**CITATION:** Palmer v. Teva Canada Ltd., 2022 ONSC 4690
**COURT FILE NO.:** CV-18-00601555-00CP
**DATE:** 20220812

**ONTARIO**
**SUPERIOR COURT OF JUSTICE**

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| **BETWEEN:** | |
| **GLORIA PALMER, JO-ANNE WILLS, DIANE PEREHUDOFF, BRADLEY HALAYKA, DIANNE TIEDJE, MURRAY HALBERT, CHARLENE BOURDON, KENNETH AITCHISON, and MAY VENTURA**<br>Plaintiffs | *Theodore P. Charney, Caleb Edwards, Anthony Leoni, Rebecca Loeb*, and *Matthew Burtini* for the Plaintiffs |
| **- and –** | |
| **TEVA CANADA LIMITED, SANDOZ CANADA INC., PRO DOC LIMITÉE, SANIS HEALTH INC., and SIVEM PHARMACEUTICALS ULC**<br>Defendants | *Laura K. Fric, Robert Carson, Lauren Harper* and *Jessica Habib* for the Defendant Teva Canada Limited<br><br>*Peter J. Pliszka, Zohaib I. Maladwala*, and *Aery Raajan* for the Defendants Sandoz Canada Inc., Pro Doc Limitée, Sanis Health Inc. and Sivem Pharmaceuticals ULC |
| Proceeding under the *Class Proceedings Act, 1992* | **HEARD**: June 27-29, 2022 |

**PERELL, J.**

Contents

## REASONS FOR DECISION

## A. Preamble

[1] This certification motion raises a "what if" legal question about the greatest tort case of all time.[1] 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"?

## B. Introduction and Overview

[2] In this proposed class action pursuant to the *Class Proceedings Act, 1992*,[2] the proposed nine Representative Plaintiffs,[3] Kenneth Aitchison, Charlene Bourdon, Bradley Halayka, Murray Halbert, Gloria Palmer, Marie-Eve Pellicelli,[4] Diane Perehudoff, Dianne Tiedje, and Jo-Anne Wills sue the Defendants: (a) Teva Canada Limited, and (b) Sandoz Canada Inc., Pro Doc Limitée, Sanis Health Inc., and Sivem Pharmaceuticals ULC (collectively "Sandoz").

[3] The Defendants are respectively manufacturers of "valsartan", a prescription drug indicated to treat high blood pressure.

[4] In the summer and autumn of 2018, in Canada, the U.S., Europe, Australia, Japan, Singapore, and Brazil manufacturers of valsartan recalled some lots of their pharmaceutical product. The valsartan was recalled because to varying degrees, the lots of valsartan were

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[1] *Donoghue v. Stevenson*, [1932] A.C. 562 (H.L.); A.C. Hutchinson, *Is Eating People Wrong? Great Legal Cases and How They Shaped the World*, (Cambridge University Press, New York, New York: 2011)
[2] S.O. 1992, c. 6.
[3] At the commencement of the certification hearing, May Ventura withdrew as a proposed Representative Plaintiff. She should be removed as a party plaintiff. Order accordingly.
[4] At the commencement of the certification hearing, Marie-Eve Pellicelli from Québec was added as party plaintiff without opposition from the Defendants. Order accordingly.

contaminated with N-nitrosodimethylamine ("NDMA") and N-nitrosodiethylamine ("NDEA"). The source of the contamination was Zhejiang Huahai Pharmaceuticals ("ZHP") a Chinese manufacturer and a subcontractor supplier of valsartan.

[5] The Plaintiffs and Class Members are persons who were prescribed valsartan by their physicians. The Plaintiffs sue the Defendant pharmaceutical companies, Teva and Sandoz, for manufacturing and distributing the contaminated medicine. The causes of action are: (a) negligence/product liability; (b) strict liability; (c) toxic battery; (d) breach of consumer protection laws;[5] (e) breach of the *Civil Code of Québec*;[6] (f) breach of the *Competition Act*;[7] and (g) unjust enrichment. A claim for breach of the *Trademarks Act*[8] was abandoned during the hearing of the certification motion.

[6] By way of remedies, the Plaintiffs and the Class Members seek: (a) the costs of medical services related to the recall ("medical bills"); (b) the costs of medical consulting and screening services ("medical monitoring"); (c) refunds for the amounts paid for the drug from 2012 to 2018; (d) the costs of the unused pills thrown away after the recall; (e) psychological harm damages; and (f) punitive damages.

[7] Conspicuously, the Plaintiffs and the Class Members make no claim for compensation for consumers who, after ingesting valsartan, were diagnosed with cancer at present or in the future. Bluntly, the Plaintiffs assert that this case is about compensation for increasing the risk of a cancer diagnosis and is not about compensation for suffering cancer now or in the future as a result of ingesting valsartan. In their factum the Plaintiffs repeatedly dwell on this feature of their proposed class. For example, they state:

> 9. Notably, the proposed class action is not intended to address specific causation for class members who have or will be diagnosed with cancer. [Plaintiffs' Factum, paragraph 9]
>
> 69. Although this case has some passing similarities to "side effect" cases […], in the sense that NDMA exposure is known to be associated with cancer, it is also distinguishable because fundamentally this is a contamination case. There is no reason for NDMA or NDEA to be present in valsartan. [Plaintiffs' Factum, paragraph 69]
>
> 141. […] Notably, this case is not about whether NDMA or NDEA caused the illness of a specific person (such as cancer). This case is about toxins causing molecular changes and mutations which had the effect of increasing the risk of cancer. The Plaintiffs do not intend for the Class Members to proceed to individual issue trials to prove specific causation of harm with the exception of the claim for psychological harm which does not require class members to establish causation of cancer. [Plaintiffs' Factum, paragraph 141]

[8] In this motion, the Plaintiffs seek to certify their action as a class action. The Defendants resist certification based on the arguments that none of the certification criteria are satisfied. The Defendants make many arguments, but the predominant arguments focus on the submission that the Plaintiffs have not satisfied the cause of action criterion because of doctrinal failures of pleading any legally viable causes of action and because of the absence of legally compensable

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[5] BC: *Business Practices and Protection Act*, SBC 2004, c. 2; AB: *Fair Trading Act*, RSA 2000, c. F-27; SK: *Consumer Protection and Business Practices Act,* SS 2014, c. C-30.2; MB: *Business Practices Act*, CCSM c. B120; ON: *Consumer Protection Act, 2002*, SO 2022, c. 30; QB: *Consumer Protection Act,* RSQ c P-40.1; PEI: *Business Practices Act*, RSPEI 1988, c. B-7; NL: *Consumer Protection and Business Practices Act*, SNL 2009, c. 31.2.
[6] CQLR c. C-1991.
[7] RSC 1985, C C-34.
[8] RSC 1985, c T-13.

harm. In addition to their other challenges to certification, the Defendants assert that in the immediate case, there are no legally viable causes of action for the fear of an increased risk of cancer and that the putative class members have no compensable losses for the fear of an increased risk of cancer.

[9] For the reasons that follow, I dismiss the Plaintiffs' certification motion.

[10] The baffling and ultimately fatal feature of the Plaintiffs' proposed class action is that putting aside the claims for compensation for psychological harm, which are not certifiable for a variety of reasons, without making a claim for and without establishing some basis in fact that NDMA or NDEA causes cancer, the Plaintiffs' action is for pure economic losses for an alleged increased risk of being diagnosed with cancer after ingesting NDMA or NDEA. Such a case is not certifiable. Upon analysis, the proposed class action is an uncertifiable class action for pure economic losses from a shoddy in quality but not a proven to be imminently dangerous product.

[11] The baffling and fatal feature of the Plaintiffs' proposed class action is that unlike a products liability class action that is about compensation for concrete injuries caused by the defective product, the Plaintiffs' proposed class action is about compensation for an apprehension of an abstraction (increased risk of diagnosis of cancer) when the normative risk of a Class Member being diagnosed with cancer in his or her lifetime is 50:50, regardless of whether the Class Member ingested valsartan. What the Defendant pharmaceutical companies allowed to happen in China at their supplier's manufacturing plant and the Defendants' failures to ensure the quality of their product was shameful, but the law provides remedies for concrete injuries not abstract or speculative ones.

## C. Parallel American Class Proceedings

[12] In the United States there are two putative class actions about contaminated valsartan. On February 14, 2019, approximately seventy-five valsartan related actions from twenty jurisdictions were consolidated and transferred to the District of New Jersey and assigned to Judge Kugler. The action in the United States has survived a motion to have it dismissed.[9]

## D. Procedural and Evidentiary Background

[13] On **July 9, 2018**, Sandoz and Teva and several other pharmaceutical companies voluntarily recalled valsartan from retailer distributors of the drug. Consumers were told to continue taking their valsartan unless advised to stop by their health care provider.

[14] On **July 13, 2018**, Ms. Palmer commenced the proposed class action by Notice of Action.

[15] Proposed co-Class Counsel are Charney Lawyers PC, an Ontario law firm, and Rice Harbut Elliott LLP, a British Columbia law firm.

[16] On **August 10, 2018**, Ms. Palmer delivered her Statement of Claim.

[17] On **August 17, 2018**, Teva voluntarily expanded its recall to include eight additional lots of valsartan.

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[9] *In Re: valsartan, Losartan and Irbesartan Products Liability Litigation*, 2021 U.S. Dist. LEXIS 5908 (D.N.J. Jan. 12, 2021).

[18] On **January 15, 2019**, the Plaintiffs delivered an Amended Statement of Claim.

[19] On **June 21, 2019,** the Plaintiffs delivered a Second Amended Statement of Claim.

[20] On **February 19, 2021**, the Plaintiffs delivered their Notice of Motion and Motion Record for certification (1,227 pages).

[21] On **February 22, 2021**, the Plaintiffs delivered another Notice of Motion and Motion Record for Certification (1,104 pages).

[22] In support of their motion for certification, the Plaintiffs relied on the following evidentiary record:

a. Affidavit dated January 28, 2021 of **Ken Aitchison** of Clarence-Rockland, Ontario. Mr. Aitchison is a Plaintiff. He was prescribed Sandoz valsartan for blood pressure.

b. Affidavit dated October 27, 2020 of **Dr. Neelanjan Bose** of Foster City, California, U.S.A. Dr. Bose is an analytical chemistry and chemical biology specialist with experience in method development and validation of small molecules, which includes chemical analysis of pharmaceuticals. He reviewed the test results from the testing of the valsartan that was delivered to Rice Harbut Elliott LLP and Charney Lawyers PC on July 29, 2019 and then delivered to Dr. Bose for analysis.

c. Affidavit dated February 17, 2021 of **Charlene Rogers Bourdon** of Cornwall, Prince Edward Island. Ms. Bourdon is a Plaintiff. She was prescribed Sandoz valsartan for blood pressure.

d. Affidavit dated February 17, 2021 of **Devra Charney**. Ms. Charney is an associate lawyer at Charney Lawyers, co-Class Counsel. She was not cross-examined.

e. Affidavit dated October 28, 2020 of **Dr. Andreas Groehn** of Alexandra, Virginia., U.S.A. Dr. Groehn is a PhD economist with experience conducting surveys to assess damages in commercial litigation. He provides services through East Bay Dispute Advisory, a subsidiary of Berkeley Research Group LLC. He was not cross-examined.

f. Affidavit dated February 17, 2021 of **Bradley Halayka** of Birch Hills, Saskatchewan. Mr. Halayka is a Plaintiff. He was prescribed Sandoz valsartan for high blood pressure. He was not cross-examined.

g. Affidavit dated January 27, 2021 of **Murray Halbert** of Winnipeg, Manitoba. Mr. Halbert is a Plaintiff. He was prescribed Sanis valsartan for high blood pressure.

h. Affidavits dated November 10, 2020 and February 22, 2022 of **Dr. Sam Kacew** of Ottawa, Ontario. Dr. Kacew is a Professor of Pharmacology at the University of Ottawa and Associate Director of Toxicology at the McLaughlin Centre for Population Health Risk Assessment at the University of Ottawa.

i. Affidavits dated October 30, 2020, March 4, 2022 and April 5, 2022 of **Dr. Sid Katz** of Vancouver, B.C. Dr. Katz is a pharmacology expert with experience in toxicology.

j. Affidavit dated October 5, 2020 of **Ying Lee**. Mr. Lee is a paralegal of the law firm Rice Harbut Elliott LLP of Vancouver B.C., co-Class Counsel. He was not cross-examined.

k. Affidavits dated February 19, 2019 and May 6, 2019 of **Cisy Mahendralingham**. Ms. Mahendralingham is a law clerk at Charney Lawyers, co-Class Counsel. She was not cross-examined.

l. Affidavit dated October 27, 2020 of **Dr. Roy O'Shaughnessy** of Vancouver, B.C. Dr. O'Shaughnessy is a medical practitioner with a specialty in psychiatry. He is a clinical professor in the Department of Psychiatry at University of British Columbia. He practises forensic psychiatry, which is a law and psychiatry discipline.

m. Affidavit dated February 4, 2021 of **Gloria Palmer** of Ameliasburgh, Ontario. Ms. Palmer is a Plaintiff. She was prescribed Sandoz valsartan for high blood pressure.

n. Affidavit dated May 24, 2022 of **Marie-Eve Pellicelli** of Québec City, Québec. Ms. Pellicelli is a Plaintiff. She was prescribed Pro Doc Limitée valsartan for high blood pressure. She was not cross-examined.

o. Affidavit dated January 26, 2021 of **Diane Perehudoff** of Nelson, British Columbia. Ms. Perehudoff is a Plaintiff. She was prescribed Sanis valsartan for high blood pressure.

p. Affidavit dated January 27, 2021 of **Dianne Tiedje** of Edmonton, Alberta. Ms. Tiedje is a Plaintiff. She was prescribed Sandoz valsartan for high blood pressure.

q. Affidavit dated October 20, 2020 of **May Ventura** of Vancouver, British Columbia Ms. Ventura was a Plaintiff but withdrew. She was prescribed Sandoz valsartan.

r. Affidavit dated February 5, 2021 of **Jo-Anne Wills.** of Aurora, Ontario. Ms. Wills is a Plaintiff. She was prescribed Sandoz valsartan for high blood pressure.

[23] In response to the Plaintiffs' certification motion, the Defendant Teva Canada Limited relied on the following evidentiary record:

a. Affidavit dated January 11, 2022 of **Reni Caccamo** of Toronto, Ontario. Mr. Caccamo is the Senior Director, Market Planning, Sales Operations for Teva Canada Limited.

b. Affidavit dated December 23, 2021 of **Dr. George Johnson** of Swansea Wales in the United Kingdom. Dr. Johnson is an Associate Professor at the Swansea University with a primary appointment in the Department of Genetic Toxicology. Part of his teaching curriculum is genetic toxicology including mutagenic impurities, cancer biology and DNA repair. He is a member of the Steering Committee of the Health and Environmental Sciences Institute, Genetic Toxicology Technical Committee. He is a member of the U.K. Government's Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment. Dr. Johnson was not cross-examined.

[24] In response to the Plaintiffs' Certification the Defendants Sandoz Canada Inc., Pro Doc Limitée, Sanis Health Inc. and Sivem Pharmaceuticals ULC relied on the following evidentiary record:

a. Affidavit dated March 10, 2022 of **Martin Fournier** of LaPrairie, Québec. Mr. Fournier is the Vice President, Finance and Chief Financial Officer of Sandoz Canada Inc.

b. Affidavit dated March 14, 2022 of **Ramzi Koleilat** of Laval, Québec. Mr. Koleilat

is the Sr. Director Strategic Procurement, of Sivem Pharmaceuticals ULC.

c. Affidavit dated March 14, 2022 of **Robert Labrosse** of Pierrefonds, Québec. Mr. Labrosse is the President of Pro Doc Limitée.

d. Affidavits dated December 23, 2021 and April 6, 2022 of **Dr. Raj Padwal** of Edmonton, Alberta. Dr. Padwal is a Professor of Medicine in the Department of Medicine, Division of General Internal Medicine, at the University of Alberta. Dr. Padwal was not cross-examined.

e. Affidavit dated December 23, 2021 of the **Dr. Dennis J. Paustenbach** of Jackson, Wyoming, U.S.A., Dr. Paustenbach is the President and Senior Consultant at Paustenbach and Associates, a scientific consulting firm. He has a B.S in chemical engineering from the Rose-Hulman Institute of Technology (Terre Haute, Indiana), an M.S. in industrial hygiene and toxicology from the University of Michigan (Ann Arbour) and a PhD in toxicology from Purdue University. Dr. Paustenbach was not cross-examined.

f. Affidavit dated March 10, 2022 of **Christopher Potter** of Toronto, Ontario. Mr. Potter is the Senior Vice President, Healthcare Business, of Shoppers Drug Mart Inc. and has been involved in the operations of SDMI and Sanis Health Inc. as they relate to valsartan products.

[25] On **January 12, 2022**, Teva delivered its Responding Motion Record (86 pages).

[26] On **March 11, 2022**, the Plaintiffs delivered a Reply Motion Record (42 pages).

[27] On **March 14, 2022**, the Defendants Sandoz Canada Inc., Pro Doc Limitée, Sanis Health Inc. and Sivem Pharmaceuticals ULC delivered their Responding Motion Record (350 pages).

[28] On **April 6, 2022**, the Defendants Sandoz Canada Inc., Pro Doc Limitée, Sanis Health Inc. and Sivem Pharmaceuticals ULC delivered a Supplementary Motion Record (15 pages).

[29] On **April 8, 2022**, Mr. Aitchison, Ms. Bourdon, Mr. Halbert, and Ms. Ventura were cross-examined.

[30] On **April 12, 2022**, Ms. Palmer, Ms. Perehudoff, Ms. Tiedje, and Ms. Will were cross-examined.

[31] On **April 13, 2022**, Mr. Caccamo, Mr. Fournier, Mr. Koleilat, Mr. Labrosse, and Mr. Potter were cross-examined.

[32] On **April 14, 2022**, Dr. Bose, Dr. Kacew, and Dr. Katz were cross-examined.

[33] On **April 20, 2022**, Dr. O'Shaughnessy was cross-examined.

[34] On **May 6, 2022**, the Plaintiffs delivered their Factum (85 pages).

[35] On **May 24, 2022**, the Plaintiffs delivered the Third Amended Statement of Claim.

[36] On **June 10, 2022**, Sandoz (85 pages) and Teva (35 pages) respectively delivered their Responding Factums. Sandoz's authorities casebook was 3,277 pages; Teva's authorities casebook was 782 pages.

[37] On **June 17, 2022**, the Plaintiffs delivered a Supplementary Motion Record (204 pages). (The transcript brief for the certification motion was 855 pages.)

[38] On **June 20, 2022**, the Plaintiffs delivered their Reply Factum (78 pages). (The authorities

brief was a hypertexted index of 168 cases.)

[39] On **June 24, 2022**, Teva delivered a Sur-Reply Factum (8 pages).

[40] The Plaintiffs propose the following revised class definition:

> All persons in Canada who purchased or ingested one or more of the valsartan products manufactured and/or distributed by the defendants identified by the DINs listed on the Health Canada Recall List dated November 28, 2018 (the "Class Members") between January 1, 2012 and December 1, 2018 (the "Class Period");

[41] The Plaintiffs' originally proposed class definition was:

> *Class Definition*
>
> [A]ll persons in Canada who purchased or ingested one or more of the valsartan products identified by Health Canada in the Recall List dated July 9, 2018 or in any future such recall lists.

[42] The Plaintiffs propose the common issues set out in Schedule "A" to these Reasons for Decision.

## E. Class Size

[43] To date, 3,375 putative Class Members have registered with Plaintiffs' counsel.

[44] A study on the recall as it affected Albertans found that, at the time of the recall, 34,726 Albertans were taking valsartan. The Alberta study found that the mean age of individuals taking valsartan was 67, with three quarters of them having prescriptions filled for a period of 90 days or longer.

[45] Based on extrapolations from the Alberta study, Class Counsel estimates that at the time of the recall more than 315,000 Canadians were taking valsartan on at least a daily basis.

## F. Facts

### 1. The Defendants

[46] **Pro Doc Limitée** ("Pro Doc") is a pharmaceutical company with its head office in Laval, Québec. It manufactured and distributed Pro Doc-valsartan. (Pro Doc, Sandoz, Sanis, and Sivem are collectively "Sandoz").

[47] **Sandoz Canada Inc.** ("Sandoz") is a pharmaceutical company with its head office in Boucherville, Ontario. It manufactured and distributed Sandoz-valsartan. (Sandoz, Pro Doc, Sanis, and Sivem are collectively "Sandoz").

[48] **Sanis Health Inc.** ("Sanis") is a pharmaceutical company with its head office in Brampton, Ontario. It manufactured and distributed Sanis-valsartan. (Sanis, Sandoz, Pro Doc, and Sivem are collectively "Sandoz").

[49] **Sivem Pharmaceuticals ULC** ("Sivem") is a pharmaceutical company with its head office in St.-Laurent, Québec. It manufactured and distributed Sivem-valsartan. (Sivem, Sandoz, Pro Doc, and Sanis, are collectively "Sandoz").

[50] **Teva Canada Limited** ("Teva") is a pharmaceutical company with its head office in

Toronto, Ontario. In 2016, Teva acquired **Actavis Pharma Company**, which is the entity that Health Canada identifies as the market authorization holder for the Actavis products. Teva manufactured and distributed Teva-valsartan and Act-valsartan.

[51] Each of the Defendants retained **Zhejiang Huahai Pharmaceuticals** ("ZHP"), a Chinese pharmaceutical company to manufacture, export, and supply the active ingredients for valsartan.

[52] The Defendants held themselves out as manufacturers of high-quality generic medications, Teva represented that "[our] dedication to quality in everything we do is uncompromising." Sandoz represented that "[w]e offer a broad line of high-quality generic, biosimilar consumer and specialty products."

[53] Teva's declarations on its webpage are perhaps the most self-laudatory, but the webpage is indicative of the quality control assurances of all the Defendant generic drug manufacturers. Teva's web page stated:

> Our state-of-the-art manufacturing facilities feature the most advanced testing equipment to guarantee the quality of our products. Equipment is tested and certified, and every manufacturing process is validated. All supplier procedures are strictly supervised to ensure that only the highest grade materials are used in our products. Teva's impeccable adherence to Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) is recognized by FDA approval of 26 of our plants, and EMA approval of 31 of our plants. Moreover, each of our pharmaceutical manufacturing facilities is inspected and approved by at least two regulatory authorities worldwide.

[54] The Plaintiffs plead that the Defendant pharmaceutical companies represented that the valsartan Drugs were: (a) of high quality; (b) free of defects, including being free of any dangerous contaminants; and (c) fit for human consumption. The Plaintiffs plead that these representations were false, misleading, deceptive and an unfair practice under the consumer protection because: (a) the valsartan was not safe or free from defects; (b) it was not of a high quality; and (c) it contained a contaminant that can cause, materially contribute, and/or materially increase the risks of contracting cancer, liver disease, and other health conditions.

