UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

EVIE COLLAZA, on behalf of herself and all others similarly situated,

Plaintiff,

Case No.:

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

JOHNSON & JOHNSON CONSUMER INC.,

v.

Defendant.

CLASS ACTION COMPLAINT

Plaintiff Evie Collaza, individually and on behalf of all others similarly situated, brings this action against Defendant Johnson & Johnson Consumer Inc. The following allegations are based upon personal knowledge as to Plaintiff's own conduct, the investigation of counsel, and upon information and belief as to the acts of others.

INTRODUCTION

1. Defendant Johnson & Johnson Consumer Inc ("J&J") produces, manufactures, markets, and distributes over-the-counter products to families, children, and other consumers worldwide, including analgesic or pain-relieving medicines under the Tylenol[®] brand name.

2. In 2005, J&J introduced Tylenol[®] Extra Strength Rapid Release Gels specially designed with "laser-drilled holes to release medicine quickly."¹

3. Since 2005, J&J has misled and continues to mislead consumers about the nature, quality, and effectiveness of its so-called rapid release Tylenol[®] products through its marketing and labeling. J&J explicitly promises faster relief than before and goes to great lengths to convince

¹ <u>https://www.tylenol.com/products/tylenol-rapid-release-gels</u> (last accessed June 29, 2023); <u>https://www.sportsbusinessjournal.com/en/Journal/Issues/2010/06/07/This-Weeks-News/Rapid-Release-Tylenol-Wont-Renew-With-NASCAR</u> (last accessed June 29, 2023).

consumers that Tylenol[®] rapid release gelcaps work faster than other acetaminophen products with marketing statements like:



4. Despite what J&J's marketing and labeling would have consumers believe, the term "rapid release" does not actually mean that the drug works faster for consumers than non-rapid release products.

5. J&J has long known that traditional, non-rapid release acetaminophen products can be equally effective in the same time period (if not in a faster time period) than its Tylenol[®] rapid release gelcaps.

6. In fact, a new study demonstrates that Tylenol[®] rapid release gelcaps dissolve *more slowly* than J&J's non-rapid release products.³

- 7. Yet, J&J charges a premium for its rapid release gelcaps.
- 8. J&J sells its Tylenol[®] rapid release gelcaps with false, misleading, deceptive

³ Kucera, Jessop, Alvarez, Gortler, Light, *Rapid and Fast-Release Acetaminophen Gelcaps Dissolve Slower Than Acetaminophen Tablets*, Adv Inv Pha The Medic, 1:63-71 (Nov. 12, 2018) accessible at <u>http://www.kenkyugroup.org/article/8/173/Rapid-and-Fast-Release-Acetaminophen-Gelcaps-Dissolve-Slower-Than-Acetaminophen-Tablets</u> (last accessed June 29, 2023).

² *E.g.*, <u>https://www.samsclub.com/p/tylenol-extra-strength-rapid-release-gels-290-ct/prod21000961?bvstate=pg:3/ct:r</u> (last accessed June 29, 2023).

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labeling and marketing in an effort to dupe consumers into purchasing these gelcaps for prices that exceed their true value. J&J has pursued and continues to pursue this course of conduct in order to profit off of unassuming, unwitting consumers looking for the fastest pain relief possible from an over-the-counter acetaminophen product.

9. Plaintiff and Class Members are consumers who were misled or deceived by J&J's false, misleading, and deceiving representations and, as a result, purchased the Tylenol[®] rapid release gelcaps ("Class Rapid Release Gelcaps").

10. Plaintiff and Class Members would not have purchased the Class Rapid Release Gelcaps had J&J disclosed accurate, truthful 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 Tylenol[®] tablets.

11. Plaintiff thus brings this class action against J&J on behalf of herself and on behalf of all individuals who purchased the Class Rapid Release Gelcaps (the "Class") seeking damages and appropriate equitable relief given that J&J's conduct violates well-established contract, tort, and consumer protection laws of New York and the United States.

THE PARTIES

12. Plaintiff Evie Collaza is a citizen and resident of Bronx, Bronx County, New York.

13. Defendant Johnson & Johnson is a New Jersey corporation that maintains its principal place of business at 199 Grandview Road, Skillman, Somerset County, New Jersey 08558. The relevant division of Johnson & Johnson Consumer Inc. is McNeil Consumer Healthcare Division, which is located at 7050 Camp Hill Road, Fort Washington, Montgomery County, Pennsylvania 19034. Accordingly, Defendant Johnson & Johnson is a citizen of the State of New Jersey.

JURISDICTION AND VENUE

14. This Court has original jurisdiction pursuant to the Class Action Fairness Act, 28 U.S.C. §1332(d), because at least one member of the proposed class is a citizen of a state different from J&J; the amount in controversy exceeds \$5,000,000, exclusive of interests and costs; the proposed class consists of more than 100 members; and none of the exceptions under the subsection apply to this action.

15. This Court has jurisdiction over J&J, because J&J conducts substantial business in New York and has systematic and continuous contacts with New York such that exercise of jurisdiction by this Court is proper and necessary.

16. Venue is proper in this District under 28 U.S.C. § 1391, because a substantial part of the events or omissions giving rise to the claims occurred in this District.

FACTUAL ALLEGATIONS

ACETAMINOPHEN GENERALLY

17. 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, tablets, capsules, and gelcaps.⁴

18. In any form, acetaminophen is used to treat a variety of common conditions including headaches, muscle aches, arthritis, backaches, toothaches, colds, fevers, ⁵ chronic pain, ⁶ etc.

⁴ *Id*.

⁵ <u>https://www.drugs.com/acetaminophen.html</u> (last accessed June 29, 2023).

⁶ <u>https://www.mayoclinic.org/chronic-pain-medication-decisions/art-20360371</u> (last accessed June 29, 2023).

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19. Typically, it is the first treatment recommended for *any* mild to moderate pain.⁷

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.⁸ It is even included on the World Health Organization's List of Essential Medicines.⁹

20. Given the widespread use of acetaminophen, both the *quality* and *value* of acetaminophen products present important public health, consumer safety, and economic concerns.¹⁰

J&J'S NAME BRAND ACETAMINOPHEN: TYLENOL®

21. Tylenol[®] is the well-recognized and trusted¹¹ brand name of acetaminophen¹² established by the McNeil family business.

