

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

STATE OF WISCONSIN
By Attorney General Brad D. Schimel

STATE OF ALABAMA
STATE OF ALASKA
STATE OF ARKANSAS
STATE OF CALIFORNIA
STATE OF COLORADO
DISTRICT OF COLUMBIA
STATE OF CONNECTICUT
STATE OF DELAWARE
STATE OF FLORIDA
STATE OF GEORGIA
STATE OF HAWAII
STATE OF IDAHO
STATE OF ILLINOIS
STATE OF IOWA
STATE OF KANSAS
COMMONWEALTH OF KENTUCKY
STATE OF LOUISIANA
STATE OF MAINE
STATE OF MARYLAND
COMMONWEALTH OF MASSACHUSETTS
STATE OF MICHIGAN
STATE OF MINNESOTA
STATE OF MISSISSIPPI
STATE OF MISSOURI
STATE OF NEBRASKA
STATE OF NEW HAMPSHIRE
STATE OF NEW MEXICO
STATE OF NEW YORK
STATE OF NORTH CAROLINA
STATE OF OHIO
STATE OF OKLAHOMA
STATE OF OREGON
COMMONWEALTH OF PENNSYLVANIA
STATE OF RHODE ISLAND
STATE OF SOUTH CAROLINA
STATE OF TENNESSEE
STATE OF UTAH
STATE OF VERMONT
COMMONWEALTH OF VIRGINIA
STATE OF WASHINGTON

No.2:16-CV-5073(MSG)

STATE OF WEST VIRGINIA

Plaintiffs,

v.

INDIVIOR INC. f/k/a RECKITT BENCKISER PHARMACEUTICALS, INC.;
RECKITT BENCKISER HEALTHCARE (UK) LTD.;
INDIVIOR PLC; and
MONOSOL RX, LLC

Defendants.

FIRST AMENDED COMPLAINT

The States of Wisconsin, Alabama, Alaska, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, Tennessee, Utah, Vermont, Washington, West Virginia, the Commonwealths of Kentucky, Massachusetts, Pennsylvania, and Virginia, and the District of Columbia, by their Attorneys General, (collectively “Plaintiff States”), complain against Defendants Indivior Inc., f/k/a Reckitt Benckiser Pharmaceuticals, Inc.; Reckitt Benckiser Healthcare (UK) LTD.; Indivior PLC (collectively “Reckitt” or “Reckitt Defendants”); and MonoSol Rx, LLC (“MonoSol”) as follows:

Nature of the Action

1. Plaintiff States bring this action with respect to the prescription drug Suboxone® (“Suboxone”) and its generic equivalent, co-formulated buprenorphine hydrochloride and naloxone hydrochloride dehydrate (“co-formulated buprenorphine/naloxone”).

2. Co-formulated buprenorphine/naloxone is a combination drug product consisting of two active pharmaceutical ingredients that are used together as an opioid replacement therapy for the treatment of opioid dependency (e.g., heroin addiction). Defendants are engaged in the manufacture or sale of co-formulated buprenorphine/naloxone under the brand-name Suboxone.

3. Plaintiff States allege that Defendants employed an unlawful, multi-pronged scheme designed to prevent or delay less expensive generic versions of Suboxone from entering the market to preserve their monopoly profits from the sale of Suboxone. The scheme included product hopping, unfounded allegations of safety issues with the Tablet form of Suboxone, intentional delays involving the U.S. Food and Drug Administration's (the "FDA") requirement of a Risk Evaluation and Mitigation Strategy ("REMS"), and filing a sham citizen petition to delay would-be competitors.

4. As a result of their unlawful scheme to keep generic versions of Suboxone off the market, and in violation of federal and state antitrust laws and state consumer-protection laws, Defendants illegally maintained monopoly power in the market for co-formulated buprenorphine/naloxone opioid treatments in the United States from October 8, 2009 until generic entry in March 2013, and continue to dominate the market for co-formulated buprenorphine/naloxone film.

5. Defendants' scheme to delay generic competition intended and had the purpose of, preventing generic substitution to Suboxone, and denying consumer choice for generic versions of Suboxone.

6. As a result of Defendants' anticompetitive conduct, consumers and state governments have been limited in their treatment options for opioid addiction and continue to be

deprived of the benefits of generic competition while Defendants continue to reap monopoly profits from the sale of Suboxone.

7. Defendants' conduct is deceptive and unconscionable, includes unfair trade practices and unfair methods of competition, or is otherwise unlawful under the antitrust and consumer protection laws of the Plaintiff States. Their conduct causes harm to Plaintiff States, governmental entities, and consumers by forcing them to pay more for Suboxone than they otherwise would in a competitive market, and limits their options for the treatment of opioid addiction.

8. Consequently the Plaintiff States, by and through their Attorneys General, bring this action to seek injunctive relief, penalties, and disgorgement for the Defendants' unlawful conspiracy and monopolization of the market for co-formulated buprenorphine/naloxone for treating opioid addiction.

Jurisdiction & Venue

9. This Court has subject matter jurisdiction under 15 U.S.C. §§ 1 and 2, 15 U.S.C. § 26, and 28 U.S.C. §§ 1331 and 1337 over the federal antitrust claims. This Court also has supplemental jurisdiction over the state law claims under 28 U.S.C. § 1367 because those claims are so related to the federal claims that they form part of the same case or controversy. The exercise of supplemental jurisdiction avoids unnecessary duplication and multiplicity of actions and is in the interests of judicial economy, convenience, and fairness.

10. Venue is proper in the Eastern District of Pennsylvania under 15 U.S.C. § 22 and 28 U.S.C. §§ 1391(b) and (c). Each Defendant transacts business or committed an illegal or tortious act in this district, or has an agent or can be found in this district, and the interstate trade and commerce, hereinafter described, is carried out in substantial part in this district.

Parties

11. Defendant Indivior Inc. f/k/a Reckitt Benckiser Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business located at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia 23235. Indivior Inc. is a wholly-owned subsidiary of Indivior PLC. Indivior Inc. is engaged in the development, manufacture, and sale of Suboxone throughout the United States, and is in whole or in part responsible for some or all of the conduct alleged in this Complaint and attributed to Reckitt.

12. Defendant Reckitt Benckiser Healthcare (UK) Ltd. 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 is engaged in the development and manufacture of pharmaceuticals, including Suboxone, and health care products and services made and sold subject to FDA approval, and is in whole or in part responsible for some or all of the conduct alleged in this Complaint and attributed to Reckitt. This conduct includes but is not limited to the execution of the initial contract with MonoSol Rx, LLC in December 2006 that initiated the joint venture to create and manufacture Suboxone Film. Reckitt Benckiser Healthcare (UK) Ltd. also established the parameters for the timing of the launch and the formulation of Suboxone film, gathers, and investigates all consumer complaints as to Suboxone products, trademarked the names for the financial programs to encourage the switch from Suboxone tablets to film, and obtained patents together with MonoSol related to Suboxone film development. Reckitt Benckiser Healthcare (UK) Ltd. monitored the taste and quality of Suboxone film, prepared materials for regulatory approval of Suboxone film, manufactured and supplied the ingredients for Suboxone film, and provided grants for the study of Suboxone.

13. Defendant Indivior 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 is engaged in the development, manufacture, and sale of Suboxone throughout the United States, and is in whole or in part responsible for some or all of the conduct alleged in this Complaint and attributed to Reckitt. Indivior PLC was formed in 2014 as a new company. Shortly thereafter, Reckitt Benckiser Group plc (“RB Group”) sold the assets of a collection of companies, including Defendant Indivior, Inc., from RB Group to Indivior PLC. By the terms of the sale, ownership of all assets and operations related to the production of Suboxone transferred to Indivior PLC. Additionally, RB Group shareholders received one share of stock in Indivior PLC for each share of RB Group stock that they owned. Indivior PLC has expressly agreed to indemnify RB Group in respect to any claims and expenses incurred by any company within the Indivior Group or the RB Group arising out of or associated with the Indivior business prior to the transfer. Indivior PLC holds itself out as the manufacturer of Suboxone, and describes itself as the successor company to Reckitt Benckiser Pharmaceuticals, Inc., which was the company that manufactured Suboxone during the period of time in which most of the relevant conduct occurred. Indivior PLC has current and former overlapping directors with Reckitt Benckiser Pharmaceuticals, Inc. and Indivior, Inc., and many of the individuals who participated in the conduct alleged herein are now employed by Indivior PLC. Indivior PLC, and Indivior Inc. completed work orders initially received by Reckitt Benckiser Pharmaceuticals, Inc. and inherited its customers. Unless identified individually, Reckitt Benckiser Healthcare (UK) Ltd., Indivior PLC, and Indivior, Inc., f/k/a Reckitt Benckiser Pharmaceuticals, Inc., are collectively referred to as “Reckitt.”

14. Defendant MonoSol Rx, LLC is a Delaware limited liability company with its principal place of business located at 6560 Melton Road, Portage, Indiana, 46368. This defendant is engaged in the development, manufacture, and sale of pharmaceuticals, including Suboxone, throughout the United States.

15. Reckitt's actions described in this Complaint are part, and in furtherance of, the illegal monopolization, attempted monopolization, conspiracy to monopolize, restraint of trade, and unfair and deceptive trade practices alleged herein. All actions described herein were authorized, ordered, or performed 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 with the actual, apparent, and ostensible authority of Reckitt.

16. MonoSol's actions described in this Complaint are part, and in furtherance of, the monopolization conspiracy and unfair and deceptive trade practices alleged herein. All actions described herein were authorized, ordered, or performed by MonoSol's various officers, agents, employees or other representatives while actively engaged in the management of MonoSol's affairs, or that of their predecessors-in-interest, within the course and scope of their duties and employment, and with the actual, apparent, and ostensible authority of MonoSol.

17. Government entities and consumers residing throughout the Plaintiff States purchased or provided reimbursement for Suboxone Film and Suboxone Tablets at supra-competitive prices as a result of Defendants' conduct alleged herein.

18. Plaintiff States bring this action, by and through their Attorneys General, in their sovereign and quasi-sovereign capacities to enforce their own laws and to protect the economic well-being of the States and their residents from the harm that results from the violations of law.

Relevant Market

19. The relevant product market is any drug with co-formulated buprenorphine/naloxone as the active ingredients for the treatment of opioid addiction. There are no feasible substitutes for co-formulated buprenorphine/naloxone in the pharmacological intervention of opioid dependence. This market includes Suboxone Film and Tablets and any AB-rated generics that can be substituted for them.

20. Suboxone Tablets and Suboxone Film do not exhibit significant, positive price cross-elasticity of demand with any opioid dependence treatment or other product other than AB-rated generic versions of buprenorphine/naloxone tablets. Suboxone is categorized as a schedule III drug and co-formulated with an opioid antagonist to deter abuse. Until 2013, Suboxone was the only replacement maintenance therapy that could be prescribed in an office setting and taken by patients at home. By contrast, Methadone, is a Schedule II drug and must be administered in a clinic. Subutex, another opioid treatment drug marketed by Reckitt, is not interchangeable because it lacks naloxone, the opioid antagonist that deters abuse. Zubsolv (a generic buprenorphine/naloxone tablet) and Bunavail (a generic buprenorphine/naloxone film) entered the market after generic Suboxone Tablets. Zubsolv and Bunavail are not AB-rated to the Film or Tablets.

