UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

I.B.E.W. 292 HEALTH CARE PLAN, on behalf of itself and all others similarly situated, Plaintiff, v. RECKITT BENCKISER, INC.; RECKITT BENCKISER LLC; RECKITT BENCKISER PHARMACEUTICALS, INC.; RECKITT BENCKISER HEALTHCARE (UK) LTD.; and RECKITT BENCKISER GROUP PLC, Defendants.	END-PAYOR CLASS ACTION COMPLAINT Jury Trial Demanded

CLASS ACTION COMPLAINT

Plaintiff I.B.E.W. 292 Health Care Plan ("Plaintiff") brings this class action on behalf of itself and all others similarly situated against Reckitt Benckiser, Inc., Reckitt Benckiser LLC, Reckitt Benckiser Pharmaceuticals, Inc., Reckitt Benckiser Healthcare (UK) Ltd., and Reckitt Benckiser Group plc (together, "Reckitt"), and alleges 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 damages arising out of Reckitt's anticompetitive overall scheme to exclude competition from the market for co-formulated buprenorphine hydrochloride and naloxone hydrochloride dihydrate ("co-formulated buprenorphine/naloxone"), which Reckitt sells under the brand-name Suboxone. As alleged herein, Reckitt used various acts and practices as part of an overall scheme to improperly maintain and extend its monopoly power in the market for Suboxone, to the detriment of Plaintiff

and the class of end-payors it seeks to represent (as defined below), causing them to pay overcharges.

2. Reckitt's overall scheme consisted of at least three anticompetitive tactics designed to delay entry of generic Suboxone tablets in the market:

i. **Product Hopping**. Reckitt introduced a slightly modified delivery mechanism for Suboxone (in a film formulation instead of its original tablet formulation) to the market and then destroyed demand for the tablets by a) raising the price of Suboxone tablets and then b) withdrawing them from the market. Reckitt then claimed patent protection on the film formulation of Suboxone;

ii. **Sabotaging Generics' FDA Application**. Reckitt sabotaged generic manufacturers' FDA drug applications by refusing to cooperate with them on a risk mitigation plan, despite having been ordered to do so by the FDA; and

iii. **Sham Citizen's Petition**. Reckitt filed a citizen's petition that was objectively baseless solely because it knew it would delay the FDA's approval of the generic manufacturers' applications for generic Suboxone.

3. Reckitt's anticompetitive acts were intended to and did delay the entry of generic Suboxone in the market. Generic entry was more than three years later than it otherwise should have been absent Reckitt's scheme. Consumers and end payors overpaid substantially because of the delay. Prior to the entry of generic Suboxone in the market, Suboxone was approximately $10 per pill. Now, generic Suboxone is approximately $2.85 per pill and name-brand Suboxone is $3.53 per pill—far less than the $10 Reckitt could command when it was the exclusive Suboxone provider to the market.

II. FACTS PERTAINING TO RECKITT'S ANTICOMPETITIVE SCHEME

4. Co-formulated buprenorphine/naloxone is a unique combination drug product composed of two active pharmaceutical ingredients used together as opioid replacement therapy for the maintenance treatment of opioid dependence (e.g., heroin addiction). The buprenorphine supplies the patient with a maintenance dose of a semi-synthetic opioid, absorbed through the oral mucosa. The naloxone, in theory at least, serves to prevent the patient from abusing the buprenorphine, by blocking the action of the buprenorphine and thereby precipitating immediate withdrawal symptoms if the buprenorphine is, for instance, ground, put into solution, and injected intravenously. The naloxone in Suboxone will not have such a blocking effect, however, if the buprenorphine is used sublingually, as directed—naloxone is poorly absorbed through the oral mucosa.

5. When Reckitt introduced Suboxone, buprenorphine and naloxone were no longer innovative drugs; in fact, they were quite old. Naloxone was first approved by the Food and Drug Administration ("FDA") in the 1970s. Buprenorphine was first approved by the FDA in 1982 as an injectable analgesic (pain) drug, first marketed by a predecessor to Reckitt. 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. Thus, when it introduced Suboxone sublingual tablets in 2002, Reckitt knew that neither Suboxone's components nor their use in opioid replacement therapy had any patent protection. In fact, in its application to the FDA for approval of Suboxone, Reckitt stated that it "has no knowledge of any patent that claims the drugs or any methods of using the drugs that are the subject of this application."

6. Reckitt did have some protection against generic competition to Suboxone, however. When Suboxone was approved, FDA granted Reckitt a 7-year period of regulatory

exclusivity, categorizing Suboxone as a so-called "orphan drug." *See* 21 U.S.C. § 360aa-dd. During that period of exclusivity, Reckitt marketed Suboxone tablets free from competition from generic co-formulated buprenorphine/naloxone, garnering United States sales of over $1 billion per year, far above the commercial potential that typically entitles a drug company to orphan drug exclusivity, and contrary to 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 (most of which, as stated above, were borne by taxpayers, in any event).

7. Reckitt's 7-year orphan drug exclusivity for Suboxone tablets was set to expire on October 8, 2009, and with the end of that exclusivity Reckitt knew would come less expensive generic competition to Suboxone. This prospect was alarming to Reckitt, because Suboxone formed a substantial portion of Reckitt's revenue and profits. Reckitt knew that generic competition posed a substantial threat to those profits. Since generics are generally priced significantly below that of the brand-name drug, such products typically take the vast majority of the brand-name version's sales directly and quickly after their introduction into the marketplace.

8. Not satisfied with 7 years of government-bestowed exclusivity for a drug largely developed and reimbursed by taxpayer money, Reckitt concocted a multifaceted anticompetitive scheme, executed over the course of several years, to maintain and extend its monopoly power over co-formulated buprenorphine/naloxone, by illegally preventing generic manufacturers from effectively competing with Suboxone. Reckitt's scheme was executed through a purposeful and planned manipulation of the complex distribution and regulatory approval systems for pharmaceutical products in the United States. The scheme comprised a number of steps.

