IN THE SUPREME COURT OF BRITISH COLUMBIA

Citation: *Dussiaume v. Sandoz Canada Inc.,*
2023 BCSC 795

Date: 20230511
Docket: S1911469
Registry: Vancouver

Between:

Gary Dussiaume

Plaintiff

And

Sandoz Canada Inc., Apotex Inc., Pro Doc Limitée. Sanis Health Inc., Sivem Pharmaceuticals ULC/Sivem Produits Pharmaceutiques ULC, London Drugs Limited, Shoppers Drug Mart Inc., Rexall Pharmacy Group Ltd., Rexall/Pharma Plus Pharmacies Ltd., McKesson Canada Corporation/La Corporation McKesson Canada, McKesson Pharmacy Systems Canada ULC, Pharmasave Drugs Ltd., Loblaws Inc., Westfair Drugs B.C. Ltd., Teva Canada Limited Teva Canada Limitee, Sanofi Consumer Health Inc./Sanofi Sante Grand Public Inc.; 115013 Canada Inc. aka Dominion Pharmacal, Laboratoire Riva Inc., Pharmascience Inc., Vita Health Products Inc., Ranbaxy Pharmaceuticals Canada Inc., GlaxoSmithKline Inc., Save-On-Foods & Drugs Ltd., Wal-Mart Canada Corp., and Costco Wholesale Canada Ltd.

Defendants

Before: The Honourable Madam Justice Wilkinson

Reasons for Judgment

Counsel for the Plaintiff:	A. Leoni M. Burtini T.P. Charney C. Edwards J. Boyd A. Dimson
Counsel for Sandoz Canada Inc.:	P. Pliszka A. Borrell Z. Maladwala
Counsel for Apotex Inc., Pro Doc Limitée, Sanis Health Inc., Sivem Pharmaceuticals ULC, Shoppers Drug Mart Inc., Rexall Pharmacy Group Ltd., Rexall/Pharma Plus Pharmacies Ltd., McKesson Canada Corporation, McKesson Pharmacy Systems Canada ULC, Loblaws Inc. and Westfair Drugs B.C. Ltd.:	C.E. Hunter, K.C. A. Boctor J.-M. Boudreau S. Penney
Counsel for London Drugs Limited:	K. Smiley E. Grant
Counsel for Teva Canada Limited and Ranbaxy Pharmaceuticals Canada Inc.:	L. Fric C. Lockwood
Counsel for Sanofi Consumer Health Inc.:	C. Zayid B. Shaw A.E. Cocks H. Mallabone
Counsel for Vita Health Products Inc.:	D. Woodfield S. Barton P. Brooks
Counsel for 115013 Canada Inc. aka Dominion Pharmacal, Pharmascience Inc. and Laboratoire Riva Inc.:	J. Shore C.M. Woodin A.C. Payne T. Feore
Counsel for Save-On-Foods & Drugs Ltd.:	C.M. Rusnak, K.C. J.A. Morris

Counsel for Wal-Mart Canada Corp.:	M. Jilesen J. Chen J. Kras
Counsel for Costco Wholesale Canada Ltd.:	J. Cytrynbaum D. DiPardo
Counsel for GlaxoSmithKline Inc.:	R. Sutton E. Friedman

No other appearances

Place and Dates of Trial:	Vancouver, B.C. October 3-7, 11-14, 2022
Supplemental Written Submissions Received:	March 10, 2023
Place and Date of Judgment:	Vancouver, B.C. May 11, 2023

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[1] These are my reasons for judgment an application by a number of defendants to dismiss or strike all or portions of the plaintiff's claims in this proposed class action relating to negligence and failure to warn, as set out in the second amended notice of civil claim approved for filing by me on October 14, 2022 and filed October 26, 2022 (the "NOCC").

[2] For the reasons that follow, I grant the application of the defendants.

Background

[3] The plaintiff, Mr. Gary Dussiaume, proposes to certify a national class action pursuant to the *Class Proceedings Act*, R.S.B.C. 1996, c. 50 [*CPA*] on behalf of individuals who purchased or ingested a heartburn medication containing ranitidine, a histamine H2-receptor antagonist, under the brand name of Zantac, as well as under generic formulations manufactured, sold, or distributed by one or more of the defendants ("Ranitidine"). The plaintiff alleges that ranitidine transforms over time, and under certain conditions, into N-Nitrosodimethylamine ("NDMA") which they submit is a carcinogen, giving rise to a number of causes of action.

[4] Ranitidine is effective in addressing the health concerns for which it is manufactured and consumed: relief of heartburn.

[5] Some of the defendants are manufacturers of ranitidine products: GlaxoSmithKline Inc., Sandoz Canada Inc., Apotex Inc., Pro Doc Limitée, Sanis Health Inc., Sivem Pharmaceuticals ULC/Sivem Produits Pharamceutiques ULC, Teva Canada Limited/Teva Canada Limitée, Sanofi Consumer Health Inc./Sanofi Sante Grand Public Inc., 115013 Canada Inc. (i.e., Dominion Pharamcal), Laboratoire Riva Inc., Pharmascience Inc., Vita Health Products Inc., Ranbaxy Pharmaceuticals Canada Inc. (collectively, the "Defendant Manufacturers"). The plaintiff adjourned generally its application for certification with respect to GlaxoSmithKline Inc., which is the original innovator of the impugned product.

[6] The others are retailers of the impugned product: London Drugs Limited, Shoppers Drug Mart Inc., Rexall Pharmacy Group Ltd., Rexall/Pharma Plus Pharmacies

Ltd., McKesson Canada Corporation/La Corporation McKesson Canada, McKesson Pharmacy Systems Canada ULC, Pharmasave Drugs Ltd., Loblaws Inc., Westfair Drugs B.C. Ltd., Costco Wholesale Canada Ltd., Wal-Mart Canada Corp., Save-On-Foods & Drugs Ltd. (collectively, the “Defendant Retailers”).

[7] Mr. Dussiaume alleges that the product monograph for Ranitidine does not list NDMA as a component or by-product, nor does it list cancer as a risk to consumers using the product. Mr. Dussiaume alleges that each of the defendants manufactured, produced, and/or distributed Ranitidine in Canada that was the subject of a voluntary recall (the "Recall") by Health Canada.

[8] Mr. Dussiaume seeks damages, on his own behalf, and on behalf of a proposed class consisting of: all persons who purchased and/or ingested one or more of the drugs distributed by the defendants containing the active pharmaceutical ingredient ranitidine as identified in a list of recalled lots from October 2004 to the present (the "Class Period"), along with persons entitled to bring an action on behalf of deceased potential class members pursuant to provincial wrongful death legislation.

[9] Mr. Dussiaume claims damages for: the tort of battery; personal injury including “prolonged and serious mental distress,” and “the increased material risk of developing [certain] cancer[s]”; special damages for “medical monitoring and medical tests”; and “the cost of purchasing Ranitidine that was unfit for the purpose intended”.

[10] In support of the application for certification, Mr. Dussiaume has submitted affidavits from proposed class members and from purported experts seeking to establish that Mr. Dussiaume and the proposed class members suffered from or, in some cases, may suffer in the future from, worry, upset, mental distress, stress, and/ or anxiety as a result of learning that they had possibly ingested what they believe to be a potential carcinogen.

[11] While not explicitly set out in the NOCC, Mr. Dussiaume also submits that the proposed class action alleges that ranitidine causes certain cancers, or could otherwise be amended to specify the types of cancer.

[12] The applicant defendants submit that Mr. Dussiaume's claims for damages for (a) an alleged increased risk of harm, (b) the mental upset and anxiety arising therefrom, and (c) medical monitoring in connection with the alleged increased risk of harm, discloses no genuine issues for trial, are doomed to fail, and should be dismissed or struck.

Is it permissible, just, and convenient to hear the summary applications simultaneously with certification?

