CANADA

PROVINCE OF QUÉBEC
DISTRICT OF MONTREAL

No.: 500-06-001262-233

SUPERIOR COURT
(Class Actions)

ANDREW KRASKA, natural person residing [redacted]

Applicant

v.

KENVUE CANADA INC., (FORMERLY KNOWN AS JOHNSON & JOHNSON INC.), legal person having its head office at 88 McNabb Street, Markham, Ontario, L3R 5L2, Canada

and

PROCTER & GAMBLE INC., legal person having its head office at 4711 ST Younge, Toronto, Ontario, M5W 1C5, Canada

and

HALEON CANADA ULC, (FORMERLY KNOWN AS GLAXOSMITHKLINE CONSUMER HEALTH CARE ULC ~~SRL),~~ legal person having its head office at 2600-595 Burrard Street, Vancouver, BC, V7X 1L3, Canada

and

RB HEALTH (CANADA) INC. legal person having its head office at 2300-550, Burrard Street, Box 30, Vancouver, BC, V6C 2B5, Canada

and

PFIZER CANADA ULC (D.B.A. PFIZER CONSUMER HEALTHCARE), legal person having its head office at 1800-510 West Georgia Street, Vancouver, BC, V6B 0M3, Canada

and

PFIZER INC., legal person having its place of business at 1209 Orange Street, Wilmington, DE, 19801, USA

and

JOHNSON & JOHNSON CONSUMER INC., legal person having its place of business at 1209 Orange Street, Wilmington, DE, 19801, USA

and

KENVUE INC., legal person having its place of business at 1209 Orange Street, Wilmington, DE, 19801, USA

and

THE PROCTER & GAMBLE COMPANY, legal person having its place of business at 4400 Easton Commons Waysuite 125, Columbus, OH, 43219, USA

and

RB HEALTH (US) LLC, legal person having its place of business at 251 Little Falls Drive, Wilmington, DE, 19808, USA

Defendants

AMENDED APPLICATION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION AND APPOINT APPLICANT AS CLASS REPRESENTATIVE
(Art. 571 C.C.P. and following)

TO ONE OF THE HONOURABLE JUSTICES OF THE SUPERIOR COURT, SITTING IN AND FOR THE DISTRICT OF MONTREAL YOUR APPLICANT STATES AS FOLLOWS:

A. OVERVIEW

1. Consumers in Quebec have been misled about the performance and efficiency of orally administered over-the-counter cold and cough medicine containing the ingredient phenylephrine ("**Cold Medicine**"), represented to act as a decongestant and alleviate nasal congestion, fever, sneezing, sinus pressure, runny nose and cough (collectively "**Cold/Cough Symptoms**").

2. ~~Unbeknownst to the consumer,~~ The Defendants' have falsely represented to Quebec consumers that these products will provide them relief of their Cold/Cough Symptoms, notably that when administered at recommended dosages, as this ingredient is ~~t~~ completely ineffective. These Cold Medicine products impacted by the false and misleading statements about their efficacy are listed in **Schedule A** to this claim.

2.1 Since at least 2007, if not before, scientific evidence demonstrates that oral phenylephrine is no more effective than placebo at relieving nasal congestion. As manufacturers of Cold Medicine containing phenylephrine, the Defendants knew or ought to have known of the scientific consensus. However, despite their knowledge of this scientific consensus, the Defendants continued to manufacture, market, and sell Cold Medicine to consumers and represented that these products would alleviate nasal decongestion.

2.2 In manufacturing and/or selling Cold Medicine, the Defendants have breached sections 36 and 52 of the *Competition Act*, RSC 1985, c C-34, sections 37, 38, 40, 41, 53, 219, 220(a), 228, 253, and 272 of the *Consumer Protection Act*, CQLR c P-40.1, and articles 6, 7, 1375, 1401, 1407, 1457, 1726, 1728, and 1730 of the *Civil Code of Quebec* through their negligent conduct and civil conspiracy.

3. As a result of false representations about the efficacy of ~~the~~ Cold Medicine, the Applicant and putative Class Members ~~has~~ have lost money and time spent purchasing and using these products for nasal congestion relief without receiving full or any value in return. Applicant seeks authorization of a class action against the Defendants on behalf of themselves and the following group:

> All persons in Quebec who purchased, between ~~January~~ February 1, 2007 and date this case is authorized as a class action, any ~~Cough~~ Cold Medicine listed in Schedule A to the Application for Authorization.

The "**Class**" and "**Class Members**" and the "**Class Period**"

B. DEFENDANTS AND THEIR ACTIVITIES

4. At all material times, the Defendant Kenvue Canada Inc., formerly known as Johnson & Johnson ~~("**J&J**")~~ under the division of McNeil Consumer Healthcare ("McNeil") manufactured and distributed in Quebec Cold Medicine ~~medication~~ under the brand names of Tylenol and Benylin, as appears on the copies of the ~~J&J~~ Drug Product Pages retrieved from Health Canada website **Exhibit P-1**, and the corporate history information ~~of J&J~~ retrieved from CIDREQ as **Exhibit P-2**.

4.1 The defendants Johnson & Johnson Consumer Inc. and Kenvue Inc. are American entities whose corporate registration information can be seen in **Exhibits P-30 and P31.** Kenvue Canada Inc., Kenvue Inc., and Johnson & Johnson Consumer Inc. each have business practices that are inextricably interwoven, and each is the agent of the other for the purposes of the causes of action described below. They are hereby collectively referred to as ("**Kenvue**").

5. At all material times, the Defendant Procter & Gamble Inc. ~~("**P&G**")~~ manufactured and distributed in Quebec Cold Medicine ~~medication~~ under the brand name of Vicks, as appears on the copy of ~~P&G~~ Drug Product Pages retrieved from the Health Canada website **Exhibit P-3**, and the corporate history information ~~of P&G~~ retrieved from CIDREQ as **Exhibit P-4.**

5.1 The defendant The Procter & Gamble Company is an American entity whose corporate registration information can be seen in **Exhibit P-32.** Procter & Gamble Inc. and the Procter & Gamble Company each have business practices that are inextricably interwoven, and each is the agent of the other for the purposes of the causes of action described below. They are hereby collectively referred to as ("**P&G**").

6. At all material times, the Defendant Haleon Canada ULC, formerly known as Glaxosmithkline Consumer Health Care sri ~~("**Glaxo**")~~ ("**Haleon**"), manufactured and distributed in Quebec ~~Cough~~ Cold Medicine under the brand name of NeoCitran, as appears on the copy of ~~Glaxo~~ Drug Product Pages retrieved from the Health Canada website **Exhibit P-5**, and the corporate history information ~~of Glaxo~~ retrieved from CIDREQ as **Exhibit P-6.**

7. At all material times, the Defendant RB Health (Canada) Inc. ~~("**RB**")~~ manufactured and distributed ~~Cough~~ Cold Medicine in Quebec under the brand name of Mucinex, as appears on

the copy of RB Drug Product Pages retrieved from the Health Canada website **Exhibit P-7**, and the corporate history information of RB retrieved from CIDREQ as **Exhibit P-8.**

7.1 The defendant RB Health (US) LLC is an American entity whose corporate registration information can be seen in **Exhibits P-36,** RB Health (Canada) Inc., RB Health (US) LLC, each have business practices that are inextricably interwoven, and each is the agent of the other for the purposes of the causes of action described below. They are hereby collectively referred to as ("**RB**").

7.2 At all material time Defendant Pfizer Canada ULC (d.b.a. Pfizer Consumer Healthcare) designed, manufactured, labelled, marketed, sold, distributed and/or placed into the stream of commerce Cold Medicine in Quebec under the brand names, Benylin, Dimetapp, Dristan, and Robitussin, as appears on Health Canada's Product Database, as seen in **Exhibit P-39**, and the corporate history information retrieved from CIDREQ as **Exhibit P-40.**

7.3 The defendant Pfizer Inc. is an American entity whose corporate registration information can be seen in **Exhibit P-41.** Pfizer Canada ULC (d.b.a. Pfizer Consumer Healthcare) and Pfizer Inc. each have business practices that are inextricably interwoven, and each is the agent of the other for the purposes of the causes of action described below. They are hereby collectively referred to as ("**Pfizer**").

