UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

Kim Jones, individually and on behalf of all others similarly situated, Plaintiff, v. Veridian Healthcare, LLC., Defendant.	CASE NO. **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Kim Jones ("Plaintiff"), brings this action on behalf of herself and all others similarly situated against Defendant Veridian Healthcare, LLC. ("Defendant"). Plaintiff makes the following allegations pursuant to the investigation of her counsel and based upon information and belief, except as to the allegations specifically pertaining to herself, which are based on her personal knowledge.

INTRODUCTION

1. This is a putative class action lawsuit on behalf of purchasers of Defendant's lidocaine patches[1] (the "Lidocaine Patches") as well as Defendant's lidocaine creams[2] (the "Lidocaine Creams," and collectively, the "Lidocaine Products"[3]). Defendant markets, sells, and

[1] The Lidocaine Patches include Defendant's "TheraCare Pain Relief Lidocaine Patch"; "HealthWise Lidocaine Pain Relief Patch"; and "HealthWise Lidocaine and Menthol Pain Relief Patch."
[2] The Lidocaine Creams include Defendant's "TheraCare 4% Lidocaine Cream" and "TheraCare 4% Lidocaine and 1% Menthol Cream."
[3] The Lidocaine Products also include Defendant's "TheraCare 24hr Lidocaine Patch" which is independently misleading based on its "Maximum Strength" representation.

distributes the Lidocaine Products through numerous brick-and-mortar retail locations and online websites.

2. Lidocaine is a topical anesthetic that is used to treat pain by blocking the transmission of pain signals from nerve endings in the skin to the spinal cord and brain. Specifically, lidocaine functions by blocking sodium channels located on nerve endings which prevents action potential from propagating in the nerve cell and thereby interrupts the transmission of pain signals.

3. Although lidocaine patches and creams are often prescribed by doctors, Defendant offers its Lidocaine Products over-the-counter to unsuspecting consumers under false pretenses. Defendant takes advantage of these consumers by prominently displaying on the packaging of the Lidocaine Products that they deliver a "Maximum Strength" dose of lidocaine and that the Lidocaine Patches provide pain relief for 12 hours. Plaintiff and the proposed class members relied on those representations when making their purchases. To their dismay, however, Defendant's Lidocaine Patches regularly peel off their bodies within a few hours, and oftentimes minutes, after being properly applied. Furthermore, none of Defendant's Lidocaine Products contain or deliver the maximum amount of lidocaine available with, or without, a prescription.

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

JURISDICTION AND VENUE

5. This Court has original jurisdiction over the claims asserted herein individually and on behalf of the class pursuant to 28 U.S.C. § 1332, as amended by the Class Action Fairness Act of 2005. Subject matter jurisdiction is proper because: (1) the amount in controversy in this

class action exceeds five million dollars, exclusive of interest and costs; (2) there are more than 100 Class members; (3) at least one member of the Class is diverse from the Defendant; and (4) the Defendant is not a governmental entity.

6. This Court has personal jurisdiction over Defendant because it conducts substantial business within New York, including the sale, marketing, and advertising of the Lidocaine Products. Furthermore, a substantial portion of the events giving rise to Plaintiff's claims occurred in this State, including Plaintiff's purchases.

7. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because Defendant does substantial business in this District and a substantial part of the events giving rise to Plaintiff's claims took place within this District.

THE PARTIES

8. Plaintiff Kim Jones is a citizen of New York, residing in Westchester County, New York. Plaintiff purchased Defendant's TheraCare Pain Relief Lidocaine Patch for her personal use for approximately $9.99 on various occasions within the applicable statute of limitations, with her most recent purchase taking place on or about September of 2020. Plaintiff Jones made these purchases from local pharmacies located in Westchester County, New York. Prior to her purchases, Plaintiff saw that the Lidocaine Patches were labeled and marketed as providing a "Maximum Strength" dose of lidocaine and as a "Stay-Put Flexible Patch" capable of providing "12 HR. PAIN RELIEF." Further, Plaintiff read the directions on the back label of the Lidocaine Patch, which indicated that she could "Use one patch for up to 12 hours." Plaintiff relied on Defendant's representations when she decided to purchase the Lidocaine Patches over comparable and less expensive pain-relieving patches or creams. Plaintiff saw those representations prior to and at the time of her purchases and understood them as a representation

