

**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF MISSOURI  
EASTERN DIVISION**

**PRECISION RX COMPOUNDING, LLC, )  
C & M HEALTH PRO, LLC, NORTHERN )  
VA COMPOUNDERS, PLLC, TOTH )  
ENTERPRISES II, PA, THE DAILY )  
DOSE, LP, and CPRX PHARMACY, LP, )  
Plaintiffs, )**

Case No. 4:16-cv-0069

v. )

**JURY TRIAL DEMANDED**

**EXPRESS SCRIPTS HOLDING COMPANY,) )  
and EXPRESS SCRIPTS, INC., )  
Defendants. )**

**COMPLAINT**

Plaintiffs Precision Rx Compounding, LLC, C&M Health Pro, LLC, Northern VA Compounding, PLLC, TOTH Enterprises II, P.A., The Daily Dose, LP, and CPRx Pharmacy, LP (collectively referred to as “Plaintiffs”), by and through their undersigned attorneys, bring this action for trebled compensatory damages and injunctive relief under the antitrust laws of the United States against Express Scripts Holding Company and its wholly owned subsidiary, Express Scripts, Inc. (collectively referred to as “Defendants” or “Express Scripts”), demanding a trial by jury. For their Complaint, Plaintiffs allege as follows:

**NATURE OF THE CASE**

1. This case involves an ongoing and multi-faceted conspiracy between the nation’s largest pharmacy benefit managers (“PBMs”)—including Express Scripts, CVS Health Corporation, OptumRx, Inc., and Prime Therapeutics, LLC—to jointly boycott compounding pharmacies to eliminate Plaintiffs from the market for pharmaceuticals covered by group and individual health plans (at times referred to as a “plan” or “plans” herein). Therefore, Express Scripts and its co-conspirators shifted the filling of patients’ prescriptions to pharmacies in which

the Defendants and their co-conspirators hold an economic interest. This manner of horizontal group boycott is a well-established naked restraint of trade barred *per se* under the federal antitrust laws.

2. Each of the Plaintiffs own and operate independent pharmacies that do a significant amount of work filling prescriptions for compounded medicines. Such compounding pharmacies combine ingredients to create drugs tailored to a patient's unique needs.

3. Compounded medicines play a critical role in meeting the patients' medical needs. For example, some people are allergic to specific, inactive ingredients in mass-produced drugs—compounding pharmacies replace the troublesome ingredient. Many children, and some adults, are unable to swallow pills—compounding pharmacies create a liquid equivalent of commercially available drugs that are only manufactured in pill form. Similarly, an individual may have obtained relief from drugs that are no longer mass-produced but are otherwise safe—compounding pharmacies are able to create medications on an individualized basis.

4. Compounded medicines even serve as an alternative to opioid narcotics and are, thus, a vital tool in responding to the FDA's 2012 mandate to seek alternative methods of pain relief to counter the growing epidemic of opioid narcotic addiction.

5. Therefore, compounded drugs offer competitive alternatives to mass-produced drugs for patients who desire and/or need tailored medications prescribed by their licensed physicians, and for plan sponsors who desire to offer such beneficial products to their members.

6. Express Scripts and its co-conspirators have collectively employed tactics designed to ensure that the compounding pharmacy industry, and Plaintiffs in particular, cannot survive. Through their role as claim administrators for group and individual health plans, Express Scripts and its co-conspirators improperly decide whether and to what extent pharmacies

are reimbursed for prescribed and filled drugs. Although health plans are financially responsible for covered prescription drugs it is the PBMs that make the decision on whether a certain drug is covered by a specific group or individual health plan. The PBMs such as Express Scripts have inserted themselves as middlemen and act as gatekeepers when patients submit prescriptions to pharmacies. PBMs also adjudicate claims, design the formulary, manage and negotiate branded drug rebates, and manage the network of pharmacies through which pharmacies gain access to patients, and operate their own specialty and home-delivery pharmacies.

7. In other words, PBMs act as gatekeepers to Plaintiffs' access to the relevant market. The antitrust laws, therefore, mandate that PBMs compete on the merits contracting with the Plaintiffs and, therefore, must unilaterally establish their drug reimbursement and coverage policies. At the heart of this lawsuit is the fact that Express Scripts and its co-conspirators have done just the opposite. They have conspired with each other to boycott compounding pharmacies by eliminating coverage for compounding ingredients, cutting off network access, and through a specific set of other tactics discussed herein, certainly have caused and will continue to cause on an accelerated basis the significant financial decline (if not elimination) of the Plaintiffs and other independent compounding pharmacies from the market for prescription drugs covered by plans.

8. Express Scripts and its co-conspirators have gained the ability, through sheer market power, to dictate the terms of repayment to pharmacies that fill prescriptions. Express Scripts is the largest PBM in the nation and its primary co-conspirators are the second, third, and fourth largest PBMs. Taken together, these PBMs review and make reimbursement decisions on more than 80% of prescription drug claims covered by group and individual plans in this country. Approximately 95% of all prescription drug sales are covered by plans. Thus, if

Plaintiffs fill prescriptions from plan-covered patients—and they must to survive—they are forced to deal with Express Scripts, its co-conspirators and the terms set by those PBMs.

9. Unfortunately for patients and pharmacies, the largest PBMs are conflicted in their gatekeeper role. Express Scripts and its co-conspirators maintain or are affiliated with their own pharmacies. For example, Express Scripts owns a mail-order pharmacy that mails medications to patients throughout the country and also controls various specialty pharmacies. The elimination of competing independent compounding and specialty pharmacies from the prescription drug market directly benefits Express Scripts and its co-conspirators.

10. To effectuate the elimination of competition from Plaintiffs and other compounding pharmacies, Express Scripts and its co-conspirators agreed to deploy a series of unreasonable restrictions and rules that would make it impossible for Plaintiffs and other pharmacies to fill prescriptions for plan-covered patients and obtain reimbursements that would cover their costs. For example, pursuant to their agreement, Express Scripts and its co-conspirators: (i) identified and targeted doctors that prescribed compounded drugs and made false and misleading statements to cause them to stop; (ii) made misleading statements to patients about the safety and legality of compounded drugs; (iii) eliminated coverage or denied claims for compounded drugs, even when no changes had been made to the underlying health plans; (iv) drastically reduced the amount compounding pharmacies would be reimbursed for prescribed compounded drugs; (v) orchestrated onerous procedural and administrative obstacles for the compounding pharmacies to fill prescriptions and obtain reimbursement; (vi) audited Plaintiffs on claims the PBMs had approved many months earlier and then withheld reimbursement of unrelated claims; (vii) restricted and/or eliminated the use of mail-order

delivery of compounded drugs; and (viii) removed pharmacies from the networks altogether by terminating the provider agreements, without cause or on a pretextual basis.

11. These coordinated tactics have devastated Plaintiffs. As a result of the agreement between Express Scripts and its co-conspirators to exclude Plaintiffs and other compounding pharmacies from various prescription drug markets, competition in those markets has been reduced, the supply of medically beneficial compounded products has decreased and faces near elimination, and patients are purposefully being driven to inferior products at Express Scripts' and its co-conspirators' own pharmacies.

12. The illegal agreement between Express Scripts and its co-conspirators has caused injury to both Plaintiffs and the relevant market. Plaintiffs have experienced significant losses in revenue and profits. Moreover, patients requiring compounded drugs have been deprived of those medications or are forced to use less effective drugs often sold by entities related to Express Scripts and its co-conspirators.

### **THE PARTIES**

13. Plaintiff Precision Rx Compounding, LLC ("Precision") is a Florida limited liability company with a principal place of business in Tampa, Florida. The sole member of Precision is Nagi Yorssef, a resident of the State of Florida.

14. Plaintiff C&M Health Pro, LLC ("C&M") is a Florida limited liability company with a principal place of business in Kissimmee, Florida. C&M's members are Nagi Yorssef and Tamer Girgis, both residents of the State of Florida.

15. Plaintiff Northern VA Compounders, PLLC ("NVC"), doing business as Akina Pharmacy, is a Virginia limited liability company with a principal place of business in Chantilly, Virginia. NVC's members are Bassem Girgis, a resident of the Commonwealth of Virginia,

Tamer Girgis, a resident of the State of Florida and Wadid Girgis, a resident of the State of New Jersey.

16. Plaintiff TOTH Enterprises II, P.A., doing business as Victory Medical Center (“VMC”), is a Texas professional association with a principal place of business in Austin, Texas. The sole member of VMC is William Franklin, a resident of the State of Texas.

17. Plaintiff The Daily Dose, LP (“Daily Dose”), formerly known as QVL Pharmacy #181, is a Texas limited partnership with a principal place of business in Austin, Texas. The general partner of Daily Dose is Daily Pharmacy GP, LLC and the sole limited partner is Daily Pharmacy, LLC, both of which are wholly owned by Kimberli Wiley, a resident of the State of Texas.

18. Plaintiff CPRx Pharmacy, LP (“CPRx”), formally known, as QVL Pharmacy #162, is a Texas limited partnership with a principal place of business in Cedar Park, Texas. The General Partner of CPRx is Asclepius Panacea GP, LLC and the sole limited partner is Asclepius Panacea, LLC, both of which are wholly owned by Kimberli Wiley, a resident of the State of Texas.

19. Defendant Express Scripts Holding Company is a Delaware corporation with a principal place of business at One Express Way, St. Louis, Missouri.

20. Defendant Express Scripts, Inc. is a Delaware corporation with a principal place of business at One Express Way, St. Louis, Missouri.

21. The Express Scripts Defendants constitute the largest PBM in the country. Annually, approximately 86 million individuals fill more than 1.4 billion prescriptions through Express Scripts. Express Scripts’ operations include mail-order/home deliver and specialty

pharmacies. In 2014 Express Scripts' annual revenue exceeded \$100 billion, constituting approximately 50% of all revenues received by PBMs that year.