7.4 Collectively the Defendants acted in concert and coordination to further their common unlawful objectives, rendering them solidarily liable for all damages flowing from their collective misconduct, this is notably demonstrated by the creation of Task Group (**Exhibit P-42, see slide CO-3**)

C. ~~THE INEFFECTIVENESS OF THE COLD MEDICINE~~ DEFENDANTS' KNOWLEDGE OF ORAL PHENYLEPHRINE'S INEFFECTIVENESS

8. Nasal congestion is a persistent and bothersome cold symptom which can either appear acutely or chronically in the daily lives of people of all ages. The ingredient phenylephrine, which is found in many popular decongestant products, was first introduced into the market after being approved by the US Food and Drug Administration ("**FDA**") in 1976, see the copy of the 1976 Monograph, at PDF pages 110-111 or page 38399-38400 included in support of this claim as **Exhibit P-9.**

8.1 The Defendants knew or should have known about the questionable efficacy of orally ingested phenylephrine as a nasal decongestant. Well before the original 1976 Monograph, the FDA's review of scientific studies raised significant doubts about orally ingested phenylephrine's effectiveness for nasal decongestion at any dosage.

8.2 The lack of scientific consensus apparent from the FDA's analysis put the Defendants on notice of this issue at least as early as 1976. Indeed, many pre-1976 studies concluded that orally administered phenylephrine failed to demonstrate any statistically significant benefit compared to placebo, as seen on the copy of the 1976 Monograph included in support of this Application as **Exhibit P-9** (see pages 38399 and 38400).

9. The FDA's 1994 Supplemental Information further crystallized these concerns. In 1982, the US Advisory Review Panel on OTC Oral Cavity Drug Products reviewed the safety and effectiveness data on two oral nasal decongestant ingredients, including phenylephrine hydrochloride and classified it as a nasal decongestant in Category III - a regulatory designation signifying *insufficient* evidence to establish safety and effectiveness, mandating additional rigorous clinical investigation, as seen on the copy of the 1994 Federal Register for

the FDA, the Final Monograph for OTC Nasal Decongestant Drug Products, Final Rule included in support as **Exhibit P-10** (see pages 43386 and 43387)**.**

10. ~~I~~On February 1, 2007, a Citizen's Petition was submitted to the US Food and Drug Administration requesting that there be an amendment to the dosage of orally ingested phenylephrine listed in the Final Monograph on oral decongestants citing that phenylephrine is unlikely to relieve nasal stuffiness at the maximum FDA approved dose of 10 mg, see **Exhibit P-11** for a copy of the 2007 Citizen's Petition.

11. In March 2007, a systematic review and meta-analysis led by Randy C Hatton et al. ("2007 Hatton Study"), was released reporting that the orally ingested phenylephrine of 10mg did not significantly affect nasal airway resistance compared to placebo in unpublished studies involving 138 patients, as appears on the copy of the 2007 Hatton Study included in support of this claim as **Exhibit P-12**. The 2007 Hatton Study used 8 of the 14 original efficacy studies and did not confirm the original FDA panel's findings.

12. While two studies published in June and August 2007 (respectively the "2007 ~~Glaxo~~ Industry Meta-Analysis" and the "2007 Wyeth Study"), found the opposite conclusion that the studies support the effectiveness of a single oral dose of phenylephrine 10 mg as a decongestant in adults with acute nasal congestion associated with the common cold, it ought to be noted that these studies were conducted by the Defendants ~~pharmaceutical companies~~ themselves, see **Exhibit P-13** for a copy of the 2007 ~~Glaxo~~ Industry Meta-Analysis and **Exhibit P-14** for a copy of the 2007 Wyeth Study**.**

13. In December 2007, the FDA convened a *Nonprescription Drugs Advisory Committee* ("NDAC") meeting to evaluate the safety and effectiveness of orally administered phenylephrine as nasal decongestants, as appears on the minutes of the hearing dated December 14, 2007, retrieved from the FDA website and filed in support of this application as **Exhibit P-15.**

13.1 By February 2007, the Defendants possessed, or could not reasonably have ignored, conclusive scientific evidence demonstrating that phenylephrine hydrochloride was ineffective as an oral decongestant.

14. Notably, as seen on page 5 of **Exhibit P-15**, the NDAC concluded that additional studies were needed to support the effectiveness of phenylephrine in a 10mg immediate release formulate when dosed every 4 hours for treatment of nasal congestion and the committee made the following notes:

> *It was noted by the committee that the standard to support "effectiveness" was not clearly defined. The committee noted that individual studies show some benefit of the 10 mg strength, but the results are not consistent across studies for NAR and are even murkier for symptom measures. The committee agreed that symptoms are the essential primary endpoint. While one half the studies were positive and one half negative, in none of the studies was the placebo superior to PEH, adding support to the effectiveness of PEH. The committee felt that efficacy may not be generalizable to a wide population based on small studies. The committee noted that the available evidence consists primarily of studies conducted 40 years ago and included fewer than 200 people across all the studies.*

15. In July 2015, an article by Meltzer et al. ("2015 Meltzer Study") further confirming the inefficacy of orally ingested phenylephrine for the treatment of nasal congestion was published online detailing findings that phenylephrine hydrochloride doses of up to 40mg every 4 hours are not

significantly better than placebo in reducing subjective nasal congestion scores, as appears on a copy of the 2015 Meltzer Study proffered in support of this Application as **Exhibit P-16**.

16. In November 2015, another Citizen's Petition was submitted to the FDA requesting that orally ingested phenylephrine be removed from the Final Monograph for over-the-counter nasal decongestant products and provided the results of four reported studies after 2007 that found that phenylephrine was no more effective than placebo in decreasing nasal congestion and increasing the dose fourfold provided no additional benefit, as seen on pages 2-6 of the copy of the Hatton Hendeles 2015 Citizen's Petition included in support of this claim as **Exhibit P-17.**

17. In October 2020, the Joint Task Force Rhinitis Practice Parameter of the American Academy of Allergy, Asthma and Immunology and the American College of Allergy, Asthma and Immunology indicated that doses of phenylephrine up to 40 mg a day are ineffective, as seen on page 746 of the copy of the October 2020 Rhinitis Practice Parameter Update included in support of this claim as **Exhibit P-18.**

18. In 2022, a paper by Hatton and Hendeles published in the journal *Annals of Pharmacotherapy* questioned why orally ingested phenylephrine remained on the market despite compelling evidence of its ineffectiveness as a decongestant, as seen on the copy of this article proffered in support of this Application as **Exhibit P-19**.

19. Also in 2022, the American Academy of Allergy, Asthma & Immunology and the American College of Allergy, Asthma & Immunology submitted a Statement of Support to the FDA in support of for the 2015 Citizen's Petition. requesting the removal of orally ingested phenylephrine hydrochloride from over-the-counter nasal decongestant products), as appears in the copy of this Statement of Support as **Exhibit P-20**.

20. On September 12, 2023, the FDA released a Briefing Document on the efficacy of orally ingested phenylephrine as a nasal decongestant prepared for the panel members of the Advisory Committee which states at page 33:

> *As a result of our evaluation, we believe that the new efficacy data far outweigh the data provided to the Agency as part of the original Panel review. These results suggest that: 1) oral PE at monographed dosages is not effective as a decongestant (i.e., in the face of the new data, the original data are likely not sufficient to support a GRASE determination), 2) oral doses up to 40 mg would also not be effective, 3) finding an effective oral dose that is also safe is not feasible (meaning that doses higher than 40 mg would need to be explored but would also not be safe to study due to effects on blood pressure), and 4) an appropriate dosing interval for oral PE has not been established (meaning that, based on the PK data, an every-4-hour dosing interval is likely too long). Therefore, in addition to lack of efficacy, there may be no path to evaluating higher doses of oral PE as a nasal decongestant.*

As seen on the copy of September 11-12, 2023 Briefing Document filed in support of this claim as **Exhibit P-21**.

C.1. TASK GROUP DEFENDANTS CONSPIRED TO DECEIVE CLASS MEMBERS

20.1 Since 2006, the United States passed legislation, the *Combat Methamphetamine Epidemic Act,* that required retailers to move products containing pseudophedrine – a nasal

decongestant that could be used in manufacturing methamphetamine – to behind the counter. The restriction of products containing pseudoephedrine created an opportunity for companies that sold products containing phenylephrine to increase their share of the cold medicines market.

20.2 Following the introduction of the *Combat Methamphetamine Epidemic Act*, the Consumer Health Products Association ("CHPA") established a strategic task group through which to develop their understanding of, and coordinate their responses to, scientific developments regarding the efficacy of oral phenylephrine (hereinafter "the **Task Group**").

20.3 The members of the Task Group included defendants Johnson & Johnson Consumer Inc., Kenvue, Inc., The Procter & Gamble Company, RB Health (US) LLC, and Pfizer Inc[1] (the "**Task Group Defendants**"). While these named defendants formed the core of the task group, additional unnamed corporations, partnerships, and individuals were also integral to its operations, as seen on the copy of the CHPA's Powerpoint slides presented at the FDA's September 11-12, 2023, meeting included as **Exhibit P-42, see slide CO-3**)

20.4 Following the 2007 Citizen's Petition questioning phenylephrine's efficacy, the Task Group Defendants orchestrated a campaign of evidence suppression and generated what they referred to as a "meta-analysis" to purportedly analyze studies of the effectiveness of oral phenylephrine, already referred to in this claim as the 2007 Industry Meta-Analysis and included in support as **Exhibit P-13**. The outcome of the 2007 Industry Meta-Analysis – which the Task Group asserted supported their position on the efficacy of oral phenylephrine – conflicted with evidence in support of the 2007 Citizen's Petition.