and warranty that the Lidocaine Patches would reliably adhere to her body and provide pain relief for 12 hours. Initially, Plaintiff became frustrated when her Lidocaine Patches peeled off her body while engaging in regular activities—such as walking, stretching, and sleeping—well before the represented 12 hours, through no fault of her own. Having given the Lidocaine Patches the benefit of the doubt, Plaintiff stopped purchasing the Lidocaine Patches when she realized that they consistently failed to "Stay-Put" and provide pain relief for 12 hours. For example, on a couple of occasions, the Lidocaine Patches that Plaintiff bought peeled off her body within an hour or two after she properly applied them pursuant to the directions contained on the products—delivering little to no analgesic effect to her sore muscles. Plaintiff relied on Defendant's representations and warranties in deciding to purchase the Lidocaine Patches. Accordingly, those representations and warranties were part of the basis of her bargains, in that she would not have purchased the Lidocaine Patches on the same terms had she known those representations and warranties were false. Additionally, in making her purchases, Plaintiff paid a substantial price premium due to Defendant's false and misleading claims regarding the qualities of its Lidocaine Patches in comparison to less expensive lidocaine products that did not contain those representations. However, Plaintiff did not receive the benefit of her bargains because her Lidocaine Patches did not, in fact, contain a "Maximum Strength" dose of lidocaine; nor did they "Stay-Put" or provide her the represented "12 HR. PAIN RELIEF."

9. Defendant Veridian Healthcare, LLC. ("Defendant") is an Illinois limited liability corporation with its principal place of business in Gurnee, Illinois. Defendant markets, sells, and distributes the Lidocaine Products and is responsible for the advertising, marketing, trade dress, and packaging of the Lidocaine Products. Defendant marketed, distributed, and sold the Lidocaine Products during the class period.

FACTUAL ALLEGATIONS

Defendant's False Advertising

10. Defendant markets, sells, and distributes the Lidocaine Products through numerous retail stores and online marketplaces. On the Lidocaine Patches packaging, Defendant represents that its Lidocaine Patches are "Stay-Put Flexible" patches that "Lasts Up to 12 Hours" or provide "12 Hr. PAIN RELIEF," depending on the product. The Lidocaine Patches are all substantially similar, in that they all share the same adhesiveness misrepresentations:

11. By representing that Lidocaine Patches are "Stay-Put Flexible" patches capable of providing pain relief for 12 hours[4]—a very specific number—Defendant induced Plaintiff and the proposed class members into believing that the Lidocaine Patches: (1) would continuously adhere to their bodies for 12 hours; (2) were sufficiently flexible to withstand regular activities for a person suffering from sore muscles (such as walking, stretching, and sleeping); and (3) would provide pain relief throughout the specified amount of time represented therein.

12. Furthermore, by representing that the Lidocaine Products provide a "Maximum Strength" dose of lidocaine, Defendant induced Plaintiff and the proposed class members into

[4] In the directions panel on the back label of each of the Lidocaine Patches, Defendant also represents that consumers can "Use one patch for up to 12 hours."

believing that the Lidocaine Products: (1) contain and deliver the maximum amount of lidocaine available in the market; and (2) that they are superior, or at least equivalent, in efficacy and results to other over-the-counter and/or prescription-strength lidocaine products.

13. Despite those representations, however, Defendant's Lidocaine Patches: (1) systematically fail to adhere to its consumers' bodies for 12 hours; (2) are insufficiently flexible to withstand regular activities (such as walking, stretching, and sleeping); (3) fail to continuously relieve pain throughout the specified amount of time represented therein due to their partial or complete detachment; (4) do not contain or deliver the maximum amount of lidocaine available in the market; and (5) are not superior, or at least equivalent, in efficacy and results to other over-the-counter and/or prescription-strength lidocaine products.

Defendant's Knowledge of the Defective Lidocaine Patches

14. Defendant knew that its Lidocaine Patches did not live up to their adhesiveness representations based on hundreds of complaints posted on multiple online websites: such as www.amazon.com, which Defendant actively monitors. For example, on February 22, 2022, a verified purchaser of the HealthWise Lidocaine Pain Relief Patch complained that the product provided "[n]o relief and didn't stay stuck on my back for more than an hour."[5] Similarly, on February 11, 2022, another verified purchaser of the HealthWise Lidocaine Pain Relief Patch expressed their frustration using the product, stating that "I put one of the patches on my back and when I tried to put on my clothes, it rolled up like a window shade. The adhesion wasn't very good. Thus, I got no pain relief from it."[6] Hundreds of other reviews echo the HealthWise

[5] https://www.amazon.com/HealthWise-Maximum-Strength-Relief-Lidocaine/product-reviews/B07CJH7Z3R/ref=cm_cr_getr_d_paging_btm_next_7?ie=UTF8&reviewerType=all_reviews&sortBy=recent&pageNumber=7 (last accessed March 17, 2022).
[6] *Id.*

