COURT OF APPEAL FOR ONTARIO

CITATION: Palmer v. Teva Canada Limited, 2024 ONCA 220
DATE: 20240327
DOCKET: COA-22-CV-0085

Huscroft, Miller and Paciocco JJ.A.

BETWEEN

Gloria Palmer, Jo-Anne Wills, Diane Perehudoff, Bradley Halayka, Dianne Tiedje, Murray Halbert, Charlene Bourdon, Kenneth Aitchison, and May Ventura

Plaintiffs (Appellants)

and

Teva Canada Limited, Sandoz Canada Inc., Pro Doc Limitee, Sanis Health Inc., and Sivem Pharmaceuticals ULC

Defendants (Respondents)

Proceeding under the *Class Proceedings Act, 1992*

Paul Bates, Anthony Leoni and Caleb Edwards, for the appellants

Laura Fric, Robert Carson and Jessica Habib, for the respondent Teva Canada Limited

Peter Pliszka, Zohaib Maladwala and Raajan Aery, for the respondents Sandoz Canada Inc., Pro Doc Limitee, Sanis Health Inc., and Sivem Pharmaceuticals ULC

Heard: June 27, 2023

On appeal from the order of Justice Paul M. Perell of the Superior Court of Justice, dated August 12, 2022, with reasons reported at 2022 ONSC 4690.

B.W. Miller J.A.:

I. OVERVIEW

[1] The law of torts serves to compensate those who have suffered damage from the harmful wrongdoing of others. But not every instance of wrongdoing will support a viable cause of action. Compensable damage is an essential component to recovery.

[2] Gloria Palmer, Jo-Anne Wills, Diane Perehudoff, Bradley Halayka, Dianne Tiedje, Murray Halbert, Charlene Bourdon, Kenneth Aitchison, and May Ventura (the "appellants" or "plaintiffs") seek to certify a class proceeding under s. 5 of the *Class Proceedings Act, 1992*, S.O. 1992, c. 6, against Teva Canada Limited, Sandoz Canada Inc., Pro Doc Limitee, Sanis Health Inc., and Sivem Pharmaceuticals ULC (the "respondents" or "defendants") for negligently manufacturing a medication used to treat high blood pressure, known as valsartan. The plaintiffs and proposed class members are persons who were prescribed and ingested valsartan.

[3] Beginning in 2012, the defendants' supplier of the active pharmaceutical ingredient for their generic valsartan changed its manufacturing process and as a result, certain lots of the valsartan were contaminated with N-nitrosodimethylamine ("NDMA") and N-nitrosodiethylamine ("NDEA"), two contaminants that the appellants allege are toxic carcinogens. In 2018, the defendants voluntarily recalled the contaminated lots.

[4] The proposed class action is *not* a claim for compensation for consumers who have been or may be diagnosed with cancer as a result of consuming contaminated valsartan. The claim *is* for damages for the potential increased risk of being diagnosed with cancer in the future as a result of ingesting contaminated valsartan. The plaintiffs seek damages for costs of medical services and monitoring; refunds for the drugs consumed; costs for the drugs thrown away after the drugs were recalled; and psychological damages and punitive damages.

[5] The motion judge dismissed the plaintiffs' certification motion. He found it was plain and obvious that the causes of action pleaded by the plaintiffs were not viable because they were not based on concrete injury, but on speculation or the "apprehension of an abstraction" – an increased risk of diagnosis of cancer over the baseline risk of cancer diagnosis over the course of one's life. Moreover, the motion judge found that the proposed class action failed on the commonality and preferability criteria needed to warrant certification.

[6] I would dismiss the appeal. This is a case where the wrongful conduct on the part of the drug manufacturers is non-compensable not only because, as the motion judge found, physical harm has yet to materialize, but also because the harm that had materialized - psychological harm from the shock of the recall – was not sufficiently serious to be compensable in tort law.

II. FACTUAL SUMMARY AND PROCEDURAL HISTORY

[7] The following summary draws heavily on the reasons of the motion judge.

[8] Valsartan is an antihypertensive drug prescribed to regulate blood pressure and prevent heart failure and stroke. Since about 2011, valsartan has been “off patent” and manufactured by generic pharmaceutical companies like the defendants.

[9] The defendants, Sandoz and Teva, were supplied with the active pharmaceutical ingredient of valsartan by Zhejiang Huahai Pharmaceuticals (ZHP), a Chinese drug manufacturer and supplier. After changes in ZHP’s manufacturing process in 2012, the valsartan supplied by ZHP and sold by Sandoz and Teva contained the nitrosamines NDMA and NDEA.

[10] NDMA and NDEA can be found in certain processed foods, such as packaged/preserved meats and cheeses, preserved or canned fish, preserved vegetables, and malt-containing alcohols such as beer and whisky. NDMA and NDEA are also found in the environment, in drinking water and in the air.

[11] In 2016, inspectors from the United States’ Food and Drug Administration (FDA) inspected ZHP’s manufacturing plant and identified numerous failures, including failures to follow quality control procedures to ensure drug purity. The inspections continued and in July and August 2018, the FDA found that ZHP had not adequately evaluated the effect of its changed manufacturing process.

On July 9, 2018, Sandoz and Teva voluntarily recalled certain lots of valsartan products because it had been discovered that the active pharmaceutical ingredient of the drug supplied by ZHP might contain NDMA. The recall was later expanded after it was determined that the valsartan supplied by ZHP might also contain NDEA.

The Health Canada Recall Notices

[12] Health Canada issued multiple bulletins to consumers related to the recall. The overall message was that, although NDMA had been identified as a potential carcinogen, consumers should continue taking their medication unless advised to the contrary by a physician or pharmacist.

> **Health Canada Advisory - July 9, 2018**
>
> *Issue*
>
> Several drugs containing the ingredient valsartan are being recalled by their manufacturers. An impurity [NDMA], was found in the valsartan used in these products… NDMA is a potential human carcinogen, which means that it could cause cancer with long-term exposure…
>
> *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.

Health Canada Advisory - August 18, 2018

Health Canada is advising Canadians that, as a precautionary measure, Teva Canada is expanding its voluntary recall…

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.

…

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.

Health Canada Update – September 10, 2018

…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.

…

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…

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.

What you should do

Patients taking affected valsartan medication should:

…

- 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.

[13] On September 13, 2018, Health Canada advised of the second impurity (NDEA) linked to the recalled valsartan from ZHP. Again, the advice was to continue taking the medication unless advised to stop by a health care provider. This was the consistent message conveyed in subsequent updates 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."

Expert Evidence

[14] The plaintiffs filed evidence from Dr. Sid Katz, a pharmacology expert with experience in toxicology, who explained that NDMA and NDEA are genotoxins which can produce carcinogenesis – the formation of cancer. The motion judge found that Dr. Katz's evidence provided a scientific theory for how or why NDMA and NDEA might be carcinogens but did not provide a basis in fact for the conclusion that NDME and NDMA are carcinogens in humans. Dr. Katz expected that more definitive results would be available in the future, as studies on carcinogenicity of NDMA exposure via valsartan and other medications were ongoing.

