IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

NICOLE SAPIENZA, on behalf of herself and all others similarly situated, Plaintiff, v. ALBERTSONS COMPANIES, INC., SHAW'S SUPERMARKETS, INC., SAFEWAY, INC., BETTER LIVING BRANDS, LLC, and LNK INTERNATIONAL, INC., Defendants.	Civil Action No.:

CLASS ACTION COMPLAINT

Jury Trial Demanded

Plaintiff Nicole Sapienza ("Plaintiff") brings this action on behalf of herself and all others similarly situated against Defendants Albertsons Companies, Inc., Shaw's Supermarkets, Inc., Safeway, Inc., Better Living Brands, LLC, and LNK International, Inc. (collectively, "Defendants" or "Albertsons"). Plaintiff makes the following allegations pursuant to the investigation of her counsel and based upon information and belief, except as to allegations specifically pertaining to herself and her counsel, which are based on personal knowledge.

NATURE OF THE ACTION

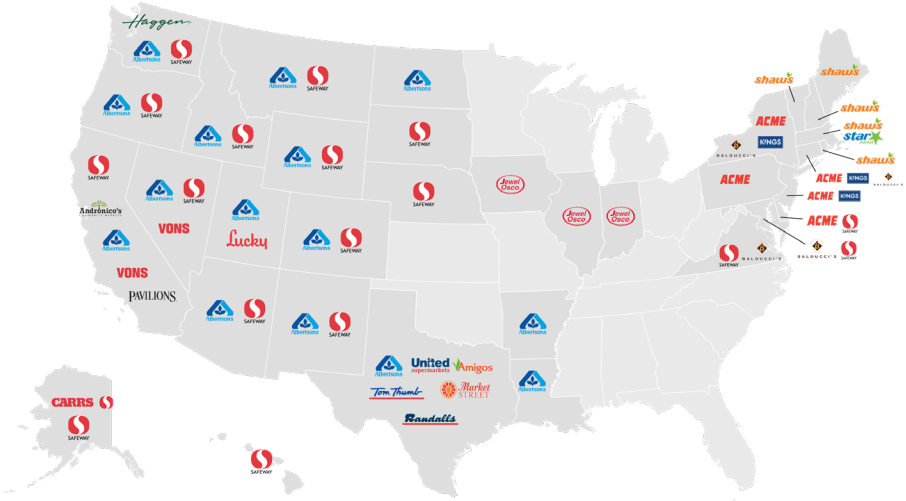
1. This is a putative class action lawsuit against Defendants for cheating customers by uniformly advertising, marketing, and selling generic versions of certain over-the-counter drugs, including analgesic or pain-relieving medicines using acetaminophen under the brand name "Signature Care" (the "Class Rapid Release Gelcaps" or the "Products"), prominently bearing the misrepresentation "Rapid Release" (the "Rapid Release Claims" or

"Misrepresentation"). However, contrary to Defendants' claims, the purported "Rapid Release" Products actually dissolve *slower* than Signature Care-branded non-rapid release acetaminophen products made and sold in tablet and caplet form.

2. Albertsons is the second largest supermarket chain in the United States.[1] As of February 2022, Albertsons "operated 2,276 retail stores … across 34 states and the District of Columbia with 24 banners including Albertsons, Safeway, Vons, Jewel-Osco, Shaw's, Acme, Tom Thumb, Randalls, United Supermarkets, Pavilions, Star Market, Haggen, Carrs, Kings Food Markets and Balducci's Food Lovers Market."[2] At each of these stores and banners, Defendants sell a variety of health and wellness products, including over-the-counter pharmaceuticals. Relevant here, in addition to selling brand name over-the-counter drugs, Defendants also produce, manufacture, market, distribute, and sell the Class Rapid Release Gelcaps.

[1] *See, e.g.*, Statista Research Department, *Revenues of Albertsons Companies U.S. 2020, by segment* (Jan. 27, 2022), https://www.statista.com/statistics/1167551/albertsons-revenue-by-segment-us/ ("As the second-largest supermarket chain in the North America, Albertsons generated retail sales and other revenues exceeding 69 billion U.S. dollars in 2020."); Statista Research Department, *Net sales of Albertsons Companies U.S. 2015-2020* (Jan. 27, 2022), https://www.statista.com/statistics/1167526/albertsons-net-sales-us/; *see also* Statista Research Department, *Albertsons Companies Statistics & Facts* (Jan. 24, 2022), https://www.statista.com/topics/6931/albertsons-companies/#dossierKeyfigures ("Today, Albertsons Companies operates over 2,270 stores throughout the United States and employs around 300,000 people, making it one of the largest supermarket chains in North America.").

[2] *Albertsons Companies, Inc. Reports Fourth Quarter and Full Year Results* (Apr. 12, 2022), *available at* https://www.albertsonscompanies.com/newsroom/press-releases/news-details/2022/Albertsons-Companies-Inc.-Reports-Fourth-Quarter-and-Full-Year-Results/default.aspx. *See also* Albertsons Companies, *Q4 2021 Latest Quarterly Results: Earnings Release Infographic* (Apr. 2022), *available at* https://s29.q4cdn.com/239956855/files/doc_financials/2021/q4/ALBCIV184062_CORP_ACI_InvestorRelations_April2022-FINAL.pdf; Albertsons Companies, *Company Fact Sheet* (Apr. 2022), *available at* https://s29.q4cdn.com/239956855/files/doc_downloads/2022/04/ALBCIV181099_CORP_ACI_FactSheet_FY2021_April2022-_-FINAL.pdf; Albertsons Companies, "Investors," *available at* https://www.albertsonscompanies.com/investors/overview/default.aspx.



3. In 2005, Johnson & Johnson Consumer Inc. introduced the name brand Tylenol® Extra Strength Rapid Release Gels to the American public, purporting that its "Gelcaps [] are specially designed with holes to allow [for] the release of powerful medicine *even faster than before*."[3] Three years later, in 2008, Tylenol® PM Rapid Release Gels were launched with the same promises.[4]

4. Relevant to these allegations, Tylenol® is the branded name for acetaminophen. In other words, acetaminophen is "generic Tylenol®."

[3] https://www.tylenol.com/news/about-us (last accessed May 5, 2022) (emphasis added).

[4] *Id*.

5. Defendants then introduced their own version of the Tylenol® Extra Strength Rapid Release Gels called "Signature Care Rapid Release Gelcaps:"[5]

[5] *See, e.g.*, https://www.acmemarkets.com/shop/product-details.960326318.html; https://www.albertsons.com/shop/product-details.960189576.177.html; https://www.safeway.com/shop/product-details.157050117.html.

6. Defendants also introduced their own version of the Tylenol® Extra Strength PM Rapid Release Gels called "Signature Care PM Rapid Release Gelcaps" (together with Signature Care Rapid Release Gelcaps, the "Class Rapid Release Gelcaps"):[6]

7. Since the release of the Class Rapid Release Gelcaps, Defendants have misled, and continue to mislead, consumers about the nature, quality, and effectiveness of the Products through their advertising and labeling. Specifically, Defendants market the Class Rapid Release Gelcaps as "comparable to Tylenol® Extra Strength Rapid Release Gels," even though they actually dissolve *slower* than Defendants' acetaminophen in traditional tablet and caplet form.

8. More importantly, following Tylenol's lead, Defendants prominently label every Product sold in the United States as "Rapid Release" Gelcaps.

9. But Defendants' Rapid Release Claims concerning the Products are false, misleading, and deceptive to consumers, who reasonably understand such claims to mean that the Products work faster for consumers than non-rapid release products with the same active ingredients and of the same dosage. However, despite what Defendants' marketing and labeling

[6] *See, e.g.*, https://www.acmemarkets.com/shop/product-details.960019790.html; https://www.albertsons.com/shop/product-details.960019790.html; https://www.safeway.com/shop/product-details.960171151.html.

would have consumers believe, the Class Rapid Release Gelcaps do not provide faster pain relief than their non-rapid release counterparts.

10. In fact, independent testing conducted by Valisure, LLC ("Valisure")[7] demonstrates that the Class Rapid Release Gelcaps dissolve *slower* than the Signature Care-branded non-rapid release acetaminophen products made and sold in caplet form. A true and correct copy of these test results is attached hereto as **Exhibit A**.

11. These test results are consistent with the findings of a 2018 study – also conducted by Valisure – which demonstrates that generic acetaminophen rapid release gelcaps sold by Walgreens, Walmart, and Rite Aid dissolve slower than these companies' non-rapid release versions of acetaminophen sold in tablet or caplet form.[8] "Results [of the study] indicate that acetaminophen gelcaps marketed as rapid or fast-release are slower acting under *in vitro* dissolution conditions compared to the company-matched tablet dose."[9] A true and correct copy

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[7] Valisure is an "independent laboratory and partner for quality that is committed to increasing transparency and quality assurance throughout the healthcare industry." https://www.valisure.com/#Independent-Analysis. In service of that mission, Valisure "offers independent certification, analytical studies and advocacy, vendor validation, consulting and other specialty projects that focus on science-based product quality." *Id.*; *see also* "About Us," https://www.valisure.com/about ("In response to rising concerns and quality issues in the global supply chain, Valisure's team of Harvard- and Yale-trained scientists developed proprietary analytical technologies to independently test products, identify critical issues, and offer services to help distinguish quality stakeholders and products.").

[8] *See* Jessop Kucera, et al., *Rapid and Fast-Release Acetaminophen Gelcaps Dissolve Slower Than Acetaminophen Tablets*, ADV. INV. PHA. THE. MEDIC., 1:63-71 (Nov. 12, 2018) [hereinafter "2018 Valisure Acetaminophen Study"], *available at* http://www.kenkyugroup.org/article/8/173/Rapid-and-Fast-Release-Acetaminophen-Gelcaps-Dissolve-Slower-Than-Acetaminophen-Tablets; *see also* Washington Post, *'Rapid release' Tylenol gelcaps are slower to dissolve than cheaper tablets, study finds* (Nov. 14, 2018), https://www.washingtonpost.com/health/2018/11/14/rapid-release-tylenol-gelcaps-are-slower-dissolve-than-cheaper-tablets-study-finds/.

[9] 2018 Valisure Acetaminophen Study; *see also id.* ("To better understand the influence of gelatin coatings on gelcap dissolution, four gelcaps from each of the twenty-five lots tested during the primary study (n = 100) were examined with their red and blue encapsulation removed. … Results suggest that the removal of a gelcap's red and blue coating speeds up, on average, the time required for fully dissolving by 26%. This faster dissolution time suggests that gelcaps are a barrier for dissolution.") (emphasis added) (internal citations omitted); *id.* ("The results of the study suggest that acetaminophen gelcaps packaged with marketed claims of rapid or fast-release tend to dissolve slower than tablets of identical dosage sold by the same company."); *id.* ("Our results suggest that the gelatin coating added to rapid or fast-release gelcaps delays in vitro release of medication.").

of the 2018 Valisure Acetaminophen Study is attached hereto as **Exhibit B**.

12. Defendants have long known or should have known that traditional, non-rapid release acetaminophen products can be equally effective in the same, if not faster, in the same time period than the Class Rapid Release Gelcaps.

13. Nevertheless, Defendants sell the Class Rapid Release Gelcaps as an alternative to their traditional Signature Care-branded acetaminophen caplets, which are sold at a lower price and do not contain the "rapid release" language on the label. In other words, Defendants charge a premium for the Class Rapid Release Gelcaps.[10]

14. By prominently featuring the Rapid Release Claims on the labeling and/or packaging of the Class Rapid Release Gelcaps, Defendants intended to induce consumers to pay more than they would pay for other comparable products that are not falsely labeled with Rapid Release Claims, and consumers are so induced as a result of these claims.

15. Defendants knew or should have known about the mislabeling. According to Shane Sampson, Defendants' Chief Marketing and Merchandising Officer, "[a]t Albertsons Companies, we won't put our Signature label on just anything; a product has to meet rigorous quality standards and be an exceptional value to carry the Signature brand."[11] Additionally, Defendants claim that "[a]ll our stores—no matter under which banner they operate—were founded on the philosophy of offering customers the products they want at a fair price[.]"[12]

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[10] *See infra*. *See also* Ex. B, 2018 Valisure Acetaminophen Study, *supra* ("These rapid or fast-release labeled medications are sold at an average of a 23% higher price[.]"); Washington Post, *'Rapid release' Tylenol gelcaps are slower to dissolve than cheaper tablets, study finds* (Nov. 14, 2018) ("Overall, the rapid-release gels carried a 23 percent higher price than the tablets[.]").

[11] Business Wire, *Signature Offers a Wide Range of Quality Products Helping Customers Create Their Own Signature Moments with Pride* (Apr. 4, 2016), *available at* https://www.businesswire.com/news/home/20160404005193/en/Albertsons-Companies-Introduces-the-New-Signature-Family-of-Brands (internal quotation marks omitted).

[12] https://www.shaws.com/about-us.html.

16. Plaintiff and members of the putative Class and Subclass would not have purchased the Class Rapid Release Gelcaps had Defendants disclosed accurate information about the products and not misled them into believing that the Class Rapid Release Gelcaps would provide faster relief than other, cheaper acetaminophen products, such as the traditional Signature Care non-rapid release acetaminophen sold in caplet and tablet form.

17. Plaintiff brings this suit to now end Defendants' deceptive practices as described above and to recover the ill-gotten gains obtained by Defendants through this deception.

18. For the foregoing reasons, Plaintiff brings this action individually and on behalf of similarly situated individuals against Defendants for: (i) violation of the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A, *et seq*.; (ii) breach of express warranty; (iii) breach of the implied warranty of merchantability; (iv) unjust enrichment / restitution; (v) negligent misrepresentation; and (vi) fraud.

