

2. ESI is the nation's largest prescription benefit manager ("PBM"). Working in concert with other large PBMs, ESI has actively worked to exclude Plaintiff and other independent compounding pharmacies from the relevant pharmacy services and prescription drug market, thereby reducing competition in that market. This reduction in competition directly benefited ESI by driving patients to its own and other large PBMs' specialty and mail-order pharmacies.

3. Defendant ESI effectuated this conspiracy by coercing physicians to stop prescribing prescription medications compounded by Plaintiff and other independent compounding pharmacies, disseminating false and misleading information to patients and physicians regarding the safety and regulatory status of compound medications, imposing insurmountable administrative obstacles to obtain reimbursement for compound prescription medications, ending insurance coverage for compound medications and/or their constituent drugs, and improperly withholding reimbursements on prescriptions already filled and submitted to Defendant ESI by other independent compounding pharmacies.

4. Defendant ESI, along with its co-conspirators, was able to carry out this plan because they enjoy tremendous market power, allowing them to dictate the terms of reimbursement to independent pharmacies. ESI is the largest PBM in the country, and its chief co-conspirators are the second, third, and fourth largest PBMs in the country. Together, these four market players review and determine the right to reimbursements on more than 80% of prescription drug claims covered by group and individual plans in this country. Further, roughly 95% of all prescription drug sales are covered by plans. In other words, independent pharmacies, such as Plaintiff, simply cannot remain in business, providing an important service to patients, unless they work with ESI and its co-conspirators.

5. Defendant ESI's concerted conduct was intended to, and in fact did, push Plaintiff to the brink of going out of business, generally harm all independent pharmacies, drive business to Defendant ESI and other PBMs' mail-order and specialty pharmacies, and corner the relevant market for pharmacy services and prescription drugs, including compounded drugs.

6. Defendant ESI's concerted conduct has substantially harmed competition in the relevant market for pharmacy services and prescription drugs and has adversely affected the health of patients by depriving them of medications needed to treat their individual and specialized needs.

7. As a result, Plaintiff is entitled to an injunction enjoining Defendant ESI from engaging in such unlawful conduct, as well as an award of monetary damages suffered by Plaintiff as a result of Defendant ESI's wrongful conduct, together with other appropriate legal and equitable relief.

PARTIES

8. Plaintiff ZMS 1 LLC d/b/a The Medicine Shoppe, is a Florida limited liability company with a principal place of business in Kissimmee, Florida.

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

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

11. Together, Express Scripts Holding Company and Express Scripts, Inc., constitute a PBM providing integrated pharmacy benefit management services, including network pharmacy claims processing, home delivery pharmacy services, specialty pharmacy benefit management, formulary management, and medical and drug analysis services, to manage drug

plans for health plans, among others. Upon information and belief, ESI is the nation's largest PBM, filling more than 1.4 billion prescriptions annually nationwide for approximately 86 million individual patients throughout the country. Upon information and belief, in 2014 ESI earned more than \$100 billion in revenue, or roughly half of all revenue earned by PBMs that year.

12. Upon information and belief, ESI also owns and operates various specialty and mail-order pharmacies, including compounding pharmacies providing compound medications and pharmacy services to patients nationwide.

JURISDICTION AND VENUE

13. Plaintiff brings this action, in part, pursuant to Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26, to recover treble damages, injunctive relief, and the costs of this suit, including reasonable attorneys' fees, for Defendant ESI's violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

14. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1331 and 28 U.S.C. § 1337 because Plaintiff asserts claims arising under Section 1 of the Sherman Act, 15 U.S.C. § 15.

15. This Court has personal jurisdiction over Defendant ESI because ESI resides in this district.

16. Venue is proper under Section 12 of the Clayton Act, 15 U.S.C. § 22, under 29 U.S.C. § 1132(e)(2), and under 28 U.S.C. § 1391, in that the Defendant ESI resides in this district.

CO-CONSPIRATORS

17. CVS Health Corporation (“CVS”) is a Delaware corporation with its principal place of business in Woonsocket, Rhode Island. Upon information and belief, CVS is the nation’s second largest PBM, providing comprehensive prescription benefit management services for over 2,000 health plans nationwide. In addition, it operates a national retail pharmacy network with over 60,000 participating pharmacies, as well as numerous specialty and mail-order pharmacies.