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

22. Before October 8, 2009, Suboxone was the only co-formulated buprenorphine/naloxone opioid treatment because of its orphan drug status, so Reckitt enjoyed 100 percent market share in the United States and its territories. After the exclusivity period expired, Reckitt's branded Suboxone products, including the Suboxone Film it introduced in September 2010, remained the sole source of co-formulated buprenorphine/naloxone until two

generic manufacturers introduced generic tablets in March 2013. An additional generic tablet manufacturer was approved in September 2016. When Suboxone-branded Tablets and Film were sold alongside one another, Reckitt successfully converted most of the Suboxone market to its Film, for which there are no generic substitutes. After the introduction of the two generic tablet products in 2013, Reckitt's market share for co-formulated buprenorphine/naloxone dropped to 68 percent.

Trade and Commerce

23. Since 2002, Reckitt has sold Suboxone in interstate commerce throughout the United States.

24. Reckitt sold Suboxone in interstate commerce in each of the States. Reckitt's unlawful activities alleged in this Complaint occurred in and had a substantial effect upon interstate commerce. According to Reckitt's own annual reports, Reckitt's revenues for Suboxone sold in the United States surpassed \$2 billion.

25. MonoSol entered into a series of agreements with Reckitt, beginning in 2006, for the development and manufacture of Suboxone Film. MonoSol manufactures all Suboxone Film sold in interstate commerce in each of the States. MonoSol's unlawful activities alleged in this Complaint have occurred in and have had a substantial effect on interstate commerce. MonoSol has received fixed payments as well as royalties associated with the sales of Suboxone Film.

Factual Background

I. Generic Drug Approval Process

26. The manufacture and commercial sale of pharmaceutical drugs are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. The manufacturer of a new drug must submit a new drug application ("NDA") that demonstrates,

among other things, a drug's safety, clinically proven effectiveness, composition, and patent coverage.

27. To speed the entry of generic drugs and to facilitate price competition with branded drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"). Under the Hatch-Waxman Act, generic drug manufacturers may receive FDA approval for generic drugs without replicating the costly and time-consuming clinical trials involved in an NDA.

28. Instead of submitting an NDA, a generic drug manufacturer may submit an abbreviated new drug application ("ANDA") and incorporate data, such as clinical studies, that the NDA filer submitted to the FDA.

29. To be approved, an ANDA must demonstrate that the generic drug: (a) has the same active ingredients as; (b) is pharmaceutically equivalent to (same dosage form and strength); and (c) is bioequivalent to (exhibiting the same drug absorption characteristics) the previously approved drug.

30. Oral drugs that are proven to be both pharmaceutically equivalent and bioequivalent to a branded oral drug receive an "AB" rating from the FDA, indicating they are therapeutically equivalent to other drugs with the same rating in the same category. In most circumstances, only oral drugs that carry the FDA's AB generic rating in a particular category may be substituted by pharmacists for a physician's prescription for a brand-name drug without the physician's approval.

31. The FDA publishes a list of all approved drugs and therapeutic equivalents in the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the "Orange Book").

32. Once the FDA approves an ANDA for a generic drug and determines that it is AB-rated to the branded drug, state laws govern how the generic may be substituted for the brand name drug prescribed by physicians. In most States and under most health plans, a pharmacist may (and often must) substitute an AB-rated generic drug for a prescribed brand name drug.

II. Suboxone's Orphan Drug Designation

33. In 2002, Reckitt introduced Suboxone as a sublingual tablet ("Suboxone Tablets"). At that time, the two component ingredients of Suboxone were not subject to any patent protection. Naloxone was first approved by the FDA in 1971, and buprenorphine was first approved by the FDA in 1982 as an injectable analgesic drug. Reckitt acknowledged that it had no knowledge of any existing patent protection for Suboxone Tablets at the time of its FDA application.

34. Instead of exclusivity through patent protection, Reckitt's Suboxone Tablets were granted a 7-year period of exclusivity as an "orphan drug" by the FDA.

35. A drug can be designated as an "orphan drug" when the FDA determines that either (a) the drug is intended for the safe and effective treatment, diagnosis or prevention of a rare disease or disorder that affects fewer than 200,000 people in the United States; or (b) the disease or disorder affects greater than 200,000 people, but the manufacturer is not reasonably expected to recover the costs of developing and marketing the treatment drug from sales in the United States.

36. Reckitt argued that its drug Suboxone would be used for the treatment of fewer than 200,000 people, but the FDA rejected that argument. Instead, the FDA granted orphan drug status to Suboxone Tablets based on Reckitt's representations that it would be unlikely to recover

the costs of developing and marketing the drug. After designation as an orphan drug by the FDA, the FDA approves the drug for marketing. It is then eligible for a period of orphan drug regulatory exclusivity for 7 years, allowing it to be marketed as a brand-name drug, free from generic competition.

37. Suboxone was designated as an orphan drug in 1994, but was not approved for 7-year marketing exclusivity until 2002. Reckitt's 7-year exclusivity expired on October 8, 2009. During that time, Reckitt was able to market sublingual tablet Suboxone without any threat of competition from any generic co-formulated buprenorphine/naloxone for the treatment of opioid addiction.

38. Although Reckitt secured an orphan drug designation for Suboxone Tablets on the basis of a cost recovery designation, Reckitt quickly began earning profits on Suboxone Tablets, earning more than \$2 billion by 2010. Its successor in interest, Indivior Inc., derived almost all of its revenue from the sales of Suboxone.

III. Reckitt's Product-Hopping Scheme

A. Suboxone Tablet Market Share Threatened by Generic Entry

39. As the orphan drug exclusivity period for Suboxone Tablets neared expiration, Reckitt knew generic manufacturers would seek FDA approval to sell lower-priced generic versions of co-formulated buprenorphine/naloxone in direct competition to Suboxone Tablets.

40. As AB-rated generic drugs become available, lower-priced generic competitors are rapidly substituted for their brand-name counterparts because the Hatch-Waxman Act and most state drug product selection laws permit (or require) pharmacists to substitute an AB-rated generic drug for the branded version unless the prescription is specifically designated otherwise.

41. Manufacturers of brand-name drugs typically lose 80 percent or more of their sales to AB-rated generic competition soon after a generic competitor enters the market. Until an AB-rated generic becomes FDA approved, however, a branded manufacturer may continue to charge supra-competitive prices.

42. Reckitt was concerned that generic entry would significantly reduce the company's sales and revenue of its Suboxone Tablets. In its annual reports between 2008 and 2010, Reckitt stated:

- “As with all prescription drugs, the protection of this business has a finite term unless replaced with new treatments or forms. Therefore, the revenue and income of this business may not be sustained going forward unless replaced with new treatments or forms, on which the Company is actively working.”
- “The Group continues to search for ways to offset the impact of the loss of exclusivity [of Suboxone] in the USA at the end of September 2009, up to 80% of the revenues and profits of that business might be lost to generic competition in 2010, with the possibility of further erosion thereafter.”
- “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.”
- “The expiry of the Group's exclusive license for Suboxone in the United States in 2009 and in the rest of the world in 2016 could expose the business to competition from generic variants.”

43. FDA regulations allow branded manufacturers to seek FDA approval to modify the dosage form and strength of their existing products. Changing the dosage form and strength

of a branded drug changes its pharmaceutical equivalence and will alter the AB-rating of any proposed or available generic substitutes.

44. [REDACTED]

[REDACTED]

45. Faced with the impending loss of exclusivity and related drops in profit, [REDACTED]

[REDACTED]

B. Suboxone Film Enters the Market

46. In July 2007, Reckitt informed the FDA that it planned to file a new drug application to market Suboxone in a sublingual Film. [REDACTED]

[REDACTED]

47. [REDACTED]

[REDACTED]

48. MonoSol encouraged Reckitt and other pharmaceutical companies to engage in illegal and anticompetitive product-hopping on its website:

- “Patient-friendly delivery with no generic substitution”
- “Partnering with MonoSol Rx offers pharmaceutical companies the ability to introduce products that are highly differentiated from other dosage forms, both in performance and marketability, creating fresh, dynamic revenue-generating opportunities.”
- Mock quote used in advertisement: “We launched this brand 5 years ago. We’re not just letting it go over the cliff. It’s time for the new strategy.”
- “PharmFilm formulations represent revenue-life cycle extensions for products with patent lives that have expired or are approaching expiration.”
- “If patient-friendly delivery, patent expiry, or launching the next blockbuster is on your agenda, the time is right to consider the advantages of PharmFilm.”
- “Because PharmFilm is a unique, patent-protected delivery technology, it can be an ideal strategy for extending the life of a brand as generic incursion approaches.”
- “PharmFilm drug technology allows: no generic substitution.”

49. 


50. Reckitt and MonoSol’s development of the new sublingual Film was intended to thwart generic entry, and to maintain Suboxone’s market share by extending Reckitt’s exclusivity on a co-formulated buprenorphine/naloxone product.

51. In April 2008, MonoSol applied for a patent, which was issued as patent number 8,017,150 entitled “Polyethylene Oxide-Based Films and Drug Delivery Systems Made Therefrom” and was listed by Reckitt in the FDA’s Orange Book.

52. Reckitt listed the ‘150 patent as well as patent numbers 8,475,832, and 8,603,514 in the FDA Orange Book, and alleged that they cover Suboxone Film. The earliest patent expires in 2023, and all are the subject of several lawsuits brought by MonoSol and Reckitt against the many companies that sought FDA approval to make generic Suboxone Film. These patents are also the subject of multiple inter-partes proceedings challenging their validity. Reckitt and MonoSol have also sued their potential Suboxone Film rivals for infringement on two additional patents, patent numbers 8,900,497, and 8,906,277, which were not listed in the Orange Book. The U.S. District Court of Delaware has invalidated the ‘832 patent.

53. [REDACTED]

54. Throughout the Suboxone Film development process, MonoSol was aware that the timing of both FDA approval and final product development was crucial to bring the Suboxone Film to market prior to the entry of generic co-formulated buprenorphine/naloxone tablets. MonoSol actively strategized with Reckitt to minimize various manufacturing delays to beat the generic tablets to market.

55. On October 20, 2008, Reckitt submitted NDA 022410 to the FDA to market the sublingual Film version of Suboxone, which was received by the FDA on October 21, 2008. Because Suboxone Film is in a different dosage form than Suboxone Tablets, the two are not pharmaceutically equivalent.

56. Without pharmaceutical equivalency, drugs cannot be AB-rated substitutes for one another. Thus, any tablet form of generic co-formulated buprenorphine/naloxone would not be an AB-rated generic substitute for Suboxone Film, and typically a pharmacist may not automatically provide a patient with generic co-formulated buprenorphine/naloxone tablets when presented with a prescription for Suboxone Film.

57. On August 21, 2009, less than two months before the October 2009 expiration of exclusivity on the tablet formulation, the FDA rejected Reckitt's application to market Suboxone Film due to concerns that the Film could be abused by patients or others and could result in accidental exposure to children.

58. The Food and Drug Administration Amendments Act of 2007 gives the FDA the authority to require a Risk Evaluation and Mitigation Strategy ("REMS"), which is a document submitted by the manufacturer that contains a risk management plan or risk-minimization strategy that goes beyond the professional labeling to ensure that the benefits of a drug outweigh the risks.

59. In response to the FDA's rejection of the Suboxone Film application, Reckitt submitted a revised REMS to the FDA to address safety concerns related to the Film form.

60. The FDA approved Reckitt's NDA for Suboxone Film on August 30, 2010.

61. MonoSol remained active in the NDA-approval process and committed to doing everything possible to enable FDA approval as quickly as possible, [REDACTED]

[REDACTED]

62. Reckitt's Film offers no significant actual benefits for patients over its Tablet. FDA approval of Suboxone Film was based on the studies Reckitt used to establish safety and efficacy of the Tablets, and Reckitt's representation that the Film had sufficient equivalent

bioavailability to the Tablets. The FDA confirmed that Reckitt's NDA contained no new efficacy studies. In fact, Reckitt even represented to the FDA that any differences between the two formulations were "clinically insignificant." Until August 2012, the dosage strengths of the two Suboxone products were identical.