THE PARTIES

19. Plaintiff Nicole Sapienza is a natural person and a citizen of Massachusetts who resides in Newton, Massachusetts. In or around January 2022, and before then about once a year during the Class Period, Plaintiff Sapienza purchased the Signature Care Rapid Release Acetaminophen Gelcaps from a Shaw's Supermarkets brick-and-mortar retail store located in Waltham, Massachusetts. Prior to her purchases, Plaintiff Sapienza reviewed the labeling, packaging, and marketing materials for the Products and saw the Misrepresentations that the Product contains acetaminophen in the form of purportedly "Rapid Release" gelcaps. Plaintiff Sapienza relied on that labeling and packaging to choose the Product over less expensive, non-rapid release counterparts of the same dosage. Plaintiff Sapienza saw these Rapid Release Claims prior to and at the time of purchase, and she understood them as representations and

warranties by Defendants that the Products release acetaminophen into the body faster and thus provide quicker pain relief than non-rapid release products with the same active ingredients and of the same dosage. Based on that understanding, Plaintiff Sapienza purchased the Products because she believed that the Gelcaps would work faster than their non-rapid release tablet and caplet counterparts and specifically sought the fastest pain relief available. Plaintiff Sapienza therefore reasonably relied on Defendants' Rapid Release Claims when she purchased her Products. Accordingly, these representations and warranties were part of the basis of the bargain, in that Plaintiff Sapienza would not have purchased the Products on the same terms had she known these representations were not true. In making her purchases, Plaintiff Sapienza paid a substantial price premium due to the false and misleading Rapid Release Claims. However, Plaintiff Sapienza did not receive the benefit of her bargain, because Defendants' purportedly "Rapid Release" Products do not, in fact, work faster than their less expensive, non-rapid release counterparts in caplet or table form containing acetaminophen in the same dosage.

20. Defendant Albertsons Companies, Inc. ("ACI") is a Delaware corporation with its principal place of business and headquarters at 250 Parkcenter Blvd, Boise, Idaho 83706. As "one of the largest food and drug retailers in the United States,"[13] ACI owns and operates more than 2,200 retail stores across the country under 24 different banners, including Albertsons and Safeway.[14] In addition, in 2016, ACI launched "its new store brand, Signature, the largest

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[13] *See* Albertsons Companies, "Investors," *available at* https://www.albertsonscompanies.com/investors/overview/default.aspx. *See also* Albertsons Companies, Inc., Form S-1/A (Jun. 10, 2020), https://sec.report/Document/0001193125-20-165122/ ("We hold a #1 or #2 position by market share in 68% of the 121 metropolitan statistical areas ("MSAs") in which we operate. … We believe this local market presence, coupled with brand recognition, drives repeat traffic and helps create marketing, distribution and omni-channel efficiencies that enhance our profitability.").

[14] On information and belief, Defendant ACI controls the marketing and pricing practices of the more than 2,200 ACI-owned retail stores located throughout the United States, and all banners under which those stores operate. *See, e.g.*, Albertsons Companies, Inc., 2021 Annual Report (Form 10-K), at 8-9, *available at* https://annualreport.stocklight.com/NYSE/ACI/21864714.pdf ("Our retail operating divisions are geographically based, have similar economic characteristics and similar expected long-term financial performance. … Across all

private label across [its more than 2,200] stores."[15] The Signature line "is exclusive to Albertsons Companies and is carried by all [of its] banners."[16] Relevant here, ACI owns and operates the "Signature Care" brand, the health products segment of ACI's Signature label, and it manufactures, labels, sells, and distributes all Signature Care-branded products to consumers in Massachusetts and throughout the United States, including the Class Rapid Release Gelcaps, which are generic versions of pain-relieving medicines sold under the Signature Care brand name. ACI is also responsible for in-store signage, promotion, advertisement, and marketing of the Class Rapid Release Gelcaps, and it owns and operates the websites for Shaw's, Albertsons, Safeway, and all other ACI banner stores. At all relevant times, acting alone or in concert with others, ACI has done business in Massachusetts and throughout the United States. At all

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operating segments, the Company operates primarily one store format. Each division offers, through its stores and digital channels, the same general mix of products with similar pricing to similar categories of customers, have similar distribution methods, operate in similar regulatory environments and purchase merchandise from similar or the same vendors. … Our marketing efforts involve collaboration between our national marketing and merchandising team and local divisions and stores. We augment the local division teams with corporate resources and are focused on providing expertise, sharing best practices and leveraging scale in partnership with leading consumer packaged goods vendors. … We have recently deployed and are continuing to refine cloud-based enterprise solutions to quickly process proprietary customer, product and transaction data and efficiently provide our local managers with targeted marketing strategies for customers in their communities. By leveraging customer and transaction information with data driven analytics, our 'personalized deal engine' is able to select, out of the thousands of different promotions offered by our suppliers, the offers that we expect will be most compelling to each of our more than 30 million weekly customers. In addition, we use data analytics to optimize shelf assortment and space in our stores[.]"); *see also* Albertsons Companies, Inc., Form S-1/A (Jun. 10, 2020), https://sec.report/Document/0001193125-20-165122/ ("We have integrated systems and converted stores and distribution centers to create a common platform. We believe our common platform gives us greater transparency and compatibility across our network, allowing us to better serve our customers and employees while enhancing our supply chain. We continue to sharpen our in-store execution, increase our Own Brands penetration and expand our omni-channel and digital capabilities.").

[15] Business Wire, *Signature Offers a Wide Range of Quality Products Helping Customers Create Their Own Signature Moments with Pride* (Apr. 4, 2016), *available at* https://www.businesswire.com/news/home/20160404005193/en/Albertsons-Companies-Introduces-the-New-Signature-Family-of-Brands ("Signature is a multi-category brand developed to address consumers' growing appetite for quality private label products from stores they trust. … Albertsons Companies has created quality items for the Signature brand across six product sectors – **Signature SELECT™**, **Signature Kitchens™**, **Signature Farms™**, **Signature Cafe®**, **Signature Home™**, and **Signature Care™**. The line includes a wide assortment of pantry staples, prepared foods, fresh produce and ingredients that bring delight to any dish, as well as a broad range of paper goods, laundry products, personal care, and other items.") (bolding in original; underlining added for emphasis).

[16] *Id*.

relevant times, acting alone or in concert with others, ACI advertised, marketed, sold, and distributed the Class Rapid Release Gelcaps to consumers in Massachusetts and throughout the United States. Further, acting alone or in concert with others, ACI has, at all relevant times, formulated, directed, controlled, had the authority to control, and/or participated in the acts and practices set forth in this Complaint.

21. Defendant Shaw's Supermarkets, Inc. ("Shaw's") is a Massachusetts corporation with its principal place of business and headquarters located in Boise, Idaho. Shaw's is a subsidiary of Defendant ACI. Shaw's is a supermarket chain that sells grocery items, food, and general merchandise to consumers regionally, including the Class Rapid Release Gelcaps. Shaw's, which is "one of the oldest continuously-operated supermarkets in the US[,]"[17] "operates 150 [brick-and-mortar] stores throughout New England" under the Shaw's and Star Markets banners as "part of [ACI's] 2,200+ store operation[.]"[18] Of those 150 stores, Shaw's maintains 55 retail locations in Massachusetts (including the Waltham, MA location where Plaintiff purchased her Products). Shaw's sells Signature Care-branded products to consumers in Massachusetts and throughout the United States, including the Class Rapid Release Gelcaps. Shaw's is also responsible for the in-store signage, promotion, advertisement, and marketing of the Class Rapid Release Gelcaps. Additionally, at all relevant times, acting alone or in concert with others, Shaw's advertised, marketed, sold, and distributed the Class Rapid Release Gelcaps to consumers in Massachusetts and throughout the United States. Acting alone or in concert with others, Shaw's formulated, directed, controlled, had the authority to control, and/or participated

[17] https://www.dnb.com/business-directory/company-profiles.shaws_supermarkets_inc.35dc9f909975b474fbc94b9358bf5c48.html.

[18] https://www.shaws.com/about-us.html; *see also* https://www.dnb.com/business-directory/company-profiles.shaws_supermarkets_inc.35dc9f909975b474fbc94b9358bf5c48.html.

in the acts and practices set forth herein.

22. Defendant Safeway, Inc. ("Safeway") is a Delaware corporation with its principal place of business and headquarters located in Pleasanton, California. Safeway is a wholly owned subsidiary of, and "operates as a banner of [, ACI], one of the largest food and drug retailers in the United States."[19] Safeway sells grocery items, food, and general merchandise to consumers regionally, and it provides a variety of specialty departments, such as bakery, delicatessen, floral and pharmacy. Together with Defendant ACI, Safeway owns and operates the "Signature Care" trademark. Acting alone or in concert with others, Safeway formulated, directed, controlled, had the authority to control, and/or participated in the acts and practices set forth herein.

23. Defendant Better Living Brands, LLC ("BLB") is a limited liability company organized under Delaware law with its principal place of business and headquarters located in Pleasanton, California 94566. BLB is a wholly owned subsidiary of Defendant Safeway. At all relevant times, BLB, acting alone or in concert with others, has manufactured, marketed, and distributed Signature Care-branded products, including the Class Rapid Release Gelcaps, to consumers in Massachusetts and throughout the United States. Indeed, BLB is listed as the labeler of some or all of the Class Rapid Release Gelcaps directly on the Products' labeling.

24. Defendant LNK International, Inc. ("LNK") is a New York for-profit corporation with its principal place of business and headquarters located at 22 Arkay Drive, Hauppauge, New York 11788. LNK is "one of the nation's largest manufacturers of solid and liquid dose, over-the-counter (OTC) pharmaceuticals."[20] LNK's operation includes providing, among other things, laboratory services, manufacturing services, packaging services, and marketing services

[19] https://www.safeway.com/about-us.html.

[20] https://www.lnkintl.com/.

for store brands like Signature Care.[21] Relevant here, LNK, acting alone or in concert with others, manufactures, designs, labels, markets, and/or supplies the Class Rapid Release Gelcaps to consumers in Massachusetts and throughout the United States.

25. Together, Defendants ACI, Shaw's, Safeway, BLB, and LNK (collectively, "Defendants") manufacture and distribute all Signature Care-branded products, including the Class Rapid Release Gelcaps, which are generic versions of pain-relieving medication sold under the Signature Care brand name exclusively at ACI banner stores. Defendants are also responsible for the promotion, advertisement, marketing, and distribution of the Products in Massachusetts and throughout the United States. Further, Defendants sell, and at all relevant times have sold, the Class Rapid Release Gelcaps to consumers in Massachusetts and throughout the United States. Defendants have thus transacted in Massachusetts and throughout the United States at all times during the Class Period.

26. Plaintiff reserves the right to amend this Complaint to add different or additional defendants, including without limitation any officer, director, employee, supplier, or distributor of Defendants who has knowingly and willfully aided, abetted, and/or conspired with them in the false and deceptive conduct alleged herein.

JURISDICTION AND VENUE

27. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d)(2)(A), as amended by the Class Action Fairness Act of 2005 ("CAFA"), because this case is a class action where the aggregate claims of all members of the proposed class are in excess of $5,000,000.00, exclusive of interest and costs, there are over 100 members of the putative class, and there is at least minimal diversity in that Plaintiff, as well as most members of the proposed

[21] *See* https://www.lnkintl.com/our-operation; https://www.lnkintl.com/about-lnk.

class, is a citizen of a state different from most Defendants.

28. This Court has personal jurisdiction over Defendants have, at all times relevant hereto, sufficient minimum contacts with this state and District in that they have systematically and continually conducted business in Massachusetts, including within this District, and/or have intentionally availed themselves of the benefits and privileges of the Massachusetts consumer market through the promotion, marketing, and sale of their products and/or services to residents within this District and throughout Massachusetts. Plaintiff Sapienza is also citizen of Massachusetts, purchased the Class Rapid Release Gelcaps from Defendants while in Massachusetts, and submits to the jurisdiction of the Court.

29. Pursuant to 28 U.S.C. § 1391, this Court is the proper venue for this action because a substantial part of the events, omissions, and acts giving rise to the Plaintiff's claims occurred in this District. Also, Plaintiff resides in this District and purchased the Class Rapid Release Gelcaps from Defendants from a brick-and-mortar Shaw's retail location in this District. Moreover, Defendants systematically conduct business in this District and throughout the State of Massachusetts, and they distributed, advertised, and sold the Class Rapid Release Gelcaps to Plaintiff and other members of the proposed Nationwide Class and Massachusetts Subclass in this State and District.

FACTUAL ALLEGATIONS

A. Acetaminophen, Generally

30. Acetaminophen, also called paracetamol or N-acetyl-para-aminophenol (APAP), is an over-the-counter pain reliever and fever reducer that comes in a variety of forms: liquid suspension, capsules, tablets (including "caplets," *i.e.*, capsule-shaped tablets), and gelcaps.[22]

[22] *See* Ex. B, 2018 Valisure Acetaminophen Study, *supra*.

31. In any form, acetaminophen is used to treat a variety of common conditions including headaches, muscle aches, arthritis, backaches, toothaches, colds, fevers, acute pain, chronic pain, etc.[23] Typically, it is the first treatment recommended for any mild to moderate pain. Therefore, acetaminophen is one of the most commonly used drugs in the world when it comes to pain mitigation, representing an estimated global market value of over $350 million annually.[24] It is even included on the World Health Organization List of Essential Medicines.[25]

32. Given the wide-spread use of acetaminophen, both the *quality* and *value* of acetaminophen products present important public health, consumer safety, and economic concerns.[26]

B. Defendants Seek To Capitalize Off Of Johnson & Johnson's Successful "Tylenol"-Brand Acetaminophen Products By Creating Generics

33. Tylenol® is the well-recognized brand name of acetaminophen that is produced, manufactured, and distributed by Johnson & Johnson.

34. Johnson & Johnson currently lists 34 Tylenol® products on its Tylenol® website, including: 1 non-medicative device, 13 liquid products, 1 chewable product, 1 tablet product, 1 coated tablet product, 13 caplet products, and 2 gelcap products.[27] All but two of the 34 products contain acetaminophen.[28] Johnson & Johnson has profited and continues to profit greatly from this Tylenol® product line.