[55] The Plaintiffs plead for the Class Members and the individual Plaintiffs deposed that but for the Defendants' representations, they and the putative Class Members would not have purchased or ingested the Defendants' valsartan.

## 2. The Manufacture and Distribution of valsartan

[56] Novartis, a pharmaceutical company, developed a drug containing the active pharmaceutical ingredient known as valsartan.

[57] Valsartan is an antihypertensive drug belonging to the angiotensin receptor blocker class for the treatment of high blood pressure and the prevention of heart attacks. Typical dosage of valsartan ranges from 40 mg to 320 mg per day.

[58] Valsartan was first approved for distribution in Canada in 1997, and it was marketed under the brand name Diovan®. Since about 2011, valsartan has been "off patent", and generic pharmaceutical companies began to manufacture and market drugs containing valsartan.

[59] The Defendants are manufacturers of bioequivalent generic drugs. Pursuant to the *Food and Drug Regulation*, they were under a duty to disclose a "list of the ingredients of the new drug, stated quantitatively, and the specifications for each of those ingredients". They were required to

provide a product that was "unadulterated" and "bioequivalent with the Canadian reference product." If a generic drug contains non-medicinal ingredients that differ from the reference product, the manufacturer must demonstrate to Health Canada that the non-medicinal ingredients have not changed the quality, safety, or effectiveness of the generic drug. In the immediate case, the Defendants filed product monographs that included a list of all the active and non-active ingredients in their products.

[60] Manufacturers of generic medication are required by statute in the United States and in Canada to ensure that their products are: (a) absent of significant differences (bioequivalent) to their name-brand counterpart;[10] and (b) manufactured in accordance with Good Manufacturing Practices ("GMP"); and (c) free of contamination.[11] GMPs are internationally accepted standards to ensure that drugs are manufactured, tested, stored, and distributed in a way that meets safety and quality standards.

[61] Sandoz and Teva were supplied with the active pharmaceutical ingredient ("API") of valsartan by Zhejiang Huahai Pharmaceuticals ("ZHP") a Chinese drug manufacturer and supplier.

[62] Commencing in 2012, ZHP changed its manufacturing process. ZHP had a history of deviations from GMP standards.

[63] As described in more detail below, the valsartan supplied by ZHP and sold by Sandoz and Teva contained the nitrosamines NDMA and NDEA.

[64] The Plaintiffs plead that if the Defendants had complied with the GMP regulations designed to ensure quality, safety, and effectiveness, they likely would have discovered the impurities and contaminants in the valsartan as of 2012, when the contaminants were likely first introduced into the valsartan because it was at that time that ZHP changed its manufacturing processes to reduce the costs of production.

## 3. The Centerpiece Epidemiological Issues

[65] Etiology is the study of cause or causes, and epidemiology is the branch of medical science that studies the etiology of diseases and that identifies risk factors for disease or medical conditions. Epidemiology focuses on "general causation;" i.e., whether or not an agent has the capacity to cause a disease or medical condition rather than on "specific causation;" *i.e.,* whether or not an agent did cause a disease or medical condition to be suffered by a specific person.

[66] The furiously contentious evidentiary centerpieces of this certification motion are twofold: (a) whether NDMA and NDEA are a cause of cancer in humans; and (b) whether the exposure to NDMA or NDEA in the contaminated valsartan increases the risk of being diagnosed with cancer.

[67] The Plaintiffs' position is that there was some basis in fact for both centerpiece propositions. The Defendants' position is that there was no basis in fact for either proposition, and therefore the Plaintiffs' action is not certifiable.

[68] It is highly important to keep in mind that whether NDMA and NDEA cause cancer in humans and whether exposure to NDMA and NDEA in the contaminated valsartan increases the risk of being diagnosed with cancer are related but different concepts. It is highly important to

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[10] *Food and Drugs Regulations,* C.R.C., c. 870, s.08.002.1(1)(a) and (b).
[11] *Food and Drugs Act,* R.S.C., 1985, c. F-27, ss. 8, 9.

keep in mind that both concepts are studied and evaluated using statistical techniques and by the scientific analyses of experiments and studies of animals and humans.

[69] It is highly important to keep in mind that if the statistics from the studies and experiments indicate that exposure to NDMA and NDEA increases the experience of cancer, that is a necessary but not a sufficient basis for concluding that NDMA and NDEA are carcinogens in humans. Statistics indicating an increase in the experience of cancer reveal only that there may be a relationship between NDMA and NDEA and cancer. Whether that relationship is incidental, coincidental, catalytical, associative, or causative remains to be determined. It is an axiom of epidemiology that statistical association does not equate to proof of a causative relationship. Thus, both the Plaintiffs and the Defendants and their respective experts agreed that from an epidemiological perspective, a statistical association between NDMA and NDEA is not proof of causation.

[70] To foreshadow my conclusion on these two centerpiece evidentiary controversies, my review of the evidence described below is that at this moment in scientific time, while there is some basis in fact for concluding that exposure to NDMA and NDEA increases the risk of being diagnosed with cancer, there is no basis in fact for concluding that NDMA and NDEA cause cancer.

[71] The current state of scientific knowledge is that the measure of the increased risk to humans from exposure to NDMA and NDEA is very small having regard to the already existing very high risk of human beings experiencing cancer of a lifetime. The current state of scientific knowledge is that the relationship between NDMA and NDEA and cancer remains to be determined but the relationship is worthy of being studied further, and in the meantime, prudence dictates that exposure to NDMA and NDEA be minimized.

## 4. Nitrosamines, NDMA, and NDEA

[72] Turning then to the evidence about the nature of N-nitrosodimethylamine ("NDMA") and N-nitrosodiethylamine ("NDEA"), they are chemical compounds known as nitrosamines.

[73] Nitrosamine exposure can occur through ingestion, inhalation, and absorption through skin. Nitrosamines are also formed endogenously within the human body's digestive system, following ingestion of foods that contain nitrites or nitrates.

[74] NDMA and NDEA are found in packaged/preserved meats and cheeses, preserved or canned fish, preserved vegetables, and malt-containing alcohols such as beer and whiskey. NDMA and NDEA are also found in drinking water and in the air.

[75] At any given time, an average person may have varying quantities of NDMA in her or his system based on lifestyle choices, diet, geographical location, occupation, and endogenous production. NDMA or NDEA do not remain in the body, and they are eliminated in the feces or urine within 24-48 hours.

[76] Nitrosamines have been shown to produce liver damage, hemorrhagic lung lesions, convulsions, and comas in rats. Acute, which is to say extraordinarily high exposure to NDMA may cause liver damage in humans.

[77] Dr. Katz explained the process through which NDMA and NDEA could cause harm to humans:

> Nitrosamines such as NDMA and NDEA produce various adverse biological effects, including induction of tumours, following metabolic conversion (breakdown) by liver enzymes into reactive intermediates. This process releases an active carbonium ion which then seeks out cellular components such as DNA, RNA and Proteins. The fact that DNA and RNA form part of the gene classifies these chemicals as genotoxins which can produce carcinogenesis. The breakdown and conversion of these compounds in the body produces even more harmful chemicals than those ingested; this process is considered as a critical step in the cancer-causing activity of the nitrosamines.

[78] Dr. Katz's evidence satisfies a necessary first step in the process of determining whether NDMA and NDEA can cause cancer in humans. By itself, however, his evidence is not some basis in fact for the proposition that NDMA and NDEA are carcinogens in humans. This part of his evidence only goes so far as showing that there is a scientific basis or theory for how or why they might be carcinogens. That theoretical underpinning, however, is insufficient by itself to draw the conclusion that there is some basis in fact that NDMA and NDEA are cancer carcinogens in humans.

### 5. Is There Some Basis in Fact that NDMA and NDEA are a Cause of Cancer in Humans?

[79] The FDA called NDMA and NDEA a "genotoxic impurity". Based on extrapolation from results of animal studies, Health Canada, the International Agency for Research on Cancer, the US Agency for Toxic Substances and Disease Registration, and the US National Toxicology Program classify NDMA and NDEA as "chemicals belonging to the probable category of carcinogens where there is sufficient evidence of a carcinogenic effect, regardless of the dose."

[80] It may be noted that none of these classifications are definitive. Although the carcinogenicity of NDMA and NDEA in humans has been scientifically examined for decades, no scientific or regulatory body has definitively classified NDMA or NDEA as a carcinogen for human beings. Conversely, no scientific or regulatory body has definitively classified NDMA or NDEA as a non-carcinogen for human beings. Based on extrapolation from results of animal studies, the International Agency for Research on Cancer ("IARC") and Health Canada prudently and cautiously classify NDMA and NDEA as "probable carcinogens".

[81] Dr. Johnson, who is a toxicologist, testified for the certification hearing for the Defendants. Dr. Johnson's opinion was that the available scientific evidence and literature do not support a causal association between exposure to the amount of NDMA or NDEA found in the Defendants' valsartan and cancer risk in humans. I shall discuss Dr. Johnson's opinion further below.

[82] Dr. Padwal, who is an epidemiologist, testified for the certification hearing for the Defendants. He was not cross-examined. It was Dr. Padwal's opinion that there is no strong scientific evidence to support the proposition that exposure to NDMA or NDEA can cause cancer, or materially increase the risk of contracting cancer, in humans. He deposed that there is no direct scientific evidence establishing that valsartan that is potentially contaminated with NDMA or NDEA is a cause of cancer in humans. It was his opinion that the best scientific evidence available is that there is no statistically significant association between potentially contaminated valsartan products and overall cancer risk. He deposed that the best available evidence is a cohort study in Denmark (5,150 valsartan users over a 4.6 year median follow up) and a cohort study in Germany (780,871 valsartan users over a 3.1 year mean follow-up period) and these studies do not prove general causation.

[83] It is the Plaintiffs' internally inconsistent and contradictory position that: (a) there is some basis in fact that NDMA and NDEA cause cancer, although (b) it is presently undetermined whether NDMA or NDEA can cause cancer in humans, but with longer follow up periods for the studies, there will be sufficient evidence to conduct a meta-analysis to determine whether there is an association between NDMA or NDEA and cancer in humans.

[84] Thus, Dr. Katz in his reply report, noted that: "the issue of carcinogenicity of NDMA exposure via valsartan and other medications is being investigated on an ongoing basis" and he "would expect that […] a meta-analysis of studies with greater than a seven-year latency period should yield more definitive results."

[85] Thus, while Dr. Katz conceded that a causative relationship remains unproven, he nevertheless testified that NDMA is considered to be a human carcinogen and has been implicated in the induction of stomach, liver, and pancreatic cancers. He said there is considerable evidence that NDMA is the etiological agent for bladder cancer associated with schistosomiasis, a parasitic infection.

[86] Pausing here, it is necessary to emphasize that the Plaintiffs simultaneously submit that there is some basis in fact for NDMA or NDEA being carcinogens while conceding that there is at present no basis in fact that NDMA or NDEA can cause cancer. It is precisely because of this indeterminacy and illogic that the Plaintiffs construct their proposed class action based just on the evidence that there is some basis in fact that exposure to NDMA or NDEA increases the risk of being diagnosed with cancer.

[87] Therefore, based on my review of the evidence proffered for this certification motion, on the first issue of whether valsartan causes cancer, I find that there is no basis in fact to come to that conclusion.

[88] This conclusion about no basis in fact for a causal relationship between valsartan and cancer is not based on favouring the Defendants' experts over the Plaintiffs' and my conclusion is not meant to and does not resolve any battle of the experts. On the certification motion, both parties agreed that from an epidemiological perspective, an association - and in this case, the contemporary statistical evidence was modest in favour of a statistically significant relationship between valsartan and cancer - does not establish general causation. I repeat my legal conclusion is that at this moment in scientific time, there is no basis in fact for concluding that NDMA and NDEA cause cancer.

### 6. Is There Some Basis in Fact that Exposure to NDMA or NDEA Increases the Risk of Being Diagnosed with Cancer?

[89] Moving on and separating or isolating the centerpiece issue of whether ingesting valsartan increases the risk of being diagnosed with cancer, from the issue of whether valsartan causes cancer, the Plaintiffs' position is consistent. Their consistent position is that there is some basis in fact for the proposition that exposure to the Defendants' valsartan contaminated with NDMA or NDEA increases the likelihood of being diagnosed with cancer.

[90] In understanding the parties competing evidence on this issue, it is helpful to know that that nanogram (ng) is a unit of mass derived of grams and kilograms (kg) and that one ng equals 0.000000001 ($1.0 \times 10^{-9}$) grams, or one billionth of a gram and that "ppm" means "parts per million."

[91] In refocusing their proposed class action on increased risk and not on a causative relationship between the contaminated valsartan and cancer, the Plaintiffs relied on the fact that the amount of contamination in the valsartan exceeded the regulators advice about the acceptable daily intake ("ACI") of NDMA and NDEA.

[92] The FDA set the ACI of NDMA at 96 ng per day and NDEA at 26.5 ng per day. Health Canada has not set its own acceptable daily intake levels, but its public statements reference the FDA levels. Based on its extrapolation from results of animal studies, Health Canada and the FDA have advised that individuals exposed to NDMA and NDEA in pharmaceuticals at or below the recommended ADI levels each and every day for 70 years are not expected to have any increased risk of cancer.

[93] Health Canada's study on the alleged theoretical increased risk from valsartan containing NDMA found that the theoretical additional cancer risk in a worst case scenario, range between one additional cancer case in every 11,600 persons to one additional cancer case in every 93,400 persons (i.e. a theoretical increased risk of cancer between 0.0086% and 0.0011%) which, as Health Canada points out, must be considered in the context of the existing lifetime risk of a 50:50 (50%) chance of developing cancer.

[94] In contrast to the Plaintiffs' experts, it was Dr. Johnson's opinion that the regulators use of ACI as a measure of the risk of cancer was not supported by the scientific evidence and ignored that the underlying DNA mechanisms of humans that can re pair NDMA and NDEA damage.

[95] It was Dr. Johnson's opinion that there is no increased risk of being diagnosed with cancer in humans based on the regulators' measurements using the ACI measure. It was his opinion that the available scientific evidence and literature do not support a causal association between exposure to low doses of NDMA or NDEA in valsartan and cancer risk in humans. Instead of calculating an ACI, Dr. Johnson calculated a Permitted Daily Exposure ("PDE"), and it was his opinion that a 50kg patient exposed to NDMA below 6,200 ng and a 100kg patient exposed to NDMA below 12,400 ng do not have an increased risk of cancer.

[96] Dr. Paustenbach, one of the Defendants' toxicology experts, stated in his report, that estimating the quantitative risk to humans from animal data is problematic because the data is unreliable and because humans have DNA repair mechanisms that don't exist in animals. He testified that the ADI is artificial, not based on a scientific methodology, and is not predicative of the human cancer risk.

[97] As was noted by Dr. Paustenbach, the Defendants' toxicology expert, every day through food and beverage consumption, humans are exposed to NDMA and NDEA far above the regulators' ACI. Moreover, every day NDMA and NDEA can be compounded in the stomach (endogenous production) in amounts that enormously exceed the ACI. (NDMA has been found to be produced endogenously in the stomach in amounts ranging from 22,900 ng of NDMA per day to 1,260,000 ng of NDMA per day.) It may also be noted that if Canadians followed the ACI recommendation for NDMA (96 ng) and NDEA (26.5 ng), they would forgo eating: (a) fish, which was a 315 ng exposure to NDMA; (b) cooked bacon, which has a 774 ng exposure to NDMA; (c) meat, which has 1,290 ng exposure to NDMA; and (d) cheese, which has a 3,400 ng exposure to NDMA.

[98] Pausing here, while I do not ignore it, I do not find the evidence and the analysis of the evidence of ADI determinative or particularly helpful in determining whether exposure to NDMA

or NDEA increases the likelihood of a cancer diagnosis. However, that does not end the analysis because there was helpful and probative evidence about whether the exposure to the contaminated valsartan increased the risk of a cancer diagnosis.

[99] While conceding that a causative relationship is not known to exist, the Plaintiffs relied on a variety of studies to establish an increased risk of cancer diagnosis from exposure to NDMA and NDEA. Visualize:

a. Hidajat *et. al* followed 36,000 subjects who worked in the rubber industry and were exposed to NDMA through rubber dust and fumes. Hidajat *et. al* found a statistically higher risk of cancer including prostate, esophagus, stomach, and pancreas cancers.

b. Larsson *et. al* followed 61,000 Swedish subjects for 18 years. Larsson *et. al* found that the high intake of NDMA contained in processed meats was associated with an almost two-fold increase in the level of stomach cancer following adjustment for potential confounding variables (age, body mass index, vegetable intake).

c. Knekt *et. al*. found that subjects with a high intake of NDMA have a higher risk of colorectal cancer compared to those exposed to lower doses.

d. Canadian studies conducted by Zhu *et. al*. reported that NDMA increases the risk of gastrointestinal cancer in humans.

e. In the German study, (also mentioned by Dr. Padwal), the results indicated that although there was no association found between exposure to NDMA-contaminated valsartan and the overall risk of cancer, there was a significant association found between potentially NDMA-contaminated valsartan and liver cancer.

f. Pottegard *et. al.* in a study of valsartan contaminated with NDMA, concluded that increases in risk were observed for colorectal cancer and for uterine cancer but that uncertainty persists about single cancer outcomes, and studies with longer follow-up are needed to assess long term cancer risk.

g. Gomm *et al* in a study of valsartan contaminated with NDMA detected a small, yet statistically significant increase in the risk of liver cancer and monitoring and studies with longer follow-up were needed.

h. Based on ingesting valsartan for a three-year period, Health Canada calculated the risk to affected individuals of developing cancer as up to one additional case per 11,600 people. The FDA calculated it as one additional case per 8,000 people. Dr. Katz opined that this is considered to be a high risk. Dr. Kacew described it as a medically significant risk.

[100] In addition to the evidence from scientific studies, some of them directed precisely at NDMA and NDEA in valsartan, there was evidence from the immediate case about linking contaminated valsartan to a diagnosis of cancer.

[101] Dr. Kacew, who testified for the Plaintiffs, was asked based on the data from Emery Pharma laboratories (discussed below) and based on his own expertise, whether consumers of the Defendants' valsartan are at risk of developing cancer. His answer is set out below:

> In dealing with cancer, it is important to bear in mind that the designation of a chemical as a probable carcinogen reflects the fact that the amount of the carcinogen within the pill is not a key factor but

> rather the knowledge that the chemical induces carcinogenesis and that over time the presence of the chemical will increase the risk of cancer development.
>
> The consumers of valsartan consumed NDMA in the range of 540 to 32,457 ng per tablet. To place this in perspective, the Health Canada 60 ppm or 60,000 ng inducing increased cancer risk in 1 in 11,600 occurs for patients ingesting valsartan (320 mg) containing 60,000ng daily for a 3 year period over a lifetime. For patients taking the lowest valsartan dose (40mg) containing 60,000ng daily for a 3 year period, the increased cancer risk is 1 in 93,400 over a lifetime.
>
> Taking the Health Canada risk assessment 60 ppm (60,000 ng) value as the standard, the concentrations of NDMA are lower in Emery Pharmacy lab tested pills (7), however the risk of cancer induction is still increased in patients ingesting these pills over a lifetime based upon our knowledge that NDMA and NDEA are probable carcinogens. It is recognized that even in the absence of epidemiologic data sufficient evidence exists that NDMA and NDEA for practical purposes should be regarded as if these chemicals are carcinogenic to humans.

[102] In addition to their analysis of these case studies, on the matter of risk assessment, the Plaintiffs and their experts rely on the statements of Health Canada and of the FDA. In particular, they rely on a document published on April 9, 2019 entitled "Transcript: Angiotensin II Receptor Blockers (ARBs) – A Message for Patients" which was part of the FDA's announcements "Recalls of Angiotensin II Receptor Blockers (ARBs) including valsartan, Losartan and Irbesartan" which document stated:

> Hello. I'm Janet Woodcock, Director of the Center for Drug Evaluation and Research at the FDA. I'd like to talk to you about the ongoing recall of drugs called ARBs. You may know them as valsartan, Losartan, or Irbesartan, or perhaps you just call them "my blood pressure medicine" or "my heart medicine."
>
> For over 35 years, ARBs have been helping people who have heart conditions, high blood pressure, or may be at risk of a stroke or heart attack. These medicines help control the conditions, and they don't have a lot of terrible side effects. […]
>
> In July, the FDA learned that some of these ARBs may contain chemicals known as nitrosamines. These chemicals can cause cancer when taken for long periods of time, even in relatively small amounts. You may have heard of the chemical names like NDEA or NDMA in connection with these ARBs. These chemicals are forms of nitrosamines. As soon as the FDA discovered that some ARBs contained nitrosamines, we moved quickly to remove them from the market. We know from all the calls we've received that people are worried that they might get cancer from these drugs. So, I want to talk to you about that risk for a moment.
>
> The FDA calculated that if you took the very highest dose of one of the affected medicines over four years, and you took the medicine that was the most contaminated, the risk is an additional one case in 8,000 people. To put this in context, currently one out of every three people in the U.S. will experience cancer in their lifetimes. Here's the reality for all of us.
>
> We're exposed to these nitrosamines every day in small amounts in our food, our water, and our soil. For example, low levels of nitrosamines are present in smoked foods like bacon and grilled and processed meats. They also occur naturally in fresh vegetables and water.
>
> The risk estimate is a worst-case scenario, and in fact no one would have been exposed to that much nitrosamine from ARBs, because most batches of the drugs contained much lower levels. Nitrosamines are allowed in our food and water supply in small amounts, and we seldom give it much thought. But, they shouldn't be in our drug supply, and the FDA is going to make sure that they are removed completely from any drug that you might take.

> There have been nearly 40 recalls of ARBs since last July. This is happening as the FDA and companies continue to test medicines to make sure none of these medicines contain the nitrosamines. What can you do to be safe? Well, first, don't stop taking your medicine! The risk of exposure to cancer is so much lower than your risk of a heart-related or other problem if you would stop your medicine.
>
> […]

[103] Based on my review of all this evidence on the issue of whether ingesting valsartan increases the risk of being diagnosed with cancer, I reach the following conclusion. Although the standard of proof would be different at a common issues trial, based on the evidence on this certification motion, I conclude that as a general matter, there is some basis in fact for the proposition that the exposure to NDMA and NDEA in the Defendants' contaminated valsartan very modestly increases the risk of being diagnosed with cancer.

## 7. The Recall and the Advice of Health Canada

[104] In **2016,** inspectors from the United States' Food and Drug Administration ("FDA") inspected ZHP's manufacturing plant. The FDA identified violations of GMPs which it described in its Inspectional Observations (Form FDA 483). The FDA identified numerous failures, including failures to follow quality control procedures to ensure drug purity. The inspections continued, and in **July and August 2018**, the inspector's reports, among other things, found that ZHP had not adequately evaluated the effect of its changed manufacturing process.

[105] In the **summer of 2018**, Sandoz and Teva (which includes Actavis) recognized that its valsartan did not comply with the requirements of the American *Food and Drugs Act*. On **July 9, 2018**, Sandoz and Teva voluntarily recalled valsartan because it had been discovered that the active pharmaceutical ingredient of the drug supplied by Zhejiang Huahai Pharmaceuticals ("ZHP") might contain NDMA. The Recall was later expanded after it was determined that the valsartan supplied by ZHP might also contain NDEA. Not all Teva and Actavis valsartan products were recalled. The recalls were to retailers and applied only to certain lots of certain valsartan products.

