File No. CI23-01- 43851

THE KING'S BENCH
Winnipeg Centre

BETWEEN:

BARB EORI

Plaintiff

and

JOHNSON & JOHNSON INC., d.b.a. McNeil Consumer Healthcare, PROCTER & GAMBLE INC., GLAXOSMITHKLINE CONSUMER HEALTHCARE ULC, PFIZER CANADA ULC, d.b.a. Pfizer Consumer Healthcare

Defendants

Proceeding under *The Class Proceedings Act*, CCSM c C130

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STATEMENT OF CLAIM

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STATEMENT OF CLAIM

TO THE DEFENDANT:

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiff. The claim made against you is set out in the following pages.

IF YOU WISH TO DEFEND THIS PROCEEDING, you or a Manitoba lawyer acting for you must prepare a statement of defence in Form 18A prescribed by the *King's Bench Rules*, serve it on the plaintiff's lawyer or where the plaintiff does not have a lawyer, serve it on the plaintiff, and file it in this court office, WITHIN TWENTY DAYS after this statement of claim is served on you, if you are served in Manitoba.

If you are served in another province or territory of Canada or in the United States of America, the period for serving and filing your statement of defence is forty days. If you are served outside Canada and the United States of America, the period is sixty days.

IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGEMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

November 10, 2023

Issued _____
Deputy Registrar

D. CHAMPAGNE
DEPUTY REGISTRAR
COURT OF KING'S BENCH
FOR MANITOBA

To: **JOHNSON & JOHNSON INC., d.b.a. McNeill Consumer Healthcare**
88 McNab Street
Markham, ON L3R 5L2

And to: **PROCTER & GAMBLE INC.**
4711 Yonge Street
North York, ON M2N 6K8

And to: **GLAXOSMITHKLINE CONSUMER HEALTHCARE ULC**
3500 – 1133 Melville Street
Vancouver, BC V6C 4E5

And to: **PFIZER CANADA ULC, d.b.a. Pfizer Consumer Healthcare**
17300 Trans-Canada Highway
Kirkland, QC H9J 2M5

CLAIM

I. RELIEF SOUGHT

1. The plaintiff claims, on her own behalf and on behalf of the Class:

(a) An order certifying this action as a class proceeding and appointing the plaintiff as the representative plaintiff under the *CPA*;

(b) Restitution or return of all or part of the purchase prices of Ineffective Drugs, or damages, under:

(i) Section 36 of the *Competition Act*, RSC 1985, c C-34;

(ii) Sections 23(2)(a) and 23(2)(d) of *The Business Practices Act*, CCSM c B120;

(iii) Sections 13(1), 13(2)(a), 13(2)(d)(ii), 142.1(1), 142.1(2)(a), and 142.1(2)(c)(ii) of the *Consumer Protection Act*, RSA 2000, c C-26.3;

(iv) Section 171(1) and 172(3)(a) of the *Business Practices and Consumer Protection Act*, SBC 2004, c 2;

(v) Section 10(2)(b) and 10(2)(e) of the *Consumer Protection and Business Practices Act*, SNL 2009, c C-31.1;

(vi) Section 18(2) of the *Consumer Protection Act, 2002*, SO 2002, c 30, Sch A;

(vii) Section 4(1) of the *Business Practices Act*, RSPEI 1988, c B-7;

(viii) Article 272 of the *Consumer Protection Act*, CQLR c P-40.1;

(ix) Article 1457 of the *Civil Code of Québec*, CQLR c CCQ-1991;

(x) Sections 93(1)(a)-(b) of *The Consumer Protection and Business Practices Act*, SS 2013, c C-30.2; and

(xi) The common law for the claim in unjust enrichment.

(c) Exemplary or punitive damages under:

(i) Section 23(4) of *The Business Practices Act*, CCSM c B120;

(ii) Sections 13(2)(c) and 142.1(2)(b) of the *Consumer Protection Act*, RSA 2000, c C-26.3;

(iii) Section 10(2)(b) of the *Consumer Protection and Business Practices Act*, SNL 2009, c C-31.1;

(iv) Section 18(11) of the *Consumer Protection Act, 2002*, SO 2002, c 30, Sch A;

(v) Article 272 of the *Consumer Protection Act*, CQLR c P-40.1;

(vi) Section 93(1)(b) of *The Consumer Protection and Business Practices Act*, SS 2013, c C-30.2; and

(vii) The common law for the claim in unjust enrichment;

(d) A declaration under section 172(1)(a) of the *Business Practices and Consumer Protection Act*, SBC 2004, c 2 that the Defendants breached that statute;

(e) If and to the extent necessary, relief from notice requirements under:

(i) Section 7.2(3) of the *Consumer Protection Act*, RSA 2000, c C-26.3; and

(ii) Section 18(15) of the *Consumer Protection Act, 2002*, SO 2002, c 30, Sch A;

(f) A reference to determine any individual issues after the determination of the common issues, pursuant to section 27(1) of the *CPA*;

(g) Costs of notice and distribution, pursuant to sections 19(3)(a), 24(1), and 33(6) of the *CPA*;

(h) Costs of this action on a full or substantial indemnity basis;

(i) Pre-judgment and post-judgment interest pursuant to sections 78-87 of *The Court of Queen's Bench Act*, CCSM c C280; and

(j) Such further and other relief as this court may deem just.

II. DEFINITIONS

2. In addition to terms defined elsewhere in this Statement of Claim, the following terms are defined:

(a) "**Class**" means all persons in Canada who purchased an Ineffective Drug. "**Consumer Subclass**" means all members of the Class who purchased an Ineffective Drug for their own consumption or for the consumption of a friend or family member.

(b) "***CPA***" means the *Class Proceedings Act*, CCSM c C130;

(c) "**Ineffective Drugs**" means any drug:

(i) Manufactured, imported, marketed, or sold by the defendants or any related corporation;

(ii) Marketed as a decongestant, as having a decongestant effect, or as treating congestion;

(iii) Intended to be taken orally;

(iv) Containing phenylephrine; and

(v) Not containing any of the following:

(1) Brophenramine;

(2) Chlorphenramine;

(3) Diphenhydramine;

(4) Doxylamine;

(5) Guaifenesin;

(6) Hammelis Virginiana;

(7) Hydrocodone;

(8) Pheniramine;

(9) Phenylpropanolamine; or

(10) Thenyldiamine.

(vi) For greater certainty, but without limiting the generality of the foregoing, Ineffective Drugs include, but are not limited to the drugs listed in Schedule A.

III. OVERVIEW

3. In 1976, the FDA approved phenylephrine for use as an oral decongestant. It relied on research that (1) did not show that phenylephrine was effective; (2) used clearly flawed methodologies; and (3) probably included fabricated data.

4. For decades, researchers and regulators have identified flaws in the 1976 approval, showing that phenylephrine does not work as an oral decongestant. Most recently, in 2023, the FDA reversed its 1976 approval, concluding that phenylephrine is not effective as an oral decongestant at *any* safe dose.

5. The defendants have made billions of dollars selling drugs with phenylephrine and marketing them as decongestants. None of those products ever worked as a decongestant, as has been made apparent by the 2023 FDA decision, but the defendants continue to sell these products and market them as decongestants.

IV. FACTS

A. <u>The defendants</u>

(i) Johnson & Johnson

6. Johnson & Johnson Inc. is a corporation incorporated under the laws of Canada. It manufactures, imports, markets, and sells Ineffective Drugs across Canada, including in Manitoba, both under its own name and under the name McNeil Consumer Healthcare. Its products include the ones listed in Schedule A under the brand names Benylin, Sudafed PE, and Tylenol.

