UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

In re: SUBOXONE ANTITRUST LITIGATION	**MDL No. 2445**
THIS DOCUMENT RELATES TO: **All Direct Purchaser Class Actions**	**Master Docket No. 2:13-md-02445-MSG** **SECOND CONSOLIDATED AMENDED CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

SECOND CONSOLIDATED AMENDED CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

TABLE OF CONTENTS

Plaintiffs Burlington Drug Company, Inc., Meijer, Inc., Meijer Distribution, Inc., and Rochester Drug Co-Operative, Inc. (collectively "Direct Purchasers" or "Plaintiffs"), on behalf of themselves and all others similarly situated, for their complaint brought under Sections 4 and 16 of the Clayton Act, 15 U.S.C. § 15(a), for injuries sustained from violations of Section 2 of the Sherman Act, 15 U.S.C. § 2, by Defendants Reckitt Benckiser Pharmaceuticals, Inc. and Reckitt Benckiser Group, plc (collectively, "Reckitt" or "Defendants") allege as follows based on: (a) personal knowledge; (b) the investigation of counsel; and (c) information and belief.

I. NATURE OF THE ACTION

1. This is a civil antitrust action seeking treble damages arising out of Reckitt's unlawful anticompetitive exclusion of competition from the market for co-formulated buprenorphine hydrochloride and naloxone ("BPN/NLX"), a drug manufactured and sold by Reckitt under the brand-name "Suboxone" and used for the maintenance treatment of opioid dependence (*e.g.*, heroin addiction) in humans.

2. Reckitt has sold branded Suboxone in two forms: orally dissolving Tablets ("Suboxone Tablets" or "Tablets") and orally dissolving Film strips ("Suboxone Film" or "Film"). Although all patent and regulatory exclusivity for Suboxone Tablets expired on or before October 8, 2009, due to Reckitt's anticompetitive behavior generic versions of Suboxone Tablets were foreclosed from entering the United States market until about March 6, 2013, and their ability to unlawfully compete suppressed thereafter.

3. Reckitt's overall scheme: (a) economically coerced doctors and/or patients to switch prescriptions from Suboxone Tablets to Suboxone Film, a new patent-protected form of BPN/NLX that in fact offers no additional clinical benefits, but rather raises new and additional safety and diversion issues not associated with Tablets, and (b) delayed market entry of less-

expensive generic versions of Suboxone Tablets in order to facilitate Reckitt's conversion of the market from Tablets to Film. Reckitt intentionally prevented meaningful competition from less-expensive generic versions of Suboxone Tablets. As a result, Reckitt unlawfully maintained and extended its monopoly power in the market for Suboxone, all to the detriment of Direct Purchasers and the Class. A short summary follows.

4. In 2002, Reckitt obtained Food and Drug Administration ("FDA") approval to sell Suboxone Tablets for long-term use in treating addiction. At the time, Suboxone was the only drug available for the long-term, post-induction treatment of opioid dependence that could be taken by patients outside of specialized clinic, such as at home or at work. Prior to the Drug Addiction Treatment Act ("DATA") of 2000, all approved opioid dependence treatments were required to be dispensed and consumed in clinics specializing in addiction treatment. Suboxone Tablets rapidly became the dominant drug product prescribed in the U.S. for opioid dependence treatment outside of the clinical setting, and Reckitt quickly garnered substantial revenues from the sale of Suboxone Tablets (*e.g.*, approximately $800 million in U.S. sales from August 2010 to August 2011). Today Suboxone has annual sales of over one billion dollars, and accounts for approximately 20% of Reckitt's profits.

5. When it began marketing Suboxone Tablets in 2002, Reckitt had no patent protection for this drug. Reckitt did, however, receive a seven-year period of "orphan drug" exclusivity, which protected Suboxone Tablets from generic competition until October 8, 2009. During those years, Reckitt knew that with no patent protection and the large sales volume for Suboxone Tablets, generic manufacturers would file and seek FDA approval of Abbreviated New Drug Applications ("ANDAs") to sell lower-priced generic versions of Suboxone Tablets. As a sophisticated pharmaceutical manufacturer, Reckitt knew that once generic Suboxone

Tablets became available a dramatic market shift would immediately occur through operation of state substitution laws which, by mandating generic substitution, cause brand-name drugs to typically lose 90-95% of their market share to less-expensive generic equivalents within the first year of competition. Reckitt understood that it stood to lose hundreds of millions of dollars in revenues per year once generic Suboxone Tablets came to market.

6. In the face of this harsh competitive reality, Reckitt devised a multifaceted anticompetitive scheme, that it executed over several years, to illegally maintain and extend its monopoly power in the BPN/NLX market and protect its lucrative Suboxone revenue stream. Reckitt understood that to accomplish this goal it had to switch the vast majority of the BPN/NLX market from Suboxone Tablets to Suboxone Film before generic BPN/NLX Tablets entered the market. The more that Reckitt could convert the market from Tablets to Film, the less of the market was left to switch to generic BPN/NLX tablets because Film prescriptions cannot be automatically filled with tablets under the state substitution laws. In furtherance of the scheme, during the course of the product conversion process, Reckitt: (a) improperly caused a delay in the market entry of less-expensive generic versions of BPN/NLX Tablets; and (b) prevented generic manufacturers from effectively and efficiently competing in the Suboxone market once generic Tablets eventually entered the market. These acts abused, and contravened the intention, of the statutory provisions enacted by Congress in the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (commonly referred to as the "Hatch-Waxman Act" or "Hatch-Waxman") and state substitution laws (discussed below). Reckitt's anticompetitive scheme included, among other things: (1) a coercive and predatory market switch from Suboxone Tablets to the Suboxone Film formulation; (2) improper manipulation of the Single Shared Risk Evaluation and Mitigation Strategy ("SSRS/REMS")

process to delay generic competition and buy time to implement the anticompetitive product switch; and (3) filing a sham Citizen Petition with the FDA to further delay the entry of generic Tablet competition.

7. In July 2007, Reckitt announced that it planned to market a new BPN/NLX film formulation, and ultimately obtained FDA approval to market this product as Suboxone Film on August 31, 2010. Suboxone Film, however, provides no medical benefit in effectiveness over Suboxone Tablets (Suboxone Film contains the same active ingredients as Suboxone Tablets, and there is no clinically demonstrated improvement in effectiveness of the film formulation over the tablet formulation). Moreover, Suboxone Film has additional serious safety and diversion issues that Suboxone Tablets do not have: the Film version can be more easily converted to a liquid for inappropriate diversionary injections and is more difficult for children to spit out if accidental pediatric exposure occurs. Prior to marketing the Film version, Reckitt was aware that the Film provided no clinical benefits over Suboxone Tablets and was equally aware of the additional safety and diversion issues. This new dosage form, however, allowed Reckitt to "game the system" by moving the market from tablets to film and doing other things to destroy the competitive environment for less-expensive generic BPN/NLX tablets before they entered the market.

8. Knowing that there would be very little demand for Suboxone Film if the Film were marketed on its own (lack of) merits in an unconstrained and untainted fair market, Reckitt implemented a scheme before generic entry could occur, which included: (a) economically coercing doctors to prescribe Film instead of Tablets and (b) coercively and/or deceptively destroying demand for branded and generic Suboxone Tablets by raising false and misleading safety issues; and (c) improperly creating barriers and impediments to both branded and generic

Suboxone Tablets relative to Film in the marketplace. Reckitt's conduct to push doctors (and the market) away from Reckitt's more profitable Suboxone Tablets and towards the less profitable Suboxone Film was economically irrational absent its effect of blocking and suppressing generic Tablet competition.

9. *Reckitt penalizes doctors who do not switch patients to the Film in order to coerce them to do so*. Reckitt understood that the doctors were critical to Suboxone's distribution, and that if it could disincentivize doctors from prescribing Tablets, and at the same time incentivize them to prescribe the Film, the doctors would greatly accelerate the switch from Tablets to Film. Reckitt understood that a small group of doctors controlled the vast majority of Suboxone prescriptions and these doctors in most instances had the power to determine whether a prescription was to be written for Suboxone Tablets or Film. By [redacted] to lay the groundwork for the Film introduction, [redacted]

10. For several years, [redacted]

11. In addition, before the Film was launched, Reckitt created a program it called "Here to Help" ("HTH"), [redacted] In so doing, Reckitt: (a) economically coerced doctors to prescribe Film instead of Tablets by penalizing those doctors who prescribed Suboxone Tablets with the loss of patients and financially valuable services; and (b) rewarded and incentivized doctors to prescribe Suboxone Film to continue to receive the increased revenue provided by the services that Reckitt offered. The effect of Reckitt's conduct was to align the doctors' economic interests with Reckitt's, so as to effectuate the market shift from Tablets to Film

12. Other than as a scheme to improperly profit in the long run from thwarting generic competition, Reckitt's efforts to move the market from Suboxone Tablets to Suboxone Film made no sense. Suboxone Tablets were more profitable on a per-unit basis than Suboxone Film because Suboxone Tablets had a decidedly lower marginal cost to make than Suboxone Film and Suboxone Tablets were priced higher than Suboxone Film. Even though Reckitt could make more money on the tablets than the film, it was shifting the market to the less-profitable film. Why? Because Reckitt was willing to not maximize its profits in the short run so that it could gain in the long run by improperly impeding competition from generic BPN/NLX tablets which would have otherwise been caused by the state substitution laws.

13. Throughout this process – both before and after the Film was introduced – Reckitt repeatedly touted to doctors that they (and not the patient) "owned the choice" of which product would be prescribed, and that the "patient should not have a choice in which formulation they are prescribed." Moreover, Reckitt evaluated (and closely tracked) doctors' prescribing habits based on their willingness to prescribe Film, and the doctors' agreement with Reckitt's position that the patient should not be given any choice about whether Film or Tablets would be prescribed.

14. To further coerce doctors to switch prescriptions to Film, Reckitt threatened doctors that they might invite U.S. Drug Enforcement Administration ("DEA") scrutiny if they did not start writing prescriptions for Suboxone Film instead of Suboxone Tablets, [redacted]

15. *Other deceptive and coercive tactics*. Additionally, in furtherance of its anticompetitive scheme, Reckitt: (i) relied on a study created solely to deceive third-party payors like Pharmacy Benefit Managers ("PBMs") and Health Maintenance Organizations ("HMOs") (collectively "Payors") into giving Film a favorable formulary status; (ii) implemented a nationwide fraudulent marketing campaign to malign the safety of Suboxone Tables by falsely claiming that Suboxone Tablets were unsafe because they were not sold in unit-dose packaging (even though Reckitt could have packaged Suboxone Tablets in unit dose packaging but deliberately chose not to do so); (iii) informed doctors that Suboxone Tablets would be withdrawn from the market and then formally announced in September 2012 its plans to discontinue selling Suboxone Tablets as of March 2013 due to its purported safety concerns; (iv) sought a formal FDA determination that Reckitt's planned discontinuation of Suboxone Tablets was for legitimate safety reasons and then using the mere filing of the petition to delay FDA approval of generic versions of Suboxone Tablets – even though Reckitt continued to sell

allegedly unsafe Suboxone Tablets without unit dose packaging for six more months after the announcement; and (v) ultimately removed Suboxone Tablets from the market despite FDA's determination that the Tablet product was safe and effective for its intended use.

16. To maximize the anticompetitive effect of this "product hopping" scheme, Reckitt needed to delay market entry of less-expensive generic versions of Suboxone Tablets for as long as possible to provide time to convert as many prescriptions as possible to Suboxone Film prior to generic entry. Reckitt was able to do so by fraudulently feigning cooperation with manufacturers of generic Tablets in the development of a SSRS/REMS for Suboxone Tablets, as the FDA had directed Reckitt and the manufacturers of generic Tablets to do in January 2012. For nearly a year, Reckitt sabotaged the process, knowing that dragging its feet while feigning cooperation would delay approval of its would-be competitors' generic Suboxone Tablet ANDAs. Reckitt's actions were in violation of 21 U.S.C. §355-1(f)(8), which specifically prohibits brand-name drug manufacturers from using REMS to block or delay approval of generic ANDAs.

17. To obtain even more time for the product hop to work, on September 25, 2012, Reckitt filed an objectively baseless Citizen Petition with FDA in an attempt to delay FDA approval of ANDAs for generic Suboxone Tablets even further. Reckitt's Citizen Petition lacked any reasonable regulatory, scientific, or medical basis. Reckitt, however, got the delay it sought. FDA denied Reckitt's Citizen Petition on February 22, 2013, after a five-month petition review. FDA found that Reckitt's Citizen Petition lacked supporting evidence, and referred Reckitt's behavior to the Federal Trade Commission ("FTC") for antitrust investigation. The timing of the filing of Reckitt's Citizen Petition was no accident. It intentionally delayed that filing to

coincide with the near end point of its ability to frustrate and delay the SSRS/REMS process so as to maximize the delay of generic launch.

18. Reckitt's scheme to delay and eliminate generic competition worked: less-expensive generic Suboxone Tablets did not enter the United States market until March 2013. Further, as a result of Reckitt's anticompetitive scheme, once generic Tablets were able to enter, the full benefits of unconstrained competition were not available since Reckitt had improperly switched the market to a different product, thereby subverting the state substitution laws. Upon entry of these generics, Reckitt finally made true on its statement made many months earlier to withdraw its branded Suboxone Tablets from the market, despite FDA's confirmation that Suboxone Tablets (brand and generic) were safe and effective.

19. In a market unconstrained by Reckitt's anticompetitive scheme and without introduction of Suboxone Film, Reckitt projected that it would [redacted] of the market to cheaper generic Tablets. If Reckitt merely introduced Suboxone Film – but otherwise did not engage in anticompetitive conduct – Reckitt itself projected that the Film would capture [redacted] of the Suboxone market, leaving [redacted] for generic Tablets and [redacted] for Reckitt's branded Tablets. However, as a result of Reckitt's anticompetitive product hop scheme, Reckitt's Film captured approximately [redacted] of the Suboxone market prior to generic entry. Thus, in addition to delaying generic entry, the success of Reckitt's anticompetitive scheme meant that although the generic Tablets captured virtually all of the Tablet portion of the market (branded and generic Tablets), they were [redacted] able to capture [redacted] of the overall Suboxone market (branded/generic Tablets plus brand Film).

20. But for Reckitt's anticompetitive conduct, one or more less-expensive generic versions of Suboxone Tablets would have received final FDA approval and been launched in the

U.S. market no later than the first half of 2012, and would have competed fairly and efficiently (as intended by the antitrust laws, the Hatch-Waxman Act, and state substitution laws) in the BPN/NLX market. Because of Reckitt's predatory product hopping, destruction of demand for Suboxone Tablets through coercive and fraudulent acts, feigned cooperation in the SSRS/REMS process, and sham and intentionally delayed Citizen Petition, competition from less-expensive versions of Suboxone Tablets has been suppressed. Even though less-expensive generic equivalents typically capture 90% or more of the sales of its branded counterpart in its first year on the market, Reckitt's scheme has caused the manufacturers of generic Suboxone Tablets on the market to capture only a small fraction of the BPN/NLX (Tablet and Film) market.

21. If Reckitt had been simply and solely interested in introducing a new Suboxone Film product, which was supposedly superior to the existing Tablet formulation, it could have done so without taking the additional, affirmative steps to: (a) delay the market entry of less-expensive generic versions of Suboxone Tablets; (b) interfere with the normal competition that routinely occurs between branded products and their generic counterparts as contemplated by the Hatch-Waxman Act and state substitution laws; and (c) substantially destroy the market for Suboxone Tablets through various coercive and deceptive tactics. Moreover, Reckitt's purported safety concerns about its own Tablet version (and corresponding claims of Film superiority) are pretextual, as they: (a) are completely contrived; and (b) to the extent not contrived, could have been efficiently and effectively cured by less restrictive means through implementing unit-dose packaging for the Tablet product as Reckitt has done in other countries and admitted was feasible for Tablets sold in the U.S.

22. Reckitt's scheme to illegally hold and extend its monopoly power in the BPN/NLX market was maintained through willful exclusionary conduct, as distinguished from

growth or development as a consequence of a legally-obtained valid patent, other legally-obtained market exclusivity, a superior product, business acumen, or historic accident.

23. Through its illegal scheme and abuse of the legitimate processes whereby generic drugs are expeditiously approved and compete against brand name drugs for the competitive benefit of U.S. purchasers, Reckitt: (a) illegally maintained and extended its monopoly of the BPN/NLX market in the U.S.; (b) fixed, raised, maintained, and/or stabilized the price of BPN/NLX at supra-competitive levels; and (c) deprived Direct Purchasers of BPN/NLX products (Tablets and Film) of the benefits of full and efficient competition from less-expensive generic versions of Suboxone Tablets, thereby causing Direct Purchasers of BPN/NLX products (Tablets and Film) to be overcharged on those products.

II. PARTIES

A. Plaintiffs.

24. Plaintiff Burlington Drug Company, Inc. ("Burlington") is a corporation organized under the laws of the state of Vermont and is located at 91 Catamount Drive, Milton, Vermont 05468. Burlington purchased Suboxone directly from Reckitt during the Class Period as defined below, and was injured by the illegal conduct described herein.

25. Plaintiffs Meijer, Inc., and Meijer Distribution, Inc., (collectively, "Meijer") are corporations organized under the laws of the state of Michigan, with their principal place of business located at 2929 Walker Avenue, NW, Grand Rapids, Michigan 49544. Meijer is the assignee of the claims of a direct purchaser that purchased Suboxone directly from Reckitt during the Class Period and resold that Suboxone to Meijer. Meijer was injured by the illegal conduct described herein.