63. The most important factor identified by Reckitt in bringing Suboxone Film to market was avoiding competition from generic entrants.

64. Suboxone Film has disadvantages compared to Suboxone Tablets:

- Film is easier to conceal and smuggle into jails and prisons;
- Increased naloxone bioavailability in the Film version, increasing the risk of unwanted opioid withdrawal symptoms;
- Film's rapid dissolution creates barriers to removal if accidentally ingested.
- Film is more dangerous because less unpleasant taste compared to Tablets, making children less likely to spit it out;
- Film is more likely to become stuck on the tongue if accidentally ingested by a child;
- Film's increased strength of 12mg increased dosage exposure to children;

65. The FDA found that Suboxone Film had no demonstrable safety advantage over Suboxone Tablets. The FDA also concluded that the studies Reckitt offered to the contrary were flawed, stating:

- "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 safety exams, inconsistent

recording of findings, treatment of participants with dosing regimens not recommended in the proposed labeling, and a high drop-out rate;”

- “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;” and
- “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.”

66. Furthermore, the FDA expressed concerns that the Suboxone Film actually presented increased safety issues: “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.” This concern was based upon the fact that once in the mouth, the Suboxone Film hydrates into a gel in 30 seconds and is completely absorbed in 3 minutes, releasing all of the buprenorphine contained in the Film. Suboxone Tablets, however, may take up to 10 minutes to fully dissolve. Many children who accidentally ingest Suboxone Tablets spit them out quickly, but even when they do succeed in swallowing the Tablets, the buprenorphine is absorbed to a far lesser extent in the tablet formulation than in the Film. These factors make Suboxone Tablets potentially less dangerous than Film in accidental pediatric exposure.

67. The FDA also noted the possible increase of potential for abuse with the Film; that the Film is both easier to conceal or divert, and that it is easier to dissolve and inject. "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." In fact, almost 6,000 Suboxone Film strips (46 percent of those dispensed to study subjects) were "missing" after the limited clinical studies performed by Reckitt to gain FDA approval.

68. Reckitt is aware of the advantages that Suboxone Tablets have over Suboxone Film, as evidenced by the fact that Reckitt markets Suboxone exclusively in tablet form in almost all of the countries where it is sold. This continues to be true even after Reckitt removed the Tablets from the U.S. market. For instance, Reckitt is currently applying to sell Suboxone Tablets in China, rather than in the Film.

C. Reckitt Converts the Market From Tablets to Film

69. Reckitt's reformulation, as devised by MonoSol, was designed for the purpose of defeating the AB-rated substitutability that generic co-formulated buprenorphine/naloxone tablets would enjoy once Suboxone's orphan drug exclusivity period expired October 8, 2009.

70. [REDACTED]

[REDACTED]

71. [REDACTED]

[REDACTED]

72. To complete their plan to extend Suboxone's exclusivity by the patent protection claimed for the Film, Reckitt then engaged in a multi-faceted campaign to convert the co-formulated buprenorphine/naloxone market to Suboxone Film.

73. Reckitt purposefully based its campaign to convert the market on unfounded safety concerns about the Tablets, including concerns regarding accidental exposure to children. These concerns were a sham developed to convince prescribers and payors that the Suboxone Film provided increased safety and efficacy over the Tablets. [REDACTED]

[REDACTED]

74. Reckitt communicated to the public and to the medical community that single-dose or unit-dose packaging was necessary to prevent potential exposure to multiple doses in the case of accidental pediatric exposure. Reckitt then began marketing Suboxone Film in unit-dose packaging.

75. Reckitt partnered with consulting firm Venebio Group, LLC to develop its “Film is safer” platform. Venebio’s website states that the project “evaluated effectiveness of innovative pharmaceutical packaging in reducing pediatric exposure.” [REDACTED]

[REDACTED]

76. Reckitt’s Suboxone Tablets have been sold in unit-dose packaging outside of the United States since 2005. Reckitt did not make any attempt to convert its tablet packaging to unit-dose packaging in the United States. Rather, despite its claimed safety concerns, Reckitt continued to sell Tablets in multi-unit bottles, contrary to its practices in other countries, until it withdrew its Tablets from the United States market upon the entry of generic versions.

77. Reckitt began a multi-front offensive to drive the Film to market before the generics could enter with their version of the Suboxone Tablet. [REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

78. [REDACTED]

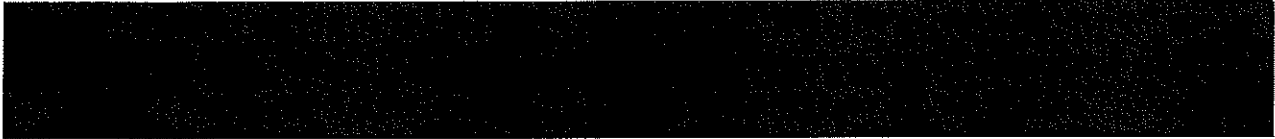
79. [REDACTED]

80. [REDACTED]

81. In September 2012, Reckitt issued a press release advising the public and prescribing physicians that Reckitt intended to withdraw the Tablets from the market within the next six months. Reckitt's press release falsely stated that the withdrawal was due to the "pediatric exposure safety issue." Reckitt was aware that its assertions of pediatric safety concerns regarding the Tablet formulation were unfounded.

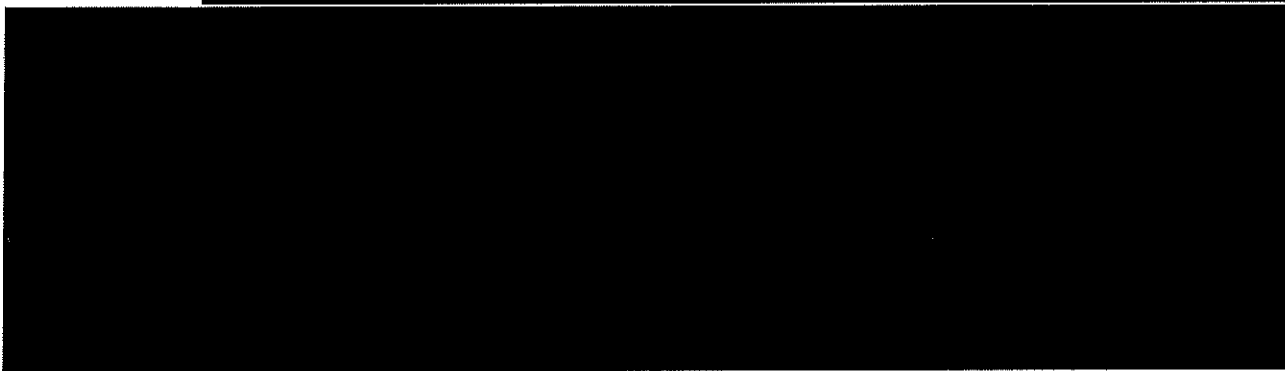
82. Reckitt also sought a declaration from the FDA that Suboxone Tablets were being voluntarily pulled from the market by Reckitt due to safety issues.

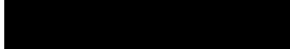
83. As another part of its plan to convert the market from Tablets to Film, Reckitt utilized a patient assistance program called "Here to Help," that provided qualified individuals with free or low-cost drugs. [REDACTED]

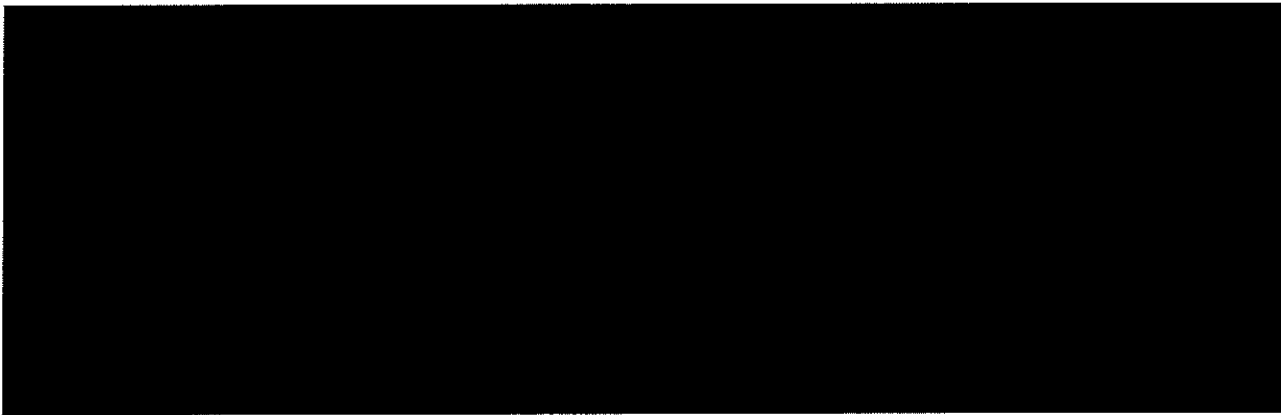


84. Finally, Reckitt induced conversion of the market to the Film by raising the price of its Suboxone Tablets before the introduction of the AB-rated generic tablet product into the market. As a result, the Film was initially cheaper than the branded tablets. Reckitt also developed programs that provided discounts and rebates to consumers who purchased the Film.

85. 



86. Reckitt engaged in each of these actions with the purpose of converting the prescription market for Suboxone from Tablets to the Film to thwart generic competition once AB-rated generic substitutes became available for Suboxone Tablets. 



87. Reckitt's product-hopping scheme was successful. By mid-2012, the Film accounted for over 70 percent of Suboxone prescriptions, and by the time the generic tablets

received FDA approval in February 2013, 85 percent of Suboxone prescriptions were written for the Film instead of for Suboxone Tablets.

88. Reckitt withdrew Suboxone Tablets from the market on March 18, 2013.

IV. Reckitt Delays Generic Entry

89. ANDAs for approval to sell generic Suboxone were filed in 2009. Although the orphan drug exclusivity period on branded Suboxone Tablets expired on October 8, 2009, generic buprenorphine/naloxone tablets did not gain FDA approval until February 2013. This delay was due in large part to Reckitt's tactics, which were intended to delay generic entry while Reckitt continued and completed its product-hopping scheme.

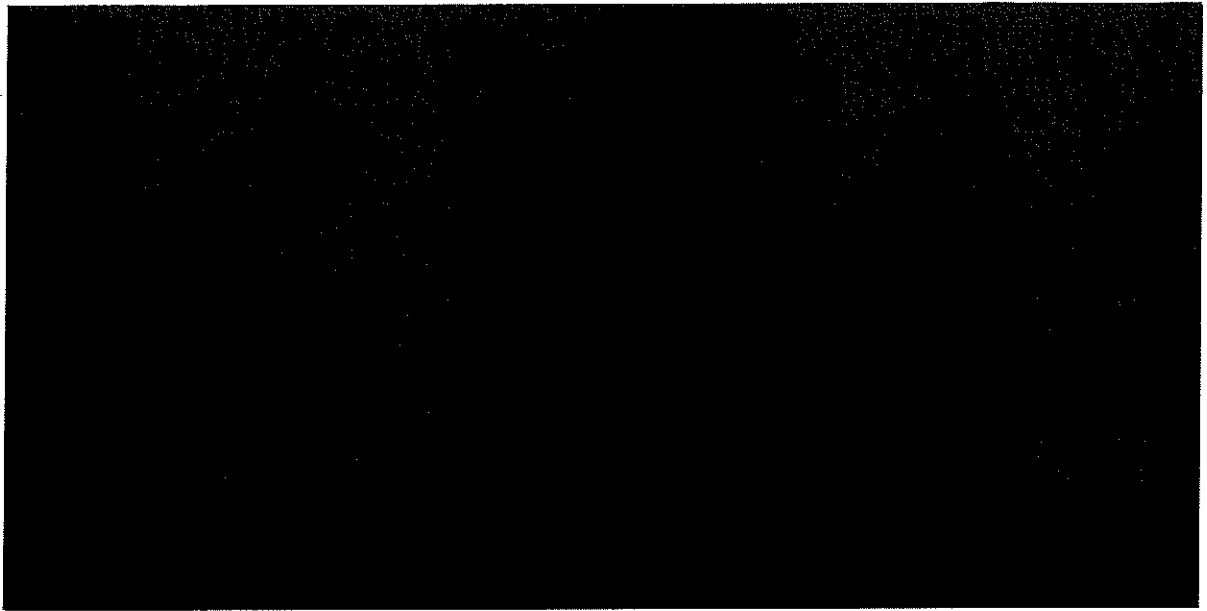
90. In late 2011, while certain potential generic competitors (referred to collectively as "Buprenorphine Products Manufacturers Group") were awaiting FDA approval of their ANDAs for generic co-formulated buprenorphine/naloxone tablets, Reckitt submitted a REMS for Suboxone Tablets, which was approved by the FDA in December 2011.

