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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

BRANDON MILLER, on behalf of himself, all others similarly situated, and the general public,

Plaintiff,

v.

SCOPE HEALTH, INC.,

Defendant.

Case No: 26-cv-02796

CLASS ACTION COMPLAINT

COMPLAINT FOR CONSUMER FRAUD AND UNJUST ENRICHMENT

DEMAND FOR JURY TRIAL

Plaintiff BRANDON MILLER, individually, and on behalf of all others similarly situated, brings this action against Defendant SCOPE HEALTH, INC. ("Scope") and alleges the following upon his own knowledge, or where he lacks personal knowledge, upon information and belief, including the investigation of his counsel.

INTRODUCTION

1. Scope manufactures, markets, distributes, and sells a line of ophthalmic products under the OPTASE brand throughout California.

2. As relevant here, the OPTASE-branded products include MGD Advanced Dry Eye Drops, Dry Eye Intense Drops (multi-use bottle and single dose), Allegro Eye Drops, HYLO Night Eye Ointment, Tea Tree Oil Eyelid Wipes, Tea Tree Oil Eyelid Gel, and Protect Eyelid Cleansing Spray (the "Optase Products").

3. Scope markets the Optase Products as treatments for dry eye disease and related conditions. However, the U.S. Food and Drug Administration ("FDA") has determined they are unapproved new drugs for which no approved new drug applications exist and, in many instances, are misbranded under federal law.

4. Because the Optase Products could not lawfully be introduced into interstate commerce, California law likewise prohibited their sale. Nevertheless, Scope marketed and sold, and continues to market and sell the Optase Products to consumers throughout California.

5. Plaintiff and reasonable consumers purchasing over-the-counter ophthalmic products reasonably expect that those products are ***lawfully*** marketed and sold. Had Plaintiff and reasonable consumers known that the Optase Products were unlawfully marketed and sold in violation of federal and California law, they would not have purchased them or would have paid less for them.

6. Scope's conduct caused Plaintiff and the Class to suffer economic injury and constitutes unlawful, unfair, and fraudulent business practices under California law.

JURISDICTION & VENUE

7. This Court has original jurisdiction over this action under 28 U.S.C. § 1332(d)(2) (the Class Action Fairness Act) because the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs, the proposed Class consists of more than 100 members, and at least one member of the proposed Class is a citizen of a State different from Defendant.

8. The Court has personal jurisdiction over Scope because it has purposely availed itself of the benefits and privileges of conducting business activities within California, including by distributing and selling the Optase Products in California.

9. Venue is proper in the Eastern District of California pursuant to 28 U.S.C. § 1391(b) and (c), because Defendant resides (*i.e.*, is subject to personal jurisdiction) in this district, and because a substantial part of the events or omissions giving rise to the claims occurred in this district.

PARTIES

10. Plaintiff Brandon Miller is a citizen and resident of Fresno County, California.

11. Defendant Scope Health, Inc. is a New York corporation with its principal place of business in New York, New York.

STATUTORY FRAMEWORK

12. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. ("FDCA"), prohibits the "introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded." 21 U.S.C. § 331(a).

13. A drug is misbranded if it fails to comply with the requirements applicable to nonprescription drugs marketed without an approved application, including compliance with an applicable OTC monograph. 21 U.S.C. § 352(ee).

14. A drug is also misbranded if its labeling fails to bear adequate directions for use or otherwise fails to satisfy applicable labeling requirements. 21 U.S.C. § 352(f)(2).

15. The FDCA prohibits the introduction into interstate commerce of any "new drug" unless an FDA-approved application is in effect for that drug. 21 U.S.C. §§ 331(d), 355(a).

16. A drug product is a "new drug" within the meaning of the FDCA if it is not "generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p).

17. California's Sherman Food, Drug, and Cosmetic Law, Cal. Health & Safety Code §§ 109875 et seq. ("Sherman Law"), incorporates many provisions of the FDCA into California law and independently regulates the manufacture, labeling, advertising, and sale of drugs within California.

