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United States District Court
Southern District of New York

1:20-cv-10272

Luz Sanchez, individually and on behalf of all others similarly situated,

Plaintiff,

- against -

Avadim Health, Inc.,

Defendant

Class Action Complaint

Plaintiff by attorneys alleges upon information and belief, except for allegations pertaining to plaintiff, which are based on personal knowledge:

1. Avadim Health, Inc. ("defendant") manufactures, distributes, markets, labels and sells Theraworx Muscle Cramp & Spasm Relief Foam ("Theraworx MCS" or "Product"), sold with a compression knee garment, with the active ingredient magnesium sulfate.

2. The Product is sold to consumers from retail and online stores, and directly by Defendant, in containers of various sizes.

3. The Product and its advertising contain numerous false, deceptive and misleading claims about its ability to provide pain relief.

4. These claims were recently the subject of a decision by the National Advertising Division (NAD) which concluded the claims and marketing were not accurate and misleading.

5. The Product is similar to external analgesic products which contain the active ingredients capsaicin, trolamine salicylate, and/or lidocaine.

6. The relevant FDA Monograph for these products limit the indications for use: “For the temporary relief of minor aches and pains of muscles and joints" [which may be followed by: "associated with" (select one or more of the following: ‘simple backache,’ ‘arthritis,’ ‘strains,’ ‘bruises,’ and ‘sprains.’).”

7. The Monograph states, “the indications for OTC external analgesic drug products should emphasize that these products relieve only minor pain and have an action that is only temporary.”

8. Defendant’s Product emphasizes its ability to provide pain relief of a more significant and enduring type than those covered by the Monograph, even though its active ingredient, magnesium sulfate, has not been reviewed or found to be generally recognized as safe or effective by the FDA to diagnose, treat, cure, prevent or mitigate any diseases or conditions.

9. The front label representations include “Muscle Cramp and Spasm Relief,” “Prevents Cramps & Spasms,” “Releases Muscle Tightness,” “Reduces Muscle Soreness” and “Foam with Magnesium Sulfate.”

10. Defendant's online marketing proclaims: "Apply as Needed for Fast Relief – As soon as you feel a muscle cramp or spasm coming on, use Theraworx Relief to quickly release muscle tightness and reduce the soreness afterwards. There's no limit to how many times you can apply it per day!"

11. Other online marketing describes the Product as "Fast-Acting Muscle Cramp Relief."

12. The Product claims it "Prevents cramps and spams, Releases muscle tightness, [and] Relieves muscle soreness."

13. The representations on the packaging and website include:

- "REDUCES the severity of symptoms associated with RLS [restless leg syndrome]."
- "PREVENTS cramps and spasms when used daily."
- "[Q]uickly relieves muscle cramps and even prevents them when used daily."
- "Use Theraworx Relief twice daily (in the morning and before bedtime) to prevent nighttime muscle cramps and spasms, or three times daily if you also experience cramps or spasms during the day."
- "Theraworx Relief for Muscle Cramps and Spasms can be used as a companion product to manage the leg cramps associated with many important, commonly prescribed medications."

14. The Product's marketing – on the packaging and in various media – touts its unique ability to deal with leg pain:

- "Theraworx Relief is better than any product out there for leg cramps or spasms or even muscle soreness."
- "Nothing Else Like It on the Shelves."
- "Theraworx Relief is unique because it can be used prophylactically to prevent muscle spasms as well as to treat muscle spasms and cramps."
- "Before Theraworx Relief there wasn't really a lot of options on the market…nothing really to get to the root of the problem."
- "And it works really quickly, like no other product I've ever seen on the market. And I love that there's no side effects associated with it."
- "Non-opioid, non-centrally acting Theraworx Relief products offer real relief for those suffering from nocturnal cramps, symptoms associated with restless legs syndrome, and inflammation associated with arthritis or other joint conditions."
- "HEALTHCARE PROFESIONALS RECOMMEND THERAWORK RELIEF."

15. The side of the Product's packaging states it is "Clinically proven to prevent and relieve muscle cramps and spasms, and symptoms associated with Restless Legs Syndrome."