A. **Step One: Reckitt Develops Suboxone Film**

9. First, in July of 2007, more than two years before its orphan drug exclusivity expired, Reckitt announced to the FDA that it planned to apply to market a sublingual film version of Suboxone. Reckitt ultimately filed its application in October 2008. Medically speaking, the film was equivalent to the tablets. Its dosage strengths were the same as the tablets. In fact, Reckitt obtained FDA approval of the film version of Suboxone based almost entirely on previous studies by which the safety and efficacy of the tablets was demonstrated. Reckitt performed no efficacy studies on Suboxone film itself. Reckitt simply showed that the film version had sufficiently equivalent bioavailability compared with the tablet version. Reckitt itself told the FDA any differences between the film and the tablet were "clinically insignificant."

10. Reckitt developed Suboxone film in advance of its upcoming loss of Suboxone tablet exclusivity for one reason and one reason alone: it knew that generic Suboxone tablets would not and could not be considered "AB-rated" to branded Suboxone film and that pharmacists would not and could not legally substitute 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 means by which generic competition is supposed to reduce drug prices. Disrupting this competitive mechanism was Reckitt's entire reason for introducing Suboxone film: to the extent it could introduce its film version of Suboxone and cause the prescription base of branded Suboxone tablets to disappear, Reckitt would be able to hobble generic Suboxone tablet competition and prevent prices for co-formulated buprenorphine/naloxone from dropping to competitive levels.

11. Reckitt met with difficulty getting Suboxone film approved by the FDA. The FDA rejected Reckitt's application to market a film formulation of Suboxone on August 21,

2009—less than two months before Reckitt's exclusivity on its tablet formulation was set to expire—because the FDA was concerned that the film formulation could be misused or abused. Ultimately, after Reckitt submitted a Risk Evaluation and Mitigation Strategy ("REMS") to address these issues, the film formulation was approved by FDA on August 30, 2010, and Reckitt proceeded to market Suboxone film.

1. Suboxone Film Was Inferior to Suboxone Tablets

12. The new film formulation offered no medical or clinical benefits over the existing tablets, something the FDA expressly recognized. On the contrary: the film formulation had numerous drawbacks. Naloxone bioavailability with the film version was increased relative to the tablet version, risking unwanted precipitation of opioid withdrawal—the very condition Suboxone is supposed to stem—and therefore unsuccessful induction and stabilization of patients taking the film. The new film formulation was easier to conceal than was the tablet version, and thus more susceptible to diversion. The new film formulation was easier to dissolve and inject than the tablet formulation, defeating a major virtue of Suboxone: a low abuse potential. The new film formulation was also more dangerous for children who accidentally ingest Suboxone: because the film dissolves rapidly, children who accidentally place Suboxone film in their mouths tend to absorb the buprenorphine it contains quickly and completely, and the film cannot be spit out or removed from the mouth. 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 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 exposure to buprenorphine. When tablets are

swallowed by children, the buprenorphine in Suboxone tablets is absorbed to a far lesser extent compared with film.

13. Even the packaging of the film presented drawbacks relative to the packaging of the tablets. Each dose of film was packaged in a child-resistant sleeve. Once the sleeve was opened, it no longer afforded any child resistance. Reckitt supplied no child-resistant bottle or other container into which unused portions of doses of film—those that would be left over for that significant fraction of patients who, Reckitt knew, took their Suboxone in divided doses—could safely be placed. By contrast, Suboxone tablets were supplied in a childproof bottle into which a patient could safely place unused portions of split Suboxone tablets. Moreover, the child-resistant sleeve increased the street value of diverted product because it guaranteed product identity, and, therefore, purity.

14. Patients did not prefer Suboxone film to Suboxone tablets, either; they preferred the tablets by a wide margin. The film formulation was more irritating to a patient's oral mucosa than the tablet. Reckitt could not profitably charge more for Suboxone film than it was charging for Suboxone tablets. Reckitt had to charge less for Suboxone film in order to transition the market away from its tablets. It readily offered coupons to cover patients' out-of-pocket costs, making Suboxone film more affordable than the tablets.

2. Reckitt's Motives for Introducing Suboxone Film Were Predatory

15. Even from Reckitt's perspective, the new film formulation was more costly and difficult to manufacture than the existing tablet formulation. Reckitt did not expect the new film formulation to garner it any additional sales or revenues, lower its costs, or increase its efficiency, over and above the tablet formulation. Reckitt did not expect to be able to charge more for Suboxone film than Suboxone tablets. In fact, Reckitt fully expected to lose sales and

revenues, increase its costs, and decrease its efficiency by developing and marketing Suboxone film. And that is precisely what happened.

16. But none of that mattered to Reckitt. Reckitt was willing to sacrifice profits on Suboxone because the sole purpose and effect of its costly plan to develop the film were not to provide a better or improved product, but simply to protect Reckitt's Suboxone profits by thwarting, delaying and/or mitigating the impact of competition from generic Suboxone tablets by raising would-be generic competitors' costs and excluding them from the most efficient means of distributing their generic Suboxone tablet products, via the automatic pharmacy substitution mechanism.

B. **Step Two: Reckitt Destroys Demand for Suboxone Tablets**

17. After the FDA approved the film version of Suboxone, Reckitt took affirmative (and costly) steps to destroy demand for Suboxone tablets and simultaneously coerce physicians to prescribe, and patients to take, Suboxone film, which did not face imminent generic competition.

18. First, Reckitt raised the price for Suboxone tablets, in order to make it unattractive to patients and payors and thereby drive demand to Suboxone film.

19. Second, Reckitt purposely refrained from packaging Suboxone tablets in childproof unit-dose packaging, a packaging configuration it had already used (since 2005) for its co-formulated buprenorphine/naloxone tablets in Canada and the United Kingdom. Reckitt refrained from implementing unit dose packaging for Suboxone tablets in the United States—despite knowing as early as December 2006, if not earlier, that pediatric exposure rates were very high for Suboxone—simply in an attempt to degrade the quality of Suboxone tablets

relative to Suboxone film and to further drive demand towards Suboxone film. Indeed, Reckitt has admitted that unit-dose packaging of tablets is "feasible" in the United States but it purposefully sacrificed profits to develop and launch the Suboxone film product in the United States in order to thwart generic competition from Suboxone tablets.

