IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

Sami Petros, individually and on behalf of all others similarly situated, Plaintiff, v. Rahal Biosciences, Inc., Defendant.	Civil Action No. **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Sami Petros ("Plaintiff") brings this action on behalf of himself and all others similarly situated against Rahal Biosciences, Inc. ("Defendant"). Plaintiff makes the following allegations pursuant to the investigation of his counsel and based upon information and belief, except as to the allegations specifically pertaining to himself, which are based on his personal knowledge.

NATURE OF THE ACTION

1. Defendant formulates, manufactures, advertises, and sells its "ARMRA Colostrum" dietary supplements (the "Products")[1] throughout the United States, including in New York. Defendant primarily sells its Products through its own website and on amazon.com for the exorbitant price of $109.99 (for the Bulk Jar) or $44.99 (for the Stick Packs) for just a one-month supply. Throughout its pervasive advertising campaign, Defendant uses a common fraudulent scheme that deceives consumers into believing that the Products are "research-backed" to "strengthen immunity," "ignite metabolism," "fortify gut health," "restore sleep,"

[1] The Products include Defendant's flavored and unflavored "Bulk Jar" and "Stick Packs." Exhibit A.

"improve mood, focus & energy," "support sinus health," "enhance skin radiance," "activate hair growth," and "fuel performance & recovery."[2] Defendant's Products are depicted below:

2. By using this deceitful scheme, Defendant creates a false aura of scientific and pharmaceutical legitimacy to sell the Products at a premium price—violating New York law at least in two ways. First, Defendant' Products are not, in fact, "Research-Backed"—as evidenced by the deeply flawed studies that Defendant relies on in making those statements. To make matters worse, Defendant's Products were never tested in any peer-reviewed clinical trial, and

[2] *Id.*

Defendant's references to other "clinical trials" are nowhere to be found, not even on its website. Second, Defendant markets the Products by making an array of improper disease claims without mandated disclaimers next to its marketing statements in violation of the Food and Drug Administration ("FDA") regulations. As such, the Products are considered unapproved and misbranded "new drugs" under the Food, Drug, and Cosmetic Act ("FDCA") which are illegal to sell and worthless.

3. As a result of its deceptive conduct, Defendant is, and continues to be, unjustly enriched at the expense of its customers.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(a) because this case is a class action where the aggregate claims of all members of the proposed class are in excess of $5,000,000.00 exclusive of interest and costs, there are over 100 members of the putative class, and at least one class member is a citizen of a state different than Defendant.

5. This Court has personal jurisdiction over Defendant because Defendant maintains its principal place of business in New York. Furthermore, a substantial portion of the events giving rise to Plaintiff's claims occurred in New York, including Plaintiff's purchase of the Products.

6. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(1) because Defendant resides in this District.

PARTIES

7. Plaintiff Sami Petros is a citizen of New York, residing in New York, New York. Plaintiff purchased Defendant's "Immune Revival Unflavored Stick Packs" for his personal use

on September 30, 2022. Plaintiff Petros made this purchase from Defendant's listing posted on www.tryarmra.com (the "Website") while residing in New York, New York. Prior to making his purchase, Plaintiff Petros saw that the Product was labeled and marketed for "Immune Revival" and that it was "research-backed" in purporting to, among other things, "strengthen immunity, "ignite metabolism," "fortify gut health," "restore sleep," "improve mood, focus & energy," "support sinus health," "enhance skin radiance," "activate hair growth," and "fuel performance & recovery." Plaintiff Petros also saw that the Website claimed that the Product functioned by stimulating the microbiome to help prevent viruses and bacterial infections. Plaintiff Petros relied on Defendant's representations when he decided to purchase the Product. Plaintiff saw those representations prior to and at the time of his purchase and understood them as representations and warranties that the Product's benefits were substantiated by reliable "research." Accordingly, those representations and warranties were part of the basis of his bargain, in that he would not have purchased the Product on the same terms had he known that those representations were not true. Furthermore, in making his purchase, Plaintiff Petros paid a substantial price premium due to Defendant's false and misleading claims regarding the Product's "research-backed" ability to provide the touted health benefits. Plaintiff Petros, however, did not receive the benefit of his bargains because the Product was not, in fact, "research-backed" to achieve those results. In fact, Plaintiff Petros did not experience any meaningful immune or other health benefits despite using the Product as directed. Had Plaintiff Petros known that Defendant's representations and warranties were false, he would not have purchased the Product or paid substantially less for it.

8. In addition, in making his purchase, Plaintiff Petros did not see any disclaimer that the Product's claims and representations had not been "evaluated by the Food and Drug

Administration" or that the Products were "not intended to diagnose, treat, cure, or prevent any diseases." Those omissions were material to Plaintiff Petros because had he known that Defendant's representations and warranties were qualified by those disclaimers, he would not have relied on them or believed that the Products were equally efficacious to other FDA over-the-counter or medical-grade products in the market. As such, Plaintiff Petros would not have purchased the Products or would have paid substantially less for them had he seen the FDA-required disclosures on the Product's labeling and marketing.

9. Finally, had Plaintiff known that Defendant's Products were adulterated, misbranded, and illegal to sell under the FDCA, he would not have purchased them at all.

10. Defendant Rahal Biosciences, Inc., is a Delaware corporation with its principal place of business in Brooklyn, New York. Defendant manufactures, markets, and sells the Products throughout New York and the United States.

GENERAL ALLEGATIONS

Overview of Defendant's Hair Growth Business

11. Colostrum is a nutrient-rich pre-milk produced by mothers immediately after giving birth. This pre-milk is packed with immune-boosting ingredients that are vital for newborns, rightfully earning its moniker "liquid gold."[3] All female mammals produce colostrum after giving birth, including cows. In a recent marketing trend, there has been a notable uptick in consumer interest surrounding cow-based ("bovine") colostrum dietary supplements for adults. Companies advertising these supplements tout their ability to confer a vast amount of benefits – from fortifying the immune system and gut health to improving sleep and hair growth.