91. On January 6, 2012, the FDA ordered Reckitt to cooperate with the Buprenorphine Products Manufacturers Group in a shared REMS. Shared REMS are utilized like individual REMS—to address safety concerns of pharmaceutical products. When multiple manufacturers are marketing a generic product that is an AB-rated substitute for a reference drug, the FDA requires that the manufacturers work together to submit a shared REMS. The companies' filing ANDAs and comprising the Buprenorphine Products Manufacturers Group were Actavis, Inc.; Amneal Pharmaceuticals LLC; Ethypharm USA Corp.; Mylan Inc.; Roxane Laboratories Inc.; Sandoz Inc.; Sun Pharmaceuticals Industries, Ltd; and Teva Pharmaceuticals USA, Inc.

92. Approved NDA holders must participate in a shared REMS process with ANDA applicants, and NDA holders may not use safety concerns to block or delay ANDA approval under 21 U.S.C. § 355-1(f).

93. Although Reckitt's Suboxone Tablet REMS was only approved by the FDA in December 2011, Reckitt did not cooperate with the generic manufacturers in the finalization and submission of a shared REMS. Reckitt also did not indicate outright that it refused to participate in the shared REMS process. Instead, Reckitt engaged in multiple delay tactics and made misleading statements to conceal its true intent, which was to prolong the approval of the ANDAs for generic Suboxone Tablets.

94. 

95. Reckitt falsely represented to the FDA and the Buprenorphine Products Manufacturers Group that it would cooperate. Reckitt never intended to participate in a single shared REMS program with the generic manufacturers, engaging in the process for the sole purpose of delaying generic approval.

96. Because the FDA could not approve the ANDA applications without an approved REMS, Reckitt's refusal to cooperate was intended to and did in fact delay generic entry past the date when entry otherwise would have occurred.

97. Reckitt's refusal to cooperate successfully delayed submission of the shared REMS until August of 2012, when the generic ANDA filers finally obtained an unprecedented waiver allowing them to submit a shared REMS program of their own without Reckitt's cooperation. Absent such delay tactics, the shared REMS program would have been completed no later than May 6, 2012.

98. Reckitt knew that once the FDA approved the ANDAs, generic Suboxone Tablets would become available and immediately substitutable for branded Suboxone Tablets. To gain

more time to complete its product hop scheme, Reckitt engaged in another delay tactic by filing a citizen petition with the FDA.

99. Under § 505(q) of the Food, Drug and Cosmetic Act, any individual may submit a petition, commonly known as a “citizen petition,” asking the FDA take, or refrain from taking, certain administrative action. Citizen petitions are commonly used to express concerns about the safety or legality of a product.

100. The FDA is granted a 150-day period to respond to each citizen petition under 21 C.F.R. § 10.30.

101. During the 150-day period, FDA approval of any ANDA pending for a product that is the subject of the citizen petition is typically delayed. Although 21 U.S.C. § 355(q)(1)(A) provides that the Secretary “shall not delay approval” of a pending ANDA, subpart (ii) requires that “the Secretary, upon reviewing the petition,” must determine whether a further delay is necessary to protect public health. Thus, the filing of a citizen petition in and of itself creates a delay insofar as the FDA must actually review the allegations made in the petition, enabling brand-name manufacturers to file a baseless citizen petition to prolong their monopoly on a particular branded drug. This abuse of the petition process has been repeatedly acknowledged by FDA officials.

102. On September 25, 2012, Reckitt filed a citizen petition asking the FDA to withhold approval of the ANDAs for generic Suboxone Tablets unless: (1) the ANDA contained a targeted pediatric exposure education program; (2) the ANDA product had child-resistant unit-dose packaging; and (3) the FDA had determined whether Reckitt had discontinued Suboxone Tablets for safety reasons.

103. In the same week that it filed the citizen petition, Reckitt announced its intent to permanently withdraw Suboxone Tablets from the market for purported safety reasons even though the FDA stated that it could not determine whether the Film was safer, and that the cause for any alleged decline in unintended pediatric exposures to the Film was unverified.

104. Reckitt did not disclose these alleged safety concerns about Suboxone Tablets to the generic manufacturers during the shared REMS negotiation process, and refused to engage in any meaningful way with the generics during that process even after being ordered to do so by the FDA. In fact, Reckitt used information gained from the generic manufacturers through the shared REMS negotiation to form its citizen petition and time its filing to increase delay.

105. The same alleged safety concerns raised in its citizen petition regarding the generic manufacturers' tablet product was dismissed by Reckitt less than a month prior with regard to its own Suboxone Tablets. Specifically, on August 30, 2012 Reckitt represented to the FDA in a combined REMS assessment that its tablet REMS was successful and needed no further changes. In fact, Reckitt considered and rejected converting its Suboxone Tablets to unit-dose packaging for pediatric safety reasons as early as February 2008.

106. [REDACTED]

107. [REDACTED]

108. The FDA ultimately denied Reckitt's citizen petition on February 22, 2013, noting that it was not supported by evidence and was inconsistent with Reckitt's own behavior. The FDA also said that it did not have the authority to issue some of the relief requested by Reckitt. The FDA acknowledged in its ruling that it had no authority to grant Reckitt's request to have Suboxone ANDAs contain targeted pediatric exposure program because the labeling for an ANDA must be the same as the labeling for the approved listed drug, pursuant to 21 U.S.C. § 355(j)(2)(A)(v) and (4)(G).

109. The FDA further stated in its denial that the close proximity of Reckitt's withdrawal of Suboxone Tablets to the "period in which generic competition for this product was expected to begin cannot be ignored."

110. The FDA referred Reckitt's conduct to the FTC for antitrust investigation.

111. Reckitt's baseless citizen petition did, in fact, delay the approval of the pending ANDAs—even though the FDA ultimately determined that a further delay was not necessary to protect public health—due to the passage of the 150-day period allowed for the FDA to review the petition under 21 U.S.C. § 355(q)(1)(A)(ii).

112. 


113. Reckitt's conduct in submitting and pursuing the baseless citizen petition had the intended effect of delaying FDA approval of the pending ANDAs and the entry of generic competition for co-formulated buprenorphine/naloxone tablets. But for Reckitt's baseless citizen petition, coupled with its dilatory and deceptive conduct with regard to the shared REMS that

caused the generic group's REMS approval to be delayed, competitors would have marketed generic co-formulated buprenorphine/naloxone tablets before they actually did.

114. On February 22, 2013, the FDA granted the generics-only, waiver-based REMS and approved Amneal and Activis' ANDAs for tablet sales.

115. On March 6, 2013, generic co-formulated buprenorphine/naloxone tablets entered the market. By that time, Reckitt had successfully converted the vast majority of co-formulated buprenorphine/naloxone prescriptions being written in the United States from its branded Suboxone Tablet to the patent-protected Film, for which the newly approved generic competitors are not AB-rated substitutes.

Effects on Competition

116. Generic versions of brand-name drugs are typically priced significantly lower than the brand-name versions. As AB-rated generic competition enters the market for a particular drug, the brand-name versions are quickly replaced by the lower-priced generics. Under most state laws, this generic substitution occurs automatically, unless the prescribing physician has indicated that the brand-name product must be "dispensed as written."

117. The introduction of generic competition results in significant losses in profit for the brand-name manufacturers as consumers are switched to the lower-priced generics and the brand-name drug is no longer able to command a higher price. Conversely, the longer a branded manufacturer is able to delay the entry of generic competition to the market, the longer it can continue to charge supra-competitive prices profitably without losing all or a substantial portion of its brand-name sales.

118. Reckitt's conspiracy with MonoSol and its acts, practices, and scheme described herein were for the purposes of, and had the effect of, restraining competition unreasonably by

preventing the entry of generic co-formulated buprenorphine/naloxone and destroying the market for the tablet formulation by the time the generic competitors gained FDA approval.

119. But for Reckitt and MonoSol's illegal conduct, generic competition to Suboxone Tablets would have been available after orphan exclusivity expired in October, 2009. Thus, Defendants' conduct delayed and prevented the savings that Suboxone purchasers would have enjoyed from that point until present date.

120. By causing a hard product switch, Reckitt avoided, and continues to avoid, automatic substitution of AB-rated generics under state generic substitution laws and, therefore, has limited, and continues to limit, competition with generic substitutes for Suboxone Tablets.

121. Had generic competition to Suboxone Tablets entered the market earlier—and not been delayed while Defendants converted the market to Suboxone Film—government entities and consumers would have substituted lower-priced generic Suboxone Tablets for the higher-priced branded Suboxone Tablets, and would have paid lower prices for some or all of their branded Suboxone purchases.

122. Reckitt's anticompetitive scheme to delay FDA approval of generic Suboxone Tablets while converting the Suboxone market to its patent-protected Suboxone Film unlawfully enabled, and continues to enable, Reckitt to sell Suboxone at supra-competitive prices, and allowed, and continues to allow, Reckitt and MonoSol to enjoy ill-gotten gains from the sales of Suboxone Film and branded Tablets, while Suboxone tablets were on the market.

123. By delaying generic competitors' entry into the market, Reckitt and MonoSol have deprived Plaintiff States, government entities, and consumers the benefits of competition in violation of the federal and state antitrust laws, consumer protection laws, and unfair competition statutes.

Injury

124. As a direct and proximate result of the unlawful conduct alleged above, government entities and consumers in Plaintiff States were not and are not able to purchase, or pay reimbursements for purchases of co-formulated buprenorphine/naloxone at prices determined by a market unhindered by the impact of Defendants' anticompetitive behavior. Instead, they have been and continue to be forced to pay artificially high monopoly prices. Consequently, they have suffered substantial injury in their business and property, and have suffered harms to their general economies in that, *inter alia*, they have paid more and continue to pay more for co-formulated buprenorphine/naloxone than they would have paid in a competitive market.

125. As a direct and proximate result of the unlawful conduct alleged above, the general economies of the States have sustained injury and the Plaintiff States are threatened with continuing injury to their business and property unless Reckitt and MonoSol are enjoined from this unlawful conduct.

126. As a direct and proximate result of the unlawful conduct alleged above, Reckitt and MonoSol have unjustly profited through inflated profit margins and will continue to do so.

127. Reckitt's unlawful conduct is continuing and will continue unless the injunctive and equitable relief requested by the Plaintiff States is granted.

128. MonoSol's unlawful conduct is continuing and will continue unless the injunctive and equitable relief requested by the Plaintiff States is granted.