20.5 Describing the Meta-Analysis in submissions to the NDA Committee, the Task Group asserted that they had come together to "critically evaluate all studies reviewed by the 1976 OTC expert advisory review panel and additional data on the efficacy and safety of phenylephrine in adults." However, this was false. The Task Group Defendants did not "critically evaluate" the studies or data that existed in 2007 and instead identified and relied upon studies that supported their assertion about the efficacy of oral phenylephrine, while intentionally ignoring the recent evidence showing that oral phenylephrine is ineffective, In short, far from being an unbiased and scientific "critical assessment", the Meta-Analysis was a flawed and inaccurate piece of advocacy prepared for the purpose of misleading the NDA Committee, as seen in more detail in the 2016 letter authored by the Task Group **Exhibit P-43**.

20.6 In a briefing document published in support of its 2023 finding that oral phenylephrine is ineffective, the NDA Committee sharply criticized the studies on which the 2007 Industry Meta-Analysis relied, stating that these studies suffered from "significant methodological and statistical issues, as well as potential data integrity issues", as seen in more detail on **Exhibit P-21**, page 54.

20.7 For example, after noting that six of the seven studies that formed the Meta-Analysis originated from the Sterling-Winthrop Research Institute, the manufacturer of Neo-Synephrine, the NDA Committee questioned the integrity of five studies conducted at a single laboratory – Elizabeth Biochemical – noting that two of the studies "appear to have been outliers in that, not only do their results not match the results obtained in other studies, there

[1] Pfizer Inc. was a member of the Task Group at material times through its ownership of Pfizer Consumer Healthcare, which merged with GlaxoSmithKline plc in 2019 to form a joint venture. The consumer healthcare business of GlaxoSmithKline plc was demerged in 2022, forming a new entity – Haleon plc.

are internal inconsistencies such that they do not match what would be expected in such studies" (see **Exhibit P-21**, page 63).

20.8 Ultimately, the NDA Committee concluded that the older studies touted by the Task Group in support of the efficacy of phenylephrine were unreliable, concluding:

> *And, in fact, we believe that the multiple methodological and statistical issues inherent in the studies reviewed by the Panel make the original studies evaluated for efficacy unacceptable as continued support for the efficacy of monographed doses of oral PE.*
>
> As seen on **Exhibit P-21**, page 55.

20.9 In contrast to their submissions to the NDA Committee, the Task Group Defendants did not "critically assess" the studies or data that existed prior to 2007 and instead relied only on studies that supported their assertion about the efficacy of oral phenylephrine.

20.10 Moreover, the Task Group Defendants also engaged in coordinated efforts to discredit the prevailing science that oral phenylephrine is ineffective following the 2015 Citizen's Petition requesting that oral phenylephrine be taken off the market. In its submissions to the NDA Committee in 2016, the Task Group, as seen in more detail on **Exhibit P-43**.

a) falsely asserted that the 2015 Citizen's Petition "did not provide sufficient scientific evidence to refute the established efficacy of phenylephrine at the 10 mg dose";

b) mischaracterized the NDA Committee's findings in response to the 2007 Citizen's Petition, asserting that the NDA Committee had concluded that the fourteen clinical studies assessed in 1976 "documented the effectiveness of phenylephrine hydrochloride as an oral nasal decongestant." This statement is inaccurate. The NDA Committee in 2007 concluded that additional clinical data was necessary to evaluate the efficacy of oral phenylephrine; and

c) incorrectly stated that there were "significant concerns with design aspects and the interpretation of results in the [new] studies that were cited [in the 2015 Citizen's Petition]" and that "[n]one of the studies cited in the Citizen Petition is adequately designed to provide data that would reverse the previous determination regarding the efficacy of phenylephrine." The Task Group's characterization of the studies demonstrating the ineffectiveness of oral phenylephrine was false and further served to mislead the NDA Committee and public about the efficacy of the Task Group Defendants' Cold Medicines.

20.11 Moreover, notwithstanding the NDA Committee's feedback in 2007 that more clinical data was necessary to assess the efficacy of oral phenylephrine, the Task Group in its response to the 2015 Citizen's Petition did not identify any new studies initiated by the CHPA or any of its members in the nine years following the NDAC meeting in 2007.

20.12 The Task Group also engaged in coordinated efforts to mislead the public as to the efficacy of oral phenylephrine through press releases. For example, following the release of a study demonstrating the safety of Cold Medicines for children, in a May 4, 2017, press release, the Task Group exploited this opportunity to perpetuate false efficacy claims about Cold Medicine generally. Though the study exclusively examined safety parameters, the Task Group, through their senior vice president Barbara Kochanowski, PhD, made calculated representations about both "efficacy and safety," which are two different concepts, declaring:

> *When OTC medicines are used as directed and labeled, they provide the efficacy and safety that consumers demand (...) This study should be reassuring healthcare*

professionals who recommend OTC medicines, parents who use them, and retailers who sell them.

This all appears in more detail from a copy of the CHPA's May 4, 2017 Press Release included in support of this Application as **Exhibit P-44**.

20.13 On May 4, 2017, the Task Group knew that oral phenylephrine was ineffective when it publicly disseminated that press release.

20.14 Four days before the NDA Committee's planned meeting to discuss and vote on the efficacy of oral phenylephrine in September 2023, the Task Group issued a press release again touting the claim that oral phenylephrine is effective, stating therein:

Oral phenylephrine (PE) has been relied upon as a beneficial nasal decongestant by American families for decades, and FDA has repeatedly concluded the ingredient is safe and effective. This determination, established by multiple double-blind, placebo-controlled trials and supported by two previous FDA advisory panels, has also been validated by a meta-analysis of relevant clinical studies.

As seen on the copy of the September 7, 2023 press release, included in support of this Application as **Exhibit P-45**.

20.15 This statement ignored the studies regarding oral phenylephrine presented by the Task Group on which the NDA Committee previously stated were not credible and that the NDA Committee in 2007 recommended that additional studies be conducted.

20.16 Once again, in a press release issued on September 12, 2023 in response to the NDA Committee's finding that oral phenylephrine is ineffective, the Task Group stated that it was "concerned about previous clinical evidence being inappropriately dismissed and discounted." This statement ignored that the previous evidence in favour of the efficacy of oral phenylephrine were over 40 years old and that the Task Group Defendants did not submit or rely on any new clinical data demonstrating the efficacy of oral phenylephrine since 2007. As seen in more detail on the copy of the September 12, 2023 press release, included in support of this Application as **Exhibit P-46**.

20.17 In November 2024, the Task Group Defendants once again continued to release public statements regarding oral phenylephrine as an effective ingredient, flying in the face of the scientific consensus that it is not. As stated in a November 7, 2024 press release, the Task Group Defendants criticized the FDA Proposed Order Regarding the status of over-the-counter phenylephrine and inferred that phenylephrine is effective: "PE should remain an available option for consumers, because Americans deserve the option to choose the safe and effective OTC medicines they prefer and rely on" as seen on the copy of this press release dated November 7, 2024 included in support of this claim as **Exhibit P-52**.

20.18 The FDA Nonprescription Drugs Advisory Committee meeting transcript from September 11, 2023 (**Exhibit P-47)** reveals evidence suggesting a pattern of data suppression regarding phenylephrine's efficacy. This evidence includes:

- The defendants implemented contractual restrictions in clinical trials that explicitly prevented the Principal Investigators, the scientist responsible for leading the clinical trials, from "discuss[ing] or publish[ing] the trial results" (**Exhibit-P-47**, page 262) and (**Exhibit P-48, p. 26**).
- Multiple phenylephrine efficacy studies registered on clinicaltrials.gov were left incomplete and unpublished (**Exhibit-P-47**, page 262).

- Early efficacy data used to support phenylephrine's marketing contained statistically improbable results, with standard deviations "10 times or more smaller" than comparable study sites - a discrepancy that could not be replicated by other research centers (**Exhibit P-47**page 99**).** exposed the Defendants' systematic efforts to suppress unfavorable data.

20.19 In summary, since 2006, the Task Group Defendants carried out a coordinated conspiracy to suppress scientific evidence of their products' ineffectiveness. They deliberately concealed unfavorable research while actively promoting misleading studies to maintain inflated prices and market dominance. The Defendants orchestrated this deceptive scheme through systematic evidence suppression and coordinated misrepresentation of their products' efficacy to consumers.

