UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK WHITE PLAINS COURTHOUSE

Edward Fuller, individually and on behalf of all others similarly situated,

7:22-cv-09824

Plaintiff,

- against -

Class Action Complaint

The Stop & Shop Supermarket Company LLC,

Defendant

Jury Trial Demanded

Plaintiff alleges on information and belief, except for allegations about Plaintiff, which are based on personal knowledge:

1. The Stop & Shop Supermarket Company LLC ("Defendant") markets, labels and sells adhesive lidocaine patches under the CareOne brand ("Product").

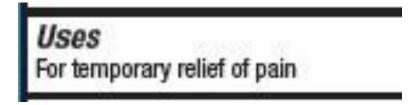


2. The front label representations include "Maximum Strength," "Lidocaine Pain Relief Patches," "4% Lidocaine/Topical Anesthetic," "Desensitizes Aggravated Nerves," "Up To 8 Hours Numbing Relief," a seal with the Rx symbol stating "Our Pharmacists Recommend," and a picture of a body with a patch applied to the lower back.

I. PRODUCT FAILS TO DELIVER LIDOCAINE IN PROMISED WAY

- 3. Lidocaine is a topical anesthetic used to treat pain by blocking the transmission of pain signals from nerve endings in the skin to the spinal cord and brain.
- 4. Although lidocaine patches can be prescribed by doctors, they are available to consumers as an over-the-counter ("OTC") product.
- 5. In 2003, the Food and Drug Administration ("FDA") initiated rulemaking to classify Product which delivered lidocaine through the skin in a patch form.
- 6. This was because there was no data on "[t]he safe and effective concentration" of lidocaine in this format, and uncertainties regarding the frequency of application considered safe and effective.
- 7. However, the FDA concluded that transdermal drug delivery systems, such as the patches used in the Product, systematically fail to adhere to the body.
- 8. Adequate adhesion is critical for topical delivery systems, because if the patch lifts or detaches while walking, sleeping or exercising, dosing will be compromised.
- 9. The FDA Adverse Events Reporting System reports that approximately 70% of concerns stemming from lidocaine patches involve their poor adhesion.
- 10. A 2021 peer-reviewed study in the Journal of Pain Research found that approximately half of lidocaine patches promising adhesion for eight hours failed to completely adhere to the participant's skin for the entire time.

- 11. The study required that users be sedentary while the patches were applied, as they are prone to much greater detachment when engaging in regular activities such as walking, stretching, and sleeping.
- 12. Although the study published by the Journal of Pain Research only tested generic prescription lidocaine patches, upon information and belief, the Product have not undergone the rigorous approval process required by the FDA and use the same outdated and defective adhesion technology as the lidocaine patches studied.
- 13. The claim that the Product provide "Pain relieving ointment on a breathable adhesive pad" is misleading
- 14. Consumers expect that when they are told the Product will provide "Up to 8 Hours" of relief, the patches will adhere to their bodies for no less than eight hours or even longer.
- 15. However, the Product cannot adhere to the skin for more than four hours, which renders the "Up To 8 Hours" misleading, a significant disparity.
- 16. The "Up To 8 Hours" claim is also inconsistent with the "Uses" disclosed on the Drug Facts which indicates it can only provide "Temporary relief" which consumers will understand as a short time, less than eight hours.



II. MAXIMUM STRENGTH CLAIMS

- 17. The representation of "Maximum Strength" is misleading for multiple reasons.
- 18. First, this statement tells consumers the Product contains and delivers the maximum amount of lidocaine available in patch form and is superior or equivalent in efficacy and results to

other OTC and prescription-strength lidocaine patches.

- 19. However, newly developed adhesive technology can deliver the bioequivalence of 5% lidocaine in patch form and maintain adhesion for at least eight hours under normal conditions.¹
- 20. Second, numerous studies and reports revealed that users of adhesive lidocaine patches using the same technology used by the Product regularly peel off a user's skin within three to four hours, and sometimes in minutes, after being applied.
- 21. Since, according to the FDA, the actual strength of a lidocaine patch is measured by the "mass of drug relative to the mass of the adhesive per patch" delivered to the target area, these adhesion deficiencies cause the delivery and absorption of lidocaine to be greatly reduced.
- 22. This inability to adhere for anywhere close to eight hours means the Product cannot deliver the "Maximum Strength" amount of lidocaine.