### **CO-CONSPIRATORS**

22. Various other persons, firms and corporations, not named as defendants, have participated as co-conspirators with Express Scripts and have performed acts and made statements in furtherance of the conspiracy. Co-conspirators include, but are not limited to:

- a. CVS Health Corporation, formally known as CVS Caremark Corp. ("CVS Health"), is a Delaware corporation with a principal place of business in Woonsocket, Rhode Island. CVS Health is the nation's second largest PBM, managing the prescription benefits for over 2,000 health plans nationwide. CVS Health also operates a national retail pharmacy network with over 60,000 participating pharmacies as well as numerous specialty and mail-order pharmacies.
- b. OptumRx, Inc. ("OptumRx"), is a California corporation with a principal place of business in Irvine, California. OptumRx is a wholly owned subsidiary of UnitedHealth Group Inc. In or about July 2015, UnitedHealth, Inc. acquired another PBM, Catamaran Corp., and merged it with OptumRx. At that time, OptumRx was the third largest PBM and Catamaran was the fourth largest PBM in the country. With the acquisition of Catamaran, OptumRx now controls prescriptions filled by more than 65 million patients nationwide. The merger grew the annual number of prescriptions filled through OptumRx to approximately one billion per year. With the merger, OptumRx continues to be the nation's third largest PBM. OptumRx and/or corporate affiliates owned by UnitedHealth Group,

Inc. operate mail-order and specialty pharmacies. In 2014 OptumRx's annual revenues were approximately \$32 billion and those of Catamaran were more than \$21.5 billion.

- c. Prime Therapeutics, LLC ("Prime") is a Delaware limited liability company with a principal place of business in Eagan, Minnesota. Prime is owned by 13 Blue Cross Blue Shield companies. Prime provides services to more than 26 million people nationwide. Prime and/or its corporate affiliates operate mail-order and specialty pharmacies, including "Primemail®" and "Prime Therapeutics Specialty Pharmacy™".

23. Various other individuals and entities, known and unknown, and not named in this Complaint, participated as co-conspirators in the violations alleged herein and performed acts and made statements in furtherance thereof. Such persons or entities include other PBMs and other persons or entities that stand to benefit from the elimination of compounding pharmacies from the pharmacy services and prescription drug market and with whom Defendant Express Scripts, the co-conspirators, and/or other PBMs have commercial relationships. Such persons or entities acted as co-conspirators and aided, abetted, or participated with Express Scripts and the named co-conspirators in the commission of the wrongful acts alleged in this Complaint.

#### **JURISDICTION AND VENUE**

24. Plaintiffs bring this action, in part, pursuant to Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 26, for Express Scripts' and its co-conspirators' violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

25. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question) and 28 U.S.C. § 1337 (commerce and antitrust regulation).



26. This Court has original subject matter jurisdiction pursuant to 28 U.S.C. § 1332, because the parties are of diverse citizenship and the amount in controversy is over \$75,000, exclusive of interest and costs.

27. This Court has personal jurisdiction over Express Scripts and venue is proper in the Eastern District of Missouri pursuant to Section 12 of the Clayton Act, 15 U.S.C. § 22 and 28 U.S.C. § 1391 because Express Scripts is an inhabitant of, and resides in, this District.

28. Express Scripts and its co-conspirators are engaged in, and their activities substantially affect, interstate trade and commerce.

**THE GROUP AND INDIVIDUAL PLAN-COVERED  
PRESCRIPTION DRUG INDUSTRY**

29. Compounding pharmacies play an essential and necessary role in the plan-covered prescription drug industry and ensure that patients receive appropriate and required medications.

30. When doctors examine a patient and prescribe a drug tailored to the patient's need and requirements, the patient turns to pharmacies to fill those prescriptions.

31. Because many patients participate in group or individual health plans that include coverage for prescription drugs, patients do not typically pay the full retail price of drugs to pharmacies that fill prescriptions. When the patient does have prescription drug benefits, third-party payors ("TPPs") such as private health insurers, health and welfare plans sponsored by their employers, and self-insured employers, are often responsible for paying pharmacies for most of the costs of prescribed drugs. However, the patient is often required to pay a smaller portion, or co-pay, of the drug's cost directly to the pharmacy at the time the prescription is filled.

32. Before a pharmacy dispenses a drug to a patient, the pharmacy determines if and how much it will be paid for filling the specific prescription through the PBMs.

33. Once the pharmacy determines the extent to which it will be reimbursed for filling the prescription, it receives the co-pay from the patient (if any), dispenses the drug, and turns to the PBM to provide reimbursement on behalf of the relevant TPP. The PBM also charges a fee to the pharmacy for each filled prescription.

A. **The Dominant Role of Pharmacy Benefit Managers**

34. TPPs do not administer this process on their own. TPPs rarely review claims submitted by pharmacies and reimburse those pharmacies directly. Instead, TPPs contract with PBMs to administer the prescription drug portion of health care benefit programs. Services provided by PBMs include claims adjudication, formulary design, management and negotiation of branded drug rebates, management and negotiation of networks of retail pharmacies (*i.e.*, PBMs enter contracts with pharmacies through which pharmacies gain access to patients in plans administered by the PBM), review of drug utilization processing claims from pharmacies for payment, and the operation of specialty and home-delivery pharmacies such as mail-order pharmacies used to dispense medications directly to patients.

35. PBMs dominate and control the market for administering prescription drug payments to pharmacies. PBMs control approximately 95% of all the plan-covered drugs prescribed in the country. According to the Pharmaceutical Care Management Association, an industry group representing PBMs, “PBMs administer prescription drug plans for more than 253 million Americans with health coverage provided through Fortune 500 employers, health plans, labor unions, and Medicare Part D.” The PBM industry is itself dominated by four entities: Express Scripts, CVS Health, OptumRx, and Prime, who, according to recent Congressional testimony before the House Judiciary Subcommittee on Regulatory Reform, Commercial and Antitrust Law, constitute approximately 80% of the PBM market.

36. Express Scripts and the co-conspirators not only function as PBMs that administer benefit plans, audit independent pharmacies, and set prices for the prescriptions filled by independent pharmacies, but they also own and operate large retail pharmacy businesses, in the form of a brick-and-mortar national retail chain, specialty pharmacy businesses, and mail-order/on-line pharmacy operations. Through their own pharmacies, the large PBMs directly compete with Plaintiffs and other independent compounding pharmacies.

***B. The Critical Role of Compounding Pharmacies***

37. Although compounding pharmacies play a unique and critical role within the prescription drug industry, they are generally subject to the processes for filling prescriptions and obtaining reimbursement discussed above.

38. Compounding pharmacies combine, mix, or alter ingredients of a drug to create a product that, in accordance with a physician's prescription, is tailored to the needs of a patient. Like all pharmacies, they are regulated by the states in which they are licensed as well as the U.S. Federal Drug Administration ("FDA").

39. Millions of patients require specific drugs or individualized delivery systems that are not commercially available. Patients turn to compounding pharmacies for a variety of reasons, including for example:

- a. Some patients have allergies to inactive ingredients (such as gluten) that are present in mass-manufactured, commercially available drugs. Compounding pharmacies can create a compounded medicine that removes the troublesome ingredient;

- b. Many children, and some adults, are unable to swallow drugs that come in pill form. Compounding pharmacies can create easily digestible liquid forms of such medicines;
- c. Mass-produced, commercially available doses are sometime too strong. Compounding pharmacies create lower doses of the same drug;
- d. Some patients experience skin irritation from mass-produced, commercially available topical creams. Compounding pharmacies can create topical cream medicines with the same medical benefits that eliminate skin irritation by eliminating, substituting or removing the ingredient(s) causing the problem;
- e. Some patients obtained relief from drugs that are no longer mass-produced but are otherwise safe. Compounding pharmacies are able to create those medications on an individualized basis;
- f. Some children, elderly patients and other adults are unwilling to take medicines due to their taste. Compounding pharmacies can add flavors to make it more palatable.

40. Compounded medicines also play an important role in the fight against opioid narcotic addiction and are an important tool in responding to the FDA's 2012 mandate to seek alternatives to addictive opioid narcotics. Mass-produced, commercially available drugs prescribed for pain management in pill or injectable form may lead to dependency issues. Compounding pharmacies can, instead, create topical creams that target the specific location of injury while minimizing opioid addiction concerns because the medicine does not enter the bloodstream.

41. Plaintiffs, like almost all other pharmacies, rarely deal directly with TPPs. Rather, pharmacies are required to seek reimbursement from the TPPs' PBM middlemen. To gain access to patients whose plans include pharmacy benefits, compounding pharmacies must enter into provider agreements with the PBMs administering the drug benefits ("Provider Agreements"). Plaintiffs entered into Provider Agreements either directly with PBMs or indirectly with PBMs through third parties known as Pharmacy Services Administrative Organizations ("PSAOs") that assist pharmacies with administrative tasks including the execution of Provider Agreements. Whether Plaintiffs entered the Provider Agreement directly or indirectly with Express Scripts and its co-conspirators, the contracts were nearly identical, non-negotiable, and permitted PBMs to unilaterally amend the Provider Agreements at will.

42. Express Scripts and its co-conspirators also have "pharmacy manuals" or "provider manuals", which set forth various terms and conditions, and purport to be incorporated by reference into the Provider Agreements.

43. Through the Provider Agreements with Express Scripts, Plaintiffs agreed to provide pharmacy services to Express Scripts' members in exchange for Express Scripts' promise to compensate Plaintiffs for those services, including for dispensing compounded medicines. The process was intended to work as follows:

- a. Patients present prescriptions for compounded drugs to Plaintiffs;
- b. Plaintiffs electronically submit claims to Express Scripts before filling prescriptions;
- c. Express Scripts responds by electronically transmitting information to Plaintiffs regarding, among other things, the amount Express Scripts would pay the Plaintiffs to fill the prescriptions;

- d. Express Scripts charges Plaintiffs a transaction fee for each claim;
- e. Plaintiffs dispense the drugs to the patients; and
- f. Within a short amount of time, Plaintiffs are reimbursed for the dispensed medication.

