member. Reckitt contends that Dr. Lamb admitted that he had neither “calculated the damages that should be awarded to any specific class member” nor developed “a formula or a methodology for determining the damages by any specific class member. (Def’s Opp’n DPPs’ Class Cert., Ex. 2, 175:2–176:2 (“I haven’t analyzed individual class member damages. That wasn’t part of my assignment.”).) Reckitt thus contends that individual issues regarding individual class members’ damages will predominate and, thus, preclude certification.

Issues regarding allocation of individual damages are insufficient to defeat class certification. In re Flonase, 284 F.R.D. at 233. Rather, as noted above, plaintiffs “must show that a reliable method is available to prove damages on a class-wide basis.” In re Wellbutrin, 282 F.R.D.

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<sup>23</sup> Notably, “the inability to show injury as to a few does not defeat class certification where the plaintiffs can show widespread injury to the class.” Meijer, Inc. v. Warner Chilcott Holdings Co. III, Ltd., 246 F.R.D. 293, 310 (D.D.C. 2007) (quotations omitted).

at 144. “Significantly, a number of courts have been satisfied that a common methodology for proving class-wide damages exists in actions alleging delayed or impeded entry of generic pharmaceuticals.” Meijer, Inc. v. Warner Chilcott Holdings Co. III, Ltd., 246 F.R.D. 293, 312 (D.D.C. 2007).

Dr. Lamb’s expert report satisfies this standard. His report measures overcharge damages based on the difference between the actual price class members paid for branded Suboxone tablets and film and the prices the class would have paid for branded and generic tablets absent the allegedly anticompetitive conduct. (Lamb Report ¶ 125.) To calculate these damages, Dr. Lamb relies on transaction-level data for a set time period from both Reckitt and from various third-party generic manufacturers. (Id. ¶ 127.) He then adjusts the data to exclude certain types of sales that were not relevant to class, and to account for rebates, price adjustments, and chargebacks on a transaction-level basis. (Id. ¶ 128.) While he acknowledges that some class members, who purchased branded Suboxone tablets in the actual world, would have continued to purchase branded Suboxone tablets, rather than film or generic tablets, in the “No Hard Switch Scheme But-For World” and the “No Hard Switch Scheme No Delay But-For World,” he opines that, in the absence of Reckitt’s allegedly-anticompetitive conduct, those branded tablets would have been priced lower. (Id. ¶ 130.) He then sets forth a benchmark methodology, based on common, class-wide evidence, to calculate those but-for prices using various analogs. (Id. ¶¶ 131–167.)

As set forth in detail in connection with Reckitt’s Motion to Exclude Dr. Lamb, the viability of this model is reliable and requires no need to show individual damages for individual plaintiffs. Reckitt’s challenges go only to the weight to be accorded to Dr. Lamb’s model and do not show that his methodology is “so insubstantial as to amount to method at all.” In re Lorazepam & Clorazepate Antitrust Litig., 202 F.R.D. 12, 30 (D.D.C. 2001). In short, Dr. Lamb’s model permits classwide proof of measurable damages, thereby satisfying the predominance requirement.



### 3. Rule 23(b)(3) Superiority

In addition to predominance, plaintiffs seeking certification under Rule 23(b)(3) must show that “a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.” Fed. R. Civ. P. 23(b)(3). To determine whether plaintiffs have met their burden on superiority, courts consider “class members’ interests in pursuing separate actions, the extent of any independent litigation already begun by class members, the desirability of concentrating the litigation in this forum, and the difficulties likely to be encountered in the management of a class action.” In re Mushrooms, 319 F.R.D. at 208 (quotations omitted).

The DPPs posit that the superiority requirement is met because the case concerns common issues and evidence, and certification avoids up to seventy-one individual suits, prevents inconsistent results, and allows class members with smaller claims an opportunity for redress they would likely otherwise be denied. Reckitt has not challenged this superiority element.

I agree that superiority has been satisfied. First, there is no evidence that any specific direct purchaser would prefer to bring a separate lawsuit. In fact, I note that many of the DPPs are smaller clinics that possibly would not otherwise pursue an action on their own. See In re Namenda Direct Purchaser Antitrust Litig., 331 F. Supp. 3d 152, 220 (S.D.N.Y. 2018) (“Class treatment is appropriate in such ‘negative value cases,’ in which each class members’ interest in the litigation is less than the cost to maintain an individual action.”). Second, I am not aware of any other litigation concerning this precise conduct that has been brought by any of the DPPs. Third, the concentration of the litigation in this forum is desirable given that this action has been pending here for approximately six years, and is consolidated with both an action by the end-payors and an action by various States’ Attorneys General. Finally, this case presents no manageability concerns that would weigh against certification, and the DPPs have set forth a plan for cohesively presenting these issues at trial. Accordingly, I deem the superiority element satisfied.

#### 4. Conclusion as to Class Certification

Following a “rigorous analysis,” I find that the DPPs have proven that class certification is warranted and proper. The DPPs have established all of the Rule 23(a) elements of numerosity, commonality, typicality, and adequacy of class representations. Moreover, common, class-wide issues will predominate, and the DPPs have adduced sufficient classwide evidence to prove anticompetitive conduct, antitrust impact, and damages. Finally, I conclude that a class action is a superior method to fairly and efficiently adjudicate this controversy. Accordingly, the DPPs’ Motion for Class Certification will be granted.

#### **C. End-Payor Plaintiffs’ Motion for Class Certification**

The putative End-Payor Plaintiffs (“EPPs”) Class consists of consumers and third-party-payors who purchased, paid for, and/or were reimbursed for co-formulated buprenorphine hydrochloride and naloxone hydrochloride dehydrate for their own use. Like the DPPs, the EPPs allege that they would have paid significantly less for Suboxone but for the anticompetitive conduct of Reckitt.

