

**August 22, 2022**

**ATTORNEY GENERAL RAOUL ANNOUNCES SIGNIFICANT VICTORY IN LITIGATION AGAINST  
SUBOXONE MANUFACTURER**

***Ongoing Lawsuit Alleges Indivior Inc. Conspired to Maintain Monopoly Profits***

**Chicago** — Attorney General Kwame Raoul today announced that the U.S. District Court in the Eastern District of Pennsylvania ruled that 42 states, including Illinois, can proceed with their litigation against the makers of Suboxone, a prescription drug used to treat opioid addiction. Raoul and the coalition have alleged Indivior Inc. (Indivior) unlawfully engaged in a scheme to block generic competitors, forcing people to pay artificially high prices during a time when the manufacturing companies reaped more than \$3 billion in profits.

“Our lawsuit alleges that at a time when our country was grappling with a massive opioid epidemic, Indivior was working behind the scenes to limit competition and maximize profits for its drug used to treat opioid addiction,” Raoul said. “I am committed to holding accountable companies that unlawfully took advantage of the opioid crisis, and I am pleased that this lawsuit will continue.”

[In a sweeping ruling](#), Judge Mitchell Goldberg denied Indivior’s motions for summary judgment, holding that the plaintiff states’ lawsuit may proceed. Noting that the volume of facts required “enormous judicial resources” to wade through, the court’s 86-page opinion denied all of Indivior’s motions for summary judgment, and ruled in the states’ favor.

The Illinois Attorney General’s office [filed a bipartisan lawsuit](#) against Indivior, previously Reckitt Benckiser Pharmaceuticals Inc., in 2016. The lawsuit alleges that in order to preserve its drug monopoly, Indivior used illegal means to switch Suboxone from a tablet version to a film that dissolves in the mouth, while attempting to destroy the market for tablets. A trial has not yet been scheduled but is expected next year.

In 2021, Attorney General Raoul announced a \$300 million national settlement with Indivior to resolve a separate lawsuit over allegations Indivior inappropriately marketed Suboxone, which resulted in millions of dollars in improper state Medicaid spending. In that lawsuit, Raoul and a coalition of state attorneys general alleged Indivior and its subsidiaries used deceptive marketing tactics – namely, knowingly promoting the sale and use of Suboxone for uses that were unsafe, ineffective and medically unnecessary – to boost sales of Suboxone. The company’s aggressive practices resulted in false claims being submitted to states’ Medicaid programs.

Suboxone is a brand-name prescription drug used to treat heroin addiction and other opioid addictions by easing addiction cravings. Suboxone and its active ingredient, buprenorphine, are powerful and addictive opioids.

Attorney General Raoul is joined in this victory by the attorneys general of Alabama, Alaska, Arkansas, California, Colorado, District of Columbia, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, West Virginia and Wisconsin.

Bureau Chief Elizabeth L. Maxeiner is handling the litigation for Raoul’s Antitrust Bureau.



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## **MEMORANDUM OPINION**

Defendant Reckitt Benckiser, Inc. (“Reckitt”) manufactures Suboxone, a drug commonly used to combat opioid addiction.<sup>1</sup> Suboxone previously came in tablet form, but in 2010, citing safety concerns, Reckitt effectuated a change in the administration of this drug, switching from tablet to sublingual film. Various purchasers/consumers of Suboxone—including a group of direct purchasers, a group of ultimate consumers, and a group of States’ Attorneys General (collectively, “Plaintiffs”)—claimed that this switch was anticompetitive and solely designed to maintain Reckitt’s market exclusivity, a scheme known as a “product hop.” These claims have resulted in multi-district, antitrust litigation before this Court.

Before me are two Motions for Summary Judgment filed by Reckitt, one pertaining to all claims and a second pertaining to specific plaintiffs and remedies. Because I find that issues of material fact exist, I will deny both motions. This Opinion sets forth my reasoning.

### **I. FACTUAL AND PROCEDURAL BACKGROUND**

In connection with the summary judgment briefing, Reckitt has submitted 126 pages of “undisputed facts,” while Plaintiffs have submitted 339 pages of “responses and objections” as well as 159 pages of “additional” facts. In response, Reckitt submitted another 53 pages of “responses” to Plaintiffs’ additional facts. Aside from requiring an enormous amount of judicial resources, any attempt to synthesize these submissions would essentially amount to a trial on the papers. Accordingly, the following factual recitation sets forth a more concise version of the pertinent facts. To the extent a review of additional evidence is necessary, I will examine that evidence in the “Discussion” section.

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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 Indivior as “Reckitt.”

For purposes of general background, the following facts are derived from the evidence submitted by the parties. Where there is conflicting evidence about a particular fact, Federal Rule of Civil Procedure 56 requires that I view such evidence in the light most favorable to Plaintiffs.<sup>2</sup>

**A. Regulatory Background**

To understand the claims and defenses in this case, a brief overview of certain regulatory processes is necessary. As previously set forth in my Memorandum Opinion granting class certification:

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 (“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.

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, . . . [i]f 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.

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

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<sup>2</sup> References to the parties’ pleadings will be made as follows: Defendant Reckitt’s Statement of Undisputed Facts (“DSUF”); Plaintiffs’ Response (“PR”), Plaintiffs’ Additional Statement of Facts (“PASF”), and Defendant Reckitt’s Response (“DR”). To the extent a statement is undisputed by the parties, I will cite only to the parties’ submissions. If a statement is disputed and the dispute can be easily resolved by reference to the exhibits, I will cite the supporting exhibits. If a statement is disputed, but the dispute cannot be resolved by reference to the exhibits, I will note the dispute. I will not rely on any statement of fact that is unsupported by reference to a specific exhibit.

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.

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.

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.

## 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.

## 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.

In re Suboxone Antitrust Litig., 421 F. Supp. 3d 12, 26–28 (E.D. Pa. 2019) (internal citations omitted).

**B. 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. (DSUF ¶ 3; PR ¶ 3.)

The FDA approved Subutex tablets and Suboxone tablets for the treatment of opioid dependence on October 8, 2002. (DSUF ¶ 2; PR ¶ 2.) These products were developed in cooperation with the United States National Institute on Drug Abuse under a Cooperative Research and Development Agreement. (Pls.’ Ex. 30.) The FDA awarded Reckitt “orphan drug exclusivity” for these products, which precluded approval of certain competing products during the exclusivity period. (DSUF ¶ 4; PR ¶ 4.) That orphan drug exclusivity period for both Suboxone tablets and Subutex tablets expired on October 8, 2009. (DSUF ¶ 6; PR ¶ 6.)

**C. Plans for a New Formulation of Suboxone and Withdrawal of Suboxone Tablets**

By April 2006, a group of executives from Reckitt and its UK parent, Reckitt Benckiser Group (“RBG”)—jointly known as the Buprenorphine Business Group—began exploring the introduction of a new buprenorphine product. (Pls.’ Ex. 108.) As a part of what it termed its “Generic Defense Strategy,” RBG executives considered a new formulation developed by a company called MonoSol,

Inc. (“MonoSol”).<sup>3</sup> (Pls.’ Ex. 183.) MonoSol communicated that it could create a new formulation of buprenorphine as a sublingual film—a formulation which would not be AB-rated with the tablet form of Suboxone and, therefore, could not automatically be substituted by a pharmacist with a generic tablet or any other non-film dosage form delivering the same active ingredients. (Pls.’ Ex. 188.) The RBG executives were “excited by the potential the development ha[d] regarding the level of [intellectual property] protection and managed care benefit.” (Id.)

Originally, Buprenorphine Business Group executives questioned whether MonoSol film would provide an effective generic defense in the United States, and Reckitt executives expected that film would be more expensive than tablets to make and sell. (Pl.’s Exs. 184, 187.) Accordingly, Reckitt sought a Regulatory Strategy Opinion from an independent consultant, who observed that Reckitt “wishes to strengthen their market position and defend against generic intrusion.” (Pls.’ Exs. 185, 426.) The Opinion noted that, in order to be successful, the plan would require Reckitt to “replace the current sublingual tablet product with an ODF [rapidly dissolving film] formulation and then withdraw the tablet from market. This would prevent generic companies from achieving an AB-rated product using the sublingual tablet as the reference listed drug (RLD).” (Id.)

Ultimately, after development of the film formulation, Reckitt opted to launch the film at least in part to mitigate the impact of impending generic competition to the Suboxone tablet. (Pls.’ Ex. 289.) At the same time, and in accordance with MonoSol’s proposal, Reckitt planned to withdraw the Suboxone tablet from the market so that no generic tablets could be registered with reference to Suboxone. (Pls.’ Ex. 192.) Reckitt, however, recognized that it would need to have a sound basis for its decision to withdraw the Suboxone tablet from the market, noting in its internal emails:

[T]his plan was dependent upon safety benefits of the film over the tablet – which are needed to justify withdrawal of the tablets from the markets. However, the benefits need to be demonstrated and this may

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<sup>3</sup> MonoSol is now known as Aquestive Therapeutics, Inc. and is a named Defendant in the States’ action. As the relevant evidence uses the name “MonoSol,” I will, for purposes of this Memorandum Opinion, refer to Aquestive as “MonoSol.”



push the project delivery date beyond 2009 if e.g., some studies on safety are required. If this is the case then the plan falls down because the generics will be able to reference Suboxone and gain access to the market. This may need to be explored further e.g. question which elements of the formulation/packaging may improve safety; timing of safety studies (parallel with license applications etc.).

(Pls.' Ex. 192.)

In connection with the plan to withdraw the tablet on safety grounds, Reckitt's CEO, Shaun Thaxter, realized that there was "a high level of sensitivity at the moment to unintentional childhood exposure to buprenorphine." (Pls.' Ex. 164.) Accordingly, he decided to "leverage this to [Reckitt's] advantage by getting the FDA to mandate that all drugs qualifying under DATA 200 of the treatment of addiction should have each dose wrapped in its own child-proof pack." (Id.) He remarked that this worked perfectly for the sublingual film because Reckitt could introduce child-proof packs with the film and have it mandated that generic tablet manufacturers do the same. (Id.) As such, Reckitt developed a plan to introduce the film in June 2009, transition patients from tablet to film, and then withdraw the tablets altogether prior to October 2009, when its orphan drug exclusivity expired. (Pls.' Ex. 267.)

In a January 2009 presentation regarding film marketing strategy, Reckitt set forth its strategies with respect to the launch of film:

- Create understanding of the Strip's [film's] benefits while compound is under review at the FDA (clinicians and patients)
- Leverage combined HTH/Strip benefits to persuade prescribers to transition existing Suboxone patients to the Strip upon approval and to write new scripts for the Strip
- *Post-launch*, market *against* Suboxone tablets to minimize market share loss to ANDA [abbreviated new drug application] generics
- Position Strip as less liable to abuse & pediatric exposure, more traceable for diversion than Suboxone tablets
- Maximize Suboxone brand equity through new line extension
- By emphasizing Reckitt's commitment to removing barriers to success, raise corporate profile as leader in addiction medicine.

(Pls.' Ex. 287, at slide 16.)

**D. Reckitt Markets Film’s Superiority to Tablet in Terms of Safety**

In an October 2009 draft Marketing Plan, Reckitt intended to “[e]stablish the public health value of the 2<sup>nd</sup> generation of Suboxone treatment in 2010 in the USA.” (Pls.’ Ex. 229, at slide 27.) To do so, Reckitt proposed to emphasize that film would “[r]educ[e] the number of unintended pediatric exposures to Suboxone . . . [i]mprove quality of care for patients to optimize their compliance with treatment . . . [d]ecrease the incidence of diversion & misuse . . . [and] [m]aintain current levels of access to Suboxone treatment for patients.” (Id. at slide 28.) Reckitt recognized, however, that to support a marketing plan that one form of Suboxone had a safety benefit over another, it would need a strong scientific data set. (PASF ¶¶ 37–40.)

In connection with Reckitt’s NDA for Suboxone film, the FDA considered film’s potential for abuse and diversion. (Pls.’ Ex. 79.) The FDA remarked that, based on the findings in Reckitt’s clinical trial data, “expanded use of this product [film] will result in significant abuse and diversion that needs to be considered.” (Id.) The FDA noted a “high incidence of drug unaccountability in subjects who completed the trial and those who were discontinued in each of the three clinical sites. This is predictive of the likely occurrence of diversion after the drug is approved and marketed.” (Id.) Because the FDA found that Reckitt’s clinical study was poorly designed and conducted, it found that it was “not useful for demonstrating any difference in the safety profile or abuse potential of these two formulations [tablet and film].” (Id.)

Reckitt remained cognizant that Suboxone film had the potential for misuse and diversion. (Pls.’ Ex. 29, Reuter Dep., 45:16–22; PASF ¶ 47.) Indeed, Reckitt received reports that film could be dissolved in water and ingested through the nose. (PASF ¶ 46.) Yet, Reckitt did no studies to determine the injectability potential of film or the number of film patients who were injecting the film. (Pls.’ Ex. 29, Reuter Dep. 157:18–24, 173:6–11.) Vickie Seeger, Reckitt’s employee responsible for collecting and reviewing data on abuse, misuse, and diversion, and pediatric exposures, told several Reckitt executives, on December 20, 2011, that “I am not aware of any data to indicate any differences

in the abuse/diversion of Suboxone tablets versus Suboxone film.” (Pls.’ Ex. 104.) Nonetheless, Patti Weston, Reckitt’s Rule 30(b)(6) witness, testified that, despite the information in its possession, Reckitt’s objective was to get 100% of the highest ranking doctors to accept that the film is less abusable than the tablet because it could not be snorted. (Pls.’ Ex. 41, Weston Dep., 65:8–66:23.) She stated that Reckitt did not have any statistically significant data at the time it released its marketing statements that film reduced the risk of misuse and diversion compared to tablets. (Id. at 67:22–68:5.)

The parties offer conflicting evidence regarding Reckitt’s knowledge of the risks of pediatric exposure in film versus tablet. According to Plaintiffs, Reckitt had received reports of children being exposed to Suboxone film after the foil pouch containing film was opened. (Pls.’ Ex. 104.) Moreover, the FDA, in a March 2010 advice letter, specifically rejected any notion that film was safer than tablets with respect to pediatric exposure, noting that:

[W]e do not agree that the packaging for buprenorphine HCl and naloxone HCl [Suboxone] sublingual film provides meaningful incremental protection against pediatric exposure. Although the foil pouches fulfill the child resistant effectiveness standards and the foil pouch bears warning statements alerting patients to keep out of reach of children, no data were provided to support that these measures will encourage patients to store buprenorphine HCl and naloxone HCL sublingual film in a manner which prevents accidental pediatric ingestion. Because patients are known to divide tablets, it may be expected that patients will remove films from the package and have partial doses that are neither in the child-resistant pouch or in a child-resistant medication bottle. Furthermore, because the film cannot be spit out (unlike a tablet) it is possible that a child who obtains access to even one dose might be more adversely affected than a child who obtains access to a single tablet.

(Pls.’ Ex. 77.) In a May 14, 2012 email, Kim Daly, a senior brand manager for Reckitt, emphasized that based on subsequent studies by Reckitt, “[u]nder no circumstances can we make the claim that Suboxone Film is safer or better at reducing pediatric exposures than Suboxone Tablet.” (Pls.’ Ex. 161.)

According to Reckitt, however, it had sufficient evidence that film was, from a safety perspective, superior to tablets. In support of its position, Reckitt references several pieces of evidence:

- A 2013 study conducted by Reckitt that showed tablets could be prepared for abuse by nasal insufflation (snorting) while film would be more difficult to abuse in this manner. (Def.'s Ex. 187.)
- Two peer-reviewed articles from 2014 and 2017 that found fewer instances of abuse, misuse, and diversion associated with Suboxone film relative to Suboxone tablets and its generic alternatives. (Def.'s Exs. 330, 186.)
- Surveillance data of abuse, misuse, and diversion for Suboxone film as compared to branded and generic tablets from 2011 to 2017 corroborating Reckitt's safety claims. (Def.'s Ex. 170.)

Reckitt's draft 2011 marketing plan proposed to "[p]osition Suboxone tablets as obsolete technology that create a higher risk to public health." (Pls.' Ex. 170; see also Pls.' Ex. 31, Dep of Patti Weston, 95:13–96:10.) Consistent with that plan, Reckitt's sales representatives repeatedly told prescribing physicians that Suboxone film had a lower risk of diversion, abuse, and pediatric exposure. (PASF ¶¶ 71–72.) According to a summary report of this marketing plan prepared for Reckitt, physicians were convinced by these representations and attributed their preference for film in large part to its alleged ability to minimize unintentional pediatric exposure and reduction in the likelihood of misuse and diversion. (Pls.' Ex. 172, slides 49–50; see also Pls.' Ex. 177, slide 9.)

#### **E. Reckitt's Marketing of Film to Insurers**

The parties agree that Reckitt sought to induce insurers to disadvantage tablets by giving film a more favorable placement on formularies of Managed Care Organizations ("MCO"s). Reckitt effectuated this strategy through two primary methods. First, Reckitt pushed a Film-Fail-First policy, which required that a patient must first try the film and "fail" on that treatment before the patient could receive insurance coverage for tablets. Second, Reckitt encouraged MCOs to downgrade tablets from Tier 2 on the formularies to Tier 3, thus increasing the patient copay for tablets. (PASF ¶¶ 111–125; DR ¶¶111–125.)

For example, in September 2011, when some health plans applied the Film-Fail-First policies, the average copay for tablets went from approximately \$41 for a thirty-day supply to the full cash price of approximately \$300. (Pls.' Exs. 236, 242.) Plaintiffs' expert, Dr. Berndt opined that "[t]he

difference between the co-pay for a drug and its full, uncovered cost can be so large that it can make the uncovered product economically out of reach for some (if not many) patients. For such patients, the uncovered product has effectively been withdrawn as an economically feasible option, even if the product is still technically available.” (Def.’s Ex. 1, Berndt Market Effects Rep. ¶ 31.)

Plaintiffs contend that Reckitt also used similar tablet-danger/film-superiority claims to induce the MCOs to adopt policies that would restrict tablet coverage. The final version of Reckitt’s “2009 Business Plan” for the public sector described efforts to ensure that film remained an unrestricted option “due to the benefits of: minimizing diversion and abuse, improving patient outcomes, and improving patient adherence.” (Pls.’ Ex. 200, at slide 37.)

**F. Reckitt’s Steps Towards Withdrawal of the Suboxone Tablet**

As of 2009, Reckitt’s “Managed Care and Public Sector Strategic Intent” was to “[p]repare the payer market for potential tablet withdrawal – Film only offering.” (Pls.’ Ex. 230, at slide 5; see also Pls.’ Ex. 234.) Reckitt planned to tell the market that it would effectuate this withdrawal for safety reasons. In a June 2009 Suboxone Tablet withdrawal strategy “roadmap,” Debby Betz, Reckitt’s Marketing Director, noted, “I would prefer the FDA to ask us to pull the tablets or require that they be packaged in individual child resistant unit dose. . . . If we can build a safety story with [film] it would appear almost unethical to not take the tablet off the market.” (Pls.’ Ex. 246, at slides 6, 8.)

In conjunction with implementing its Film-Fail-First strategy, Reckitt informed insurers that it planned to discontinue the Suboxone tablet. In January 2011, Reckitt told MCO Highmark that, “[w]e are moving away from the Suboxone Tablet. All available resources are being devoted to the manufacturing and marketing of the Suboxone Film. We have not received an official word on when the Tablet will be discontinued but all our actions are moving in that direction.” (Pls.’ Ex. 296.) Reckitt’s president, Gary Phillips, instructed the Managed Care team to tell insurers that “we will be moving to discontinue the Suboxone tab by year end, so they should be helping us to move share to the

film.” (Pls.’ Ex. 93.) By September of 2011, payors were told that Reckitt would be removing the tablet from the market in the first quarter of 2012. (Pls.’ Ex. 224; Def.’s Ex. 191.)

Several MCO executives indicated that their companies made formulary decisions based, at least in part, in reliance on these withdrawal statements. For example, Sarah Marche of Highmark testified that the fact that Suboxone tablets were being pulled from the market affected formulary decisions. (Pls.’ Ex. 20, Marche Dep. 93:24–96:10, 100:9–14.) Similarly, Sandra Reinhardt from Prime Therapeutics stated that her company agreed to remove tablet rebates with the understanding that the tablets were going to be removed from the market. (Pls.’ Ex. 28, Reinhardt Dep., 71:9–15.)

In September 2012, Reckitt provided the FDA with a formal notice of discontinuance for Suboxone tablets. (Def.’s Ex. 188.) On September 25, 2012, Reckitt made a public announcement noting that it was voluntarily discontinuing the supply of Suboxone tablets due the “increasing concerns with pediatric exposure.” (Def.’s Ex. 189.) It remarked that “[w]hile the data do not isolate the root cause of these findings, the child resistant, unit-dosed packaging of Suboxone Film may be one of the key contributing factors to the decrease in exposure rates compared to Suboxone Tablets that are distributed in a multi-dose bottle containing 30 tablets, since the active ingredient of both products is the same. Other factors may include [Reckitt’s] community and healthcare professional education initiatives in addition to the company’s Risk Evaluation and Mitigation Strategy program.” (Id.)

**G. Reckitt Increases the Price of Tablets**

When Reckitt originally launched film, it was priced at parity with tablets, even though film was more expensive to produce. (Pls.’ Ex. 239; see also Pls.’ Ex. 249 (Reckitt’s Chief Financial Officer, Martyn Gibson remarking that “[t]he [costs of goods] for film are also higher than the tablet as the manufacturing supply chain involves a 3<sup>rd</sup> party manufacturer and a secondary packer as opposed to complete in house production per tablets.”).) As of May 2012, however, the tablet began being priced higher per mg than film due to Reckitt’s “increasingly aggressive price increases” on the tablet. (Pls.’ Ex. 249) According to Reckitt, this was a purposeful strategy. (Id.)