[13] Under R. 9-5 of the *Supreme Court Civil Rules*, B.C. Reg. 168/2009 [*Rules*], a claim may be struck if it is plain and obvious, assuming the facts pleaded to be true, that the pleading discloses no reasonable cause of action: *Hunt v. Carey Canada Inc*., [1990] 2 S.C.R. 959 at 980, 1990 CanLII 90; *R v. Imperial Tobacco Canada Ltd.*, 2011 SCC 42 at paras. 17–26. Plaintiffs must plead all material facts in support of each cause of action alleged.

[14] Bald assertions of conclusions are not allegations of material fact and cannot support a cause of action: *Canada v. John Doe*, 2016 FCA 191 at para. 23. As well, allegations based on assumption and speculation do not need to be taken as true, and the court may look behind such allegations and analyze them skeptically: *James v. Johnson & Johnson Inc.*, 2021 BCSC 488 at para. 56; *Union Road Properties Ltd. v. British Columbia (Agricultural Land Commission)*, 2018 BCSC 1349 at paras. 3–4.

[15] Rule 9-6(4) of the *Rules* allows an answering party in an action to apply for summary judgment on all or part of a claim in the claiming party's originating pleading. The defendants apply under R. 9-6(4) for summary judgment on part of a claim made in Mr. Dussiaume's NOCC.

[16] On hearing an application under R. 9-6(4), the court must pronounce judgment or dismiss a claim if satisfied that there is no genuine issue for trial with respect to a claim or defence pursuant to R. 9-6(5)(a). The test is whether:

a) there is a *bona fide* issue to be determined, with the assumption that the uncontested material facts plead by the plaintiff are true and with factual disputes not to be weighed; and

b) the court being satisfied that it is plain and obvious the plaintiff's claim will not succeed: *Sandhu v. Sun Life Assurance Company of Canada*, 2016 BCSC 1077 at para. 12.

[17] Rule 9-6(5)(c) allows the court, if satisfied that the only genuine issue is a question of law, to determine the question and pronounce judgment accordingly.

[18] The summary judgment rule prevents claims or defences that have no chance of success from proceeding to trial. It is essential to the proper operation of the justice system that claims that have no chance of success be weeded out at an early stage: *Canada (Attorney General) v. Lameman*, 2008 SCC 14 at para. 10. A claim will not survive an application to strike simply because it is novel: *Atlantic Lottery Corp. Inc. v. Babstock*, 2020 SCC 19 at para. 19 [*Babstock*].

[19] Determination of questions of law is appropriate where doing so will permit disposal of all or part of a claim, and when a broader factual inquiry will not provide clarity or assist the court: *Mohr v. National Hockey League*, 2021 FC 488.

[20] At certification, the court can and should be prepared to resolve complex questions of law and policy to determine whether a claim is doomed to fail: *Babstock* at para. 19.

[21] It is appropriate, and in the interests of justice, for a summary disposition to be heard in conjunction with a class action certification application: *Consumers' Association v. Coca-Cola Bottling Company*, 2005 BCSC 1042 at paras. 46–53. A proposed class proceeding has no special status and, until certified, it is to be treated as any other individual action. Nothing requires a certification hearing from being held first. Appropriate circumstances include:

a) where the court has the opportunity to simplify and define a proposed class action in advance, saving on costly procedures for the litigants: *Consumers' Association* at para. 48;

b) where there may be prejudicial effects upon the applicant's business and customers if that portion of the allegations remains outstanding through a lengthy conventional class-action trial: *Consumers' Association* at paras. 49–52; and

c) where the summary application may reduce what remains for certification or may reduce the number or scope of outstanding triable common issues: *Consumers' Association* at paras. 46–53; *Gill v. Yahoo! Canada Co.*, 2018 BCSC 290; *Lui v. Transportation Investment Corporation*, 2016 BCSC 827; *Tucci v. Peoples Trust Company*, 2015 BCSC 987.

[22] Section 12 of the *CPA* states that "[t]he court may, at any time, make any order it considers appropriate respecting the conduct of a class proceeding to ensure its fair and expeditious determination and, for that purpose, may impose on one or more of the parties the terms it considers appropriate". The words "any order" includes the discretion to order that a summary judgment application on part of a plaintiff's claim may be held in conjunction with a class certification application.

[23] Narrowing the issues to be determined at trial if required, depending upon the ultimate result of the certification application, is in the interests of judicial economy and efficiency: *Lui* at paras. 15–17. Canadian courts serve a 'gatekeeping' function at the class-action certification stage to ensure allegations with no basis in fact are not certified as common issues: *Finkel v. Coast Capital Savings Credit Union*, 2017 BCCA 361 at paras. 15 and 19; *Azar v. Strada Crush Limited*, 2018 ONSC 4763 at para. 39.

[24] Mr. Dussiaume submits that a R. 9-5 application to strike is, for all intents and purposes, the same analysis undertaken in a certification application pursuant to s. 4(1)(a) of the *CPA*, and as such the application would serve no purposes. I disagree. An application to strike pursuant to R. 9-5 can result in very different relief. In an

application to strike pleadings, some or all of the pleadings may be dismissed and therefore put an end to certain claims.

[25] Mr. Dussiaume raises the concern that the application under R. 9-6 was filed before responses to civil claim were filed and as such the application is a nullity. They do not submit that the timing of the filing and subsequent responses to civil claim has placed them under any disadvantage by the time of the hearing of the application for certification. The applicants amended their application in response to amendments to the originating claim. Mr. Dussiaume has had ample opportunity to respond to the application. As the defendants point out, the R. 9-6 application is focused on the expert scientific evidence, and that evidence will not change retroactively with future discovery. Here, the expert evidence has been subject to cross-examination. Where there has been non-compliance with the *Rules* regarding the timing of the filing I find that it has not prejudiced the plaintiff and it is not a “nullity”.

[26] I find that the relief sought by the applicants would significantly narrow, and perhaps dispose of entirely, the issues to be determined at certification and trial. It is appropriate to hear and determine the applications under R. 9-5 and R. 9-6 in conjunction with the certification application.

The Claims of the Plaintiff

[27] The proposed class as described in the application is defined as all persons who purchased and/or ingested one or more of the drugs distributed by the defendants containing Ranitidine and recalled from October 2004 to the present and where deceased, persons entitled to maintain a claim under family compensation legislation (the “Class” or “Class Members”).

[28] The plaintiff claims in negligent design against manufacturer GlaxoSmithKline Inc.

[29] As against all of the Defendant Manufacturers, the plaintiff claims for loss and damages suffered by reason of negligence, failure to warn, strict liability, battery, deceptive acts and practices under the *Business Practices and Consumer Protection*

Act, S.B.C. 2004, c. 2 and similar legislation; and by reason of knowingly or recklessly making materially false or misleading representations under the *Competition Act*, R.S.C. 1985, c. C-34,

[30] As against all Defendant Retailers, the plaintiff claims in breach of implied conditions under the *Sale of Goods Act*, R.S.B.C. 1996, c. 410 and similar legislation or otherwise breach of contract.

[31] With respect to the impugned product and knowledge of the Defendant Manufacturers, the plaintiff pleads the following facts:

> Description of Zantac/Ranitidine
>
> 53. Ranitidine, sold under the trade name Zantac as well as numerous generic formulations in Canada, is a histamine H2-receptor antagonist commonly used to treat gastroesophageal reflux disease and gastric and duodenal ulcers. Zantac was the top over-the-counter H2-receptor brand in the USA in 2013, and is consistently ranked among the top 20 sold-list of prescribed drugs in several European countries and Australia.
>
> 54. A toxin, N-nitrosodimethylamine (NDMA), has been detected in the Ranitidine products designed, tested, researched, manufactured, marketed, distributed, imported, labelled, packaged, handled, stored, and sold by the Defendants. NDMA is a potential human carcinogen, which means that it could cause cancer with long-term exposure.
>
> 55. The World Health Organization has stated that scientific testing indicates that NDMA consumption is positively associated with particular types of cancers and suggests that humans may be especially sensitive to the carcinogenicity of NDMA.
>
> 56. Every dosage and form of Ranitidine products, including Zantac, exposes users to high levels of NDMA. The high levels of NDMA produced by Ranitidine are inherent to the molecular structure of Ranitidine, which the Defendant GSK created and elected to use as the active ingredient in Zantac.
>
> 57. The Ranitidine molecule contains both a nitrite (N) and a dimethylamine (DMA) group, which combine to form NDMA. The Ranitidine molecule is thus inherently unstable and reacts with itself to form NDMA. When ingested, Ranitidine forms NDMA in the human body.
>
> 58. Further, or in the alternative, NDMA is present in the active pharmaceutical ingredient manufactured by the Defendant Manufacturers, as a result of flaws or defects in the manufacturing process.
>
> 59. In the further alternative, NDMA forms when Ranitidine products are exposed to elevated temperatures, high humidity, or other adverse environmental conditions.

