SUPERIOR COURT

CANADA
PROVINCE OF QUEBEC
DISTRICT OF MONTRÉAL

No.: **500-06-001201-223**

DATE: November 23, 2026

BY THE HONOURABLE ELENI YIANNAKIS, J.S.C.

JADE CORBEIL
MERIEME HAMZI

Plaintiffs

v.

JOHNSON & JOHNSON
KENVUE CANADA INC. (formerly known as Johnson & Johnson Inc.)

Defendants

JUDGMENT
ON APPLICATION FOR AUTHORIZATION OF A CLASS ACTION[1]

« *The saddest aspect of life right now is that science gathers knowledge faster than society gathers wisdom.* »

Isaac Asimov

JY0083

[1] La version française de ce jugement est disponible.

OVERVIEW

[1] At the core of the proposed class action lies the contention that, because an association has been demonstrated between prenatal exposure to acetaminophen and the development of autism in children, the Defendants failed to fulfill their duty to warn of that risk on the labelling of their Tylenol products.

[2] Let's start with the conclusion: The legal syllogism put forward by Plaintiffs is doomed to fail.

[3] It is supported by vague allegations which are also in large part manifestly inaccurate and consist of speculation or mere opinions. They do not appear to justify the conclusions sought (art. 575(2) CCP).

[4] Allowing this class action to proceed would inevitably give rise to a scientific debate regarding the validity of the conclusions advanced in the studies relied upon by the Plaintiffs, to which the U.S. Food and Drug Administration ("FDA") gave some credence during a highly publicized press conference held in September 2025.

[5] However, such a debate is neither necessary nor useful in the particular circumstances of this case. The relevant scientific questions have already been carefully examined by the competent Canadian regulatory authorities and reopening that debate through a class action risks generating confusion rather than advancing the search for truth in an era increasingly marked by misinformation and the erosion of confidence in objective scientific evidence.

[6] The Court refuses to go down this rabbit hole.

[7] This is a unique case.

[8] The Court's refusal to authorize this class action in this very particular set of circumstances should not be interpreted as a departure from the fundamental principle that a regulator's approval of a product's labelling does *not*, in itself, shield a manufacturer from civil liability.

[9] Rather, in this particular case, faced with *the exact same scientific evidence* Plaintiffs are presenting here, Health Canada did not only choose not to mandate any update to the product's label, but it also proactively issued a public advisory statement stating the absence of any conclusive evidence that the use of acetaminophen causes autism or similar disorders and reiterating that acetaminophen remains a recommended treatment of pain or fever in pregnancy. Compounding the clarity of the Canadian regulator's position is the unequivocal consensus statement made by the Society of Obstetricians and Gynaecologists of Canada ("SOGC") rebutting the association between prenatal exposure to acetaminophen and autism, signaling that the evidence in this regard is fundamentally flawed.

[10] The role of regulators and experts such as Health Canada and the SOGC is to review all the scientific literature and to protect the Canadian public. Their position differs significantly from the one recently adopted by the U.S. FDA. They conclude that there is no danger and no causation, thus there can be no failure relating to the duty to warn. As such, because of their positions rebutting the "association" that Plaintiffs are putting forward, there can be no arguable case.

[11] While the courts have an important supervisory role in ensuring compliance with the law and sanctioning conduct that falls short of legal requirements, it is certainly not their function to substitute their judgment for that of specialized regulators. In the present context, authorizing this class action would be tantamount to transforming the proceedings into a broad public inquiry into the state of the scientific debate surrounding acetaminophen and autism, which is not the purpose of a class action.

[12] While the threshold to authorize class actions is indeed low, it is a bar that must nevertheless be crossed. Courts must remain alive to the social impacts class actions cause and only authorize those that meet the required criteria.

[13] In short, the proposed class action is simply frivolous.

CONTEXT

[14] On October 20, 2022, the original Application for Authorization to Institute a Class Action was filed.[2] Since then, it has been modified two times, and a few days before the authorization hearing, a third request to amend the Application was filed.[3]

[15] Plaintiffs allege that the regular use of Tylenol, whose principal ingredient is acetaminophen, during pregnancy exposes the unborn child to an increased risk of developing autism spectrum disorder (ASD) or attention-deficit/hyperactivity disorder (ADHD).

[16] The proposed group is as follows:

> All parents in Quebec (including any deceased parent and/or their estate) with a child whose biological mother regularly ingested during the pregnancy (a) Tylenol or (b) any other product(s) of the Defendant(s) containing acetaminophen alone or in combination with other medications, as listed below (hereinafter collectively referred to as the "PRODUCTS"), where the said child then developed autism

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2 In addition to amending the Application, the original Plaintiff, Ms. Chouinard, was substituted on April 3, 2024, by the two current Representatives, Jade Corbeil and Merieme Hamzi pursuant to a judgment of the Court.

3 *Application for leave to Amend the Amended 2 Application for Authorization to Institute a Class Action and to Appoint Representative Plaintiffs*, dated September 4, 2026. If leave is granted, the result is the *Amended 3 Application for Authorization to institute a class action and to appoint Representatives Plaintiffs*, dated September 1, 2026 (the "**Application**").

> spectrum disorder (ASD) or attention deficit hyperactivity disorder (ADHD) [and their children].[4]

[17] The Court heard and decided several preliminary motions in order to determine the appropriate evidence that should be filed for the authorization hearing.

[18] In this regard, the Court allowed a limited written examination of the Plaintiffs regarding their family history and certain risk factors associated to autism and ADHD.[5] It also authorized the filing of the consensus statement of the SOGC dated September 12, 2025, regarding the use of acetaminophen during pregnancy.[6]

[19] The Court refused to allow the lengthy expert evidence sought to be filed by Defendants vigorously contesting the findings of the scientific articles filed by Plaintiffs in support of their position.[7]

[20] The Court concluded that authorization was not the appropriate stage to allow for a robust scientific expert debate.[8]

ANALYSIS

[21] Prior to tackling the authorization analysis, the Court will first deal with the preliminary applications filed by the parties. It will then turn to the analysis of the authorization criteria, focusing on article 575(2) CCP.

I. PRELIMINARY APPLICATIONS

[22] Plaintiffs filed a last-minute application requesting leave to amend their Application for authorization to institute a class action. They also filed a motion requesting certain confidentiality measures. For their part, Defendants filed a request to adduce new evidence in response to Plaintiffs' application for leave to amend. Finally, Defendants included certain documents in their Book of Authorities that warrant closer scrutiny by the Court to determine whether they constitute an attempt to introduce additional evidence without prior authorization.

A. Application for Leave to Amend the Application for Authorization to Institute a Class Action

[23] In their request to amend the Application, Plaintiffs essentially seek to introduce three new exhibits which stem from errors made in previous versions of their proceeding.

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4 Application, par. 1.

5 *Corbeil* v. *Johnson & Johnson*, 2025 QCCS 4470; see also: *Corbeil* v. *Johnson & Johnson*, 2026 QCCS 1084 where the Court maintained the vast majority of the Plaintiffs' objections regarding additional questions asked by Defendants.

6 Exhibit R-3; *Corbeil* v. *Johnson & Johnson*, 2026 QCCS 2403.

7 *Corbeil* v. *Johnson & Johnson*, 2026 QCCS 2403, par. 5.

8 *Corbeil* v. *Johnson & Johnson*, 2026 QCCS 2403, par. 13, 18-21.

