UNITED STATES DISTRICT COURT WESTERN DISTRICT OF NEW YORK BUFFALO DIVISION

GEORGIANN JORDAN, individually and on behalf of all others similarly situated,

Plaintiff,

1:23-cv-00979

- against -

CVS PHARMACY, INC.,

Defendant

Class Action Complaint

Jury Trial Demanded

Plaintiff Georgiann Jordan ("Plaintiff") alleges upon information and belief,

except for allegations about Plaintiff, which are based on personal knowledge:

1. CVS Pharmacy, Inc., ("Defendant"), sells "Pink Eye Drops" advertised

to "Relieve[]: Redness, Burning, Watery discharge (and) Gritty sensation" under the CVS Health brand ("Product").



Case 1:23-cv-00979 Document 1 Filed 09/17/23 Page 2 of 15

2. The Product's website further describes it as "a homeopathic formula that stimulates the body's ability to relieve redness, burning, watery discharge, and sensations of grittiness."

3. Defendant continues, "When your eyes are dry, itching, or burning, it can be a big problem that you want relief from right away. These Irritated Eye Drops from CVS Health can provide you with the rapid relief you need."

4. Finally, it describes the Product as "very helpful for relieving irritation, redness, burning, and dryness. The homeopathic formula is safe for use in the eyes and easy to apply . . . These drops are gentle enough for frequent use and even for use on children."

5. In response to consumer outcry based on an unregulated environment where dangerous drugs were sold to the public, the Pure Food and Drug Act of 1906 ("PFDA") established minimum standards of safety and disclosure to protect the public.

6. These requirements by the Federal Food, Drug and Cosmetic Act ("FFDCA") in 1938, which set standards for what companies were required to tell the public about over-the-counter ("OTC") drugs. 21 U.S.C. § 301 *et seq.*; 21 C.F.R. Parts 200 and 300.

7. These laws were adopted by this State in their entirety, so its citizens could make informed decisions about the OTC drugs they buy.

Case 1:23-cv-00979 Document 1 Filed 09/17/23 Page 3 of 15

8. By marketing the Product with these representations, consumers will expect it is a drug, as it appears to be "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or intended to affect the structure or any function of the body." 21 U.S.C. § 321(g)(1).

9. This was the conclusion of the Food and Drug Administration ("FDA") in September 2023, when it warned Defendant that the Product "is an unapproved new drug," even though it was not preceded by a required new drug application. 21 U.S.C. 355(a); 21 U.S.C. § 331(d).¹

10. Although the Product is a "new drug," it is not generally recognized as safe and effective ("GRASE") for its promoted uses, because it has not been evaluated by experts qualified by scientific training and experience to render such a determination. 21 U.S.C. § 321(p)(1).

11. The Product is not capable of "Reliev[ing]: Redness, Burning, Watery discharge (and) Gritty sensation," nor providing any of the other benefits promoted on its website.

12. The Product is "misbranded" because its labeling is false or misleading with respect to its ability to relieve the identified symptoms. 21 U.S.C. § 352(a)(1);N.Y. EDN § 6815(2)(a).

¹ Center for Drug Evaluation and Research ("CDER"), <u>Warning Letter to CVS</u> <u>Health</u>, MARCS-CMS 663246, Sept. 11, 2023.

Case 1:23-cv-00979 Document 1 Filed 09/17/23 Page 4 of 15

13. Despite labeling the Product as a homeopathic drug with active ingredients measured in homeopathic strengths, the term "drug" includes articles recognized in the official Homeopathic Pharmacopeia of the United States ("HPUS"), or any supplement to it. 21 U.S.C. § 321(g)(1)(A).

14. The FDA emphasized that "Homeopathic drug products are subject to the same statutory requirements as other drugs," and are prohibited from being adulterated, misbranded, and marketed to the public without approval.

15. The Product is misbranded because it is marketed to consumers as if it were safe and effective for the identified conditions, even though its use poses a public health risk.

