

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

KRISTIN DiCROCE, Individually and on Behalf of all Persons Similarly Situated,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. _____
)	
MCNEIL NUTRITIONALS, LLC, and JOHNSON & JOHNSON CONSUMER, INC.,)	
)	
Defendants.)	
)	

CLASS ACTION COMPLAINT AND DEMAND FOR TRIAL BY JURY

Plaintiff Kristin DiCroce, by and through her counsel, on behalf of herself and all other persons similarly situated nationwide (the “Class”), alleges the following facts and claims upon personal knowledge as to matters relating to herself, and, upon information and belief, as to all other matters based upon the investigation of counsel as follows:

INTRODUCTION

- Plaintiff Kristin DiCroce brings this class action against McNeil Nutritionals, LLC (“McNeil”), a subsidiary of Johnson & Johnson Consumer, Inc. (“J&J”) (collectively “Defendants”), for their dietary supplement Lactaid products (the “Lactaid Supplements” or “Supplements”) that are unlawfully and misleadingly labeled and advertised in violation of the Food, Drug, and Cosmetic Act of 1938 (“FDCA”), 21 U.S.C. §§ 301–399f, and U.S. Food and Drug Administration (“FDA”) regulations and guidance. (Defendants also sell lactose-free food/dairy products under the name Lactaid, but those are not part of this action; only the Supplements are at issue in this lawsuit).

2. Defendants unlawfully and misleadingly label and advertise the Lactaid Supplements with claims that it prevents, treats, cures, or mitigates lactose intolerance and/or symptoms associated with being lactose intolerant (the “Disease Claims”) in violation of 21 U.S.C. § 343(r) and 21 C.F.R. § 101.14.
3. While there is no private right of action under federal law for Defendants’ violations, there are private rights of action under state laws, such as in Massachusetts General Laws, Chapter 93A and M.G.L. c. 266, § 91, and other states’ substantially similar consumer protection statutes.

PARTIES

4. Plaintiff Kristin DiCroce is an individual who resides in Cohasset, Norfolk County, Massachusetts.
5. Defendant McNeil Nutritionals, LLC is a limited liability company organized under the laws of Delaware with a principal place of business at Fort Washington, PA. McNeil is a wholly-owned subsidiary of Johnson & Johnson Consumer, Inc.
6. Defendant Johnson & Johnson Consumer, Inc. is a corporation organized under the laws of Delaware with a principal place of business in New Brunswick, New Jersey. J&J is the parent company of its subsidiary McNeil.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d) because the amount in controversy for the Class exceeds \$5 million and there is diversity between some Class members and the Defendants.

8. Venue is proper here pursuant to 28 U.S.C. § 1391(a) because Defendants have transacted business here and a substantial part of the events or omissions giving rise to the claims in this lawsuit occurred here.

SUBSTANTIVE FACTUAL ALLEGATIONS

9. DiCroce purchased the Lactaid Supplements near her home in Massachusetts on multiple occasions within the past four years based on the mislabeling statements described herein. Had the Lactaid Supplements been labeled in compliance with applicable state and federal law, the Disease Claims would not have appeared on the products, DiCroce would not have been misled by these claims on the Supplements' label, and this would have affected her purchasing decisions.
10. Dietary supplements are considered to be a food subject to the laws and regulations applicable to food. The FDCA provides that a food is "misbranded," among other things, "if its labeling is false or misleading in any particular" or if its label or labeling bears an unauthorized "health claim", *i.e.*, a claim that expressly or impliedly characterizes the relationship between a nutrient and a disease or health-related condition. 21 U.S.C. § 343(a)(1) & (r).
11. The FDCA prohibits all health claims on food labels or labeling, except those that the FDA has expressly authorized by regulation. *Id.* § 343(r)(1)(B); *see also* 21 C.F.R. § 101.14(e)(1)–(2) ("[n]o expressed or implied health claim may be made on the label or in labeling for a food, regardless of whether the food is in conventional food form or dietary supplement form, unless: (1) The claim is specifically provided for in subpart E of this part; and (2) The claim conforms to all general provisions of this section as well as to all specific provisions in the appropriate section of subpart E of this part . . .").