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[23] *See, e.g.*, https://www.drugs.com/acetaminophen.html; https://www.mayoclinic.org/chronic-pain-medication-decisions/art-20360371.

[24] *See* Ex. B, 2018 Valisure Acetaminophen Study, *supra.*

[25] World Health Organization ("WHO"), *Model List of Essential Medicines* (Aug. 2017 ed.), http://www.who.int/medicines/publications/essentialmedicines/en/2017.

[26] *See* Ex. B, 2018 Valisure Acetaminophen Study, *supra*.

[27] https://www.tylenol.com/products (last accessed May 5, 2022).

[28] *Id*. SmartCheck™ Digital Ear Scope From Children's Tylenol® (an at-home digital ear scope containing no medication) and Tylenol® PM Simply Sleep Nighttime Sleep Aid do not contain acetaminophen.

35. Generic brands, like Signature Care, thus seek to mimic the product offerings of Johnson & Johnson, selling generic versions of the Tylenol® products. Indeed, Defendants have done this with respect to several Tylenol® products, mimicking the Tylenol® Extra Strength Rapid Release gels.

C. The Marketing Of Rapid Release Acetaminophen

36. Johnson & Johnson introduced Tylenol® Extra Strength Rapid Release Gels in 2005, claiming that these rapid release gelcaps are "specially designed…to allow the release of powerful medicine *even faster than before*."[29] In 2008, Tylenol® PM Rapid Release Gels launched utilizing the same "rapid release" technology and the same or similar advertising.[30] Thus, this claim – that these rapid release gelcaps worked even faster than before – became associated with the regular and PM versions of Tylenol® Extra Strength Rapid Release Gels.

37. Then, in 2009, Tylenol's rapid release gels were recalled and were not re-released until 2017.[31] "The national return to the market of the rapid release gels represented Tylenol's biggest product launch in years" and, thus, the marketing campaign "involved triple the investment" that Johnson & Johnson would normally spend all to encourage consumers to find "fast working pain relief."[32] "In the first month, [the campaign] reached over 25 million shoppers on their mobile devices across five key markets, resulting in both category and Tylenol share growth at Walgreens."[33] Consumers were inundated with the campaign messaging in

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[29] https://www.tylenol.com/news/about-us (last accessed May 5, 2022) (emphasis added).

[30] *Id*.

[31] Consumer Goods Technology, *Headache Sufferers Directed to Walgreens* (Jun. 1, 2017), https://consumergoods.com/headache-sufferers-directed-walgreens (last accessed Jan. 27, 2021).

[32] *Id*.

[33] *Id*.

stores and online.[34]

38. In its marketing, Johnson & Johnson used buzz words that emphasized the speed, fast-acting nature, and unique laser-drilled holes of the rapid release gelcaps. For example, Johnson & Johnson advertised that "only Tylenol rapid release gels have laser-drilled holes" and claimed that they "release medicine fast for fast pain relief" and that the product supposedly "works at the speed of life."

39. This marketing campaign has been successful in getting the public to believe that the rapid release gelcaps are faster acting than traditional formulations, when in fact they may be slower in certain circumstances – such as the formulation sold by Defendants. Consumer reviews and comments indicate that consumers have been deceived and confused by these representations; and some even notice after purchase that certain "rapid release" gelcaps do not work faster than regular, non-rapid release formulations.

D. Defendants' False, Misleading, Unfair, And Deceptive Marketing, Labeling, And Sale Of The Signature Care Rapid Release Gelcaps

40. Numerous companies, including Defendants, have followed Johnson & Johnson's lead with respect to the labeling, marketing, advertising, and pricing of their acetaminophen products, including the Products at issue in this case. Now, in general, acetaminophen gelcap products labeled, advertised, or marketed as "rapid release," "fast-release," or the like, are sold on average at a price 23% higher than those traditional acetaminophen products sold in caplet or tablet form that do not make any Rapid Release Claims.

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[34] *Id*. ("In stores, shoppers found Tylenol messaging at every turn, from displays in-aisle to endcaps to the pharmacy counter to checkout. In 3,200 Walgreens stores, motion-activated video units installed for the campaign featured a 15-second video spot customized for the retailer. The video unit and off-shelf placement remained for six months. * The spot also ran for 12 weeks on YouTube, demonstrating how the laser-drilled gelcaps release medicine quickly for fast relief. The launch also was supported via Walgreens.com, email blasts, the retailer's Facebook page, a Google campaign, FSIs and paid search.").

41. As noted above, Defendants are, collectively, one such entity that followed Johnson & Johnson's lead. Defendants sell their Class Rapid Release Gelcaps at a higher price than their other, faster acting acetaminophen products not featuring the Rapid Release Claims.

42. Defendants currently list 5 Class Rapid Release Gelcap products on their websites, including: Signature Care Extra Strength Acetaminophen Rapid Release Gelcaps in quantities of 24, 100, and 225 gelcaps; and Signature Care Extra Strength PM Acetaminophen Gelcaps in quantities of 20 and 80 gelcaps.[35] Additionally, Defendants' websites currently show that they sell 9 traditional acetaminophen products at the same dosage (500 mg) that do not feature the Rapid Release Claims, including: Signature Care Extra Strength Acetaminophen Caplets in quantities of 24, 50, 100, 150, 250, and 500 caplets; and Signature Care Extra Strength PM Acetaminophen Caplets in quantities of 24, 100, and 200 caplets.[36]

43. A comparison of the average unit market price of the Class Rapid Release Gelcaps and the traditional Signature Care-branded acetaminophen caplets of the same dosage demonstrates that Defendants charge more for the Class Rapid Release Gelcaps than their equivalent non-rapid release acetaminophen products. For example, out of all products currently in stock and listed on the Shaw's website – specifically, taking into consideration all Class Rapid

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[35] *See, e.g.*, https://www.shaws.com/shop/search-results.html?q=signature%20care%20gelcap; https://www.albertsons.com/shop/search-results.html?q=signature%20care%20gelcaps; https://www.safeway.com/shop/search-results.html?q=signature%20care%20rapid%20release%20gelcap; *see* https://www.acmemarkets.com/shop/search-results.html?q=signature%20care%20gelcap.

[36] *See, e.g.*, https://www.shaws.com/shop/search-results.html?q=signature%20care%20pain%20relief%20acetaminophen%20extra%20strength%20caplets; https://www.albertsons.com/shop/search-results.html?q=signature%20care%20pain%20relief%20acetaminophen%20extra%20strength%20caplets; https://www.safeway.com/shop/search-results.html?q=signature%20care%20pain%20relief%20acetaminophen%20extra%20strength%20caplets; https://www.acmemarkets.com/shop/search-results.html?q=signature%20care%20pain%20relief%20acetaminophen%20extra%20strength%20caplets.

Release Gelcaps[37] and all traditional non-rapid release caplets[38] (including PM acetaminophen gelcap and caplet products) – the average regular price of a single gelcap is approximately $0.17 per unit, whereas the average regular price of a single caplet is approximately $0.12 per unit, for a price differential of about 5 cents per unit. Likewise, at Safeway, the average regular price of a single gelcap is approximately $0.19 per unit, whereas the average price of a single caplet is approximately $0.16 per unit, for a price differential of almost 3 cents per unit. Thus, based on average unit price, the Class Rapid Release Gelcaps are more expensive as the traditional non-rapid release caplets of the same.

44. The price premium attributable to Defendants' Rapid Release Claims is also reflected by comparison of the market prices of the Class Rapid Release Gelcaps and the traditional Signature Care-branded acetaminophen products sold in caplet form of the same dosage and quantity. For instance, currently at Albertsons, a regularly priced 100-count bottle of Signature Care Extra Strength Acetaminophen Rapid Release Gelcaps costs $11.49[39] (about $0.11 per unit), while a regularly priced 100-count bottle of Signature Care Extra Strength Acetaminophen caplets costs $5.99[40] (about $0.06 per unit). Thus, with respect to the 100-count bottles, there is a $5.50 price difference between the Class Rapid Release Gelcaps and the non-rapid release Signature Care products sold at Albertsons, a difference of approximately 5 cents

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[37] *See* https://www.shaws.com/shop/product-details.960189576.html; https://www.shaws.com/shop/product-details.157050117.html; https://www.shaws.com/shop/product-details.960326318.html; https://www.shaws.com/shop/product-details.960171151.html; https://www.shaws.com/shop/product-details.960019790.html (last accessed Jun. 2, 2022).

[38] *See* https://www.shaws.com/shop/product-details.157050019.html; https://www.shaws.com/shop/product-details.157050035.html; https://www.shaws.com/shop/product-details.157050006.html; https://www.shaws.com/shop/product-details.960171152.html; https://www.shaws.com/shop/product-details.157050030.html; https://www.shaws.com/shop/product-details.157050042.html; https://www.shaws.com/shop/product-details.960189578.html; https://www.shaws.com/shop/product-details.960189579.html; https://www.shaws.com/shop/product-details.960189580.html (last accessed Jun. 2, 2022).

[39] *See* https://www.albertsons.com/shop/product-details.157050117.html (last accessed June 2, 2022).

[40] *See* https://www.albertsons.com/shop/product-details.157050006.html (last accessed June 2, 2022).

per unit. Likewise, currently at Safeway, a regularly priced 100-count bottle of Signature Care Extra Strength Acetaminophen Rapid Release Gelcaps costs $10.99[41] (about $0.11 per unit), while a regularly priced 100-count bottle of Signature Care Extra Strength Acetaminophen caplets costs $7.99[42] (about $0.08 per unit), a price difference of $3.00 per product or approximately 3 cents per unit.

45. Thus, the Class Rapid Release Gelcaps are more expensive than the non-rapid release Signature Care products, even though independent testing commissioned by Plaintiff's counsel reveals that the Class Rapid Release Gelcaps are, in reality, *slower* acting compared to the Signature Care-brand caplet and tablet doses. *See* Ex. A.

46. Yet, consumers are willing to pay this price premium because, as a result of Defendants' false, misleading, unfair, and/or deceptive labeling concerning Rapid Release Claims (and other related advertising), they believe the Class Rapid Release Gelcaps work faster than other, cheaper acetaminophen products when in fact, they do not.

47. As a generic brand of acetaminophen, Defendants introduced the Class Rapid Release Gelcaps under the Signature Care brand name as counterparts to the Tylenol® products, but only after the public had already become familiar with the Tylenol® versions. Thus, with respect to the Class Rapid Release Gelcaps, Defendants relied on Johnson & Johnson's massive marketing campaigns and the success of its rapid release products before entering the market, thereby reaping the benefits of Johnson & Johnson's marketing efforts while avoiding the substantial investment capital associated with such efforts.

48. One way in which Defendants did this was by producing the Class Rapid Release

[41] *See* https://www.safeway.com/shop/product-details.157050117.html.

[42] *See* https://www.safeway.com/shop/product-details.157050006.html.

Gelcaps to look the same as or substantially similar to their counterpart Tylenol® rapid release products. Indeed, Defendants' extra strength, non-PM "Rapid Release" acetaminophen gelcaps are approximately the same size and shape as the Tylenol® products, and utilize the same distinct color pattern: red on one end, blue on the other end, and a bit of white in the middle. Thus, by the time Defendants entered the market with the Class Rapid Release Gelcaps, consumers were already accustomed to the look of the Tylenol® rapid release products and familiar with the claims that they were fast-acting.

49. Defendants did nothing to correct the perception that their "rapid release" gelcaps worked faster than other, cheaper acetaminophen products. Instead, Defendants capitalized on that thinking and sought to further consumer deceit by adding their own prominent false, misleading, unfair, and/or deceptive Rapid Release Claims to the labeling and packaging of the Class Rapid Release Gelcaps. Defendants also explicitly liken the Class Rapid Release Gelcaps to their Products' Tylenol® counterparts on the Products' labeling and packaging and in other marketing materials for the Products.

50. Consumers purchase the Signature Care Class Rapid Release Gelcaps because they are labeled "rapid release," which they reasonably understand to mean that the Products are faster-acting than Defendants' non-rapid release Signature Care-branded acetaminophen product in caplet and tablet forms, and because they are cheaper than their Tylenol® rapid release counterparts.

E. Independent Lab Testing Demonstrates The Labeling And Marketing Of The Class Rapid Release Gelcaps Are False, Misleading, Unfair, And/Or Deceptive

51. Notwithstanding Defendants' claims to the contrary regarding the Class Rapid Release Gelcaps, they do not work faster than other, cheaper non-rapid release Signature Care acetaminophen products sold in tablet and/or caplet form. Rather, as shown in the images below,

independent testing commissioned by Plaintiff's counsel revealed that the Products not only fail to work faster, they actually work slower than their traditional acetaminophen caplet counterparts:

Figure: Dissolution shown as a proportion of label claim acetaminophen (500 mg) released into solution over time shown in minutes (min). Red is caplet (lot 1ME1938) data and blue is gelcap (lot P126037) data.

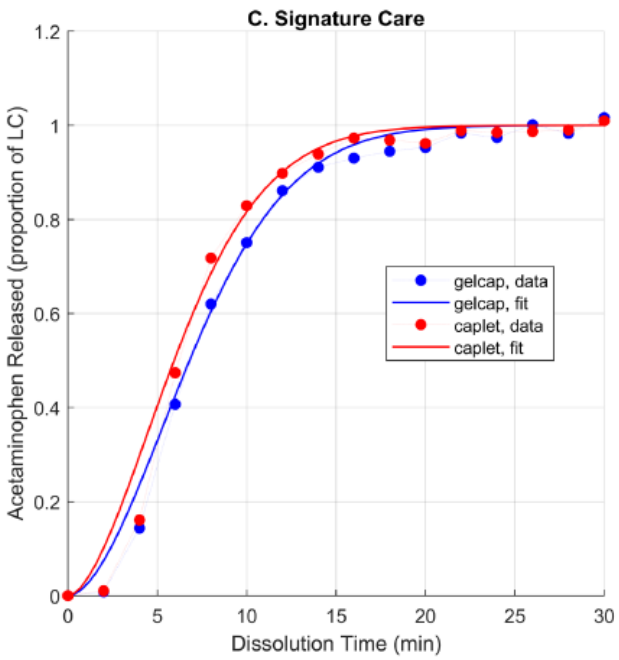

Table: Time (minutes) for 75-95% dissolution by product.