[24] More specifically, they wish to file the JAMA Psychiatry study alleged at paragraphs 21 and 22 of the Application, which was inadvertently not filed.[9] They also seek to file an additional study referred to in paragraph 27 of the Application, which was likewise not filed with the Application itself.[10] Finally, they ask permission to file the FDA News release further to the press conference held on September 22, 2025, and which was already alleged at paragraph 14.2 of the Application.[11] In addition, the filing of these exhibits necessarily entails changes to certain paragraphs of the Application in order to correct the mistakes made in previous versions of the proceedings.

[25] Defendants contest the request to amend the Application, essentially arguing that the request is exceedingly late – filed 6 days prior to the hearing - and is contrary to the judicial contract agreed upon between the parties. Defendants refer to Plaintiffs' undertaking made on November 20, 2025, during a case management conference where their attorney indicated that no additional amendments would be made unless new scientific developments arose or an unexpected situation affected one of the representatives.[12]

[26] While it is true that the requested amendments are undeniably tardy, the Court will nevertheless allow them, as they are relevant to the analysis of the authorization criteria.[13] Moreover, the Court cannot penalize the Plaintiffs for the errors made by their attorneys in the preparation of the proceedings. Most of the proposed amendments merely correct those errors and do not cause unfair surprise to the Defendants, as the information and documents introduced are, for the most part, neither new nor previously unknown to them.

B. Defendants' Application to Adduce New Evidence

[27] Defendants argue that should the Court allow the proposed amendments, they seek to be allowed to file additional evidence.[14]

[28] They wish to file two screen shots from the U.S. FDA's Web site dated July 2026 containing information about acetaminophen.[15] More specifically, they draw the Court's attention to the fact that in these recent postings, the FDA states that to date, they have found no clear evidence that appropriate use of acetaminophen during pregnancy causes adverse developmental outcomes and continues to recommend consultation with a health professional.[16]

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9 Plaintiffs wish to file this study under Exhibit P-4B.
10 This study would be filed as Exhibit P-7B.
11 The FDA News Release would be Exhibit P-9B.
12 Procès-verbal of November 20, 2025.
13 *Hazan* v. *Micron Techonology inc.*, 2021 QCCS 847, par. 12.
14 The additional evidence was filed in the form of a Certified Report dated September 9, 2026, prepared by a bailiff, consisting of Exhibits A to E. It outlines the steps the bailiff took to obtain the FDA screen shorts, which are filed as Exhibits D and E.
15 Exhibits D and E.
16 Exhibit D, p. 5.

[29] The Court will not allow the filing of this evidence, as it is not essential to the analysis of the authorization criteria.[17]

C. "Authorities" filed by Defendants are in fact Evidence

[30] Defendants have filed in their Book of Authorities excerpts from Health Canada's Web site regarding labelling requirements.[18]

[31] These documents cannot be considered as "authorities", they are evidence that should have been introduced through an application to adduce appropriate evidence.[19]

[32] Defendants also included in their authorities, the notice of a civil claim in the case of *Bottrell* v. *Johnson & Johnson*, a parallel class action filed in British Columbia, which was discontinued on April 20, 2026.[20]

[33] Here too the Court believes that in the absence of authorities filed by Defendants indicating that such proceedings can be filed without a formal request to adduce appropriate evidence, the Court will not consider these proceedings in its assessment of the authorization criteria.

D. Plaintiffs' Application to obtain certain Confidentiality Measures

[34] Finally, on June 25, 2026, Plaintiffs filed a *Demande d'ordonnance de confidentialité, de mise sous scellé et de non-publication*, requesting confidentiality measures concerning Plaintiffs' children and their medical records. More specifically, they seek orders that: (i) the Plaintiffs' children be identified only by their initials and that any information that could reveal their identity be redacted and (ii) Plaintiffs' and their children's medical records be filed under seal.

[35] Defendants do not contest this application, leaving it to the Court to decide.[21]

[36] The Court will grant this application, since in accordance with the principles set out in *Sherman*, this request reveals an important interest to protect the minor children's identities, the measures sought are reasonable and as a matter of proportionality, the benefits of the order outweigh its negative effects.[22]

[37] The Court will now turn to the authorization analysis.

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17 *Ward* v. *Procureur général du Canada*, 2021 QCCS 109, par. 17.
18 Defendants' Book of Authorities, tabs 22, 24 and 25.
19 *Kraska* v. *RB Health (Canada) Inc.*, 2026 QCCS 2768, par. 11, 30-35.
20 Defendants' Book of Authorities, tabs 27 and 28.
21 Email exchanges with the parties on September 11, 2026.
22 *Sherman Estate* v. *Donovan*, 2021 SCC 25,. par. 38.

II. CRITERIA AT THE AUTHORIZATION STAGE

[38] Authorization to institute a class action is subject to the four criteria set out at article 575 CCP:

> 38.1. The claims of the members of the class raise identical, similar or related issues of law or fact;
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> 38.2. The facts alleged appear to justify the conclusions sought;
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> 38.3. The composition of the class makes it difficult or impracticable to apply the rules for mandates to take part in judicial proceedings on behalf of others or for consolidation of proceedings; and
>
> 38.4. The class member appointed as representative plaintiff is in a position to properly represent the class members.

[39] The Supreme Court of Canada has provided extensive guidance regarding the analysis of the authorization criteria. The trilogy of decisions that summarizes the applicable parameters in this area consists of *Infineon*[23], *Vivendi*[24], and *L'Oratoire St-Joseph*.[25] These principles were subsequently consolidated in *Asselin*.[26] More recently, the Court of Appeal, in *Royer*[27], once again summarized the approach that must govern the determination of an application for authorization.

[40] Essentially, at the authorization stage, the Court performs a screening function aimed at dismissing frivolous applications that clearly do not meet the requirements for the institution of a class action (art. 575 CCP).[28] The threshold remains low. The Court must adopt a flexible, liberal, and generous approach to the authorization criteria in order to facilitate the exercise of class actions, whose social objectives include compensating victims, deterrence, access to justice, and the modification of harmful conduct.[29]

[41] It is the plaintiff's responsibility to demonstrate that the criteria set out in article 575 CCP are met. The plaintiff's burden is one of demonstration rather than proof. He must show that the application presents an arguable case supported by sufficient factual allegations.[30]

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23 *Infineon Technologies AG* v. *Option consommateurs*, 2013 SCC 59 (« ***Infineon*** »).
24 *Vivendi Canada Inc.* v. *Dell'Aniello*, 2014 SCC 1 (« ***Vivendi*** »).
25 *L'Oratoire Saint-Joseph du Mont-Royal* v. *J.J.*, 2019 SCC 35 (« ***Oratoire*** »).
26 *Desjardins Cabinet de services financiers inc.* v. *Asselin*, 2020 SCC 30 (« ***Asselin*** »).
27 *Royer* v. *Capital One Bank (Canada Branch)*, 2025 QCCA 217 (« ***Royer*** »).
28 *Oratoire*, par. 56; *Infineon*, par. 61, 125 and 150; *Asselin*, par. 27 and 31; *Royer*, par. 23.
29 *Royer*, par. 23; *Hollick* v. *Toronto (Ville de)*, 2001 SCC 68, par. 27.
30 *Asselin*, par. 30; *Infineon*, par. 59 and 61; *Vivendi*, par. 37; *Royer*, par. 26.

[42] Once the four criteria are met, the Court has no discretion to refuse authorization[31]. Moreover, if any doubt remains at the conclusion of the analysis of the authorization criteria, that doubt must be resolved in favour of the plaintiff, and authorization must be granted.[32]

[43] In the present case, Defendants have not raised any objections regarding the first and the third criteria of 575 CCP. Rather, Defendants argue that the second and fourth criteria of 575 CCP are not met since the Plaintiffs have not demonstrated that the alleged facts seem to justify the conclusions sought (art. 575 (2) CCP) and that they do not have the required personal interest in the proposed class action to act as representatives since they do not have a valid personal claim (art. 575(4) CCP).