60. Recent independent testing by Valisure LLC and ValisureRX LLC of samples of Ranitidine products designed, tested, researched, manufactured, marketed, distributed, imported, labelled, stored, or sold by the Defendants has confirmed NDMA is present in the products in quantities which may present serious health risks to consumers.

61. There are several H2 blockers on the market. In Canada, these include; (i) Ranitidine (Zantac), (ii) cimetidine, (iii) famotidine (Pepcid), and (iv) nizatidine; there are also numerous generic forms available. Multiple H2 blockers other than Ranitidine, including cimetidine and famotidine, do not contain or emit NDMA.

The Defendants Were Aware of the Risks of Ranitidine

62. At all relevant times, each of the Defendant Manufacturers were aware of, or ought to have been aware of, numerous scientific studies showing, among other things, that Ranitidine poses a serious health risk to consumers. For example:

a. a study by De Flora, et al., published in 1981 stated that when Ranitidine was exposed to human gastric fluid in combination with nitrites it showed “toxic and [mutagenic] effects” which may have been caused by “the formation of more than one nitroso derivative [which includes NDMA]”;

b. a study by Wagner, D.A., et al., published in 1983 specifically suspected the carcinogenic nature of Ranitidine in combination with nitrite;

c. a 1987 update from the International Agency for Research on Cancer stated that NDMA should be regarded as if it were carcinogenic to humans, and labelled it with a carcinogenic classification of “Group 2A: probably carcinogenic to humans”;

d. in 1989, the Agency for Toxic Substances and Disease Registry stated that “NDMA is very harmful to the liver of animals and humans…high level short-term damage and/or cancer in animals also usually resulted in internal bleeding and death” and “it is reasonable to expect that exposure to NDMA by eating, drinking, or breathing could cause cancer in of the study participants after taking Ranitidine for only four weeks.” The researchers noted that nitrosamines belong to the most potent known carcinogens and no organisms had been found which would be resistant to its harmful effects, which might include lesions, tumors, and symptoms of acute poisoning;

e. in 2003, a scientific article by Mitch, W., et al., which suggested that elevated levels of NDMA in drinking water produced by American wastewater treatment plants may be associated with Ranitidine;

f. a scientific study by Shen, R., and Andrews, S.A., published in 2011 found that, out of eight pharmaceuticals that were observed, “Ranitidine showed the strongest potential to form N-nitrosodimethylamine (NDMA)” when present in drinking water during chloramine disinfection;

g. a 2014 scientific article by Zhang, A., et al., that examined the formation mechanisms of NDMA acknowledged the consensus about the dangers posed by Ranitidine, observing that Ranitidine and two other

> pharmaceuticals had "recently caused much concern because they are NDMA precursors";
>
> h. a peer-reviewed study published by Zheng, T., and Mitch, W.A., in 2016 "confirmed the production of N-nitrosodimethylamine (NDMA), a potent carcinogen, by nitrosation of Ranitidine under stomach-relevant pH conditions in vitro" and also showed that, during the 24 hours following Ranitidine intake, the quantity of NDMA in urine excreted by the patient "increased 400-folds from 110 to 47600 ng." The authors also identified that PPIS were less likely to result in that danger, noting that "alternative medications such as a proton pump inhibitors (PPIs), would less likely promote in vivo nitrosation because of the lack of amines in their structure". This study was recalled in 2021;
>
> i. a 2018 scientific review by Pottegard, A., et al., "summariz[ing] major findings over the last decade related to N-Nitro[s]odimethylamine (NDMA)" pointed out that Ranitidine had a high rate of NDMA formation "upon chloramination"; and
>
> j. 2020 research reports by Adamson, R. and Chabner, B., that Ranitidine use is associated with a significant increase in the risk of bladder, breast, colorectal/intestinal, esophageal, gastric, kidney, liver, lung, pancreatic, and prostate cancer.
>
> 63. The Defendant Manufacturers designed, tested, researched, manufactured, marketed, distributed, imported, labelled, packaged handled, stored, and sold Ranitidine products to consumers notwithstanding the evidence that Ranitidine exposes users to NDMA and that NDMA poses a serious health risk to consumers.

[32] The plaintiff refers to the product monograph, filed in support of approval for manufacture and distribution by Health Canada and provided with the product or otherwise available to consumers:

> 65. The product monograph for Zantac Ranitidine does not list NDMA as a component of the Ranitidine nor does it list cancer as a risk to consumers using the product. The product monographs relating to generic Ranitidine provided by the Defendant Manufacturers state that "[t]here is no evidence that Ranitidine is a carcinogen" and do not disclose the presence of NDMA.

[33] Beginning in 2019, Health Canada began investigating the presence of NDMA in some ranitidine drugs and published a series of general public information updates. In his pleadings, Mr. Dussiaume states that an information update was issued on or about September 13, 2019, advising that Health Canada is investigating the presence of NDMA in some ranitidine drugs and will take action as needed and keep Canadians informed. Another information update was issued on or about September 17, 2019, which informed Canadians that current evidence suggests that NDMA may be present

in Ranitidine and that Health Canada has requested companies marketing ranitidine products in Canada to stop any further distribution until evidence is provided to demonstrate that they do not contain NDMA above acceptable levels. Health Canada stated that this information update was not a recall. Mr. Dussiaume points out that in the same information update, "… all lots of Ranitidine 150mg and 300mg tablets were being recalled by the Defendant Sandoz, one of the leading manufacturers of the drug."

[34] Following the information updates from Health Canada, some or all of the Defendant Manufacturers conducted their own investigations, and voluntarily recalled lots either on their own initiative or at the request of Health Canada pending further investigation.

[35] The NOCC sets out the following facts regarding the Health Canada information updates and recalls:

> 70. The information on the Health Canada website regarding the Recall included advice as to the following:
>
> > • Talk to your doctor or pharmacist at your earliest convenience about alternative, non-Ranitidine treatment options appropriate for your health circumstances. There are many prescription and over-the-counter drug alternatives in Canada that are authorized for the same or similar uses as Ranitidine.
> >
> > • Individuals taking a prescription Ranitidine drug, including a recalled product, **should not stop** taking it unless they have spoken to their health care provider and obtained alternative treatment, as the risk of not treating the condition may be greater than the risk related to NDMA exposure.
> >
> > • Contact your health care provider if you have taken a Ranitidine product and you have concerns about your health.
>
> 71. On or about October 17 and 18, 2019, Health Canada expanded the Recall to include Ranitidine drugs manufactured by Sanofi (who at this time controlled the rights to brand-name over-the-counter Zantac® in Canada) and Teva.
>
> 72. On or about October 23 and 24, 2019, Health Canada expanded the Recall to include Ranitidine drugs manufactured by Dominion, Riva, Pharmascience, and Vita Health.
>
> 73. On or about October 29, 2019, Health Canada expanded the Recall to include Ranitidine drugs manufactured by Ranbaxy.
>
> 74. On or about July 23, 2020, Health Canada issued an advisory stating as follows:

> In September 2019, Health Canada directed companies to stop distributing Ranitidine drugs in Canada as an interim, precautionary measure while it assessed the risk of NDMA detected in some drugs. Since then, companies have recalled products from the Canadian market because they contained or potentially contained NDMA above acceptable levels.
>
> […]
>
> As a result of its assessment of this additional information, Health Canada is now directing companies wishing to sell Ranitidine products in Canada to undertake the following safety measures:
>
> • continue to test every batch of Ranitidine product before releasing it and test it regularly throughout its shelf life;
>
> • conduct more frequent testing if NDMA is detected within a certain range below the accepted limit, to enable faster detection of any increases in NDMA;
>
> • conduct additional testing to evaluate the potential for NDMA formation under different storage conditions (e.g., above room temperature); and
>
> • provide all of the above test data to Health Canada, along with any information to help further evaluate the potential formation of NDMA from Ranitidine in the body.