22. J&J acquired the McNeil family business in 1959¹³ and began selling Tylenol[®] as an over-the-counter pain reliever in 1961.¹⁴

23. In 2018, J&J designated the McNeil branch of the company located in Fort

⁷ Id.

⁸ Kucera, Jessop, Alvarez, Gortler, Light, *supra* n.3.

⁹ The World Health Organization, WHO Model List of Essential Medicines, 20th List (Pub. March 2017, Amended August 2017),

https://apps.who.int/iris/bitstream/handle/10665/273826/EML-20-eng.pdf?ua=1 (last accessed June 29, 2023).

¹⁰ Kucera, Jessop, Alvarez, Gortler, Light, *supra* n.3.

¹¹ <u>https://johnsonandjohnson.gcs-web.com/news-releases/news-release-details/johnson-johnson-</u> <u>consumer-inc-announces-agreement-acquire-zarbees</u> (last accessed June 29, 2023).

¹²<u>https://www.mayoclinic.org/chronic-pain-medication-decisions/art-20360371</u> (last accessed June 29, 2023).

¹³ <u>https://ourstory.jnj.com/johnson-acquires-mcneil-laboratories</u> (last accessed June 29, 2023).

¹⁴<u>http://www.brandsearch.superbrands.com/wp-admin/admin-</u>

ajax.php?juwpfisadmin=false&action=wpfd&task=file.download&wpfd_category_id=1190&wp fd_file_id=80217&token=d3ee8a0c555749f1e9bb1f3427339271&preview=1 (last accessed June 29, 2023).

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Washington, Pennsylvania the McNeil Consumer Healthcare Division of Johnson & Johnson Consumer Inc., which is Defendant J&J in this action.

24. Today, J&J is one of the largest consumer health and personal care products companies in the world¹⁵ with Tylenol[®] as one of its most familiar product lines.

25. It is, on information and belief, also one of the world's largest manufacturers and distributors of acetaminophen products with acetaminophen "[a]t the heart of every Tylenol pain reliever."¹⁶

26. J&J currently lists 33 Tylenol[®] medications on its Tylenol[®] product website, including: 2 external cream products, 12 liquid products, 1 chewable product, 15 pill products, 1 liquid gel product, and 2 dissolve pack products.¹⁷ All but 3 of the 33 products contain acetaminophen.¹⁸ The 3 products that do not contain acetaminophen include 2 topical analgesics and 1 sleep aid.¹⁹

27. Over the past 60 years, Tylenol[®] products have had great success. In 1979, Tylenol became the bestselling product in the health and beauty aid category in the United States.²⁰ As of 2005, adult Tylenol was the "fastest-growing brand in the Internal Analgesics category — making

¹⁷ <u>https://www.tylenol.com/products</u> (last accessed June 29, 2023).

¹⁵ <u>https://johnsonandjohnson.gcs-web.com/news-releases/news-release-details/johnson-johnson-</u> <u>consumer-inc-announces-agreement-acquire-zarbees</u> (last accessed June 29, 2023).

¹⁶<u>http://www.brandsearch.superbrands.com/wp-admin/admin-</u>

ajax.php?juwpfisadmin=false&action=wpfd&task=file.download&wpfd_category_id=1190&wp fd_file_id=80217&token=d3ee8a0c555749f1e9bb1f3427339271&preview=1 (last accessed June 29, 2023).

 $^{^{18}}$ *Id*.

¹⁹ *Id*.

²⁰<u>http://www.brandsearch.superbrands.com/wp-admin/admin-</u>

ajax.php?juwpfisadmin=false&action=wpfd&task=file.download&wpfd_category_id=1190&wp fd_file_id=80217&token=d3ee8a0c555749f1e9bb1f3427339271&preview=1 (last accessed June 29, 2023).

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it a bigger brand than Crest, Gillette, Dove, or Listerine."²¹ At that time, consumers had purchased Tylenol "in such record numbers that it ha[d] bec[o]me the only pharmaceutical franchise over \$1 billion available without a prescription."²² Last year, J&J's full year sales for all products totaled about \$94.9 billion.²³ Consumer Health worldwide adjusted operational sales showed an increase of 3.9%, "predominately driven by over-the-counter (OTC) products. Major contributors to growth in OTC were TYLENOL and MOTRIN analgesics, as well as upper respiratory products and digestive health products in the international markets."²⁴

28. J&J has profited and continues to profit greatly from the Tylenol[®] product line.

29. But J&J's profitability on the Class Rapid Release Gelcaps comes at much too high a price, both figuratively and literally: consumer deception about the true nature, quality, and value of the product.

30. J&J sells its Class Rapid Release Gelcaps at a higher price than its other equally effective and equally fast-acting acetaminophen products that are not classified as "rapid release."

31. For example, currently at CVS, a regularly priced 100 count bottle of Tylenol Extra Strength Rapid Release gelcaps costs \$13.99,²⁵ while a regularly priced 100 count bottle of Tylenol Extra Strength caplets costs \$12.99²⁶ and a regularly priced 100 count bottle of Tylenol

²¹ *Id*.

²² Id.

²³<u>https://www.jnj.com/johnson-johnson-reports-q4-and-full-year-2022-results</u> (last accessed June 29, 2023).

 $^{^{24}}$ *Id*.

²⁵ <u>https://www.cvs.com/shop/tylenol-extra-strength-rapid-release-gels-with-acetaminophen-prodid-1280097?skuId=176462</u> (last accessed June 29, 2023).

²⁶ <u>https://www.cvs.com/shop/tylenol-extra-strength-caplets-with-500-mg-acetaminophen-prodid-1080178?skuId=154815</u> (last accessed June 29, 2023).

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Regular Strength tablets costs \$12.49.27

32. Currently on Amazon, a regularly priced 100 count bottle of Tylenol[®] Extra Strength Rapid Release gelcaps costs \$12.47 (or \$.12/count), while a regularly priced 225 count bottle of Tylenol[®] Extra Strength caplets costs \$18.34 (or \$.08/count).²⁸

33. On information and belief, other retailers similarly sell the Class Rapid Release Gelcaps at a price higher than other non-rapid release Tylenol[®] acetaminophen products.