Lidocaine Pain Relief Patch's deficient adhesiveness, including a review from February 26, 2022, which stated that the product "kept creeping down my back like one of those wall crawling sticky things our kids used to get out of the vending machine."[7]

15. Similarly, purchasers of Defendant's TheraCare Pain Relief Lidocaine Patch have expressed the same grievances regarding the product's defective adhesion. For example, on February 9, 2022, a verified purchaser of the TheraCare Pain Relief Lidocaine Patch posted a review stating that "I've tried many different pain patches In the past and this one has been one of the worst. It didn't stick to my skin. It didn't relieve my pain on any level and if I could have giving it zero stars I would have."[8] Similarly, on January 18, 2022, another verified purchaser of the TheraCare Pain Relief Lidocaine Patch posted a review stating that "I've gotten several of these in different brands and this one is my least favorite. They would not stay on at all. I used them on my back, as I do the others, with minimum activity and they kept coming off after like an hour or so."[9] Hundreds of other verified purchasers have posted similar reviews expressing their frustration regarding the TheraCare Pain Relief Lidocaine Patch's poor adhesion technology.

16. Furthermore, Defendant knew, or should have known, that its Lidocaine Patches were defectively designed based on FDA reports and scientific studies regarding the efficacy of the products.

17. Specifically, Defendant's Lidocaine Patches work by delivering lidocaine through a topical delivery system—i.e., by delivering the analgesic chemical "through the dermis, or

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[7] *Id.*
[8] https://www.amazon.com/Maximum-Strength-Pain-Relief-Lidocaine/product-reviews/B07NKTQTQG/ref=cm_cr_arp_d_viewopt_srt?ie=UTF8&reviewerType=all_reviews&sortBy=recent&pageNumber=1 (last accessed March 17, 2022).
[9] *Id.*

skin…in ointment or patch form."[10] According to FDA reports, topical delivery systems, such as the one used by Defendant, systematically fail to adhere to the body.[11] To that end, the FDA is in the process of finalizing an industry guidance on "Transdermal and Topical Delivery Systems" to address, *inter alia*, "considerations for areas where quality is closely tied to product performance and potential safety issues, such as adhesion failure…"[12]

18. Even more alarming, the FDA Adverse Events Reporting System evidences that approximately 70% of concerns stemming from lidocaine patches involve their poor adhesion.[13]

19. Furthermore, a peer-reviewed study published in January of 2021 by the Journal of Pain Research found that 0% of generic prescription lidocaine patches had a >90% adhesion rate to the study's subjects after 12 hours (i.e., essentially no part of the product lifting off the skin).[14] The study also found that after 12 hours, "37.5% of subjects experienced substantial

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[10] https://medical-dictionary.thefreedictionary.com/transdermal (last accessed March 17, 2022).
[11] *See* Yellela S.R. Krishnaiah *FDA Perspectives on Product Quality of Transdermal Drug Delivery Systems*, PhD Division of Product Quality Research OTR/OPQ/CDER US Food and Drug Administration Silver Spring, MD, USA AAPS 2015_Sunrise Session (2015). https://healthdocbox.com/Deafness/74997073-Fda-perspectives-on-product-quality-of-transdermal-drug-delivery-systems.html (last accessed March 17, 2022).
[12] *See* 84 FR 64319 - *Transdermal and Topical Delivery Systems-Product Development and Quality Considerations; Draft Guidance for Industry*; Availability (2019) https://www.regulations.gov/document/FDA-2019-D-4447-0001 (last accessed March 17, 2022).
[13] *See* Gudin J, Nalamachu S. *Utility of lidocaine as a topical analgesic and improvements in patch delivery systems*. *Postgrad Med*. 2020;132(1):28–36. doi:10.1080/00325481.2019.1702296 https://www.tandfonline.com/doi/full/10.1080/00325481.2019.1702296 (last accessed March 17, 2022).
[14] See Gudin J, Webster LR, Greuber E, Vought K, Patel K, Kuritzky L. *Open-Label Adhesion Performance Studies of a New Lidocaine Topical System 1.8% versus Lidocaine Patches 5% and Lidocaine Medicated Plaster 5% in Healthy Subjects*. *J Pain Res*. 2021;14:513-526. Published 2021 Feb 23. doi:10.2147/JPR.S287153. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7914064/ (last accessed March 17, 2022). The study measured the adhesion of the patches "immediately after application (0 hours) and at 3, 6, 9, and 12 hours (±15 minutes; before product removal) after application. Assessments in Study 1 were performed by a trained scorer using the FDA-recommended 5-point adhesion scale. The FDA scale ranges from 0 to 4, where 0 represents ≥90% of the product adhered (essentially no part of the product lifting off the skin), 1 represents 75% to <90% adhered (only some edges of

detachment (to <10% adhesion) while using the generic lidocaine patch 5%, including 7 (29.1%) complete detachments." The study also found that the mean adhesiveness score of the generic lidocaine patches after 12 hours was 37.67% (where 0% reflects complete detachment and 50% reflects half the product lifting off the skin but not detached). In contrast, the study found that a newly developed 1.8% lidocaine patch technology, which is bioequivalent to 5% lidocaine patches,[15] maintained a mean adhesion >90% across all time points (0, 3, 6, 9, and 12 h).