The EPPs request certification of two different classes. First, they define a nationwide class, seeking injunctive relief under Federal Rule of Civil Procedure 23(b)(2), consisting of:

All persons or entities in the United States who purchased and/or paid for some o[r] all of the purchase price for Co-Formulated Buprenorphine/Naloxone (“Suboxone”) in any form for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries at any time during the period January 1, 2012 through the date of class certification.

(EPPs’ Mem. Supp. Mot. Class Cert. 7.)

Second, they define a state antitrust/consumer protection issues class under Federal Rule of Civil Procedure 23(c)(4), consisting of:

All persons or entities who purchased and/or paid for some o[r] all of the purchase price for Co-Formulated Buprenorphine/Naloxone

(“Suboxone”) in California, Florida, Iowa, Michigan, Minnesota, Mississippi, Nevada, New York, Pennsylvania, Virginia, and Wisconsin in any form for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries at any time during the period January 1, 2012 through the date of class certification.

(EPPs’ Mem. Supp. Mot. Class Cert. 7.) As to this latter class, the EPPs seek certification of only the following issues:

- a. Whether Defendant engaged in anticompetitive and deceptive conduct;
- b. Whether Defendant willfully maintained monopoly power through such conduct;
- c. Whether Defendant had a specific intent to monopolize;
- d. Whether Defendant has offered a non-pretextual procompetitive justification that could not have been obtained through less restrictive means, and if so;
- e. Whether the anticompetitive effects of Defendant’s conduct outweigh their proffered procompetitive benefits, if any.

(Id. at 7–8.)<sup>24</sup>

I will jointly address the Rule 23(a) elements as to both proposed classes, and then will separately consider whether the Rule 23(b) and 23(c) elements are satisfied as to each class.

1. Rule 23(a) Elements

a. *Numerosity*

As set forth in detail above (*supra* pp. 36–37), a plaintiff seeking certification must demonstrate that the class is so numerous that joinder of all members is impracticable. Fed. R. Civ. P. 23(a)(1).

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<sup>24</sup> Notably, both classes exclude: (1) Pharmacy Benefit Managers; (2) Defendant and their officers, directors, management, employees, subsidiaries, and affiliates; (3) all governmental entities, except for government funded employee benefit plans; (4) all persons or entities who purchased Suboxone for purposes of resale or directly from Defendant or its affiliates; and (5) the judges in this case and any members of their immediate families.

Here, I find—and Reckitt does not dispute—that numerosity has been satisfied. Although the EPPs do not identify an exact number of class members, they suggest that they seek to certify a class of thousands of consumer and third-party payors. (Decl. of Kenneth Wexler (“Wexler Decl.”), Ex. 3.) “No minimum number of plaintiffs is required to maintain a suit as a class action, but generally if the named plaintiff demonstrates that the potential number of plaintiffs exceeds 40, the first prong of Rule 23(a) has been met.” Stewart v. Abraham, 275 F.3d 220, 226–27 (3d Cir. 2001). Where, as here, plaintiffs seek a to certify a class of thousands of consumer class members and third-party payor class members, numerosity is easily satisfied. See In re Wellbutrin, 282 F.R.D. at 137 (finding numerosity met where plaintiff class involved hundreds of thousands of consumer class members and thousands of TPP class members).

*b. Commonality*

As set forth above (*supra* pp. 38–39), Rule 23(a)(2) next requires Plaintiffs to demonstrate that “there are questions of law or fact common to the class.” Fed. R. Civ. P. 23(a)(2). “[C]ommonality does not require perfect identity of questions of law or fact among all class members. Rather, ‘even a single common question will do.’” Reyes v. Netdeposit, LLC, 802 F.3d 469, 486 (3d Cir. 2015) (quoting Dukes, 564 U.S. at 359).

The EPPs argue that this action is cabined by the specific issues sought for certification here, including: (1) whether Reckitt’s anticompetitive scheme suppressed generic competition to Suboxone; (2) whether Reckitt had the ability to control prices and exclude competition; (3) whether Reckitt’s deceptive introduction of Suboxone film and destruction of the prescription base for Suboxone tablets was predatory and anticompetitive; (4) whether Reckitt’s sabotage of the development process for a shared REMS was anticompetitive; (5) whether a reasonable petitioner would have expected the arguments made in Reckitt’s Citizen’s Petition to succeed; and (6) whether Reckitt submitted the Citizen’s Petition for the purpose of interfering with competition.

Resolution of each of these issues depends entirely on Reckitt's conduct and, thus, on evidence common to the class. As such, these common questions are capable of class-wide resolution because they require no inquiry into individualized issues. Reckitt does not challenge the commonality element of Rule 23(a)(2), but rather reserves its argument regarding the prevalence of common issues for the Rule 23(b)(2) elements and Rule 23(c)(4) requirements. Therefore, I find that Rule 23(a)(2) is satisfied.

*c. Typicality*

The third Rule 23(a) factor considers typicality, which as noted above (*supra* pp. 41–42), aids a court in determining whether “maintenance of a class action is economical and whether the named plaintiff's claim and the class claims are so interrelated that the interests of the class members will be fairly and adequately protected in their absence.” Marcus v. BMW of N. Am., 687 F.3d 583, 597–98 (3d Cir. 2012) (citing Gen. Tel. Co. of the Sw. v. Falcon, 457 U.S. 147, 158 n.13 (1982)).

Reckitt does not dispute typicality. Rather, it generally acknowledges that the claims of the named Plaintiffs and the absent class members rely on the same legal theories and arise from the same “core pattern” of alleged conduct by the Defendants, *i.e.*, that Reckitt's “hard switch” scheme combined with the “sham” citizen petition and its actions during the SSRS process delayed generic entry and resulted in direct purchasers allegedly paying higher prices for Subxone tablets. As I can discern no obvious conflicts between the named representatives and the class members, I find this factor to be satisfied.