34. Consumers have been willing to and continue to pay this premium because, as a result of J&J's false, misleading, unfair, and/or deceptive labeling and other advertising, they believe the Class Rapid Release Gelcaps work faster than other, cheaper acetaminophen products when in fact they do not.

35. Other companies have followed J&J's labeling, marketing, advertising, and pricing lead and now, in general, acetaminophen products labeled, advertised, or marketed as "rapid release" or "fast-release" are sold on average at a price 23% higher than those acetaminophen products not making these rapid or fast-release representations.²⁹

THE INTRODUCTION & DECEPTIVE MARKETING OF RAPID RELEASE TYLENOL®

36. The Tylenol[®] line of products first expanded to include rapid release gelcaps in 2005 with the introduction of Tylenol[®] Extra Strength Rapid Release Gels.

37. In doing so, J&J touts on its website that these rapid release gelcaps are specially

²⁷ <u>https://www.cvs.com/shop/tylenol-regular-strength-acetaminophen-325-mg-tablets-100-ct-prodid-410579</u> (last accessed June 29, 2023).

²⁸ See

https://www.amazon.com/s?k=tylenol&crid=7NOW8JXTPUXH&sprefix=tylenol%2Caps%2C1 41&ref=nb_sb_noss_2 (last accessed June 29, 2023).

²⁹ Kucera, Jessop, Alvarez, Gortler, Light, *supra* n.3.

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designed with "laser-drilled holes to release medicine quickly."³⁰

38. J&J advertises the tablets as allowing "the release [of] powerful medicine even faster than before:³¹



39. This claim – that these rapid release gelcaps work even faster than before – became associated with the Tylenol[®] Extra Strength Rapid Release Gels. In fact, even a brand case study described the gels as "a new form of Tylenol that releases pain medicine even faster than before."³²

40. In 2009, the rapid release gels were recalled and were not re-released until 2017.³³

³⁰ <u>https://www.tylenol.com/products/tylenol-rapid-release-gels</u> (last accessed June 29, 2023).

³¹ <u>https://debarchambault.com/Tylenol-Rapid-Release</u> (last accessed June 29, 2023).

³²<u>http://www.brandsearch.superbrands.com/wp-admin/admin-</u>

ajax.php?juwpfisadmin=false&action=wpfd&task=file.download&wpfd_category_id=1190&wp fd_file_id=80217&token=d3ee8a0c555749f1e9bb1f3427339271&preview=1 (last accessed June 29, 2023).

 ³³ <u>https://consumergoods.com/headache-sufferers-directed-walgreens</u> (last accessed June 29, 2023).

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41. 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 J&J would normally spend.³⁴

42. The marketing campaign encouraged consumers to find "fast working pain relief."³⁵

43. "In the first month, [the campaign] reached over 25 million shoppers on their mobile device across five key markets, resulting in both category and Tylenol share growth at Walgreens."³⁶

44. In stores, the campaign inundated consumers with its messaging, "from displays inaisle to endcaps to the pharmacy counter to checkout" and even "motion-activated video units."³⁷

45. Customers were also targeted "via Walgreens.com, email blasts, the retailer's Facebook page, a Google campaign, FSIs and paid search."³⁸

46. The campaign's "success was measured largely on brand share and category growth, and it exceeded expectations on these measures."³⁹

47. With its marketing, product labeling, and affirmative representations, J&J sought and continues to seek to further this falsehood: that rapid release Tylenol[®] actually provides faster relief than other cheaper acetaminophen products.

48. J&J did this not only by explicitly making the claim, but also by using buzz words

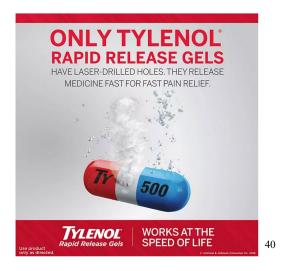
- ³⁵ *Id*.
- 36 *Id*.
- 37 Id.
- ³⁸ Id
- $\int_{30}^{30} Id.$
- ³⁹ *Id*.

³⁴ *Id*.

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that emphasized the speed, fast-acting nature, and unique laser-drilled holes of the rapid release gelcaps.

49. For example, J&J advertised the rapid release gelcaps claiming it "works at the speed of life" and "only Tylenol® Rapid Release Gels have laser-drilled holes" that "release medicine fast for fast pain relief":



50. Moreover, J&J ran a commercial using car racing drivers emphasizing speed in which the drivers try to figure out why another driver was so fast, only to find out it was allegedly because the driver was using Tylenol[®] Rapid Release Gels.⁴¹

- 51. Other marketing statements include, but are not limited to, the following:
 - a. "Tylenol® Rapid Release Gels start to dissolve in seconds and effectively

relieve pain at rapid speed"⁴²

b. "TYLENOL® Rapid Release Gels start to dissolve in seconds and effectively

⁴⁰<u>https://www.samsclub.com/p/tylenol-extra-strength-rapid-release-gels-290-ct/prod21000961?bvstate=pg:3/ct:r</u> (last accessed June 29, 2023).

⁴¹ <u>https://www.youtube.com/watch?v=D4cuoC2DgE8</u> (last accessed June 29, 2023).

⁴² <u>https://www.youtube.com/watch?v=_bZcPNyYu1o</u> (last accessed June 29, 2023).

relieve pain at rapid speed. Its unique laser drilled holes help release medicine faster!"43

- c. "Rapid release. Rapid relief."⁴⁴
- d. "Fast Working Pain Relief"



e. "New Tylenol® Rapid Release Gels. Gelcaps with specially designed holes to release powerful medicine even faster than before."46

f. "When you have pain from a pounding headache and you need relief, trust Tylenol[®] Rapid Release... Tylenol[®] Rapid Release Gelcaps dissolve quickly and relieve your headache pain fast."47

52. J&J's false, misleading, and deceptive marketing campaign has been successful in getting the public to believe that the rapid release gelcaps are faster acting than other Tylenol®

⁴³ https://www.tylenol.ca/products/headache-migraine/tylenol-rapid-release-gels (last accessed June 29, 2023).

⁴⁴ *Id*.