18. OptumRx, Inc. (“ORx”), is a California corporation with its principal office located in Irvine, California. ORx is a wholly owned subsidiary of UnitedHealth Group, Inc. Upon information and belief, ORx is the third largest PBM in the United States, providing pharmacy benefit management services for more than 65 million people nationwide and filling more than 1 billion prescriptions annually. ORx, or corporate affiliates owned by UnitedHealth Group, also own and operate mail-order and specialty pharmacies.

19. Prime Therapeutics, LLC (“Prime”), is a Delaware limited liability company with its principal place of business in Eagan, Minnesota. It is an independent pharmacy benefit manager owned by 13 not-for-profit Blue Cross and Blue Shield health plans, subsidiaries, or affiliates of those plans that processes claims and delivers medicine to more than 25 million members nationwide. Among other things, Prime, or its corporate affiliates, also operates mail-order and specialty pharmacies, including Primemail and Prime Therapeutics Specialty Pharmacy.

20. Various other individuals and entities not named in this Complaint also participated as co-conspirators in the illegal conduct alleged. These unnamed entities include other PBMs and other persons or entities that stand to benefit from the reduction in competition

in the relevant market caused by the elimination of independently owned and operated compounding pharmacies.

BACKGROUND

Overview of the Plan-Covered Prescription Drug Industry

21. Compounding pharmacies ensure that patients are not denied essential prescription drugs because they are unable to consume mass-produced products. In this way, compounding pharmacies play a critical and necessary role in the plan-covered prescription drug industry.

22. After a doctor determines that a particular prescription medication is appropriate, patients often turn to pharmacies to fill that prescription.

23. However, pharmacies do not charge patients with prescription drug benefits the full retail price of the prescribed drugs. Instead, for patients with these benefits, third-party payors (“TPPs”) are responsible for paying most of the associated cost. Common examples of TPPs include private health insurers, employer-sponsored health and welfare plans, and self-insured employers. The patient, on the other hand, is required to pay a smaller portion of the drug’s cost directly to the pharmacy. This is commonly known as a “co-pay.”

24. When the patient presents the prescription to the pharmacy, the pharmacy uses PBM- provided software or other technology to determine if and how much it will be paid for filling the prescription. Once this process is complete, and the pharmacy receives the co-pay (if any) from the patient, the pharmacy will dispense the drug to the patient and seek reimbursement for the remainder of the cost from the PBM on behalf of the relevant TPP.

Pharmacy Benefit Managers (PBMs)

25. PBMs administer the prescription pharmaceutical portion of healthcare benefit

programs, which are typically purchased by a plan sponsor. As part of their functions, PBMs provide bundled services related to the administration of pharmaceutical benefits, including claims adjudication, formulary design, management and negotiation of branded drug rebates, management and negotiation of networks of retail pharmacies, 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. Some chain pharmacies, such as CVS, have merged with PBMs. Since their inception, PBMs have become multi-billion dollar businesses.

26. PBMs dominate the process of administering prescription drug payments to pharmacies. They manage 95% of all prescription drugs covered by insurance. In addition, the market is highly concentrated in a small number of players. ESI, CVS, ORx and Prime dominate the PBM market in the United States with a market share of more than 80%. On information and belief, CVS and Defendant ESI control drug plans for over 40 of the Fortune 50 companies and between 80 and 90 percent of the commercial employer market. According to the Pharmaceutical Care Management Association, the industry's trade group, "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."

27. However, in addition to facilitating transactions between TPPs and independent pharmacies, – a function that includes setting the prices for prescriptions filled by pharmacies – PBMs, including ESI, also own and operate retail pharmacies. Through these retail pharmacies, large PBMS compete directly with independently-owned pharmacies, such as ZMS.

Compounding Pharmacies

28. Drug compounding is a practice in which a licensed pharmacist, a licensed

physician, or in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Plaintiff ZMS is an independent compounding pharmacy providing patients with medications tailored to their specific needs pursuant to and in accordance with the instructions provided by the patient's physician.

29. Compounding is an integral part of pharmacy, the science and technique of preparing and dispensing drugs and medicines, and has historically been recognized as a legal and vitally important core component of traditional pharmacy practice and services.

30. Millions of patients have unique health needs that over-the-counter drugs ("OTCs") and FDA-approved prescription medications cannot meet. For these patients, personalized medication solutions prescribed by licensed physicians and prepared by trained and licensed pharmacists are the only way to achieve the health benefits required by the patient as prescribed by their physician.

31. Unlike commercially available drugs, which are manufactured on a large-scale basis and are not alterable or appropriate for certain patients, compounding allows the medication to be tailored to the needs of the patient who, for whatever reason, cannot or should not take the mass-produced drug.