20. Third, using its sales force that visits doctors (called "detailers"), Reckitt falsely disparaged Suboxone tablets to doctors and payors.

21. Fourth, with generic Suboxone tablets poised to enter the market, Reckitt announced in or around September 2012 that it would discontinue the sale of Suboxone tablets altogether.

22. Reckitt took these actions before generic versions of Suboxone were available in the market. Thus, Reckitt was affecting the switch, by disparaging and raising the price of Suboxone, when no competing manufacturer had the ability to counter that message. Reckitt knew that it was essential to its anticompetitive scheme to make the market switch from the tablets to the film before generics entered the market.

23. Because of Reckitt's anticompetitive scheme, by the time generic manufacturers started selling their generic tablet versions of Suboxone, the prescription base for Suboxone tablets has been almost entirely destroyed due to Reckitt's coercive tactics; more prescriptions are already being written for the film version of Suboxone than the tablets.

24. Reckitt took each and every one of these steps with a single goal in mind: to destroy demand, and the prescription base, for Suboxone tablets and thereby prevent generic versions of Suboxone tablets from effectively competing with branded Suboxone using the most efficient means by which that competition is intended to take place: generic substitution at the pharmacy counter.

C. **Step Three: Reckitt Holds ANDA Approvals Hostage**

25. Third, Reckitt engaged in anticompetitive actions to block and delay would-be generic Suboxone tablet manufacturers from obtaining FDA approval of their Abbreviated New Drug Applications ("ANDAs") for generic Suboxone tablets. Reckitt did this by sabotaging the process by which it and the generic Suboxone tablet ANDA applicants needed to finalize and submit an FDA-required shared Risk Evaluation and Mitigation Strategies ("REMS") for Suboxone tablets. REMS is a program the FDA sometimes requires to manage a known or potential serious risk associated with a drug. The requirement of a shared REMS was communicated by the FDA on January 6, 2012. The FDA required the shared REMS, but did not contemplate, much less authorize, that Reckitt would use the requirement of a shared REMS to try to block and delay ANDA approval. In fact, given that it had just approved Reckitt's Suboxone tablet REMS in December of 2011, the FDA contemplated rapid development of a shared REMS and projected that the collaboration would result in a shared REMS within five months.

26. But Reckitt, knowing that such a joint submission to FDA was the final prerequisite to FDA approval of the pending Suboxone tablet ANDAs, and realizing that it was a required participant, sabotaged the joint process by slowing it down, running the clock, and drawing it out for as long as it could, refusing to participate, placing pretextual conditions on its participation, and asserting thin pretexts to disguise its transparently anticompetitive intentions.

27. Reckitt's sabotage of the joint process has been documented in writing by the various generic drug companies holding Suboxone tablet ANDAs. Those companies are Actavis, Inc. (located in Parsippany, New Jersey), Arnneal Pharmaceuticals LLC (located in Bridgewater, New Jersey), Ethypharm USA Corp. (located in Philadelphia, Pennsylvania), Mylan Inc. (located in Canonsburg, Pennsylvania), Roxane Laboratories Inc. (located in Columbus, Ohio), Sandoz

Inc. (located in Princeton, New Jersey), Sun Pharmaceuticals Industries, Ltd. (located in Cranbury Township, New Jersey), and Teva Pharmaceuticals USA, Inc. (located in North Wales, Pennsylvania). One or more of those companies have reported to the FDA that Reckitt:

a. merely feigned cooperation with the shared REMS development process;

b. refused to participate in meetings with the generic ANDA filers;

c. when it did attend meetings, refused to discuss any substantive issues with the generic ANDA filers pertaining to the shared REMS;

d. placed conditions on its cooperation with the shared REMS development process that it knew the ANDA filers could not agree to (such as to assume Reckitt's tort liability by contract, which had nothing to do with the development of a joint REMS and would have caused the ANDA filers' liability insurers to disclaim coverage);

e. refusing to share information with the generic ANDA filers about the existing REMS program that was essential to the shared REMS development process;

f. just before a shared REMS was to be submitted to the FDA in August of 2012, raised a last-minute issue merely to cause still further delay; and

g. stopped participating altogether in September of 2012.

28. Reckitt's sabotage of the shared REMS development process was intended to, and did, delay the FDA's approval of one or more Suboxone tablet ANDAs.

D. **Step Four: Reckitt Files a Sham "Citizen Petition"**

29. After the generic Suboxone tablet ANDA filers submitted a shared REMS program of their own without Reckitt to the FDA in August of 2012, Reckitt knew that the possibility existed that the FDA would decide to accept the generics-only shared REMS, as submitted or with modification, and then approve one or more generic Suboxone tablet ANDAs. In an attempt to prevent that from occurring, Reckitt changed tactics. On September 25, 2012,

Reckitt filed an objectively baseless "citizen petition" with the FDA in an attempt to further delay FDA approval of ANDAs for generic Suboxone tablets. Reckitt's petition asked the FDA to withhold approval of generic Suboxone tablet ANDAs unless (1) the ANDA contains a targeted pediatric exposure education program, (2) the ANDA product has child-resistant unit-dose packaging, and (3) the FDA determines that Reckitt did not discontinue marketing branded Suboxone tablets for reasons of safety.

30. Reckitt's petition was filed for the sole purpose of interfering with competition by delaying FDA approval of generic Suboxone tablet ANDAs only when its strategy of sabotaging the shared REMS development process was no longer working. In the months preceding Reckitt's petition, while Reckitt was feigning cooperation with the shared REMS development process, at no time did Reckitt share with the generic Suboxone tablet ANDA filers any of the information regarding purported safety issues contained in Reckitt's petition. Instead, Reckitt kept its petition and its contents a tactical surprise. Given the purported safety-related bases of Reckitt's petition, Reckitt's secrecy—as well as its failure to take the very actions to protect patients that it sought to require of the generic tablet sellers—exposes the tactical, anticompetitive nature of the petition. Companies with genuine safety concerns do not keep them a secret. Companies with genuine safety concerns seek to adjust their own existing products, not just the products of other companies. Companies with genuine safety concerns do not use them tactically.

