

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK**

Monique Bell, Tree Anderson, and Melissa Conklin, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

CVS Pharmacy, Inc.,

Defendant.

CASE NO. 21-cv-06850-PK

**FIRST AMENDED CLASS
ACTION COMPLAINT**

JURY TRIAL DEMANDED

Plaintiffs Monique Bell, Tree Anderson, and Melissa Conklin (“Plaintiffs”) bring this action on behalf of themselves and all others similarly situated against Defendant CVS Pharmacy, Inc. (“Defendant”). Plaintiffs make the following allegations pursuant to the investigation of their counsel and based upon information and belief, except as to the allegations specifically pertaining to themselves, which are based on personal knowledge.

INTRODUCTION

1. This is a putative class action lawsuit on behalf of purchasers of Defendant’s maximum strength lidocaine products, including lidocaine patches (the “Lidocaine Patches”) as well as Defendant’s lidocaine creams and sprays (the “Lidocaine Creams” and Lidocaine Sprays,” and collectively with the Lidocaine Patches, the “Lidocaine Products”).¹ Defendant

¹ The Lidocaine Products include: CVS Lidocaine Plus Pain Relief Spray (SKU 383998), CVS Pain Relief Roll-on Liquid (SKU 256563), Lidocaine Dry Spray (SKU 249024), CVS Lidocaine Patch (SKU 197229), CVS Lidocaine Spray (SKU 256518), CVS Health Lidocaine Pain-Relieving Unscented Patches (SKU 371271), CVS Lidocaine Plus Pain Relieving Cream (SKU 384034), CVS Health XL Maximum Strength Lidocaine Pain Relief Patch (SKU 385037), CVS Lidocaine & Menthol Patch (SKU 234274), CVS Lidocaine Roll-On with Lavender (SKU

markets, sells, and distributes the Lidocaine Products through numerous brick-and-mortar CVS retail locations and online through www.cvs.com.

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 interrupting the transmission of the pain signal.

3. Although lidocaine patches 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 adhere to consumers’ bodies up to 12 or 8 hours. Plaintiffs and the proposed class members relied on those representations when making their purchases. To their dismay, however, Defendant’s Lidocaine Products do not deliver a “Maximum Strength” amount of lidocaine, and the Lidocaine Patches regularly peel off their bodies within a few hours, and oftentimes minutes, after being properly applied.

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

188721), CVS Cold & Hot Dry Spray with Lidocaine (SKU 250483), CVS Lidocaine Pain Patch (SKU 450467), Lidocaine Pain Relief Roll-On (SKU 328522), Lidocaine Plus Pain Relieving Liquid (SKU 196728), CVS Hot & Cold Combo Pack (SKU 405623), CVS Lidocaine Cream (SKU 405343), CVS Lidocaine Menthol Cream (SKU 235554), CVS Lidocaine Pain Relief Cream (SKU 977934), CVS Lidocaine Pain Relieving Antiseptic Spray (SKU 376649), CVS Max Strength Pain & Itch Relief Cream (SKU 238921), CVS Max Strength Lidocaine Burn Gel (SKU 834344), CVS Lidocaine Foot Cream (SKU 388642). The Product names may vary. To the extent there is a discrepancy between the SKU and the Product name, the SKU will govern.

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 the Plaintiffs' claims occurred in this State, including Plaintiffs' purchases of Defendant's Lidocaine Products.

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 Plaintiffs' claims took place within this District.

THE PARTIES

8. Plaintiff Monique Bell is a citizen of New York, residing in Brooklyn, New York. Plaintiff Bell purchased Defendant's Lidocaine Pain Relief Patch for her personal use for approximately \$9.79 on various occasions within the applicable statute of limitations, with her most recent purchase taking place in September of 2021. Plaintiff Bell made these purchases at a CVS store located in Brooklyn, New York. Prior to her purchases, Plaintiff Bell saw that the Lidocaine Patches she purchased were labeled and marketed as "Maximum Strength" patches capable of delivering a 4% lidocaine dose for "UP TO 12 HOURS" and read the directions on the back label, which indicated that she could use "1 patch for up to 12 hours." Plaintiff Bell