18. California Health and Safety Code section 111550 provides that "[n]o person shall sell, deliver, hold, or offer for sale any new drug unless an application with respect thereto has become effective" under section 505 of the FDCA. Accordingly, California independently prohibits the sale of any new drug that lacks an effective FDA approval.

19. California Health and Safety Code section 110100 provides that regulations adopted pursuant to the FDCA "shall be the food, drug, and cosmetic regulations of this state."

20. California Health and Safety Code section 111330 prohibits the sale, delivery, or holding for sale of any misbranded drug.

21. California's Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200 *et seq.* ("UCL"), prohibits any unlawful, unfair, or fraudulent business act or practice.

22. The UCL's "unlawful" prong borrows violations of other laws and independently makes those violations actionable as unfair competition.

23. Accordingly, the sale of unapproved new drugs and misbranded drugs in violation of the Sherman Law constitutes an unlawful business practice under the UCL.

FACTS

I. FDA DETERMINED THE OPTASE PRODUCTS ARE UNAPPROVED NEW DRUGS, MISBRANDED, AND NOT LAWFULLY MARKETABLE

24. On July 9, 2025, FDA, through its Center for Drug Evaluation and Research, issued Warning Letter No. 695085 to Scope after reviewing the labeling and marketing of the Optase Products.[1]

25. FDA explained that the Optase Products were marketed with claims demonstrating that they were intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, including claims concerning dry eye disease, meibomian gland dysfunction, and blepharitis. As a result, FDA determined that the products were drugs within the meaning of the FDCA.

26. FDA determined that Scope's MGD Advanced Dry Eye Drops, Dry Eye Intense Drops (multi-use bottle and single dose), Allegro Eye Drops, HYLO Night Eye Ointment, Tea Tree Oil Eyelid Wipes, Tea Tree Oil Eyelid Gel, and Protect Eyelid Cleansing Spray were "unapproved new drugs introduced or delivered for introduction into interstate commerce" in violation of sections 505(a) and 301(d) of the FDCA.

27. FDA further determined that the Optase Products were not generally recognized as safe and effective ("GRASE") for their labeled uses and therefore constituted "new drugs" under the FDCA. Specifically, FDA explained that it was "not aware of any adequate and well-controlled clinical trials in the published literature" supporting a determination that the products were GRASE for their intended uses.

28. The Scope Warning Letter identified seven Optase Products as unapproved new drugs. FDA further determined that four of those products were also misbranded for the reasons described below.

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[1] U.S. Food & Drug Admin., Warning Letter to Scope Health Inc. (MARCS-CMS 695085) (July 9, 2025), *available at* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/scope-health-inc-695085-07092025 (the "Scope Warning Letter")

A. MGD Advanced Dry Eye Drops

29. FDA determined that MGD Advanced Dry Eye Drops did not conform to the applicable OTC ophthalmic monograph because it contained active ingredients—including sacha inchi seed oil, trehalose, and sodium hyaluronate—that are not permitted active ingredients for OTC ophthalmic demulcent drug products.

B. Dry Eye Intense Drops

30. FDA determined that Dry Eye Intense Drops likewise did not conform to the applicable OTC monograph because it contained sodium hyaluronate as an active ingredient, which is not permitted under the monograph.

31. FDA further determined that the multi-use bottle was misbranded because its labeling omitted the required warning: "If solution changes color or becomes cloudy, do not use."

C. Allegro Eye Drops

32. FDA determined that Allegro Eye Drops did not conform to the applicable OTC monograph because Ectoin® functioned as an active ingredient but is not a permitted active ingredient for OTC ophthalmic demulcent products.

D. HYLO Night Eye Ointment

33. FDA determined that HYLO Night Eye Ointment did not conform to the applicable OTC monograph because vitamin A functioned as an active ingredient but is not a permitted active ingredient for OTC ophthalmic emollient drug products.