⁴⁵ https://www.effie.org/case database/case/SME 2018_E-375-981 (last accessed June 29, 2023). 46

https://www.voutube.com/watch?v=cKp4xPNTrPY (last accessed June 29, 2023).

⁴⁷ https://www.voutube.com/watch?v=LN0GeRuMouk (last accessed June 29, 2023).

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products, when in fact they are *slower*.

53. It was reported that the "rapid release gels differ from other Tylenol products mainly in its delivery mechanism."⁴⁸

54. Consumer reviews and comments indicate that consumers decide to try and buy the Class Rapid Release Gels because of the represented fast-acting nature of the products. For example, one individual from New York reviewed the product and stated that he/she "just deci[d]ed to try them because they were rapid relief[.]"⁴⁹

55. Consumers reviews and comments indicate that consumers have been deceived or confused by J&J's representations; are likely to be deceived or confused given J&J's representations; and some even notice after purchase that the Class Rapid Release Gelcaps do not work faster than regular, non-rapid release, acetaminophen Tylenol[®] products that are cheaper. Examples include, but are not limited to the following:

a.

★★★☆☆☆ catalina_eddy · a month ago

Gimmicky

I think the rapid release part of these tablets is just get back. They don't seem to work any faster than any other type of ibuprofen tablets.

influenster Originally posted on influenster.com

50

b.

⁴⁸ <u>https://consumergoods.com/headache-sufferers-directed-walgreens</u> (last accessed June 29, 2023).

⁴⁹ <u>https://www.tylenol.com/products/tylenol-rapid-release-gels#bv-product-reviews</u> (last accessed June 29, 2023).

⁵⁰ <u>https://www.tylenol.com/products/tylenol-rapid-release-gels</u> (last accessed June 29, 2023).

★★★★★ S23 · 3 years ago

Definitely met (but didn't surpass) my expectations

[This review was collected as part of a promotion.] When this product was introduced, there was something about the commercials featuring those little drilled holes releasing the medication that captured my attention like I was a toddler glued to the TV.

I was really excited to try these, and finally got a bottle last month after running out of another brand's generic tablets. I did find these to be faster acting, although the ad may have been a little TOO effective - I'm not sure anything could live up to that idea of *immediate* relief that stuck with me from the animation! Still, I appreciated the effectiveness and lack of stomach upset, and I'd buy it again.

51

c.

★★★★ Julianna89 · 6 years ago About as good as any other OTC pain pill

I can't really tell that they work any faster than any other pain relief pill, but they are easy to take capsules and they do provide stong relief. I used them mainly for a toothache and they worked after about 20 minutes to decrease the pain.

52

d.

★★★☆☆ Deceptive hype... these are just TABLETS with a gel casing to help you swallow them easier. Reviewed in the United States on January 4, 2019

Size: 100 Count (Pack of 1)

There is no gel inside, there isn't even powder inside, these are rock hard TABLETS with a capsule casing to help them go down easier, that's all! They make it all sound so special, "laser" holes to release the medication faster, very misleading and annoying! The medication is just plain old acetaminophen in tablet form, but with the dosage raised to 500 mg each. No different from the caplets, which are just tablets shaped like capsules. So much fuss and hype. If acetaminophen works for you, I'm sure you'll like these, but don't expect anything fancy, they're just hard white pills with fancy gel casing to make them LOOK like something special. Bah humbug!

53

e.

Jim1960

★★★☆☆ Not a substitute for capsules

Reviewed in the United States on September 23, 2022 Size: 100 Count (Pack of 1)

Tylenol can help these all they want all they are is gel coated pills they are not Rapid Release no faster than regular Tylenol. For the life of me I cannot understand why Tylenol will not come out with capsules again yes there was a problem years ago you can buy capsules and every other medication except for Tylenol. Just bring back Tylenol capsules please.

54

⁵¹ *Id*.

⁵² Id

53

https://www.amazon.com/product-

reviews/B01HI7WP0U/ref=cm_cr_getr_d_paging_btm_next_4?ie=UTF8&filterByStar=three_st ar&reviewerType=all_reviews&pageNumber=4#reviews-filter-bar (last accessed June29, 2023). ⁵⁴ *Id*.

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f.		
Sue says :		
There is no difference between these pills and the regular tylenol. The company is making them that the extra 2-3 dollars per bottle for the quick release. The other night my husband dropped the bottle open. I kept looking for the powder. All this is, is a regular tylenol with a coating over it, so you will body has to first break down the capsule material, then the tylenol has to break down???? it's twice people off right under our noses	on the floor and on think it's a caspule.	e broke So you
reply agree ? disagree +1 highlight hide	ReviewStream.com	
Joanna says : Why should I trust?		
Hi Sue,		
There actually is a bit of a difference in the coating of the caplets. The rapid release coating dis the tablet itself to dissolve faster. I thought the same thing as you the first time I tried them, but the difference to me.		0
Hope this helps.		
Sincerely,		
Joanna		
reply agree +1 disagree ? highlight hide	ReviewStream.com	55

g.

 $\star \star \star \star \star$ Elsie63 · 6 years ago

Continued quality for Tylenol

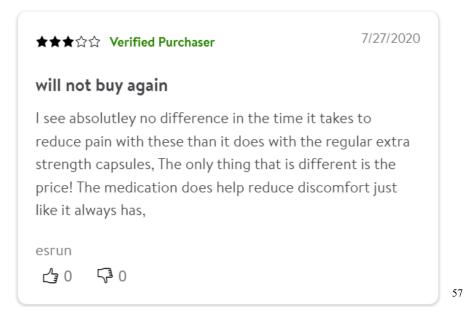
The gel tabs are a good size - no so big they are hard to swallow and not so small they are easily lost and the red and blue makes them clearly identifiable. So I could put several in a small travel pill case in my purse for emergencies or surprise headaches (when are they not a surprise?) and not be worried about forgetting what it was when I open the case and having to toss them because I've forgotten what they were. They work just as good as any other Tylenol or acetaminophen I've taken too.

56

h.

⁵⁵ <u>https://www.reviewstream.com/reviews/?p=46385</u> (last accessed June 29, 2023).