In order to effectuate this plan, Reckitt ended rebates on tablets and terminated the “Here to Help” patient assistance program for tablets, offering both to only film patients. (PASF ¶ 160.) Reckitt also increased the price on the tablets in order to “accelerate film conversion.” (Pls.’ Ex. 232.) Although Reckitt recognized that it would “take [a] hit on price protection,” it believed it would realize a “positive [return on investment]” due to film conversion across all accounts. (Id.) Chief Financial Officer Gibson informed CEO Shaun Thaxter that the result of this price increase was to sacrifice short term profits enjoyed from selling lower cost tablets in order to reap the gains of shifting the market to film for which there was no generic competition. (Pls.’ Ex. 249.)

In a November 16, 2010 presentation on “Payer Competitive Strategies,” which described the plan for the December 2010 tablet price increase, Reckitt emphasized that “[c]linical, market, and plan specific data, along with pricing and rebate actions can now be used to further ‘drive a wedge’ between [f]ilm and tablet.” (Pls.’ Ex. 300.) One of the main objectives was to “[d]rive further differentiation from competition by creating a cost differential between tablets and film to drive 50% of payers to prefer film over tablet through formulary actions and pull through programs.” (Id.) Among other strategies, Reckitt intended to “[u]tilize pricing and rebates to drive cost differential for [f]ilm with payers and patients to accelerate conversion and protect our market position.” (Id.) Reckitt planned to then “[c]ommunicate the comparative cost impact to payers using a Budget Impact Model for tablet, Film and Generic to gain payer agreement to prefer Film.” (Id.)

In the fall of 2010, Reckitt sent letters to doctors and patients telling them that, to remain in Reckitt’s patient assistance program (the “Here to Help” program), they needed to switch from tablet to film. (Pls.’ Ex. 310.) This program was designed to help “with patient encouragement, problem solving, and other facilitative interactions to ultimately enhance quality of care and improve treatment outcomes.” It included a live program led by Care Coordinators and Care Coaches, as well as a personalized web-based program. (Pls.’ Ex. 112.)

In addition, starting in 2010, Reckitt negotiated rebate “sunset” agreements with MCOs that would eliminate any tablet rebates by the end of 2010, even though film rebates would continue through the end of 2011. (Pls.’ Exs. 214, 127, 263.) As one of Reckitt’s executives noted, the “Tablet sunset in all contracts forces the payer (in many instances) to move [the tablet] to tier 3 [on the formulary] and Film tier 2 for 2012. These developments, coupled with the Film uptick in the contracted accounts has improved the position.” (Pls.’ Ex. 286.)

#### **H. Reckitt’s Alleged Delay in the Shared REMS System**

As part of Reckitt’s overall generic defense strategy, Plaintiffs also assert that Reckitt actively worked to delay generic entry through its actions during the shared REMS program.

As noted above, a Single Shared REMS System (“SSRS”) is a single Risk Evaluation and Mitigation Strategy (“REMS”) that encompasses multiple drug products, including a brand drug and its generic versions, which is developed and implemented by two or more sponsors. (Def.’s Ex. 31, Zettler Rep. ¶¶ 31–39.) The FDA prefers that brand and generic versions of the same drug use an SSRS because of efficiency and public health benefits. Thus, if an ANDA holder is seeking approval for a generic version of a drug that is subject to a REMS, the FDA requires the brand and generic to cooperate in developing and implementing an SSRS. (*Id.*)

On August 21, 2009, the FDA informed Reckitt that it required submission of a REMS for the Suboxone tablet and that it would not approve Reckitt’s New Drug Application for Suboxone film without a REMS. (Pls.’ Exs. 160, 168.) Internally, Reckitt executives began to discuss the probability that they would be legally obligated to have a shared REMS, or an SSRS, with generics, and the fact that they could use this to their advantage. (Pls.’ Ex. 245.) Ju Yang, Reckitt’s Global Head of Regulatory Affairs noted, “Why don’t we propose an outrageous high price for generic to participate in our REMS? This way it can be viewed by FDA that we are collaborative (at least to a certain extent). . . . Not allowing generic to participate may be viewed as an [sic] negative act by FDA.” (Pls.’ Ex. 245.)



During a September 2010 phone call between Reckitt's executives and members of the FDA, CEO Thaxter stated that while Reckitt intended to take complete responsibility for its own products and complete its own REMS, it did "not feel that it should be held accountable for the safe use of competitors' products, particularly when those products are expected to have a significant negative impact on [Reckitt]." (Def.'s Ex. 244.) Thereafter, on May 26, 2011, Matt Sullivan of the FDA reached out to John Song, Reckitt's Manager of Regulatory Affairs, to see if Reckitt would be willing to participate in a "single-shared REM system" for opioid dependence buprenorphine tablets. (Def.'s Ex. 245.) Following discussion with other of Reckitt's executives, Song indicated that Reckitt was still not interested in participating in a shared REMS with ANDA holders of generic Suboxone tablets. (Id.)

Given Reckitt's response, the FDA invited Reckitt's employees to a face-to-face meeting to "focus on the need for a single, shared system REMS for buprenorphine products in the interest of public health and to reduce the burden on the healthcare system from having to conduct multiple REMS programs." (Def.'s Ex. 247.) At that meeting, Reckitt representatives continued to express their disinterest in a single, shared REMS with the ANDA holders but agreed to have an internal discussion with senior management about collaboration. (Def.'s Ex. 250.) Ultimately, Reckitt appeared to feel that it had little choice but to participate in a shared REMS. (Pls.' Ex. 120.)

In January 2012, Reckitt told generic companies that it would cooperate with the SSRS and would be in touch with each of them as to the next steps. (Pls.' Ex. 277.) In early February, Candis Edwards from Amneal Pharmaceutical reached out to Reckitt about a teleconference between the Generic manufacturers and Reckitt regarding the shared REMS, and Reckitt indicated that it was waiting on information from the FDA and would follow up after it received such information. (Pls.' Ex. 158.) Thereafter, on February 27, 2012, Reckitt's General Counsel, Javier Rodriguez, contacted the Generics and stated that he was handling all further REMS communication due to the potential for antitrust issues. He inquired whether the Generics had engaged antitrust counsel to supervise the discussions. (Pls.' Ex. 159.) When counsel for the Generics requested a meeting, Rodriguez responded

that “we are in the process of determining the right [Reckitt] individuals to serve on this effort and also sorting out the significant liability concerns both from a patient safety and an antitrust perspective.” (Pls.’ Ex. 160.)

Reckitt and the Generics did not meet to discuss development until April 2, 2012. (Pls.’ Ex. 76.) At that time, only Reckitt’s attorneys attended, and Reckitt declined to discuss anything but legal and governance issues. (Pls.’ Ex. 256; Def.’s Ex. 258, ¶ 24.) Following that meeting, Reckitt sent a list of “gating issues” involving governance and legal concerns to be resolved before substantive discussions could begin. (Pls.’ Ex. 36.) The Generics believed this discussion to be a delay tactic by Reckitt, while Reckitt viewed these matters as crucial to proceeding with the shared REMS. (See Pls.’ Exs. 257, 258.) The parties’ inability to resolve the “gating issues” stalled progress on the creation of an SSRS between April 2012 and June 2012. (Pls.’ Ex. 62.)

As a result of this impasse, Reckitt and the Generics had a meeting with the FDA on June 18, 2012. (Pls.’ Ex. 311.) The Generics urged that Reckitt was using the “gating” issues to delay the SSRS process and, in turn, the approval of generic tablets. (Def.’s Ex. 258, ¶ 26.) After reviewing the parties’ written materials and listening to their oral presentations, the FDA concluded that, due to Reckitt’s refusal to share information about its REMS, the parties should develop a wholly new SSRS based on publicly-available documents. It also warned the parties about using tactics to delay the SSRS. Reckitt responded that it would cooperate. (Pls.’ Ex. 76.)

By the end of August 2012, the Generics provided the FDA with a first draft of a proposed SSRS. (Def.’s Exs. 210, 267; Pls.’ Ex. 59.) Around that time, Reckitt confirmed that it was “fully engaged and involved in the negotiations.” (Def.’s Ex. 275.) In August 2012, however, Reckitt presented numerous concerns inhibiting its participation in the SSRS. (See PASF ¶ 207.) Finally, on August 23, 2012, Reckitt told the Generics that they should seek a waiver from the shared REMS requirement. (Pls.’ Ex. 48.)

On August 24, 2012, the FDA scheduled both a Generics-only meeting and a Reckitt-only meeting on the issue of an SSRS waiver. (Pls.' Ex. 64.) One day prior to the FDA-Reckitt meeting, however, Reckitt formally announced that it would be discontinuing Suboxone tablets and filing a Citizen Petition urging the FDA not to approve any generic forms of Suboxone. (Def.'s Ex. 52.) Generics Amneal and Actavis submitted their waiver requests on October 3 and 4, 2012, setting forth their beliefs that Reckitt had intentionally delayed the SSRS process. (Pls.' Ex. 47.) Approximately one month later, on November 15, 2012, Reckitt formally withdrew from the shared REMS program. (Pls.' Ex. 61.)

On February 22, 2013, the FDA granted the Generics' SSRS waivers and approved the Generics' REMS program. (Pls.' Exs. 76, 458.) In doing so, the FDA determined that "the burden of creating an [SSRS] for these products outweighs the benefit of an [SSRS]. The lack of restrictive elements in the REMS program for buprenorphine products (e.g., enrollment requirements, certifications, restricted distribution, etc.), and [Reckitt's] efforts that appeared to be designed to delay agreement on an [SSRS] program were significant factors in this determination." (Pls.' Ex. 76.) The FDA further remarked that "[i]n addition to the delays caused by Reckitt in the negotiations over the SSRS, [Reckitt] took actions in the Fall of 2012 that appear to have been designed to delay approval of the pending ANDAs for generic Subutex® (buprenorphine HCl) and Suboxone® (buprenorphine HCL-naloxone HCL) sublingual tablets," including discontinuing marketing Suboxone tablets based on an alleged higher rate of accidental pediatric exposure, submitting a citizen petition regarding the dangers of tablets, requesting that the FDA not approve any ANDA for generic Suboxone tablets, and withdrawing as a member of the group originally tasked with designing the SSRS. (*Id.*) The FDA found that "a waiver is necessary . . . to ensure that [Reckitt] does not infinitely delay approval of the pending buprenorphine ANDAs—and deny patient access to affordable generic drug products in the process—by refusing to cooperate with the Buprenorphine ANDA Applicant Holders on the development of an [SSRS]." (*Id.*)

**I. The Citizen Petition**

On September 25, 2012, the same day that Reckitt publicly announced its withdrawal of Suboxone tablets, Reckitt filed a Citizen Petition requesting that the FDA refrain from approving any ANDA for Suboxone (a) unless the ANDA includes a targeted pediatric exposure program; (b) unless the ANDA has child-resistant unit-dose packaging; and (c) until the FDA determines whether Reckitt withdrew its tablets for safety reasons. (Def.'s Ex. 52, at p. 6.)

The parties point to differing evidence as to whether Reckitt had a basis for petitioning the FDA to require generics to use unit-dose packaging or voluntary educational programs. (PASF ¶ 220; DR ¶ 220.) Reckitt relies heavily on a study conducted by the Researched Abuse, Diversion and Addiction-Related Surveillance (“RADARS”) Stem and Venebio Group, which stated that the rates of accidental exposure in children under six to Suboxone tablets were greater than to Suboxone film. (Pls.’ Ex. 330.)

The FDA denied the Citizen Petition on February 22, 2013. With respect to Reckitt’s request for educational initiatives and child-resistant unit-dose packaging (requests (a) and (b)), the FDA noted that Reckitt had submitted no studies regarding the impact of educational interventions and packaging on the decline in pediatric exposures. (Def.’s Ex. 71, at p. 9.) As to Reckitt’s request that the FDA determine that the tablets were withdrawn for safety reasons (request (c)), the FDA noted that although Reckitt “declared its intention to withdraw SUBOXONE tablets from sale in the future, our understanding is that this product continues to be shipped and sold.” (*Id.* at 14–15.) Moreover, the FDA determined, “on the basis of data available,” that withdrawal of Suboxone tablets was not necessarily for reasons of safety and that, despite Reckitt’s claims that tablets were subject to an increasing rate of accidental pediatric exposure, Reckitt “did not seek to discontinue marketing of the tablet in multi-dose containers for more than two years.” (*Id.* at 15.) Indeed, the FDA commented that “[t]he timing of [Reckitt’s] September 2012 announcement that it would discontinue marketing of the tablet product because of pediatric exposure issues, given its close alignment with the period in which generic competition for this product was expected to begin, cannot be ignored.” (*Id.*) The FDA

referred the matter to the Federal Trade Commission to investigate allegations of anticompetitive behavior by Reckitt. (Id. at 16.)

**J. Generic Launches**

1. Actavis

On May 8, 2009, generic manufacturer Actavis submitted its ANDA No. 91-422 for generic Suboxone. (Pls.' Ex. 313.) By September 10, 2010, the FDA found that the Chemistry, Manufacturing and Controls ("CMC") portion of the ANDA was acceptable, and the Risk Minimization Action Plan ("Risk MAP") review was pending. (Pls.' Ex. 43.) Actavis requested expedited review of its application. (Pls.' Ex. 314.)

On January 6, 2012, the FDA notified Actavis of its requirements of a REMS for oral buprenorphine products, that Reckitt's REMS had been approved, and that Actavis would also need to submit a REMS for its ANDA. (Def.'s Ex 209.) Actavis submitted its proposed REMS on January 18, 2012. (Pls.' Ex. 315.)

The FDA notified Actavis regarding the last non-labeling deficiency to final approval of its ANDA on February 17, 2012. (Pls.' Ex. 317.) Actavis responded on March 6, 2012. (Pls.' Ex. 318.) Thus, according to Plaintiffs, at that point, the sole remaining holdup to approval was the REMS submissions. Actavis submitted a formal waiver request from an SSRS with Reckitt on October 4, 2012. (Pls.' Ex. 44.) On February 22, 2013, after that waiver was granted by the FDA, the FDA granted final approval to the Actavis ANDA. (Def.'s Ex. 74.)

2. Amneal

Amneal submitted its ANDA for generic Suboxone on May 11, 2011 and, as part of its filing, requested expedited review of its application. (Pls.' Exs. 319. 325.) On June 13, 2011, the FDA granted that expedited review. (Pls.' Ex. 323.)

As with Actavis, the FDA notified Amneal, on January 6, 2012, that it required a REMS for all oral buprenorphine products before the ANDA could be approved. (Pls.' Ex. 322.) On May 17, 2012,

Amneal submitted its Amneal-only proposed REMS and requested a temporary waiver of an SSRS. (Pls.' Ex. 320.) On February 22, 2013, the FDA granted a waiver from the SSRS requirement and gave final approval to Amneal's ANDA. (Def.'s Ex. 220.)

**K. Procedural History**

In 2013, various direct and indirect purchasers of Suboxone filed multiple suits against Reckitt, setting forth claims under the Sherman Act, the Clayton Act, state antitrust laws, and state common law. Thereafter, the action was converted into a multi-district litigation and consolidated into one action before me. In 2016, a group of States Attorneys General filed their own suit against Reckitt and Defendant MonoSol raising similar claims, and these lawsuits have proceeded jointly through litigation.

On September 27, 2019, I certified a class of Direct Purchaser Plaintiffs ("DPPs") and an issues class of End Payor Plaintiffs ("EPPs"). In re Suboxone Antitrust Litig., No. 13-md-2445, 2019 WL 4735520 (E.D. Pa. Sept. 27, 2019). The United States Court of Appeals for the Third Circuit affirmed that decision on July 28, 2020. In re Suboxone Antitrust Litig., 967 F.3d 264 (3d Cir. 2020).

Reckitt now seeks summary judgment as to all claims against it and, alternatively, as to specific Plaintiffs and specific remedies.

**II. STANDARD OF REVIEW**

Federal Rule of Civil Procedure 56 states, in pertinent part:

A party may move for summary judgment, identifying each claim or defense—or the part of each claim or defense—on which summary judgment is sought. The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. The court should state on the record the reasons for granting or denying the motion.

Fed. R. Civ. P. 56(a). "Through summary adjudication, the court may dispose of those claims that do not present a 'genuine dispute as to any material fact' and for which a jury trial would be an empty and unnecessary formality." Capitol Presort Servs., LLC v. XL Health Corp., 175 F. Supp. 3d 430, 433

(M.D. Pa. 2016). A factual dispute is “material” if it might affect the outcome of the suit under the applicable law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). An issue is “genuine” only if there is a sufficient evidentiary basis to allow a reasonable fact-finder to return a verdict for the non-moving party. Id.

The initial burden is on the moving party to adduce evidence illustrating a lack of genuine, triable issues. Hugh v. Butler Cnty. Family YMCA, 418 F.3d 265, 267 (3d Cir. 2005). Once the moving party satisfies its burden, the non-moving party must, in rebuttal, present sufficient evidence of a genuine issue. Santini v. Fuentes, 795 F.3d 410, 416 (3d Cir. 2015). The court must then resolve all doubts as to the existence of a genuine issue of material fact in favor of the non-moving party. Saldana v. Kmart Corp., 260 F.3d 228, 232 (3d Cir. 2001). Unsubstantiated arguments made in briefs are not considered evidence of asserted facts. Versarge v. Twp. of Clinton, 984 F.2d 1359, 1370 (3d Cir. 1993).

### **III. RECKITT’S MOTION FOR SUMMARY JUDGMENT AS TO ALL ISSUES**

Reckitt’s first Motion seeks dismissal of all of Plaintiffs’ claims, setting forth three broad grounds. First, it contends that, under the rule of reason burden-shifting framework, Plaintiffs have failed to prove that anticompetitive harm to consumers outweighed the procompetitive benefits of Reckitt’s alleged conduct. Second, Reckitt asserts that Plaintiffs cannot prove exclusion and, thus, cannot maintain an antitrust claim. Finally, Reckitt urges that the challenged conduct, taken either individually or as a whole, is lawful and, therefore, cannot serve as a basis for a cognizable antitrust claim.

#### **A. Whether the Anticompetitive Harm to Consumers Outweighed the Procompetitive Benefits of Reckitt’s Alleged Conduct**

Reckitt’s first argument contends that Plaintiffs have failed to meet their burden of proof under all steps of the “rule of reason” burden-shifting framework.

The Third Circuit has instructed that in addressing allegations of anticompetitive conduct based on alleged “product hops”—*i.e.*, switching from one formulation of a drug to another—the reviewing court must apply the well-known “rule of reason” burden-shifting framework established in United States v. Microsoft Corp., 253 F.3d 34 (D.C. Cir. 2001). Mylan Pharms. Inc. v. Warner Chilcott Public Ltd. Co., 838 F.3d 421, 438 (3d Cir. 2016) (“Doryx”). “Under that framework, the party seeking to impose liability must initially provide evidence of both the anticompetitive nature of a defendant’s conduct,” and the substantial anticompetitive effect caused by the challenged restraint. Id.; Nat’l Coll. Athletic Assoc. v. Alston, 141 S. Ct. 2141, 2160 (2021). Once a plaintiff makes these initial showings, “the defendant then has the burden of ‘proffer[ing] “nonpretextual” procompetitive justifications for its conduct.’” Doryx, 838 F.3d at 438 (quoting Microsoft, 253 F.3d 34). If the defendant puts forth the requisite, nonpretextual proof, “the burden shifts back to the plaintiff to demonstrate that the procompetitive efficiencies could be reasonably achieved through less competitive means.” Nat’l Coll. Athletic Assoc., 141 S. Ct. at 2160.

These steps “do not represent a rote checklist, nor may they be employed as an inflexible substitute for careful analysis.” Id. “The whole point of the rule of reason is to furnish ‘an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint’ to ensure that it unduly harms competition before a court declares it unlawful.” Id. (quotations omitted). Always, “[t]he goal is to distinguish between restraints with anticompetitive effect that are harmful to the consumer and restraints stimulating competition that are in the consumer’s best interest.” Id. at 2151 (quoting Ohio v. Am. Express, 138 S. Ct. 2274, 2284 (2018)).

In the context of a “product hopping” allegation, the Third Circuit has affirmatively recognized that “certain insignificant design or formula changes, combined with other coercive conduct,” could establish antitrust liability under the rule of reason. Doryx, 838 F.3d at 440. In such a case, after applying the burden-shifting framework, “courts may need to consider a number of additional, non-exhaustive factors.” For instance,



[C]ourts might need to balance the important public interest in encouraging innovation in the pharmaceutical industry with our obligations to protect consumers and to ensure fair competition under the antitrust laws. At the same time, courts should also be wary both of second-guessing Congress’s legislative judgment and of turning courts into tribunals over innovation sufficiency. Moreover, courts may need to be cognizant of the unique separation between consumers and drug manufacturers in the pharmaceutical market, especially in cases where there is evidence of extreme coercion of physician prescribing decisions or blatant misrepresentation about a generic manufacturer’s version of a drug. With all of this said, even in more difficult cases, the disposition of each claim will necessarily turn on the facts and circumstances surrounding a company’s alleged anticompetitive conduct.

Id. at 440–41 (footnotes omitted).

For purposes of its first summary judgment argument only, Reckitt concedes that it did everything that Plaintiffs allege and that its conduct was anticompetitive in nature. It contends that Plaintiffs’ antitrust claims nonetheless fail under the rule of reason framework on several grounds. Primarily, Reckitt asserts that Plaintiffs have failed to establish that Reckitt’s challenged conduct has caused an anticompetitive effect. Reckitt also avers that it has adequately proffered procompetitive justifications for its conduct. Finally, Reckitt argues that Plaintiffs have not produced sufficient evidence to demonstrate that the anticompetitive harm resulting from the alleged conduct outweighs the procompetitive benefit.

1. Whether Plaintiffs Have Produced Evidence of Anticompetitive Effect in the Form of Marketwide Harm to Consumers

Under the burden-shifting framework, “the plaintiff has the initial burden to prove that the challenged restraint has a substantial anticompetitive effect that harms consumers in the relevant market.” Ohio v. Am. Express, 138 S. Ct. 2274, 2284 (2018). A plaintiff can make this showing directly or indirectly. Id. “Direct evidence of anticompetitive effects would be proof of actual detrimental effects on competition . . . such as reduced output, increased prices, or decreased quality in the relevant market.” Id. (internal quotation marks and alterations omitted). “Indirect evidence would be proof of market power plus some evidence that the challenged restraint harms competition.” Id.

