UNITED STATES DISTRICT COURT WESTERN DISTRICT OF NEW YORK ROCHESTER DIVISION

Patricia Donadio, individually and on behalf of all others similarly situated,

Plaintiff,

- against -

Bayer Healthcare LLC,

Defendant

6:22-cv-06521-EAW-MJP

First Amended Class Action Complaint

Jury Trial Demanded

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

1. Bayer Healthcare LLC ("Defendant") manufactures mix-in powder packets under the Alka-Seltzer Plus brand promoted for relief of "Severe Cold & Flu" containing "Honey Lemon Zest" indicated by a picture of a honey dipper and lemon wedge ("Product").



- 2. Sales figures of over-the-counter ("OTC") medications indicate that consumers are increasingly purchasing nontraditional or "Natural OTCs" for relief of colds and coughs.¹
- 3. This term refers to "self-care products that consumers use either to prevent or treat minor ailments that are drug-free, [and] may contain natural, plant-, or herb-based ingredients."
 - 4. The reasons for this shift are several.
- 5. First, according to a survey by Mintel, 37% of consumers said traditional OTC products posed safety risks and could cause unwanted side effects.
- 6. Second, almost 60% believed natural ingredients in this emerging class of products are equally, if not more effective, in treating colds and coughs.
- 7. One academic publication cited "the increased consumption of [natural ingredients like honey and lemon]" in response to the coronavirus pandemic.²
- 8. For example, a majority of consumers believe that because "[L]emons are an excellent source of vitamin C [,] an antioxidant [] known to help [the] immune system [and] reduce the risk of complications from a cold or flu," their addition to OTC products is beneficial.³
- 9. One recent study even showed that "honey was more effective in relieving the symptoms of cold and flu-like illnesses than the usual commercial remedies."⁴

¹ IRI Worldwide, "Natural" Trends and Drivers in the Self-care Space, 2017.

² Pieroni, Andrea, et al. "Taming the pandemic? The importance of homemade plant-based foods and beverages as community responses to COVID-19." Journal of ethnobiology and ethnomedicine 16.1 (2020): 1-9.

³ Dominic Hernandez, The health benefits of lemon, Vital Record, News from Texas A&M Health, August 18, 2016; Immunity boosters: Abundant opportunities for health halo ingredients as wellness trends prevail, Food Ingredients First, Sept. 14, 2022; Dr. A. Elizabeth Sloan & Dr. Catherine Adams Hutt, Getting Ahead of the Curve: Herbs & Botanicals, Sloan Trends, Inc., Nutraceuticals World, July 1, 2016.

⁴ Rob Picheta, Honey may be better at treating coughs and colds than over-the-counter medicines, CNN, Aug. 19, 2020 citing H. Abuelgasim et al., Effectiveness of honey for symptomatic relief in upper respiratory tract infections: a systematic review and meta-analysis, BMJ Evidence-Based Medicine 2021;26:57-64.

- 10. A British trade journal recommended that "[B]rands can capitalize on this increased holistic approach by promoting the use of natural ingredients in their products."
- 11. Competitor brands of cough and cold medications from Robitussin, Maty's Organic and the Target Up&Up brand contain honey and lemon ingredients sought by consumers, confirmed by their ingredient lists.







12. Other cold and cough products that do not contain honey and lemon ingredients may contain pictures of a honey dipper and lemon wedge, but disclose on their front labels this only means they have "Honey Lemon Flavors."

⁵ Grocery Trader, <u>Bouncing back – The OTC category is getting back to normal</u>, Oct. 4, 2022.