*d. Adequacy of Representation*

The last Rule 23(a) factor considers adequacy of representation. As detailed above (*supra* pp. 42–43), “[t]he principal purpose of the adequacy requirement is to determine whether the named plaintiffs have the ability and the incentive to vigorously represent the claims of the class.” In re Cmty. Bank of N. Va. Mortg. Lending Practices Litig., 795 F.3d 380, 393 (3d Cir. 2015). The

adequacy requirement has two components: (1) the interests and incentives of the representative plaintiffs; and (2) the experience and performance of class counsel. Dewey v. Volkswagen Aktiengesellschaft, 681 F.3d 170, 181 (3d Cir. 2012) (citation omitted).

As to the first portion of this factor, Reckitt does not identify, and I cannot find, any likelihood of conflict of interest among the class members. Nor is there any evidence that any of the named Plaintiffs will not adequately represent the class's interests.

In support of the second portion of this element, the EPPs have provided resumés for the various firms and attorneys who will be representing the proposed class. (Wexler Decl., Ex. 2.) These resumés demonstrate that class counsel have significant experience litigating complex class actions. Moreover, over the lengthy course of this litigation, counsel have vigorously represented the proposed class's interests. Finding no basis on which to doubt the adequacy of the class representatives here, I deem this element satisfied.

## 2. Rule 23(b)(2) Class

Having found that the EPPs have met their burden on the Rule 23(a) factors, I must next consider whether each of the EPPs' proposed classes meets the requirements of Rule 23(b). The first class that the EPPs seek to certify is an injunction class under Federal Rule of Civil Procedure 23(b)(2).

Rule 23(b)(2) was written with the purpose of "remedying systemic violations of basic rights of large and often amorphous classes." Baby Neal for and by Kanter v. Casey, 43 F.3d 48, 64 (3d Cir. 1994). In other words, Rule 23(b)(2) permits class actions for declaratory or injunctive relief where "the party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole." Fed. R. Civ. P. 23(b)(2)); see also Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 614 (1997).

“While 23(b)(2) class actions have no predominance or superiority requirements, it is well established that the class claims must be cohesive.” Barnes v. Am. Tobacco Co., 161 F.3d 127, 143 (3d Cir. 1998). This cohesiveness requirement serves two interests: (1) protecting unnamed class members, who “are bound by the action without the opportunity to withdraw and may be prejudiced by a negative judgment in the class action,” and (2) ensuring that the litigation is not unmanageable, such that “little value would be gained in proceeding as a class action.” Id.

For a court to find a class cohesive, it must find that the “class’s claims are common ones and that adjudication of the case will not devolve into consideration of myriad individual issues.” 2 Newberg on Class Actions § 4:34 (5th ed.). “In other words, Rule 23(b)(2) applies only when a single injunction or declaratory judgment would provide relief to each member of the class. It does not authorize class certification when each individual class member would be entitled to a *different* injunction or declaratory judgment against the defendant.” Dukes, 564 U.S. at 360 (emphasis in original). Any “disparate factual circumstances of class members’ may prevent a class from being cohesive.” Gates v. Rohm & Haas, 655 F.3d 255, 264 (3d Cir. 2011) (quoting Carter v. Butz, 479 F.2d 1084, 1089 (3d Cir. 1973)). Thus, “[t]he key to the (b)(2) class is ‘the indivisible nature of the injunctive or declaratory remedy warranted—the notion that the conduct is such that it can be enjoined or declared unlawful only as to all of the class members or as to none of them.’” Dukes, 564 U.S. at 360 (quotations omitted).

The EPPs’ request for injunctive relief has been somewhat fluid. In their initial Motion for Class Certification, the EPPs sought “an injunction that would help remedy the ongoing anticompetitive effect of Reckitt’s misconduct, such as, for example, compulsory licensing of the film patents to generic competitors, a mandated reduction in Reckitt’s price of the branded film, and/or corrective disclosures concerning the pretextual safety concerns that Reckitt espoused regarding the Suboxone tablet.” (EPPs’ Mem. Supp. Mot. Class Cert. 14.) Thereafter, in their Reply

Brief, the EPPs modified and narrowed their requested relief to “certification of an injunctive class to compel [Reckitt] to issue correction disclosures to remediate the effect of its fabricated safety concerns on Suboxone tablets.” (EPPs’ Reply Supp. Class Cert. 14.) In support of this relief, the EPPs assert that the harm from Reckitt’s misinformation campaign persists because Reckitt never retracted its false statements related to the pediatric safety of Suboxone tablets. As these misrepresentations were allegedly instrumental in moving prescriptions to film, the EPPs assert that they have a “strong interest” in correcting the false impression Reckitt has fostered over the years related to the safety of Suboxone tablets. (Id.)

Such requested relief is not proper for certification under Rule 23(b)(2) for two reasons. First, plaintiffs seeking Rule 23(b)(2) certification must demonstrate “a significant threat of injury from an impending violation . . . or from a contemporary violation likely to continue or recur.” In re Processed Egg Prods., 321 F.R.D. at 559 (quotations omitted). “The threatened injury must be an injury for which the plaintiff would be entitled to compensation if the injury actually occurred.” In re New Motor Vehicles Canadian Export Antitrust Litig., 522 F.3d 6, 13 (1st Cir. 2008). Class certification under Rule 23(b)(2) is “inappropriate when the majority of the class does not face future harm.” Maldonado v. Ochsner Clinic Found., 493 F.3d 521, 525 (5th Cir. 2007) (citation omitted); see also In re Processed Egg Prods., 312 F.R.D. at 169 (declining to certify a 23(b)(2) class where plaintiffs failed to provide the court with sufficient evidence of the defendants’ current policies that are ongoing and threaten future harm, and how an injunction could benefit the class; plaintiffs’ evidence focused on past actions and past harm with only a mere allegation that some of activities were ongoing); Federal Trade Comm’n v. Qualcomm, Inc., No. 17-220, 2019 WL 2206013, at 130–31 (N.D. Cal. May 21, 2019) (holding that although injunctive relief may be appropriate when the unlawful conduct has ceased, the court must consider whether “there exists some cognizable danger of recurrent violation” (quotations omitted)).