12. The FDCA provides that a statement on a dietary supplement's label or labeling "may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases." 21 U.S.C. § 343(r)(6). Moreover, labeling of a food is deemed misleading, and thus misbranded, if it omits information that is material in light of the claims made for the product or the consequences that may result from using the product, such as failing to disclose known adverse effects or other information necessary for consumers to safely use the product. 21 C.F.R. § 1.21(a).
13. Through its labeling and advertising, including on their website, Defendants misrepresent that the Lactaid Supplements are effective to diagnose, prevent, treat, cure, or mitigate, or provide a beneficial effect on lactose intolerance and/or the characteristic symptoms associated with being lactose intolerant. Specifically, Defendants make the following virtually identical Disease Claims for each of the Lactaid Supplements:
 - a. LACTAID Fast Act Chewables – (claims that it is "For the Prevention of ● Gas ● Bloating ● Diarrhea associated with digesting dairy", that by taking this Supplement a consumer suffering from lactose intolerance can "Enjoy Dairy Again!", and by taking this Supplement "nothing can stop you from eating the foods you love. Our delicious vanilla chewables should be taken with your first bite of dairy, so that milk doesn't mess with you"), *see* label attached hereto as Exhibit 1;
 - b. LACTAID Fast Act Caplets – (claims that it is "For the Prevention of ● Gas ● Bloating ● Diarrhea associated with digesting dairy", that by taking this Supplement a consumer suffering from lactose intolerance can "Enjoy Dairy Again!", and "Don't let that annoying lactose get in the way of eating." LACTAID Fast Act Caplets make dairy easier to digest so you can enjoy your favorite foods anytime, anywhere"), *see* label attached hereto as Exhibit 2; and
 - c. LACTAID Original Strength Caplets (claims that it is "For the Prevention of ● Gas ● Bloating ● Diarrhea associated with digesting dairy", that by taking this Supplement a consumer suffering from lactose intolerance can "Enjoy Dairy Again!" and "Experience the Total Joy of Dairy", and that by taking this Supplement it will be "easier than ever to manage your lactose intolerance. Take up to three caplets with your first sip or bite of dairy to

ensure that milk doesn't mess with you. LACTAID Original Strength Caplets lets you enjoy dairy anytime, anywhere"), with label attached hereto as Exhibit 3.

14. By claiming that the above Supplements are effective to diagnose, prevent, treat, cure, or mitigate lactose intolerance and/or the characteristic symptoms associated with being lactose intolerant, *i.e.*, gas, bloating, and diarrhea associated with digesting dairy, Defendants are holding the Supplements out as drugs.
15. It is well established that lactose intolerance is a digestive disease, since, among other things, it can cause harm to a person's small intestine. *See, e.g.*, National Institute of Health, National Institute of Diabetes and Digestive and Kidney Diseases, <https://www.niddk.nih.gov/health-information/digestive-diseases/lactose-intolerance> (listing lactose intolerance as a digestive disease) (last visited September 15, 2021).
16. The labeling of the Lactaid Supplements with Disease Claims constitutes materially misleading labeling and marketing practices because Defendants are labeling and marketing the Supplements as drugs, which the FDCA defines, in part, as any article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal." 21 U.S.C. § 321(g)(1)(B).
17. Unlike approved drugs, however, the Supplements have not received the requisite FDA approval as being safe and effective for their advertised purpose, and thus do not include the attendant "Drug Facts" information the FDA deems material to consumers. This end-run around the FDCA's certification requirement makes the Disease Claims illegal drug claims and the use of these claims to market and promote the Supplements amounts to "Health Fraud," as defined by the FDA.

18. Accordingly, representations by Defendants that the Lactaid Supplements are effective to diagnose, prevent, treat, cure, or mitigate lactose intolerance and/or the symptoms associated with being lactose intolerant are per se disease claims. *See, inter alia*, FDA, Guidance for Industry, available at: <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm103340.htm>.
19. These misrepresentations and acts give rise to private rights of action under state law, including M.G.L. c. 93A and other similar state consumer protection statutes.

THE DISCOVERY RULE/FRAUDULENT CONCEALMENT

20. By prominently displaying the Disease Claims on its labels and website, Defendants created the misleading impression that the Disease Claims met all the regulatory requirements.
21. Plaintiff was unable to discover earlier that Defendants' Disease Claims were fraudulent and a violation of federal and state laws because she had no reason to believe Defendants were not complying with all its legal and regulatory requirements and legal duties.

CLASS ACTION ALLEGATIONS

22. Plaintiff brings this suit as a class action on behalf of herself and on behalf of other similarly situated persons pursuant to Fed. Civ. P. Rule 23 and Mass. Gen. Laws c. 93A for the 93A claim and states with substantially similar consumer protection acts. Subject to additional information obtained through further investigation and/or discovery, the foregoing definition of the Class may be expanded or narrowed. The proposed Class is defined as follows:

Class: Plaintiff seeks to represent a nationwide class of all persons who purchased the Lactaid Supplements and are from states with a consumer protection statute substantially similar to M.G.L. c. 93A.