7. If and to the extent that any related corporations manufactured, imported, marketed, or sold ineffective Drugs in Canada, Johnson & Johnson Inc. is responsible for their conduct as master, employer, partner, joint venturer, or alter ego. The business of these related corporations was inextricably interwoven. To the extent that any predecessor corporations manufactured, imported, marketed, or sold ineffective Drugs in Canada, Johnson & Johnson Inc. is responsible for their conduct as a successor. This claim uses the term "**Johnson & Johnson**" to refer collectively to Johnson & Johnson Inc. and all of its related and predecessor corporations that are or were involved with the manufacture, import, marketing, or sale of Ineffective Drugs in Canada.

(ii) Procter & Gamble

8. Procter & Gamble Inc. is a corporation incorporated under the laws of Canada. It manufactures, imports, markets, and sells Ineffective Drugs across Canada, including in Manitoba. Its products include the ones listed in Schedule A under the brand names DayQuil, Vicks, and Vicks DayQuil.

9. If and to the extent that any related corporations manufactured, imported, marketed, or sold ineffective Drugs in Canada, Procter & Gamble Inc. is responsible for their conduct as master, employer, partner, joint venturer, or alter ego. The business of these related corporations was inextricably interwoven. To the extent that any predecessor corporations manufactured, imported, marketed, or sold ineffective Drugs in Canada, Procter & Gamble Inc. is responsible for their conduct as a successor. This claim uses the term "**Procter & Gamble**" to refer collectively to Procter & Gamble Inc. and all of its related and predecessor corporations that are or were involved with the manufacture, import, marketing, or sale of Ineffective Drugs in Canada.

(iii) GlaxoSmithKline

10. GlaxoSmithKline Consumer Healthcare ULC is a corporation incorporated under the laws of British Columbia. It manufactures, imports, markets, and sells Ineffective Drugs across Canada, including in Manitoba. Its products include the ones listed in Schedule A under the brand names Contac, NeoCitran, and Triaminic Thin Strips.

11. If and to the extent that any related corporations manufactured, imported, marketed, or sold ineffective Drugs in Canada, GlaxoSmithKline Consumer Healthcare ULC is responsible for their conduct as master, employer, partner, joint venturer, or alter ego. The

business of these related corporations was inextricably interwoven. To the extent that any predecessor corporations manufactured, imported, marketed, or sold ineffective Drugs in Canada, GlaxoSmithKline Consumer Healthcare ULC is responsible for their conduct as a successor. This claim uses the term "**GlaxoSmithKline**" to refer collectively to GlaxoSmithKline Consumer Healthcare ULC and all of its related and predecessor corporations that are or were involved with the manufacture, import, marketing, or sale of Ineffective Drugs in Canada.

(iv) Pfizer

12. Pfizer Canada ULC is a corporation incorporated under the laws of Nova Scotia. It manufactures, imports, markets, and sells Ineffective Drugs across Canada, including in Manitoba, both under its own name and under the name Pfizer Consumer Healthcare. Its products include the ones listed in Schedule A under the brand names Benylin D and Robitussin.

13. If and to the extent that any related corporations manufactured, imported, marketed, or sold ineffective Drugs in Canada, Pfizer Canada ULC is responsible for their conduct as master, employer, partner, joint venturer, or alter ego. The business of these related corporations was inextricably interwoven. To the extent that any predecessor corporations manufactured, imported, marketed, or sold ineffective Drugs in Canada, Pfizer Canada ULC is responsible for their conduct as a successor. This claim uses the term "**Pfizer**" to refer collectively to Pfizer Canada ULC and all of its related and predecessor corporations that are or were involved with the manufacture, import, marketing, or sale of Ineffective Drugs in Canada.

14. Collectively, Johnson & Johnson, Procter & Gamble, GlaxoSmithKline, and Pfizer – as those terms are defined above – are the "**Defendants**".

B. Phenylephrine

15. Phenylephrine hydrochloride ("**phenylephrine**") is an alpha-1 adrenergic receptor agonist. In other words, when phenylephrine is able to reach those receptors, it activates them, restricting blood vessels, thereby preventing fluid from draining into sinuses.

16. When administered nasally, most of the phenylephrine reaches the receptors and can have an effect. By contrast, when administered orally, it first goes through the gut, and then the bloodstream. This reduces the phenylephrine that reaches the receptors. This is known as a first pass effect. It is one of the most basic effects in pharmacokinetics, taught in every first-year pharmacology course. All of the defendants fully appreciated the importance of this effect.

17. Phenylephrine was monographed (i.e. approved for use) at:

(a) 10 mg every 4 hours for anyone over age 12;

(b) 5 mg every 4 hours for children aged 6-12; and

(c) 2.5 mg every 4 hours for children aged 2-6.

18. All of the Ineffective Drugs have between 1.25 and 10 mg of phenylephrine.

19. At those levels, almost no phenylephrine ultimately reaches the receptors, so these drugs do not work as oral decongestants.

20. Even at a much higher dose – 40 mg – almost no phenylephrine would reach the receptors. In other words, even if you took 4 times the maximum dose of any of the Ineffective Drugs, it would still not work as an oral decongestant.

C. The 1976 FDA Decision

(i) The decision and its effects

21. In 1976, the Advisory Review Panel on Over-the-Counter Cold, Cough, Allergy, Bronchodilator, and Anti-asthmatic Products (the "**Cough-Cold Panel**") of the United States Food and Drugs Administration ("**FDA**") assessed the safety and efficacy of various alleged decongestants, including phenylephrine, and made a recommendation to the FDA (the "**1976 FDA Decision**").

22. The FDA relied on the Cough-Cold Panel's conclusions to authorize the sale of phenylephrine in 1985. The FDA's decision did not say that phenylephrine was effective. In fact, the FDA concluded that the evidence was "not strongly indicative of efficacy". However, in the absence of a safety concern, it saw no reason to deny approval, even if it did not work.

(ii) The underlying studies

23. The Cough-Cold Panel looked at 14 studies on the efficacy of phenylephrine.

24. Of the 14 studies, only 7 reported positive, measurable efficacy results. In other words, only half of the studies claimed that phenylephrine was effective.

25. All of the positive studies were conducted by manufacturers of products with phenylephrine: 6 by Winthrop Labs (owned by the manufacturer of Neo-Synephrine) and 1 by Whitehall Labs (owned by Wyeth, which has since been purchased by Pfizer's parent company).

26. The negative studies – including two by Winthrop Labs which were unable to replicate the positive studies – were largely ignored.

(iii) Issues with Winthrop Labs studies

27. The studies finding efficacy by Winthrop Labs had clear flaws:

(a) They were never published or peer-reviewed, and the protocols they used were never even made available to the FDA;

(b) They took patients with the common cold (instead of rhinitis) and measured congestion using nasal airway resistance (instead of clinical symptom scores), both of which result in high variability which can only be solved by having a very large sample size;

(c) They had small sample sizes (the largest study gave phenylephrine to only 33 people); and

(d) There is strong evidence of a data integrity issue (i.e. data being deleted and/or fabricated).

28. Even if one ignores all of those issues, at every dose, the studies found that half of the subjects were unaffected (i.e. it was not effective for them).