This burden “necessarily involves an inquiry into the actual effect of the [challenged conduct] on competition [in the tied market].” Brokerage Concepts, Inc. v. U.S. Healthcare, Inc., 140 F.3d 494, 519 (3d Cir. 1998) (quotations omitted) (alterations in original).<sup>4</sup>

The Third Circuit has “consistently held that an individual plaintiff personally aggrieved by an alleged anti-competitive agreement has not suffered an antitrust injury unless the activity has a wider impact on the competitive market.” Eichorn v AT&T Corp., 248 F.3d 131, 140 (3d Cir. 2001) (citing cases). “While a plaintiff may have individually suffered an antitrust injury as a result of defendants’ actions, the antitrust laws were designed to protect market-wide anticompetitive activities.” Id. “Thus, it is clear that under Third Circuit jurisprudence, anticompetitive effects must be shown to *impact the market as a whole*.” Deborah Heart & Lung Ctr. v. Virtua Health Inc., No. 11-cv-1290, 2015 WL 1321674, at \*12 (D.N.J. Mar. 24, 2015) (emphasis in original) (citing Eichorn v. AT&T Corp., 248 F.3d 131 (3d Cir. 2001)).

Reckitt contends that Plaintiffs have failed to show any market-wide harms to consumers as a result of Reckitt’s expansion of the film’s market share at the expense of generic manufacturers of Suboxone products. Reckitt first posits that Plaintiffs failed to show that the alleged safety claims harmed consumers because no single expert has opined that film did not possess the safety attributes that Reckitt claimed. Reckitt also asserts that Plaintiffs failed to show that Reckitt’s conduct defeated consumer choice. Finally, Reckitt contends that Plaintiffs failed to show that Reckitt’s conduct increased the average price consumers paid for their prescriptions, or that consumers were unwilling to pay more for film.

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<sup>4</sup> Typically, a threshold step in assessing antitrust harm requires a definition of the relevant market, which refers to the area of effective competition. Am. Express, 138 S. Ct. at 2285. If a plaintiff can make a showing of actual anticompetitive effects, however, then “[a] full-blown market analysis is not necessary.” Bhan v. NME Hosps., Inc., 929 F.2d 1404, 1413 (9th Cir. 1991).

Here, Plaintiffs allege actual effects on competition. Moreover, for purposes of the present analysis only, the parties avoid definition of the relevant market and assume that it consists of only Suboxone products and their generic equivalents.

Reckitt's argument misunderstands Plaintiffs' burden at this stage of the burden-shifting framework. Plaintiff need not rebut all potential benefits resulting from the conduct at issue. Rather, Plaintiffs need only produce evidence that the challenged restraint had a substantial anticompetitive effect that harms consumers in the relevant market. Am. Express, 138 S. Ct. at 2284.

To that end, I conclude that Plaintiffs have produced evidence that, if accepted, could establish that Reckitt's conduct harmed consumer welfare through the combined effects of Reckitt's switch from tablet to film, increase in the price of the tablet, fabrication and marketing of a "safety story" about the dangers of the tablet, and the subsequent withdrawal of the tablet prior to generic entry. Plaintiffs assert that by inflating film share and impeding the cost-efficient means of competition from brand tablets and generic tablets, the price of tablets was significantly higher than it would have been but for Reckitt's actions. According to Plaintiffs, generic manufacturers initially set their prices as a percentage of the brand drug for which they are substitutable. (Pls.' Ex. 19, Luce Dep., 237:21–240:17; Pls.' Ex. 5, Clark Dep., 99:3–10, 18:2–19:6.) Reckitt affirmatively elected to raise its tablet prices before generic launch to "force" the generics to raise the price of their tablets and be closer to film price. (Pls.' Ex. 118.) Plaintiffs' expert, Dr. Ernst Berndt, opined that "had [Reckitt] not taken the price increases on the Tablets, the prevailing brand Suboxone tablet prices at the time of generic entry would have been lower and Suboxone Tablets would not have been withdrawn." (Def.'s Ex. 1, Berndt Market Effects Rep. ¶ 122; see also Def.'s Ex. 19, Lamb Rep. ¶ 217 (same).) Plaintiffs' experts also opined that but for Reckitt's anticompetitive scheme, lower-priced generic Suboxone tablets would have been substituted for a much larger percentage of total Suboxone sales (tablets and film) than actually occurred. (Lamb Rep. ¶¶ 221–25, 240–47; Def.'s Ex. 2, Berndt Disgorgement Rep. ¶¶ 25–37.)

According to Plaintiffs, because film and generic tablets were not AB-rated—and thus not subject to automatic substitution at the pharmacy counter—the only way for generic tablets to win back market share was to use therapeutic substitution. But this process at the retail pharmacy level takes over fifteen minutes and imposes additional transaction costs of over \$8.00 per prescription, and thus

does not result in generic substitution/usage anywhere near that achieved by AB-related generics. (Def.'s Ex. 26, Verscharen Rep. ¶¶ 48–50, 55–58.) Moreover, according to Dr. Berndt, Reckitt's campaign of disparaging the safety of tablets regarding potential pediatric abuse, misuse, and diversion added to the obstacles for any therapeutic substitution campaign. (Berndt Market Effects Rep. ¶¶ 170, 178; see also Pls.' Ex. 240, at slide 69 (safety messages were intended to "prevent unintended switching of Film.")) Ultimately, Plaintiffs' experts concluded that Reckitt's scheme caused substantial harm to consumer welfare because (a) consumers and payers would have purchased more lower-priced generic tablets in place of the brand film they actually purchased, (b) they would have substituted lower-priced generic tablets for their more expensive brand tablet purchases starting in September 2012, and (c) they would have paid lower prices for brand tablets. (Berndt Market Effects Response Rep. ¶¶ 22, 29; Def.'s Ex. 20, Lamb Rebuttal Rep. ¶¶ 144–48.) Dr. Berndt further noted that, despite the initial effect of Reckitt's brand tablet price increases that briefly inflated the actual generic tablet list prices, generic tablets have been cheaper than film for years. Yet, Reckitt has retained its share of the market through its disparagement campaign. (Berndt Market Effects Rep. ¶ 20; Berndt Market Effects Response Rep. ¶ 21.)

In sum, Plaintiffs have produced sufficient evidence that Reckitt's conduct could have resulted in higher consumer prices for use of Suboxone tablets and its generic counterparts. In affirming my ruling on class certification, the Third Circuit has, in fact, noted that Reckitt did "not dispute that [Plaintiffs] provided common evidence showing that the class paid more for Suboxone products." In re Suboxone, 967 F.3d 264, 270 (3d Cir. 2020). Plaintiffs' experts connect such higher consumer prices to marketwide competitive harm by opining that, but for Reckitt's conduct, consumers would have been able to purchase lower-priced generic tablets in place of either brand film or brand tablets. Reckitt's own expert, Dr. Normann, conceded that if conduct raises consumer prices or affects consumer welfare, there is anticompetitive harm. (Pls.' Ex. 23, Norman Dep. 16:19–25.)

I remain cognizant of Reckitt's evidence that its conduct did not cause higher prices. But, for purposes of summary judgment, I cannot weigh this evidence against that produced by Plaintiffs.

2. Procompetitive Justifications for the Alleged Anticompetitive Conduct

Reckitt next posits that, even assuming it engaged in anticompetitive behavior that had a marketwide anticompetitive effect, its challenged conduct should be insulated from liability because, under the second step of the "rule of reason," it has advanced procompetitive motives and objectives for such conduct.

Pursuant to the second step of the "rule of reason," once a plaintiff has presented evidence that a defendant took exclusionary action to maintain its monopoly power, liability turns on whether "valid business reasons" can explain the defendant's actions. Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451, 483 (1992). Procompetitive benefits are those that "enhance[] consumer welfare and competition in the marketplace" and are "consistent with the procompetitive aspirations of antitrust law." Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 309 (3d Cir. 2007). Under the "rule of reason" burden-shifting framework, the defendant, at this step, has the burden of "proffer[ing] 'nonpretextual' procompetitive justifications for its conduct." Doryx, 838 F.3d at 438. Moreover, the defendant must "persuad[e] the jury that its conduct was justified by any normal business purpose." LePage's Inc. v. 3M, 324 F.3d 141, 164 (3d Cir. 2003) (quotation omitted). "Maintaining a monopoly is not the type of valid business reason that will excuse exclusionary conduct." Id.

Where factual questions exist about the validity and sufficiency of each claimed justification, summary judgment is not appropriate. Eastman Kodak, 504 U.S. at 483. "[I]nconsistencies in and contrasts between the internal and public explanations [for the challenged actions]" may suggest that a defendant "was attempting to disguise the true reason for its actions" and are grounds for finding pretext. Alvord-Polk, Inc. v. F. Schumacher & Co., 37 F.3d 996, 1012 (3d Cir. 1994). Where a plaintiff presents sufficient evidence to rebut a defendant's procompetitive justifications and raises a genuine factual dispute as to whether certain anticompetitive conduct was reasonably necessary to

achieve the procompetitive benefits, summary judgment should be denied. See King Drug Co. of Florence, Inc. v. Cephalon, Inc., 88 F. Supp. 3d 402, 419 (E.D. Pa. 2015).

Reckitt contends that the conduct alleged by Plaintiffs to be anticompetitive actually resulted in two procompetitive benefits and that this evidence justifies granting summary judgment. I consider each individually, along with the contrary evidence offered by Plaintiffs.

*a) Increasing Consumer Choice*

First, Reckitt posits that the concept of choice is procompetitive, and the ability to choose film over tablets, whether brand or generic, improved public health and gave patients an alternative treatment option. Reckitt's expert, Dr Westreich, opined that "a range of treatment options is optimal," and that it is a medical benefit if doctors have a broad range of treatment options available "to manage different patient characteristics and preferences." (Def.'s Ex. 29, Westreich Reb. Rep., at 49; Def.'s Ex. 28, Westreich Rep. ¶ 57.) Given this undisputed procompetitive benefit, Reckitt claims that it cannot be held liable under the antitrust statutes.

Plaintiffs cite to evidence, which they assert undermines the alleged procompetitive, pro-choice nature of Reckitt's actions and creates an inference that Reckitt's conduct was merely pretext for anticompetitive efforts. According to this evidence, Reckitt recognized, as early as 2006, that patients wanted "no change" from the tablet form of Suboxone, and physicians reported high satisfaction with the Suboxone tablet. (Pls.' Exs. 81, 186.) On advice from an independent consultant, however, Reckitt's executives began exploring the idea of developing film and withdrawing tablets, with the key concerns focused on a defense against generic entry, not the improvement of consumer choice and pricing. (Pls.' Exs. 190, 289, 416.)

Plaintiffs have pointed to evidence that, in connection with its generic entry defense plan, Reckitt's executives sought a "safety story" to establish a basis for withdrawal of the tablet prior to generic launch, leaving film as the only Suboxone product on the market. (PASF ¶¶ 25–28; see also Pls.' Exs. 90, 125, 177.) In the earliest plan phases, Reckitt's executives knew that formulation

changes from tablet to film would need to show (and be proved) that film is less abuseable/divertible. (Pls.' Ex. 251.) Even though Reckitt had to have substantial evidence or substantial clinical experience to support its "safety story"—as required by the applicable regulations—as of 2009–2010, Reckitt had not performed any clinical studies and had no direct data to determine if film would be more susceptible to diversion. (Pls.' Ex. 29, at 49:21–51:3.) In fact, Reckitt only began to design such a study in January 2011. (Pls.' Ex. 199.)

Plaintiffs also provide evidence that the final safety story was premised on the fact that film used Unit Dose Packaging, while tablets came in a thirty-dose bottle. According to Plaintiffs, however, Reckitt could have used Unit Dose Packing on tablets in the United States, like it does in other countries, but chose not to in order to justify removal of tablets from the market. (Pls.' Ex. 164; Pls.' Ex. 253 n. 57; Pls.' Ex. 30, 38:15–25.) In September 2012, Reckitt provided the FDA with a formal notice of discontinuance for Suboxone tablets. (Def.'s Ex. 188.) On September 25, 2012, Reckitt made a public announcement noting that it was voluntarily discontinuing the supply of Suboxone tablets due the "increasing concerns with pediatric exposure." (Def.'s Ex. 189.) The FDA specifically observed that the timing of Reckitt's September 2012 tablet withdrawal announcement—based on alleged pediatric exposure issues—was suspiciously aligned with the period in which generic competition for the tablet was about to begin. (Def.'s Ex. 71.)

Viewing this evidence in the light most favorable to Plaintiffs, as the non-moving parties, I conclude that a genuine issue of fact exists as to whether Reckitt's switch from tablet to film was a mere pretext for anticompetitive motivations. A factfinder could draw the reasonable inference that Reckitt was not seeking to improve consumer choice, but rather to block the entry of generics and/or decrease the potential generic erosion of its brand sales by removing and destroying the market for the tablet. In addition, such conduct could be deemed to have actually deprived consumers of choice as it resulted in a planned removal of the tablet prior to generics coming onto the market, leaving only the film version of Suboxone. While Reckitt cites contrary expert testimony and criticizes the quality of

Plaintiffs’ evidence on this issue—calling it “anecdotal”—it is outside of my province on summary judgment review to determine credibility and weight.

b) *Reduced Costs for Film*

As an alternative, procompetitive justification, Reckitt argues that its conduct caused patients to pay less for film through two separate mechanisms. Reckitt points to Plaintiffs’ expert Yvonne Tso, who admitted that Reckitt’s interactions with managed care organizations (“MCO”s) “likely resulted in decisions that gave film favorable formulary placement. (Def.’s Ex. 24, “Tso Rep.” ¶ 17.) Thus, absent the challenged conduct, “payors would not have been as likely to place film on or advantage film on their formularies, causing patients to file higher co-pays for film.” (Berndt Market Effects Rep. ¶ 74.) Additionally, Reckitt offered co-pay coupons that defrayed, and often eliminated entirely, the co-pay cost borne by patients. (Def.’s Ex. 45; Def.’s Ex. 22, “Lamb Dep.” 481:13–20.) Overall, Reckitt asserts that without these allegedly anticompetitive actions, patients who preferred film would have had to pay more for film and, therefore, Reckitt’s conduct saved them money.

Reckitt’s argument fails to establish an entitlement to summary judgment. First, the class-wide harm which Plaintiff seeks to remedy involves only those purchasers that actually purchased branded Suboxone tablets during a particular time period. Thus, the fact that consumers who bought film may have paid less for that product does not eradicate the harm suffered by the class member tablet purchasers.

Second, Plaintiffs have pointed to countervailing evidence suggesting that the reduction in the price of film (a) was a mere pretext to switch the prescription market to the film form of Suboxone and away from the tablet form so as to avoid generic competition, and (b) actually resulted in a monetary loss to the overall Suboxone market, which paid substantially more for tablets:

- When Reckitt originally launched film, it was priced at parity with tablets. (Pls.’ Ex. 239.) A Reckitt presentation, however, noted that as of May 2012, the tablet became more expensive per mg than film, not due to the fact that film is cheap, but rather due to Reckitt’s “increasingly aggressive price increases” on the tablet. (Id.) This was a purposeful strategy employed since



the launch of film. (*Id.*) Indeed, Reckitt’s Chief Financial Officer, Martyn Gibson, remarked that the cost of goods for film were actually higher. (Pls.’ Ex. 249.)

- Reckitt’s reductions in the price of film were matched with corresponding increases on the price of tablets. In a March 2012 presentation, Reckitt stated that “Price is a key lever creating further Film and Tablet differentiation to drive conversion . . . Appropriate Tablet pricing actions will help to *drive patients away from Tablet for safety and quality care reasons.*” (Pls.’ Ex. 132 (emphasis in original).) Reckitt specifically remarked that it was trying to get away from the Tablet, noting that “Any payer has an easy solution: Moving Tab to Film, which is 34% less expensive.” (*Id.*)
- Reckitt had no non-competitive basis for increasing the price of or ending rebates on tablets, particularly since tablets were cheaper to manufacture. (Pls.’ Ex. 117.) Indeed, Reckitt recognized that it would take a short term financial hit by increasing tablet prices but could accelerate film conversion. (Pls.’ Exs. 232, 249.)
- In a February 2011 presentation by Reckitt—created four months after film launch—Reckitt admitted that it was not seeking to lower the costs of film for consumers, but rather simply to “[w]iden[] the price differential between Suboxone tablet and film . . . [to] drive commercial payors to switch patients to film to save costs.” (Pls.’ Ex. 114.) Indeed, much of the movement came on the tablet end with tablet price increases of 7% in April 2010 and 10% in December 2010. (*Id.*) For most MCOs, the monetary gains realized from lower film prices and higher film rebates did not compensate them for the monetary losses suffered as a result of the increase in tablet prices and the removal of tablet rebates, thus negating any positive effect on the market. (PSAF ¶ 167.)

From this evidence, a factfinder could draw the reasonable inference that the reduction in the price of film, accompanied by increases in the price of tablets, resulted in an artificial and temporary benefit to those who switched to film. For those payors and consumers that continued to use the tablet, their costs were increased. These increased costs resulted not from an increase in price of the ingredients or manufacturing costs, but rather from Reckitt’s efforts to drive the market away from the tablet—for which there was soon to be less-expensive generic competitors—and towards film, for which no generic competition was available.

At this stage of the rule of reason analysis, Reckitt bears the burden of putting forth sufficient evidence of a non-pretextual, procompetitive basis for the challenged actions. While Reckitt has identified procompetitive benefits, Plaintiffs have come forth with countervailing evidence that these actions were (a) a mere pretext for the anticompetitive activity and (b) actually harmed the payors and consumers. Although Reckitt’s focus on protecting their name-brand franchise does not alone render

Reckitt's justifications "anticompetitive" for purposes of an antitrust analysis, see Doryx, 838 F.3d at 439 n.80, Plaintiffs' evidence creates a factual issue as to whether Reckitt had an "objectively legitimate business justification" at all for its conduct. Mylan Pharms, Inc. v. Celgene Corp., No. 14-cv-2094, 2018 WL 11299447, at \*15 (D.N.J. Oct. 3, 2018).

3. Balancing Procompetitive Benefits vs. Anticompetitive Harm

Even assuming that Reckitt had met its burden of establishing non-pretextual, procompetitive benefits (step two), this would not end my inquiry under a rule of reason analysis. The final step in the rule of reason requires balancing the harm to competition against the procompetitive justifications. This step "involves determining whether the challenged [conduct] is necessary to achieve its purported goals." U.S. v. Brown Univ. in Providence in State of R.I., 5 F.3d 658, 678 (3d Cir. 1993). "Even if an anticompetitive restraint is intended to achieve a legitimate objective, the restraint only survives a rule of reason analysis if it is reasonably necessary to achieve the legitimate objectives proffered by the defendant." Id. at 678–79; see also In re Wellbutrin XL Antitrust Litig., 133 F. Supp. 3d 734, 760 (E.D. Pa. 2015).

Thus, "[o]nce a defendant demonstrates that its conduct promotes a legitimate goal, the plaintiff, in order to prevail, bears the burden of proving that there exists a viable less restrictive alternative." Id. at 679. "To determine if a restraint is reasonably necessary, courts must examine first whether the restraint furthers the legitimate objectives, and then whether comparable benefits could be achieved through a substantially less restrictive alternative." Id. at 678–79.

Here, as noted above, Plaintiffs allege in part that the introduction of a new product, which is preferred by at least "some" patients, is part of the overarching antitrust scheme. Relying heavily on the opinion of the Honorable Paul Diamond in Doryx, Reckitt contends that such an allegation would require juries "to determine which product changes were 'sufficiently innovative' to justify their anticompetitive effects." (Def.'s Mem. Supp. Summ. J. 20 (quoting Mylan Pharms, Inc. v. Wilcott Ltd. Co. ("Doryx"), No. 12-3829, 2015 WL 1736957, at \*15 (E.D. Pa. Apr. 16, 2015), aff'd, 838 F.3d 421

(3d Cir. 2016).) According to Reckitt, such an attempt to weigh the benefits of an improved product design against resulting injuries to competitors “is not just unwise, it is unadministrable. There are no criteria courts can use to calculate the ‘right amount of innovation . . . .’” (*Id.* (quoting *Doryx*, 2015 WL 1736957, at \*15).) Reckitt urges that Plaintiffs cannot establish that the harm from the alleged overarching scheme outweighs the benefits brought about by marketing film “since there is no scale upon which such benefits can be weighed.” (*Id.*)

Contrary to Reckitt’s argument, however, Judge Diamond did not hold that, in a product hopping case, a court or factfinder could never weigh the anticompetitive effects of a product hop against the procompetitive benefits of innovation or product changes. Rather, Judge Diamond stopped at the first step of the rule of reason analysis, finding that the plaintiff had not substantiated its claims that the defendant’s change from one formulation of a branded drug to another, non-AB-rated formulation with no ostensible improvements, standing alone, constituted anticompetitive conduct. The plaintiff in *Doryx* alleged no other coercive conduct and generics were already on the market. *Id.* at \*12–14. Judge Diamond declined to find that the mere switch from one formulation to another was anticompetitive, expressing his concern that “[a]doption of [the plaintiff’s] ‘anticompetitive product redesign’ could well have adverse, unintended consequences. *Any* time a pharmaceutical manufacturer changes the formulation of a branded drug and so compels a manufacturer to reformulate (or, as in the instant case, formulate for the first time) its generic, this could trigger a Microsoft burden-shifting contest.” *Id.* at \*15 (emphasis in original). Judge Diamond went on to comment that use of the rule of reason in such scenarios would be unworkable because “[o]nce the branded drug manufacturer offered a procompetitive justification for the product change that the generic manufacturer could not rebut, courts and juries would have to determine which product changes were ‘sufficiently innovative’ to justify their anticompetitive effects.” *Id.* To that end, Judge Diamond found that the plaintiff had “failed to offer an intelligible test of innovation ‘sufficiency.’” *Id.* Ultimately, Judge Diamond concluded that “Congress certainly could have created barriers to brand-name drug changes that could

delay generic entry, but, perhaps understanding the adverse effects this could have on innovation, it did not. Courts should not seek to substitute their ‘legislative judgment’ for that of Congress.” Id. at \*16. The Third Circuit subsequently affirmed Judge Diamond’s ruling. Doryx, 838 F.3d 421 (3d Cir. 2016).