* * *

34. Based on those findings, FDA concluded that Allegro Eye Drops, MGD Advanced Dry Eye Drops, Dry Eye Intense Drops (multi-use bottle and single dose), and HYLO Night Eye Ointment were misbranded because they failed to satisfy the requirements for lawful marketing under the applicable OTC monograph and were not the subject of approved applications under section 505 of the FDCA.

35. FDA concluded that introducing or delivering these misbranded drugs into interstate commerce violated 21 U.S.C. § 331(a).

36. FDA further determined that "there are no FDA-approved applications in effect for any of the [Optase Products] identified above."

37. Because the Optase Products were unapproved new drugs and, in many instances, misbranded drugs, their sale in California violated the Sherman Law and constituted unlawful business practices under the UCL.

II. PLAINTIFF'S PURCHASE, RELIANCE, AND INJURY

38. In November 2024, Plaintiff Brandon Miller purchased Optase Dry Eye Intense Drops from Amazon for his own, personal household use.

39. In making his purchase, Plaintiff sought an over-the-counter product to relieve dry eye symptoms.

40. In purchasing the Optase Dry Eye Intense Drops, Plaintiff reasonably expected that it was lawfully marketed and sold in California and the United States and complied with applicable federal and California laws governing over-the-counter drug products.

41. Plaintiff was unaware that FDA had determined the Optase Dry Eye Intense Drops to be an unapproved new drug and, further, that FDA had determined the product to be misbranded under the FDCA.

42. Plaintiff acted reasonably in purchasing the Optase Dry Eye Intense Drops. Nothing about the labeling, packaging, or sale would have informed a reasonable consumer that it was being marketed and sold in violation of federal and California law.

43. Had Plaintiff known that FDA found the Optase Dry Eye Intense Drops to be an unapproved new drug and misbranded, rendering it unlawful to introduce into interstate commerce and unlawful to sell in California, Plaintiff would not have purchased it or would have paid less for it.

44. Scope received money from Plaintiff and other Class Members through the sale of the Optase Products that could not lawfully be marketed or sold. As a result, Scope obtained revenues it otherwise would not have received.

45. Because the Optase Products were unlawfully marketed and sold, Plaintiff and other Class Members did not receive the benefit of the bargain. Plaintiff and other Class

Members paid money for a product that was not legally marketable and therefore was worth less than the amount paid.

46. Plaintiff and the Class suffered economic injury by spending money on products that could not lawfully be marketed or sold. Such economic injury is sufficient to confer standing under Article III and California's consumer protection statutes. *Franz v. Beiersdorf, Inc.*, 745 F. App'x 47, 48 (9th Cir. 2018).

47. Plaintiff continues to suffer from dry eye symptoms and wishes to purchase ***lawful*** over-the-counter ophthalmic products in the future. Plaintiff would consider purchasing Scope's Optase Products again if they were lawfully marketed and sold. However, absent injunctive relief, Plaintiff cannot reasonably determine whether Scope's future ophthalmic products comply with applicable federal and California law and therefore cannot rely on Scope's future marketing.

CLASS ACTION ALLEGATIONS

48. While reserving the right to redefine or amend the class definition prior to or as part of a motion seeking class certification, pursuant to Federal Rule of Civil Procedure 23, Plaintiff seeks to represent a class of all persons in California who, at any time from four years prior to the date of filing of this Complaint to the time a class is notified (the "Class Period"), purchased, for personal or household use, and not for resale or distribution, the Optase Products (the "Class").

49. The members of the proposed Class are so numerous that individual joinder of all members is impracticable, and the disposition of the claims of all Class Members in a single action will provide substantial benefits to the parties and Court.

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

a. whether FDA determined that the Optase Products are unapproved new drugs;

b. whether FDA determined that some or all of the Optase Products are misbranded;

c. whether Scope's conduct violates any state or federal statute and is therefore unlawful;

d. whether reasonable consumers expect that over-the-counter ophthalmic products offered for sale are lawfully marketed and sold;

e. whether Plaintiff and the Class suffered economic injury by purchasing Optase Products that were unlawfully marketed and sold;

f. whether Scope was unjustly enriched by selling the Optase Products to Plaintiff and the Class;

g. whether Plaintiff and the Class are entitled to restitution, disgorgement and/or other equitable and injunctive relief, and the proper scope of relief.