relied on Defendant's representations when she decided to purchase the Lidocaine Patches over comparable and less expensive pain-relieving patches or gels. Plaintiff Bell 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 deliver a 4% lidocaine dose for 12 hours. Initially, Plaintiff Bell became frustrated when her Lidocaine Patches peeled off her body while engaging in regular activities—such as walking, sitting, stretching, and sleeping—well before the represented 12 hours, through no fault of her own. Plaintiff Bell, nonetheless, continued to purchase other Lidocaine Patches, believing that such failures were the result of one-off manufacturing flukes. After giving the Lidocaine Patches the benefit of the doubt, however, Plaintiff Bell stopped purchasing them altogether after realizing that the Lidocaine Patches consistently failed to provide pain relief by delivering a “Maximum Strength” lidocaine dose for “UP TO 12 HOURS.” For example, on a couple of occasions, the Lidocaine Patches that Plaintiff Bell 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 Bell relied on Defendant's representations and warranties in deciding to purchase her Lidocaine Patches. Accordingly, those representations and warranties were part of the basis of her bargain, in that she would not have purchased her Lidocaine Patches on the same terms had she known those representations and warranties were false. However, Plaintiff Bell remains interested in purchasing Defendant's Lidocaine Patches and would consider the Lidocaine Patches in the future if Defendant ensured the products actually provide pain relief by delivering a “Maximum Strength” lidocaine dose to her body for “UP TO 12 HOURS.” Additionally, in making her purchases, Plaintiff Bell paid a substantial price premium due to Defendant's false and misleading claims regarding the qualities of its

Lidocaine Patches. However, Plaintiff Bell did not receive the benefit of her bargains because her Lidocaine Patches did not, in fact, provide pain relief by delivering a “Maximum Strength” dose of lidocaine to her body for “UP TO 12 HOURS.”

9. Plaintiff Tree Anderson is a citizen of New York, residing in Brooklyn, New York. Plaintiff Anderson purchased Defendant’s Lidocaine Pain Relief Creams for his personal use for approximately \$8.99 on various occasions within the applicable statute of limitations, with his most recent purchase taking place in the first quarter of 2022. Plaintiff Anderson made these purchases at a CVS store located in Brooklyn, New York. Prior to his purchases, Plaintiff Anderson saw that the Lidocaine Creams he purchased were labeled and marketed as containing a “Maximum Strength” dose of lidocaine. Plaintiff Anderson saw those representations prior to and at the time of his purchases and understood them as a representation and warranty that the Lidocaine Creams contained the maximum amount of lidocaine available in cream form. Plaintiff Anderson relied on Defendant’s representations when he decided to purchase the Lidocaine Creams over comparable and less expensive pain-relieving creams or gels. Accordingly, those representations and warranties were part of the basis of his bargains, in that he would not have purchased the Lidocaine Creams on the same terms had he known that those representations and warranties were false. However, Plaintiff Anderson remains interested in purchasing Defendant’s Lidocaine Creams and would consider the Lidocaine Creams in the future if Defendant ensured the products actually provide pain relief by delivering a “Maximum Strength” dose of lidocaine. Additionally, in making his purchases, Plaintiff Anderson paid a substantial price premium due to Defendant’s false and misleading claims regarding the qualities of its Lidocaine Creams. However, Plaintiff Anderson did not receive the benefit of his bargains because his Lidocaine Creams did not, in fact, provide a “Maximum Strength” dose of lidocaine.

10. Plaintiff Melissa Conklin is a citizen of New York, residing in Brooklyn, New York. Plaintiff Conklin purchased Defendant's Lidocaine Pain Relief Sprays for her personal use for approximately \$10.99 on various occasions within the applicable statute of limitations, with her most recent purchase taking place in the first quarter of 2021. Plaintiff Conklin made these purchases at a CVS store located in Brooklyn, New York. Prior to her purchases, Plaintiff Conklin saw that the Lidocaine Sprays she purchased were labeled and marketed as containing a "Maximum Strength" dose of lidocaine. Plaintiff Conklin saw those representations prior to and at the time of her purchases and understood them as a representation and warranty that the Lidocaine Sprays contained the maximum amount of lidocaine available in spray form. Plaintiff Conklin relied on Defendant's representations when she decided to purchase the Lidocaine Sprays over comparable and less expensive pain-relieving sprays. Accordingly, those representations and warranties were part of the basis of her bargains, in that she would not have purchased the Lidocaine Sprays on the same terms had she known that those representations and warranties were false. However, Plaintiff Conklin remains interested in purchasing Defendant's Lidocaine Sprays and would consider the Lidocaine Sprays in the future if Defendant ensured that the products actually provide pain relief by delivering a "Maximum Strength" dose of lidocaine. Additionally, in making her purchases, Plaintiff Conklin paid a substantial price premium due to Defendant's false and misleading claims regarding the qualities of its Lidocaine Sprays. However, Plaintiff Conklin did not receive the benefit of her bargains because her Lidocaine Sprays did not, in fact, provide a "Maximum Strength" dose of lidocaine.