C.2. DEFENDANTS' STRONG INCENTIVES FOR PROMOTING ORAL PHENYLEPHRINE

20.20 The Defendants possessed substantial financial motivation to maintain phenylephrine's market position. As set forth in the OTC Final Monograph of 1994, the FDA had approved only three drugs for oral nasal decongestants: phenylephrine hydrochloride, pseudoephedrine hydrochloride, and pseudoephedrine sulfate (**Exhibit P-10, page 28/40**).

20.21 Following the enactment of the *Combat Methamphetamine Epidemic Act* in March 2006, which mandated that pseudoephedrine products be placed behind pharmacy counters, phenylephrine hydrochloride became the only remaining active ingredient for oral nasal decongestion available without prescription. (**Exhibit P-49**).

20.22 This legislative change led to significant growth in sales of oral nasal decongestant products containing phenylephrine. For instance, Johnson & Johnson's 10-K filing in February 2007 attributed sales growth to the re-launch of TYLENOL Upper Respiratory products with phenylephrine instead of pseudoephedrine **(Exhibits P-50).**

20.23 The Defendants had a strong financial motivation to protect phenylephrine's position in the oral OTC nasal decongestant market. According to a letter from the Phenylephrine Task Group dated April 21, 2016, removing phenylephrine from the OTC monograph would have significant economic consequences. The letter noted that phenylephrine-containing products generated $1.5 billion in sales during the 52-week period ending July 12, 2015, accounting for approximately 20% of all OTC products in the cough, cold, allergy, and sinus treatment categories. The Task Group emphasized that eliminating phenylephrine would substantially reduce available non-prescription treatment options for consumers (**Exhibits P-43).**

20.24 In a press release issued on September 7, 2023, the Defendants further exploited their market position by emphasizing phenylephrine as "the only oral nonprescription medicine available without restrictions," strategically capitalizing on pseudoephedrine's restricted status while knowingly marketing an ineffective alternative to Quebec consumers. **Exhibits P-45).**

D. THE DEFENDANTS' FALSE REPRESENTATIONS AND LIABILITY

21. At all material times, each of the Defendants deliberately, or willfully and/or recklessly made representations to the proposed Class Members that their respective Cold Medicine products

were effective for the treatment and relief of nasal congestion and set these representations out in the dosage indicated on the labelling of each of their Cold Medicine products.

22. However, the Cold Medicine is not effective for the relief of nasal congestion, as was concluded by the US FDA on September 12, 2023, see **Exhibit P-21**.

23. The Defendant ~~J&J~~ Kenvue represents that their Cold Medicine product Benylin Extra Strength Cold & Sinus will "clear your head". ~~J&J~~ Kenvue's advertising will lead a consumer to understand that their product is an effective decongestant:

> *Trust the effective and fast relief of BENYLIN EXTRA STRENGTH Cold & Sinus DAY/NIGHT Tablets. This portable and convenient solution will relieve your worst symptoms during the day and help you rest at night.*

As appears on **Exhibit P-22**, a copy of ~~J&J~~ Kenvue product representation.

24. The representations go on to describe the product will relieve symptoms including nasal congestion and indicates in the dosage that the active ingredient of 5mg of phenylephrine is a decongestant, all as appears on **Exhibit P-22** ~~J&J~~ Kenvue product representation.

25. The Defendant ~~J&J~~ Kenvue represent that their Cold Medicine products Tylenol Extra Strength Cold Daytime and Tylenol Extra Strength Cold Nighttime each have 5mg of the active ingredient phenylephrine hydrochloride whose purpose is to act as a decongestant, as appears from the screenshot of the ingredients filed in support of this claim as **Exhibit P-23**.

26. The Defendants P&G hold out to consumers that performance is one of the three main factors that goes into choosing their product ingredients and note that "*every ingredient has a role in delivering the performance you expect from our products. We seek to use the best ingredients for our products for you can use them with confidence,*" as appears on **Exhibit P-24** representations about ingredients performance.

27. Further, P&G represent to consumers that their ~~Cough~~ Cold Medicine product Vicks DayQuil Cold & Flu Multi-Symptom Relief Non-Drowsy Liquid has a medicinal ingredient of 10 mg of phenylephrine hydrochloride which acts as a nasal decongestant and relieves nasal congestion, among other effects, as appears on **Exhibit P-25**, Vicks Dayquil product representation.

28. The Defendants ~~Glaxo~~ Haleon represented that their NeoCitran Extra Strength Cold & Sinus Night, their most popular formula of NeoCitran, is destined for use to relieve cold and flu symptoms that include sinus and nasal congestion and indicate that phenylephrine of a 10mg dosage acts as a nasal decongestant, see **Exhibit P-26,** ~~Glaxo~~ Haleon NeoCitran Extra Strength Night product representation.

29. The Defendant ~~Glaxo~~ Haleon made a similar representation about their other product NeoCitran Extra Strength Total Cold Night, by also indicating it is used for nasal and sinus congestion and that phenylephrine is an active ingredient for nasal decongestant, see **Exhibit P-27,** ~~Glaxo~~ Haleon NeoCitran Total Night product representation.

30. The Defendant RB represented to consumers that their Cold Medicine MUCINEX Multi-Action Cold & Sinus Caplets "helps relieve your cold and flu symptoms in 1 simple solution", "temporarily relieves symptoms of nasal and chest congestion due to common cold" and lists phenylephrine hydrochloride in a 5mg dosage as a nasal decongestant, as appears on **Exhibit P-28**, RB Health Mucinex product representation.

30.1 The Defendant Pfizer represented to consumers that its Cold Medicine products containing phenylephrine hydrochloride would provide effective relief from nasal congestion. According

to Health Canada's Drug Product Database, as shown in **Exhibit P-39**, Pfizer marketed the following products:

Adult-strength products (5mg phenylephrine hydrochloride):

- Dristan Extra Strength Caplets (DPN 02049198, marketed 1994-2016)
- Dristan Tablets (DPN 02092964, marketed 1994-2020)
- Dimetapp Nighttime Cold Extra Strength Caplets (DPN 02243091, marketed 2001-2017)
- Robitussin Complete Daytime (DPN 02449196, marketed 2017-2019)

Children's products:

- Dimetapp Chewables for Kids (DPN 02277239, 2.5mg phenylephrine hydrochloride, marketed 2006-2017)

30.2 For each product, Pfizer represented phenylephrine hydrochloride as an effective decongestant ingredient that would provide relief from nasal congestion, either alone or in combination with other active ingredients. Based on these representations in Health Canada's authorized product information, consumers would have reasonably understood that the phenylephrine hydrochloride in these products would effectively treat their nasal congestion symptoms.

30.3 Further, the defendant Pfizer represents to consumers that the medicinal ingredient phenylephrine hydrochloride (5mg) functions as a decongestant providing fast, effective, and temporary relief of nasal congestion, sinus pain, sinus pressure, and runny nose. As shown in **Exhibit P-51**, Pfizer prominently displays these therapeutic claims on its cold medicine product packaging, marketing phenylephrine hydrochloride as an effective decongestant for symptomatic relief.

31. ~~Throughout the Class Period, each of the Defendants consistently made inaccurate representations, including by omission, regarding the efficacy of orally administered phenylephrine as a nasal decongestant. The Defendants made their respective false or misleading representations knowingly or recklessly throughout the Class Period.~~

E. THE APPLICANT'S PERSONAL CLAIM AGAINST THE DEFENDANTS

32. The Applicant, Andrew Kraska, was subjected to the Defendant ~~J&J~~ Kenvue's misleading and deceitful marketing practices.~~,~~ During the winter months of years 2020-2022, ~~t~~the Applicant routinely purchased the Cold Medicines Tylenol Extra Strength Cold and Sinus Daytime and Tylenol Extra Strength Cold and Sinus Nighttime, listed at items No. ~~9~~ 3 and No. ~~10~~ 4 of Schedule A.

32.1 The Applicant primarily preferred Tylenol and Benylin products but also recalls using other Cold Medicine such as NeoCitran. Additionally, he purchased various Cold Medicine products that were on special offer at retailers like Jean Coutu, Walmart, and Costco.

33. As a physical person who acquired this Cold Medicine product for their own personal use, the Applicant is a consumer under section 1e) of the *Consumer Protection Act.*

34. When purchasing and using the above listed Cold Medicines, the Applicant saw on the product label of the Cold Medicine product that the dosage of phenylephrine was 5mg, and that this active ingredient, as a decongestant, would alleviate his symptoms of nasal congestion.

35. The Tylenol Extra Strength Cold and Sinus Daytime and Tylenol Extra Strength Cold and Sinus Nighttime products are Cold Medicines manufactured by the Defendant ~~J&J~~ Kenvue and each contain 5mg of phenylephrine hydrochloride per tablet, as seen on the screenshot of the ingredients listed on this product, **Exhibit P-23.**

36. The Applicant purchased this product under the pretense that he was obtaining a medicinal product containing an active ingredient that would provide decongestion.