16. As an ophthalmic drug product administered into the eyes, the Product poses a greater risk of harm because the route of administration bypasses some of the body's natural defenses.

17. Specifically, the FDA expressed "significant concerns regarding [the] safety" of its use of the preservative, silver sulfate.

18. This is consistent with general medical guidance that "Long term use of medicinal compounds containing silver may cause argyria, which is a blueish-gray discoloration of the skin and eyes that is irreversible."

19. Moreover, "granular deposits of silver in the conjunctiva and cornea may cause decreased night vision."

Case 1:23-cv-00979 Document 1 Filed 09/17/23 Page 5 of 15

20. Based on the addition of silver sulfate, the FDA declared the Product violated 21 C.F.R. § 200.50(b)(1), under which ophthalmic preservatives should be "suitable and harmless."

21. The FDA also warned Defendant that the Product is adulterated based on "significant violations of Current Good Manufacturing Practice (CGMP) requirements observed at [the factory where it was made]."

22. Federal and state law prohibit the sale of the Product because it is adulterated, as it was "not manufactured in conformance with CGMPs." 21 U.S.C. § 351(a)(2)(B).

23. By selling the Product to consumers, Defendant violated 21 U.S.C. §§ 331(a) and (c), which prohibit introducing and receiving such a product into interstate commerce.

24. As a result of the false and misleading representations, the Product is sold at a premium price, approximately no less than no less than approximately \$8.99 per 0.33 oz (10 mL), excluding tax and sales, higher than similar products, represented in a non-misleading way, and higher than it would be sold for absent the misleading representations and omissions.

JURISDICTION

25. Jurisdiction is based on the Class Action Fairness Act of 2005 ("CAFA"). 28 U.S.C. § 1332(d)(2).

Case 1:23-cv-00979 Document 1 Filed 09/17/23 Page 6 of 15

26. The aggregate amount in controversy exceeds \$5 million, including any statutory or punitive damages, exclusive of interest and costs.

27. Plaintiff is a citizen of New York.

28. Defendant is a citizen of Delaware based on its corporate formation.

29. Defendant is a citizen of Rhode Island based on its principal place of business.

30. The class of persons Plaintiff seeks to represent includes persons who are citizens of a different state from which Defendant is a citizen.

31. The members of the proposed class Plaintiff seeks to represent are more than one hundred, because the Product has been sold at over 550 CVS stores in this State and online to citizens of this State.

32. The Court has jurisdiction over Defendant because it transacts business within New York and sells the Product to consumers within New York from over 550 CVS stores in this State and online to citizens of this State.

33. Defendant transacts business in New York, through the sale of the Product to consumers within New York from over 550 CVS stores in this State and online to citizens of this State.

34. Defendant has committed tortious acts within this State through the distribution and sale of the Product from over 550 CVS stores in this State and online to citizens of this State, which is misleading to consumers in this State.

Case 1:23-cv-00979 Document 1 Filed 09/17/23 Page 7 of 15

35. Defendant has committed tortious acts within this State by labeling, representing and selling the Product in a manner which causes injury to consumers within this State by misleading them as to its contents, amount and/or quality, by regularly doing or soliciting business, or engaging in other persistent courses of conduct to sell the Product to consumers in this State, and/or derives substantial revenue from the sale of the Product in this State.

36. Defendant has committed tortious acts outside this State by labeling the Product in a manner which causes injury to consumers within this State by misleading them as to its contents, amount and/or quality, through causing the Product to be distributed throughout this State, such that it expects or should reasonably expect such acts to have consequences in this State and derives substantial revenue from interstate or international commerce.

VENUE

37. Venue is in this Court with assignment to this Division because Plaintiff is a resident of Erie County.

38. Venue is in this Court because a substantial part of the events or omissions giving rise to these claims occurred in Erie County, which is where Plaintiff's causes of action accrued.