26. Plaintiff Rochester Drug Co-Operative, Inc. ("Rochester") is a stock corporation organized under the laws of the state of New York and is located at 50 Jet View Drive,

Rochester, New York 14624. Rochester purchased Suboxone directly from Reckitt during the Class Period, and was injured by the illegal conduct described herein.

B. Defendants.

27. Defendant Reckitt Benckiser Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business located at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia 23235. This defendant sells Suboxone in the United States and manufactures and markets numerous products, including pharmaceuticals subject to FDA approval, and was in whole or in part responsible for some or all of the conduct alleged herein and attributed to Reckitt.

28. Defendant Reckitt Benckiser Group plc is a British corporation incorporated under the laws of England and Wales, with its registered office located at 103-105 Bath Road, Slough, Berkshire, SL1 3UH. This defendant manufactures and markets numerous products, including pharmaceuticals subject to FDA approval, and was in whole or in part responsible for some or all of the conduct alleged herein and attributed to Reckitt.

29. All of Reckitt's actions described in this complaint are part of, and in furtherance of, the illegal monopolization and attempted monopolization alleged herein, and were authorized, ordered, and/or done by Reckitt's various officers, agents, employees, or other representatives while actively engaged in the management of Reckitt's affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Reckitt.

III. JURISDICTION AND VENUE

30. This action arises under section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover threefold damages, costs of suit and reasonable attorneys' fees for the injuries sustained by Direct Purchasers and members of the Class (defined herein) of direct purchasers of

Suboxone from Reckitt, resulting from violations by Reckitt, as hereinafter alleged, of Section 2 of the Sherman Act, 15 U.S.C. § 2. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 15.

31. Reckitt transacts business within this district, and carries out interstate trade and commerce, in substantial part, in this district and/or has an agent and/or can be found in this district. Venue is appropriate within this district under section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. §§ 1391(b), (c) and (d) because during the class period, Reckitt transacted business in this district as stated above.

32. During the class period, Reckitt manufactured, sold, and shipped Suboxone in a continuous and uninterrupted flow of interstate commerce. Reckitt's conduct, as described in this complaint, was within the flow of, was intended to, and did have a substantial effect on, the interstate commerce of the U.S., including in this district.

33. This Court has personal jurisdiction over each Defendant, because each Defendant transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of this illegal scheme. The scheme was directed at, and had the intended effect of, causing injury to persons residing in, located in, and/or doing business throughout the U.S., including in this district.

IV. CLASS ACTION ALLEGATIONS

34. Plaintiffs bring this action on behalf of themselves and, under Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure, as representatives of a Class defined as follows:

> All persons or entities in the United States and its territories who purchased branded Suboxone in any form directly from Reckitt at any time during the period January 1, 2012 through the time when the effects of Defendants' anticompetitive conduct cease (the "Class").

Excluded from the Class are Reckitt, its officers, directors, management, employees, subsidiaries, and affiliates, and all federal governmental entities.

35. Members of the Class are so numerous that joinder is impracticable. Further, the Class is readily identifiable from information and records in the possession of Reckitt.

36. Plaintiffs' claims are typical of the claims of the members of the Class. Plaintiffs and all members of the Class were damaged by the same wrongful conduct of Reckitt, *i.e.*, they paid artificially inflated prices for BPN/NLX products and were deprived of the benefits of fair and efficient competition from less-expensive generic versions of Suboxone Tablets as a result of Reckitt's wrongful conduct.

37. Plaintiffs will fairly and adequately protect and represent the interests of the Class. Plaintiffs' interests are coincident with, and not antagonistic to, those of the Class.

38. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation in the pharmaceutical industry.

39. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members because Reckitt has acted on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Reckitt's wrongful conduct.

40. Questions of law and fact common to the Class include:

a. Whether Reckitt possessed monopoly power;

b. Whether Reckitt unlawfully maintained monopoly power through all or part of its overarching scheme;

c. Whether Reckitt's anticompetitive scheme suppressed generic competition to Suboxone;

d. Whether Reckitt's introduction of Suboxone Film and destruction of the prescription base for Suboxone Tablets were predatory and anticompetitive;

e. Whether Reckitt's Citizen Petition was objectively baseless;

f. Whether Reckitt's Citizen Petition was submitted with the subjective intent to interfere with competition;

g. Whether Reckitt fraudulently delayed the filing of its Citizen Petition;

h. As to those parts of Reckitt's challenged conduct for which procompetitive justifications may be offered, whether the justifications are pretextual, whether Reckitt's challenged conduct was the least restrictive means of achieving any procompetitive benefits, and whether any procompetitive justifications are offset by the anticompetitive harm;

i. Whether direct proof of Reckitt's monopoly power is available, and if available, whether it is sufficient to prove Reckitt's monopoly power without the need to also define a relevant market;

j. To the extent a relevant market or markets must be defined, what that definition is or those definitions are;

k. Whether Reckitt's scheme, in whole or in part, has substantially affected interstate commerce;

l. Whether Reckitt's scheme, in whole or in part, caused antitrust injury to the business or property of Plaintiffs and the members of the Class in the nature of overcharges; and

m. The quantum of overcharge damages incurred by the Class in the aggregate.

41. Class action treatment is a superior method for the fair and efficient adjudication of the controversy in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

42. Plaintiffs know of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

V. FACTUAL ALLEGATIONS

A. REGULATORY BACKGROUND

(1) The Hatch-Waxman Framework

43. Under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301-392) ("FDC Act"), a manufacturer who creates a new drug must obtain the approval of the 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.

44. In 1984, Congress amended the FDC Act with the enactment of the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly referred to as the Hatch-Waxman Act.

45. Hatch-Waxman provides brand-name manufacturers with several means, in addition to traditional patent rights, to obtain protection from generic competition for set, and specifically limited, periods of time. For example, for pioneer drugs that are truly new or innovative in that they make use of a never-before-approved chemical entity or moiety – as opposed to an NDA relating to the far more common reformulations or dosage changes for existing drugs – FDA grants a "new chemical entity" ("NCE") exclusivity period of five years. If an NDA drug treats a rare condition, FDA may grant seven years of orphan drug exclusivity during which time no corresponding ANDA drug may be approved or commercialized.

46. Hatch-Waxman 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. Instead, based on well-established scientific

principles, FDA provides an expedited scientific review process by which generic manufacturers may file and gain approval for their drugs through the filing of an ANDA.

47. The ANDA relies on the scientific findings of safety and efficacy included by the brand-name drug manufacturer in the original NDA. The ANDA filer, however, must scientifically demonstrate to FDA that the generic drug it is going to market is just as safe and effective as the corresponding brand-name drug through demonstrations of bioequivalence. A demonstration of bioequivalence means that, within certain set parameters of variability, 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. The range of acceptable variability afforded to generic drugs for demonstrating bioequivalence is the same lot-to-lot (*i.e.*, batch-to-batch) range of variability afforded to brand companies when manufacturing their own brand drug.

48. Generally speaking, ANDA filers that demonstrate bioequivalence are seeking to have their generic products deemed to be "AB-rated" to the corresponding brand-name drug, sometimes referred to as the "reference listed drug" ("RLD"). AB-rated generics are those that have been determined by FDA to be therapeutically equivalent (*i.e.*, bioequivalent) and pharmaceutically equivalent to their brand-name counterparts. Pharmaceutical equivalence means the generic drug and branded RLD have, among other things, the same active ingredient, same strength, same route of administration, and same dosage form (e.g. Tablet, capsule, Film).

49. Generic drugs that are not pharmaceutically equivalent to a branded drug cannot be deemed to be AB-rated and cannot be automatically substituted for the brand by pharmacists. Thus, for example, a Tablet formulation cannot be AB-rated to a Film formulation, even if it is bioequivalent to the Film.

(2) Characteristics of the Pharmaceutical Marketplace

50. The marketplace for the sale of prescription pharmaceutical products in the United States contains a unique and significant feature that can be exploited by manufacturers in order to extend a monopoly in the sale of a particular pharmaceutical composition. In most industries, the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the price of the product plays a predominant role in the person's choice of products and, consequently, manufacturers have a strong incentive to lower the price of their products to maintain profitability.

51. The pharmaceutical marketplace, by contrast, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Suboxone, to patients without a prescription written by the patient's physician. The prohibition on dispensing certain products without a prescription introduces a "disconnect" in the pharmaceutical marketplace between the payment obligation and the product selection. The patient (and in many cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's physician chooses which product the patient will buy.

52. Many pharmaceutical manufacturers, including Reckitt, exploit this feature of the pharmaceutical marketplace. The so-called "brand manufacturers" (i.e., the manufacturers of branded, as opposed to generic, pharmaceuticals) employ large forces of sales representatives, known as "detailers," who visit physicians' offices in an effort to persuade physicians to prescribe the manufacturer's products. Importantly, these detailers do not advise the physicians of the cost of the branded products. Studies show that physicians typically are not aware of the relative costs of branded pharmaceutical products and that, even when physicians are aware of

the relative cost, they are typically insensitive to price differences, because they do not pay for the products themselves. The result is a marketplace in which price typically plays a comparatively unimportant role in product selection.

53. In situations in which two manufacturers each sell a drug that serves a similar medical function and each manufacturer uses a significant detailer force, those products are often sold at very similar, high prices, thus eliminating any consumer benefit from that "competition." This is in stark contrast to the situation in which the competing seller of an AB-rated, bioequivalent drug is a generic company without a detailer force. In that case, the generic price is significantly lower than the brand price, and consumers benefit as Congress intended by the Hatch-Waxman Act and states intended through state substitution laws.

54. When the relative importance of the price between two branded pharmaceuticals, or pharmaceuticals that otherwise are not AB-rated to one another, is low, the price elasticity of demand — the extent to which sales go down when price goes up — is by definition also low, which in turn gives brand manufacturers the ability to raise or maintain price substantially above competitive levels without losing sales. The ability to raise price above competitive levels without losing sales is referred to by economists and antitrust courts as market power or monopoly power. Thus, the net result of the pharmaceutical industry features and marketing practices described above often is to allow brand manufacturers to gain and maintain monopoly power.

55. Congress sought to ameliorate the "disconnect," and to restore some of the normal competitive pressures to the pharmaceutical marketplace, by authorizing the manufacture and sale of generic pharmaceuticals under the Hatch-Waxman Act, discussed below. When a pharmacist receives a prescription for a branded pharmaceutical product, and an AB-rated

generic version of that product is available, state substitution laws permit (or in some cases require) the pharmacist automatically to dispense the generic product in lieu of the branded product. In this way, the importance of price is reintroduced to the product selection decision at the pharmacy counter, and the pharmaceutical marketplace "disconnect" is ameliorated between the AB-rated generic product and the corresponding branded product. When an AB-rated generic product is introduced and is not prevented from competing unfettered, branded pharmaceutical manufacturers are no longer able to exploit the features of the pharmaceutical industry, their monopoly power dissipates, and some of the normal competitive pressures are restored resulting in lower prices.

(3) AB-Rated Generic Versions of Brand-Name Drugs are Significantly Less Expensive Than, and Take Significant Sales Directly From, the Corresponding Brand-Name Versions

56. Competition from lower-priced AB-rated generic drugs saves American consumers billions of dollars a year. These consumer savings, however, mean lower profits for brand drug companies. It is well-established that when AB-rated generic entry occurs, the brand company suffers a rapid and steep decline in sales and profits on its corresponding brand drug. The threat of AB-rated generic competition thus creates a powerful incentive for brand companies to protect their revenue streams. This incentive can prompt brand companies to create innovative new products or new versions of old products that offer real medical benefits to patients. Conversely, it may also drive, as it did in this case, brand companies to seek to improperly obstruct generic drug competition by making changes to existing products that offer patients little or, as here, no clinical advantages whatsoever, but are intended to interfere with the normal brand-to-generic competition contemplated and encouraged by the Hatch-Waxman Act and state substitution laws.

57. Such tactics, often referred to as "product switching" or "product hopping," can be an effective, albeit improper, anticompetitive way to game the regulatory structure that governs the approval and sale of generic drugs, thereby frustrating the efforts of federal and state laws designed to promote and facilitate price competition in pharmaceutical markets. As discussed in detail below, a brand company can interfere with the mechanism by which generic drugs compete by making non-therapeutic changes to its branded product, and can effectively prevent generic competition, not because the reformulated product is an improvement over the original version of the product or is preferred by consumers, but simply because it differs in strength, route of administration, or, as here, dosage form.

58. Typically, AB-rated generic versions of brand-name drugs are priced significantly below their brand-name counterparts. Because of the price differentials and other institutional features of the pharmaceutical market, including state substitution laws, AB-rated generic drugs are rapidly and substantially substituted for their more expensive brand-name counterparts. When multiple generic manufacturers enter the market, prices for generic versions of a drug predictably decrease even more significantly because of competition among the generic manufacturers, and the loss of sales volume by the brand-name drug to the corresponding generics is dramatic.

59. An AB-rating is particularly significant to a generic manufacturer because, under Hatch-Waxman and most state substitution laws, pharmacists may (and in many states, must) substitute an AB-rated generic version of a drug for the brand-name drug without seeking or obtaining permission from the prescribing physician (unless the prescription is denominated "Dispense as Written" or "DAW"). Indeed, both Congress and state legislatures have actively encouraged generic substitution because of their recognition that the economics of the

pharmaceutical industry prevent generic manufacturers from simultaneously: (a) engaging in the type of heavy promotion or "detailing" typically done by brand-name manufacturers; and (b) providing the enormous cost savings to purchasers and consumers generated by generic drugs.

60. AB-rated generic competition enables direct purchasers to: (a) purchase generic versions of brand-name drugs at substantially lower prices; and/or (b) purchase the brand-name drug at reduced prices. However, until generic manufacturers enter the market with an AB-rated generic product, there is no bioequivalent generic drug which competes with the brand-name drug and therefore, the brand-name manufacturer can continue to charge supra-competitive prices profitably without losing all or a substantial portion of its brand-name sales.

61. This statutorily mandated process, however, can be anticompetitively manipulated and its purposes contravened when brand-name manufacturers, like Reckitt here, introduce a new version of an already-existing drug that is no safer and no more effective than the original version; and switch the market to the "new" version by coercing the conversion of prescriptions for the original drug to be written for the "new" version. The result is that, by the time generic versions of the original brand-name drug reach the market, there are few, if any, prescriptions being written for the original brand version. Where there are slight differences between a generic drug and the "new" brand drug (*e.g.*, dosage form) the drugs cannot be AB-rated, and pharmacists cannot automatically substitute the less-expensive generic for the more-expensive brand prescriptions, even when (as in this case) the differences are clinically meaningless. Thus, by shifting the vast majority of prescriptions to the new product, a brand company can substantially reduce (if not eliminate) the automatic substitution processes created through the federal Hatch-Waxman Act and state substitution laws, even when (as here) there is no clinical benefit from the new branded product versus generic versions of the existing products. This

leaves the generic manufacturer with a couple of choices, all of which result in significantly higher prices for purchasers and frustrate the purpose of Hatch-Waxman and DPS laws: (a) implement its own extensive sales and marketing campaign for its generic drug, which dramatically increases the price for its product (and, as a practical matter, acts as a barrier to meaningful market entry)[1]; (b) abandon altogether its generic product, meaning no generics are available; or (c) enter as a normal generic in a greatly and artificially diminished segment of the market resulting in dramatically lower sales and savings to purchasers. This anticompetitive result is only exacerbated when the brand company, as Reckitt here, takes additional steps to delay the market entry of generics while it implements the switch scheme.

(4) SSRS/REMS

62. Under the FDA Amendments Act of 2007, FDA has the authority to require 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 (*e.g.*, by requiring practitioners, pharmacies, or healthcare settings to obtain special certifications in order to dispense the drug).

63. If REMS is required for a particular generic product, FDA will withhold ANDA approval until such time that an appropriate REMS has been created by the ANDA sponsor.

[1] The barriers to entry by a generic drug manufacturer are high. Such companies must first formulate a non-infringing generic version of the brand name drug; conduct bioequivalence studies and other studies needed to support the ANDA; file the ANDA and work with FDA on any issues that arise regarding approval; either challenge relevant patents or wait for them to expire; wait for expiration of any applicable regulatory exclusivities; and invest in manufacturing facilities for the commercialization of the product. It is not economically rational for generic manufacturers to engage in these costly activities until regulatory and patent exclusivity expirations near. This is all the more so when generic companies have already heavily invested in formulating and pursuing FDA approval of a generic version of a brand name drug only to have the brand name manufacturer make a therapeutically meaningless formulation change and switch the market to that new formulation for the anticompetitive purpose of thwarting meaningful competition from the existing generic product. This puts the generic manufacturer in the position of having to scrap its investment in the initial generic version of the drug and re-invest in developing a second generic product equivalent to the next version of the branded counterpart drug, all in the hopes that additional switches will not take place prior to approval and launch of the second generation generic product. *See generally Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006).

64. As occurred here, FDA can also require that ANDA sponsors coordinate with the manufacturer of the branded counterpart drug for the purposes of creating a SSRS/REMS program, which as the name implies is an identical single REMS program to be used by both sellers of the brand drug and AB-rated generic equivalents.

65. In enacting the REMS framework, Congress anticipated that brand-name drug manufacturers like Reckitt would attempt to use REMS programs as a basis for impeding generic competition by delaying ANDA approval. Accordingly, Congress enacted Section 505-1(f)(8) of the FDC Act (21 U.S.C. § 355-1(f)(8)) which prohibits a brand-name drug manufacturer from using REMS "to block or delay approval of" ANDAs.

(5) Citizen Petitions

66. Pharmaceutical companies have multiple avenues and opportunities through which to communicate their views to the FDA. For example, FDA holds public advisory meetings, which can be requested by pharmaceutical companies, to address issues regarding specific drug products or more generalized issues that pertain to many products. Additionally, there are industry and FDA forums for discussion that permit interaction and debate on pharmaceutical issues.