75. On or about August 27 and 28, 2020, Health Canada expanded the Recall to include further lots of Ranitidine drugs manufactured by Sandoz and Pharmascience.

76. On or about January 8, 2021, Pharmascience recalled 13 lots of prescription and over-the-counter Ranitidine drugs after tests found NDMA at above accepted level.

77. On or about January 30, 2021, Health Canada expanded the Recall to include further lots of Ranitidine drugs manufactured by Pharmascience.

78. On or about February 4, 2021, Pharmascience recalled 13 lots of prescription and over-the-counter Ranitidine drugs (150 mg tablets) after tests found NDMA, a nitrosamine impurity, at below but close to the accepted level.

79. On February 5, 2021, Health Canada announced that:

> OTTAWA – Health Canada recently informed Canadians that it is assessing the issue of an impurity called N-nitrosodimethylamine (NDMA) detected in some Ranitidine drugs. Current evidence suggests that NDMA may be present in Ranitidine, regardless of the manufacturer. As a result, and at Health Canada's request, companies marketing Ranitidine products in Canada have stopped any further distribution until evidence is provided to demonstrate that they do not contain NDMA above acceptable levels.
>
> The request to stop distribution means that the existing stock of Ranitidine products currently available in pharmacies or at retail stores may continue to be sold. This is different from a recall, since products that are being recalled can no longer be sold.

> […]
>
> Companies have agreed with Health Canada's precautionary request to stop distributing all Ranitidine drugs in Canada. A complete list of Ranitidine products marketed in Canada is available by searching Health Canada's Drug Product Database.
>
> 80. Since February 5, 2021, there have been additional recalls by Health Canada.…
>
> [Emphasis in original.]

[36] A 10-page schedule is attached to the NOCC. The schedule contains a table detailing the dates which recalls on various Ranitidine products were posted on Health Canada's recalls and safety alerts website.

[37] Mr. Dussiaume took the affected Ranitidine. The facts and claim for relief relating to his claim are as follows:

> 81. The Plaintiff was taking Ranitidine. His prescription was for Sanis Ranitidine Hydrochloride 150mg with Drug Identification Number (DIN) of 02353016. He had been taking it since January 2019 up until about September 26, 2019 when his family doctor switched his medication.
>
> 82. All lots of Sanis Health Inc. Ranitidine 150mg with DIN 02353016 are on the Health Canada recall list and were recalled as of September 25, 2019.
>
> 83. As a result of the defective nature of the Ranitidine that he received, the Plaintiff has incurred damages including:
>
> (a) General damages for the tort of battery;
>
> (b) Personal injury including damage to genes and prolonged and serious mental distress as a result of learning about the Recall and that he had been ingesting substances that placed him at, and the an increased material risk of developing cancer;
>
> (c) Special damages for medical monitoring and medical tests;
>
> (d) The cost of purchasing Ranitidine that was unfit for the purpose intended; and
>
> (e) Such further and other damages as shall be proven at trial.
>
> 84. The Plaintiff would not have purchased or used Ranitidine had he been provided accurate information and/or warnings. Further, the Ranitidine should never have been sold as it was adulterated and otherwise in breach of the *Food and Drugs Act* and *Regulations*.

[38] The NOCC pleads the following with respect to the Class Members:

> 85. Hundreds of thousands of Canadians, potentially millions, have been exposed to Ranitidine which contained a known carcinogen.

> 86. As a result of the defective nature of the Ranitidine that they received, the Class Members have incurred damages including:
>
> (a) General damages for the tort of battery;
>
> (b) Prolonged and serious mental distress as a result of learning about the Recall and that they had been ingesting substances that placed them at an increased material risk of developing cancer;
>
> (c) Special damages for medical monitoring and medical tests, past and future;
>
> (d) The cost of purchasing Ranitidine that was unfit for the purpose intended; and
>
> (e) Such further and other damages as shall be proven at trial.
>
> 87. The Class Members would not have purchased or used Ranitidine had they been provided accurate information and/or warnings. Further, the Ranitidine should never have been sold as it was adulterated and otherwise in breach of the *Food and Drugs Act* and *Regulations*.

[39] With respect to the Defendant Manufacturers, the plaintiff claims for the Class the following relief:

> 194. As a result of the Defendant Manufacturers' strict liability, negligence, battery and the Defendant Manufacturers' breach of the BPCPA (and equivalent legislation), and/or the [*Competition Act*] the Plaintiff and Class Members have suffered and will continue to suffer loss and damage. Such loss and damage was foreseeable by the Defendant Manufacturers. Particulars of the loss and damage suffered by the Plaintiff and Class Members which were caused or materially contributed to by the aforementioned acts of the Defendant Manufacturers include:
>
> (a) General damages for the tort of battery;
>
> (b) Damages for battery and personal injury including:
>
> i. Consuming a carcinogenic, toxic product on a repetitive and prolonged basis;
>
> ii. Being at a materially increased risk of experiencing adverse health effects going forward;
>
> iii. Being subject to the real possibility of future adverse health effects;
>
> iv. Suffering shock and serious and prolonged anxiety, mental distress and worry from learning of the Recalls and that they had been ingesting a carcinogen in medication; and
>
> v. Changes to internal bodily composition at a cellular or molecular level, through the release of active carbonium ions which seek out cellular components such as DNA, RNA and proteins, a genotoxic process which results in physical damage to genes, and can cause cancer;

> (c) A real and substantial increased risk of contracting cancer and/or other health conditions such as damage to organs as a result of ingesting the Ranitidine Products;
>
> (d) Past and future damages for medical monitoring and medical services, including consultations with physicians about the health ramifications, the costs of medical screening/monitoring, counselling, and other healthcare expenses as well as associated travel costs, on an annual basis to provide early detection of any adverse health effects caused by the consumption of NDMA and to reduce the level of anxiety, mental distress and worry;
>
> (e) A refund for the cost of the medications containing carcinogens, that class members would not have otherwise purchased had they been properly warned;
>
> (f) Disgorgement of profits;
>
> (g) A refund for the costs thrown away for medications purchased which were recalled before the class member consumed the drugs.
>
> (h) Loss of both past and prospective income;
>
> (i) Cost of future care …

[40] With respect to the Defendant Retailers, the claim for relief pleads:

> (a) Damages for breach of warranty pursuant to s. 56 of the SGA and equivalent legislation in other provinces;
>
> (b) Damages for costs thrown away of the purchased Ranitidine pursuant to s. 57 of the SGA and equivalent legislation in other provinces;
>
> (c) Nominal damages for breach of contract; and
>
> (d) Damages for the breach of the warranty of quality pursuant to ss. 1726-1729 of the Civil Code of Québec.

[41] Mr. Dussiaume also seeks punitive damages against all defendants.

[42] A claim is also made under the provincial health care cost recovery legislation as applicable.

Are the claims in negligence and failure to warn bound to fail?

[43] In order to disclose a reasonable cause of action in negligence, a plaintiff must plead that a defendant owed the plaintiff a duty of care, the defendant's conduct fell below the applicable standard of care, and this conduct caused the plaintiff – in law and in fact – to sustain a compensable loss: *Mustapha v. Culligan of Canada Ltd.*, 2008 SCC 27 at para. 3.