[15] The defendants' expert toxicologist (Dr. George Johnson) and epidemiologist (Dr. Raj Padwal) opined that the available scientific evidence and literature do not support a causal association between exposure to the amount of NDMA and NDEA found in the defendants' valsartan and cancer risk in humans.

[16] The motion judge found that 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 humans. Neither have NDMA nor NDEA been definitively classified as a non-carcinogen. Instead, the International Agency for Research on Cancer (IARC) and Health Canada had cautiously classified them as "probable carcinogens" based on extrapolation from the results of animal studies.

[17] The FDA set the acceptable daily intake of NDMA at 96 ng per day and NDEA at 26.5 ng per day. Health Canada has not set a daily acceptable intake level, but its public statements reference the FDA levels.

[18] Although there was conflicting evidence from the defendants' experts, the motion judge accepted that, based on the evidence at the certification motion, 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.

The Plaintiffs' Claim

[19] The plaintiffs' claim alleges that exposure to NDMA or NDEA can increase one's risk of developing cancer: It is not based on a claim that ingesting NDMA or NDEA will necessarily or probably cause cancer.

[20] More precisely, the essence of the claim is that the defendants breached their duty of care to the plaintiffs by failing to ensure that the valsartan they produced was free of the contaminants NDMA and NDEA. As a result of these breaches, the plaintiffs claim that the class suffered psychological harm and pure economic loss of medical bills, medical monitoring, refunds, and costs for drugs thrown away.

The Reasons of the Motion Judge

[21] The motion judge dismissed the plaintiffs' certification motion. He found there was no basis in fact for concluding that there is a causal relationship between valsartan and cancer, but some basis in fact for the proposition that exposure to NDMA and NDEA in the contaminated valsartan very modestly increases the risk of being diagnosed with cancer. He also found some basis in fact that a small proportion of class members will have sustained psychological harm for a relatively short period as a result of learning about the contamination of valsartan that they had been ingesting.

[22] However, the motion judge found it was plain and obvious that in the immediate case, the negligence claim for damages for psychological harm was not certifiable because neither the risk of future physical or psychological harm nor the present anxiety occasioned by the risk of future harm is compensable in tort law. He dismissed the negligence cause of action, which was the essence of the claim, under s. 5(1)(a) of the *Class Proceedings Act, 1992*. The motion judge also dismissed as doomed to fail the claims for toxic battery, breach of consumer protection laws, breach of competition laws, and unjust enrichment.

[23] Finally, although there was some basis in fact for the propositions that NDMA and NDEA cause or contribute to an increased risk of cancer and that some class members experienced psychological distress upon learning that they had been ingesting valsartan contaminated with NDMA and NDEA, the motion judge found that the plaintiffs failed to satisfy the commonality and preferability criteria for certification required by s. 5(1)(c) and 5(1)(d) of the *Class Proceedings Act, 1992*.

III. ISSUES ON APPEAL

[24] The issues are addressed in the following order:

1. Did the motion judge err in holding that the pleadings disclosed no viable cause of action?

2. Did the motion judge err in holding the proposed action did not meet the common issues and/or preferable procedure criteria and thereby err by not certifying the class action?

[25] I conclude the motion judge committed neither error and would dismiss the appeal.

IV. ANALYSIS

A. Governing legal principles regarding certification

[26] Section 5(1) of the *Class Proceedings Act, 1992* sets out five statutory criteria that must be established for a claim to be certified as a class action: (a) the pleadings must disclose a cause of action; (b) there must be an identifiable class; (c) there must be common issues; (d) the class action must be the preferable procedure; and (e) the proposed representative plaintiff must be appropriate. For the first element, the court must ask whether it is plain and obvious that no claim exists, assuming the facts alleged in the pleadings are true: *Hollick v. Toronto (City)*, 2001 SCC 68, [2001] 3 S.C.R. 158, at para. 25. For all the other elements, the representative plaintiff must establish some basis in fact that the requirement is met: *Hollick*, at para. 25.

[27] The certification motion is not meant to test the merits of the action – its focus is on the form of the action. The question is not whether the claim is likely to succeed but whether the suit is appropriately brought as a class action: *Hollick*, at

para. 16; *Pro-Sys Consultants Ltd. v. Microsoft Corporation*, 2013 SCC 57, [2013] 3 S.C.R. 477, at para. 102.

[28] The criteria relevant to this appeal are the cause of action criterion (s. 5(1)(a)), the common issues criterion (s. 5(1)(c)), and the preferable procedure criterion (s. 5(1)(d)). I will address each in turn.

B. The holding that the pleadings disclosed no viable cause of action

[29] The standard of review applicable to a motion judge's determination of law that a claim discloses no reasonable cause of action is correctness: *Bowman v. Ontario*, 2022 ONCA 477, 162 O.R. (3d) 561, at para. 26.

[30] The appellants contend the motion judge made a number of legal errors. At the outset, they raise the threshold issue that the motion judge erred by collapsing his analyses of s. 5(1)(a), 5(1)(c), and 5(1)(d) together (the "ensemble" approach), leading him to go beyond the pleading and inappropriately consider evidence to conclude it was plain and obvious that no viable claim exists. The appellants allege further errors in the motion judge's dismissal of each of their pleaded causes of action, with the viability of the negligence claim being the crux of the appeal. In what follows, I will address the threshold issue before considering the arguments on each of the individual causes of action.

(1) Error in the “ensemble” approach

[31] The test to determine whether the pleadings disclose a cause of action for the purposes of s. 5(1)(a) of the *Class Proceedings Act, 1992* is, assuming the facts as stated in the statement of claim can be proved, it is “plain and obvious” the claim cannot succeed.

[32] Section 5(1)(a) is designed to weed out claims that, on the pleadings, have no chance of success. It is not an inquiry into the merits of the action, and the facts pleaded in the statement of claim are deemed to be true: *Pro-Sys Consultants*, at para. 63. The question is not whether the claim is likely to succeed, but whether the suit is appropriately brought as a class action: *Hollick*, at para. 25. If a claim has no reasonable prospect of success, it should not be allowed to proceed to trial: *R. v. Imperial Tobacco Canada Ltd.*, 2011 SCC 42, [2011] 3 S.C.R. 45, at para. 17.

[33] From paras. 143 to 154 of his reasons, the motion judge set out the above principles and authorities governing the application of the test for certification. He also identified that it would be “both convenient and necessary” in this case to approach the cause of action criterion together with the common issues and preferable procedure criteria: at para. 141.

[34] The appellants do not allege the motion judge erred by using this holistic approach to structure his analysis, which was within his discretion. The appellants

submit, however, that the motion judge erred in practice by allowing the “some basis in fact” standard applicable to the commonality and preferability criteria to taint his analysis of whether the pleadings disclosed a cause of action under s. 5(1)(a).