11. Defendant CVS Pharmacy, Inc. ("Defendant") is a Rhode Island corporation with its principal place of business in Woonsocket, Rhode Island. 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 Patches during the class period.

FACTUAL ALLEGATIONS

Defendant's False Advertising

12. Defendant markets, sells, and distributes the Lidocaine Products through numerous brick-and-mortar CVS retail locations and online through www.cvs.com. On the Lidocaine Products packaging, Defendant represents that its Lidocaine Products deliver a “Maximum Strength” dose of lidocaine, and that its Lidocaine Patches last up to 12 or 8 hours, depending on the product. By way of example, the Lidocaine Products include, but are not limited to, those depicted by below:



13. By representing that the Lidocaine Patches can be applied “UP TO 12 HOURS”

or “UP TO 8 HOURS”—a very specific number²—Defendant induced Plaintiff Bell and the

² The back labels of some Lidocaine Patches reinforce this misrepresentations by instructing consumers to “use 1 patch for up to 12 hours.” Exhibit A.

proposed class members into believing that the Lidocaine Patches: (1) would continuously adhere to their bodies up to 12 or 8 hours; (2) were sufficiently flexible to withstand regular activities (such as walking, stretching, and sleeping) for someone who is suffering from sore muscles; and (3) would continuously relieve pain by providing a 4% lidocaine dose throughout the specified amount of time represented therein. Furthermore, by representing that the Lidocaine Products provide a “Maximum Strength” dose of lidocaine, Defendant induced Plaintiffs and the proposed class members into believing that the Lidocaine Products contain and deliver the maximum amount of lidocaine available in that product form. Those representations, however, are false and misleading, as set forth in greater detail below.

Defendant’s Knowledge of the Defective Lidocaine Patches

14. Defendant knew that its Lidocaine Patches did not live up to the adhesiveness representations contained therein based on dozens of complaints posted on its own website, www.cvs.com, which Defendant actively monitors.

15. For example, in May of 2021, a buyer explained their issue trying to get a Lidocaine Patch to adhere to their body:

“Absolutely awful. Active ingredient doesn’t matter because the delivery method doesn’t stick at all. Post-it notes have better adhesion. Spend a couple extra bucks and get something that will stay on.”³

16. In June of 2020, yet another consumer expressed their frustration using Defendant’s Lidocaine Patch:

“If I could give negative stars I would. These simply do not stay on. Obviously this is a real problem with this product since so many reviews reflect the same opinion. If you’re going to claim that your product is comparable to another, you

³ <https://www.cvs.com/shop/cvs-health-lidocaine-patch-max-strength-5-ct-prodid-1910091> (last accessed December 10, 2021).

should at least assure that it is able to be compared to said product. I am unable to compare it when it won't even stay put! Complete waste of money.”⁴

17. 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.

18. Specifically, Defendant's Lidocaine Patches work by delivering lidocaine through a transdermal mechanism—i.e., by delivering the analgesic chemical “through the dermis, or skin...in ointment or patch form.”⁵ According to FDA reports, transdermal drug delivery systems, such as the one used by Defendant, systematically fail to adhere to the body.⁶ 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...”⁷

19. Even more alarming, the FDA Adverse Events Reporting System reports that approximately 70% of concerns stemming from lidocaine patches involve their poor adhesion.⁸

⁴ <https://www.cvs.com/shop/cvs-health-maximum-strength-pain-relief-patch-3-5-16-x-5-1-2-10-cm-x-14-cm-5-ct-prodid-1730040> (last accessed December 10, 2021).

⁵ <https://medical-dictionary.thefreedictionary.com/transdermal> (last accessed December 10, 2021).

⁶ 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 Krishnaiah, October 2015_Sunrise Session (2015). <https://healthdocbox.com/Deafness/74997073-Fda-perspectives-on-product-quality-of-transdermal-drug-delivery-systems.html> (last accessed December 10, 2021). at pg. 8.

⁷ 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 December 10, 2021).

⁸ 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 December 10, 2021).

20. 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).⁹ The study also found that after 12 hours, "37.5% of subjects experienced substantial 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,¹⁰ maintained a mean adhesion >90% across all time points (0, 3, 6, 9, and 12 h).