⁵⁶ <u>https://www.tylenol.com/products/tylenol-rapid-release-gels#bv-product-reviews</u> (last accessed June 29, 2023).



THE SCIENCE BEHIND RAPID RELEASE TYLENOL® PRODUCTS DEMONSTRATES J&J'S MARKETING OF THE CLASS RAPID RELEASE GELCAPS IS FALSE, MISLEADING, AND/OR DECEPTIVE

56. Despite what J&J represents to the public about the Class Rapid Release Gelcaps,

they do not work faster than other, cheaper Tylenol® acetaminophen products.

57. A 2018 study of the "rapid release" or "fast release" claims of acetaminophen products, including Tylenol[®] Extra Strength Rapid Release Gels, revealed that these products not only fail to work faster, they actually work *slower* than their traditional acetaminophen counterparts, such as tablets.⁵⁸

58. The 2018 study demonstrates that J&J's representations and advertisings are false,

misleading, deceptive, and unfair.

59. The level of deception and unfairness is elevated given that J&J has long known or should have known that there is scant or conflicting evidence about the correlation of the speed

⁵⁷ <u>https://www.walmart.com/ip/Tylenol-Extra-Strength-Acetaminophen-Rapid-Release-Gels-100-ct/156205102?athbdg=L1200&adsRedirect=true</u> (last accessed June 29, 2023).

⁵⁸ Kucera, Jessop, Alvarez, Gortler, Light, *supra* n.3.

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and efficacy of its acetaminophen products to its rapid release gelcap design.

60. J&J knew or should have known of the existence of "contradictory claims for rapid or fast-release [acetaminophen] products."⁵⁹

61. There is no difference between J&J's Tylenol[®] rapid release gelcaps and its nonrapid release products to warrant J&J's deceptive and misleading representations that the Class Rapid Release Gelcaps work faster than the non-rapid release Tylenol[®] products.

62. J&J knew or should have known that its representations about the Class Rapid Release Gelcaps were false, misleading, and/or deceptive. For example, J&J product testing, analysis, and/or research and development should have alerted J&J to the false, misleading, and/or deceptive nature of its representations pertaining to the Class Rapid Release Gelcaps. Moreover, J&J should have conducted studies or had a basis for the representations it made on and in its labeling, packaging, advertising, and other marketing.

63. Despite that J&J knew or should have known that the Class Rapid Release Gelcaps did not work faster than its other products, J&J falsely marketed the Class Rapid Release Gelcaps as "rapid release" for "fast pain relief," including marketing campaigns which touted the Class Rapid Release Gelcaps as providing relief *faster than ever before*, in order to induce unwitting consumers to buy the product for a premium price – a price that exceeded its actual value.

PLAINTIFF'S EXPERIENCE

Plaintiff Evie Collaza

64. Plaintiff Collaza purchased Tylenol[®] Extra Strength Rapid Release Gelcaps, 100 count in or around February 2023 at Walgreens located at 1710 Crosby Avenue, Bronx, New York for

⁵⁹ Id.

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approximately \$12.98 – a cost more than J&J's other, non-rapid release acetaminophen products in the same count.

65. Pictures of Plaintiff Collaza's last purchased Class Rapid Release Gelcaps appear

below:



66. This was not the first time she purchased the Class Rapid Release Gelcaps or other acetaminophen products, since she suffers and has suffered from sciatica for many years.

67. She purchased the Class Rapid Release Gelcaps over other Tylenol[®] brand and other acetaminophen products because they were advertised and labeled as "rapid release" offering "rapid relief" and she hoped for faster relief of pain.

68. J&J's marketing, including its labeling and advertising, of the product misled Plaintiff Collaza to believe that the Class Rapid Release Gelcaps she purchased would provide faster relief than other, cheaper non-rapid release Tylenol[®] acetaminophen products.

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69. Plaintiff Collaza's experience was that the Class Rapid Release Gelcaps did not work faster for her than other, cheaper acetaminophen products.

70. Had Plaintiff Collaza known that the Class Rapid Release Gelcaps did not act any faster than other, cheaper non-rapid release Tylenol[®] products, she would not have purchased the Class Rapid Release Gelcaps, or else would have paid substantially less for them. Instead, she would have purchased a cheaper, just as effective and just as fast-acting acetaminophen product.

71. Plaintiff Collaza intends to purchase the Class Rapid Release Gelcaps again in the future if properly and truthfully labeled.

72. The cost of the Class Rapid Release Gelcaps exceeded the value of the product and Plaintiff Collaza did not receive the benefit of the bargain.

CLASS ACTION ALLEGATIONS

73. J&J's conduct violates the law. Specifically, J&J conduct violates consumer protection laws, constitutes breach of warranties, and J&J has unjustly enriched itself to the detriment of consumers. J&J's conduct is ongoing and is the basis for Plaintiff's class action allegations.

74. Plaintiff represents a proposed class of hundreds of thousands of consumers who purchased and used the Class Rapid Release Gelcaps manufactured and distributed by J&J and sold under the Tylenol[®] brand name.

75. Plaintiff brings this action individually and as a class action pursuant to Fed. R. Civ. P. 23(a), 23(b)(2), and 23(b)(3), against J&J, on her own and on behalf of a New York Class defined below. Plaintiff proposes the New York Class in the interest of judicial economy and efficiency.

New York Class:

During the fullest period allowed by law, all persons who purchased the Class Rapid Release Gelcaps in the state of New York at any and all of the following physical location

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stores: Walmart, CVS, Walgreens, Target, Rite Aid, Health Mart, Duane Reade Pharmacy, GNC, The Vitamin Shop, Hannaford, Kroger, Wegmans, Whole Foods, King Kullen, and IGA.

76. At the class certification stage, in response to discovery and pursuant to any instruction by the Court, Plaintiff reserves the right to modify these class definitions.

77. "Class Rapid Release Gelcaps" includes Tylenol[®] Extra Strength Rapid Release Gels.

78. Excluded from the proposed Classes are: (a) any Judge or Magistrate presiding over this action and members of their families; (b) J&J and any entity in which it has a controlling interest or which has a controlling interest in it; (c) the officers and directors of J&J; (e) J&J's legal representatives, assigns, and successors; and (f) all persons who properly execute and file a timely request for exclusion from the Classes.