[35] I do not agree that the motion judge erred. The motion judge’s reasons carefully indicate what stage of the analysis is underway and which standard is being applied. There is nothing in the motion judge’s reasons that support the argument that he slipped from the “plain and obvious” standard to the “some basis in fact” standard, or that he relied on evidence rather than taking the pleadings as true. A judge who hears evidence on a certification motion is quite capable of disabusing himself of that evidence in connection with the s. 5(1)(a) criterion. The appellants have not pointed to any aspect of the motion judge’s reasons that would convince me that the motion judge here did otherwise.

[36] Turning to the specific causes of action, they can be categorized as negligent manufacture, negligent breach of the duty to warn, strict liability, breach of the applicable consumer protection in each province, battery, breach of s. 52(1) of the *Competition Act*, R.S.C. 1985, c. C-34, waiver of tort and unjust enrichment, breaches of articles 1726 and 1730 of the *Civil Code of Quebec*, S.Q. 1991, c. 64,

and civil liability on behalf of Quebec Class Members.[1] The essence of the claim, however, is product liability in negligence, which will be addressed first.

(2) The viability of the claim in negligence

The Claim

[37] In their Third Amended Statement of Claim, the appellants plead that the respondents owed a duty of care to class members who ingested valsartan contaminated by NDMA and NDEA, to ensure the medication was manufactured free of impurities that could cause bodily harm. They contend that valsartan contaminated with NDMA and NDEA can cause, materially contribute to, and/or materially increase the risks of contracting cancer, liver disease, and other health conditions.

[38] The appellants plead personal injury, economic loss, and punitive damages. They set out their personal injuries as:

- Consuming a carcinogenic, toxic product on a repetitive and prolonged basis;
- Being at a materially increased risk of experiencing adverse health effects going forward;

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[1] The statement of claim also pleaded breach of section 7(d) of the *Trademarks Act*, R.S.C. 1985, c. T-13, but this claim was abandoned at the outset of the hearing. The actions under the Quebec Civil Code and strict liability were not argued on appeal.

- Being subject to a real possibility of future adverse health effects;
- Suffering shock and serious and prolonged anxiety, mental distress and worry from fear that consuming the contaminated valsartan has led, or will lead, to adverse health effects at some point in the future; and
- Changes to internal bodily composition at a cellular or molecular level.

[39] Notably, they do not claim they have experienced adverse health effects including cancer or organ damage. Such personal injury damage, though originally pleaded in the statement of claim, was removed in a later amended iteration.

[40] The appellants also claim for economic losses, which can generally be described as subrogated costs for medical screening and monitoring to provide early detection of any adverse health effects caused by ingesting NDMA and NDEA, counselling costs, travel costs, reimbursement for wasted time and inconvenience, as well as the costs of purchasing valsartan thrown away.

[41] The appellants raise two errors related to their claim of injury from having ingested the respondents' contaminated valsartan. First, that the motion judge failed to consider genotoxicity (that is, changes to their "internal bodily composition at a cellular or molecular level") caused by ingesting NDMA and NDEA, as a present harm. Second, the motion judge erred in law by concluding that present psychological harm related to the risk of increased cancer (or a future physical injury) is not a viable cause of action. Success on either of these grounds is

important for the appellants' claim as without it, their claim in negligence becomes a claim of pure economic loss. I will consider each of the appellants' arguments in turn before turning to economic loss.

(a) Genotoxic injury

[42] The appellants allege that, as a result of ingesting valsartan contaminated with NDMA and NDEA, they suffered genotoxic injury. I will briefly review the principles underlying the damages element of a negligence claim before assessing whether the genotoxic injury alleged by the plaintiffs is compensable at law.

[43] A successful action in negligence requires plaintiffs to demonstrate that: (1) the defendants owed them a duty of care; (2) the defendants' behaviour breached the standard of care; (3) the plaintiffs sustained damage; and (4) that the damage was caused, in fact and in law, by the defendants' breach: *Mustapha v. Culligan of Canada Ltd*., 2008 SCC 27, [2008] 2 S.C.R. 114, at para. 3.

[44] This appeal turns on the nature of the injury and the question of whether damages for such an injury are recoverable, which are questions dealt with at the third and fourth stages of the negligence analysis.

[45] Damage (injury) to a plaintiff is an essential element in a claim of negligence. This is because the negligent conduct of a defendant can only ground an obligation for compensation to the extent that it causes damage or an actual materialized loss. It is the materialized loss that gives rise to a defendant's obligation to

compensate the plaintiff for the injury: *Atlantic Lottery Corp. Inc. v. Babstock*, 2020 SCC 19, [2020] 2 S.C.R. 420.

[46] In *Atlantic Lottery*, the plaintiffs claimed that they suffered injury due to an increased risk of addiction and suicidal ideation as a result of the respondent's video lottery terminals. Writing for the majority, Brown J. stated at para. 33:

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

[47] Accordingly, there is no liability "in the air" and no right to be free from the prospect of damage: *1688782 Ontario Inc. v. Maple Leaf Foods Inc*., 2020 SCC 35, [2020] 3 S.C.R. 504, at para. 44. Negligence law simply does not recognize exposure to the risk of injury or harm, or the increased risk of injury or harm, as compensable: *Setoguchi v. Uber BV*, 2023 ABCA 45, at paras. 54-57, leave to appeal refused, [2023] S.C.C.A. No. 190; *Atlantic Lottery Corp.,* at para. 33. This means that, under s. 5(1)(a) of the *Class Proceedings Act, 1992*, there can be no viable cause of action in negligence without actual damage.

[48] The claim for genotoxic injury, as pleaded by the appellants, has the same flaw as the claim for increased risk of cancer: damage has not materialized and may never materialize.

[49] Moreover, it is not clear that genotoxic injury as pleaded would amount to injury or damage that would be more than negligible. It is insufficient to assert, as the appellants do in their factum, that "molecular changes caused by negligent exposure to a toxin is an injury." This is not self-evident, and no material facts were pleaded to support the claim that any class member had suffered loss as a result of molecular change. Even if the pleadings had alleged that changes at the cellular level can cause cancer, rather than the allegation that molecular change *per se* constitutes an injury, the claim would still amount to a claim for compensation for an increased risk of cancer, as was the case in *Dussiaume v. Sandoz Canada Inc*., 2023 BCSC 795, at para. 61.

[50] The motion judge appropriately drew support from other jurisdictions that have dealt with claims from asymptomatic claimants exposed to harmful substances. In *Dow Chemical Company v. Ring, Sr*., 2010 NLCA 20, 72 C.C.L.T. (3d) 161, leave to appeal refused, [2010] S.C.C.A. No. 187, at paras. 58-59, the court found that the pleadings failed to disclose a cause of action on behalf of plaintiffs who claimed they suffered absorption of toxic chemicals, which may cause lymphomas in the future, but were asymptomatic. As the court noted, at

para. 57, “the plaintiffs seek to proceed directly from breach of a duty of care to compensation without the necessity of proving either economic or physical injury.”