129. Plaintiff States do not have an adequate remedy at law.

130. All conditions precedent necessary to the filing of this action have been fulfilled, waived or excused.

Count I: Monopolization under Sherman Act § 2 Against Reckitt Defendants

131. The preceding paragraphs are incorporated as if set forth herein.

132. From 2002 until the present, Indivior Inc., f/k/a Reckitt Benckiser Pharmaceuticals Inc., now wholly owned by Indivior PLC; Indivior PLC, as alleged above, a successor company to Reckitt Benckiser Pharmaceuticals Inc.; and Reckitt Benckiser Healthcare (UK) Ltd., (as described above, collectively referred to as “Reckitt”) have possessed monopoly power in the relevant market of co-formulated buprenorphine/naloxone in the United States as owners or licensees to use Suboxone intellectual property, or their role in the development, manufacture, and sale of Suboxone.

133. The relevant product market is any drug with co-formulated buprenorphine/naloxone as the active ingredients for the treatment of opioid addiction. This market includes Suboxone Film and Tablets and any AB-rated generics that can be substituted for them.

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

135. The conspiracy substantially affected and still affects interstate commerce.

136. Reckitt willfully and unlawfully maintained its monopoly power by engaging in exclusionary conduct which had the intent, purpose, and effect of illegally preventing and blocking competition in the United States co-formulated buprenorphine/naloxone market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

137. Beginning in 2002, Reckitt engaged in exclusionary conduct including, but not limited to: devising and implementing an anti-generic strategy by intentionally causing delays to FDA approval of ANDAs for generic co-formulated buprenorphine/naloxone, filing a baseless citizen petition to delay ANDA approval, and alleging unfounded concerns regarding the safety

of the generic product while engaging in a campaign to convert the co-formulated buprenorphine/naloxone market from tablet formulations to their patent-protected Film.

138. As a direct and proximate result of Reckitt's exclusionary scheme, Plaintiff States have suffered harm to their general economies because government entities and consumers have had to purchase Suboxone at supra-competitive prices without the reasonable availability of a lower-priced generic alternative, and Reckitt has enjoyed ill-gotten gains from the sales of Suboxone Film and Tablets.

Count II: Attempted Monopolization Under Sherman Act § 2 Against Reckitt Defendants

139. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

140. The relevant product market is any drug with co-formulated buprenorphine/naloxone as the active ingredients for the treatment of opioid addiction. This market includes Suboxone Film and Tablets and any AB-rated generics that can be substituted for them.

141. Reckitt, through its overarching anticompetitive scheme, specifically intended to maintain its pre-existing monopoly power in the relevant market. It was Reckitt's conscious objective to control prices or to exclude competition in the relevant market.

142. The natural, intended and foreseeable consequence of Reckitt's overarching anticompetitive scheme was to control prices and exclude competition in the relevant market.

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

144. As a direct and proximate result of Reckitt's exclusionary scheme, Plaintiff States have suffered harm to their general economies because government entities and consumers have had to purchase Suboxone at supra-competitive prices without the reasonable availability of a lower-priced generic alternative, and Reckitt has enjoyed ill-gotten gains from the sales of Suboxone Film and Tablets.

Count III: Conspiracy to Monopolize under Sherman Act § 2 Against All Defendants

145. The preceding paragraphs are incorporated as if set forth herein.

146. The relevant product market is any drug with co-formulated buprenorphine/naloxone as the active ingredients for the treatment of opioid addiction. This market includes Suboxone Film and Tablets and any AB-rated generics that can be substituted for them.

147. The relevant product market is the United States and its territories.

148. The conspiracy substantially affected and still affects interstate commerce.

149. Defendants Reckitt and MonoSol conspired to monopolize and did unlawfully monopolize the relevant market for co-formulated buprenorphine/naloxone products in the United States, thereby violating Section 2 of the Sherman Act, 15 U.S.C. § 2.

150. Defendants Reckitt Benckiser Healthcare UK, Ltd. and MonoSol entered into a development agreement whereby MonoSol granted Reckitt the right to use its patented sublingual film technology to manufacture Suboxone in a film version.

151. Defendant MonoSol marketed itself specifically to companies looking to extend their period of exclusivity in an illegal and anticompetitive manner.

152. Defendants Reckitt and MonoSol entered into the agreement with the specific intent and for the purpose of extending Reckitt's monopoly power, which was due to expire at

the end of Reckitt's FDA-granted "orphan status" period, and for the purpose of preventing generic competition with its branded product.

153. Defendants have acted in concert to willfully and unlawfully maintain Reckitt's monopoly power in the relevant market for co-formulated buprenorphine/naloxone drugs in the United States by engaging in unlawful exclusionary conduct, which had the purpose and effect of unreasonably restraining competition.

154. Defendants Reckitt and MonoSol engaged in their conspiracy with the specific intent to prevent generic competition in the United States co-formulated buprenorphine/naloxone market.

155. Defendant Reckitt had the specific intent to monopolize the Suboxone market when it conspired with and utilized MonoSol's services to extend its monopoly power through the use of sublingual film because this technology would not allow automatic retail generic substitution for Suboxone Tablets.

156. Defendant Reckitt committed a series of acts in furtherance of the conspiracy, including, but not limited to: devising and implementing an anti-generic strategy by intentionally causing delays to FDA approval of ANDAs for generic co-formulated buprenorphine/naloxone, filing a baseless citizen petition to delay ANDA approval, alleging unfounded concerns regarding the safety of the generic product while engaging in a campaign to convert the co-formulated buprenorphine/naloxone market from tablet formulations to its patent-protected Film, and ultimately announcing the withdrawal of Suboxone Tablets from the market.

157. The Defendants' conspiracy created a realistic threat to competition in the United States co-formulated buprenorphine/naloxone market.

158. As a direct and proximate result of Reckitt and MonoSol's conspiracy, Plaintiff States have suffered harm to their general economies because government entities and consumers have had to purchase Suboxone at supra-competitive prices without the reasonable availability of a lower-priced generic alternative, and Reckitt and MonoSol have enjoyed ill-gotten gains from the sales of Suboxone Film and Tablets.

Count IV: Illegal Restraint of Trade under Sherman Act § 1 Against All Defendants

159. The preceding paragraphs are incorporated as if set forth herein.

160. The relevant product market is any drug with co-formulated buprenorphine/naloxone as the active ingredients for the treatment of opioid addiction. This market includes Suboxone Film and Tablets and any AB-rated generics that can be substituted for them.

161. From 2006 to the present, the Reckitt Defendants entered into and maintained a contract, combination, or conspiracy with MonoSol to restrain trade in the U.S. market for co-formulated buprenorphine/naloxone drugs, and thereby violated Section 1 of the Sherman Act, 15 U.S.C. § 1.

162. From 2006 to the present, MonoSol entered into and maintained a contract, combination, or conspiracy with the Reckitt Defendants to restrain trade in the U.S. market for co-formulated buprenorphine/naloxone drugs, and thereby violated Section 1 of the Sherman Act, 15 U.S.C. § 1.

163. The contract, combination or conspiracy substantially affected and still affects interstate commerce.

164. As a direct and proximate result of Reckitt and MonoSol's scheme, Plaintiff States have suffered harm to their general economies because government entities and consumers

have had to purchase Suboxone at supra-competitive prices without the reasonable availability of a lower-priced generic alternative, and Reckitt and MonoSol have enjoyed ill-gotten gains from the sales of Suboxone Film and Tablets.

165. The anti-competitive effects of Defendants' conspiracy outweigh pro-competitive effects, if any, that their conduct may have had.

Count V: State Law Claims Against Reckitt and MonoSol Defendants

Alabama

166. Plaintiff State of Alabama repeats and realleges every preceding allegation.

167. The acts and practices by Defendants constitute unconscionable acts in violation of the Alabama Deceptive Trade Practices Act, Code of Alabama, 1975, § 8-19-5(27) for which the State of Alabama is entitled to relief.

Alaska

168. The State of Alaska repeats and realleges every preceding allegation.

169. The aforementioned practices by Defendants are in violation of the Alaska Restraint of Trade Act, AS 45.50.562 *et seq.*, and Plaintiff State of Alaska is entitled to relief for these violations under AS 45.50.576 - .578.

170. The aforementioned practices by Defendants are in violation of the Alaska Unfair Trade Practices and Consumer Protection Act, AS 45.50.471 *et seq.*, and Plaintiff State of Alaska is entitled to relief for these violations under AS 45.50.501, .531, and .537.

Arkansas

171. The Plaintiff State of Arkansas repeats and realleges each and every allegation contained in paragraphs 1 through 165.

172. Defendants' acts violate, and Plaintiff State of Arkansas is entitled to relief under, The Arkansas Unfair Practices Act, Arkansas Code Annotated § 4-75-201 *et seq.*, The Arkansas Statute on Monopolies, Ark. Code Ann. § 4-75-301 *et seq.*, The Arkansas Deceptive Trade Practices Act, §4-88-101 *et seq.*, and the Common Law of Arkansas.

California

173. California realleges and incorporates all of the allegations above from paragraphs 1 through 165.

174. The aforementioned conduct practices by Defendants were and are in violation of the Cartwright Act, Cal. Bus. & Prof. Code sections 16700, *et seq.*, and the California Unfair Competition Act, Cal. Bus. & Prof. Code sections 17200, *et seq.* The afore-alleged representations and statements of Reckitt to doctors, payors, providers, pharmacists and others regarding the existence of safety concerns of the Suboxone Tablets, which representations Reckitt knew or by the exercise of reasonable care should have known to be unfounded, untrue and misleading also constitute violations of Cal. Bus. & Prof. Code sections 17500 *et seq.*

175. Accordingly, the State of California in its law enforcement capacity, seeks all relief available under California's Cartwright Act and the Unfair Competition Act, including all available monetary and equitable relief, injunctive relief pursuant to Cal. Bus & Prof. Code § 16754.5 to restore and preserve fair competition and bar any continued conduct that is wrongful, among other things, civil penalties pursuant to Cal. Bus. & Prof. Code § 17206 of \$2,500 per each and every act, prescription and victim of any violation of the California Unfair Competition Act (and under Cal. Civil Code § 3345, trebled for senior citizens and disabled victims of the violation), and disgorgement of all revenues, profits, and gains achieved in whole or in part through the violations of the Acts complained of herein, including disgorgement, unjust

enrichment, injunctions, costs, reasonable attorneys' fees, and civil penalties, and any such other relief that might be available under statute or equity, penalties, and any such other equitable or monetary relief that might be available under statute or equity.

Colorado

176. Plaintiff State of Colorado repeats and realleges each and every allegation contained in paragraphs 1 through 165.

177. Defendants' acts violate, and Plaintiff State of Colorado is entitled to relief under, the Colorado Antitrust Act of 1992, § 6-4-101, *et seq.*, Colo. Rev. Stat.

Connecticut

178. Plaintiff State of Connecticut repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

179. Defendants' actions as alleged herein violate the Connecticut Antitrust Act, Conn. Gen. Stat. §§ 35-26 and 35-28, in that they have the purpose and/or effect of unreasonably restraining trade and commerce within the State of Connecticut and elsewhere.

180. Defendants' actions as alleged herein violate Conn. Gen. Stat. §§ 35-27 and 35-29 in that they represent monopolization of or attempts to monopolize trade or commerce within the State of Connecticut and elsewhere and/or have the purpose and effect of substantially lessening competition within the State of Connecticut and elsewhere.

181. Defendants' acts and practices as alleged herein constitute unfair methods of competition in violation of the Connecticut Unfair Trade Practices Act, Conn. Gen. Stat § 42-110b.