31. Reckitt's petition was also objectively baseless. No reasonable petitioner could possibly expect to succeed on the merits of the petition Reckitt filed. Reckitt's petition lacked any reasonable regulatory, scientific, medical, or other reasonable basis. FDA lacked the statutory authority to withhold approval of generic Suboxone tablet ANDAs on the bases cited

by Reckitt, or to require the actions Reckitt sought to impose on the ANDA filers. Reckitt's petition lacked clinically meaningful evidence that lent support to its assertions or that bore on the approvability of generic Suboxone ANDAs. Reckitt's petition stood no chance of affecting FDA policy or procedure. In short, it was a sham, albeit one that required the FDA to look into its contentions, causing a delay in the approval of the generic manufacturers' Suboxone tablet ANDAs.

32. Evidence demonstrating the absence of a reasonable basis for Reckitt's petition abounds. Regarding Reckitt's pediatric exposure education program, there existed no statutory or regulatory basis for requiring its inclusion in any Suboxone ANDA. Reckitt had not included such an education program in its own New Drug Application ("NDA") or any supplement to its NDA. Reckitt's proposed educational program has not been approved or otherwise required by the FDA as part of its formally approved labeling or REMS. The FDA has no statutory or regulatory authority to require ANDA filers, as a condition of approval, to create labeling or REMS materials different than that approved for the reference listed drug. Nor is there any regulatory or statutory support for Reckitt's "risk-benefit profile" argument; there is no such standard for the evaluation of ANDAs.

33. Regarding unit-dose packaging, Reckitt's petition did not reference the FDA's previously stated positions, but instead flatly ignored them. Reckitt knew from a letter the FDA wrote to it in March of 2010 that the FDA had long since concluded that, because of the high percentage of patients that took Suboxone in divided daily doses, unit-dose packaging did not ameliorate, and might even exacerbate, the known high incidence of accidental pediatric buprenorphine exposure. "Because patients are known to divide tablets, it may be expected that patients will remove films from the package and have partial doses that are neither in the

child-resistant pouch nor in a child-resistant medication bottle," the FDA said. Moreover, the FDA could not grant the relief requested because the packaging request falls within the exclusive jurisdiction of the Consumer Product Safety Commission.

34. Regarding the issue of whether Reckitt's removal of Suboxone tablets from the market is for reasons of safety, there exists no statutory or regulatory grounds for such a determination based on the container closure system employed to package a drug, the sole basis upon which Reckitt premised its request—as opposed to the safety of the drug itself. And as Reckitt well knows, it is not removing Suboxone tablets from the market for reasons of safety; Reckitt simply lied to the FDA.

35. Reckitt's sham petition successfully delayed generic Suboxone market entry, but failed to prevent it entirely. On February 22, 2013, the FDA denied Reckitt's petition on all counts, including Reckitt's request that the FDA declare that Reckitt discontinued Suboxone tablets for safety reasons. Although Reckitt's petition was denied, its submission forced the FDA to evaluate Reckitt's claims, delaying approval of generic manufacturers' entry into the market. Particularly revealing is that the FDA not only denied Reckitt's petition, but it also referred the matter to the Federal Trade Commission because it "has the administrative tools and the expertise to investigate and address anticompetitive business practices."

E. Reckitt's Scheme Was Intended To, And Did, Harm Competition

36. Reckitt's scheme, as a whole and in its individual parts, was intended to, and has, blocked and delayed generic Suboxone competition, disrupted the normal channels, and the statutory and regulatory mechanisms, by which generic competition takes place and was prescribed by Congress to take place, and excluded would-be generic competitors from the most efficient means of distributing their products.

37. Reckitt's exclusionary motive is also illustrated by its willingness to sacrifice profits as part of its product change strategy. Reckitt's decisions to incur the extra costs (and suffer the revenue losses) associated with the change in Suboxone's dosage form from tablets to film and the discontinuation of Suboxone tablets were economically rational only because those changes had the exclusionary effect of suppressing generic competition. But for the impact on generic competition, Reckitt would not have invested the resources necessary to develop Suboxone film and destroy the prescription base for Suboxone tablets, because it would have been economically irrational to do so.

38. Reckitt's exclusionary motive is betrayed by its prior conduct. Reckitt's pattern and modus operandi is to respond to the threat of competition by deploying anticompetitive schemes containing precisely the signature features its Suboxone scheme had. For instance, in the case of its drug Gaviscon (marketed in the United Kingdom), just before the inception of generic competition to Gaviscon Original Liquid, Reckitt discontinued that product, to force physicians and patients to prescribe its new Gaviscon formulation, Gaviscon Advance Liquid, which pharmacists could not substitute with pending generic versions of Gaviscon Original Liquid. Reckitt was fined for its conduct and admitted that its conduct was anticompetitive.

39. To the extent it is even permitted to do so, Reckitt cannot justify its scheme by pointing to any offsetting consumer benefit. The enormous cost savings offered by generic drugs (and, correspondingly, the anticompetitive harm caused by suppressing generic competition to Suboxone) outweigh any cognizable, nonpretextual procompetitive justifications Reckitt could possibly offer.

40. Any cognizable justifications Reckitt could offer for its scheme are, in fact, pretexts. And, whatever justifications Reckitt may offer, Reckitt did not need to engage in the conduct challenged in this lawsuit to achieve them.

41. If Reckitt were simply and solely interested in introducing a new Suboxone film product to compete on the merits with Suboxone tablets, it could have done so without taking the additional, affirmative steps described herein 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 (c) destroy the prescription base for Suboxone tablets.

42. If Reckitt were simply and solely interested in modifying the container closure system for Suboxone in the United States to contain a unit-dose packaging feature, it could have done so, as it has done in several other countries since 2005, without reformulating Suboxone's dosage form into a film and destroying the prescription base for Suboxone tablets.