44. As discussed in greater detail below, Express Scripts and its co-conspirators have not followed those agreed-upon procedures but have instead created obstacles and imposed restrictions intended to eliminate Plaintiffs and other independent compounding pharmacies as competitors in the pharmacy market.

#### **ANTITRUST ALLEGATIONS**

45. The Express Scripts Defendants and their co-conspirators combined, conspired and engaged in a concerted effort to unreasonably restrain trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, *et seq.*, to end all coverage for compounded prescription medications apart from those products offered by Defendants, and to eliminate Plaintiffs and other independent compounding pharmacies as competitors in the relevant market. Defendants' agreements and conduct are *per se* violations of the Sherman Act, but even if Defendants' group boycott is analyzed under the rule of reason, or any intermediate standard, it is a transparently unreasonable and an unlawful restraint of trade.

#### **INTERSTATE COMMERCE**

46. The provision and sale of many of the pharmaceutical services and products, and coverage for such services and products under group and individual health plans related to Plaintiffs, are each in, and affect, interstate commerce.

47. Many of the activities of Express Scripts and its co-conspirators in administering and processing the prescription drug benefits for employers, unions, and health plans in every

state are in the regular, continuous, and substantial flow of interstate commerce, and have a substantial effect upon interstate commerce.

48. Many of the acts in the conspiracy described herein between and among Express Scripts and its co-conspirators had, and continue to have, a direct, substantial and reasonably foreseeable impact on United States commerce.

### **PRODUCT AND GEOGRAPHIC MARKETS**

49. The relevant product market in which to evaluate Express Scripts and its co-conspirators' conduct is prescription drugs that are reimbursed by group and individual health plan sponsors, including, but not limited to, compounded prescription drugs.

50. There may also be sub-markets in which Defendants' conduct has destroyed or impaired competition. Such markets may include markets for (a) compounded, mail-order and specialty drugs and (b) markets for drugs based on indications or conditions (*e.g.*, drugs for chronic pain and allergies). In any of these markets, Defendants' concerted attack on Plaintiffs is designed to and will irreparably harm competition to the detriment of patients and Plaintiffs.

51. Prescription drugs not covered by group or individual health plans are not part of the relevant product market because there are too few patients who are not covered by group or individual health plans to which Plaintiffs and other compounding pharmacies can turn to offset the devastating effects of being excluded from the covered patient population by Defendants and their co-conspirators or to make the challenged conspiracy unprofitable.

52. The relevant geographic market for activity that impacts Plaintiffs is no broader than the United States. Absent the limitations on providing mail-order services and other restrictions imposed by Express Scripts and its co-conspirators, Plaintiffs would be able to utilize

mail-order to provide patients with their medications in every state in which they are licensed, which collectively include almost every state in the country.

53. Each and every state in which one or more of the Plaintiffs are licensed to fill prescriptions is also a relevant geographic market. Smaller markets within the boundaries of many states exist as well, as will be proven at trial.

54. Express Scripts and its co-conspirators maintain their own pharmacies, or are affiliated with pharmacies, that compete directly with Plaintiffs.

55. The unlawful conspiracy between Express Scripts and its co-conspirators is unreasonably restraining, suppressing, and eliminating competition in all markets in which Plaintiffs did, do and could operate in interstate commerce.

#### **CONCERTED ACTION**

56. Express Scripts and its co-conspirators combined, conspired, and agreed to unreasonably restrain trade in the relevant markets by, among other actions, entering into a horizontal agreement to boycott and/or refusing to deal with Plaintiffs and other independent compounding pharmacies.

57. Express Scripts and its co-conspirators used an agreed upon and overlapping set of tools to implement the plan to cut off revenues to the Plaintiffs and other independent compounding pharmacies. While the specific mix of techniques utilized by the individual PBMs with respect to any specific pharmacy varied, each served the common goal of their conspiracy. The impact of the coordinated efforts by Express Scripts and the co-conspirators was the agreed upon goal of inflicting crippling losses on each of the Plaintiffs and many other independent compounding pharmacies by destroying their ability to provide compounded medicines through the group and individual health plan market.



58. As explained more fully below, Express Scripts and the other co-conspirators each used some combination of the following techniques:

- a. Drastically increasing the rejection rates for claims submitted for compounded medicines;
- b. Sending misleading letters to patients who used compounded medicines containing specious claims that the drugs they were prescribed lacked approval from the FDA and that they were, thus, unsafe;
- c. Instructing doctors to cease writing prescriptions for compounded medicines;
- d. Creating significant bureaucratic obstacles for compounding pharmacies to receive reimbursements;
- e. Undertaking abusive document requests (“desk audits”) and onsite audits regarding prescriptions that had already been electronically approved for reimbursement at the time the prescriptions were filled months earlier, resulting in demands for recoupment, delayed payments and unilateral withholding of reimbursement for completely unrelated prescriptions provided to different patients;
- f. Prohibiting independent compounding pharmacies from using the U.S. Postal service or delivery services to provide medications to patients; and
- g. Unilaterally expelling independent compounding pharmacies from PBMs’ networks and terminating their provider agreements without cause and/or based on pretextual assertions of cause.

59. Defendants' and their co-conspirators' boilerplate adhesion contracts are highly similar, and intended to be so. This contracting strategy ensures that the conspirators are familiar

with each other's contractual provisions and results predictably in each having the same bag of tricks from which to pull. The parallel, pretextual and bad faith use of contractual provisions at the core of the conspiracy was made easy, not just plausible, due to this transparency. Similarly, the detection and enforcement of any breaches of the unlawful agreements were made far easier due to this same transparency.

**A. The Pharmaceutical Care Management Association**

60. Express Scripts and each of its co-conspirators are, and at all relevant times have been, active member of the Pharmaceutical Care Management Association (“PCMA”), a trade association representing PBMs.

61. Executives from Express Scripts and each of the co-conspirators serve on the PCMA’s Board of Directors: George Paz (Chairman & Chief Executive Officer of Express Scripts Holding Company); Jon Roberts (Executive Vice President of CVS Health and President of its PBM operation “CVS/Caremark”); Jim DuCharme (President & Chief Executive Officer of Prime Therapeutics); and Mark Thierer (Chief Executive Officer of OptumRx).

62. The PCMA’s own statements make clear that it facilitates communication and collaboration among leaders in the PBM industry:

- a. It claims to “set the industry direction” — “PCMA’s members shape the industry’s direction and positions on a broad range of public policy issues that affect your business. No other trade group in America has more depth and influence on PBM issues.”
- b. It asks potential members to “Join Industry Leaders” — “PCMA’s Membership includes PBM CEOs and other industry leaders. Becoming a PCMA Member puts

you in touch with this motivated and influential group of leaders that is shaping the future of PBMs nationwide.”

- c. It also notes that members of the PCMA have “tremendous access to policymakers;” “have the opportunity to guide the industry’s research agenda;” “help shape and drive [] legal initiatives;” and “shape crucial regulations.”
- d. The PCMA hosts various meetings at which PCMA members gather, providing opportunities to reach consensus on strategies and tactics. The PCMA touts the numerous “Networking Opportunities” available to members: “PCMA provides one-of-a-kind conference events that bring together PBM industry leaders and their partners in pharmaceutical care to explore collaborative solutions to issues such as e-prescribing, specialty pharmacy, and Medicare Implementation.”

63. Upon information and belief, Express Scripts and its co-conspirators joined together beginning in approximately mid-2013—through the PCMA and otherwise—to study the market for compounded prescription medications and to collectively determine how to eliminate coverage for compounded medications.

**B. The Express Scripts “Compound Management Solution” Document**

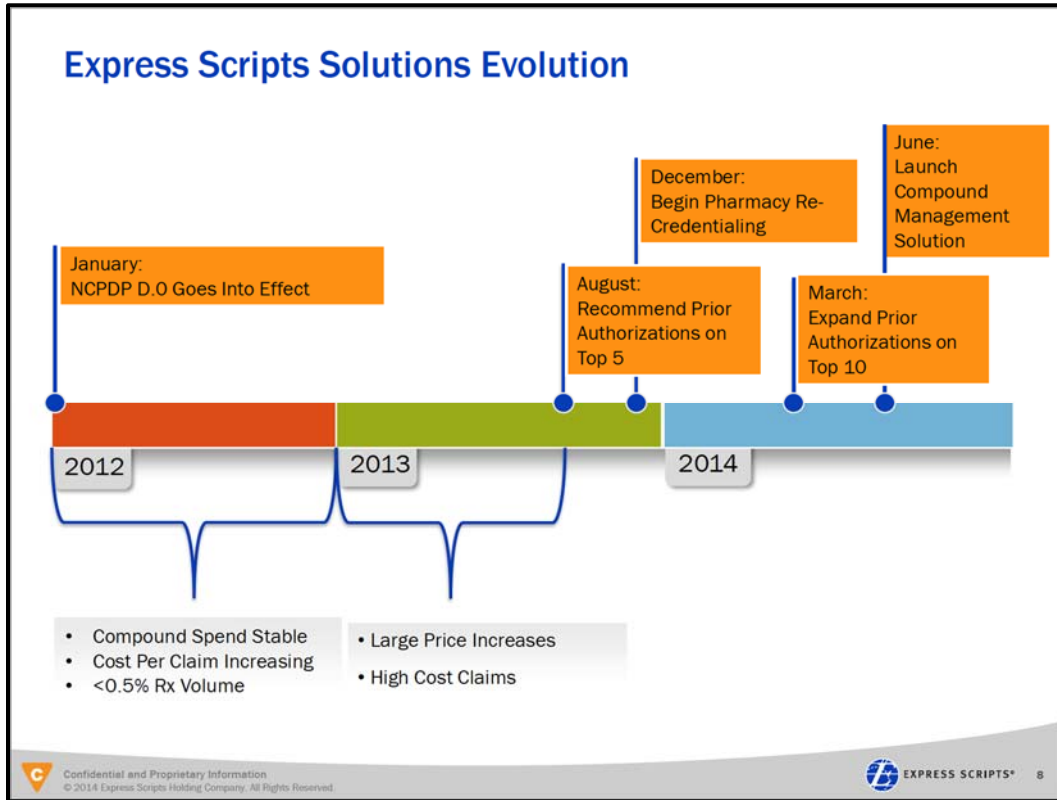
64. In mid-2014, Express Scripts and each of its co-conspirators began implementing their coordinated effort against Plaintiffs and other independent compounding pharmacies.