67. One such mechanism is to file a petition with FDA requesting, among other things, that FDA take, or refrain from taking, any form of administrative action. This mechanism is commonly referred to as a Citizen Petition or "FDA Petition." Citizen Petitions provide a forum for individuals or businesses to express and support genuine concerns about safety, scientific, or legal issues regarding a product any time before, or after, market entry.

68. A Citizen Petition may be filed to request that the FDA take action regarding drug approval requirements, including those involving generic drugs. To move the FDA to grant this

type of request, the petition must include supportive, clinically meaningful data and the requested relief must be consistent with the Hatch-Waxman statutory and regulatory framework.

69. FDA regulations concerning Citizen Petitions require the FDA Commissioner to respond to each Citizen Petition within 180 days after the date on which the petition was submitted. That response may be to approve the request in whole or in part, or to deny the request. The Commissioner may also provide a tentative response with a full response to follow.

70. Reviewing and responding to Citizen Petitions is a resource-intensive and time-consuming task because, no matter how baseless a petition may be, FDA must research the petition's subject, examine scientific, medical, legal, and sometimes economic issues, and coordinate internal agency review and clearance of the petition response. A response to a Citizen Petition and the approval of generic drugs are each considered final FDA actions that can be appealed under the Administrative Procedures Act. Meaning, a petitioner who does not agree with the FDA's response to a petition can sue (and many have sued) the FDA, alleging that the agency's action was arbitrary and capricious. The FDA therefore desires to have a complete administrative record reflecting that its decision was based on sound science, in part, to defend itself from such an allegation. The FDA also must base its decisions about the fundamental safety and efficacy of drug products on sound science in order to protect those who take the drug products falling under its jurisdiction.

71. These activities strain FDA's limited resources, and Citizen Petition reviews can delay FDA approval of generic products even if those petitions ultimately are found to lack any reasonable evidentiary, regulatory, statutory, or scientific basis.

72. Indeed, in July 2006, Gary Buehler, R.Ph., former Director of the Office of Generic Drugs, Center for Drug Evaluation and Research at FDA, noted that of 42 Citizen

Petitions raising issues about the approvability of generic products, "very few…have presented data or analysis that significantly altered FDA's policies." Of these 42, only three petitions led to a change in FDA policy on the basis of data or information submitted in the petition.

73. Abusive and anticompetitive Citizen Petitions have become an increasingly common problem in the last several years, as brand-name companies have sought to compensate for dwindling new product pipelines. In some such cases, Citizen Petitions have been filed with respect to ANDAs that have been pending for more than a year, long after the brand-name manufacturer received notice of the ANDA filing, and have had the (intended) effect of delaying the approval of generic drugs while FDA evaluates the Citizen Petition.

74. Delaying generic competition is a lucrative strategy for a brand-name manufacturer. Given the marketplace's preference for generic over brand-name products, the cost of filing an improper Citizen Petition may be trivial compared to the value of securing even a few months of delay in a generic rival's entry into the market.

75. FDA officials have further acknowledged abuses of the Citizen Petition process. Former FDA Chief Counsel Sheldon Bradshaw noted that in his time at the agency he had "seen several examples of citizen petitions that appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application but rather to try to delay the approval simply by compelling the agency to take the time to consider arguments raised in the petition whatever their merits and regardless of whether or not the petitioner could have made those very arguments months and months before."

76. It is well known in the pharmaceutical industry that it is FDA practice to withhold ANDA approvals until after its consideration of, and response to, a Citizen Petition is complete. On this subject, Director Buehler acknowledged that "[i]t is very rare that petitions present new

issues that CDER has not fully considered, but the Agency must nevertheless assure itself of that fact by reviewing the citizen petitions."

77. In an effort to deal with the potential anticompetitive abuse of the citizen petition process, Congress passed the Food and Drug Administration Amendments Act ("FDAAA"), which was enacted on September 27, 2007.[2] The FDAAA adds new section 505(q) to the FDC Act. Section 505(q)(1)(A) provides that the FDA may not delay approval of an ANDA application because of any request to take any form of action related to the pending ANDA unless "a delay is necessary to protect the public health." *See* FDC Act 505(q)(1)(A). The Act, however, did not provide the FDA with significant additional resources to deal with petitions. Thus, a branded firm may still be able to delay generic approval while the FDA considers whether the relevant Citizen Petition implicates issues of public health, regardless of whether the petition actually does or not, and regardless of whether the petition is as sham or not. In the high-stakes world of pharmaceuticals, even relatively short delays of a few days or a couple of weeks can cost generic firms and consumers millions of dollars in lost sales and overpayment of prescription drugs, respectively.

78. Even after several years of experience under the FDAAA, FDA continues to express concerns that Citizen Petitions are being filed for the purpose of delaying ANDA approvals: "FDA will continue to gain additional experience and monitor trend data in the FY 2012 reporting period to assist Congress in determining whether section 505(q) is accomplishing the stated goals of the legislation. Based on the petitions that FDA has seen to date, however, the agency is concerned that section 505(q) may not be discouraging the submission of petitions that

[2] Public Law 110-85 (as amended by Public Law 110-316).

do not raise valid scientific issues and are intended primarily to delay the approval of competitive dug products."[3]

(6) Background and FDA Approval of Suboxone Tablets

79. Opioid addiction and abuse (*e.g.*, heroin addiction) is a pervasive public health problem that plagues patients, families, and communities.[4] In 2010, the Substance Abuse and Mental Health Services Administration ("SAMHSA") reported in the National Survey on Drug Use and Health that over 1.9 million Americans suffer from opioid dependence or abuse.[5]

80. Prior to 2002, patients who suffered from opioid addiction were primarily referred to a narcotic treatment program ("NTP") for opioid maintenance treatment using methadone. Methadone is a Schedule II controlled substance[6] and a full opioid receptor agonist similar to other highly abused opiates such as heroin.[7] To mitigate the risk of diversion (*i.e.*, use for non-treatment purposes) associated with prescribing methadone to opioid-addicted patients, methadone may only be administered to treat addiction in a facility specifically registered by the DEA as a NTP.[8]

81. Many opioid dependent patients avoid NTPs due to privacy concerns and the perceived stigma attached to those programs, rendering methadone an incomplete answer to the

[3] Report to Congress, Fourth Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2011, Department of Health and Human Services, Food and Drug Administration.
[4] Guide to Drug Abuse Epidemiology, Department of Mental Health and Substance Dependence, Noncommunicable Diseases and Mental Health Cluster, World Health Organization (2000), available at http://whqlibdoc.who.int/hq/2000/a58352_PartA.pdf.
[5] Buprenorphine. Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, Results from the 2010 National Survey on Drug Use and Health: Summary of National Findings, NSDUH Series H-41, HHS Publication No. (SMA) 11-4658, available at http://www.samhsa.gov/data/NSDUH/2k10NSDUH/2k10Results.htm.
[6] *See* 21 U.S.C. § 812(c) (2010). The U.S. DEA places drugs and other substances in a respective schedule according to their relative abuse potential and accepted medical use. For example, Schedule I controlled substances have no currently accepted medical use and a high potential for abuse, and Schedule II controlled substances have a currently accepted medical use but a higher potential for abuse than Schedule III, IV, or V controlled substances. *Id.* at (b).
[7] About Buprenorphine Therapy, U.S. Dep't of Health and Human Services, http://buprenorphine.samhsa.gov/about html.
[8] *See* 21 C.F.R. § 1306.07 (2012).

demand for opioid addiction treatment.[9] Accordingly, in 2000, Congress sought to improve access to opioid addiction treatment via the Drug Addiction Treatment Act ("DATA"). DATA enabled practitioners who obtained specialized training to administer Schedule III, IV, or V controlled substances to a certain number of patients in an office-based setting.[10]

82. 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 drug for post-induction maintenance treatment. Prior to these drugs being approved in 2002 by FDA, buprenorphine was rescheduled from Schedule V to Schedule III, and Subutex Tablets and Suboxone Tablets became the first opioid addiction treatments available outside an NTP setting pursuant to DATA 2000.

B. THE EVOLUTION OF RECKITT'S PRODUCT-HOPPING SCHEME

(1) Reckitt Develops Suboxone Film, Which is not Medically Superior To Tablets But Which Provides An Anticompetitive Advantage Because It Cannot Be Automatically Substituted With Generic Tablets

83. When Reckitt introduced Suboxone, buprenorphine and naloxone were no longer innovative drugs; in fact, they were quite old. Naloxone was first approved by FDA in the 1970s, and buprenorphine in 1982. Much of the research to investigate buprenorphine's utility in opioid dependence was paid for by taxpayers, through grants to Reckitt from the National Institutes of Health.

84. Although Reckitt's NDA for Suboxone Tablets was approved by FDA in 2002, it had no patent protection and instead relied primarily on seven years of orphan drug exclusivity.

---

[9] *See* Elisa F. Cascade et al., *Prescribing for Buprenorphine in the Treatment of Opioid Addiction*, 4(1) Psychiatry 15, 15-16 (2007).

[10] *See* DATA, Pub. L. No. 106-310, § 3502, 114 Stat. 1222-7 (2000).

FDA designated Suboxone Tablets as an orphan drug for the treatment of opioid addiction on October 27, 1994. Orphan drug designation and approval may be granted: (a) on the basis that a product is intended to treat a disease or condition that has a U.S prevalence of less than 200,000 persons;[11] or (b) where the sponsor can show that there is no reasonable expectation that the costs of developing and making available the drug will be recovered from U.S. sales, despite the fact that the product treats a disease or condition that has a U.S. prevalence of 200,000 or more individuals.[12] Here, Reckitt put forth arguments for orphan designation based on FDC Act § 526 (a)(2)(A) (prevalence) and § 526 (a)(2)(B) (cost recovery). Although FDA did not agree with Reckitt's prevalence figures, the FDA concluded that the economic analysis and supporting documentation submitted by Reckitt were sufficient to support a cost recovery designation. Suboxone's orphan drug exclusivity expired on October 8, 2009.

85. Despite Reckitt's representation in its successful application for orphan drug exclusivity that there was no reasonable expectation that Reckitt could recover the costs associated with making and developing the drug, Suboxone quickly became a blockbuster prescription drug product for Reckitt.

86. Once multiple generics enter the market, the generic price frequently falls to a 90% discount (or more) compared with the price of the branded product. Internal Reckitt documents show that during 2007 and early 2008, Reckitt expected Suboxone sales [redacted] Based on the assumption that [redacted] Reckitt expected that [redacted]

[11] *See* FDC Act § 526 (a)(2)(A).
[12] *See* FDC Act § 526 (a)(2)(B).

87. It was around that time that Reckitt started considering shifting the U.S. market to Film. [redacted] Other costs, such as third party licensing [redacted] would be incurred with the Film and not the Tablet.

88. Ultimately, Film was even less profitable than Tablets than Reckitt initially expected, because, as alleged below, part of Reckitt's scheme involved dramatically raising Tablet prices [redacted] over a 3 year period, while it raised Film prices only [redacted] Thus, Film not only cost more to make, but Film also had a substantially lower price and profit margin than the branded Suboxone Tablets. In light of Reckitt's purported claims that the Film has benefits over the Tablets (which Plaintiffs dispute), the economically rational decision would have been for Reckitt to charge a higher price for Film over Tablets in order to recover the higher manufacturing costs, the R&D expenses to develop the product, and to fully capture the premium for the Film's purported benefits. But Reckitt did the exact opposite.

89. Because Reckitt recognized that Film cost more to make, it initially planned to introduce Film only outside the U.S. However, in early 2007, Reckitt came to understand that [redacted]

[redacted] Thereafter, Reckitt started actively exploring a strategy in the United States to coerce and induce doctors to prescribe and pharmacists to dispense Film in lieu of Tablets, with the specific goal [redacted]"[13]

90. Significantly, it was the Film's anticompetitive effect that prompted Reckitt's plan to introduce Film in the U.S. and to remove Tablets based on the pretext that there was a safety problem with Tablets. The fact that the Film's economic benefit to Reckitt stemmed solely from its negative effect on generic competition is reflected by the facts that: [redacted] and (c) the Suboxone Film sales that Reckitt would make would be less profitable than Reckitt's existing Suboxone Tablet sales. However, Reckitt did not care if it shrunk the Suboxone market, and therefore smaller total amounts of Suboxone were sold, so long as Reckitt was able to keep the vast majority of sales for itself by excluding and impeding generic competition.

91. On October 20, 2008, Reckitt submitted an NDA for a sublingual Film formulation of Suboxone. This formulation was approved on August 30, 2010. The fact that thwarting generics was Reckitt's real goal in reformulating Suboxone is evident from Reckitt's 2010 Annual Report, which states that, "[I]n the event of generic competition to the Suboxone

[13] This is not the first product with which Reckitt was accused of engaging in a scheme to thwart generic competition by changing formulations. According to The Guardian, in 2011 Reckitt was fined £10.2m by the Office of Unfair Trading (OFT) in the UK after it was found to have engaged in remarkably similar anti-competitive behavior following the expiry of a patent on its heartburn drug Gaviscon. The penalty followed whistleblower revelations that helped prove Reckitt had hoped to prosper by removing Gaviscon Original Liquid from a list of prescription drugs available to NHS patients shortly after the expiration of the patent. The OFT concluded that the delisting was designed to make it harder for chemists to identify cheaper generic alternatives and to boost sales of Reckitt's new variant Gaviscon Advance Liquid, which was patent protected.

Tablet, the Group expects that the Suboxone sublingual Film will help to mitigate the impact thereof." The Report continues, "It is well known that by far the largest part of the Pharmaceuticals business, the Suboxone Tablets in the USA, can become subject to generic competition at any time. To mitigate the potential impact of this, in August 2010 we launched a patent-protected…Suboxone Film."

92. The three-year regulatory exclusivity for Suboxone Film extended to August 2013. In addition, Film is covered by patent 8,017,150, entitled "Polyethylene Oxide-Based Films and Drug Delivery Systems Made Therefrom," which will not expire until September 2023. Because Suboxone Film does not make use of a never-before-used active ingredient, it does not qualify for the five-year new chemical entity exclusivity.

93. Medically speaking, Suboxone Film is not superior to Suboxone Tablets in terms of efficacy. In fact, Reckitt obtained FDA approval for Suboxone Film based almost entirely on previous studies that Reckitt used to demonstrate the safety and efficacy of the Tablets. FDA confirmed that Reckitt's NDA for Suboxone Film "includes no new efficacy studies."[14] In order to obtain approval, Reckitt primarily demonstrated that the Film version had sufficiently equivalent bioavailability compared with the Tablet version, meaning the same relative amount of active ingredients reached patients' bloodstreams.[15] Even Reckitt "conclude[d] that the two formulations are *comparable according to PK [i.e., pharmacokinetic] parameters and equivalent in effectiveness* for treating opioid dependence."[16]

94. In terms of safety, FDA found that there had been no demonstration that the Film version and unit-dose packaging were superior in safety to Tablets packaged in bulk containers,

[14] FDA Memorandum of June 26, 2009, regarding Suboxone Film NDA, attached hereto as Exhibit "A", at 2.
[15] FDA Cross Discipline Team leader Review of August 20, 2010, regarding Suboxone Film NDA, attached hereto as Exhibit "B", at 3 ("The NDA rests primarily on a program of Phase 1 pharmacokinetic (PK) studies evaluating bioavailability, doses proportionality, and comparisons to Suboxone Tablets…").
[16] Exhibit "A" at 2 (emphasis added).

but that the studies employed by Reckitt in an attempt to make demonstrations of superior safety were deeply flawed: (1) "Almost all of the safety experience with the proposed new formulation was derived from a single study. This study had a number of flaws, including inadequate training of personnel conducting the safety exams, inconsistent recording of findings, treatment of participants with dosing regimens not recommended in the proposed labeling, and a high drop-out rate;"[17] (2) "After review of the clinical study report and database for the study RB-US-07-0001 [used to support Reckitt's NDA for Suboxone Film], our overall conclusion is that the study was poorly designed and conducted and was not useful for demonstrating any difference in the safety profile or abuse potential of the two formulations;"[18] and (2) "There was no positive control arm (Suboxone Tablet group) in this study. *So, it would be impossible to claim any potential advantages of Suboxone strip [Film] over the current Suboxone Tablet product.*"[19]

95. FDA did, however, express new concerns over the Film formulation (that are not associated with Suboxone Tablets) in the context of accidental pediatric exposures: "It should be noted that the proposed Filmstrip product cannot be spit out easily and dissolves quickly. Therefore, to the extent that some cases may be mitigated by the child spitting out the Tablet before full absorption, the Filmstrip product could be more hazardous than the Tablet."[20] This is because, upon introduction into the mouth, Suboxone Film hydrates to a gel within approximately 30 seconds, and erodes completely over the course of 3 minutes, releasing all of the buprenorphine. In contrast, Suboxone Tablets have a much longer oral residence time (each Tablet may take up to 10 minutes to dissolve), and children often spit them out, terminating their

[17] Exhibit "B" at 6.
[18] Exhibit "A" at 4.
[19] *Id.* (emphasis added). In addition, the label for Suboxone Film notes the lack of differences in adverse events between Tablets and Film. *See* Highlights of Prescribing Information, http://suboxone.com/hp/ ("Few differences in the adverse events profile were noted among SUBOXONE sublingual Film, SUBOXONE (buprenorphine and naloxone) sublingual Tablets…").
[20] Exhibit "B" at 6.

exposure to buprenorphine. When children do swallow Tablets, the buprenorphine in Suboxone Tablets is absorbed to a far lesser extent compared with the Film version, making Suboxone Tablets potentially less dangerous than the Film in this type of accidental exposure.[21]

96. FDA also noted in its review of the Suboxone Film NDA that new and additional concerns about diversion were associated with the Film version that were not associated with the Tablet: "Taken together, these findings suggest 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."[22] The significant abuse and diversion potential of the Film is attributable to several factors inherent in that formulation: (a) the Film version is easier to conceal (*e.g.*, behind postage stamps) as Reckitt itself learned before Suboxone Film was approved by FDA – almost 6,000 strips (46% of those dispensed to study patients) were "missing" after the limited clinical studies Reckitt performed to gain FDA approval[23]; and (b) the Film is easier to dissolve and inject.