32. For example, if a patient is allergic to a particular ingredient in a commercially available product, the medication can be compounded without the ingredient. If a patient is unable to swallow a commercially available pill, a liquid form can be compounded. If a dosage is too strong for an infant, a lower dosage can be compounded. Flavors can be added to make the medicine more palatable for a child so that the child will take the medicine. Additives for topical creams can be used to prevent skin irritation. Nonessential ingredients such as gluten or

dye can be eliminated. Topical creams enable a physician to treat a patient's pain at the site of the pain, often avoiding the need for oral or injected narcotic drugs which can result in dependency.

33. Without access to the compounded medications, those patients who require medications tailored to meet their individualized needs are denied the treatment needed to address their health situations.

34. In recent years, compound medications have been prescribed in response to the FDA's 2012 mandate to seek alternatives to addictive opioid narcotics. Topical pain-management medicines compounded by ZMS and other independent compounding pharmacies provide physicians with a critical tool to accomplish this objective. Such topical medications, which typically do not penetrate the bloodstream, facilitate delivery of the medicine to the desired location while allowing patients to reduce or avoid the use of oral narcotics that affect the entire body and can lead to opioid dependency and abuse.

ZMS's Relationship with ESI

35. Although compounding pharmacies like ZMS play a unique role in the prescription drug industry, they are subject to the same process for receiving reimbursements for filled prescriptions described above.

36. The relationships between pharmacies and PBMs are governed by contracts known as "provider agreements." Typically, these agreements are supplemented by "provider manuals," which are incorporated into the provider agreements. Sometimes pharmacies enter into these agreements directly with PBMs. Pharmacies may also elect to enter into these agreements through Pharmacy Services Administrative Organizations ("PSAOs"), third parties that assist pharmacies with the implementation and execution of their agreements with PBMs. In

either case, however, pharmacies have little to no opportunity to negotiate the terms of either the provider agreements or provider manuals because the market dominance of the PBMs allows them to dictate unfavorable terms to the pharmacies. These agreements are highly standardized throughout the industry, non-negotiable, and allow the PBMs to unilaterally alter the terms of the agreement at will.

37. The agreement between ZMS and ESI was one of these industry standard agreements. It purported to include a promise from ESI to compensate ZMS for filling plan members' valid prescriptions according to the following procedure:

- a. A patient presents a prescription for a compound drug to ZMS;
- b. Before doing anything else, ZMS electronically submits a claim to ESI;
- c. ESI responds informing ZMS of the amount ESI will pay ZMS to fill the prescription;
- d. ESI charges ZMS a transaction fee for each claim;
- e. Plaintiff collects the patient's co-pay (if any) and dispenses the drug;
- f. ESI reimburses ZMS in the amount stated in its response.

38. In the case of independently-owned compounding pharmacies, however, ESI and their co-conspirators failed to follow these procedures by manufacturing unnecessary obstacles and restrictions designed to eliminate Plaintiff ZMS and other independent compounding pharmacies from the relevant market.

ANTITRUST ALLEGATIONS

39. Defendant ESI and the 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 reasonable coverage for compound prescription medications and eliminate Plaintiff ZMS and other independent compounding pharmacies as competitors in the

Relevant Market. This behavior constitutes a per se violation of the Sherman Act, and is also an unlawful restraint of trade under an intermediate standard, such as the rule of reason.

Trade and Interstate Commerce

40. The provision and sale of many of the pharmaceutical services and products, and insurance coverage for such services and products related to ZMS, are each in, and affect, interstate commerce.

41. Many of the activities of Defendant ESI and the 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.

42. Many of the acts in the conspiracy described herein between and among Defendant ESI and the co-conspirators had, and continues to have, a direct, substantial and reasonably foreseeable impact on United States commerce.

The Relevant Market

43. The relevant service market affected by Defendant ESI and the co-conspirator's conduct is pharmacy services that are reimbursed by insurance, including, but not limited to, the compounding, filling, and dispensing of prescription medications. The relevant product market affected by Defendant ESI and the co-conspirator's conduct is prescription drugs that are reimbursed by insurance, including, but not limited to, compounded prescription drugs. Affected sub-markets may include markets for compounded, mail-order, and other specialty drugs, as well as markets for drugs for certain indications, such as drugs for chronic pain and allergies.

44. The relevant product market is limited to prescription drugs that are covered by insurance because there are not enough uncovered individuals ZMS could turn to in order to

make up for the business lost from being excluded from the relevant market by ESI and its co-conspirators.