20. Although the study published by the Journal of Pain Research only tested generic prescription lidocaine patches, upon information and belief, Defendant's over-the-counter Lidocaine Patches—which have not undergone the rigorous approval process required by the FDA and use the same outdated and defective adhesion technology as the generic lidocaine patches[16] —fair no better.

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the product lifting off the skin), 2 represents 50% to <75% adhered (less than half the product lifting off the skin), 3 represents >0% to <50% adhered (more than half the product lifting off the skin but not detached), and 4 represents 0% adhered (complete product detachment). The mean cumulative adhesion score was calculated by summing the scores at 3, 6, 9, and 12 hours and dividing the total by the total number of observations per subject." *Id.*

[15] Gudin J, Argoff C, Fudin J, Greuber E, Vought K, Patel K, Nalamachu S. *A Randomized, Open-Label, Bioequivalence Study of Lidocaine Topical System 1.8% and Lidocaine Patch 5% in Healthy Subjects*. J Pain Res. 2020 Jun 22;13:1485-1496. doi: 10.2147/JPR.S237934. PMID: 32606914; PMCID: PMC7319520. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7319520/ (last accessed March 17, 2022).

[16] Defendant, whose Lidocaine Patches are manufactured in China, has not been approved by the FDA to market or sell its Lidocaine Patches despite being required to do so. The FDA is currently reviewing a Citizen Petition filed by Scilex Pharmaceuticals Inc. (a manufacturer of FDA-approved lidocaine patches) to remove from the market all over-the-counter lidocaine patches that lack FDA approval. *See* https://www.regulations.gov/docket/FDA-2019-P-0417/document (last accessed March 17, 2022).

21. Furthermore, while certain companies have innovated their technology based on clinical studies to ensure that their lidocaine patches reliably adhere to a consumer's body,[17] even while exercising,[18] upon information and belief, Defendant has not.

22. In complete disregard of the wealth of information to the contrary, however, Defendant continues to misrepresent that its Lidocaine Patches can provide pain relief to its consumers' bodies for 12 hours when, in fact, they cannot, given their poor adhesion technology. This is crucial because "[a]dequate adhesion is a critical quality attribute for topical delivery systems; if the product lifts or detaches during wear, dosing may be compromised and there is an increased risk of inadvertent exposure to others."[19]

23. Defendant also failed to inform its consumers that the Lidocaine Patches are prone to even greater detachment when they engage in regular daily activities (such as walking, stretching, and sleeping).

Defendant's "Maximum Strength" Lidocaine Patches Misrepresentations

24. In 1983, the FDA published a Tentative Final Monography for External Analgesic Drug Products for Over-the-Counter Human Use, 48 Fed. Reg. 5852-01 (Feb. 8, 1983) (the "1983 TFM"), which provides permissible language for the labeling, ingredients, and doses for over-the-counter external analgesic products, including those containing 0.5% to 4% lidocaine.

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[17] https://www.scilexpharma.com/scilex-presents-ztlido-data-on-superior-adhesion-over-lidocaine-patch-formulation/ (last accessed March 17, 2022).

[18] A separate study demonstrated that Scilex's lidocaine patches were able to reliably adhere when subjects engaged in moderate physical exercise (e.g., bike exercise) and heat (heating pad). *See* Fudin J, Wegrzyn EL, Greuber E, Vought K, Patel K, Nalamachu S. *A Randomized, Crossover, Pharmacokinetic and Adhesion Performance Study of a Lidocaine Topical System 1.8% During Physical Activity and Heat Treatment in Healthy Subjects*. *J Pain Res*. 2020;13:1359-1367. Published 2020 Jun 10. doi:10.2147/JPR.S238268. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7293912/#CIT0007 (last accessed March 17, 2022).