	Brand:	Signature Care	
	Lot:	P126037	1ME1938
	Description:	gelcap	caplet
Percent dissolved	75%	10.0	8.9
	80%	10.9	9.7
	85%	12.0	10.7
	90%	13.3	12.0
	95%	15.5	14.0

Ex. A.

52. These results are consistent with the 2018 Valisure Acetaminophen Study, in which Valisure investigated "rapid release" or "fast release" medications from five major U.S. companies selling acetaminophen (Rite Aid, Walgreens, CVS, Johnson & Johnson Tylenol, and Walmart Equate), compared to company-matched tablets that do not have claims of rapid or fast-release characteristics. *See* Ex. B. Valisure did this through dissolution testing, which is commonly used in the pharmaceutical industry to test the quality and effectiveness of drug release from solid oral medications. *Id*. Ultimately, Valisure's 2018 testing revealed that, like the Class Rapid Release Gelcaps at issue in this case, the "rapid release" gelcap products not only failed to work faster than the company-matched tablet dose, but in fact the gelcaps actually worked *slower* than their non-rapid release counterparts.[43] *Id*.

53. Thus, the science demonstrates that Defendants' Rapid Release Claims are false, misleading, unfair, and/or deceptive on their face. *See, e.g.*, Exs. A-B.

54. Defendants knew or should have known of the existence of their "contradictory claims for rapid or fast-release [acetaminophen] products."[44]

55. The level of deception and unfairness is elevated given that Defendants have long known or should have known that there is scant or conflicting evidence about the correlation of the speed and efficacy of its acetaminophen products to its rapid release gelcap design.

56. There is no proven significant efficacy difference between the Signature Care rapid release products and the Signature Care non-rapid release products to warrant Defendants' representations that the Class Rapid Release Gelcaps work faster than their non-rapid release counterparts. To the contrary, these laboratory results reveal that the Class Rapid Release

[43] *See* Ex. B, 2018 Valisure Acetaminophen Study, *supra*.

[44] *Id*.

Gelcaps dissolve significantly slower than Defendants' traditional, non-rapid release formulation. *See* Exs. A-B.

57. Defendants knew or should have known that their Rapid Release Claims were false, misleading, unfair, and/or deceptive. Yet, Defendants falsely marketed the Products with the Rapid Release Claims, deliberately and falsely suggesting to consumers that the Class Rapid Release Gelcaps worked faster than their other, cheaper, non-rapid release acetaminophen products.

58. Defendants' conduct induced, and continues to induce, unwitting consumers to buy the Class Rapid Release Gelcaps at a price that exceeds the actual value of the Product, and comes at a significant price premium when compared to traditional, non-rapid release formulations.

CLASS ACTION ALLEGATIONS

59. ***Class Definition***: Plaintiff brings this action pursuant to Rule 23(a) of the Federal Rules of Civil Procedure on behalf of a class and subclass of similarly situated individuals, defined as follows:

(a) ***Nationwide Class.*** Plaintiff seeks to represent a nationwide class of similarly situated individuals, defined as all persons in the United States who, within the applicable statute of limitations period, up to and including the date of final judgment in this action, purchased any of the Products at issue (the "Nationwide Class" or "Class").

(b) ***Massachusetts Subclass.*** Plaintiff also seeks to represent a subclass of all Class members who, within the applicable statute of limitations period, up to and including the date of final judgment in this action, purchased any of the Products at issue in Massachusetts (the "Massachusetts Subclass" or "Subclass").

60. Specifically excluded from the Class and Subclass are Defendants and any entities in which Defendants have a controlling interest, Defendants' agents and employees, the judge to whom this action is assigned, members of the judge's staff, and the judge's immediate family.

61. Plaintiff reserves the right to amend the definitions of this Class and Subclass if discovery or further investigation reveals that the Class and Subclass should be expanded or otherwise modified.

62. ***Numerosity.*** Members of the Class and Subclass are so numerous that their individual joinder herein is impracticable. On information and belief, the members of the Nationwide Class number in the millions of consumers throughout the United States, and the Subclass comprises at least thousands of consumers throughout Massachusetts. The precise number of Class and Subclass members and their identities are unknown to Plaintiff at this time but may be determined through discovery. Class and Subclass members may be notified of the pendency of this action by mail and/or publication through the distribution records of Defendants and third-party retailers and vendors.

63. ***Commonality and Predominance***. Common questions of law and fact exist as to all Class and Subclass members and predominate over questions affecting only individual Class and Subclass members. Common legal and factual questions include, but are not limited to: (a) whether Defendants warranted the Products as "Rapid Release;" (b) whether Defendants breached these warranties; (c) whether Defendants committed the statutory and common law violations alleged against them herein by doing so; (d) whether Plaintiff and members of the Class and Subclass are entitled to damages and/or restitution; (e) whether Defendants should be enjoined from further engaging in the misconduct alleged herein; and (f) whether Plaintiff and members of the Class and Subclass are entitled to attorneys' fees and costs.

64. ***Typicality.*** The claims of Plaintiff are typical of the claims of the Class and Subclass in that Plaintiff and members of the proposed Class and Subclasses purchased Defendants' Products in reliance on the representations and warranties described above and suffered a loss as a result of Defendants' uniform wrongful conduct.

65. ***Adequacy***. Plaintiff is an adequate representative of the Class and Subclass because Plaintiff has no interests antagonistic to Class and Subclass members' interests, Plaintiff has retained competent counsel with considerable experience and success in prosecuting complex class actions and consumer protection cases, and Plaintiff and the undersigned counsel intend to prosecute this action vigorously. The interests of the Class and Subclass members will be fairly and adequately protected by Plaintiff and Plaintiff's counsel.

66. ***Superiority***. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy. Each individual Class and Subclass member may lack the resources to undergo the burden and expense of individual prosecution of the complex and extensive litigation necessary to establish Defendants' liability. Individualized litigation increases the delay and expense to all parties and multiplies the burden on the judicial system presented by the complex legal and factual issues of this case. Individualized litigation also presents a potential for inconsistent or contradictory judgments. In contrast, the class action device presents far fewer management difficulties and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court on the issue of Defendants' liability. Class treatment of the liability issues will ensure that all claims and claimants are before this Court for consistent adjudication of liability issues. Thus, the Class and Subclass are readily definable and prosecution as a class action avoids repetitious litigation and duplicative litigation costs, conserves judicial resources, ensures uniformity of decisions, and

permits claims to be handled in an orderly and expeditious manner.

67. Defendants have acted or failed to act on grounds generally applicable to the Class and Subclasses, thereby making appropriate final injunctive relief with respect to the Class and Subclass as a whole.

68. Without a class action, Defendants will continue a course of action that will result in further damages to Plaintiff and members of the Class and Subclass and will likely retain the benefits of their wrongdoing.

69. Based on the foregoing allegations, Plaintiff's claims for relief include those set forth below.

COUNT I
Violation Of The Massachusetts Consumer Protection Act ("MCPA"),
Mass. Gen. Laws ch. 93A, *et seq*.
(On Behalf Of The Massachusetts Subclass)

70. Plaintiff re-alleges and incorporates by reference every allegation set forth in the preceding paragraphs as though alleged in this Count.

71. Plaintiff brings this claim individually and on behalf of the members of the proposed Massachusetts Subclass against Defendants.

72. The MCPA prohibits "[u]nfair or deceptive acts or practices in the conduct of any trade or commerce." Mass. Gen. Laws ch. 93A, § 2(a). An act is "deceptive" under Chapter 93A "if it could reasonably be found to have caused a person to act differently from the way [s]he otherwise would have acted." *Tagliente v. Himmer*, 949 F.2d 1, 7 (1st Cir. 1991).

73. The MCPA also provides that, "[a]ny person … who has been injured by another person's use or employment of any method, act or practice declared to be unlawful by section two … may bring an action … for damages and such equitable relief, including an injunction, as the court deems to be necessary and proper." Mass. Gen. Laws ch. 93A, § 9(1). The MTPA

further provides that "[a]ny persons entitled to bring such action may, if the use or employment of the unfair or deceptive act or practice has caused similar injury to numerous other persons similarly situated …, bring the action on behalf of himself and such other similarly injured and situated persons[.]" *Id*. § 9(2).

74. Defendants are each a "person" as defined in Mass. Gen. Laws ch. 93A, § 1(a). Defendants are engaged in "trade" and "commerce" as defined in Mass. Gen. Laws Ann. ch. 93A, § 1(b) because Defendants have, at all relevant times, advertised, offered for sale, sold, and/or distributed the Class Rapid Release Gelcaps to consumers in Massachusetts, thereby directly or indirectly affecting the people of Massachusetts.

75. By engaging in the acts and omissions alleged above and incorporated herein, Defendants have engaged, and continue to engage, in unfair or deceptive acts or practices in the conduct of trade or commerce. Mass. Gen. Laws ch. 93A, § 2.

76. Defendants' unfair and deceptive scheme to mislead consumers was comprised of unfair and deceptive acts or practices, including, but not limited to, uniformly representing to Plaintiff and the Class, by means of their labeling of the Products, that the Products provide faster-acting pain relief than their non-rapid release counterparts when, in fact, they did not. This unfair and deceptive act and practice has the capacity, tendency, and/or likely to deceive or mislead reasonable consumers.

77. Defendants' conduct, as alleged herein, constitutes unfair or deceptive acts or practices and unfair methods of competition in trade or commerce in violation of Mass. Gen. Laws ch. 93A, § 2 and the regulations promulgated thereunder, including without limitation, 940 C.M.R. § 3.02, 3.05(1), 3.05(2), 3.16(2), and 3.16(3).

78. Defendants' conduct, as alleged herein, violates various regulations promulgated by the Massachusetts Attorney General pursuant to Mass. Gen. Laws ch. 93A, § 2(c), including the following: (i) 940 C.M.R. § 3.02 (prohibiting, among other things, statements or illustrations used in advertisements which create a false impression of the grade, quality, value, or usability of the product offered); (ii) 940 C.M.R.§ 3.05(1) (prohibiting claims or representations "made by any means concerning a product which, directly, or by implication, or by failure to adequately disclose additional relevant information, has the capacity or tendency or effect of deceiving buyers or prospective buyers in any material respect"); (iii) 940 C.M.R. §3.05(2) (prohibiting the use of any advertisement "which would mislead or tend to mislead buyers or prospective buyers, through pictorial representations or in any other manner, as to the product being offered for sale"); (iv) 940 C.M.R. § 3.16(2) (providing that it is a violation of ch. 93A, § 2 to "fail to disclose to a buyer or prospective buyer any fact, the disclosure of which may have influenced the buyer or prospective buyer to enter into the transaction"); and 940 C.M.R. § 3.16(3) (providing that an act or practice violates ch. 93A, § 2 if it "fails to comply with existing statutes, rules, regulations or laws, meant for the protection of the public's health, safety or welfare promulgated by the Commonwealth or any political subdivision thereof intended to provide consumers of this Commonwealth protection").

79. As a direct and proximate result of Defendants' unfair and deceptive acts, Plaintiff Sapienza and members of the Massachusetts Subclass incurred economic injuries and suffered damages as a direct result of Defendants' violations of Mass. Gen. Laws ch. 93A, *et seq*., because: (a) they would not have purchased the Products on the same terms if they had known that the Rapid Release Claims were not true; (b) they paid a price premium for the

Products; and (c) the Products do not have the characteristics, use, benefits, or quantities as promised by Defendants.

80. Defendants' unfair or deceptive acts or practices, as alleged herein, were willful or knowing violations of Mass. Gen. Laws ch. 93A, § 2, within the meaning of Mass. Gen. Laws ch. 93A, § 9(3).

81. Plaintiff Sapienza and the Massachusetts Subclass are also entitled to injunctive relief in the form of an order directing Defendants to cease their false and misleading labeling and advertising, retrieve existing false and misleading advertising and promotional materials, and publish corrective advertising

82. In compliance with the provisions of Mass. Gen. Laws Ann. ch. 93A, § 9(3), Plaintiff Sapienza sent written notice to Defendants on April 13, 2022, identifying Plaintiff Sapienza as the claimant, reasonably describing the unfair or deceptive act or practice relied upon and the injury suffered, and informing Defendants of Plaintiff Sapienza's intention to seek damages under the MCPA. The letter was sent via certified mail, return receipt requested, and advised Defendants that they were in violation of the MCPA and demanded that Defendants cease and desist from such violations and make full restitution by refunding the monies received therefrom. The letter expressly stated that it was sent on behalf of Plaintiff Nicole Sapienza and "all other persons similarly situated." Defendants did not take action to rectify the injuries caused by their unlawful conduct as described in the 4/13/22 letter on a class-wide basis within 30 days of its receipt. Accordingly, Plaintiff Sapienza, individually and on behalf of the proposed Massachusetts Subclass, seeks monetary damages from Defendants as permitted by Mass. Gen. Laws Ann. ch. 93A, § 9 for Defendants' violations of the MCPA. A true and correct copy of Plaintiff's letter is attached hereto as **Exhibit C**.

83. Accordingly, pursuant to Mass. Gen. Laws ch.93A, § 9, Plaintiff Sapienza and Massachusetts Subclass members are entitled to recover their actual damages or statutory damages of $25.00 each, whichever results in a greater recovery, and to recover double or treble the amount of their actual damages, plus their reasonable attorneys' fees and the costs of this action.