16. The Product's website contains numerous representations that it is "clinically proven" for the purpose which it is marketed:

- "Clinically proven to prevent foot and leg cramps when used daily."
- "In multiple clinical studies, Theraworx Relief has been proven to: Provide fast acting relief of muscle cramps and spasms, as well as post-cramp soreness -- most people get relief within minutes . . . [and] Reduce symptoms associated with restless leg syndrome (RLS)."
- "In a research study including patients diagnosed with RLS, Theraworx Relief was shown to reduce symptoms commonly associated with and accompanying RLS, including muscle cramps and spasms."

- "In a clinical study, participants noticed a significant reduction in the frequency of their leg & foot cramps within the first 2 weeks of daily use."
- "All Theraworx Relief products are clinically proven safe and effective."
- "Clinically proven."

17. Defendant's "clinically proven" claims mean it is promising that scientific evidence proves or "establishes" the truth of its claims.

18. These types of claims are required to be proven with double-blind, randomized studies.

19. Even the claims relating to efficacy that do not claim clinical proof are required by the FDA to be based on double-blind randomized evidence because the claims involve pain relief.

20. A competent and reliable study must include blinding, randomization, and be appropriately-controlled, demonstrating that the treatment group experienced statistically significant difference to the 95% confidence level as compared to the control group, to mitigate bias and avoid placebo effects.

21. Defendant has offered five studies in support of its claims, which fail to establish the Product is effective in support of its muscle cramp and spasm relief claims.[1]

22. The studies focus on treating leg cramps/spasms and symptoms associated with RLS and nocturnal leg cramps.

23. However, Defendant's advertising is focused on relieving muscle cramps and spams more generally (i.e., everyday muscle cramps and spams).

[1] "The effect of Theraworx® Relief [MCS] on night-time cramps and associated symptoms." "The Effect of a Topical Homeopathic Solution on Nocturnal Leg Cramps and Associated Symptoms," "Nocturnal Cramps and Introduction of a Novel Topical Therapy," "Effect of a Topical, Non-Systemic, Non-Centrally Acting Anti-Spasmodic on Division-One Athletes in Competition After Crossing Individual Muscle Spasm Threshold and Experiencing Exercise-Associated Muscle Cramps (EAMC)" and "Restless Leg Syndrome: The Efficacy of a Non-Systemic, Non-Centrally Acting Topical Treatment

24. None of the studies evaluated the Product's efficacy on "muscle soreness," "post-cramp soreness," "foot cramps," "muscle tightness" or "leg cramps associated with many important, commonly prescribed medications."

25. None of the studies were designed to assess whether the Product prevents muscle cramps.

26. None of the studies support the Product's claims of "fast-acting muscle cramp and spasm relief" or "quick[] release [o]f muscle tightness," since the time to relief was not measured.

27. In fact, the time period of the studies were several weeks long, which is inconsistent with the "fast-acting" claims.

28. The studies were not consistent with typical consumer usage based on the Product's instructions, i.e., whether the product was used with the accompanying compression garment.

29. The subject populations in many of the submitted studies were not relevant to the target audience of the challenged advertising – i.e., Division I college athletes.

30. The studies failed to account for potential confounding factors.

31. More than half of the studies were not blinded, which calls into question whether results were biased by either the technician or study participants.

32. No evidence was presented about adequate controls or safeguards in the studies to prevent bias.

33. Where one study had an adequate sample size, it otherwise failed to support the claims due to other reasons, such as not being randomized or blinded.

34. There is no genuine scientific research and no scientifically reliable studies that support the extraordinary claims that the Product can provide the effects indicated.

35. Defendant makes Product claims based on the recommendations of medical

professionals: "HEALTHCARE PROFESSIONALS RECOMMEND THERAWORX RELIEF."

36. Such claims are significant to consumers, yet they are not supported by reliable evidence such as statistically significant surveys showing that a substantial portion of them recommend the product.

37. The message to consumers is that the consensus among healthcare professionals is a recommendation of the Product.

38. Defendant's website makes misleading use of testimonials by pharmacists, in violation of the FTC's Guides Concerning Use of Endorsements and Testimonials in Advertising ("FTC Endorsement Guides").