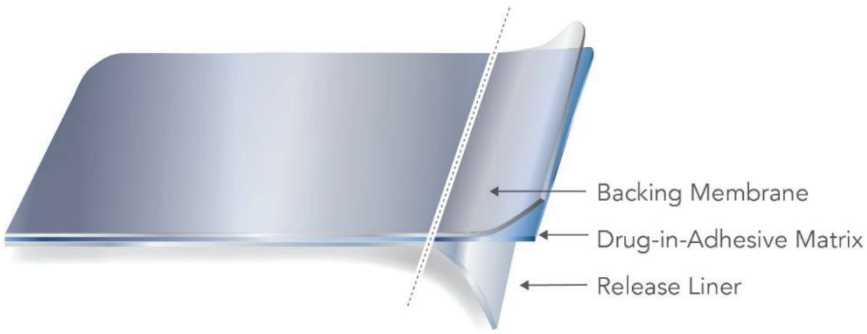
[19] *See supra* footnote 15.

The 1983 TFM, however, was solely concerned with regulating the use of lidocaine creams and ointments as a treatment for minor burns, cuts, and skin irritations; it did not consider, much less regulate, the safety or efficacy of lidocaine patches for muscle pain relief. After seeing dozens of new lidocaine patches were introduced into the market, the FDA issued a proposed rule in 2003 to amend the 1983 TFM seeking to exclude patches from the TFM; and it requested information—including the "Labeling of currently marketed products"—to determine if patches are "generally recognized as safe and effective." *See* External Analgesic Drug Products for Over-the-Counter Human Use; Reopening of the Administrative Record and Amendment of Tentative Final Monograph, 68 Fed. Reg. 42324-01, 42326 (July 17, 2003). The FDA, however, never finalized that process: an oversight that has permitted Defendant to mislabel its Lidocaine Patches as containing "Maximum Strength" without regulatory enforcement.

25. Specifically, the 1983 TFM limited 4% as the permitted lidocaine dose for over-the-counter lidocaine creams and ointments. Under the 1983 TFM, the strength of lidocaine products could be easily calculated by multiplying the 4% lidocaine limit per 1 gram of a cream or ointment (i.e., 40 milligrams of lidocaine per gram). Lidocaine patches, however, use transdermal/topical delivery systems ("TDS"), a different drug delivery method whose actual strength cannot be discerned using the 1983 TFM 4% lidocaine limit.

26. Unlike lidocaine creams and ointments, TDS patches are comprised of three main parts: (1) an outer protective backing membrane, (2) a drug-in-adhesive layer, and (3) a release liner that controls the rate and extent of drug administration:[20]

Figure 1. Matrix Type Transdermal or Topical Delivery System



27. As currently marketed, manufacturers of lidocaine patches attempt to shoehorn the strength of their patches using the 1983 TFM 4% benchmark using a "mass of drug relative to the mass of the adhesive per patch."[21] However, this drug-to-adhesive ratio is a useless metric for determining the amount of lidocaine contained in lidocaine patches unless the manufacturer explicitly states the drug content contained in the product. Specifically, "[b]ecause there are no constraints on patch dimensions or adhesive thickness, the amount of drug in the product can be arbitrarily, and significantly, increased by increasing the patch size or adhesive thickness while maintaining the drug-to-adhesive ratio at 4%."[22] Thus, unlike creams and ointments, a lidocaine patch labeled as having 4% lidocaine has no bearing on its actual strength; and it permits

[20] https://www.fda.gov/media/132674/download (last accessed March 17, 2022).
[21] *See* Citizen Petition from Scilex Pharmaceuticals Inc at pg. 19. https://www.regulations.gov/document/FDA-2019-P-0417-0001 (last accessed March 17, 2022).
[22] *Id.* at pg. 21.

corporations, like Defendant, to mislead consumers into believing that their patches contain the same amount of lidocaine as competitor brands, when, in fact, they do not.[23]

28. In its Lidocaine Patches' packaging, Defendant misrepresents, without providing adequate disclaimers, that its Lidocaine Patches provide a "Maximum Strength" dose of lidocaine, when, in fact, there are superior prescription lidocaine patches in the market that deliver a higher amount of lidocaine: including the previously mentioned 5% and 1.8% prescription-strength lidocaine patches.[24]

29. Furthermore, Defendant's Lidocaine Patches do not contain, nor do they deliver, a greater dose of lidocaine in comparison to other over-the-counter lidocaine products, including those without a "maximum strength" label.