The concerns expressed by Judge Diamond about weighing the sufficiency of innovation are not at play here. Certainly, had Plaintiffs, like the plaintiff in Doryx, simply challenged Reckitt’s development of Suboxone film and discontinuation of Suboxone tablets, Doryx’s rationale might be persuasive. But, Plaintiffs have pointed to evidence that could establish that the “product hop” here was effectuated along with other alleged anticompetitive behavior—a combination the Third Circuit, in affirming Judge Diamond’s decision, affirmatively recognized could result in antitrust liability. Doryx, 838 F.3d at 440. Indeed, much of this additional anticompetitive behavior involves circumstances that the Third Circuit has expressly recognized could trigger application of the burden-shifting framework, such as: “evidence of extreme coercion of physician prescribing decisions;” “blatant misrepresentation about a generic manufacturer’s version of a drug; and whether a “patent-cliff” is present “especially when a defendant’s actions are paired with weak or inconsistent evidence of procompetitive justifications.” Id. at 440 & n.89.

In declining to proceed with a rule of reason analysis, the Third Circuit distinguished the Doryx facts from those in the Second Circuit’s decision in New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638 (2d Cir. 2015) (“Namenda”). In Namenda, the brand manufacturer was facing a “patent cliff,” *i.e.*, the end of its patent exclusivity period. Id. at 642. As a result, and prior to generic entry, it introduced a new version of its drug and withdrew the original version from the market to force patents who depended on the drug to switch to the new version before generics became available. Id. The new version of the drug was not AB-rated with either the prior version or any generics. Id. at 647.

On appeal, the Second Circuit recognized that while “neither product withdrawal nor product improvement alone is anticompetitive,” where a defendant “*combines* product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the

merits . . . and to impede competition . . . its actions are anticompetitive.” Id. at 653–54 (emphasis added). The Second Circuit noted that the combination of the hard switch from the old version to the new version of the drug—without generics yet available on the market—deprived consumers of choice because doctors and patients were not free to decide whether the benefits of the new, higher-priced, once-daily version of the drug outweighed the benefits of adhering to the old, twice-daily, lower-priced regimen. Id. at 654. At the third step of the rule of reason framework, the Second Circuit expressly remarked that the defendant presented “no evidence to support their argument that antitrust scrutiny of the pharmaceutical industry will meaningfully deter innovation. To the contrary . . . immunizing product hopping from antitrust scrutiny may deter significant innovation by encouraging manufacturers to focus on switching the market to trivial or minor product reformulations rather than investing in the research and development necessary to develop riskier, but medically insignificant innovations.” Id. at 659.

Here, taking all facts in the light most favorable to Plaintiff, this case is far more akin to Namenda than to Doryx. Like in Namenda, Reckitt was facing a “patent cliff,” *i.e.*, the expiration of orphan drug exclusivity on Suboxone tablets. Prior to the expiration of this exclusivity period, and prior to the entry of generics, Reckitt introduced a minor product formulation in the form of Suboxone film—which was not AB-rated with tablets—and then withdrew the tablet, effectively forcing patients that depended on Suboxone to switch to the film version. In addition, Reckitt then allegedly disseminated false safety concerns with Suboxone tablets, made irrational price increases on tablets, delayed the SSRS process, and filed an purportedly sham Citizen Petition—all facts not present in Namenda. And, Plaintiffs have presented evidence that this conduct resulted in the market paying artificially high prices for Suboxone tablets. Accordingly, allowing this case to proceed to the third step of the rule of reason analysis would not require a jury to determine whether the development of film and product switch was “sufficiently innovative.” Rather, a jury would weigh whether the procompetitive benefits of this overarching scheme outweighed its anticompetitive harms.

In the face of this evidence, Reckitt reiterates its claim that its actions had multiple procompetitive benefits, including reduction in the price of film for those who preferred film and creating consumer choice between film and tablets. Reckitt goes on to contend that Plaintiffs have not pointed to any evidence that these benefits were outweighed by any market-wide harm. Reckitt asserts that: (a) about 35% of all patients, according to Plaintiffs' calculations, still would have purchased film absent the alleged anticompetitive conduct; (b) Plaintiffs have failed to produce evidence reflecting prices paid by end payors; and (c) many patients who bought film with coupons were better off than if they had bought generic tablets, and many patients actually preferred film and would have happily paid more.

Even assuming Reckitt's conduct had these procompetitive benefits, any claimed benefit "cannot outweigh its harm to competition, if a reasonable, less restrictive alternative to the policy exists that would provide the same benefits" as the challenged policies. See Sullivan v. NFL, 34 F.3d 1091, 1103 (1st Cir. 1994). Indeed, the suggested ABA model instructions establishes the contours for how a jury should weigh such conflicting evidence in a civil antitrust case:

If you find that the challenged restraint does result in competitive benefits, then you also must consider whether the restraint was reasonably necessary to achieve the benefits. If the plaintiff proves that the same benefits could have been readily achieved by other, reasonably available alternative means that create substantially less harm to competition, then they cannot be used to justify the restraint.

ABA Model Jury Instructions in Civil Antitrust Cases, Instruction 3C (2016).

As noted above, Plaintiffs have produced evidence that any consumer benefit identified by Reckitt could have been achieved through less restrictive, more procompetitive means that would have allowed branded film to compete on the merits with generic tablets without effectively excluding generics from the market. "This difficult balancing of potentially legitimate business justifications against what plaintiffs contend are exclusionary effects are fact-bound questions that generally cannot be resolved on summary judgment." United States v. Microsoft Corp., No. 98-cv-1232, 1998 WL

614485, at \*22 (D.D.C. Sept. 14, 1998); see also Betaseed, Inc. v. U&I, Inc., 681 F.3d 1203, 1228–29 (9th Cir. 1982) (reversing summary judgment in rule of reason claim and explaining that “the reasonableness of a restrictive practice is a paradigm fact question”); Abbott Labs v. Teva Pharms. USA, Inc., 432 F. Supp. 2d 408, 422 (D. Del. 2006) (finding balancing of benefits and harm must occur where plaintiffs established that defendants prevented consumers from making choice among products by removing the old formulation from the market while introducing new formulations). While my conclusion in no way signals that Plaintiffs will ultimately be successful on the merits of their claim, it recognizes that the final decision regarding the propriety of Reckitt’s conduct within the highly competitive pharmaceutical market is properly resolved by a factfinder.

**B. Whether Plaintiffs Can Prove Exclusion**

In order to have standing to assert an antitrust claim, a plaintiff is required to show it suffered antitrust injury. See City of Pittsburgh v. W. Penn Power Co., 147 F.3d 256, 264 (3d Cir. 1998). Substantial foreclosure is a form of antitrust injury, especially where the foreclosure is by a monopolist. LePages Inc. v. 3M, 324 F.3d 141, 157–58 (3d Cir. 2003). Reckitt now asserts that Plaintiffs cannot prove that any of Reckitt’s conduct resulted in “substantial foreclosure” of generics from the market. Therefore, according to Reckitt, Plaintiffs cannot show that they suffered antitrust injury caused by the absence of generic Suboxone.

The Third Circuit has described what constitutes “substantial foreclosure,” noting that “[a]lthough ‘[t]he test is not total foreclosure,’ the challenged practices must ‘bar a substantial number of rivals or severely restrict the market’s ambit.’” Eisai, Inc. v. Sanofi Aventis U.S., LLC, 821 F.3d 394, 403 (3d Cir. 2016) (quoting United States v. Dentsply Int’l, Inc., 399 F.3d 181, 191 (3d Cir. 2005)). “In analyzing the amount of foreclosure, [the] concern is not about which products a consumer chooses to purchase, but about which products are reasonably available to that consumer . . . if customers are free to switch to a different product in the marketplace but choose not to do so,

competition has not been thwarted—even if a competitor remains unable to increase its market share.” Id. at 403–04.

Although it is “generally ‘assume[d] that a customer will make [its] decision only on the merits,’” it is also well established that “a monopolist may use its power to break the competitive mechanism and deprive customers of the ability to make a meaningful choice.” ZF Meritor, LLC v. Eaton Corp., 696 F.3d 254, 285 (3d Cir. 2012) (internal quotations omitted). Generics need not be barred “from all means of distribution” if they are “bar[red] . . . from the cost-efficient ones.” Namenda, 787 F.3d at 656 (quoting Microsoft, 253 F.3d at 64). Indeed, “[t]he mere existence of other avenues of distribution is insufficient [to refute substantial foreclosure] without an assessment of their overall significance to the market.” Dentsply, 399 F.3d at 196; see also ZF Meritor, 696 F.3d at 287 (same).

Courts have recognized that where a product hop scheme has seriously weakened demand for a generic and rendered the generic not automatically substitutable at the pharmacy counter, the scheme may have destroyed an “economically meaningful market” and deprived customers of the ability to make a meaningful choice. See, e.g., Namenda, 787 F.3d at 654 (“Here, Defendants’ hard switch . . . forced Alzheimer’s patients who depend on memantine therapy to switch to XR (to which generic IR is not therapeutically equivalent) and would likely impact generic competition by precluding generic substitution through state drug substitution laws.”); Abbott Labs. v. Teva Pharms. USA, Inc., 432 F. Supp. 2d 408, 422, 423 (D. Del. 2006) (“[W]hile [generic manufacturers] may be able to market their own branded versions of the old TriCor formulations, they cannot provide generic substitutes for the current TriCor formulation, which is alleged to be their cost-efficient means of competing in the pharmaceutical drug market. That opportunity has allegedly been prevented entirely by Defendants’ allegedly manipulative and unjustifiable formulation changes. Such a restriction on competition, if proven, is sufficient to support an antitrust claim in this case.”); In re Loestrin 24 Fe Antitrust Litig., 433 F. Supp. 3d 274, 330 (D.R.I. 2019) (rejecting the defendant’s argument that no anticompetitive



conduct occurred because generics entered the market; “[t]hat Loestrin generics eventually entered the market does not preclude a finding of anticompetitive conduct—the jury could still find that [defendant] may have engaged in anticompetitive conduct by obstructing automatic generic substitution, a cost-efficient means of increasing competition.”); New York v. Actavis, PLC, No. 14-cv-7473, 2014 WL 7015198, at \*39 (S.D.N.Y. Dec. 11, 2014) (noting that “if a generic cannot be substituted at the pharmacy counter, the economically meaningful market for the generic product disappears.” (internal quotations omitted)).

Reckitt contends that when generic tablets launched in March 2013, they offered a “meaningful choice” for consumers and were available for first purchase at pharmacies across the country. It asserts that generic tablets were covered by almost every insurer and were available for purchase at pharmacies across the country. Although the generic market share lagged, Reckitt states that generics were able to prosper by charging higher prices. Reckitt notes that, by 2016, the two generic products had earned \$420 million in gross profits. Ultimately, Reckitt reasons that: generic products were reasonably available to consumers; generics vigorously advertised their products; and generic tablets were given near-universal insurance coverage, actually charging higher prices than brand film. Reckitt also cites to evidence that doctors were willing to prescribe generic tablets, were aware that generic tablets were available, and knew that generic tablets were financially available. As such, Reckitt posits that, absent evidence of exclusion, Plaintiffs cannot succeed on their claims and summary judgment should be granted.

Reckitt’s argument, however, oversimplifies the analysis. The mere availability of generic tablets on the market and some doctors’ willingness to prescribe those tablets do not undermine the potential for exclusion resulting from Reckitt’s actions. According to Plaintiffs’ expert, Dr. Berndt, “automatic substitution of AB-rated generics is one of the foundations of the drug distribution system in the US, relied upon by all levels of the pharmaceutical distribution chain to operate seamlessly and

efficiently.”<sup>5</sup> (Def.’s Ex. 1 ¶ 154.) Plaintiffs have adduced evidence that by developing film, disparaging the tablet, raising the price of the tablet, and then ultimately withdrawing the tablet from the market—all prior to generic entry—Reckitt’s film was able to attain an 80% market share. (Def.’s Ex. 19, ¶¶ 221–25, 241–43) Plaintiffs’ other expert, Dr. Lamb, opined, that absent Reckitt’s conduct, film share would have only been between 31% and 35% of all Suboxone sales. (Lamb Rep. ¶¶ 221–25, 241–43.)

Although generic tablets were able to enter the market, Plaintiffs have produced evidence that Reckitt’s conduct precluded the existence of an “economically meaningful market” and effectively deprived customers of the ability to make a meaningful choice. As discussed by Plaintiff’s expert, Robert Verscharen, absent AB-rated, automatic substitution, generics must rely on the less efficient and far less effective method of therapeutic substitution. Mr. Verscharen opined that therapeutic substitution programs are “difficult, inefficient, and rarely successful,”<sup>6</sup> and therapeutic substitution seldom occurs because of “the economics of pharmacy.” (Def.’s Ex. 26, Rep. of Robert Verscharen Rep. § B.) While filling a prescription through AB-rated substitution entails no time or monetary cost to the pharmacy, filling a prescription through therapeutic substitution costs over \$8.00 per prescription and takes over fifteen minutes. (Id. ¶¶ 55–56.)

When these inefficiencies are considered in conjunction with concerns over the safety of the generic, therapeutic substitution becomes even more difficult. (Def.’s Ex. 1, ¶ 170.) Mr. Verscharen opined that “the more that doctors believe that a branded product (such as Suboxone film) is

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<sup>5</sup> As noted above, generic drugs that are bioequivalent to, and of the same dosage size, form (*i.e.*, tablet, capsule, film), and administration as a brand drug are designated as “AB” rated to the brand drug. (Def.’s Ex. 1, ¶ 54.) In all fifty states, pharmacists are permitted to, and in most states are required to, substitute generic drugs that are AB-rated to brand drugs without consulting the prescribing physician. (Def.’s Ex. 26, ¶¶ 24–26.)

<sup>6</sup> In order for therapeutic substitution to occur, the patient must be asked if they want the lower-cost generic, the pharmacist has to check insurance coverage, the pharmacist has to discuss costs and benefits with the patient, the physician must be contacted about the substitution and will often not be reached immediately, the pharmacist must document the revised prescription, and the new prescription must be transmitted to the store. (Def.’s Ex. 26, Rep. of Robert Verscharen ¶¶ 50–52.)

significantly different than a non-AB-rated generic product (such as generic Suboxone tablets) then the more doctor resistance there likely will be to therapeutic substitution. In such a situation, the number of successful calls will drop, meaning that the pharmacist will face a high ratio of unsuccessful calls to each successful call.” (Verscharen Rep. ¶ 57.) For that reason, Mr. Verscharen indicated that “therapeutic interchange programs in general are rarely successful” and “therefore do not deliver anywhere near the cost savings that AB-rated substitution provides.” (*Id.* ¶ 58.)

Viewing all of this evidence in the light most favorable to Plaintiffs, a reasonable jury could find that Reckitt’s combined actions effectively broke the competitive mechanism in the market, severely restricted the market’s ambit, and deprived consumers of the ability to make a meaningful choice. A jury could also conclude that once Reckitt—using the entirety of its alleged hard switch scheme—moved 80% of the market to prescriptions for Suboxone film, which is not AB-rated to Suboxone tablets, it was neither economically feasible nor reasonably possible for generics to recapture any of the market upon entry. The fact that generics actually entered the market does not disprove the existence of a genuine issue of material fact as to whether generics were barred from all “cost-efficient” means of distribution. Accordingly, I will deny summary judgment on this ground.

**C. Whether the Challenged Conduct is Lawful**

Reckitt’s final argument in support of its Motion for Summary Judgment on All Claims returns to the first prong of the rule of reason analysis and echoes a familiar argument previously raised both in its litigation with the States and during class certification proceedings. Reckitt contends that all of the challenged conduct, individually or taken as a whole, is lawful. Reckitt posits that a proper antitrust analysis requires breaking down Plaintiffs’ allegations of a unitary conspiracy into its component parts. Reckitt again presses that none of its alleged anticompetitive actions were either exclusionary or illegal.

In general terms, “a firm engages in anticompetitive conduct when it attempts ‘to exclude rivals on some basis other than efficiency’ or when it competes ‘on some basis other than the merits.’” W. Penn Allegheny Health Sys., Inc. v. UPMC, 627 F.3d 85, 108 (3d Cir. 2010) (quoting Aspen Skiing

Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 605 (1985) and LePage’s, Inc. v. 3M, 324 F.3d 141, 147 (3d Cir. 2003)). “Conduct that impairs the opportunities of rivals and either does not further competition on the merits or does so in an unnecessarily restrictive way may be deemed anticompetitive.” Broadcom Corp. v. Qualcomm, Inc., 501 F.3d 297, 308 (3d Cir. 2007). Mere harm to competitors will not suffice; rather the alleged exclusionary acts must harm the competitive process and must actually have the requisite anticompetitive effect. Id. “The challenge for an antitrust court lies in stating a general rule for distinguishing between exclusionary acts, which reduce social welfare, and competitive acts, which increase it.” United States v. Microsoft Corp., 253 F.3d 34, 58 (D.C. Cir. 2001).

“‘Anticompetitive conduct’ can come in too many different forms, and is too dependent upon context, for any court or commentator ever to have enumerated all the varieties.” LePage’s Inc. v. 3M, 324 F.3d 141, 152 (3d Cir. 2003) (quoting Caribbean Broad. Sys., Ltd. v. Cable & Wireless PLC, 148 F.3d 1080, 1087 (D.C. Cir. 1998)). Indeed,

It is not the form of the combination or the particular means used but the result to be achieved that the statute condemns. It is not of importance whether the means used to accomplish the unlawful objective are in themselves lawful or unlawful. Acts done to give effect to the conspiracy may be in themselves wholly innocent acts. Yet, if they are part of the sum of the acts which are relied upon to effectuate the conspiracy which the statute forbids, they come within its prohibition.

Am. Tobacco Co. v. United States, 328 U.S. 781, 809 (1946).

Alleged antitrust conduct must be scrutinized as a whole “without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each.” Continental Ore Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 699 (1962). “If a plaintiff can allege that a series of actions, when viewed together, were taken in furtherance and as an integral part of a plan to violate the

antitrust laws, that series of actions, as an overall scheme, may trigger antitrust liability.”<sup>7</sup> In re Gabapentin Patent Liab., 649 F. Supp. 2d 340, 359 (D.N.J. 2009).

These tenets are particularly applicable in the context of an alleged product hopping scheme. “As a general rule, courts are properly very skeptical about claims that competition has been harmed by a dominant firm’s product design changes.” United States v. Microsoft Corp., 253 F.3d 34, 65 (D.C. Cir. 2001). “In a competitive market, firms routinely innovate in the hope of appealing to consumers, sometimes in the process making their products incompatible with those of rivals; the imposition of liability when a monopolist does the same thing will inevitably deter a certain amount of innovation.” Id. Nonetheless, “[j]udicial deference to product innovation . . . does not mean that a monopolist’s product design decisions are per se lawful.” Id. Although neither product withdrawal nor product improvement alone is anticompetitive, “when a monopolist combines product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits . . . and to impede competition . . . its actions are anticompetitive under the Sherman Act.” Namenda, 787 F.3d at 654. Indeed, the Third Circuit has explicitly recognized that independently lawful conduct—*i.e.*, discount programs, rebates, exclusive dealing contracts—can have an

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<sup>7</sup> Reckitt relies on In re Processed Egg Products, 962 F.3d 719, 728 (3d Cir. 2020) to argue that the Third Circuit requires a court’s individual assessment of the legality of the various components of an alleged conspiracy. This characterization is incorrect. In reality, the Third Circuit held that, “[c]ourts can consider the differing components of an alleged conspiracy separately *when determining which mode of antitrust analysis to apply*,” *i.e.*, rule of reason or *per se* standard. Id. at 728 (emphasis added). The Court rejected the plaintiffs’ argument that because they alleged a single overarching scheme and because some of the components of that scheme called for application of the *per se* standard, then the *per se* standard must apply to the entirety of the scheme. Rather, “[w]hen different stratagems are alleged to have furthered an antitrust conspiracy, the court is free to determine which analytical standard should apply to each.” Id. at 728. Were it otherwise, “[a] plaintiff with a bucket full of allegations about behavior rightly subject to the rule of reason could easily, by adding a single allegation of behavior that its anticompetitive *per se*, demand *per se* analysis of the whole.” Id.

Simply stated, In re Processed Eggs requires courts to disaggregate an anticompetitive scheme only for purposes of determining which analytical standard to apply, not to determine the legality of each component. Here, neither party argues for application of the *per se* rule to any part of the alleged anticompetitive conduct at issue. Rather, both sides appear to agree that the rule of reason applies to the entirety of the antitrust scheme. Given that agreement, In re Processed Eggs has no applicability here.

anticompetitive effect that is actionable under antitrust law. LePage's, 324 F.3d at 158–59; see also In re Keurig Green Mtn. Single-Serve Coffee Antitrust Litig., 383 F. Supp. 3d 187, 230 (E.D.N.Y. 2019) (recognizing that defendant's product design changes, combined with allegations of exclusive dealing, tying agreements, and product disparagement, purportedly coerced customers to purchase K-cups over comparable cups, rather than competing on the merits).<sup>8</sup>

The Third Circuit addressed a similar argument on appeal of my class certification decision in this case. Reckitt contended that Plaintiffs had not provided common evidence of injury or damages that matched a viable theory of liability. In re Suboxone, 967 F.3d 264, 270 (3d Cir. 2020). Rejecting this challenge, the Third Circuit noted that Plaintiffs' theory was not premised on solely one action; rather Plaintiffs alleged "that the totality of [Reckitt's] actions, such as raising prices, withdrawing tablets from the market, providing rebates only for film, disparaging the safety of tablets, and delaying the generics' entry by filing a citizen petition and not cooperating in the REMS process, suppressed generic competition and thus violated the antitrust laws." Id. Declining to examine each act individually, the Third Circuit found that it must "look at 'all the acts taken together [to determine whether they] show the willful acquisition or maintenance of a monopoly.'" Id. (quoting Bonjorno v. Kaiser Aluminum & Chem. Corp., 752 F.2d 802, 813 (3d Cir. 1984)<sup>9</sup> and citing Phila. Taxi Ass'n, Inc.