[44] As we will see, Plaintiffs' personal causes of action can be analyzed under the second criterion of 575 CCP, most notably with regard to the absence of causation.

[45] As such, the Court will only analyse the second criteria of article 575 CCP, which leads to the conclusion that this class action cannot be authorized.

III. LEGAL FRAMEWORK REGARDING 575(2) CCP

[46] Under article 575(2) CCP, the plaintiff must demonstrate, using precise allegations of fact that the claim shows "a good colour of right" or an "arguable case" in light of the facts and the applicable law.[33]

[47] The plaintiff does not need to show that he will be successful on the merits, but only a mere "possibility" of succeeding, as not even a "realistic" or "reasonable" possibility is required.[34]

[48] While the facts alleged are taken to be true when they are sufficiently precise[35], the authorization judge must disregard allegations that are overly vague or general, as well as those that appear implausible or manifestly inaccurate.[36] The judge must also set aside allegations or elements that amount to opinion or argument, or that are plainly contradicted by the evidence.[37]

[49] In this case, Plaintiffs allege that Defendants failed to inform their customers and the end users of their Tylenol products of known significant health hazards associated with their use during pregnancy, thus breaching their duty to warn, as well as knowingly providing false and misleading information about their products.

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31 *Asselin*, par. 27.
32 *Infineon*, par. 59 and 135.
33 *Oratoire*, par. 58.
34 *Oratoire*, par. 58.
35 *Oratoire*, par. 24, 59.
36 *Karras* v. *Société des loteries du Québec*, 2019 QCCA 813, par. 28.
37 *Karras* v. *Société des loteries du Québec*, 2019 QCCA 813, par. 28.

[50] Their action is based on three legal foundations[38]: (i) articles 1457, 1468 and 1469 CCQ, (ii) sections 53, 219, 228 and 272 of the *Consumer Protection Act* ("CPA")[39] and (iii) sections 52(1) and 36(1) of the *Competition Act*[40]. They seek compensatory and punitive damages.[41]

[51] Since the Court concludes that authorization should not be granted, in accordance with *Gauthier* v. *Bombardier*, it must consider all the legal grounds advanced.[42] However, the Court will focus primarily on the alleged breach of the duty to warn, as the vast majority of the parties' submissions centered on that issue.

IV. LEGAL PRINCIPLES GOVERNING THE DUTY TO WARN AT THE AUTHORIZATION STAGE

[52] The parties agree that the leading Court of Appeal cases setting out the applicable legal regime with respect to a product liability claim are *Brousseau*[43] and *Bourassa*[44], both of which were rendered in a class action context.

[53] The plaintiff must demonstrate three cumulative criteria: (i) that the product at issue presents a danger, (ii) that the user sustained an injury, and (iii) that there is a causal link, namely that the injury represents the concrete realization of the danger.[45]

[54] It is important to note that the first criterion does not require proof of fault, but a danger must nevertheless be present.[46]

[55] Moreover, the plaintiff is not required to establish these criteria in accordance with the civil standard of proof on a balance of probabilities, his burden is simply one of demonstration that the proposed legal syllogism is tenable.[47]

[56] In summary, at the authorization stage of a proposed product liability class action arising out of a safety defect, the plaintiff must demonstrate, through precise allegations of fact, that the product at issue presents a danger, that they (and other class members) sustained an injury, and that there is a causal link between the use of the product and the injury.

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38 Application, par. 31 and 94.
39 *Consumer Protection Act*, L.R.Q., c. P-40-1.
40 *Competition Act*, R.S.C., 1985, c. C-34.
41 Application, par. 95.
42 *Gauthier* v. *Bombardier inc.*, 2026 QCCA 148, par. 24.
43 *Brousseau* v. *Laboratoires Abbott limitée*, 2019 QCCA 801 (leave to appeal to the SCC denied, 2020 CanLII 26452) ("***Brousseau***"). *Brousseau* was a class action judgement rendered on the merits.
44 *Pharmascience inc.* v. *Bourassa*, 2024 QCCA 1403 ("***Bourassa***"). *Bourassa* was rendered at the authorization stage of a class action.
45 *Bourassa*, par. 20; *Brousseau*, par. 9.
46 *Bourassa*, par. 20.
47 *Oratoire*, par. 58.

[57] The Court must deal with the following main issues:

1. Have the Plaintiffs demonstrated the existence of an alleged danger?

2. In this very particular case, what is the impact of the regulator's position on authorization?

3. Have the Plaintiffs demonstrated a causal link between the use of the product and the injury?

1. HAVE PLAINTIFFS DEMONSTRATED THE EXISTENCE OF AN ALLEGED DANGER?

[58] At the authorization stage, the existence of a danger is demonstrated through precise allegations alleging the propensity of a medication to cause an undesirable side effect.[48]

[59] Here, Plaintiffs claim that Defendants failed to adequately warn consumers and healthcare providers of the reasonably foreseeable neurodevelopmental risks associated with prenatal acetaminophen exposure.[49] Accordingly, the danger alleged is the development of the autism or ADHD as a result of prenatal use of acetaminophen, and incidentally, the use of Tylenol products.

[60] Plaintiffs rely on several studies filed[50] which would point to a "link" or an "association" between the significant use of Tylenol or acetaminophen during pregnancy and higher rates of autism or ADHD by 20%.[51] They further allege that the "perception" that Tylenol was a safe over-the-counter pain drug during pregnancy[52] changed drastically in 2021 with the publication of new medical research warning that the use of Tylenol or acetaminophen during pregnancy was not safe and could increase the risk of a child developing autism or ADHD.[53]

[61] They conclude by alleging that the U.S. FDA **and** Health Canada have sent advisories in response to this "growing body" of evidence:

> 29. (...) Based on this growing body of (..) research leading to the most recent guidance from the U.S. Food and Drug Administration (EXHIBIT P-9) and Health Canada (EXHIBIT P-10) whereby (...) advising healthcare professionals and the

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48 *Bourassa*, par. 20; *Brousseau*, par. 110.
49 Application, par. 36b).
50 Exhibits P-12, P-5, P-6, P-8, P-4B, P-3, P-7B, P-2 and P-11.
51 Application, par. 17.
52 Application, par. 14.
53 Application, par. 15.

> public (...) that women (...) limit taking acetaminophen during pregnancy to the lowest effective dose and for the shortest duration necessary (...).[54]

[62] Thus, Plaintiffs argue that the facts alleged meet the very low threshold to demonstrate the existence of a danger.

[63] With all due respect, the Court disagrees.

[64] Plaintiffs' allegations regarding the increased danger posed by the use of acetaminophen during pregnancy cannot be taken as true since they are manifestly contradicted by Plaintiffs' own evidence and by the appropriate evidence allowed by the Court.