(iv) Issues with Whitehall Labs studies

29. The study by Whitehall Labs also had clear flaws:

(a) The scoring was based on the subjective opinion of the investigator;

(b) There was no protocol for scoring, and it may have been done infrequently and after-the fact; and

(c) There was no methodology to reduce bias in scoring.

30. Even if one ignores all of those issues, the studies did not consider whether the changes identified were clinically meaningful.

D. Studies between 1976 and 2023

31. Since 1976, many studies have been published showing that phenylephrine is not effective at treating congestion, at least when administered orally, even at doses of 40 mg. Those studies include:

(a) A 2005 article in the *Journal of Allergy and Clinical Immunology* titled "Oral phenylephrine: An ineffective replacement for pseudoephedrine?";

(b) A 2007 article in the *Annals of Pharmacotherapy* titled "Efficacy and Safety of Oral Phenylephrine: Systematic Review and Meta-Analysis";

(c) Two 2009 articles in the *Annals of Allergy, Asthma & Immunology* titled "A placebo-controlled study of the nasal decongestant effect of phenylephrine and pseudoephedrine in the Vienna Challenge Chamber" and "Efficacy of

loratadine-montelukast on nasal congestion in patients with seasonal allergic rhinitis in an environmental exposure unit";

(d) A 2015 article in *The Journal of Allergy and Clinical Immunology* titled "Oral Phenylephrine HCL for Nasal Congestion in Seasonal Allergic Rhinitis: A Randomized, Open-label, Placebo-controlled study";

(e) A 2016 article in the *Annals of Allergy, Asthma & Immunology* titled "Phenylephrine hydrochloride modified-release tablets for nasal congestion: a randomized, placebo-controlled trial in allergic rhinitis patients";

(f) A 2018 article in *Allergy and Asthma Proceedings* titled "Nonprescription medications for respiratory symptoms: Facts and marketing fictions"; and

(g) A 2022 article in the *Annals of Pharmacotherapy* titled "Why is Oral Phenylephrine on the Market After Compelling Evidence of Its Ineffectiveness as a Decongestant?".

E. The 2023 FDA Decision

32. On September 12, 2023, the FDA released a briefing document (the "**2023 FDA Decision**") on the efficacy of oral phenylephrine as a nasal decongestant. It found that:

> "orally administered PE is not effective at any dose that can be developed and still provide a reasonable margin of safety"

33. The FDA broke that conclusion down further as follows:

> "oral [phenylephrine] at monographed dosages is not effective as a decongestant"

"oral doses up to 40 mg would also not be effective"

"finding an effective oral dose that is also safe is not feasible"

"Therefore, in addition to lack of efficacy, there may be no path to evaluating higher doses of oral PE as a nasal decongestant."

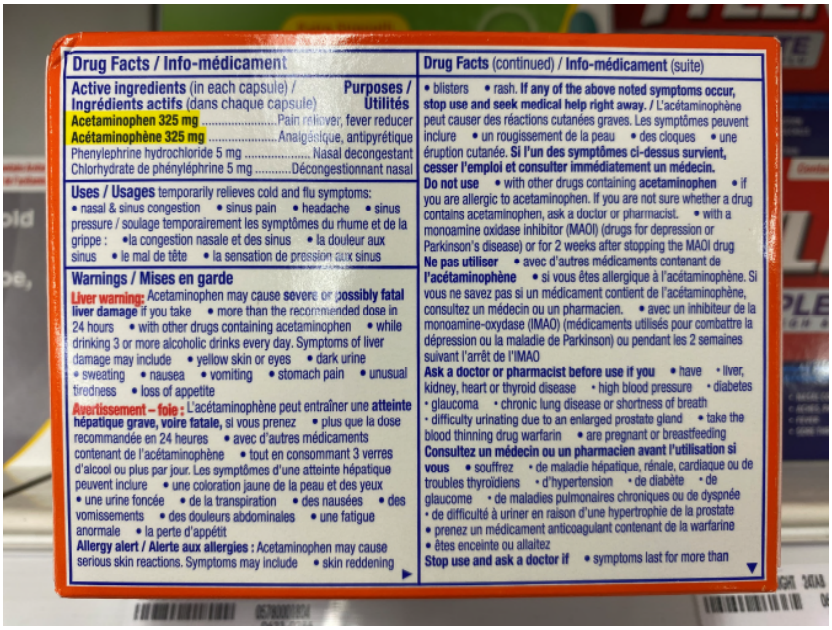
F. The Misrepresentations

34. Since 1985 – and continuing after the 2023 FDA Decision – the Defendants marketed the Ineffective Drugs as oral decongestants.

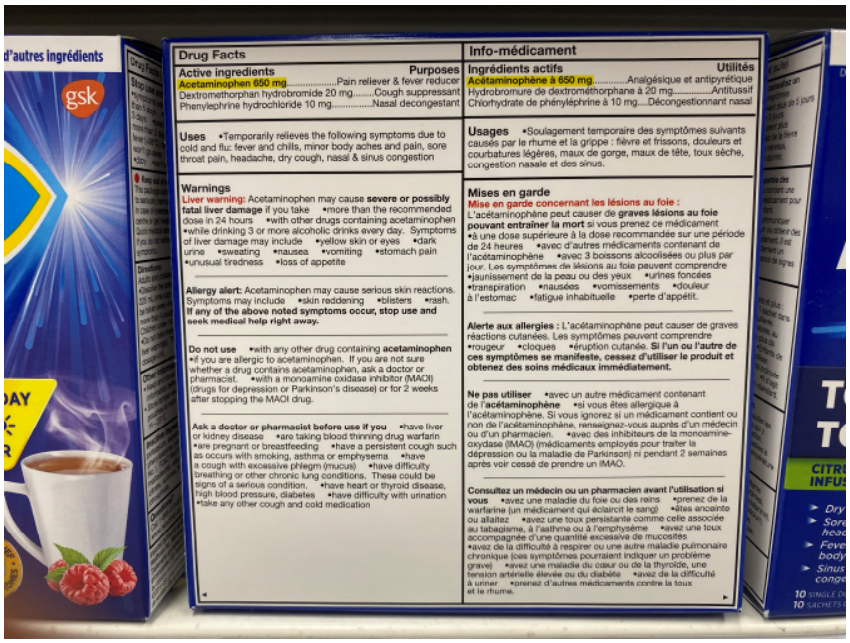
35. Such representations were prominently displayed on the packaging.

36. For example, after the 2023 FDA Decision, the following packaging was on the shelves at Shoppers Drug Mart and Rexall.

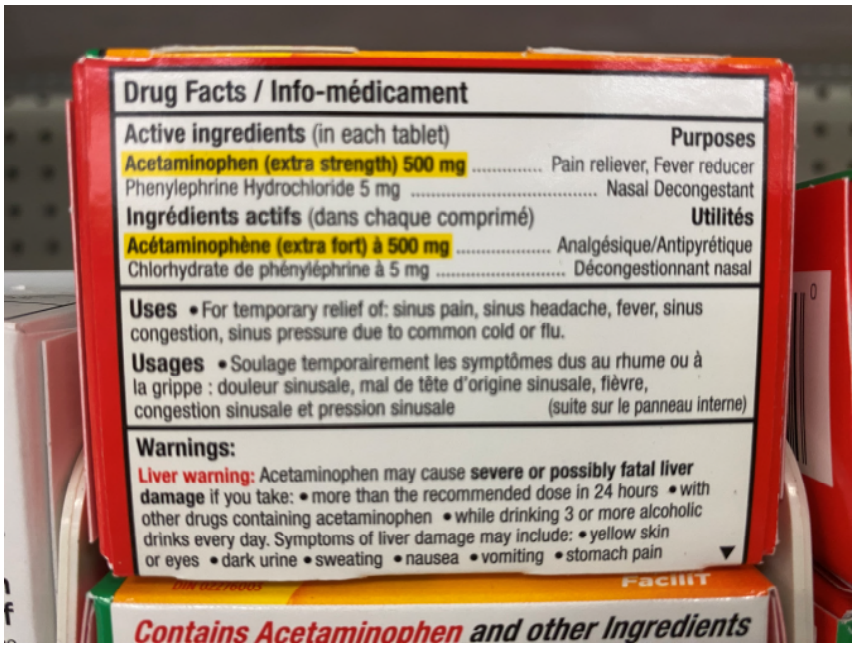
(a) **DayQuil Sinus Liquicaps**: Note that the first item listed on the front of the packaging is "Sinus Congestion" and the "Uses" on the back of the packaging include "temporarily relieves … nasal & sinus congestion".