97. Regarding the unit-dose packaging for Suboxone Film, FDA specifically informed Reckitt that it did "not agree that the packaging for [Suboxone Film] provides meaningful incremental protection against pediatric exposure."[24] As Reckitt knew, a significant fraction of patients took their Suboxone in divided doses, and then placed the unused portion of their dose back into the container. With Suboxone Tablets, any unused dose portions can be placed back into the child-resistant bottle. The same is not the case with Suboxone Film in unit-dose packaging. While each Film dose is packaged in a child-resistant sleeve, once the sleeve is opened, it no longer affords any child resistance protection and Reckitt supplies no child-

[21] *Id.*
[22] Exhibit "A" at 3.
[23] *Id.* at 5.
[24] FDA letter to Reckitt, May 6, 2010, at 4, attached hereto as Exhibit "C". FDA made this statement in specific response to Reckitt's question, "[d]oes FDA agree that the packaging for Suboxone Sublingual Film provide[] meaningful incremental protection against pediatric exposure?"

resistant bottle or other container into which unused portions of doses of Film can safely be placed.[25] Moreover, the child-resistant sleeve increased the street value of diverted product because it guaranteed product identity and, therefore, purity. By contrast, Suboxone Tablets were supplied in a childproof bottle into which a patient could place unused portions of split Suboxone Tablets. This was not news to Reckitt as it had successfully sold Suboxone Tablets in FDA-approved bulk bottle packaging for years in the U.S.

98. Even assuming that unit-dose packaging provided some sort of incremental safety benefit over Tablets (which it does not), there was no need to use that packaging configuration with a Film variety of Suboxone – which itself was not safer or more effective than Tablets, as articulated above – since it was equally usable with the Tablet version. Reckitt has sold Suboxone Tablets in unit-dose packaging in foreign markets for years and admitted to FDA that doing so with Tablets in the U.S. may be feasible.[26]

99. Upon information and belief, the Board of Directors of Defendant Reckitt Benckiser Group plc were advised of the generic-impairing purpose of the product hop from Suboxone Tablets to Film, and of the related anticompetitive tactics, and specifically approved the scheme and its purpose. The Board of Directors approved and directed this anticompetitive scheme over several years, including the mid-2000s.

(2) Reckitt Implements A Coercive and Deceptive Scheme To Shift The Market To Film Even Though Reckitt Knew That Most of the Market Would Not Otherwise Choose To Buy Suboxone Film

[25] Exhibit "B" at 6 ("...the unit-dose packaging will help protect against this as long as the medication is not removed from the packaging and left out. (This may occur if patients use fractions of a strip, which is apparently common practice with Tablets.)").

[26] Reckitt's September 25, 2012 Citizen Petition ("Reckitt's Citizen Petition") at 22 n. 57, attached hereto as Exhibit "D".

100. During 2007, Reckitt conducted a series of market surveys of patients, doctors, and Payors regarding the Film's market appeal. The surveys found that: [redacted]

101. Without the improper acts alleged herein, Reckitt expected that Film could grow to [redacted] market share in the first 12 months, but that Film growth would plateau at approximately [redacted] market share. Reckitt expected that [redacted]

102. There was one quality, however, that Suboxone Film possessed that made it significantly different from Suboxone Tablets and which was crucial to Reckitt's anticompetitive scheme – that difference was dosage form, Film versus Tablets. Reckitt exploited this difference for one reason: it knew that generic Suboxone Tablets would not and could not be considered "AB-rated" to branded Suboxone Film, and thus pharmacists would not and could not legally substitute the less-expensive generic Suboxone Tablets when presented with a prescription for Suboxone Film. Such automatic substitution of less-expensive AB-rated generics at the pharmacy counter is the efficient market means by which generic competition reduces drug prices. However, Reckitt could only take advantage of this distinction if it could get physicians to switch patients to Film. As alleged herein, Reckitt used a series of coercive, deceptive and otherwise improper tactics to effectuate such a market switch, to protect its prescription base from generic competition.

103. With fair competition, Reckitt expected that generic Tablets would capture [redacted] of the Suboxone market, Film would capture [redacted] share, and the branded Suboxone Tablets

would retain [redacted] market share. However, the ultimate reality was [redacted] because of the improper tactics and acts alleged herein. By the time generic Tablets entered in March 2013, Reckitt had converted approximately [redacted] of the Suboxone volume to Film (based on volume not dollars) as a result of its anticompetitive product hop scheme.

(a) Reckitt's Coercive And Deceptive Tactics To Drive Patients To Suboxone Film

104. By [redacted] Reckitt started developing a strategy [redacted] Reckitt's strategy focused on using both [redacted]

(i) The Vast Majority of Suboxone Prescriptions Are Controlled By A Concentrated Group of Doctors Who Have Significant Influence over their Patients' Prescription Purchases.

105. After Suboxone was introduced in 2002, Reckitt spent several years building the market by: (a) generating public acceptance/demand for office-based treatment; and (b) building a network of doctors that were able and willing to offer Suboxone treatments to addicts. Before the DATA was passed in 2000, it was illegal for doctors to prescribe narcotics to addicts to treat their addictions outside of clinics. Thus, when Suboxone was launched there were no doctors who had experience or certifications needed to prescribe it and no way for patients to receive it. Consequently, Suboxone sales could not grow until Reckitt built a network of doctors willing and able to write Suboxone prescriptions.

106. However, it was not enough to simply have patients who wanted treatment and a network of doctors able to provide it. It was critical that potential patients actually find their way to available doctors. Obviously, patients who never started treatment would never receive

Suboxone. But beyond simply ensuring that current patients were dispensed Suboxone, Reckitt also had to ensure that its doctor network remained profitable and growing so that doctors would remain motivated to treat Suboxone patients generally, and expand their practices. Thus, [redacted]

107. First, Reckitt developed a website [redacted]

108. [redacted]

109. The way that the Suboxone market evolved – combined with the effects from the regulatory structure – has led to a concentrated group of doctors with an even greater ability to determine which drug their patients would take. Because of the way the Suboxone market developed, the vast majority of Suboxone prescriptions are concentrated among a limited set of doctors. For example, in 2007, Reckitt determined that: (a) [redacted]

[redacted]

110. Furthermore, these doctors have even more influence over the product selection decision than is usually the case. In many parts of the country, Suboxone demand has grown much faster than the supply of doctors who are willing or able to prescribe it. Only 12,800 doctors have government certification to treat Suboxone patients, but in reality far fewer doctors actually do treat Suboxone patients. Moreover, under the DATA there are significant limits on how many Suboxone patients a doctor can treat at any one time. Because of the limited number of doctors who can prescribe Suboxone, and the limited number of patients that each doctor can treat, in many parts of the country patients are locked into their existing doctors because it is very difficult to switch doctors. [redacted] November 17, 2013 *New York Times* article noted that, in some areas of the country "specialists routinely turn away addicts begging for help," and at least one clinic had a waiting list of 1,000 patients.

(ii) Reckitt Penalized Doctors Who Do Not Push Their Patients To The New Film Product and Rewarded Doctors Who Did.

111. Reckitt understood that the doctors were critical to the distribution of Suboxone, and that [redacted]

112. By [redacted] Starting about a year before the Film was launched, Reckitt deviated from its prior historical practices, [redacted]

[redacted]

113. [redacted] Furthermore, Reckitt redesigned its website [redacted] Thus, Reckitt deviated from its prior practices [redacted]

114. Given the higher price and better margins for Tablets, it was economically irrational for Reckitt to shift the market to the Film in this manner but for Reckitt's scheme to impede generic competition for the Tablets.

115. In addition to using economic disincentives to penalize doctors who did not push their patients to Film, Reckitt also developed a program to give economic incentives to doctors who did push their patients to Film.

116. Part and parcel of Reckitt's product hop scheme was [redacted]

[redacted]

117. The HTH program [redacted]

118. [redacted]

[redacted]

119. [redacted] As a result, Reckitt: (a) economically coerced doctors to prescribe Film instead of Tablets by penalizing those doctors who prescribed Suboxone Tablets with the loss of patients and financially valuable services; and (b) rewarded and incentivized doctors to prescribe Film to continue to receive the increased revenue provided by the services that Reckitt offered.

120. In light of the higher price and lower marginal cost for the Tablets, it was economically irrational for Reckitt to impair sales of the Tablets by terminating these valuable services in favor of the Film unless it was in anticipation of impeding competition. Moreover, it improperly penalized doctors who prescribed the Tablets and conversely incentivized doctors to prescribe the Film, aligning the doctors' interests with Reckitt to effectuate the market shift from

Tablets to Film. This constitutes economic coercion of doctors and patients who would otherwise have preferred to prescribe and take, respectively, Tablets.

121. As part of its initial efforts to grow the Suboxone market, [redacted]

(3) Reckitt provides kickbacks to doctors and touts a phony study.

122. Reckitt's strategy to influence doctors centered on the use of a program that was inherently illegal under the Medicaid-Medicare Anti-Kickback Statute (the "Anti-Kickback Statute"), 42 U.S.C.S § 1320a-7b(b). That statute makes it illegal for anyone to knowingly and willfully offer any remuneration (whether in the form of cash, free business services, or patient referrals) in order to induce anyone (including but not limited to a doctor) to purchase or recommend the purchase of a drug covered by a Federal Healthcare program (such as Suboxone). The statute is violated by an intentional and willful offer to induce a doctor to switch patients to a different drug, even if no payment or remuneration is actually given, even if the doctors' prescription decision is not because of such a payment or remuneration, and even if there are other legitimate reasons for the offer. [redacted]

[redacted]

123. Even though: (a) the Anti-Kickback statute makes it illegal to offer anything of value that is intended to induce doctors to prescribe a particular drug; and [redacted]

124. Because the offer to doctors of [redacted] was illegal under the Anti-Kickback statute, [redacted]

125. Furthermore, even [redacted] was legal under the Anti-Kickback statute (which is not the case), there was no legitimate basis for Reckitt's assertions that the program

provided significant medical benefits. Reckitt falsely and/or deceptively touted that [redacted] Contrary to Reckitt's assertions, the study was unreliable and invalid for various reasons.

126. Dr. Jeffrey Junig (an addiction doctor who participated in the study) acknowledged that the study suffered in many respects, including design bias, lack of true "blinding" and participation selection issues, writing:

> Today I received a brochure describing the results of a 'study' that claims that patients in the 'Here to Help' program had improved compliance as measured by maintaining appropriate use of prescribed buprenorphine. As some of you may know I got my PhD in Neurochemistry doing basic science research and I have served as a Peer Reviewer for Academic Psychiatry for a number of years, so I know how to evaluate whether a study is 'sound' or is instead misleading. Even in the material that I received today, R-B refers to the findings as coming from *a 'quasi-study design'*—so they at least apparently recognize that the findings are biased. *I participated in the data collection for the study,* actually; those of us who participated would invite new patients to participate, and the patients who accepted the invitations would then be randomized so that one group would get the 'here to help' info and the other group would not. R-B found that the here to help group had better compliance and fewer drop-outs than the other group. One problem I have is that I don't know what they did for the 'non-study' group. For example if they told the non-here to help group 'Suboxone will kill you if you keep taking it', then the difference in compliance would be meaningless! I'm sure they didn't say that, but what DID they say?
>
> Second, there was no way to 'blind' the study on either side—both the addict and the phone person knew which group the study person was in. We like studies to be 'double-blind', and this one was not even single-blind.
>
> Finally, participation in the study was voluntary, and we don't know anything about the factors that caused some people to enroll and others to avoid enrolling. Let me explain how that bias could have affected the results. Patients were paid to participate in the study, so I would guess that the addicts who were

unemployed were more likely to participate. Likewise, the addicts who were, say, executives from a high-profile company or physicians or attorneys would be less likely to participate, as they would be more concerned about disclosure of their status as addicts. So at best, the 'here to help' study looked at a specific subset of addicts—those who were interested in making $100 by talking on the phone for a half hour. Would the here to help program be of any value for a person who is still [redacted]

127. Reckitt's *"quasi-study"* was created [redacted]

128. Furthermore, [redacted]

[redacted]

129. If Reckitt truly believed that the HTH program decreased relapse rates and/or improved patient outcomes, then it was economically irrational for Reckitt to not offer the program to Tablet patients during the 30-month period before generic Tablets ultimately entered the market. The profit-maximizing decision – apart from impairing competition from generic Tablets – would have been to use [redacted] to promote the sale of branded Suboxone Tablets, Reckitt's most profitable product. Reckitt's decision to prevent Tablet patients from participating [redacted] during the 30 months before generic Tablets entered the market was not driven by the desire to maximize profits during that period, but was instead designed to undermine the Tablet market prior to generic competition at the expense of short term profits.

(4) Other Coercive Tactics

130. Commensurate with FDA approval of the Suboxone Film NDA in 2010, Reckitt implemented a massive fraudulent sales and marketing campaign to advance the conversion of all or substantially all BPN/NLX prescriptions from Tablets to Film. Reckitt's product-hopping marketing campaign included, among other things: (a) a wide ranging fraudulent marketing campaign in which Reckitt's sales representatives promoted only the Film formulation and discouraged physicians from writing prescriptions for the original Tablet formulation under the pretext of alleged safety concerns with the Tablet and alleged Film superiority; (b) publicly announcing that Reckitt was pulling Suboxone Tablets from the market due to the false safety issues; and (c) publicly seeking an FDA determination that Suboxone Tablets were voluntarily

pulled from the market by Reckitt due to the contrived safety issues (even though Reckitt had not actually pulled the Tablets from the market).

(a) Reckitt further Destroyed Demand for Suboxone Tablets by Publicly Announcing Their Discontinuation due to False Safety Issues.

131. On September 25, 2012, Reckitt publicly announced it would discontinue selling branded Suboxone Tablets in the U.S., and used as a pretext the purported, but false, safety reasons it had created. This public announcement was simply another vehicle for Reckitt to say what it had been telling doctors for months. Reckitt's discontinuation statements to doctors and public announcement regarding its branded Suboxone Tablets had an anticompetitive purpose and a profound anticompetitive effect. Reckitt was aware that once prescribers, pharmacists, and patients learned of Reckitt's discontinuation notice (regardless of the truth of the safety representation), they would understand that there was simply no choice but to convert from Tablets to Film. Raising the purported "safety issues" regarding the Tablets and announcing the discontinuation of the Tablets provides further justification for the doctors to expedite the switch from Tablets to Film. Through this tactic, Reckitt further ensured that by the time generic Tablets entered the marketplace, there would be a greatly reduced volume of prescriptions being written for Suboxone Tablets for which the less-expensive generic Suboxone Tablets could be substituted. Reckitt's public announcement had the intended effect as it was widely reported.[27]

132. While Reckitt issued its discontinuation announcement in September 2012 due to an alleged serious safety issue, it ***continued selling*** the allegedly dangerous product until early March of 2013 in order to continue to reap the benefit from the now rapidly declining Tablet market while it implemented the anticompetitive conversion to Film. The continued sale of the Tablets after announcing their discontinuation belies Reckitt's concern about safety issues. This

[27] *See, e.g.*, http://www.bloomberg.com/news/2012-09-25/reckitt-benckiser-to-stop-selling-suboxone-Tablets.html.

continued sale of the Suboxone Tablet product highlights that Reckitt's alleged safety concerns regarding the Tablet version were not legitimate, but simply part of its anticompetitive switch strategy that it was implementing over time while it simultaneously worked to prevent FDA approval of ANDAs for generic versions of Suboxone Tablets. Reckitt attempted to justify this continued Tablet sale by arguing to FDA that would-be generic competitor and ANDA filer "Amneal seems unconcerned about the devastating effect on patients and the treatment community that would be caused by a precipitous removal, and ignores the mandatory 6-month notice period required under section 506C of the FDC Act."[28] Reckitt's justification was a ruse to hide its true anticompetitive motives since: (a) the applicable statutory provision Reckitt quotes, 21 U.S.C. § 356c, allows for the reduction of the 6-month period in instances where "a public health problem may result from continuation of the manufacturing for the 6-month period" – upon information and belief, Reckitt did not seek FDA permission to shorten this period due to purported serious safety concerns arising from Tablets; (b) at the time of the September 2012 discontinuation announcement, Reckitt had been selling the Film version for over two years, thus there would be no precipitous absence of Suboxone on the market; and (c) Suboxone Tablets were not listed on FDA's public list of drugs to be discontinued, suggesting that Reckitt did not actually provide formal notice of discontinuation to FDA as mandated by section 506C of the FDA Act when it made its announcement (and further suggesting that Reckitt's public announcement of discontinuation was simply a ruse).

133. FDA took notice. In its denial of Reckitt's Citizen, FDA wrote:

> Since approval of the Suboxone Film REMS in 2010 (and subsequent approval of the same REMS for Suboxone and Subutex Tablets in 2011), Reckitt has not

[28] Exhibit "F" at 4 n. 5. Amneal Pharmaceuticals, LLC's ("Amneal") October 22, 2012 response to Reckitt's Citizen Petition is attached hereto as Exhibit "E". Reckitt's reply to Amneal's response, sent to FDA on November 16, 2012, is attached hereto as Exhibit "F".