65. In June 2014, Express Scripts publicly announce a new “Compound Management Solution” intended to slash revenues paid to Plaintiffs and other compounding pharmacies for compounded medicines by 95%. For example, on or about June 18, 2014, Express Scripts posted text and a video announcing its Compound Management Solution on its public website, The Lab (<http://lab.express-scripts.com/insights/drug-options/closing-the-compounding-loophole>).

66. A PowerPoint document created by Express Scripts dated June 3, 2014, (attached as Exhibit 1) set out the goals, timing and some of the techniques to be used in the coordinated campaign against independent compounding pharmacies. Upon information and belief, copies of the Compound Management Solution document were distributed and used as part of presentations by Express Scripts to TPPs and others. Portions of the document were published on the above-referenced website.

67. The material posted by Express Scripts on its website, distribution of the PowerPoint, and other public presentations regarding the Compound Management Solution constitute public comments and signaling behavior.

68. The PowerPoint provides a timeline identifying the sequence of events leading up to Express Scripts' initiation of the plan to effectively eliminate payments for compounded medicines (the "Evolution Timeline Slide"). According to the Compound Management Solution document, the first step occurred in August 2013 when Express Scripts began requiring compounding pharmacies to obtain prior approval before filling prescriptions for the "Top 5" compounded drugs or ingredients. In March 2014, the prior approval requirement was expanded to "Top 10" compounded medicines or ingredients.



69. The PowerPoint further explains in another slide that the prior approval (referred to as “PA”) process undertaken in August 2013 and expanded in June 2014 served as a trial balloon precursor to implementation of the Compound Management Solution to test patient reaction. Express Scripts reported “**Compound PA Successfully Implemented for 200 Clients with No Member Noise**” (emphasis in original).

**Compound Solution Comparison**  
Compound PA vs. Compound Management

	Current Compound Prior Authorization	New Compound Management
<b>Bulk Powders Targeted</b>	10	1,000+
<b>Compound Ingredients Targeted</b>	Primary ingredient	All ingredients
<b>Mechanism</b>	Prior Authorization	Rx "Not Covered" reject
<b>Program Fee</b>	\$0.03 PMPM (Fee to be eliminated)	No Charge

**Compound PA Successfully Implemented for 200 Clients with No Member Noise**

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70. Returning to the Evolution Timeline Slide, Express Scripts explained that as part of the evolution of the Compound Management Solution it “Began Pharmacy Re-Credentialing” in December 2013. Express Scripts uses the re-credentialing process as a basis for terminating provider agreements and excluding the independent compounding pharmacies from the Express Scripts network.

71. In the Evolution Timeline Slide, Express Scripts also identified June 2014 as the date when it “Launch[ed] Compound Management Solution.” Upon information and belief, this June 2014 date refers to Express Scripts’ public communications regarding its strategy for the elimination of compounded medicines.

72. Another tactic identified as part of Express Scripts’ Compound Management Solution was to significantly increase the rate of rejections when independent compounding pharmacies submit electronic reimbursement claims. Specifically, part of Express Scripts’

strategy was to dramatically increase the number of ingredients in compounded medicines “Targeted” for rejection from 10 to over 1,000. Initially, compounded medicines had been targeted only if the **primary ingredient** had been on the top 10 list, but under the Compound Management Solution, Express Scripts targeted a compounded drug if **any ingredient** was on the new list of 1,000+ ingredients. Notably, under the Compound Management Solution, Express Scripts changed the method for targeting compounded medicines from requiring prior authorization by Plaintiffs and other independent pharmacies to automatically rejecting electronic reimbursement submissions with “**Rx ‘Not Covered’ reject**” (emphasis added).

73. The purpose of the “*New and More Robust Compound Management Solution*” was unambiguously stated by Express Scripts—it “Eliminates 95% Compound Spend.”

**New and More Robust Compound Management Solution**

- Evaluates ALL Ingredients
  - Bulk Powders
  - Bases (Creams, Ointments)
  - Tablets, Capsules
  - Vitamins & Minerals
- Targets Over 1,000 Ingredients
- Ongoing Updates
- Prenotification
- Client Opt-Out
  - No Charge
  - No Penalty

**» Eliminates 95% Compound Spend**

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74. Another tool identified in the PowerPoint to be used by Express Scripts and its co-conspirators to eliminate payments to independent compounding pharmacies was to use “A

Robust Communication Plan Target[ing] Compound Users.” In fact, in the PowerPoint, Express Scripts identified the specific text to be used in form letters sent to patients who used compounded medicines:

**Why your coverage is changing**

The U.S. Food and Drug Administration (FDA) defines a compound medication as one that requires a licensed pharmacist to combine, mix or alter the ingredients of a medication when filling a prescription. *The FDA does not verify the quality, safety and/or effectiveness of compound medications* (emphasis in original).

**Prenotification Member Letter**

**Letter calls out needed change to member with:**

1. Specific medication
2. Rationale for change
3. Call-to-action

**60-day member notice**

Benefit coverage change notice: Please talk with your doctor about your prescription.

Dear <<First Name>>:

We want you to know about an important change coming to your prescription drug coverage on <<Effective Date>>. As of this date, your prescription benefit will no longer cover prescriptions for compounded medications containing the following:

- <<Drug name>>
- <<Drug name>>

**Why your coverage is changing**  
 The U.S. Food and Drug Administration (FDA) defines a compound medication as one that requires a licensed pharmacist to combine, mix or alter the ingredients of a medication when filling a prescription. The FDA does not verify the quality, safety and/or effectiveness of compound medications.

**To avoid paying the full cost of your medication, you should:**

- Ask your doctor for a new prescription for an FDA-approved drug before your next fill.
- Be aware that this new prescription may still require further review and/or approval to be covered under your plan.

Please understand that because the medication you're currently taking will no longer be covered under your plan, you could pay the full cost if you continue taking it. So, it's important that you ask your doctor for a new prescription before <<Effective Date>>. For any questions, please call the number on your member ID card.

Sincerely,  
 Andrew R. Behm, Doctor of Pharmacy  
 Vice President of Pharmacy Services  
 Express Scripts

<Express Scripts manages your prescription benefit for your employer, plan sponsor, health plan or benefit fund.>

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Thus, although the only identified purpose of the Compound Management Solution in the PowerPoint was to reduce payments for compounded medicines by 95%, integral to Express Scripts’ strategy was to speciously inform members of the plans it administered that compounded drugs were no longer being covered in order to protect patient safety.

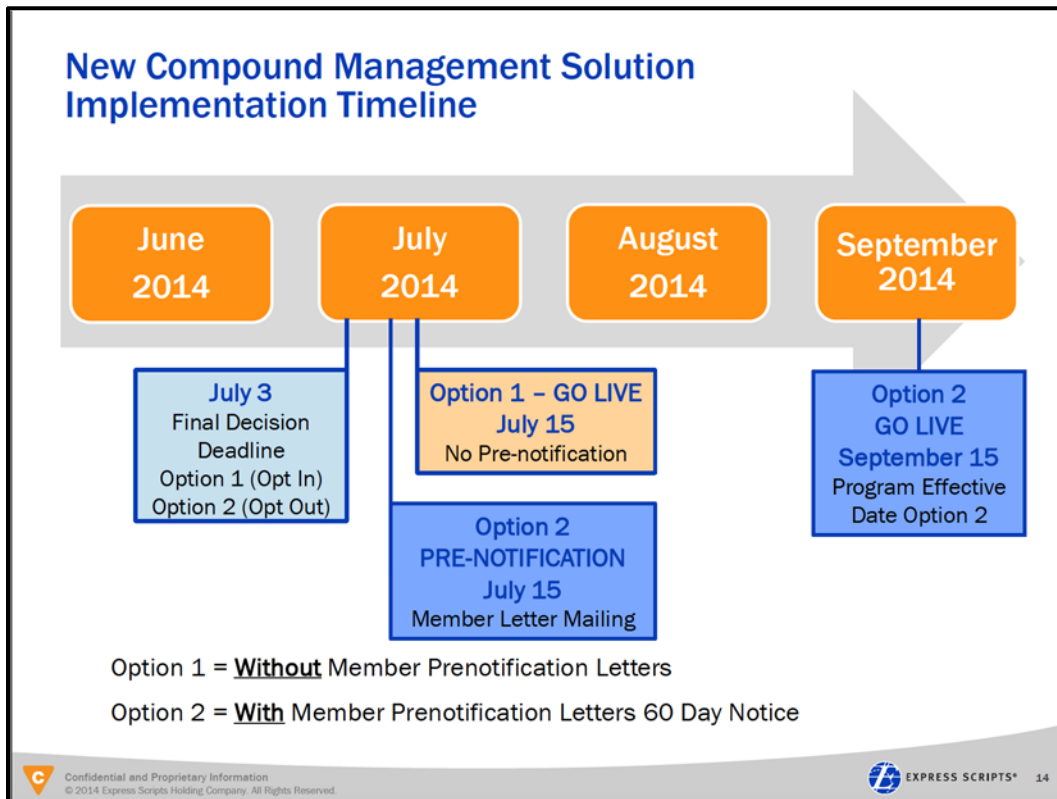


75. Informing patents that compounded medicines lack FDA approval was materially misleading and deceptive. Express Scripts and each of the other co-conspirators were well aware that compounded medicines are exempt from FDA approval requirements.