(b) **NeoCitran Extra Strength Total Cold**: Note that the third item listed on the front of the packaging is "Sinus & nasal **congestion**" and the "Uses" on the back of the packaging include "Temporarily relieves … nasal & sinus congestion".



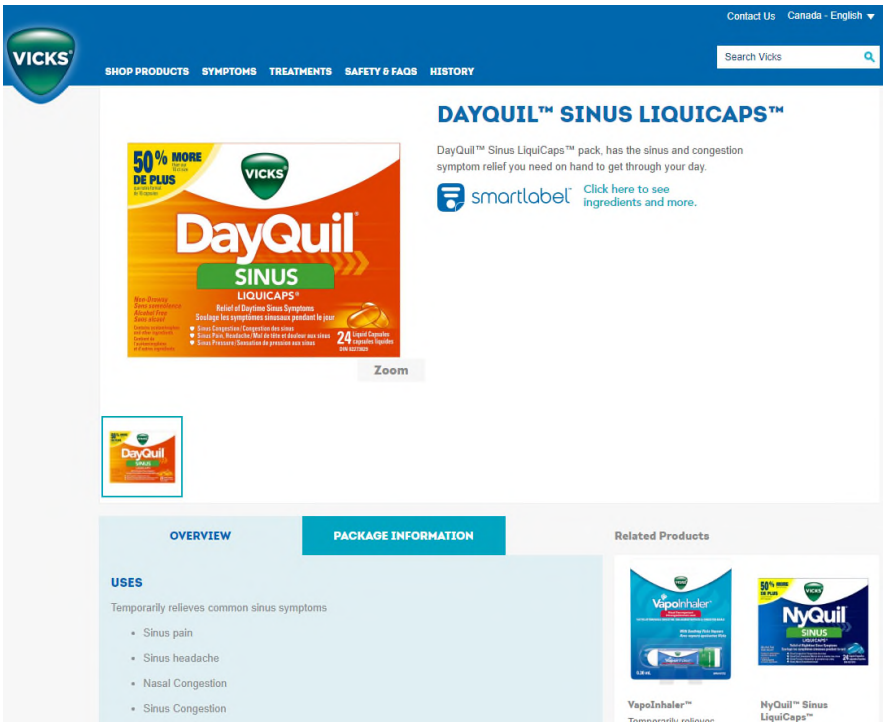
(c) **Tylenol Extra Strength Sinus Daytime**: Note that the product is called "Sinus", indicating an effect on sinus congestion; the third **item** listed on the front of the packaging is "Sinus congestion"; and the "Uses" on the back of the packaging include "For temporary relief of … sinus congestion".



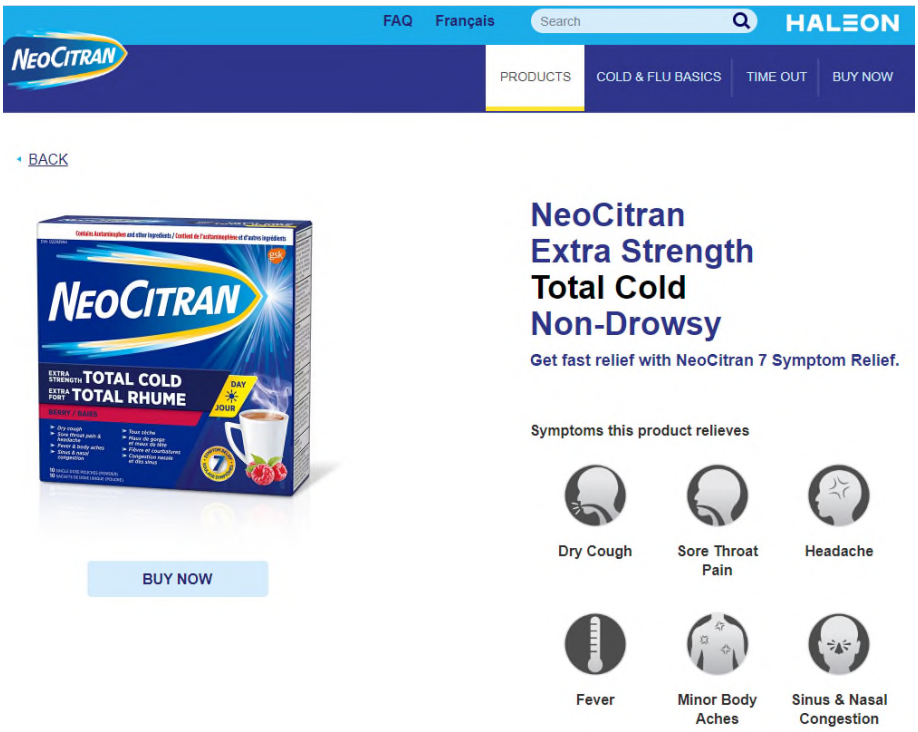
37. The packaging of all the Ineffective Drugs contained and continue to contain similar representations.

38. Similar representations were made on the defendants' websites. For example, as of the date of issuance, the following webpages are live:

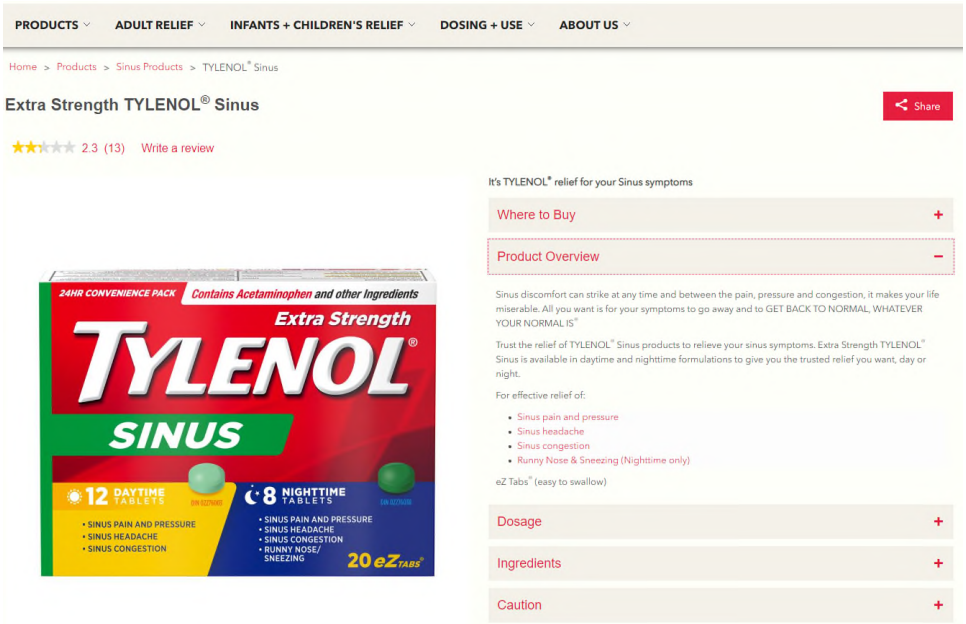
(a) **DayQuil Sinus Liquicaps**: Note that the first paragraph says that the product "has the sinus and congestion symptom relief you need", and the list of "USES" includes "Temporarily relieves … Nasal Congestion … [and] Sinus Congestion".