12. Defendant is among the major players that have capitalized on this demand.

[3] https://my.clevelandclinic.org/health/body/22434-colostrum (last accessed April 25, 2024).

According to its most recent Amazon listing, Defendant has sold over 10,000 Products in the past month alone and Defendant touts on that same listing that it has sold "50+ Million Scoops."[4] Despite making bold health claims about the Products, including that they are "Physician-Developed" and "Research-Backed," Defendant lacks any reliable data to support those claims. To make matters worse, Defendant's Products make illegal disease claims rendering them adulterated under the FDCA.

Defendant's Representation that the Products are "Research-Backed" is False and Misleading.

13. In order to differentiate their products and gain a competitive edge, manufacturers and advertisers routinely mislead consumers by claiming the efficacy of their products is backed by science (*i.e.*, "establishment claims"), when, in fact, it is not. Thus, Courts are particularly wary of claims by manufacturers that their product has been scientifically proven to be effective.

14. An advertiser's health-related claims about the efficacy of a product must "be supported with "competent and reliable scientific evidence," which the Federal Trade Commission ("FTC") defines as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results."[5] As the FTC has stated, "well-controlled human clinical studies are the most reliable form of evidence."[6]

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[4] Amazon.com: ARMRA Colostrum™ Premium Powder, Grass Fed, Gut Health Bloating Immunity Skin & Hair, Contains 400+ Bioactive Nutrients, Potent Bioavailable, Keto, Gluten & Fat Free (Unflavored | 30 Servings) : Health & Household (last accessed April 25, 2024).
[5] *Health Products Compliance Guide*, Section II(B) (Dec. 2022), https://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplements-advertising-guide-industry.
[6] *Dietary Supplements: An Advertising Guide to Industry*, Section II(B)(2) (Apr. 2001), https://www.ftc.gov/system/files/documents/plain-language/bus09-dietary-supplements-advertising-guide-industry.pdf

15. As discussed in a recent Truth In Advertising ("TINA") article regarding the Products, Defendant's claim that the Products are "Research-Backed" is a hoax. Instead, Defendant relies on four "studies" which merely analyze the potential benefits of colostrum based on an overview of other studies. As such, the conclusions drawn by Defendant's "studies" are based on inferences and conjecture rather than reliable scientific evidence. In fact, one of Defendant's studies, which examined nine scientific studies regarding the efficacy of bovine colostrum on leaky guts, concluded that more research is needed:

> "BC supplementation may be highly beneficial in improving gut permeability in athletes. However, well-designed, placebo-controlled, and randomized studies are needed to evaluate the long-term safety and efficacy and to determine the optimal dose schedules of BC supplementation in high-performance athletes."[7]

16. Defendant also links a "technical paper" that discusses the Products' effectiveness based on their interaction with extracted "human immune cells."[8] Aside from the fact that this "technical paper" was not peer-reviewed, nor a randomized controlled trial ("RCL"), the results from the research project concluded that the Products had "promising" effects "suggesting a potential" mechanism of action in humans.[9]

17. Notably, contrary to Defendant's representations that the Products are "Research-Backed," as mentioned above, even the conclusions of Defendant's own "studies" suggest that more reliable research is needed to confirm any of the health benefits promised by the Products.

18. Separately, Defendant claims that a "3RD Party Clinical Trial" found that users of

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[7] Dziewiecka, Hanna et al. "A Systematic Review of the Influence of Bovine Colostrum Supplementation on Leaky Gut Syndrome in Athletes: Diagnostic Biomarkers and Future Directions." *Nutrients* vol. 14,12 2512. 17 Jun. 2022, doi:10.3390/nu14122512

[8] Biological_activities_of_a_novel_bovine_colostrum-based_proprietary_concentrate_ARMRA_at_the_cellular_level_Gitte_S._2021_1_1.pdf (shopify.com)

[9] *Id.*

the Products experienced "Powerful Benefits," including "Less Bloating," "Better Focus & Energy," 'Thicker Hair," "Reduction In Their Waist Circumference," and "Improved Their Lean Muscle Mass, Strength & Endurance."[10] Yet, that "Clinical Trial" is nowhere to be found –even on Defendant's website. Furthermore, to the extent that such a study exists, Defendant's report indicates that instead of using objective measurements by blinded investigators, the trial's results were based on the participant's subjective self-assessments: *i.e*, indicating that the participants "***experienced*** less bloating"; "***noticed*** better focus"; ***reported*** thicker hair." It is self-evident that this alleged "Clinical Trial" was anything but a double-blind randomized controlled trial.

19. Other studies also support the conclusion that the key ingredients in the Products (*i.e.*, bovine colostrum) do not provide immune or gut health benefits, further bolstering Defendant's representations that the Products are "research-backed" as false and misleading. For instance, a peer-reviewed article published on February 26, 2024 analyzing the therapeutic effects of bovine colostrum on gastrointestinal diseases found that while some clinical trials indicated that bovine colostrum could ameliorate certain GI symptoms (such as frequency of a diarrhea episode), other clinical trials found no meaningful benefits in reducing similar symptoms (such as abdominal pain).[11] Importantly, the study concluded by indicating that its findings had "major limitations" due to "the limited number of RCTs with small sample sizes" and "the need for studies on this subject and differences in BC doses, outcomes, and study populations"; a "lack of unpublished evidence" and the fact that "most of the included studies

[10] Exhibit A.