30. Shockingly, and by way of illustration, Defendant labels its Lidocaine Patches as containing "Maximum Strength," although they have the exact specifications and contain the same amount of lidocaine as non-maximum-strength labeled over-the-counter lidocaine patches. For example, all of Defendant's non-menthol Lidocaine Patches have the same measurement dimensions and lidocaine dose as Walgreens' "Pain Relieving Lidocaine Patch"— the products (1) measure 10 cm x 14 cm; (2) have a drug mass of 9 grams per patch; and (3) contain a

[23] "It is emphasized that most of these patch products are labeled as a percentage strength, without providing the total drug content per patch. For other topical dosage forms like creams, ointments, and lotions, the amount of drug administered can easily be determined by weighing the mass of product and applying the strength factor as illustrated in the table below. In contrast, the amount of drug applied for patch products cannot easily be determined because the exact mass of adhesive applied cannot be estimated due to the contributing mass of the backing materials. In as much as patches are manufactured in a variety of sizes and thicknesses, the drug exposure from patches is unknown and cannot be estimated by reviewing the product label, unless the manufacturer discloses the drug mass. Many of the patch products exclude this from their labels, and the absence of this information on unapproved OTC product labels creates a safety risk." *Id.* at pg. 20.

[24] *See supra* footnote 15.

lidocaine strength of 4 grams for every 100 grams.[25] Translated into milligrams, both products contain 360 milligrams of lidocaine per patch[26]—although Defendants' Lidocaine Patches claims to possess "Maximum Strength," while Walgreen's "Pain Relieving Lidocaine Patch" does not.

31. Similarly, Defendant's "HealthWise Lidocaine and Menthol Pain Relief Patch" claims to contain a comparable amount of lidocaine per patch as the "Icy Hot Lidocaine Plus Menthol Patch," and it expressly invites consumers to compare the two products' "Active Ingredients." Yet, despite having the exact measurement dimensions (10 cm x 14 cm), Defendant's "HealthWise Lidocaine and Menthol Pain Relief Patch" contains 200 milligrams of lidocaine per patch,[27] while the "Icy Hot Lidocaine Plus Menthol Patch" contains 240 milligrams of lidocaine per patch.[28]

32. Further, all of Defendant's Lidocaine Patches contain less lidocaine than other over-the-counter lidocaine patches: which range from 411.4 to 4,500 milligrams.[29] For example, Hisamitsu's "Salonpas Lidocaine Patch," one of the leading products in the market, has the exact measurement dimensions as Defendant's Lidocaine Patches (10 cm" x 14 cm), yet it contains

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[25] *Compare* https://www.accessdata.fda.gov/spl/data/d0ec6823-26da-4208-af16-9ce73e1f283c/d0ec6823-26da-4208-af16-9ce73e1f283c.xml *with* https://www.accessdata.fda.gov/spl/data/ce647e79-57ee-804b-e053-2995a90afa25/ce647e79-57ee-804b-e053-2995a90afa25.xml (last accessed March 17, 2022).

[26] Because the FDA mandates that lidocaine patches maintain a 4% lidocaine drug mass relative to the total mass of the patch, and the mass of the at-issue patches is 9 grams, the maximum amount of lidocaine that could be contained in those patches is at most 360 milligrams.

[27] Because the FDA mandates that lidocaine patches maintain a 4% lidocaine drug mass relative to the total mass of the patch, and the mass of the at-issue patches is 5 grams with a lidocaine strength of 4 grams for every 100 grams, the maximum amount of lidocaine that could be contained therein is at most 200 milligrams. *See* https://www.accessdata.fda.gov/spl/data/ce2ea2f0-bd68-6051-e053-2995a90a31da/ce2ea2f0-bd68-6051-e053-2995a90a31da.xml (last accessed March 17, 2022).

[28] https://www.accessdata.fda.gov/spl/data/e2daaeaa-0b33-4c4f-af8c-075a598b2e69/e2daaeaa-0b33-4c4f-af8c-075a598b2e69.xml (last accessed March 17, 2022).

[29] *See* Attachment 1 re Citizen Petition from Scilex Pharmaceuticals Inc https://www.regulations.gov/document/FDA-2019-P-0417-0003 (last accessed March 17, 2022).

560 milligrams, rather than 360 milligrams, of lidocaine per patch (i.e., 64% more lidocaine that Defendant's non-menthol Lidocaine Patches).[30]

Defendant's "Maximum Strength" Lidocaine Creams Misrepresentations

33. Like its Lidocaine Patches, Defendant also misleads consumers into believing that its "Maximum Strength" Lidocaine Creams contain a greater dose of lidocaine than other over-the-counter lidocaine creams, including those without a "maximum strength" label. Specifically, Defendant's Lidocaine Creams have a strength of 4% lidocaine,[31] yet dozens of comparable over-the-counter lidocaine creams contain a strength of 5% lidocaine. Most of these stronger lidocaine creams are available online and in retail pharmacies.[32] Similarly, prescription-strength lidocaine creams contain more lidocaine than Defendant's Lidocaine Creams: some of which contain up to 7% lidocaine.