Here, the EPPs have not alleged that Reckitt is engaged in any ongoing “misinformation campaign” about the safety of tablets, such that injunctive relief would be halt an impending threat of future misrepresentations. Rather, the EPPs acknowledge that they seek only “corrective disclosures” to correct the “false impression” Reckitt previously fostered over the years related to the safety of Suboxone tablets. As such, the class members face no impending violation or any non-speculative threat of future injury.

The EPPs also have not presented evidence demonstrating how such relief would provide appropriate final relief to the class as a whole. It is well settled that “relief to each member of the class” does not “require that the relief to each member of the class be identical, only that it be beneficial.” Sykes v. Mel S. Harris & Assoc., LLC, 780 F.3d 70 (2d Cir. 2015); see also Brown v. District of Columbia, 928 F.3d 1070, 1083 (2019) (holding that Rule 23(b)(2) requires that a single injunction or declaratory judgment provide relief to each member of the class). Yet, the EPPs have not shown the availability of common evidence establishing that doctors chose to prescribe film over tablets due solely to the alleged safety concern promulgated by Reckitt, or that doctors continue to rely on the past information received from Reckitt in making their prescribing decisions. In turn, without individually determining whether the EPPs received and continue to receive their prescriptions for Suboxone film because of unwarranted concerns about the safety of the tablet, the EPPs cannot establish that “corrective disclosures”—which they do not otherwise define—will remedy the situation or cause medical professionals to start prescribing generic tablets.

Moreover, the proposed injunctive relief in the form of “corrective disclosures” will not benefit patients who no longer take Suboxone film and, thus, no longer will require a prescription. The EPPs claim, without citation to any evidentiary support, that “[a]ddiction is a recurring disease that is rarely defeated in the first instance, and accurate information on potential treatment options, especially when cheaper, equally efficacious alternatives are available, will not only facilitate the

price savings envisioned by the Hatch-Waxman Act but also help alleviate public health burdens related to opioid addiction.” (EPPs’ Reply Supp. Class Cert. 15.) Such speculation, however, does not satisfy the rigorous burden on a motion for class certification. Indeed, Reckitt produces contrary evidence indicating that most patients stop taking Suboxone within a few months, and that about 80% of the patients who started brand Suboxone film therapy in 2012 were no longer using brand Suboxone film by 2017. (Reckitt’s Sur-Reply Opp’n EPPs’ Class Cert., Exs. G & H.) Thus, the EPPs have failed to show that the proposed injunctive relief would inure to the benefit of all EPP class members.

In short, the EPPs have not established that the Rule 23(b)(2) factors favor certification of an injunctive class. The EPPs relegated their request for 23(b)(2) certification to a mere two paragraphs in their Motion and two more brief paragraphs in their reply brief. In doing so, they failed cite to any evidence showing that Reckitt “has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole.” Fed. R. Civ. P. 23(b)(2). Given the deficiencies identified above, I decline to certify the proposed 23(b)(2) class.

### 3. Rule 23(c)(4) Class

The EPPs also seek limited certification of an “issues class” under Federal Rule of Civil Procedure 23(c)(4), of certain individual issues. As noted above, they define the class as:

All persons or entities who purchased and/or paid for some o[r] all of the purchase price for Co-Formulated Buprenorphine/Naloxone (“Suboxone”) in California, Florida, Iowa, Michigan, Minnesota, Mississippi, Nevada, New York, Pennsylvania, Virginia, and Wisconsin in any form for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries at any time during the period January 1, 2011 through the date of class certification.

(EPPs' Mem. Supp. Mot. Class Cert. 7.) With respect to this class, however, the EPPs seek certification of only the following issues:

- a. Whether Defendant engaged in anticompetitive and deceptive conduct;
- b. Whether Defendant willfully maintained monopoly power through such conduct;
- c. Whether Defendant had a specific intent to monopolize;
- d. Whether Defendant has offered a non-pretextual procompetitive justification that could not have been obtained through less restrictive means, and if so;
- e. Whether the anticompetitive effects of Defendant's conduct outweigh their proffered procompetitive benefits, if any.

(Id. at 7–8.) For the following reasons, I find certification to be proper.

Rule 23(c)(4) provides that, “[w]hen appropriate, an action may be brought or maintained as a class action with respect to particular issues.” Fed. R. Civ. P. 23(c)(4). Certification of particular issues under Rule 23(c)(4) is only proper if the other requirements of Rule 23(a) and (b) are first met. 7A C. Wright, A. Miller, & R. Kane, *Federal Practice & Procedure* § 1790, at 590 (2005). “Courts frequently use Rule 23(c)(4) to certify some elements of liability for class determination, while leaving other elements to individual adjudication.” Carroll v. Stettler, No. 10-2262, 2011 WL 5008349, at \*4 (E.D. Pa. Oct. 19, 2011) (citing Chiang v. Veneman, 385 F.3d 256, 267 (3d Cir. 2004)). The Third Circuit has instructed that when certifying an issue class, the issues to be tried should be clearly enumerated. Gates v. Rohm & Haas Co., 655 F.3d 255, 273 (3d Cir. 2011) (citing Wachtel v. Guardian Life Ins. Co. of Am., 453 F.3d 179, 184–85 (3d Cir. 2006)). Likewise, the district court should explain how class resolution will “fairly and efficiently” advance the resolution of the class members’ claims. Id. (citing *Principles of the Law of Aggregate Litigation* §§ 2.02(e) (2010)). Finally, issue certification is a matter left to the court’s discretion, but the decision to certify a particular issue, like any other certification decision under Rule 23, “must be supported by rigorous analysis.” Hohider v. United Parcel Serv., Inc., 574 F.3d 169, 201 (3d Cir. 2009).