> proposed any revisions to the REMS for the products to further address the risk of accidental pediatric exposure. . . .
>
> ---
>
> Reckitt's own actions also undermine, to some extent, its claims with respect to the severity of this safety issue. Notwithstanding the availability of data showing (according to the Petition) an increasing rate of accidental pediatric exposure through at least the first part of 2010, and the first report of a pediatric death in June 2010, Reckitt did not seek to discontinue marketing of the Tablet in multi-dose containers for more than two years.[29]

Indeed, FDA went so far as to refer Reckitt's conduct to the FTC for antitrust investigation.

C. ABUSE OF THE SSRS/REMS PROCESS.

134. Reckitt understood that the key to its scheme's success was that the product switch had to occur prior to generic entry. Thus, in furtherance of its improper conversion scheme, Reckitt undertook a series of acts to delay generic competition to increase the amount of time it had to convert the market to Film.

135. In 2009, Actavis, Inc. ("Actavis") filed an ANDA for generic Suboxone Tablets and Amneal filed in May 2011. These filings were of no surprise to Reckitt given the size of sales pertaining to branded Suboxone Tablets. By 2011, Reckitt saw that it had a big problem – generic Suboxone Tablets were expected to enter the market by early 2012, [redacted] This left more than [redacted] of Reckitt's annual Suboxone revenue exposed to immediate loss to generic competition. Reckitt therefore bought itself more time to destroy demand for Suboxone Tablets and switch the market to Suboxone Film by sabotaging the process by which it and the generic manufacturers were required to finalize and submit an FDA-mandated SSRS for

[29] FDA letter to Reckitt, dated February 22, 2013, denying Reckitt's Citizen Petition ("FDA CP Denial Letter") at 6, 15, attached hereto as Exhibit "G".

Suboxone Tablets. The approval of this shared risk mitigation plan was at that time the only thing preventing at least two generic Suboxone Tablets from receiving final FDA approval.

136. On December 22, 2011, having considered and evaluated Reckitt's data on reported pediatric exposures associated with Suboxone Tablets, FDA approved Reckitt's proposed REMS for branded Suboxone Tablets. The agency addressed the pediatric exposure issue in the REMS, requiring that Reckitt address pediatric exposures associated with Suboxone Tablets through FDA-approved labeling. FDA did not require that the pediatric exposure issues be addressed outside the realm of the FDA-approved product labeling and REMS.

137. On January 6, 2012, two weeks after approval of the Suboxone Tablet REMS, FDA sent all sponsors of pending ANDAs for Suboxone Tablets a REMS Notification Letter explaining that all branded and generic Suboxone products would be subject to a single REMS program (SSRS/REMS).

138. The Notification Letter advised the generic ANDA filers to contact Reckitt to collaborate on the creation and implementation of an SSRS program. The Notification Letter also stated that pediatric exposure would be addressed in the REMS. FDA mandated a compliance date of May 6, 2012, for approved products, by which time it expected that the SSRS with Reckitt would be accomplished.

139. Upon information and belief, top executives and counsel at Defendant Reckitt Benckiser Pharmaceuticals, Inc. and Defendant Reckitt Benckiser Group plc jointly conceived and implemented the sabotaging of the SSRS process as a means of delaying generic entry.

140. FDA reasonably expected that the approved Suboxone REMS could be amended to add generic manufacturers in a relatively short time. Indeed, there would have been no reason for FDA to withhold approval for REMS for generic Suboxone that were identical in all material

respects to the REMS it had approved one month earlier for branded Suboxone Tablets. In order to make that submission, however, the generic Tablets needed access to Reckitt's information regarding the recently approved Suboxone Tablet REMS.

141. Because the SSRS was a precondition to the approval of Suboxone Tablet ANDAs, generic ANDA filers promptly notified Reckitt of FDA's Notification Letter and requirement.[30]

142. Reckitt was thereby informed that generic companies had pending Suboxone Tablet ANDAs. Reckitt took full advantage of its access to this proprietary information by feigning cooperation in the SSRS development process in order to delay the ANDA approvals.

143. During the next six months, ANDA applicants for generic Suboxone Tablets (along with ANDA holders for the single ingredient buprenorphine-containing products) sought to negotiate the SSRS process with Reckitt in good faith and with due urgency to secure prompt approvals of their products. Reckitt, however, used every opportunity to undermine and delay the process, making unnecessary, unprecedented, and unreasonable demands on the generic companies as a precondition to Reckitt's cooperation in the development of the SSRS, all in violation of 21 U.S.C. § 355-1(f)(8).

144. Specifically, as stated by generic ANDA filer Amneal to FDA:

> [Reckitt] initially informed the generic companies that it would wait until it received confirmation from FDA of the requirement for a SSRS before working on it. While waiting for a response from [Reckitt], the ANDA sponsors joined together as a group in early February 2012 to form a Buprenorphine Products Manufacturing Group (BPMG), and submitted formal correspondence to [Reckitt] on February 8, 2012, regarding a request for collaboration on a SSRS. On February 14, 2012, [Reckitt] informed the

[30] As noted by FDA in denying Reckitt's Citizen Petition, the REMS for the Film product was "essentially identical" to the one for branded Tablets. But, while the REMS for the Film was finalized by August 2010, the REMS for branded Tablets was not finalized for another sixteen months, December 2011. *See* Exhibit "G" at 5. Upon information and belief, it is alleged that Reckitt delayed the finalization of the branded Tablets REMS until December 2011 in order to delay the start of the SSRS process with the filers of ANDAs for generic Suboxone Tablets, and thereby delay ultimate generic entry.

> BPMG that it had received the communication from FDA, but that, due to purported antitrust issues, its legal department would handle future communications regarding the SSRS. While waiting for a response from [Reckitt's] legal representative, the generic members of the BPMG initiated weekly meetings beginning on February 23, 2012. [Reckitt] turned down numerous invitations to participate in the meetings. On March 20, 2012, [Reckitt's] legal representative provided the BPMG with a list of legal and governance issues that it demanded be resolved before [Reckitt] would engage in any substantive discussions involving an SSRS. In particular, [Reckitt's] "gating issues" involved: (1) a mission statement describing the BPMG's commitment to patient safety; (2) an upfront agreement on cost-sharing for REMS implementation and activities; and, (3) an upfront agreement that all manufacturers would share the costs of product liability for future potential lawsuits. These demands made clear that [Reckitt] was seeking to leverage access to its REMS program to its own commercial advantage. [Reckitt] finally agreed to meet with the BPMG in person on April 2, 2012. But at the meeting, [Reckitt] refused to engage in any substantive discussions about the REMS and would only provide legal staff to attend the meetings until the "gating issues" were resolved to [Reckitt's] satisfaction. Consistent with past experience and to expedite the process, the generic companies sought to develop the REMS in parallel with the discussions and negotiation of legal issues. [Reckitt] undermined the effort by refusing this approach while also refusing to share non-public information, documentation, or any description of its REMS program – despite having entered into a confidentiality agreement with the BPMG – until its "gating issues" were resolved. Although the gating issues had nothing to do with the content or administration of an SSRS, in a good faith effort at cooperation, the generic members of the BPMG worked on the issues for weeks with [Reckitt]. Ultimately, the BPMG members could not commit to a binding agreement on cost sharing until they reviewed the costs associated with [Reckitt's] program (which [Reckitt] refused to provide) and could not agree to [Reckitt's] unprecedented demand on product liability sharing as a required precursor to SSRS discussions.[31]

145. In May 2012, after months of futile discussions with Reckitt regarding an SSRS, during which period Reckitt refused to share any non-public information about its existing REMS program, Amneal and the other generic Tablet ANDA applicants jointly requested a meeting with FDA to discuss the delays created by Reckitt. FDA scheduled the meeting for June 18, 2012, and invited Reckitt.[32]

146. After reviewing the written materials submitted by Reckitt and the BPMG, and hearing each party's oral presentation, FDA agreed at the meeting with Amneal and the other generic ANDA filers that, as a result of Reckitt's refusal to cooperate and share information

[31] Exhibit "E" (Amneal letter to FDA) at 4 n. 3.
[32] *Id.*

about its REMS and FDA's inability to compel Reckitt to share the information, the only viable alternative would be for the generic companies and Reckitt to develop a new SSRS based upon the requirements set forth in the REMS Notification Letter, without utilizing any of Reckitt's existing information (which Reckitt refused to provide). Reckitt advised FDA at the meeting that it would cooperate with the generic sponsors to develop this new SSRS, which Reckitt knew was necessary for generic sponsors to obtain approval of its respective ANDAs. At that same meeting, "FDA implored the parties to recognize that actions designed to 'block or delay' approval of the BPMG member's ANDAs, or otherwise preventing the application of an SSRS to an ANDA drug, were prohibited by FDCA § 505-1(f)(8)."[33]

147. Through Reckitt's participation, Reckitt again obtained proprietary information regarding the generic ANDAs as well as the filing status, timing, and content of the proposed new SSRS. Despite its commitment to cooperate, Reckitt's intransigence and delay tactics continued. For instance, Reckitt refused to sign a governing Memorandum of Understanding for the group unless it was given veto authority or a super-majority vote for all issues relating to the administration of the SSRS. Reckitt also demanded that each BPMG member agree to share a pre-specified percentage of all product liability claims, regardless of fault, despite the fact that no other shared REMS program has adopted this approach. The FDA-negotiated Extended Release Long Acting Opioid SSRS does not have any provision dealing with the issue of sharing product liability claims, and other SSRS programs have standard cross-indemnification provisions for fault-based claims. Yet Reckitt insisted on unprecedented commercial obligations on the generic members of the BPMG for future product liability claims. Indeed, as certain generic members of the BPMG explained to Reckitt, the upfront agreement being sought by Reckitt would deprive these companies of coverage under its product liability insurance policies.

[33] *Id.* at 5 n.4.

148. In mid-August 2012, Amneal, together with other generic ANDA applicants, filed the SSRS with FDA as part of their respective ANDAs. Despite its active involvement in the development of the SSRS, Reckitt refused at the last second to submit the new SSRS with its NDA filing. As Amneal explained to FDA:

> Two days before the scheduled submission of the REMS documents to FDA in mid-August, [Reckitt] suddenly raised an issue regarding a prescriber outreach component of the SSRS involving the use of a field-force, arguing that an important element of the REMS had been omitted. *The ANDA sponsors were astonished that [Reckitt] raised this matter only a few hours before finalization of the REMS documents.* The ANDA sponsors had no objection to exploring this option, but believed that it should be tabled until the group received comments from the FDA's review of the REMS documents about to be submitted.[34]

149. In mid-September 2012, FDA provided comments regarding the proposed new SSRS. Within two weeks, Amneal and the other generic sponsors jointly responded to FDA's comments. Despite Reckitt's refusal to file the SSRS as part of its NDA, Reckitt maintained that it desired to continue collaborating on the SSRS development. Such continued involvement allowed Reckitt to maintain its awareness of the status of the SSRS and to use such information to the detriment of the generic Tablet ANDA filers as described herein.

150. On October 3, 2012, as a result of Reckitt's intransigence in the development of the SSRS, Amneal and the other generic Tablet ANDA filers elected to file a Waiver Request with FDA, seeking the approval of a generics-only SSRS.

D. THE SHAM CITIZEN PETITION

151. Using the information that it gained by feigning cooperation in the SSRS process, Reckitt learned that the FDA would likely grant final approval to several generic Tablets in the fall of 2012. By that time, Reckitt had still converted only about [redacted] of its Suboxone unit sales

[34] *Id.* at 5 n.6 (emphasis added).

from the Tablet to the Film, thus leaving more than [redacted] in annual revenue exposed to generic competition.

152. On September 25, 2012, just prior to the submission of the Waiver Request by the generic ANDA sponsors, Reckitt formally announced its intent to permanently withdraw Suboxone Tablets from the U.S. market for purported reasons of safety. On the exact same day, Reckitt filed a Citizen Petition with the FDA to block approval of all pending Suboxone ANDAs on alleged safety grounds. Reckitt's petition unconvincingly argued that, after 10 years on the market, Reckitt had discovered a safety issue so severe as to require the removal of Suboxone Tablets, just as the generic SSRS process was coming to its expected close and the pending generic Tablet ANDAs were ripe for approval as noted by FDA.[35]

153. Reckitt's Citizen Petition raised purported safety issues with generic versions of Suboxone Tablets. The petition was a meritless sham filed by Reckitt with the intent to use a government process to delay ANDA approval and market entry of generic versions of Suboxone Tablets in order to artificially protect and extend its Suboxone monopoly even further. Reckitt also fraudulently delayed filing its Citizen Petition with FDA with the subjective intent of maximizing the delay of the approval of less-expensive generic versions of Suboxone Tablets and market entry thereof.

154. In its Citizen Petition, Reckitt requested that FDA take three actions. Each request was objectively baseless, meaning that no reasonable pharmaceutical manufacturer would have realistically expected that the FDA would adopt the specific positions espoused by

[35] Exhibit "G" (FDA Citizen Petition Denial letter) at 15 ("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.") (emphasis added).

Reckitt. And, in fact, FDA denied each of these requests as covered in more detail below.

Reckitt's requests for relief were:

> a. That FDA refrain from approving any buprenorphine NDA or ANDA for the treatment of opioid addiction that did not include a targeted pediatric exposure education program because such applications allegedly would not be approvable pursuant to sections 505(b) and (j) of the FDC Act, despite the fact that the educational programs raised by Reckitt are not required by the FDA for branded Suboxone Tablets and pediatric exposure issues were already dealt with to FDA's satisfaction in the FDA-approved REMS and labeling for branded Suboxone.
>
> b. That FDA refrain from approving applications for buprenorphine for opioid addiction that lacked unit-dose packaging, despite the fact that Reckitt had known about the risk of accidental pediatric exposure for over ten years, had sold and continued to sell Suboxone Tablets in bulk containers during that entire period, knew that FDA did not consider unit-dose packaging to be safer than bulk packaging, had no reliable scientific support for the proposition that unit-dose packaging was safer than child-resistant bottles, knew that unit-dose packaging actually presented additional and new pediatric exposure issues, could have easily employed unit-dose packaging for its U.S. Tablet product long ago if it was an actual issue (as it had for Tablet products sold in other countries), and had already adequately addressed the pediatric exposure issue to FDA's satisfaction through REMS and child-resistant bottles.
>
> c. That FDA not approve any buprenorphine/naloxone ANDA for addiction treatment until the FDA determined whether the reference listed drug, Suboxone Tablets, had been discontinued for safety reasons, despite the fact that Reckitt was still selling Suboxone Tablets in the U.S., and the reason for the alleged severe safety defect (*i.e.*, lack of unit-dose packaging) was a fabrication that Reckitt had created.[36]

155. While Reckitt's positions set forth in the petition were wholly devoid of merit, the FDA could not approve the pending generic Suboxone Tablet ANDAs without assuring itself that Reckitt's petition was baseless, which the FDA did on February 22, 2013.[37] In the meantime, however, Reckitt made another several hundred million dollars in Suboxone sales.

[36] Exhibit "D" (Reckitt Citizen Petition) at 6.

[37] In delaying approval of pending generic Tablet ANDAs while the petition was pending, the FDA failed to comply with FDC Act Section 505(q)(1)(A).

(1) The Citizen Petition was baseless since FDA had no statutory or regulatory authority to require ANDA filers to use Reckitt's educational programs.

156. Reckitt requested that FDA "refrain from approving any buprenorphine NDA or ANDA for the treatment of opioid addiction that does not include a targeted pediatric exposure education program because those applications are not approvable pursuant to sections 505(b) and (j) of the FDC Act."[38] This request was baseless since FDA had no statutory or regulatory authority to grant this relief.

157. Reckitt was well aware that it's "targeted pediatric exposure education program" was not part of the FDA-approved REMS or labeling for Suboxone Tablets, and that the FDA-approved REMS and labeling for Suboxone Tablets already contained the substantive material that had to be mimicked by ANDA filers in order for them to gain final FDA approval. FDA had no statutory or regulatory ability to require ANDA filers to mimic non-approved labeling and REMS materials in order to obtain approval. Reckitt could obtain this relief only by having Congress alter the statutory provisions that state the requirements that an ANDA must meet in order to obtain approval.

158. More specifically, the FDA-approved Suboxone labeling and REMS provided to patients, pharmacists, and prescribers cautions about keeping the product out of the reach of children. Reckitt's proposed educational program was not incorporated by Reckitt into its own REMS program and had not been approved or otherwise required by the FDA as part of its formally approved labeling or REMS. As relevant to this issue, Section 505(j)(4)(G) of the FDC Act and 21 C.F.R. § 314.127(a)(7) require that ANDA filers mimic "the labeling approved for the listed drug referred to in the [ANDA]." In submitting ANDAs, applicants are required to

[38] *Id.*

provide a copy of the proposed label and labeling for the product.[39] The regulations make clear that the "[l]abeling (including the container label, package insert, and, if applicable, Medication Guide) proposed for the drug product must be the same as the labeling approved for the [reference listed brand drug]," with limited enumerated exceptions not applicable here.[40] The approved labeling for the reference listed brand drug is publicly available on the Drugs@FDA website, which is the primary source for identifying and locating the labeling that must be mimicked by ANDA filers.[41] Regarding Suboxone Tablets, the Drugs@FDA website included the currently-approved labeling, REMS, and medication guide distributed by Reckitt, but contained no references to or information about the "education program" that Reckitt improperly asked FDA to require of ANDA filers.

159. Had Reckitt desired to have such educational programs be part of its formally approved labeling and REMS – and hence, make them mandatory for ANDA filers – it could have filed a supplement to its NDA for Suboxone Tablets with FDA seeking such approval. But, no such supplement was approved during the Citizen Petition process. Upon information and belief, no such supplement was ever filed by Reckitt. As a result, these educational programs were not required of ANDA filers and Reckitt's Citizen Petition asking FDA to mandate that these programs be instituted by ANDA filers as part of their approval process was objectively baseless.