[51] Similarly, in *Rothwell v. Chemical & Insulating Co. Ltd.*, [2007] UKHL 39, 99 B.M.L.R. 139, the plaintiffs experienced fibrous thickening of the pleural membrane (pleural plaques) following exposure to asbestos in the course of their employment. In most cases, pleural plaques cause no symptoms, although they signal the presence of asbestos fibres in the lungs, which may independently cause fatal disease. In finding the damage of pleural plaques not actionable, the court stated, at para. 47:

> But it can at least be said that an injury which is without any symptoms at all because it cannot be seen or felt and which will not lead to some other event that is harmful has no consequences that will attract an award of damages. Damages are given for injuries that cause harm, not for injuries that are harmless.

[52] The allegations of genotoxicity are similar to the injuries raised by the plaintiffs in *Dow Chemical Company* and *Rothwell*. A physical change with no perceptible effect upon one’s health is not compensable in negligence.

(b) Psychological injury

[53] The appellants argue the motion judge erred in law by mischaracterizing their claim in psychological harm as one of future harm.

[54] I disagree. The motion judge stated the plaintiffs' claim correctly throughout his reasons. For example, at paras. 162 and 186, the motion judge differentiated psychological harm from future harm:

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

[55] The motion judge thus explicitly acknowledged that the claim was for present anxiety resulting from notification that the appellants had ingested contaminated valsartan.

[56] There is more merit to the appellants' argument that the motion judge erred in concluding that psychological distress based on a fear of future harm (i.e., the manifestation of cancer), is non-compensable. To the extent that the motion judge reasoned there could be no cause of action for present psychological harm occasioned by the risk of future physical harm (i.e., a cancer diagnosis), this was an error. Psychological distress caused by even a speculative concern of an increased risk is still harm.

[57] The common law's path to accepting the concept of negligently caused mental harm was canvassed by Brown J. in *Saadati v. Moorhead*, 2017 SCC 28, [2017] 1 S.C.R. 543. It is an error to dismiss mental injury arising from fear of future harm without first assessing the mental injury against the criteria generally applicable to the tort of negligence. In other words, recoverability for mental injury depends upon the plaintiff satisfying the same elements required for any successful action in negligence: *Saadati*, at para. 19.

[58] The principles for analyzing negligence claims for mental injury are set out in *Mustapha*. In that case, a plaintiff who purchased bottled water from the defendant, discovered dead flies floating in an unopened, unused bottle of drinking water. The plaintiff did not drink the water. But the plaintiff became obsessed with the event, sustaining psychiatric injuries including a major depressive disorder with associated phobia and anxiety. The question of liability in *Mustapha* did not turn on whether the plaintiff's psychological injury was based on an imagined harm or

a risk of harm or a speculative worry. The question, answered in the negative, was whether the plaintiff's damages (psychological injury) were reasonably foreseeable.

[59] There are two guiding principles set out in *Mustapha*. First, not all psychological injuries rise to the level of being compensable in tort law. To qualify, they must be "serious and prolonged" and rise above the "ordinary annoyances, anxieties and fears": *Mustapha*, at para. 9; *Saadati*, at para. 37. The appellants must pass a basic threshold noted in *Mustapha*, at para. 9:

> … 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 … The law does not recognize upset, disgust, anxiety, agitation or other mental states that fall short of injury … Quite simply, minor and transient upsets do not constitute personal injury, and hence do not amount to damage.

[60] Second, not all mental injury will necessarily be caused, in fact or in law, by the defendant's negligent conduct. Even where a plaintiff's claim establishes a duty of care, breach of the duty, damage and factual causation, the plaintiff must still address legal causation. Legal causation is an inquiry into remoteness or foreseeability of the injury. This threshold question asks "whether the occurrence of mental harm in a person of ordinary fortitude was the reasonably foreseeable result of the defendant's negligent conduct": *Saadati*, at para. 20; *Mustapha*, at paras. 14-16.

[61] In *Mustapha*, for example, the plaintiff's psychological injury was "serious and prolonged"; however, the claim failed on the last element of the negligence analysis: the plaintiff's damage was too remote to have been caused in law by the defendant's breach. The plaintiff's extreme psychological reaction and ensuing harm exceeded the mental harm that would have been reasonably foreseeable from a person of ordinary fortitude seeing flies in the bottle of water: *Mustapha*, at paras. 14 and 18.

[62] Although I agree with the appellants that the motion judge did not conduct this analysis in relation to their claim for present psychological distress before dismissing the negligence claim as not viable and doomed to fail, I do not accept the appellants' argument – based on *Anderson v. Wilson* (1999), 44 O.R. (3d) 673 (Ont. C.A.) – that the proposed action for mental injury satisfies the s. 5(1)(a) criterion.

[63] In *Anderson*, this court allowed the certification of a class action for nervous shock caused by a notice sent by public health authorities advising class members that, while they were receiving treatment at certain clinics, they had been exposed to hepatitis B and faced possible infection. This court held that it was arguably foreseeable that the notice would result in shock. Given the "uncertain state of the law on tort relief for nervous shock", it was not plain and obvious that the claim for the tort of mental distress standing alone would fail: *Anderson*, at p. 679.

[64] However, at the time this court decided *Anderson*, it did not have the benefit of the doctrinal development provided by *Mustapha*: the articulation of (1) the basic threshold of injury needed to garner recovery, and (2) the “ordinary fortitude” test. The law is thus more determinate than it was when *Anderson* was decided. A claim that yesterday was allowed to proceed due to its novelty may have since been rendered hopeless by further developments in the law and appropriately weeded out. Such was the case in *Capelet v. Brookfield Homes (Ontario) Limited*, 2018 ONCA 742, where the plaintiff’s claim for mental injury sustained due to mould found within his house was summarily dismissed on the person of “ordinary fortitude” test: at para. 13; and in *Healey v. Lakeridge Health Corp*., 2011 ONCA 55, 103 O.R. (3d) 401, where the plaintiffs’ claim for mental injury sustained upon reading notices from the hospital that they had been exposed to tuberculosis did not meet the threshold of sufficient gravity and duration set out in *Mustapha* to qualify for compensation: at para. 64.