[44] The NOCC references compensable physical injury as follows:

a) “being at a materially increased risk of experiencing adverse health effects going forward”;

b) “being subject to the real possibility of future adverse health effects”;

c) “suffering shock and serious and prolonged anxiety, mental distress and worry from learning of the Recalls and that they had been ingesting a carcinogen in medication”;

d) “changes to internal bodily composition at a cellular or molecular level, through the release of active carbonium ions which seek out cellular components such as DNA, RNA and proteins, a genotoxic process which results in physical damage to genes, and can cause cancer”; and

e) “a real and substantial increased risk of contracting cancer and/or other health conditions such as damage to organs as a result of ingesting the Ranitidine Products”.

[45] Apart from the shock and anxiety claims, Mr. Dussiaume does not plead a claim for any injury that has manifested in adverse health effects or health conditions. He further submits in argument that he also pleads for general damages for the pain and suffering of Class Members who have experienced physical injury for such things as the so called “nine signal cancers”. However, that is not quite the case. The plaintiff specifically pleads relief for increased risk of contracting cancer or other damaging health conditions. He also pleads damage to cells which “can cause cancer”. However, at paragraph 7 of the NOCC in the overview portion of the statement of claim, the plaintiff pleads that “Ranitidine consumption has caused scores of consumers to develop cancer”.

[46] The claims are for adverse health effects or health conditions that might, and by necessity might not, occur in the future. In doing so, the plaintiff seeks compensation for a potential and future harm.

[47] The defendants submit these claims fail for two general and related reasons. First, is that "the fatal flaw in seeking damages for the harm of an increased risk is that the creation of risk is not wrongful conduct": *Palmer v. Teva Canada Ltd.,* 2022 ONSC 4690 at para. 165, citing *Kaissieh v. Done*, 2022 ONSC 425 at para. 86; *1688782 Ontario Inc. v. Maple Leaf Foods Inc.*, 2020 SCC 35 at para. 44 [*Maple Leaf Foods*]; *Babstock* at para. 33; *Dow Chemical Company v. Ring, Sr.*, 2010 NLCA 20 at paras. 52–59, leave to appeal to SCC ref'd, 33711 (21 October 2010); *Rothwell v. Chemical & Insulating Co. Ltd.*, [2007] UKHL 39.

[48] Second, the defendants submit that potential future injuries are not compensable. Personal injury at law connotes a present "serious trauma or illness": *Mustapha* at para. 9. Minor and transient upsets do not constitute personal injury, and hence do not amount to damage. As summarised by Justice Verbeem in *Kaissieh* at para. 86:

> The common law does not recognize a right to be free from the *prospect of damage*. Rather, it recognizes "a right not to suffer damage that results from exposure to an unreasonable risk" (emphasis in original): see *Atlantic Lottery*, at para. 33; *Maple Leaf Foods*, at para. 44. Therefore, negligence law does not recognize "the risk of injury or harm" or, "increased risk of injury or harm" as compensable types of damage. The tort of negligence does not offer compensation for "damage" that has not yet occurred, absent a negligently created risk that exposes the plaintiff to an imminent, real and substantial danger to health and safety: see *Del Giudice*, at para. 232.
>
> [Emphasis in original.]

[49] As stated above, the Supreme Court of Canada has specifically held in *Babstock* that the creation of risk is not compensable:

> [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" (*Clements v. Clements*, 2012 SCC 32, [2012] 2 S.C.R. 181, at para. 16). 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 (E. J. Weinrib, *The Idea of Private Law* (rev. ed. 2012), at pp. 153 and 157-58; R. Stevens, *Torts and Rights* (2007), at pp. 44-45 and 99). 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" (Weber, at p. 424). It would be a radical and uncharted development, "[giving] birth to a new tort over night" (Barton, Hines and Therien, at p. 147).

> [Emphasis in original.]

[50] Canadian courts have recognized this important limitation on claims in negligence, in different contexts, including class actions alleging negligence in respect of pharmaceutical products.

[51] In *Del Giudice v. Thompson*, 2021 ONSC 5379 at para. 225, the Ontario court considered the viability of a proposed class proceeding relating to the public exposure or potential exposure of personal and confidential information of 106 million applicants for credit cards. Justice Perell found that:

> [225] The overwhelming majority of the six million Canadians affected by the data breach will not have suffered any compensable damages because negligence law does not recognize as compensable harm the risk of injury or harm or the increased risk of harm or injury.
>
> [Emphasis in original.]

[52] Recently, in *Palmer*, a class action focusing on the same alleged impurity as the one in this case, NDMA, albeit in a different pharmaceutical product (i.e., "Valsartan"), the Ontario Superior Court of Justice considered whether damages could be awarded for an alleged increased risk of harm. As Justice Perell put the issue:

> [1] This certification motion raises a "what if" legal question about the greatest tort case of all time. As every law student, law professor, lawyer, and judge in the common law world knows, on a summer evening in 1928, at an ice-cream parlor in Glasgow, Scotland, May Donoghue was served an ice-cream float of two scoops of ice-cream covered in ginger beer. After she had eaten one scoop, more ginger beer was poured from an opaque glass bottle. To May Donoghue's dismay, out poured the remains of a decomposed snail. The "what if" legal question is: "What if the 29-year-old May Donoghue went to her doctor to be examined, would the manufacturer of the ginger-beer be liable to pay the doctor's bill if the diagnosis was "May, as far as I know, you're quite fine after that distressing incident; here's my bill"?
>
> [Emphasis added.]

[53] Applying *Babstock*, Justice Perell held that an alleged increased risk of harm is not compensable, finding that "negligence law does not recognize the risk of injury or harm or the increased risk of harm or injury as a compensable type of damages": *Palmer* at para. 176.

[54] The plaintiff's claim for damages in respect of a potential future physical harm is similarly flawed. Future harms that might – or might not – occur are not compensable. The conduct of a defendant in negligence is only wrong to the extent that it causes an actual materialized loss: *Babstock* at para. 37.

[55] In advancing a claim for a potential future harm, the plaintiff has failed to allege a present materialized loss. In doing so, the plaintiff has failed to allege a complete tort.

[56] Like in *Babstock*, a claim with no actual individual loss "has no reasonable chance of success", because there are no compensable damages for an allegation of wrongdoing in the absence of a present manifestation of the harm: *Babstock* at para. 38.

[57] The Supreme Court of Canada reiterated the principle that negligence law does not recognize potential future injuries in *Maple Leaf Foods*. Justices Brown and Martin confirmed that the "liability rule" from *Winnipeg Condominium Corporation No. 36 v. Bird Construction Co.*, [1995] 1 S.C.R. 85, 1995 CanLII 146 [*Winnipeg Condominium*] is consonant with finding that "[t]here is no right to be free from the prospect of damage", i.e., a potential future harm: *Maple Leaf Foods* at para. 44.

[58] Explaining the liability rule in *Winnipeg Condominium*, the Court in *Maple Leaf Foods* at para. 45 described the exception for recovery for economic loss as being based on a plaintiff "having sustained an actual injury to its right in person or property because of the necessity of taking measures to put itself or its other property 'outside the ambit of perceived danger'" due to the imminent risk of physical harm to the person or property as a result of a defect in design or construction. The normative basis for the duty to be free from injury to one's person or property also delimits its scope because this basis vanishes where the defect presents no imminent threat:

> [46] As we see it, then, recovery for the economic loss sustained in *Winnipeg Condominium* was founded upon the idea that, in the eyes of the law, the defendant negligently interfered with rights in person or property. We see this as having been La Forest J.'s point in *Winnipeg Condominium* where he explained:
>
> > If a contractor can be held liable in tort where he or she constructs a building negligently and, as a result of that negligence, the building causes damage to persons or property, it follows that the contractor

> should also be held liable in cases where the dangerous defect is discovered and the owner of the building wishes to mitigate the danger … In both cases, the duty in tort serves to protect the bodily integrity and property interests of the inhabitants of the building.
>
> In our view, this normative basis for the duty's recognition - that it protects a right to be free from injury to one's person or property - also delimits its scope. This is because this basis vanishes where the defect presents no imminent threat.
>
> [Emphasis in original.]

[59] Therefore, the plaintiff's claim for negligent supply of defective goods fails if the defect does not pose an imminent risk of physical harm.

[60] Mr. Dussiaume claims the present injury of psychological distress and anxiety. However, those injuries are due to the alleged future risk of contracting cancer or other health conditions.