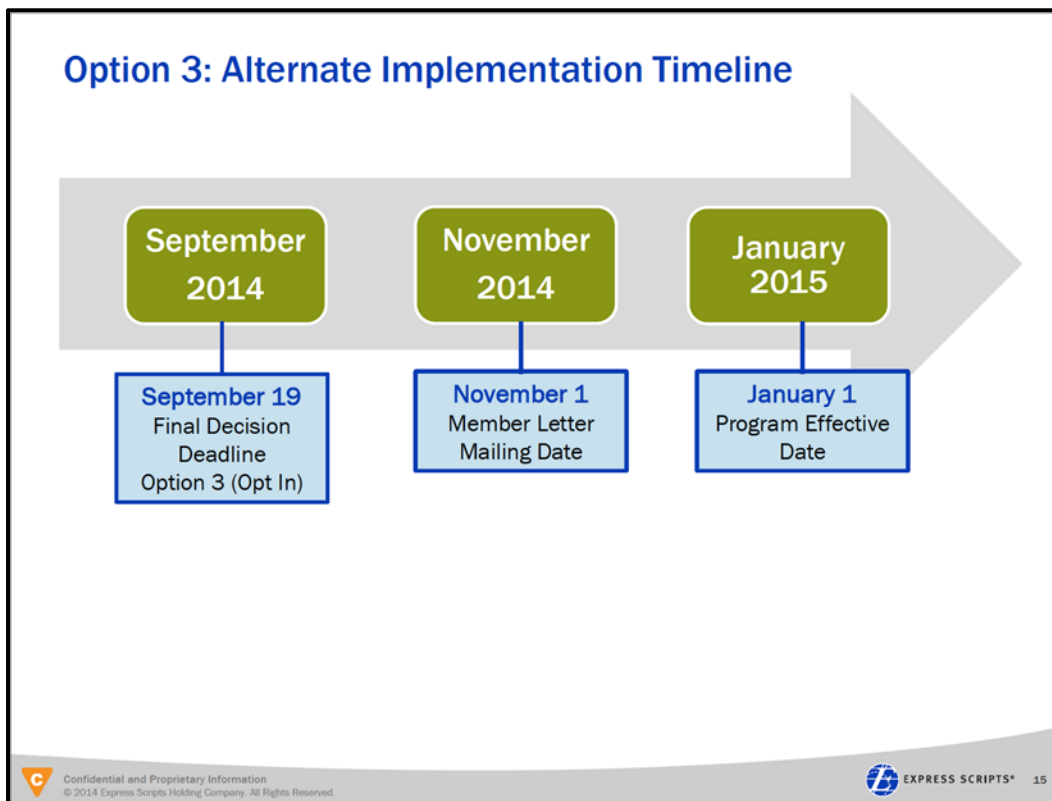
76. Indeed, the disingenuous nature of the statements regarding FDA approval was demonstrated by the announcement in December 2015 that Express Scripts is itself working on the development of a compounded alternative medicine to Daraprim in response to recent increases in the cost of that drug.

77. In two “Implementation Timeline” slides contained in the PowerPoint, Express Scripts set out three separate options for timing of the implementation for its Compound Management Solution:

- a. “Option 1” would initiate the scheme on July 15, 2014 and would “GO LIVE” without first providing pre-notification letters to members.
- b. “Option 2” would also initiate the scheme on July 15, 2014 but would include mailing of a 60 day pre-notification letter to members and therefore the scheme would actually “GO LIVE” on September 15, 2014.



- c. “Option 3” would initiate the scheme on November 1, 2014 with the mailing of a 60 day pre-notification letter and therefore the scheme would become effective on January 1, 2015.



78. Express Scripts assigned most TPPs to Option 2, meaning that if no action was affirmatively taken by a TPP, its members would begin receiving the rejection notices on the September 15, 2014 date.

79. Express Scripts informed the TPPs for whom it administered pharmacy benefit plans that “[p]harmacies will receive instructions but will not be allowed to dispute the program.”

**C. The Defendants and Their Co-Conspirators Undertake Concerted Action to Cut Off Revenue to Compounding Pharmacies**

80. Express Scripts used the methods described in the Compound Management Solution PowerPoint, along with a limited number of additional techniques, to reduce to the point of elimination the reimbursements paid to Plaintiffs and other independent compounding pharmacies.

81. Each of the co-conspirators also used a very similar playbook of tactics against the Plaintiffs to implement the common goal of eliminating the reimbursements paid to Plaintiffs and other independent compounding pharmacies.

82. Through these concerted efforts to exclude independent compounding pharmacies from the relevant market, each Plaintiff began to suffer significant decreases in reimbursements received from Express Scripts and its co-conspirators. Reimbursements to Plaintiffs first began to drop during the summer in 2014, accelerated during the autumn of 2014, and became even more pronounced during the first quarter of 2015, with devastating impact on all Plaintiffs.

83. For the twelve-month period beginning on October 1, 2014, and ending on September 30, 2015, the economic impact of the wrongful conduct by Express Scripts and its co-conspirators exceeds \$100 million, approximately half of which is attributable to unlawfully diminished business from Express Scripts.

84. The specific mix of techniques used by Express Scripts and its co-conspirators against Plaintiffs varied somewhat by co-conspirator and by individual pharmacy, but each of the co-conspirators utilized some combination of the following:

(i) **The Defendants and Their Co-Conspirators Drastically Increased Rejection Rates and Limited the Ability to Fill Prescriptions for Compounded Medicines**

85. Upon information and belief, after gathering and reviewing data on compounded medication prescriptions, Express Scripts and its co-conspirators instituted policies requiring prior authorizations. In some cases, prior authorizations were required for prescriptions that contained any of the ingredients most often used in compounded medications.

86. Upon information and belief, additionally, or alternatively, Express Scripts and its co-conspirators required prior authorization for compounded medications that exceeded a

threshold dollar amount intentionally set at such a low level that all, or almost all, claims for compounded medications would require prior authorization.

87. Upon information and belief, claims subject to prior authorizations were almost never paid on behalf of the patients. The requirement was, in fact, merely a pretext to deny patients access to the compounded medicines prescribed by their doctors. This tactic forced patients to instead use mass-produced commercially available drugs.

88. Express Scripts and its co-conspirators continued to rigorously monitor and adjust the list of ingredients and/or threshold costs to ensure that most compounded medication claims would categorically be denied.

89. For example, in or about July 2014, without prior announcement, Express Scripts began rejecting prescriptions submitted by Plaintiffs and other independent compounding pharmacies for plans in the first phase (Option 1) of its scheme to cut 95% of payments for compounding medicines. Each of the Plaintiffs experienced steadily increasing rejection rates for prescriptions submitted through Express Scripts thereafter.

90. Similarly, the other co-conspirators implemented outright prohibitions on certain ingredients or created a process requiring preapprovals. In Plaintiffs' experience, such preapprovals were frequently denied.

91. For example, in or about August 2014, Precision and C&M were informed by CVS Health that prior authorization from CVS Health was required for any compounded medication with a cost of \$300 or more. This effectively required preauthorization for all compounded drugs dispensed by those Plaintiffs. Further, because only a miniscule percentage of the patients served by Precision and C&M were able to obtain such prior authorizations, this practice was merely a thinly veiled form of denial.

92. The rejections occurred on new prescriptions, as well as on refills for patients who had taken medications over time. Thus, after months or years of approved prescription refills by Express Scripts and its co-conspirators, beginning in July 2014, some patients suddenly received a rejections simply stating that the compounded medication was “not covered – reject.”

(ii) **The Defendants and Their Co-Conspirators Sent Misleading Letters to Patients Regarding Lack of FDA Approval Making Compounded Medicines Unsafe**

93. As set forth in its Compound Management Solution PowerPoint, in July 2014 Express Scripts began implementing its “Robust Communication Plan Target[ing] Compound Users” by sending letters to patients that had previously filled prescriptions for compounded medicines informing them that compounded drugs would no longer be covered by their prescription benefit policies. The Express Scripts letters included misleading and false statements about compounded medicines.

94. For example, Express Scripts sent letters to patients containing the following statements:

To help safeguard your health and protect you from taking medication that are not approved by the Federal Drug Administration (FDA), we periodically review your prescription drug claims history . . . Compounded drugs may contain ingredients that are not FDA-approved for a specific condition and can be subject to quality and potency issues that can be a safety concern. Such compounded drug products are unproven, and are generally for experimental or investigational use . . . . [Y]ou will need to replace your compound prescriptions with a prescription for an FDA-approved product. This will protect your health . . . . Please ask your doctor to prescribe an oral or topical FDA-approved product as an alternative to the compounded prescription.

95. For example, CVS Health sent letters to patients that contained the following statements:

At CVS/caremark, we're committed to helping you on your path to better health . . . Our records show that you have been prescribed a medication that requires compounding by the pharmacy . . .

Due to lack of U.S. Food and Drug Administration (FDA) approval for many ingredients included in compounds and the high cost of these compounded medications, we want to let you know that effective **January 1, 2015**, these will no longer be covered through your plan.

If you do not wish to cover the cost of your compounded prescription, please speak with your doctor about the use of other available FDA-approved medication that may be used for treatment of your condition. (Emphasis in original).