[65] The operation of these principles is also illustrated in *Rothwell*, where the House of Lords found that in the absence of a manifestation of harm, there could be no compensable damages for the wrongdoing of increasing the risk of harm. The House of Lords adopted a similar approach to *Mustapha* on the issue of whether a claim for present anxiety is actionable. As canvassed above, the House of Lords found that neither the physical injury of pleural plaques nor the mental injury of anxiety due to concern that exposure to asbestos could result in fatal

disease, were actionable injuries. The anxiety about the potential future onset of a life-threatening disease by itself did not rise to a level to attract the attention of the law of tort: at para. 73. However, in that action, the House of Lords also considered – separate from the claims of co-plaintiffs – a claim for non-trivial mental injury on the part of a plaintiff whose anxiety caused clinical depression. The court assessed his claim against a standard similar to the person of "ordinary fortitude", or, as the U.K. court described it, "a person of 'sufficient fortitude' or 'customary phlegm'": *Rothwell*, at para. 30 quoting Lord Porter in *Hay or Bourhill v. Young*, [1942] 2 All E.R. 396 at 409, [1943] A.C. 92, at p. 117. Ultimately, and similar again to *Mustapha*, the U.K. court concluded the severe depression experienced by the plaintiff was not actionable because it was an unforeseeable response beyond that of a person of "ordinary fortitude." This is the correct approach to mental injury damages in a negligence action: 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.

[66] Returning to the pleadings in this case, the appellants have failed to demonstrate that their mental injuries rise above the anxieties and fears commonly experienced from time to time by people living together in society. The extent of the appellants' pleadings on this point is that class members will "inevitably experience worry, anxiety, upset and mental distress over not knowing whether prolonged ingesting of a toxic chemical has caused or will cause them to develop

cancer or organ damage" and for each representative plaintiff plead standard language of experiencing "on a prolonged basis shock, worry, great mental distress and anxiety since learning of the Recall." However, stock repetition of words echoing the legal test are not enough. The appellants have failed to plead the material facts needed to support damages recoverable under the tort, like those detailed for the plaintiffs in *Mustapha* or *Saadati*. Bare assertions of prolonged mental distress must be supported by material facts detailing the injury, otherwise a court cannot conduct the necessary analysis to conclude that mental injury has met the legal threshold: *Imperial Tobacco*, at para. 22. Since the facts as pleaded by the appellants are inadequate, the result reached by the motion judge is justified. The claim in negligence should not proceed.

[67] Even had the injuries pleaded met the threshold for recoverable damages, they would have foundered on the person of "ordinary fortitude" standard. The appellants pleaded that shock came from reading the recall announcement, and the court was directed in oral submissions to the wording of the Health Canada notices. These notices are incorporated by reference in the pleading, they are central enough to the negligence claim to form an integral part of the claim itself and may form part of the assessment of the pleadings: *McCreight v. Canada (Attorney General)*, 2013 ONCA 483, 116 O.R. (3d) 429, at para. 32.

[68] I agree with the motion judge's assessment that the notices seem intended to assuage concern. The class members were advised of the NDMA

contamination, that NDMA is a potential human carcinogen that may cause cancer with long-term exposure, but told to continue taking their medications unless otherwise advised by their health care provider. Within approximately two months of its first notice, Health Canada further advised that its scientists had assessed the available data to determine the potential increased risk of developing cancer and released the information to help put the risk into context for Canadians. The risk was between 0.0086% and 0.0011%, which, as Health Canada pointed out, must be considered in the context of a 50% existing lifetime risk of developing cancer. I agree that the recall would not cause a person of reasonable fortitude to sustain a psychological injury at the level compensable in tort. I also defer to the motion judge's discretion not to permit the appellants to amend their pleadings. As explained below, amending the pleadings would not cure the other defect of the case, namely that the psychological injuries would founder on the common issues criterion.

[69] In sum, I find no error in dismissing the motion for certification of the negligence claims for physical harm (including genotoxicity) and psychological harm not yet materialized. While I find the motion judge erred in his analytical treatment of the negligence claim vis-à-vis present psychological harm, it is an error without consequence. Having applied the correct analysis from *Mustapha*, the negligence claim for present psychological harm damages was not reasonably foreseeable in law and doomed to fail. I would dismiss the appeal of the plaintiffs'

negligence claims for physical and psychological harm damages, which cause of action is not certifiable.

(c) Pure economic loss

[70] The remaining aspect of the appellants' negligence claim is damages for medical services and monitoring, costs thrown away, and refunds. Without any viable negligence claim for physical or psychological harm damages, the damages they seek are purely economic. The question before the motion judge was whether these damages are the type of economic losses that should be recoverable in tort?

[71] The motion judge concluded they are not. He determined it was plain and obvious that the plaintiffs' claim for manufacturing negligence was doomed to fail both as a matter of pleading and also because there is no basis in fact for this cause of action.

[72] Relying on *Maple Leaf Foods*, where the Supreme Court recognized that pure economic loss is recoverable in limited circumstances, the motion judge found that, once compensatory damages for physical and psychological injuries were removed, the claim for pure economic loss failed because the product was not imminently dangerous.

[73] The appellants contend the motion judge erred by adding "imminence" of harm as a requirement to recover for pure economic loss. In their view, the liability

rule for pure economic loss is “real and substantial harm” as set out in *Winnipeg Condominium Corp. No. 36 v. Bird Construction Co*., [1995] 1 S.C.R. 85.

[74] I do not agree. Brown and Martin JJ., for the majority in *Maple Leaf Foods*, at para. 45, explained and clarified the test from *Winnipeg Condominium Corp*. to include the concept of imminent risk:

> Where a design or construction defect poses a real and substantial danger – that is, what Fraser C.J.A. and Côté J.A. described in *Blacklaws v. 470433 Alberta Ltd.*, 2000 ABCA 75, 261 A.R. 28, at para. 62, as “imminent risk” of “physical harm to the plaintiffs or their chattels” or property – *and* the danger “would unquestionably have caused serious injury or damage” if realized, given the “reasonable likelihood that a defect … will cause injury to its inhabitants”, it makes little difference whether the plaintiff recovers for an injury actually suffered or for expenditures incurred in preventing the injury from occurring. Thus, the economic loss incurred to avert the danger “is analogized to physical injury to the plaintiff’ person or property”. The point is that the law views the plaintiff as having sustained actual injury to its right in person or property because of the necessity of taking measures to put itself or its other property “outside the ambit of perceived danger”. [Citations omitted.]

[75] The court thus clarified that the liability rule is consistent with the general principle that there 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”: *Maple Leaf Foods*, at para. 44 citing *Atlantic Lottery Corp*., at para. 33 (emphasis in original). The basis for recovery for pure economic loss – that the plaintiff must

take steps to prevent an imminent injury that it would otherwise suffer – “vanishes where the defect presents no imminent threat”: *Maple Leaf Foods*, at para. 46.

[76] It is in this context that the motion judge found there could be no liability where there was no proof of causation of harm. Having reviewed the pleadings, I see no error in this conclusion. The pleadings do not address the imminence (or latency) of the physical harm arising from ingesting valsartan contaminated with NDMA and NDEA. Even on a less exacting conception of “real and substantial harm”, the pleadings founder. The plaintiffs failed to plead “real” harm and instead propose to redefine harm to include the prospect of “increased risk”, “increased likelihood”, “probable carcinogen”, etc. Interpreting the pleadings generously, the allegations of the product not being fit for human consumption and dangerously defective due to its contamination by toxic or carcinogenic chemicals may constitute “real and substantial harm.” But, as I will explain below in the discussion of the other certification criteria, such an interpretation would not satisfy the common issues criterion.