[61] Mr. Dussiaume submits that the tort of negligence is being advanced on the basis that the tainted drugs caused bodily injury by virtue of the carcinogens causing mutations at the cellular level from ingesting the toxins on a daily or prolonged basis. Mr. Dussiaume goes on to plead that these cellular changes "can cause cancer". This confirms that Mr. Dussiaume's allegation of cellular change is a potential future harm or increased risk of harm claim in different clothes. That theory fails for the same reasons as claims for potential future harm and an increased risk of harm.

[62] In *Palmer*, Justice Perell applied *Babstock*, *Maple Leaf Foods*, and other lower court decisions, finding that:

> [186] Moving on to a conclusion, in my opinion, based on this case law, it is plain and obvious that in the immediate case, the products liability claim for damages for psychological harm is not certifiable as pleaded or at all. Neither the risk of future physical or psychological harm nor the present anxiety occasioned by the risk of future physical or psychological harm is a compensable harm, and, thus, it is plain and obvious that the damages constituent element of a negligence cause of action is missing that and accordingly the cause of action criterion is not satisfied in the immediate case. This impediment cannot be cured by the Plaintiffs' amending their pleadings.

[63] There is other Canadian jurisprudence finding that claims for potential future physical injuries cannot succeed in the absence of a materialized present injury,

including in claims of alleged exposure to carcinogens. Other Canadian courts have found that:

a) "the risk of a future disease is not actionable in the absence of a present injury": *Dow Chemical Company* at para. 58;

b) "the only allegations of fact concerning the losses and damages of the plaintiff… [are] associated with the risk of future harm, as distinct from actual harm that the plaintiff has suffered, in fact. That is not enough to complete the tort of negligence": *Kaissieh* at para. 85; and

c) "the risk of a future injury developing—a hypothetical injury—is not an injury that can be compensated": *Setoguchi v. Uber B.V.*, 2021 ABQB 18 at para. 55.

[64] Similar to the plaintiff's increased risk of harm damages theory, it is plain and obvious that his claim for potential future harm is bound to fail. No complete tort is pleaded. It has no prospect of success.

[65] Mr. Dussiaume submits that if it appears that the claim for causation of cancer is not adequately pleaded, then it is a matter of amending the claim: *Dow Chemical Company* at para. 51. The plaintiff suggests a similar finding to that in *Dow Chemical Company* would be applicable: "for those who have been diagnosed with [cancer] and who allege that the [cancer] is the result of exposure to the toxic chemicals, the pleadings disclose a cause of action": *Dow Chemical Company* at para. 51.

[66] The problem with the plaintiff's submission is that Mr. Dussiaume has had the opportunity to make such an amendment for a few years. Yet, he has not pled that anyone has actually been diagnosed with cancer and that they allege that cancer is a result of consuming Ranitidine. In *Dow Chemical Company*, there were specific pleaded facts that some proposed class members were diagnosed with lymphoma and alleged a causal link to their exposure to the toxic chemicals distributed in the specified area, which was the subject of the action.

[67] Mr. Dussiaume has an affidavit from one proposed Class Member providing evidence of his consumption of Ranitidine during the Class Period and developing cancer. But the type of cancer developed by the proposed Class Member is not one of the "nine signal cancers" which the plaintiff seeks to link to the affected Ranitidine consumption.

[68] I cannot see how amending the pleading to set out a hypothetical fact at this late stage would be useful.

Psychological Injury

[69] Mr. Dussiaume alleges a claim for psychological injury caused "as a result of learning about the recall" and the proposed class's ingestion of "substances that placed them at an increased material risk of developing cancer".

[70] The law does not recognize upset, disgust, anxiety, agitation, or other mental states that fall short of injury: *Mustapha* at para. 9; *Saadati v. Moorhead*, 2017 SCC 28 at paras. 21–22, 35–38.

[71] Just as claims for increased risks of physical harm are not compensable, claims for worries about increased risk of physical harm are also not compensable, regardless of how they are pleaded or what evidence might be adduced to support them. The plaintiff's claim for psychological injury arising out of a risk of harm has the same flaw as his claim for physical injury arising out of a risk of harm. Different forms of personal injury, mental and physical, should be afforded identical treatment: *Saadati* at para. 35

[72] It follows that if the risk of a potential future physical harm is not compensable, neither is a harm one step removed, i.e., anxiety occasioned by the risk of a future harm. As stated in *Palmer* and *Dow Chemical Company*, "[p]ersons exposed to radiation or toxic chemicals must await the onset of injury if any, and even damages for cancerphobia or the cost of medical surveillance appear foreclosed": *Palmer* at para. 179; *Dow Chemical Company* at para. 52.

[73] The principle that damages for psychological injuries are unavailable in the context of an alleged increased risk of harm, or an unmaterialized harm, has been applied in claims alleging psychological harm arising out of the ingestion of pharmaceuticals and an alleged increased risk of cancer.

[74] Most recently, in *Palmer*, the plaintiffs submitted that "the shock and trauma of learning that one has been ingesting a carcinogen on a daily basis for months or years is self-evidently a traumatic event that rises above the ordinary annoyances of life": *Palmer* at para. 166. In finding that such claims disclosed no reasonable cause of action, Justice Perell applied *Babstock*, finding that the alleged "… suffering of psychological harm is not compensable in law because it arises from anxiety associated with an increased feeling of risk and is not anxiety associated with the materialization of that risk": *Palmer* at para. 135.

[75] In this case, like in *Palmer*, the plaintiff's mental distress claims ultimately seek compensation for "… an apprehension of an abstraction (the increased risk of diagnosis of cancer)": *Palmer* at para. 11. That claim has no basis at law and cannot succeed. To find otherwise would raise indeterminacy concerns, and would create a legal asymmetry between the availability of damages for a physical risk of harm and the availability of damages for mental harm flowing from a risk of harm, contrary to the established jurisprudence: *Saadati* at para. 35.

[76] The plaintiff's mental distress claim accordingly fails under R. 9-5(1)(a) because it discloses no reasonable claim.

The Plaintiff's Claim for Medical Monitoring

[77] Mr. Dussiaume claims damages in the form of past and future costs of medical monitoring of Class Members to provide early detection of any adverse health effects caused by the consumption of NDMA, and to reduce the level of anxiety, mental distress, and worry.

[78] In *Williamson v. Johnson & Johnson*, 2020 BCSC 1746, this Court addressed such claims:

> [171] … They contend that some members of the class will require surgical or medical monitoring. The defendants contend there is no recognized cause of action for medical monitoring in Canada and no basis for an order requiring a medical monitoring regime.
>
> [172] Rejection of this type of claim is based on the exclusionary principle that claims for contingent, future pure economic loss are by their very nature indeterminate contingent and speculative and cannot be included in a class proceeding claim: See *Winnipeg Condominium Corporation No. 36 v. Bird Construction Co.*, [1995] 1 S.C.R. 85, 1995 CanLII 146 [*Winnipeg Condominium Corporation*] and *Brooks v. Canada*, 2009 SKQB 509 at para. 114; *Ring v Canada (A.G.)*, 2010 NL's the 20 at paras. 56-59, leave to appeal to the SCC refused [2010] S.C.C.A. No 187.
>
> [173] In *Winnipeg Condominium Corporation*, the Court allowed recovery for economic loss to repair dangerous products creating risks of harm already remediated but disallowed for recovery of future economic loss, that is for repairs not yet completed.
>
> [174] I am satisfied that the claim advanced by the plaintiff respecting future medical monitoring or medication costs cannot be certified based on the authorities including *Brooks v. Canada*, 2009 SKQB 509 at para. 114, leave to appeal refused, 2010 SKCA. Claims for past expenses and losses are recoverable.