96. In another version of the letter to patients, CVS Health used identical language, except that it provided for a preauthorization process rather than an outright prohibition on compounded medicines, stating in relevant part:

Due to lack of U.S. Food and Drug Administration (FDA) approval for many ingredients included in compounds and the high cost of these compounded medications, they may not be covered by your prescription plan without a prior authorization as of **March 1, 2015**. **This means that you could be responsible for the full cost of some or all of the ingredients used in the compound medication that was prescribed for you.** (Emphasis in original).

97. OptumRx sent patients letters with the following statements:

**Effective July 1, 2014, your compound medications prepared by your pharmacy is no longer covered under your pharmacy benefit plan because it contains a bulk chemical or ingredient that has not been approved by the U.S. Food and Drug Administration (FDA).** Prescription Drug Products covered under your pharmacy benefit plan must be approved by the FDA. FDA-approved medications are available to treat conditions for which some doctors prescribe compound medications. (Emphasis in original).

98. Upon information and belief, Express Scripts and each of its co-conspirators sent similar letters to patients that contained similarly materially deceptive and false statements.

99. The letters sent by Express Scripts and its co-conspirators with statements about compounded drugs lacking FDA approval were intentionally misleading because, through amendments to the Federal Food, Drug and Cosmetic Act (“FDCA”) contained in the Drug Quality and Security Act of 2013 (“DQSA”), compounding facilities are exempted from sections of the FDCA relating to: (i) compliance with current good manufacturing practices; (ii) labeling with adequate direction for use; and (iii) FDA approval prior to marketing.

100. Despite their knowledge of the DQSA exemptions, Express Scripts and its co-conspirators intentionally misled patients in an effort to scare and dissuade them from seeking to fill prescriptions for compounded drugs.

**(iii) The Defendants and Their Co-Conspirators Instructed Doctors to Stop Prescribing Compounded Medicines**

101. Each of the Plaintiffs experienced significant increases in the number and breadth of audits conducted by Express Scripts and its co-conspirators beginning in approximately mid-2013. Upon information and belief, Express Scripts and each its co-conspirators used the information obtained through these audits to identify physicians that prescribed compounded medicines.

102. Express Scripts and each of its co-conspirators targeted physicians that prescribed compounded medicines and sent intimidating communications to coerce them to stop prescribing compounded drugs or face accusations of fraud and/or abuse. Express Scripts and its co-conspirators also threatened termination of their provider agreements despite the fact that compounded medicines were covered under those provider agreements and the underlying health plans.



103. Physicians or administrative staff from doctors' offices informed each of the Plaintiffs of written and/or telephonic communications by Express Scripts and each of its co-conspirators containing misleading and false information about compounded medicines.

104. For example, CVS Heath sent letters to doctors that contained the following statements:

Starting **January 1, 2015**, certain ingredients commonly used in prescription compounds will be excluded from coverage . . . This means the member will be responsible for some or all costs related to compound prescriptions.

Compounds can contain substances that have not been rigorously tested for safety or effectiveness. Additionally, not all compounds are approved by the FDA for the prescribed route of administration. This benefit change helps to ensure that coverage is provided for compound ingredients that are safe and likely to be effective for their intended use.

105. Upon information and belief, Express Scripts and each of its co-conspirators sent similar letters containing false and misleading information regarding compounded medications to doctors that prescribed compounded drugs.

106. Upon information and belief, Express Scripts and each of its co-conspirators also contacted physicians by telephone to communicate false and misleading information regarding compounded medicines and to tacitly or explicitly intimidate the doctors and threaten them with retaliation if they continued to prescribe compounded drugs.

(iv) **The Defendants and Their Co-Conspirators Created Significant Bureaucratic Obstacles to Filing and Receiving Reimbursement for Compounded Medicine Prescriptions**

107. Express Scripts and its co-conspirators intentionally created significant obstacles to obtaining reimbursement for compounded medicines in order to implement their plan to eliminate reimbursements to Plaintiffs and other independent compounding pharmacies.

108. An example of meritless obstacles created to undermine the Plaintiffs' ability to fill prescriptions and obtain reimbursements for compounded medicines was that on or about April 1, 2015, OptumRx unilaterally revised its Pharmacy Manual to list 21 "prohibited activities" related to compounded drug claims and required network pharmacies to immediately change their practices to comply. One of the new prohibited activities was "[d]ispensing compound drugs without literature on file that supports the clinical/therapeutic value of the compound ingredients." Thus, although licensed physicians were issuing the prescriptions, OptumRx mandated that VMC and other independent pharmacies undertake the burden of conducting research and maintaining records on that research for every type of compounded medicine prescription filled. Upon information and belief, OptumRx knew this requirement could not be fully met due to the lack of articles published in medical literature about compounded medicines and their individual ingredients. Thus, the literature requirement serves as a means of prohibiting compounding pharmacies from filling valid prescriptions issued by licensed physicians for compounded medicines. On or about April 14, 2015, OptumRx sent a letter to VMC restating the new prohibited activities and threatening possible termination of its provider agreement for any violations.

109. Like VMC, on or about April 14, 2015, Daily Dose and CPRx also received a letter from OptumRx concerning the new list of prohibited activities related to compounded drug claims, including the requirement that pharmacies were prohibited from "[d]ispensing compound drugs without literature on file that supports the clinical/therapeutic value of the compound ingredients."

110. CVS Health also created obstacles by mandating that compounding pharmacies present literature supporting the clinical/therapeutic value of compounded medicines, even

though the prescriptions were issued by licensed physicians. For example, in or about May 2015, Precision was informed that to complete the re-credentialing process, it was required to submit to CVS Health a list of its top 25 compounded medicines and provide journal articles/literature supporting the validity of those medicines. NVC was also required to go through this same process of documenting supporting literature during its CVS Health re-credentialing in or about February 2014.

111. Express Scripts and each of its co-conspirators also adopted new tactics regarding requirements to collect co-payments from patients who filled prescriptions for compounded medications. Express Scripts and its co-conspirators enforced onerous requirements on Plaintiffs and other independent compounding pharmacies. When Plaintiffs were ultimately unable to collect co-payments, Express Scripts and its co-conspirators would retroactively reject the corresponding claims long after the medication had been provided to the patient, and demand repayment or refuse to reimburse any portion of the prescription's cost. For example, in January 2015, CVS conducted an onsite audit of NVC, looking at prescriptions filled in 2013 and 2014. CVS demanded recoupment of the full amount paid for all prescriptions that CVS claimed lacked sufficient documentation that NVC collected patient co-payments. This amount exceeded \$150,000 dollars.

(v) **The Defendants and Their Co-Conspirators Conducted Abusive Audits Resulting in Recoupment Demands and Withheld Payments on Unrelated Prescriptions and Patients**

112. With increasing frequency, Express Scripts and each of its co-conspirators have subjected Plaintiffs to intrusive and disruptive audits, both desk audits (requiring documents to be sent in for review) and on-site audits. These audits often examine months-, even years-old

prescriptions that had previously been approved for payment at the time the medications were dispensed to the patients.

113. The audits often result in demands from Express Scripts or its co-conspirators for reimbursement by Plaintiffs totaling hundreds of thousands of dollars. Often Express Scripts or its co-conspirators will illegally withhold or set-off payments owed to Plaintiffs for unrelated prescriptions and patients.

114. Express Scripts and its co-conspirators have sought to recoup reimbursements from the Plaintiffs for medications on the asserted basis that the medications contain “Non-FDA approved” ingredients despite exemptions from the FDCA. The recoupments were then unilaterally applied to payments due on unrelated and otherwise proper claims.

(vi) **The Defendants and Their Co-Conspirators Prohibited Plaintiffs From Using the United States Postal Service or Delivery Services to Provide Medications to Patients**

115. Express Scripts and its co-conspirators began to strictly enforce a prohibition on the use by Plaintiffs and other independent compounding pharmacies of the United States Postal Service or other delivery services to deliver compounded medicines to patients.

116. Express Scripts and its co-conspirators operate mail-order pharmacies and use the United States Postal Service to deliver medications, including compounded medicines, to patients.

117. Upon information and belief, there is no legitimate reason why Plaintiffs and other independent compounding pharmacies should be prohibited from using the United States mail or other delivery services to deliver medications to patients.

118. Upon information and belief, Express Scripts and its co-conspirators enforce the no mail fulfillment restriction, and its application to other non-mail methods of delivery, to decrease the amount of revenue paid to independent compounding pharmacies, including

Plaintiffs. Furthermore, by requiring patients who wish to receive home delivery of their compounded prescriptions to obtain them only from Express Scripts or one of its co-conspirators, they also eliminate competition for their own mail-order services from Plaintiffs and other independent compounding pharmacies.

**(vii) The Defendants and Their Co-Conspirators Terminated Provider Agreements and Expelled Independent Compounding Pharmacies from Provider Networks with Impunity**

119. To implement their unified plan to decrease reimbursements to independent compounding pharmacies, Express Scripts and its co-conspirators unilaterally expelled pharmacies from their networks, terminating their provider agreements on pretextual bases.

120. Precision fell victim to this tactic in May 2015. It had originally entered into a Provider Agreement with Express Scripts in or about October 2012. In or about April 2014, Precision provided notice to Express Scripts that one of the owners of the pharmacy had bought out the other owner's interest. In the spring of 2015, Express Scripts informed Precision that because of the change in ownership structure a year earlier, Precision was required to use an online re-credentialing process. After Precision filled out the online form—that included questions regarding the percentage of Precision's business that involved compounding—Express Scripts responded by terminating Precision's agreement, stating:

We have reviewed your change of ownership application. You have indicated on your application that your pharmacy will be dispensing compound prescriptions. At this time, we are not accepting any new Compounding pharmacies into our provider network. As a result, your pharmacy application has been denied.

121. Similarly, in May 2015, Precision was expelled from Prime's network based on the results of an audit. Just a few weeks earlier, Prime had reported Precision to the pharmacy regulator in the State of Minnesota, falsely asserting that Precision filled prescriptions for residents of that state though it was not licensed to do so. In fact, the prescriptions were filled for

a person who was, at the time, living in Florida and who picked up the prescriptions at Precision's Florida office.