45. The relevant geographic market for ESI's anticompetitive activities includes the United States. The relevant geographic market for ESI's anticompetitive activity that affects ZMS is the Eastern United States, including, but not limited to, Florida. More specifically, any state in which ZMS is licensed to fill prescriptions is also a relevant geographic market. Further, smaller markets within the boundaries of Florida and/or other states exist as well.

46. The unlawful conspiracy between Defendant ESI and the co-conspirators has had the effect of unreasonably restraining, suppressing, and eliminating competition in the provision of pharmacy services and the dispensation of prescription drugs covered by insurance in all markets in which Plaintiff ZMS did and could operate in interstate commerce.

**Concerted Action by Defendant ESI and the Co-Conspirators to
Unreasonably Restrain Trade in the Relevant Market**

47. Defendant ESI and the co-conspirators combined, conspired, and agreed to unreasonably restrain trade in the Relevant Market by, among other actions, entering into a horizontal agreement to boycott and/or refuse to deal with ZMS and other, independent compounding pharmacies.

48. As explained more fully below, ESI and their co-conspirators have used some combination of the following techniques:

- a. Dramatically increasing rejection rates for claims relating to compounded medications;
- b. Sending letters to patients misinforming them about the safety, efficacy, and legal status of compounded medications;
- c. Improperly causing doctors to stop prescribing compounded medications;
- d. Manufacturing unnecessary, and often insurmountable, bureaucratic obstacles

to receiving reimbursements for compounded medications;

- e. Initiating abusive audits of independent compounding pharmacies regarding prescriptions that had already been approved for reimbursement and actually dispersed months earlier, resulting in crippling demands for recoupment, delayed payment, and withholding of future, otherwise unobjectionable, reimbursements;
- f. Prohibiting independent compounding pharmacies from using the U.S. Postal Service or other delivery services so as to prevent independent pharmacies from competing with ESI and their co-conspirators' own privately held mail-order pharmacies; and
- g. Expelling or suspending independent compounding pharmacies from their provider networks without legitimate cause.

49. The similarities between ESI's and their co-conspirators' boilerplate contracts aided in this concerted activity. They ensured that each co-conspirator would have the same seemingly legitimate grounds to undertake this activity, and made the detection of any supposed breaches of the agreements by independent compound pharmacies easy to detect.

A. The Pharmaceutical Care Management Association

50. Defendant ESI and each of the co-conspirators is an active member of the Pharmaceutical Care Management Association ("PCMA"), "the national association representing America's pharmacy benefit managers (PBMs)."

51. Executives from Defendant ESI and each of the co-conspirators serve on the PCMA's Board of Directors: George Paz (Chairman & Chief Executive Officer, ESI) is the Chairman of the PCMA Board of Directors and Jim DuCharme (President & Chief Executive Officer, Prime), Jon Roberts (President, CVS/Caremark & Executive Vice President, CVS), and Mark Thierer (Chief Executive Officer, ORx), are all members of the PCMA Board of Directors.

52. The PCMA's website makes clear that the PCMA facilitates communication and collaboration among leaders in the PBM industry to "shape the industry's direction" and

“explore collaborative solutions” to industry issues, including, for example, “specialty pharmacy”:

- a. “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. “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. “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.”

53. The PCMA hosts various meetings and summits at which PCMA members convene to discuss industry issues and strategies for addressing those issues.

54. Upon information and belief, Defendant ESI and the co-conspirators joined together in approximately 2013—through the PCMA and otherwise—to study the market for compound prescription medications and compound medicine prescribing trends, and to collectively determine how to best eradicate coverage for compound medications in 2014.

55. Upon information and belief, after surreptitiously gathering information about physician prescribing trends and compound pharmacy dispensing practices, Defendant ESI and the co-conspirators joined together to jointly exclude independent compounding pharmacies from the Relevant Market by employing various, anticompetitive means, including, but not limited to: intimidating physicians who prescribed compound medications and the patients who take them; effectuating insurmountable obstacles for pharmacies to receive reimbursement for compound prescriptions; eliminating coverage for all compound medications by denying coverage for the ingredients used to prepare them; terminating ZMS and other independent compounding pharmacies from their respective networks without cause; and putting independent

compounding pharmacies out of business.

56. The conduct of Defendant ESI and the co-conspirators in excluding 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 ZMS and independent compounding pharmacies.