COUNT II
Breach Of Express Warranty
(On Behalf of the Nationwide Class)

84. Plaintiff re-alleges and incorporates by reference every allegation set forth in the preceding paragraphs as though alleged in this Count.

85. Plaintiff brings this claim individually and on behalf of the members of the proposed Nationwide Class against Defendants.

86. Defendants, as the designer, manufacturer, marketer, distributor, and/or seller of the Products, expressly warranted in the Rapid Release Claims that the Class Rapid Release Gelcaps provide faster-acting pain relief than their non-rapid release counterparts.

87. However, the Class Rapid Release Gelcaps are *not*, in fact, faster acting than their less expensive non-rapid release counterparts. Rather, independent testing commissioned by Plaintiff's counsel reveals that the Products are actually *slower* acting than their less expensive non-rapid release counterparts than the cheaper Signature Care caplets of the same dosage.

88. As a direct and proximate cause of Defendants' breach of express warranty, Plaintiff and the Class have been injured and harmed because: (a) they would not have purchased the Products on the same terms if they knew that the Rapid Release Claims were not true; (b) they paid a price premium for the Products due to the Rapid Release Claims; and (c) the Products do not have the characteristics, uses, benefits, or quantities as promised in that the

purportedly "rapid release" Products are in reality slower than their non-rapid release counterparts.

89. On April 13, 2022, prior to filing this action, a pre-suit notice letter was served on Defendants which complies in all respects with U.C.C. § 2-607. *See* Ex. C. Plaintiff, individually and on behalf of the putative Class, sent Defendants a letter via certified mail, return receipt requested, advising Defendants that they breached numerous warranties and violated state consumer protection laws, and demanding that Defendants cease and desist from such violations and make full restitution by refunding the monies received therefrom. *Id*.

COUNT III
Breach Of The Implied Warranty Of Merchantability
(On Behalf of the Nationwide Class)

90. Plaintiff re-alleges and incorporates by reference every allegation set forth in the preceding paragraphs as though alleged in this Count.

91. Plaintiff brings this claim individually and on behalf of the members of the proposed Nationwide Class against Defendants.

92. Defendants, as the designer, manufacturer, marketer, distributor, and/or seller of the Products, affixed Rapid Release Claims to each Product and impliedly warranted that the Class Rapid Release Gelcaps provide faster acting pain relief than their non-rapid release counterparts.

93. Defendants breached the warranty implied in the contract for the sale of the Products because they could not pass without objection in the trade under the contract description, the goods were not of fair average quality within the description, and the goods were unfit for their intended and ordinary purpose because the Products do not, and in fact, could never provide faster acting pain relief than their non-rapid release counterparts as advertised.

Rather, independent testing commissioned by Plaintiff's counsel reveals that the Products are, in reality, *slower* acting than their less expensive non-rapid release counterparts than the cheaper Signature Care caplets of the same dosage. As a result, Plaintiff and Class members did not receive the goods as impliedly warranted by Defendants to be merchantable.

94. Plaintiff and Class members purchased the Products in reliance upon Defendants' skill and judgment and the implied warranties.

95. The Class Rapid Release Gelcaps were not altered by Plaintiff and Class members.

96. The Class Rapid Release Gelcaps were defective when they left the exclusive control of Defendants.

97. Defendants knew that the Products would be purchased and used without additional testing by Plaintiff and Class members.

98. The Products were defectively designed and manufactured and unfit for their intended purpose, and Plaintiff and Class members did not receive the goods as warranted.

99. As a direct and proximate cause of Defendants' breach of the implied warranty, Plaintiff and Class members have been injured and harmed because: (a) they would not have purchased the Products on the same terms if they knew that the Rapid Release Claims were not true; (b) they paid a price premium for the Products due to the Rapid Release Claims; and (c) the Products do not have the characteristics, uses, benefits, or quantities as promised in that the purportedly "rapid release" Products are in reality slower than their non-rapid release counterparts.

COUNT IV
Unjust Enrichment / Restitution
(On Behalf of the Nationwide Class)

100. Plaintiff re-alleges and incorporates by reference every allegation set forth in the preceding paragraphs as though alleged in this Count.

101. Plaintiff brings this claim individually and on behalf of the members of the proposed Nationwide Class against Defendants.

102. Plaintiff and the Class conferred benefits on Defendants by purchasing the Class Rapid Release Gelcaps.

103. Defendants have been unjustly enriched in retaining the revenues derived from Plaintiff's and Class Members' purchases of the Class Rapid Release Gelcaps. Retention of those monies under these circumstances is unjust and inequitable because Defendants' inclusion of material misrepresentations of fact on the Products' labeling and/or packaging (*i.e.*, the Rapid Release Claims) induced Plaintiff and the Class to purchase the Class Rapid Release Gelcaps. These misrepresentations caused injuries to Plaintiff and the Class because they would not have purchased the Class Rapid Release Gelcaps at all, or would not have purchased them on the same terms, if the true facts were known.

104. Because Defendants' retention of the non-gratuitous benefits conferred on them by Plaintiff and the Class is unjust and inequitable, Defendants must pay restitution to Plaintiff and the Class for their unjust enrichment, as ordered by the Court.

COUNT V
Negligent Misrepresentation
(On Behalf of the Nationwide Class)

105. Plaintiff re-alleges and incorporates by reference every allegation set forth in the preceding paragraphs as though alleged in this Count.

106. Plaintiff brings this claim individually and on behalf of the members of the proposed Nationwide Class against Defendants.

107. As discussed above, Defendants made misrepresentations in their advertisements and related statements made in connection with the Class Rapid Release Gelcaps, specifically that the Products are "Rapid Release" gelcaps, which a reasonable consumer would understand such claims to mean that the Products work faster and thus provide quicker pain relief than Defendants' non-rapid release products with the same active ingredients and of the same dosage. However, as noted above, despite what Defendants' marketing and labeling of the Products would have consumers believe, the Class Rapid Release Gelcaps do not, in fact, provide faster pain relief than their non-rapid release counterparts. Additionally, Defendants omitted, failed to disclose, and/or intentionally concealed from such advertisements and related statements material facts concerning the qualities, characteristics, and benefits associated with the Class Rapid Release Gelcaps, namely that the Products are actually *slower* acting as compared to their non-rapid relief counterparts.

108. At the time Defendants made these representations, Defendants knew or should have known that these representations were false or made them without knowledge of their truth or veracity.

109. At an absolute minimum, Defendants negligently misrepresented and/or negligently omitted material facts about the Class Rapid Release Gelcaps and their associated characteristics, qualities, and benefits.

110. The negligent misrepresentations and omissions made by Defendants, upon which Plaintiff and Class members reasonably and justifiably relied, were intended to induce

and actually induced Plaintiff and Class members to select and purchase the Class Rapid Release Gelcaps over their less expensive, non-rapid release counterparts.

111. Plaintiff and Class members would not have purchased the Class Rapid Release Gelcaps, or would not have purchased them on the same terms, if the true facts had been known.

112. The negligent actions of Defendants caused damage to Plaintiff and Class members, who are entitled to damages and other legal and equitable relief as a result.

COUNT VI
Fraud
(On Behalf of the Nationwide Class)

113. Plaintiff hereby re-alleges and incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

114. Plaintiff brings this claim individually and on behalf of the members of the proposed Nationwide Class against Defendants.

115. As discussed above, Defendants provided Plaintiff and Class members with false and misleading material information and failed to disclose material facts about the Class Rapid Release Gelcaps and their associated characteristics, qualities, and benefits. These misrepresentations and omissions were made by Defendants with knowledge of their falsehood.

116. The misrepresentations and omissions made by Defendants, upon which Plaintiff and Class members reasonably and justifiably relied, were intended to induce and actually induced Plaintiff and Class members to purchase the Class Rapid Release Gelcaps.

117. The fraudulent actions of Defendants caused damage to Plaintiff and the members of the Class, who are entitled to damages and other legal and equitable relief as a result.

PRAYER FOR RELIEF

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

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

(b) For an order declaring the Defendants' conduct violates the statutes and laws referenced herein;

(c) For an order finding in favor of Plaintiff and the Class and Subclass on all counts asserted herein;

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

(e) For prejudgment interest on all amounts awarded;

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

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

(h) For an order awarding Plaintiff and the Class and Subclass 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 of right.

Dated: June 21, 2022

Respectfully submitted,

REARDON SCANLON LLP

By: */s/ James J. Reardon, Jr.*
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** Pro hac vice application forthcoming*

Attorneys for Plaintiff and the Putative Class

EXHIBIT A

Valisure, LLC
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analysis@valisure.com

VALISURE REPORT

CLIENT INFORMATION

Standard: ISO/IEC 17025:2017	**Report ID:** 20220222 C	**Sample Type**: Acetaminophen, 500 mg	**ATTN:** Julia K. Venditti, Bursor & Fisher, P.A	**Reference:** 2111-0025
Receipt Date:	**NDC Package**	**Description:**	**Lot:**	**Expiration Date:**
January 28, 2022	21130-919-12	Better, Signature Care, Rapid Release, Extra Strength 	P126037	07/2024
January 28, 2022	21130-111-78	Better, Signature Care 	1ME1938C	06/2023

DISSOLUTION ANALYSIS SUMMARY

Analysis details for each test performed can be found on the following pages. Gelcap is gelatin coated tablet and Caplet is coated tablet.

Replicates: One Sample (n = 1) each	**Method:** Dissolution Analysis: USP Acetaminophen Tablets Pharmacopeial Forum: Volume No. 43(3), Official 1-Oct-2021
Test Date: February 15, 2022	**Operator:** Alex Reimers
Analysis Date: February 21, 2022	**Analyst:** Amber Hudspeth
Operator Notes: Dissolution is performed at 50 rpm paddle speed and 37.5 ± 0.1°C using 900 ml of dissolution buffer: 50 mM monobasic potassium phosphate and sodium hydroxide to reach pH 5.8 at 37.5°C in deionized water. Samples were collected every 2 minutes for a total of 30 minutes. Samples are analyzed for ultraviolet light (UV) absorbance at 243 nm corresponding to the peak absorbance of acetaminophen. Data is processed using MatLab with the Statistics and Machine Learning Toolbox and the Curve Fitting Toolbox. Dissolution profiles are normalized to the average of endpoint data values and fit using a Weibull Model (cumulative distribution function for drug dissolved as a function of time equal to f(t)=1-exp[-a(t-T)^b], where a and b are parameters for time-scale and shape of curve progression, respectively, t is time, and T is lag time as a result of the dissolution process and was assumed to be zero). The fits are used to calculate times corresponding to percent of acetaminophen dissolved in solution.	**Approval Signature:** Kaury Kucera, CSO

DISSOLUTION ANALYSIS RESULTS

Figure: Dissolution shown as a proportion of label claim acetaminophen (500 mg) released into solution over time shown in minutes (min). Red is caplet (lot 1ME1938) data and blue is gelcap (lot P126037) data.

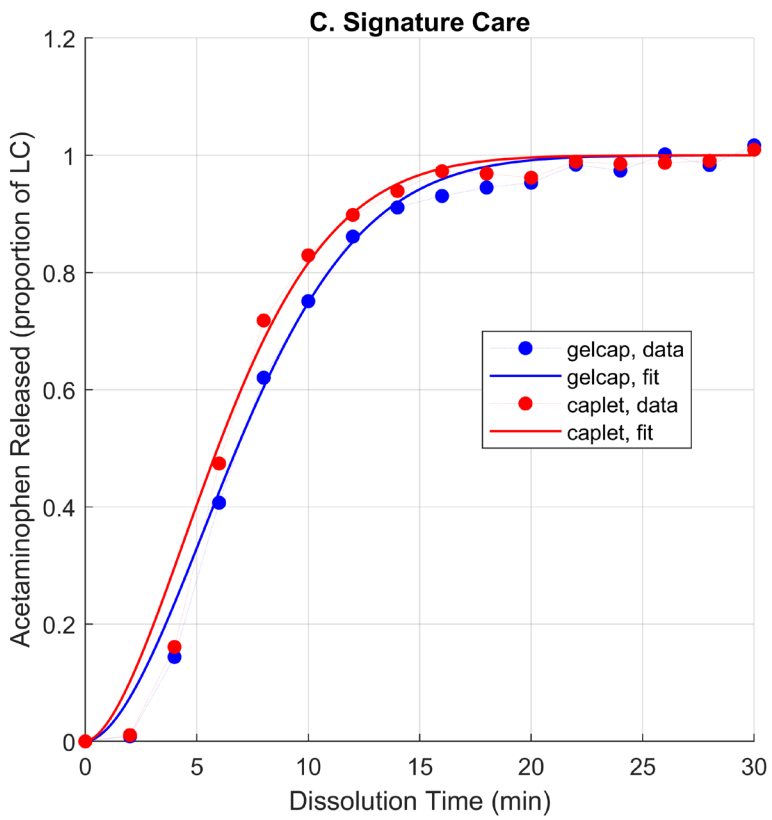

Table: Time (minutes) for 75-95% dissolution by product.

	Brand:	Signature Care	
	Lot:	P126037	1ME1938
	Description:	gelcap	caplet
Percent dissolved	75%	10.0	8.9
	80%	10.9	9.7
	85%	12.0	10.7
	90%	13.3	12.0
	95%	15.5	14.0

CONFORMITY STATEMENTS

All products tested meet USP tolerance for dissolution because greater than 80% of the labeled amount of acetaminophen is dissolved in under 30 minutes.