182. The State of Connecticut seeks injunctive relief pursuant to Conn. Gen. Stat. § 35-34, civil penalties pursuant to Conn. Gen. Stat. § 35-38 for each and every violation of the

Connecticut Antitrust Act, civil penalties pursuant to Conn. Gen. Stat. § 42-110o of \$5,000 for each and every willful violation of the Connecticut Unfair Trade Practices Act, and disgorgement of all revenues, profits, and gains achieved in whole or in part through the unfair methods of competition complained of herein, pursuant to Conn. Gen. Stat. § 42-110m.

Delaware

183. Plaintiff State of Delaware repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

184. The aforementioned practices by Defendants are in violation of Section 2103 of the Delaware Antitrust Act, 6 Del. c. § 2101, *et seq.*

185. The State of Delaware through the Attorney General brings this action pursuant to Sections 2105 and 2107, and seeks civil penalties and equitable relief pursuant to Section 2107 of the Delaware Antitrust Act, 6 Del. C. § 2101, *et seq.*

District of Columbia

186. Plaintiff District of Columbia repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

187. The aforementioned practices by Defendants are in violation of the District of Columbia Antitrust Act, D.C. Code §§ 28-4502 and 28-4503.

188. Plaintiff District of Columbia has been and continues to be injured by Defendants' actions, and is entitled to relief for these violations under D.C. Code § 28-4507(a).

Florida

189. Plaintiff State of Florida repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

190. Defendants' acts violate Section 542.18, Florida Statutes, for their contract, combination, or conspiracy in restraint of trade or commerce in Florida as alleged in Count IV. Plaintiff State of Florida is entitled to relief under the Florida Antitrust Act of 1980, Section 542.15, Florida Statutes, *et seq.*

191. Defendants' acts violate Section 542.19, Florida Statutes, because they monopolized, attempted to monopolize, and combined or conspired with each other to monopolize any part of trade or commerce in Florida as alleged in Counts I, II and III. Plaintiff State of Florida is entitled to relief under the Florida Antitrust Act of 1980, Section 542.15, Florida Statutes, *et seq.*

192. Defendants' acts violate Florida Deceptive and Unfair Trade Practices Act, Section 501.204, Florida Statutes, because they constituted unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of trade or commerce in Florida, as alleged in Counts I through IV. Plaintiff State of Florida is entitled to relief under the Florida Deceptive and Unfair Trade Practices Act, Section 501.201, Florida Statutes, *et seq.*

Georgia

193. Plaintiff State of Georgia repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

194. The aforementioned practices by Defendants violate, and Plaintiff State of Georgia is entitled to relief under, O.C.G.A. §§ 10-1-390, *et seq.*

Hawaii

195. Plaintiff State of Hawaii repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

196. The aforementioned practices by Defendants were and are in violation of the Hawaii Antitrust Act, Hawaii Revised Statutes section 480-1 *et seq.*

197. Plaintiff State of Hawaii is entitled to injunctive relief, disgorgement to deprive defendants of ill-gotten gains unjustly obtained, civil penalties of not less than \$500 nor more than \$10,000 for each violation pursuant to Hawaii Revised Statutes section 480-3.1, attorney's fees together with the costs of suit, and any other remedies available under the Hawaii Antitrust Act, Hawaii Revised Statutes section 480-1 *et seq.* and any other provision in the Hawaii Revised Statutes.

Idaho

198. Plaintiff State of Idaho repeats and realleges each and every allegation contained in paragraphs 1 through 165.

199. Defendants' actions violate the Idaho Competition Act (the "Act"), Idaho Code § 48-104, in that they have the purpose or the effect (or both) of unreasonably restraining Idaho commerce, as that term is defined by Idaho Code § 48-103(1) of the Act.

200. Defendants' actions violate the Act, Idaho Code § 48-105, in that they represent monopolization of, or attempts to monopolize, or a conspiracy to monopolize, a line of Idaho commerce, as that term is defined by Idaho Code § 48-103(1) of the Act.

201. Plaintiff State of Idaho is entitled to all relief available under the Act, Idaho Code §§ 48-108, 48-112, for those violations, including, but not limited to, injunctive relief, civil penalties, disgorgement, attorneys' fees, and costs.

Illinois

202. Plaintiff State of Illinois repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

203. By engaging in the conduct described above, the Defendants violate sections 3(2) and 3(3) of the Illinois Antitrust Act, 740 ILCS 10/1 *et seq.* and cause the State and its residents to pay more for Suboxone.

204. Plaintiff State of Illinois, under its antitrust enforcement authority in 740 ILCS 10/7, is entitled to an injunction, disgorgement, civil penalties, and any other remedy available at law for these violations under sections 7(1), 7(2), and 7(4) of the Illinois Antitrust Act.

Iowa

205. Plaintiff State of Iowa repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

206. The alleged practices by Defendants violate the Iowa Competition Law, Iowa Code Chapter 553.

207. Iowa seeks an injunction for these practices pursuant to Iowa Code § 553.12, and civil penalties pursuant to Iowa Code § 553.13.

208. Defendants' acts and practices as alleged herein also constitute an unfair practice in violation of the Iowa Consumer Fraud Act, Iowa Code § 714.16(1)(n)

209. Pursuant to Iowa Code § 714.16(7), the State of Iowa, seeks disgorgement and other equitable relief for these violations. In addition, pursuant to Iowa Code § 714.16(11) the Attorney General seeks reasonable fees and costs for the investigation and court action.

Kansas

210. Plaintiff State of Kansas repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

211. The aforementioned acts and practices by the Defendants violate the Kansas Restraint of Trade Act, Kan. Stat. Ann. §§ 50-101, *et seq.*, and Plaintiff State of Kansas is entitled to relief under Kan. Stat. Ann. §§ 50-103, 50-160, 50-161, and 50-163.

Kentucky

212. Plaintiff Commonwealth of Kentucky repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

213. The aforementioned acts or practices by Defendants violate the Consumer Protection Act Kentucky Rev. Stat. Ann. 367.110 *et seq.* The violations were willfully done.

214. Plaintiff Commonwealth of Kentucky, under its statutes, is entitled to injunction, disgorgement, civil penalties, and any other relief the court deems proper.

Louisiana

215. The State of Louisiana repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

216. The practices of Defendants described herein are in violation of the Louisiana Monopolies Act, LSA-R.S. 51:121 *et seq.*, and the Louisiana Unfair Trade Practices Act, LSA-R.S. 51:1401 *et seq.*

217. The State of Louisiana is entitled to injunctive relief and civil penalties under LSA-R.S. 51:1407 as well as disgorgement and any other equitable relief that the court deems proper under LSA-R.S. 51:1408.

Maine

218. Plaintiff State of Maine repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

219. The aforementioned practices by Defendants are in violation of the Maine Monopolies and Profiteering Law, 10 M.R.S. §§ 1101 and 1102, and Plaintiff State of Maine is entitled to relief for these violations under 10 M.R.S. § 1104.

220. The aforementioned practices by Defendants are intentional and in violation of the Maine Unfair Trade Practices Act, 5 M.R.S. § 207, and Plaintiff State of Maine is entitled to relief for these violations under 5 M.R.S. § 209.

Maryland

221. Plaintiff State of Maryland repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

222. The aforementioned practices by Defendants are in violation of the Maryland Antitrust Act, Md. Commercial Law Code Ann. § 11-201 *et seq.*

223. Further, § 11-209(a)(3) provides that the court may exercise all equitable powers necessary to remove the effects of any violation including injunction, restitution, disgorgement and divestiture. The Plaintiff State of Maryland is entitled to costs, reasonable attorney's fees and civil penalties. §§ 11-209(b)(3), 11-209(a)(4).

Massachusetts

224. Plaintiff Commonwealth of Massachusetts repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

225. The aforementioned practices by Defendants constitute unfair methods of competition or unfair or deceptive acts or practices in violation of the Massachusetts Consumer Protection Act, M.G.L c. 93A, § 2 *et seq.*

226. Plaintiff Commonwealth of Massachusetts is entitled to relief under M.G.L. c. 93A, § 4.

227. Plaintiff Commonwealth of Massachusetts notified the defendants of this intended action more than five days prior to the commencement of this action and gave the Defendants an opportunity to confer in accordance with M.G. L. c. 93A, § 4.

Michigan

228. Plaintiff State of Michigan repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

229. The aforementioned practices by Defendants constitute violations of the Michigan Antitrust Reform Act, MCL 445.771 *et seq.*

230. Plaintiff State of Michigan is entitled to disgorgement of profits, penalties, costs, and fees under Section 8 of the Michigan Antitrust Reform Act, MCL 445.778.

Minnesota

231. Plaintiff State of Minnesota repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

232. Defendants' acts violate, and Plaintiff State of Minnesota is entitled to an injunction, disgorgement, and civil penalties and any other remedy available at law for these violations under the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.46-.66, the Uniform Deceptive Trade Practices Act of 1973, Minn. Stat. §§ 325D.43-.48, Minn. Stat. Ch. 8, and Minnesota common law for unjust enrichment.

Mississippi

233. Plaintiff State of Mississippi repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

234. Defendants' acts violate Miss. Code Ann. § 75- 21-1 *et seq.*, and Plaintiff State of Mississippi is entitled to relief under Miss. Code Ann. § 75- 21-1 *et seq.*

235. Defendants' acts violate the Mississippi Consumer Protection Act, Miss. Code Ann. § 75-24-1, *et seq.*, and Plaintiff State of Mississippi is entitled to relief under the Mississippi Consumer Protection Act, Miss. Code Ann. § 75-24-1, *et seq.*

236. Pursuant to Miss. Code Ann. § 75-21-1 *et seq.*, and the Mississippi Consumer Protection Act, Miss. Code Ann. § 75-24-1, *et seq.*, Plaintiff State of Mississippi seeks and is entitled to injunctive relief, disgorgement, civil penalties, costs, and any other just and equitable relief which this Court deems appropriate.

Missouri

237. Plaintiff State of Missouri repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

238. The aforementioned practices by Defendants violate the Missouri Antitrust Law, Missouri Rev. Stat. §§ 416.011 *et seq.*, and Missouri's Merchandising Practices Act, Missouri Rev. Stat. §§ 407.010 *et seq.*, as further interpreted by 15 CSR 60-8.010 *et seq.* and 15 CSR 60-9.01 *et seq.*, and the State of Missouri is entitled to an injunction, disgorgement, civil penalties and any other relief available under the aforementioned Missouri statutes and regulations.

239. The State of Missouri also seeks its costs and attorney fees incurred in the prosecution of this action.

Nebraska

240. Plaintiff State of Nebraska repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

241. The aforementioned acts and practices by Defendants were, and are, in violation of the following Nebraska statutes: Unlawful Restraint of Trade Act, Neb. Rev. Stat. § 59-801 *et seq.*; Consumer Protection Act, Neb. Rev. Stat. § 59-1601 *et seq.*; and Uniform Deceptive Trade

Practices Act, Neb. Rev. Stat. § 87-301 *et seq.* Specifically, Defendants' acts and practices were, and are, in violation of Neb. Rev. Stat. §§ 59-801, 59-802, 59-1602, 59-1603, 59-1604, 87-302(5), 87-302(6), 87-302(8), 87-303.01. Defendants' acts and practices as alleged herein have had an impact, directly and indirectly, upon the public interest of the State of Nebraska.

242. Accordingly, Plaintiff State of Nebraska seeks all relief available under the Unlawful Restraint of Trade Act, the Consumer Protection Act, the Uniform Deceptive Trade Practices Act, and Neb. Rev. Stat. § 84-212. Plaintiff State of Nebraska is entitled to relief including but not limited to: disgorgement, injunctions, civil penalties, and its costs and attorney's fees pursuant to Neb. Rev. Stat. §§ 59-803, 59-819, 59-821, 59-1608, 59-1609, 59-1614, 84-212, 87-303, 87-303.05, and 87-303.11.