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

58. Only by agreeing to act in a concerted manner to uniformly exclude compound prescription medications from coverage would Defendant ESI and the co-conspirators be able to exclude independent compounding pharmacies from the Relevant Market while simultaneously maintaining their respective spheres of control over the prescription drug benefit market.

B. ESI's Plan to Undermine Independent Compound Pharmacies

59. Throughout 2014 ESI and its co-conspirators began rolling out their multi-faceted effort to harm ZMS and other independent compounding pharmacies.

60. In June 2014, ESI unveiled its "Compound Management Solution" – a plan to decrease reimbursements and other expenses paid to ZMS and other independent compounding pharmacies by 95%.

61. A PowerPoint created by ESI at that time describes the goals, timing, and techniques to be employed to bring about this "solution." A copy of that PowerPoint is attached to this Complaint as Exhibit A and incorporated herein by reference. Portions of the document

were made public via ESI's website. That material, and other public presentations regarding the Compound Management Solution, constitute public comments and signaling behavior.

62. The PowerPoint plainly describes the increase in the number of targeted ingredients from only the top 5 most common bulk powders in August 2013, to the top 10 most common in March of 2014, to more than 1,000 under the Compound Management Solution launched in June 2014. Notably, prior to June 2014, targeted ingredients would only require prior authorization, but under the Compound Management Solution, any medications including the 1,000-plus targeted ingredients would be automatically rejected.

63. Further, the PowerPoint shows that the prior "top 5" and "top 10" prior authorization requirements had merely been trial run to gauge patient reaction to significantly hampering the prescription of compounded medications. The PowerPoint reports that these two introductory steps occurred "with no member noise."

64. Additionally, the PowerPoint discloses another tactic used by ESI and its co-conspirators. According to the PowerPoint ESI planned to "begin pharmacy re-credentialing" in December 2013. Upon information and belief, pharmacy re-credentialing was employed by ESI and its co-conspirators as a back-door means of terminating their agreements.

65. The PowerPoint also includes a sample letter to be sent to patients explaining the reason for the new policies disfavoring compounded medications. The letter describes compounds disingenuously and attempts to scare patients by noting that the Food and Drug Administration (FDA) "does not verify the quality, safety, and/or effectiveness of compound medications." This is materially deceptive because ESI – along with its co-conspirators – knows that compound medications are exempt from FDA approval requirements.

66. Finally, the PowerPoint explicitly states the actual purpose of the new policy – it

“eliminates compound spend by 95%.”

C. Concerted Action By Co-Conspirators

67. ESI’s co-conspirators employed a similar set of tactics against ZMS and other independent compounding pharmacies to further their collective goal of reducing reimbursements for compound medications to the point of effectively eliminating them entirely.

68. Beginning in 2014, each of the co-conspirators took steps to dramatically increase rejection rates for compound prescriptions. For example, 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. Similarly, the other co-conspirators implemented outright prohibitions on certain ingredients or created a process requiring pre-approvals. In Plaintiff’s experience, such pre-approvals were frequently denied. Further, in or about August 2014, certain independent pharmacies were informed by CVS that prior authorization was required for any compounded medication with a cost of \$300 or more. Effectively, this required prior authorization for all compounded drugs dispensed by those pharmacies. Further, under CVS’s requirements for obtaining prior authorization, only a tiny number of patients qualified, and this practice was really a thinly-veiled form of denial.

69. This behavior was not limited to new prescriptions. In fact, the co-conspirators’ conduct applied to all patients and their prescriptions, regardless of how long they had been using a particular compound medication. Thus, after months or years of approved prescription refills by ESI and its co-conspirators, beginning in July 2014, some patients suddenly received rejections simply stating that the compounded medication was “not covered – reject.”

70. The co-conspirators also adopted ESI’s idea to send misleading information to

patients. Both CVS and ORx sent letters directly to patients informing them that compound drugs would no longer be covered *because* they contained ingredients that were not approved by the FDA. Similarly to ESI, these letters also failed to mention that no such FDA approval was required for these medications.

71. Defendant ESI and the co-conspirators employed similar tactics against the doctors prescribing the compound medications. Upon information and belief, in approximately 2013, ESI and other co-conspirators began targeting independent compounding pharmacies through extensive and rigorous auditing processes designed to identify network providers that prescribe compounded medicines and the network providers that prepare them. Physicians were instructed to cease writing prescriptions for compound medications regardless of the individual patient's needs and regardless of the prescribing physician's assessment of the treatment most effective for the individual patient. Upon information and belief, doctors also received letters from each of the co-conspirators containing false and misleading information regarding compound medications.