[11] Hajihashemi, P., Haghighatdoost, F., Kassaian, N. *et al. Therapeutics effects of bovine colostrum applications on gastrointestinal diseases: a systematic review*. *Syst Rev* **13**, 76 (2024). https://doi.org/10.1186/s13643-024-02489-1, https://systematicreviewsjournal.biomedcentral.com/articles/10.1186/s13643-024-02489-1#citeas (last accessed April 25, 2024).

had a high risk of bias, which seriously weakens confidence in the results."[12] In short, this recent peer-reviewed article illustrates that **there is no reliable "research"** to support the claims made by the Products. Similarly, another peer-reviewed article published on March 10th, 2022, indicated that while the mechanism of bovine colostrum demonstrated hair growth in mice, no clinical trials have been conducted on the use of bovine colostrum as a therapy for hair growth in humans.[13] As summarized by the New York Times in a recent article discussing the surge in bovine colostrum supplements:

> "There's no rigorous, published data yet to back up claims that the supplement can support skin regeneration, lead to weight loss or reverse age-related changes. And experts said that even the studies that have been done provide only limited evidence: While some report positive findings, others have failed to replicate the observations or found no benefit."[14]

20. It is thus unsurprising that Plaintiff did not experience any of the so-called "Research-Based" benefits falsely advertised in the Products.

Defendant's Products are Unapproved "New Drugs" under the FDCA

21. To make matters worse, in addition to its false claims that the Products are backed by reliably research, Defendant markets the Products with unlawful disease claims that suggest the Products mitigate, treat, cure, or prevent diseases.

22. The FDCA defines a "drug" as any article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1). The FDCA and its

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[12] *Id.*

[13] Kim H, Jang Y, Kim EH, et al. Potential of Colostrum-Derived Exosomes for Promoting Hair Regeneration Through the Transition From Telogen to Anagen Phase. *Front Cell Dev Biol*. 2022;10:815205. Published 2022 Mar 10. doi:10.3389/fcell.2022.815205, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8960251/ (last accessed April 25, 2024).

[14] New York Times, *It's 'Liquid Gold' for Newborns. But Can It Help Your Health?* (Feb. 5, 2024), https://www.nytimes.com/2024/02/05/well/eat/bovine-colostrum-supplements.html (last accessed April 25, 2024).

implementing regulations are explicit that "dietary supplements '***intended*** for use in diagnosis, cure, mitigation, treatment, or prevention of disease' remain within the definition of a 'drug.'" 65 Fed. Reg. at 1001; *see also* 21 U.S.C. § 321(g)(1)(B). Pursuant to FDA regulations, the "intended use" of an article is determined based on the "objective intent of the person legally responsible for the labeling of the drug," and may be determined for example, "by labeling claims, advertising matter, or oral or written statements by such persons or their representatives." 21 C.F.R. § 201.128. The FDCA defines "label" as, among other things, "a display of written, printed, or graphic matter upon the immediate container of any article," 21 U.S.C. § 321(k); and "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

23. Here, Defendant's Products are "drugs" rather than dietary supplements for multiple reasons, including the fact that they are marketed to induce "hair growth." FDA regulations expressly establish that hair growth products are "new drugs." 21 C.F.R. § 310.527(b) ("Any OTC drug product that is labeled, represented, or promoted for external use as a hair grower or for hair loss prevention is regarded as a new drug [under the FDCA] for which an approved new drug application…is required."). Defendant has not filed an application with the FDA for approval of its Products, although they qualify as "new drugs." As a result of the "absence of an approved new drug application," Defendant's Products are "also misbranded under the [FDCA]." *Id.*

24. Indeed, the FDA has repeatedly admonished companies who labeled and/or advertised their dietary supplements and cosmetic products for hair growth or hair loss prevention, like Defendant's Products, as unapproved drugs that are not generally recognized as

safe and effective for the uses and claims made by Defendant.[15]

25. Finally, Defendant's extensive marketing and disease claims, discussed in greater depth below, demonstrate Defendant's intent to sell the Products as drugs rather than dietary supplements. In fact, Defendant touts throughout its advertising that the Products are "physician-developed" to cure multiple diseases and that they are "3X more effective than the flu vaccine at preventing flu."[16]

Defendant's Products Make Disease Claims in Violation of the FDCA

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[15] *See, e.g.*, ***FDA warning letter to Santhigram Kerala Ayurvedic Co. of U.S., Inc.***, (May 19, 2022) ("Examples of claims observed on your website and social media websites that establish the intended use of your Santhigram ayurvedic products as drugs included, but are not limited to, the following: … 'Benefits: Triphala has several health benefits, such as; … stimulates hair growth…'"), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/santhigram-kerala-ayurvedic-co-us-inc-625892-05192022 ; ***FDA warning letter to Speedwinds Nutrition, Inc.***, (Dec. 22, 2020) ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include the following: …'With Sephren, you can feel confident that Sephren will: . . . Stop the root causes of hair [sic] female hair loss.'"), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/speedwinds-nutrition-inc-609298-12222020 ***; FDA warning letter to Star Health & Beauty LLC***, (May 26, 2017), ("Examples of some of the claims that provide evidence that your products are intended for use as drugs include: … 'HGH has been found to reverse and/or slow down the aging process by: … Restoring lost hair growth' … 'Fuller Thicker Hair In As Little As Two Months,' '[A] natural alternative to combat hair loss…,' 'Restore thinning hair with visible results,' '[R]estores and maintains healthy hair.,'… '[T]o restore thickness and prevent more hair from falling out.,' 'Nugen HP – The All-Natural Hair Restoration System?,' '[R]evitalizes your hair follicles stimulating fuller, thicker hair.'"), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/star-health-beauty-llc-516206-05262017; ***FDA warning letter to Soleo*** (Dec. 13, 2018) ("Unapproved New Drugs 'GEN+LE THERAPY Shampoo' Examples of claims … that establish the intended uses of the product as defined in 21 CFR 201.128 include, but may not be limited to, the following: … 'Prevents Hair Loss…Hair Loss Prevention…' … Based on the above claims, 'GEN+LE THERAPY Shampoo' is a 'drug' as defined by section 201(g)(1)(B) of the FD&C Act (21 U.S.C. 321(g)(1)(B)) because it is intended for the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or under section 201(g)(1)(C) of the FD&C Act (21 U.S.C. 321(g)(1)(C)) because it is intended to affect the structure or any function of the body. Specifically, this product is intended as a hair growth, hair loss prevention, and anti-dandruff drug product."), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/soleo-567046-12132018

[16] Exhibit A.