New Hampshire

243. New Hampshire realleges and incorporates all of the allegations above from paragraphs 1 through 165.

244. The aforementioned practices by Defendants were and are in violation of the New Hampshire Antitrust Provisions, Revised Statutes Annotated (RSA), 356:1 *et seq.*

245. Plaintiff State of New Hampshire is entitled to relief under N.H. RSA 356:4 *et seq.*

New Mexico

246. Plaintiff State of New Mexico repeats and re-alleges each and every allegation contained in paragraphs 1 to 165.

247. The aforementioned actions and practices by Defendants were and are in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. § 57-1-1 *et seq.*, and the New Mexico Unfair Practices Act, § 57-12-1 *et seq.*

248. Accordingly, the State of New Mexico is entitled to remedies available to it under the New Mexico Antitrust Act and the New Mexico Unfair Practices Act, including injunctive relief, restitution, disgorgement, unjust enrichment, civil penalties, costs, attorney's fees, and any other appropriate monetary and injunctive relief. *See* N.M. Stat. Ann. §§ 57-1-3, -7, -8; N.M. Stat. Ann. § 57-12-8, -10, -11.

New York

249. Plaintiff State of New York realleges and incorporates each and every allegation contained in paragraphs 1 through 165 as if fully set forth herein.

250. Defendants' acts violate the Donnelly Act, New York's antitrust law, N.Y. Gen. Bus. Law § 340 *et seq.*

251. Defendants have engaged in repeated fraudulent or illegal acts in the carrying on, conducting, or transaction of business, in violation of Section 63(12) of the New York Executive Law, N.Y. Exec. Law § 63(12).

252. Because of Defendants' illegal conduct, New York State is entitled to legal and equitable remedies including but not limited to injunctive relief, equitable monetary relief, and penalties pursuant to Sections 340-342(c) of the New York General Business Law and Section 63(12) of the New York Executive Law.

North Carolina

253. Plaintiff State of North Carolina repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

254. Defendants' acts violate North Carolina's Unfair and Deceptive Trade Practices Act, N.C. Gen. Stat. § 75-1 *et seq.* Plaintiff State of North Carolina is entitled to relief under N.C. Gen. Stat. § 75-1 *et seq.*

255. Plaintiff State of North Carolina is entitled to recover its costs and attorneys' fees pursuant to N.C. Gen. Stat. § 75-16.1.

Ohio

256. Plaintiff State of Ohio repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

257. The Attorney General brings this action in his sovereign capacity as the chief law enforcement officer of the State of Ohio.

258. Pursuant to Ohio Rev. Code § 1331.11, the Ohio Attorney General is authorized to institute and prosecute actions on behalf of the State to enforce the provisions and remedies of Ohio's antitrust law, the Ohio Valentine Act, codified in Ohio Rev. Code Chapter 1331.

259. The aforementioned practices by Defendants violate Ohio Rev. Code §§ 1331.01 *et seq.* These violations substantially affect the people of Ohio and have impacts within the State of Ohio.

260. Pursuant to Ohio Rev. Code § 109.81, the Ohio Attorney General is authorized to do all things necessary to properly conduct any antitrust case and to seek equitable relief as provided in Revised Code §§ 109.81 and 1331.11. Based on Defendant's conduct, the State of Ohio is entitled to an injunction, disgorgement, and civil penalties and any other remedy available at law or equity for these violations under Ohio law or the laws of the United States.

Oklahoma

261. Plaintiff State of Oklahoma repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

262. The aforementioned practices by the Defendants are in violation of the Oklahoma Antitrust Reform Act, 79 O.S. § 201 *et seq.*, and the Oklahoma Consumer Protection Act, 15 O.S. § 751 *et seq.*, and Plaintiff State of Oklahoma is entitled to relief under 79 O.S. § 205 and 15 O.S. § 756.1 respectively.

Oregon

263. Oregon realleges and incorporates all of the allegations above from paragraphs 1 through 165.

264. The aforementioned practices by Defendants were and are in violation of the Oregon Antitrust Law, Oregon Revised Statutes (“ORS”) 646.705, *et seq.* These violations had impacts within the State of Oregon and substantially affected the people of Oregon.

265. Plaintiff State of Oregon seeks all relief available under the Oregon Antitrust Act, including injunction, civil penalties, equitable relief including but not limited to disgorgement and unjust enrichment, the State of Oregon’s costs incurred in bringing this action, plus reasonable attorney fees, expert witness fees, and costs of investigation, and any other remedy available at law for these violations under ORS 646.760, ORS 646.770, ORS 646.775, and ORS 646.780.

Pennsylvania

266. Plaintiff Commonwealth of Pennsylvania repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

267. The aforementioned practices by Defendants violate the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1, *et seq.* (“PUTPCPL”) and Pennsylvania antitrust common law. The Pennsylvania Office of Attorney General has reason to believe that the Defendants have engaged in a method, act or practice declared by 73 P.S. § 201-3 to be unlawful, and that this proceeding would be in the public interest pursuant to 71 P.S. § 201-4.

268. On behalf of the Commonwealth and its citizens pursuant to 71 Pa. C.S.A. § 732-204 (c), Pennsylvania seeks injunctive relief, restoration, disgorgement and attorneys’ fees and costs pursuant to 73 P.S. § 201-4 and 4.1 and civil penalties of not exceeding \$3,000 for each such willful violation pursuant to 73 P.S. § 201-8 (b). Pennsylvania also seeks injunctive relief and disgorgement under antitrust common law.

Rhode Island

269. Rhode Island realleges and incorporates all of the allegations above from paragraphs 1 through 165.

270. Defendant’s acts violate the Rhode Island Antitrust Act, and Plaintiff State of Rhode Island is entitled to injunctive relief, civil penalties, reasonable attorneys’ fees, costs and statutory interest pursuant to R.I. Gen. Laws § 6-36-1 *et seq.* These violations substantially affect the people of Rhode Island and have impacts within the State of Rhode Island.

271. Defendant’s acts violate the Rhode Island Deceptive Trade Practices Act, and Plaintiff State of Rhode Island is entitled to injunctive relief, civil penalties, reasonable attorneys’ fees, costs and statutory interest pursuant to R.I. Gen. Laws § 6-13.1-1 *et seq.* These violations substantially affect the people of Rhode Island and have impacts within the State of Rhode Island.

South Carolina

272. Plaintiff State of South Carolina repeats and realleges every preceding allegation.

273. The aforementioned practices by Defendants constitute an “unfair method of competition and unfair or deceptive acts or practices” under §39-5-20 of the South Carolina Code of Laws. Plaintiff State of South Carolina, as *parens patriae* for the citizens of South Carolina, is entitled to relief for these violations under §39-5-50, §39-5-110(a) and any other remedy available at law or equity.

274. South Carolina seeks attorneys’ fees and costs under §39-5-50(a).

Tennessee

275. Plaintiff State of Tennessee repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

276. The aforementioned practices by Defendants are in violation of Tennessee’s antitrust law, the Tennessee Trade Practices Act, Tenn. Code Ann. §§ 47-25-101 *et seq.*

277. Defendants’ aforementioned practices are in violation of the Tennessee Consumer Protection Act of 1977, Tenn. Code Ann. §§ 47-18-101 *et seq.*

278. By Defendants’ actions or omissions during the FDA approval process and by Defendants’ actions or omissions when converting the market from Suboxone Tablets to Suboxone Film, Defendants in numerous instances represented, directly or indirectly, expressly or by implication, that there were legitimate health and safety concerns with Suboxone Tablets that warranted a switch to Suboxone Film, which Defendants represented did not pose similar health and safety risks. These representations were made in connection with the federal approval application, advertising, marketing, promotion, offering for sale, or sale of Suboxone Film.

279. In truth and in fact, the health and safety concerns that Defendants represented with respect to Suboxone Tablets were inaccurate and unfounded, the Suboxone Tablets did not present the negative characteristics that the Defendants represented, the Suboxone Film did present health and safety concerns, and the Suboxone Tablets were potentially safer than the Suboxone Film.

280. Defendants failed to accurately and reasonably represent the characteristics of Suboxone Tablets and Suboxone Film to the FDA, doctors, payers, and pharmacists.

281. Defendants' practices caused or are likely to cause substantial injury to consumers that consumers cannot reasonably avoid themselves and that is not outweighed by countervailing benefits to consumers or competition.

282. Specifically, Defendants violated the following statutory provisions:

- Tenn. Code Ann. § 47-18-104(a), which prohibits unfair or deceptive acts or practices affecting the conduct of any trade or commerce;
- Tenn. Code Ann. § 47-18-104(b)(5), which prohibits representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have, or that a person has a sponsorship approval, status, affiliation or connection that the person does not have;
- Tenn. Code Ann. § 47-18-104(b)(7), which prohibits representing that goods or services are of a particular standard, quality, or grade, if they are of another; and
- Tenn. Code Ann. § 47-18-104(b)(27), which prohibits engaging in any other act or practice which is deceptive to the consumer or to any other person.

Utah

283. Plaintiff State of Utah repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

284. Defendants' acts violate the Utah Antitrust Act, Utah Code §§ 76-10-3101, *et seq.* (the "Act"), and Plaintiff State of Utah is entitled to all relief available under the Act for those violations, including, but not limited to, injunctive relief, civil penalties, disgorgement, attorneys' fees, and costs.

Vermont

285. Plaintiff State of Vermont repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

286. The aforementioned practices by Defendants are in violation of the Vermont Consumer Protection Act, 9 V.S.A § 2453, and Plaintiff State of Vermont is entitled to relief for these violations under 9 V.S.A. §§ 2458 and 2465.

Virginia

287. The aforementioned practices by Defendants are in violation of the Virginia Antitrust Act, Va. Code Ann. §§ 59.1-9.1 *et seq.* These violations had impacts within the Commonwealth of Virginia and substantially affected the people of Virginia.

288. Plaintiff Commonwealth of Virginia is entitled to relief under the Virginia Antitrust Act, Va. Code Ann. §§ 59.1-9.11 and 59.1-9.15.

Washington

289. Plaintiff State of Washington repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

290. The aforementioned practices by Defendants were, and are in, violation of the Washington Consumer Protection Act, Wash. Rev. Code 19.86 *et seq.* These violations had impacts within the State of Washington and substantially affected the people of Washington. Plaintiff State of Washington is entitled to an injunction, disgorgement, and civil penalties under the Consumer Protection Act, Wash. Rev. Code 19.86.080 and 19.86.140.

West Virginia

291. Plaintiff State of West Virginia repeats and re-alleges each and every allegation contained in paragraph 1 through 165.

292. Defendants' acts violate the West Virginia Antitrust Act, *see* W. Va. Code § 47-18-1 *et seq.* These violations substantially affected the State of West Virginia and had impacts within the State of West Virginia. In addition, defendants were unjustly enriched by their violations of West Virginia law.

293. Plaintiff State of West Virginia is entitled all equitable relief (including injunctive relief and disgorgement), as well as civil penalties (including treble damages), under West Virginia Code § 47-18-1 *et seq.*

294. Plaintiff State of West Virginia is also entitled to recover its costs and attorneys' fees under West Virginia Code § 47-18-9.

Wisconsin

295. Plaintiff State of Wisconsin repeats and re-alleges each and every allegation contained in paragraphs 1 through 165.