39. These endorsements include statements such as:

- "Theraworx Relief is better than any product out there for leg cramps or spasms or even muscle soreness"
- "Theraworx Relief is unique because it can be used prophylactically to prevent muscle spasms as well as to treat muscle spasms and cramps."
- "[b]efore Theraworx Relief there really weren't a lot of options on the market... it was just some supplements that you could try or other over-the-counter medications that would be able to distract the nerve endings…nothing really to get to the root of the problem"
- "it works really quickly, like no other product I've ever seen on the market."
- "I've never seen a product that works as well [as Theraworx Relief] for muscle cramps and muscle spasms."
- "Theraworx works so fast, usually within thirty seconds to a minute,"
- "it can help prevent the actual muscle cramp by being applied before activity or

before you have night cramps, before you go to bed at night."

40. Even if endorsements are the accurate sentiments of an endorser, §255.1(a) of the FTC Endorsement Guides states that "an endorsement may not convey any express or implied representation that would be deceptive if made directly by the advertiser."

41. Where the honest opinion of an endorser "would not be enough to substantiate a claim…the endorsement should also be supported by competent and reliable scientific evidence."

42. The endorsements are so broad that they reasonably can be understood to compare the Product to FDA-approved prescription medications.

43. However, there is no reliable data showing that the Product exceeds all other competitors with respect to the attributes for which superiority is claimed

44. Defendant's claims are harmful and misleading because they cause consumers relying on their claims about the therapeutic benefit of the Product to forgo proven treatments.

45. This results in painful and potentially serious underlying muscle or joint affliction and moderate to severe joint inflammation from arthritis or other causes going untreated or inadequately treated.

46. Even if the Product has no harmful side effects, consumers are still harmed due to the failure to seek proven treatments and the economic deception through purchasing the Product based on false and misleading claims.

47. Defendant's branding, marketing and packaging of the Product is designed to – and does – deceive, mislead, and defraud plaintiff and consumers.

48. Defendant sold more of the Product and at higher prices than it would have in the absence of this misconduct, resulting in additional profits at the expense of consumers.

49. The value of the Product that plaintiff purchased and consumed was materially less

than its value as represented by defendant.

50. Had plaintiff and class members known the truth, they would not have bought the Product or would have paid less for it.

51. As a result of the false and misleading labeling, the Product is an sold at a premium price, approximately no less than $18.99 per 7.1 OZ compared to other similar products represented in a non-misleading way, and higher than the price of the Product if it were represented in a non-misleading way.

Jurisdiction and Venue

52. Jurisdiction is proper pursuant to Class Action Fairness Act of 2005 ("CAFA"). 28 U.S.C. § 1332(d)(2)

53. Under CAFA, district courts have "original federal jurisdiction over class actions involving (1) an aggregate amount in controversy of at least $5,000,000; and (2) minimal diversity[.]" *Gold v. New York Life Ins. Co.*, 730 F.3d 137, 141 (2d Cir. 2013).

54. Plaintiff Luz Sanchez is a citizen of New York.

55. Defendant Avadim Health, Inc. is a Delaware corporation with a principal place of business in Asheville, Buncombe County, North Carolina and is a citizen of North Carolina.

56. "Minimal diversity" exists because plaintiff Luz Sanchez and defendant are citizens of different states.

57. Upon information and belief, sales of the Product exceed $5 million during the applicable statutes of limitations, exclusive of interest and costs.

58. Venue is proper a substantial part of the events or omissions giving rise to the claim occurred in this District.

59. Plaintiff Tracey Jones purchased the Product on numerous occasions including but

not limited to between August and November 2020, at stores including Rite Aid, 282 8th Ave New York, NY 10001.

60. Plaintiff bought the Product at or exceeding the above-referenced price because she liked the product for its intended use and relied upon its "clinically proven" claims and other health claims, as described herein.

61. Plaintiff was deceived by and relied upon the Product's deceptive labeling and marketing.

62. Plaintiff would not have purchased the Product in the absence of Defendant's misrepresentations and omissions or would have paid less for it.

63. Plaintiff intends to, seeks to, and will purchase the Product again when she can do so with the assurance that Product's labels are consistent with the Product's components.

Class Allegations

64. The class will consist of all purchasers of the Product who reside in New York during the applicable statutes of limitations.

65. Plaintiff seeks class-wide injunctive relief based on Rule 23(b) in addition to a monetary relief class.

66. Common questions of law or fact predominate and include whether defendant's representations were and are misleading and if plaintiff and class members are entitled to damages.