(b) **NeoCitran Extra Strength Total Cold**: Note that "Sinus & Nasal Congestion" is listed under "Symptoms this product relieves".



(c) **Tylenol Extra Strength Sinus Daytime**: Note that this webpage says that the product provides “effective relief” of “Sinus congestion”.



(d) The last webpage refers to both the Daytime and the Nighttime versions of this drug. Only the Daytime drug is an Ineffective Drug. Thus, anyone who purchased the combined product is a member of **the** Class, but the claims are limited to the Daytime drug within the combined product, and the remedy sought relates only to the portion of the purchase price attributable to the Daytime drug. Note that the webpage identifies one of the effects as "Nighttime only", but it does not apply this qualification to "effective relief of … Sinus congestion".

39. The webpages of each of the Defendants with respect to the Ineffective Drugs contained and continue to contain similar representations.

40. Each of the Defendants made similar representations to wholesalers, retailers, and distributors.

41. Each of the Defendants failed to disclose that phenylephrine – the only active ingredient in the Ineffective Drugs alleged to have a decongestant effect – does not work as an oral decongestant.

42. Collectively, the representations described above at paragraphs 34-41 are the "**Misrepresentations**".

G. Ms. Eori's experience

43. Barb Eori has been a nurse for 33 years. She currently works at the Health Sciences Centre in Winnipeg, Manitoba.

44. Throughout her life, Ms. Eori has purchased Ineffective Drugs for herself, her husband, and her three children – especially those branded as Tylenol or NeoCitran. In a normal year, she would purchase anywhere between six to eight of the Ineffective Drugs each flu season, plus others as needed throughout the year.

45. At the time of each purchase, Ms. Eori believed that the Ineffective Drugs would be effective at treating congestion. She would not have bought these products if she knew that they did not work when taken orally.

V. CAUSES OF ACTION

A. Statutory misrepresentation

(i) For all Class members

46. The Misrepresentations were made to the public within the meaning of section 52 of the *Competition Act*, RSC 1985, c C-34 because:

(a) They were expressed on the packaging of the Ineffective Drugs;

(b) They were expressed on public-facing websites; and

(c) Representations to wholesalers, retailers, and distributors are deemed to be made to the public pursuant to section 52(3).

47. The Misrepresentations created a general impression that the Ineffective Drugs were effective as oral decongestants.

48. For reasons set out above at paragraphs 16-33, the Misrepresentations were false or misleading.

49. The falsity was material. Consumers would not have purchased the Ineffective Drugs if they had known that they did not work as oral decongestants. In the alternative, consumers would not have paid prices for the Ineffective Drugs that reflected their effectiveness as oral decongestants if they had known that they did not work.

50. The Defendants made the Misrepresentations to promote three business interests: (1) to increase their sales of the Ineffective Drugs; (2) to allow them to continue to charge prices reflecting effectiveness of oral decongestants; and (3) to protect their reputations as manufacturers of drugs that actually worked.

51. The Defendants knew or were reckless to the fact that the Misrepresentations were false or misleading in a material respect. The concerns with the 1976 FDA Decision were apparent, either on their face or due to the analysis in the studies between 1976 and 2023. The 2023 FDA Decision confirmed the falsity of the Misrepresentations, and yet the Defendants have not changed their packaging or websites.

52. Thus, the Defendants breached section 52, and are liable under section 36 of *Competition Act*, RSC 1985, c C-34.

(ii) For Consumer Subclass members in Manitoba

53. The analysis in this section applies to members of the Consumer Subclass who reside in or purchased Ineffective Drugs in Manitoba.

54. The Ineffective Drugs are “goods”, the Defendants are “suppliers”, the members of the Consumer Subclass are “consumers”, and sales of Ineffective Drugs to consumers are “consumer transactions” within the meaning of section 1 of *The Business Practices Act*, CCSM c B120.

55. Making the Misrepresentations was an unfair business practice because:

(a) For reasons set out above at paragraphs 16-33, the Misrepresentations were false and might reasonably deceive consumers, in breach of sections 2(1) and 5 of *The Business Practices Act*, CCSM c B120;

(b) The Misrepresentations suggested that the Ineffective Drugs acted as an oral decongestant – a performance characteristic, use, or benefit that they did not have, in breach of sections 2(3)(a) and 5 of *The Business Practices Act*, CCSM c B120;

(c) The Misrepresentations suggested that the Ineffective Drugs “relieve” congestion, which exaggerates a material fact – namely the benefits of Ineffective Drugs – in breach of sections 2(3)(p) and 5 of *The Business Practices Act*, CCSM c B120; and

(d) The Misrepresentations included a failure to disclose that the Ineffective Drugs were not effective as oral decongestants, in breach of sections 2(1)(a), 2(3)(p) and 5 of *The Business Practices Act*, CCSM c B120.

56. Manitoba members of the Consumer Subclass who purchased primarily for their alleged decongestant effects are entitled to the return of the full amount they paid for

Ineffective Drugs under section 23(2)(d), or damages in the same amount under section 23(2)(a) of *The Business Practices Act*, CCSM c B120.

57. All other Manitoba members of the Consumer Subclass are entitled to return of part of the amount they paid for Ineffective Drugs under section 23(2)(d), or damages under section 23(2)(a) of *The Business Practices Act*, CCSM c B120.

58. Manitoba members of the Consumer Subclass deserve exemplary or punitive damages under section 23(4) of The *Business Practices Act*, CCSM c B120. The Defendants have known that phenylephrine is not effective as an oral decongestant for decades and continued to make the Misrepresentations after the 2023 FDA Decision. They have not conducted any studies with appropriate methodologies to test the efficacy of phenylephrine as an oral decongestant in decades, even as the evidence against efficacy mounted, and so they cannot be said to have exercised due diligence.

(iii) For Consumer Subclass members in Alberta

59. The analysis in this section applies to members of the Consumer Subclass who reside in or purchased Ineffective Drugs in Alberta.

60. The Ineffective Drugs are “goods”, the Defendants are “suppliers”, the members of the Consumer Subclass are “consumers”, and sales of Ineffective Drugs to consumers are “consumer transactions” within the meaning of section 1(1) of the *Consumer Protection Act*, RSA 2000, c C-26.3.