39. Plaintiff purchased, used and/or consumed the Product in reliance on the labeling identified here in New York.

40. Plaintiff became aware the labeling was false and misleading in Erie County.

PARTIES

41. Plaintiff Cassandra Thompson is a citizen of New York County, New York.

42. Defendant CVS Pharmacy, Inc., is a Delaware corporation with a principal place of business in Rhode Island.

43. Founded as Consumer Value Stores almost sixty years ago in Massachusetts, CVS has consistently been a place for consumers to fill their most important needs.

44. Originally selling a variety of goods, CVS became focused on meeting the healthcare needs of Americans and is now a leading pharmacy and healthcare company.

45. From the almost ten thousand CVS stores in all 50 states, consumers have confidence CVS is looking out for their health.

46. Consumers consistently rank CVS as giving them the most value for their money, in addition to relying on the advice of their trained staff and pharmacists.

47. While CVS stores sell leading national brands, they also sell many products under one of their private label brands, CVS Health.

48. Private label products are made by third-party manufacturers and sold

under the name of the retailer, or its sub-brands.

49. Previously referred to as "generic" or "store brand," private label products have increased in quality, and often are superior to their national brand counterparts.

50. Products under the CVS Health brand have an industry-wide reputation for quality and value.

51. In releasing products under the CVS Health brand, Defendant's foremost criteria was to have high-quality products that were equal to or better than the national brands.

52. Defendant gets national brands to produce its private label items due its loyal customer base and tough negotiating.

53. That CVS Health branded products met this high bar was or would be proven by focus groups, rating them above the name brand equivalent.

54. Private label products generate higher profits for retailers because national brands spend significantly more on marketing, contributing to their higher prices.

55. A survey by The Nielsen Co. "found nearly three out of four American consumers believe store brands are good alternatives to national brands, and more than 60 percent consider them to be just as good."

56. Private label products under the CVS Health brand benefit by their

Case 1:23-cv-00979 Document 1 Filed 09/17/23 Page 10 of 15

association with consumers' appreciation for CVS overall.

57. The development of private label items is a growth area for CVS, as they select only top suppliers to develop and produce CVS Health products.

58. Plaintiff purchased the Product between September 2020 and the present, at CVS stores in Erie County.

59. Plaintiff read and relied on the front label which said "Relieves: Redness, Burning, Watery discharge (and) Gritty sensation" and thought the Product would do what it claimed.

60. Plaintiff did not expect the Product would not relieve redness, burning, watery discharge and gritty sensations in her eyes, and it did not.

61. Plaintiff was not aware that the Product contained a potentially harmful ingredient in silver sulfate.

62. Plaintiff expected the Product to be safe and effective because it was sold to her from a respected, credible store under the CVS Health brand.

63. Plaintiff bought the Product at or exceeding the above-referenced price.

64. Plaintiff paid more for the Product than she would have had she known it was labeled in a misleading way, was not safe nor effective, as she would not have bought it or would have paid less.

65. The Product was worth less than what Plaintiff paid, and she would not have paid as much absent Defendant's false and misleading statements and

omissions.

CLASS ALLEGATIONS

66. Plaintiff seeks to represent the following class:

All persons in the State of New York who purchased the Product in New York during the statutes of limitations for each cause of action alleged.

67. Common questions of issues, law, and fact predominate and include whether Defendant's representations were and are misleading and if Plaintiff and class members are entitled to damages.

68. Plaintiff's claims and basis for relief are typical to other members because all were subjected to the same unfair, misleading, and deceptive representations, omissions, and actions.

69. Plaintiff is an adequate representative because her interests do not conflict with other members.

70. No individual inquiry is necessary since the focus is only on Defendant's practices and the class is definable and ascertainable.

71. Individual actions would risk inconsistent results, be repetitive and are impractical to justify, as the claims are modest relative to the scope of the harm.