79. Plaintiff meets the prerequisites of Rule 23(a) to bring this action on behalf of the proposed Class.

80. **Numerosity**: While the exact number of Class Members cannot yet be determined, the Classes consist at a minimum of hundreds of people dispersed throughout the State of New York, such that joinder of all members (the "Class Members") is impracticable. The exact number of Class Members can readily be determined by review of information maintained by J&J.

81. **Commonality**: Common questions of law and fact exist as to all members of the Class. Among the questions of law and fact common to the Class are:

a. Whether J&J knew, or reasonably should have known, that the Class Rapid Release Gelcaps it placed into the stream of commerce would not function as advertised;

b. Whether the advertised "rapid release" feature of the Class Rapid Release Gelcaps is a material fact that reasonable purchasers would have considered in deciding whether to purchase the Class Rapid Release Gelcaps;

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c. Whether the Class Rapid Release Gelcaps are of the quality and character
J&J promised to consumers;

d. Whether J&J breached express warranties relating to the Class Rapid Release Gelcaps;

e. Whether J&J breached implied warranties relating to the Class Rapid Release Gelcaps;

f. Whether J&J mispresented the characteristics, qualities, and capabilities of the Class Rapid Release Gelcaps;

g. Whether J&J made fraudulent, false, deceptive, misleading and/or otherwise unfair and deceptive statements in connection with the sale of the Class Rapid Release Gelcaps on its labeling, in its advertising, and on its website, including those relating to speed and comparing the Class Rapid Release Gelcaps to other acetaminophen products not classified as "rapid release";

h. Whether J&J engaged in unfair and deceptive trade practices pertaining to the Class Rapid Release Gelcaps;

i. Whether J&J was unjustly enriched as a result of selling the Class Rapid Release Gelcaps;

j. Whether J&J should be ordered to disgorge all or part of the profits it received from the sale of the Class Rapid Release Gelcaps;

k. Whether Plaintiff and Class Members are entitled to damages including compensatory, exemplary, and statutory damages, and the amount of such damages;

1. Whether Plaintiff and Class Members are entitled to equitable relief, including an injunction and requiring that J&J engage in a corrective notice campaign

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and/or a recall of the Class Rapid Release Gelcaps to address misrepresentations and misleading statements on the packaging; and

m. Whether Plaintiff and Class Members are entitled to an award of reasonable attorneys' fees and pre-judgment interest, post-judgment interest, and costs.

82. **Typicality**: Plaintiff has substantially the same interest in this matter as all other proposed Class Members and her claims arise out of the same set of facts and conduct as all other Class Members. Plaintiff and all Class Members purchased the Class Rapid Release Gelcaps. Plaintiff's and Class Members' claims arise out of J&J's false, misleading, deceptive, and unfair conduct. Common to Plaintiff's and Class Members' claims arise facts and class Gelcaps and Plaintiff's and Class Members' purchase of the Class Rapid Release Gelcaps.

83. Adequacy of Representation: Plaintiff is committed to pursuing this action and has retained competent counsel experienced in products liability, deceptive trade practices, and class action litigation. Plaintiff and her counsel will fairly and adequately protect the interests of Class Members. Plaintiff's claims are coincident with, and not antagonistic to, those of the other Class Members they seek to represent. Plaintiff has no disabling conflicts with Class Members and will fairly and adequately represent the interests of Class Members.

84. The elements of Rule 23(b)(2) are met. J&J will continue to commit the violations alleged, and Plaintiff, Class Members and the general public will be subject to and continue to suffer from the same or substantially similar deceitful marketing. J&J has acted on grounds that apply generally to Class Members so that final injunctive relief and corresponding declaratory relief are appropriate respecting the Class as a whole.

85. The elements of Rule 23(b)(3) are met. Here, the common questions of law and fact

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enumerated above predominate over the questions affecting only the individual Class Members and a class action is the superior method for fair and efficient adjudication of the controversy. Although many other Class Members have claims against J&J, the likelihood that individual Class Members will prosecute separate actions is remote due to the time and expense necessary to conduct such litigation. Serial adjudication in numerous venues is not efficient, timely, or proper. Judicial resources would be unnecessarily depleted by prosecution of individual claims. Joinder on an individual basis of thousands of claimants in one suit would be impractical or impossible. Individualized rulings and judgments could result in inconsistent relief for similarly situated plaintiffs. Plaintiff's counsel, highly experienced in class action litigation, foresee little difficulty in the management of this case as a class action.

TOLLING AND ESTOPPEL OF STATUTES OF LIMITATIONS

86. Any applicable statutes of limitations have been tolled by J&J's knowledge, actual misrepresentations, and/or denial of the facts as alleged herein.

87. Alternatively, the facts alleged herein give rise to estoppel. J&J was and is under a continuous duty to disclose to Plaintiff and Class Members the true character, quality, and nature of the Class Rapid Release Gelcaps. At all relevant times and continuing to this day, J&J knowingly, affirmatively, and actively misrepresented the true character, quality, and nature of the Class Rapid Release Gelcaps. Plaintiff and Class Members reasonably relied on J&J's affirmative misrepresentations of material facts. Based on the allegations contained herein, J&J is estopped from prevailing on any statute of limitations defense in this action.

88. Additionally, J&J is estopped from raising any defense of laches due to its own unclean hands.

ALLEGATIONS REGARDING POTENTIAL PREEMPTION DEFENSE

89. J&J's marketing and sale of Tylenol generally, and its Rapid Release Gelcaps specifically, is regulated by the U.S. Food and Drug Administration. The FDA exercises regulatory control over prescription and over-the-counter medications in the United States, including acetaminophen.

90. It is anticipated that J&J may attempt to argue that Plaintiff's claims are preempted by federal law, specifically the Food Drug and Cosmetic Act.