- 13. Notwithstanding the front label disclosure of active ingredients, the Product's front label emphasis on honey and lemon through the wedge of fresh lemon and dripping honey dipper, described as "Honey Lemon Zest" next to a cup of steaming tea "creates an impression of value [on honey and lemon] greater than their true functional role in the formulation," because these are inactive ingredients and present in de minimis amounts. 21 C.F.R. § 201.10(c)(4).
- 14. Unlike the labeling of competitor products, Defendant fails to disclose that "honey" and "lemon zest" are absent and these terms only refer to how it purports to taste.
- 15. Consumers such as Plaintiff expected the Product to contain honey and lemon ingredients, in the form of honey and lemon zest, the outermost layer of the lemon peel, recognized as a rich source of antioxidants.
- 16. However, the full active and inactive ingredient lists on the reverse side of the packaging reveal the absence of honey and any lemon ingredients.

| Active ingredients (in each packet) | Purposes |
|-------------------------------------|--------------------|
| Acetaminophen 650 mg | |
| Dextromethorphan hydrobromide 20 mg | |
| Doxylamine succinate 12.5 mg | Antihistamine |
| Phenylephrine hydrochloride 10 mg | Nasal decongestant |
| | |

| Active ingredients (in each packet) | Purposes |
|-------------------------------------|-----------------------------|
| Acetaminophen 650 mg | Pain reliever/fever reducer |
| Dextromethorphan hydrobromide 20 mg | |
| Doxylamine succinate 12.5 mg | Antihistamine |
| Phenylephrine hydrochloride 10 mg | Nasal decongestant |

Inactive ingredients acesulfame potassium, anhydrous citric acid, compressible sugar, D&C yellow #10, dental-type silica, FD&C red #40, flavors, pregelatinized starch, sodium citrate, sucralose, tartaric acid, tribasic calcium phosphate

Inactive ingredients acesulfame potassium, anhydrous citric acid, compressible sugar, D&C yellow #10, dentaltype silica, FD&C red #40, flavors, pregelatinized starch, sodium citrate, sucralose, tartaric acid, tribasic calcium phosphate

17. Though relevant statutes and regulations allow use of the term "flavors" where a compounded mixture of substances may contain a de minimis amount of lemon and honey, this is inconsistent with the front label representations depicting their presence in a meaningful amount, sufficient to confer therapeutic benefits. See i.e., 21 U.S.C. § 352(e)(1)(A)(iii).

Jurisdiction and Venue

- 18. Jurisdiction is pursuant to Class Action Fairness Act of 2005 ("CAFA"). 28 U.S.C. § 1332(d)(2).
- 19. The aggregate amount in controversy exceeds \$5 million, including any statutory damages, exclusive of interest and costs.
 - 20. Plaintiff is a citizen of New York.
 - 21. Defendant is a Delaware limited liability company with a principal place of business

in Whippany, New Jersey, Morris County.

- 22. The member of Defendant is Bayer Corporation, an Indiana corporation with a principal place of business in Pittsburgh, Pennsylvania, Allegheny County.
 - 23. Defendant is a citizen of Indiana and Pennsylvania.
- 24. The class of persons Plaintiff seeks to represent includes persons who are citizens of different states from which Defendant is a citizen.
- 25. 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, from thousands of locations including grocery stores, big box stores, drug stores, convenience stores, club stores and online, across the States covered by Plaintiff's proposed classes.
- 26. Venue is in this District with assignment to the Rochester Division because a substantial part of the events or omissions giving rise to these claims occurred in Ontario County, including Plaintiff's purchase and/or use of the Product and awareness and/or experiences of and with the issues described here.

<u>Parties</u>

- 27. Plaintiff Patricia Donadio is a citizen of Farmington, Ontario County, New York.
- 28. Defendant Bayer Healthcare LLC is a Delaware limited liability company with a principal place of business in Whippany, New Jersey, Morris County.
- 29. Defendant manufactures products under the Alka-Seltzer brand, one of the most well-known and respected names in the OTC industry.
- 30. As a result of the false and misleading representations, the Product is sold for a premium price of not less than \$8.99 for six packets, excluding tax and sales, a higher price than it would otherwise be sold for, absent the misleading representations and omissions.