72. Plaintiff's counsel is competent and experienced in complex class action litigation and intends to protect class members' interests adequately and fairly.

CAUSES OF ACTION

Case 1:23-cv-00979 Document 1 Filed 09/17/23 Page 12 of 15

COUNT I New York General Business Law ("GBL") §§ 349 and 350

73. Plaintiff incorporates by reference paragraphs 1-24.

74. The purpose of the GBL is to protect consumers against unfair and deceptive practices.

75. The labeling of the Product violated the GBL because the representations were false, deceptive, misleading, unfair and deceptive to consumers.

76. Plaintiff paid more for the Product, would not have purchased it or paid as much if she knew that it was labeled in a misleading way, was neither safe nor effective.

77. Plaintiff seeks to recover for economic injury and/or loss she sustained based on the misleading labeling and packaging of the Product, a deceptive practice under this State's consumer protection laws, by paying more for it than she otherwise would have.

78. Plaintiff will produce evidence showing how she and consumers paid more than they otherwise would have paid for the Product, relying on Defendant's representations and omissions, using statistical and economic analyses, hedonic regression, and other advanced methodologies.

79. Defendant's false and deceptive representations and omissions are material in that they are likely to influence consumer purchasing decisions.

COUNT II

Breach of Express Warranty

80. Plaintiff incorporates by reference paragraphs 1-24.

81. The Product was manufactured, identified, marketed, and sold by Defendant and expressly warranted to Plaintiff and class members that it was safe and effective for the identified symptoms.

82. Defendant directly marketed the Product to Plaintiff and consumers through its advertisements and marketing, through various forms of media, on the packaging, in print circulars, direct mail, and/or targeted digital advertising.

83. Defendant knew the product attributes that potential customers like Plaintiff were seeking, such as eye drops which would be safe and effective for the identified symptoms and developed its marketing and labeling to directly meet those needs and desires.

84. Defendant's representations affirmed and promised that the Product was safe and effective for the identified symptoms.

85. Defendant described the Product so Plaintiff and consumers believed it was safe and effective for the identified symptoms, which became part of the basis of the bargain that it would conform to its affirmations and promises.

86. Plaintiff recently became aware of Defendant's breach of the Product's express warranty.

87. Plaintiff provided or will provide notice to Defendant, its agents,

Case 1:23-cv-00979 Document 1 Filed 09/17/23 Page 14 of 15

representatives, retailers, and/or their employees.

88. Plaintiff hereby provides notice to Defendant that it breached the Product's express warranty.

89. Defendant received notice and should have been aware of these issues due to complaints by third parties, including regulators like the FDA, competitors, and consumers, to its main offices, and by consumers through online forums.

90. The Product did not conform to its affirmations of fact and promises due to Defendant's actions, because it was not safe and effective for the identified symptoms.

91. Plaintiff and class members would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

Jury Demand and Prayer for Relief

Plaintiff demands a jury trial on all issues.

WHEREFORE, Plaintiff prays for judgment:

- Declaring this a proper class action, certifying Plaintiff as representative and the undersigned as counsel for the class;
- 2. Awarding monetary and/or statutory damages and interest;
- 3. Awarding costs and expenses, including reasonable fees for Plaintiff's attorneys and experts; and

Case 1:23-cv-00979 Document 1 Filed 09/17/23 Page 15 of 15

4. Other and further relief as the Court deems just and proper.

Dated: September 17, 2023

Respectfully submitted,

/s/ Spencer Sheehan

Sheehan & Associates, P.C. 60 Cuttermill Rd Ste 412 Great Neck NY 11021 (516) 268-7080 spencer@spencersheehan.com

Notice of Lead Counsel Designation:

Lead Counsel for Plaintiff

Spencer Sheehan

Sheehan & Associates, P.C.

ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: <u>Class Action Alleges CVS Pink Eye Drops</u> <u>Are Misbranded, Require FDA Approval</u>