Reckitt challenges the certification of the “issues” class on two grounds. First, it contends that the liability issues class is not ascertainable. Second, it asserts that the class is not cohesive. I address each challenge individually.

*a. Ascertainability*

“[A]scertainability” is closely tied to the requirement that plaintiffs provide a proper class definition. Byrd v. Aaron’s, Inc., 784 F.3d 154, 164 (3d Cir. 2015). “A trial court . . . needs a class to be ‘defined with reference to objective criteria’ and some assurance that there can be ‘a reliable and administratively feasible mechanism for determining whether putative class members fall within the class definition,’ in order to rigorously analyze the explicit Rule 23(a) and (b) certification requirements.” Id. at 164–65 (internal citations omitted). The separate ascertainability requirement ensures that class members can be identified after certification and, therefore, “prepares a district court to direct to class members the best notice that is practicable under the circumstances.” Id. at 165 (quotations omitted). “If class members are impossible to identify without extensive and individualized fact-finding or ‘mini-trials,’ then a class action is inappropriate.” Marcus v. BMW of N. Am., LLC, 687 F.3d 583, 593 (3d Cir. 2012).

The Third Circuit has clarified that the ascertainability inquiry is “narrow.” Byrd, 784 F.3d at 165. “If defendants intend to challenge ascertainability, they must be exacting in their analysis and not infuse the ascertainability inquiry with other class-certification requirements.” Id. “[A]scertainability only requires the plaintiff to show that class members can be identified.” Carerra v. Bayer Corp., 727 F.3d 300, 308 n.2 (3d Cir. 2013). The proposed method for identifying class members must be “administratively feasible,” meaning that “identifying class members is a

manageable process that does not require much, if any individual factual inquiry.”<sup>25</sup> Carrera, 727 F.3d at 307–08.

Reckitt contends that the class is not ascertainable because there is no list of class members, that the EPPs never served any subpoenas that might have yielded the data necessary to generate a list of class members, and that the EPPs refused to provide the patient names that were known to them.<sup>26</sup> Reckitt further argues that the EPPs should not be permitted to re-open discovery to serve subpoenas in order to generate a list of class members, and that the EPPs provided no explanation as to why they think new subpoenas will yield data when previous such subpoenas served by Reckitt were refused on HIPAA grounds.<sup>27</sup>

Reckitt’s argument imposes too high a burden. The EPPs need not identify the class members at this juncture of the litigation. As noted above, ascertainability only requires a showing of a process through which class members can be successfully identified.<sup>28</sup> For the following reasons, I find that the EPPs have done so.

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<sup>25</sup> The parties dispute whether this ascertainability requirement applies to a class under Rule 23(c)(4). Reckitt contends that such a class must be ascertainable to be certifiable. The EPPs counter that the ascertainability inquiry has no place in certification of an issues class.

The parties have cited to no legal guidance on this issue, and the Third Circuit has yet to address whether ascertainability must be analyzed in Rule 23(c)(4) issues class. Because I find that the ascertainability requirements have been met, I need not resolve this question.

<sup>26</sup> (See Reckitt’s Opp’n EPPs’ Class Cert., Ex. 1, Decl. of Nicolas Hidalgo (“Hidalgo Dep.”).)

<sup>27</sup> The Health Insurance Portability and Accountability Act (“HIPAA”) puts limitations on the ability of covered entities, such as health plans and health care providers, to use protected health information. Citizens for Health v. Leavitt, 428 F.3d 157, 173 (3d Cir. 2005).

<sup>28</sup> Reckitt’s case citations in support of their argument are distinguishable. In Vista Healthplan, Inc. v. Cephalon, Inc., No. 06-1833, 2015 WL 3623005 (E.D. Pa. June 10, 2015), the plaintiffs merely provided their own “assurances” that “comprehensive records documenting any purchase of Provigil can be easily obtained from any number of reliable objective sources,” without detailing any reliable methodology for identifying class members. Id. at \*9. In Fenwick v. Ranbaxy Pharms., Inc., 353 F. Supp. 3d 315, 327–28 (D.N.J. 2018), the plaintiffs proposed a methodology for

First, the EPPs have provided the unchallenged Declaration of Myron Winkelman, the president of a company providing pharmacy benefit management services to commercial and governmental health plans, and federal and state governmental agencies. (EPPs’ Mot. Class Cert., Ex. 4, Decl. of Myron Winkelman (“Winkelman Decl.”), ¶ 1.) According to Mr. Winkelman, the EPP class is comprised of two types of class members: third-party payors (“TPPs”)—who are health and welfare plans or insurance companies that pay and/or reimburse for prescription drug purchases of their members—and consumers—who are individuals who purchase prescription drugs. (Id. ¶ 18.) Winkelman states that pharmacy benefit managers (“PBMs”) and pharmacies maintain data that can be used to identify TPPs and consumers, including the prices each paid and/or reimbursed for Suboxone or generic Suboxone. (Id. ¶¶ 22–38.) This data includes the total amount paid by the TPP’s member, as well as the total amount paid by the TPP for each prescription the PBM processes. (Id. ¶ 29.) In addition, PBMs are able to identify consumers with flat co-payment benefit plans, and can also identify the name and address of the consumer who made the purchase of Suboxone and generic Suboxone. (Id.) Even in instances where an insurer is acting as its own PBM, large insurers must still comply with processing standards set by the National Council for Prescription Drug Programs (“NCPDP”) and will maintain these records in their own database. (Id. ¶ 33.) The EPPs have submitted exemplar purchase data reflecting their ability to determine who purchased Suboxone during the relevant time period. (Id. ¶ 35, EPPs’ Mot. Class Cert., Ex. 3.) According to Winkelman, only a small percentage of fully uninsured, cash-paying consumers would not show up in the various databases. (Winkelman Decl. ¶¶ 21, 37.) The EPPs note that these individuals can self-identify with their own records at a claims process.