21. 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

⁹ See Gudín 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 December 10, 2021). The study measured 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 $\geq 90\%$ of the product adhered (essentially no part of the product lifting off the skin), 1 represents 75% to <90% adhered (only some edges of 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.*

¹⁰ Gudín 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 December 10, 2021).

FDA and use the same outdated and defective adhesion technology as the generic lidocaine patches¹¹ —fair no better.

22. 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,¹² even while exercising,¹³ upon information and belief, Defendant has not.

23. In complete disregard of the wealth of information to the contrary, however, Defendant continues to misrepresent that its Lidocaine Patches reliably adhere to its consumers' bodies up to 12 or 8 hours when, in fact, they do not. Defendant also failed to inform its consumers that the Lidocaine Patches are prone to even greater detachment when they engage in certain activities (such as walking, stretching, and sleeping). Nor is Defendant's representation that its Lidocaine Patches are capable of continuously relieving pain by providing a 4% lidocaine dose throughout the specified time periods true: given that they systematically fail to fully adhere. This is crucial because “[a]dequate adhesion is a critical quality attribute for topical

¹¹ 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 any over-the-counter lidocaine patches that lack FDA approval. *See* <https://www.regulations.gov/docket/FDA-2019-P-0417/document> (last accessed December 10, 2021).

¹² <https://www.scilexpharma.com/scilex-presents-ztlido-data-on-superior-adhesion-over-lidocaine-patch-formulation/> (last accessed December 10, 2021).

¹³ A separate study demonstrated that Scilex's lidocaine patches were able to reliably adhere when subjects engaged in moderate physical exercise (exercise bike) 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 December 10, 2021).

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.”¹⁴

Defendant’s “Maximum Strength” Lidocaine Patches Misrepresentations

24. To make matters worse, Defendant misrepresents, without providing adequate disclaimers, that the Maximum Strength Lidocaine Patches provide a “Maximum Strength” dose of lidocaine, when, in fact, there are superior lidocaine patches in the market that deliver a higher amount of lidocaine: including the previously mentioned 5% and 1.8% prescription-strength lidocaine patches.¹⁵ Defendant compounds this problem by indicating that its “MAXIMUM STRENGTH LIDOCAINE Cold & Hot Patch” is “Medicated”—thereby leading reasonable consumers to believe that the product is comparable to prescription-strength lidocaine patches.

25. Furthermore, nothing in Defendant’s Maximum Strength Lidocaine Patches indicates that they provide a greater dose of lidocaine in comparison to other over-the-counter lidocaine patches, including its own. Specifically, Defendant’s representation that its Patches contain “4% lidocaine” is misleading because the actual strength of a lidocaine patch is measured by the “mass of drug relative to the mass of the adhesive per patch.”¹⁶ In other words, Defendant’s representation that its Lidocaine Patches contain “4% lidocaine” does not indicate the *actual* amount of lidocaine milligrams that its Patches deliver to a consumer’s body.¹⁷

¹⁴ See *supra* footnote 13.

¹⁵ See *Id.*

¹⁶ See Scilex Pharmaceuticals Inc.’s Citizen Petition. Exhibit B at pg. 19.

¹⁷ “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. inasmuch 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,

26. Shockingly, and by way of illustration, Defendant labels its “MAXIMUM STRENGTH LIDOCAINE Cold & Hot Patch” as possessing “MAXIMUM STRENGTH LIDOCAINE” although it has a lesser amount of lidocaine per patch (240 milligrams)¹⁸ than its “MAXIMUM STRENGTH Lidocaine Pain Relief Patch” and “MAXIMUM STRENGTH Lidocaine Pain-Relieving Patch,” both of which contain 567 milligrams of lidocaine per patch.¹⁹²⁰ Further, all of Defendant’s Lidocaine Patches contain less lidocaine than other over-the-counter lidocaine patches: which range from 600 to 4,500 milligrams.²¹

Defendant’s “Maximum Strength” Lidocaine Creams and Sprays Misrepresentations

27. Like its Lidocaine Patches, Defendant also misleads consumers into believing that its “Maximum Strength” Lidocaine Creams and Sprays contain a greater dose of lidocaine than other over-the-counter lidocaine products, including those without a “maximum strength” label.

28. Specifically, Defendant’s Lidocaine Creams and Sprays have a strength of 4% lidocaine, yet dozens of comparable over-the-counter lidocaine creams and sprays contain a strength of 5% lidocaine. Most of these stronger lidocaine products are available online and in retail pharmacies.²² Similarly, prescription-strength lidocaine creams and sprays contain more lidocaine than Defendant’s Lidocaine Creams: some of which contain up to 7% lidocaine.