26. Assuming that Defendant's Products do not qualify as "new drugs"—despite the FDA's abundant warning letters and its clear intention under 21 C.F.R. § 310.527(b) that they do—the Products nonetheless make improper "disease" claims in contravention to the FDA's regulations governing dietary supplements. A dietary supplement is a product that is "intended to supplement the diet" and "contains one or more [] dietary ingredients." 21 U.S.C. § 321(ff). Under the FDCA, dietary supplements can make "structure or function" claims but not "disease claims." 21 U.S.C. § 343(r)(6). A structure/function is a statement that, *inter alia*, "describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, which characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient." 21 U.S.C. § 343(r)(6)(A).

27. Manufacturers of dietary supplements are prohibited from making any statement that "claims to diagnose, mitigate, treat, cure, or prevent disease," either explicitly or implicitly. 21 C.F.R. § 101.93(g). The FDA defines "disease" as "damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition." *Id.* Generally, a statement is a disease claim if it states explicitly or implicitly that the product:

(a) has an effect on a disease, a characteristic sign or symptom of a disease, or an abnormal condition that is either uncommon or can cause significant harm;

(b) has an effect on a disease by implication through, for example, the product name, an ingredient in the product, citation to literature referencing a disease or

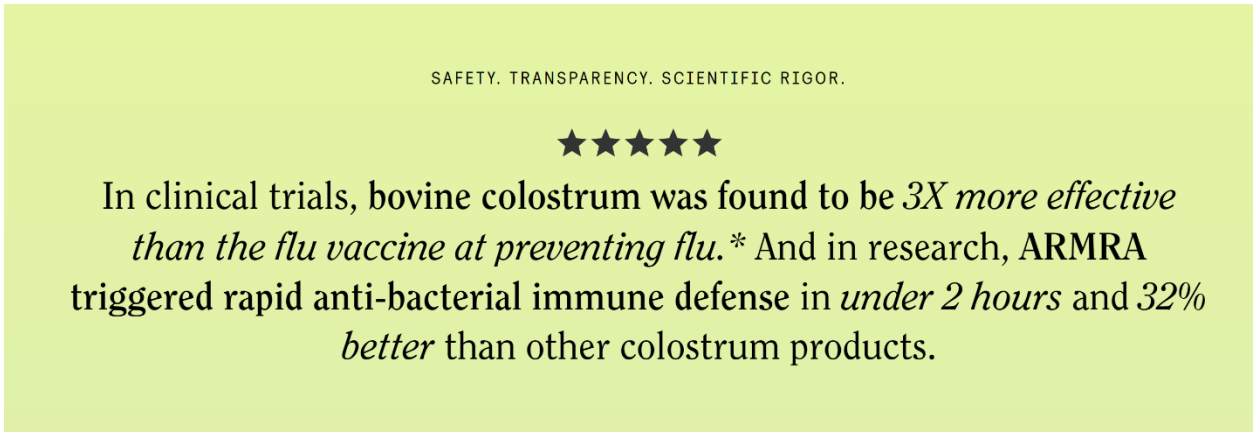
other product label details implying connection to a disease;

(c) is a substitute for, is similar to, or augments a product that does diagnose, treat, or prevent a disease;

(d) has a role in the body's response to a disease; or e treats, prevents, or mitigates adverse events associated with a therapy for a disease, if the adverse events themselves constitute diseases.

21 C.F.R. § 101.93(g)(2).

28. Applying these criteria to Defendant, the Products go beyond structure/function claims by making statements related to the causes, symptoms, and treatment of a group of diseases. For instance, Defendant prominently claims that the Products are "3X more effective than the flu vaccine at preventing flu" and "trigger[] rapid anti-bacterial immune defense"[17]



29. Defendant's immune system claims, do not stop there. Alarmingly, Defendant claims throughout its website that the Products' bovine colostrum:

(1) "has been found to inhibit influenza and rotaviruses, and neutralize toxins from

[17] *Id.*

bacteria like C. difficile and E. Coli."[18]

(2) can combat "harmful particles like viruses and bacteria to block them from crossing the barrier."[19]

(3) "has been shown to have a strong anti-viral effect against the influenza virus."[20]

(4) "provides structure, modulates neural development, and is involved in learning and memory formation. Deficits in SA have been linked to aging and several brain diseases."[21]

(5) "has been shown to have powerful efficacy in healing wounds."[22]

30. Furthermore, Defendant claims that the Products are adequate substitutes for "drugs" intended to treat hair-loss diseases. For example, Defendant claims throughout its marketing that the Products can help reverse hair loss and stimulate hair growth, even going as far as claiming that the Products' are the "first" non-prescription drug to do so.

31. Alopecia areata is an autoimmune disease that causes the immune system to attack healthy hair follicles, leading to hair loss.[23] The FDA has paid special attention to alopecia areata when it held a focus group on the topic—hearing from patients and doctors alike. According to the FDA:

> "Alopecia areata is an autoimmune disease which targets the hair follicles, causing hair loss. The hair loss usually occurs on the scalp, but can also affect the beard, eyebrows, and other areas of the body. In the United States, approximately 500,000

[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *Id.*
[23] https://www.health.harvard.edu/blog/what-is-alopecia-areata-and-how-is-it-managed-202204282732 (last accessed April 25, 2024).

individuals have alopecia areata."[24]

32. Although the exact causes of alopecia areata are still being researched, there is a scientific consensus that the disease can be triggered by environmental factors—including emotional distress arising from stressful life events,[25] heavy metals contained in diets,[26] hormonal imbalances resulting from childbirth,[27] and menopause.[28] On June 13, 2022, the FDA approved the first oral tablets for the treatment of alopecia areata under the brand Olumiant ("baricitinib").[29]

33. Telogen effluvium is an abnormal condition that disrupts the normal balance of hair follicles by causing a large number of hair follicles to enter their resting phases (telogen) prematurely, leading to a temporary cessation of hair growth and subsequent hair loss. Telogen effluvium shares many of the core roots as alopecia areata—including acute psychological stress, dietary irregularities (*e.g.*, consumption of heavy metals), childbirth, and postpartum.[30]

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[24] FDA, The Voice of the Patient Alopecia Areata (March 2018), https://www.fda.gov/files/about%20fda/published/Alopecia-Areata--The-Voice-of-the-Patient.pdf (last April 25, 2024).