37. Had the Applicant known that the Cold Medicine product was ineffective to treat the symptoms of nasal congestion, he would not have purchased these Cold Medicine products.

38. As a result, Defendant ~~J&J~~ Kenvue has made a false and misleading representation in breach of section 52 of the *Competition Act* and/or in breach of articles 219, 221(g), 228 of the *Consumer Protection Act,* and their conduct is considered a prohibited business practice under article 215 of the *Consumer Protection Act.*

39. The Applicant hereby claims to be returned the amount of monies he paid for the purchase of this Cold Medicine product (including moral punitive damages), subject to adjustment by the Court.

F. FACTS GIVING RISE TO CLAIMS HELD BY CLASS MEMBERS

40. The facts that give rise to the personal claim of the Applicant are the same as each personal claim belonging to members of the Class as against the Defendants.

41. Each Class Member purchased a ~~Cough~~ Cold Medicine product manufactured or distributed by the Defendants, as set out in **Schedule A**, about which the Defendants made false and misleading representations, knowingly and/or recklessly, regarding the efficacy of the active ingredient, phenylephrine, notably that doses of 5 to 10 mg every four hours would provide decongestion.

42. Each Class Member was exposed to these representations because they saw any or all of the following:

    a. The representations made on the labelling on the side of the physical bottles of the products;
    b. The representations that were displayed on the Canadian websites of each of these Defendants listing the dose and ingredients in each of these products

43. As such, each Class Member is also justified in claiming damages, including punitive damages, as these are a direct result of the Defendants' conduct.

44. Class Members, as credulous and inexperienced consumers with rights under the *Consumer Protection Act,* were each subjected to the Defendants' ignorance, carelessness, or serious negligence with respect to the obligations they owe to customers.

45. Each Class Member has a common interest in liability, the determination of which could be assessed collectively in a single trial as liability in this case focuses on the conduct of the Defendants without consideration for any circumstances of individual class members.

46. None of the Class Members could have reasonably understood the ineffectiveness of the phenylephrine ingredient in these Cold Medicine products until the FDA's Briefing Document of September 11-12, 2023, was widely disseminated in the media, as appears on this Canadian CBC News Article dated September 12, 2023, included in this claim as **Exhibit P-29**.

47. Under the principles set out in article 2904 CCQ regarding the impossibility to act, none of the Class Members had the necessary information to act for themselves until such news was widely and publicly disseminated on September 12, 2023. The postponement of prescription is justified as the Class Members were unable to act due to this impossibility of knowing about the ineffectiveness of phenylephrine. ~~As a result, the prescription period is postponed until September 12, 2023 when this information was circulated as such on Canadian news outlets. The doctrines of postponement, discoverability, fraudulent concealment, and CCQ articles 2880 & 2904 all apply to postpone the running of any prescription period~~.

G. IDENTICAL, SIMILAR OR RELATED QUESTIONS OF FACT OR LAW

48. The conclusions sought by each class member are the same and raise identical, similar or related questions of fact and law, namely:

~~a. Does the ingredient phenylephrine contain medical properties that treat symptoms of nasal decongestion effectively, or at all?~~

~~b. During the Class Period, did the Defendants, or any of them, make representations to Class Members that the ingredient phenylephrine contains medical properties that effectively treat nasal congestion? If yes, for which Cold Medicines in Schedule A and during what time periods?~~

~~c. Were any of the Defendants' representations regarding the efficacy of phenylephrine during the Class Period false or misleading representations within the meaning of the *Consumer Protection Act* or the *Competition Act*? If yes, for which Cold Medicines in Schedule A and during what time periods?~~

~~d. If phenylephrine is not effective for treating symptoms of nasal decongestion, or minimally effective, is that a latent defect under the *Consumer Protection Act* or the *Civil Code of Quebec*?~~

~~e. Do any of the Defendants' representations regarding the efficacy of phenylephrine during the Class Period constitute a civil fault under section 1457? If so, did the civil fault cause injury to Class Members?~~

~~f. What is the value of any damages, and can the damages, or any portion of them, be aggregated?~~

~~g. Are the Defendants liable to pay punitive damages to the Class Members? If so, in what amount?~~

a. During class period, did the Defendants, or any of them engage in prohibited practices by misrepresenting phenylephrine's efficacy, contrary to: The *Consumer Protection Act*, sections 219, 220(a), 228, 253, and 272; and/or the *Competition Act*, sections 36 and 52; and and/or the *Civil Code of Quebec*, articles 6, 7, 1375, 1401, and 1407?

b. Does the phenylephrine's therapeutic ineffectiveness constitute a latent defect in the Cold Medicine Products that render them unfit for their intended purpose pursuant to: The *Consumer Protection Act* sections 37, 38, 40, and 41 and/or the *Civil Code of Quebec*, articles 1726, 1728, and 1730?

c. Do the Defendants' representations regarding phenylephrine's efficacy during the Class Period constitute a civil fault under Article 1457 CCQ? If so, did this fault cause injury to Class Members?

d. During Class Period, did the Defendants, or any of them engage in civil conspiracy by either coordinating efforts to suppress and/or discredit scientific evidence regarding phenylephrine's ineffectiveness and/or maintain false therapeutic claims regarding phenylephrine's efficacy; if so, does that constitute a fault under article 1457 CCQ and did it cause injury to Class Members?

e. Did phenylephrine, as formulated in the Defendants' Cold Medicine Products, lack therapeutic efficacy as a nasal decongestant at the marketed dosages when taken orally during the Class Period?

f. Are the Defendants solidarily liable for damages caused by their coordinated misconduct in manufacturing and marketing ineffective Cold Medicine Products?

g. What compensatory damages have Class Members suffered from purchasing ineffective Cold Medicine Products, and can these damages, or any of them, be aggregated?

h. Are the Defendants liable to pay punitive damages to the Class Members? If so, in what amount?

H. COMPOSITION OF CLASS MAKES RULES OF MANDATE IMPRACTICAL

49. The composition of the Class makes it difficult and/or impractical to apply the rules of mandates to take part in judicial proceedings on behalf of others for consolidation of proceedings pursuant to articles 59 or 67 C.C.P.

50. The historical and current sales data set out in the September 2023 Briefing Document of the FDA estimates there were between approximately 184 and 242 million bottles/packaging sold for over-the-counter ~~cough/cold/allergy~~ Cold Medicine oral products containing phenylephrine from U.S. retail stores to consumers between 2018 and 2022, as appears from page 70, Figure 26 of **Exhibit P-21** filed in support of this claim.

51. The size of the class is unknown to the Applicant but estimated to be above one million. Based on the data in Exhibit P-21, assuming that the all-Canada population is 10% of the American population, and that the population of Quebec is 23% of the all-Canada population, leads to an estimate that there were between 4,232,000 - 5,566,000 bottles/packages sold of over-the-counter ~~cough/cold/allergy~~ Cold Medicine oral products containing phenylephrine in Quebec between 2018-2022.

52. The Applicant is ignorant of the identities of most of the Class Members sought to be included in this action.

53. In the circumstances, it would be impracticable and impossible for the Applicant to obtain a mandate from each Class Member or to join them all into a single action.

54. Moreover, the modest amount that each Class Member is likely entitled to claim against the Defendants makes it likely that the majority of these Class Members would hesitate to file their own individual action against the Defendants, never mind the fact that the costs associated with launching an individual claim to pursue one’s right before the courts would be largely

more significant than the amount each member can hope to obtain as a result of such individual actions.

55. In the circumstances, the class action procedure is the only appropriate procedure for the proposed class members to access justice and pursue their respective claims against the Defendants effectively and efficiently.

I. PROPOSED CLASS REPRESENTATIVE

56. The Applicant seeks to be appointed the status of representative Applicant for the following reasons.

57. As a class member himself, the Applicant has a personal interest in seeking the conclusions sought.

58. The Applicant has the time, energy, will and determination to assume and perform the duties incumbent upon him that are required to carry out the proposed class action.

59. The Applicant acts in good faith with the only goal in accessing justice and the relief sought for themselves and for the other class members.

59.1 The Applicant's use of various Cold Medicine products containing phenylephrine, including but not limited to Tylenol, Benylin, and NeoCitran, as well as products purchased on special offer from retailers like Jean Coutu, Walmart, and Costco, demonstrates his representativeness of the broader class. This diverse product usage aligns him with the experiences of many class members who may have purchased different brands or formulations of phenylephrine-containing Cold Medicines.

60. The Applicant does not have any circumstances that would put them in conflict with the other members of the class.

J. NATURE OF THE CLASS ACTION AND CONCLUSIONS SOUGHT

61. The nature of the action the Applicant intends to bring on behalf of the class members is an action in compensatory and punitive damages.