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.” Ex. B at pg. 20.

¹⁸ <https://ndclist.com/ndc/66902-220> (last accessed December 10, 2021).

¹⁹ <https://ndclist.com/ndc/66902-215> (last accessed December 10, 2021).

²⁰ <https://ndclist.com/ndc/66902-276> (last accessed December 10, 2021).

²¹ See Attachment 1 to Scilex Pharmaceuticals Inc.’s Citizen Petition. Exhibit C.

²² See e.g., <https://www.amazon.com/Ebanel-Lidocaine-Topical-Numbing-%20Menthol/dp/B08TJ3LMC3> ; https://www.amazon.com/Lido-Lidocaine-Strength-Relief-Anesthetic/dp/B08BZVGXPB/ref=sr_1_9?crid=23JVWLZXC�WQS&keywords=lidocaine+5%25+spray&qid=1671568523&sprefix=lidocaine+5%25+spray%2Caps%2C265&sr=8-9 (last accessed December 20, 2022).

29. Defendant's arbitrary and patently false claim regarding the strength of its Lidocaine Products goes beyond the pale.

30. Had Defendant not made the false, misleading, and deceptive misrepresentations and omissions alleged herein, Plaintiffs and the proposed class members would not have purchased the Lidocaine Products or would not have paid as much as they did for those purchases. Thus, Plaintiffs and the proposed class members suffered an injury in fact and lost money or property as a result of Defendant's wrongful conduct.

CLASS ACTION ALLEGATIONS

31. Plaintiffs bring this action on behalf of themselves and all other similarly situated persons pursuant to Federal Rules of Civil Procedure 23(a), (b)(1), (b)(2), and (b)(3).

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

33. Plaintiffs seek to represent all persons in the United States who purchased Defendant's Lidocaine Products (the "Class").

34. Plaintiffs also seek 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").

35. 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.

36. Plaintiffs reserve 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.

37. ***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.

38. ***Numerosity:*** While the exact number of members of the Classes is unknown to Plaintiffs 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 Plaintiffs 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.

39. ***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 Products are defective;
- (b) Whether Defendant knew of the Lidocaine Products' defective nature;
- (c) Whether Defendant breached the express warranties on the Lidocaine Products' packaging;
- (d) Whether Defendant's representations that the Lidocaine Products provide a "Maximum Strength" dose of lidocaine or otherwise adhere "Up To 12 Hours" or "Up To 8 Hours" is false and misleading in violation of state consumer-protection statutes;
- (e) Whether Plaintiffs and the members of the Classes have suffered damages as a result

of Defendant's actions and the amount thereof;

- (f) Whether Plaintiffs and the members of the Classes are entitled to restitution;
- (g) Whether Plaintiffs and the members of the Classes are entitled to injunctive relief to enjoin Defendant from further engaging in these wrongful practices; and
- (h) Whether Plaintiffs and the members of the Classes are entitled to attorney's fees and costs.

40. **Typicality:** The claims of the named Plaintiffs are typical of the claims of other members of the Classes in that the named Plaintiffs were exposed to Defendant's false and misleading marketing, purchased Defendant's defective Lidocaine Products, and suffered a loss as a result of those purchases.

41. **Adequacy:** Plaintiffs will fairly and adequately represent and protect the interests of the Classes as required by Federal Rule of Civil Procedure Rule 23(a)(4). Plaintiffs are adequate representatives of the Classes because they have no interests which are adverse to the interests of the members of the Classes. Plaintiffs are committed to the vigorous prosecution of this action and, to that end, Plaintiffs have retained skilled and experienced counsel.

42. **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

Quasi-Contract / Unjust Enrichment (On Behalf of Plaintiffs and the Class)

43. Plaintiffs incorporate by reference each of the allegations contained in the foregoing paragraphs of this Complaint as though fully set forth herein.

44. To the extent required by law, this cause of action is alleged in the alternative to legal claims, as permitted under Fed. R. Civ. P. 8.

45. Plaintiffs and the Class Members conferred benefits on Defendant by purchasing the Lidocaine Products.

46. Defendant was unjustly enriched in retaining the revenues derived from Plaintiffs and Class Members' purchases of the Lidocaine Products.

47. Retention of those moneys under these circumstances is unjust and inequitable because Defendant Lidocaine Products do not possess a "Maximum Strength" dose of lidocaine and do not adhere to consumers' bodies as represented on the packaging of the Lidocaine Patches. These misrepresentations and omissions caused injuries to Plaintiffs and the Class Members because they would not have purchased (or paid a premium for) the Lidocaine Products if the true facts were known.