61. Making the Misrepresentations was an unfair business practice because:

(a) For reasons set out above at paragraphs 16-33, the Misrepresentations might reasonably deceive a consumer, in breach of section 6(4)(a) of the *Consumer Protection Act*, RSA 2000, c C-26.3;

(b) The Misrepresentations suggested that the Ineffective Drugs acted as an oral decongestant – a performance, characteristic, use, benefit, or "other attribute" that they did not have, in breach of section 6(4)(c) of the *Consumer Protection Act*, RSA 2000, c C-26.3;

(c) The Misrepresentations suggested that the Ineffective Drugs acted as an oral decongestant – a claim about performance that was not based on adequate and proper independent testing, in breach of section 6(4)(x) of the *Consumer Protection Act*, RSA 2000, c C-26.3; and

(d) The Misrepresentations suggested that the Ineffective Drugs "relieve" congestion, which exaggerates a material fact – namely the benefits of Ineffective Drugs – in breach of section 6(2)(c) of the *Consumer Protection Act*, RSA 2000, c C-26.3.

62. Alberta members of the Consumer Subclass who purchased Ineffective Drugs primarily for their alleged decongestant effects are entitled to restitution of the full amount they paid for Ineffective Drugs under sections 13(2)(d)(ii) and 142.1(2)(c)(ii), or damages in the same amount under sections 13(1), 13(2)(a), 142.1(1), and 142.1(2)(a) of the *Consumer Protection Act*, RSA 2000, c C-26.3.

63. All other Alberta members of the Consumer Subclass are entitled to return of part of the amount they paid for Ineffective Drugs under sections 13(2)(d)(ii) and 142.1(2)(c)(ii), or damages under sections 13(1), 13(2)(a), 142.1(1), and 142.1(2)(a) of the *Consumer Protection Act*, RSA 2000, c C-26.3.

64. For the same reasons set out above in paragraph 58, Alberta members of the Consumer Subclass deserve exemplary or punitive damages under sections 13(2)(c) and 142.1(2)(b) of the *Consumer Protection Act*, RSA 2000, c C-26.3.

65. A letter has been sent to all of the defendants on behalf of all members of the Consumer Subclass who reside in or purchased Ineffective Drugs in Alberta. They received no response for 15 days. This qualifies as the notice required under section 7.1 of the *Consumer Protection Act*, RSA 2000, c C-26.3. In the alternative, the filing of action number 500-06-001262-233 in the Superior Court of Québec on September 14, 2023 and action S-236558 in the Supreme Court of British Columbia on September 22, 2023 qualifies as the notice required under section 7.1 of the *Consumer Protection Act*, RSA 2000, c C-26.3. In the further alternative, if this does not satisfy section 7.1, then the plaintiff asks for an order under section 7.2(3) of the *Consumer Protection Act*, RSA 2000, c C-26.3 disregarding this requirement.

(iv) For Consumer Subclass members in British Columbia

66. The analysis in this section applies to members of the Consumer Subclass who reside in or purchased Ineffective Drugs in British Columbia.

67. The Ineffective Drugs are “goods”, the Defendants are “suppliers”, the members of the Consumer Subclass are “consumers”, and sales of Ineffective Drugs to consumers are “consumer transactions” within the meaning of section 1(1) of the *Business Practices and Consumer Protection Act*, SBC 2004, c 2.

68. Making the Misrepresentations was a deceptive act or practice because:

(a) For reasons set out above at paragraphs 16-33, the Misrepresentations had the capability, tendency or effect of deceiving or misleading a consumer, in breach of sections 4(1) and 5(1) of the *Business Practices and Consumer Protection Act*, SBC 2004, c 2; and

(b) The Misrepresentations suggested that the Ineffective Drugs acted as an oral decongestant – a performance characteristic, use, or benefit that they did not have, in breach of sections 4(3)(a)(i) and 5(1) of the *Business Practices and Consumer Protection Act*, SBC 2004, c 2.

69. British Columbia members of the Consumer Subclass who purchased Ineffective Drugs primarily for their alleged decongestant effects are entitled to restitution of the full amount they paid for Ineffective Drugs under section 172(3)(a), or damages in the same amount under section 171(1) of the *Business Practices and Consumer Protection Act*, SBC 2004, c 2.

70. All other British Columbia members of the Consumer Subclass are entitled to return of part of the amount they paid for Ineffective Drugs under section 172(3)(a), or damages

under section 171(1) of the *Business Practices and Consumer Protection Act*, SBC 2004, c 2.

(v) For Consumer Subclass members in Newfoundland & Labrador

71. The analysis in this section applies to members of the Consumer Subclass who reside in or purchased Ineffective Drugs in Newfoundland & Labrador.

72. The Ineffective Drugs are "goods", the Defendants are "suppliers", the members of the Consumer Subclass are "consumers", and sales of Ineffective Drugs to consumers are "consumer transactions" within the meaning of section 2 of the *Consumer Protection and Business Practices Act*, SNL 2009, c C-31.1.

73. Making the Misrepresentations was a deceptive act or practice because:

(a) For reasons set out above at paragraphs 16-33, the Misrepresentations might reasonably have the effect of deceiving or misleading a consumer, in breach of sections 7(1) and 9(1) of the *Consumer Protection and Business Practices Act*, SNL 2009, c C-31.1;

(b) The Misrepresentations suggested that the Ineffective Drugs acted as an oral decongestant – a performance characteristic, use, or benefit that they did not have, in breach of sections 7(1)(a) and 9(1) of the *Consumer Protection and Business Practices Act*, SNL 2009, c C-31.1; and

(c) The Misrepresentations suggested that the Ineffective Drugs "relieve" congestion, which exaggerates a material fact – namely the benefits of

Ineffective Drugs – in breach of sections 7(1)(w) and 9(1) of the *Consumer Protection and Business Practices Act*, SNL 2009, c C-31.1.

74. Newfoundland & Labrador members of the Consumer Subclass who purchased Ineffective Drugs primarily for their alleged decongestant effects are entitled to restitution of the full amount they paid for Ineffective Drugs under section 10(2)(e), or damages in the same amount under section 10(2)(b) of the *Consumer Protection and Business Practices Act*, SNL 2009, c C-31.1.

75. All other Newfoundland & Labrador members of the Consumer Subclass are entitled to return of part of the amount they paid for Ineffective Drugs under section 10(2)(e), or damages under section 10(2)(b) of the *Consumer Protection and Business Practices Act*, SNL 2009, c C-31.1.

76. For the same reasons set out above in paragraph 58, Newfoundland & Labrador members of the Consumer Subclass deserve exemplary or punitive damages under section 10(2)(b) of the *Consumer Protection and Business Practices Act*, SNL 2009, c C-31.1.

(vi) For Consumer Subclass members in Ontario

77. The analysis in this section applies to members of the Consumer Subclass who reside in or purchased Ineffective Drugs in Ontario.

78. The Ineffective Drugs are “goods”, the Defendants are “suppliers”, the members of the Consumer Subclass are “consumers”, and sales of Ineffective Drugs to consumers are “consumer transactions” within the meaning of section 1 of the *Consumer Protection Act, 2002*, SO 2002, c 30, Sch A.

79. Making the Misrepresentations was an unfair practice because:

(a) For reasons set out above at paragraphs 16-33, the Misrepresentations were false, misleading or deceptive representations, in breach of sections 14(1) and 17 of the *Consumer Protection Act, 2002*, SO 2002, c 30, Sch A;

(b) The Misrepresentations suggested that the Ineffective Drugs acted as an oral decongestant – a performance characteristic, use, or benefit that they did not have, in breach of sections 14(2)(1) and 17 of the *Consumer Protection Act, 2002*, SO 2002, c 30, Sch A;

(c) The Misrepresentations suggested that the Ineffective Drugs "relieve" congestion, which exaggerates a material fact – namely the benefits of Ineffective Drugs – in breach of sections 14(2)(14) and 17 of the *Consumer Protection Act, 2002*, SO 2002, c 30, Sch A; and

(d) The Misrepresentations included a failure to disclose that the Ineffective Drugs were not effective as oral decongestants, in breach of sections 14(2)(14) and 17 of the *Consumer Protection Act, 2002*, SO 2002, c 30, Sch A.