62. The facts alleged the exhibits preferred in support justify the conclusions sought, which the Applicant wishes to introduce by way of an originating application, that read as follows:

a. **GRANT** the Representative Plaintiff's action against the Defendants on behalf of all the Class Members.

b. **CONDEMN** the Defendant to pay, solidarily, the Representative Plaintiff and the Class Members damages, including punitive damages in an amount to be determined by the Court.

c. **DECLARE** that an award of aggregate damages should be made.

d. **ORDER** the collective recovery of all damages to Class Members.

e. **CONDEMN** the Defendants, solidarily, to pay interest and additional indemnity on the above sums as provided for by law in accordance with article 1619 CCQ from the date of service of the *Application for Authorization to Institute a Class Action.*

f. **RENDER** any other order that this Honourable Court shall determine and that is in the interest of the members of the Class;

g. **THE WHOLE WITH** costs, including all expert fees, notice fees, and expenses of the administrator, if any.

FOR THESE REASONS, MAY IT PLEASE THE COURT:

GRANT the present application;

AUTHORIZE the bringing of a class action in the form of an originating application in damages;

APPOINT the Applicant, Mr. Andrew Kraska, the status of Representative Applicant of the persons included in the Class herein described as follows:

> All persons in Quebec who purchased, between ~~January~~ February 1, 2007 and date this case is authorized as a class action, any ~~Cough~~ Cold Medicine listed in Schedule A to the Application for Authorization.

IDENTIFY the principle questions of fact and law to be treated collectively as the following:

~~a. Does the ingredient phenylephrine contain medical properties that treat symptoms of nasal decongestion effectively, or at all?~~

~~b. During the Class Period, did the Defendants, or any of them, make representations to Class Members that the ingredient phenylephrine contains medical properties that effectively treat nasal congestion? If yes, for which Cold Medicines in Schedule A and during what time periods?~~

~~c. Were any of the Defendants' representations regarding the efficacy of phenylephrine during the Class Period false or misleading representations within the meaning of the *Consumer Protection Act* or the *Competition Act*? If yes, for which Cold Medicines in Schedule A and during what time periods?~~

~~d. If phenylephrine is not effective for treating symptoms of nasal decongestion, or minimally effective, is that a latent defect under the *Consumer Protection Act* or the *Civil Code of Quebec*?~~

~~e. Do any of the Defendants' representations regarding the efficacy of phenylephrine during the Class Period constitute a civil fault under section 1457 CCQ? If so, did the civil fault cause injury to Class Members?~~

~~f. What is the value of any damages, and can the damages, or any portion of them, be aggregated?~~

~~g. Are the Defendants liable to pay punitive damages to the Class Members? If so, in what amount?~~

a. During class period, did the Defendants, or any of them engage in prohibited practices by misrepresenting phenylephrine's efficacy, contrary to: The *Consumer Protection Act*, sections 219, 220(a), 228, 253, and 272; and/or the *Competition Act*, sections 36 and 52; and and/or the *Civil Code of Quebec*, articles 6, 7, 1375, 1401, and 1407?

b. Does the phenylephrine's therapeutic ineffectiveness constitute a latent defect in the Cold Medicine Products that render them unfit for their intended purpose pursuant to: The *Consumer Protection Act* sections 37, 38, 40, and 41 and/or the *Civil Code of Quebec*, articles 1726, 1728, and 1730?

c. Do the Defendants' representations regarding phenylephrine's efficacy during the Class Period constitute a civil fault under Article 1457 CCQ? If so, did this fault cause injury to Class Members?

d. During Class Period, did the Defendants, or any of them engage in civil conspiracy by either coordinating efforts to suppress and/or discredit scientific evidence regarding phenylephrine's ineffectiveness and/or maintain false therapeutic claims regarding phenylephrine's efficacy; if so, does that constitute a fault under article 1457 CCQ and did it cause injury to Class Members?

e. Did phenylephrine, as formulated in the Defendants' Cold Medicine Products, lack therapeutic efficacy as a nasal decongestant at the marketed dosages when taken orally during the Class Period?

f. Are the Defendants solidarily liable for damages caused by their coordinated misconduct in manufacturing and marketing ineffective Cold Medicine Products?

g. What compensatory damages have Class Members suffered from purchasing ineffective Cold Medicine Products, and can these damages, or any of them, be aggregated?

h. Are the Defendants liable to pay punitive damages to the Class Members? If so, in what amount?

IDENTIFY as follows the conclusions sought by the class action in relation thereof:

a. **GRANT** the Representative Plaintiff's action against the Defendants on behalf of all the Class Members.

b. **CONDEMN** the Defendant to pay, solidarily, the Representative Plaintiff and the Class Members damages, including punitive damages in an amount to be determined by the Court.

c. **DECLARE** that an award of aggregate damages should be made.

d. **ORDER** the collective recovery of all damages to Class Members.

e. **CONDEMN** the Defendants, solidarily, to pay interest and additional indemnity on the above sums as provided for by law in accordance with article 1619 CCQ from the date of service of the *Application for Authorization to Institute a Class Action.*

f. **RENDER** any other order that this Honourable Court shall determine and that is in the interest of the members of the Class;

g. **THE WHOLE WITH** costs, including all expert fees, notice fees, and expenses of the administrator, if any.

DECLARE that any member who has not requested his exclusion from the class be bound by any judgment to be rendered on the class action, in accordance with law;

FIX the delay for exclusion from the Class at 60 days from the date of notice to the Class and after the expiry of such delay the members of the class who have not requested exclusion be bound by any such judgment;

ORDER the publication of a notice to the members of the Class according to the terms to be determined by the Court;

REFER the record to the Chief Justice so that he may fix the district in which the class action is to be brought and the judge before whom it will be heard and In the event that the class action is to be brought in another district, that the clerk of this Court be ordered, upon receiving the decision of the Chief Justice, to transmit the present record to the clerk of the district designated.

THE WHOLE with legal costs, including the cost of all notices.

Montréal, August 1, 2025

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SCHEDULE A – List of Cold Medicine Products Containing Phenylephrine

No.	Defendant	Product	DPN	Dosage
1	KENVUE ~~JOHNSON & JOHNSON INC.~~	BENYLIN EXTRA STRENGTH COLD & SINUS DAY	02273462	5mg
2	KENVUE ~~JOHNSON & JOHNSON INC.~~	BENYLIN EXTRA STRENGTH COLD & SINUS NIGHT	02306409	5mg
3 ~~9~~	KENVUE ~~JOHNSON & JOHNSON INC.~~	EXTRA STRENGTH TYLENOL COLD DAYTIME	02276186	5mg
4 ~~10~~	KENVUE ~~JOHNSON & JOHNSON INC.~~	EXTRA STRENGTH TYLENOL COLD NIGHTTIME	02276259	5mg
5 ~~11~~	KENVUE ~~JOHNSON & JOHNSON INC.~~	EXTRA STRENGTH TYLENOL FLU DAYTIME	02275996	5mg
6 ~~12~~	KENVUE ~~JOHNSON & JOHNSON INC.~~	EXTRA STRENGTH TYLENOL SINUS DAYTIME	02276003	5mg
7 ~~13~~	KENVUE ~~JOHNSON & JOHNSON INC.~~	EXTRA STRENGTH TYLENOL SINUS NIGHTTIME	02276038	5mg
8	KENVUE	BENYLIN ALL-IN-ONE COLD AND FLU NIGHT PE CAPLETS	02273934	5mg
9	KENVUE	BENYLIN EXTRA STRENGTH COLD & SINUS PLUS	02273470	5mg
10	KENVUE	CHILDREN'S BENADRYL-D SYRUP	02280612	5mg
11	KENVUE	EXTRA STRENGTH TYLENOL ALLERGY	02276054	5mg
12	KENVUE	EXTRA STRENGTH TYLENOL FLU NIGHTTIME	02276046	5mg
13	KENVUE	REGULAR STRENGTH TYLENOL COLD DAYTIME	02275627	5mg
14	KENVUE	REGULAR STRENGTH TYLENOL COLD NIGHTTIME	02275716	5mg
15	KENVUE	REGULAR STRENGTH TYLENOL SINUS DAYTIME	02275708	5mg
16	KENVUE	SUDAFED PE EXTRA STRENGTH	02250217	10mg
17	KENVUE	TYLENOL COLD AND FLU DAYTIME	02276658	10mg
18	KENVUE	TYLENOL COLD AND FLU NIGHTTIME	02276879	10mg