[77] Before moving from pure economic loss, I will address the types or heads of damages pleaded by the plaintiffs: costs of medical services and medical monitoring, costs thrown away from discarding contaminated pills, and refunds. It is clear from *Maple Leaf Foods*, at para. 48, that the basis for the duty of establishing liability for pure economic loss also serves as a principled basis for limiting the scope of recovery. In the context of pure economic loss for dangerous

products (or defects in building structures) this means the plaintiff can only recover the cost of averting the danger: *Maple Leaf Foods*, at paras. 49 and 57.

[78] Here, the defect is in the product, valsartan. No one is seeking to correct the dangerous defect. Instead, the plaintiffs state they discarded the product. This presents a difficulty for their claim. *Maple Leaf Foods* directs that "where it is feasible for the plaintiff to simply discard the defective product, the danger to the plaintiff's rights, along with the basis for recovery, falls away": at para. 50. Since the plaintiffs claim no costs for disposing of the product, it is plain and obvious on the pleadings that discarding the pills was feasible and sufficient to avert any danger. The liability rule does not extend to other loss, such as replacement value for the contaminated product (or refund): *Maple Leaf Foods*, at para. 55.

[79] Nor is there a path for recovery of medical expenses or medical monitoring without a viable claim in negligence for physical or psychological damages. Medical monitoring costs do not fall within the *Maple Leaf Foods* liability rule because they do not repair the defect to make the dangerous product safe. Medical monitoring presumes a physical injury: *Dow Chemical Company*, at para. 57; see also *Dussiaume*, at para. 79. Where there is no present injury, allowing damages for pure economic loss in the nature of medical monitoring and medical services costs is contrary to the principle that there is no liability for negligence "in the air."

[80] Accordingly, I would dismiss the appeal from the motion judge's decision not to certify the appellants' negligence claim grounded in pure economic loss.

(3) Claim for battery

[81] The tort of battery protects bodily integrity. It asserts the right of persons to control their bodies, and allows damages where a person interferes with the body of another: *Non-Marine Underwriters, Lloyd's of London v. Scalera*, 2000 SCC 24, [2000] 1 S.C.R. 551, at para. 15. A battery occurs when a defendant causes a direct, offensive, physical contact with the plaintiff, which is the immediate cause of the harm to the plaintiff: *Barker v. Barker*, 2022 ONCA 567, 162 O.R. (3d) 337, at paras. 138 and 154. Directness is an essential requirement for liability: *Non-Marine Underwriters*, at para. 11. Although battery is often conceived of as an intentional tort, battery can be committed either intentionally or negligently: *Non-Marine Underwriters*, at para. 5; see also Lewis Klar and Cameron Jefferies, *Tort Law*, 7th ed. (Toronto: Thomson Reuters, 2023), at p. 66; Allen M. Linden, *et al*., *Canadian Tort Law*, 12th ed. (Toronto: LexisNexis, 2022), at s. 2.03.

[82] Nothing done directly by the respondents is alleged to be the immediate cause of the harm alleged by the appellants. At best, the pleadings allege that the respondents "exposed" the plaintiffs to the contaminated valsartan, but exposure is not direct physical contact. Although the appellants' claim seems to sound in negligence, negligent battery nevertheless requires directness. The appellants

have provided no theory to address this constituent element of their claim in battery. Neither have they pleaded material facts in support. Moreover, there is no authority that a battery can be committed by a failure to act, which is what is here alleged. Accordingly, I see no error in the motion judge's ultimate conclusion that there was no certifiable cause of action in battery.

(4) Claim under the *Consumer Protection Act*

[83] The appellants also claim that the respondents breached ss. 14 and 15 of the *Consumer Protection Act, 2002*, S.O. 2002, c. 30, Sched. A (*CPA*), by making false, misleading, deceptive, or unconscionable representations that their product was of high quality, free of defects, and fit for human consumption when the respondents knew, or ought to have known, that because of the presence of NDMA and NDEA, the contaminated valsartan was not safe and could cause or materially increase the risk of contracting cancer, liver disease, and other health conditions. The appellants plead that they are entitled to damages under s. 18 of the *CPA*.[2]

[84] The motion judge ruled that the consumer protection causes of action were not certifiable. He found it was plain and obvious that the damages sought were

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[2] The pleadings also rely on ss. 4, 8, and 171-172 of the *Business Practices and Consumer Protection Act*, S.B.C. 2004, c. 2; Sections 2, 7, and 23 of *The Business Practices Act*, C.C.S.M., c. B120; Sections 6, 7, and 93 of the *Consumer Protection and Business Practices Act*, S.S. 2014, c. C-30.2; Sections 6, 7, and 13 of the *Fair Trading Act*, R.S.A. 2000, c. F-27; Sections 2, 7, and 10 of the *Consumer Protection and Business Practices Act*, S.N.L. 2009, C-31.1; Sections 2 and 4 of the *Business Practices Act,* R.S.P.E.I. 1988, c. B-7; Section 272 of the *Consumer Protection Act*, C.Q.L.R. c. P-40.1. The appellants do not distinguish between the provisions in their submissions except to raise s. 172 of the BC *Business Practices and Consumer Protection Act*. I will do the same.

either not available or would be so *de minimis* as to not satisfy the preferable procedure criterion.

[85] The appellants state that the motion judge made three errors: first, by requiring intention and misinterpreting the pleadings to say intention was not pleaded; second, by finding damages were not available; and third, by requiring privity as a component of s. 18 of the *CPA*.

[86] It is not necessary to address the issue of intention. On a generous interpretation of the pleadings, the defendants are alleged to have known of the contamination. Nor is it necessary to consider the question of privity, which only applies to consumer protection legislation in some provinces and not others so would not be dispositive in this case.

[87] Rather, I rest my conclusion, as did the motion judge primarily, on the interpretation of s. 18 of the *CPA* and the issue of damages. Subsections 18(1) and (2) provide:

> Any agreement, whether written, oral or implied, entered into by a consumer after or while a person has engaged in an unfair practice may be rescinded by the consumer and the consumer is entitled to any remedy that is available in law, including damages.
>
> A consumer is entitled to recover the amount by which the consumer's payment under the agreement exceeds the value that the goods or services have to the consumer or to recover damages, or both, if rescission of the agreement under subsection (1) is not possible,
>
> > (a) because the return or restitution of the goods or services is no longer possible; or

> (b) because rescission would deprive a third party of a right in the subject-matter of the agreement that the third party has acquired in good faith and for value.

[88] The appellants do not seek rescission. Nor would such a remedy be available since it is no longer possible to return the contaminated valsartan. Instead, they claim damages in the amount by which their payment for the drugs exceeded the value of the drugs, as well as damages for mental distress, anxiety, and costs of medical screening/monitoring.