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<sup>8</sup> Defendant contends that in LePage's, the Third Circuit, before considering the "overall combined effect" of the defendant's anticompetitive conduct, first determined that all of the conduct at issue was in fact exclusionary. Defendant's argument is inaccurate. In LePage's, the Third Circuit did not disaggregate the alleged anticompetitive conduct. Rather it recognized that "[t]he relevant inquiry is the anticompetitive effect of 3M's exclusionary practices considered together." Id. at 162. It reiterated the Supreme Court's mandate, in Cont'l Ore, that courts "must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation." Id. Citing with approval the Ninth Circuit decision in City of Anaheim v. S. Cal. Edison Co., 955 F.2d 1373, 1376 (9th Cir. 1992), the Third Circuit expressly noted that "it would not be proper to focus on specific individual acts of an accused monopolist while refusing to *consider their overall combined effect* . . . We are dealing with what has been called the 'synergistic effect' of the mixture of the elements." Id. (quoting Anaheim, 955 F.2d at 1376).

<sup>9</sup> Reckitt attempts to recharacterize the holding in Bonjorno. It argues that Bonjorno only held that there was no need for a *damages* jury to determine what effect was caused by each unlawful act by the defendant only because a prior liability jury had already "found causation from only those acts

v. Uber Techs., Inc., 886 F.3d 332, 339 (3d Cir. 2018) (explaining that we “look to the monopolist’s conduct taken as a whole rather than considering each aspect in isolation”), cert denied., 139 S. Ct. 211 (2018)). The Court further remarked that Reckitt’s alleged monopolistic conduct was best described “as a multifaceted yet single scheme to move the market to Suboxone film to stifle competition from generic tablets.” Id. at 271, n.11. It expressly held that “while [Reckitt] would argue that each of the six allegedly anticompetitive actions represents a different theory of liability, in fact there is one theory of liability proven by a variety of acts resulting in one antitrust injury.” Id.

Against this precedential backdrop, I find that Plaintiffs have set forth sufficient evidence of a “hard switch” scheme that, when considered collectively, could constitute anticompetitive conduct that violated the antitrust laws. The Third Circuit has previously agreed that Plaintiffs need not disaggregate “legal” conduct from “illegal conduct.” Doing so would result in the untenable proposition that just because a defendant engaged in various actions or business decisions that, considered in isolation, may potentially be legal, the antitrust laws cannot touch a defendant’s attempt to use the cumulative effect of these actions/decisions to constrain the market and preclude competition. The case law cited above belies any such conclusion.

Nonetheless, I recognize that when faced with allegations of a broad antitrust scheme, it is still appropriate to consider the individual components of the scheme and whether those components could constitute anticompetitive conduct, so long as I keep “the larger scope of the scheme in context.” In re

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which could evince the defendants’ willful acquisition or maintenance of a monopoly.” Bonjorno v. Kaiser Aluminum & Chem. Corp., 752 F.2d 802, 813 (3d Cir. 1984).

Reckitt’s interpretation of that case is inaccurate. In Bonjorno the plaintiffs’ theory of its antitrust case was “not that any one act in itself is unlawful, but that all the acts taken together show the willful acquisition or maintenance of a monopoly which damaged and forced [another company] out of business.” Id. at 813. The Third Circuit noted that “[w]hen the antitrust injury is of an indivisible nature, and the jury properly found that the injury was caused by the defendant’s monopolization or attempt to monopolize, and when the plaintiffs’ proof of damages does not require distinguishing the various acts by the defendants, then it is unnecessary to segregate the damages according to the specific causes.” Id.

Asacol Antitrust Litig., 233 F. Supp. 3d 247, 261 (D. Mass. 2017) (citing cases). As the United States Court of Appeals for the Ninth Circuit has remarked:

[I]f all we are shown is a number of perfectly legal acts, it becomes much more difficult to find overall wrongdoing. Similarly, a finding of some slight wrongdoing in certain areas need not by itself add up to a violation. We are not dealing with a mathematical equation. We are dealing with what has been called the “synergistic effect” of the mixture of the elements.

City of Anaheim v. S. Cal. Edison Co., 955 F.2d 1373, 1376 (9th Cir. 1992) (quoting City of Groton v. Conn. Light & Power Co., 662 F.2d 921, 929 (2d Cir. 1981)). The outcomes of other cases reflect these principles of considering individual components in light of the overall scheme. Compare In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. 14–md–02503, 2015 WL 5458570, at \*13 (D. Mass. Sept. 16, 2015) (dismissing overall monopolization scheme because every allegation independently failed to allege a plausible anticompetition claim) and Intergraph Corp. v. Intel Corp., 195 F.3d 1346, 1366–67 (Fed. Cir. 1999) (same), with In re Asacol Antitrust Litig., No. 15-cv-12730, 2016 WL 4083333, at \*11 (D. Mass. July 20, 2016) (denying dismissal as to the citizen petition claims because while that conduct was immune from antitrust liability, it could still serve to illustrate the context and motive underlying the overall anticompetitive conduct). Thus, the Court may assess “the specific claims” while “ruminat[ing] upon the effect of combining those claims.” City of Anaheim, 955 F.2d at 1376.<sup>10</sup>

Consistent with that concept, both parties engage in individualized consideration of each component of the alleged anticompetitive scheme. Reckitt persists in its argument that because the challenged conduct individually is legal, it cannot support an antitrust claim. Plaintiffs respond that

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<sup>10</sup> These concepts are consistent with the authority submitted by Reckitt in its recent Notice of Supplemental Authority. See In re Epipen (Epinephrine Injection, USP Mktg, Sales Prac. & Antitrust Litig., – F.4<sup>th</sup> –, 2022 WL 3273055, at \*16 (10th Cir. July 29, 2022) (“For the sake of accuracy, precision, and analytical clarity, we must evaluate Mylan’s alleged exclusionary conduct separately . . . . Only then can we evaluate the evidence in totality to see if any ‘synergistic effect’ saves Sanofi’s case.” (internal citations omitted)); Mayor & City Council of Baltimore, et al., v. Abbvie Inc., et al., – F.4<sup>th</sup> –, 2022 WL 3030833, at \*5 (7th Cir. Aug. 1, 2022) (“Neither individually nor collectively do these [separate patent] settlements state a claim under § 1 of the Sherman Act.”).



each component of the scheme was to some degree exclusionary and, thus, such conduct is a cognizable part of the overall scheme. For the sake of comprehensiveness, I address each element of the alleged scheme to determine whether a genuine issue of material facts exists as to its exclusionary nature.

1. Introduction of Film

Reckitt first contends that, “taken in isolation, ‘simply introducing a new product on the market, whether it is a superior product or not, does not, by itself, constitute exclusionary conduct.’” (Def.’s Mem. Supp. Summ. J. 29.) Reckitt asserts that to overcome the antitrust law’s policy of “encouraging innovation,” Plaintiffs must show that the new product’s benefits are “insignificant” and that such efforts necessarily fail where, as here, the new product “provided some new benefit to consumers.” Reckitt claims that because Plaintiffs have admitted that film possessed some procompetitive benefits, and because Plaintiffs neither measured these benefits nor showed that they were outweighed by other effects of the alleged conduct, the introduction of film cannot be deemed anticompetitive as a matter of law. Reckitt posits that to hold that the development of film was anticompetitive would be “contrary to the pro-innovation policies expressly written into the Hatch-Waxman Amendments” and would undermine the pro-innovation principle endorsed by the Third Circuit. (Def.’s Mem. Supp. Summ. J. 32.)

The cases Reckitt cites in support of these arguments are inapposite. For example, Reckitt relies on Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP, 592 F.3d 991, 999 (9th Cir. 2010) where the sole alleged anticompetitive conduct was the introduction of an improved product design that was incompatible with the existing products on the market. Id. at 999–1000. The Ninth Circuit declined to weigh the benefits of an improved product design against resulting injuries to competitors, noting that [t]here are no criteria that courts can use to calculate the ‘right’ amount of innovation, which would maximize social gains and minimize competitive injury.” Id. at 1000. In so holding, however, the Ninth Circuit recognized “that introduction of a new and improved product

design *could* constitute a violation of [the antitrust laws] where ‘some associated conduct . . . supplies the violation.’” Id. (emphasis added) (quotation omitted). The Court observed that to state a claim for relief under Section 2 of the Sherman Act, “product introduction must be alleged to involve some associated conduct which constitutes an anticompetitive abuse or leverage of monopoly power, or a predatory or exclusionary means of attempting to monopolize the relevant market, rather than aggressive competition on the merits.” Id. at 999 (quotation omitted).

Reckitt also cites to In re iPod iTunes Antitrust Litig., 796 F. Supp. 2d 1137, 1143 (N.D. Cal. 2011) for the proposition that summary judgment is appropriate on a Sherman Act § 2 claim where there is no genuine issue of material fact that an update in a software product was an improvement. The Court concluded that because the new product was a genuine improvement, the Court could “not balance the benefits or worth” of the new product against its anticompetitive effects. Id. at 1144. In reaching this decision, the Court recognized that the defendant’s design changes to its software could be a violation of § 2 of the Sherman Act “[i]f Plaintiffs can prove that some conduct of Defendant associated with its introduction of [the new product] constituted ‘an anticompetitive abuse or leverage of monopoly power, or a predatory or exclusionary means of attempting to monopolize the relevant market.’” Id. (quotations omitted).

Finally, Reckitt relies on the Third Circuit opinion in Doryx, supra, for the proposition that courts cannot become “tribunals over innovation sufficiency.” Doryx, 838 F.3d at 440. As noted above, however, Doryx involved only an allegation that defendant changed from one formulation of a branded drug to another formulation, that was not AB-rated to the first and had no ostensible improvements over the first. The plaintiff alleged no other coercive conduct, no “patent cliff” was on the horizon, and generics were already on the market. The Third Circuit made clear that “we do not rule out the possibility that certain insignificant design or formula changes, combined with other coercive conduct, could present a close call with respect to establishing liability in future cases.” Id. at

440. It recognized that, in such “closer call” cases, courts would need to consider a multitude of additional facts. Id. at 440–41.

The facts before me are different than those in the cases cited by Reckitt. Plaintiffs do not deny that the innovation of film may have offered some benefit, and they do not ask me to weigh the benefit of the introduction of film against the costs to competition. Rather, Plaintiffs provide evidence, if accepted, that establishes that Reckitt combined the introduction of a new product, which was not AB-rated to the existing product, with the withdrawal of the existing product. The facts could also show that Reckitt engaged in a marketing campaign to disparage the safety of the existing product, increased the price of the existing product, withdrew the existing product from the market, delayed the shared REMS, and filed a false Citizen Petition. Plaintiffs assert that Reckitt did all of these actions in the face of an impending patent cliff in order to effectively destroy the market for tablets and switch the market to film prior to generics ever coming onto the market. These facts fall within the scenarios envisioned in Allied Orthopedic, iPod, and Doryx where the new product introduction involves some associated conduct “which constitutes an anticompetitive abuse or leverage of monopoly power, or a predatory or exclusionary means of attempting to monopolize the relevant market, rather than aggressive competition on the merits.” iPod, 796 F. Supp. 2d at 1144.

2. Reckitt’s Pricing Conduct

Reckitt next contends that all of its pricing conduct was both legal and non-exclusionary. It asserts that, on appeal to the Third Circuit, Plaintiffs expressly admitted that purchaser copay coupons and indirect purchaser rebates on Suboxone film were not part of the alleged anticompetitive scheme. Reckitt also asserts that its increases on the price of Suboxone tablets were lawful. Reckitt then returns to its oft-repeated refrain in this litigation—that its pricing of tablets was above-cost and, as such, cannot constitute unlawful “predatory-pricing.” Ultimately, Reckitt concludes that because its pricing practices were not improperly anticompetitive, and because Plaintiffs have failed to prove that price is not the “predominant method of exclusion,” the entire antitrust scheme must be dismissed.

In Eisai, Inc. v. Sanofi Aventis U.S., LLC, 821 F.3d 394 (3d Cir. 2016), the Third Circuit discussed the use of pricing allegations in the antitrust context. It noted that, “[u]nlawful predatory pricing occurs when a firm reduces its prices to below-cost levels to drive competitors out of the market and, once competition is eliminated, reduces output and raises its prices to supracompetitive levels.” Id. at 408. It further recognized that, “[r]educing prices to only above-cost levels . . . however, generally does not have an anticompetitive effect because ‘the exclusionary effect of prices above a relevant measure of cost . . . reflects the lower cost structure of the alleged predator, and so represents competition on the merits.’” Id. (quotations omitted). The Third Circuit went on to observe that, “[w]hile there may be situations where above-cost prices are anticompetitive, it is ‘beyond the practical ability of a judicial tribunal’ to ascertain this ‘without courting intolerable risks of chilling legitimate price-cutting.’” Id. (quotations omitted). Thus, where a plaintiff’s *primary allegation* of anticompetitive behavior relies on claims of predatory pricing, that claim can succeed only if the plaintiff can show that “(1) the rival’s low prices are below an appropriate measure of its costs and (2) the rival had a dangerous probability of recouping its investment in below-cost prices,” *i.e.*, the “price-cost test.” Id.

Consistent with Eisai, courts have repeatedly held that where pricing allegations are clearly the predominant mechanism of exclusion, an antitrust plaintiff must satisfy the price-cost test and show that the scheme at issue does not simply involve above-cost pricing. See, e.g., Philadelphia Taxi Assoc., Inc. v. Uber Techs., Inc., 886 F.3d 332, 340 (3d Cir. 2018) (holding that defendant’s ability to operate at a lower cost was not anticompetitive because such “economic efficiency . . . often translates to enhanced competition among market players, better products, and lower prices for consumers”); Federal Trade Comm’n v. Qualcomm Inc., 969 F.3d 974, 1001 (9th Cir. 2020) (“We . . . are aware of no authority holding that a monopolist may not lower its rates in response to a competitor’s entry into the market with a lower-priced product.”); Concord Boat Corp. v. Brunswick Corp., 207 F.3d 1039, 1061 (8th Cir. 2000) (“Because cutting prices in order to increase business often is the very essence of

competition, which antitrust laws were designed to encourage, it ‘is beyond the practical ability of a judicial tribunal to control [above-cost discounting] without courting intolerable risks of chilling legitimate price cutting.’” (quotation omitted)); see also ZF Meritor, LLC v. Eaton Corp., 696 F.3d 254, 276–77 (3d Cir. 2012) (holding where the “essence” of a plaintiff’s claim is that its “rival ha[d] priced its products in an unfair manner with an object to eliminate or retard competition and thereby gain and exercise control over prices in the relevant market, the plaintiff had an obligation to show that the defendant’s prices were below its costs.”).

Where, however, price is *not* clearly the predominant mechanism of exclusion, the price-cost test does not apply. Id. at 269. In such a case, “the price-cost tests are inapposite, and the rule of reason is the proper framework within which to evaluate [the] claims.” Id. at 277, 278 (“Although the Supreme Court has created a safe harbor for above-cost discounting, it has not established a *per se* rule of non-liability under the antitrust laws for *all* contractual practices that involve above-cost pricing.”). Indeed, “[n]othing in the Supreme Court’s recent predatory pricing decisions indicate[s] that the Court intended to overturn decades of other precedent holding that conduct that does not result in below-cost pricing may nevertheless be anticompetitive . . . [r]ather . . . [those cases] . . . each involved an allegation that the defendant’s pricing itself operated as the exclusionary tool.” Id. at 280; see also Eisai, Inc., 821 F.3d at 408–09 (“[N]ot all contractual practices involving above-cost prices are *per se* legal under the antitrust laws”; in factual circumstances where pricing is part of larger anticompetitive scheme, and not the primary exclusionary tool, above-cost pricing may be deemed exclusionary under the rule of reason).

Here, price is not the primary exclusionary tool but rather a part of a broader and more extensive exclusionary scheme. Plaintiffs present evidence that Reckitt used “economically-irrational” tablet price increases to coerce insurers to adopt policies forcing patients and physicians to shift to film. In particular, Plaintiff notes that when Reckitt first launched film, it priced film at parity with tablets. (Pls.’ Ex. 239.) Reckitt then undertook a purposeful strategy to enact “increasingly aggressive price

increases” on the tablet despite the fact that (a) tablets did not cost any more to make and (b) the cost of goods for film were higher than the tablet. (Pls.’ Ex. 249.) According to Plaintiffs’ evidence, these price increases were taken to “accelerate film conversion.” (Pls.’ Ex. 232.) Although Reckitt recognized that it would “take [a] hit on price protection,” it believed it would realize a “positive [return on investment] due to film conversion across all accounts.” (Id.; see also Pls.’ Ex. 249 (Chief Financial Officer Gibson informing CEO Shaun Thaxter that the result of this price increase was to sacrifice short term profits enjoyed from selling lower cost tablets in order to reap the gains of shifting the market to film for which there was no generic competition); Pls.’ Ex. 300 (noting that one of the main objectives of the tablet price increases was to “[d]rive further differentiation from competition by creating a cost differential between tablets and film to drive 50% of payers to prefer film over tablet through formulary actions and pull through programs.”).)

I also find no merit to Reckitt’s argument that Plaintiffs have failed to prove that price is not the “predominant mechanism of exclusion.” Reckitt contends that Plaintiffs’ expert has consistently insisted that they have no idea how much of the anticompetitive effect that they claim to have detected resulted from pricing, as compared to other factors. Absent such evidence, Reckitt argues that Plaintiffs have failed to prove that they have presented anything beyond a defective predatory pricing case.

As I previously found, where the “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 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.” In re Suboxone, 421 F. Supp. 3d at 37 (quoting Bonjorno, 752 F.2d at 812). “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. As set forth in great detail

above, that I need not rehash here, these pricing allegations could be viewed as part of a larger anticompetitive scheme.

3. Safety Claims

Reckitt next contends that Plaintiffs' allegations regarding Reckitt's unsubstantiated marketing safety claims do not support a cognizable antitrust claim. Reckitt posits that for statements to be actionable, those statements must be clearly or demonstrably false. According to Reckitt, Plaintiffs do not provide any expert testimony that Reckitt's statements about the safety of tablets versus film with respect to abuse, misuse, diversion, and pediatric exposure were in fact false or wrong. Absent any evidence that the statements in question were "clearly false" or "blatant misrepresentations"—even in the presence of other anticompetitive acts—Reckitt argues that such statements are not actionable as part of an antitrust scheme.

The law regarding false or fraudulent advertising in the antitrust context has been somewhat fluid. As a general rule, "deception, reprehensible as it is, can be of no consequence so far as the Sherman Act is concerned." E.R.R. Presidents Conf. v. Noerr Motor Freight, Inc., 365 U.S. 127, 145 (1961). The policy for this general principle is two-fold. First, "false advertising simply 'set[s] the stage for competition in a different venue: the advertising market.'" Retractable Techs., Inc. v. Becton Dickinson & Co., 842 F.3d 883, 895 (5th Cir. 2016) (quoting Sanderson v. Culligan Int'l Co., 415 F.3d 620, 623 (7th Cir. 2005)). "In such a setting, a business that is maligned by a competitor's false advertising may counter with its own advertising to expose the dishonest competitor and turn the tables competitively against the malefactor." Id. "Second, it will often be difficult to determine whether such false statements induced reliance by consumers and produced anticompetitive effects, or whether the buyer attached little weight to the statements and instead regarded them as biased and self-serving." Id.

Relying on the Supreme Court's decision in E.R.R. Presidents Conference, the Third Circuit, in Santana Prods., Inc. v. Bobrick Washroom Equip., Inc., 401 F.3d 123 (3d Cir. 2005), held that wrong, misleading, or debatable statements by one competitor about another competitor's products are

indicative of competition on the merits and, thus, do not constitute a “restraint of trade” for purposes of an antitrust violation. Id. at 132. The Court observed that such “wrong, misleading, or debatable” statements to potential customers are indicative of competition on the merits where competitors are free to persuade consumers and consumers are free to weigh the statements and make their own decisions. Id. at 132–33.

Subsequently, in West Penn Allegheny Health Sys., Inc. v. UPMC, 627 F.3d 85 (3d Cir. 2010), the Third Circuit modified its holding in Santana and sought to clarify the line between what type of marketing constitutes vigorous competition on the merits and what constitutes anticompetitive conduct. The Third Circuit viewed this as a critical distinction because the Sherman Act “directs itself not against conduct which is competitive, even severely so, but against conduct which unfairly tends to destroy competition itself.” Id. at 158 (quoting Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 458 (1993)). Identifying some of the conduct that could be deemed anticompetitive, the Court remarked that such conduct could include “making false statements about a rival to potential investors and customers.” Id. at 109. In doing so, the Court sought to limit the scope of its previous ruling in Santana. Id. at 109 n.14. Acknowledging that the Santana holding was phrased in “overly broad terms,” the Third Circuit clarified that “in some cases, such defamation, which plainly is not competition on the merits, can give rise to antitrust liability, especially when it is combined with other anticompetitive acts.”<sup>11</sup> Id. (finding that hospital system’s false statements about competitor’s financial health to investors were actionable as part of a larger anticompetitive scheme).

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<sup>11</sup> In an effort to avoid West Penn’s holdings, Defendant argues that “Santana remains binding authority” because “[t]o the extent that the decision of a later panel conflicts with existing circuit precedent, [the Court is] bound by the earlier, not the later decision.” (Def.’s Mem. Supp. Summ. J. on All Claims 42.) I disagree. West Penn does not conflict with Santana. Rather, it clarifies that the statement in Santana was phrased too broadly and that deceptive statements can, in fact, rise to the level of anticompetitive conduct in certain circumstances. Accordingly, I am bound by the most recent clarification by the Third Circuit.



In Doryx, the Third Circuit expanded further on the inclusion of deceptive statements in the context of an antitrust scheme, particularly in the pharmaceutical context. As noted above, the Court declined to “rule out the possibility that certain insignificant design or formula changes, combined with other coercive conduct, could present a closer call with respect to establishing liability in future cases.” Doryx, 838 F.3d at 440. In doing so, the Third Circuit emphasized that courts would “need to be cognizant of the unique separation between consumers and drug manufacturers in the pharmaceutical market, especially in cases where there is evidence of extreme coercion of physician prescribing decision or blatant misrepresentation<sup>12</sup> about a generic manufacturer’s version of a drug.” Id. at 440–41.