[65] First, Plaintiffs' statement in its proceeding that Health Canada has somehow "endorsed" this body of scientific evidence is completely false and contradicted by Health Canada's public advisory, filed by Plaintiffs, stating quite the opposite.[55]

[66] The Health Canada advisory issued on September 23, 2025, rather indicates that:

- There is no conclusive evidence that using acetaminophen as directed during pregnancy causes autism or other neurodevelopmental disorders.
- Acetaminophen is commonly used to relieve pain and reduce fever. It has been used by millions of Canadians for decades, including during pregnancy and while breastfeeding.
- Acetaminophen is a recommended treatment of plain or fever in pregnancy when used as directed. It should be used at the lowest effective dose for the shortest duration needed. Untreated fever and pain in pregnant women can pose risks to the unborn child.[56]

[67] Contrary to the allegations put forward by Plaintiffs, there has been no change in medical practices in Canada, the Health Canada public advisory stating that acetaminophen should continue to be used for pain or fever during pregnancy.[57]

[68] Furthermore, Health Canada states that its advice is based on robust and rigorous assessments of the available scientific evidence. It emphasizes that all Canadian non-

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54 Noteworthy is that the previous version of this paragraph stated as follows: "29. Based on this new research, many doctors now recommend that women ***avoid*** or limit taking acetaminophen during pregnancy unless medically indicated". The term "avoid" was removed.

55 Exhibit P-10.

56 Exhibit P-10.

57 Exhibit P-10.

prescription acetaminophen products already carry clear warnings about safe use during pregnancy, as well as the risk of serious liver injury if too much is taken.[58]

[69] It concludes as follows:

> If new scientific evidence demonstrates a risk, Health Canada would take action to update labels, inform health professionals, and provide advice to Canadians.[59]

[70] As such, contrary to the stance taken by the U.S. FDA at a press conference held on September 22, 2025, Health Canada **did not** issue a letter to physicians asking them to "consider minimizing the use of acetaminophen during pregnancy for low-grade fevers"[60] nor did Health Canada undertake any steps to change the labelling of acetaminophen products.[61]

[71] Rather, Health Canada's position has remained unchanged, maintaining that there is no danger or increased risk between prenatal use of acetaminophen and adverse neurological conditions in the child.

[72] Moreover, the Society of Obstetricians and Gynaecologists of Canada ("SOGC") issued its own unequivocal statement in response to the FDA's position, which is entirely aligned with Health Canada's public advisory.[62]

[73] The SOGC states that *after revisiting all the evidence*, it re-affirms its recommendation that acetaminophen be used as a first-line option for fever and pain in pregnancy when medically indicated at recommended doses for the shortest duration required. It goes further by stating that the SOGC, as well as a number of other international societies, recognizes that the evidence for this claim of causality is weak and has many fundamental flaws:

> The controversy regarding the association between in utero exposure to acetaminophen and adverse neurological outcomes in the child, including ASD and attention deficit-hyperactivity disorder, is not new. Available studies have been critically analyzed previously by scientific and regulatory bodies, including the Society of Maternal Fetal Medicine and the U.S. Food and Drug Administration. These critical reviews concluded that the evidence for causality is weak and that the **results of the studies claiming a causal link should not alter current clinical practice. Recent findings provide further support that acetaminophen does not increase risks in pregnancy**.
>
> Reputable medical organizations, including the European Network of Teratology Information Services and the American College of Obstetrics and Gynecology, have firmly stated that current clinical practice should not be altered and that

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58 Exhibit P-10.
59 Exhibit P-10.
60 Exhibit P-9A.
61 Exhibit P-9B.
62 Exhibit R-3.

> acetaminophen should continue to be used for managing fever and/or pain in pregnancy, when indicated. The SOGC's current opinion, based on the available evidence, agrees with this recommendation.[63]

[74] The SOGC cautions that opinions based on limited or flawed evidence should not promote unwarranted fear and guilt in pregnant women.[64]

[75] It is noteworthy that the SOGC statement refers to several other reputable medical organizations, including the Society for Maternal-Fetal Medicine, the European Network of Teratology Information Services, and the American College of Obstetricians and Gynecologists, all of which share the SOGC's position on this issue. The SOGC further underscores that the U.S. FDA had previously shared that position and only recently departed from it.[65]

[76] In that context, the SOGC's statement leaves little doubt as to its view that the FDA's revised 2025 position is not the product of a change in the scientific evidence but is instead politically driven.

[77] Based on the foregoing, even if the Court were to accept that the studies relied upon by the Plaintiffs point to the existence of a certain risk, those studies cannot be considered in isolation from the clear positions adopted by Health Canada and the SOGC, both of which state that they have specifically reviewed the relevant body of scientific evidence and rejected the existence of an increased risk or a causal association.

[78] In seeking authorization to institute this class action, Plaintiffs are effectively asking this Court to revisit that scientific assessment itself, reweigh the scientific literature, and reach a different conclusion to that reached by the Canadian regulator and the relevant independent medical experts.

[79] That is not the Court's role.

[80] Institutions matter. So does expertise.

[81] The Court cannot transform its adjudicative function into an independent scientific inquiry or assume the role of scientific adjudicator. To do so would be to embark upon an exercise much more akin to a public inquiry into the state of the science, which is not the object of a class action.[66]

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63 Exhibit R-3.
64 Exhibit R-3.
65 Exhibit R-3.
66 *Tessier* v. *Economical, compagnie mutuelle d'assurance*, 2023 QCCA 688, par. 79.

2. IN THIS VERY PARTICULAR CASE, WHAT IS THE IMPACT OF THE REGULATOR'S PUBLIC ADVISORY ON AUTHORIZATION?

2.1 Regulatory Process Explained

[82] Plaintiffs argue that Health Canada's public advisory and the SOGC's statement cannot, prevent this class action from being authorized.

[83] They rely on the general principle set out in *Brousseau*, which states that regulatory compliance does not, in and of itself, have the effect of exempting a manufacturer from the ordinary law of civil liability.[67] In other words, a pharmaceutical manufacturer will not have satisfied its civil duty to warn merely because it has satisfied the regulatory requirements established by Health Canada.[68]

[84] We are not in such a situation.

[85] This is an exceptional case, and these are particular times.

[86] Health Canada has done more than merely approve the products and their labelling. It has issued a public advisory directly addressing the very concerns raised in this action, confirming that the products pose no risk to pregnant women and expressly rejecting the same scientific studies upon which the proposed class action relies. An exceptionally proactive approach.

[87] Let's take a step back.

[88] To appreciate the fundamental flaw in Plaintiffs' argument, one must first understand the role Health Canada plays in the regulatory process and with regard to the information found on the drug's labelling.

[89] Drug manufacturers are subject to a series of federal regulatory requirements that must be considered in connection with their extra-contractual duty to warn about the risks of the medications they develop and market.[69] When a manufacturer wishes to market a drug, it must submit a drug submission to Health Canada and a draft monograph, which notably outlines warnings and precautions about the medication as well as side effects.[70]

[90] If the submission and monograph are deemed compliant, Health Canada will issue a notice of compliance, and the manufacturer will be entitled to sell the drug in Canada[71]. The manufacturer has a duty to revise the monograph each time updates are necessary, for example to add new post-market side effects.[72]

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67 *Brousseau*, par. 156.
68 *Brousseau*, par. 158.
69 *Brousseau*, par. 138.
70 *Brousseau*, par. 139-140, 145-153.
71 *Brousseau*, par. 141-142.
72 *Brousseau*, par. 142-143.

[91] In parallel, Health Canada conducts its own monitoring of the safety regarding approved medicines.[73]

[92] Noteworthy here is that Plaintiffs have chosen not to file the labels appearing on Tylenol products.[74] However, the parties agree that these labels do not and have never contained any particular warnings regarding the use of acetaminophen during pregnancy and the development of autism or ADHD in children.