[89] As stated above, I agree with the motion judge that the claim for damages for mental distress, anxiety, and costs of medical screening/monitoring are fatally flawed on the same basis as in the negligence cause of action: damages for an increase of a risk of harm and damages for mental injury that do not meet the required threshold of severity are not compensable in law.

[90] A claim brought under the *CPA* against a person who has allegedly engaged in an unfair practice is a statutory action. The primary method of righting the wrong is rescission, but s. 18 also provides that "the consumer is entitled to any remedy that is available in law, including damages" (emphasis added). This means that a court may award damages that "would be appropriate at common law": *Ramdath v. George Brown College of Applied Arts and Technology*, 2015 ONCA 921, 392 D.L.R. (4th) 490, at para. 94 citing Steven M. Waddams, *The Law of Damages*, 2nd ed. (Toronto: Canada Law Book, 1991) (loose-leaf updated 2015), at paras. 5.690 to 5.700.

[91] There is no error in the motion judge's reasoning that the statutory remedies sought by the plaintiffs – damages for payment for the drugs in excess of value, damages for diminished benefit of the bargain under s. 18 of the *CPA*, and restoration of profits received under s. 172 of the British Columbia *Business Practices and Consumer Protection Act*, SBC 2004, c. 2 – are not available to the plaintiffs. There is simply no allegation or material facts to support an allegation that the drugs at issue were unfit for their intended purpose of treating hypertension or that the contaminated valsartan was a useless or ineffective drug for the purpose of treating hypertension. As already noted, notices from Health Canada advised putative class members to continue taking the drugs despite the contamination, unless a physician advised to the contrary.

[92] This case is thus distinguishable from those class actions brought under consumer protection provisions for unfair practices, such as *WN Pharmaceuticals Ltd. v. Krishnan*, 2023 BCCA 72, leave to appeal refused, [2023] S.C.C.A. No. 152 and *Drynan v. Bausch Health Companies Inc*., 2021 ONSC 7423, leave to appeal to Div. Ct. refused 2022 ONSC 1586. In those cases, the plaintiffs established that what was advertised was not what they received; the elements that induced the plaintiffs to purchase the products were absent and the products were therefore valueless.

[93] This case is fundamentally different. Its essence is a negligence claim for a contaminated product, not a deceptive misrepresentation. It is not obvious, and

need not be decided, whether consumer protection legislation applies to this set of facts at all. It does not easily fit together with the examples of false, misleading, deceptive, or unconscionable representations set out in ss. 14 and 15 of the *CPA*. For this case, it is sufficient to say that asserting statutory breaches without pleading the underlying material facts necessary to support them is insufficient to cross even the low hurdle present in s. 5(1)(a) of the *Class Proceedings Act, 1992*.

(5) Claim under the *Competition Act*

[94] The appellants plead that the respondents contravened s. 52(1) of the *Competition Act* by knowingly or recklessly making representations as to the quality of their pharmaceutical products that were false or misleading in a material respect. Subsection 36(1) of the *Competition Act* creates a civil cause of action for a person who has suffered loss or damages as a result of conduct contrary to s. 52(1).

[95] Section 52 requires that there be a "representation." This court has previously held that failure to disclose a non-dangerous defect cannot constitute a "representation": *Arora v. Whirlpool Canada LP*, 2013 ONCA 657, 118 O.R. (3d) 113, at paras. 50-51 citing *Williams v. Canon Canada Inc*., 2011 ONSC 6571, at para. 227, aff'd on other grounds, 2012 ONSC 3692 (Div. Ct.). The object of s. 52(1) is to target deceptive marketing practices, not create liability for defective products.

[96] The motion judge did not err in finding that none of the pleaded misrepresentations are capable of sustaining a cause of action as a breach of s. 52(1) of the *Competition Act*.

(6) Claim for unjust enrichment

[97] The motion judge did not err in concluding that the pleadings do not disclose a viable cause of action for unjust enrichment. On the face of the Third Amended Statement of Claim, the appellants pleaded “waiver of tort and unjust enrichment.” *Atlantic Lottery Corp.* held that there is no cause of action for disgorgement based on the doctrine of waiver of tort in Canadian law, and the claim is therefore doomed to fail: at para. 27. Although the appellants pleaded “waiver of tort and unjust enrichment” as opposed to “disgorgement”, as Brown J. noted at para. 23 of *Atlantic Lottery Corp.*, this terminology is frequently (and incorrectly) used interchangeably. That appears to be the case here. The cause of action as pleaded by the appellants has no reasonable chance of success.

[98] Because the motion judge also dealt with a cause of action in “unjust enrichment” and the appellants argued unjust enrichment on appeal, I will briefly address it here. For a claim of unjust enrichment to succeed, the plaintiffs must establish three elements: (i) an enrichment of or benefit to the defendants; (ii) a corresponding deprivation of the plaintiffs, and (iii) the absence of a juristic reason

for the enrichment: *Moore v. Sweet*, 2018 SCC 52, [2018] 3 S.C.R. 303, at para. 37.

[99] The appellants' claim for unjust enrichment of the defendants fails because any benefit the defendants received from class members was indirect. The law of unjust enrichment does not permit recovery for incidental collateral benefits: *Peel (Regional Municipality) v. Canada*; *Peel (Regional Municipality) v. Ontario*, [1992] 3 S.C.R. 762, at para. 47. This court has previously struck claims for unjust enrichment brought against a drug manufacturer for an allegedly defective drug where the reimbursement sought was paid to a retailer and not the drug manufacturer. Unjust enrichment simply does not extend to permit such recovery: *Boulanger v. Johnson & Johnson Corp*., 174 O.A.C. 44 (C.A.), at para. 20.

[100] Moreover, the appellants did not plead a deprivation on the part of class members and the motion judge did not err in so concluding. To the contrary, the material facts pleaded in support of the claim are that the class members paid for valsartan and received it. Purchasers of defective products do not suffer a "deprivation" for the purpose of the law of restitution when they in fact received the products in issue: *Spring v. Goodyear Canada Inc*., 2021 ABCA 182, 459 D.L.R. (4th) 315, at para. 49; *Nissan Canada Inc. v. Mueller*, 2022 BCCA 338, at para. 115, leave to appeal refused, [2022] S.C.C.A. No. 446. Liability for a claim arising from a defective product is better found in negligence.

[101] I therefore conclude that the appeal must be dismissed on this ground. The motion judge was correct to find that the pleading did not disclose a cause of action for unjust enrichment.

C. The remaining issues of commonality and preferability

[102] Having disposed of this appeal by finding that the motion judge did not err in dismissing the action under s. 5(1)(a) of the *Class Proceedings Act, 1992*, it is not necessary to address the remaining issues of commonality and preferability. However, since the parties spent some time reviewing the evidence, it is prudent to comment on the motion judge's finding that the allegation that NDMA and NDEA are human carcinogens did not meet the standard of some basis in fact. I will also briefly comment on the common issues and preferable procedure criteria.