80. Ontario members of the Consumer Subclass who purchased Ineffective Drugs primarily for their alleged decongestant effects are entitled to recover the full amount they paid for Ineffective Drugs, or damages in the same amount, under section 18(2) of the *Consumer Protection Act, 2002*, SO 2002, c 30, Sch A.

81. All other Ontario members of the Consumer Subclass are entitled to recover part of the amount they paid for Ineffective Drugs, or damages, under section 18(2) of the *Consumer Protection Act, 2002*, SO 2002, c 30, Sch A.

82. For the same reasons set out above in paragraph 58, Ontario members of the Consumer Subclass deserve exemplary or punitive damages under section 18(11) of the *Consumer Protection Act, 2002*, SO 2002, c 30, Sch A.

83. A letter has been sent to all of the defendants on behalf of all members of the Consumer Subclass who reside in or purchased Ineffective Drugs in Ontario. This qualifies as the notice required under section 18(3) of the *Consumer Protection Act, 2002*, SO 2002, c 30, Sch A. In the alternative, the filing of action number 500-06-001262-233 in the Superior Court of Québec on September 14, 2023, and action S-236558 in the Supreme Court of British Columbia on September 22, 2023, qualifies as the notice required under section 18(3) of the *Consumer Protection Act, 2002*, SO 2002, c 30, Sch A. In the further alternative, if this does not satisfy section 18(3), then the plaintiff asks for an order under section 18(15) of the *Consumer Protection Act, 2002*, SO 2002, c 30, Sch A disregarding this requirement.

(vii) For Consumer Subclass members in Prince Edward Island

84. The analysis in this section applies to members of the Consumer Subclass who reside in or purchased Ineffective Drugs in Prince Edward Island.

85. The Ineffective Drugs are “goods” and the members of the Consumer Subclass are “consumers” within the meaning of section 1 of the *Business Practices Act*, RSPEI 1988, c B-7.

86. Making the Misrepresentations was an unfair practice because:

(a) For reasons set out above at paragraphs 16-33, the Misrepresentations were false, misleading or deceptive representations, in breach of sections 2(a) and 3 of the *Business Practices Act*, RSPEI 1988, c B-7;

(b) The Misrepresentations suggested that the Ineffective Drugs acted as an oral decongestant – a performance characteristic, use, or benefit that they did not have, in breach of sections 2(a)(i) and 3 of the *Business Practices Act*, RSPEI 1988, c B-7;

(c) The Misrepresentations suggested that the Ineffective Drugs “relieve” congestion, which exaggerates a material fact – namely the benefits of Ineffective Drugs – in breach of sections 2(a)(xiii) and 3 of the *Business Practices Act*, RSPEI 1988, c B-7; and

(d) The Misrepresentations included a failure to disclose that the Ineffective Drugs were not effective as oral decongestants, in breach of sections 2(a)(xiii) of the *Business Practices Act*, RSPEI 1988, c B-7.

87. Prince Edward Island members of the Consumer Subclass who purchased Ineffective Drugs primarily for their alleged decongestant effects are entitled to recover the

full amount they paid for Ineffective Drugs, or damages in the same amount, under section 4(1) of the *Business Practices Act*, RSPEI 1988, c B-7.

88. All other Prince Edward Island members of the Consumer Subclass are entitled to recover part of the amount they paid for Ineffective Drugs, or damages, under section 4(1) of the *Business Practices Act*, RSPEI 1988, c B-7.

89. A letter has been sent to all of the defendants on behalf of all members of the Consumer Subclass who reside in or purchased Ineffective Drugs in Prince Edward Island. This qualifies as the notice required under sections 4(5) and 4(6) of the *Business Practices Act*, RSPEI 1988, c B-7. In the alternative, the filing of action number 500-06-001262-233 in the Superior Court of Québec on September 14, 2023, and action S-236558 in the Supreme Court of British Columbia on September 22, 2023, qualifies as the notice required under sections 4(5) and 4(6) of the *Business Practices Act*, RSPEI 1988, c B-7. In the further alternative, if this does not satisfy sections 4(5) and 4(6) of the *Business Practices Act*, RSPEI 1988, c B-7, then the service of this Statement of Claim on the defendants satisfies those sections.

(viii) For Consumer Subclass members in Québec

90. The analysis in this section applies to members of the Consumer Subclass who reside in or purchased Ineffective Drugs in Québec.

91. The Defendants are “merchants” and “manufacturers” and the members of the Consumer Subclass are “consumers” within the meaning of Title II of the *Consumer Protection Act*, CQLR c P-40.1.

92. For reasons set out above at paragraphs 16-33, the Misrepresentations were false or misleading representations, in breach of article 219 of the *Consumer Protection Act*, CQLR c P-40.1.

93. The Misrepresentations suggested that the Ineffective Drugs acted as an oral decongestant – ascribing to them a special advantage and a characteristic of performance that they did not have, in breach of articles 220(a) and 221(g) of the *Consumer Protection Act*, CQLR c P-40.1.

94. The Misrepresentations included a failure to disclose that the Ineffective Drugs were not effective as oral decongestants, in breach of article 228 of the *Consumer Protection Act*, CQLR c P-40.1.

95. Québec members of the Consumer Subclass who purchased Ineffective Drugs primarily for their alleged decongestant effects are entitled to recover the full amount they paid for Ineffective Drugs, or damages in the same amount, under article 272 of the *Consumer Protection Act*, CQLR c P-40.1 and article 1457 of the *Civil Code of Québec*, CQLR c CCQ-1991.

96. All other Québec members of the Consumer Subclass are entitled to recover part of the amount they paid for Ineffective Drugs, or damages, under article 272 of the *Consumer Protection Act*, CQLR c P-40.1 and article 1457 of the *Civil Code of Québec*, CQLR c CCQ-1991.

97. For the same reasons set out above in paragraph 58, Québec members of the Consumer Subclass deserve exemplary or punitive damages under article 272 of the *Consumer Protection Act*, CQLR c P-40.1.

(ix) For Consumer Subclass members in Saskatchewan

98. The analysis in this section applies to members of the Consumer Subclass who reside in or purchased Ineffective Drugs in Saskatchewan.

99. The Ineffective Drugs are "goods", the Defendants are "suppliers", and the members of the Consumer Subclass are "consumers" within the meaning of section 2 of *The Consumer Protection and Business Practices Act*, SS 2013, c C-30.2.

100. Making the Misrepresentations was an unfair practice because:

(a) For reasons set out above at paragraphs 16-33, the Misrepresentations were statements or omissions which might reasonably deceive or mislead a consumer, in breach of sections 6(a) and 8(1) of *The Consumer Protection and Business Practices Act*, SS 2013, c C-30.2;

(b) The Misrepresentations suggested that the Ineffective Drugs acted as an oral decongestant, which was a false claim, in breach of sections 6(b) and 8(1) of *The Consumer Protection and Business Practices Act*, SS 2013, c C-30.2;

(c) The Misrepresentations suggested that the Ineffective Drugs acted as an oral decongestant – a performance characteristic, use, or benefit that they did not have, in breach of sections 7(a) and 8(1) of *The Consumer Protection and Business Practices Act*, SS 2013, c C-30.2;

(d) The Misrepresentations suggested that the Ineffective Drugs "relieve" congestion, which exaggerates a material fact – namely the benefits of Ineffective Drugs – in breach of sections 7(o) and 8(1) of *The Consumer Protection and Business Practices Act*, SS 2013, c C-30.2; and

(e) The Misrepresentations included a failure to disclose that the Ineffective Drugs were not effective as oral decongestants, in breach of sections 7(o) and 8(1) of *The Consumer Protection and Business Practices Act*, SS 2013, c C-30.2.