[106] On **July 9, 2018**, Health Canada issued a public advisory that the Defendants were recalling specified lots of drugs containing valsartan because a contaminant had been found. The Health Canada advisory stated:

> **Public advisory**
>
> **Several drugs containing valsartan being recalled due to contamination with a potential carcinogen**
>
> *Issue*
>
> Several drugs containing the ingredient valsartan are being recalled by their manufacturers. An impurity, N-nitrosodimethylamine (NDMA), was found in the valsartan used in these products. The valsartan was supplied by Zhejiang Huahai Pharmaceuticals. NDMA is a potential human carcinogen, which means that it could cause cancer with long-term exposure. Five companies have affected products, which are being recalled (identified in table below).
>
> Drugs containing valsartan are used to treat patients with high blood pressure to help prevent heart attacks and stroke. These drugs are also used in patients who have had heart failure or a recent heart attack.

*What you should do*

- Keep taking your medicine if it contains valsartan unless you have been told to stop by your doctor or pharmacist.
- If you are taking any medication containing valsartan, speak to your pharmacist who can tell you if your medicine is being recalled.
- If you have been using an affected product, contact your health care practitioner as soon as possible to discuss your treatment options.
- If you are in a clinical trial with a product containing valsartan and have any questions, speak to the doctor treating you in the trial.
- Report side effects (adverse events) to health products to Health Canada by […]
- Report complaints about health products to Health Canada by […].

*Who is affected*

Consumers who use any valsartan products in the table below.

[…]

[107] On **August 18, 2018,** Health Canada issued another advisory stating that as a precautionary measure, Teva Canada was expanding its voluntary recall to include eight additional lots of valsartan products because they might contain NDMA. The advisory stated:

> OTTAWA – Health Canada is advising Canadians that, as a precautionary measure, Teva Canada is expanding its voluntary recall to include eight additional lots of valsartan products in Canada because they may contain an impurity, N-nitrosodimethylamine (NDMA).
>
> valsartan is used to treat high blood pressure and heart failure.
>
> This latest action is further to an initial recall of certain valsartan products because of the presence of NDMA in the active ingredient (valsartan). All of the recalled products use a valsartan ingredient manufactured by Zhejiang Huahai Pharmaceuticals in China.
>
> **Products containing the valsartan ingredient from Zhejiang Huahai Pharmaceuticals**
>
> Health Canada is reviewing the long-term potential health impacts of the NDMA impurity on patients. NDMA is classified as a probable human carcinogen based primarily on animal studies, which means that exposure above acceptable levels over the long term could increase the risk of cancer. The review, which will be completed in the coming weeks, will include an assessment of how much NDMA patients may have been exposed to and for how long. Although Health Canada believes that the NDMA was introduced as a result of a change in manufacturing processes at Zhejiang Huahai Pharmaceuticals in 2012, some Canadian companies may have been using the affected valsartan active ingredient for less time.
>
> The additional Teva Canada products are being recalled after sample testing of the active ingredient by Zhejiang Huahai Pharmaceuticals identified trace levels of NDMA. Testing is ongoing. In the meantime, Health Canada has asked Teva Canada to recall these additional products as a precautionary measure, and to conduct a full investigation to determine the root cause of this most recent issue.

Health Canada is monitoring the recalls. The Department continues to work with the companies and its international regulatory partners to gather and assess information to determine whether additional actions are necessary. We will keep Canadians updated. This includes communicating the results of our health risk assessment once it is complete in the coming weeks.

A complete list of recalled products is provided below.

**Products containing valsartan ingredient from other suppliers NOT impacted by the recall**

Health Canada has contacted all companies selling valsartan medications in Canada and has confirmed that all of the products NOT being recalled:

- do not contain valsartan manufactured by Zhejiang Huahai Pharmaceuticals, and
- were manufactured using different processes from the ones that have been identified as having introduced the impurity.

[…]

A complete list of products that are NOT recalled is provided below.

*What you should do*

Patients taking affected valsartan medications should:

- Continue taking their valsartan medication unless they have been advised to stop by their health care provider.
- Contact their health care provider as soon as possible to discuss treatment options if they have been using an affected product. Pharmacists may be able to provide a product not affected by the recall, or doctors may prescribe a different medication for their patients' conditions.
- Ask their pharmacist if they are unsure whether they are using a recalled product.

[…]

[108] On **September 10, 2018**, as promised in the earlier releases, Health Canada issued an update on the health risks for recalled valsartan. The update stated:

**Health Canada updates Canadians on estimates of health risks for recalled valsartan drugs containing NDMA**

*Issue*

OTTAWA –Health Canada is sharing the results of its review of potential long-term health effects involving valsartan drugs that were found to contain the impurity N-nitrosodimethylamine (NDMA). Health Canada scientists have assessed the available data to determine the potential increased risk of developing cancer, to help put the risk into context for Canadians.

Based primarily on animal studies, NDMA is classified as a probable human carcinogen. This means that exposure over the long term could increase the risk of cancer. We are all exposed to low levels of NDMA. NDMA can be found in some foods (such as meats, dairy products and vegetables) and in drinking water. It is not expected to cause harm when ingested in very low levels.

Health Canada believes that NDMA was introduced to the affected valsartan drugs as a result of a change in manufacturing processes at Zhejiang Huahai Pharmaceuticals (the manufacturer of the

valsartan ingredient) in 2012. The longest time affected products were on the Canadian market was approximately three years.

The amounts of NDMA present in the valsartan active ingredient varied, but on average were higher than levels that are considered reasonably safe, which is why the valsartan products were recalled. Health Canada has derived estimates of the possible increased cancer risk using internationally accepted methods and information available to the Department at this time. The estimates are based on the following assumptions:

- the valsartan active ingredient contained 60 parts per million (ppm) NDMA. This is the average reported level of NDMA in a sampling of batches.

- the exposure was approximately 3 years.

It is important to keep in mind that the actual health risk varies from person to person, and depends on factors including daily dose, how long the affected valsartan was taken, and the actual level of NDMA present in the finished product.

**Estimated potential increased cancer risk for patients taking various doses of NDMA-containing valsartan products for 3 years**

| **valsartan dose (mg/day) containing 60 ppm NDMA** | **Risk estimate** |
|---|---|
| 40 | 1 additional case per 93,400 people |
| 80 | 1 additional case per 46,700 people |
| 160 | 1 additional case for 23,300 people |
| 320 | 1 additional case per 11,600 people |

For patients taking the highest dose of valsartan (320 mg) containing 60 ppm NDMA per tablet once daily for three years, Health Canada estimates that the potential increased risk of cancer over a lifetime could be 1 additional case of cancer for every 11,600 people taking the product. For patients taking the lowest valsartan dose (40 mg) containing 60 ppm NDMA per tablet once daily for three years, Health Canada estimates that the potential increased risk of cancer over a lifetime could be 1 additional case for every 93,400 people taking the product. To put these estimates into a broader context, nearly 1 in 2 Canadians is expected to develop cancer during their lifetime.

Health Canada is working closely with international partners to share information and coordinate efforts on inspections, risk assessments and public communications. Notably, Health Canada's estimated potential increased cancer risk is lower than those reported by the United States (US) Food and Drug Administration (FDA) and the European Medicines Agency (EMA) because the contaminated valsartan products were on the Canadian market for a shorter period of time, compared to the exposure timelines used in the assessments communicated by the FDA and EMA. Health Canada will take action should any new safety issue be identified and will continue to keep Canadians updated.

[…]

**What you should do**

People taking valsartan drugs should check these lists of valsartan products that have and have NOT been recalled to see if their medication is affected.

Patients taking affected valsartan medications should:

- Ask their pharmacist if they are unsure whether they are using a recalled product.

- Contact their health care provider as soon as possible to discuss treatment options if they have been using an affected product. Pharmacists may be able to provide a product not affected by the recall, or doctors may prescribe a different medication for their patients' conditions.

- Continue taking their valsartan medication **unless** they have been advised to stop by their health care provider. Since the risk of cancer is with long term exposure to the NDMA impurity, there is no immediate health risk, and patients can continue to take this drug to treat their medical condition until they can discuss treatment options with their health care provider.

- Contact their health care provider if they have taken recalled valsartan products and they have concerns about their health.

[109] On **September 13, 2018**, Health Canada advised of the second impurity linked to the recalled valsartan drugs from ZHP. The Health Canada advisory stated:

> **Impurities found in certain angiotensin II receptor blocker (ARB) products, also known as sartans**
>
> *Overview*
>
> In the summer of 2018, several valsartan products were recalled in Canada and worldwide because of the impurity, N-nitrosodimethylamine (NDMA), found in the active ingredient manufactured by Zhejiang Huahai Pharmaceuticals in China.
>
> Since that time, NDMA and other similar impurities, N-nitrosodiethylamine (NDEA), N-Nitrosodiisopropylamine (NDIPA) and N-Nitrosomethyl-n-butylamine (NMBA), have been found in valsartan or other drugs in the same class as valsartan (referred to as angiotensin II receptor blockers or ARBs) made by several different manufacturers in different countries and has prompted additional recalls in Canada and worldwide.
>
> ARBs are used to treat patients with high blood pressure to help prevent heart attacks and stroke. NDEA, NDMA, NDIPA and NMBA are nitrosamines that are classified as probable or potential human carcinogens, which means that long-term exposure could increase the risk of cancer. Since the risk of cancer is with long-term exposure, there is no immediate health risk associated with the use of ARBs containing these impurities.
>
> Health Canada recognizes the stress caused by this issue to Canadians who rely on these important medications. The Department has been working with companies and international regulatory partners to determine the root cause of the issue and to verify that appropriate actions are taken to prevent it from happening again.
>
> Health Canada continues to hold manufacturers responsible for the safety and effectiveness of drugs sold on the Canadian market and has taken several actions to mitigate the risk to Canadians, including:
>
> - Requested, confirmed and monitored the effectiveness of recalls due to this issue. A list of recalled products is provided below and will be updated as needed.
>
> […]
>
> - Determined that the Chuannan site of Zhejiang Huahai Pharmaceuticals and Hetero Laboratories Limited, Unit 1 are Non-Compliant with Good Manufacturing Practices requirements. This means that no products can be imported from those sites, unless they are considered medically necessary.

- Tested samples of ARBs on the Canadian market. Test results are provided below and will be updated as additional test results become available.

[…]

Recalls

Health Canada is publishing a complete list of angiotensin II receptor blocker (ARB) products recalled in Canada due to the presence of or the potential for nitrosamine impurities. […]

Patients taking recalled medications should:

- Continue taking your medication unless you have been advised to stop by your health care provider.
- Contact your health care provider to discuss treatment options if you have been using an affected product.
- Ask your pharmacist if you are unsure whether you are taking a recalled product.
- Contact your health care provider if you have taken a recalled product and you have concerns about your health.

[…]

[110] On **October 2, 2018**, Health Canada announced that based on a review of an inspection conducted by the FDA, ZHP's manufacturing site was determined to be non-complaint with requirements for GMPs for the manufacture of the valsartan. The Health Canada announcement stated:

**Health Canada finds Zhejiang Huahai Pharmaceuticals site non-compliant with requirements for the manufacture of drug ingredients**

Health Canada has found the Chuannan manufacturing site of Zhejiang Huahai Pharmaceuticals located in Linhai, China, to be non-compliant with requirements for Good Manufacturing Practices (GMPs) for the manufacture of active pharmaceutical ingredients. Health Canada's decision is based on a review of information from a recent inspection conducted by the U.S. Food and Drug Administration (FDA).

GMPs are internationally accepted standards that help ensure that drugs are consistently manufactured, tested, stored and distributed in a way that meets Canada's high safety and quality standards.

A non-compliant rating means that Canadian companies can no longer import drugs that contain active pharmaceutical ingredients from this site unless they are medically necessary. Health Canada will allow the continued importation of medically necessary drugs under conditions that verify their safety, such as additional testing. At this time, no products containing active pharmaceutical ingredients from this site have been identified as medically necessary.

[…]

Zhejiang Huahai Pharmaceuticals is the manufacturer of the valsartan active pharmaceutical ingredient that, to date, is the only active ingredient from this site found to contain the impurities N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA).

> Health Canada reviewed the FDA inspection as part of its continuing assessment of the issue with valsartan. All drugs containing valsartan manufactured by Zhejiang Huahai Pharmaceuticals have already been recalled in Canada. […]
>
> *Background*
>
> […]
>
> Canadians with questions or concerns about any health product they are taking should speak to a health care professional. Canadians should not make any changes to their medication without first consulting with a healthcare professional.

[111] On **November 29, 2018**, the Center for Drug Evaluation and Research, United States, issued a warning letter to ZHP, which is stated, in part:

> Failure to evaluate the potential effect that changes in the manufacturing process may have on the quality of your API. In November 2011 you approved a valsartan API process change […] that included the use of the solvent (b)(4). Your intention was to improve the manufacturing process, increase product yield, and lower production costs. However, you failed to adequately assess the potential formation of mutagenic impurities when you implemented the new process. […] According to your ongoing investigation, (b)(4) is required for the probable human carcinogen NDMA to form during the valsartan API manufacturing process. NDMA was identified in valsartan API manufactured at your facility.

[112] On **December 20, 2018**, Health Canada released an information update entitled, "Health Canada releases test results of certain sartan drugs". The information update states, in part:

> **Health Canada releases test results of certain sartan Drugs**
>
> *Issue*
>
> Health Canada has released the results […] of its testing of sartan drugs in Canada. Health Canada tested samples of certain sartan drugs (valsartan, candesartan, irbesartan, losartan, and olmesartan), which represent numerous products, as part of its ongoing collaborative work to address impurities found in some sartan drugs in Canada and internationally.
>
> Sartans, also known as angiotensin II receptor blockers (ARBs), are a class of drugs used as a treatment for patients with high blood pressure to help prevent heart attacks and stroke. They are also used in patients who have had heart failure or a recent heart attack.
>
> Several valsartan products have been recalled in Canada since this summer, after the impurities N-nitrosodiethylamine (NDEA) and N-nitrosodimethylamine (NDMA) were found in the active pharmaceutical ingredient. Both NDEA and NDMA are classified as probable human carcinogens, which means that long-term exposure could increase the risk of cancer. Health Canada has previously communicated cancer risk estimates (http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67734a-eng.php) for NDMA based on the levels detected in certain recalled valsartan products.
>
> Health Canada tested 48 samples representing 43 different products and did not identify any new safety concerns. Of the 48 samples, six valsartan samples representing four products were found to contain levels of impurities that were, on average, higher than what is considered to be reasonably safe. All four of the products have already been recalled from the Canadian market.
>
> […]
>
> *What you should do*

> As with previous communications regarding NDEA and NDMA, Health Canada is advising that there is no immediate risk to patients taking these medications, since the risk of cancer is with long-term exposure to the impurities that exceed safe levels. Patients should not stop taking their medication unless on the advice of their healthcare provider.

[113] Health Canada's test results of some of the recalled lots were as set out in the chart below:

| Market Authorization Holder | Product Name | Strength (mg) | NDMA RESULT ng/tablet | NDEA RESULT ng/tablet |
|---|---|---|---|---|
| Actavis Pharma Company | ACT VALSARTAN | 320 | 15,242 | 12.78 |
| Actavis Pharma Company | ACT VALSARTAN | 320 | 10,770.8 | 186.67 |
| Sandoz Canada Inc. | SANDOZ VALSARTAN | 320 | 2,703.76 | Not detected |
| Teva Canada Limited | TEVA-VALSARTAN/HCTZ | 320 | 14,538.35 | Not detected |
| Teva Canada Limited | TEVA-VALSARTAN/HCTZ | 320 | 258.19 | 1,770.87 |
| Teva Canada Limited | TEVA-VALSARTAN/HCTZ | 320 | 13,367.64 | Not detected |

[114] Since 2018, Health Canada's advisories have been consistent in their messaging. In **April 2022**, Health Canada posted an updated guidance advisory about nitrosamine impurities in medications. The advisory stated:

> **Nitrosamine impurities in medications: Overview**
>
> […]
>
> *Background*
>
> In the summer of 2018, several medications containing the active ingredient valsartan were recalled in Canada and elsewhere in the world. This was because the nitrosamine impurity, N-nitrosodimethylamine (NDMA), was found in the active pharmaceutical ingredient (API). APIs are the substances in pharmaceutical medications that are responsible for the beneficial health effects experienced by patients or consumers. Since then, some other medications made by different manufacturers have been found to contain NDMA or other similar nitrosamine impurities, such as: *N*-nitrosodiethylamine (NDEA) […]
>
> *About nitrosamine impurities*
>
> Based primarily on animal studies, nitrosamine impurities are probable human carcinogens. This means that long-term exposure to a level above what is considered safe may increase the risk of cancer.
>
> 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.
>
> The actual health risk varies from person to person. The risk depends on several factors, such as:
>
> - the daily dose of the medication
> - how long the medication is taken
> - the level of the nitrosamine impurity in the finished product

> 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.
>
> […]

## 8. The Plaintiffs' Testing of the valsartan

[115] In this certification motion, the extent to which the valsartan was contaminated was another highly contentious and complicated issue. Some of the complications were that: (a) not all Teva valsartan products were recalled; and (b) neither Sandoz nor Teva supplied any test results of their own testing of lots of their valsartan that were recalled.

[116] As noted above, Health Canada did limited testing, and it provided the information set out in the above chart of the test results.

[117] In August and September 2018, the Plaintiffs retained a laboratory to conduct testing on a collection of leftover pills from various lots manufactured by the Defendants.

[118] Dr. Neelanjan Bose of Emery Pharma tested the samples. His testing provided the following information:

a. No samples were found to contain NDEA.

b. One sample did not contain NDMA.

c. The other samples contained NDMA ranging from 540 ng to 32,457 ng per tablet.

[119] More precisely, Dr. Bose's findings are set out in the following chart:

| Name | DIN | #Tablets | Dose | Ng NMMA | Ng NDMA/tablet |
|---|---|---|---|---|---|
| Meszaros | 2356651 | 1 | 80 | 0 | 0 |
| Fournier | 2367734 | 1 | 80 | 540 | 540 |
| Aitchison | 2356758 | 5 | 80 | 2,842 | 568 |
| Tiedje | 2356767 | 2 | 160 | 2,335 | 1,168 |
| Palmer | 2356767 | 2 | 160 | 3,718 | 1,856 |
| Creighton | 2384531 | 5 | 80 | 15,451 | 3,090 |
| Halbert | 2366959 | 5 | 80 | 16,782 | 3,66 |
| Halbert | 2366959 | 5 | 80 | 28,131 | 5,626 |
| Tremblay | 2356767 | 2 | 160 | 17,575 | 8,785 |
| Ventura | 2356775 | 1 | 320 | 2,335 | 13,135 |
| Perehudoff | 2386975 | 1 | 320 | 25,534 | 25,534 |
| Perehudoff | 2366975 | 2 | 320 | 64,914 | 32,457 |

## 9. Physical Harm

[120] As noted, several times above, the Plaintiffs do not propose to advance claims of damages for bodily harm caused by the ingestion of the contaminated valsartan. Class Counsel acknowledged during oral argument that persons with such claims or persons anticipating such a sad prospect would have to opt out of the class proceeding to preserve the claim for physical injuries.

[121] In this regard, it should be noted that the doctrine of *res judicata* bars not only the causes of action that were brought but also the causes of action that could or ought to have been brought based on the same factual footprint. The idea of *res judicata* ("a matter adjudicated") is the legal rule and the public policy that a final judgment on the merits by a court of competent jurisdiction is binding and determinative of the rights of the parties or their privies in all later suits with respect

to fundamental issues decided in the former suit (issue estoppel),[12] and with respect to causes of actions and defences that were decided (cause of action estoppel) or could and ought to have been decided in the former suit (the rule from *Henderson v. Henderson*).[13]

[122] Class Counsel during oral argument and in its factum acknowledged that in the notice of certification, the putative Class Members would be advised that if they chose to be Class Members, then they would forgo a claim for damages for actually experiencing cancer from ingesting valsartan.

## 10. Psychological Harm

[123] The Plaintiffs advance a claim for compensation for the psychological harm of having ingested valsartan and then being advised of it probably being a carcinogen in humans. More precisely, the Class Members claim that they suffered compensable psychiatric harm from being advised that their risk of a cancer diagnosis had increased because they had ingested valsartan.

[124] In *Mustapha v. Culligan of Canada Ltd.*[14] and in *Saadati v. Moorhead,*[15] the Supreme Court of Canada established the contemporary approach of the law with respect to damages for psychological harm.

[125] Before the *Saadati v. Moorhead* decision, the conventional view was that recovery for psychological harm required a claimant to prove with expert medical opinion evidence a recognized psychiatric illness, which came to mean an illness within the classification of mental disorders contained in the *Diagnostic and Statistical Manual of Mental Disorders* ("DSM"), published by the American Psychiatric Association, and the *International Statistical Classification of Diseases and Related Health Problems* ("ICD"), published by the World Health Organization.

[126] After *Saadati v. Moorhead*, while an expert's opinion is relevant, it is not a necessity, and to establish a compensable psychological injury, the claimant need not prove that he or she was suffering a recognized psychiatric illness. Rather, the claimant needs to prove that as a result of the defendant's negligence he or she suffered a mental disturbance that is serious and prolonged and that rises above the ordinary annoyances, anxieties and fears that come with living in civil society.

[127] In the immediate case, anticipating the challenge that did in fact come from the Defendants that the Plaintiffs' action was vulnerable to the argument that it should not be certified in the absence of some evidence of compensable harm having occurred, the Plaintiffs marshalled evidence to show some basis in fact that a significant portion of the membership of the class will have sustained compensable psychological harm and that the Class Members or their surrogates would suffer the pure economic loss of medical bills, medical monitoring, refunds, and costs for drugs thrown away.

[128] The Plaintiffs retained Dr. O'Shaughnessy, who has a specialty in psychiatry. He

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[12] *Penner v. Niagara (Regional Police Services Board)*, 2013 SCC 19; *British Columbia (Workers' Compensation Board) v. Figliola*, 2011 SCC 52; *Danyluk v. Ainsworth Technologies Inc.*, [2001] 2 S.C.R. 460; *Angle v. M.N.R.* (1974), 47 D.L.R. (3d) 544 (S.C.C.).
[13] (1843), 67 E.R. 313, 3 Hare 100 (V.C. Ct.); *Hoque v. Montreal Trust Co. of Canada*, [1997] N.S.J. No. 430, (C.A.), leave to appeal refused, [1997] S.C.C.A. No. 656; *Grandview (Town) v. Doering*, [1976] 2 S.C.R. 621.
[14] 2008 SCC 27.
[15] 2017 SCC 28.

interviewed eight of the Plaintiffs and provided reports. He diagnosed four of the group as having had adjustment disorders and the others as having had no problems after learning about the contamination of the valsartan. At the time of the interviews by Dr. O'Shaughnessy, none of the Plaintiffs had any symptoms of psychological harm. Every single person Dr. O'Shaughnessy interviewed was so-to-speak "better" two years after the recall.