EXHIBIT B

KenKyu

Advances in Investigational Pharmacology and Therapeutic Medicine 1:63-71 (2018)

Research

Rapid and Fast-Release Acetaminophen Gelcaps Dissolve Slower Than Acetaminophen Tablets

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Received August 23, 2018**; Accepted** November 07, 2018**; Published** November 12, 2018

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Abstract

The dissolution properties of oral medicinal drugs are affected by formulation and used to market over-the-counter medications. Acetaminophen is one of the most commonly used over-the-counter pain and fever-reducing medications with an estimated global yearly market value of over $350 million US dollars [1]. Acetominophen gelcaps are, in general, sold at higher prices than company-matched standard tablets. Standard acetaminophen tablets and rapid or fast-release gelcaps from five major US companies were analyzed using the industry standard test for dissolution. Results indicate that acetaminophen gelcaps marketed as rapid or fast-release are slower acting under *in vitro* dissolution conditions compared to the company-matched tablet dose.

Keywords: dissolution; acetaminophen; rapid release; fast-release; quick release; standard release; medication release; over-the-counter; generic drugs.

Introduction

The release of active ingredients from drug products is an essential component of pharmacokinetics of absorption, distribution, metabolism, and excretion that influences onset of drug action after oral administration. Following the widely accepted standard set by the United States Pharmacopeia (USP) for *in vitro* drug release rate, or dissolution analysis, we investigated rapid (or fast) release medications from five major US companies (Rite Aid, Walgreens, CVS, Johnson & Johnson Tylenol, and Walmart Equate) selling acetaminophen, also called paracetamol or N-acetyl-para-aminophenol, compared to company-matched tablets that do not have claims of rapid or fast-release characteristics.

The specific formulation of individual drug products including excipients, binders, and sustained release materials is propriety knowledge. Many companies sell over-the-counter drug products in multiple forms including those advertised as “fast-release,” or “rapid release”. Modified release drug products can control the pharmacokinetic and pharmacodynamic properties of drug administration, which is also applicable to extended release forms [2]. The *in vitro* release of drugs into solution over time is studied for solid oral drug dosages with dissolution testing. Dissolution testing is commonly used in the pharmaceutical industry to test the quality and effectiveness of drug release from solid oral medications.

Formulating pure medicinal drugs for oral delivery requires non-active ingredients that affect dissolution properties [3]. These

excipients may include any of a wide variety of regulated substances including sugars, cellulose, magnesium stearate, starch, talc, and polyethylene glycols that bind the active ingredient of an individual drug dose in solid form from mixed powders following mold-based processing [4]. Excipients can comprise 90% of a medication's mass depending on the drug type [5]. Additionally, many solid oral drug products are coated with non-active ingredients that may regulate dissolution [6]. Coatings may range in thickness of gelatin or other polymer-based material that have a pronounced effect on dissolution in viscous solutions [7]. Generally, polymer coatings may help to shield the taste of medication, allow for recognition by color, and/or aid in the comfort of swallowing [8]. In the case of acetaminophen, coated capsule-shaped tablets, or caplets, are commonly marketed as gelcaps.

Acetaminophen is included on the World Health Organization List of Essential Medicines and is the most commonly used medication for fever reduction and pain mitigation in the US and Europe [9,10]. Acetaminophen can be purchased over-the-counter in many forms including tablet, caplet, capsule, gelcap, and liquid suspension and is typically dosed in 325 mg, 500 mg, or 650 mg solid forms. As a Biopharmaceutical Classification System type III drug, acetaminophen bioavailability is limited by permeation rate and not solubility. Therefore, *in vitro* dissolution studies are considered safe determinants of bioequivalence for acetaminophen formulation [11].

Acetaminophen medications are manufactured and distributed through a variety of marketplaces. Post manufactured products are marketed for sale online or in person with proprietary labelling containing drug identity and dosage amount. All commercial drugs are tracked through unique lot numbers assigned by manufacturers to each individual lot or batch of the medication. Additionally, a National Drug Code (NDC) is commonly included on US medication labelling. The NDC Directory is maintained by the FDA and used to identify the pharmaceutical establishment that manufactured or processed the drug for commercial distribution (see Section 510 of the Federal Food, Drug, and Cosmetic Act) [12]. Knowing the authenticity of medications does not guarantee the measure of quality or consistency between individual lots of medication. In the case of acetaminophen, the claims for rapid or fast-release products have been scrutinized previously [13]. Our work provides a thorough comparison of five of the top acetaminophen branded and generic products marketed and sold in the US.

Given wide-spread use of over-the-counter and prescription medications, the quality and value of medications are an important public health, consumer safety, and economic concern.

Methods

For this study, all acetaminophen samples were purchased from pharmacies as over-the-counter medications in the United States New York Tri-State Area. Medications were rejected if the time of testing was within a year of the labelled expiration date. Medications with 100 dosage units at a concentration of 500 mg were purchased. Standard release tablets (herein tablets) and rapid-release or fast-release gelatin coated tablets (herein gelcaps) sold by five companies and from five lots per company were tested. Companies were chosen to represent the top branded version of acetaminophen [14] and the top 4 retail pharmacy chains selling their own generic acetaminophen products [15]. Companies were Rite Aid (company #1), Walgreens (company #2), CVS (company #3), Johnson & Johnson Tylenol (company #4), and Walmart Equate (company #5). Six tablets and six gelcaps from a single company were tested together alternating through companies until each lot from each company of either tablets or gelcaps were tested twenty-four times. In total, 1,200 units of medication were tested in the primary study controlling for variables within and between companies' lots to determine differences in dissolution rates between tablets and gelcaps.

Primary Study Variable	Companies	Lots per Company	Units tested per Lot	Total
Tablets	5	5	24	600
Rapid or Fast-Release Gelcaps	5	5	24	600

Table 1: Experimental Design. This study compares dissolution between 500 mg acetaminophen tablets and gelcaps controlling for variability in tests, lots, and between major companies in the United States.

Two follow-up studies were performed. First, additional rapid or fast-release tablets without coating were purchased from company #3, which, after reasonable search of retail pharmacies in the New York Tri-State Area, appeared to be the only company evaluated that markets additional rapid-release acetaminophen products beyond gelcaps. These were analyzed side-by-side with gelcaps and standard-release tablets of the company #3. Furthermore, 100 additional gelcaps sampled from all twenty-five study lots were analyzed following the removal of their coating (four gelcaps from each lot).

Dissolution Testing

Dissolution tests were performed in accordance with the United States Pharmacopeia (USP) standard for dissolution [16] and monograph for acetaminophen tablets, a common test between medications labelled tablet or gelcap. Dissolution Tester RC-6 (Tianjin Guoming Medicinal Equipment) instruments that hold six test vessels each were used with testing apparatus II (paddle type). The temperature and pH of dissolution buffer was verified using a dual probe calibrated and certified to ISO 17025:2005 standards (Mettler Toledo).

Dissolution was performed at 50 rpm paddle speed and 37.5 ± 0.1°C using 900 ml of dissolution buffer: 50 mM monobasic potassium phosphate (KH2PO4, 99% ACS Reagent, Sigma-Aldrich) and sodium hydroxide (NaOH, Sigma-Aldrich) to reach pH 5.8 at 37.5°C in deionized water. Although the USP monograph only requires one sampling at the 30-minute time point, greater resolution is needed to evaluate release claims in acetaminophen. For this study, samples were collected every 120 ± 2 seconds for a total of 30 minutes, which enabled sufficient resolution to ascertain differences in acetaminophen products. 0.5 ml samples were aspirated from 50% vessel depth and greater than 2 cm from the vessel wall and filtered using 0.45 µm PVDF membrane (Denville Scientific) to remove undissolved acetaminophen and particulate excipients. Full dissolution was verified for all medication by comparison to a standard curve prepared using reference standard acetaminophen (Sigma-Aldrich, data not shown). To control for potential variability in vessel position, crossover methodology was used where tablets and gelcap's were tested side-by-side in alternating order and tests alternated between tablet or gelcap in the first vessel position. The results of *in vitro* dissolution are shown in Figures 1 and 2.

For analysis of gelcaps with their coating removed, the gelatin coating was manually removed from the inner tablet and all components were added to the dissolution vessel at time zero of sample collection (see Figure 3). Results are shown in Figure 4.

UV Analysis

Samples were analyzed for ultraviolet light or UV absorbance at 243 nm corresponding to the peak absorbance of acetaminophen using an Epoch microplate spectrophotometer (BioTek). Samples were consistently diluted in an appropriate amount of dissolution buffer to reach the working range of the spectrophotometer. Greiner UV-Star 96-well plates were used for sample measurement. Prior to sample analysis, the optical interference at 243 nm for UV-Star plates was tested side-by-side with quartz and determined negligible (data not shown).

Standard curves using pure acetaminophen in dissolution buffer (USP Reference Standard, Sigma-Aldrich) confirmed that all acetaminophen medications analyzed reached a dissolved drug concentration corresponding to full dissolution. Endpoint samples were within acceptable range of 500 mg acetaminophen in solution (data not shown).

Data Analysis

Dissolution samples were company de-identified and data was processed and analyzed by a separate researcher.

Data was processed using MatLab with the Statistics and Machine Learning Toolbox and the Curve Fitting Toolbox (Release 2018a, The MathWorks, Inc). Dissolution profiles were normalized to the average of the last five data points and fit using a Weibull Model (cumulative distribution function for drug dissolved as a function of time equal to $f(t)=1-\exp[-a(t-T)^b]$, where a and b are parameters for time-scale and shape of curve progression, respectively, t is time, and T is lag time as a result of the dissolution process and was assumed to be zero). The fits were used to calculate times corresponding to percent of acetaminophen dissolved in solution. Time for 80% dissolution is reported following the USP monograph for acetaminophen dissolution at the time of this study, which specifies tolerance as greater or equal to 80% dissolution within 30 minutes [16].

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Results

The comparative efficacy of over-the-counter oral dosage acetaminophen products with marketing claims of rapid or fast-release was investigated using industry standard dissolution methods. Our comparative dissolution analysis revealed that rapid or fast-release gelatin coated acetaminophen tablets (gelcaps) from five major US companies dissolve on average 37 seconds slower than company-matched standard tablets (see Figure 1). 1,200 solid acetaminophen products for oral administration were analyzed throughout 30-minute intervals to provide strong statistical confidence in these results.

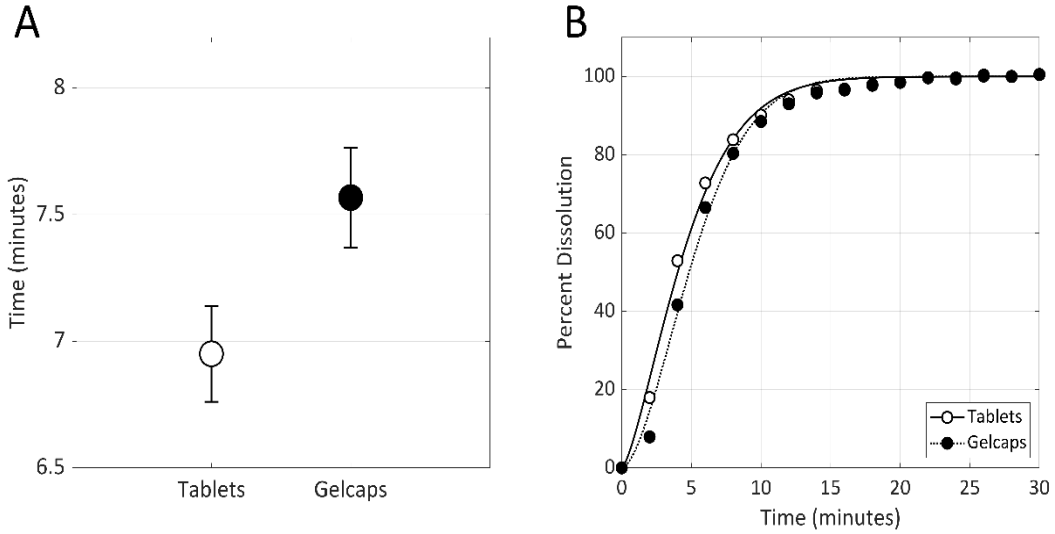

Figure 1: A) Time for 80% dissolution of over-the-counter acetaminophen comparing 600 standard tablets and 600 rapid or fast-release gelcaps across five companies reveals that rapid or fast-release gelcaps (black) take longer to dissolve compared to standard tablets (white). The p-value of 1.12E-05 suggests this time difference is strongly statistically significant. Error bars are 1.96 times standard error, indicating 95% confidence interval under the central limit theorem. B) Averaged and normalized UV absorption by acetaminophen in solution monitors percent dissolution as a function of time for all five companies.

Sampling every two minutes ensured a high accuracy in curve fitting using the Weibull model, which has been previously used to model the mechanics of dissolution for solid oral medications [17].

	Tablet (minutes)	Gelcap (minutes)	% Difference	p-value
Avg Company #1	7.47 ± 0.10	9.18 ± 0.17	+21.9%	3.63E-17
Avg Company #2	7.71 ± 0.10	8.73 ± 0.14	+12.4%	9.36E-09
Avg Company #3	9.08 ± 0.19	7.56 ± 0.19	-18.2%	5.66E-08
Avg Company #4	3.56 ± 0.05	3.94 ± 0.03	+10.0%	4.18E-09
Avg Company #5	7.04 ± 0.25	8.43 ± 0.14	+18.0%	1.20E-08
Medication Average	6.95 ± 0.21	7.57 ± 0.20	+8.5%	1.12E-05

Table 2: Time for 80% dissolution comparing tablets (n = 120) and rapid or fast-release gelcaps (n = 120).