[79] The Court of Appeal of Newfoundland and Labrador also considered, and rejected, such a claim in *Dow Chemical Company*. The plaintiff in that case alleged exposure to a toxic chemical that increased the risk of lymphoma. The Court of Appeal rejected claims for medical testing for the proposed class members who had no compensable physical or psychological injuries. The critical issue driving the Court of Appeal's analysis was that, as here, there was an absence of compensable harm. Instead, by seeking damages for medical monitoring, the plaintiff had effectively attempted to short circuit the negligence analysis by presuming that the defendant's conduct had caused a physical injury that warranted such monitoring. The Court of Appeal found that in advancing a claim for medical monitoring "the plaintiffs seek to proceed directly from breach of a duty of care to compensation without the necessity of proving either economic or physical injury": *Dow Chemical Company* at para. 57.

[80] Given my findings above regarding the plaintiff's injury claims, the same result would follow.

[81] In *Palmer*, Justice Perell found that “the heads of damages for medical bills and for medical monitoring arising from an increased risk of experiencing cancer are not recoverable”: *Palmer* at para. 232. Justice Perell applied the liability rule from *Winnipeg Condominium*, which precludes compensation for damages that have not yet occurred in the absence of an imminent and serious threat to an individual’s person or property. Justice Perell concluded that:

> [204] In the immediate case, where Class Members likely ingest NDMA and NDEA and compose it endogenously in amounts that astronomically exceed the average daily intake ("ADI") recommended by the public health regulators and where the science has yet to conclude that NDMA and NDEA are carcinogenic in humans, there is no imminent real and substantial danger to the health and safety of the Class Members. Latent but presently unproven causation of harm is the opposite of imminent danger.

[82] Imminent and serious threat is not pleaded. From the regulatory warning and science, it would appear that such a threat could not be pleaded.

Is there a *bone fide* triable issue on the materials and applicable law under R. 9-6?

[83] In support of the R. 9-6 application the following evidence was submitted.

[84] The defendants submit the evidence of Dr. Laurent Azoulay (epidemiologist), Dr. Sapna Syngal (gastroenterologist specialising in cancer genetics and prevention), Dr. Sharlene Gill (oncologist), Dr. Annette Santamaria (toxicologist), Dr. Barry Gilbert (psychiatrist), and Dr. William Zamboni (pharmacologist).

[85] The plaintiff submits the opinion evidence of Dr. Sidney Katz (pharmacologist), Dr. Mahyar Etminan (epidemiologist), and Dr. Jennifer Mosher (pharmacist).

[86] The expert opinion evidence tendered must be admissible in order to be considered on the application.

Expert Evidence on Ranitidine, NDMA, and Cancer

[87] The defendants argue that there is an absence of scientific evidence that ranitidine or NDMA cause cancer in humans. They submit the current state of scientific knowledge is that there is no consistent or reliable association between either ranitidine,

or NDMA, and cancer in humans. Even if there were, evidence of an association is not evidence of causation: *Wise v. Abbott Laboratories, Limited*, 2016 ONSC 7275 at para. 75.

[88] Dr. Etminan and Dr. Katz do not actually opine that ranitidine causes any type of cancer. They confine their opinions to whether ranitidine or NDMA is associated with certain cancers or whether long-term exposure to ranitidine can increase the risk of certain cancers. To the extent that either opines on cancer biology, cause, diagnosis, treatment and prevention of cancer, they are not qualified to do so and such opinion evidence is inadmissible.

[89] Dr. Gill concludes that it is biologically implausible, and the scientific evidence does not support a causal or reliable association between ranitidine and cancer risk, including the cancers within the six organs identified by Dr. Etminan and Mr. Dussiaume.

[90] Dr. Gill and Dr. Syngal opine that cancer is not a single disease, but more than 100 diseases, and that different types of cancer have different prevalence, risk factors, presentations, and treatment.

[91] In response to the expert evidence of the defendants, Dr. Etminan and Dr. Katz concede that more studies would be needed to determine whether there is a reliable association between ranitidine and the risk of any cancers in humans.

[92] Dr. Etminan concludes in an affidavit sworn on May 27, 2022, regarding the literature on the risk of cancer with NDMA as well as ranitidine:

> Future studies with adequate follow-up and long-term exposure to ranitidine that can allow for a dose-response analysis and control for over-the-counter-ranitidine use will be better equipped to answer this question.

[93] Dr. Katz concludes in an affidavit sworn on May 3, 2022:

> This and other data in the literature suggest that a longer latency period between NDMA exposure and the development of cancer is required in order to determine a <u>possible</u> link.

> The issue of carcinogenicity of NDMA exposure via Ranitidine and other medications is being investigated on an ongoing basis with increasingly available dat[a] regarding long-term outcomes … Given the volume of studies that are ongoing, I would expect that within 7 to 10 years from the initial recalls, a meta-analysis – an examination of data from a number of independent studies addressing the same question in order to determine overall trends – with longer latency periods should yield more definitive results."
>
> [Emphasis added.]

[94] This Court has repeatedly found that applications for summary judgment "cannot be defeated by vague references to what may be adduced in the future, if the matter is allowed to proceed": *Williams v. Audible Inc.*, 2022 BCSC 834 at para. 56, citing *Canada (Attorney General) v. Lameman*, 2008 SCC 14 at paras. 11 and 19; *Pantusa v. Parkland Fuel Corporation*, 2022 BCSC 322 at para. 58.

[95] Given the uncontroverted evidence that neither ranitidine nor NDMA are reliably associated with increased cancer risk, and the absence of evidence that ranitidine or NDMA cause cancer in humans, the plaintiff has failed to raise a *bona fide* triable issue regarding injury due to the ingestion and/or purchase of ranitidine.

The Claim of Battery due to Alleged Cellular Damage

[96] The defendants submit that the cellular change damages theory fails because it falls far short of "serious trauma or illness": *Mustapha* at para. 9.

[97] The uncontroverted evidence before me is that humans are exposed to cellular changes, including from nitrosamines such as NDMA, on a regular basis throughout their lives.

[98] Importantly, there is no scientific support for the notion that "injury to human cells", on its own, causes meaningful or lasting harm (i.e., serious trauma or illness).

[99] In an affidavit sworn on March 1, 2022, Dr. Santamaria opined that:

> The human body has evolved efficient defense mechanisms to repair DNA and cells that may be damaged by mutagenic substances, particularly in the case of naturally occurring substances in the diet and substances that are produced endogenously, such as NDMA.

[100] In an affidavit sworn on February 28, 2022, Dr. Zamboni opined that:

> … Studies evaluated the ability of NDMA to form DNA adducts in hepatic microsomes from rats, NHPs, and human (Davis 1993). DNA adduct formation; however, is not equivalent to carcinogenesis as the body has a number of mechanisms, including cell death and DNA repair processes, to repair such adducts before proliferation (Li 2016). Thus, the initial formation of DNA adducts has a low likelihood of causing mutations in DNA (Hwa Yun 2020). Moreover, the development of cancer is a multistep process requiring more than a single DNA insult (Basu 2018; Sutherl 1984). In other words, insults to DNA or mutations do not inevitably lead to cancer.

[101] In summary, these studies of NDMA exposure are not reliably informative of the question of whether ranitidine (with any associated NDMA) causes cancer of any type. As such, there is no scientific support for the conclusion that ranitidine at therapeutic doses gives rise to mutagenicity or is carcinogenetic. In addition to no contrary expert evidence offered by the plaintiff, he does not adduce evidence of actual genetic mutation in any of the proposed Class Members. Ultimately, such evidence may not have assisted the claim for compensable injury: *Rainer v. Union Carbide Corporation*, [2005] USCA6 145 at paras. 62–63, 402 F.3d 608; *Parker v. Wellman*, 230 Fed. App'x. 878 at 881 (11th Cir. 2007). "Damages are given for injuries that cause harm, not for injuries that are harmless": *Rothwell* at para. 47.

[102] Mr. Dussiaume's claims for compensation for a physical injury in the form of cellular damage has no prospect of success and are dismissed.