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identifying potential class members, but that methodology included within it consumers who did not purchase any of the recalled pills at issue. Id. at 327–28. Neither of these problems exists here.

Given the availability of this information, Interim Co-Lead counsel for the EPPs then explain that if the class is certified, the Court could issue subpoenas pursuant to 45 C.F.R. § 164.512(e)(1)<sup>29</sup> in order to overcome the HIPAA protections on the materials. (EPPs’ Mot. Class Cert., Ex. 1, Decl. of Kenneth Wexler (“Wexler Decl.”), ¶ 11.) Such subpoenas would be directed to the top six PBMs, the ten largest TPPs, the top ten chain store pharmacies, and the top five mail order pharmacies to request the production of records identifying purchasers of branded and generic Suboxone during the relevant period. (Id. ¶ 11.) Counsel explain that they would then retain OnPoint Analytics (“OnPoint”) to analyze the data, under a protective order, and compile a list reflecting the identities of those in the data who fit the class definition. (Id. ¶¶ 12–13.)

Reckitt does not dispute the efficacy of this methodology and, in fact, concedes that it may have been persuasive had EPPs filed their motion for class certification prior to fact discovery. Reckitt asserts, however, that the closing of fact discovery precludes the issuance of new subpoenas to combine the data into a usable list of class members. Reckitt posits that the EPPs have not explained why they failed to gather this crucial information during the years before fact discovery closed and that the absence of any current list of class members precludes the EPPs from using discovery to obtain one.

This argument confuses discovery with class notice. Post-discovery, post class-certification subpoenas are permissible to identify class members and issue notice of the class action. See, e.g., In re Relafen Antitrust Litig. v. Smithkline Beecham, No. 01-12239, 2004 U.S. Dist. LEXIS 29834, at \*17–19 (D. Mass. Nov. 24, 2004) (authorizing end-payor plaintiffs, after class certification, to issue subpoenas to providers of retail pharmacy services and providers of PBM services to obtain

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<sup>29</sup> See 45 C.F.R. § 164.512(e)(1) (“A covered entity may disclose protected health information in the course of any judicial or administrative proceeding: [i]n response to an order of a court or administrative tribunal, provided that the covered entity disclosed only the protected health information expressly authorized by such order.”).

access to electronic files of the names and addresses of consumers of the relevant drug, as well as information regarding the consumer's expenditures). Indeed, the EPPs have submitted a Declaration from Carla Peak, Vice President of Legal Notification Services at KCC, LLC—a national class action notice provider and class administrator—who identifies more than twenty class actions in which her firm has implemented such class action notice. Reckitt identifies no authority for its contention that the class member list should have been compiled prior to the actual certification of the class.

As I find that the EPPs have identified a feasible methodology for identifying class members, I reject Reckitt's ascertainability argument.

*b. Cohesiveness*

The Third Circuit has indicated that when deciding whether a proposed issues class is cohesive, the trial court should consider:

[T]he type of claim(s) and issue(s) in question; the overall complexity of the case; the efficiencies to be gained by granting partial certification in light of realistic procedural alternatives; the substantive law underlying the claim(s), including any choice-of-law questions it may present and whether the substantive law separates the issue(s) from other issues concerning liability or remedy; the impact partial certification will have on the constitutional and statutory rights of both the class members and the defendant(s); the potential preclusive effect or lack thereof that resolution of the proposed issue class will have; the repercussions certification of an issue(s) class will have on the effectiveness and fairness of resolution of remaining issues; the impact individual proceedings may have upon one another, including whether remedies are indivisible such that granting or not granting relief to any claimant as a practical matter determines the claims of others; and the kind of evidence presented on the issue(s) certified and potentially presented on the remaining issues, including the risk subsequent triers of fact will need to reexamine evidence and findings from resolution of the common issue(s).



Gates v. Rohm and Haas Co., 655 F.3d 255, 273 (3d Cir. 2011) (the “Gates factors”). This list is non-exclusive. Id.

In challenging the cohesiveness of the proposed issues class, Reckitt focuses on three of the foregoing elements. Primarily, it contends that the EPPs cannot show that liability is capable of classwide treatment when they concede that injury is not. Second, Reckitt asserts that the common issues here are not divisible from the individual issues. Finally, it claims that resolution of the common issues will not materially advance the litigation.

i. Separation of Liability and Injury

Reckitt first contends that the EPPs’ effort to separate “liability issues” from “antitrust injury and damages” fails because individual injury, also known as antitrust impact, is an element of the cause of action, *i.e.*, every class member must prove at least some antitrust impact resulting from the alleged violation in order to prevail on the merits. Reckitt asserts that the EPPs effectively concede that antitrust injury cannot be proven through common evidence. Rather, such issues would need to be resolved following individual trials regarding reliance and causation.

Reckitt’s argument fails in its mis-characterization of the proposed class as a “liability class.” Reckitt is correct that, to prove liability, an antitrust plaintiff must demonstrate “(1) a violation of the antitrust laws . . . , (2) individual injury resulting from that violation, and (3) measurable damages.” In re Hydrogen Peroxide Antitrust Litig., 552 F.3d 305, 311 (3d Cir. 2008). But, the EPPs’ Motion for Class Certification does not—and need not—seek to prove all of these required liability elements through common evidence. See Chiang v. Veneman, 385 F.3d 256, 267 (3d Cir. 2004) (“[C]ourts commonly use Rule 23(c)(4) to certify some elements of liability for class determination, while leaving other elements to individual adjudication—or, perhaps more realistically, settlement.”), abrogated on other grounds, Marcus v. BMW of N. Am., 687 F.3d 583

(2012). Rather, the request for class certification focuses solely on the first element—a violation of the antitrust laws through monopoly power and exclusionary conduct.