43. As a result of some or all of its illegal scheme, Reckitt (1) illegally maintained and extended its monopoly in the market for co-formulated buprenorphine/naloxone; (2) fixed, raised, maintained, and/or stabilized the price of co-formulated buprenorphine/naloxone at supracompetitive levels; and (3) overcharged Plaintiff and other end-payors of Suboxone by millions of dollars by depriving them of the benefits of competition from cheaper generic versions of Suboxone.

44. Reckitt's monopoly power, as alleged more fully below, was maintained through willfully exclusionary conduct, as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident. Neither Reckitt's scheme as a whole, nor any of its constituent parts, constituted competition on the merits.

45. As alleged in more detail below, Reckitt violated state statutory and common law as enumerated below through its overarching scheme to improperly maintain and extend its monopoly power by foreclosing or delaying competition from lower-priced generic versions of Suboxone.

III. JURISDICTION AND VENUE

46. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which the aggregate amount in controversy exceeds $5,000,000 and at least one member of the putative class is a citizen of a state different from that of Reckitt.

47. Reckitt transacts business within this district, and its unlawful monopolizing and restraint of trade and competition in the market for Suboxone has substantially affected both intrastate and interstate trade and commerce. Venue is appropriate within this district under 28 U.S.C. § 1391(b) and (c).

IV. THE PARTIES

48. Plaintiff I.B.E.W. 292 Health Care Plan is a Taft-Hartley multiemployer welfare fund, organized and operating in the State of Minnesota, which provides reimbursement for health, vision, dental, and prescription drug claims incurred by its plan member electricians, power limited technicians, broadcasting and electrical manufacturing employees in Minnesota and Maine. The Fund maintains its principal place of business in Minneapolis, Minnesota and, thus, is a citizen of Minnesota. Plaintiff has purchased and/or provided reimbursement for some or all of the purchase price for Suboxone, other than for re-sale, at supracompetitive prices during the Class Period, and has thereby been injured.

49. Defendant Reckitt Benckiser, Inc. is a Delaware corporation with its principal place of business located at Morris Corporate Center IV, 399 Interpace Parkway, Parsippany, New Jersey 07054. 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 above and below and attributed to Reckitt.

50. Defendant Reckitt Benckiser LLC is a Delaware limited liability company with its principal place of business located at Morris Corporate Center IV, 399 Interpace Parkway, Parsippany, New Jersey 07054. 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 above and below and attributed to Reckitt.

51. 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 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 above and below and attributed to Reckitt.

52. Defendant Reckitt Benckiser Healthcare (UK) Ltd. is a British corporation incorporated under the laws of England and Wales, with its registered office located at Dansom Lane, Hull, North Humberside HUS 7DS. 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 above and below attributed to Reckitt.

53. 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, SLl 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 above and below attributed to Reckitt.

54. 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.

V. CLASS ACTION ALLEGATIONS

55. Plaintiff brings this action on behalf of itself and, under Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure, as representative of a Class defined as follows:

> All persons or entities who purchased and/or paid for some or all of the purchase price of Suboxone or generic Suboxone in Alabama, Arkansas, Arizona, California, Colorado, Delaware, District of Columbia, Florida, Georgia, Hawaii, Iowa, Idaho, Illinois, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Maine, Michigan, Minnesota, Missouri, Mississippi, Montana, North Carolina, North Dakota, Nebraska, New Jersey, New Mexico, Nevada, New York, Ohio, Oklahoma, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Vermont, Washington, West Virginia, and Wisconsin for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries at any time during the period October 8, 2009 through and until the anticompetitive effects of Defendants' unlawful conduct cease (the "Class"). For purposes of the Class definition, persons or entities "purchased" Suboxone or generic Suboxone if they paid or reimbursed some or all of the purchase price.

56. The following persons or entities are excluded from the proposed Class:

a. Defendants and their officers, directors, management, employees, subsidiaries, or affiliates;

b. All governmental entities, except for governmental funded employee benefit plans;

c. All persons or entities who purchased Suboxone or its AB-rated generic equivalent for purposes of resale or directly from Defendants or their affiliates;

d. Fully insured health plans (i.e., Plans that purchased insurance from another third-party payor covering 100% of the Plan's reimbursement obligations to its members);

e. Any "flat co-pay'' consumers whose purchases were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price; and

f. The judges in this case and any members of their immediate families.

57. Members of the Class are so numerous that joinder is impracticable. Plaintiff believes the Class includes hundreds of thousands of consumers, and thousands of third-party payors.

58. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct by Reckitt, i.e., they paid artificially inflated prices for co-formulated buprenorphine/naloxone products and were deprived of the benefits of competition from less-expensive generic versions of Suboxone tablets as a result of Reckitt's wrongful conduct.

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

60. Plaintiff is represented by counsel who is experienced and competent in the prosecution of class action antitrust litigation, and has particular experience with class action monopoly litigation.

61. 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.

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

a. whether Reckitt unlawfully maintained monopoly power through all or part of its overall scheme;

b. whether Reckitt's anticompetitive scheme suppressed generic competition to Suboxone;

c. whether Reckitt's introduction of Suboxone film and destruction of the prescription base for Suboxone tablets were predatory and anticompetitive;

d. whether Reckitt's sabotage of the development process for a shared REMS was anticompetitive;

e. whether a reasonable petitioner would have expected that the arguments made in Reckitt' s "citizen petition" would succeed;

f. whether Reckitt' s "citizen petition" was submitted to interfere with competition;

g. as to those parts of Reckitt's challenged conduct for which such justifications may be offered, whether there exist cognizable, non-pretextual procompetitive justifications, which Reckitt's challenged conduct was the least restrictive means of achieving, that offset the harm to competition in the market(s) in which Suboxone is sold;

h. 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;

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

j. whether Reckitt's scheme, in whole or in part, has substantially affected intrastate commerce in those states in which Plaintiff alleges violations of antitrust and consumer protection statutes;

k. whether Reckitt's overall scheme, in whole or in part, caused antitrust injury to the business or property of Plaintiff and the members of the Class in the nature of overcharges; and

l. the quantum of overcharges paid by the Class in the aggregate.

63. 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.

64. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

VI. OTHER FACTUAL ALLEGATIONS

A. Characteristics of the Pharmaceutical Marketplace

65. The marketplace for the sale of prescription pharmaceutical products in the United States contains a 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.

66. 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 co-formulated buprenorphine/naloxone, 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.

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

68. 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, discussed below.

69. 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.

70. 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 laws permit (or in some cases require) the pharmacist 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.

71. If Reckitt's unlawful conduct had not prevented generic manufacturers from successfully entering the market with generic versions of Suboxone, end-payors like Plaintiff and members of the Class would have saved millions of dollars in the purchase of co-formulated buprenorphine/naloxone. Reckitt's anticompetitive scheme purposely manipulated generic competition to Suboxone.

B. The Regulatory Structure Pursuant to Which Generic Substitutes for Brand-Name Drugs Are Approved

72. Under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301-392), manufacturers who create a new, pioneer 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 effectiveness of the drug, as well as any information on applicable patents.

73. In 1984, Congress amended the Food, Drug and Cosmetic Act with the enactment of the Hatch-Waxman amendments, called the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman").

74. Recognizing the importance of generic drug availability, Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file a lengthy and costly NDA in order to obtain FDA approval. Instead, the FDA provides an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application ("ANDA").

75. The ANDA relies on the scientific findings of safety and effectiveness included by the brand-name drug manufacturer in the original NDA.

76. In order to be substitutable for a branded product at the pharmacy counter, and approvable by FDA as AB-rated to a particular branded product, a generic product must be, among other things, "pharmaceutically equivalent" (same dosage form and strength) and "bioequivalent" (exhibiting the same drug absorption characteristics) as the branded product.

77. FDA regulations, which are concerned only with safety and efficacy and not with effects on competition, permit branded manufacturers to seek FDA approval to modify the dosage form and strength of their existing products. An unscrupulous brand manufacturer that anticipates the onset of generic competition to its drug could modify the dosage form, strength, or some other characteristic of its product from, say, A to A1, for no reason other than to prevent generic competition to A. Before the generic manufacturer receives FDA approval for the generic version of A and enters the market, the brand manufacturer might get approval for A1 and use various coercive tactics to cause physicians to write prescriptions only for A1 instead of A. The branded manufacturer's modification of A to A1 may thereafter cause the manufacturer of the generic version of A to garner few or no sales, because its product is not substitutable for A1.

C. **The Availability of Citizen Petitions to Delay FDA Approval of Generic Drugs**

78. Section 505(j) of the Food, Drug and Cosmetic Act creates a mechanism by which a person may file a petition with the FDA requesting, among other things, that the agency take, or refrain from taking, any form of administrative action. This mechanism is commonly referred to as a "citizen petition."

79. Citizen petitions provide a forum for individuals to express and support their genuine concerns about safety, scientific, or legal issues regarding a product anytime before, or after, its market entry.

80. Other than the form of such citizen petition, the regulations place no restrictions on the subject matter of a citizen petition.

81. The FDA regulations concerning citizen petitions require the FDA Commissioner to respond to each citizen petition within 180 days of receipt. That response may be to approve the request in whole or in part, or deny the request. The Commissioner also may provide a tentative response with an estimate on a time for a full response.

82. Reviewing and responding to citizen petitions is a resource-intensive and time-consuming task because, no matter how baseless a petition may be, the 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. These activities strain the FDA's limited resources, and lengthy citizen petitions can delay FDA approval of generic products even if those petitions ultimately are found to lack any reasonable evidentiary, regulatory, statutory or scientific basis.

83. 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 a year or more, long after the brand name manufacturer received notice of the ANDA filing, and have had the (intended) effect of delaying the approval of the generic product while the FDA evaluates the citizen petition.'

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

85. FDA officials have acknowledged abuses of the citizen petition process. Former FDA Chief Counsel Sheldon Bradshaw noted that when he was 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."

86. Similarly, 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 citizens petitions raising issues about the approvability of generic products, ''very few of these petitions on generic drug matters 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.

87. It is the practice of the FDA, well known in the pharmaceutical industry, to withhold ANDA approval 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."

D. **Generic Versions of Brand-Name Drugs are Significantly Less Expensive, and Take Significant Sales Directly From the Corresponding Brand-Name Versions**

88. Typically, generic versions of brand-name drugs are priced significantly below the brand-name versions. Because of the price differentials, and other institutional features of the pharmaceutical industry, generic versions are liberally and substantially substituted for their brand-name counterparts. In particular, generic drugs that are pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to their brand name counterparts are given an "AB" rating by the FDA. Pharmacists substitute an AB-rated generic product for the corresponding brand-name product unless the doctor has indicated that the prescription for the brand-name product must be "dispensed as written." As more generic manufacturers enter the market, prices for generic versions of a drug predictably decrease even further because of competition among the generic manufacturers, and the loss of sales volume by the brand-name drug to the corresponding generics accelerates.

89. Reckitt was well aware of this impending loss of Suboxone sales volume. As reflected in Reckitt' s 2008 Annual Report, Reckitt knew that Suboxone tablets would lose 80% or more of their sales to less-expensive generic equivalents within the first year of competition, and that it stood to lose hundreds of millions of dollars after generic Suboxone tablets entered the market.

90. Generic competition enables all members of the proposed Class to: (a) purchase generic versions of a drug at substantially lower prices; and/or (b) purchase the brand-name drug at a reduced price. However, until a generic manufacturer enters the market, there is no bioequivalent generic drug to compete with the brand-name drug, and therefore the brand-name

manufacturer can continue to charge supracompetitive prices profitably without losing all or a substantial portion of its brand-name sales. Consequently, brand-name drug manufacturers have a strong incentive to use various tactics, including those alleged above, to delay the introduction of generic competition into the market.

E. **Effects on Competition and Damages to Plaintiff and the Class**

91. Reckitt's overall anticompetitive scheme to suppress generic competition to Suboxone tablets has, both as a whole and in its individual parts, delayed and prevented the sale of generic Suboxone by delaying its availability and, through Reckitt's destruction of demand for Suboxone tablets, by suppressing the ability of generic Suboxone tablets to compete by depriving would-be generic versions of the most efficient means of competition under the governing statutory and regulatory regime.