Against this legal landscape,<sup>13</sup> I conclude, for several reasons, that a reasonable jury could find that Reckitt’s alleged false “safety story” campaign was plainly not competition on the merits.

First, it bears repeating that Plaintiffs do not bring stand-alone deception claims. Rather, Reckitt’s allegedly unsubstantiated safety statements constitute part of the multiple types of conduct resulting in an illegal product hop—an actionable scheme under the Sherman Act.

Second, in the out-of-circuit cases relied upon by Reckitt, one of the concerns in allowing an antitrust claim to rest on false advertising or deception was the difficulty of determining “whether such false statements induced reliance by consumers and produced anticompetitive effects, or whether the

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<sup>12</sup> Defendant seizes on the “blatant misrepresentation” phrase and characterizes it as a hard and fast standard for reliance on deceptive statements in an antitrust case. No fair reading of these cases suggests that the Third Circuit was opining that only “blatant misrepresentations” could be anticompetitive.

<sup>13</sup> Defendant urges me to adopt the approach used in several circuits, which involves a rebuttable presumption that false advertising has only a *de minimis* effect on competition. These circuits have relied upon a variable six-part test that a plaintiff must satisfy to support an antitrust claim premised on false advertising: the statements at issue must be (1) clearly false; (2) clearly material; (3) clearly likely to induce unreasonable reliance; (4) made to unsophisticated parties; (5) continued for long periods; and (6) not readily cured by rivals. Retractable Techs., Inc. v. Becton Dickinson Co., 842 F.3d 883, 896 (5th Cir. 2016) (citing cases).

Defendant has not cited, and I have not found, any Third Circuit case that has adopted this approach. Accordingly, I remain bound by the dictates set forth in Santana, as modified by West Penn and Doryx.

buyer attached little weight to the statements and instead regarded them as biased and self-serving.” Retractable Techs., 842 F.3d at 895; see, e.g., Santana Prods. v. Bobrick Washroom Equip., 401 F.3d 123 (3d Cir. 2005) (toilet partition manufacturer suing competitor and sales representative, alleging scheme to discredit manufacturer’s products to government architects); Schachar v. Am. Acad. of Ophthalmology, 870 F.2d 397 (7th Cir. 1989) (ophthalmologists bringing antitrust action against American Academy of Ophthalmology alleging violation of antitrust laws by attaching the label “experimental” to radial keratotomy); The Medical Ctr. at Elizabeth Place, LLC v. Atrium Health Sys., 922 F.3d 713 (6th Cir. 2019) (physician-owned hospital suing healthcare network for per se violation of Sherman Act alleging in part that network’s “dear physician” letter to area doctors informing of network’s opposition to new physician-owned hospital in area did not constitute restraint); Avaya Inc., RP v. Telecom Labs, Inc., 838 F.3d 354, 395 (3d Cir. 2016) (manufacturer of telecommunications equipment alleging anticompetitive conduct based in part on dissemination of truthful statements that sowed “fear, uncertainty, and doubt”). Unlike any of those cases, however, this case exists in the unique and complicated regulatory market for pharmaceutical drugs where there is a “unique separation between consumers and drug manufacturers,” allowing for “extreme coercion of physician prescribing decisions or blatant misrepresentation about a generic manufacturer’s version of a drug.” Doryx, 838 F.3d at 440–41. Given this separation, and unlike other industries where consumers can credit or discredit disparagement as they see fit, the ultimate consumers of the drug at issue did not have the opportunity to evaluate the statements and decide whether or not to rely upon them.

Plaintiffs have produced evidence that Reckitt actively sought to deprive consumers of the ability to actively evaluate safety claims and make the choice between film and tablets. Reckitt’s own expert testified that, in the relevant period of 2010, physicians were less mindful of and more reliant on statements made by pharmaceutical companies and their representatives. (Pls.’ Ex. 14, 235:6–237:1.) Reckitt’s documents showed that many physicians viewed Reckitt as a “trusted advisor” and relied upon Reckitt’s sales representatives for information and training. (PASF ¶ 16.) Physicians who

allowed their patients to choose between film and tablets were disparagingly referred to as the “Choice Brigade,” and Reckitt used a “red flag” campaign to convince such doctors to stop giving patients a choice in the form of Suboxone. (Id. ¶ 77.) Plaintiffs further cite to evidence reflecting that Reckitt encouraged doctors to push back on any requests for tablets and warned physicians to distrust patients who preferred tablets because those patients could be misusing or diverting the tablets.<sup>14</sup> (Id. ¶¶ 78–80.)

Third, as noted in the cases relied upon by Reckitt, false claims are generally deemed not actionable because such false advertising simply sets the stage for competition in the advertising market and provides an opportunity for a competitor to counter with its own advertising, leaving consumers free to evaluate the competing claims. Here, however, the unique characteristics of the pharmaceutical market removed that stage. At the time Reckitt engaged in the allegedly false or unsubstantiated safety campaign, the only buprenorphine-naloxone products on the market were Suboxone tablets and Suboxone film; there were no generic products. Under FDA regulations, the generic manufacturers were therefore foreclosed from competing in the advertising market. See 21 C.F.R. § 312.7 (stating that a sponsor or investigator of a drug may not advertise or represent in a promotion context that an investigational new drug is safe or effective for the purposes for which it is under investigation). Reckitt remained the lone voice pitting one of its products against the other and controlling the entire flow of information to physicians, insurers, and the public. Accordingly, unlike in the cases upon which Reckitt relies, the alleged false advertising at issue actually eliminated the forum for competition in the advertising market.

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<sup>14</sup> For example, a November 2010 letter to physicians remarked that “[s]pecific demands or requests for sublingual tablets (mono or combo) in lieu of film may indicate risk for patient misuse due to crushing and snorting, and should be investigated by the prescribing MD.” (Pls.’ Ex. 206; see also PASF ¶¶ 81–88.) In addition, based on Reckitt’s claims of safety risks with the tablet, Reckitt sales representatives told doctors that prescribing tablets could cause the government to reclassify Suboxone and eliminate Office-based Opioid Therapy. As such, representatives encouraged doctors to deny tablets to patients in order to safeguard such Office-based Opioid Therapy. (PASF ¶ 90.)

Finally, “[a]ntitrust analysis must always be attuned to the particular structure and circumstance of the industry at issue. Part of that attention to economic context is an awareness of the significance of regulation.” Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 411 (2004). Therefore, I must look to the FDA’s marketing rules to determine whether Reckitt's safety statements were indeed “false” or “misleading.” Under the relevant regulations:

An advertisement for a prescription drug is false, lacking in fair balance, or otherwise misleading, or otherwise violative of section 502(n) of the act, among other reasons, if it:

...

(ii) Contains a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience.

...

(iv) Contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated.

...

(v) Presents information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does.

21 C.F.R. § 202.1(e)(6). Thus, pharmaceutical manufacturers understand that the standard for whether the drug marketing statements are “false, lacking in fair balance, or otherwise misleading” is whether the manufacturer has “substantial evidence or substantial clinical experience to support those statements.” In re Suboxone, No. 13-md-2445, 2020 WL 6887885, at \*41 (E.D. Pa. Nov. 24, 2020). In other words, under the FDA regulations, a false or misleading promotional statement is one that does not have the support of substantial evidence or statistically significant data from head-to-head clinical trials.

Plaintiffs have produced evidence that Reckitt did not have substantial scientific data to support any claims of superiority of the film over the tablets, and Reckitt's executives were aware of the lack of such data when they made the claims.

- In 2009 to 2010, Reckitt had not performed any clinical tests and had no “direct data” on whether Suboxone film would be less capable of diversion, only a subjective belief based on the characteristics of film, including unit dose packaging, dissolution rates, and strong adherence to the sublingual mucosa. Nor did Reckitt have any data to suggest that film had less pediatric exposure potential. (Pls.’ Ex. 29, Reuter Dep. at 49:21–52:18; 59:10–25.)
- In a June 26, 2009 FDA memo regarding Reckitt’s Film New Drug Application, the FDA found that the data submitted by Reckitt did not allow for any comparison of the safety profile of the Suboxone tablet to the safety profile of the Suboxone film, and expressly noted that “it would be impossible to claim any potential advantages of Suboxone [film] over the current Suboxone tablet product.” To the contrary, the FDA noted that the evidence “suggest[ed] that expanded use of this product will result in significant abuse and diversion that needs to be considered with any anticipated benefits the drug may offer.” (Pls.’ Ex.79.)
- In a March 29, 2010 memo, the FDA told Reckitt, “No, we do not agree that the packaging for [film] provides meaningful incremental protection against pediatric exposure . . . . Furthermore, because the film cannot be spit out (unlike a tablet) it is possible that a child who obtains access to even one dose might be more adversely affected than a child who obtains access to a single tablet.” (Pls.’ Ex. 77.) Indeed, when it was making statements about film being safer than tablets, Reckitt was aware that Suboxone film was also at risk for abuse. (Pls.’ Ex. 29, Reuter Dep. at 45:16–22; Pls.’ Ex. 98; Pls.’ Ex. 199.)
- As of December 20, 2011, Reckitt was “not aware of any data to indicate any differences in the abuse/diversion of Suboxone tablets versus Suboxone film.” (Pls.’ Ex. 104.) When Reckitt ultimately obtained “safety studies” in September 2012, these studies, according to Plaintiffs, were not only inconclusive, but were inherently unreliable. (PASF ¶¶ 56, 262–266.) As the FDA found in denying Reckitt’s Citizen Petition, “[b]oth the Petition and the Executive Summary of the RADARS study submitted in support of it acknowledge that the impact of educational interventions and packaging on the decline in pediatric exposure was not evaluated, and that definitive conclusions about these measures could not be reached.” (Def.’s Ex. 71.)

Such evidence, if accepted, is sufficient to allow Plaintiffs to survive summary judgment.

Reckitt strenuously objects to the importation of FDA standards of “false or misleading” into the antitrust context. Specifically, it notes that, under antitrust law, it is irrelevant whether a statement is merely “unsubstantiated” and thus does not comply with FDA regulations. Rather, for a statement to be “false” or “blatantly misleading” for purposes of being anticompetitive, Reckitt urges me to look at the more colloquial definitions of those terms and actually find that the statements were untrue. It

posits that because none of Plaintiffs' experts are able to opine that the safety statements were in fact false, such statements may not be considered as part of an antitrust claim.

Applying this reasoning in the context of the pharmaceutical market would make little sense. In the real world, pharmaceutical manufacturers must perform adequate studies and provide sufficient data to substantiate marketing statements about its drug. Reckitt's legal construct would flip that burden and require that an antitrust plaintiff *disprove* the validity of marketing statements by the manufacturer. In other words, a pharmaceutical manufacturer could, as part of an antitrust scheme, make unsupported claims about its drugs without doing any studies to substantiate those claims but be insulated from potential antitrust exposure because no contrary studies exist. See generally Am. Council of Certified Podiatric Physicians & Surgeons v. Am. Bd. of Podiatric Surgery, Inc., 323 F.3d 366, 372 (6th Cir. 2003) (recognizing the possibility that false advertising could damage competition and hence be a violation of the Sherman Act if it was "so difficult for the plaintiff to counter that it could potentially exclude competition.").

Moreover, Plaintiffs have produced evidence that Reckitt—as a pharmaceutical manufacturer—understood that, under controlling regulations, in order for it to make any marketing claims equivalent to the ones at issue, it required the support of substantial evidence or substantial clinical evidence. One of Reckitt's representatives testified that Defendant knew it "would need data to support any claim that was made" as to safety, and "to support a benefit of one over another, you would need a strong scientific data set to support that," meaning the study must be "[u]nder scientific principles . . . with scientific acceptance criteria." (Pls.' Ex. 4, Cairns Dep. at 158:9–159:2; 142:4–9; see also Pls.' Ex. 182 (Tim Baxter, Reckitt's Chief Medical Officer, stating that "unless we have done an analysis to determine statistical significance of the differences between film and tablet you cannot make claims like longer, faster, safer etc.")). Yet, taking the facts in the light most favorable to Plaintiffs, Reckitt made the safety statements to the pharmaceutical industry disregarding whether they were true, thereby creating the false perception that it actually had statistical support for the claims. To the extent that

Reckitt did not have such substantial evidence or substantial clinical support, Reckitt would—under the colloquial definition of the word—be making a “misrepresentation.” In other words, if accepted the facts could show that it is not Reckitt’s technical violation of the FDA regulation that was anticompetitive, but rather Reckitt’s false representation to the pharmaceutical community that it actually had scientific support for its claims.

To that end, I find that Reckitt’s use of an allegedly false or unsubstantiated safety marketing campaign could be deemed exclusionary. In turn, it may be considered part of the overall anticompetitive scheme set forth by Plaintiffs.

#### 4. Withdrawal of Branded Tablets

Reckitt next challenges Plaintiffs’ reliance on the withdrawal of branded tablets as part of the alleged exclusionary scheme. It reasons that the mere withdrawal of drug products, to the detriment of generic competitors, is not inherently competitive.

Reckitt’s overarching premise is correct: “[a] business’s decision to not produce a product, *simpliciter*, is not a violation of the antitrust laws.” Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc., 171 F.3d 912, 925 n.7 (3d Cir. 1999). “[A]s a general rule, ‘any firm, even a monopolist, may . . . bring its products to market whenever and however it chooses.’” Id. (quoting Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 286 (2d Cir. 1979)); see also Namenda, 787 F.3d at 653–54 (“[N]either product withdrawal nor product improvement alone is anticompetitive.”). When, however, when a brand manufacturer with monopoly power “*combines* product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than to persuade them on the merits, and to impede competition, its actions are anticompetitive under the Sherman Act.” Id. at 654 (emphasis in original) (citations omitted).

But again, this case involves evidence that could establish a combination of product withdrawal with other coercive activity. According to the undisputed evidence, between the 2010 launch of film and the September 2012 tablet withdrawal announcement, Reckitt discussed the possibility of

withdrawing tablets with insurers and other payors. Indeed, in conjunction with implementing its Film-Fail-First strategy, Reckitt was informing insurers that it planned to discontinue the Suboxone tablet. Specifically, in January 2011, Reckitt told MCO Highmark that, “[w]e are moving away from the Suboxone Tablet. All available resources are being devoted to the manufacturing and marketing of the Suboxone Film. We have not received an official word on when the Tablet will be discontinued but all our actions are moving in that direction.” (Pls.’ Ex. 296.) Reckitt’s president, Gary Phillips, instructed the Managed Care team to tell insurers that “we will moving to discontinue the Suboxone tab by year end, so they should be helping us to move share to the film.” (Pls.’ Ex. 93.)

Thereafter, in September 2012, Reckitt announced that it planned to withdraw branded tablets based on its understanding that Suboxone tablets were subject to significantly higher rates of accidental pediatric exposure. It remarked that,

While the data do not isolate the root cause of these findings, the child resistant, unit-dosed packaging of Suboxone Film may be one of the key contributing factors to the decrease in exposure rates compared to Suboxone Tablets that are distributed in a multi-dose bottle containing 30 tablets, since the active ingredient of both products is the same. Other factors may include [Reckitt’s] community and healthcare professional education initiatives in addition to the company’s Risk Evaluation and Mitigation Strategy program.

(Def.’s Ex. 189.) Despite these alleged safety concerns, Reckitt continued to sell tablets side-by-side with film. (Pls.’ Ex. 224; Def.’s Ex. 191.) Finally, in March 2013, after the launch of generic tablets, Reckitt discontinued its sale of Suboxone tablets.

Reckitt now contends that this conduct should not be deemed anticompetitive on five different grounds, none of which entitle it to summary judgment on this issue.

First, Reckitt asserts that only statements announcing the “imminent discontinuation” of a drug can constitute withdrawal, and what Reckitt announced to insurers was not sufficiently “imminent.” Reckitt posits that its pre-September 2012 comments about when the withdrawal would occur were vague and had no coercive effect on the market.



But, according to the evidence cited by Plaintiffs, the remarks constituted clear notification to the market that the Suboxone tablet was going to be withdrawn. Indeed, Reckitt's own executive testified:

Q. What is your understanding about how putting out notification of the ultimate or eventual discontinuation would force conversion to the film?

A. Well, putting out notification—does really two things. It—it allows physicians who are treating, you, patients on the tablets to get a head start on considering moving them to a different product, and it also puts the mind—will, puts us into the mind of the payors as to what their plan is going to be moving forward as the contracts expire or as this product moves off market where they're going to go in terms of getting this product available. So it really serves on two levels; the physician level as well as on the payor level.

(Pls.' Ex. 21, Marks Dep. at 262:23–63:17.)

When further asked whether the statements were an effort to prepare the payors for potential tablet withdrawal, another Reckitt executive testified:

A. Payors said, “If you ever choose to [withdraw the tablet], please give us a heads up notice so we can notify our members and we can prepare.” And, you know, payors did say that they would prefer a good six months advance notification if that ever did happen.

Q. And what was your understanding about how payors might prepare once they received notification or—or knowledge that the tablets were going to be withdrawn from the market?

A. If it happened, they would certainly notify members. They would notify providers letting them know that, “Look, you know, this is going to be out—or gone in—in—in months, the next few months or months to come, six months,” whatever it may be, whatever time frame. Notification, they'd say, you know, “You may have X amount of months left of inventory or refills allowed.” It would be member and provider notification.

Q. . . . Would payors attempt to do that to minimize patient disruption from the tablets' withdrawal?

A. Would payors do—yeah, they would—they would certainly not want members caught off guard just overnight saying, “Hey, your product's not available anymore for refill.” They would want to give

folks adequate advance notice to be—to avoid that. And you could classify that as disruption, yes.

(Pls.’ Ex. 24, Philo Dep. at 124:12–125:22.) Although many of Reckitt’s pre-September 2012 statements did not specify an exact date for withdrawal, they were issued with the precise intent of preparing the market for the inevitable withdrawal of the tablet.

Second, Reckitt contends that there is no evidence that these withdrawal statements had any effect on payors’ formulary decisions. Plaintiffs, however, have cited to testimony from several MCO executives who testified that their companies made formulary decisions based, at least in part, in reliance on these withdrawal statements. For example, Sarah Marche of Highmark testified that the fact that Suboxone tablets were being pulled from the market affected formulary decisions. (Pls.’ Ex. 20, Marche Dep. 93:24–96:10, 100:9–14.) Similarly, Sandra Reinhardt from Prime Therapeutics indicated that Prime agreed to remove tablet rebates with the understanding that the tablets were going to be removed from the market. (Pls.’ Ex. 28, Reinhardt Dep., 71:9–15.) Such evidence is sufficient to create a genuine issue of material fact.

Third, Reckitt posits that, during the relevant time period, “there were no patent cliffs on the horizon” since the exclusivity period protecting the Suboxone tablet had already expired in 2009. As such, Reckitt claims that during the 2010-2011 time period, generic companies were free to engineer their own versions of Suboxone tablets. This argument disregards Plaintiff’s evidence that (a) Reckitt had already moved the market from tablet to film as a result of the expiration of the exclusivity period, and (b) Reckitt allegedly took affirmative actions to delay the entry of generics further.

Fourth, Reckitt asserts that Plaintiffs have failed to prove that the September 2012 withdrawal announcement was unjustified. It contends that discovery has shown that its safety concerns were based on statistical data that FDA scientists found persuasive, including a study it received from a consultant, Venebio, which analyzed data from the Researched, Abuse, Diversion and Addiction-Related Surveillance (“RADARS”) System’s Poison Center Program regarding unintentional exposure

to buprenorphine and buprenorphine/naloxone products. (Def.'s Ex. 159.) The report concluded that “the risk of unintentional pediatric exposure to . . . tablets was 2.5 and 7.8 times higher, respectively, than the risk for combination film.” (Id.)

Plaintiff offers contrary evidence that the Venebio report was not reliable based on Venebio's long-standing business relationship with Reckitt and based on Reckitt's employees' active role in preparation of the report. (Pls.' Ex. 375, Murrelle 30(b)(6) Dep. at 25:6–26:4.) Indeed, the initial RADARS study provided by Venebio in early September 2012 was significantly less conclusive. (Pls.' Ex. 364.) According to this evidence, Reckitt's executives were disturbed by the lack of conclusive scientific support for the preconceived plan to find safety concerns, which would allow Reckitt to justifiably withdraw the tablet by mid-September 2012. (Pls.' Ex. 365.) Only following pressure from Reckitt did Venebio produce a study, less than two weeks later, that opined that tablets were more susceptible to pediatric exposure than film. (Id.)

When Reckitt submitted these identical studies in connection with its Citizen Petition, the FDA concluded that “withdrawal of SUBOXONE tablets is not necessary for reasons of safety. The RADARS study on which the Petition relies does not add substantial new information to the data review in connection with the SUBOXONE film NDA, which led to REMS requirements and labeling modifications for both the film and tablet products to address this issue. In fact, this data suggests an encouraging downward trend in accidental pediatric exposure that could be attributed to a variety of factors as discussed above.” (Def.'s Ex. 71.) The FDA further found that “[Reckitt's] own actions also undermine, to some extent, its claims with respect to the severity of this safety issue . . . . The timing of [Reckitt's] September 2012 announcement that it would discontinue marketing of the tablet product because of pediatric exposure issues, given its close alignment with the period in which generic competition for this product was expected to begin, cannot be ignored.” (Id.) Such conflicting evidence raises a genuine issue of material fact as to whether Reckitt's withdrawal announcement and decision were justified and subjectively motivated by genuine safety concerns.

Finally, Reckitt asserts that it marketed film and tablets side-by-side from 2010 through March 2013. As such, it claims to have “preserved the freedom of consumer choice because both products remained on the market contemporaneously for . . . years.” In re Asacol Antitrust Litig., 233 F. Supp. 3d 247, 269 (D. Mass. 2017). This argument takes a myopic view of the record and disregards the contemporaneous activity that Plaintiffs allege destroyed the market for generic tablet makers that entered the market in February 2013. These facts have already been thoroughly detailed above.

In short, I find that Reckitt’s tablet withdrawal statements and its actual tablet withdrawal are cognizable parts of the alleged antitrust scheme.