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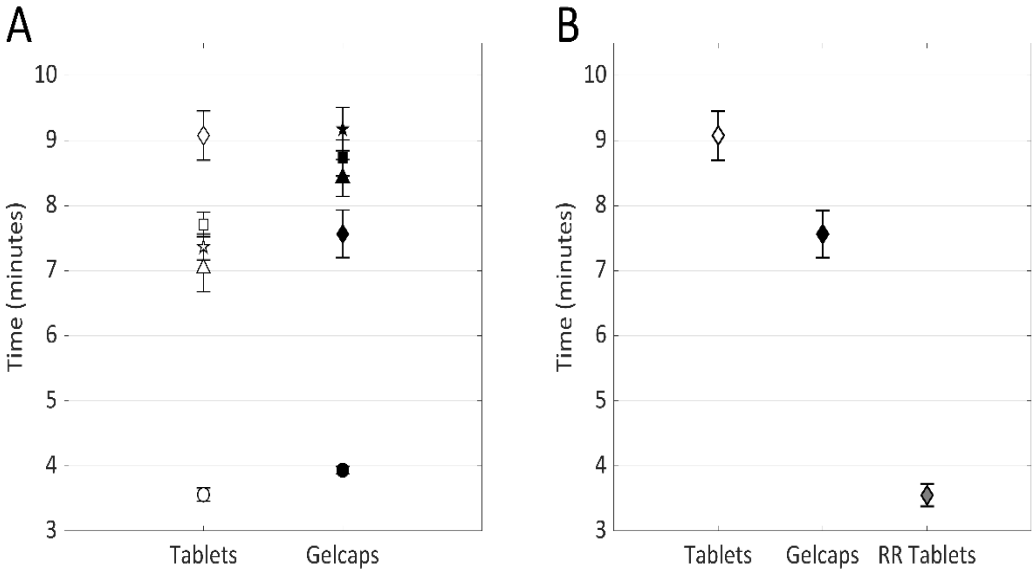

Figure 2: Time for 80% dissolution reveals significant company variability between companies and between medication type. A) Comparison of companies and tablet vs gelcaps: company #1 (stars), company #2 (squares), company #3 (diamonds), company #4 (circles), and company #5 (triangles). B) Company #3 comparison of time for 80% dissolution for tablets (n = 120, white), rapid or fast-release gelcaps (n = 120, black), and rapid-release tablets (n = 8, grey) shows that company #3 rapid or fast-release gelcaps are slower to dissolve compared to rapid-release tablets (p-value 1.79E-07).

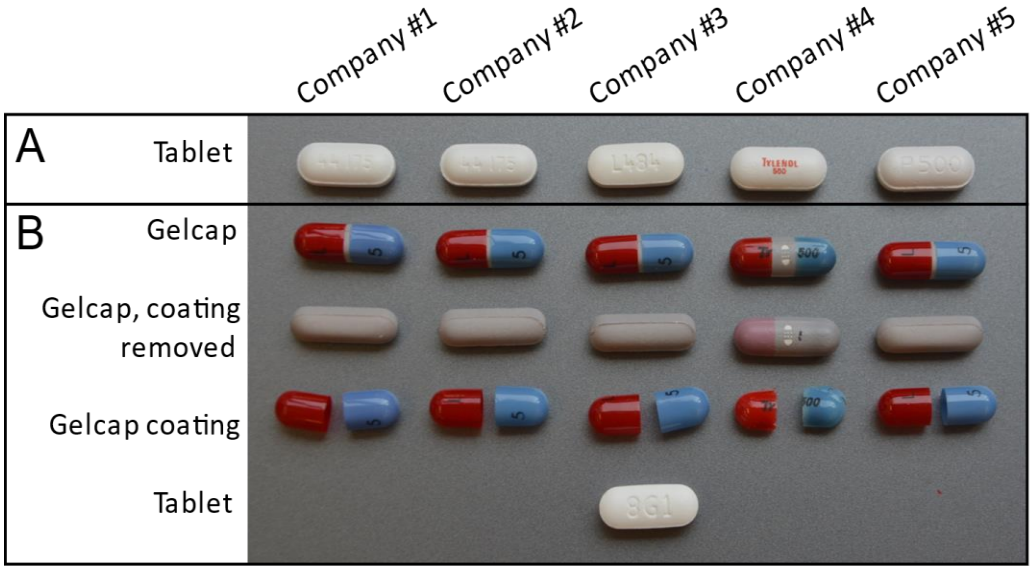

Figure 3: Examples of individual medications used in the study. A) Standard release products and B) rapid or fast-release products showing intact gelcaps and gelcaps with coating removed.

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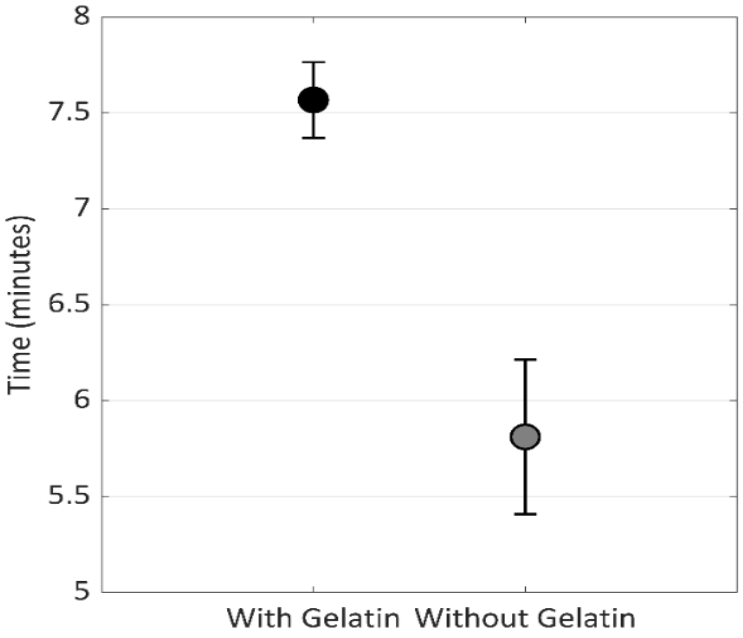

Figure 4: Removing the gelatin coating of rapid or fast-release gelcaps without gelatin, (n = 20), significantly decreases the time for acetaminophen to dissolve compared to rapid or fast-release gelcaps (with gelatin, n = 120). The p-value for the average time for dissolution of all companies between with coating and coating removed is 3.53E-11 underscoring a very strong statistical significance for these results.

	Gelcap With Coating (minutes)	Gelcap, Coating Removed (minutes)	% Difference	p-value
Avg Company #1	9.18 ± 0.17	7.47 ± 0.32	-20.6%	1.39E-04
Avg Company #2	8.73 ± 0.14	6.96 ± 0.24	-22.7%	2.20E-06
Avg Company #3	7.56 ± 0.20	5.66 ± 0.32	-28.8%	1.05E-04
Avg Company #4	3.94 ± 0.04	2.56 ± 0.07	-42.6%	5.67E-36
Avg Company #5	8.43 ± 0.14	6.42 ± 0.25	-27.1%	2.35E-07
Medication Average	7.57 ± 0.20	5.81 ± 0.21	-26.3%	3.53E-11

Table 3: Time for 80% dissolution comparing gelcaps with (n = 120) and without (n = 20) gelatin coating. Average dissolution times for 20 gelaps from each company are shown.

For only one of the five companies (company #3), rapid or fast-release gelcaps dissolved faster than company-matched standard tablets. Company #3 standard tablets were, on average, the slowest dissolving medications. Notably, company #3 is, as far as we were able to reasonably determine in the New York Tri-State Area, the only company included in

this study that has also marketed an additional rapid or fast-release actetaminophen tablet that is not gelatin coated. Comparative analysis of this additional company #3 product from two different lots with company #3 gelcaps demonstrated that the gelcaps are statistically significantly slower than company-matched tablets (see Figure 2), preserving the trend that gelcaps dissolve slower than tablets.

To better understand the influence of gelatin coatings on gelcap dissolution, four gelcaps from each of the twenty-five lots tested during the primary study (n = 100) were examined with their red and blue encapsulation removed. All components were added to the dissolution vessel at the same time to ensure that the only variable changed was the physical attachment of the gelatin coating to the solid medication surface. Results suggest that the removal of a gelcap's red and blue coating speeds up, on average, the time required for fully dissolving by 26% (see Table 3). This faster dissolution time suggests that gelcaps are a barrier for dissolution (see Figure 4).

An unanticipated study result concerns variability between companies. Specifically, the variability of gelcaps and tablets between the five major US companies was surprisingly high. For example, at 80% dissolution and averaged over 120 gelcaps and 120 tablets, products sold by company #4 dissolve 2.4 (gelcaps) and 2.1 (tablets) times faster when compared with products sold by company #1 (see Figure 2A and Table 2).

Discussion and Conclusions

Dissolution of orally administered solid therapeutic drugs is a critical step leading to the release of active drug and is rarely studied in detail. This study investigated over-the-counter oral medication with marketed claims of rapid or fast-release. These rapid or fast-release labeled medications are sold at an average of a 23% higher price [18], which make the claims associated with these medications of particular interest from a consumer perspective.

The results of the study suggest that acetaminophen gelcaps packaged with marketed claims of rapid or fast-release tend to dissolve slower than tablets of identical dosage sold by the same company.

All medications used for this study passed industry standards for full dissolution in under 30 minutes and are therefore predicted to be pharmacologically effective. Most drugs taken orally are absorbed in the small intestine due to high permeability and large surface area compared to the stomach [19]. As an early rate-limiting step, stomach emptying renders any oral medication that dissolves in 30 minutes or less essentially as rapid as possible in terms of dissolution. Indeed, unless oral medications are engineered for extended release, those that dissolve or disintegrate in the gastrointestinal tract are generally considered rapidly dissolving formulations. In these cases, bioavailability is dependent on drug permeability [20].

Acetaminophen is one of the most commonly used drugs in the world to treat acute and chronic pain [21]. In the US, acetaminophen currently costs between 0.01 and 0.43 USD per dose depending on quantity sold according to drugs.com market research [22]. Furthermore, a 2002 survey reported that 89% of consumers read over-the-counter drug package labels prior to purchase, which suggests that marketing claims like 'rapid release' or 'fast-release' may impact purchasing decisions [23]. Rapid or fast-release acetaminophen purchased for this study cost an average of 23% more than standard tablets of equivalent dose sold by the same company, suggesting there may be an economic impact for consumers choosing gelcaps over tablets.

Our results suggest that the gelatin coating added to rapid or fast-release gelcaps delays *in vitro* release of medication. We conclude that on average the gelcaps tested were approximately half a minute slower to dissolve compared to the company-matched tablets tested.

The results of this study warrant additional targeted investigations into acetaminophen products and, more generally, oral over-the-counter drugs marketed with release claims.

Acknowledgements

The authors would like to acknowledge Dr. William Sessa, Professor of Pharmacology and Medicine and Vice Chairman for the Department of Pharmacology, Yale University, for helpful review and comments as well as Valisure staff for support and feedback throughout this study.

Disclaimer

Valisure LLC does not conduct drug development or participate in clinical trials. Valisure LLC's affiliated companies include a laboratory that tests pharmaceutical samples and a pharmacy that dispenses batch-tested pharmaceuticals.

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Supplemental Information		Lot 1	Lot 2	Lot 3	Lot 4	Lot 5
Standard Tablets	Company #1 (Rite Aid)	P106590	P105172	P107562	P104073	P107150
	Company #2 (Walgreens)	P103544	P107562	P106924	P108010	P107810
	Company #3 (CVS)	7HE1087	8BE1514B	7ME1046	7LE1239A	7ME1152
	Company #4 (Tylenol)	LFA122	LLC215	LPC209	LHA052	LSA023
	Company #5 (Equate)	C03724	C08966	C10960	7ME1482C	F00054
Rapid Release Gelcaps	Company #1 (Rite Aid)	P106810	P105884	P107030	P107550	P107208
	Company #2 (Walgreens)	P105691	P107030	P103593	P107341	P107676
	Company #3 (CVS)	71670091AB	P105483	P106329	P102607	P108184
	Company #4 (Tylenol)	LHA032	LMA021	LJA091	LEA011	MAA003
	Company #5 (Equate)	P107790	P108183	P108696	P108536	P108038
Rapid Release Tablets	Company #3 (CVS)	7MR0309	7MR0310	--	--	--

Supplemental Table 4: Lot numbers for medications used in the study.

EXHIBIT C

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April 13, 2022

Via Certified Mail – Return Receipt Requested

Albertsons Companies, Inc.
250 E. Parkcenter Blvd.
Boise, ID 83706

Albertsons Companies, Inc.
c/o C.T. Corporation System
921 S. Orchard Street
Suite G
Boise, ID 83705

Albertson's LLC
250 E. Parkcenter Blvd.
Boise, ID 83706

Albertson's LLC
c/o C.T. Corporation System
921 S. Orchard Street
Suite G
Boise, ID 83705

Safeway Inc.
11555 Dublin Canyon Road
Pleasanton, CA 94588

Safeway Inc.
c/o C.T. Corporation System
330 N. Brand Blvd.
Suite 700
Glendale, CA 91203

Albertsons Safeway LLC
250 E. Parkcenter Blvd.
Boise, ID 83706

Albertsons Safeway LLC
c/o C.T. Corporation System
330 N. Brand Blvd.
Suite 700
Glendale, CA 91203

Shaw's Supermarkets, Inc.
750 W. Center Street
West Bridgewater, MA 02379

Shaw's Supermarkets, Inc.
c/o C.T. Corporation System
155 Federal Street
Suite 700
Boston, MA 02110

Better Living Brands, LLC
11555 Dublin Canyon Road
Pleasanton, CA 94588

LNK International, Inc.
22 Arkay Drive
Hauppauge, NY 11788

Re: *Notice and Demand Letter Pursuant to U.C.C. §§ 2-313, 2-314, 2-607;*
California's Consumers Legal Remedies Act, Cal. Civil Code §§ 1750, et seq.;
California's Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200, et seq.;
California's False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, et seq.;
The Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A, et seq.;
Oregon's Unlawful Trade Practices Act, O.R.S. §§ 646, et seq.;
Washington's Consumer Protection Act, RCW §§ 19.86, et seq.; and
All other applicable consumer protection statutes

To Whom It May Concern:

This letter serves as a preliminary notice and demand for corrective action to Albertsons Companies, Inc., Alberton's LLC, Safeway Inc., Albertsons Safeway LLC, Shaw's Supermarkets, Inc., Better Living Brands, LLC, and LNK International, Inc. (collectively, "You"), concerning breaches of express and implied warranties on behalf of our clients, Renee Morgan, Monica Charles, Nicole Sapienza, Jason Lucier, and Jennifer Ayala (collectively, the "Clients"), and a class of all similarly situated purchasers of certain Signature Care-branded acetaminophen products (the "Class"). This letter also serves as notice of violation of California's Consumers Legal Remedies Act ("CLRA"), Cal. Civil Code §§ 1750, *et seq.*, including subsections 1770(a)(5), (7), and (9); California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200, *et seq.*; California's False Advertising Law ("FAL"), Cal. Bus.