19	KENVUE	TYLENOL COLD NIGHTIME RAPID RELEASE	02322838	5mg
20	KENVUE	TYLENOL COLD RAPID RELEASE	02305917	5mg
21 ~~3~~	PROCTER & GAMBLE INC.	DAYQUIL COLD & FLU	02300842	10mg
22 ~~4~~	PROCTER & GAMBLE INC.	DAYQUIL COMPLETE	02503638	10mg
23 ~~5~~	PROCTER & GAMBLE INC.	DAYQUIL COMPLETE + VICKS VAPOCOOL	02481936	5mg
24 ~~6~~	PROCTER & GAMBLE INC.	DAYQUIL COMPLETE + VICKS VAPOCOOL COLD & FLU LIQUID	02482428	10mg
25 ~~7~~	PROCTER & GAMBLE INC.	DAYQUIL COUGH DM + CONGESTION	02503247	10mg
26 ~~8~~	PROCTER & GAMBLE INC.	DAYQUIL SINUS LIQUICAPS	02273829	5mg
27 ~~23~~	PROCTER & GAMBLE INC.	NYQUIL COMPLETE	02503549	10mg
28 ~~24~~	PROCTER & GAMBLE INC.	NYQUIL COMPLETE + VICKS VAPOCOOL	02481928	5mg
29 ~~25~~	PROCTER & GAMBLE INC.	NYQUIL COMPLETE + VICKS VAPOCOOL COLD & FLU LIQUID	02482401	10mg
30 ~~26~~	PROCTER & GAMBLE INC.	NYQUIL COUGH DM + CONGESTION	02503611	5mg
31 ~~27~~	PROCTER & GAMBLE INC.	NYQUIL KIDS	02520419	5mg
32 ~~28~~	PROCTER & GAMBLE INC.	NYQUIL SINUS LIQUICAPS	02273810	5mg
33 ~~31~~	PROCTER & GAMBLE INC.	VICKS DAYQUIL COLD & FLU MULTI-SYMPTOM RELIEF LIQUICAPS	02272784	5mg
34 ~~32~~	PROCTER & GAMBLE INC.	VICKS DAYQUIL COMPLETE COLD & FLU LIQUICAPS	02483378	5mg
35 ~~33~~	PROCTER & GAMBLE INC.	VICKS DAYQUIL COMPLETE COLD & FLU LIQUID	02409534	10mg
36 ~~34~~	PROCTER & GAMBLE INC.	VICKS DAYQUIL HOT REMEDY	02531518	10mg
37 ~~35~~	PROCTER & GAMBLE INC.	VICKS NYQUIL COMPLETE COLD & FLU	02409542	10mg

38 ~~36~~	PROCTER & GAMBLE INC.	VICKS NYQUIL COMPLETE COLD & FLU LIQUICAPS	02483351	5mg
39 ~~37~~	PROCTER & GAMBLE INC.	VICKS NYQUIL HOT REMEDY	02531488	10mg
40 ~~16~~	HALEON ~~GLAXOSMITHKLINE CONSUMER HEALTHCARE ULC~~	NEOCITRAN COLD & SORE THROAT NIGHT	02246602	10mg
41 ~~17~~	HALEON ~~GLAXOSMITHKLINE CONSUMER HEALTHCARE ULC~~	NEOCITRAN EXTRA STRENGTH COLD & CONGESTION	00843792	10mg
42 ~~18~~	HALEON ~~GLAXOSMITHKLINE CONSUMER HEALTHCARE ULC~~	NEOCITRAN EXTRA STRENGTH COLD & SINUS NIGHT - APPLE CINNAMON	02456982	10mg
43 ~~19~~	HALEON ~~GLAXOSMITHKLINE CONSUMER HEALTHCARE ULC~~	NEOCITRAN EXTRA STRENGTH COLD & SINUS NIGHT	02215403	10mg
44 ~~20~~	HALEON ~~GLAXOSMITHKLINE CONSUMER HEALTHCARE ULC~~	NEOCITRAN EXTRA STRENGTH TOTAL COLD	02293994	10mg
45 ~~21~~	HALEON ~~GLAXOSMITHKLINE CONSUMER HEALTHCARE ULC~~	NEOCITRAN EXTRA STRENGTH TOTAL COLD NIGHT	02409178	10mg
46 ~~22~~	HALEON ~~GLAXOSMITHKLINE CONSUMER HEALTHCARE ULC~~	NEOCITRAN TOTAL COLD NIGHT	02413280	10mg
47 ~~29~~	HALEON ~~GLAXOSMITHKLINE CONSUMER HEALTHCARE ULC~~	ROBITUSSIN CHILDREN'S COLD	02394693	5mg
48 ~~30~~	HALEON ~~GLAXOSMITHKLINE CONSUMER HEALTHCARE ULC~~	ROBITUSSIN CHILDREN'S COUGH & COLD BEDTIME	02394707	5mg

49	HALEON	CONTAC COLD NASAL CONGESTION	02276690	5mg
50	HALEON	NIGHTTIME REGULAR STRENGTH CONTAC COLD NASAL CONGESTION	02276100	5mg
51	HALEON	ROBITUSSIN CHILDREN'S COLD	02394693	5mg
52	HALEON	THERAFLU COLD AND FLU	02278294	10mg
53	HALEON	TRIAMINIC THIN STRIPS COLD & COUGH	02271745	2.5mg
54	HALEON	TRIAMINIC THIN STRIPS NASAL CONGESTION	02271737	2.5mg
55	HALEON	TRIAMINIC THIN STRIPS NIGHTTIME COLD & COUGH	02294354	5mg
56	HALEON	EXTRA STRENGTH NEOCITRAN COLD SYRUP WITH MUCUS RELIEF	02304740	10mg
57	HALEON	EXTRA STRENGTH NEOCITRAN FLU SYRUP	02275961	10mg
58	HALEON	EXTRA STRENGTH NEOCITRAN TOTAL SYMPTOM RELIEF - SUGAR FREE	02319195	10mg
59	HALEON	EXTRA STRENGTH NEOCITRAN TOTAL SYRUP	02275988	10mg
60	HALEON	NEOCITRAN COLD & COUGH NIGHT	01906704	10mg
61	HALEON	NEOCITRAN THIN STRIPS DAYTIME COUGH AND COLD	02278715	10mg
62	HALEON	NEOCITRAN THIN STRIPS NIGHTTIME COUGH AND COLD	02278693	10mg
63	HALEON	TRIAMINIC CHEST AND NASAL CONGESTION	02278308	2.5mg
64	HALEON	TRIAMINIC DAYTIME COUGH & COLD	02278073	2.5mg
65	HALEON	TRIAMINIC NIGHTTIME COUGH AND COLD	02278170	2.5mg

66	HALEON	TRIAMINIC TODDLER CONGESTION THIN STRIPS	02278782	2.5mg
67	HALEON	TRIAMINIC TODDLER COUGH AND COLD THIN STRIPS	02278774	2.5mg
68	KENVUE	BENYLIN D FOR INFANTS	02281341	1.25mg
69 ~~14~~	RB HEALTH ~~(CANADA) INC.~~	MUCINEX MULTI-ACTION CONGESTION, COLD & COUGH	02433435	5mg
70 ~~15~~	RB HEALTH ~~(CANADA) INC.~~	MUCINEX MULTI-ACTION CONGESTION, COLD & FLU	02433451	5mg
71	RB HEALTH	MUCINEX MULTI-ACTION CONGESTINO, COLD & COUGH SOLUTION	02433419	10mg
72	RB HEALTH	MUCINEX MULTI-ACTION CONGESTION, STUFFY NOSE & COUGH LIQUID	02433249	10mg
73	PFIZER	DIMETAPP CHEWABLES FOR KIDS	02277239	2.5 mg
74	PFIZER	DIMETAPP NIGHTTIME COLD EXTRA STRENGTH CAPLETS	02243091	5mg
75	PFIZER	DRISTAN EXTRA STRENGTH CAPLETS	02049198	5mg
76	PFIZER	DRISTAN TABLETS	02092964	5mg
77	PFIZER	ROBITUSSIN COMPLETE DAYTIME	02449196	5mg

SUMMONS
(Articles 145 and following CCP)

Filing of a judicial application

Take notice that the Applicant has filed this Application for Authorization to Institute a Class Action and to Appoint the Status of Representative Plaintiff in the office of the Superior Court in the judicial district of Montreal.