23. Excluded from the Class are: (1) Defendants, Defendants' subsidiaries, affiliates, officers, directors, assigns and successors, and any entity which the Defendants have a controlling interest; (2) the Judge to whom this case is assigned and any member of the Judge's immediate family; (3) anyone who purchased Defendants' Lactaid Supplements for the purpose of resale; and (4) anyone asserting claims for personal injury. Plaintiff reserves the right to modify the Class as further investigation and/or discovery warrant.
24. This action has been brought and may properly be maintained as a class action pursuant to Federal Rule of Civil Procedure 23 and case law thereunder.
25. **Numerosity:** The members of the Class are so numerous that joinder of all members is impracticable. Plaintiff reasonably believes that the Class is comprised of thousands of consumers throughout the United States. In *Daley v. McNeil Consumer Products Co.*, 164 F.Supp.2d 367, 374 (S.D.N.Y. 2001), the court recognized that "McNeil has sold over 600 million caplets of Lactaid" (citing "Temple Aff. at ¶ 7"). Those numbers have only increased over the past twenty years.
26. **Commonality:** Common questions of law and fact exist as to all members of the Class and any State Subclasses. These common questions predominate over any questions affecting only individual Class members. The common legal and factual questions include, but are not limited to, the following:
 - a. Whether Defendants make Disease Claims in violation of federal law;
 - b. Whether any violations of federal law are in turn violations of the relevant states' laws;

- c. Whether the Lactaid Supplements as actually provided, *i.e.*, without FDA approval of the Disease Claims, were of less value than the Lactaid Supplements as represented with the Disease Claims;
 - d. Whether Class members are entitled to money damages, and the measure of those damages; and
 - e. Whether equitable relief is also appropriate to prevent the continuation of the alleged wrongdoing.
27. In making the illegal Disease Claims, Defendants have acted or refused to act on grounds that apply generally to the Class so that final injunctive relief or corresponding declaratory relief is appropriate respecting the Class as a whole.
28. **Typicality:** Plaintiff's claims are typical of those of the other members of the Class because they all purchased the Lactaid Supplements making Disease Claims so the harm sustained by Plaintiff and all of the members of the Class arises from and was caused by the same course of conduct in which Defendants engaged.
29. **Adequacy:** Plaintiff's claims are made in a representative capacity on behalf of the other members of the Class. Plaintiff has no interests antagonistic to the interests of the other members of the proposed Class and is subject to no unique defenses.
30. Plaintiff is similarly situated in interest to all members of the proposed Class and is committed to the vigorous prosecution of this action and has retained competent counsel experienced in consumer class actions. Accordingly, Plaintiff is an adequate representative of the proposed Class and will fairly and adequately protect the interests of the Class.
31. This suit may be maintained as a class action under Fed. Civ. P. Rule 23 (b) because there are questions of law or fact that are common to the members of the Class that predominate over any questions affecting only individual members and a class action is

superior to other available methods for the fair and efficient adjudication of the controversy. The injury suffered by each individual class member is relatively small in comparison to the burden and expense of individual prosecution of the complex and extensive litigation necessitated by the Defendants' conduct. It would be virtually impossible for members of the Class individually to effectively redress the wrongs done to them. Even if the members of the Class could afford such litigation, the court system could not individualize litigation inasmuch as it presents a potential for inconsistent or contradictory judgments. Individualized litigation increases the delay and expense to all parties, and to the court system when presented by complex legal and factual issues such as those in this case. By contrast, the class action device presents no management difficulties, and provides the benefits of single adjudication, economy of scale and comprehensive supervision by a single court.

32. In addition, the M.G.L. Chapter 93A claim should be certified under Chapter 93A, § 9(2) for all Chapter 93A claims (and similar sections for other states with a substantially similar provision) because Defendants have caused similar injury to numerous other persons similarly situated and Plaintiff will adequately and fairly represent such other persons.

COUNT I

Violations of the Massachusetts Consumer Protection Act (M.G.L. c. 93A, § 1, et seq.) And Other States Consumer Protection Statutes

33. Plaintiff incorporates herein the allegations contained in the preceding paragraphs as if fully set forth herein.
34. Plaintiff brings this claim on behalf of herself and all members of the Class.

35. More than 30 days prior to filing this complaint, a proper demand for relief was made on Defendants under M.G.L. c. 93A on behalf of Plaintiff and the Class.
36. Defendants did not make a reasonable offer of settlement to either Plaintiff or the Class.
37. Defendants' acts and practices as set forth herein constitute unfair methods of competition and unfair and deceptive practices in the conduct of its business in violation of M.G.L. c. 93A, §§ 2 and 9, and other states' substantially similar consumer protection statutes.
38. These violations of M.G.L. c. 93A and other state consumer protection statutes include, without limitation, Defendants' marketing and selling the mislabeled Lactaid Supplements containing the illegal Disease Claims described herein.
39. Defendants' violations of M.G.L. c. 93A and other substantially similar state consumer protection statutes were willful and knowing.
40. Defendants' use or employment of the unfair or deceptive acts or practices described herein (a) have caused similar injury to numerous other persons similarly situated and (b) Plaintiff will adequately and fairly represents such other persons.
41. Plaintiff and the Class have suffered damages as a result of Defendants' unfair or deceptive acts, and are entitled to equitable relief, treble damages or statutory damages of \$25 per violation in Massachusetts (and other amounts in other states), attorneys' fees and costs per state law.
42. Plaintiff requests that this Court enjoin Defendants from continuing to engage in the unlawful and deceptive practices and acts alleged above, pursuant, *inter alia*, to M.G.L. c. 93A, § 6, along with appropriate court costs and attorneys' fees pursuant to Chapter 93A and other substantially similar state consumer protection statutes. If Defendants are not