[25]Sellami, R., Féki, I., Masmoudi, R., Hentati, S., Turki, H. and Masmoudi, J., 2020. *Stressful life events in alopecia areata patients: A case control study*. Our Dermatol Online, 11., https://pdfs.semanticscholar.org/d836/c943d481a6f383e104571c081f6fc14eb51d.pdf (last accessed April 25, 2024).

[26] Paolo Daniele Pigatto, Silvia Mariel Ferrucci, Lucia Brambilla, Gianpaolo Guzzi; *Alopecia Areata and Toxic Metals.* Skin Appendage Disord 15 June 2020; 6 (3): 177–179.

[27] Cho SI, Yu DA, Kim SI, Lee SM, Kwon O. *Pregnancy Outcomes in Female Patients with Alopecia Areata: A Nationwide Population-Based Study.* J Invest Dermatol. 2021 Jul; https://www.jidonline.org/article/S0022-202X(20)32412-X/fulltext (last accessed April 25, 2024).

[28] Grymowicz, M.; Rudnicka, E.; Podfigurna, A.; Napierala, P.; Smolarczyk, R.; Smolarczyk, K.; Meczekalski, B. *Hormonal Effects on Hair Follicles.* Int. J. Mol. Sci. 2020, 21, 5342, https://www.mdpi.com/1422-0067/21/15/5342 (last accessed April 25, 2024).

[29] FDA, *FDA Approves First Systemic Treatment for Alopecia Areata* (June 13, 2022), https://www.fda.gov/news-events/press-announcements/fda-approves-first-systemic-treatment-alopecia-areata (last accessed April 19, 2024).

[30] https://www.ncbi.nlm.nih.gov/books/NBK430848/ (last accessed April 25, 2024)

Physicians regularly prescribe minoxidil (Rogaine) to help patients combat telogen effluvium.[31]

34. Defendant makes disease claims in violation of the FDA by recommending the Products' use as a substitute for baricitinib, minoxidil and other clinical therapies in treating alopecia areata and telogen effluvium. For instance, Defendant prominent claims that:

> "ARMRA Colostrum is **the first non-drug solution to fully address** the modern, root causes that compromise hair health."[32] (emphasis added)

In yet another article on its website's FAQ section—captioned *Can ARMRA Colostrum™ help with hair growth?*— Defendant claims that the Products:

> "reactivate hair follicle growth while also combatting the root causes of why hair loss occurs in the first place. In fact, studies show the bioactives in colostrum can stimulate hair regrowth by activating hair follicle stem cells."[33]

35. These statements imply that the Products can treat alopecia areata and telogen effluvium by comparing the Products with other products and interventions that diagnose, treat, or prevent those diseases. Defendant's statements also imply that the Products could be used to substitute or augment existing therapies used to treat these diseases. In so doing, Defendant has made improper disease claims in violation of 21 C.F.R. § 101.93(g)(2).

Defendant Does Not Provide FDA Mandated DSHEA Disclaimers

36. Finally, all of Defendant's statements about its Products fail to include a mandatory disclaimer that those claims have not been evaluated by the FDA nor are intended to diagnose, cure, or prevent a disease (the "DSHEA Disclaimer."). 21 U.S.C. §§ 343(f),[34]

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[31] https://www.drugs.com/health-guide/telogen-effluvium.html (last accessed April 25, 2024).
[32] https://tryarmra.com/pages/clinical-trials (last accessed April 25, 2024).
[33] https://help.tryarmra.com/en-US/can-armra-colostrum-help-with-hair-growth-238703 (last accessed April 25, 2024).
[34] 21 U.S.C. § 343(f) ("If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with

343(r)(1)(B), 343(r)(6); 21 C.F.R. § 101.93(d) ("On product labels and in labeling (e.g., pamphlets, catalogs), the disclaimer shall appear on each panel or page where there [is a structure/function claim].").

37. The DSHEA Disclaimer must be prominent and bolded, and it must read:

> **These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**

21 U.S.C. § 343(r)(6)(C); *see also* 21 C.F.R. § 101.93(c)(2).

38. To be prominent, the disclaimer may not be crowded with voluntary information or imagery and additionally must be bolded font *at least* 1/16th of an inch in size. 21 C.F.R. § 101.93(e).

39. The disclaimer must appear on <u>all panels with structure/function claims</u>. The Food and Drug Administration has specifically rejected the proposition "that repetition of the disclaimer on every panel or page where a statement [is] made…is unnecessary." 62 Fed. Reg. 49,859, 49,864 (Sept. 23, 1997) To meet statutory requirements, "**the disclaimer must be within the same field of vision as the statement itself**." *Id.* at 49865 (emphasis added). *see also id.* at 49,864 ("FDA has evaluated the comments and concludes that the placement of the disclaimer on a panel other than where the statement is made would not meet the statutory requirement for the placement of the disclaimer….Based on its experience with asterisks within the nutrition label, the agency concludes that consumers are accustomed to using asterisks on labels to associate two discrete pieces of important information when they are in the ***same field of vision***.") (emphasis added) (citation omitted).