[129] Dr. O'Shaughnessy found a significant range in psychological reaction to the recall with some individuals describing modest symptoms, while others had more persistent and disturbing symptoms of anxiety and/or depressed mood that he thought met the criteria for an Adjustment Disorder with Anxiety and Depression.

[130] There was also survey evidence from Dr. Groehn, an economist, that Dr. O'Shaughnessy reviewed and that the Plaintiffs relied on in support of certification of their claim for psychological harm damages.

[131] Dr. Groehn surveyed putative Class Members that had registered with Class Counsel. Of the 3,275 registrants/respondents, 1,497 (46%) responded to the survey. Dr. Groehn designed a survey not as a diagnostic tool but to detect psychological distress symptomatology in the putative Class Members.

[132] Dr. Groehn's survey results revealed:

a. 48.0% of the respondents to the survey learned of the recall from their pharmacist; 20.6% from social media; 20.5% from a physician; 17% from a TV advertisement; 13.2% from print media; the balance of 10.5% learned from word of mouth, notice from the regulator, or did not know how they found out about the recall (The total percentage exceeds 100% because the Class Members could select more than one source.). (In assessing the shock value of the notice, it may be observed that 68.5% of the respondents learned about the recall from a pharmacist or physician.)

b. 80.1% of the respondents reported that the recall was a great burden to them.

c. 76.5% of respondents reported feeling "nervous, anxious, worried, or on edge about their health" during the first three months after the recall.

d. 67.7% of respondents reported having a consultation with their physician within the first three months of the recall.

e. 10% of the respondents reported physician consultations related to the recall two years after the recall.

[133] With respect to the medical monitoring claim, the Plaintiffs led evidence that early diagnosis from medical monitoring or screening is critical to prevent Class Members from developing diseases and to treat diseases caused by the valsartan. The Plaintiffs submitted that the medical monitoring would ameliorate their anxiety whether the ingestion of valsartan has caused or will cause them to develop cancer or organ damage.

[134] My conclusion from all this evidence about psychological harm is that as medical/psychological matter, the Plaintiffs have succeeded in showing some basis in fact that a small proportion of the membership of the class will have sustained psychological harm for a relatively short period of time as a result of learning about the contamination of the valsartan that they had been ingesting.

[135] However, although there is some basis in fact that the mental harm occurred for a small proportion of the class, as I shall explain later in this judgment - as a legal matter – this 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.

## G. Certification: General Principles

[136] The court has no discretion and is required to certify an action as a class proceeding when the following five-part test in s. 5 of the *Class Proceedings Act, 1992* is met: (1) the pleadings disclose a cause of action; (2) there is an identifiable class of two or more persons that would be represented by the representative plaintiff; (3) the claims of the class members raise common issues; (4) a class proceeding would be the preferable procedure for the resolution of the common issues; and (5) there is a representative plaintiff who: (a) would fairly and adequately represent the interests of the class; (b) has produced a plan for the proceeding that sets out a workable method of advancing the proceeding on behalf of the class and of notifying class members of the proceeding, and (c) does not have, on the common issues for the class, an interest in conflict with the interests of other class members.

[137] On a certification motion, the question is not whether the plaintiff's claims are likely to succeed on the merits, but whether the claims can appropriately be prosecuted as a class proceeding.[16] The test for certification is to be applied in a purposive and generous manner, to give effect to the goals of class actions; namely: (1) to provide access to justice for litigants; (2) to encourage behaviour modification; and (3) to promote the efficient use of judicial resources.[17]

[138] For certification, the plaintiff in a proposed class proceeding must show "some basis in fact" for each of the certification requirements, other than the requirement that the pleading discloses a cause of action.[18] The some-basis-in-fact standard sets a low evidentiary standard for plaintiffs, and a court should not resolve conflicting facts and evidence at the certification stage or opine on the strengths of the plaintiff's case.[19] In particular, there must be a basis in the evidence to establish the existence of common issues.[20] To establish commonality, evidence that the alleged misconduct actually occurred is not required; rather, the necessary evidence goes only to establishing whether the questions are common to all the class members.[21]

[139] The some-basis-in-fact standard does not require evidence on a balance of probabilities and does not require that the court resolve conflicting facts and evidence at the certification stage and rather reflects the fact that at the certification stage the court is ill-equipped to resolve conflicts in the evidence or to engage in the finely calibrated assessments of evidentiary weight and that the certification stage does not involve an assessment of the merits of the claim and is not intended to

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[16] *Hollick v. Toronto (City)*, 2001 SCC 68 at para. 16.
[17] *Hollick v. Toronto (City),* 2001 SCC 68 at paras. 15 and 16; *Western Canadian Shopping Centres Inc. v. Dutton*, 2001 SCC 46 at paras. 26 to 29.
[18] *Hollick v. Toronto* (City), [2001] 3 S.C.R. 158 at para. 25; *Pro-Sys Consultants Ltd. v. Microsoft Corporation*, 2013 SCC 57 at paras. 99-105; *Taub v. Manufacturers Life Insurance Co*., (1998) 40 O.R. (3d) 379 (Gen. Div.), aff'd (1999), 42 O.R. (3d) 576 (Div. Ct.).
[19] *Pro-Sys Consultants Ltd. v. Microsoft Corporation*, 2013 SCC 57; *McCracken v. CNR Co*., 2012 ONCA 445.
[20] *Singer v. Schering-Plough Canada Inc*., 2010 ONSC 42 at para. 140; *Fresco v. Canadian Imperial Bank of Commerce*, [2009] O.J. No. 2531 at para. 21 (S.C.J.); *Dumoulin v. Ontario*, [2005] O.J. No. 3961 at para. 25 (S.C.J.).
[21] *Pro-Sys Consultants Ltd. v. Microsoft Corporation*, 2013 SCC 57 at para. 110.

be a pronouncement on the viability or strength of the action.[22]

[140] Although it has recently garnered renewed attention, it has been for a long time, and it continues to be a fundamental principle that for an action to be certified as a class proceeding there must be some evidence that two of more putative Class Members suffered compensable harm.[23]

## H. The Cause of Action, the Common Issues, and the Preferable Procedure Criteria Ensemble

[141] Given the nature of the Defendants' arguments and the Plaintiffs' response to them, it is both convenient and necessary to consider the cause of action criterion (s. 5 (1) (a) of the *Class Proceedings Act, 1992* together with the common issues criterion (s. 5 (1)(c)) and the preferable procedure criterion (s. 5 (1)(d)). Simultaneously analyzing the Plaintiffs' causes of action through the lens of these three criteria reveals that all the various causes of action are not certifiable.

[142] I will also return later to the common issues criterion and the preferable procedure criterion discretely to address some miscellaneous issues about these criteria in the immediate case.

### 1. General Principles: Cause of Action Criterion

[143] The first criterion for certification is that the plaintiff's pleading discloses a cause of action.

[144] The "plain and obvious" test for disclosing a cause of action from *Hunt v. Carey Canada*,[24] is used to determine whether a proposed class proceeding discloses a cause of action for the purposes of s. 5(1)(a) of the *Class Proceedings Act, 1992*.[25]

[145] In a proposed class proceeding, in determining whether the pleading discloses a cause of action, no evidence is admissible, and the material facts pleaded are accepted as true, unless patently ridiculous or incapable of proof. The pleading is read generously, and it will be unsatisfactory only if it is plain, obvious, and beyond a reasonable doubt that the plaintiff cannot succeed.[26]

[146] Bare allegations and conclusory legal statements based on assumption or speculation are not material facts; they are incapable of proof and, therefore, they are not assumed to be true for

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[22] *Pro-Sys Consultants Ltd. v. Microsoft Corporation*, 2013 SCC 57 at para. 102.
[23] *Marcinkiewicz v. General Motors of Canada Co*., 2022 ONSC 2180; *MacKinnon v. Volkswagen*, 2021 ONSC 5941; *Maginnis v. FCA Canada Inc* 2021 ONSC 3897 (Div. Ct.), aff'g 2021 ONSC 3897, leave to appeal dismissed April 8, 2022 (Ont. C.A.); *Setoguchi v. Uber B.V.*, 2021 ABQB 18; *Atlantic Lottery Corp Inc. v. Babstock*, 2020 SCC 19; *Richardson v. Samsung Electronics Canada Inc.*, 2018 ONSC 6130, aff'd 2019 ONSC 6845 (Div. Ct.); *Pro-Sys Consultants Ltd. v. Microsoft Corporation*, 2013 SCC 57; *Singer v. Schering-Plough Canada Inc.*, 2010 ONSC 42.
[24] [1990] 2 S.C.R. 959.
[25] *Wright v. Horizons ETFS Management (Canada) Inc*., 2020 ONCA 337 at para. 57; *Amyotrophic Lateral Sclerosis Society of Essex County v. Windsor (City)*, 2015 ONCA 572; *Hollick v. Metropolitan Toronto (Municipality)*, 2001 SCC 68.
[26] *Cloud v. Canada (Attorney General)* (2004), 73 O.R. (3d) 401 at para. 41 (C.A.), leave to appeal to the S.C.C. refused, [2005] S.C.C.A. No. 50, rev'g, (2003), 65 O.R. (3d) 492 (Div. Ct.); *Hollick v. Toronto (City)*, 2001 SCC 68 at para. 25; *Abdool v. Anaheim Management Ltd.* (1995), 21 O.R. (3d) 453 at p. 469 (Div. Ct.).

the purposes of a motion to determine whether a legally viable cause of action has been pleaded.[27]

[147] Matters of law that are not fully settled should not be disposed of on a motion to strike an action for not disclosing a reasonable cause of action,[28] and the court's power to strike a claim is exercised only in the clearest cases.[29] The law must be allowed to evolve, and the novelty of a claim will not militate against a plaintiff.[30] However, a novel claim must have some elements of a cause of action recognized in law and be a reasonably logical and arguable extension of established law.[31]

## 2. General Principles: Common Issues Criterion

[148] The third criterion for certification is the common issues criterion. For an issue to be a common issue, it must be a substantial ingredient of each class member's claim and its resolution must be necessary to the resolution of each class member's claim.[32]

[149] The underlying foundation of a common issue is whether its resolution will avoid duplication of fact-finding or legal analysis of an issue that is a substantial ingredient of each class member's claim and thereby facilitate judicial economy and access to justice.[33]

[150] An issue is not a common issue, if its resolution is dependent upon individual findings of fact that would have to be made for each class member.[34] Common issues cannot be dependent upon findings which will have to be made at individual trials, nor can they be based on assumptions that circumvent the necessity for individual inquiries.[35] All members of the class must benefit from the successful prosecution of the action, although not necessarily to the same extent. The answer to a question raised by a common issue for the plaintiff must be capable of extrapolation, in the same manner, to each member of the class.[36]

[151] The common issue criterion presents a low bar.[37] An issue can be a common issue even if

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[27] *Deluca v. Canada (AG),* 2016 ONSC 3865; *Losier v. Mackay, Mackay & Peters Ltd*., [2009] O.J. No. 3463 at paras. 39-40 (S.C.J.), aff'd 2010 ONCA 613, leave to appeal ref'd [2010] SCCA 438; *Grenon v. Canada Revenue Agency,* 2016 ABQB 260 at para. 32; *Merchant Law Group v. Canada Revenue Agency*, 2010 FCA 184 at para. 34.
[28] *Dawson v. Rexcraft Storage & Warehouse Inc.* (1998), 164 D.L.R. (4th) 257 (Ont. C.A.).
[29] *Temelini v. Ontario Provincial Police (Commissioner)* (1990), 73 O.R. (2d) 664 (C.A.).
[30] *Johnson v. Adamson* (1981), 34 O.R. (2d) 236 (C.A.), leave to appeal to the S.C.C. refused (1982), 35 O.R. (2d) 64n.
[31] *Silver v. Imax Corp.*, [2009] O.J. No. 5585 (S.C.J.) at para. 20; *Silver v. DDJ Canadian High Yield Fund*, [2006] O.J. No. 2503 (S.C.J.).
[32] *Hollick v. Toronto (City),* 2001 SCC 68 at para. 18.
[33] *Western Canadian Shopping Centres Inc. v. Dutton*, 2001 SCC 46 at paras. 39 and 40.
[34] *Fehringer v. Sun Media Corp*., [2003] O.J. No. 3918 at paras. 3, 6 (Div. Ct.).
[35] *McKenna v. Gammon Gold Inc.*, [2010] O.J. No. 1057 at para. 126 (S.C.J.), leave to appeal granted [2010] O.J. No. 3183 (Div. Ct.), var'd 2011 ONSC 3882 (Div. Ct.); *Nadolny v. Peel (Region)*, [2009] O.J. No. 4006 at paras. 50-52 (S.C.J.); *Collette v. Great Pacific Management Co.*, [2003] B.C.J. No. 529 at para. 51 (B.C.S.C.), var'd on other grounds (2004) 42 B.L.R. (3d) 161 (B.C.C.A.).
[36] *Batten v. Boehringer Ingelheim (Canada) Ltd*., 2017 ONSC 53, aff'd, 2017 ONSC 6098 (Div. Ct.), leave to appeal refused (28 February 2018) (C.A.); *Amyotrophic Lateral Sclerosis Society of Essex County v. Windsor (City),* 2015 ONCA 572 at para. 48; *McCracken v. CNR,* 2012 ONCA 445 at para. 183; *Merck Frosst Canada Ltd. v. Wuttunee*, 2009 SKCA 43 at paras. 145-46 and 160, leave to appeal to S.C.C. refused, [2008] S.C.C.A. No. 512; *Ernewein v. General Motors of Canada Ltd.,* 2005 BCCA 540 (C.A.), leave to appeal to S.C.C. ref'd, [2005] S.C.C.A. No. 545; *Western Canadian Shopping Centres Inc. v. Dutton,* 2001 SCC 46 at para. 40.
[37] *203874 Ontario Ltd. v. Quiznos Canada Restaurant Corp*., [2009] O.J. No. 1874 (Div. Ct.), aff'd [2010] O.J. No. 2683 (C.A.), leave to appeal to S.C.C. refused [2010] S.C.C.A. No. 348; *Cloud v. Canada (Attorney General)*

it makes up a very limited aspect of the liability question and even though many individual issues remain to be decided after its resolution.[38] Even a significant level of individuality does not preclude a finding of commonality.[39]A common issue need not dispose of the litigation; it is sufficient if it is an issue of fact or law common to all claims and its resolution will advance the litigation.[40]

[152] From a factual perspective, the plaintiff must show that there is some basis in fact that: (a) the proposed common issue actually exists; and (b) the proposed issue can be answered in common across the entire class, which is to say that the Plaintiff must adduce some evidence demonstrating that there is a colourable claim or a rational connection between the Class Members and the proposed common issues.[41] The plaintiff must establish some basis in fact for the existence of the common issues in the sense that there is some factual basis for the claims made to which the common issues are connected.[42]

### 3. General Principles – Preferable Procedure

[153] Under the *Class Proceedings Act, 1992*, the fourth criterion for certification is the preferable procedure criterion. Preferability captures the ideas of: (a) whether a class proceeding would be an appropriate method of advancing the claims of the class members; and (b) whether a class proceeding would be better than other methods such as joinder, test cases, consolidation, and any other means of resolving the dispute.[43]

[154] In *AIC Limited v. Fischer*,[44] the Supreme Court of Canada emphasized that the preferability analysis must be conducted through the lens of judicial economy, behaviour modification, and access to justice. Thus, for a class proceeding to be the preferable procedure for the resolution of the claims of a given class, it must represent a fair, efficient, and manageable procedure that is preferable to any alternative method of resolving the claims.[45] Whether a class proceeding is the preferable procedure is judged by reference to the purposes of access to justice, behaviour modification, and judicial economy and by taking into account the importance of the common issues to the claims as a whole, including the individual issues.[46] To satisfy the preferable procedure criterion, the proposed representative plaintiff must show some basis in fact that the proposed class action would: (a) be a fair, efficient and manageable method of advancing the claim;

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(2004), 73 O.R. (3d) 401 at para. 52 (C.A.), leave to appeal to the S.C.C. ref'd, [2005] S.C.C.A. No. 50, rev'g (2003), 65 O.R. (3d) 492 (Div. Ct.); *Carom v. Bre-X Minerals Ltd*. (2000), 51 O.R. (3d) 236 at para. 42 (C.A.).

[38] *Cloud v. Canada (Attorney General)*, (2004), 73 O.R. (3d) 401 (C.A.), leave to appeal to the S.C.C. ref'd, [2005] S.C.C.A. No. 50, rev'g (2003), 65 O.R. (3d) 492 (Div. Ct.).

[39] *Hodge v. Neinstein*, 2017 ONCA 494 at para. 114; *Pro-Sys Consultants Ltd. v. Microsoft Corporation*, 2013 SCC 57 at para. 112; *Western Canadian Shopping Centres Inc. v. Dutton*, 2001 SCC 46 at para. 54.

[40] *Harrington v. Dow Corning Corp.*, [2000] B.C.J. No. 2237 (C.A.), leave to appeal to S.C.C. ref'd [2001] S.C.C.A. No. 21.

[41] *Jensen v. Samsung Electronics Co. Ltd.*, 2021 FC 1185; *Kuiper v. Cook (Canada) Inc.*, 2020 ONSC 128 (Div. Ct.).

[42] *Simpson v. Facebook, Inc.* 2022 ONSC 1284 at para. 25 (Div. Ct.); *Jensen v. Samsung Electronics Co. Ltd.*, 2021 FC 1185; *Singer v. Schering-Plough Canada Inc.*, 2010 ONSC 42 at para. 140.

[43] *Markson v. MBNA Canada Bank*, 2007 ONCA 334 at para. 69, leave to appeal to SCC ref'd [2007] S.C.C.A. No. 346; *Hollick v. Toronto (City)*, 2001 SCC 68.

[44] 2013 SCC 69 at paras. 24-38.

[45] *Cloud v. Canada (Attorney General)* (2004), 73 O.R. (3d) 401 at para. 52 (C.A.), leave to appeal to the S.C.C. ref'd, [2005] S.C.C.A. No. 50, rev'g (2003), 65 O.R. (3d) 492 (Div. Ct.).

[46] *Markson v. MBNA Canada Bank*, 2007 ONCA 334; *Hollick v. Toronto (City)*, 2001 SCC 68.

(b) be preferable to any other reasonably available means of resolving the class members' claims; and (c) facilitate the three principal goals of class proceedings; namely: judicial economy, behaviour modification, and access to justice.[47]

## 4. Products Liability

[155] The analysis of the certifiability of the Plaintiffs' various causes of action may begin with the critical core claims in negligence, more precisely, product liability negligence. In its existential essence, the Plaintiffs' proposed class action is a product liability claim.

[156] The fundamental constituent elements of any type of negligence cause of action are: (1) the defendant owes the plaintiff a duty of care; (2) the defendant's behaviour breached the standard of care; (3) the plaintiff suffered compensable damages; (4) the damages were caused in fact by the defendant's breach; and (5) the damages are not too remote in law.[48]

[157] By way of a preliminary point, it should be noted that there are four established genres of product liability causes of action in negligence.[49]

[158] First, there is design negligence; manufacturers have a duty of care in designing the product to avoid safety risks and to make the product reasonably safe for its intended purposes.[50]

[159] Second, there is manufacturing negligence; manufacturers have a duty of care to consumers to see that there are no defects in manufacture that are likely to give rise to injury in the ordinary course of use.[51]

[160] Third, manufacturers have a duty of care to compensate consumers for the cost of repairing a dangerous product that presents an imminent real and substantial danger.[52]

[161] Fourth, there is a duty to warn; manufacturers have a duty of care to warn consumers of dangers inherent in the use of the product of which the manufacturer has knowledge or ought to have knowledge.[53]

[162] In the immediate case, the Plaintiffs' products liability claim has two branches to it. The first branch is a personal injury claim for psychological harm. The Plaintiffs purposefully eschew a physical injury claim for damages for valsartan causing cancer; rather, the Plaintiffs' case is built

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[47] *Musicians' Pension Fund of Canada (Trustee of) v. Kinross Gold Corp.*, 2014 ONCA 901; *AIC Limited v. Fischer*, 2013 SCC 69; *Hollick v. Toronto (City)*, 2001 SCC 68.
[48] *Mustapha v. Culligan of Canada Ltd*., 2008 SCC 27 at para. 3.
[49] *Harris v. Bayerische Motoren Werke Aktiengesellschaft*, 2020 ONSC 1647; *Vester v. Boston Scientific Ltd.*, 2015 ONSC 7950; *Arora v. Whirlpool Canada LP*, 2012 ONSC 4642, aff'd 2013 ONCA 657, leave to appeal ref'd [2013] S.C.C.A. No. 498; *Goodridge v. Pfizer Canada Inc*., 2010 ONSC 1095; *Hollis v. Dow Corning Corp*., [1995] 4 S.C.R. 634; *Rentway Canada Ltd. v. Laidlaw Transport Ltd.*, [1989] O.J. No. 786 (H.C.J.), aff'd [1994] O.J. No. 50 (C.A.).
[50] *Vester v. Boston Scientific Ltd.*, 2015 ONSC 7950; *Ragoonanan v. Imperial Tobacco Canada Ltd.* (2000), 51 O.R. (3d) 603 (S.C.J.); *Rentway Canada Ltd. v. Laidlaw Transport Ltd.*, [1989] O.J. No. 786 (H.C.J.), aff'd [1994] O.J. No. 50 (C.A.); *Nicholson v. John Deere Ltd*. (1986), 58 O.R. (2d) 53 (H.C.J.), aff'd [1989] O.J. No. 495 (C.A).
[51] *Donoghue v. Stevenson*, [1932] A.C. 562 (H.L.).
[52] *1688782 Ontario Inc. v Maple Leaf Foods Inc.*, 2020 SCC 35; *Arora v. Whirlpool Canada LP*, 2012 ONSC 4642, aff'd 2013 ONCA 657, leave to appeal ref'd [2013] S.C.C.A. No. 498; *Winnipeg Condominium Corporation No. 36 v. Bird Construction Co*., [1995] 1 S.C.R. 85.
[53] *Andersen v. St. Jude Medical, Inc*., 2012 ONSC 3660; *Bow Valley Husky (Bermuda) Ltd. v. Saint John Shipbuilding Ltd.*, [1997] 3 S.C.R. 1210; *Hollis v. Dow Corning Corp*., [1995] 4 S.C.R. 634; *Lambert v. Lastoplex Chemicals Co*., [1972] S.C.R. 569.

on the notion that the putative class members have a claim for psychological harm arising from the contaminated valsartan being recalled and their being advised that NDMA and NDEA are possible carcinogens increasing the risk that the Class Members will be diagnosed with cancer.

[163] The second branch of the Plaintiffs' products liability claim is the claims for the pure economic losses of medical bills, medical monitoring, refunds, and costs for the drugs thrown away.