101. Saskatchewan members of the Consumer Subclass who purchased Ineffective Drugs primarily for their alleged decongestant effects are entitled to restitution of the full amount they paid for Ineffective Drugs under section 93(1)(a), or damages in the same amount under section 93(1)(b) of *The Consumer Protection and Business Practices Act*, SS 2013, c C-30.2.

102. All other Saskatchewan members of the Consumer Subclass are entitled to return of part of the amount they paid for Ineffective Drugs under section 93(1)(a), or damages under section 93(1)(b) of *The Consumer Protection and Business Practices Act*, SS 2013, c C-30.2.

103. For the same reasons set out above in paragraph 58, Saskatchewan members of the Consumer Subclass deserve exemplary or punitive damages under section 93(1)(b) of *The Consumer Protection and Business Practices Act*, SS 2013, c C-30.2.

B. Negligent misrepresentation

104. The defendants made the Misrepresentations on the packaging of Ineffective Drugs seen by end users, on their websites targeted at end users, and to wholesalers, retailers, and distributors who they expected would rely on these representations to communicate with end users. The Misrepresentations were therefore targeted at end users of the Ineffective Drugs, and the defendants owed a duty of care to those end users, including the Class.

105. The Misrepresentations constituted an undertaking that the Ineffective Drugs would be effective at treating congestion. The defendants both expected and intended that end users would rely on this undertaking by buying the Ineffective Drugs to treat congestion.

106. The Class reasonably relied on this undertaking by purchasing Ineffective Drugs to treat congestion.

107. For reasons set out above at paragraphs 16-33, the Misrepresentations were false. The Ineffective Drugs were not effective at treating congestion.

108. The Class suffered damages by purchasing products to treat their congestion that did not have that effect. They consequently suffered damages equal to the purchase price of the Ineffective Drugs.

C. Unjust enrichment

109. The Defendants were enriched by selling the Ineffective Drugs.

110. The Class suffered a corresponding deprivation by buying Ineffective Drugs, which did not work for the purpose – or in the alternative, one of the purposes – for which it was purchased, namely decongestion.

111. The contracts to purchase the Ineffective Drugs are not juristic reasons for the enrichment because they are void for illegality, for the following reasons:

(a) As described above at paragraphs 46-103, the Defendants breached:

(i) The *Competition Act*, RSC 1985, c C-34;

(ii) *The Business Practices Act*, CCSM c B120;

(iii) The *Consumer Protection Act*, RSA 2000, c C-26.3;

(iv) The *Business Practices and Consumer Protection Act*, SBC 2004, c 2;

(v) The *Consumer Protection and Business Practices Act*, SNL 2009, c *C-31.1;*

(vi) The Consumer Protection Act, 2002, SO 2002, c 30, Sch A;

(vii) The Business *Practices Act*, RSPEI 1988, c B-7;

(viii) The *Consumer Protection* Act, CQLR c P-40.1; and

(ix) *The* Consumer *Protection and Business Practices Act*, SS 2013, c C-30.2.

(b) The Defendants also breached the *Food and Drugs Act*, RSC 1985, c F-27 for the following reasons:

(i) The Ineffective Drugs are “drugs” within the meaning of section 2 of the *Food and Drugs Act*, RSC 1985, c F-27;

(ii) As described above at paragraphs 35-37, the Defendants labelled / packaged the Ineffective Drugs to suggest that they were effective as oral decongestants;

(iii) As described above at paragraphs 38-41, the Defendants advertised the Ineffective Drugs to suggest that they were effective as oral decongestants; and

(iv) As described at paragraphs 16-33, these labels, packages, and advertising were false, misleading, deceptive, and likely to create an erroneous conception about the value and merit of the Ineffective Drugs, in breach of section 9(1) of the *Food and Drugs Act*, RSC 1985, c F-27.

112. There is no juristic reason for the defendant’s enrichment.

D. Discoverability and fraudulent concealment

113. The plaintiff and the Class could not reasonably have discovered that the Misrepresentations were false until the publication of the 2023 FDA Decision on September 12, 2023. Thus, the doctrine of discoverability forestalled the running of any relevant limitation periods until that date.

114. The Defendants actively, intentionally, and fraudulently concealed the fact that phenylephrine does not work as an oral decongestant. Thus, the doctrine of fraudulent concealment forestalled the running of any relevant limitation periods until at least September 12, 2023.

VI. STATUTES TO BE RELIED UPON

115. The plaintiff relies on the following statutes:

(a) *The Business Practices Act*, CCSM c B120;

(b) The *Business Practices Act*, RSPEI 1988, c B-7;

(c) The *Business Practices and Consumer Protection Act*, SBC 2004, c 2;

(d) The *Civil Code of Québec*, CQLR c CCQ-1991;

(e) The *Class Proceedings Act*, *CCSM* c C130;

(f) The *Competition Act*, RSC 1985, c C-34;

(g) The *Consumer Protection Act*, *CQLR* c P-40.1;

(h) The *Consumer Protection Act*, RSA 2000, c C-26.3;

(i) The *Consumer Protection Act, 2002*, SO 2002, c 30, Sch A;

(j) The *Consumer Protection and Business Practices Act*, SNL 2009, c C-31.1;

(k) *The Consumer Protection and Business Practices Act*, SS 2013, c C-30.2;

(l) *The Court of Queen's Bench Act*, CCSM c C280; and

(m) The *Food and Drugs Act*, RSC 1985, c F-27.

116. Such other and further grounds as the applicants may advise and this court may accept.

November 10, 2023

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SCHEDULE A

Brand	Product	Health Canada DIN
Benylin	Extra Strength Cold & Sinus Day	02273462
Benylin D	For Infants	02281341
Contac	Cold Nasal Congestion	02276690
	Cold & Sinus Extra Strength	02313820
	Cold & Sinus Hot Medicated Drink	02319713
	Extra Strength Cold & Sinus Hot Medicated Drink	02319721
	Super Strength Cold & Sinus Hot Medicated Drink	02319748
DayQuil	Cold & Flu	02300842
	Sinus Liquicaps	02273829
NeoCitran	Extra Strength Cold & Congestion	00843792
	Extra Strength Total Cold	02293994
Robitussin	Complete Daytime	02449196
Sudafed PE	Extra Strength	02250217
Triaminic Thin Strips	Cold & Cough	02271745
	Nasal Congestion	02271737
	Nighttime Cold & Cough	02294354
Tylenol	Cold and Flu Daytime	02276658
	Cold Rapid Release	02305917
	Extra Strength Cold Daytime	02276186
	Extra Strength Flu Daytime	02275996
	Extra Strength Sinus Daytime	02276003
	Regular Strength Cold Daytime	02275627
	Regular Strength Sinus Daytime	02275708
	Sinus Liquicaps	02273829
Vicks	Custom Care Nasal Congestion	02272776
	Sinex Pressure & Pain	02459841

Vicks DayQuil	Cold & Flu Multi-Symptom Relief Liquicaps	02272784
	Hot Remedy	02531518