91. Plaintiff's claims are not preempted because of the following facts:

a. The FDA released a "Tentative Final Monograph" for acetaminophen in 1988 titled "Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph." *See* 53 Fed. Reg. 46204 (Nov. 16, 1988). The TFM adds acetaminophen as an approved active ingredient for analgesic over-the-counter drugs, and includes proposed regulations regarding acetaminophen labeling. 53 Fed. Reg. at 46255-58 (proposed amendments to 21 C.F.R. Part 343.10, 343.50). As of the date of this complaint, the TFM has still not been finalized and remains a proposed rule.

b. Because no final monograph has been issued for acetaminophen, there is no federal requirement with respect to "rapid release" acetaminophen.

c. Even if the Court were inclined to consider the potential preemptive effect of the non-final rule, the TFM incorporates a dissolution standard for acetaminophen tablets, but not for any other form of acetaminophen. Furthermore, the TFM is silent with respect to claims of "rapid release" acetaminophen.

CLAIMS FOR RELIEF

COUNT I

VIOLATION OF NEW YORK GENERAL BUSINESS LAW § 349 (Plaintiff individually and on behalf of the New York Class)

92. Plaintiff incorporates by reference all allegations of the preceding paragraphs as though fully set forth herein.

93. N.Y. Gen. Bus. Law §349 prohibits "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service[.]"

94. J&J's actions occurred in the conduct of business, trade, or commerce.

95. J&J's conduct, as described in this Complaint, constitutes "deceptive acts or practices" within the meaning of N.Y. Gen. Bus. Law § 349.

96. J&J's deceptive acts and practices were intended to mislead consumers in a material way in the process of purchasing the Class Rapid Release Gelcaps. A reasonable consumer would be misled by J&J's deceptive acts and practices because a reasonable consumer would believe that the Class Rapid Release Gelcaps provide for the rapid release of medication or provide rapid relief faster than J&J's cheaper, non-rapid release acetaminophen products, when, in fact, that is not the case.

97. All of J&J's deceptive acts and practices constitute conduct directed at consumers.

98. J&J intended that Plaintiff and each of the other members of the New York Class would rely upon their deceptive conduct and false advertising, and consumers, including Plaintiff and putative Class Members, did in fact rely upon such deceptive conduct and false advertising.

99. J&J's foregoing deceptive and unfair acts and practices, including its omissions, were and are deceptive acts or practices in violation of the N.Y. Gen. Bus. Law § 349, in that J&J manufactured, labeled, packaged, marketed, advertised, distributed, and/or sold, the Class Rapid

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Release Gelcaps, misrepresenting that Class Rapid Release Gelcaps provide rapid release or provide rapid relief faster than J&J's cheaper, non-rapid release acetaminophen products.

100. J&J's unconscionable, deceptive, and/or unfair practices caused actual damages and injury to Plaintiff and the Class Members, who were unaware that the Class Rapid Release Gelcaps fail to provide rapid release as advertised and do not provide faster pain relief than J&J's cheaper, non-rapid release acetaminophen products. Had J&J disclosed the true nature of the Class Rapid Release Gelcaps—namely, that they do not provide rapid release or do not provide faster pain relief than J&J's cheaper, non-rapid release acetaminophen products—Plaintiff would not have purchased the Product, or else would have paid substantially less for them.

101. As a direct and proximate result of J&J's deceptive acts and practices, including its omissions, Plaintiff and the Class Members have been damaged as alleged herein and are thus entitled to recover fifty dollars (\$50) for each violation.

102. Through its conduct, J&J willfully or knowingly engaged in deceptive acts and practices, including through its omissions. Accordingly, a punitive award is appropriate, such that the damages be increased in an amount three times actual damages up to one thousand dollars (\$1,000), for each violation.

103. In addition, Plaintiff and Class Members seek equitable and injunctive relief against J&J, in addition to reasonable attorneys' fees and costs.

COUNT II

VIOLATION OF NEW YORK GENERAL BUSINESS LAWS § 350 (Plaintiff individually and on behalf of the New York Class)

104. Plaintiff incorporates by reference all allegations of the preceding paragraphs as though fully set forth herein.

105. N.Y. Gen. Bus. Law §350 prohibits "[f]alse advertising in the conduct of any

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business, trade or commerce or in the furnishing of any service[.]" False advertising means "advertising, including labeling, of a commodity . . . [that is] misleading in a material respect." N.Y. Gen. Bus. Law § 350-a. The omission of material facts also constitutes false advertising. *Id.*

106. J&J's actions occurred in the conduct of business, trade, or commerce.

107. J&J's foregoing acts and practices, including advertising, were directed at consumers.

108. J&J's conduct, as described in the Complaint, constitutes "false advertising" within the meaning of the N.Y. Gen. Bus. Law §350, because J&J publicly disseminated and continues to disseminate to consumers materially misleading false statements and labeling regarding the attributes of the Class Rapid Release Gelcaps through its advertising, marketing, labeling, packaging, and other representations (including through omissions).

109. Specifically, J&J falsely advertises that the Class Rapid Release Gelcaps provide for a rapid release of medication, as compared to other cheaper, non-rapid release acetaminophen products, when, in fact, that is not the case. In reality, the Class Rapid Release Gelcaps fail to provide rapid release as advertised and do not provide faster pain relief than J&J's cheaper, nonrapid release acetaminophen products. Despite its knowledge of these facts, J&J still falsely advertised the Class Rapid Release Gelcaps.

110. J&J's false, misleading, and deceptive advertising and representations of fact, including its omissions, were and are directed at consumers.

111. J&J's false, misleading, and deceptive advertising and representations of fact, including its omissions, were intended to mislead consumers in a material way in the process of purchasing the Class Rapid Release Gelcaps. A reasonable consumer would be misled by J&J's false, misleading, and deceptive advertising and representations of fact, including its omissions,

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because a reasonable consumer would believe that the Class Rapid Release Gelcaps provide for the rapid release of medication or provide rapid relief faster than J&J's cheaper, non-rapid release acetaminophen products, when, in fact, that is not the case.

112. J&J's false, misleading, and deceptive advertising and representations of fact, including its omissions, have resulted in consumers overpaying for specific product features—namely, the rapid release of medication—that they never received, causing injury and harm to the public interests.

113. J&J intended that Plaintiff and the other members of the New York Class rely upon their deceptive conduct and false advertising. And a reasonable person would in fact be misled by J&J's deceptive conduct and false advertising.