[103] Substantial deference is owed to the motion judge's application of the test for certification and his determination of the common issues and preferability. On such questions, appellate court intervention should be restricted to matters of general principle: *Fehr v. Sun Life Assurance Company of Canada*, 2018 ONCA 718, 84 C.C.L.I. (5th) 124, at para. 39, leave to appeal refused, [2018] S.C.C.A. No. 489.

(1) Some Basis in Fact

[104] The class representatives in a class action must show "some basis in fact" for each of the certification requirements set out in s. 5(1)(b) through (e) of the

Class Proceedings Act, 1992: *Hollick*, at para. 25. While the “some basis in fact” test is a low evidentiary standard, and a court should not resolve conflicting facts and evidence, the court retains a gatekeeping function and certification will be denied if there is an insufficient evidentiary basis for the facts to establish the existence of common issues: *Pro-Sys Consultants*, at para. 103.

[105] The appellants state that no deference is owed to the motion judge’s assessment of the common issues or preferable procedure criterion because he engaged in an impermissible comparative evaluation of the evidence. The appellants contend the motion judge erred by not following the legal parameters of the “some basis in fact” principle when evaluating the common issues and preferable procedure criteria because he veered into weighing evidence and determining the merits of the claim rather than the lower threshold of looking for some plausible evidence to support proceeding by way of class action.

[106] I disagree. The motion judge clearly understood the task before him and correctly applied the “some basis in fact” principle, as he explained at para. 88 of his reasons:

> 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.

[107] While the motion judge found no basis in fact for the proposition that NDMA and NDEA cause cancer, he did find some basis in fact for the appellants' allegation that NDMA and NDEA cause an increased risk for developing cancer. This finding accorded with the actual claim. Indeed, as was noted in many places in the reasons below and not contested before this court, the appellants' claim is not based on NDMA and NDEA having caused cancer, but instead causing an increased risk of cancer. Their proposed common issues make this plain at questions 2, 3, and 4 as follows:

> Did the Valsartan Drugs contain nitrosamine impurities above the acceptable intake limits for NDMA and/or NDEA, as defined by the FDA?
>
> 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*?
>
> Do the Valsartan Drugs, used as indicated, cause or contribute to an increased cancer risk?

[108] The appellants have failed to show that the finding of the motion judge that there was no basis in fact at this point that NDMA and NDEA cause cancer was palpably wrong. Even if it was, it was certainly not an overriding error because this

question is beside the point when the claim, as it is framed here, is about increased risk of cancer and the motion judge found that there was some basis in fact for that proposition.

[109] As I stated above, psychological injuries from the shock and stress caused by being notified of this increased risk of cancer also fail at s. 5(1)(a) of the *Class Proceedings Act, 1992*. Since I agree with the motion judge that leave to amend the pleadings should not be granted, I explain below why the claim as it relates to psychological injury would also fail on the common issue criterion.

(2) Common Issues Criterion

[110] An issue will be common "only where its resolution is necessary to the resolution of each class member's claim." In other words, it "will not be 'common' in the requisite sense unless the issue is a 'substantial…ingredient' of each of the class members' claims": *Hollick*, at para. 18.

[111] For a claim to be certified, there must be a "methodology" through which the common issue may plausibly be proven at trial. As Rothstein J. explained in *Pro-Sys Consultants*, at para. 118: "This means that the methodology must offer a realistic prospect of establishing loss on a class-wide basis so that, if the [head of damage] is eventually established at the trial of the common issues, there is a means by which to demonstrate that it is common to the class."

[112] The appellants contend that the motion judge erred by failing to consider whether the immediate psychological distress experienced by some class members upon the revelation of the contamination met the definition of a common issue.

[113] The motion judge committed no such error. Although he dismissed the claim for psychological distress for failing to disclose a viable cause of action, he went on to consider whether the damages for psychological harm would be certifiable as a common issue. He concluded that there was not a common issue because the plaintiffs had failed to show some basis in fact to meet this criterion.

[114] Given the nature of the claims advanced here, it is apparent that the assessment of psychological damages requires proof of the harm suffered by the individual class members because the claims are inherently individual in nature and idiosyncratic: *Healey*, at para. 71.

[115] Claims for psychological harm are often individual: a claimant must prove mental distress that is serious, prolonged, and rises above the ordinary annoyances, anxieties, and fears of life. At most, the motion judge found that the evidence of the psychological effect of the recall caused a minority of the class to have suffered the upsets and anxieties that would be compensable under tort law. Accordingly, as the motion judge found, “the hard work remains for individual

issues trials and the common issues trial is of marginal utility." I see no error in this conclusion.

[116] The appellants have failed to demonstrate palpable and overriding error in the motion judge's findings, which led him to conclude the plaintiffs had failed to show some basis in fact in support of the common issues criterion. To the contrary, the evidence indicated that the issue of psychological injury was not common to the class.

[117] First, the evidence disclosed that any adverse biological effects that may occur from ingesting valsartan in terms of genotoxicity were "idiosyncratic" and, in any event, despite any such risk, class members were advised to continue to take their medication until advised not to do so by their physician.

[118] Second, the Health Canada notices and updates were "tempered and seemed designed to calm and not agitate the audience." The announced theoretical increased risk of cancer was between 0.0086% and 0.0011%, which, as Health Canada pointed out, must be considered in the context of the existing lifetime risk of a 50% chance of developing cancer.

[119] Third, Dr. Roy O'Shaughnessy, a forensic psychiatrist retained by the plaintiffs, conducted assessments on eight of the proposed representative plaintiffs and found that all 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 all.

[120] Fourth, there was evidence from Dr. Andreas Groehn, an economist retained by the plaintiffs to propose a methodology, surveyed approximately 1,500 individuals who had been prescribed valsartan and found that roughly 75 percent of the survey respondents reported feeling “nervous, anxious, worried, or on edge” about their health for the first three months after learning of the recalls.

[121] Having reviewed this evidence, I see no error in the motion judge’s conclusion that the plaintiffs failed to meet the “some basis in fact” threshold to show commonality. Even had I not concluded there was no viable cause of action in relation to psychological harm, the plaintiffs’ claim for psychological harm damages is not certifiable because it does not meet the common issue criteria.

(3) Preferable Procedure Criterion

[122] Having disposed of this appeal on s. 5(1)(a) and 5(1)(c) of the *Class Proceedings Act, 1992*, it is not necessary to address the preferable procedure criterion and I decline to do so.

V. Disposition

[123] For these reasons, I would dismiss the plaintiffs' appeal from the order dismissing their motion for certification. The parties advised at the hearing that they sought no costs for the appeal. Accordingly, I would not award costs.

Released: March 27, 2024 SA

J.A.

I agree.

I agree. J.A.