[164] In the following discussion of the cause of action, common issues, and preferable procedure criteria ensemble, I shall consider the two branches of the Plaintiffs' products liability claim separately, beginning with the psychological harm damages cause of action.

### (a) Products Liability and the Claim for Psychological Harm

[165] The Plaintiffs seek damages for the psychological harm arising from their learning of the increased risk of being diagnosed with cancer as a consequence of ingesting the contaminated valsartan. The fatal flaw in seeking damages for the harm of an increased risk is that the current law is that the creation of risk is not wrongful conduct.[54]

[166] The Plaintiffs submit 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. As noted above, the Plaintiffs marshalled evidence in an effort to show some basis in fact that a significant portion of the membership of the class sustained compensable psychological harm. The Plaintiffs submit that the Defendants' argument regarding a negligible risk cannot form part of the section 5(1)(a) test and that the degree of risk is a matter that goes to the merits and not to the certifiability of the proposed class action.

[167] The Plaintiffs' efforts to establish a cause of action and some basis in fact for a claim for psychological harm, however, avail them naught, because as explained in *Atlantic Lottery Corp. Inc. v. Babstock*,[55] the contemporary law is that the creation of risk as such is not wrongful conduct.

[168] *Atlantic Lottery Corp. Inc. v. Babstock*, was a proposed class action against the Atlantic Lottery Corp. The action was on behalf of persons who played video lottery terminal games operated by the Atlantic Lottery. The plaintiffs alleged that the video games were inherently dangerous.

[169] In *Atlantic Lottery Corp. Inc. v. Babstock,* it was a litigation strategy feature of the Plaintiffs' case – similar to the case at bar – that the plaintiffs purposefully did not propose to prove that the video games action actually caused psychological harm (addiction or suicides). The Plaintiffs' allegation rather was that all the putative class members suffered the injury of an increased risk of addiction and suicidal ideation. They alleged that the Atlantic Lottery had a duty to warn about the risk of addiction and of suicidal ideation. The plaintiffs advanced three causes of action: waiver of tort, breach of contract, and unjust enrichment. The alleged breached terms of contract were, among other things to provide video games that were safe.

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[54] *Kaissieh v. Done*, 2022 ONSC 425; *1688782 Ontario Inc. v Maple Leaf Foods Inc.*, 2020 SCC 35; *Atlantic Lottery Corp. Inc. v. Babstock*, 2020 SCC 19; *Ring v.* Canada *(A.G.)*, 2010 NLCA 20, leave to appeal ref'd [2010] S.C.C.A. No. 187; *Rothwell v. Chemical & Insulating Co. Ltd*. [2007] UKHL 39.

[55] 2020 SCC 19 (Justice Brown, Abella, Moldaver, Côté and Rowe, JJ. concurring; Justice Karakatsanis,(Wagner, C.J., Martin and Kasirer, JJ, dissenting in part).

[170] In the result, the Supreme Court would not allow certification. The action was dismissed because the plaintiffs failed to satisfy the cause of action criterion. The Supreme Court was unanimous that the waiver of tort, disgorgement, and unjust enrichment claims did not have any reasonable chance of success. A majority of the Court comprised of Justice Brown with Justices Abella, Moldaver, Côté, and Rowe concurring, also held that there was no reasonable cause of action for breach of contract. A minority, Justice Karakatsanis with Chief Justice Wagner, Justices Martin and Kasirer concurring, dissenting in part, would have certified only the breach of contract claim.

[171] In *Atlantic Lottery Corp. Inc. v. Babstock*, the Supreme Court was unanimous that waiver of tort was not a cause of action and as a legal term it should be abandoned. In discussing the demise of waiver of tort as a doctrine and in discussing in what circumstances, there might be a gains-based remedy requiring a defendant to disgorge its ill-gotten gains, Justice Brown discussed the nature of culpable wrongdoing. Justice Brown stated at paragraph 33:

> 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). […]

[172] For present purposes, what is particularly important to observe is that the Plaintiffs' approach in *Atlantic Lottery Corporation* is similar to the approach of the Plaintiffs in the immediate case that focuses on damages from an increased risk of physical harm rather than actual damages having been occasioned by the manifestation of actual harm.

[173] *Atlantic Lottery Corporation v. Babstock* demonstrates that for negligence actions not to be doomed to fail there must be wrongful conduct causing actual harm. As Justice Brown noted at paragraph 34 of his judgment "Tort law does not treat plaintiffs "merely as a convenient conduit of social consequences" but rather as "someone to whom damages are owed to correct the wrong suffered"" and, in a passage that could be applied to the immediate case, Justice Brown stated at paragraph 37 of his judgment:

> 37. Causation of damage is a required element of the tort of negligence. As I have explained, the conduct of a defendant in negligence is wrongful only to the extent that it causes damage (*Clement*s, at para. 16). While the plaintiffs allege that ALC had a duty to warn of the inherent dangers associated with VLTs, including the risk of addiction and suicide, those dangers are not alleged to have materialized. […]

[174] The principle that legally culpable wrongdoing cannot be based just on conduct increasing the plaintiff's risk of harm and that for a legally viable tort claim there must be actual physical injury to person or property or psychological harm to person that has actually materialized has been recognized in cases both before and after *Atlantic Lottery Corporation v. Babstock*.[56]

[56] In addition to the cases discussed next see: *Kaissieh v. Done*, 2022 ONSC 425; *Kane v. FCA US LLC*, 2022 SKQB 69; *Carter v Ford Motor Company of Canada*, 2021 ONSC 4138.

[175] In *1688782 Ontario Inc. v. Maple Leaf Foods Inc.*,[57] discussed further below, in a majority decision written by Justices Brown and Martin, the Supreme Court dismissed a negligence claim in a proposed class action by Mr. Submarine franchisees, whose supply chain for sandwich meats was disrupted for several months when the defendant Maple Leaf Foods, the franchisor's supplier, recalled its goods because of a listeria outbreak at its processing plant.

[176] *1688782 Ontario Inc. v. Maple Leaf Foods Inc.* demonstrates that the legal policy of the law of negligence is that with a few exceptions that can be justified on public policy grounds, tort law leaves pure economic losses to be addressed by the law of contract. I shall discuss the Plaintiffs' claims for pure economic losses in the next part of this decision, but for present purposes, in *Maple Leaf Foods*, in their explanation of the law, Justices Brown and Martin confirmed the "liability rule" from *Atlantic Lottery Corp. Inc. v. Babstock*,[58] 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. Justices Brown and Martin stated at paragraphs 44 of their judgment:

> 44. At first glance, the liability rule in *Winnipeg Condominium* may appear curious, since it appears as though liability is imposed not in respect of damage that has occurred to the plaintiff's rights, but in respect of a real and substantial danger thereto. As a general principle, there is no liability for negligence "in the air", for "[t]here is no right to be free from the prospect of damage" but "only a right not to suffer damage that results from exposure to unreasonable risk" (*Atlantic Lottery Corp. Inc. v. Babstock*, 2020 SCC 19, at para. 33 (emphasis in original); *Clements v. Clements*, 2012 SCC 32, at para. 16; *Ratych v. Bloomer*, [1990] 1 S.C.R. 940, at p. 964).

[177] I appreciate that before the clarification of the law provided by *Atlantic Lottery Corp. Inc. v. Babstock* and *1688782 Ontario Inc. v. Maple Leaf Foods Inc.*, there were cases in which claims for pure economic loss for an increase of the potentiality harm from a defective pharmaceutical or medical product or safety product were certified,[59] but this law does not represent the current state of the law in Canada.

[178] In *Ring v. Canada (A.G.)*,[60] a class action was brought on behalf of persons who were at the Gagetown, New Brunswick, Canadian Forces Base ("CFB") during the period when CFB Gagetown was sprayed with a toxic herbicide. The class action was brought on behalf of the persons: (a) who had been diagnosed with lymphoma and (b) who had been at the military base but who were lymphoma asymptomatic. It was not disputed that for those who have been diagnosed with lymphoma and who alleged that the lymphoma was the result of exposure to the toxin, the Plaintiff had pleaded a reasonable cause of action. However, the Court of Appeal of Newfoundland and Labrador held that there was no reasonable cause of action for the asymptomatic proposed class members who were not claiming damages for physical or psychological injuries but were claiming the costs of medical testing to determine whether there was agent orange in their bodies. The Court of Appeal also concluded that the entire proposed

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[57] 2020 SCC 35. (Brown and Martin, JJ, Moldaver, Côté, and Rowe JJ, concurring; Karakatsanis, J., Wagner C.J. and Abella, and Kasirer JJ, dissenting).
[58] 2020 SCC 19.
[59] *Banerjee v. Shire Biochem Inc*., 2010 ONSC 889; *Anderson v. St. Jude Medical Inc*. [2003] O.J. No. 3556 (S.C.J.); *Hughes v. Sunbeam Corp (Canada) Ltd*. (2002), 61 O.R. (3d) 433 (C.A.); *Wilson v. Servier Canada Inc.* (2000) 50 OR. (3d) 219 (S.C.J.), leave to appeal ref'd [2001] O.J. No. 4716 (Div. Ct.); *Nantais v. Telectronics Proprietary (Canada) Ltd*., [1995] O.J. No. 2592 (Gen. Div.), leave to appeal ref'd [1995] O.J. No. 3069 (Div. Ct.); *Anderson v. Wilson* (1999), 44 O.R. (3d) 673 (C.A.).
[60] 2010 NLCA 20, leave to appeal ref'd [2010] S.C.C.A. No. 187, rev'g [2007] N.J. No. 273 (SCTD).

class action was not certifiable for other reasons.

[179] The Court of Appeal of Newfoundland and Labrador concluded that the motions judge had erred in certifying the claims of the asymptomatic putative class members. The Court stated that the critical problem of the plaintiff's claim for this group was that there was an absence of compensable damages. Justice Cameron for the Court stated at paragraph 52:

> 52. […] For this group, or for those of them who will be able to establish they were in a "toxic" area of CFB Gagetown, the remedy sought is the cost of testing to determine whether there is evidence of the presence of certain chemicals in their bodies. The traditional view of such claims is expressed in Fleming, *The Law of Torts*, 9th ed. (North Ryde, N.S.W.: LBC Information Services, 1998). At p. 216, the author observed: "Persons 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." Ring was not able to provide any Canadian jurisprudence which would support the granting of a remedy in the case of this group. […]

[180] The same Class Counsel that commenced *Ring v. Canada (A.G.)* in Newfoundland and Labrador commenced eight other similar actions across Canada, of which all but two went dormant. The active actions were in New Brunswick, the situs of Gagetown CFB, and in Saskatchewan. The New Brunswick action, *Bryson v. Canada (Attorney General)*[61] was not certified, and then went dormant as the leave to appeal motion was adjourned on consent *sine die*.[62] The Saskatchewan action, *Brooks v. Canada (Attorney General)*[63] was not certified where Justice Zarzeczny specifically addressed the claim for medical monitoring, which he held was a claim for pure economic losses that did not demonstrate a legally viable cause of action.

[181] Moving on in the discussion of the caselaw, on the issue of liability for increasing the risk of harm, in the immediate case, both parties debated the relevance to the issues in the immediate case of the English House of Lords' decision in *Rothwell v. Chemical & Insulating Co. Ltd*.[64]

[182] The law and facts of *Rothwell v. Chemical & Insulating Co. Ltd*. are neatly summarized in the opening paragraphs of the judgment of Lord Hoffman, one of the five law lords[65] who delivered judgments dismissing negligence actions for exposure to asbestos when the plaintiffs were asymptomatic of life-threatening diseases caused by exposure to asbestos. What was common in the plaintiffs in the *Rothwell* case was that because of the exposure to asbestos, they had developed thickened membranes around the lungs known as pleural plagues. The membranes themselves were not harmful, but their presence signaled an exposure to asbestos that might independently cause asbestos diseases.

[183] Lord Hoffman's summary is a succinct two paragraphs. He stated:

> *Summary*
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> 1. The question is whether someone who has been negligently exposed to asbestos in the course of his employment can sue his employer for damages on the ground that he has developed pleural plaques. These are areas of fibrous thickening of the pleural membrane which surrounds the lungs. Save in very exceptional cases, they cause no symptoms. Nor do they cause other asbestos-related diseases. But they signal the presence in the lungs and pleura of asbestos fibres which may independently cause life-threatening or fatal diseases such as asbestosis or mesothelioma. In

[61] [2009] N.B.J. No. 237 (Q.B.).
[62] *Bryson v. Canada (Attorney General)*, [2009] N.B.J. No. 309 (NBCA).
[63] 2009 SKQB 509, leave to appeal ref'd 2010 SKCA 55.
[64] *Rothwell v. Chemical & Insulating Co. Ltd*. [2007] UKHL 39.
[65] Lord Hoffman, Lord Hope of Craighead, Lord Scott of Foscote, Lord Rodger of Earlsferry and Lord Mance.

> consequence, a diagnosis of pleural plaques may cause the patient to contemplate his future with anxiety or even suffer clinical depression.
>
> 2.Proof of damage is an essential element in a claim in negligence and in my opinion the symptomless plaques are not compensatable damage. Neither do the risk of future illness or anxiety about the possibility of that risk materialising amount to damage for the purpose of creating a cause of action, although the law allows both to be taken into account in computing the loss suffered by someone who has actually suffered some compensatable physical injury and therefore has a cause of action. In the absence of such compensatable injury, however, there is no cause of action under which damages may be claimed and therefore no computation of loss in which the risk and anxiety may be taken into account. It follows that in my opinion the development of pleural plaques, whether or not associated with the risk of future disease and anxiety about the future, is not actionable injury. The same is true even if the anxiety causes a recognised psychiatric illness such as clinical depression. The right to protection against psychiatric illness is limited and does not extend to an illness which would be suffered only by an unusually vulnerable person because of apprehension that he may suffer a tortious injury.

[184] I do not propose to engage in any discussion of *Rothwell v. Rothwell v. Chemical & Insulating Co. Ltd.*, save to say that it is entirely supportive of Justice Brown's and Martin's decisions in *Atlantic Lottery Corp. Inc. v. Babstock* and *1688782 Ontario Inc. v. Maple Leaf Foods Inc.* and *Rothwell* asserts the principle that there are no compensable damages for the wrongdoing of increasing the risk of harm in the absence of the manifestation of the harm.

[185] *Atlantic Lottery Corp. Inc. v. Babstock* was applied in *Spring v. Goodyear Canada Inc.*,[66] where the Alberta Court of Appeal reversed the motions judge and refused to certify a proposed products liability negligence class action. The plaintiff was injured in a motor vehicle accident when the tread of his vehicle's tires failed because of a manufacturing defect. For present purposes, the reasons for non-certification of the action are not of interest and the point of interest is what the Court of Appeal had to say in the context of its discussion of the unjust enrichment claim, where the Court (Slatter, Veldhuis, and Strekaf, JJ.A.) stated at paragraphs 44 and 46:

> 44. The claim for unjust enrichment is pleaded as follows:
>
> > 30. Goodyear has been unjustly enriched by profit earned from the sale of Tires it knew were defective, dangerous and unfit for use, to the deprivation of the Plaintiff and Class Members and at risk to the general public, and there is no juristic reason for Goodyear's enrichment.
>
> The remedies claimed in the statement of claim are "restitution and disgorgement of profits wrongfully earned or retained by Goodyear from the sale of defective Tires".
>
> […]
>
> 46. As a threshold issue, the pleading of "risk to the general public" supports neither a claim for restitution nor for disgorgement of profit. Mere "risk" to the "general public" (or, for that matter, a class member) is not a cause of action; a remedy based on negligence requires damage: *Atlantic Lottery* at para. 33.

[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

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[66] 2021 ABCA 18, rev'g 2020 ABQB 252.

immediate case. This impediment cannot be cured by the Plaintiffs' amending their pleadings.

[187] But there is more, moving on in the analysis, in the immediate case there is a second cause of action criterion failure conjoined to common issues and preferable procedure criteria failures that explain why the Plaintiffs' claim for psychological harm damages is not certifiable.

[188] The second reason is complex and begins by assuming that there is a legal basis for the psychological injury damages claim. Thus, the cause of action criterion would be satisfied, and the identifiable class criterion would be satisfied because the fact that some class members may ultimately be unsuccessful in establishing a psychological injury claim against the defendants does not make the class overbroad, but the rub is that the common issues and the preferable procedure are, at best, only tenuously satisfied, if they are satisfied at all.

[189] The problem for the Plaintiffs is that their evidence on the certification motion reveals that a significant portion of the class, including possibly the Plaintiffs themselves, will not be able to show that as a matter of fact, they have a compensable claim for a psychological injury, and in the immediate case there is no basis to make an aggregate minimum award for psychological harm damages across the class. In the immediate case, the hard work remains for individual issues trials and the common issues trial is of marginal utility for advancing those individual issues claims, some of which would be *de minimis*.

[190] In the immediate case, the evidence of the psychological effect of the recall notice demonstrates, at most, that some minority of the class would have suffered the upsets and anxieties that would be compensable under tort law even if there was compensation for the anxiety caused by increased risk. In *Mustapha v. Culligan of Canada Ltd*.,[67] in her judgment for the Supreme Court of Canada, Chief Justice McLachlin stated at paragraph 9:

> This said, psychological disturbance that rises to the level of personal injury must be distinguished from psychological upset. Personal injury at law connotes serious trauma or illness: see *Hinz v. Berry*, [1970] 2 Q.B. 40 (C.A.), at p. 42; *Page v. Smith*, at p. 189; Linden and Feldthusen, at pp. 425-27. The law does not recognize upset, disgust, anxiety, agitation or other mental states that fall short of injury. I would not purport to define compensable injury exhaustively, except to say that it must be serious and prolonged and rise above the ordinary annoyances, anxieties and fears that people living in society routinely, if sometimes reluctantly, accept. The need to accept such upsets rather than seek redress in tort is what I take the Court of Appeal to be expressing in its quote from *Vanek v. Great Atlantic & Pacific Co. of Canada* (1999), 48 O.R. (3d) 228 (C.A.): "Life goes on" (para. 60). Quite simply, minor and transient upsets do not constitute personal injury, and hence do not amount to damage.

[191] In the immediate case, the announcement from Health Canada was tempered and seemed designed to calm and not agitate the audience. As noted above, close to 70% of the putative class learned about the risks from a learned health professional. The announced theoretical increased risk of cancer was between 0.0086% and 0.0011%, which, as Health Canada points out, must be considered in the context of the existing lifetime risk of a 50% chance of developing cancer. (For further contextualization of reaction to risk, the 2019 report of the American National Safety Council states that the lifetime odds of dying in a motor vehicle driving accident are 0.91%.)

[192] Dr. O'Shaughnessy noted that all eight proposed representative Plaintiffs that he interviewed had fully recovered from any alleged psychological harm within a few months of the recall. Four of the proposed representative Plaintiffs did not suffer any psychological injuries at

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[67] 2008 SCC 27

all.

[193] As noted above, after *Saadati v. Moorhead*, to establish a compensable psychological injury, the claimant needs to prove that as a result of the defendant's negligence he or she suffered a mental disturbance that is serious and prolonged and that rises above the ordinary annoyances, anxieties and fears that come with living in civil society. The evidence filed on this motion does not demonstrate any such mental injury of a serious and prolonged nature for the overwhelming majority of the class.

[194] The immediate case is not like the cases involving solitary confinement ("administrative segregation") where in violation of their *Charter* rights, prison and penitentiary inmates were incarcerated in conditions that met the *Mandela* definition of torture. In these cases, it could be said that all class members suffered some compensable harm and for which a base line minimum award could be established with more compensation to follow at individual issues trials.[68] The purposes of the class proceedings legislation were well served in those cases. The same cannot be said of the immediate case, where in my opinion, the common issues criterion and the preferable procedure criterion are not satisfied for a psychological damages products liability cause of action.

[195] For all of the above reasons involving the cause of action, common issues, and preferable procedure criteria ensemble, the Plaintiffs' claim for psychological harm damages is not certifiable.

### (b) Negligence/product liability

[196] The Plaintiffs seek damages for the pure economic losses arising from their learning of the increased risk of being diagnosed with cancer as a consequence of ingesting the contaminated valsartan.

[197] Putting aside the Plaintiffs' negligence claims for psychological harm damages, which cause of action is not certifiable for non-satisfaction of the cause of action, common issues, and preferable procedure criteria, the essence of what is left is a products liability negligent manufacturing class action for the pure economic losses of medical bills, medical monitoring, refunds, and costs of drugs thrown away.

[198] The case at bar is a products liability case for negligent manufacturing. It is not a design negligence products liability case. The defect in the immediate case is that the valsartan was contaminated with NDMA and NDEA when they were manufactured in China. Valsartan was not designed to contain these nitrosamines. They are not part of the formula for valsartan, and they are not incidental non-medicinal ingredients added to the tablets. Of the four genres of products liability causes of action, listed above, it is readily apparent, and it is plain and obvious that the case at bar is not a design negligence case since the NDMA and the NDEA were not in the valsartan as a matter of design choice.

[199] It is also plain and obvious that the case at bar is not a duty to warn products liability case. There is no duty to warn of a danger that is not inherent in the use of the drug. The manufacturer's duty is to design and manufacture a drug that is not dangerous or whose dangers have been

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[68] *Francis v. Ontario*, 2020 ONSC 1644, aff'd 2021 ONCA 197; *Reddock v. Canada (Attorney General)*, 2019 ONSC 5053, varied 2020 ONCA 184; *Brazeau v. Attorney General (Canada)*, 2019 ONSC 1888, varied 2020 ONCA 184.

identified and declared to users.

[200] In the immediate case, there is no suggestion that the Defendants failed to warn about a danger inherent in the use of valsartan as it was designed and as it should have been manufactured. There is no suggestion that the Defendants failed to recall the contaminated valsartan. In the immediate case, it is a *non sequitur* to submit that the Defendants had a duty to warn of a danger inherent in the use of the valsartan, when the presence of NDMA and NDEA was aberrant not inherent in the use of the drug. The negligence of the Defendants is that they breached the duty of care to ensure that there were no defects in the manufacture of the valsartan. If that duty had not been breached, there would have been no need to recall the valsartan or to give any warning about using the drug.

[201] However, it is plain and obvious that the Plaintiffs' claim for manufacturing negligence is doomed to fail both as a matter of pleading and also as matter that there is no basis in fact for this cause of action. The existential problem for the Plaintiffs is that once the matter of compensatory damages for physical and psychological injuries is removed, the case at bar is just a products liability claim for pure economic losses for shoddy and not imminently dangerous goods.[69]

[202] Returning to the discussion of the Supreme Court of Canada's decision in *1688782 Ontario Inc. v. Maple Leaf Foods Inc.,*[70] in that case, Justices Brown and Martin explained that the liability rule from *Winnipeg Condominium Corp No 36 v. Bird Construction Co.,*[71] which would compensate a person for the pure economic loss of repairing defective goods that have not caused any physical harm, was only rationalizable with the general legal principle that there is no compensation for damages that have not yet occurred by recognizing a legal right not to suffer damages from the exposure to an imminent and serious threat to a person's person or property.