Exhibits supporting the application

In support of the *Application for authorization to Institute a Class Action,* the Applicant relies on the following exhibits:

Exhibit P-1:	Copy of the ~~J&J~~ Kenvue Drug Product Pages retrieved from Health Canada website
Exhibit P-2:	Copy of the corporate history information of ~~J&J~~ Kenvue retrieved from CIDREQ
Exhibit P-3:	Copy of the P&G Drug Product Pages retrieved from the Health Canada website
Exhibit P-4:	Copy of the corporate history information of P&G retrieved from CIDREQ
Exhibit P-5:	Copy of the ~~Glaxo~~ Haleon Drug Product Pages retrieved from the Health Canada website
Exhibit P-6:	Copy of the corporate history information of ~~Glaxo~~ Haleon retrieved from CIDREQ
Exhibit P-7:	Copy of the RB Drug Product Pages retrieved from the Health Canada website
Exhibit P-8	Copy of the corporate history information of RB retrieved from CIDREQ
Exhibit P-9	Copy of the FDA 1976 Monograph
Exhibit P-10	Copy of the FDA 1994 Monograph
Exhibit P-11	Copy of the 2007 Citizen's Petition to the FDA
Exhibit P-12	Copy of the 2007 Hatton Study
Exhibit P-13	Copy of the 2007 ~~Glaxo~~ Haleon Study

Exhibit P-14 Copy of the 2007 Wyeth Study

Exhibit P-15 Copy of the NDAC meeting minutes of the hearing dated December 14, 2007, retrieved from the FDA website

Exhibit P-16 Copy of the 2015 Meltzer Study

Exhibit P-17 Copy of the Hatton Hendeles 2015 Citizen's Petition

Exhibit P-18 Copy of the October 2020 Rhinitis Practice Parameter Update

Exhibit P-19 Copy of the 2022 article by Hatton and Hendeles published in the journal *Annals of Pharmacotherapy*

Exhibit P-20 Copy of the 2022 American Academy of Allergy, Asthma & Immunology and the American College of Allergy, Asthma & Immunology Statement of Support

Exhibit P-21 Copy of the September 11 and 12, 2023 FDA Briefing Document

Exhibit P-22 ~~J&J~~ Kenvue Screenshot of Product Representation

Exhibit P-23 ~~J&J~~ Kenvue Screenshot of Extra Strength Tylenol Product Representation

Exhibit P-24 P&G Representations about Ingredients Performance

Exhibit P-25 P&G Vicks DayQuil Product Representation

Exhibit P-26 ~~Glaxo~~ Haleon NeoCitran Extra Strength Night Product Representations

Exhibit P-27 ~~Glaxo~~ Haleon NeoCitran Total Night Product Representation

Exhibit P-28 RB Health Mucinex Product Representation

Exhibit P-29 Copy of CBC News Article dated September 12, 2023

Exhibit P-30 Copy of the corporate history information of Johnson & Johnson Consumer Inc. retrieved from the DE Division of Corporations

Exhibit P-31 Copy of the corporate history information of Kenvue Inc. retrieved from the DE Division of Corporations

Exhibit P-32 Copy of the corporate history information of The Procter & Gamble Company retrieved from the OH Office of Secretary of State

Exhibit P-36	Copy of the corporate history information of RB Health US LLC retrieved from the DE Division of Corporations
Exhibit P-39	Binder of Health Canada's Product Database - Pfizer Products
Exhibit P-40	Copy of the corporate history information of Pfizer Canada ULC retrieved from CIDREQ
Exhibit P-41	Copy of the corporate history information of Pfizer Inc. retrieved from the DE Division of Corporations
Exhibit P-42	CHPA PowerPoint Slides - September 11-12, 2024
Exhibit P-43	Copy of the Phenylephrine Task Group Letter April 21, 2016
Exhibit P-44	Copy of the Phenylephrine Task Group Presse Release May 4, 2017
Exhibit P-45	Copy of the Phenylephrine Task Group Press Release September 7, 2023
Exhibit P-46	Copy of the Phenylephrine Task Group Press Release September 12, 2023
Exhibit P-47	Copy of the Transcript NDAC September 11, 2023
Exhibit P-48	Copy of Study NCT03339726 by J&J
Exhibit P-49	Copy of The Combat Methamphetamine Epidemic Act
Exhibit P-50	Copy of Johnson & Johnson's 10-K, 2007
Exhibit P-51	Printscreen of Product: PFIZER - Dristan Cold & Sinus Tablets, 24 tablets – Green Valley Pharmacy
Exhibit P-52	Copy of CHPA Response to FDA Proposed Order Regarding

The exhibits in support of the application are available upon request.

Defendants' answer

You must answer the application in writing, personally or through a lawyer, at the courthouse of Montreal situated at 1 Rue Notre-Dame Est, Montreal, Québec, H2Y 186, within 15 days of service of the Application or, if you have no domicile, residence or establishment in Québec, within 30 days. The answer must be notified to the Applicant’s lawyer or, if the Applicant is not represented, to the Applicant.

Failure to answer

If you fail to answer within the time limit of 15 or 30 days, as applicable, a default judgement may be rendered against you without further notice and you may, according to the circumstances, be required to pay the legal costs.

Content of answer

In your answer, you must state your intention to:

- negotiate a settlement;
- propose mediation to resolve the dispute;
- defend the application and, in the case required by the Code, cooperate with the Applicant in preparing the case protocol that is to govern the conduct of the proceeding. The protocol must be filed with the court office in the district specified above within 45 days after service of the summons or, in family matters or if you have no domicile, residence or establishment in Québec, within 3 months after service;
- propose a settlement conference.

The answer to the summons must include your contact information and, if you are represented by a lawyer, the lawyer's name and contact information.

Change of judicial district

You may ask the court to refer the originating Application to the district of your domicile or residence, or of your elected domicile or the district designated by an agreement with the plaintiff.

If the application pertains to an employment contract, consumer contract or insurance contract, or to the exercise of a hypothecary right on an immovable serving as your main residence, and if you are the employee, consumer, insured person, beneficiary of the insurance contract or hypothecary debtor, you may ask for a referral to the district of your domicile or residence or the district where the immovable is situated or the loss occurred. The request must be filed with the special clerk of the district of territorial jurisdiction after it has been notified to the other parties and to the office of the court already seized of the originating application.

Transfer of application to Small Claims Division

If you qualify to act as a plaintiff under the rules governing the recovery of small claims, you may also contact the clerk of the court to request that the application be processed according to those rules. If you make this request, the plaintiff's legal costs will not exceed those prescribed for the recovery of small claims.

Calling to a case management conference

Within 20 days after the case protocol mentioned above is files, the court may call you to a case management conference to ensure the orderly progress of the proceeding. Failing this, the protocol is presumed to be accepted.

Notice of presentation of an application

If the application is an application in the course of a proceeding or an application under Book III, V, excepting an application in family matters mentioned in article 409, or VI of the Code, the establishment of a case protocol is not required; however, the application must be accompanied by a notice stating the date and time it is to be presented.

Montréal, August 1, 2025

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NOTICE OF PRESENTATION

TO:

KENVUE CANADA INC., FORMERLY KNOWN AS JOHNSON & JOHNSON INC., legal person having its head office at 88 McNabb Street, Markham, Ontario, L3R 5L2, Canada

PROCTER & GAMBLE INC., legal person having its head office at 4711 ST Younge, Toronto, Ontario, M5W 1C5, Canada

HALEON CANADA ULC, FORMERLY KNOWN AS GLAXOSMITHKLINE CONSUMER HEALTH CARE SRI, legal person having its head office at 2600-595 Burrard Street, Vancouver, BC, V7X 1L3, Canada

RB HEALTH (CANADA) INC. legal person having its head office at 2300-550, Burrard Street, Box 30, Vancouver, BC, V6C 2B5, Canada

PFIZER CANADA ULC., legal person having its head office at 1800-510 West Georgia Street, Vancouver, BC, V6B 0M3

PFIZER INC., legal person having its place of business at 1209 Orange Street, Wilmington, DE, 19801, USA

JOHNSON & JOHNSON CONSUMER INC., legal person having its place of business at 1209 Orange Street, Wilmington, DE, 19801, USA

KENVUE INC., legal person having its place of business at 1209 Orange Street, Wilmington, DE, 19801, USA

THE PROCTER & GAMBLE COMPANY, legal person having its place of business at 4400 Easton Commons Waysuite 125, Columbus, OH, 43219, USA

RB HEALTH (US) LLC, legal person having its place of business at 251 Little Falls Drive, Wilmington, DE, 19808, USA

TAKE NOTICE that Applicant's *Application for Authorization to Institute a Class Action and to Appoint the Status of Representative Plaintiff* will be presented before the Superior Court at 1 Rue Notre-Dame E, Montréal, Quebec, H2Y 1B6, on the date set by the coordinator of the Class Action chamber.

GOVERN YOURSELF ACCORDINGLY.

Montréal, August 1, 2025

Slater Vecchio

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No. 500-06-001262-233

SUPERIOR COURT
DISTRICT OF MONTRÉAL
(Class Actions)

ANDREW KRASKA

Plaintiff

v.

KENVUE CANADA INC., FORMERLY KNOWN AS JOHNSON & JOHNSON INC. et al

Defendants

AMENDED APPLICATION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION AND APPOINT APPLICANT AS CLASS REPRESENTATIVE

O R I G I N A L

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Our file: CA0085-2