5. Reckitt’s Efforts to Obtain Coverage for Suboxone Film from State Medicaid Agencies

In its next challenge, Reckitt argues that Plaintiff’s efforts to obtain coverage for Suboxone film from state Medicaid agencies are immune from antitrust scrutiny. Relying on the Noerr-Pennington doctrine, Reckitt contends that a court cannot aggregate the effects of conduct immunized from antitrust liability with the effects of conduct not so immunized.

“The Noerr-Pennington doctrine takes its name from a pair of Supreme Court cases that placed a First Amendment limitation on the reach of the Sherman Act.” Campbell v. Pa. Sch. Bds. Assoc., 972 F.3d 213, 218 (3d Cir. 2020), cert. denied, 141 S. Ct. 2854 (2021). In the Noerr case, the Supreme Court held that the First Amendment right to petition the government must override statutory limitations on anticompetitive behavior. Id. (citing E.R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961)). In the Pennington case, the Supreme Court held that “efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition.” Id. (quoting United Mine Workers of Am. v. Pennington, 381 U.S. 657 (1965)).

“Noerr-Pennington immunity applies to actions which might otherwise violate the Sherman Act because “[t]he federal antitrust laws do not regulate the conduct of private individuals in seeking anticompetitive actions from the government.” A.D. Bedell Wholesale Co., Inc. v. Philip Morris Inc.,

263 F.3d 239, 251 (3d Cir. 2001) (quoting City of Columbia v. Omni Outdoor Advert., Inc., 499 U.S. 365, 379–80 (1991)). “The antitrust laws are designed for the business world and ‘are not at all appropriate for application in the political arena.’” Id. (quoting Noerr, 365 U.S. at 141). Thus, the Noerr-Pennington doctrine “immunizes private parties against antitrust liability based on the petitioning of government entities, even if there is an improperly anti-competitive motive or purpose behind the petition.” Byers v. Intuit, Inc., 600 F.3d 286, 298 (3d Cir. 2010).

Nonetheless, the Noerr doctrine does not immunize “every concerted effort that is genuinely intended to influence governmental action.” Allied Tube & Conduit Corp. v. Indian Head, Inc., 486 U.S. 492, 503 (1988). In order for the doctrine to apply there must be some sort of valid “petitioning activity.” See Hill v. Borough of Kutztown, 455 F.3d 225, 243 (3d Cir. 2006). The scope of Noerr-Pennington immunity depends “on the source, context, and nature of the competitive restraint at issue.” Allied Tube & Conduit Corp. v. Indian Head, Inc., 486 U.S. 492, 499 (1988)). On one hand, parties may be immune from liability for “the antitrust injuries which result from the petitioning itself” or “the antitrust injuries *caused by* government action which results from the petitioning.” A.D. Bedell, 263 F.3d at 251 (emphasis added). On the other hand, “[i]f the restraint directly results from private action there is no immunity.” Id. “That is, immunity will not categorically apply to private actions somehow involving government action.” In re Lipitor Antitrust, 868 F.3d 231, 264 (3d Cir. 2017). Immunity applies to “political activity with a commercial impact” but not “commercial activity with a political impact.” Ticor Title Ins. Co. v. FTC, 998 F.2d 1129, 1138 (3d Cir. 1993).

Here, Reckitt argues that its efforts to convince Medicaid agencies to place film on their Preferred Drug Lists by offering supplemental rebates that lowered the cost of film are immune from antitrust scrutiny under Noerr-Pennington. Reckitt contends that this conduct clearly had an objectively reasonable basis since Reckitt’s efforts were successful. Accordingly, Reckitt contends that Plaintiffs cannot premise antitrust liability on such conduct.

I decline to find that Noerr-Pennington precludes consideration of this type of conduct as part of Reckitt's overall antitrust scheme for several reasons. First, Plaintiffs assert that the campaign to move the market to film was directed to both *private* MCOs and governmental Medicaid agencies through the use of rebates. Reckitt's alleged governmental petitioning actions thus comprise only a small part of its efforts to obtain favorable coverage for Suboxone film. According to Reckitt, prescriptions paid by State Medicaid agencies made up only 25% of Suboxone sales. (DSUF ¶ 147.) Therefore, even if the efforts to convince the Medicaid agencies to give formulary preference to film are immunized, the efforts to convince private MCOs to give such formulary preference are not.

Moreover, Reckitt has not explained how a finding that this activity is subject to Noerr-Pennington protection<sup>15</sup> entitles it to summary judgment on the entirety of Plaintiffs' antitrust claim. "It is well settled that First Amendment rights are not immunized from regulation when they are used as an integral part of conduct which violates a valid statute." Calif. Motor Transport Co. v. Trucking Unlimited, 404 U.S. 508, 514 (1972); see also Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau, Inc., 690 F.2d 1240, 1263 (9th Cir. 1982) ("An antitrust violation does not enjoy immunity simply because an element of that violation involves an action which itself is not illegal"; "[W]hen there is a conspiracy prohibited by the antitrust laws, and the otherwise legal litigation is nothing but an act in furtherance of that conspiracy, general antitrust principles apply, notwithstanding the existence of Noerr immunity."). Where certain conduct is immunized from antitrust liability, a court must still "consider evidence of the remaining challenged conduct in the aggregate to see if it is sufficient to support antitrust liability." Mercatus Grp., LLC v. Lake Forest Hosp., 641 F.3d 834, 839 (7th Cir. 2011).

Plaintiffs are not seeking to hold Reckitt liable based on its statements to the Medicaid agencies. Rather, they are alleging that Reckitt engaged in a hard-switch product hop combined with

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<sup>15</sup> The parties offer little briefing on whether Reckitt's actions actually constitute a governmental petition which is immunized by Noerr-Pennington. I decline to resolve that issue since whether such conduct is immunized has no bearing on the resolution of the summary judgment motion before me.

alleged false safety statements, an increase in the price of tablets, a baseless Citizen Petition, and delay in the shared REMS process. The fact of Reckitt's petitioning—and its role in the overall scheme—does not become untrue simply because the conduct is not independently non-actionable. And certainly, Plaintiffs are permitted to establish that this activity, lawful or not, was just another building block in causing the overall anticompetitive injury. And, even if I were to find that Reckitt's petitioning of State Medicaid agencies was immunized, Plaintiffs' evidence of the remaining challenged conduct, considered in the aggregate, would still be sufficient to support antitrust liability.

6. Reckitt's Citizen Petition

In its next challenge, Reckitt contends that Plaintiffs' reliance on the Citizen Petition filed by Reckitt with the FDA as part of the larger antitrust scheme is improper on two grounds. First, Reckitt contends that Plaintiffs have failed to show that the Petition caused any delay in approval of generic tablets. Second, Reckitt posits that the Citizen Petition is also immunized under Noerr-Pennington.

a) *Whether the Citizen Petition Caused Delay*

Reckitt first contends that the Citizen Petition caused no delay in approval of generic tablets, as shown by testimony from the FDA, FDA's reports to Congress, the laws, and FDA policies governing citizen petitions. Specifically, Reckitt notes that the FDA approved the first generic alternatives to Suboxone Tablets on the same day it denied the Citizen Petition—February 22, 2013. (Def.'s Exs. 71, 75, 220.) Reckitt notes that, under FDA regulations, ANDA approval will not be delayed by citizen petitions and the court should presume that FDA officials followed the law. See 21 U.S.C. § 355(q)(1)(A); (Def.'s Ex. 51.) Reckitt points to the deposition of Dr. Kellie Taylor, an FDA scientist who evaluated the Citizen Petition and reviewed REMS-related elements of the ANDAs. Ms. Taylor testified that the Petition did not delay the approval of the ANDAs. (Def.'s Ex. 53, Kellie Taylor Dep., 131:3–20, 165:9–13.) Moreover, the FDA's 2012 and 2013 reports to Congress, covering the time period from October 1, 2011 through September 30, 2013, stated that only two ANDA approvals were delayed because of citizen petitions, neither of which related to buprenorphine products. (Def.'s Exs.

229, 231.) Reckitt thus posits that, absent any contrary evidence, Plaintiffs have failed to show a causal link between the Citizen Petition and the launch date of generic Suboxone Tablets.

While this evidence may be favorable in front of a factfinder, Reckitt has failed to prove an entitlement to summary judgment on this issue. “The causation requirement requires a plaintiff to show that the defendant’s antitrust violation was a ‘material cause’ of the plaintiff’s injury.” In re Flonase Antitrust Litig., 798 F. Supp. 2d 619, 627 (E.D. Pa. 2011) (quoting Am. Bearing Co. v. Litton Indus., Inc., 729 F.2d 942, 952 (3d Cir. 1984)). “An antitrust violation is a ‘material cause’ of an injury if it is a proximate cause of that injury.” Id. A plaintiff “need not allege proximate cause or antitrust injury separately for each component of the alleged scheme . . . [rather] [t]he injuries inflicted by [the defendant’s] allegedly anticompetitive activities should, instead be viewed as a whole.” In re Remicade Antitrust Litig., 345 F. Supp. 3d 566, 577 (E.D. Pa. 2018) (quoting In re Gabapentin Patent Litig., 649 F. Supp. 2d 340, 355–56 (D.N.J. 2009)). Moreover, an antitrust violation can be the proximate cause of a plaintiff’s injury even if there are additional independent causes of the injury. In re Flonase, 798 F. Supp. 2d at 628; see also Spear Pharm, Inc. v. William Blair & Co., 610 F. Supp. 2d 278, 284–87 (D. Del. 2009) (holding that the FDA’s delay in approving a generic manufacturer’s ANDA did not break the chain of causation originating from the defendant’s citizen petition). Ultimately, “[w]hether conduct constitutes intervening conduct that breaks the chain of causation and whether intervening conduct is a foreseeable consequence of a defendant’s actions are questions of fact to be submitted to the jury.” Flonase, 798 F. Supp. 2d at 628.

Against this backdrop, I find that summary judgment is inappropriate on this portion of the alleged antitrust scheme for several reasons. Primarily, as noted numerous times, the alleged anticompetitive conduct at issue is not confined to the Citizens Petition alone, but rather includes various actions by Reckitt in an effort to effectuate its product hop. I have already found that Plaintiffs “need not explicitly state that the delay they alleged violated the FDA’s statutory duties under 21 U.S.C. § 355(q)(1)(A).” Suboxone, 2017 WL 36371, at \*11.



Moreover, Reckitt's reliance on FDA regulations to argue that the FDA is prohibited from delaying ANDA approvals for pending citizen petitions is misplaced. The FDA regulation to which Reckitt cites provides that:

The Secretary shall not delay approval of a pending application submitted under subsection (b)(2) or (j) of this section or section 262(k) of Title 42 because of any request to take any form of action relating to the application, either before or during consideration of the request, *unless—*

(i) the request is in writing and is a petition submitted to the Secretary pursuant to section 10.30 or 10.35 of title 21, Code of Federal Regulations (or any successor regulations); and

**(ii) the Secretary determines, upon reviewing the petition, that a delay is necessary to protect the public health.**

Consideration of the petition shall be separate and apart from review and approval of any application.

21 U.S.C. § 355(q)(1)(A) (emphasis added).

This provision is revealing in two respects. First, the FDA may delay an ANDA if, after reviewing a petition, it determines that public health requires such delay. Thus, if the FDA believed, on first review of Reckitt's Citizen Petition, that there may have been a public health concern, it may have delayed the approval of the Generics. Second, the FDA defines the term "delay" narrowly as whether "would the ANDA . . . be ready for approval but for the issues raised by the petition." <https://www.fda.gov/media/130878/download>. As such, § 505(q) is implicated where the citizen petition delays FDA *approval* of an ANDA but not the situation where the filing of a citizen petition delays the FDA's *review* of an ANDA.<sup>16</sup> To the extent Reckitt's actions delayed the FDA's beginning its review of the Generic ANDAs, thereby resulting in a delay of the ultimate approval of the Generics, this conduct could be considered by a factfinder.

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<sup>16</sup> In its Eighth Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action, the FDA explicitly noted that it "continued to be concerned that section 505(q) may not be discouraging the submission of petitions that are intended primarily to delay the approval of competing drug products and do not raise valid scientific issues." <https://www.fda.gov/media/99871/download>.

As I find that a genuine issue of material fact remains on the question of whether Reckitt's Citizen Petition caused anticompetitive harm in the context of the entire antitrust scheme, I will deny summary judgment on this ground.

b) Noerr-Pennington Protection

Alternatively, Reckitt argues that the Citizen Petition also has Noerr-Pennington immunity because it involves petitioning the Government for a redress of grievances. Reckitt contends that it had ample reason to believe that at least one of the claims in its Citizen Petition were valid and may succeed on its merits. As such, it claims that any antitrust claims based on the alleged delay caused by the Citizen Petition must be dismissed.

Plaintiffs respond that the Citizen Petition was a sham and, therefore, is not entitled to immunity. Where the Noerr-Pennington doctrine applies, the only exception is for a petition which, in reality "is a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." Campbell v. Pa. Sch. Bds. Assoc., 972 F.3d 213, 218–19 (3d Cir. 2020) (quoting Noerr, 365 U.S. at 144). The Supreme Court set out a two-pronged test to determine whether a party's conduct is a sham and therefore not entitled to Noerr-Pennington immunity: (1) the lawsuit or other petition must be objectively baseless in the sense that no reasonable litigant could reasonably expect success on the merits, and (2) if not, whether the baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor through the use of governmental process. Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60–61 (1993). Where a plaintiff provides some evidence to invoke the sham exception, the question whether a petition is a sham "is generally a question of fact for the jury[.]" Indep. Taxicab Drivers' Emps. v. Greater Hous. Transp. Co., 760 F.2d 607, 612 n.9 (5th Cir.1985); see also Kravco Co. v. Valley Forge Ctr. Assocs., No. 91-cv-4932, 1992 WL 97926, at \*3 (E.D. Pa. Apr. 30, 1992) ("Whether or not the acts of the defendants fit the sham exception is a factual issue. . .").

Here, a genuine dispute of material fact exists over whether Reckitt had a sufficient basis to bring the Citizen Petition at issue. For its part, Reckitt posits that the Citizen Petition asked the FDA to (1) mandate targeted educational programs regarding pediatric exposure, (2) mandate the use of Unit-Dose Packaging in buprenorphine products, and (3) declare that Suboxone tablets, which did not have Unit-Dose Packaging, were being discontinued for safety reasons. Reckitt asserts that it had a sound basis to make these requests even if the FDA did not fully implement them.

In response, Plaintiffs' produce contrary evidence suggesting that Reckitt's Citizen Petition was not based on statistically significant data and was motivated solely by a desire to delay generic approval. Indeed, as noted above, in denying all of the requests in the Citizen Petition on their merits, the FDA specifically called into question Reckitt's motives, commenting that "[t]he timing of [Reckitt's] September 2012 announcement that it would discontinue marketing of the tablet product because of pediatric exposure issues, given its close alignment with the period in which generic competition for this product was expected to begin, cannot be ignored." (Def.'s Ex. 71.) The FDA referred the matter to the Federal Trade Commission to investigate allegations of anticompetitive behavior by Reckitt. (*Id.*)

Given the prohibition on a district court weighing competing evidence under Federal Rule of Civil Procedure 56, I need not engage in a detailed discussion of the parties' lengthy evidentiary submissions on this issue. Although Plaintiffs bear the burden of proving the sham exception to the Noerr-Pennington doctrine, the ultimate determination of whether they have done so rests with the jury rather than the court.

7. Delay in the Shared REMS Negotiations

Reckitt's final argument in support of its Motion for Summary Judgment on All Claims contends that the evidence relating to the Shared REMS or "SSRS" negotiations does not support an antitrust claim. As noted above, an SSRS is a single Risk Evaluation and Mitigation Strategy ("REMS") that encompasses multiple drug products, including a brand drug and its generic versions,

which is developed and implemented by two or more sponsors. If an ANDA holder is seeking approval for a generic version of a drug that is subject to a REMS, the FDA requires the brand and generic to cooperate in developing and implementing an SSRS. Plaintiffs allege that Reckitt feigned cooperation in the SSRS in order to delay the approval of generic products.

Reckitt argues that this conduct cannot be included as part of the anticompetitive scheme. It contends that even assuming Reckitt made false statements about its willingness to negotiate, Plaintiffs cannot prove that any such statement was made to an unsophisticated party, that anyone relied on the statements, or that Reckitt's rivals had no opportunity to correct the statements. Absent such proof, Reckitt urges that the REMS conduct is not actionable.

Reckitt again turns to the Third Circuit decision in Eisai, In v. Sanofi Aventis U.S., LLC, 821 F.3d 394 (3d Cir. 2104), wherein a drug manufacturer was alleged to have suppressed competition by using, among other things, a marketing campaign to cast doubt on the safety and effectiveness of competing drugs. Id. at 399. The Third Circuit found that false or deceptive statements only violate the antitrust laws in rare circumstances. Id. at 407 n.40. The Court went on to note that “[t]he District Court held that [plaintiff] failed to put forth evidence demonstrating reliance and [plaintiff] does not explicitly challenge this finding . . . [and even if plaintiff had done so, plaintiff] has given us no reason to believe that it could not have corrected [defendant’s] misstatements by supplying the hospitals with accurate information.” Id.

As discussed above, reliance on Eisai and other similar cases is inapposite. Unlike in Eisai, Plaintiffs do not allege an anticompetitive scheme premised on false or deceptive statements/advertisement. Nor is this a case, as in Eisai, where the alleged victim of the false or deceptive statements could go into the marketplace and rebut the misstatements with accurate information. Rather, Plaintiffs allege a multi-faceted scheme of which the SSRS conduct and its impact on the approval of generic tablets was a part. The SSRS conduct at issue involves Reckitt's refusal to

cooperate in the shared REMS process, despite its representations, both to generics and to the FDA, that it intended to do so. To that end, Plaintiffs adduce evidence of such conduct:

- When Reckitt first learned that a new REMS program was required, Reckitt's CEO Shaun Thaxter suggested that Reckitt should "[a]djust the existing RB [Reckitt Benckiser] REMS strategy to exploit the new opportunity of the FDA response. The door is not open to work in closer alignment with the FDA to achieve our public health objectives. This may create the opportunity to bring forward the timing, and increase the probability of success, in effecting a switch from tablet to film. Assuming that we can substantiate our assumption that this is going to significantly delay competitor entry, we intend to create a plan which is commercially more attractive than the current 3 year view." (Pls.' Ex. 276.)
- In March 2010, Tony Goodman from Reckitt circulated to other of Reckitt's executives an "interesting" article," noting that "[t]he need for generic manufacturers to comply with some (non-clinical) aspects of Risk Evaluation and Mitigation Strategies (REMS) during abbreviated new drug application (ANDA) submission can significantly delay generic market entry in the event that branded manufacturers fails to cooperate . . . (Pls.' Ex. 197.)
- In June 2011, Reckitt's executives were determining how to respond to the FDA's inquiry regarding a shared REMS with ANDA applicants. Ju Yang, Reckitt's Global Head of Regulatory Affairs, suggested, "[w]hy don't we propose an outrageous high price for generic to participate in our REMS? This way it can be viewed by FDA that we are collaborative (at least to a certain extent)." (Def.'s Ex. 245.) John Song, the Manager of NA Regulatory Affairs Operations, responded "That's correct Ju. FDA doesn't want to review multiple REMS. We can open dialog with the generic company and propose outrageous cost to them in which we know what the outcome to that would be." (Id.)
- From late September 2010 to May 2011, the FDA and Reckitt communicated about conducting a shared safety study. Repeatedly, Reckitt stated that it was not interested in participating in such a shared study. (Def.'s Ex. 244; Def.'s Ex. 245.) Ultimately, however, in January 2012, Reckitt told at least one of the generics, Amneal, that it was open to discuss a single-shared REMS and would be in touch. (Pls.' Ex. 277.) Subsequently, on February 10, 2012, Reckitt expressly told the FDA that it intended to "fully engage in these [REMS] discussions and collaborate with the ANDA holders." (Def.'s Ex. 107.)

Plaintiffs have also pointed to evidence that, despite Reckitt's representations, Reckitt ultimately acted in a contrary fashion and declined to participate in the shared REMS. As such, it is not the misrepresentations themselves that constitute the anticompetitive conduct, but the efforts at delaying and ultimately stalling the shared REMS process that caused the anticompetitive effect.

The FDA recognized the anticompetitive nature of these actions when granting the generic companies' request that the shared REMS procedure be waived. Specifically, it noted that, "[t]he lack of restrictive elements in the REMS program for buprenorphine products (e.g., enrollment

requirements, certifications, restricted distribution, etc.), and [Reckitt's] efforts that appeared to be designed to delay agreement on an [SSRS] program were significant factors in this determination.” (Pls.’ Ex. 76.) The FDA further remarked that “[i]n addition to the delays caused by Reckitt in the negotiations over the [SSRS], [Reckitt] took actions in the Fall of 2012 that appear to have been designed to delay approval of the pending ANDAs for generic Subutex® (buprenorphine HCl) and Suboxone® (buprenorphine HCL-naloxone HCL) sublingual tablets,” including the discontinuation of Suboxone tablet marketing based on an alleged higher rate of accidental pediatric exposure, submission of a citizen petition regarding the dangers of tablets, a request that the FDA not approve any ANDA for generic Suboxone tablets, and withdrawal as a member of the group originally tasked with designing the SSRS. (*Id.*) The FDA ultimately approved the waiver, finding that “a waiver is necessary . . . to ensure that [Reckitt] does not infinitely delay approval of the pending buprenorphine ANDAs—and deny patient access to affordable generic drug products in the process—by refusing to cooperate with the Buprenorphine ANDA Applicant Holders on the development of an [SSRS].” (*Id.*)

Accordingly, I will deny summary judgment on this ground.

#### **IV. RECKITT’S MOTION FOR SUMMARY JUDGMENT PERTAINING TO SPECIFIC PLAINTIFFS AND REMEDIES**

Reckitt’s second Motion seeks summary judgment as to specific Plaintiffs and specific remedies. As its numerous arguments are unrelated, I will consider each argument separately.

##### **A. Whether MonoSol and Reckitt Could Enter into an Unlawful Conspiracy**

Reckitt’s first argument challenges the States’ claim of conspiracy—in violation of the Sherman Act and state antitrust laws—against Reckitt and MonoSol. Reckitt’s Motion contends that MonoSol and Reckitt could not, and did not, enter into an unlawful conspiracy for two reasons: (1) because MonoSol had no actual or potential presence in the relevant market, other than as a contractor to Reckitt, an agreement between these parties could not “deprive the marketplace of independent centers of decisionmaking,” and (2) the States have failed to prove that the written agreements between

Reckitt and MonoSol had an anticompetitive element. For the following reasons, I find no merit to either argument.