[203] Justices Brown and Martin noted that the liability rule in *Winnipeg Condominium* protects a right to be free of a negligently-caused real and substantial danger. In other words, it is a predicate for recovery for the pure economic loss that the goods present an imminent real and substantial danger to health and safety.

[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.

[205] In the immediate case, when the powerful rhetoric of connection to cancer is removed, the case is not much different than *Arora v. Whirlpool Canada LP*,[72] the case of the front-loading washing machines that stunk. In *Arora*, the washing machines were stinky because they did not drain as well as top-loading machines and the poor drainage encouraged stinky mould. At the outset of the litigation, the allegation was that the mould was a danger to health as a toxic pathogen, but this allegation of the danger of the design of the front-loading washing machines causing personal or property danger was abandoned, and the case became a tort case just for pure economic

[69] *Arora v. Whirlpool Canada LP*, 2012 ONSC 4642, aff'd 2013 ONCA 657, leave to appeal ref'd [2013] S.C.C.A. No. 498.
[70] 2020 SCC 35.
[71] [1995] 1 S.C.R. 85.
[72] 2012 ONSC 4642, aff'd 2013 ONCA 657, leave to appeal ref'd [2013] S.C.C.A. No. 498.

losses.

[206] In the case at bar the death knell for any and all of the genres of products liability is that the valsartan with its contaminants did not cause any immediate harm nor pose an imminent threat of harm. It is plain and obvious that even if, as appears to be the situation, that the Defendants had a duty of care and breached the standard of care, there is no proof of causation of harm; in short, no harm, no liability. As I have already explained above, the current Canadian law is that there is compensation for the actuality of harm; however, there is no compensation for an increase in the potentiality of harm.

[207] It follows that it is plain and obvious that the Plaintiffs' products liability negligence claim for pure economic losses does not satisfy the common issues criterion and accordingly the claim is not certifiable.

[208] Before concluding the discussion about the Plaintiffs' negligence claims, I need to address the Plaintiffs' submission that for goods manufactured for human consumption such as foods and pharmaceuticals, the law extracts a high standard of care approaching a strict liability. There is good authority supporting that proposition;[73] however, setting a high standard of care does not assist the Plaintiffs in the immediate case. The above fatal problems remain whatever the standard of care.

[209] I conclude that the Plaintiffs' products liability negligence claims, the fundamental core of the proposed class action, are not certifiable.

### 5. Strict Liability

[210] In addition to pleading that for goods manufactured for human consumption such as foods and pharmaceuticals, the law extracts a high standard of care approaching a strict liability, the Plaintiffs advance strict liability as a free-standing cause of action for goods for human consumption including foods and pharmaceuticals.

[211] There is a tort of strict liability associated with nuisance and damage to real property based on the case of *Rylands v. Fletcher*;[74] however, Canadian law has not extended the principles of strict liability to personal property, and products liability is based on negligence with its elements of a duty of care, a breach of the standard of care, causation of damages, and the existence of damages.

[212] The rule of strict liability of *Rylands v. Fletcher* is a land or real property tort that is not applicable to products liability claims. The rule from *Rylands v. Fletcher*, which is a sister tort to the land law tort of nuisance, is that a person who makes a non-natural use of his or her land and who brings onto his or her property something that will cause harm if it escapes from the property is liable for the damage caused if the thing escapes.[75] Under Canadian law, products liability is a

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[73] *Buchan v. Ortho Pharmaceutical (Canada) Ltd*. (1984), 46 O.R. (2d) 113 (H.C.J.), aff'd (1986), 54 O.R. (2d) 92 (C.A.).
[74] (1866), L.R. 1 Ex. 265, aff'd (1868), L.R. 3 H.L. 330.
[75] *Smith v. Inco Limited*, 2011 ONCA 628; *Gersten v. Municipality of Metropolitan Toronto* (1973), 2 O.R. (2d) 1 (H.C.J.); *Dahlberg v. Naydiuk* (1969), 72 W.W.R.(N.S.) 210 (Man. C.A.); *Rylands v. Fletcher* (1866), L.R. 1 Ex. 265, aff'd (1868), L.R. 3 H.L. 330.

matter of negligence not strict liability.[76]

[213] Apart from the legal fact that the Plaintiffs do not have a cause of action based on strict liability, there is also the fatal impediment that if the strict liability claim was available to them, it would require damage to have incurred from the drug being ingested, but in the immediate case, as noted above, no compensable damage has occurred.

[214] Thus, it is plain and obvious that the claim for strict liability is doomed to failure and this claim does not satisfy the cause of action criterion.

### 6. Toxic Battery

[215] The Plaintiffs plead that by knowingly or recklessly exposing class members to contaminated valsartan, the Defendants committed the tort of toxic battery. The Statement of Claim pleads that "By ingesting the contaminated valsartan Drugs, Class Members were exposed to toxic carcinogens, constituting a harmful and offensive contact to the person." The claim also pleads that Class Members did not consent to ingesting the carcinogens, and that the defendants intended class members to be exposed or were willfully blind or recklessly indifferent to the risk that they would be exposed.

[216] A person will be liable for battery, which is a type of trespass to the person, if he or she intentionally inflicts unlawful force, unconsented physical contact, on the plaintiff whether or not damage is caused.[77] Actions of battery in respect of surgical or other medical treatment are confined to cases where surgery or treatment has been performed or given to which there has been no consent at all or where, emergency situations aside, surgery or treatment has been performed or given beyond that to which there was consent.[78]

[217] Given the problems discussed above about compensable damages, the Plaintiffs in the immediate case seem almost desperate to have one of their causes of action be a battery, which does not necessarily involve physical harm but focuses on the acts of violation – trespass to the person. In other words, the Plaintiffs rely on the cause of action in battery to satisfy the cause of action criterion because unlike the other causes of action, damages is not a constituent element of the cause of action for battery.

[218] However, it is plain and obvious that there is no certifiable battery cause of action in the immediate case for at least three reasons.

[219] First, the type of battery alleged does not fit the model for either conventional battery or battery in respect of surgical or other medical treatment, which are intentional torts. The pleaded material facts are allegations of negligence, which is not an intentional tort, and it is a perversion of the material facts to construe them to amount to an advertent act when the force of the pleaded

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[76] *Price v. Smith & Wesson Corp*., 2021 ONSC 1114 *St Isidore Co-Op Limited v. AG Growth International Inc*, 2019 ABQB 763 at para. 38; *McCluskey v. Ford Motor* Co., 2017 PEISC 17 at para. 26; *Dahlberg v. Naydiuk*, (1969), 72 W.W.R.(N.S.) 210 (Man. C.A.); *Ayoub v. Beaupre* [1964] S.C.R. 448; *Read v. J. Lyons & Co*., [1947] A.C. 156.

[77] *Piresferreira v. Ayotte* 2010 ONCA 384; *Miguana v. Toronto (City) Police Services Board*, 2008 ONCA 799; *Non-Marine Underwriters, Lloyd's of London v. Scalera*, [2000] 1 S.C.R. 551; *Norberg v. Wynrib*, [1992] 2 S.C.R. 226 at paras. 26, 53; *Bettel v. Yim* (1978), 20 O.R. (2d) 617 (Co. Ct.); *Schweitzer v. Central Hospital* (1974), 6 O.R. (2d) 606 (H.C.J.)

[78] *Reibl v. Hughes*, [1980] 2 S.C.R. 880 at pp. 890-92.

acts of commission or omission is inadvertence.

[220] In *Non-Marine Underwriters, Lloyd's of London v. Scalera,*[79] the primary authority relied on by the Plaintiffs in support of their toxic battery cause of action, the Supreme Court of Canada observed that a court is not bound by the legal labels chosen by the plaintiff and a "plaintiff cannot change an intentional tort into a negligent one by choice of words or *vice versa*."

[221] In *Non-Marine Underwriters, Lloyd's of London v. Scalera,* the plaintiff, who was a victim of a sexual battery, pleaded a negligence claim. The plaintiffs likely made this pleading in order to have access to the defendant's insurance coverage, which was available for negligence but not for intentional torts. On the defendant's application to require his insurer to defend the negligence claim, the Supreme Court reviewed the pleading and concluded that the plaintiff's claim was genuinely for sexual battery and not for negligence.

[222] In the immediate case, the Plaintiffs' gambit is to label their claim as a battery when it is genuinely a negligence claim. This gambit fails. It is plain and obvious that the Defendants did not wilfully or recklessly intend to harm patients prescribed with valsartan. The Defendants did not manufacture valsartan with the intent that it contain NDMA or NDEA and the presence of these contaminants was not an advertent act but an inadvertent one because, to quote the Plaintiffs' Statement of Claim the Defendants "failed to adequately, sufficiently and properly inspect the safety and quality of the valsartan Drugs", and "failed to identify the valsartan Drugs as a safety hazard".

[223] Second, the type of battery alleged in the immediate case is in respect of medical treatment, and it is plain and obvious that a claim for battery in respect of medical treatment cannot be made out in the immediate case. The valsartan was consensually prescribed by physicians for the treatment of hypertension, and there is no evidence that the ingestion of the drug failed to treat hypertension.

[224] Third, even if there was material facts to support the intentionality of harming the Class Members, no purpose would be served by having a common issues trial about battery because the class members would have occasioned no psychological harm from the battery, which anatomically they would not even be aware but for the human biology evidence at the common issues trial about the metabolization of NDMA and NDEA. Further, no economic losses were occasioned by the metabolization of the contaminated valsartan.

[225] The Plaintiffs do not plead that NDMA and NDEA have actually caused damage and they purport to advance a class action for battery without ever needing to prove that the ingestion of valsartan caused any Class Member physical harm. In other words, even if the battery claim were held to satisfy the cause of action criterion, it would not satisfy the common issues and the preferable procedure criterion because as was the case in *Arora v. Whirlpool Canada LP*,[80] discussed above, and *Rothwell v. Chemical and Insulating Co*.,[81] also discussed above, an action for compensation should not be set in motion on account of a trivial injury, *de minimis non curat lex*.

[226] I conclude that the battery cause of action is not certifiable.

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[79] [2000] 1 S.C.R. 551.
[80] 2012 ONSC 4642, aff'd 2013 ONCA 657, leave to appeal ref'd [2013] S.C.C.A. No. 498.
[81] [2007] UKHL 39.

## 7. Breach of Consumer Protection Laws[82]

[227] The Plaintiffs' goal in advancing claims under the various provincial consumer protection statutes is to recover various heads of economic loss damages and most obviously the claims for refunds and the wasted expense of unused pills.

[228] The Plaintiffs submit that in the context of consumer protection legislation, a manufacturer's failure to state a material fact about its product is sufficient to ground a consumer protection claim.[83] The Plaintiffs submit that the Defendants' failure to disclose that valsartan contained NDMA and NDEA was a failure to state a material fact. The crux of the Plaintiffs' claim, as set out in paragraphs 154, 156, and 157 of the Plaintiffs' Third Amended Statement of Claim, is that Defendants' respectively made false representations and but for these representations, the putative class members would not have purchased valsartan. Paragraphs 154, 156, and 157 state:

> 154 Each defendant made, approved or authorized a number of consistent, common and uniform representations regarding the valsartan drugs it manufactured and distributed. Specifically, each defendant represented that the valsartan drugs it manufactured and distributed was of high quality, was free of defects including free of any dangerous contaminants, and was fit for human consumption (collectively, the "Representations").
>
> […]
>
> 156. The Representations were false, misleading, deceptive and constituted an unfair practice under all of the Applicable Consumer Protection Legislation:
>
> (i) the valsartan drugs were not safe or free from defects;
>
> (ii) the valsartan drugs were not of high quality; and
>
> (iii) the valsartan drugs were contaminated and contained a contaminant which can cause, materially contribute, and/or materially increase the risks of contracting cancer, liver disease, and other health conditions.
>
> 157. But for the Representations, the Class Members never would have purchased or ingested valsartan drugs or would have stopped if subsequently warned.

[229] Although there are some significant differences, the general approach of the consumer protection statutes is similar across the country. Using the Ontario *Consumer Protection Act, 2002* as illustrative of consumer protection claims across the country, Part III of the Ontario Act addresses "Unfair Practices" and provides in s. 17 that no person shall engage in an unfair practice. Section 14 (1) provides that it is an unfair practice for a person to make a false, misleading, or deceptive "representation". A "representation" is defined in s. 1 as a representation, claim, statement, offer, request or proposal that is or purports to be: (a) made respecting or with a view to the supplying of goods or services to consumers, or (b) made for the purpose of receiving payment for goods or services supplied or purporting to be supplied to consumers. Section 14(2)(14) states that "a representation using exaggeration, innuendo or ambiguity as to a material

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[82] BC: *Business Practices and Protection Act*, SBC 2004, c. 2; AB: *Fair Trading Act*, RSA 2000, c. F-27; SK: *Consumer Protection and Business Practices Act*, SS 2014, c. C-30.2; MB: *Business Practices Act*, CCSM c. B120; ON: *Consumer Protection Act, 2002*, SO 2022, c. 30; QB: *Consumer Protection Act*, RSQ c P-40.1; PEI: *Business Practices Act*, RSPEI 1988, c. B-7; NL: *Consumer Protection and Business Practices Act*, SNL 2009, c. 31.2.

[83] *Matoni v. C.B.S. Interactive Multimedia Inc. (Canadian Business College)*, [2008] O.J. No. 197 (S.C.J.).

fact or failing to state a material fact if such use or failure deceives or tend to deceive" is a false, misleading or deceptive representation.

[230] It is plain and obvious that the breach of consumer protection statutes from across the country are not the silver bullet within the arsenal for certification that the Plaintiffs had hoped. There are plain and obvious and serious flaws, which I shall detail below, and there is the fundamental flaw that reliance on these consumer laws misses the Plaintiffs' own chosen target of compensation for the pure economic losses of medical bills, medical monitoring, refunds, and cost of drugs thrown away.

[231] For the reasons described above, the law, as it exists in Canada, does not provide compensation for an increase of risk of harm as such. As noted above, compensation is for actualities not an increase in potentiality. Further, in the immediate case there is no basis in fact for claiming compensation for refunds and for wasted pills and there is no social utility in advancing these *de minimis* claims.

[232] To the extent that any of the consumer protection statutes require damages as a constituent element for liability, there is no basis in fact that any Class Members have suffered any compensable harm. The heads of damages for medical bills and for medical monitoring arising from an increased risk of experiencing cancer are not recoverable. As for refunds and wasted pills, the advice from Health Canada was to continue taking the valsartan medication unless advised to stop by a health care provider and so there may not have been many returned or wasted drugs. The voluntary recall was directed at retailers, and some of the consumers who were personally out-of-pocket might as a matter of commonsense return their valsartan for a refund when they got a replacement for their prescription. The heads of damages for refunds and the expense of bills thrown away are *de minimis* and do not satisfy the preferable procedure criterion.

[233] In *Arora v. Whirlpool Canada LP*,[84] discussed above, the Plaintiffs attempted to support their claims for pure economic losses based on the assertion that the odiferous washing machines damaged the laundry with a foul smell. In the Court of Appeal, Justice Hoy concluded that the plaintiff's genuine claim was for pure economic losses and that such a *de minimis* claim to damage to property would not support an actionable negligence claim. She stated at paragraphs 76-77:

> 76, Moreover, the appellants who alleged that their clothing was damaged because a smell was imparted on them did not plead that the smell was in any way lasting, that they were unable to wear their clothing as a result, or that there was any physical damage to the clothing. The proposition that such de minimis harm could give rise to an actionable negligence claim is dubious.
>
> 77. In *Rothwell v. Chemical and Insulating Co*., [2007] UKHL 39, [2008] 1 A.C. 281, at para. 8, [discussed above] Lord Hoffman affirmed the familiar principle that "[a]n action for compensation should not be set in motion on account of a trivial injury. *De minimis non curat lex*."

[234] Just as the products liability negligence claim in *Arora v. Whirlpool Canada LP*, did not justify a certifiable claim, the consumer protection claim is for damages that are non-compensable or *de minimis.* That the heads of damages for medical bills and medical monitoring are not recoverable is explained above in the context of the tort claims.

[235] Whether the Plaintiffs' breach of consumer protection statutes claims discloses a certifiable cause of action should be considered in light of the remedies the Plaintiffs actually seek,[85] and in

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[84] 2012 ONSC 4642, aff'd 2013 ONCA 657, leave to appeal ref'd [2013] S.C.C.A. No. 498.
[85] *Atlantic Lottery Corp. Inc. v. Babstock*,2020 SCC 19 at para.49.

the immediate case there is no basis in fact or in law that damages are a remedy for the breach of the consumer protection statutes because there are no compensable damages for an increase of a risk of a personal injury and the damages for refunds and for the expense of pills thrown away are *de minimis* and the claims do not satisfy the preferable procedure criterion.

[236] As for the claim for refunds and the cost of unused pills, it should also be observed that the valsartan is not alleged to be unfit for its intended purpose of treating hypertension and there is no suggestion that the contaminated valsartan was a useless or ineffective drug for the purpose to treating hypertension. Rather, the valsartan is alleged to be unfit and misrepresented or sold contrary to the consumer protection statutes because it was impure, but there is no compensation for just shoddy goods. This circumstance makes the claim for refunds and the wasted pills *de minimis* and the preferable procedure criterion unsatisfied. A class proceeding is overkill and would not be an efficient and manageable method of advancing what are insubstantial individual claims for damages.

[237] The circumstance that the valsartan was an effective drug for its represented purposes and that the damages claimed from the *Consumer Protection Act* wrongdoing are not compensable distinguishes the case at bar from more conventional consumer protection class actions like *Krishnan v. Jamieson Laboratories Inc.*,[86] a decision of the British Columbia Supreme Court, much relied on by the Plaintiffs in the immediate case.

[238] In *Krishnan,* Justice Branch, certified the plaintiffs' proposed class action. In *Krishnan,* the plaintiffs and the class members suffered from joint pain, and they purchased a natural health product represented by the defendants to contain "glucosamine sulphate," which is one of several forms of glucosamine, but the only glucosamine known to be effective in managing osteoarthritis. The plaintiffs and the class members, however, did not receive a health product containing "glucosamine sulphate;" rather, they received a different and therapeutically ineffective glucosamine.

[239] In *Krishnan,* the plaintiffs sued for negligent misrepresentation (not a products liability tort claim) and for breaches of the various provincial consumer protection statutes. In contrast, in the immediate case, the Plaintiffs sue for products liability negligence and for breaches of the various provincial consumer protection statutes. In contrast to the useless natural health product in *Krishnan,* in the immediate case, the valsartan was therapeutically effective, and it cannot be said that the valsartan was useless notwithstanding its diminished quality.

[240] I do not disagree with Justice Branch's decision, in *Krishnan.* I just would not adopt it for the immediate case, which I regard as presenting a different problem having regard to the way that the Plaintiffs have designed their class action, which design is not to claim damages for the valsartan actually causing cancer (or from failing to treat hypertension). Accordingly, for the consumer protection statutes that have damages as a constituent element, the claim is doomed to fail and does not satisfy the cause of action criterion, or the claim does not satisfy the common issues or preferable procedure criterion.

[241] The circumstance that the valsartan was an effective drug for its represented purposes and that the damages claimed from the *Consumer Protection Act* wrongdoing are not compensable also distinguishes the case at bar from Justice Glustein's decision in *Drynan v. Bausch Health*

[86] 2021 BCSC 1396.

*Companies Inc.*,[87] once again, a more conventional consumer protection class action that bears some similarity to *Krishnan v. Jamieson Laboratories Inc.*

[242] Although I disagree with *Drynan* on the matter of whether the Ontario consumer protection statute requires privity, I do not disagree with how Justice Glustein dealt with the unfair practice aspects of the proposed class action; however, *Drynan* is distinguishable from the case at bar where the crux of the matter is failure to disclose rather than disclosing something that may turn out to have been untrue.

[243] In *Drynan v. Bausch Health Companies Inc.*, the defendants sold a natural health product containing an extract derived from the roots of ginseng. The product was marketed as a supplement to reduce the chance of catching cold and flu and to reduce the frequency, severity, and duration of cold and flu symptoms by boosting the immune system. The *Drynan* case is not about a contaminated product. It is about a pure product that allegedly was misrepresented as effective when it was actually useless, which uselessness does make a reasonable case for refunds. It remains to be determined at a common issues trial in *Drynan* whether the science supports the defendant's representations about the medicinal and therapeutic efficiency of the product, but the case at bar presents a much different legal problem.

[244] These conclusions about the consumer protection causes of action do not condone any wrongdoing of the Defendants. The Defendants are just fortunate that the law does not compensate for abstract injuries, but there is no social or legal utility in authorizing the behemoth of a class proceeding when its major purpose will yield no meaningful compensation for the class members.

[245] Moreover, and in any event, there are other flaws in the Plaintiffs' causes of action based on consumer protection statutes as described next.

[246] The consumer protection statutes (also the misrepresentation provisions of the *Competition Act)* aim at prohibiting and punishing intentional acts of misrepresentation and unfair business practices. However, in the immediate case, the genuine essence of the Plaintiffs' action is a products liability action based on inadvertent conduct not intentional conduct. I, therefore, agree with the argument at paragraphs 111-113 of the Defendant Sandoz's factum, which are adopted by the Defendant Teva:

> 111. Both the *Competition Act* at the federal level, and consumer protection legislation at the provincial level, include provisions prohibiting the making of false or misleading representations to prospective purchasers of goods and services in order to protect the proper functioning of a competitive market.[88]
>
> 112. These provisions apply where the defendant knows of certain shortcomings in its goods or services, and intentionally misrepresents that those shortcomings do not exist, rather than improving the product to remove those shortcomings, so as to deceive purchasers into erroneously choosing an inferior product over a competitive product that is superior, either in price or quality.
>
> 113. The facts of the present case have nothing to do with such an intentional distortion of the competitive market. Once again, the Plaintiffs' essential allegation is that the Defendants were negligent in not knowing that valsartan was contaminated with NDMA and NDEA. This allegation is fundamentally inconsistent with the Plaintiffs' misleading advertising claims under the

[87] 2021 ONSC 7423, leave to appeal ref'd 2022 ONSC 1586 (Div. Ct.).

[88] *Commissioner of Competition v. Premier Career Management Group Corp*., 2009 FCA 295 at paras. 61-62; *R. v. Stucky*, 2009 ONCA 151 at para. 39.

> *Competition Act* and consumer protection legislation, to the effect that they intentionally concealed the fact of that contamination.

[247] Moving on to another problem, although privity of contract is not required in British Columbia, Saskatchewan, and Manitoba, privity of contract is required for a consumer protection claim in Ontario,[89] and in the immediate case, there is no privity between the Defendants and any Class Members.

[248] *Richardson v. Samsung Electronics Canada Inc.*,[90] which was affirmed by the Divisional Court, *Williams v. Canon Canada Inc*,[91] which was affirmed by the Divisional Court, and *Singer v. Schering-Plough*,[92] are authority that consumers who do not have a contractual relationship with the supplier do not have a claim for unfair practices under Ontario's *Consumer Protection Act, 2001*. Until the above line of cases is expressly overturned by the Court of Appeal, they are binding decisions.[93] I, therefore, cannot and do not follow the lower court decisions that assert that the point remains unsettled.[94] While I agree with the Plaintiffs' argument that I can depart from *stare decisis* and reconsider "settled rulings" of higher courts where a new legal issue is raised;[95] however, the proper interpretation of Ontario's *Consumer Protection Act, 2001* is not a new legal issue.