34. Defendant's arbitrary and patently false claim regarding the strength of its Lidocaine Products goes beyond the pale. Had Defendant not made the false, misleading, and deceptive misrepresentations and omissions alleged herein, Plaintiff and the proposed class members (1) would not have purchased the Lidocaine Products: (2) would not have paid as much as they did for those purchases; or (3) would have purchased less expensive lidocaine products that do not charge a premium for the "maximum strength," or durational representations contained in Defendant's Lidocaine Products. Thus, Plaintiff and the proposed class members

[30] https://www.accessdata.fda.gov/spl/data/39b310ac-4be6-4b3d-85a7-7d30c99ba7d1/39b310ac-4be6-4b3d-85a7-7d30c99ba7d1.xml (last accessed March 17, 2022).
[31] https://www.accessdata.fda.gov/spl/data/c8088c02-49f7-4d04-e053-2995a90ab9e3/c8088c02-49f7-4d04-e053-2995a90ab9e3.xml ; https://www.accessdata.fda.gov/spl/data/c80ba263-3d5f-0953-e053-2a95a90ae80b/c80ba263-3d5f-0953-e053-2a95a90ae80b.xml (last accessed March 17, 2022).
[32] *See e.g.*, https://www.amazon.com/Ebanel-Lidocaine-Topical-Numbing-Menthol/dp/B08TJ3LMC3 (last accessed March 17, 2022).

suffered an injury in fact and lost money or property as a result of Defendant's wrongful conduct.

CLASS ACTION ALLEGATIONS

35. 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), (b)(2), and (b)(3).

36. The class periods shall be defined from the date of the filing of this Complaint, back to any such time the Court deems appropriate.

37. Plaintiff seeks to represent all persons in the United States who purchased Defendant's Lidocaine Products (the "Class").

38. Plaintiff also seeks to represent a subclass of all Class members who purchased Defendant's Lidocaine Products in New York (the "New York Subclass") (collectively with the Class, the "Classes").

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

40. 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.

41. ***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.

42. ***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.

43. ***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 Lidocaine Patches are defective;

(b) Whether Defendant knew of the Lidocaine Patches' defective nature;

(c) Whether Defendant breached the express warranties on the Lidocaine Products' packaging;

(d) Whether Defendant's representations that the Lidocaine Patches are "Stay-Put Flexible" patches that can be applied for 12 hours are false and misleading in violation of New York's consumer-protection statutes;

(e) Whether Defendant's representation that the Lidocaine Products contain a "Maximum Strength" dose of lidocaine is false and misleading in violation of New York's consumer-protection statutes;

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

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

(h) Whether Plaintiff and the members of the Classes are entitled to restitution; and

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

costs.

44. ***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 defective Lidocaine Products, and suffered a loss as a result of those purchases.

45. ***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 she 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.

46. ***Superiority:*** 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 The Magnuson-Moss Warranty Act, 15 U.S.C. § 2301, *et seq.*
(On Behalf of Plaintiff and the Class)

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

48. 15 U.S.C. § 2310(d) is satisfied because Plaintiff properly invokes jurisdiction under the Class Action Fairness Act ("CAFA").

49. 15 U.S.C. § 2310(d)(1) provides a cause of action to "a consumer who is damaged by the failure of a supplier, warrantor, or service contractor to comply with any obligation… under a written warranty, implied warranty, or service contract."

50. Defendant's Lidocaine Patches are consumer products as defined under 15 U.S.C. § 2301(1).

51. Plaintiff and the Class members are consumers as defined under 15 U.S.C. § 2301(3).

52. Defendant is a supplier and warrantor as defined under 15 U.S.C. §§ 2301(4) and (5).

53. 15 U.S.C. § 2301(6)(A) defines "written warranty" as "any written affirmation of fact or written promise made in connection with the sale of a consumer product by a supplier to a buyer which relates to the nature of the material or workmanship and affirms or promises that such material or workmanship…will meet a specified level of performance over a specified period of time."

54. Defendant provided Plaintiff and the Class members "written warranties" within the meaning of 15 U.S.C. § 2301(6) by providing written promises and affirmations of fact on

the Lidocaine Patches' packaging that the Lidocaine Patches are: (1) "Stay-Put Flexible" patches; (2) which contain and deliver a "Maximum Strength" dose of lidocaine; and (3) are capable of providing an adequate amount of pain relief in order to be fit as an analgesic for sore muscles. Further, Defendant qualified that the above-referenced qualities of its Lidocaine Patches would remain effective for "12 HR." or "Last[ing] Up to 12 Hours," depending on the product. These durational affirmations are further bolstered by the language on the Lidocaine Patches back label, which indicates that consumers can "Use one patch for up to 12 hours."