296. The aforementioned practices by Defendants are in violation of Wisconsin's Antitrust Act, Wis. Stat. Ch. § 133.03 *et seq.* These violations substantially affect the people of Wisconsin and have impacts within the State of Wisconsin.

297. Plaintiff State of Wisconsin, under its antitrust enforcement authority in Wis. Stat. Ch. 133, is entitled to an injunction, disgorgement, and civil penalties and any other remedy available at law for these violations under Wis. Stat. §§ 133.03, 133.14, 133.16, 133.17, and 133.18.

Prayer for Relief

Accordingly, the Plaintiff States request that this Court:

1. Adjudge and decree that Defendants violated sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2;
2. Adjudge and decree that the foregoing activities violated each of the State statutes enumerated in this Complaint;
3. Enjoin and restrain, pursuant to 15 U.S.C. §26 and state law, Defendants, their affiliates, assignees, subsidiaries, successors, and transferees, and their officers, directors, partners, agents and employees, and all other persons acting or claiming to act on their behalf or in concert with them, from continuing to engage in any anticompetitive conduct and from adopting in the future any practice, plan, program, or device having a similar purpose or effect to the anticompetitive actions set forth above;
4. Award to each Plaintiff State statutory or equitable disgorgement or any other relief as the court finds appropriate to redress violations for state antitrust or consumer protection laws or to restore competition;
5. Award to each Plaintiff State the maximum civil penalties allowed by law;
6. Award to each Plaintiff State its costs, including reasonable attorneys' fees; and
7. Order any other relief that this Court deems proper.

Jury Demand

298. Pursuant to Fed. R. Civ. P. 39(b), Plaintiff States request a trial by the Court.

Dated: November __, 2016

Respectfully submitted,

STATE OF WISCONSIN
BRAD D. SCHIMEL
Attorney General of Wisconsin

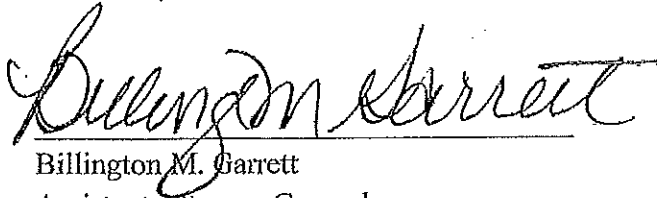
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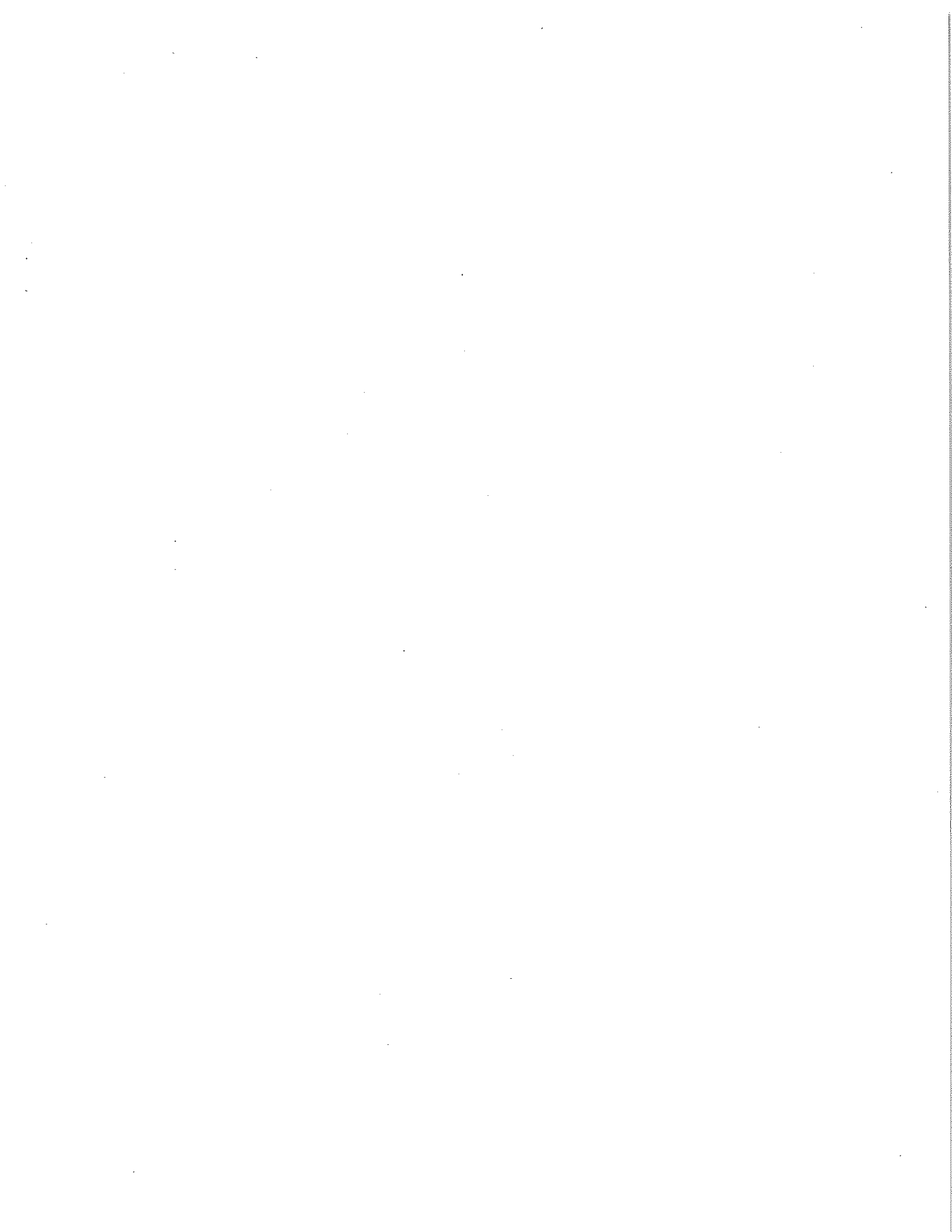
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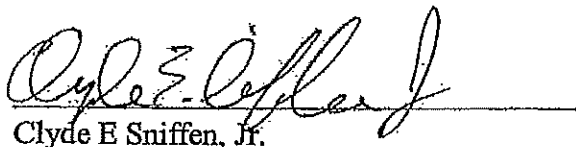
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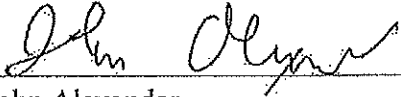
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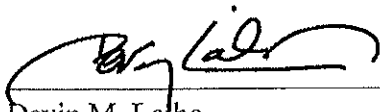


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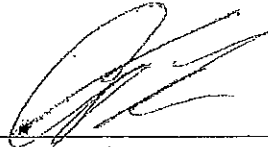
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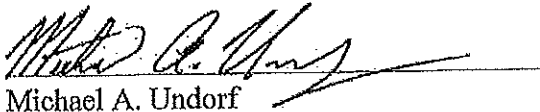
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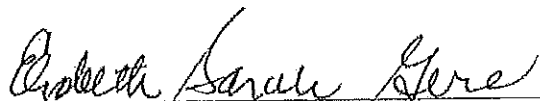
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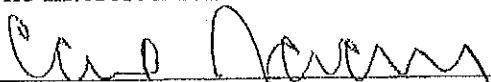


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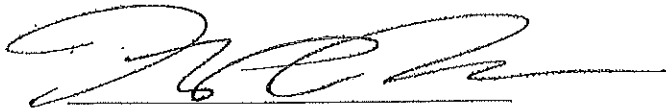


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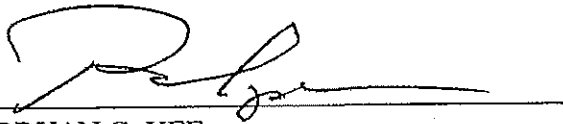
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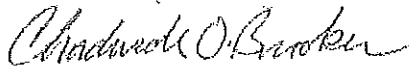
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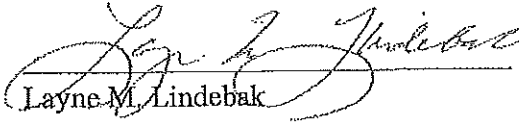
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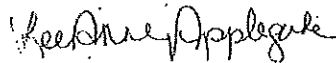
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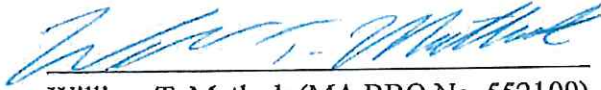
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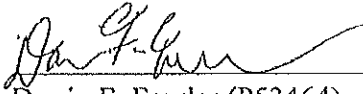
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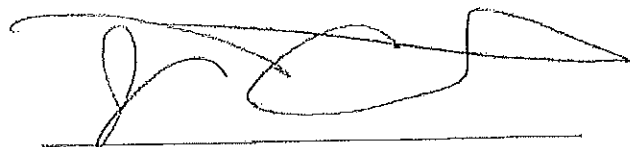
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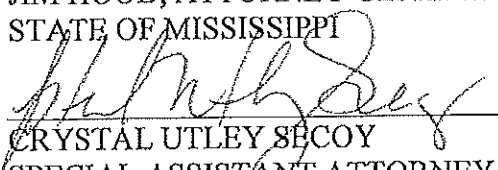
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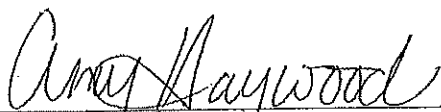
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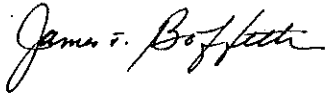
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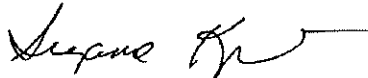
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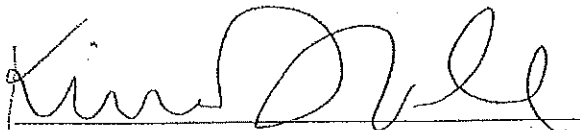


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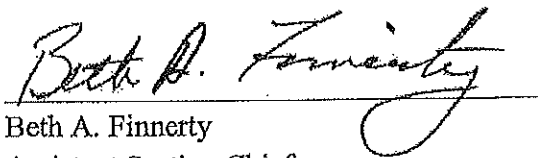
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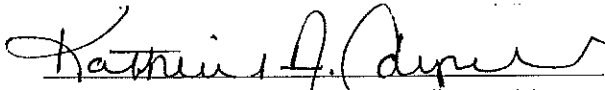
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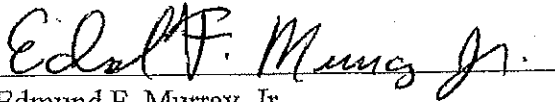
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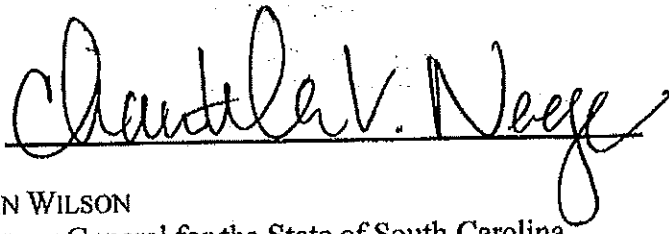
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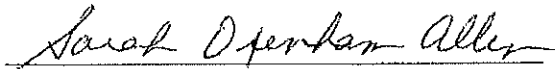
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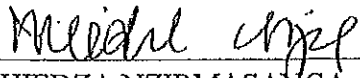
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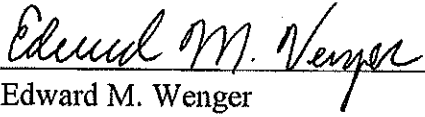
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