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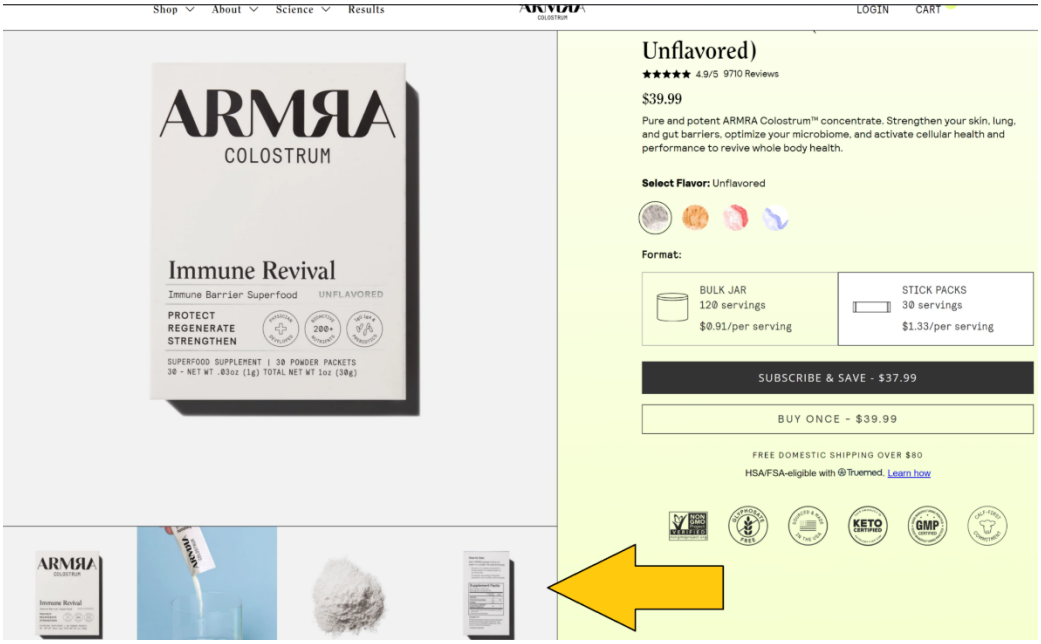
such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customer conditions of purchase and use.").

40. Defendant fails to abide by the disclaimer requirements in labeling and marketing its Products.

41. First, Defendant omits the DSHEA disclaimer altogether from the front panel of the external packaging of all of its Products, despite the presence of claims on that panel.[35] Further, although there is a disclaimer on the "Supplement Facts" label of the Products, it is not prominently displayed and is otherwise buried at the bottom of the label; and the hieroglyphic accompanying the disclosure is untethered to any of the Products' statements. Furthermore, because Defendant sells the Products through its Website and Amazon.com listings, a customer would need to scroll through various pictures before even seeing the Supplement Facts labels of the Products.[36] Defendant's Products, as advertised on its Website, is displayed below by way of illustration (yellow arrow for emphasis):



42. Even assuming that Defendant's DSHEA Disclaimers on the Products' labeling comply with the FDA, they do not, most consumers, like Plaintiff, who purchased the Products

[35] All of the Products are identical in overall design including the claims made on their respective panels.
[36] Exhibit A.

online would only have been able to see them after paying for them and receiving them in the mail. Specifically, Defendant fails to include the DSHEA Disclaimer on its Website listings in visual proximity to the multiple health and disease claims that it makes about the Products. Instead, the DSHEA disclosure is buried at the very bottom of the webpages in nine-point font—which is also unliked to the majority of health statements littered throughout the Website.[37] Similarly, on its Amazon.com listings, Defendant DSHEA disclaimer is buried at the bottom of the webpage and is unliked to the myriad of text and images containing disease claims.[38] Furthermore, the disclosure is easy to miss because most consumers click the "Add to Cart" or "Buy Now" buttons without scrolling to the very bottom of the listing to reach Defendant's inadequate DSHEA disclosure.

Defendant's Products are Adulterated and Illegal to Sell under the FDCA and Worthless

43. Because Defendant intended to sell the Products as drugs, or, alternatively, made improper "disease" claims and failed to include adequate DSHEA disclaimers within the Products' labeling and marketing, the Products constitute "new drugs" under the FDCA. 21 U.S.C. § 321(p). A new drug may not be introduced into interstate commerce unless it is approved by the FDA through a New Drug Application ("NDA") or an Abbreviated New Drug Application ("ANDA"). 21 U.S.C. § 355(a). Defendant's Products were not approved by the FDA under an NDA or ANDA. Furthermore, Defendant's Products are "misbranded "under the FDCA because they are intended for the treatment of one or more diseases that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. As such, it is

[37] Exhibit A.

[38] Amazon.com: ARMRA Colostrum™ Premium Powder, Grass Fed, Gut Health Bloating Immunity Skin & Hair, Contains 400+ Bioactive Nutrients, Potent Bioavailable, Keto, Gluten & Fat Free (Unflavored | 30 Servings) : Health & Household (last accessed April 25, 2024).

impossible to write adequate directions for the Products' intended purposes as required under 21 U.S.C. 352(f)(1).

44. New York's Agriculture and Marketing law similarly provides in relevant part that food shall be deemed misbranded "[i]f its labeling is false or misleading in any particular," and incorporates the FDCA's labeling provisions found in 21 C.F.R. part 101. Agriculture and Markets Law § 201(1); N.Y. Comp. Codes R. & Regs. tit. 1, § 259.1(a)(3).

45. Based on the foregoing, Defendant's Products are illegal to sell because they are both adulterated and unapproved new drugs, which are illegal to sell under the FDCA. 21 U.S.C. §§ 331(a), (d). Such illegally sold Products are worthless and have no value. *See Debernadis v. IQ Formulations, LLC*, 942 F.3d 1076, 1085 (11th Cir. 2019).

46. Defendant's misleading representations and illicit sale of the Products proximately caused harm to Plaintiff and the proposed class members who suffered an injury in fact and lost money or property as a result of Defendant's conduct.

CLASS ACTION ALLEGATIONS

47. Plaintiff brings this action on behalf of herself and all other similarly situated persons pursuant to Federal Rules of Civil Procedure 23(a), (b)(1), and (b)(3). Specifically, the Classes are defined as:

> **Nationwide Class:** All persons in the United States who, during the maximum period of time permitted by law, purchased Defendant's Products primarily for personal, family or household purposes, and not for resale.
>
> **New York Subclass:** All persons residing in New York who, during the maximum period of time permitted by the law, purchased Defendant's Products primarily for personal, family or household purposes, and not for resale.