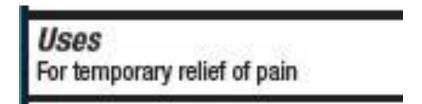
III. DESENSITIZING CLAIMS

- 23. The Product's promise to "Desensitize[s] Aggravated Nerves" and provide "[] Numbing Relief" is misleading because it implies its use will completely block and numb nerves and pain receptors, eliminate responses to painful stimuli, and treat neuropathic and musculoskeletal pain, including back and spinal pain.
- 24. The FDA determined that statements about desensitizing nerves and numbing pain were misleading in the context of transdermal patch delivery systems.
- 25. This is because consumers, such as Plaintiff, associate such statements with medical treatments requiring a prescription and FDA approval.
 - 26. However, the Product is available without a prescription and has not been approved

¹ In studies, this technology maintained a mean adhesion >90% across all time points (0, 3, 6, 9, and 12 h).

by the FDA.

- 27. Finally, its front label promise to "Desensitize[s] Aggravated Nerves" and provide "[] Numbing Relief" is inconsistent with what it is authorized by law to say, i.e., that it can be used to "temporarily relieve[s] minor pain."
- 28. As the Product's "Uses" purports to provide "temporary relief of pain," without qualifying the pain it purports to relieve as "minor," even consumers who scrutinize the Drug Facts on the back label will be misled.



IV. MISLEADING SEAL

- 29. Recognizing the value of independent certification, the Federal Trade Commission ("FTC") has warned companies to be careful in making representations about independent certification. *See* 16 C.F.R. § 260.1.
- 30. The FTC guidelines against deceptive marketing regarding "Certifications and Seals of Approval" state:

It is deceptive to misrepresent, directly or by implication, that a product, package, or service has been endorsed or certified by an independent third party.

16 C.F.R. § 260.6(a) (emphasis added).

- 31. Seals are distinguishable to consumers because they are written in a typeface and font wholly different from the surrounding text.
- 32. Despite the FTC's warnings, the front label contains a seal with the universally recognized symbol for a prescription, "Rx," based on the Latin word "recipe" meaning "to take," customarily part of the superscription (heading) of a prescription.

- 33. Even though the seal states "Our Pharmacists Recommend," this text is written in small print and could be difficult to read.
- 34. Despite the "Rx" seal, the Product does not require a prescription yet consumers will expect it is "prescription strength," when this is false and/or misleading.

V. CONCLUSION

- 35. Defendant makes other representations and omissions with respect to the Product which are false and misleading.
- 36. Had Plaintiff known the truth, he would not have bought the Product or would have paid less for it.
- 37. As a result of the false and misleading representations, the Product are sold at a premium price, approximately no less than no less than \$9.79 per box of six patches, excluding tax and sales, higher than similar Product, represented in a non-misleading way, and higher than it would be sold for absent the misleading representations and omissions.

Jurisdiction and Venue

- 38. Jurisdiction is pursuant to Class Action Fairness Act of 2005 ("CAFA"). 28 U.S.C. § 1332(d)(2).
- 39. The aggregate amount in controversy exceeds \$5 million, including any statutory damages, exclusive of interest and costs.
 - 40. Plaintiff is a citizen of New York.
- 41. Defendant is a Delaware limited liability company with a principal place of business in Quincy, Massachusetts, Norfolk County.
- 42. The member of Defendant is Ahold U.S.A., Inc. a Maryland corporation with a principal place of business in Landover, Prince Georges County, Maryland.

- 43. Defendant is a citizen of Maryland.
- 44. The class of persons Plaintiff seeks to represent includes persons who are citizens of different states from which Defendant is a citizen.
- 45. The members of the class Plaintiff seeks to represent are more than 100, because the Product has been sold for several years with the representations described here, in hundreds of Defendant's stores and online, across the States covered by Plaintiff's proposed classes.
- 46. Venue is in this District with assignment to the White Plains Courthouse because a substantial part of the events or omissions giving rise to these claims occurred in Rockland County, including Plaintiff's purchase and/or use of the Product and awareness and/or experiences of and with the issues described here.