72. ESI and its co-conspirators also created unnecessary, burdensome requirements for the coverage of compound drugs. For example, on or about April 1, 2015, ORx 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 "dispensing compound drugs without literature on file that supports the clinical/therapeutic value of the compound ingredients." Thus, although licensed physicians were issuing the prescriptions, ORx mandated that pharmacies undertake the burden of conducting research and maintaining records on that research for every type of compounded medicine prescription filled. Around this same time, CVS created a similar hurdle requiring

pharmacies to submit “at least (2) scientifically valid studies in peer-reviewed journals supporting the clinical efficacy of the additional ingredients” for each ingredient to be compounded and make those available for CVS review upon request.

73. With increasing frequency, ESI and each of its co-conspirators have subjected ZMS to intrusive and disruptive 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. Upon information and belief, many other independent compound pharmacies have experienced the same disruptive audits with the same disastrous results.

74. ESI and its co-conspirators began to strictly enforce a prohibition on the use by ZMS and other independent compounding pharmacies of the United States Postal Service or other delivery services to deliver compounded medicines to patients. There is no legitimate reason why ZMS and other independent compounding pharmacies should be prohibited from operating mail-order pharmacies. At the same time they exclude independent pharmacies from this market, ESI and its co-conspirators operate their own mail-order pharmacies, including compounded pharmacy services, to patients. Upon information and belief, ESI and its co-conspirators enforce the no mail fulfillment restriction, and its application to other non-mail methods of delivery, to restrict competition in the mail-order pharmacy market to their own pharmacies.

75. Finally, ESI and its co-conspirators unilaterally expelled or suspended pharmacies from their networks, terminating their provider agreements on pretextual bases. Upon information and belief, ESI and its co-conspirators manufactured reasons and opportunities to terminate or suspend ZMS and other independent compound pharmacies to further its goals of decreasing “compound spend” overall and funneling what remained to their own privately-held

pharmacies.

D. The Co-Conspirators Could Not All Have Acted This Way Without an Agreement to Do So

76. ESI's and its co-conspirators' conduct can only be explained through a joint, anticompetitive agreement. If ESI or any of its co-conspirators acted unilaterally to virtually eliminate compound drug coverage, 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. Only through concerted action could the PBMs achieve the desired results.

77. Further, the agreement between ESI and its co-conspirators can also be inferred because of:

- a. The timing, specifics, and similarity of anticompetitive conduct by ESI and its co-conspirators;
- b. The public behavior of ESI and its co-conspirators, including but not limited to the public communications regarding the Compounding Management Solution;
- c. Their common motive to increase the profitability of their own privately-held compound and mail-order pharmacy operations;
- 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

78. The relevant market is highly concentrated and becoming even more so. PBMs manage 95% of all the drugs prescribed and covered under group and individual health plans in the country. Approximately 80% of the PBM market is controlled by ESI and its co-conspirators.

79. This degree of concentration creates a very strong assumption that when acting in concert, the ESI and its co-conspirators have market power.

80. ESI and its co-conspirators also, in fact, actually use 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; and
- c. Collectively suppressing the reimbursement rates paid to ZMS and withholding substantial payments for covered drugs unilaterally and with impunity, which drastically impaired and destroyed its business and competitiveness.

Barriers to Entry

81. A multitude of significant barriers to entry make the anticompetitive conspiracy between ESI and its co-conspirators achievable along with the elimination of independent compound pharmacies possible.

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

83. Due to recent mergers in the industry, fewer PBMs now have larger market

shares. Independent pharmacies, including compounding pharmacies, are left with little choice—if they want to dispense prescription medication, they must agree on the terms set by the PBMs.

84. To become a part of the pharmacy networks created and controlled by the large PBMs, including ESI, CVS, ORx, and Prime, independent pharmacies must accept adhesion contracts that are subject to unilateral change at any time. If not, they are effectively alienated from the group and individual health plan market, which would be suicidal to the ZMS's businesses.

85. New PBMs or entities controlling the reimbursement of compounded drugs entering the market is highly unlikely as demonstrated by the complete absence of entry in recent years. As previously stated, the market is consolidating rapidly.

86. Furthermore, the likelihood that new compounded drugs will enter the market and be covered is non-existent due to the fact that ESI and its co-conspirators dictate whether or not they will allow this to happen, and they have decided that it will not.