permanently enjoined from continuing to engage in such violations of the Chapter 93A, future consumers will be damaged by Defendants' acts and practices in the same way as have Plaintiff and the putative Class.

COUNT II

Unjust Enrichment

43. Plaintiff incorporates herein the allegations contained in the preceding paragraphs as if fully set forth herein.
44. Plaintiff brings this claim on behalf of herself and all members of the Class.
45. Plaintiff and Class members conferred a tangible economic benefit upon Defendants by purchasing Defendants' Lactaid Supplements. Plaintiff and Class members would have expected remuneration from Defendants at the time this benefit was conferred had they known that the Lactaid Supplements were marketed and sold as misbranded products containing illegal Disease Claims.
46. As a direct and proximate result of Defendants' misconduct as set forth above, Defendants have been unjustly enriched at the expense of Plaintiff and Class members.
47. It would be inequitable for Defendants to retain the profits, benefits and other compensation obtained by its wrongful conduct in marketing and selling the Lactaid Supplements that are misbranded.

COUNT III

False Advertising in Violation of Mass. Gen. Laws c. 266, § 91

48. Plaintiff incorporates herein the allegations contained in the preceding paragraphs as if fully set forth herein.
49. Plaintiff brings this claim on behalf of herself and all members of the Class.
50. Defendants used advertising on the packaging of the Lactaid Supplements at issue in this lawsuit to sell said products, and other advertising of the products, including, without limitation, the section of its website for the Lactaid Supplements.

51. Defendants are disseminating advertisements about the Lactaid Supplements that by its nature are deceptive or misleading within the meaning of M.G.L. c. 266, § 91.
52. Defendants' Lactaid Supplements are misbranded by making illegal Disease Claims on the products' label and other advertising of the products, including, without limitation, through its website.
53. The advertising statements on the labeling of the Lactaid Supplements described herein are misleading and likely to deceive Class Members and the general public.
54. Defendants knew or should have known that the statements they made and disseminated on the Supplements' packaging and labels, Defendants' website and other marketing materials for the Lactaid Supplements were deceptive and/or misleading by the inclusion of the illegal Disease Claims described herein in violation of M.G.L. c. 266, § 91, in said advertising.
55. Plaintiff seeks an Order of this court enjoining Defendants from continuing to violate the Massachusetts false advertising law or violating it in the same fashion in the future as discussed herein, and a declaration that the Supplements' labels are in violation of M.G.L. c. 266, § 91.

PRAYERS FOR RELIEF

WHEREFORE, Plaintiff, on behalf of herself and all members of the Class defined herein, by the undersigned attorney, prays for judgment as follows:

- (i) Certification of a nationwide Class and appointment of Plaintiff as representative of the Class and her legal counsel as Class legal counsel;
- (ii) Grant judgment for Plaintiff and against Defendants on all Counts;
- (iii) Award Plaintiff multiple damages, attorneys' fees and costs pursuant to M.G.L. c. 93A § 9, and other state consumer protection statutes;
- (iv) A declaration that the Defendants' labels for the Lactaid Supplements at issue in this lawsuit containing the false and misleading statements

described herein are in violation of Massachusetts law and federal regulations as specified in this Complaint;

- (v) An Order enjoining Defendant from selling its Lactaid Supplements at issue in this lawsuit in the Commonwealth of Massachusetts and throughout the United States with labels and other advertising containing the false and misleading statements that are in violation of Massachusetts law and federal regulations as specified in this Complaint;
- (vi) Restitution of all money paid to Defendants by Plaintiff and the Class, as a result of the wrongs alleged herein in an amount to be determined at trial;
- (vii) Disgorgement of the ill-gotten gains derived by Defendants from their misconduct described herein;
- (viii) Award Plaintiff her costs and disbursements incurred in maintaining this action, including reasonable attorneys' and experts' fees and other expenses, and pre-and post-judgment interest; and
- (ix) Any other relief as this Court deems just and proper.

JURY DEMAND

Plaintiff demands a trial by jury on all counts so triable.

Plaintiff Kristin DiCroce,

By her attorneys,

ADKINS, KELSTON & ZAVEZ, P.C.,

Dated: October 12, 2021

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