- 31. Plaintiff purchased the Product at locations including Walmart, 441 Commerce Dr, Victor, NY 14564, between November 2021 and November 2022, among other times.
- 32. Plaintiff read the words on the front label of Defendant's Product, including honey and lemon zest, saw the picture of the honey dipper, lemon wedge, and steaming cup of tea, and believed it contained honey and lemon ingredients beyond a de minimis amount.
- 33. Plaintiff relied on labeling to disclose on the front panel whether a product contained the identified ingredients or just tasted like them.
- 34. Plaintiff read "Honey Lemon Zest" as referring to "honey" and "lemon zest," two separate ingredients.
- 35. Plaintiff viewed and/or was aware of how competitor products truthfully represented they only had "honey lemon flavors" instead of honey and lemon ingredients.
- 36. 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.
 - 37. Plaintiff bought the Product at or exceeding the above-referenced price.
- 38. Plaintiff paid more for the Product than she would have had she known the representations and omissions were false and misleading, or would not have purchased it.
- 39. The value of the Product that Plaintiff purchased was materially less than its value as represented by Defendant.

Class Allegations

40. 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 Kansas, New Mexico, Utah, Idaho, North Dakota, West Virginia, Montana, Mississippi and Arkansas who purchased the Product during the statutes of limitations for each cause of action alleged.

- 41. 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.
- 42. 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.
- 43. Plaintiff is an adequate representative because her interests do not conflict with other members.
- 44. No individual inquiry is necessary since the focus is only on Defendant's practices and the class is definable and ascertainable.
- 45. 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.
- 46. 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 (New York Class)

47. Plaintiff incorporates by reference all preceding paragraphs.

- 48. Plaintiff believed the Product contained honey and lemon ingredients beyond a de minimis amount.
- 49. Defendant's false, misleading and deceptive representations and omissions are material in that they are likely to influence consumer purchasing decisions.
- 50. 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> (Consumer Fraud Multi-State Class)

- 51. 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.
- 52. 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.
- 53. 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.

- 54. The Product was manufactured, identified, marketed and sold by Defendant and expressly and impliedly warranted to Plaintiff that it contained honey and lemon ingredients beyond a de minimis amount.
- 55. 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.

- 56. 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, to capitalize on demand for what IRI called "natural OTCs," by purporting to contain honey and lemon ingredients beyond a de minimis amount.
- 57. Defendant's representations were conveyed in writing and promised the Product would be defect-free, and Plaintiff understood this meant it contained honey and lemon ingredients beyond a de minimis amount.
- 58. Defendant's representations affirmed and promised that the Product contained honey and lemon ingredients beyond a de minimis amount.
- 59. Defendant described the Product as containing honey and lemon ingredients beyond a de minimis amount, which became part of the basis of the bargain that it would conform to its affirmations and promises.
- 60. Defendant had a duty to disclose and/or provide non-deceptive descriptions and marketing of the Product.
- 61. This duty is based on Defendant's outsized role in the market for OTC products, as custodian of the recognized and trusted Alka-Seltzer brand.
- 62. Plaintiff recently became aware of the Product's breach of its warranties, and has provided or provides notice to Defendant, its agents, representatives, retailers, and their employees of this breach.
- 63. 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.
 - 64. The Product did not conform to its affirmations of fact and promises due to

Defendant's actions, as it did not contain honey and lemon ingredients beyond a de minimis

amount.

65. 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 its

promises or affirmations of fact made on the packaging, container or label, because it was marketed

as if it contained honey and lemon ingredients beyond a de minimis amount.

66. The Product was not merchantable because Defendant had reason to know the

particular purpose for which it was bought by Plaintiff, because she expected it contained honey

and lemon ingredients beyond a de minimis amount, and she relied on Defendant's skill and

judgment to select or furnish such a suitable product.

Fraud

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

that it contained honey and lemon ingredients beyond a de minimis amount.

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: April 19, 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