[249] I, therefore, conclude for the above reasons that the consumer protection causes of action are not certifiable in the immediate case.

## 8. Breach of the *Competition Act*[96]

[250] The Plaintiffs plead that the Defendants' representations of quality pharmaceutical products were false and misleading and made knowingly or recklessly. The Plaintiffs allege a breach of s. 52 (1)(4) of the *Competition Act* in support of a statutory claim for damages pursuant to s. 36 (1) of the Act. Sections 52 (1)(4) and 36 (1) of the *Competition Act* are set out below:

> *False or misleading representation — sender or subject matter information*
>
> 52.01 (1) No person shall, for the purpose of promoting, directly or indirectly, any business interest or the supply or use of a product, knowingly or recklessly send or cause to be sent a false or misleading representation in the sender information or subject matter information of an electronic message.
>
> […]

[89] *James Richardson v. Samsung Electronics Canada Inc.*, 2019 ONSC 6845, aff'd 2012 ONSC 3692 (Div. Ct.); *Williams v. Canon Canada Inc*., 2011 ONSC 6571; *Singer v. Schering-Plough Canada Inc*., 2010 ONSC 42.
[90] 2018 ONSC 6130, aff'd 2019 ONSC 6845 (Div. Ct.).
[91] 2011 ONSC 6571, aff'd 2012 ONSC 3692 (Div. Ct.).
[92] 2010 ONSC 42.
[93] *Marcinkiewicz v. General Motors of Canada Co*., 2022 ONSC 2180 at para. 145.
[94] *Drynan v. Bausch Health Companies Inc.*, 2021 ONSC 7423, leave to appeal ref'd 2022 ONSC 1586 (Div. Ct.); *Rebuck v. Ford Motor Company*, 2018 ONSC 7405; *Kalra v. Mercedes Benz*, 2017 ONSC 3795.
[95] *Carter v. Canada (Attorney General)*, 2015 SCC 5; *Canada (Attorney General) v. Bedford*, 2013 SCC 72
[96] RSC 1985, C C-34.

*Proof of deception not required*

(4) For greater certainty, in establishing that any of subsections (1) to (3) was contravened, it is not necessary to prove that any person was deceived or misled.

{*****}

*Recovery of damages*

36 (1) Any person who has suffered loss or damage as a result of

(a) conduct that is contrary to any provision of Part VI, or

(b) the failure of any person to comply with an order of the Tribunal or another court under this Act,

may, in any court of competent jurisdiction, sue for and recover from the person who engaged in the conduct or failed to comply with the order an amount equal to the loss or damage proved to have been suffered by him, together with any additional amount that the court may allow not exceeding the full cost to him of any recall in connection with the matter and of proceedings under this section.

[251] In advancing their claim for a breach of the *Competition Act*, the Plaintiffs rely on the alleged misrepresentations set out in the facts portion of these Reasons for Decision, but at the heart of the misrepresentation allegations is the accusation that notwithstanding their statements of high quality control practices, the Defendants did not disclose that they had manufactured and distributed a contaminated product.

[252] In the immediate case, it is plain and obvious that a claim for breach of s. 52 (1) of the *Competition Act* in support of the statutory cause of action under s. 36 (1) will fail for two reasons.

[253] First, the claim fails because the *Competition Act* does not impose a general duty of disclosure, and the failure of the Defendants to warn that the valsartan was shoddy product but not an imminently dangerously defective drug is not a misrepresentation for the purposes of s. 52 of the *Competition Act*.[97] A failure to disclose a non-dangerous defect in a product is not a representation for the purposes of s. 52 of the *Competition Act*.[98]

[254] Second, the claim fails because to establish a breach of section 52 (1) and to obtain damages under section 36 (1), a plaintiff must prove actual loss or damage caused by a materially false or misleading representation.[99] In the immediate case, the Plaintiffs seek damages for the psychological harm and for the pure-economic losses suffered by Class Members due to the alleged *increased risk* of developing cancer as a consequence of ingesting valsartan that contains NDMA or NDEA, but the claim for psychological harm is uncertifiable and there is no compensation for the harm of an increased risk and thus there can be no causal connection to damages when there are no damages.

[255] Therefore, I conclude that the *Competition Act* causes of action is not certifiable.

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[97] *Arora v. Whirlpool Canada LP*, 2012 ONSC 4642, aff'd 2013 ONCA 657, leave to appeal ref'd [2013] S.C.C.A. No. 498; *Williams v. Canon Canada Inc*., 2011 ONSC 6571.

[98] *Arora v. Whirlpool Canada LP*, 2012 ONSC 4642, aff'd 2013 ONCA 657, leave to appeal ref'd [2013] S.C.C.A. No. 498; *Williams v. Canon Canada Inc*., 2011 ONSC 6571.

[99] *Drynan v. Bausch Health Companies Inc*., 2021 ONSC 7423, leave to appeal ref'd 2022 ONSC 1586 (Div. Ct.); *Pioneer Corp v Godfrey*, 2019 SCC 42; *Singer v. Schering-Plough Canada Inc*., 2010 ONSC 42 at paras. 107-108; *Matoni v. C.B.S. Interactive Multimedia Inc. (Canadian Business College)*, [2008] O.J. No. 197 (S.C.J.).

## 9. Breach of the *Civil Code of Québec*[100]

[256] The Plaintiffs plead breaches of sections 1726 and 1730 of the *Civil Code of Québec* and breaches of the Québec *Consumer Protection Act*.

[257] Section 1726 of the *Civil Code of Québec* provides that: "The seller is bound to warrant the buyer that the property and its accessories are, at the time of the sale, free of latent defects which render it unfit for the use for which it was intended or which so diminish its usefulness that the buyer would not have bought it or paid so high a price if he had been aware of them."

[258] Section 1730 of the *Civil Code of Québec* provides that, "The manufacturer, any person who distributes the property under his name or as his own, and any supplier of the property, in particular the wholesaler and the importer, are also bound to a seller's warranty."

[259] Apparently out of an abundance of caution, the Plaintiffs plead both the *Civil Code of Québec* and breaches of the Québec *Consumer Protection Act.* The reason for this caution is in that *Brousseau c. Laboratoires Abbot limitée,*[101] the plaintiff brought a proposed class action for undisclosed side effects of a drug and the Québec Court of Appeal held that the relationship between a pharmaceutical manufacturer and the consumer of a drug was not governed by the Quebec *Consumer Protection Act*, but by the provisions of the *Civil Code of Québec* dealing with manufacturer liability. However, in *Gauthier c. Johnson & Johnson Inc.*,[102] without reference to *Brousseau,* a proposed class action for undisclosed side effects was certified under the Québec *Consumer Protection Act*. In subsequent decisions, Québec courts have read the *Brousseau* decision narrowly to mean that professionals, such as veterinarians and pharmacists are not covered by the Québec *Consumer Protection Act.*[103]

[260] Relying on my decision in *Das v George Weston Limited*,[104] where I discuss the principles about the proof of foreign law, which is treated as an issue of fact, the Defendants assert that it is plain and obvious that Québec law has not been proven in the immediate case and therefore the cause of action criterion has not been satisfied.

[261] While I shall conclude that the Québec causes of action are not certifiable, it is not because of want of evidentiary proof. *Das v George Weston Limited* was not a conventional certification motion because the defendants challenged the pleading not only pursuant to rule 21.01(1)(b), where the material in the statement of claim is treated as proven but also under rule 21.01(1)(a) as an issue of law for which the *Rules of Civil Procedure* permit evidence. In other words, the Defendants moved outside of the cause of action criterion of s. 5(1)(a) of the *Class Proceedings Act, 1992* in their challenge of the foreign law. In the immediate case, the Defendants' challenge is the more conventional challenge, and in the immediate case, the Plaintiffs have pleaded the substantive content of Québec law, which I can properly assume to be a pleaded material fact that can be taken as true.

[262] Turning then to the Defendants' challenge to the Plaintiffs' causes of action based on

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[100] CQLR c. C-1991.
[101] 2019 QCCA 801 at paras. 66, 72.
[102] 2020 QCCS 690, aff'd 2020 QCCA 1666
[103] *Croteau c. Marchand*, 2022 QCCQ 880 at para. 13; *Gagnon c. Intervet Canada Corp.*, 2021 QCCA 251 at para. 15.
[104] 2017 ONSC 4129.

Québec law, the discussion can be very brief.

[263] For the same reasons that the Plaintiffs' breach of consumer protection laws and *Competition Act* causes of action are not certifiable, the Québec causes of action are not certifiable.

## 10. Unjust enrichment

[264] The elements of a restitutionary claim in unjust enrichment are: (1) the defendant has been enriched; (2) the plaintiff has suffered a deprivation that corresponds to the defendant's enrichment; and (3) the absence of any juristic reason justifying the defendant's retention of that transfer of value.[105] In *Moore v Sweet*,[106] the Supreme Court of Canada stated that for an unjust enrichment, it must be shown that something of value – a tangible 'benefit' – passed from the plaintiff to the defendant.[107]

[265] It is plain and obvious that the Plaintiffs' claim for unjust enrichment is doomed to fail.

[266] There is no viable unjust enrichment claim pleaded against the pharmaceutical company defendants in the immediate case for three reasons.

[267] First, there has been no transfer of money, goods, or valuable services from the Class Members to the Defendants. The Class Members dealt directly with the pharmacies or hospital dispensaries that dispensed valsartan, which is a prescription drug. Thus, an unjust enrichment claim does not sound at all for this type of product liability case.[108]

[268] I appreciate that in *Pro-Sys Consultants Ltd. v. Microsoft Corporation*,[109] the Supreme Court of Canada did not close the door on a transfer of wealth that was indirect between the plaintiff and the defendant as providing the basis for an unjust enrichment claim. There, however, is no direct or indirect transfer of wealth in the immediate case because up until the recall, the Class Members received value in exchange for what they paid or what was paid for them for the drugs, which no one suggests did not serve their indicated purpose of treating hypertension.

[269] Second, the unjust enrichment claim is bound to fail because the deprivation that the Class Members suffered in the immediate case was non-monetary; it was a deprivation in the quality of the valsartan that had been purchased. The valsartan was not as safe as it should have been. Courts in recent decisions in proposed products liability class actions, which I would adopt, such as *Kane v. FCA US LLC*,[110] and *Spring v. Goodyear Canada Inc*.,[111] have recognized that the loss from a shoddy good is not the type of deprivation or transfer of wealth that is amenable to an unjust enrichment claim.

[270] In *Kane v. FCA US LLC*, Justice Elson stated at paragraph 143:

> [T]he plaintiff's pleaded allegations do not disclose the required elements of an unjust enrichment claim. Following the analysis articulated in *Spring*, the proposed class members could not be said to have sustained a deprivation when they purchased a class vehicle. Instead of the tires acquired in

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[105] *Moore v. Sweet*, 2018 SCC 52; *Kerr v. Baranow*, 2011 SCC 10; *Garland v. Consumers' Gas Co*., 2004 SCC 25; *Peel (Regional Municipality) v. Canada*, [1992] 3 S.C.R. 762; *Pettkus v. Becker*, [1980] 2 S.C.R. 834.
[106] 2018 SCC 52 at para. 41.
[107] See also *Apotex Inc. v. Eli Lilley and Company*, 2015 ONCA 305 at paras 39-46.
[108] *Marcinkiewicz v. General Motors of Canada Co*., 2022 ONSC 2180
[109] 2013 SCC 57.
[110] 2022 SKQB 69.
[111] 2021 ABCA 18, rev'g 2020 ABQB 252.

> *Spring*, the class members received vehicles. The fact that one or more of the vehicles may have had safety defects, for which another remedy may be available, does not create the kind of deprivation contemplated in a claim for unjust enrichment. Moreover, any enrichment FCA may have contractually received from the sale of a class vehicle, whether defective or not, cannot be said to have occurred in the absence of juristic reason.

[271] Third, as mentioned in *Kane v. FCA US LLC,* even if the deprivation in the immediate case was a type of deprivation for unjust enrichment and even if there has been a transfer of wealth to the Defendants, then the contract of sale between the Defendants and the retailer of the pharmaceuticals is a juristic reason for the transfer of wealth.[112]

[272] I, therefore, conclude that the unjust enrichment cause of action is not certifiable.

### 11. Punitive Damages

[273] Although strictly speaking not a matter for discussion in the context of the cause of action criteria, I foreshadow here my discussion later under the common issues criteria that there are doctrinal reasons for concluding that the claim for punitive damages is not certifiable.

## I. Identifiable Class Criterion (s. 5 (1)(b))

### 1. General Principles – Identifiable Class Criterion

[274] The second certification criterion is the identifiable class criterion. The definition of an identifiable class serves three purposes: (1) it identifies the persons who have a potential claim against the defendant; (2) it defines the parameters of the lawsuit so as to identify those persons bound by the result of the action; and (3) it describes who is entitled to notice.[113]

[275] In defining the persons who have a potential claim against the defendant, there must be a rational relationship between the class, the cause of action, and the common issues, and the class must not be unnecessarily broad or over-inclusive.[114] An over-inclusive class definition binds persons who ought not to be bound by judgment or by settlement, be that judgment or settlement favourable or unfavourable.[115] The rationale for avoiding over-inclusiveness is to ensure that litigation is confined to the parties joined by the claims and the common issues that arise.[116] A proposed class definition, however, is not overbroad because it may include persons who ultimately will not have a successful claim against the defendants.[117]

[276] The class must also not be unnecessarily narrow or under-inclusive. A class should not be

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[112] See also: *Marcinkiewicz v. General Motors of Canada Co*., 2022 ONSC 2180; *Spring v. Goodyear Canada Inc*., 2021 ABCA 18, rev'g 2020 ABQB 252; and *Atlantic Lottery Corp. Inc. v. Babstock* 2020 SCC 19 at para. 71 confirms that "a defendant that acquires a benefit pursuant to a valid contract is justified in retaining that benefit".
[113] *Bywater v. Toronto Transit Commission*, [1998] O.J. No. 4913 (Gen. Div.).
[114] *Pearson v. Inco Ltd.* (2006), 78 O.R. (3d) 641 at para. 57 (CA), rev'g [2004] O.J. No. 317 (Div. Ct.), which had aff'd [2002] O.J. No. 2764 (SCJ).
[115] *Robinson v. Medtronic Inc*., [2009] O.J. No. 4366 at paras. 121-146 (SCJ).
[116] *Frohlinger v. Nortel Networks Corporation*, [2007] O.J. No. 148 at para. 22 (SCJ).
[117] *Silver v. Imax Corp*., [2009] O.J. No. 5585 at para. 103-107 (SCJ) at para. 103-107, leave to appeal to Div. Ct. refused 2011 ONSC 1035 (Div. Ct.); *Boulanger v. Johnson & Johnson Corp*., [2007] O.J. No. 179 at para. 22 (SCJ), leave to appeal ref'd [2007] O.J. No. 1991 (Div. Ct.); *Ragoonanan v. Imperial Tobacco Inc.* (2005), 78 O.R. (3d) 98 (S.C.J.), leave to appeal ref'd [2008] O.J. No. 1644 (Div. Ct.); *Bywater v. Toronto Transit Commission*, [1998] O.J. No. 4913 at para. 10 (Gen. Div.).

defined wider than necessary, and where the class could be defined more narrowly, the court should either disallow certification or allow certification on condition that the definition of the class be amended.[118]

### 2. Analysis – Identifiable Class Criterion

[277] In the notice of motion for certification, and the recently amended Claim, the plaintiffs proposed the following class definition:

> [A]ll persons in Canada who purchased or ingested one or more of the valsartan products identified by Health Canada in the Recall List dated July 9, 2018 or in any future such recall lists.

[278] In their factum, the plaintiffs propose a broader class:

> All persons in Canada who purchased or ingested one or more of the valsartan products manufactured and/or distributed by the defendants identified by the DINs listed on the Health Canada Recall List dated November 28, 2018 (the "Class Members") between January 1, 2012 and December 1, 2018 (the "Class Period").

[279] The proposed class period begins in 2012 and the end date is when the drugs subject to the last recalls issued August 17, 2018, would likely have been withdrawn or consumed, being December 2018.

[280] Teva argues that the revised class definition improperly expands the size of the class by including Class Members who ingested valsartan manufactured by the Defendants between 2012 and 2015. Teva argues that this is an expansion because these putative Class Members were not part of the original class definition and as such their claims would be statute-barred if they are added to the action in 2022.

[281] It is one of the ironies of class proceedings that at the certification stage defendants seek to reduce the class size by excluding putative Class Members that will be added back when the action settles so that the defendant gets more bang from the releases, but, in any event, I agree with the Plaintiffs that since their pleading identified facts to support the torts as commencing in 2012, there is no merit to Teva's argument that the claims extending back to 2012 are statute-barred. Since these claims were adequately identified with material facts, the claims are not new claims or new causes of action,[119] and, in any event, pursuant to s. 28 of the *Class Proceedings Act, 1992*, the running of the limitation period has been suspended.

[282] In a related argument, the Defendants argue that the class is over-inclusive because Health Canada stated in its August 18, 2018 release that: "Although Health Canada believes that the NDMA was introduced as a result of a change in manufacturing processes at Zhejiang Huahai Pharmaceuticals in 2012, some Canadian companies may have been using the affected valsartan active ingredient for less time." And in its September 10, 2018 release it stated: "The longest time affected products were on the Canadian market was approximately three years." In my opinion, this uncertainty does not negate that there is some basis in fact for the temporally longer class period.

[283] Thus, standing alone, as a technical matter, the class definition criterion is satisfied in the

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[118] *Fehringer v. Sun Media Corp*., [2002] O.J. No. 4110 at paras. 12-13 (SCJ), aff'd [2003] O.J. No. 3918 (Div. Ct.); *Hollick v. Toronto (City)*, 2001 SCC 68 at para. 21.
[119] *Dugal v. Manulife Financial*, 2013 ONSC 4083.

immediate case. However, if there are no certifiable causes of action, it follows that practically speaking, the satisfaction of the class definition criterion is a moot point, and the claim cannot be certified. I, therefore, conclude that the identifiable class criterion cannot be satisfied in the immediate case.

## J. Common Issues Criterion (s. 5 (1)(c)) Redux

[284] The Plaintiffs fail to satisfy the common issues criterion because there are no certifiable causes of action in part because: (a) apart from the matter of damages for emotional distress, there is no basis in fact that the putative Class Members suffered any compensable harm; and (b) insofar as genuine emotional distress was experienced, it was connected to fear of an increased risk of potential harm, and the Canadian law is against compensation for increased potentiality. Thus, there are no causes of action upon which to construct common issues.

[285] Assuming, however, that there were certifiable causes of action in the immediate case, I make the following three findings with respect to some of the Plaintiffs' proposed 27 questions. (The questions are set out in Schedule "A" to these Reasons for Decision.)

### 1. General Causation

[286] The Plaintiffs submit that the questions of general causation (questions 2, 3, 4) are necessary to answer because the answers will ground the Class Members' claims for medical monitoring, may inform the contact element of the battery tort and may inform the foreseeability element of psychological harm. They submit that these answers will significantly advance the proceedings. The proposed common issues about general causation are:

> *General Causation*
>
> (2) Did the valsartan Drugs contain nitrosamine impurities above the acceptable intake limits for NDMA and/or NDEA, as defined by the FDA?
>
> (3) Do NDMA and/or NDEA cause harm to human cells on a microscopic or molecular level (also known as genotoxicity) if ingested? If so, is an injury to human cells beyond *de minimus*?
>
> (4) Do the valsartan Drugs, used as indicated, cause or contribute to an increased cancer risk?

[287] I mean no disrespect or irony, but in the immediate case, the Plaintiffs' questions about general causation suffer from what might be called a common issue dissociative disorder, a split personality. The proposed general causation questions are about whether the contaminated valsartan can increase the risk of cancer, but this is conflated and confused with a general causation question of whether the valsartan can cause harm to human cells all the while not asking whether or not the harm caused to the cells by the valsartan caused or contributed to a diagnosis of cancer, a more normative general causation issue.

[288] The problems in the immediate case are not a matter of a Plaintiff's obligation to show only a workable methodology to prove general causation; although where a methodology about increased risk leads is a mystery, rather, the problem is that the issue of general causation has dissociated itself from any legal reality and does little to advance the individual trials where the real work of determining causation and quantification of harm would be done.

[289] As noted in the introduction of this judgment, the Plaintiffs emphasize that they do not

intend for the Class Members to proceed to individual issues trials to prove specific causation of harm with the exception of the claim for psychological harm which does not require Class Members to establish causation of cancer. In fashioning common issues by asserting that there is some basis in fact for an increased risk of cancer while conceding it is premature to conclude that valsartan causes cancer is confounding, confusing, and baffling and makes the general causation issue uncertifiable. The incongruity of these assertions is that if the Class Members are not required to establish causation of cancer from the valsartan, then why wait for the science to catch up to the issues to be decided at the common issues trials about whether valsartan can increase the risk of a diagnosis of cancer? The common issues turn out to be just a contrivance for the purposes of getting the action certified.

[290] To abuse the famous football trope about common issues, in the immediate case, the court should flag the play because the common issues about general causation are offside. In the immediate case the yardsticks are moved backward. The general causation questions in the immediate case are not certifiable.

### 2. Aggregated Damages

[291] Pursuant to s. 24 (1)(b) of the *Class Proceedings Act*, for there be a determination of aggregate damages, no question of fact or law other those relating to the assessment of the defendant's monetary liability must remain to be determined in order to establish the defendant's liability. This prerequisite means that a plaintiff must be able to prove all the elements of his or cause of action at the common issues trial to have a common issue about aggregate damages.[120] In the immediate case, with an exception for battery, which does not have damages as a constituent element, all of Plaintiffs' causes of action require the proof of damages, which would entail individual issues trials. Thus, the Plaintiffs rely on the battery claim as the basis for a common issue on aggregate damages.

[292] Relying on the *Good v. Toronto (Police Services Board)*,[121] the Plaintiffs posit that there is a basis for the assessment of a non-pecuniary general damages based on a sampling of the harm experienced by individual class members and thus a minimum award of damages could be determined.

[293] However, the Plaintiffs' proposed common issue on aggregate damages is not certifiable for two reasons. First, this common issue is based on the battery cause of action which is not certifiable. Second, even if the battery cause of action was certifiable, a question on aggregate damages would not have been certifiable.

[294] In *Good v. Toronto (Police Services Board*), the class members were comprised of persons who gathered in downtown Toronto in June 2010 to protest the G20 summit. The protests got out of control and some protestors damaged property. The police responded and approximately 1,000 persons were rounded up, detained, arrested, and taken to a specially constructed detention centre. The conditions at the centre were poor. There were delays, overcrowding and a breakdown in prisoner care. The putative class members sued for false imprisonment; battery; assault; conversion

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[120] *Fulawka v Bank of Nova Scotia*, 2012 ONCA 443 at paras. 111-114, 139, leave to appeal ref'd, [2012] SCCA No 326.