48. The Classes do not include (1) Defendant, their officers, and/or its directors; or (2) the Judge to whom this case is assigned and the Judge's staff.

49. Plaintiff reserves the right to amend the above class definitions and add additional classes and subclasses as appropriate based on investigation, discovery, and the specific theories of liability.

50. ***Community of Interest***: There is a well-defined community of interest among members of the Classes, and the disposition of the claims of these members of the Classes in a single action will provide substantial benefits to all parties and to the Court.

51. ***Numerosity***: While the exact number of members of the Classes is unknown to Plaintiff at this time and can only be determined by appropriate discovery, upon information and belief, members of the Classes number in the millions. The precise number of the members of the Classes and their identities are unknown to Plaintiff at this time but may be determined through discovery. Members of the Classes may be notified of the pendency of this action by mail and/or publication through the distribution records of Defendant and third-party retailers and vendors.

52. ***Existence and predominance of common questions of law and fact***: Common questions of law and fact exist as to all members of the Classes and predominate over any questions affecting only individuals of the Classes. These common legal and factual questions include, but are not limited to:

(a) Whether the Products are illegal to sell in violation of the FDCA;

(b) Whether the marketing, advertising, packaging, labeling, and other promotional materials for the Products make disease claims in violation of the FDCA;

(c) Whether Defendant fraudulently induced Plaintiff and the members of the Classes into purchasing the Products by claiming that the Products were "research-backed" purporting to

provide a wide array of unsubstantiated health benefits;

(d) Whether Plaintiff and the members of the Classes have suffered damages as a result of Defendant's actions and the amount thereof;

(e) Whether Plaintiff and the members of the Classes are entitled to statutory damages;

(f) Whether Plaintiff and the members of the Classes are entitled to attorney's fees and costs.

53. ***Typicality:*** The claims of the named Plaintiff are typical of the claims of other members of the Classes in that the named Plaintiff was exposed to Defendant's false and misleading marketing, purchased Defendant's illegal Products, and suffered a loss as a result of those purchases.

54. ***Adequacy***: Plaintiff will fairly and adequately represent and protect the interests of the Classes as required by Federal Rule of Civil Procedure Rule 23(a)(4). Plaintiff is an adequate representative of the Classes because he has no interests which are adverse to the interests of the members of the Classes. Plaintiff is committed to the vigorous prosecution of this action and, to that end, Plaintiff has retained skilled and experienced counsel.

55. Moreover, the proposed Classes can be maintained because they satisfy both Rule 23(a) and 23(b)(3) because questions of law or fact common to the Classes predominate over any questions affecting only individual members and that a Class Action is superior to all other available methods of the fair and efficient adjudication of the claims asserted in this action under Federal Rule of Civil Procedure 23(b)(3) because:

(a) The expense and burden of individual litigation makes it economically unfeasible for members of the Classes to seek to redress their claims other than through the procedure of a

class action;

(b) If separate actions were brought by individual members of the Classes, the resulting duplicity of lawsuits would cause members of the Classes to seek to redress their claims other than through the procedure of a class action; and

(c) Absent a class action, Defendant likely will retain the benefits of its wrongdoing, and there would be a failure of justice.

CAUSES OF ACTION

COUNT I
Violation of State Consumer Protection Statues[39]
(On Behalf of Plaintiff and the Nationwide Class)

56. Plaintiff incorporates by reference each of the allegations contained in the foregoing paragraphs of this Complaint as though fully set forth herein.

[39] While discovery may alter the following, Plaintiff asserts that the states with similar consumer fraud laws under the facts of this case include but are not limited to: Alaska Stat. § 45.50.471, et seq.; Ariz. Rev. Stat. §§ 44-1521, et seq.; Ark. Code § 4-88-101, et seq.; Cal. Bus. & Prof. Code § 17200, et seq.; Cal. Civ. Code §1750, et seq.; Colo. Rev. Stat. Ann. § 6-1-101, et seq.; Colo. Rev. Stat. Ann. § 6-1-101, et seq.; Conn. Gen Stat. Ann. § 42- 110, et seq.; 6 Del. Code § 2513, et seq.; D.C. Code § 28-3901, et seq.; Fla. Stat. Ann.§ 501.201, et seq.; Ga. Code Ann. § 10-1-390, et seq.; Haw. Rev. Stat. § 480-2, et seq.; Idaho Code. Ann. § 48-601, et seq.; 815 ILCS 501/1, et seq.; Ind. Code § 24-5-0.5-2, et seq.; Kan. Stat. Ann. § 50-623, et seq.; Ky. Rev. Stat. Ann. § 367.110, et seq.; LSA-R.S. 51:1401, et seq.; Me. Rev. Stat. Ann. Tit. 5, § 207, et seq.; Md. Code Ann. Com. Law, § 13-301, et seq.; Mass. Gen Laws Ann. Ch. 93A, et seq.; Mich. Comp. Laws Ann. § 445.901, et seq.; Minn. Stat. § 325F, et seq.; Mo. Rev. Stat. § 407, et seq.; Neb. Rev. St. §§ 59-1601, et seq.; Nev. Rev. Stat. § 41.600, et seq.; N.H. Rev. Stat. § 358-A:1, et seq.; N.J. Stat. Ann. § 56:8, et seq.; N.M. Stat. Ann. § 57-12-1, et seq.; N.Y. Gen. Bus. Law § 349, et seq.; N.C. Gen Stat. § 75-1.1, et seq.; N.D. Cent. Code § 51-15, et seq.; Ohio Rev. Code Ann. § 1345.01, et seq.; Okla. Stat. tit. 15 § 751, et seq.; Or. Rev. Stat. § 646.605, et seq.; 73 P.S. § 201-1, et seq.; R.I. Gen. Laws § 6-13.1- 5.2(B), et seq.; S.C. Code Ann. §§ 39-5- 10, et seq.; S.D. Codified Laws § 37-24-1, et seq.; Tenn. Code Ann. § 47-18-101, et seq.; Tex. Code Ann., Bus. & Con. § 17.41, et seq.; Utah Code. Ann. § 13-11-175, et seq.; 9 V.S.A. § 2451, et seq.; Va. Code Ann. § 59.1-199, et seq.; Wash. Rev. Code § 19.86.010, et seq.; W. Va. Code § 46A, et seq.; Wis. Stat. § 100.18, et seq.; and Wyo. Stat. Ann. § 40-12-101, et seq.