160. Similarly, Reckitt's request that FDA not approve ANDAs for generic versions of Suboxone Tablets that did not contain the educational materials referenced above, since such ANDAs allegedly would "lack the same risk-benefit profile" as Suboxone Tablets, was also objectively baseless in that: (a) there was no statutory or regulatory support for such a "risk-

[39] 21 C.F.R. § 314.94(a)(8)(ii).
[40] 21 C.F.R. § 314.94(a)(8)(iv).
[41] *See* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/.

benefit sameness" evaluation of ANDAs; and (b) incorporation of such a standard would have required that FDA either change or violate the Hatch-Waxman Act, which it does not have the power to do – only Congress can do that.

(2) Reckitt's Request that FDA not approve any ANDAs until FDA determined whether Suboxone Tablets were withdrawn for safety reasons was baseless.

161. Reckitt's Citizen Petition also asked that FDA not approve any ANDAs for generic versions of Suboxone Tablets until FDA determined whether Suboxone Tablets had been withdrawn from the market for safety reasons. This request was also baseless.

162. Although Reckitt raised this issue in the Citizen Petition as though it had actually discontinued the sale of Suboxone Tablets, it in fact continued to sell the product. At a minimum, the request was not ripe for adjudication by FDA. Neither the FDC Act nor FDA regulations permit FDA to engage in advisory opinions about the reasons why a drug had been discontinued when in fact it had not actually been discontinued. Further, at the time of the filing of the Citizen Petition, Suboxone Tablets were not included on FDA's list of drugs to be discontinued, which suggests that Reckitt had not formally advised FDA of its alleged discontinuance or intent to discontinue.

163. To the extent Reckitt had actually discontinued selling Suboxone Tablets, its request would still have been baseless since: (a) Reckitt had successfully sold Suboxone Tablets in bulk containers for over ten years, despite its knowledge of the risks of accidental pediatric exposures; (b) Suboxone Tablets sold in child-resistant bottles were and had been safe and effective when used as directed; (c) Suboxone Tablets had FDA-approved labeling and REMS in place to reduce the risk of accidental pediatric exposures to the satisfaction of FDA; (d) FDA did not believe that unit-dose packaging was superior to child-resistant bottles; and (e) Reckitt did not present clinically significant, well-controlled studies demonstrating that Suboxone Tablets in

bulk containers were unsafe or that Film contained in unit-dose packaging was incrementally safer.

(3) Reckitt's alleged safety issues were objectively baseless.

164. Reckitt argued in the Citizen Petition that FDA should refrain from approving ANDAs for generic versions of Suboxone Tablets that lacked unit-dose packaging. Reckitt argued that it had demonstrated a safety issue regarding Suboxone Tablets based on various graphic presentations of data regarding pediatric exposures of products identified as buprenorphine, Suboxone Tablets, and Suboxone Film, and an executive summary of a study conducted by the Venebio Group.[42]

165. Reckitt's alleged safety issues and the specific relief requested were baseless. First and foremost, Reckitt's arguments were disingenuous in that Reckitt still sold Suboxone Tablets in bulk packaging in the U.S. If Reckitt truly believed that selling Suboxone Tablets in bulk packaging was unsafe, it would have either: (a) discontinued the sale of this product years ago, instead of simply feigning to do so for posturing purposes to compel prescriptions of Suboxone Film; or (b) changed over to unit-dose packaging for its Tablet product.

166. Also, the Citizen Petition on this point was facially inadequate because it failed to include any of the data and analyses upon which it relied. Under section 505(q), for petitions that could delay approvals of pending applications the petitioner is required to certify, *inter alia*, that the petition "includes all information and views upon which the petition relies."[43]

167. Although Reckitt provided this certification, it failed to include any data, case notes, or actual analyses upon which it relied. Reckitt's failure to comply with Section 505(q) and with its own certification denied the ANDA applicants, who were targeted by the petition, an

[42] *See* Exhibit "D" (Reckitt Citizen Petition) at Exhibit "1" thereto.
[43] FDC Act § 505(q)(1)(H).

opportunity to comment on the core data and analyses that Reckitt proposed should delay or preclude approval of its applications.

168. Further, Reckitt's data and analyses were based ultimately on spontaneous reports of pediatric exposures which could not, in and of themselves, demonstrate the nature, incidence, or cause of a reported event or the level of injury associated with the event, particularly for the types of reporting-rate comparisons in Reckitt's petition.

169. Reckitt's petition not only failed to acknowledge the FDA's previously stated positions, but flatly ignored them. [redacted]

170. As concerns the Venebio Group work, even Reckitt acknowledged that evaluations were still underway and that there was insufficient information from which to draw definitive conclusions.[44] The Venebio Group executive summary itself made the same concessions.

171. In sum, Reckitt failed to provide well-controlled, statistically significant scientific support for its call for FDA to refuse to approve ANDAs for generic Suboxone Tablets, which made the Citizen Petition a sham.

172. Moreover, as alleged above, in its review of the Suboxone Film NDA, the FDA plainly informed Reckitt that Suboxone Film unit-dose packaging did not provide "meaningful

[44] *Id.* at 24-25.

incremental protection against pediatric exposure," and that pediatric exposures to Film "could be more hazardous than Tablets."

(4) The Citizen Petition included a false certification regarding its timeliness and independence of support; Reckitt intentionally delayed raising safety issues (to the extent they were ever legitimate).

173. Reckitt was aware of pediatric exposure issues regarding Suboxone as early as 2002.[45] Indeed, Reckitt has sold Suboxone Tablets in blister packaging in Canada and Europe for years.[46]

174. Rather than making a simple change to unit-dose packaging in the U.S. years ago for Suboxone Tablets, Reckitt recognized that it could use the packaging issue to delay and impede the successful launch of generic competitors to its enormous Suboxone Tablet franchise in the U.S. by: (1) unit-dose packaging an alternative dosage formulation (Suboxone Film) while not unit-dose packaging Suboxone Tablets; and then (2) waiting until the last possible moment to raise safety issues with the FDA relating to the Tablet packaging, which ANDA filers were required to mimic. Reckitt did just that.

175. Based on a comparison of the respective package inserts, it appears that Reckitt manufactured and packaged Suboxone Tablets for the U.S. in the same manufacturing site in Hull, U.K. that is utilized for manufacture of the unit-dose blister packaged Tablet product sold by Reckitt in the U.K. and elsewhere.[47]

176. If it had been legitimate, Reckitt's Citizen Petition request that the FDA require unit-dose packaging to prevent pediatric exposure could have been raised years prior to September 2012 to the proper agency, and Reckitt could have directly addressed the issue by

[45] Exhibit "F" (Reckitt reply in support of Citizen Petition) at 2 ("Amneal states in its comment, as if it somehow discredits the data, that both [Reckitt] and FDA were aware of the risk of pediatric exposure to buprenorphine even before buprenorphine was approved. [Reckitt] does not deny that this is true.").

[46] *See* for example, Canadian Suboxone Monograph at 22, available at http://freepdfhosting.com/d721c1d74a.pdf.

[47] Exhibit "E" (Amneal letter) at 8 n.13.

providing Suboxone Tablets in the same or similar unit-dose packaging that it sells in Europe and elsewhere. Instead, Reckitt continued to sell billions of dollars of Tablets in child-resistant bottles in the U.S. without concern, only to proffer a last-minute demand that its competitors should be precluded from the market because of the absence of such packaging. Reckitt did not raise the unit-dose packaging issue to prevent pediatric exposure years ago because Reckitt knew this was a safe product, but desired to delay generic Tablets so as to afford itself the maximum amount of time to switch the BPN/NLX market from Tablets to Film.

177. Reckitt elected to delay raising these concerns with the FDA in a Citizen Petition format, while transitioning patients and prescribers to Film and feigning engagement in the development of the SSRS, all in an effort to further delay generic entry. Then, on what Reckitt knew to be the eve of generic entry in September 2012 (despite the above-described efforts to delay generic approval via the SSRS process), it filed the Citizen Petition, making the knowingly false certification to the FDA that the information on which Reckitt based its Citizen Petition first became known to Reckitt on or about September 15, 2012. Indeed, Reckitt's Citizen Petition itself reveals the false nature of this representation. The Citizen Petition goes on at length to describe the history of accidental pediatric exposure to Suboxone and Reckitt's knowledge about that issue over a long period of time. Just a few of the concessions in the Citizen Petition are as follows: "[A]s addressed in Subutex's and Suboxone's labeling, the effects of exposure are particularly acute in young children and can be severe;" "A report based on data from AAPCC showed 53 exposures to buprenorphine in children under six in 2004;" "By 2006, the number reported by AAPCC had jumped to 204 exposures among children under the age of six;" "By June of 2007, [Reckitt] had developed materials for an education campaign to inform patients and providers of the unique risks of pediatric exposure to buprenorphine;" "[I]n

March 2008, [Reckitt] amended its labeling for Suboxone to include a warning that patients should 'always store buprenorphine-containing medications safely and out of the reach of children…"; "This was not the first time that [Reckitt] recognized the value of unit-dose packing of buprenorphine. [Reckitt] had been working to develop unit-dose packaging for Suboxone Tablets since before the product was first approved for marketing….[A]lthough later studies revealed unit-dose packaging of Suboxone may be feasible, [Reckitt] focused its resources on the development of Suboxone Film."[48]

178. Nevertheless, Reckitt certified under penalty of perjury that the "information upon which [it] based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: September 15, 2012."[49]

179. Reckitt also portrayed the Venebio Group as "independent experts" in the Citizen Petition.[50] But, the reality was that Reckitt itself "hired" them, as admitted by Reckitt's lawyers in filings made in the United States District Court for the District of Vermont – a fact, however, apparently not admitted by Reckitt or the Venebio Group to FDA during the Citizen Petition process.

180. Reckitt's concerns in the Citizen Petition over pediatric exposure and the need for unit-dose packaging were transparently disingenuous and were delayed for anticompetitive purposes. Rather than work with generic companies on the SSRS to address pediatric exposures, Reckitt sought to transform such exposures into a competitive advantage by: (a) not changing the packaging of its Tablet product years ago; (b) encouraging patients, physicians, and managed care entities to switch from Tablets to the patent-protected and unit-dose packaged Film, although the Film version in and of itself does not constitute a safer or more effective product;

[48] Exhibit "D" (Reckitt Citizen Petition) at 10, 18-19, 22 n.57.
[49] Exhibit "D" (Reckitt Citizen Petition) at 48.
[50] *Id.* at 2, 24.

and (c) manipulating the ANDA approval process to obstruct, forestall or prevent altogether generic competition, allowing Reckitt to more thoroughly convert the market from the branded Tablets to the branded Film.

181. As alleged above, not long after the generic Suboxone Tablet ANDA filers submitted a generics-only SSRS of their own to FDA in August of 2012, Reckitt knew the possibility existed that FDA would decide to accept the generics-only SSRS, as submitted or with modification, and then approve one or more generic Suboxone Tablet ANDAs. In an attempt to prevent that from happening, Reckitt implemented the next phases of its anticompetitive scheme by announcing the discontinuation of Suboxone Tablets and then filing the Citizen Petition.

(5) Not Surprisingly, FDA denied the Citizen Petition, finding it was not supported by evidence.

182. FDA denied the Citizen Petition, noting the lack of evidentiary support, inconsistency between Reckitt's Citizen Petition and its prior behavior and the suspicious timing of Reckitt's discontinuation announcement, and went so far as to refer Reckitt's conduct to the FTC for antitrust investigation:

> a. "While Reckitt requests that we refuse to approve any drug applications for buprenorphine products for opioid dependence that lack targeted educational interventions and unit-dose packaging, *the petition is not supported by evidence* that these measures (rather than others undertaken to address this issue) caused the decline in accidental pediatric exposures."[51]
>
> b. With respect to Reckitt's request that unit-dose packaging be mandated for generics, FDA noted that "[w]hile Reckitt requests that we refuse to approve any drug applications for buprenorphine products for opioid dependence that lack…unit-dose packaging, the Petition is *not supported by evidence* that these measures (rather than others undertaken to address this issue) caused the decline in accidental pediatric exposures."[52] FDA further noted that "Reckitt has *not*

[51] Exhibit "G" (FDA Citizen Petition Denial) at 9.
[52] *Id.* (emphasis added).

> *provided evidence* demonstrating that the use of unit-dose packaging…caused the decline in accidental pediatric exposure."[53]
>
> c. And, with respect to Reckitt's request that FDA not approve any generic Suboxone Tablet ANDAs until it had been determined whether Reckitt had "discontinued" branded Tablets for safety reasons, FDA responded as follows: "Reckitt's own actions also undermine, to some extent, its claims with respect to the severity of the safety issue. Notwithstanding the availability of data showing (according to the Petition) an increasing rate of accidental pediatric exposure through at least the first part of 2010, and the first report of a pediatric death in June 2011, Reckitt did not seek to discontinue marketing of the Tablet in multi-dose containers for more than two years. *As recently as August 2012, Reckitt indicated to FDA its view that the Suboxone REMS, which is designed to mitigate the risks associated with that drug, had been successfully implemented and that it was not proposing any changes*; and that "the Agency has determined…that withdrawal of SUBOXONE Tablets is not necessary for reasons of safety."[54]

183. FDA also called into question the timing of Reckitt's Tablet discontinuation announcement which was made on the same day as the Citizen Petition filing:

> …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.[55]

E. THE TABLET WITHDRAWAL

184. Once FDA denied Reckitt's sham Citizen Petition on February 22, 2013, FDA immediately granted final approval to the ANDAs of two generic manufacturers, Amneal and Actavis, for generic versions of Suboxone Tablets, and they came to market almost immediately with less-expensive generic versions.

185. Three weeks later, on March 18, 2013 Reckitt finally made good on its discontinuation notice and withdrew its Suboxone Tablets from the market, despite the fact that FDA had confirmed again in its Citizen Petition denial the safety of the Tablet. This was done by Reckitt as a last ditch effort to impair generic competition. Because Reckitt withdrew

[53] *Id.* at 13 (emphasis added).
[54] *Id.* at 15 (emphasis added).
[55] *Id.* (emphasis added).

branded Tablets from the market, a patient will receive the generic Suboxone Tablets only if a doctor goes through the process of specifically prescribing the generic Tablets. Doctors were even less likely to do so because of Reckitt's disparagement of generic Tablets as discussed above.

F. EFFECTS ON COMPETITION AND DAMAGES TO DIRECT PURCHASERS AND THE CLASS.

186. The purpose and effect of Reckitt's strategy was to foreclose or severely limit generic competition to Suboxone (BPN/NLX). By engaging in this scheme, Reckitt did not simply delay sales of generic Suboxone Tablets; it took additional steps that had the purpose and effect of impeding those generic Tablets from ever meaningfully and efficiently competing in the Suboxone market, even once generic competitors were legally permitted to begin sales, by substantially destroying demand for Suboxone Tablets before generic Tablets entered the market.

187. Had Reckitt not anticompetitively coerced the market switch from Tablets to the non-superior Film version, generic versions of Suboxone Tablets would have competed head-to-head with branded Suboxone Tablets for the entire Suboxone market, and substantial purchases would have migrated from the more expensive brand to the less-expensive generic, thereby resulting in enormous costs savings to all purchasers.

188. Further, had generic manufacturers been able to start selling their less-expensive versions of Suboxone Tablets earlier, the generic manufacturers would have successfully captured significant sales. This is because, if a generic BPN/NLX formulation had been available and on the market before Reckitt implemented or fully implemented the switch to Films, prescriptions for Suboxone Tablets would have been automatically substituted with AB-rated generic Tablets in much greater volumes. By taking actions that improperly delayed the launch date for generic Suboxone Tablets, Reckitt barred generic competitors from the market entirely

for a period of time, again effectively preserving the BPN/NLX market solely for the benefit of Reckitt's monopoly profits.

189. Reckitt's exclusionary conduct has delayed, prevented, and impeded the efficient sale of and competition from generic Suboxone in the United States, and unlawfully enabled Reckitt to sell Suboxone at artificially inflated prices. But for Reckitt's illegal market destruction, generic competitors would have been able to more successfully market generic versions of Suboxone Tablets by the first half of 2012, if not earlier. Reckitt's scheme to change product formulations, undermine, and then discontinue the already existing Tablet product, while simultaneously delaying generic entry, as alleged above, is exclusionary and an unreasonable restraint on competition.

190. To the extent that Reckitt has any valid business purpose for its conduct, that purpose could have been achieved by means that are, and were, less restrictive of competition. Among other things, Reckitt could have launched a new Film product without taking affirmative steps to coerce the market to the Film version and destroy the demand for the existing Tablet product. Reckitt could have also unit-dose packaged its U.S. Suboxone Tablet product many years ago, just as Reckitt sells Suboxone Tablets in Canada and Europe and admits was feasible for Tablets sold in the U.S., if that packaging configuration actually represented a superior safety design.

191. Instead, Reckitt's conduct has allowed, and continues to allow, it to maintain a monopoly and substantially exclude or impede competition in the relevant market, to the detriment of all Suboxone purchasers, including Plaintiff, members of the Class, and consumers. Accordingly, the anticompetitive effects of Reckitt's conduct clearly outweigh the purported procompetitive benefits (if any) of such conduct.

192. Similarly, Reckitt cannot justify its conduct with any supposed consumer benefit, as the enormous cost savings offered by generic drugs outweigh any supposed benefit from Suboxone Film, which benefits are illusory and/or could have been obtained without taking affirmative steps to destroy demand for Suboxone Tablets.