48. Because Defendant's retention of the non-gratuitous benefits conferred on them by Plaintiffs the Class Members is unjust and inequitable, Defendant has been unjustly enriched in an amount to be determined at trial.

COUNT II
Violation of the State Consumer Protection Statutes²³
(On Behalf of Plaintiffs and the Class)

49. Plaintiffs incorporate by reference each of the allegations contained in the foregoing paragraphs of this Complaint as though fully set forth herein.

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

51. By the acts and conduct alleged herein, Defendant engaged in deceptive, unfair, and misleading acts and practices by representing on the packaging of its Lidocaine Products that they deliver a “Maximum Strength” dose of lidocaine and that the Lidocaine Patches provide pain relief “Up to 12 Hours” or “Up to 8 Hours.”

52. Despite those representations, however, the Lidocaine Patches: (1) systematically fail to adhere to its consumers’ bodies well before 12 or 8 hours; (2) are insufficiently flexible to

²³ While discovery may alter the following, Plaintiffs assert 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.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.

withstand moderate exercise and other regular activities (such as walking, stretching, and sleeping); and (3) fail to continuously relieve pain throughout the specified amount of time represented therein due to their partial or complete detachment. Furthermore, none of the Lidocaine Products contain or deliver the maximum amount of lidocaine available in the market; and are not superior, or at least equivalent, in efficacy and results to other over-the-counter and/or prescription-strength lidocaine products.

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

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

55. As a result of Defendant's deceptive practices, Plaintiffs and the Class Members suffered an economic injury because they would not have purchased (or paid a premium for) the Lidocaine Products had they known the veracity of Defendant's misrepresentations and omissions.

56. On behalf of themselves and the Class Members, Plaintiffs seek to recover their actual damages, statutory damages, punitive damages, and reasonable attorneys' fees and costs.

COUNT III
Violation of State Warranty Acts²⁴
(On Behalf of Plaintiffs and the Class)

57. Plaintiffs incorporate by reference each of the allegations contained in the foregoing paragraphs of this Complaint as though fully set forth herein.

58. Defendant's Lidocaine Patches are goods as defined under the State Warranty Acts of the Class.

59. Plaintiffs and the Class Members are buyers as defined under the State Warranty Acts of the Class.

60. Defendant is a seller as defined under the State Warranty Acts of the Class.

61. The State Warranty Acts provides a cause of action to buyers when sellers breach express warranties.

62. On the Lidocaine Products' packaging, Defendant expressly warranted that its Lidocaine Products deliver a "Maximum Strength" dose of lidocaine and that the Lidocaine Patches provide pain relief "Up to 12 Hours" or "Up to 8 Hours."

²⁴ While discovery may alter the following, Plaintiff assert that the states with similar consumer warranty laws under the facts of this case include but are not limited to: Code of Ala. § 7-2-313; Alaska Stat. § 45.02.313; A.R.S. § 47-2313; A.C.A. § 4-2-313; Cal. Comm. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. § 42a-2-313; 6 Del. C. § 2-313; D.C. Code § 28:2-313; Fla. Stat. § 672.313; O.C.G.A. § 11-2-313; H.R.S. § 490:2-313; Idaho Code § 28-2-313; 810 I.L.C.S. 5/2-313; Ind. Code § 26-1-2-313; Iowa Code § 554.2313; K.S.A. § 84-2-313; K.R.S. § 355.2-313; 11 M.R.S. § 2-313; Md. Commercial Law Code Ann. § 2-313; 106 Mass. Gen. Laws Ann. § 2-313; M.C.L.S. § 440.2313; Minn. Stat. § 336.2-313; Miss. Code Ann. § 75-2-313; R.S. Mo. § 400.2-313; Mont. Code Anno. § 30-2-313; Neb. Rev. Stat. § 2-313; Nev. Rev. Stat. Ann. § 104.2313; R.S.A. 382-A:2-313; N.J. Stat. Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.C. Gen. Stat. § 25-2-313; N.D. Cent. Code § 41-02-30; II. O.R.C. Ann. § 1302.26; 12A Okl. St. § 2-313; Or. Rev. Stat. § 72-3130; 13 Pa. Rev. Stat. § 72-3130; R.I. Gen. Laws § 6A-2-313; S.C. Code Ann. § 36-2-313; S.D. Codified Laws, § 57A-2-313; Tenn. Code Ann. § 47-2-313; Tex. Bus. + Com. Code § 2.313; Utah Code Ann. § 70A-2-313; 9A V.S.A. § 2- 313; Va. Code Ann. § 59.1-504.2; Wash. Rev. Code Ann. § 6A.2-313; W. Va. Code § 46-2-313; Wis. Stat. § 402.313; and Wyo. Stat. § 34.1-2-313.