Claims for Psychological Injury

[103] To be legally compensable, a psychological injury must be serious and prolonged, and rise above the ordinary annoyances, anxieties, and fears that people living in society must deal with. This threshold requirement alone disposes of the majority, if not all, of Mr. Dussiaume's and the proposed Class Member's mental distress claims. The undisputed expert psychiatric evidence is that learning of a product recall is a stressor of comparatively low severity. In an affidavit report sworn on March 1, 2022, Dr. Gilbert opines that:

> The most common response to a stressor, particularly one of comparatively low severity such as the stressor at issue in this case, is to mobilize emotional,

> behavioural and cognitive resources and adapt to it, a concept known as "resilience."

[104] As found by the Supreme Court of Canada in *Saadati*:

> [20] Indeed, the claim in *Mustapha* failed on that last element: the claimant's damage was not caused in law by (that is, it was too remote from) the defendant's breach. *Mustapha* thus serves as a salutary reminder that, even where a duty of care, a breach, damage and factual causation are established, there remains the pertinent threshold question of legal causation, or remoteness — that is, whether the occurrence of mental harm in a person of ordinary fortitude was the reasonably foreseeable result of the defendant's negligent conduct (*Mustapha*, at paras. 14-16). And, just as recovery for physical injury will not be possible where injury of that kind was not the foreseeable result of the defendant's negligence, so too will claimants be denied recovery (as the claimant in *Mustapha* was denied recovery) where mental injury could not have been foreseen to result from the defendant's negligence.

[105] A valid claim for psychological injury requires that a person of ordinary fortitude would have a "real risk" of sustaining the loss alleged, being psychological injury: *Mustapha* at paras. 13–16; *Saadati* at para. 20. The real risk must be "one which would occur to the mind of a reasonable [person] in the position of the defendant": *Mustapha* at para. 13.

[106] The essential "reasonable foreseeability" or proximity criterion as it relates to legal causation is not present in this claim. It is not reasonably foreseeable that a proposed Class Member could suffer a psychological injury as a result of purchasing or ingesting Ranitidine because there is no basis in material fact or evidence to support the reason for that reaction. In this case, there is no basis in material fact or evidence to support the conclusion that ranitidine generally, or NDMA as detected in certain Ranitidine products, causes cancer in humans.

[107] Unusual or extreme reactions (such as serious and prolonged psychological injury relating to the consumption of a product that does not cause cancer) are not reasonably foreseeable: *Mustapha* at para. 15

[108] The factual foundation upon which the reasonable foreseeability analysis must be conducted is not in dispute. Dr. Santamaria's report sworn on March 1, 2022 sets out that NDMA is ubiquitous and can be detected in the environment, including air, water,

soil, and a variety of food sources, alcoholic beverages and consumer products. Human exposure to NDMA occurs on a daily basis through exogenous (external) exposure as well as natural formation in the human body or endogenous formation.

[109] Dr. Santamaria's report also further states that "based primarily on animal studies, nitrosamine impurities are classified as a probable or possible human carcinogen. We are all exposed to low levels of nitrosamines through a variety of foods (such as smoked and cured meats, dairy products and vegetables), drinking water and air pollution. Nitrosamines are not expected to cause harm when ingested at low levels. For example, a person taking a drug that contains NDMA at or below the acceptable level every day for 70 years is not expected to have an increased risk of cancer."

[110] Health Canada's communications to the public have consistently reassured ranitidine users about the implications of consuming Ranitidine that may have contained NDMA, stating:

> There is no immediate health risk associated with the use of medications containing low levels of a nitrosamine impurity. Foods such as meats, dairy products and vegetables as well as drinking water may also contain low levels of nitrosamines.
>
> We don't expect that a nitrosamine impurity will cause harm when exposure is at or below the acceptable level. For example, no increase in the risk of cancer is expected if exposure to the nitrosamine impurity below the acceptable level occurs every day for 70 years.
>
> …
>
> Patients should always talk to their health care provider before stopping a prescribed medication. Not treating a condition may pose a greater health risk than the potential exposure to a nitrosamine impurity.

[111] While the plaintiff has tendered evidence that certain proposed Class Members have had strong emotional reactions to Health Canada's statements, the plaintiff has not established (and cannot establish) reasonable foreseeability.

[112] For instance, proposed Class Member Ms. Mitchell has testified that she was "very upset" about the recall, and "very worried" about how her ranitidine usage may have affected her daughter. She is particularly concerned about "an odd birthmark [her] daughter has". Those concerns are similar to those of the plaintiffs in *Vanek v. Great*

Atlantic & Pacific Co. of Canada Ltd., 180 D.L.R. (4th) 748, 1999 CanLII 2863 (Ont. C.A.). In that case, the plaintiffs sought damages for psychiatric injury after their child ingested juice contaminated with gasoline, based on their serious concerns about their child one day experiencing "long-term effects" – a potential future harm. Justice MacPherson in *Vanek* at para. 60 found that the plaintiffs were displaying a "particular hypersensitivity" and they lacked the "reasonable fortitude and robustness" that the law expects of all its citizens, including concerned parents. The defendants in that case could not have reasonably foreseen this unusual reaction and the psychiatric damage that flowed from it.

[113] As confirmed in *Mustapha*, the law will not impose liability for the exceptional frailty of certain individuals:

> [14] The remoteness inquiry depends not only upon the degree of probability required to meet the reasonable foreseeability requirement, but also upon whether or not the plaintiff is considered objectively or subjectively. One of the questions that arose in this case was whether, in judging whether the personal injury was foreseeable, one looks at a person of "ordinary fortitude" or at a particular plaintiff with his or her particular vulnerabilities. This question may be acute in claims for mental injury, since there is a wide variation in how particular people respond to particular stressors. The law has consistently held — albeit within the duty of care analysis — that the question is what a person of ordinary fortitude would suffer: see *White v. Chief Constable of South Yorkshire Police*, [1998] 3 W.L.R. 1509 (H.L.); *Devji v. Burnaby (District)* (1999), 180 D.L.R. (4th) 205, 1999 BCCA 599; *Vanek*. As stated in *White*, at p. 1512: "The law expects reasonable fortitude and robustness of its citizens and will not impose liability for the exceptional frailty of certain individuals."

[114] In the absence of reasonable foreseeability, the plaintiff is not only missing the essential ingredient of compensable harm but also legal causation. The plaintiff's claim is an incomplete tort, which cannot be cured because of the flawed premises upon which it has been constructed.

[115] The plaintiff's psychological injury claims are bound to fail on the evidence.

The Claim for Medical Monitoring

[116] Like in *Palmer*, in this case, both on the science and as stated by Health Canada, there is no imminent and serious threat. On the contrary, Health Canada specifically

stated that "[t]here is no immediate health risk associated with the use of medications containing low levels of a nitrosamine impurity."

[117] Given the absence of any evidence of a compensable harm, as found above, the medical monitoring claim fails under the R. 9-6 analysis.

Conclusion

[118] I strike under R. 9-5 and dismiss under R. 9-6 the claims as set out in the defendants' application, listed as follows:

a) Negligence Manufacture and Distribution;

b) General Damages (Increased Risk of Harm, Potential Future Harm, Cellular Change, Psychological Injury); and

c) Special Damages (Medical Monitoring) and Recovery of Healthcare Costs.

[119] Those claims, founded upon the premise that ranitidine changes or otherwise forms the compound NDMA and causes cancer, are fundamental to all of the NOCC causes of action and claims for relief. The plaintiff proposed over 30 common questions in its application for certification as a class action. Of those, Mr. Dussiaume agreed that the following general causation question was key for the determination of the claims:

> Do the Ranitidine Drugs, used as indicated, cause or contribute to the development of breast, stomach, kidney, liver, bladder, esophagus, pancreatic or colorectal cancer?

[120] Given my findings, the NOCC is bound to fail and is struck or otherwise dismissed in its entirety.

[121] Accordingly, apart from the corresponding failure to meet the requirements of s. 4(1)(a) of the *CPA* with regard to whether there is a viable cause of action on the negligence and damages claims set out above, as a result of this decision, I make no further determinations on the plaintiff's application for certification. With the foundational claims struck or dismissed, there is no action left to certify.

[122] The defendants' application is granted. The plaintiff's application for certification is therefore dismissed.

"Wilkinson J."