193. As stated by FDA in approving the Film NDA, this product is not more effective or safer than Suboxone Tablets, and raises additional safety issues not present with Tablets. Reckitt's exclusionary motive is also illustrated by its willingness to sacrifice profits as part of the market switch strategy: despite the fact that Suboxone Tablets had much higher profit margins than Suboxone Film, Reckitt used coercive tactics to convert the market to the less-profitable Suboxone Film. This sacrifice of significant profits by steering sales to the less profitable Film product only makes business sense if Reckitt expected it would stifle competition from generic Tablets. Moreover, but for the impact on generic competition, Reckitt would not have invested the resources necessary to bring Suboxone Film to the market. But for the impact on generic competition, it would not have been economically rational to invest in the process of developing the Film formulation that was not clinically superior, seeking FDA approval of that formulation, changing the manufacturing process, and engaging in significant marketing efforts to switch the market from Tablets to Film.

194. Had Reckitt not intentionally delayed generic ANDA approval by feigning cooperation in SSRS development and filing a sham Citizen Petition, multiple less-expensive generic Suboxone products would have been FDA approved and market-launched by the first half of 2012 at the latest. Additionally, had Reckitt filed its Citizen Petition when it first became aware of the alleged safety benefits of unit-dose packaging, rather than filing on the eve of generic approval and fraudulently certifying that the petition was based on information that first

became known to Reckitt on or about September 15, 2012, any issues presented in the Citizen Petition would have been resolved many years ago, and multiple generic Suboxone products would have been approved and launched by the first half of 2012 at the latest.

195. Alternatively, even assuming that the Citizen Petition had objective merit and its filing was not fraudulently delayed, had Reckitt not delayed the generic Tablets by feigning cooperation in SSRS development, multiple generic ANDAs would have been approved and the generic products would have launched prior to the September 2012 filing date of the Citizen Petition. The previously-approved generic products would not have been removed from the market as a result of the filing of the Citizen Petition, as evidenced by the fact that Reckitt's Tablet product continued to be sold in the market while its petition remained pending and the FDA reiterating, in denying the Citizen Petition, that Tablets were safe.

196. If manufacturers of generic Suboxone Tablets had been able to enter the marketplace earlier and Reckitt had not compelled conversions to Suboxone Film through withdrawal and false disparagement of Suboxone Tablets, as set forth above, Plaintiffs and other members of the Class would have substituted lower-priced generic Suboxone Tablets for the higher-priced brand-name Suboxone Tablets for some or all of their requirements, and/or would have paid lower prices for some or all of their remaining Suboxone Tablet and Film purchases, as described below.

(1) Absent Reckitt's Improper Product Hopping Scheme a Substantial Amount of the Direct Purchasers' Suboxone Purchases Would Have Been in the Form of Lower-Priced Generic Tablets Rather Than Higher-Priced Suboxone Film.

197. The Film was launched in or about September 2010. By January 2011 (about 4 months after Film launch), Film had captured approximately [redacted] of the Suboxone market and

Tablets had approximately [redacted] of the Suboxone market.[56] Film growth thereafter was slower. During 2011, Film share grew to [redacted] of the Suboxone market and branded Tablets dropped to approximately [redacted] of total the Suboxone prescribed market. During 2012 and early 2013, Film share grew to approximately [redacted] of the Suboxone market and Tablets dropped to approximately [redacted] In the first six months after generic entry, generic Tablets captured virtually no Film share – with Film share of the total Suboxone market [redacted] (from [redacted] to [redacted]. Generic Tablets did capture approximately [redacted] of the Suboxone market, but virtually all of that was from the branded Tablets which Reckitt withdrew from the market when generic Tablets entered.

198. Had Reckitt not introduced the new Suboxone Film product absent the anticompetitive scheme, when generic Tablets entered the market they would have been automatically substitutable for most (if not all) of the units of branded Suboxone – all [redacted] billion of Reckitt's annual sales of Suboxone at that time would have been in Tablet form. Within nine months, generic Tablets would have captured almost all of those sales at vastly lower prices, delivering savings of more than [redacted] million annually to Suboxone direct purchasers. As a result of Reckitt's anticompetitive scheme, however, when generic Suboxone Tablets finally entered the market in February 2013, Reckitt had converted some [redacted] of the unit sales from Tablets to the non-substitutable Film. Consequently, less than [redacted] million of Reckitt's annual sales of Suboxone were in Tablet form and thus available for automatic generic substitution.

199. Had Reckitt not introduced the new Suboxone Film product, then generic Tablets would have captured approximately 70% of the Suboxone market within the first quarter after

[56] Market share statistics throughout are measured in terms milligrams of Suboxone product prescribed ("Suboxone Mgs").

generic Tablets entered the market. Generic Suboxone Tablet sales would have continued to grow until Generic Tablets constituted 95% of the market within the first year. Absent the product hop and the coercion of the market from Tablet to Film, generic tablets would have captured this far greater percentage of the market regardless of when they entered the market.

200. Furthermore, even if Reckitt had introduced the new Suboxone Film product, absent the improper deceptive, coercive and delaying tactics that Reckitt used to implement its product-hopping scheme, the Film would have captured only a very small percentage of the Suboxone market, and generic Tablets would have captured most of the market quickly after entering in January 2012. This means that from early 2012 forward, the vast majority of the Direct Purchasers' Suboxone purchases would have been in the form of lower-priced generic Tablets, in contrast to the actual world, where [redacted] of the Direct Purchasers' Suboxone purchases were in the form of lower-priced generic Tablets.

201. Moreover, even if the tactics that Reckitt used to encourage Tablet-to-Film conversions were legitimate (which is not the case), had Reckitt not engaged in the anticompetitive conduct challenged herein to improperly further its scheme by improperly delaying generic entry, then generic Tablets would have entered the market in or about January 2012. As of January 2012, approximately [redacted] of Suboxone Mgs were sold in Film form, and [redacted] of Suboxone Mgs were sold in Tablet form. The Suboxone Mg sales in Tablet form would have quickly converted to lower-priced generic Tablets, which means that from early 2012 forward, [redacted] of the Direct Purchasers' Suboxone purchases would have been in the form of lower-priced generic Tablets, in contrast to the actual world, where [redacted] of the Direct Purchasers' Suboxone purchases were in the form of lower-priced generic Tablets.

(2) Absent Reckitt's Improper Product Hopping Scheme Reckitt Would Not Have Taken Certain Price Increases On Suboxone Tablets and Film, and Thus Direct Purchasers Would Have Paid Lower Prices for Branded Suboxone Tablets, and Film and Generic Suboxone Tablets.

202. Absent Reckitt's improper product-hopping scheme, Direct Purchasers would have not only shifted most of their Suboxone purchases to generic Tablets starting in early 2012, but Direct Purchasers would have paid substantially less money than they actually did for all of their BPN/NLX requirements. This is because Reckitt's improper scheme involved a series of price increases for Suboxone Film and Suboxone branded Tablets which would not have occurred but for Reckitt's improper conduct.

203. Up until [redacted] This was consistent with Reckitt's historical practices. In prior years, Reckitt had taken only limited annual price increases of around [redacted] and [redacted]

204. Reckitt did not ultimately pursue its initial plan. Instead of its initial strategy [redacted] Reckitt raised Tablet prices far more aggressively than it raised Film prices. Because the Film formulation was more expensive to manufacture and package than Tablets, and the Film had higher royalty and R&D costs than the Tablets, the economically rational plan would have been charge more for Film and Tablets. But Reckitt did the opposite. It introduced Film at or near the Tablet price, and then Reckitt aggressively raised the price of Tablets in relation to Film. While Reckitt raised its branded Tablet prices [redacted] in the three-year period prior to generic entry, it raised Film prices by only [redacted] during the same period. Indeed, Reckitt raised the price of

branded Suboxone Tablets by [redacted] in 2012 alone.

205. From December 2007 to the March 2013 discontinuation, Reckitt took the following price increases on the branded Tablet (8/2 mg):

[redacted]

206. Thus, in 2010 Reckitt raised the price of branded Suboxone Tablet twice for a total of [redacted] once for [redacted] in 2011, and twice in 2012 for a total of [redacted] This ultimately drove the Wholesale Acquisition Cost ("WAC") price for branded Suboxone Tablets up to [redacted] per 30 units in Oct 2012.

207. The Film was originally introduced in October 2010 at a WAC price of [redacted] per 30 units. In July 2011, the price increased from [redacted] (an [redacted] increase). In July 2012, it increased from [redacted] (another [redacted] increase), where it has remained for almost two years.

208. Reckitt's pricing of Suboxone Film belies Reckitt's assertion that the Film provides medical benefits over Suboxone Tablets. If Suboxone Film truly provided benefits over Tablets that patients wanted, then Reckitt, as a rational profit-maximizing company, would have sought to leverage that superiority by charging a premium over Tablets. Reckitt did not attempt to capture any supposed added value by charging more for the Film relative to the Tablets, but instead: (a) raised the price of the Tablets in relation to the Film solely to convert the BPN/NLX market from the Tablet form to the Film form; and (b) took actions to delay entry of generic

forms of Suboxone Tablets that would be priced less than branded Suboxone Tablets and Film.

209. Reckitt's strategy had the desired effect. In December 2011, when Actavis was initially preparing to enter the market, it told wholesalers that it would be charging a generic WAC price of [redacted]. However, because of the 2012 Suboxone Tablet price increases, Actavis ultimately entered the market with its generic Suboxone Tablets in March 2013 with a WAC price of [redacted] per 30 units.

210. But for Reckitt's improper product-hop scheme, Reckitt would have followed its [redacted] Thus, from 2010 through 2012, Suboxone Tablet prices would have increased [redacted] - over that period, and generic Suboxone Tablets would have been cheaper as well (because, as described above, generic manufacturers use brand pricing as a benchmark in setting their prices at launch).

211. Furthermore, even if the tactics that Reckitt used to encourage Tablet-to-Film conversions were legitimate (which is not the case), had Reckitt not used the SSRS/REMS and its Citizen Petition conduct to improperly further its scheme by improperly delaying generic entry, then Direct Purchasers would have paid substantially lower prices for the brand Suboxone Tablets, Suboxone Film and generic Suboxone Tablets that the Direct Purchasers would have bought.

212. Absent the SSRS/REMS and Citizen Petition conduct that Reckitt used to improperly further its scheme, generic Suboxone Tablets would have entered the market in early 2012. In fact, however, the price increases for both Suboxone Tablets and Suboxone Film stopped when generic Suboxone Tablets entered the market in March 2013 because Reckitt wanted to maintain a narrow price-gap between Film and generic Tablets. Had generic Suboxone Tablets entered the market in early 2012 absent Reckitt's improper delaying conduct,

then generic Tablets would have entered before the last two sets of branded Tablet price increases, which means that: (a) Reckitt would not have taken [redacted] price increases for Suboxone branded Tablets in 2012; and (b) Actavis would have charged a WAC of approximately [redacted] per 30 units rather than its actual [redacted] WAC per 30 units for its generic Suboxone Tablets**.** Furthermore, had generic Suboxone Tablets entered the market in early 2012 absent Reckitt's improper delaying conduct, then Reckitt would not have raised Film prices by [redacted] in July 2012, again because Reckitt wanted to maintain a narrow price-gap between Film and generic Tablets.

213. Thus, had generic Tablets entered in early 2012 absent Reckitt's improper conduct, not only would generic Tablets have captured greater market share (because branded Suboxone Tablets would have had a greater share of the Suboxone market, which would have eventually been converted to generics), but also: (a) branded Suboxone Tablet prices would have been substantially lower; (b) generic Suboxone Tablet prices would have been substantially lower; and (c) Suboxone Film prices would have been at least [redacted] lower. Thus, even if some of the Film conversions were legitimate, direct purchasers were overcharged for *all* Film purchases, because: (a) absent Reckitt's misconduct, some of the Film conversions would have remained branded Suboxone Tablets and would have been subsequently converted to generic Suboxone Tablets at much lower prices; and (b) even for those Film conversions which were purportedly "legitimate" the price was still artificially inflated by [redacted] from July 2012 forward. That [redacted] Film overcharge did not end with generic entry in March 2013, and will continue forward into the future. Absent the product hop and the coercion of the market from Tablet to Film, Suboxone Tablets, Suboxone Film, and generic Suboxone Tablets would have been priced substantially lower.

214. As detailed above, during the relevant period, Plaintiffs and other members of the Class purchased substantial amounts of Suboxone Tablets and/or Film directly from Reckitt. As a result of Reckitt's illegal conduct alleged herein, Plaintiffs and other members of the Class were compelled to pay, and did pay, artificially inflated prices for their Suboxone requirements. Plaintiffs and the other Class members paid prices for Suboxone that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Class members were deprived of the opportunity to purchase lower-priced generic Suboxone Tablets instead of expensive brand-name Suboxone at earlier periods of time and in greater volumes; and (2) the prices of branded Suboxone Tablets, branded Suboxone Film, and generic BPN/NLX Tablets were all artificially inflated by Reckitt's illegal conduct. As a consequence, Plaintiffs and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges.

G. EFFECT ON INTERSTATE COMMERCE

215. At all material times, Suboxone, manufactured and sold by Reckitt, was shipped across state lines and sold to customers located outside its state of manufacture.

216. During the relevant time period, in connection with the purchase and sale of Suboxone, monies as well as contracts, bills, and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

217. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Reckitt, as charged in this Complaint, were within the flow of, and have substantially affected, interstate commerce.

H. MONOPOLY POWER

218. Through the anticompetitive conduct alleged herein, Reckitt has been able to charge supra-competitive prices for its Suboxone products and enjoys abnormally high price-cost margins on its sales of Suboxone products, and thus, by definition, maintains market power and/or monopoly power with respect to Suboxone sold in the United States. To the extent that Plaintiffs are required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant product market is all co-formulated Buprenorphine/Naloxone products – *i.e.*, Suboxone in all its forms and dosage strengths and their respective AB-rated generic equivalents.

219. No other opioid dependence treatments have constrained Reckitt's pricing of Suboxone to the level generic Suboxone would have produced. In other words, Reckitt has been the price setter for Suboxone and not a price taker. With no competitors constraining its price-setting behavior, Reckitt historically raised the price of Suboxone [redacted] each year, and sometimes more. Reckitt was able to raise the price of Suboxone such small but significant amounts on a nontransitory basis without losing significant sales to other opioid dependence treatments. Instead of fearing the loss of customers to less expensive such drugs, Reckitt's primary concern with regard to Suboxone price increases were public relations or reputational problems.

220. Suboxone is unique and not reasonably interchangeable with other therapies for the treatment of opioid addiction. Suboxone is unique in that it is an opioid replacement therapy (unlike naltrexone). Suboxone is unique in that it is a maintenance therapy (unlike Subutex — Reckitt's buprenorphine product not co-formulated with naloxone — which is recommended only for induction treatment, and is thus a complement to, not a substitute for, Suboxone). Suboxone is unique in that it is the only FDA-approved opioid replacement maintenance therapy (unlike methadone, which has never been formally approved by FDA). Suboxone is unique in

that it is the only opioid replacement maintenance therapy that is a Schedule III drug under the Controlled Substances Act and can be prescribed in an office setting under the Drug Addiction Treatment Act (DATA) of 2000 (unlike methadone, which is a Schedule II drug, and must be administered in a clinic setting). Suboxone is unique in that it is the only opioid replacement maintenance therapy that is co-formulated with an opioid antagonist (naloxone) to deter abuse. Suboxone is unique in that it is the only opioid replacement maintenance therapy that is only a partial (as opposed to full) agonist of the μ-opioid receptor; thus, unlike methadone or other full agonists, Suboxone's unique properties create a "ceiling effect" that prevents larger doses of buprenorphine from producing greater agonist effects, protecting patients against death by respiratory depression or overdose. This property also affords Suboxone a unique efficacy profile: unlike methadone, which is prescribed for a patient population suffering from severe forms of opioid addiction, Suboxone is suitable only for patients with mild to moderate forms of opioid addiction.

221. Suboxone is appropriate for a different patient population than is methadone, and patients for whom Suboxone is appropriate possess a different medical profile than methadone.

222. The DEA approved Suboxone's exceptional schedule III status because of the drug's "very unique pharmacological profile."

223. [redacted]

224. Reckitt recognized that non-pharmaceutical approaches to opioid dependence (e.g., counseling) were [redacted] Moreover, by definition, complements to a product are not substitutes for that product.

225. A small but significant, non-transitory price increase by Reckitt to Suboxone would not have caused a significant loss of sales to other drugs or products used for the same purposes, with the exception of AB-rated generic versions of Suboxone.

226. Suboxone does not exhibit significant, positive cross-elasticity of demand with respect to price, with any opioid dependence treatment or other product other than AB-rated generic versions of Suboxone.

227. [redacted] which reveals that Suboxone exhibits low cross-price elasticity of demand with respect to other opioid dependence treatments.

228. Reckitt needed to control only Suboxone and its AB-rated generic equivalents, and no other products, in order to maintain the price of Suboxone profitably at supra-competitive prices. Only the market entry of a competing, AB-rated generic version of Suboxone would render Reckitt unable to profitably maintain supracompetitive prices for Suboxone.

229. Proving that only an AB-rated generic version of Suboxone had the power to constrain Reckitt's pricing of Suboxone to the competitive level, Reckitt's contingency plans in the event of generic competition included [redacted] No product other than generic Suboxone ever caused Reckitt to consider lowering the price of Suboxone by this magnitude. In fact, no product other than generic Suboxone ever caused Reckitt to consider lowering the price of Suboxone at all.

230. It was Reckitt's view, during all relevant times, [redacted]

231. Reckitt also sold branded Suboxone substantially in excess of marginal costs, and in excess of competitive prices, and enjoyed unusually high profit margins. Reckitt enjoyed profit margins of [redacted] for Suboxone, an extremely high profit margin suggestive of substantial market power.