63. Those statements became the basis of the bargains for Plaintiffs and the Class Members because they are factual statements that a reasonable consumer would consider material when purchasing a lidocaine product.

64. Defendant breached these express warranties by delivering Lidocaine Patches that: (1) systematically fail to adhere to its consumers' bodies well before 12 or 8 hours; (2) are insufficiently flexible to withstand moderate exercise and other regular activities (such as walking, stretching, and sleeping); and (3) fail to continuously relieve pain throughout the specified amount of time represented therein due to their partial or complete detachment. Furthermore, Defendant breached the express warranties of the Lidocaine Products because they do not contain or deliver the maximum amount of lidocaine available in the market; and are not superior, or at least equivalent, in efficacy and results to other over-the-counter and/or prescription-strength lidocaine products.

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

COUNT IV
Violation Of The Magnuson-Moss Warranty Act, 15 U.S.C. § 2301, *et seq.*
(On Behalf of Plaintiffs and the Class)

66. Plaintiffs incorporate by reference each of the allegations contained in the foregoing paragraphs of this Complaint as though fully set forth herein.

67. 15 U.S.C. § 2310(d) is satisfied because Plaintiffs properly invoke jurisdiction under the Class Action Fairness Act ("CAFA").

68. 15 U.S.C. § 2310(e) is satisfied because Plaintiffs provided Defendant a reasonable opportunity to cure the defects contained in the Lidocaine Products by sending Defendant a cure notice outlining those defects in full via certified mail.

69. 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.”

70. Defendant’s Lidocaine Products are consumer products as defined in 15 U.S.C. § 2301(1).

71. Plaintiffs and the Class Members are consumers as defined in 15 U.S.C. § 2301(3).

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

73. 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.”

74. Defendant provided Plaintiffs 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 Products’ packaging that they could deliver a “Maximum Strength” dose of lidocaine and that the Lidocaine Patches provide pain relief “Up to 12 Hours” or “Up to 8 Hours.”

75. Those statements became the basis of the bargains for Plaintiffs and the Class members because they are factual statements that a reasonable consumer would consider material when purchasing a lidocaine patch.

76. Defendant breached these express warranties by delivering Lidocaine Patches that: (1) systematically fail to adhere to its consumers' bodies well before 12 or 8 hours; (2) are insufficiently flexible to withstand moderate exercise and other regular activities (such as walking, stretching, and sleeping); and (3) fail to continuously relieve pain throughout the specified amount of time represented therein due to their partial or complete detachment. Furthermore, Defendant breached the express warranties of the Lidocaine Products because they do not contain or deliver the maximum amount of lidocaine available in the market; and are not superior, or at least equivalent, in efficacy and results to other over-the-counter and/or prescription-strength lidocaine products.

77. As a direct and proximate result of Defendant's breach of its express warranties, Plaintiffs and the Class Members have been damaged in an amount to be proven at trial.

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

78. Plaintiffs incorporate by reference each of the allegations contained in the foregoing paragraphs of this Complaint as though fully set forth herein.

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

80. 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 intent of New York's General Business Law § 349.

81. Plaintiffs and the New York Subclass Members are consumers who purchased the Lidocaine Products from Defendant for their personal use.

82. By the acts and conduct alleged herein, Defendant engaged in deceptive, unfair, and misleading acts and practices by representing on the packaging of the Lidocaine Products that they deliver a “Maximum Strength” dose of lidocaine and that the Lidocaine Patches provide pain relief “Up to 12 Hours” or “Up to 8 Hours.”

83. Despite those representations, however, the Lidocaine Patches: (1) systematically fail to adhere to its consumers’ bodies well before 12 or 8 hours; (2) are insufficiently flexible to withstand moderate exercise and other regular activities (such as walking, stretching, and sleeping); and (3) fail to continuously relieve pain throughout the specified amount of time represented therein due to their partial or complete detachment. Furthermore, none of the Lidocaine Products contain or deliver the maximum amount of lidocaine available in the market; and are not superior, or at least equivalent, in efficacy and results to other over-the-counter and/or prescription-strength lidocaine products.