114. J&J's false, misleading, and deceptive advertising and representations of fact, including its omissions, caused actual damages and injury to Plaintiff and the Class Members, who were unaware that the Class Rapid Release Gelcaps fail to provide rapid release as advertised and do not provide faster pain relief than J&J's cheaper, non-rapid release acetaminophen products. Had J&J disclosed the true nature of the Class Rapid Release Gelcaps—namely, that they do not provide rapid release or do not provide faster pain relief than J&J's cheaper, non-rapid release acetaminophen products. Had J&J disclosed the true nature of the Class Rapid Release Gelcaps—namely, that they do not provide rapid release or do not provide faster pain relief than J&J's cheaper, non-rapid release acetaminophen products—Plaintiff would not have purchased the Product, or else would have paid substantially less for them.

115. As a direct and proximate result of J&J's false, misleading, and deceptive advertising and representations of fact, including its omissions, Plaintiff and the Class Members have been damaged as alleged herein and are thus entitled to recover five hundred dollars (\$500) for each violation.

116. Through its conduct, J&J willfully or knowingly engaged in falsely advertising the

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Class Rapid Release Gelcaps. Accordingly, a punitive award is appropriate, such that the damages be increased in an amount three times actual damages up to ten thousand dollars (\$10,000), for each violation.

117. In addition, Plaintiff and Class Members seek equitable and injunctive relief against J&J, in addition to reasonable attorneys' fees and costs.

COUNT III

UNJUST ENRICHMENT (Plaintiff individually and on behalf of the New York Class)

118. Plaintiff incorporates by reference all allegations of the preceding paragraphs as though fully set forth herein.

119. As described above, J&J sold the Class Rapid Release Gelcaps to Plaintiff and Class Members making false, misleading, and/or deceptive representations about the products' speed and capabilities as compared to J&J's cheaper, non-rapid release acetaminophen products.

120. J&J unjustly charged and continues to charge Plaintiff and Class Members a premium to purchase the Class Rapid Release Gelcaps over the non-rapid release acetaminophen Tylenol[®] products.

121. As a result of its false, misleading, unfair, and/or deceptive practices and omission about the true nature and quality about the Class Rapid Release Gelcaps, J&J obtained monies that rightfully belong to Plaintiff and Class Members.

122. J&J appreciated, accepted, and retained the non-gratuitous benefits conferred by Plaintiff and Class Members who, without knowledge of the true quality and nature of the Class Rapid Release Gelcaps, paid a higher price than what they were worth.

123. J&J also received monies for those Class Rapid Release Gelcaps that Plaintiff and Class Members would not have otherwise purchased had they known the true nature and quality

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of the products.

124. J&J's retention of these wrongfully acquired profits violates fundamental principles of justice, equity, and good conscience.

125. Plaintiff and Class Members seek restitution from J&J and an order of this Court proportionally disgorging all profits, benefits, and other compensation obtained by J&J from its wrongful conduct and establishment of a constructive trust from which Plaintiff and Class Members may seek restitution.

COUNT IV

DECLARATORY RELIEF (Plaintiff individually and on behalf of the New York Class)

126. Plaintiff incorporates by reference all allegations of the preceding paragraphs as though fully set forth herein.

127. There is a controversy between J&J and Plaintiff and Class Members concerning the true nature, quality, and capability of the Class Rapid Release Gelcaps and the false, misleading, unfair, and/or deceptive representations that J&J made about the same.

128. Pursuant to 28 U.S.C. § 2201, this Court may "declare the rights and legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought."

129. Accordingly, Plaintiff and Class Members seek a declaration that the Class Rapid Release Gelcaps do not release, provide relief, or otherwise work faster than other, cheaper non-rapid release acetaminophen Tylenol[®] products.

130. Additionally, Plaintiff and Class Members seek a declaration that as a result of J&J's false, misleading, unfair, and/or deceptive representations, consumers and Class Members did not and do not receive the benefit of their bargain.

131. J&J designed, manufactured, produced, tested, inspected, marketed, advertised,

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labeled, packaged, distributed, and sold the Class Rapid Release Gelcaps. J&J continues to do so while using false, misleading, unfair, and/or deceptive representations to ensure sales to consumers.

132. Based upon information and belief, J&J has taken no corrective action concerning the false, misleading, unfair, and/or deceptive representations described herein, and has not issued any recalls, warnings, or notices concerning the true nature, quality, and capability of the Class Rapid Release Gelcaps.

133. Plaintiff and Class Members have suffered damages or injuries due to J&J's conduct described herein.

134. J&J should be required to take corrective action to prevent further injuries, including: (a) issuing a nationwide recall of the Class Rapid Release Gelcaps to address product labeling and packaging; (b) issuing warnings and/or notices to consumers and the Class concerning the true nature, quality, and capability of the Class Rapid Release Gelcaps; and (c) immediately discontinuing any false, misleading, unfair, and/or deceptive advertising, marketing, or other representations described herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff asks the Court to enter judgment awarding the following relief:

- A. An order certifying the proposed New York Class;
- B. An order awarding Plaintiff and Class Members their actual damages, punitive damages, and/or any other monetary relief provided by law;
- C. An order awarding Plaintiff and Class Members restitution, disgorgement, or other equitable relief as the Court deems proper;
- D. An order requiring J&J to adequately represent the true nature, quality, and capability of the Class Rapid Release Gelcaps;
- E. An order (a) issuing a nationwide recall of the Class Rapid Release Gelcaps to address product labeling and packaging; (b) issuing warnings and/or

notices to consumers and the Class concerning the true nature, quality, and capability of the Class Rapid Release Gelcaps; and (c) immediately discontinuing any false, misleading, unfair, and/or deceptive advertising, marketing, or other representations described herein.

- F. An order granting declaratory and/or injunctive relief as allowable under state and federal law;
- G. An order awarding Plaintiff and Class Members pre-judgment and postjudgment interest as allowed by law;
- H. An order awarding Plaintiff and Class Members reasonable attorneys' fees and costs of suit, including expert witness fees; and
- I. An order awarding such other and further relief as this Court may deem just and proper.

JURY DEMAND

Pursuant to Fed. R. Civ. P. 38(b), Plaintiff demands a trial by jury on all issues so triable

under the law.

DATED: July 13, 2023

Respectfully submitted,

/s/ Mitchell M. Breit

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