92. Reckitt's overall anticompetitive scheme delayed or prevented the sale of generic Suboxone tablets in the United States, and unlawfully enabled Reckitt to sell Suboxone at artificially inflated prices. But for Reckitt's illegal conduct, generic competitors would have been able to compete, unimpeded, with generic versions of Suboxone tablets. Generic competitors would also have been able to compete earlier, as early as October of 2009, and additional generic competitors would have entered the market thereafter. Reckitt's challenged conduct thereby delayed and prevented the savings that purchasers of Suboxone would have experienced from unfettered generic competition.

93. Specifically, if manufacturers of generic Suboxone tablets had been able to enter the marketplace and effectively compete with Reckitt earlier or without Reckitt's having switched the market to Suboxone film, as set forth above, Plaintiff 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 co-formulated buprenorphine/naloxone

requirements, and/or would have paid lower prices for some or all of their remaining branded Suboxone purchases.

94. Reckitt's scheme has deprived the manufacturers of generic Suboxone tablets of the cost-efficient means of distribution and will continue to impinge upon the market for generic versions of Suboxone tablets.

95. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. Moreover, the institutional structure of pricing and regulation in the pharmaceutical drug industry assures that overcharges at the higher level of distribution are passed on to end-payors. Wholesalers and retailers passed on the inflated prices of Suboxone to Plaintiff and members of the Class. The complete foreclosure of generic competition at the direct purchaser level similarly injured end-payors who were equally denied the opportunity to purchaser less expensive generic Suboxone equivalents.

96. During the relevant period, Plaintiff and other members of the Class purchased substantial amounts of Suboxone. As a result of Reckitt's illegal conduct as alleged herein, Plaintiff and other members of the Class were compelled to pay, and did pay, artificially inflated prices for their co-formulated buprenorphine/naloxone. Plaintiff and the other Class members paid prices for co-formulated buprenorphine/naloxone 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; and/or (2) the price of branded Suboxone was artificially inflated by Defendants' illegal conduct.

97. As a consequence, Plaintiff and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

F. **Effect on Interstate and Intrastate Commerce**

98. 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.

99. 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.

100. 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 alleged in this Complaint, were within the flow of, and have substantially affected, interstate commerce.

101. Reckitt's anticompetitive conduct also has substantial intrastate effects in that, inter alia, retailers within each state are foreclosed from offering cheaper generic Suboxone to end-payors inside each respective state. The foreclosure of generic Suboxone directly impacts and disrupts commerce for end-payors within each state.

G. **Monopoly Power**

102. At all relevant times, Reckitt had monopoly power over co-formulated buprenorphine/naloxone, because it had the power to raise and/or maintain the price of co-formulated buprenorphine/naloxone at supracompetitive levels without losing substantial sales.

103. To the extent that Plaintiff is required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant product market is all

co-formulated buprenorphine/naloxone products, i.e., Suboxone in all its forms and dosage strengths and generic co-formulated buprenorphine/naloxone products. But for Reckitt's illegal conduct, multiple firms would be marketing co-formulated buprenorphine/naloxone.

104. 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 (other than AB-rated generic Suboxone once it became available).

105. 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.

106. 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 supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Suboxone would render Reckitt unable to profitably maintain its prices for Suboxone without losing substantial sales.

107. Reckitt also sold branded Suboxone well in excess of marginal costs, and in excess of the competitive price, and enjoyed unusually high profit margins.

108. 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.

109. The relevant geographic market is the United States and its territories.

110. At all relevant times, Reckitt enjoyed high barriers to entry with respect to the above-defined relevant market due to regulatory protections and the high costs of entry and expansion.

111. Reckitt's market share in the relevant market is and was 100% at all times. 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.

VII. CLAIMS FOR RELIEF

CLAIM I:
MONOPOLIZATION AND MONOPOLISTIC SCHEME UNDER STATE LAWS

112. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

113. At all relevant times, Reckitt possessed substantial market power (i.e., monopoly power) in the relevant market. Reckitt possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

114. Through its overall anticompetitive scheme, as alleged extensively above, Reckitt willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen or to improve Suboxone, and injured Plaintiff and the Class thereby.

115. It was Reckitt's conscious objective to further its dominance in the relevant market by and through the overall anticompetitive scheme.

116. Reckitt's scheme harmed competition as aforesaid.

117. To the extent Reckitt is permitted to assert one, there is and was no cognizable, non-pretextual procompetitive justification for Reckitt's anticompetitive scheme that outweighs the scheme's harmful effects. Even if there were a justification that Reckitt were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

118. As a direct and proximate result of Reckitt's illegal and monopolistic conduct, as alleged herein, Plaintiff and the Class were injured.

119. By engaging in the foregoing conduct, Reckitt has intentionally and wrongfully maintained monopoly power in the relevant market in violation of the following state laws:

i. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases in Arizona by members of the Class.

ii. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, and California common law with respect to purchases in California by members of the Class.

iii. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases in the District of Columbia by members of the Class.

iv. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Class.

v. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases in Illinois by members of the Class.

vi. Iowa Code § 553.5 *et seq.*, with respect to purchases in Iowa by members of the Class.

vii. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases in Maine by members of the Class.

viii. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases in Michigan by members of the Class.

ix. Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases in Minnesota by members of the Class.

x. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases in Mississippi by members of the Class.

xi. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases in Nebraska by members of the Class.

xii. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases in Nevada by members of the Class.

xiii. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases in New Mexico by members of the Class.

xiv. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases in North Carolina by members of the Class.

xv. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases in North Dakota by members of the Class.

xvi. 10 L.P.R.A. §§ 251, *et seq.*, with respect to purchases in Puerto Rico by members of the Class.

xvii. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases in South Dakota by members of the Class.

xviii. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by members of the Class.

xix. Utah code Ann. §§ 76-10-911, *et seq.*, with respect to purchases in Utah by members of the Class.

xx. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Class.

xxi. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases in West Virginia by members of the Class.

xxii. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by members of the Class.