51. These common questions of law and fact predominate over questions that affect only individual Class Members.

52. Plaintiff's claims are typical of other Class Members' claims because they are based on the same underlying facts, events, and circumstances relating to Scope's conduct. Specifically, all Class Members, including Plaintiff, were subjected to the same unlawful conduct when they purchased the Optase Products and suffered economic injury because the products were unlawfully sold. Absent Scope's business practice of unlawfully selling the Optase Products, Plaintiff and other Class Members would not have purchased them or would have paid less for them.

53. Plaintiff will fairly and adequately represent and protect the interests of the Class, has no interests incompatible with the interests of the Class, and has retained counsel competent and experienced in class action litigation, and specifically in litigation involving misbranded goods.

54. Class treatment is superior to other options for resolution of the controversy because the relief sought for each Class Member is small, such that, absent representative litigation, it would be infeasible for Class Members to redress the wrongs done to them.

55. Scope has acted on grounds applicable to the Class, thereby making appropriate final injunctive and declaratory relief concerning the Class as a whole.

56. As a result of the foregoing, class treatment is appropriate under Fed. R. Civ. P. 23(a), 23(b)(2), and 23(b)(3).

CAUSES OF ACTION

FIRST CAUSE OF ACTION

Violations of the Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200 *et seq.*

57. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if set forth fully herein.

58. The UCL prohibits any "unlawful, unfair or fraudulent business act or practice." Cal. Bus. & Prof. Code § 17200.

59. The acts, misrepresentations, practices, and non-disclosures alleged herein constitute business acts and practices.

Unlawful

60. The acts alleged herein are "unlawful" under the UCL in that they violate at least the following laws:

- The Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750 *et seq*. ("CLRA");
- The Sherman Law. The FDCA prohibits the introduction into interstate commerce of unapproved new drugs and misbranded drugs. *See* 21 U.S.C. §§ 331(a), 331(d), 352, 355(a). California has adopted these identical requirements through the Sherman Law.

Unfair

61. Scope's conduct with respect to the marketing and sale of the Optase Products was unfair because Scope's conduct was immoral, unethical, unscrupulous, or substantially injurious to consumers, and the utility of its conduct, if any, does not outweigh the gravity of the harm to its victims.

62. Scope's conduct with respect to the marketing and sale of the Optase Products was and is also unfair because it violates public policy as declared by specific constitutional, statutory or regulatory provisions, including but not necessarily limited to portions of the FDCA, portions of California's Sherman Law, and the CLRA.

63. Scope's conduct with respect to the marketing and sale of the Optase Products was and is also unfair because the consumer injury was substantial, not outweighed by benefits to consumers or competition, and not an injury that consumers themselves could reasonably have avoided. Specifically, the increase in profits obtained by Scope through the unlawful marketing and sale of the Optase Products does not outweigh the harm to Class Members who were deceived into purchasing products they believed were lawfully marketed for their represented therapeutic uses.

64. Scope profited from the sale of the unlawfully marketed and sold Optase Products to unwary consumers.

65. Plaintiff and Class Members are likely to continue to be damaged by Scope's deceptive trade practices, because Scope continues to unlawfully sell Optase Products and commands a price premium in the marketplace as a result of its deceptive practices. Thus, injunctive relief enjoining Scope's deceptive practices is proper.

66. Scope's conduct caused and continues to cause substantial injury to Plaintiff and other Class Members. Plaintiff has suffered injury in fact as a result of Scope's unlawful conduct.

67. In accordance with Bus. & Prof. Code § 17203, Plaintiff seeks an order enjoining Scope from continuing to conduct business through unlawful, unfair, and/or fraudulent acts and practices, and to commence a corrective advertising campaign.

68. Plaintiff and the Class also seek an order for the restitution of all monies from the sale of the Optase Products, which were unjustly acquired through acts of unlawful competition.