2.2 Typical Authorized Class Actions and the Impact of Regulatory Compliance

[93] *Brousseau* postulates that compliance with statutory or regulatory standards is relevant, but not conclusive in and of itself, when determining whether a pharmaceutical manufacturer acted diligently with respect to its duty to warn.[75] That said, compliance with statutory or regulatory requirements may tend to indicate that the manufacturer has satisfied its duty to warn.[76]

[94] In order to understand this proposition, it is useful to consider the various contexts in which it has been applied.

[95] The most obvious case is the one where the manufacturer changed its products' labelling because of regulatory requirements or advisories, notably coming from Health Canada. This would be the typical type of pharmaceutical case that would be the subject of an authorization to institute a class action.

[96] The case of *Imperial Tobacco* is an example of such an instance, where Health Canada had issued numerous warnings regarding tobacco's dangers and addictiveness.[77] There is also *Depuy Orthopaedics Inc.* v. *Melançon*, where Health Canada had issued a special advisory to health professionals regarding potential health risks affecting the prosthesis designed by the defendant.[78] Other examples include, *Pohoresky* c. *Otsuka Pharma*, which dealt with the drug known as Rexulti, an antipsychotic medication notably prescribed for the treatment of schizophrenia[79] and *Baratto* v. *Merck*, which concerned side effects of Proscar, a medication used to treat non-cancerous enlargement of the prostate and Propecia, a medication used to treat male pattern hair loss[80]. In both cases, regulatory authorities, including Health Canada,

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73 *Food and Drug Regulations*, CRC, c. 870, sections C.01.018 and C.01.019.
74 Procès-verbal of September 10, 2026.
75 *Brousseau*, par. 160.
76 *Brousseau*, par. 159.
77 *Imperial Tobacco Canada ltée.* v. *Conseil québécois sur le tabac et la santé*, 2019 QCCA 358, par. 546-558.
78 *Depuy Orthopaedics Inc.* v. *Melançon*, 2019 QCCA 878, par. 13-14; see also *Letarte* v. *Bayer Inc.*, 2019 QCCS 934, par. 13 and 32, where reference is made to a notice from Health Canada supporting the plaintiff's allegations (leave to appeal denied, 2019 QCCA 1108).
79 *Pohoresky* v. *Otsuka Pharmaceutical Company Limited*, 2021 QCCS 5064, par. 9, 11, 13.
80 *Baratto* v. *Merck Canada Inc.*, 2018 QCCA 1240, par. 19, 21, 25.

required changes to the product monographs to outline explicit warnings regarding certain risks.

[97] Essentially, when it comes to this type of case, the warnings coming from Health Canada tend to **support** in some way the plaintiff's allegations that there were risks that were not properly disclosed.

[98] Another particular context would be where the manufacturer had knowledge about certain risks affecting its products but concealed them or did not share it with the regulators, health professional or its users. For example, in *Hollis*, the manufacturer had been aware, for several years, of unexplained ruptures of its breast implants without conveying the information to either the medical community or the consumers.[81] In such circumstances, any regulatory approval would carry limited weight in assessing the adequacy of the manufacturer's warnings, since the regulator's decision may have been made without full and proper disclosure.

[99] Having now a proper grasp of the role of Health Canada and the contexts in which previous class actions have been authorized, let's take a closer look at the cases cited by Plaintiffs which they claim support their position that this case should be authorized, despite Health Canada and the SOGC's positions that there is no danger or causation.

2.3 Distinctions with other Pharmaceutical Class Actions cited by Plaintiffs

[100] The class actions relied upon by Plaintiffs, which were authorized despite the products having received regulatory approval from Health Canada, must be carefully scrutinized. While each case must be analyzed on its own, they reveal either governmental warnings supporting plaintiff's arguable case or the manufacturer's own conduct providing a basis for questioning whether regulatory compliance was sufficient to answer the allegations concerning its duty to warn.

[101] First, in *Bourassa*, the opioid class action, which was authorized, Plaintiffs point to a mention in the Court of Appeal decision where it is stated that compliance with government regulatory requirements is not a bar to authorization and the impact of such compliance is an issue that may be considered on the merits.[82]

[102] However, in this case, a closer look at the first instance judgment authorizing the class action reveals that in fact plaintiff had filed numerous federal government reports, including Health Canada documents and other published material regarding the dangers relating to the use of prescription opioids and the existence of Opioid Use Disorder.[83] These documents illustrate the arguable nature of plaintiff's case as regards to the issue

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81 *Hollis* v. *Dow Corning Corp.*, [1995] 4 S.C.R. 634, pp. 667-668 ("***Hollis***").

82 *Bourassa*, par. 26.

83 *Bourassa* v. *Abbott Laboratories Ltd.*, 2024 QCCS 1245, par. 198 (leave to appeal denied: *Pharmascience inc.* v. *Bourassa*, 2024 QCCA 1403).

of a safety defect and it being the cause of the disorders alleged.[84] Moreover, another basis for granting authorization to institute a class action stemmed from allegations of misrepresentations regarding the benefits of their opioid medications, as well as conspiracy to misinform allegations about their safety for long-term use and increased reliance.[85]

[103] Second, Plaintiffs rely on *Gauthier* v. *Johnson & Johnson*, a case also involving Tylenol products. In *Gauthier*, the plaintiff alleged that the defendant misled consumers in omitting to disclose and properly caution against the risks and side effects related to Tylenol products including the risk of death and acute liver failure requiring a liver transplant.[86] Even though it appeared that the labels were compliant with the requirements of the labelling standards of Health Canada[87], the allegations also revealed that the defendant had *voluntarily* disclosed these risks on its products sold in the United States and had added two warnings on the packaging in the American marketplace, while not doing so in Canada.[88] While the Court of Appeal relayed serious doubts about the merits of the case, it dismissed leave to appeal.[89]

[104] Third, Plaintiffs point to *Sigouin* v. *Merck*, a case involving the medication Vioxx, where the class action was authorized.[90] However, in that case, the manufacturer chose to *voluntarily* withdraw its product from the market because of an increased cardiovascular risk.[91] Although Health Canada had approved the medication, the manufacturer itself withdrew its products worldwide after certain studies pointed to an increased cardiovascular risk.[92] Based on these set of facts, the Court found that Health Canada's approval could not be a bar to civil liability.[93]

[105] Finally, Plaintiffs rely on *Kramar* v. *Johnson & Johnson* a class action which was authorized dealing with baby powder manufactured by the defendant and allegedly causing ovarian cancer.[94] This action however did not involve a medication and therefore regulatory approval from Health Canada was not a component of this case.

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84 *Bourassa* v. *Abbott Laboratories Ltd.*, 2024 QCCS 1245, par. 198-199, 218, 250-265 (leave to appeal denied: *Pharmascience inc.* v. *Bourassa*, 2024 QCCA 1403).

85 *Bourassa*, par. 22 and 25.

86 *Gauthier* v. *Johnson & Johnson Inc.*, 2020 QCCS 690, par. 2 (leave to appeal denied: *Johnson & Johnson Inc.* c. *Gauthier*, 2020 QCCA 1666).

87 *Gauthier* v. *Johnson & Johnson Inc.*, 2020 QCCS 690, par. 34 (leave to appeal denied: *Johnson & Johnson Inc.* v. *Gauthier*, 2020 QCCA 1666).

88 *Gauthier* v. *Johnson & Johnson Inc.*, 2020 QCCS 690, par. 28-29 (leave to appeal denied: *Johnson & Johnson Inc.* v. *Gauthier*, 2020 QCCA 1666).

89 *Johnson & Johnson Inc.* v. *Gauthier*, 2020 QCCA 1666, par. 18, 19, 21.

90 *Sigouin* v. *Merck & Co. Inc.*, 2006 QCCS 5325.