Parties

- 47. Plaintiff Edward Fuller is a citizen of Tomkins Cove, Rockland County, New York.
- 48. Defendant The Stop & Shop Supermarket Company LLC operates close to 500 Stop & Shop supermarkets in the mid-Atlantic states and New England.
- 49. While Stop & Shop sells leading national brands, they also sell a large number of OTC products under one of their private label brands, CareOne.
- 50. Private label products are made by third-party manufacturers and sold under the name of the retailer, or its sub-brands.
- 51. Previously referred to as "generic" or "store brand," private label products have increased in quality, and often are superior to their national brand counterparts.
- 52. Products under the CareOne brand have an industry-wide reputation for quality and value.
 - 53. In releasing products under the CareOne brand, Defendant's foremost criteria was

high-quality equal to or better than the national brands.

- 54. Defendant is able to get national brands to produce its private label items due its loyal customer base and tough negotiating.
- 55. That CareOne branded products met this high bar was proven by focus groups, which rated them above the name brand equivalents.
- 56. Private label products generate higher profits for retailers because national brands spend significantly more on marketing, contributing to their higher prices.
- 57. 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."
- 58. Private label products under the CareOne brand benefit by their association with consumers' appreciation for the Stop & Shop brand as a whole.
- 59. The development of private label items is a growth area for Stop & Shop, as it selects only top suppliers to develop and produce CareOne products.
- 60. Plaintiff purchased the Product at locations including Stop & Shop, 7 Samsondale Plaza, West Haverstraw, NY 10993, between May 2020 and November 2022, among other times.
- 61. Plaintiff believed and expected the Product would reliably adhere to his body to deliver 4% lidocaine for not less than eight hours, that they were the maximum strength available, would relieve pain, deliver immediate pain relief through desensitizing aggravated nerves (menthol), because that is what the representations and omissions said and implied, on the front label and the absence of any reference or statement elsewhere on the Product.
- 62. Plaintiff relied on the words, terms coloring, descriptions, layout, placement, packaging, and/or images on the Product, on the labeling, statements, omissions, claims,

statements, and instructions, made by Defendant or at its directions, in digital, print and/or social media, which accompanied the Product and separately, through in-store, digital, audio, and print marketing.

- 63. Plaintiff bought the Product at or exceeding the above-referenced price.
- 64. Plaintiff paid more for the Product than he would have had he known the representations and omissions were false and misleading, or would not have purchased it.
- 65. The value of the Product that Plaintiff purchased was materially less than its value as represented by Defendant.
- 66. Plaintiff chose between Defendant's Product and similarly represented yet truthful products which did not misrepresent their attributes, features, and/or components.

Class Allegations

67. Plaintiff seeks certification under Fed. R. Civ. P. 23 of the following classes:

New York Class: All persons in the State of New York who purchased the Product during the statutes of limitations for each cause of action alleged; and

Consumer Fraud Multi-State Class: All persons in the States of New Jersey, New Hampshire, and Rhode Island who purchased the Product during the statutes of limitations for each cause of action alleged.

- 68. 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.
- 69. 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.
 - 70. Plaintiff is an adequate representative because his interests do not conflict with other

members.

- 71. No individual inquiry is necessary since the focus is only on Defendant's practices and the class is definable and ascertainable.
- 72. 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.
- 73. Plaintiff's counsel is competent and experienced in complex class action litigation and intends to protect class members' interests adequately and fairly.