232. The relevant geographical market is the United States and its territories.

233. At all relevant times, Reckitt enjoyed high barriers to entry with respect to the above-defined relevant market due to patent and other regulatory protections, and high costs of entry and expansion. For example, Suboxone's Schedule 3 status is a high barrier to entry for potential competitors ensuring that Suboxone does not compete with Schedule 2 drugs like methadone.

234. Reckitt's market share during the entire relevant time period of its illicit actions was either 100% or well in excess of 70%. But for Reckitt's conduct, one or more firms would have earlier been marketing generic versions of co-formulated buprenorphine/naloxone and would have reduced Reckitt's share in the relevant market considerably.

235. Reckitt's actions are part of, and in furtherance of, the illegal monopolization alleged herein, and were authorized, ordered or done by Reckitt's officers, agents, employees, or representatives while actively engaged in the management of Reckitt's affairs.

236. Reckitt's illegal acts to prevent the introduction and/or dissemination into the U.S. marketplace of generic versions of Suboxone Tablets resulted in Plaintiffs and the Class paying more than they would have paid for BPN/NLX absent Reckitt's illegal conduct.

VI. CLAIMS FOR RELIEF

A. Claim 1: Monopolization in Violation of Section 2 of the Sherman Act, Unlawful Maintenance of Monopoly Power Through an Overarching Scheme To Prevent or Delay Generic Competition.

237. Plaintiffs refer to, and incorporate herein, the allegations above in ¶¶ 1-240.

238. At all relevant times, Reckitt possessed monopoly power in the relevant market.

239. Reckitt manufactured the various formulations of Suboxone described herein. Reckitt, *inter alia*, marketed and sold those various versions of Suboxone in the United States. During the relevant period, Reckitt willfully and unlawfully maintained its monopoly power by engaging in exclusionary conduct that discouraged rather than encouraged competition on the merits. As explained in detail above, Reckitt engaged in an exclusionary scheme that included, *inter alia*, each of the following (at various times):

a. coercing the conversion of the BPN/NLX market from Suboxone Tablets to Suboxone Film, which is not safer or more effective than Suboxone Tablets, but is in fact inferior in certain respects;

b. engaging in a fraudulent marketing campaign to disparage Suboxone Tablets;

c. raising the price of Suboxone Tablets in relation to Suboxone Film;

d. publicly stating an intention to withdraw Suboxone Tablets from the market;

e. feigning cooperation with manufacturers of generic Tablets regarding creation of a SSRS for Suboxone Tablets but using the SSRS process to delay generic competition for Suboxone Tablets;

f. filing a sham Citizen Petition with FDA; and,

g. fraudulently delaying the filing of the Citizen Petition.

240. The goal, purpose, and/or effect of Reckitt's scheme was to maintain and extend Reckitt's monopoly power with respect to BPN/NLX. Reckitt's illegal scheme to prevent, delay, and/or minimize the success of the introduction into the United States marketplace of any generic versions of Suboxone Tablets enabled Reckitt to continue charging supra-competitive prices for BPN/NLX without a substantial loss of sales. If manufacturers of generic BPN/NLX had been able to enter the market and fairly compete with Reckitt in a full and timely fashion, Plaintiffs and members of the Class would have substituted lower-priced generic BPN/NLX for some or all of their BPN/NLX requirements, and/or would have received lower prices on some or all of their remaining branded Suboxone purchases, at earlier periods of time and in far greater quantities.

241. As a result of Reckitt's illegal scheme, Plaintiffs and the Class paid more than they would have paid for BPN/NLX, absent Reckitt's illegal conduct. But for Reckitt's illegal conduct, competitors would have begun marketing generic versions of Suboxone well before they actually did, and/or would have marketed such versions more successfully than they actually did.

242. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of Suboxone directly from Reckitt. As a result of Reckitt's illegal conduct, alleged herein, Plaintiffs and the members of the Class were compelled to pay, and did pay, artificially inflated prices for their BPN/NLX requirements. Plaintiffs and all other Class members paid prices for BPN/NLX that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (a) class members were deprived of the opportunity to purchase lower-priced generic BPN/NLX instead of expensive brand-name Suboxone; and/or (b) the price of branded Suboxone was artificially inflated by Reckitt's illegal conduct.

243. Reckitt's scheme was in the aggregate an act of monopolization undertaken with the specific intent to monopolize the market for BPN/NLX in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

B. Claim 2: Monopolization in Violation of Section 2 of the Sherman Act, Unlawful Maintenance of Monopoly Power by Conversion of the Market from Tablet to Film Formulation.

244. Plaintiffs refer to, and incorporate herein, the allegations above in ¶¶ 1-247.

245. During the relevant period, Reckitt willfully and unlawfully maintained its monopoly power by engaging in exclusionary conduct that discouraged rather than encouraged competition on the merits. As explained in detail above, Reckitt unlawfully coerced the conversion of the BPN/NLX market from Suboxone Tablets to Suboxone Film, which is not

safer or more effective than Suboxone Tablets (but is in fact inferior in several material respects) by, *inter alia*, economically coercing doctors to shift their patients to Suboxone Film and away from branded and generic Suboxone Tablets; engaging in a massive fraudulent marketing campaign to disparage Suboxone Tablets; intentionally refusing to unit-dose pack Suboxone Tablets for the purpose of creating the illusion that Suboxone Film is a superior product; and stating its intent to withdraw Suboxone Tablets from the market and then actually withdrawing that product.

246. The goal, purpose, and/or effect of Reckitt's conduct was to maintain and extend Reckitt's monopoly power with respect to BPN/NLX. Reckitt's illegal conduct, calculated and designed to prevent, delay, and/or minimize the success of competition from any generic version of Suboxone, enabled Reckitt to continue charging supra-competitive prices for BPN/NLX without a substantial loss of sales.

247. As a result of Reckitt's illegal conduct, Plaintiffs and the Class paid more than they would have paid for BPN/NLX, absent Reckitt's illegal conduct. But for Reckitt's illegal conduct, competitors would have begun marketing generic versions of Suboxone well before they actually did, and/or would have marketed such versions more successfully than they actually did.

248. If manufacturers of generic BPN/NLX had been able to enter the market and fairly compete with Reckitt in a full and timely fashion, Plaintiffs and members of the Class would have substituted lower-priced generic BPN/NLX for some or all of their BPN/NLX requirements, and/or would have received lower prices on some or all of their remaining branded Suboxone purchases, at earlier periods of time and in far greater quantities.

249. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of Suboxone directly from Reckitt. As a result of Reckitt's illegal conduct, alleged herein, Plaintiffs and the members of the Class were compelled to pay, and did pay, artificially inflated prices for their BPN/NLX requirements. Plaintiffs and all other Class members paid prices for BPN/NLX that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (a) class members were deprived of the opportunity to purchase lower-priced generic BPN/NLX instead of expensive brand-name Suboxone; and/or (b) the price of branded Suboxone was artificially inflated by Reckitt's illegal conduct.

250. Reckitt's intentional conversion of the market from the Tablet to the Film formulation was an act of monopolization undertaken with the specific intent to monopolize the market for BPN/NLX in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

C. Claim 3: Monopolization in Violation of Section 2 of the Sherman Act, Unlawful Maintenance of Monopoly Power by Intentionally Delaying the SSRS Process and Violating 21 U.S.C. § 355-1(f)(8).

251. Plaintiffs refer to, and incorporate herein, the allegations above in ¶¶ 1-254.

252. Because the Court's December 3, 2014 Opinion dismissed the allegations that Reckitt's misconduct regarding the SSRS/REMS process constituted a separate, independent antitrust violation, Plaintiffs re-state the claims of this count for purposes of preserving Plaintiffs' appellate rights. Furthermore, Reckitt's misconduct regarding the SSRS/REMS process were component acts in furtherance of its overarching anticompetitive scheme, alleged herein.

253. During the relevant period, Reckitt willfully and unlawfully maintained its monopoly power by feigning cooperation with the sponsors of generic Suboxone Tablet ANDAs

for the intentional purpose of delaying the creation of a unified or generics-only REMS for Suboxone Tablets, which in turned delayed final FDA approval and market entry of ANDAs for generic versions of Suboxone Tablets in violation of 21 U.S.C. § 355-1(f)(8).

254. The goal, purpose, and/or effect of Reckitt's conduct was to prevent, delay, and/or minimize the success of the entry of generic competitors which would have sold generic Suboxone Tablets in the United States at prices significantly below Reckitt's prices for branded Suboxone, which would have effectively caused the average market price of Suboxone to decline dramatically.

255. As a result of Reckitt's illegal conduct, Plaintiffs and the Class paid more than they would have paid for BPN/NLX, absent that illegal conduct. But for Reckitt's illegal conduct, competitors would have begun marketing generic versions of Suboxone Tablets well before they actually did, and/or would have marketed such versions more successfully upon entry than they actually did.

256. If manufacturers of generic BPN/NLX had been able to enter the market and fairly compete with Reckitt in a full and timely fashion, Plaintiffs and members of the Class would have substituted lower-priced generic BPN/NLX for some or all of their BPN/NLX requirements, and/or would have received lower prices on some or all of their remaining branded Suboxone purchases, at earlier periods of time and in far greater quantities.

257. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of Suboxone directly from Reckitt. As a result of Reckitt's illegal conduct, alleged herein, Plaintiffs and the members of the Class were compelled to pay, and did pay, artificially inflated prices for their BPN/NLX requirements. Plaintiffs and all other Class members paid prices for BPN/NLX that were substantially greater than the prices that they

would have paid absent the illegal conduct alleged herein, because: (a) class members were deprived of the opportunity to purchase lower-priced generic BPN/NLX instead of expensive brand-name Suboxone; and/or (b) the price of branded Suboxone was artificially inflated by Reckitt's illegal conduct.

258. Reckitt's conduct in intentionally delaying the creation of an SSRS for Suboxone Tablets and violating 21 U.S.C. § 355-1(f)(8) was an act of monopolization undertaken with the specific intent to monopolize the market for BPN/NLX in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

D. Claim 4: Monopolization in Violation of Section 2 of the Sherman Act, Unlawful Maintenance of Monopoly Power by Filing a Sham Citizen Petition

259. Plaintiffs refer to, and incorporate herein, the allegations above in ¶¶ 1-186.

260. During the relevant period, Reckitt willfully and unlawfully maintained its monopoly power by filing a sham Citizen Petition with FDA on the eve of generic Suboxone Tablet ANDA approval for the intentional purpose of delaying that final FDA approval and market entry of less expensive generic versions of Suboxone Tablets, which would have effectively caused the average market price of Suboxone to decline dramatically.

261. The goal, purpose, and/or effect of Reckitt's conduct was to maintain and extend Reckitt's monopoly power with respect to BPN/NLX. Reckitt's illegal conduct, calculated and designed to prevent, delay, and/or minimize the success of the introduction into the United States marketplace of any generic version of Suboxone, enabled Reckitt to continue charging supra-competitive prices for BPN/NLX without a substantial loss of sales.

262. As a result of Reckitt's illegal conduct, Plaintiffs and the Class paid more than they would have paid for BPN/NLX, absent that illegal conduct. But for Reckitt's illegal conduct, competitors would have begun marketing generic versions of Suboxone well before

they actually did, and/or would have marketed such versions more successfully upon entry than they actually did.

263. If manufacturers of generic BPN/NLX had been able to enter the market and fairly compete with Reckitt in a full and timely fashion, Plaintiffs and members of the Class would have substituted lower-priced generic BPN/NLX for some or all of their BPN/NLX requirements, and/or would have received lower prices on some or all of their remaining branded Suboxone purchases, at earlier periods of time and in far greater quantities.

264. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of Suboxone directly from Reckitt. As a result of Reckitt's illegal conduct, alleged herein, Plaintiffs and the members of the Class were compelled to pay, and did pay, artificially inflated prices for their BPN/NLX requirements. Plaintiffs and all other Class members paid prices for BPN/NLX that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (a) class members were deprived of the opportunity to purchase lower-priced generic BPN/NLX instead of expensive brand-name Suboxone; and/or (b) the price of branded Suboxone was artificially inflated by Reckitt's illegal conduct.

265. Reckitt's conduct in intentionally and fraudulently delaying the filing of the Citizen Petition until the eve of generic ANDA approval was an act of monopolization undertaken with the specific intent to monopolize the market for BPN/NLX in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

E. Claim 5: Monopolization in Violation of Section 2 of the Sherman Act, Unlawful Maintenance of Monopoly Power by Fraudulently Delaying the Filing of the Citizen Petition

266. Plaintiffs refer to, and incorporate herein, the allegations above in ¶¶ 1-193.

267. During the relevant period, Reckitt willfully and unlawfully maintained its monopoly power by intentionally and fraudulently delaying the filing of the Citizen Petition until the eve of generic ANDA approval for the intentional purpose of delaying that final FDA approval and market entry of less expensive generic versions of Suboxone Tablets, which would have effectively caused the average market price of Suboxone to decline dramatically.

268. The goal, purpose, and/or effect of Reckitt's conduct was to maintain and extend Reckitt's monopoly power with respect to BPN/NLX. Reckitt's illegal conduct, calculated and designed to prevent, delay, and/or minimize the success of the introduction into the United States marketplace of any generic version of Suboxone, enabled Reckitt to continue charging supra-competitive prices for BPN/NLX without a substantial loss of sales.

269. As a result of Reckitt's illegal conduct, Plaintiffs and the Class paid more than they would have paid for BPN/NLX, absent that illegal conduct. But for Reckitt's illegal conduct, competitors would have begun marketing generic versions of Suboxone well before they actually did, and/or would have marketed such versions more successfully upon entry than they actually did.

270. If manufacturers of generic BPN/NLX had been able to enter the market and fairly compete with Reckitt in a full and timely fashion, Plaintiffs and members of the Class would have substituted lower-priced generic BPN/NLX for some or all of their BPN/NLX requirements, and/or would have received lower prices on some or all of their remaining branded Suboxone purchases, at earlier periods of time and in far greater quantities.

271. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of Suboxone directly from Reckitt. As a result of Reckitt's illegal conduct, alleged herein, Plaintiffs and the members of the Class were compelled to pay, and did pay,

artificially inflated prices for their BPN/NLX requirements. Plaintiffs and all other Class members paid prices for BPN/NLX that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (a) class members were deprived of the opportunity to purchase lower-priced generic BPN/NLX instead of expensive brand-name Suboxone; and/or (b) the price of branded Suboxone was artificially inflated by Reckitt's illegal conduct.

272. Reckitt's conduct in intentionally and fraudulently delaying the filing of the Citizen Petition until the eve of generic ANDA approval was an act of monopolization undertaken with the specific intent to monopolize the market for BPN/NLX in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

VII. PRAYER FOR RELIEF

273. Wherefore, Plaintiffs, on behalf of themselves and the Class, respectfully pray that:

a. The Court determine that this action may be maintained as a class action pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2) of the Federal Rules of Procedure, be given to the Class;

b. The acts alleged herein be adjudged and decreed to be an unlawful restraint of trade in violation of Section 2 of the Sherman Act;

c. Each member of the Class recover three-fold the damages determined to have been sustained by each of them, and that joint and several judgment be entered against Defendants in favor of the Class;

d. The Class recover their costs of suit, including reasonable attorneys' fees as provided by law; and

e. The Class be granted such other, further and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by the Court.

VIII. JURY TRIAL DEMAND

274. Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury of all claims and complaints in the Complaint so triable.

Dated: February 23, 2015

Respectfully submitted,

/s/ Kimberly Hennings
Garwin Gerstein & Fisher LLP
Bruce E. Gerstein
Joseph Opper
Kimberly Hennings
88 Pine Street
New York, NY 10005
(212) 398-0055

Liaison Counsel and Interim Co-Lead Counsel for the Direct Purchaser Class Plaintiffs

Thomas M. Sobol
Lauren Barnes
Hagens Berman Sobol Shapiro LLP
55 Cambridge Parkway, Suite 301
Cambridge, MA 02142
(617) 482-3700

Interim Co-Lead Counsel for the Direct Purchaser Class Plaintiffs

Peter Kohn
Joseph T. Lukens
Faruqi & Faruqi LLP
101 Greenwood Avenue, Suite 600
Jenkintown, PA 19046
(215) 277-5770

Interim Co-Lead Counsel for the Direct Purchaser Class Plaintiffs

Bruce E. Gerstein
Joseph Opper
Kimberly Hennings
Garwin Gerstein & Fisher, LLP
88 Pine Street
New York, NY 10005
(212) 398-0055

Stuart E. Des Roches
Andrew W. Kelly
Chris Letter

Odom & Des Roches, LLP
650 Poydras Street, Suite 2020
New Orleans, LA 70130
(504) 522-0077

David P. Smith
Susan Segura
David C. Raphael, Jr.
Erin R. Leger
Smith Segura & Raphael, LLP
3600 Jackson St., Suite 111
Alexandria, LA 71303
(318) 445-4480

Counsel for Burlington Drug Company, Inc.

Peter Kohn
Joseph T. Lukens
Faruqi & Faruqi LLP
101 Greenwood Avenue, Suite 600
Jenkintown, PA 19046
(215) 277-5770

Eric L. Cramer
David F. Sorensen
Berger & Montague, P.C.
1622 Locust Street
Philadelphia, PA 19103-6305
(215) 875-3000

Barry S. Taus
Archana Tamoshunas
Taus, Cebulash & Landau LLP
80 Maiden Lane, Suite 1204
New York, NY 10038
(212) 931-0704

Counsel for Rochester Drug Co-Operative, Inc.

Thomas M. Sobol
Kristen Johnson Parker
Hagens Berman Sobol Shapiro LLP
55 Cambridge Parkway, Suite 301
Cambridge, MA 02142
(617) 482-3700

Counsel for Meijer, Inc. and Meijer Distribution, Inc.