& Prof. Code §§ 17500, *et seq.*; the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A, *et seq.*; Oregon's Unlawful Trade Practices Act, O.R.S. §§ 646, *et seq.*; Washington's Consumer Protection Act, RCW §§ 19.86, *et seq.*; and all other applicable federal and state laws. Should we not receive a response to our offer of resolution set forth below, this letter provides statutory notice of our Clients' intent to file a class action lawsuit.

You uniformly advertise, market, and sell acetaminophen gelcap products prominently featuring the representation "Rapid Release" on their labeling and packaging, under the brand name Signature Care (collectively, the "Products"). Our Clients each purchased Your Products from Albertsons, Safeway, and Shaw's locations in the states of California, Massachusetts, Oregon, and Washington. Our clients understood the "Rapid Release" claims to be representations and warranties by You that the Products release acetaminophen faster – and therefore provide quicker pain relief – than cheaper non-Rapid Release formulations, such as traditional acetaminophen caplets and/or tablets. Our Clients paid a price premium for the Products over non-Rapid Release formulations. However, contrary to Your express representations, the Products are not "Rapid Release," as independent lab testing demonstrates that the Products actually release acetaminophen *slower* than Signature Care's non-Rapid Release formulations. *See* Exhibit A (2022 report from Valisure, LLC, an independent laboratory, as to the Products at issue); *see also* Exhibit B (2018 study from Kaury Kucera, *et al.*, regarding the testing and methodology). As such, our Clients and similarly situated consumers were misled and deceived by You as to the Products' true characteristics. Yet, our Clients reasonably relied on Your representations and warranties in deciding to purchase the Products, and these representations were part of the basis of the bargain in that our Clients would not have purchased the Products, or would not have purchased them on the same terms, if the true facts had been known. Thus, as a direct result of Your material misrepresentations and omissions, our Clients suffered, and continue to suffer, economic injuries. In substantially similar cases, courts have held that such facts meet the federal pleading standards and are suitable for class certification. *See* Ex. C (Order granting in part and denying in part class certification in *Bailey v. Rite Aid Corp.*).

Your conduct thus constitutes: (i) breaches of express and implied warranty pursuant to U.C.C. §§ 2-313, 2-314; (ii) common law fraud; (iii) fraudulent omission; (iv) unjust enrichment; and (v) further violations of state consumer protection statutes, discussed above. Further, the acts and practices described herein violated, and continue to violate, the CLRA in at least the following respects:

a. in violation of Section 1770(a)(5), You have represented that the Products have characteristics and benefits they do not have;

b. in violation of Section 1770(a)(7), You have represented that the Products are of a particular standard, quality, grade, style, and model, when they are of another; and

b. in violation of Section 1770(a)(9), You have advertised the Products with an intent not to sell them as advertised.

Accordingly, on behalf of our Clients and the Class, we hereby demand that You (1) issue a mandatory recall of the Products, and (2) make full restitution to all our Clients and all similarly situated purchasers of the Products of all purchase money obtained from sales thereof.

We also demand that You preserve all documents and other evidence which refer or relate to any of the above-described practices including, but not limited to, the following:

1. All documents concerning the design, packaging, labeling, and manufacturing process for the Products;

2. All documents, communications, consumer surveys, or memoranda concerning any testing of the Products or other research done concerning the ingredients in the Products, whether performed by You or any third-party entities;

3. All documents concerning the pricing, advertising, marketing, and/or sale of the Products;

4. All communications with customers involving complaints or comments concerning the Products;

5. All documents concerning communications with any retailer involved in the marketing or sale of the Products;

6. All documents concerning the identity of those individuals who purchased the Products;

7. All documents concerning communications with federal or state regulators concerning the Products; and

8. All documents concerning the total revenue derived from sales of the Products.

If You contend that any statement in this letter is inaccurate in any respect, please provide us with Your contentions and supporting documents immediately upon receipt of this letter.

This letter also serves as a thirty (30) day notice and demand requirement to seek damages under Cal. Civ. Code § 1782; Mass. Gen. Laws Ch. 93A, § 9(3); Or. R. Civ. P. 32 H; and any additionally relevant consumer protection statute. Accordingly, should You fail to rectify the situation on a class-wide basis within 30 days of receipt of this letter, our Clients will seek actual, statutory, and punitive damages against You on behalf of themselves and the Class.

Please contact me right away if You wish to discuss an appropriate way to remedy this matter. If I do not hear from You promptly, I will take that as an indication that You are not interested in doing so.

Sincerely,

Neal J. Deckant

JS 44 (Rev. 04/21)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Nicole Sapienza

(b) County of Residence of First Listed Plaintiff Middlesex
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Reardon Scanlon LLP
45 S. Main St., 3rd Flr.
West Hartford, CT 06107 860955-9455

DEFENDANTS
Albertson's Companies, Inc.,Shaw's Supermarkets, Inc., Safeway, Inc., Better Living Brands, LLC, and LNK

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- [ ] 1 U.S. Government Plaintiff
- [ ] 3 Federal Question *(U.S. Government Not a Party)*
- [ ] 2 U.S. Government Defendant
- [x] 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	[x] 1	[ ] 1	Incorporated *or* Principal Place of Business In This State	[ ] 4	[ ] 4
Citizen of Another State	[ ] 2	[ ] 2	Incorporated *and* Principal Place of Business In Another State	[ ] 5	[x] 5
Citizen or Subject of a Foreign Country	[ ] 3	[ ] 3	Foreign Nation	[ ] 6	[ ] 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- [ ] 110 Insurance
- [ ] 120 Marine
- [ ] 130 Miller Act
- [ ] 140 Negotiable Instrument
- [ ] 150 Recovery of Overpayment & Enforcement of Judgment
- [ ] 151 Medicare Act
- [ ] 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- [ ] 153 Recovery of Overpayment of Veteran's Benefits
- [ ] 160 Stockholders' Suits
- [ ] 190 Other Contract
- [ ] 195 Contract Product Liability
- [ ] 196 Franchise

REAL PROPERTY
- [ ] 210 Land Condemnation
- [ ] 220 Foreclosure
- [ ] 230 Rent Lease & Ejectment
- [ ] 240 Torts to Land
- [ ] 245 Tort Product Liability
- [ ] 290 All Other Real Property

TORTS

PERSONAL INJURY
- [ ] 310 Airplane
- [ ] 315 Airplane Product Liability
- [ ] 320 Assault, Libel & Slander
- [ ] 330 Federal Employers' Liability
- [ ] 340 Marine
- [ ] 345 Marine Product Liability
- [ ] 350 Motor Vehicle
- [ ] 355 Motor Vehicle Product Liability
- [ ] 360 Other Personal Injury
- [ ] 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- [ ] 365 Personal Injury - Product Liability
- [ ] 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- [ ] 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- [x] 370 Other Fraud
- [ ] 371 Truth in Lending
- [ ] 380 Other Personal Property Damage
- [ ] 385 Property Damage Product Liability

CIVIL RIGHTS
- [ ] 440 Other Civil Rights
- [ ] 441 Voting
- [ ] 442 Employment
- [ ] 443 Housing/ Accommodations
- [ ] 445 Amer. w/Disabilities - Employment
- [ ] 446 Amer. w/Disabilities - Other
- [ ] 448 Education

PRISONER PETITIONS

Habeas Corpus:
- [ ] 463 Alien Detainee
- [ ] 510 Motions to Vacate Sentence
- [ ] 530 General
- [ ] 535 Death Penalty

Other:
- [ ] 540 Mandamus & Other
- [ ] 550 Civil Rights
- [ ] 555 Prison Condition
- [ ] 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- [ ] 625 Drug Related Seizure of Property 21 USC 881
- [ ] 690 Other

LABOR
- [ ] 710 Fair Labor Standards Act
- [ ] 720 Labor/Management Relations
- [ ] 740 Railway Labor Act
- [ ] 751 Family and Medical Leave Act
- [ ] 790 Other Labor Litigation
- [ ] 791 Employee Retirement Income Security Act

IMMIGRATION
- [ ] 462 Naturalization Application
- [ ] 465 Other Immigration Actions

BANKRUPTCY
- [ ] 422 Appeal 28 USC 158
- [ ] 423 Withdrawal 28 USC 157

INTELLECTUAL PROPERTY RIGHTS
- [ ] 820 Copyrights
- [ ] 830 Patent
- [ ] 835 Patent - Abbreviated New Drug Application
- [ ] 840 Trademark
- [ ] 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- [ ] 861 HIA (1395ff)
- [ ] 862 Black Lung (923)
- [ ] 863 DIWC/DIWW (405(g))
- [ ] 864 SSID Title XVI
- [ ] 865 RSI (405(g))

FEDERAL TAX SUITS
- [ ] 870 Taxes (U.S. Plaintiff or Defendant)
- [ ] 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- [ ] 375 False Claims Act
- [ ] 376 Qui Tam (31 USC 3729(a))
- [ ] 400 State Reapportionment
- [ ] 410 Antitrust
- [ ] 430 Banks and Banking
- [ ] 450 Commerce
- [ ] 460 Deportation
- [ ] 470 Racketeer Influenced and Corrupt Organizations
- [ ] 480 Consumer Credit (15 USC 1681 or 1692)
- [ ] 485 Telephone Consumer Protection Act
- [ ] 490 Cable/Sat TV
- [ ] 850 Securities/Commodities/ Exchange
- [ ] 890 Other Statutory Actions
- [ ] 891 Agricultural Acts
- [ ] 893 Environmental Matters
- [ ] 895 Freedom of Information Act
- [ ] 896 Arbitration
- [ ] 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- [ ] 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

- [x] 1 Original Proceeding
- [ ] 2 Removed from State Court
- [ ] 3 Remanded from Appellate Court
- [ ] 4 Reinstated or Reopened
- [ ] 5 Transferred from Another District *(specify)*
- [ ] 6 Multidistrict Litigation - Transfer
- [ ] 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. § 1332(d) Class Action Fairness Act

Brief description of cause:
Plaintiff files this class action on behalf of purchasers of generic versions of certain over the counter "Rapid Release" drugs

VII. REQUESTED IN COMPLAINT:

[x] CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ $5,000,001

CHECK YES only if demanded in complaint:
JURY DEMAND: [x] Yes [ ] No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE: Jun 21, 2022

SIGNATURE OF ATTORNEY OF RECORD: /s/ James J. Reardon, Jr.

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

1. **Title of case (name of first party on each side only)** NICOLE SAPIENZA v. ALBERTSONS COMPANIES, INC

2. **Category in which the case belongs based upon the numbered nature of suit code listed on the civil cover sheet. (See local rule 40.1(a)(1)).**

   ☐ **I.** **160, 400, 410, 441, 535, 830*, 835*, 850, 880, 891, 893, R.23, REGARDLESS OF NATURE OF SUIT.**

   ☑ **II.** **110, 130, 190, 196, 370, 375, 376, 440, 442, 443, 445, 446, 448, 470, 751, 820*, 840*, 895, 896, 899.**

   ☐ **III.** **120, 140, 150, 151, 152, 153, 195, 210, 220, 230, 240, 245, 290, 310, 315, 320, 330, 340, 345, 350, 355, 360, 362, 365, 367, 368, 371, 380, 385, 422, 423, 430, 450, 460, 462, 463, 465, 480, 485, 490, 510, 530, 540, 550, 555, 560, 625, 690, 710, 720, 740, 790, 791, 861-865, 870, 871, 890, 950.**
   ***Also complete AO 120 or AO 121. for patent, trademark or copyright cases.**

3. **Title and number, if any, of related cases. (See local rule 40.1(g)). If more than one prior related case has been filed in this district please indicate the title and number of the first filed case in this court.**

4. **Has a prior action between the same parties and based on the same claim ever been filed in this court?**
   YES ☐ **NO** ☑

5. **Does the complaint in this case question the constitutionality of an act of congress affecting the public interest? (See 28 USC §2403)**
   YES ☐ **NO** ☑
   If so, is the U.S.A. or an officer, agent or employee of the U.S. a party?
   YES ☐ **NO** ☑

6. **Is this case required to be heard and determined by a district court of three judges pursuant to title 28 USC §2284?**
   YES ☐ **NO** ☑

7. **Do all of the parties in this action, excluding governmental agencies of the United States and the Commonwealth of Massachusetts ("governmental agencies"), residing in Massachusetts reside in the same division? - (See Local Rule 40.1(d)).**
   YES ☑ **NO** ☐

   A. **If yes, in which division do all of the non-governmental parties reside?**
   Eastern Division ☑ **Central Division** ☐ **Western Division** ☐

   B. **If no, in which division do the majority of the plaintiffs or the only parties, excluding governmental agencies, residing in Massachusetts reside?**
   Eastern Division ☐ **Central Division** ☐ **Western Division** ☐

8. **If filing a Notice of Removal - are there any motions pending in the state court requiring the attention of this Court? (If yes, submit a separate sheet identifying the motions)**
   YES ☐ **NO** ☐

(PLEASE TYPE OR PRINT)

ATTORNEY'S NAME James J. Reardon, Jr.

ADDRESS Reardon Scanlon LLP, 45 S. Main St., 3rd Flr. West Hartford, CT 06107

TELEPHONE NO. 860.955.9455