91 *Sigouin* v. *Merck & Co. Inc.*, 2006 QCCS 5325, par. 2j).

92 *Sigouin* v. *Merck & Co. Inc.*, 2006 QCCS 5325, par. 2, 13, 25.

93 *Sigouin* v. *Merck & Co. Inc.*, 2006 QCCS 5325, par. 35-36.

94 *Kramar* v. *Johnson & Johnson*, 2018 QCCS 1846, par. 1-2 (leave to appeal denied: *Valeant Pharmaceuticals International Inc.* v. *Kramar*, 2018 QCCA 1500).

[106] In short, all of these cases can easily be distinguished from the case at bar.

2.4 Conclusion regarding Regulatory Compliance and the Duty to Warn

[107] In summary, regulatory approval is not an automatic stop sign barring potential liability for a breach of the duty to warn and preventing a class action from being authorized.

[108] Rather, a more accurate way of viewing their interaction is that regulatory approval while not necessarily providing a definite answer to the civil law question, may nevertheless provide invaluable guidance.

[109] Regulatory developments may, depending on the circumstances, have various impacts on the case at hand. In many instances, Health Canada advisories or requested label changes may strengthen a plaintiff's claim. Likewise, a defendant cannot rely on regulatory approval as a shield where relevant information was withheld from the regulator or the approval was obtained on the basis of misrepresentations, since the regulator's decision may not have been fully informed. Finally, a defendant's own decision to disclose additional information or recall its product may provide some indication that the risks previously disclosed were incomplete or inadequate.

[110] So how does all of this tie into the duty to warn analysis of our specific case?

[111] Without generalizing or suggesting that one can draw up a list of all possible scenarios, it remains that the present case is unique and cannot be lumped in with all the other cases reviewed above.

[112] In our case, faced with *the exact same scientific evidence* Plaintiffs are presenting here, Health Canada did not only choose not to mandate any update to the product's label, but it also proactively issued a public advisory statement stating the absence of any conclusive evidence that the use of acetaminophen causes autism or similar disorders and reiterating that acetaminophen remains a recommended treatment of pain or fever in pregnancy.[95]

[113] The timing of its advisory is also key.

[114] It was made the following day of the U.S. FDA's press conference, in a clear attempt to disassociate itself from their position and to dispel any misinformation it felt had been vehiculated by the US agency on this issue.[96]

[115] Compounding the clarity of the Canadian regulator's position is the unequivocal consensus statement made by the SOGC rebutting the association between prenatal

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95 Exhibit P-10.
96 Exhibits P-9A and P-9B.

exposure to acetaminophen and autism, signaling that the evidence in this regard is fundamentally flawed.[97]

[116] Allowing a class action to proceed under these circumstances, and without any new facts or evidence that could justify reaching a different conclusion as to the adequacy of the warnings, would effectively invite the Court to second-guess the expert scientific judgment of Health Canada and the SOGC, substituting Health Canada's "robust and rigorous assessments of the available scientific evidence"[98] and the SOGC's view that the evidence is "limited and flawed"[99] for the Plaintiffs' speculative allegations, hypotheses and mere opinions.

[117] In summary, Plaintiffs have not demonstrated an arguable case when it comes to the existence of a danger.

3. HAVE THE PLAINTIFFS DEMONSTRATED A CAUSAL LINK BETWEEN THE USE OF THE PRODUCT AND THE INJURY?

3.1 No Arguable Case with regard to Causation

[118] Even if we were to assume that a danger had been demonstrated, the Plaintiffs do not present an arguable case with respect to causation, the third fundamental requirement of a manufacturer's liability for a safety defect.

[119] It is insufficient for Plaintiffs to simply affirm the existence of a hypothetical risk of injury and the materialization of that injury to demonstrate a tenable causal link.

[120] In fact, the allegations contained in Plaintiffs' proceeding are extremely imprecise on the notion of causation, using language that varies from the term "association"[100] to "correlation" and "causal link"[101] between the significant use of Tylenol during pregnancy and the development of child autism or ADHD. To compound the confusion, sometimes, contradictory adjectives are added such as "possible association"[102] or "clear correlation"[103].

[121] The allegations are imprecise and cannot be taken as true.

[122] They are also manifestly contradicted by Plaintiff's own evidence as well as the Health Canada public advisory and the SOGC consensus statement. More specifically, Health Canada states that there is no conclusive evidence of a causal relationship between the use of acetaminophen during pregnancy and the development of autism or

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97 Exhibit R-3.
98 Exhibit P-10, p. 2.
99 Exhibit R-3, p. 2.
100 Application, par. 22, 27, 28.1, 32.2.
101 Application, par. 18, 25.
102 Application, par. 28.4.
103 Application, par. 18.

other neurodevelopmental disorders.[104] The SOGC states that the evidence of a link between prenatal exposure to acetaminophen and autism is weak and fundamentally flawed.[105] Even the U.S. FDA acknowledges that a causal relationship has not been established and there are contrary studies in the scientific literature.[106] Lastly, several of the studies filed by Plaintiffs include cautionary language warning against drawing the hasty conclusion that acetaminophen causes autism or other similar disorders.[107]

[123] Moreover, Plaintiffs allege that the timing, amount and the length of Tylenol use during pregnancy appear to have a correlation with the risk of developing autism, stating that the studies indicate that using small doses of Tylenol during pregnancy is safe and does not increase the risk of autism.[108]

[124] However, they do not identify the alleged exposure needed to cause the injury.

[125] In *Zhen* v. *Société des alcools du Québec*, a recent decision rendered at the authorization stage, the Court weighed the sufficiency of the allegations regarding causation.[109] The plaintiffs were alleging that alcohol was one of the causes of the development of certain cancers. The Court states that while it does not require incontrovertible scientific evidence of a causal connection, there must nevertheless be a sufficient factual basis, which identifies the duration of exposure or the level of alcohol consumption necessary for an individual, or group of individuals, to develop one of the alleged diseases.[110] The Court concludes that since the plaintiffs were unable to identify a consumption threshold nor a period at which a logical, direct and immediate connection exists between alcohol consumption and the development of the alleged diseases, no causal connection was demonstrated.[111]

[126] No such factual allegations can be found in Plaintiffs' Application. Their absence is fatal to obtaining authorization to institute a class action.

[127] Finally, another important element to be considered here that was also raised in *Zhen*, is the existence of confounding factors, such as genetics and familial factors which make it difficult to isolate the potential impact that acetaminophen use during pregnancy. This element stems from Plaintiffs' own evidence and is underscored in most of the studies they have filed.[112]

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104 Exhibit P-10.
105 Exhibit R-3.
106 Exhibit P-9B.
107 Exhibit P-4A, p. 3; Exhibit P-5, p.1712.
108 Application, par. 29.
109 *Zhen* v. *Société des alcools du Québec*, 2025 QCCS 2969.
110 *Zhen* v. *Société des alcools du Québec*, 2025 QCCS 2969, par.89.
111 *Zhen* v. *Société des alcools du Québec*, 2025 QCCS 2969, par. 79-83, 90-91.
112 Exhibit P-2, pp. 759 and 762; Exhibit P-5, p. 1703; Exhibit P-6, p. 319; Exhibit P-8, p. 1824. The study filed as Exhibit P-11 minimizes this aspect, see also Application, par. 28.1.