SECOND CAUSE OF ACTION

Violations of the Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750 et seq.

69. Plaintiff realleges and incorporates by reference the allegations set forth elsewhere in this Complaint as if fully set forth herein.

70. The CLRA prohibits unfair or deceptive acts or practices in a transaction intended to result, or that results, in the sale of goods to a consumer.

71. The Scope Optase Products are a "good," Plaintiff and the Class are "consumers," and their purchases are "transactions" within the meaning of the CLRA.

72. Scope's acts and practices, as alleged herein, violated and continue to violate at least the following provisions of Cal. Civ. Code § 1770(a):

- § 1770(a)(5): representing that goods have characteristics, uses, or benefits that they do not have;
- § 1770(a)(7): representing that goods are of a particular standard, quality, or grade if they are of another;
- § 1770(a)(14): representing that a transaction confers or involves rights, remedies, or obligations that it does not have or involve, or that are prohibited by law; and
- § 1770(a)(16): representing that the subject of a transaction has been supplied in accordance with a previous representation when it has not.

73. Scope's unlawful marketing was designed to, and did, induce Plaintiff and other Class Members to purchase the Optase Products for personal, family, or household use.

74. For Scope's violations of the CLRA, Plaintiff presently seeks restitution and prospective injunctive relief, along with attorneys' fees and costs.

75. Pursuant to Cal. Civ. Code § 1782(a), more than 30 days before filing this action, Plaintiff notified Scope in writing by certified mail, return receipt requested, of the particular violations of § 1770 alleged herein and demanded that Scope correct, repair, replace, or otherwise rectify the conduct, but Scope has failed to do so.

76. In compliance with Cal. Civ. Code § 1780(d), an affidavit of venue is filed concurrently herewith.

THIRD CAUSE OF ACTION

Unjust Enrichment

77. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if fully set forth herein.

78. Plaintiff and other Class Members conferred upon Scope an economic benefit, in the form of profits resulting from the purchase and sale of the Optase Products.

79. Scope's financial benefits resulting from its unlawful and inequitable conduct are economically traceable to Plaintiff's and other Class Members' purchases of the Optase Products, and the economic benefits conferred on Scope are a direct and proximate result of its unlawful and inequitable conduct.

80. It would be inequitable, unconscionable, and unjust for Scope to be permitted to retain these economic benefits because the benefits were procured as a direct and proximate result of its wrongful conduct.

81. As a result, Plaintiff and other Class Members are entitled to equitable relief including restitution and/or disgorgement of all revenues, earnings, profits, compensation and benefits which may have been obtained by Scope as a result of such business practices.

PRAYER FOR RELIEF

82. Wherefore, Plaintiff, individually and on behalf of the proposed Class, prays for judgment as follows:

a. An Order declaring this action to be a proper class action, appointing Plaintiff as Class Representative, and appointing Plaintiff's undersigned counsel as Class Counsel;

b. An Order requiring Scope to bear the cost of Class Notice;

c. An Order compelling Scope to conduct a corrective advertising campaign;

d. An Order requiring Scope to disgorge all monies, revenues, and profits obtained by means of any wrongful act or practice;

e. An Order compelling Scope to destroy all unlawful marketing materials and product labels, and to recall all offending products;

f. An Order requiring Scope to pay restitution to restore all funds acquired by means of any act or practice declared by this Court to be an unlawful or unfair business act or practice;

g. An Order requiring Scope to pay statutory, compensatory, and punitive damages as permitted by law;

h. An Order enjoining Scope from unlawfully marketing and selling the Optase Products;

i. A judgment awarding any and all further equitable, injunctive, and declaratory relief as may be appropriate;

j. Pre- and post-judgment interest, as permitted by law;

k. An award of attorney fees and costs; and

l. Such further relief as the Court deems necessary, just, or proper.

JURY DEMAND

83. Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: July 14, 2026

/s Trevor Flynn

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ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: Class Action Lawsuit Alleges OPTASE Eye Treatments Are Misbranded Due to Lack of FDA Approval