CLAIM II:
ATTEMPTED MONOPOLIZATION UNDER STATE LAWS

120. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

121. Reckitt, through its overall anticompetitive scheme, specifically intended to maintain monopoly power in the relevant market. It was Reckitt's conscious objective to control prices and/or to exclude competition in the relevant market.

122. The natural and probable consequence of Reckitt's overall anticompetitive scheme, which was intended by it and plainly foreseeable to it, was to control prices and exclude competition in the relevant market, regardless of its success.

123. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Reckitt will succeed in and achieve its goal of maintaining monopoly power in the relevant market.

124. As a direct and proximate result of Reckitt's illegal and monopolistic conduct, Plaintiff and the Class were harmed as aforesaid.

125. By engaging in the foregoing conduct, Reckitt has intentionally and wrongfully attempted to monopolize the relevant market in violation of the following state laws:

i. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases in Arizona by members of the Class.

ii. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, and California common law with respect to purchases in California by members of the Class.

iii. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases in the District of Columbia by members of the Class.

iv. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Class.

v. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases in Illinois by members of the Class.

vi. Iowa Code § 553.5 *et seq.*, with respect to purchases in Iowa by members of the Class.

vii. Kansas Stat. Ann. § 50-161(b), *et seq.*, with respect to purchases in Kansas by members of the Class.

viii. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases in Maine by members of the Class.

ix. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases in Michigan by members of the Class.

x. Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases in Minnesota by members of the Class.

xi. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases in Mississippi by members of the Class.

xii. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases in Nebraska by members of the Class.

xiii. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases in Nevada by members of the Class.

xiv. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases in New Mexico by members of the Class.

xv. N.Y. Gen. Bus. Law §§ 340, *et seq.*, with respect to purchases in New York by members of the Class.

xvi. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases in North Carolina by members of the Class.

xvii. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases in North Dakota by members of the Class.

xviii. 10 L.P.R.A. §§ 251, *et seq.*, with respect to purchases in Puerto Rico by members of the Class.

xix. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases in South Dakota by members of the Class.

xx. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by members of the Class.

xxi. Utah code Ann. §§ 76-10-911, *et seq.*, with respect to purchases in Utah by members of the Class.

xxii. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Class.

xxiii. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases in West Virginia by members of the Class.

xxiv. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by members of the Class.

CLAIM III:
UNJUST ENRICHMENT

126. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

127. Reckitt has benefited from monopoly profits on the sale of Suboxone resulting from the unlawful and inequitable acts alleged in this Complaint.

128. Reckitt's financial benefit resulting from its unlawful and inequitable acts is traceable to overpayments for Suboxone by Plaintiff and members of the Class.

129. Plaintiff and the Class have conferred upon Reckitt an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiff and the Class.

130. It would be futile for Plaintiff and the Class to seek a remedy from any party with whom they have privity of contract.

131. It would be futile for Plaintiff and the Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which it indirectly purchased Suboxone, as they are not liable and would not compensate Plaintiff for unlawful conduct caused by Reckitt.

132. The economic benefit of overcharges and monopoly profits derived by Reckitt through charging supracompetitive and artificially inflated prices for Suboxone is a direct and proximate result of Reckitt' s unlawful practices.

133. The financial benefits derived by Reckitt rightfully belong to Plaintiff and the Class, as Plaintiff and the Class paid anticompetitive and monopolistic prices during the Class Period, inuring to the benefit of Reckitt.

134. It would be inequitable under unjust enrichment principles under state laws for Reckitt to be permitted to retain any of the overcharges for Suboxone derived from Reckitt's unfair and unconscionable methods, acts, and trade practices alleged in this Complaint.

135. Reckitt is aware of and appreciates the benefits bestowed upon it by Plaintiff and the Class.

136. Reckitt should be compelled to disgorge in a common fund for the benefit of Plaintiff and the Class all unlawful or inequitable proceeds it received.

137. A constructive trust should be imposed upon all unlawful or inequitable sums received by Reckitt traceable to Plaintiff and the Class.

138. Plaintiff and the Class have no adequate remedy at law.

VIII. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff, on behalf of itself and the proposed Class, respectfully prays that the Court:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class, and declare the Plaintiff the representative of the Class;

B. Enter joint and several judgments against Reckitt and in favor of Plaintiff and the Class;

C. Declare the acts alleged herein to be unlawful under the state statutes set forth above, and the common law of unjust enrichment under the laws of the states and territories of the United States;

D. Grant Plaintiff and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Reckitt's unjust enrichment;

E. Award the Class damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest; and

F. Award Plaintiff and the Class their costs of suit, including reasonable attorneys' fees as provided by law.

G. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by Reckitt' s unlawful conduct, as the Court deems just.

IX. JURY DEMAND

Pursuant to Fed. Civ. P. 38, Plaintiff, on behalf of itself and the proposed Class, demands a trial by jury on all issues so triable.

Dated: 5/3, 2013

TRUJILLO RODRIGUEZ & RICHARDS, LLC

Ira Neil Richards, I.D. No. 50879
1717 Arch Street, Suite 3838
Philadelphia, PA 19103
Telephone: (215) 731-9004
Facsimile: (215) 731-9044
ira@trrlaw.com

Lisa J. Rodriguez
258 Kings Highway East
Haddonfield, NJ 08033
Telephone: (856) 795-9002
Facsimile: (856) 795-9887
lisa@trrlaw.com

Renae D. Steiner
Vincent J. Esades
Katherine T. Kelly
HEINS MILLS & OLSON, P.L.C.
310 Clifton Avenue
Minneapolis, MN 55403
Telephone: (612) 338-4605
Facsimile: (612) 338-4692
rsteiner@heinsmills.com
vesades@heinsmills.com
kkelly@heinsmills.com

David S. Anderson
ANDERSON, HELGEN, DAVIS AND NISSEN P.A.
333 South Seventh Street, Suite 310
Minneapolis, MN 55402
Telephone: (612) 435-6341
dsa@andersonhelgen.com