Liability for anticompetitive conduct centers on the defendants’ conduct, not the actions of individual class members and, thus, the issue is susceptible to classwide proof. In re Warfarin Sodium Antitrust Litig., 391 F.3d 516, 528 (3d Cir. 2004); see also In re Flonase Antitrust Litig., 284 F.R.D. 207, 219–20 (E.D. Pa. 2012) (noting that the issues relevant to proving liability can be proven through class-wide, common evidence because the issues focus on the defendant’s conduct, not the conduct of the individual class members). Moreover, even though various state laws are used for the EPP issues class, these issues will utilize the same operative evidence to establish liability. See In re Flonase, 284 F.R.D. at 219 (citing Sullivan v. DB Invs., Inc., 667 F.3d 273, 301 (3d Cir. 2011) (emphasizing that any minor variations between state laws will not defeat class certification “as long as a sufficient constellation of common issues binds class members together”); In re Terazosin Hydrochloride, 220 F.R.D. 672, 697–98 (S.D. Fl. 2004) (certifying a class of indirect purchasers in part because “the same common operative facts that form the basis for each of the state classes’ antitrust claims form the basis for the unjust enrichment claims”)).

As set forth above in detail with respect to the DPP class, the EPPs also seek to offer common evidence that Reckitt engaged in a nationwide and market-wide hard switch scheme to move prescriptions from tablet to film. “If each class member pursued its claims individually, the class member would have to prove the same antitrust . . . violations using the same documents, witnesses, and other evidence.” In re Wellbutrin XL Antitrust Litig., 282 F.R.D. 126, 140 (E.D. Pa.

2011). The fact that the EPPs cannot use common evidence to prove antitrust impact is irrelevant as they do not seek to certify this issue.<sup>30</sup>

ii. Common Issues Divisible from Individual Issues

Reckitt next argues that when “issues are not susceptible to ‘proof by common evidence[,] . . . [n]o efficiencies are gained by litigating [them] on a classwide basis.” (Reckitt’s Opp’n EPPs’ Class Cert. 21 (quoting Gonzales v. Corning, 885 F.3d 186, 202 (3d Cir. 2018)).) It contends that one of the core issues identified by the EPPs is whether Reckitt engaged in “deceptive conduct” or “deception”—*i.e.*, whether Reckitt coerced purchases of Film “by making unfounded claims that tablets were unsafe,” and whether [t]his false safety issue was then . . . broadcast to the FDA, doctors, other industry participants, and the public in an effort to destroy demand for Suboxone tablets.” (Id. at 21.) Reckitt posits that deception cannot be proved in the abstract and that, for each patient in the class, one “would need to know what precisely was told to each class member’s doctor, the context in which the communications were delivered, whether those communications were portrayed as fact

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<sup>30</sup> The cases Reckitt cites in support of its argument are distinguishable. In Romero v. Allstate Ins. Co., 52 F. Supp. 3d 715 (E.D. Pa. 2014), a non-antitrust case, the plaintiffs sought to invalidate a release on the grounds that it was void as part of an illegal transaction. Id. at 721. The plaintiffs requested issue certification on the question of whether the release was “part and parcel” of the underlying transaction being challenged, but not on the crucial issue of whether the transaction being challenged was, in fact, an independent violation of the law. Id. at 737. As such, the plaintiffs “effectively concede[d] that certification of this issue would not create any efficiencies in the upcoming Release-related trial” since there would need to be “circuitous and duplicative testimony” in the subsequent trials. Id. Here, by contrast, the common evidence for the anticompetitive conduct and market power portions of the EPPs’ antitrust claim will not be relevant to antitrust impact or damages.

Reckitt also cites to In re ConAgra Foods, Inc., 302 F.R.D. 537, 581 (C.D. Cal. 2014), where the court declined to certify a class to litigate whether the defendant misled consumers, finding that the plaintiffs would need to prove individualized reliance and causation such that the requested issue class would not necessarily even determine the defendant’s liability. Id. at 581. That case, however, involved a claim of misleading marketing of a brand of cooking oils, made from GMOs as “100% natural.” Id. at 563. The court only denied certification of the issues class without prejudice, noting that “[w]hile this is an issue that is common to all members of all proposed classes . . . it is unclear, at this stage, what ultimate objective certifying a class to try this issue would advance.” Id. at 581.

or opinion, whether the scope and limits of the underlying evidence was disclosed, and whether the doctor issued a prescription because of the alleged deception.” (Id.)

This argument again conflates the element of an antitrust violation with the element of antitrust impact. “[P]roof of [an antitrust] violation and of antitrust injury are distinct matters that must be shown independently.” Atl. Richfield co. v. USA Petroleum Co., 495 U.S. 328, 344 (1990) (quotations omitted). None of the questions concerning antitrust violation sought to be certified by the EPPs require any inquiry into the individualized questions that will necessarily come into play with regard to antitrust impact. Rather, the focus of inquiry will be entirely on Reckitt’s words and actions. As I noted in an earlier decision in this case, “[t]he key question is whether the defendant combined the introduction of a new product with some other wrongful conduct, such that the comprehensive effect is likely to stymie competition, prevent consumer choice and reduce the market’s ambit.” In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig., 64 F. Supp. 3d 665, 682 (E.D. Pa. 2014). Whether any individual class member relied on the deceptive conduct or was otherwise influenced by the deceptive conduct<sup>31</sup> is completely separable from the common issue of whether Reckitt filed a baseless Citizen Petition and knowingly engaged in the deceptive conduct of manufacturing and disseminating false safety concerns about tablets in an intended effort to influence prescribing habits.<sup>32</sup> See In re Foreign Exchange Benchmark Rates

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<sup>31</sup> Reckitt engages in a lengthy discussion about Patient X and what such an individual would need to prove in order to establish antitrust injury and damages. As the EPPs do not seek to certify a class as to injury or damages, I need not address this discussion.