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

- 74. Plaintiff incorporates by reference all preceding paragraphs.
- 75. Plaintiff believed the Product would reliably adhere to his body and provide a continuous dose of maximum strength lidocaine to desensitize nerves and numb pain.
- 76. Defendant's false, misleading and deceptive representations and omissions are material in that they are likely to influence consumer purchasing decisions.
- 77. Plaintiff would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

<u>Violation of State Consumer Fraud Acts</u> (<u>Consumer Fraud Multi-State Class</u>)

- 78. The Consumer Fraud Acts of the States in the Consumer Fraud Multi-State Class are similar to the consumer protection statute invoked by Plaintiff and prohibit the use of unfair or deceptive business practices in the conduct of commerce.
- 79. The members of the Consumer Fraud Multi-State Class reserve their rights to assert their consumer protection claims under the Consumer Fraud Acts of the States they represent and/or the consumer protection statute invoked by Plaintiff.
 - 80. Defendant intended that members of the Consumer Fraud Multi-State Class would

rely upon its deceptive conduct, which they did, suffering damages.

Breaches of Express Warranty,
Implied Warranty of Merchantability/Fitness for a Particular Purpose
and Magnuson Moss Warranty Act, 15 U.S.C. §§ 2301, et seq.

- 81. The Product were manufactured, identified, marketed and sold by Defendant and expressly and impliedly warranted to Plaintiff that it would reliably adhere to his body and provide a continuous dose of maximum strength lidocaine to desensitize nerves and numb pain.
- 82. Defendant directly marketed the Product to Plaintiff through its advertisements and marketing, through various forms of media, on the packaging, in print circulars, direct mail, product descriptions distributed to resellers, and targeted digital advertising.
- 83. Defendant knew the product attributes that potential customers like Plaintiff were seeking and developed its marketing and labeling to directly meet those needs and desires.
- 84. Defendant's representations about the Product were conveyed in writing and promised it would be defect-free, and Plaintiff understood this meant it would reliably adhere to his body and provide a continuous dose of maximum strength lidocaine to desensitize nerves and numb pain.
- 85. Defendant's representations affirmed and promised that the Product would reliably adhere to his body and provide a continuous dose of maximum strength lidocaine to desensitize nerves.
- 86. Defendant described the Product so Plaintiff believed that they would reliably adhere to his body and provide a continuous dose of maximum strength lidocaine to desensitize nerves, which became part of the basis of the bargain that it would conform to its affirmations and promises.

- 87. Defendant had a duty to disclose and/or provide non-deceptive descriptions and marketing of the Product.
- 88. This duty is based on Defendant's outsized role in the market for this type of Product, a trusted company known for its high-quality CareOne Product.
 - 89. Plaintiff recently became aware of Defendant's breach of the Product's warranties.
- 90. Plaintiff provided or provides notice to Defendant, its agents, representatives, retailers, and their employees that it breached the Product's warranties.
- 91. Defendant received notice and should have been aware of these issues due to complaints by third-parties, including regulators, competitors, and consumers, to its main offices, and by consumers through online forums.
- 92. The Product did not conform to its affirmations of fact and promises due to Defendant's actions.
- 93. The Product was not merchantable because it was not fit to pass in the trade as advertised, not fit for the ordinary purpose for which it was intended and did not conform to the promises or affirmations of fact made on the packaging, container or label, because they were marketed as if they would reliably adhere and provide a continuous dose of maximum strength lidocaine to desensitize nerves and numb pain.
- 94. The Product was not merchantable because Defendant had reason to know the particular purpose for which it was bought by Plaintiff, because he expected it would reliably adhere to his body and provide a continuous dose of maximum strength lidocaine to desensitize nerves and numb pain, and he relied on Defendant's skill and judgment to select or furnish such a suitable product.

<u>Fraud</u>

95. Defendant misrepresented and/or omitted the attributes and qualities of the Product,

that it would not here for anywhere close to the hours indicated, rendering the "Maximum

Strength" claim false, and was unable to desensitize nerves and numb pain.

96. Defendant is part of one of the largest international conglomerates selling consumer

packaged goods, with immense resources and the ability to ensure the products it sold were

represented truthfully, yet willingly failed to do so.

Unjust Enrichment

97. Defendant obtained benefits and monies because the Product were 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. Awarding monetary, statutory and/or punitive damages and interest;

3. Awarding costs and expenses, including reasonable fees for Plaintiff's attorneys and

experts; and

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

Dated: November 17, 2022

Respectfully submitted,

/s/ Spencer Sheehan

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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: <u>CareOne Lidocaine Patches Fail to Provide Advertised Pain Relief, Class Action Alleges</u>