57. The Consumer Protection Statutes of the Nationwide Class members prohibit the use of deceptive, unfair, and misleading business practices in the conduct of trade or commerce.

58. By the acts and conduct alleged herein, Defendant engaged in deceptive, unfair, and misleading acts and practices by conspicuously representing on the marketing of the Products that they are "research-backed" in purporting to, among other things, "strengthen immunity, "ignite metabolism," "fortify gut health," "restore sleep," "improve mood, focus & energy," "support sinus health," "enhance skin radiance," "activate hair growth," and "fuel performance & recovery." Despite those representations, however, the Products are not backed by reliable scientific evidence. Furthermore, the Products are misbranded and unapproved "new drugs" that are illegal to sell under the FDCA.

59. The foregoing deceptive acts and practices were directed at consumers.

60. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the nature and value of the Products.

61. As a result of Defendant's deceptive practices, Plaintiff and the Nationwide Class members suffered an economic injury because they would not have purchased (or paid a premium for) the Products had they known that the Products were not supported by reliable science, did not provide the touted benefits in its marketing, and are otherwise unapproved new drugs which are misbranded and illegal to sell.

62. On behalf of himself and the Nationwide Class members, Plaintiff seeks to recover their actual damages, statutory damages, punitive damages, and reasonable attorneys' fees and costs.

COUNT II
Violation of New York G.B.L. § 349
(On Behalf of Plaintiff and the New York Subclass)

63. Plaintiff incorporates by reference each of the allegations contained in the foregoing paragraphs of this Complaint as though fully set forth herein.

64. New York's General Business Law § 349 prohibits deceptive acts or practices in the conduct of any business, trade, or commerce.

65. In its sale of Products throughout the state of New York, at all relevant times herein, Defendant conducted business and trade within the meaning and intendment of New York's General Business Law § 349.

66. Plaintiff and the New York Subclass members are consumers who purchased the Products from Defendant for their personal use.

67. By the acts and conduct alleged herein, Defendant engaged in deceptive, unfair, and misleading acts and practices by conspicuously representing on the marketing of the Products that they are "research-backed" in purporting to, among other things, "strengthen immunity, "ignite metabolism," "fortify gut health," "restore sleep," "improve mood, focus & energy," "support sinus health," "enhance skin radiance," "activate hair growth," and "fuel performance & recovery." Despite those representations, however, the Products are not backed by reliable scientific evidence. Furthermore, the Products are misbranded and unapproved "new drugs" that are illegal to sell under the FDCA.

68. Defendant also engaged in deceptive, unfair, and misleading acts by misbranding the Products, including by making unlawful implied disease claims in violation of New York's Agriculture and Marketing law, which incorporates the FDCA by reference.

69. The foregoing deceptive acts and practices were directed at consumers.

70. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the nature and value of the Products.

71. As a result of Defendant's deceptive practices, Plaintiff and the New York Subclass members suffered an economic injury because they would not have purchased (or paid a premium for) the Products had they known that the Products were not supported by reliable science, did not provide the touted benefits in its marketing, and are otherwise unapproved new drugs which are misbranded and illegal to sell.

72. On behalf of himself and the New York Subclass members, Plaintiff seeks to recover their actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees and costs.

COUNT III
Violation of New York G.B.L. §350
(On Behalf of Plaintiff and the New York Subclass)

73. Plaintiff incorporates by reference each of the allegations contained in the foregoing paragraphs of this Complaint as though fully set forth herein.

74. New York's General Business Law § 350 prohibits false advertising in the conduct of any business, trade, or commerce.

75. Defendant violated New York General Business Law § 350 by misrepresenting the Products as "research-backed" in purporting to, among other things, "strengthen immunity, "ignite metabolism," "fortify gut health," "restore sleep," "improve mood, focus & energy," "support sinus health," "enhance skin radiance," "activate hair growth," and "fuel performance & recovery." Despite those representations, however, the Products are not backed by reliable scientific evidence. Furthermore, the Products are misbranded and unapproved "new drugs" that are illegal to sell under the FDCA and New York's Agriculture and Marketing law, which

incorporates the FDCA by reference.

76. The foregoing advertising was directed at consumers and was likely to mislead a reasonable consumer acting reasonably under the circumstances.

77. Defendant's misrepresentations have resulted in consumer injury or harm to the public interest.

78. As a result of Defendant's deceptive practices, Plaintiff and the New York Subclass members suffered an economic injury because they would not have purchased (or paid a premium for) the Products had they known that the Products were not supported by reliable science, did not provide the touted benefits in its marketing, and are otherwise unapproved new drugs which are misbranded and illegal to sell.

79. On behalf of himself and the New York Subclass members, Plaintiff seeks to recover their actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees and costs.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, seeks judgment against Defendant, as follows:

(a) For an order certifying the Classes under Rule 23 of the Federal Rules of Civil Procedure; naming Plaintiff as representative of the Classes; and naming Plaintiff's attorneys as Class Counsel to represent the Classes;

(b) For an order finding in favor of Plaintiff and the Classes on all counts asserted herein;

(c) For compensatory, statutory and punitive damages in amounts to be determined by the Court and/or jury;

(d) For prejudgment interest on all amounts awarded;

(e) For an order of restitution and all other forms of equitable monetary relief; and

(f) For an order awarding Plaintiff and the Classes their reasonable attorneys' fees and expenses and costs of suit.

DEMAND FOR TRIAL BY JURY

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of any and all issues in this action so triable as of right.

Dated April 25, 2024

Respectfully submitted,

GUCOVSCHI ROZENSHTEYN, PLLC

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