<sup>32</sup> Reckitt suggests that attempting to separate common and individual issues would not only be impractical, but also unconstitutional. It explains that issues classes implicate the Seventh Amendment when they would require juries at the individual trials to reexamine issues settled at the class trial. (Reckitt’s Opp’n EPPs’ Class Cert. 22 (citing Castano v. Am Tobacco Co., 84 F.3d 734, 750 (5th Cir. 1996); Hostetler v. Johnson Controls, Inc., No. 15-226, 2018 WL 3868848, at \*87 (N.D. Ind. Aug. 15, 2018)). With little further explanation, Reckitt concludes that the division of issues here would violate the Seventh Amendment.

Antitrust Litig., No. 13-7789, 2019 WL 4171032, at \*9–10 (S.D.N.Y. Sept. 3, 2019) (declining to certify 23(b)(3) class because of individual issues regarding impact, but certifying a Rule 23(c)(4) as to the existence of an antitrust conspiracy and the defendants’ participation in the conspiracy).

iii. Materially Advancing the Litigation

In its final effort to defeat certification of a Rule 23(c)(4) class, Reckitt contends that the proposed issues class fails to materially advance the litigation because it leaves “significant and complex questions unanswered.” (Reckitt’s Opp’n EPPs’ Class Cert. 22 (quoting Gates, 655 F.3d at 273).) It posits that several questions cannot be resolved through class proceedings, including (1) causation (whether the wrongful conduct affected which product a patient purchased); (2) injury (whether individual patients would have paid less for an alternative product in the but-for world); (3) damages (the precise calculation of damages for each class member); and (4) unjust enrichment. In addition, it argues that due to variations in the consumer protection laws from state to state, it is not feasible to try such varied claims in a single trial.

Considering the factors enumerated by the Third Circuit in Gates, and set forth above, I disagree with Reckitt and conclude that certification of the proposed issues class will indeed materially advance the litigation. As explained at length here, the issue of anticompetitive conduct is wholly severable from the issues of antitrust impact and damages, as the anticompetitive conduct

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I find no such Seventh Amendment concerns here. The Seventh Amendment provides that “no fact tried by a jury, shall be otherwise reexamined in any Court of the United States, than according to the rules of the common law.” U.S. Const., amend VII. Notably, Reckitt fails to identify any common issues that would have to be reexamined and/or relitigated at any subsequent individual proceedings. Indeed, the issue of antitrust violation is “so distinct and separable” from the issue of antitrust impact that these issues “can be cleanly divided amongst separate trials without injustice.” In re Program Antitrust Litig., No. 11-2242, 2014 U.S. Dist. LEXIS 138429, at \*14 (D. Mass. June 10, 2014) (noting that litigation of an antitrust violation would focus entirely on the defendant’s conduct and state of the product market, whereas, assuming such violation, a trial of antitrust impact and damages would involve fact-finding regarding whether a particular plaintiff made a purchase of the drug at a supracompetitive price and the amount of any overcharges incurred) (internal quotation marks and quotations omitted).

inquiry looks solely at the actions of the defendant without regard to their impact on any individual class members. Proof of this issue alone is a significantly complex question that will require copious amounts of witness testimony, documents, and expert analysis, all of which will be common to each individual class member. In lieu of having each individual plaintiff produce this evidence at a separate trial, issue certification will allow these determinations to be made by a single factfinder, leaving only the individual determinations concerning impact and damages for separate trials.

Moreover, as detailed above, the differences in state law, while perhaps relevant to a plaintiff's ultimate ability to recover, will not bear significantly on whether Reckitt's conduct was unlawful. Reckitt has not persuasively identified any unconstitutional or otherwise preclusive effect that resolution of the proposed class issues will have, nor has Reckitt shown any plausible risk that subsequent triers of fact will need to reexamine evidence and findings from resolution of the common issues.

Ultimately, common resolution of the proposed class issues—whether Reckitt engaged in anticompetitive and deceptive conduct; whether Reckitt willfully maintained monopoly power through such conduct; whether Reckitt had a specific intent to monopolize; whether Reckitt has offered a non-pretextual procompetitive justification that could not have been obtained through less restrictive means, and if so; whether the anticompetitive effects of Reckitt's conduct outweigh their procompetitive justifications—will either obviate the need for further individual trials or will fairly and efficiently advance those individual trials by definitively resolving multiple questions common to the class.

c. Conclusion Regarding the EPPs' Rule 23(c)(4) Class

As I find that the proposed 23(c)(4) class is both ascertainable and cohesive, I find that the class should be certified on the questions identified by the EPPs. Accordingly, I will grant the EPPs' Motion for Class Certification in this respect.

#### **IV. CONCLUSION**

In light of the foregoing, I find that class certification for both the DPPs and the EPPs is warranted in part.

As to the DPPs, I conclude, upon “rigorous scrutiny,” that they have sufficiently established all of the Rule 23(a) factors, as well as predominance and superiority under Rule 23(b)(3). Thus, I certify the Class in its entirety. In connection with that decision, I deny Reckitt’s Motion to Exclude the Opinion of Russell Lamb.

As to the EPPs, I find that they have not proven that their requested injunctive class would provide appropriate final relief to the class as a whole. Therefore, I decline to certify their class under Rule 23(b)(2). I find, however, that the EPPs have sufficiently proven, under the myriad of considerations enumerated by the Third Circuit, that the identified issues for the Rule 23(c)(4) issues class warrant common resolution and, thus, certification.

An appropriate Order follows.