Anticompetitive Conduct and Effects

87. As previously stated, based upon information and belief, ESI and its co-conspirators joined together sometime around 2013 in order to create a strategy to eliminate coverage for compounded medications from pharmacies that were not subsidiaries or controlled by ESI and its co-conspirators.

88. ESI and its co-conspirators aligned efforts to exclude independent compounding pharmacies from the relevant markets through various anticompetitive means.

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

- a. Using information obtained from pharmacy audits in order to identify physicians that prescribed compounded drugs for the purpose of targeting

- those doctors to stop physicians from prescribing compounded drugs;
- b. Intimidating and coercing those physicians into ceasing them from prescribing compounded drugs through 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 physician's assessment of the treatment most effective for the individual patient;
 - d. Mailing letters to physicians containing false and misleading information regarding compounded drugs for the purpose to stop them from prescribing compounded drugs;
 - e. Making telephone calls to doctors to convey false and misleading information regarding compounded drugs for the purpose to stop them from prescribing compound drugs;
 - f. Sending misleading information to patients on the safety of compounded drugs, including the fallacious statement that compounded drugs were not FDA approved;
 - g. Letters such as those mentioned in the preceding sub-paragraph were misleading because compounding facilities are exempted from sections of federal law relating to: (1) compliance with current good manufacturing practices; (2) labeling with adequate direction for use; and (3) FDA approval prior to marketing;
 - h. 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 due to the fact that all so-called "off-label" use is "experimental" and PBMs continue to cover mass-produced off-label drugs, even though they are not proven as 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, yet omitting that compounded drugs are listed as specifically exempted under federal law from that requirement;
 - j. Failing to provide information regarding the federal and state oversight of compounding pharmacies in their deceptive letters to patients;
 - k. Creating substantial obstacles for compound pharmacies to receive

reimbursements including: (1) setting prior approval rates so low that compounded drugs cannot be approved; (2) establishing co-payment policies used as pretext to harass the compounding pharmacies; and (3) requiring compounding pharmacies to provide 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, ESI has sought to recoup reimbursements for medication on the basis that the medications contain “Non-FDA approved” ingredients despite the described exemptions. The recoupments are then applied to payments due on unrelated and otherwise proper claims;
- m. Prohibiting or restricting the use of U.S. mail and other delivery services by compounding pharmacies (even though pharmacies affiliated with ESI and its co-conspirators are allowed to send prescriptions by mail);
- n. Reducing or completely eliminating coverage for medications compounded by pharmacies or ingredients of those compound drugs;
- o. Completely 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.

90. ZMS encountered many of these tactics and is informed, and therefore believes, that multiple other independent compound pharmacies were subjected to many of the same tactics that ZMS encountered.

91. ESI concocted and launched, in the summer of 2014, its Compound Management Solution, the crux of which would eliminate coverage for over 1,000 compounded drug ingredients. ESI 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.

92. Furthermore, ESI never provided any copy of the list of “excluded” ingredients to ZMS. Instead they were left to discovery whether a prescription would be approved through the electronic submission process described above. Even for approved compounded medicines, ESI would subsequently add them to the excluded list, and demand that ZMS return the payments. For example, the Sinelee patch is a patch used for pain relief that was initially approved by ESI. However, in mid-2015, ESI began to reject Sinelee patch submissions. They also conducted audits and sought to recoup previously paid claims for the Sinelee patch using the basis that it was not “FDA-approved,” even though compounded drugs are exempted from FDA-approval as previously mentioned.

93. ESI’s 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. Due to the fact that compounded medications are exempted from the FDA-approval process and generally not the subject of peer-reviewed journal articles, these requirements are simply an intentional barrier to obtain coverage created by the PBMs for the sole purpose of eliminating compounded medicines from the prescription benefit drug market.

94. Similarly, there is no legitimate reason why ZMS and other compounding pharmacies are to be restricted from using the United States mail, or any other delivery services, to deliver medicines to patients in the same manner that is continually utilized by ESI and its co-conspirators. Based upon information and belief, the prohibition has been imposed with the intent to limit or eliminate competition from other pharmacies.

95. As a result of the above anticompetitive conduct, ZMS’s access to the relevant market has been limited or eliminated. Without the ability to fill prescriptions for patients in ESI’s or its co-conspirators’ networks, ZMS and other independent compounding pharmacies

will be excluded from the relevant market and driven out of business, allowing ESI to dominate the relevant market. This is the core goal of the illegal agreement of ESI and its co-conspirators.

96. 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.