55. Similarly, Defendant provided Plaintiff and the Class members "written warranties" that its Lidocaine Creams contain and deliver a "Maximum Strength" dose of lidocaine which would remain effective throughout the 6 to 8 hours of recommended application indicated on the products' direction panels.[33] These durational affirmations are further bolstered by the language on the front panel of the Lidocaine Creams, which states that they provide "Long-Lasting Relief."

56. Those statements became the basis of the bargain for Plaintiff and the Class members because they are factual statements that a reasonable consumer would consider material when purchasing a lidocaine product for pain relief.

57. Defendant breached the express warranties of its Lidocaine Patches because they: (1) systemically fail to adhere to its consumers' bodies for 12 hours; (2) are insufficiently flexible to withstand regular activities (such as walking, stretching, and sleeping); (3) fail to continuously relieve pain throughout the specified amount of time represented therein due to their partial or complete detachment; (4) do not contain or deliver the maximum amount of

[33] *See supra* footnote 31.

lidocaine available in patch form; and (5) are not superior, or at least equivalent, in efficacy and results to other over-the-counter and/or prescription-strength lidocaine patches.

58. Similarly, Defendant breached the express warranties of its Lidocaine Creams because they (1) do not contain or deliver the maximum amount of lidocaine available in cream form; and (2) are not superior, or at least equivalent, in efficacy and results to other over-the-counter and/or prescription-strength lidocaine creams.

59. As a direct and proximate result of Defendant's breach of its written warranties, Plaintiff and the Class members have been damaged in an amount to be proven at trial.

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

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

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

62. In its sale of Lidocaine 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.

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

64. By the acts and conduct alleged herein, Defendant engaged in deceptive, unfair, and misleading acts and practices, which include, without limitation, (i) misrepresenting that the Lidocaine Patches are "Stay-Put Flexible," although they are incapable of withstanding regular activities (such as walking, stretching, and sleeping); (ii) omitting that the Lidocaine Patches are

prone to even greater detachment when consumers engage in those activities;

(iii) misrepresenting that the Lidocaine Patches are capable of providing "12 HR. PAIN RELIEF" or pain relief "Last[ing] Up to 12 Hours," despite their systematic failure to do so; and

(iv) misrepresenting that the Lidocaine Products contain or deliver a "Maximum Strength" dose of lidocaine in comparison to other over-the-counter and/or prescription-strength lidocaine products when, in fact, the Lidocaine Products do not contain or deliver the maximum amount of lidocaine available in patch or cream form, and are not superior, or at least equivalent, in efficacy and results to other over-the-counter and/or prescription-strength lidocaine patches or creams.

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

66. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the intrinsic qualities of the Lidocaine Products.

67. As a result of Defendant's deceptive practices, Plaintiff and the New York Subclass members suffered an economic injury because (a) they would not have purchased the Lidocaine Products had they known the veracity of Defendant's misrepresentations and omissions, and (b) they overpaid for the Lidocaine Products on account of such misrepresentations and omissions.

68. On behalf of herself 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)

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

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

71. Defendant violated New York General Business Law § 350 by falsely advertising (i) that the Lidocaine Patches are "Stay-Put Flexible," although they are incapable of withstanding regular activities (such as walking, stretching, and sleeping); (ii) omitting that the Lidocaine Patches are prone to even greater detachment when consumers engage in those activities; and (iii) misrepresenting that the Lidocaine Patches are capable of providing "12 HR. Pain Relief" or pain relief "Last[ing] Up to 12 Hours," despite their systematic failure to do so.

72. Furthermore, Defendant violated New York General Business Law § 350 by misrepresenting that its Lidocaine Products contain or deliver a "Maximum Strength" dose of lidocaine in comparison to other over-the-counter and/or prescription-strength lidocaine products when, in fact, the Lidocaine Products do not contain or deliver the maximum amount of lidocaine available in patch or cream form, and are not superior, or at least equivalent, in efficacy and results to other over-the-counter and/or prescription-strength lidocaine patches or creams.

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

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

75. As a result of Defendant's false advertising, Plaintiff and the New York Subclass members suffered an economic injury because (a) they would not have purchased the Lidocaine Products had they known the veracity of Defendant's misrepresentations and omissions, and (b) they overpaid for the Lidocaine Products on account of such misrepresentations and omissions.

76. On behalf of herself 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 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

(g) 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: March 17, 2022

Respectfully submitted,

GUCOVSCHI ROZENSHTEYN, PLLC

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