[128] In *Zhen*, the Court states that given the confounding genetic factors, a causal link cannot be demonstrated, thus the recourse has no chance of succeeding:

> [94] Dans notre cas, toutes les caractéristiques génétiques, comportementales ou autres, d'un membre ou d'une des Maladies, feraient obstacle à l'établissement d'un lien de causalité commun au mérite. Le recours n'a donc aucune chance de réussir pour le sous-groupe B.[113]

[129] All of these principles apply here leading to the inevitable conclusions that Plaintiffs have not demonstrated an arguable case with regard to causation.

3.2 The "Association" Argument is not a Substitute for Causation

[130] Plaintiffs argue that the question of causation should be determined on the merits and that the contradictory scientific evidence regarding causality is not a bar preventing authorization. At this stage, they argue, they need only demonstrate an "association" not a "causal link", based on *Brousseau*[114] and on *Letarte* v. *Bayer*[115]. They argue that this "reduced" requirement is an application of the precautionary principle.[116]

[131] This argument is not founded. The case law does not support such an assertion, which incorrectly attempts to substitute the criterion of a causal link with that of association, a far lesser stringent criterion.

[132] Let's get back to *Brousseau*.

[133] This notion of "association", which derives from common law jurisdiction cases[117], is not invoked as a substitute to causation but rather is referenced to help establish a danger.[118] When speaking of causation, the third criterion required to obtain redress under 1468 CCQ, the Court of Appeal states that in a matter involving medication, causation is established by showing a cause-and-effect relationship between the risk and the injury suffered, which entails proving on the balance of probabilities, that the risk of a particular side effect of the medication has in fact materialized.[119] At the authorization stage, the burden remains that of demonstration.

[134] In fact, such a substitution would lead to the creation of an entirely new cause of action allowing for the compensation of potential future injuries or of pure risk. This is not the state of the law on this issue:

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113 *Zhen* v. *Société des alcools du Québec*, 2025 QCCS 2969, par. 94.
114 *Brousseau*, par. 107-109, 121.
115 *Letarte* v. *Bayer Inc.*, 2026 QCCS 803, par. 26.
116 *Brousseau*, par. 121; *Letarte* v. *Bayer Inc.*, 2026 QCCS 803, par. 26.
117 *Brousseau*, par. 112.
118 *Brousseau*, par. 107-125.
119 *Brousseau*, par. 91.

> [33] It is therefore important to consider what it is that makes a defendant's negligent conduct wrongful. As this Court has maintained, "[a] defendant in an action in negligence is not a wrongdoer at large: he is a wrongdoer only in respect of the damage which he actually causes to the plaintiff". There is no right to be free from the prospect of damage; there is only a right not to suffer damage that results from exposure to unreasonable risk. In other words, negligence "in the air" — the mere creation of risk — is not wrongful conduct. Granting disgorgement for negligence without proof of damage would result in a remedy "arising out of legal nothingness". It would be a radical and uncharted development, "[giving] birth to a new tort over night".[120] [references omitted]

[135] In this regard, it is also noteworthy that Plaintiffs' argument that even a *rare* risk must be disclosed is misleading. It ties into the argument that a mere association between a product and a dangerous condition can give rise to a duty to warn. While it is true that in *Hollis*, the Court held that a *rare risk* of occurrence must be disclosed[121], this is different from asserting that the mere existence of any type of risk requires disclosure.

[136] In *Hollis*, the manufacturer was held liable for failing to disclose the occurrence of ruptures even though the number of ruptures was statistically small (less than 0.1%) and their cause was unknown.[122] The Supreme Court dismissed the manufacturer's argument that the duty to warn only arose once definitive conclusions had been reached regarding cause and effect of the danger.[123] On the contrary, it found that because these ruptures were unexplained, the manufacturer had an obligation to include information in its literature disclosing those ruptures and their effects on the human body.[124]

[137] The present situation is markedly different from the one described in *Hollis*. We are not in a situation where although the manufacturer had received 78 reports over a ten-year span from doctors of post-operative "unexplained" breast implant ruptures, it chose not to disclose them.[125]

[138] The supposed "association" alleged in Plaintiffs' proceeding between prenatal use of acetaminophen and the development of autism is not meant to be a "rare" or "unexplained" risk. It rather falls in the category of negligence "in the air", a mere creation of risk, which does not give rise to a duty to warn.[126]

[139] Plaintiffs' proposition of a "reduced" causal link cannot stand. It is speculative and, in any event, refuted by Health Canada and the SOGC.

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120 *Dussiaume* v. *Sandoz Canada Inc.*, 2023 BCSC 795, par. 49 citing *Atlantic Lottery Corp. Inc.* v. *Babstock*, 2020 SCC 19, par. 33.
121 *Hollis*, p. 670; *Brousseau*, par. 121-124.
122 *Brousseau*, par. 122 commenting on *Hollis*.
123 *Brousseau*, par. 123 commenting on *Hollis*.
124 *Brousseau*, par. 124 commenting on *Hollis*.
125 *Hollis*, p. 667.
126 *Dussiaume* v. *Sandoz Canada Inc.*, 2023 BCSC 795, par. 49 citing *Atlantic Lottery Corp. Inc.* v. *Babstock*, 2020 SCC 19, par. 33.

[140] In short, causation remains a criterion that needs to be demonstrated to ground an arguable case under 1468 CCQ and cannot be swapped for a lesser threshold. While at the demonstration stage of authorization, causation need not be proven on the balance of probabilities, as stated above, factual elements need to support its *prima facie* existence, which is not the case here.

3.3 Plaintiffs' Personal Causes of action do not Support the Legal Syllogism on Causation

[141] Further support for the absence of any factual basis to ground a causal link can be found when one looks at the Plaintiffs' personal causes of action, which serve as test cases to assess whether the proposed class action shows an arguable case.[127] This aspect may also be analyzed through the lens of the fourth criterion set out in article 575 CCP, namely, the legal interest required to bring the class action.[128]

[142] With respect to **Plaintiff Corbeil**, it is alleged that she was diagnosed with chronic sinusitis at the onset of her pregnancy and that she used Tylenol regularly and throughout her pregnancy to reduce the symptoms of her migraine,[129] and that her son was diagnosed with autism at the age of 8 years old.[130] Based on these facts, Plaintiffs argue that "the damages suffered by Corbeil and her son are a direct and proximate result of the Defendants' conduct failing to warn about the risks of prenatal exposure to Tylenol."[131]

[143] This conclusory statement is not an allegation of fact, and amounts to nothing more than Plaintiffs unsupported opinion or hypothesis. It cannot be taken as averred.

[144] The medical and pharmaceutical records filed by Plaintiffs do not support this hypothesis. No healthcare professional has expressed the opinion or even suggested that the use of acetaminophen during pregnancy could have caused Ms. Corbeil's son to develop autism.[132] On the contrary, Corbeil's own medical records reveal genetic risk factors which cannot be ignored: her two other children have also been diagnosed with autism and ADHD[133], and she herself suffers from ADHD.[134]

[145] **Plaintiff Hamzi**'s personal right of action is similarly flawed.