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

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

86. As a result of Defendant’s deceptive practices, Plaintiffs and the New York Subclass Members suffered an economic injury because they would not have purchased (or paid a premium for) the Lidocaine Products had they known the veracity of Defendant’s misrepresentations and omissions.

87. On behalf of themselves and the New York Subclass Members, Plaintiffs seek to recover their actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees and costs.

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

88. Plaintiffs incorporate by reference each of the allegations contained in the foregoing paragraphs of this Complaint as though fully set forth herein.

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

90. Defendant violated New York General Business Law § 350 by representing on the packaging of the Lidocaine Products that they deliver a "Maximum Strength" dose of lidocaine and that the Lidocaine Patches provide pain relief "Up to 12 Hours" or "Up to 8 Hours."

91. Despite those representations, however, the Lidocaine Patches: (1) systematically fail to adhere to its consumers' bodies well before 12 or 8 hours; (2) are insufficiently flexible to withstand moderate exercise and other regular activities (such as walking, stretching, and sleeping); and (3) fail to continuously relieve pain throughout the specified amount of time represented therein due to their partial or complete detachment. Furthermore, none of the Lidocaine Products contain or deliver the maximum amount of lidocaine available in the market; and are not superior, or at least equivalent, in efficacy and results to other over-the-counter and/or prescription-strength lidocaine products.

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

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

94. As a result of Defendant's false advertising, Plaintiffs and the New York Subclass Members suffered an economic injury because they would not have purchased (or paid a premium for) the Lidocaine Products had they known the veracity of Defendant's misrepresentations and omissions.

95. On behalf of themselves and the New York Subclass Members, Plaintiffs seek to recover their actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees and costs.

COUNT VII
Violation of New York's Warranty Act, N.Y. U.C.C. § 2-313
(On Behalf of Plaintiffs and the New York Subclass)

96. Plaintiffs incorporate by reference each of the allegations contained in the foregoing paragraphs of this Complaint as though fully set forth herein.

97. Defendant's Lidocaine Products are goods as defined in N.Y. U.C.C. § 2-105(1).

98. Plaintiffs and the New York Subclass members are buyers as defined in N.Y. U.C.C. § 2-103(1)(a).

99. Defendant is a seller as defined in 15 N.Y. U.C.C. § 2-103(1)(d).

100. 15 N.Y. U.C.C. § 2-607 is satisfied because Plaintiffs provided Defendant a reasonable opportunity to cure the defects contained in the Lidocaine Products by sending Defendant a cure notice outlining those defects in full via certified mail.

101. N.Y. U.C.C. § 2-313 provides a cause of action to buyers when sellers breach express warranties.

102. On the Lidocaine Products' packaging, Defendant expressly warranted that its Lidocaine Products deliver a "Maximum Strength" dose of lidocaine and that the Lidocaine Patches provide pain relief "Up to 12 Hours" or "Up to 8 Hours."

103. Those statements became the basis of the bargains for Plaintiffs and the New York Subclass Members because they are factual statements that a reasonable consumer would consider material when purchasing a lidocaine product.

104. Defendant breached these express warranties by delivering Lidocaine Patches that: (1) systematically fail to adhere to its consumers' bodies well before 12 or 8 hours; (2) are insufficiently flexible to withstand moderate exercise and other regular activities (such as walking, stretching, and sleeping); and (3) fail to continuously relieve pain throughout the specified amount of time represented therein due to their partial or complete detachment. Furthermore, Defendant breached the express warranties of the Lidocaine Products because they do not contain or deliver the maximum amount of lidocaine available in the market; and are not superior, or at least equivalent, in efficacy and results to other over-the-counter and/or prescription-strength lidocaine products.

105. In so doing, Defendant breached N.Y. U.C.C. § 2-313.

106. As a direct and proximate result of Defendant's breach of its express written warranties, Plaintiffs and the New York Subclass Members have been damaged in an amount to be proven at trial.

PRAYER FOR RELIEF

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

(a) For an order certifying the Classes under Rule 23 of the Federal Rules of Civil

Procedure; naming Plaintiffs as representative of the Classes; and naming Plaintiffs' attorney as Class Counsel to represent the Classes;

(b) For an order finding in favor of Plaintiffs 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;

(f) For injunctive relief as pleaded or as the Court may deem proper; and

(g) For an order awarding Plaintiffs 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), Plaintiffs demand a trial by jury of any and all issues in this action so triable as of right.

Dated: April 21, 2023

Respectfully submitted,

GUCOVSKI ROZENSHTEYN, PLLC

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