122. Upon information and belief, as part of their unified plan to eliminate compounded medicines, Express Scripts and its co-conspirators jointly began manufacturing unwarranted reasons to terminate and/or suspend the contracts with independent compounding pharmacies in order to wrongfully avoid paying claims for compounded medicines, and work toward the goal of decreasing revenue paid to compounding pharmacies – like Plaintiffs – by 95% as outlined in the Compound Management Solution.

**D. *Express Scripts and Its Co-Conspirators Would Not and Could Not Behave This Way Absent an Agreement to Do So***

123. The conduct of Express Scripts and its co-conspirators in excluding Plaintiffs and other independent compounding pharmacies from the relevant market is only reasonable, explicable, or in the legitimate economic self-interests of the individual PBMs if it is the result of a conspiracy or agreement to jointly boycott Plaintiffs and other independent compounding pharmacies.

124. If Express Scripts or any of its co-conspirators acted unilaterally to exclude compounded prescription medications from its formulary or otherwise raise fees to account for the purported costs associated with compounded drugs, the services and formularies made available to plan sponsors by that individual PBM would be less comprehensive and therefore less competitive compared to those of ostensibly competing PBMs.

125. Only by agreeing to act in a concerted manner to uniformly exclude compounded prescription medications from coverage would Express Scripts and its co-conspirators be able to exclude independent compounding pharmacies from the relevant market while simultaneously

maintaining their respective spheres of control and market share over the prescription drug benefit market.

126. The agreement between Express Scripts and its co-conspirators can also be inferred because of:

- a. The timing, specifics and similarity of anticompetitive conduct by Express Scripts and its co-conspirators;
- b. Public comments, press releases and signaling behavior made by Express Scripts and its co-conspirators, including Express Scripts public communications regarding the Compounding Management Solution and the related elimination of coverage for more than 1,000 medicines or ingredients beginning in the spring of 2014;
- c. Their common motive to enter or further their interests in the compounding pharmacy market;
- d. They are all members—in fact board members—of the primary trade association acting on behalf of PBMs. That trade association provided numerous opportunities to meet, communicate and adjust their coordinated policies;
- e. Pretextual and misleading reasons for their conduct;
- f. Consolidation/concentration and structure of market, which has drastically reduced the number of PBMs and therefore made it far easier to coordinate; and
- g. The history of enforcement actions and litigation regarding collusion in the industry.

**MARKET CONCENTRATION AND MARKET POWER**

127. The relevant market is highly concentrated and becoming even more so.

128. PBMs manage 95% of all the drugs prescribed and covered under group and individual health plans in the country. Express Scripts and its co-conspirators control approximately 80% of the PBM market.

129. This degree of concentration creates a very strong presumption that when acting in concert, the Defendants have market power.

130. Express Scripts and its co-conspirators also, in fact, actually wield their control of the market in several ways including but not limited to:

- a. Requiring compounding pharmacies to enter into adhesion contracts that are alterable by the PBM at will;
- b. Dictating unilaterally which compounding ingredients and drugs are covered;
- c. Collectively suppressing the reimbursement rates paid to Plaintiffs, which drastically impairs and destroys Plaintiffs' businesses and competitiveness; and
- d. Withholding substantial payments for covered drugs unilaterally and with impunity.

### **BARRIERS TO ENTRY**

131. Numerous significant barriers to entry make the anti-competitive conspiracy between Express Scripts and its co-conspirators feasible and the elimination of independent compound pharmacies possible.

132. PBMs are the gatekeepers to the plan-covered prescription drug market. PBMs administer and control 95% of the plan-covered prescription drug market in this nation. Therefore, to gain access to patients with prescription drug coverage, pharmacies must enter agreements with PBMs.



133. Recent mergers within the industry have resulted in fewer PBMs controlling more of this market. Independent pharmacies, including compounding pharmacies, are left with little choice—if they want to dispense prescription medication, they must deal on the PBMs' terms.

134. To join the pharmacy networks created and controlled by the large PBMs, including Express Scripts, CVS Health, OptumRx, and Prime, independent pharmacies must accept adherence contracts that are subject to unilateral change at any time. The alternative is to be effectively frozen out of the group and individual health plan market, which would be terminal to the Plaintiffs' businesses.

135. The likelihood that new PBMs or entities controlling the reimbursement of compounded drugs will enter the market is virtually zero as can be seen by the complete absence of such entry in recent years. Again, this market is consolidating rapidly.

136. Moreover, the likelihood that new compounded drugs will enter the market and be covered is non-existent because Express Scripts and its co-conspirators dictate whether that can happen and have decided that it will not.

#### **ANTICOMPETITIVE CONDUCT AND EFFECTS**

137. As noted above, upon information and belief, Express Scripts and its co-conspirators joined together in approximately 2013—through the PCMA and otherwise—to create a strategy to eliminate coverage for compounded medications from pharmacies Express Scripts and its co-conspirators did not own or control.

138. Express Scripts and its co-conspirators coordinated efforts to exclude independent compounding pharmacies from the relevant markets by utilizing various anticompetitive means.

139. The actions that Express Scripts and its co-conspirators agreed to employ—and have since employed—to destroy independent compounding pharmacies include:

- a. Using information obtained from pharmacy audits to identify physicians that prescribed compounded drugs and targeting those doctors in an effort to stop physicians from prescribing compounded drugs;
- b. Intimidating and coercing those physicians to stop prescribing compounded drugs by, *inter alia*, sending them letters warning them to stop prescribing compounded drugs and leveling accusations of fraud and abuse;
- c. Instructing doctors to cease writing prescriptions for compounded drugs regardless of the individual patient's needs and regardless of the prescribing physician's assessment of the treatment most effective for the individual patient;
- d. Sending letters to physicians containing false and misleading information about compounded drugs in an effort to stop them from prescribing compounded drugs;
- e. Making telephone calls to doctors containing false and misleading information about compounded drugs in an effort to stop them from prescribing compound drugs;
- f. Sending misleading information to patients regarding the safety of compounded drugs including the specious statement that compounded drugs were not FDA approved;
- g. Letters such as those referenced in the previous sub-paragraph were misleading because, pursuant to amendments to the FDCA contained in the DQSA, compounding facilities are exempted from sections of the FDCA relating to: (1) compliance with current good manufacturing practices; (2) labeling with adequate direction for use; and (3) FDA approval prior to marketing. Express Scripts and its co-conspirators have nevertheless misled patients and the public about how

these federal regulations apply to compounded drugs in an effort to scare and dissuade patients from taking any compound drugs;

- h. Making misleading statements to patients and physicians by characterizing compounded drugs as “experimental” because they do not have FDA approval. Such statements are misleading because all so-called “off-label” use is “experimental” and PBMs continue to cover mass-produced off-label drugs, even though they are not proven safe and effective for an off-label purpose;
- i. Claiming to protect patients’ interests by rejecting all claims for drugs not approved for market by the FDA while omitting that compounded drugs are specifically exempted from that requirement under federal law;
- j. Failing, in their misleading letters to patients, to provide information regarding the federal and state oversight of compounding pharmacies;
- k. Creating significant obstacles for compound pharmacies to receive reimbursements including: (i) setting prior approval rates so low that compounded drugs cannot be approved; (ii) establishing co-payment policies that they use as pretext to harass the compounding pharmacies; and (iii) requiring compounding pharmacies to provide peer-reviewed journal articles or other literature supporting the clinical efficacy of compounding ingredients for medicines prescribed by licensed physicians
- l. Requesting documents (“desk audits”) regarding prescriptions that had previously been approved for repayment. They will often demand reimbursement for those prescriptions or illegally withhold or set-off payment due to the compounding pharmacies on improper bases. For example, Express Scripts has sought to recoup

reimbursements for medication on the basis that the medications contain “Non-FDA approved” ingredients despite exemptions from the FDCA. The recoupments are then applied to payments due on unrelated and otherwise proper claims;

- m. Restricting or prohibiting the use of U.S. mail and delivery services by compounding pharmacies (even though pharmacies affiliated with Express Scripts and its co-conspirators send prescriptions by mail);
- n. Reducing or eliminating coverage for medications compounded by pharmacies or ingredients of those compound drugs;
- o. Refusing to reimburse pharmacies for compound prescription claims; and
- p. Terminating independent compounding pharmacies from their respective networks without cause and/or based on pre-textual assertions of cause.

140. Plaintiffs have each encountered these tactics.

141. Express Scripts concocted, and in the summer of 2014 launched, its Compound Management Solution, the crux of which would eliminate coverage for over 1,000 compounded drug ingredients. Express Scripts modified the list of “excluded” ingredients, monitoring prescriptions being filled by compounding pharmacies and adding new items to the list as the amounts being reimbursed to independent compounding pharmacies began to increase, thereby furthering the illegal conspiracy by cutting off new revenue sources.

142. Furthermore, Express Scripts never provided a copy of the list to Plaintiffs. Rather they were left to discovery whether a prescription would be approved through the electronic submission process described above. Even for approved compounded medicines, Express Scripts would subsequently add them to the excluded list, and demand that the Plaintiffs return the

payments already provided. For example, the Sinelee patch is a patch used for pain relief. Initially, the Sinelee patch was approved by Express Scripts. However, in mid-2015, Express Scripts began to reject Sinelee patch submissions. They also conducted audits and sought to recoup previously paid claims for the Sinelee patch on the basis that it was not “FDA-approved.” As noted above, compounded drugs are exempted from FDA-approval.