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

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

69. No individual inquiry is necessary since the focus is only on defendant's practices

and the class is definable and ascertainable.

70. 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.

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

72. Plaintiff seeks class-wide injunctive relief because the practices continue.

New York General Business Law ("GBL") §§ 349 & 350
(Consumer Protection Statutes)

73. Plaintiff incorporates by reference all preceding paragraphs.

74. Plaintiff and class members desired to purchase and consume products which were as described and marketed by defendant and expected by reasonable consumers, given the product type.

75. Defendant's acts and omissions are not unique to the parties and have a broader impact on the public.

76. Defendant misrepresented the substantive, quantitative, qualitative, compositional and/or restorative attributes of the Product.

77. The Product's claims have a material bearing on price and consumer acceptance of the Product.

78. Plaintiff relied on the statements, omissions and representations of defendant, and defendant knew or should have known the falsity of same.

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

Negligent Misrepresentation

80. Plaintiff incorporates by reference all preceding paragraphs.

81. Defendant had a duty to disclose the absence of support for its claims and statements.

82. This duty is based on defendant's position as an entity which has held itself out as having special knowledge and experience in the production, service and/or sale of the product type.

83. The representations took advantage of consumers' cognitive shortcuts made at the point-of-sale and their trust in defendant, a well-known and respected brand or entity in this sector.

84. Plaintiff and class members reasonably and justifiably relied on these negligent misrepresentations and omissions, which served to induce and did induce, the purchase of the Product.

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

Breaches of Express Warranty, Implied Warranty of Merchantability and Magnuson Moss Warranty Act, 15 U.S.C. §§ 2301, *et seq.*

86. Plaintiff incorporates by reference all preceding paragraphs.

87. The Product was manufactured, labeled and sold by defendant or at its express directions and instructions, and warranted to plaintiff and class members that it possessed substantive, quality, restorative, and/or compositional attributes it did not.

88. Defendant had a duty to disclose and/or provide non-deceptive descriptions and marketing of the Product.

89. This duty is based, in part, on defendant's position as one of the most recognized companies in the nation in this sector.

90. Plaintiff provided or will provide notice to defendant, its agents, representatives, and their employees.

91. Defendant received notice and should have been aware of these misrepresentations due to numerous complaints by consumers to its main office over the past several years regarding

the Product, of the type described here.

92. The Product did not conform to its affirmations of fact and promises due to defendant's actions and were not merchantable because plaintiffs expected a product that was capable and proven to have the effects promised.

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

Fraud

94. Plaintiff incorporates by reference all preceding paragraphs.

95. Defendant's fraudulent intent is evinced by its failure to accurately market the Product on the packaging and in other media, when it knew its statements were neither true nor accurate and misled consumers.

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

Unjust Enrichment

97. Plaintiff incorporates by reference all preceding paragraphs.

98. Defendant obtained benefits and monies because the Product was not as represented and expected, to the detriment and impoverishment of plaintiff and class members, who seek restitution and disgorgement of inequitably obtained profits.

Jury Demand and Prayer for Relief

Plaintiff demands a jury trial on all issues.

WHEREFORE, Plaintiff prays for judgment:

1. Declaring this a proper class action, certifying plaintiff as representative and the undersigned as counsel for the class;

2. Entering preliminary and permanent injunctive relief by directing defendant to correct the challenged practices to comply with the law;
3. Injunctive relief to remove, correct and/or refrain from the challenged practices and representations, and restitution and disgorgement for members of the class pursuant to the applicable laws;
4. Awarding monetary damages, statutory damages under the GBL and interest pursuant to the common law and other statutory claims;
5. Awarding costs and expenses, including reasonable fees for plaintiff's attorneys and experts; and
6. Other and further relief as the Court deems just and proper.

Dated: December 6, 2020

Respectfully submitted,

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Pursuant to 22 NYCRR 130-1.1, the undersigned, an attorney admitted to practice in the courts of New York State, certifies that, upon information, and belief, formed after an inquiry reasonable under the circumstances, the contentions contained in the annexed documents are not frivolous.

Dated: December 6, 2020

/s/ Spencer Sheehan
Spencer Sheehan