“To prevail on a section 1 claim or a section 2 conspiracy claim, a plaintiff must establish the existence of an agreement, sometimes also referred to as a ‘conspiracy’ or ‘concerted action.’” W. Penn Allegheny Health System, Inc. v. UPMC, 627 F.3d 85, 99 (3d Cir. 2010) (quotations omitted). “An agreement exists when there is a unity of purpose, a common design and understanding, a meeting of the minds, or a conscious commitment to a common scheme.” Id. (citing Copperweld Corp. v. Indep. Tube Corp., 467 U.S. 752, 771 (1984)) (further citations omitted). To establish an agreement, a plaintiff may rely on direct or circumstantial evidence, or a combination of the two. Id.

In American Needle, Inc. v. National Football League, 560 U.S. 183 (2010), the Supreme Court emphasized that “substance, not form, should determine whether a[n] . . . entity is capable of conspiracy under § 1.” Id. at 195 (quoting Copperweld, 467 U.S. at 773 n.21). “The key is whether the alleged ‘contract, combination . . . , or conspiracy’ is concerted action—that is, whether it joins together separate decisionmakers.” Id. By way of example, the Court remarked that while the president and vice president of a firm could act in combination, their joint action generally is not the sort of combination that § 1 intended to cover. Id. The same holds true for “internally coordinated conduct of a corporation and one of its unincorporated divisions.” Id. at 195–96. The Supreme Court clarified that “[b]ecause the inquiry is one of competitive reality, it is not determinative that two parties to an alleged § 1 violation are legally distinct entities. Nor . . . is it determinative that two legally distinct entities have organized themselves under a single umbrella or into a structured joint venture. The question is whether the agreement joins together ‘independent centers of decisionmaking.’” Id. at 196.

Importantly, American Needle taught that it is crucial to look beyond a corporate relationship “in favor of a functional consideration of how the parties involved in the alleged anticompetitive conduct actually operate.” Am. Needle, 560 U.S. at 191. “Competitors ‘cannot simply get around’

antitrust liability by acting ‘through a third-party or joint venture.’” Id. at 220 (quotations omitted). The mere fact that separate entities cooperate with each other to produce a certain product does not necessarily insulate the agreement from antitrust scrutiny as “[t]he justification for cooperation is not relevant to whether that cooperation is concerted or independent action.” Id. at 199. Moreover, “a conspiracy in violation of section 1 does not require the sharing of an identical anticompetitive motive.” Fineman v. Armstrong World Indus., Inc., 980 F.2d 171, 215 (3d Cir. 1992). Rather, it suffices that an antitrust plaintiff present evidence that reasonably tends to show that the conspirators “had a conscious commitment to a common scheme designed to achieve an unlawful objective.” Monsanto Co. v. Spray-Rite Serv. Co., 465 U.S. 752, 768 (1984).

Reckitt now contends that any agreement between itself and MonoSol could not function to deprive the marketplace of actual or potential competition. It posits that MonoSol never competed with Reckitt and, indeed, had no ability to do so because it did not market finished buprenorphine products of its own, supply active ingredients, act as a sales force or distributor, purchaser or consumer of any buprenorphine product, employ doctors, or function as a third-party payor. Moreover, Reckitt asserts that MonoSol’s economic success was tied fully to Reckitt’s success and, but for its contracts with Reckitt, MonoSol would have no presence in the relevant market. Finally, citing to the written contracts between Reckitt and MonoSol, Reckitt presses that the two companies’ agreements were entirely procompetitive and designed to develop and market a new product without any written agreement regarding film pricing, rebates or coupons, tablet pricing or rebates, the discontinuation of tablet sales, safety claims, the REMS negotiations, or the Citizen Petition.

Reckitt raised a similar argument in moving to dismiss the States’ conspiracy claim under Federal Rule of Civil Procedure 12(b)(6), contending that Reckitt and MonoSol were in effect a single enterprise that could not legally conspire under the Supreme Court’s ruling in Copperweld Corp. v. Independence Tube Corp., 467 U.S. 752 (1984). In my opinion denying that argument, I declined to



find that Reckitt and MonoSol were in a joint venture in which MonoSol was effectively the agent of Reckitt. Specifically I held that:

MonoSol is a separate corporation engaged in the development, manufacture and sale of pharmaceuticals throughout the United States. . . . Neither [Reckitt] nor MonoSol were responsible for the other corporation's day-to-day operations. . . . [A]lthough [Reckitt] contracted for MonoSol to receive royalty fees on sales of Suboxone film, nothing in the complaint suggests that this was MonoSol's sole form of income or that its economic success was tied fully to [Reckitt's] economic success. Rather, the reasonable inference is that the particular agreement between the two parties created economic incentives for the parties to put forth their best efforts in carrying out their joint venture related to Suboxone film. On a broader scale, the two parties were acting for their own financial interests.

In re Suboxone, No. 16-cv-5073, 2017 WL 3967911, at \*21 (E.D. Pa. Sept. 8, 2017).

Reckitt's reformulation of that argument—alleging that MonoSol and Reckitt are non-competitors who cannot conspire to restrain trade—fares no better on summary judgment. It is undisputed that Reckitt and MonoSol are entirely distinct entities, with entirely distinct decisionmakers, engaged in entirely different businesses. Complete unity of economic interest is lacking. Although both MonoSol and Reckitt shared a joint incentive to see Suboxone film succeed in the market, and the majority of MonoSol's revenue derived from the sale of Suboxone film, their agreement involved “separate economic actors pursuing separate economic interests.” Am. Needle, 560 U.S. at 191.

Moreover, while Reckitt seeks to limit the scope of its agreement with MonoSol to the actual written contracts between the two companies, Plaintiffs point to evidence that MonoSol and Reckitt engaged in conversations regarding ways to implement Reckitt's “Generic Defense Strategy.” I need not engage in an extensive discussion of this evidence. As a purely legal matter, I find that MonoSol and Reckitt could have entered into a conspiracy in violation of the Sherman Act.<sup>17</sup>

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<sup>17</sup> Much of the evidence regarding MonoSol's alleged participation in the conspiracy is discussed in more detail in the briefing regarding MonoSol's separate Motion for Summary Judgment against the Plaintiff States. To the extent MonoSol alleges that there is no evidence to establish an improper conspiracy, I reserve discussion of that argument for MonoSol's Motion for

**B. Whether the Plaintiffs Can Seek an Injunction**

Reckitt next challenges the States' and the End Payor Plaintiffs' ("EPPs") request for an injunction precluding Reckitt from continuing to engage in any anticompetitive conduct and from adopting in the future any practice, plan, program, or device having a similar purpose or effect to the anticompetitive actions at issue. Reckitt argues that Plaintiffs have failed to demonstrate any ongoing misconduct. It contends that, without proof that a defendant is engaging in or about to engage in further violations, Plaintiffs cannot obtain injunctive relief, even against an adjudged antitrust violator.<sup>18</sup>

Under the Sherman Act, "[w]hile 'the court's power to grant injunctive relief survives discontinuance of the illegal conduct, the purpose of an injunction is to prevent future violations.'" Primepoint, LLC v. PrimePay, Inc., 401 F. App'x 663, 664 (3d Cir. 2010) (quoting United States v. W.T. Grant Co., 345 U.S. 629, 633 (1953)). "Where the illegal conduct has ceased, the party seeking the injunction bears the burden of proving 'that there exists some cognizable danger of recurrent violation, something more than the mere possibility which services to keep the case alive.'" Id. (quoting W.T. Grant, 345 U.S. at 633).

The parties' briefing does not permit any meaningful consideration of this issue. Reckitt argues that even if it violated the antitrust laws sometime in the past, Plaintiffs have no allegations or proof that the threat of a future violation is a cognizable danger. Plaintiffs respond that they have clear statutory authority to enjoin Reckitt from future conduct. Neither party provides unequivocal legal support for their position. At this juncture, it remains unclear whether there exists some cognizable danger of recurrent violation sufficient to keep the claim alive. Given that Reckitt bears the burden of

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Summary Judgment. For purposes of the current Motion, I focus solely on whether, *as a matter of law*, Reckitt and MonoSol could conspire.

<sup>18</sup> In my class certification opinion, I declined to certify a Rule 23(b)(2) class for injunctive relief. Accordingly, the only remaining request for injunctive relief is from the Plaintiff States and the individual End Payor Plaintiffs.

showing an entitlement to summary judgment, and it has not done so, I will deny this portion of its Motion for Summary Judgment.

**C. Whether the DPPs’ Damages Calculation and the States’ Disgorgement Calculation Fail to Disaggregate the Effects of Lawful Conduct**

Reckitt next contends that the Direct Payor Plaintiffs’ (“DPPs”) damages calculation and the States’ disgorgement calculation fail to disaggregate the effects of lawful conduct from the unlawful conduct. It concedes, however, that this argument only applies if I find that any of the acts included within the alleged anticompetitive scheme are unlawful.

As discussed in detail above, I have already found that all of the conduct alleged by Plaintiffs is properly considered as part of the anticompetitive scheme at issue. While the individual acts themselves, considered in isolation, may be lawful, the combination of these acts can constitute the willful acquisition or maintenance of a monopoly in violation of the Sherman Act. See Suboxone, 967 F.3d at 270 (“[W]hile [Reckitt] would argue that each of the six allegedly anticompetitive actions represents a different theory of liability, in fact there is one theory of liability proven by a variety of acts resulting in one antitrust injury.”).

Having determined that the individual exclusionary acts need not be separated in order to find that the entire alleged scheme could be anticompetitive and therefore illegal, I need not require that Plaintiffs’ experts disaggregate the effects of the various kinds of conduct that Plaintiffs assert are anticompetitive. See LePage’s Inc. v. 3M, 324 F.3d 141, 162 (3d Cir. 2003) (“The relevant inquiry is the anticompetitive effect of [defendant’s] exclusionary practices considered together,” and not the legality of its individual actions.). Id. at 162.

**D. Whether the DPPs’ Damages Calculation and the States’ Disgorgement Calculation Relies Upon Unsupported Assumptions Regarding Market Share**

Reckitt also asserts that the DPPs’ calculation of their alleged damages, and the States’ calculation of their claim for disgorgement, rely upon an intermediary calculation regarding what market share firm would have achieved but for the alleged unlawful conduct. Reckitt goes on to raise

deficiencies in the “yardstick” or “analog” model relied upon by Plaintiffs’ experts, claiming that the various “analog” products identified by the experts were not properly used. Specifically, Reckitt identifies three “fundamental flaws” in Plaintiffs’ damages experts’ reports. First, Reckitt posits, yet again, that the experts’ approach fails to isolate the effects of any particular conduct and thus includes conduct that is not illegal. Second, Reckitt asserts that the experts’ analyses fail to correct for salient factors not attributable to Reckitt’s misconduct that may have caused the harm about which Plaintiffs complain. Finally, Reckitt contends that Plaintiffs’ experts did not account for any number of variables likely to strongly influence market share.

Reckitt’s arguments are akin to Daubert challenges to expert reports. In opposing class certification, Reckitt launched an extensive challenge to the expert report of Dr. Russell Lamb. Among the arguments raised was Reckitt’s oft-repeated “failure to isolate the effects of the anticompetitive conduct” assertion. I rejected that contention, and all others raised, finding that they were largely directed at the weight to be accorded to Dr. Lamb’s report rather than the reports’ admissibility. In re Suboxone, 421 F. Supp. 3d 12, 35–45 (E.D. Pa. 2019). Notably, Reckitt did not raise the other alleged “flaws” in Dr. Lamb’s report that are identified in the current Motion for Summary Judgment.

Thereafter, I set a briefing schedule for all additional Daubert motions. On February 11, 2020, I directed that all motions involving experts that would not be impacted by resolution of issues pending at that time before the Third Circuit should be filed by April 1, 2020. Following affirmance of class certification by the Third Circuit, I issued a second order directing that all remaining Daubert motions be filed by September 28, 2020. Reckitt did not raise any additional challenges to Dr. Lamb’s expert opinions in either the “Phase I” or “Phase II” Daubert briefing. Via two opinions issued November 24, 2020 and February 19, 2021, I fully addressed all of the pending Daubert motions.

Reckitt’s current motion is a belated Daubert motion. Although Reckitt couches these arguments as a challenge to Plaintiffs’ proof of damages, they are, in reality, a new attack on Plaintiffs’

experts' methodology. Having given the parties ample opportunity to raise Daubert challenges, I decline to consider any new challenges now.<sup>19</sup>

**E. Whether DPPs Meijer, Inc. and Meijer Distribution Have a Valid Assignment of Claims**

Reckitt also urges that DPPs' class representatives Meijer, Inc. and Meijer Distribution, Inc. (collectively, "Meijer") never purchased any product directly from Reckitt. Rather, according to Reckitt, Meijer's claim depends entirely upon a purported assignment of antitrust claims to Meijer from a now-defunct wholesaler (Frank W. Kerr) that did directly purchase Suboxone products. Reckitt contends that Kerr never assigned antitrust claims relating to Suboxone tablet or film purchases during the relevant period, thereby depriving Meijer of a cognizable claim.

The evidence submitted by the parties reveals the following:

- Meijer executed a 2002 agreement with Frank W. Kerr, which provided for an assignment of antitrust claims relating to any future sales transactions between Kerr and Meijer. (Def.'s Ex. 303.)
- On January 1, 2011, Meijer and Kerr executed a new agreement that "supersede[d] all prior agreements" and set forth the following mechanism for assignment of antitrust claims:

Upon request, Kerr agrees to assign to Meijer one hundred percent (100%) of its rights with respect to antitrust claims against one or more of the pharmaceutical vendors whose products are purchased by Kerr and sold to Meijer. Any assignment of claims *shall be evidenced by an agreement between Kerr and Meijer . . . which the parties shall execute as necessary to effectuate any assignment.*

(Def.'s Ex. 304 (emphasis added).)

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<sup>19</sup> In an effort to establish that consideration of these issues is appropriate now, Reckitt cites to one sentence in my class certification opinion. Specifically, after rejecting five different challenges to Dr. Lamb's expert report, I stated that "[t]he 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." Suboxone, 421 F. Supp. 3d 12, 44–45. This sentence, however, did not give Reckitt free reign to either (a) raise new Daubert challenges outside of the Court-established Daubert-briefing schedule or (b) re-raise arguments during summary judgment that I have already explicitly found to go to the weight rather than the admissibility of the evidence, *i.e.*, arguments that are not appropriate for Rule 56 review.

- Meijer’s Rule 30(b)(6) witness—designated for testimony regarding the assignment—testified that he was not familiar with the 2011 assignment of claims. (Def.’s Ex. 79, Meijer Rule 30(b)(6) witness, 29.)

Reckitt now argues that there is no document in the record that constitutes an executed agreement for assignment under the 2011 agreement. Moreover, Reckitt asserts that, even assuming that valid assignments occurred as to pre-2011 Kerr purchases, Meijer remains without a claim because the DPPs’ damages period begins in 2012, after the 2011 assignment superseded the 2002 assignment.

As Plaintiffs point out, however, in December 2016, Kerr assigned its antitrust rights to FWK Holdings, LLC, through a court-approved bankruptcy proceeding. (Pls.’ Ex. 380.) In that assignment, Kerr expressly ratified the 2002 assignment, noting that it had previously “entered into an Agreement for the Assignment of Claims with Meijer, Inc. (“Meijer”) on October 4, 2002, by which Kerr assigned all of its rights, title, and interest in and to all causes of action and any resulting proceeds Kerr may have under the antitrust laws of the United States or the common law or statutory law of any state arising or relating to Kerr’s purchases of any pharmaceutical products that it sold or sells to Meijer (the “Meijer Assignment”).” (Pls.’ Ex. 380.) Thus, on December 9, 2016, Kerr agreed to assign “Kerr’s rights and privileges that Kerr has under any federal or state antitrust law that Kerr has not previously assigned to Meijer.” (*Id.*) Both Kerr and FWK “acknowledge[d] the validity and enforceability of the Meijer Assignment.” (*Id.*) Nothing in that Agreement mentions the 2011 Pharmaceutical Product Supply Agreement between Kerr and Meijer.

Given the limited briefing by the parties on this issue, I decline to engage in a full contractual interpretation of the intersection among the 2002 assignment, the 2011 assignment, and the 2016 assignment. Rather, taking the evidence in the light most favorable to Plaintiffs, I find that Reckitt has failed to establish, as a matter of law, that there is no valid assignment of claims from Kerr to Meijer.

**F. Whether the End Payor Plaintiffs Failed to Prove Damages or Injury**

Reckitt’s final argument in support of its summary judgment motions contends that the individual class representatives for the EPP class have failed to proffer sufficient proof regarding their

own damages and injury. Reckitt stresses that although the EPPs retained expert Dr. Rena Conti for the purpose of developing an aggregate “overcharge” model, Dr. Conti has not attempted to calculate the damages or overcharge suffered by a particular class member or class representative. As such, according to Reckitt, not one of the EPP class representatives can show that it was injured. As an antitrust claim requires a showing of antitrust injury and damages, Reckitt posits that the EPPs’ claims must be dismissed. For the same reasons that I declined to rule on Reckitt’s previous Daubert motion to preclude Dr. Conti’s expert testimony, I find this argument premature. See In re Suboxone, No. 13-md-2445, 2021 WL 662292, at \*13–14 (E.D. Pa. Feb. 19, 2021). As I noted in that ruling, the Class Certification Memorandum and Order certified the End Payor class to address only six discrete questions as to liability. Assuming antitrust liability is established, each individual End Payor Plaintiff will then have to prove antitrust impact and damages at a separate trial or trials. Id. at \*13. Because no jury has yet resolved the common class questions regarding antitrust liability, it is premature to address whether Dr. Conti’s testimony—which is strictly limited to whether the named End Payor Plaintiffs independently suffered antitrust injury—would be admissible. Should the EPPs prevail at a trial on liability, Reckitt will then have the opportunity to litigate both its motion as to Dr. Conti and its summary judgment motion as to individual damages.<sup>20</sup>

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<sup>20</sup> The EPPs correctly note that even if I were to address and grant Reckitt’s motion on this issue, that decision would have no impact on the EPP Class’s ability to pursue its claims. “Once a class has been certified, mootness of the class representative’s claims does not moot the entire action because the class acquires a legal status separate from the interest asserted by its named plaintiff.” Brown v. Phila. Hous. Auth., 350 F.3d 338, 343 (3d Cir. 2003) (quotation omitted). “Litigation may continue because the stake of other class members is attributed to the class representative.” Id.; see also Matz v. Household Int’l Tax Reduction Inv. Plan, 774 F.3d 1141, 1145 (7th Cir. 2014) (“Ordinarily when a class representative is dismissed on grounds applicable to him but not to all other members of the class, the suit is not dismissed but rather another member of the class is substituted as a class representative.”).

**V. CONCLUSION**

For the foregoing reasons, I will deny both Reckitt's Motion for Summary Judgment on All Claims and Reckitt's Motion for Summary Judgment Pertaining to Specific Plaintiffs in their entirety.

An appropriate Order follows.





September 22, 2016

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**MADIGAN FILES LAWSUIT AGAINST MAKERS OF OPIOID ADDICTION TREATMENT DRUG SUBOXONE**

***Madigan & 35 Attorneys General Accuse Company of Conspiring to Keep Monopoly Profits***

**Chicago** — Attorney General Lisa Madigan and 35 other attorneys general today filed an antitrust lawsuit against the makers of Suboxone, a prescription drug used to treat opioid addiction, over allegations that the companies engaged in a scheme to block generic competitors, which forced people to pay artificially high prices during a time when the companies reaped more than \$3 billion in profits.

The lawsuit alleges that Reckitt Benckiser Pharmaceuticals, now known as Indivior, conspired with MonoSol Rx to switch Suboxone from a tablet version to a film that dissolves in the mouth in order to prevent or delay generic alternatives and maintain monopoly profits. The companies are accused of violating state and federal antitrust laws.

“These companies rigged a system to ensure they profited at the expense of the people who depended on this drug to treat and recover from addiction,” Madigan said.

Suboxone is a brand-name prescription drug used to treat heroin addiction and other opioid addictions by easing addiction cravings. No generic alternative is currently available.

According to the lawsuit, when Reckitt introduced Suboxone in 2002 in tablet form, it had exclusivity protection that lasted seven years, which meant no generic version could enter the market during that time. Before that period ended, however, Reckitt worked with MonoSol to create a new version of Suboxone, which is a dissolvable film similar in size to a breath strip. Over time, Reckitt allegedly converted the market away from the tablet to the film through marketing, price adjustments and other methods. Ultimately, after the majority of Suboxone prescriptions were written for the film, Reckitt removed the tablet from the U.S. market.

Madigan and the other attorneys general allege that this conduct was illegal “product hopping,” where a company makes modest changes to its product to extend patent protections so other companies can’t enter the market and offer cheaper generic alternatives. According to the suit, the Suboxone film provided no real benefit over the tablet and Reckitt continued to sell the tablets in other countries after removing them from the U.S. market. Reckitt also allegedly expressed unfounded safety concerns about the tablet version and intentionally delayed FDA approval of generic versions of Suboxone.

As a result, the lawsuit alleges that consumers and purchasers have paid artificially high monopoly prices since late 2009, when generic alternatives of Suboxone might otherwise have become available. During that time, annual sales of Suboxone topped \$1 billion.

The lawsuit, filed in the U.S. District Court for the Eastern Division of Pennsylvania, accuses the companies of violating the federal Sherman Act and state laws. Counts include conspiracy to monopolize and illegal restraint of trade. In the suit, Madigan and the other attorneys general ask the court to stop the companies from engaging in anticompetitive conduct, to restore competition and to order appropriate relief for consumers and the states, plus pay the states’ costs and fees.

Joining Madigan in the lawsuit are attorneys general from: Alabama, Alaska, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, Wisconsin and the District of Columbia.

Assistant Attorney General Chad Brooker is handling the case for Madigan’s Antitrust Bureau.