[146] It is alleged that she suffered severe migraine and various infections such as tonsillitis and double otitis throughout her pregnancy and used Tylenol regularly to

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127 *Royer*, par. 27.
128 *Karras* v. *Société des loteries du Québec*, 2019 QCCA 813, par. 54; *Tessier* v. *Economical, compagnie mutuelle d'assurance*, 2023 QCCA 688, par. 29, 71-78.
129 Application, par. 59.1 and 60.
130 Application, par. 62.
131 Application, par. 68.
132 Exhibits P-16 and P-13.
133 Plaintiff's written examination, answer to question 24.
134 Plaintiff's written examination, answer to question 24.

alleviate the symptoms of her chronic migraines and other infections.[135] Nine years later, her son was diagnosed with attention deficit disorder (ADD).[136] A similar boilerplate conclusory statement respecting causation as for Plaintiff Corbeil is outlined, namely that the damages suffered are a direct and proximate result of the Defendants' failure to warn about the risks of prenatal exposure to Tylenol.[137]

[147] Here too this statement is an unsupported opinion or hypothesis that cannot be taken as averred. The medical records filed by Plaintiffs as exhibits do not include any evidence that could even suggest a link between Ms. Hamzi's use of the Tylenol products during her pregnancy and her son's ADD diagnosis.[138]

[148] In short, Plaintiffs merely allege that they consumed acetaminophen during their pregnancy and that their respective children were subsequently diagnosed with neurodevelopmental disorders. This is insufficient to establish an arguable case with respect to causation, especially considering the other various risk factors at play.

V. ANALYSIS OF OTHER CAUSES OF ACTION

[149] Finally, as already stated, given that the Court will not authorize the institution of the class action, it will proceed with the analysis of the other legal grounds put forward by Plaintiffs in support of their cause of action.[139]

1. DO PLAINTIFFS DEMONSTRATE AN ARGUABLE CLAIM UNDER THE *CONSUMER PROTECTION ACT* AND THE *COMPETITION ACT*?

[150] Plaintiffs allege that the Defendants' liability also arises from false or misleading representations contrary to sections 53, 219, 228 and 272 CPA and sections 52(1) and 36(1) of the *Competition Act.*

[151] Plaintiffs barely argued their case from the viewpoint of the CPA[140] and did not present any arguments whatsoever based on the *Competition Act.* In fact, other than mentioning these legislations in their Application[141], there are no particular factual allegations supporting these two causes of action. Plaintiffs themselves argue that the same facts alleged in support of the duty-to-warn claim also underpin their claim under the CPA.[142]

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135 Application, par. 73 and 74; see also par. 14.6 of the Application which describes ADD as one of the three possible types of ADHD, essentially "ADHD without hyperactivity".
136 Application, par. 76.
137 Application, par. 81.
138 Exhibits P-14 and P-15.
139 *Gauthier* v. *Bombardier inc.*, 2026 QCCA 148, par. 24.
140 Plan d'argumentation des demanderesses, par. 105-110.
141 Application, par. 30, 31, 32.5, 46.1 and 94.
142 Plan d'argumentation des demanderesses, par. 110.

[152] Regardless, both of these legal bases cannot support the syllogism put forward for the same reasons already set out.

[153] In both cases, the crux of the analysis hinges on false representations made by Defendants regarding the risks associated with their products when consumed during pregnancy. Having found that Plaintiffs failed to demonstrate an arguable case with regard to the existence of a danger and causation, a valid cause of action cannot exist under either legislation.

2. DO PLAINTIFFS DEMONSTRATE AN ARGUABLE CLAIM FOR PUNITIVE DAMAGES?

[154] Plaintiffs also allege that they are entitled to claim punitive damages as a result of the intentional breach by the Defendants of the class members' right to security and personal integrity arising from Defendants' intentional or grossly negligent failure to inform them of the risks inherent in the use of their products pursuant to section 49 of the *Quebec Charter*.[143]

[155] More specifically, they allege that:

> 155.1. Defendants' conduct was deliberate, reckless, and profit-driven. Despite decades of accumulating evidence suggesting neurodevelopmental risks associated with prenatal acetaminophen exposure, they continued to market Tylenol as the "safe" and recommended option for pregnant women, targeting this population through advertising and healthcare provider campaigns that omitted pregnancy-specific warnings and concealed or downplayed emerging scientific evidence.[144]
>
> 155.2. They knowingly misrepresented or omitted material information regarding the safety of the Products during pregnancy. Although Tylenol labels warned of liver-toxicity, they contained no pregnancy-specific warnings, thereby creating the false and misleading impression that the products were entirely safe for use during pregnancy.[145]
>
> 155.3. Defendants' marketing campaigns deliberately targeted pregnant women, healthcare providers, and the general public, portraying Tylenol as the only safe over-the-counter pain relief option during pregnancy. This systematic and calculated conduct was undertaken in disregard of the rights to security and integrity of unborn children and their mothers and was intended to protect market share and maximize profits at the expense of consumer safety.[146]

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[143] Application, par. 46.2.
[144] Application, par. 46.3.
[145] Application, par. 46.4.
[146] Application, par. 46.5.

[156] In light of the Court's conclusions that Plaintiffs did not present an arguable case regarding a failure of Defendants' duty to inform, a claim for punitive damages is doomed to fail.

CONCLUSION

[157] In summary, whether based on the CCQ or on other legislations, the Plaintiffs have not laid out precise allegations setting out a factual foundation which would appear to justify the conclusions sought in support of the alleged cause of action.

[158] The "association" they suggest between prenatal use of acetaminophen and the development of child autism based on studies filed is directly contradicted by the clear and unequivocal positions of Health Canada and the SOGC. Plaintiffs' legal syllogism is therefore flawed insofar as it does not demonstrate the existence of a danger nor causation, two essential components needed to argue that Defendants violated their duty to warn.

[159] In seeking to authorize this class action, Plaintiffs are essentially asking this Court to relitigate all the scientific evidence on this issue and arrive at a different conclusion than that of the Canadian regulator and its top specialized experts. This is not the Court's role. Rather, the Court chooses to rely on the expertise of Health Canada and SOCG, the scientific bodies that directly addressed these concerns in real time.

FOR THESE REASONS, THE COURT:

[160] **PERMITS** the Plaintiffs to amend the *Amended 2 Application for Authorization to institute a class action and to appoint Representatives Plaintiffs,* as set forth in the *Amended 3 Application for Authorization to institute a class action and to appoint Representatives Plaintiffs*, dated September 1, 2026.

[161] **DISMISSES** Defendants request to adduce new evidence found in the Certified Bailiff Report, dated September 9, 2026.

[162] **DISMISSES** the *Amended 3 Application for Authorization to institute a class action and to appoint Representative Plaintiffs*, dated September 1, 2026.

[163] **ORDERS** the following confidentiality measures regarding the identity of Plaintiffs' children and their medical records:

a) **AUTORISE** que les enfants mineurs des Demanderesses soient désignés par leurs initiales dans l'ensemble des actes de procédure, pièces, plans d'argumentation, incluant dans tout document déposé au dossier de la Cour, ordonnances et jugements, qu'ils aient déjà été produits ou qu'ils le soient à l'avenir, ainsi qu'au dossier de la Cour, au plumitif et au Registre des actions collectives.

b) **ORDONNE** la mise sous scellé de toute pièce contenant des renseignements médicaux concernant les Demanderesses ou leurs enfants mineurs, qu'elle ait déjà été produite ou qu'elle le soit à l'avenir.

c) **ORDONNE** le caviardage de tout renseignement permettant d'identifier les enfants mineurs des Demanderesses, notamment leurs dates de naissance complètes, adresses et tout autre renseignement identificatoire contenu dans les actes de procédure, pièces ou décisions.

d) **ORDONNE** que l'accès aux pièces visées par la présente ordonnance soit limité au Tribunal, aux parties et à leurs procureurs.

e) **ORDONNE** qu'il soit interdit à quiconque de publier, diffuser ou communiquer tout renseignement permettant d'identifier les enfants mineurs des Demanderesses ou de faire le lien entre leur identité et les renseignements médicaux visés par la présente ordonnance.

[164] **THE WHOLE**, with costs.

ELENI YIANNAKIS, J.S.C.

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Hearing date: September 10, 2026.