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

98. ESI and its co-conspirators are able to exclude ZMS 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, ESI 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.

Antitrust Injury

99. ESI's and its co-conspirators' anticompetitive conduct has caused numerous, devastating antitrust injuries to ZMS.

100. Plaintiff's revenues and profits decreased because ESI and its coconspirators:

- 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 Plaintiff 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.

101. ZMS's losses are not confined to the actual reimbursements it was denied, resulting in millions of dollars in damages, but also includes the possible future profits it no longer has the opportunity to realize because of ESI's and its co-conspirator's illegal, anticompetitive conduct.

102. ESI has been sued in the past for its anticompetitive activities in the following cases: *HM Compounding Services, LLC, et al., v. Express Scripts, Inc.*, Case No. 4:14-cv-01858 (JAR); and *Precision Rx Compounding, LLC, et al., v. Express Scripts Inc., et al.*, Case No. 4:16-cv-00069 (CEJ) in this Court.

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

103. Plaintiff ZMS incorporates by reference as though fully set forth herein paragraphs 1 through 102 of the Complaint.

104. ESI 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.

105. ESI 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 ZMS and other independent compounding pharmacies and (b) exclude ZMS and other independent compounding pharmacies from the relevant market and thus drive them out of business.

106. ESI 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.

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

108. ESI and its co-conspirators' concerted refusal to deal with and/or boycott ZMS 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).

109. As a direct and proximate result of ESI's and its co-conspirators' concerted conduct, Plaintiff ZMS has been and will continue to be irreparably injured and financially damaged in their business and property in that, among other things, ZMS has 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.

110. Due to ESI's and its co-conspirators' concerted conduct, market power, the barriers to entering the relevant market, and the resulting anticompetitive and antitrust injury, ESI 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

111. Plaintiff ZMS incorporates by reference as though fully set forth herein paragraphs 1 through 110 of the Complaint.

112. ZMS has sustained, and will continue to sustain, irreparable injuries caused by ESI's conduct set forth herein.

113. ZMS has no adequate remedy at law for the injuries and damages proximately caused by the conduct of ESI.

114. ZMS is likely to succeed on the merits of their claim against ESI.

115. ZMS, therefore, entitled to a preliminary and permanent injunction as set forth in the request for relief below.

REQUEST FOR RELIEF

WHEREFORE, the Plaintiff hereby respectfully request that judgment be entered in their favor and against the ESI Defendants, as follows:

1. As for Count I of the Complaint:
 - a. Preliminarily and permanently enjoining the ESI Defendants from engaging in illegal, anticompetitive conduct in violation of Section 1 of the Sherman Act, 15 U.S.C. §1;
 - b. Awarding Plaintiff compensatory damages in an amount to be determined at trial;
 - c. Awarding Plaintiff three times actual damages against Defendant ESI, Inc. for its violation of Section 1 of the Sherman Act;
 - d. Awarding Plaintiff interest, attorneys' fees, and costs incurred herein; and
 - e. Awarding such other and further relief as this Court deems just and proper.
2. As for Count II, issue an order as follows:
 - a. Preliminarily and permanently enjoining the ESI Defendants from refusing to process and/or pay claims submitted by Plaintiff 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;

b. Preliminarily and permanently enjoining the ESI Defendants from refusing to process and/or pay claims submitted by Plaintiff for payment of refills of an existing refillable prescription for compound drugs prescribed by licensed physicians for their patients;

c. Preliminarily and permanently enjoining the ESI Defendants from eliminating from coverage those chemicals and/or other ingredients used by Plaintiff 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;

d. Preliminarily and permanently enjoining the ESI 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 ESI for prior approval of compound drugs for a patients;

e. Preliminarily and permanently enjoining the ESI Defendants from contacting patients who seek to fill or do fill prescriptions with Plaintiff;

f. Preliminarily and permanently enjoining the ESI Defendants from seeking to claw-back, recover, or obtain recovery in any way for payments previously made to Plaintiff for compound drugs prescribed by licensed physicians for their patients;

g. Preliminarily and permanently enjoining the ESI Defendants from prohibiting Plaintiff from using the United States Postal Service or other delivery service to deliver to patients the compound drugs prescribed by their licensed physicians;

h. Awarding Plaintiff its attorneys' fees and costs incurred herein; and

i. Award such other and further relief as this Court deems just and proper.

JURY TRIAL DEMANDED

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

Dated: February 16, 2016

Respectfully submitted,

/s/ Anthony G. Simon

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