[121] 2016 ONCA 250, aff'g 2014 ONSC 4583 and 2014 ONSC 6115 (Div. Ct.), which rev'd 2013 ONSC 3026 and 2013 ONSC 5086.

and trespass to chattels; and breaches of the *Canadian Charter of Rights and Freedoms*. The Divisional Court and the Court of Appeal concluded that an aggregate damages claim awarding a base line general damages award for vindication, deterrence, and compensation could be certified. The putative class member's human dignity was manifestly infringed by a genuine assault and battery of which they would have been physically and psychologically aware.

[295] For the reasons expressed above, the battery claim in the immediate case is much different and there is no common base line minimum that could be awarded. In the immediate case, most class members would not be aware that a metabolic conversion, which could but not necessarily would produce various adverse biological effects, had even occurred when they ingested valsartan, which they were advised to continue to do until advised not to do so by their physician. This sort of trespass to the person, if that is what it is, is idiosyncratic and not susceptible to a rational assessment of a minimum base level award.

### 3. Punitive Damages

[296] The plaintiff proposes as a common issue whether one or more of the Defendants is liable to the Class for punitive damages for breaching any of the eight causes of action that were being advanced in the proposed class proceeding.

[297] My approach to punitive damages in class actions has changed over the years. In 2009, in *Robinson v. Medtronic, Inc*.,[122] I explained that it followed from Justice Binnie's decision in *Whiten v. Pilot Insurance Co.*,[123] the leading case on liability for punitive damages, that an assessment of punitive damages requires an appreciation of: (a) the degree of misconduct; (b) the amount of harm caused; (c) the availability of other remedies; (d) the quantification of compensatory damages; and (e) the adequacy of compensatory damages to achieve the objectives or retribution, deterrence, and denunciation.

[298] These factors identified in *Whiten* must be known to ensure that punitive damages are rational and to ensure that the amount of punitive damages is not greater than necessary to accomplish its purposes. To rationally determine whether punitive damages should be awarded and to determine the quantum of them, the court needs to know the quantum of compensation that otherwise would be awarded to the plaintiff and the class members. Justice Binnie at paragraph 100 of his judgment stated: "The rationality test applies both to the question of whether an award of punitive damages should be made at all, as well as to the question of quantum."

[299] Thus, in *Robinson v. Medtronic Inc.*, I concluded that, generally speaking, when the determination of the defendant's exposure to general and special damages would have to be determined after the individual issues trial, questions about punitive damages were not certifiable for the common issues trial.

[300] Subsequently, however, as I explained in the 2012 case of *Waldman v. Thomson Reuters Corp.*,[124] my approach to punitive damages for the common issues trial changed. I was persuaded by decisions out of British Columbia that while the legal justification and the quantification of punitive damages might have to await the outcome of individual issues trials, the question of

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[122] [2009] O.J. No. 4366 (S.C.J.), aff'd [2010] O.J. No. 3056 (Div. Ct.).
[123] [2002] 1 S.C.R. 595.
[124] 2012 ONSC 1138

whether the defendant's conduct warranted punitive damages could be certified as a common issue. Thus, I stated at paragraph 190 in *Waldman*:

> 190. For the reasons I expressed in *Robinson v. Medtronic Inc.*, [2009] O.J. No. 4366 (S.C.J.), aff'd [2010] O.J. No. 3056 (Div. Ct.), a claim for punitive damages will not be suitable for a common issue when the court cannot make a rational assessment about the appropriateness of punitive damages until after individual assessments of the compensatory losses of class members has been completed. However, where the ultimate determination of the entitlement and quantification of punitive damages must be deferred until the conclusion of the individual trials, the question of whether the defendants' conduct was sufficiently reprehensible or high-handed to warrant punishment is capable of being determined as a common issue at the common issues trial: *Chalmers (Litigation guardian of) v. AMO Canada Co.*, 2010 BCCA 560.

[301] Recent developments in British Columbia have further refined my thinking about the certification of questions about punitive damages. In several judgments the British Columbia Court of Appeal has pointed out that there must be some basis in fact for a common issue about punitive damages, and more to the doctrinal point, the British Columbia Court of Appeal held that a court should not certify punitive damages as a common issue based solely on the allegations contained in the pleadings.[125] The Court held that the plaintiffs must point to material beyond the pleadings to establish a basis in fact for the certification of a common issue on punitive damages.

[302] I agree with the reasoning of the British Columbia appellate court, and I would have applied it to the immediate case, if I had decided that the case might be certifiable. In the immediate case, the plaintiffs cannot and do not point to material beyond the pleadings to establish a basis in fact for the certification of a common issue on punitive damages. They just plead and speculate that there was something advertently malevolent beyond negligence in the immediate case.

[303] I appreciate that even with the low some-basis-in-fact standard, it will be difficult for a Plaintiff to go beyond the allegations in the pleadings to foray into the merits and show a basis for a common issue about the repugnance of the defendant's conduct, but there is an answer to this plight. The answer is to <u>not</u> certify the punitive damages question but to do so without prejudice to the Plaintiffs moving after examinations for discovery to have the common issues amended to add a question about punitive damages. This motion could be brought before or at the common issues trial.

## K. Preferable Procedure Criterion (s. 5 (1)(d)) Redux

### 1. Analysis – Preferable Procedure

[304] It is axiomatic that if the cause of action and or the common issues criterion are not satisfied, the preferable procedure criterion is not satisfied.[126] That precisely is the situation in the immediate case. Therefore, the case at bar does not satisfy the preferable procedure criterion.

[305] However, assuming the other certification criteria were satisfied or satisfiable, the immediate class action would not satisfy the preferable procedure criterion.

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[125] *MacKinnon v. Pfizer Canada Inc.*2022 BCCA 151, var'g 2021 BCSC 1093; *Sharp v. Royal Mutual Funds Inc.,* 2021 BCCA 307.

[126] *Batten v. Boehringer Ingelheim (Canada) Ltd*, 2017 ONSC 53, aff'd 2017 ONSC 6098 (Div. Ct.), leave to appeal to C.A. ref'd (2018), 292 ACWS (3d) 490; *O'Brien v. Bard Canada,* 2015 ONSC 2470.

[306] In *Bellaire v. Independent Order of Foresters*,[127] Justice Nordheimer stated at paragraph 33 of his judgment that "The scale and complexity of the class action process ought not to be invoked at the behest, and for the benefit, of a single complainant." While in the immediate case, there are many complainants, the scale and complexity of the class action process ought not to be invoked at their behest. Their complaints are largely idiosyncratic and their damages claims – which do not include the genuinely serious claim of a valsartan ingestion causing cancer – are either non-compensable or *de minimis*.

[307] It is not that the Plaintiffs are making much ado about nothing. Although I cannot make a merits finding at this stage, there is more than some basis in fact that the Defendants were negligent or responsible for the negligence of ZHP, and there is more than some basis in fact that the boastful quality assurance claims might take the case into the territory of misrepresentations; however, the case at bar demonstrates the problems that sometimes occurs when there is a knee-jerk reaction to a recall notice.

[308] In the case at bar, the voluntarily recall notice went out on July 9, 2018 and on July 13, 3018 Ms. Palmer commenced the proposed class action by Notice of Action followed by the Statement of Claim on August 10, 2018. That far, there was nothing to criticize in the Plaintiffs' commencing a proposed class action in the response to a serious and substantial recall of an important pharmaceutical product.

[309] But it is now four years later, and as demonstrated by the April 2022 advisory from Health Canada, the state of scientific/medical knowledge has not changed, and Health Canada still advises: "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."

[310] And it is now four years later, and the litigation design of the proposed class action is shown to be disjointed and illogical.

[311] And it is now four years later, and the scale and complexity of a class action will not serve the purposes of the *Class Proceedings Act, 1992*, which are the lens through which to gauge the preferable procedure criterion.

[312] Given the litigation design and the limitations on the available compensation, the access to justice considerations are not deserving of particular concern. If behaviour management means using the litigation process to give a defendant and other defendants an education of their responsibilities and is something more or different than just punishment for bad behaviour, the pharmaceutical companies are already heavily regulated and do not need an education about their legal responsibilities by a class action that will yield little to no compensation for the overwhelming majority of the class and ends up being little more than a licensing fee for bad behaviour. As for judicial economy, the proposed class action is a howitzer firing BBs and not mortar shots, which is an inefficiency metaphor for a class action with both inefficient overkill and inefficient underkill.

[313] In my opinion, even if all the other certification criterion were satisfied – and they are not – the proposed class action would not satisfy the preferable procedure criterion.

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[127] [2004] O.J. No. 2242 (S.C.J.)

## L. Representative Plaintiff Criterion (s. 5 (1)(e))

### 1. General Principles – Representative Plaintiff Criterion

[314] The fifth and final criterion for certification as a class action is that there is a representative plaintiff who would adequately represent the interests of the class without conflict of interest and who has produced a workable litigation plan. The representative plaintiff must be a member of the class asserting claims against the defendant, which is to say that the representative plaintiff must have a claim that is a genuine representation of the claims of the members of the class to be represented or that the representative plaintiff must be capable of asserting a claim on behalf of all of the class members as against the defendant.[128]

### 2. Analysis – Representative Plaintiff Criterion

[315] As for the representative plaintiff criterion, the Plaintiffs would have satisfied the representative plaintiff criterion, but the point is moot. It is axiomatic that if the cause of action and or the common issues criterion are not satisfied, the other certification criteria are not satisfied.[129]

[316] Also moot is the Defendants' argument that the Plaintiffs have a disqualifying conflict that precludes their being representative plaintiffs. Given the possibility of appeals, I will address this moot point.

[317] Another irony of certification motions is the frequent crocodile tears concerns of the Defendants that the representative plaintiff has a conflict and will not be able to dutifully represent the class members and therefore the class action should not be certified at all. Thus, in the immediate case, relying on Justice Hoy's judgment in *Defazio v. Ontario (Labour)*,[130] the Defendants argue that the Representative Plaintiffs have a conflict. The alleged conflict is that the Plaintiffs' litigation plan is inadequate to warn that the downside of choosing to be a member of this class action is that a Class Member must forgo compensation for being diagnosed in the future with cancer. In other words, the solicitous Defendants submit that the putative Class Members need to understand that he or she forfeits any claims for cancer damages by participating in the class action.

[318] *Defazio v. Ontario (Labour)* was a proposed class action brought on behalf of labourers who had been exposed to asbestos during the construction of a subway station in Toronto. Like the case at bar, the plaintiffs did not sue for compensation from being diagnosed with an asbestos related disease, but rather they sued for $100 million for psychological harm and for pure economic losses from the enhanced risk of disease. Justice Hoy expressed some doubt as to whether a plaintiff can maintain a claim for risk of future illness, but she assumed that the plaintiff had satisfied the cause of action criterion, and she dismissed the certification motion on the grounds that the plaintiffs did not satisfy the preferable procedure and the representative plaintiff criterion.

[319] Insofar as the representative plaintiff criterion was concerned, Justice Hoy held that the

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[128] *Drady v. Canada (Minister of Health)*, [2007] O.J. No. 2812 at paras. 36-45 (S.C.J.); *Attis v. Canada (Minister of Health)*, [2003] O.J. No. 344 at para. 40 (S.C.J.), aff'd [2003] O.J. No. 4708 (C.A.).
[129] *Batten v. Boehringer Ingelheim (Canada) Ltd*, 2017 ONSC 53, aff'd 2017 ONSC 6098 (Div. Ct.), leave to appeal to C.A. ref'd (2018), 292 ACWS (3d) 490; *O'Brien v. Bard Canada*, 2015 ONSC 2470.
[130] [2007] O.J. No. 902 (S.C.J.), aff'd [2007] O.J. No. 5021 (Div. Ct.).

representative plaintiffs would not fairly and adequately represent the interests of the class. There were a variety of reasons for arriving at that holding and amongst them was a concern that the plaintiffs' litigation plan had not adequately dealt with what Justice Hoy described as the "*res judicata* risk." The risk was that participating in the class action might bar subsequent litigation for compensation for an asbestos related discase. Justice Hoy stated that it was important that all class members be made aware of the risk and have a real opportunity to opt-out of the litigation and this circumstance was not adequately dealt with in the plaintiffs' litigation plan.

[320] Returning to the immediate case, the Plaintiffs submit that they do satisfy the representative plaintiff criterion. They do not deny the so-called "*res judicata* risk," but they say that this matter can and will be dealt with in the notice of certification.

[321] Relying on my judgment in *Berg v Canadian Hockey League*,[131] the Plaintiffs submit that there is no genuine disqualifying conflict. *Berg* was an employment law class action brought by pre-professional hockey players and the hockey team defendants argued that there was an irreconcilable conflict between the former players and current players, in that the current players would be harmed if the former players succeeded in their claims because teams might cease operations or reduce salaries and benefits. I disagreed that there was a conflict, and at paragraph 234 of my judgment, I stated:

> [234] It is not a conflict that all the class members may not desire to pursue the claim as they will have the right to opt-out of the action: *Kranjcec v. Ontario* (2004), 2004 CanLII 17687 (ON SC), 69 O.R. (3d) 231 (S.C.J.) at para. 68; *Kwicksutaineuk/Ah-Kwa-Mish First Nation v. British Columbia (Minister of Agriculture and Lands)*, 2010 BCSC 1699 at para. 131, rev'd on other grounds 2012 BCCA 193; *Chapman v. Benefit Plan Administrators Ltd.*, 2013 ONSC 3318 at para. 58. If the active players do not wish to participate in the litigation, they can opt-out of the class proceeding and pursue their rights individually or not at all. If they choose not to opt-out, then, their interest will be the same as, and not adverse to, that of the other class members.

[322] In the immediate case, the Plaintiffs say that adequate notice can be given and class members who believe they have developed cancer as a result of the contamination can choose to opt out and pursue their rights individually.

[323] I agree with the Plaintiffs that there is no disqualifying conflict in the immediate case. However, the Defendants' argument intensifies the conclusion that the class action does not satisfy the preferable procedure criterion because of its inefficiency and the meagreness of its access to justice. The Defendants' argument exposes that from an access to justice perspective, the class action is of low social utility. An enormous effort has already gone into this proposed class action and were it to be certified an even greater effort would be required but for the overwhelming majority of class members there is little in it for them. I do not say that this utility and productivity factor is determinative, it is just relevant to the analysis and supports my conclusion that the preferable procedure criterion is not satisfied in the immediate case.

[324] I conclude that the representative plaintiff criterion is not satisfied.

## M. Conclusion

[325] For the above reasons the Plaintiffs certification motion is dismissed and because of the absence of any viable causes of action, the action is dismissed.

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[131] 2017 ONSC 2608, var'd 2019 ONSC 2106 (Div. Ct.).

[326] If the parties cannot agree about the matter of costs, they may make submissions in writing beginning with the submissions of the Defendants within twenty days of the release of these Reasons for Decision followed by the Plaintiffs' submissions within a further twenty days.

[327] I alert the parties that my present inclination is to make no award as to costs.

Perell, J.

Released: August 12, 2022

## Schedule "A" – Proposed Common Issues

*Definitions*

(1) The following definitions apply:

a. "**N-nitrosodimethylamine**" or "**NDMA**" means a type of nitrosamine impurity, which Health Canada classifies as a probable human carcinogen;

b. "**N-nitrosodiethylamine**" or "**NDEA**" means a type of nitrosamine impurity, which Health Canada classifies as a probable human carcinogen;

c. "**valsartan Drugs**" means finished valsartan drugs manufactured by the Defendants and subsequently recalled because of the presence of NDMA and/or NDEA in the active pharmaceutical ingredient valsartan;

d. "**Recall**" means the recall of valsartan Drugs communicated by Health Canada on July 9, 2018 and expanded on August 18, 2018 and updated on August 21 and 31 and November 28, 2018;

e. "**FDA**" means U.S. Food and Drug Administration

*General Causation*

(2) Did the valsartan Drugs contain nitrosamine impurities above the acceptable intake limits for NDMA and/or NDEA, as defined by the FDA?

(3) Do NDMA and/or NDEA cause harm to human cells on a microscopic or molecular level (also known as genotoxicity) if ingested? If so, is an injury to human cells beyond *de minimus*?

(4) Do the valsartan Drugs, used as indicated, cause or contribute to an increased cancer risk?

*Strict Liability*

(5) Did the Defendants supply to the marketplace valsartan Drugs intended for human consumption by the Class Members?

(6) If the answer to the above question is yes, are the Defendants strictly liable for the damages sustained by the Class Members who ingested the valsartan Drugs?

*Battery*

(7) Did one or more Defendants cause the consumption of valsartan Drugs with either knowledge or reckless disregard to the presence of nitrosamine impurities above the acceptable intake limits for NDMA and/or NDEA, as defined by the FDA, so as to constitute a battery at law?

*Negligent Manufacture*

(8) Did the Defendants owe a duty of care to the Class Members with respect to the design, development, testing, manufacturing, distribution, marketing and sale of the valsartan Drugs?

(9) If the answer to the above question is yes, did one or more of the Defendants breach the standard of care owed to the Class Members?

(10) Is the standard of care for the manufacture of valsartan Drugs one of absolute liability for manufacturing defects?

(11) Is it a reasonable and foreseeable consequence that persons who learn they ingested valsartan Drugs could experience mental disturbance that is serious, prolonged, and above the ordinary annoyances, anxieties and fears that come with living in civil society?

*Negligent Breach of Duty to Warn*

(12) When did the Defendants know, or when ought the defendants to have known, that the valsartan Drugs contained nitrosamine impurities above the acceptable intake limits for NDMA and/or NDEA, as defined by the FDA?

(13) Did the Defendants have a duty to warn the Class Members that the valsartan Drugs contained nitrosamine impurities above the acceptable intake limits for NDMA and/or NDEA, as defined by the FDA, and/or a duty to warn the Class Members of an increased cancer risk from the valsartan Drugs, used as indicated?

*Breach of Consumer Protection Statutes*

(14) Did one or more of the Defendants engage in conduct that constituted deceptive and/or unconscionable acts or practices, contrary to ss. 14 and 15 of the *Consumer Protection Act,* 2002, S.O. 2002, c. 30, ss. 4 and 8 of the *Business Practices and Consumer Protection Act*, S.B.C. 2004, c.2 or equivalent legislation in other provinces?

*Breach of the Competition Act*

(15) Did one or more of the Defendants knowingly or recklessly make a representation to the public that was false or misleading in a material respect, contrary to s. 52 of the *Competition Act*, RSC, 1985, c C-34?

*Breach of Trademarks Act*

[withdrawn] (16) Did one or more of the Defendants make representations that were false in a material respect and likely to mislead the public, contrary to section 7(d) of the *Trademarks Act*, RSC, 1985, c T-13?

*Unjust Enrichment*

(17) Were one or more of the Defendants enriched by the receipt of fees from the Class Members for the purchase of valsartan Drugs during the Class Period?

(18) If the answer to the question above is yes, did the Class Members suffer a corresponding deprivation in the amount of fees collected by the Defendants from the Class Members?

(19) Is there a juristic reason why the Defendants should be entitled to retain the fees collected from the Class Members?

(20) If the answer to the question two above is yes and the answer to the question immediately above is no, what restitution, if any, is payable by one or more of the Defendants to the Class Members based on unjust enrichment?

(21) Is this an appropriate case for one or more of the Defendants to disgorge profits earned during the Class Period?

(22) If there is a finding of liability, can the amount of restitution be determined on an aggregate basis, and, if so, in what amount?

*Québec Class*

(23) Did one or more of the Defendants breach articles 1726 and 1730 of the *Civil Code of Québec*, CQLR c C-1991?

(24) Did one or more of the Defendants breach the *Consumer Protection Act*, RSQ c P-40.1?

*Damages/Remedies*

(25) Are one or more of the Defendants liable to the Class for damages (including punitive damages) for:

i. strict liability?

ii. battery?

iii. negligence?

iv. breach of the applicable consumer protection legislation?[132]

v. breach of the *Competition Act*, RSC, 1985, c C-34?

vi. breach of the *Trademarks Act*, RSC, 1985, c T-13?

vii. breach of the *Civil Code of Québec*, CQLR c C-1991?

viii. breach of the *Consumer Protection Act*, RSQ c P-40.1?

(26) If one or more of the Defendants is liable to the Class for damages, can the court assess damages in the aggregate, in whole or in part, for the Class? If so, what is the amount of the aggregate damages assessment?

*Directions Post-Common Issues Trial*

(27) If the court determines that one or more of the Defendants are liable to the Class for damages, and if the court considers that the participation of individual Class Members is required to determine individual issues, then are the following individual issues appropriate:

a. are the Class Members entitled to the cost of ongoing medical monitoring? If the answer is yes, then to what extent, and for what period of time?

b. are the Class Members entitled to damages for prolonged mental distress?

c. are the Class Members who have been diagnosed with cancer entitled to damages for increased cancer risk?

d. are the subrogated health insurers entitled to damages for funding medical services with respect to individual issues (a) to (c)?

e. are the Class Members entitled to damages for costs incurred in purchasing valsartan Drugs?

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[132] BC: *Business Practices and Protection Act*, SBC 2004, c. 2; AB: *Fair Trading Act*, RSA 2000, c. F-27; SK: *Consumer Protection and Business Practices Act*, SS 2014, c. C-30.2; MB: *Business Practices Act*, CCSM c. B120; ON: *Consumer Protection Act, 2002*, SO 2022, c. 30; QB: *Consumer Protection Act*, RSQ c P-40.1; PEI: *Business Practices Act*, RSPEI 1988, c. B-7; NL: *Consumer Protection and Business Practices Act*, SNL 2009, c. 31.2.

f. if two or more Defendants supplied valsartan Drugs to the same Class Member, should the total damages be allocated proportionally between the Defendants joint and severally, based on the time the Class Member consumed each drug?

(28) Should one or more of the Defendants pay the costs of administering and distributing any amounts awarded under ss. 24 and 25 of the *Class Proceedings Act*, 1992, S.O. 19922, c. 6? If so, what amount should be paid and to whom?

(29) Should one or more of the Defendants pay prejudgment and post judgment interest? If so at what annual interest rate? Should the interest be simple or compound?

**CITATION:** Palmer v. Teva Canada Ltd., 2022 ONSC 4690
**COURT FILE NO.:** CV-18-00601555-00CP
**DATE:** 20220812

**ONTARIO**
**SUPERIOR COURT OF JUSTICE**

**BETWEEN:**

**GLORIA PALMER, JO-ANNE WILLS, DIANE PEREHUDOFF, BRADLEY HALAYKA, DIANNE TIEDJE, MURRAY HALBERT, CHARLENE BOURDON, KENNETH AITCHISON, and MAY VENTURA**

Plaintiffs

**- and –**

**TEVA CANADA LIMITED, SANDOZ CANADA INC., PRO DOC LIMITÉE, SANIS HEALTH INC., and SIVEM PHARMACEUTICALS ULC**

Defendants

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**REASONS FOR DECISION**

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PERELL, J.

**Released:** August 12, 2022