143. Express Scripts’ and its co-conspirators’ requirements that compounded medicines be FDA-approved and supported by peer-reviewed articles are requirements that are equally impossible to meet. Because compounded medications are exempted from the FDA-approval process and generally not the subject of peer-reviewed journal articles, these requirements are simply an intentionally impossible barrier to coverage erected by the PBMs to eliminate compounded medicines from the prescription benefit drug market.

144. Likewise, there is no legitimate reason why Plaintiffs and other compounding pharmacies should be restricted from using the United States mail or other delivery services to deliver medicines to patients in the same manner utilized by Express Scripts and its co-conspirators. Upon information and belief, the reason they have imposed the prohibition is to limit or eliminate competition from other pharmacies.

145. As a result of the above anticompetitive conduct, Plaintiffs’ access to the relevant market has been limited or eliminated. Without the ability to fill prescriptions for patients in Express Scripts’ or its co-conspirators’ networks, Plaintiffs and other independent compounding pharmacies will be excluded from the relevant market and driven out of business, allowing Express Scripts to dominate the relevant market. This is the core goal of the illegal agreement of Express Scripts and its co-conspirators.

146. Another federal court judge was “deeply troubled” by the testimony of a senior manager for CVS Health and long-time attendee of meetings held by the Pharmacy Membership Review Committee, the body within CVS Health that evaluates alleged violations of the provider agreements. The CVS Health senior manager testified that the committee had at least a decade of experience evaluating pharmacy violations and no CVS Health pharmacy has ever been terminated, while a number of independent pharmacies have suffered the ultimate sanction of termination. The court noted the obvious “appearance of impropriety from the apparent disparity in treatment as between independent pharmacies and CVS Caremark's own brood” and therefore sent a copy of the court transcript and opinion to the Federal Trade Commission and the Antitrust Division of Department of Justice. *See Hopkinton Drug, Inc. v. Caremark PCS, LLC*, 77 F. Supp. 2d 237, 253 n.8 (D. Mass. 2015) (Young, J.).

147. As a result of the above anticompetitive conduct, patients requiring compounded drugs have been deprived of life-enhancing medications for which they have coverage under group or individual health plans.

148. Patients are now forced to use less effective medications because Express Scripts and its co-conspirators have eliminated or restricted compounded prescription drugs in favor of mass-produced drugs.

149. Express Scripts and its co-conspirators are able to exclude Plaintiffs from the relevant market because they control the market that purchases prescription drugs through group and individual health plans. By joining together to use their market power to control the drugs that physicians prescribe and to coerce physicians to prescribe less effective, mass-produced drugs to patients who are better served by compounded drugs, Express Scripts and its co-

conspirators are driving out compounded medicines and compounding pharmacy services as market sub-classes in the prescription drug benefit and services market.

150. Express Scripts and its co-conspirators benefit from the elimination of Plaintiffs from the relevant market in several ways. Express Scripts and its co-conspirators have a financial interest in the mass-manufactured drugs that patients will be forced to take if they are not allowed access to the more appropriate compounded drugs. Moreover, Express Scripts and its co-conspirators have financial interests in specialty and compound pharmacies that compete with Plaintiffs' pharmacies. Elimination of Plaintiffs from the market will enable Express Scripts and its co-conspirators to gain more market share.

#### **ANTITRUST INJURY**

151. Express Scripts' and its co-conspirators' anticompetitive conduct has caused numerous, devastating antitrust injuries to Plaintiffs.

152. Plaintiffs' revenues and profits have decreased because Express Scripts and its co-conspirators:

- a. Have placed unauthorized limitations on the mail-order delivery of compounded medications;
- b. Have refused to cover prescriptions that contain non-FDA approved ingredients;
- c. Have reimbursed Plaintiffs for prescription medications but later sought to recoup those funds by, *inter alia*, setting off funds due on conforming claims;
- d. Have terminated Provider Agreements with Plaintiffs; and
- e. Have decreased reimbursement amounts.

153. Plaintiffs' revenues and profits will decrease even more rapidly because Express Scripts, via unauthorized changes to provisions in its provider agreements, now prohibit Plaintiffs from engaging in any mail-order services.

154. Plaintiffs' profits have also been negatively impacted due to the increasing cost of complying with the shifting policies and baseless audits of Express Scripts and its co-conspirators.

## COUNT I

### **Violation of the Sherman Act, 15 U.S.C. § 1 (*Per Se*, Quick-look, Rule of Reason)**

155. Plaintiffs incorporate by reference as though fully set forth herein paragraphs 1 through 155 of the Complaint.

156. Express Scripts has engaged in an unlawful contract, combination, or conspiracy with its co-conspirators and others to unreasonably restrain trade and commerce in the relevant market in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

157. Express Scripts and its co-conspirators contracted, combined, and conspired to restrain trade in the relevant market by entering into a horizontal agreement to (a) boycott and/or refuse to deal with Plaintiffs and other independent compounding pharmacies and (b) exclude Plaintiffs and other independent compounding pharmacies from the relevant market and thus drive them out of business.

158. Express Scripts and its co-conspirators implemented this *per se* illegal group boycott by jointly engaging in conduct calculated to end coverage for compound drugs under group and individual health plans, and thus drive independent compounding pharmacies out of business.



159. Express Scripts and its co-conspirators' concerted refusal to deal with and/or boycott of Plaintiffs and independent compounding pharmacies constitutes a *per se* unreasonable restraints under Section 1 of the Sherman Act, 15 U.S.C. §1 (*per se*, rule of reason, quick look).

160. Express Scripts and its co-conspirators' concerted refusal to deal with and/or boycott of Plaintiffs and independent compounding pharmacies also constitutes, under the rule of reason, unreasonable restraints under Section 1 of the Sherman Act, 15 U.S.C. §1 (*per se*, rule of reason, quick look).

161. As a direct and proximate result of Express Scripts' and its co-conspirators' concerted conduct, Plaintiffs have been and will continue to be irreparably injured and financially damaged in their business and property in that, among other things, Plaintiffs have suffered and will continue to suffer significant lost revenue and profits from the substantial decrease in reimbursements from compounded medicines covered under group and individual health plans.

162. Due to Express Scripts' and its co-conspirators' concerted conduct, market power, the barriers to entering the relevant market, and the resulting anticompetitive and antitrust injury, Express Scripts also has violated Section 1 of the Sherman Act, 15 U.S.C. §1 under a quick-look and rule of reason standard.

## COUNT II

### **Declaratory and Injunctive Relief**

163. Plaintiffs incorporate by reference as though fully set forth herein paragraphs 1 through 163 of the Complaint.

164. Plaintiffs have sustained, and will continue to sustain, irreparable injuries caused by Express Scripts' conduct set forth herein.

165. Plaintiffs have no adequate remedy at law for the injuries and damages proximately caused by the conduct of Express Scripts.

166. Plaintiffs are likely to succeed on the merits of their claim against Express Scripts.

167. Plaintiffs are, therefore, entitled to a preliminary and permanent injunction as set forth in the request for relief below.

### **REQUEST FOR RELIEF**

WHEREFORE, the Plaintiffs hereby respectfully request that judgment be entered in their favor and against the Express Scripts Defendants, as follows:

1. As for Count I of the Complaint:
  - a. Preliminarily and permanently enjoining the Express Scripts Defendants from engaging in anticompetitive and illegal conduct in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, as more fully described in Count I herein;
  - b. Awarding Plaintiffs compensatory damages in an amount to be determined at trial;
  - c. Awarding Plaintiffs three times actual damages against Defendant Express Scripts, Inc. for its violations of Section 1 of the Sherman Act;
  - d. Awarding Plaintiffs interest, attorneys' fees, and costs incurred herein; and
  - e. Awarding such other and further relief as this Court deems just and proper under the circumstances.
2. As to Count II, issue an order as follows:
  - a. Preliminarily and permanently enjoining the Express Scripts Defendants from terminating the Provider Agreement between itself and any of the Plaintiffs;

- b. Preliminarily and permanently enjoining the Express Scripts Defendants from refusing to process and/or pay claims submitted by Plaintiffs for payment of prescriptions for compound drugs prescribed by licensed physicians for their patients, which had heretofore been covered under their group or individual health plans as of July 2014;
- c. Preliminarily and permanently enjoining the Express Scripts Defendants from refusing to process and/or pay claims submitted by Plaintiffs for payment of refills of an existing refillable prescription for compound drugs prescribed by licensed physicians for their patients;
- d. Preliminarily and permanently enjoining the Express Scripts Defendants from eliminating from coverage those chemicals and/or other ingredients used by Plaintiffs in the preparation of compound drugs prescribed by licensed physicians for their patients, which had heretofore been covered under their group and individual health plans as of July 2014;
- e. Preliminarily and permanently enjoining the Express Scripts Defendants from retaliating in any way against any licensed physician who writes a prescription for a compound medication and/or provides materials or information requested by Express Scripts for prior approval of compound drugs for a patients;
- f. Preliminarily and permanently enjoining the Express Scripts Defendants from contacting patients who seek to fill or do fill prescriptions with Plaintiffs;
- g. Preliminarily and permanently enjoining the Express Scripts Defendants from seeking to claw-back, recover, or obtain recovery in any way for payments

previously made to Plaintiffs for compound drugs prescribed by licensed physicians for their patients;

- h. Preliminarily and permanently enjoining the Express Scripts Defendants from prohibiting Plaintiffs from using the United States Postal Service or other delivery service to deliver to patients the compound drugs prescribed by their licensed physicians;
- i. Order the Express Scripts Defendants to reinstate the Provider Agreement with Precision Rx Compounding LLC *nunc pro tunc*;
- j. Awarding each Plaintiff their respective attorneys' fees and costs incurred herein; and
- k. Award such other and further relief as this Court deems just and proper under the circumstances.

**JURY TRIAL DEMANDED**

Plaintiffs hereby demand a trial by jury on all claims and issues so triable as a matter of right.

Dated: January 15, 2016.

Respectfully submitted,

/s/ Anthony G. Simon

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